

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**MEDICARE HOME HEALTH AGENCY
PROVIDER COMPLIANCE AUDIT:
VISITING NURSE ASSOCIATION OF
CENTRAL JERSEY HOME CARE
AND HOSPICE, INC.**

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Office of Inspector General

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

Report in Brief

Date: October 2020

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Why OIG Did This Audit

Under the home health prospective payment system (PPS), the Centers for Medicare & Medicaid Services pays home health agencies (HHAs) a standardized payment for each 60-day episode of care that a beneficiary receives. The PPS payment covers intermittent skilled nursing 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 Central Jersey Home Care and Hospice, Inc., (VNA of Central Jersey) complied with Medicare requirements for billing home health services on selected types of claims.

How OIG Did This Audit

Our audit covered over \$66 million in Medicare payments to VNA of Central Jersey for 19,603 claims for home health services provided in calendar years 2015 and 2016 (audit period). We selected a simple random sample of 100 claims and submitted these claims to independent medical review to determine whether the services met medical necessity and coding requirements.

Medicare Home Health Agency Provider Compliance Audit: Visiting Nurse Association of Central Jersey Home Care and Hospice, Inc.

What OIG Found

VNA of Central Jersey did not comply with Medicare billing requirements for 14 of the 100 home health claims that we reviewed. For these claims, VNA of Central Jersey received overpayments of \$21,553 for services provided during our audit period. Specifically, VNA of Central Jersey incorrectly billed Medicare for services provided to beneficiaries who were not homebound or did not require skilled services. It also inappropriately received reimbursement for claims for some services that were not provided, not reasonable or necessary, and incorrectly billed. On the basis of our sample results, we estimated that VNA of Central Jersey received overpayments of at least \$2 million for the audit period.

What OIG Recommends and VNA of Central Jersey Comments

We made several recommendations to VNA of Central Jersey, including that it (1) refund to the Medicare program the portion of the estimated \$2 million overpayment for claims incorrectly billed that are within the reopening period; (2) exercise reasonable diligence to identify and return overpayments, in accordance with the 60-day rule, for claims that are outside the reopening period; (3) exercise reasonable diligence to identify and return any additional similar overpayments outside of our audit period; and (4) strengthen its procedures for billing home health services. The detailed recommendations are listed in the body of the report.

In written comments on our draft report, VNA of Central Jersey disagreed with our findings and recommendations. VNA of Central Jersey retained a health care consultant to review most of 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 medical reviewer review VNA of Central Jersey's written comments and its consultant's report. Based on the results of that review and our review of additional documentation provided by VNA of Central Jersey, we reduced the sampled claims incorrectly billed from 16 to 14 and revised the related findings and recommendations. In addition, we eliminated one error category originally included in the draft report. We maintain the remaining findings and recommendations are valid, although we acknowledge VNA of Central Jersey's right to appeal the findings.

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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 Central Jersey Home Care and Hospice, Inc., (VNA of Central Jersey) was one of those HHAs.

OBJECTIVE

Our objective was to determine whether VNA of Central Jersey 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.

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)

payment codes¹ and represent specific sets of patient characteristics.² CMS requires HHAs to submit OASIS data as a condition of payment.³

CMS administers the Medicare program and contracts with four of its Medicare Administrative Contractors (MACs) 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 § 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, needs physical therapy or speech-language pathology, or has a continuing need for occupational therapy;
- under the care of a physician; and

¹ 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.

² 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.

³ 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 *Medicare Program Integrity Manual*, 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.⁴

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.⁵

⁴ The Act § 1128J(d); 42 CFR §§ 401.301–401.305; and 81 Fed. Reg. 7654 (Feb. 12, 2016).

⁵ 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.

Visiting Nurse Association of Central Jersey Home Care and Hospice, Inc.

VNA of Central Jersey is a not-for-profit HHA located in Holmdel, New Jersey. National Government Services, its Medicare contractor, paid VNA of Central Jersey approximately \$69 million for 24,024 claims for services provided to beneficiaries during CYs⁶ 2015 and 2016 (audit period) based on CMS's National Claims History (NCH) data.⁷ During the audit period, VNA of Central Jersey placed in the top 1 percent of home health providers in Medicare payments received.

HOW WE CONDUCTED THIS AUDIT

Our audit covered \$66,010,746 in Medicare payments to VNA of Central Jersey for 19,603 claims.⁸ These claims were for home health services provided during the most recent timeframe for which data was available at the start of the audit (CYs 2015 and 2016). We selected a simple random sample of 100 claims with payments totaling \$333,971 for review. We evaluated these claims for compliance with selected billing requirements and submitted them to an independent medical review contractor 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 audit 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 for each sample item.⁹

⁶ CYs were determined by the HHA claim "through" date of service. The "through" date is the last day on the billing statement covering services provided to the beneficiary. We selected these "through" dates falling within CYs 2015 and 2016, therefore claims subjected to audit could include dates of service prior to CY 2015.

⁷ On January 1, 2016, VNA Health Group combined with Mega Care, Inc. to form a new entity known as VNA of Central Jersey which operated using VNA Health Group's systems, records, policies and procedures. All home health services reviewed as part of this audit were claimed under the provider identification number associated with VNA of Central Jersey.

⁸ In developing the sampling frame, we excluded home health claim payments that: (a) were identified in the Recovery Audit Contractor (RAC) Data Warehouse as previously excluded or under review, (b) were duplicate claim numbers, (c) had the same "From" and "Through" dates of service, and (d) were Low Utilization Payment Adjustment (LUPA) claims or Partial Episode Payment (PEP) claims.

⁹ Sample items may have more than one type of error.

FINDINGS

VNA of Central Jersey did not comply with Medicare billing requirements for 14 of the 100 home health claims that we reviewed.¹⁰ For these claims, VNA of Central Jersey received overpayments of \$21,553 for services provided in CYs 2015 and 2016. Specifically, VNA of Central Jersey incorrectly billed Medicare for:

- services provided to beneficiaries who were not homebound (10 claims),
- services provided to beneficiaries who did not require skilled services (4 claims),
- services not provided (1 claim),
- services that were not reasonable and necessary (1 claim),
- claims contained incorrect HIPPS payment codes (1 claim).

Of the 14 claims that did not comply with Medicare requirements, 3 claims contained more than 1 deficiency. These errors occurred primarily because VNA of Central Jersey did not have adequate controls to prevent the incorrect billing of Medicare claims.

On the basis of our sample results, we estimated that VNA of Central Jersey received overpayments of at least \$2,015,925 for the audit period.¹¹ As of the publication of this report, this amount included claims outside of the 4-year claim-reopening period.

VISITING NURSE ASSOCIATION OF CENTRAL JERSEY BILLING ERRORS

VNA of Central Jersey incorrectly billed Medicare for 14 of the 100 sampled claims, which resulted in overpayments of \$21,553.

¹⁰ Eight of the fourteen claims qualified for partial Medicare reimbursement. For these eight claims, we questioned the difference in Medicare reimbursement between what was billed and what was eligible for reimbursement.

¹¹ 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 95 percent of the time.

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 an 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 the 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).¹² The Manual states 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 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:

Criteria 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 Criteria One conditions, then the patient must also meet two additional requirements defined in Criteria Two below.

Criteria Two

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

¹² Revision 208 of § 30.1.1 was in effect during our audit period.

VNA of Central Jersey Did Not Always Meet Federal Requirements for Home Health Services

For 10 of the sampled claims, VNA of Central Jersey incorrectly billed Medicare for home health episodes for beneficiaries who did not meet the above requirement for being homebound. The homebound requirement deficiencies applied to the full episode (6 claims) or a portion thereof (4 claims).¹³

Example 1: Beneficiary Not Homebound – Full Episode

The documentation for one beneficiary did not support that he was homebound, as he was being treated on an outpatient basis for chronic pulmonary disease, the beneficiary was functionally independent, did not require a mobility assistive device, and was living in a single-level residence with supportive family. Leaving the home would not require a considerable or taxing effort.

Example 2: Beneficiary Not Homebound – Partial Episode

For another beneficiary, the documentation supported that she was homebound at the start of care, as she had undergone a medical procedure and had a history of falls. By a later date in the episode, the beneficiary was able to walk with a cane both indoors and outdoors including on uneven ground such as grass, gravel and an asphalt driveway. The wound from the medical procedure had healed and there were no medical contraindications to leaving home. Leaving the home no longer would require a considerable or taxing effort.

These errors occurred because VNA of Central Jersey did not have adequate oversight procedures to ensure that it verified and continually monitored the homebound status of Medicare beneficiaries under its care and did not properly document the specific factors that qualified the beneficiaries as homebound.

Beneficiaries Did Not Require Skilled Services

Federal Requirements for Skilled Services

A Medicare beneficiary must be in need of 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

¹³ Of these 10 claims that did not meet homebound requirements, 1 claim was also billed with skilled need services that were not medically necessary and 1 claim was also billed when the service was not provided. Appendix E provides detail on the extent of errors, if any, per claim reviewed.

§ 409.44(b) and the Manual, chapter 7, § 40.1).¹⁴ 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).

VNA of Central Jersey Did Not Always Meet Federal Requirements for Skilled Services

For four of the sampled claims, VNA of Central Jersey incorrectly billed Medicare for a beneficiary who did not meet the Medicare requirements for coverage of skilled nursing or therapy services for a portion of the episode.¹⁵

Example 3: Beneficiary Did Not Require Skilled Services

A beneficiary with a history of stage III chronic kidney disease, gout, hypercholesterolemia, and hypertension was homebound. Services for evaluating and reassessing skilled physical therapy and skilled occupational therapy were needed. However, the medical records did not support that the beneficiary required any ongoing skilled physical therapy or skilled occupational therapy. There was no indication for skilled nursing services. The beneficiary's conditions were within his normal limits and there was no history of recent changes to medications or treatments. He had caregiver assistance available for processing information with respect to education regarding medical conditions and medications. The medical records did not support that the beneficiary required skilled services beyond those services related to the evaluations and reassessments.

These errors occurred because VNA of Central Jersey did not always provide sufficient clinical review to verify that beneficiaries required skilled services.

¹⁴ 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, administration of medications, among other things. Manual, chapter 7, § 40.1.2.

¹⁵ Of the four claims that did not meet skilled need requirements, one claim also did not meet homebound requirements and one claim included services that were not reasonable and necessary. Appendix E provides detail on the extent of errors, if any, per claim reviewed.

Services Not Provided

Federal Requirements for Claiming Reimbursement for Services

Medicare payments may not be made for services unless a provider had furnished information necessary to determine the amount due to the provider (the Act § 1833(e)).

VNA of Central Jersey Did Not Always Meet Federal Requirements for Claiming Reimbursement for Services

For one of the sampled claims, VNA of Central Jersey incorrectly billed Medicare for services that were not provided.¹⁶ Specifically, VNA of Central Jersey billed for home health services even though documentation indicated that the beneficiary was not at home at the time the services were supposedly performed. This error occurred because VNA of Central Jersey did not have adequate oversight procedures to ensure that it did not bill Medicare for services not provided.

Services Not Reasonable and Necessary

Federal Requirements for Providing Reasonable and Necessary Services

Medicare requires home health aide services to be reasonable and necessary. Further, beneficiaries must not be able to perform the needed home health aide services themselves or have a willing caregiver provide these services (42 CFR § 409.45(b)(3)).

VNA of Central Jersey Did Not Always Meet Federal Requirements for Providing Reasonable and Necessary Services

For one of the sampled claims, VNA of Central Jersey incorrectly billed Medicare for home health aide services that were not reasonable and necessary.¹⁷ Specifically, the beneficiary was able to bathe independently and was already receiving assistance from his family. This error occurred because VNA of Central Jersey did not have adequate oversight procedures to ensure that services provided to the beneficiary complied with Medicare requirements for being reasonable and necessary.

¹⁶ This sample claim also did not meet homebound requirements.

¹⁷ This claim was also billed with skilled need services that were not medically necessary.

Incorrectly Billed Health Insurance Prospective Payment System Code

Federal Billing 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 that: “In order to be processed correctly and promptly, a bill must be completed accurately” (chapter 1, § 80.3.2.2).

VNA of Central Jersey Did Not Always Meet Federal Billing Requirements

For one of the sampled claims, VNA of Central Jersey assigned an incorrect HIPPS billing code to the Medicare claim. OASIS data and other supporting medical records did not support the billing code that was assigned when the claim was submitted. This error occurred due to a clerical error made by VNA of Central Jersey staff.

OVERALL ESTIMATE OF OVERPAYMENTS

On the basis of our sample results, we estimated that VNA of Central Jersey received at least \$2,015,925 in overpayments for the audit period.

RECOMMENDATIONS

We recommend that VNA of Central Jersey:

- refund to the Medicare program the portion of the estimated \$2,015,925 overpayment for claims incorrectly billed that are within the 4-year reopening period;¹⁸
- for the remaining portion of the estimated \$2,015,925 overpayment for claims that are outside of the Medicare reopening period, exercise reasonable diligence to identify and return overpayments in accordance with the 60-day rule, and identify any returned overpayments as having been made in accordance with this recommendation;
- exercise reasonable diligence to identify and return any additional similar overpayments outside of our audit period, in accordance with the 60-day rule, and identify any

¹⁸ OIG audit recommendations do not represent final determinations by Medicare. CMS, acting through a MAC or other contractor, will determine whether overpayments exist and will recoup any overpayments consistent with its policies and procedures. Providers have the right to appeal those determinations and should familiarize themselves with the rules pertaining to when overpayments must be returned or are subject to offset while an appeal is pending. The Medicare Part A and Part B appeals process has five levels (42 CFR § 405.904(a)(2)), and if a provider exercises its right to an appeal, the provider does not need to return overpayments until after the second level of appeal. Potential overpayments identified in OIG reports that are based on extrapolation may be re-estimated depending on CMS determinations and the outcome of appeals.

returned overpayments as having been made in accordance with this recommendation;
and

- strengthen its procedures to ensure that:
 - the homebound statuses of Medicare beneficiaries are verified and the specific factors qualifying beneficiaries as homebound are documented,
 - beneficiaries are receiving only reasonable and necessary skilled and home health aide services,
 - claims for Medicare reimbursement are only made for services that are provided, and
 - appropriate billing codes are assigned when submitting claims for Medicare reimbursement.

VISITING NURSE ASSOCIATION OF CENTRAL JERSEY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, VNA of Central Jersey, through its attorney, stated that it disagreed with our findings and did not concur with our recommendations. VNA of Central Jersey retained a home health care consultant to review most of the claims we questioned and submitted to us a report prepared by the consultant. VNA of Central Jersey also provided additional documentation for one sampled claim. VNA of Central Jersey challenged our selection of VNA of Central Jersey for audit as well as our independent medical review contractor's decisions, maintaining that nearly all of the sampled claims were billed correctly. In addition, VNA of Central Jersey alleged that OIG did not consider providing VNA of Central Jersey's responses and the report prepared by its consultant to our independent medical review contractor for a second review of the sampled claims we determined as incorrectly billed. Further, VNA of Central Jersey requested that OIG issue a revised draft report so that it can respond to our independent medical review contractor's second review. VNA of Central Jersey's comments, from which we have removed six exhibits, appear as Appendix F.¹⁹ We are providing VNA of Central Jersey's comments in their entirety to CMS.

¹⁹ VNA of Central Jersey included a number of exhibits as part of its comments on our draft report. Among the exhibits was a claim-by-claim rebuttal of the findings in our draft report prepared by the home health care consultant. We provided this exhibit to our independent medical review contractor as part of our request for an additional review of claims identified as having errors. However, because this exhibit was long and contained a considerable amount of personally identifiable information, we excluded it from this report. In addition, VNA of Central Jersey hired an external statistical expert and included his opinions in another exhibit. Because VNA of Central Jersey included its concerns regarding our statistical sampling and estimation methodology in the body of its comments, we excluded this exhibit from this report. Lastly, we also excluded exhibits that included resumes of VNA of Central Jersey's external statistical expert and individuals who worked for the health care consultant.

We followed normal OIG auditing procedures and conveyed our preliminary findings to VNA of Central Jersey at our exit conference. At that meeting, we explained that VNA of Central Jersey would have an opportunity to provide its comments on our draft report and that the comments would be incorporated into our final report.²⁰ Once we received VNA of Central Jersey's written comments on our draft report, we sent our sampled claims for a second review to our independent medical review contractor and included VNA of Central Jersey's written comments and the report by its consultant. Based on the results of that second review and our review of additional documentation provided by VNA of Central Jersey, we revised our determinations, reducing the total number of sampled claims incorrectly billed from 16 to 14, and revised our related findings and recommendations accordingly. We also adjusted the finding for 4 of the 14 claims. (The overpayment amount decreased for two claims and did not change for two claims.) In addition, we eliminated one error category included in the draft report. With these actions taken, we maintain that our remaining findings and recommendations are valid, although we acknowledge VNA of Central Jersey's right to appeal the findings. We describe below the reasons that VNA of Central Jersey did not concur with our recommendations and disputed our findings, as well as our responses.

STATEMENTS OF NONCONCURRENCE WITH RECOMMENDATIONS

Visiting Nursing Association of Central Jersey Comments

VNA of Central Jersey did not concur with our recommendations. Regarding our first recommendation, VNA of Central Jersey stated that our findings are flawed. VNA of Central Jersey stated that the audited claims were supported by the medical records and were billed correctly and should not be used as a basis to calculate an extrapolated overpayment. VNA of Central New Jersey also stated that it intends to challenge our sampling methodology and extrapolation on appeal.

VNA of Central Jersey stated that it did not concur with our second and third recommendations and that it plans to appeal our overpayment assessment through the Medicare appeals process for the reasons described above. VNA of Central Jersey did not concur with our fourth recommendation because, even if it accepted our findings, the error rate found in the audit (roughly 9 percent) is significantly less than the industry-wide improper payment rate for home health claims (42 percent) such that its compliance when measured against other providers is exemplary.

²⁰ We subsequently reiterated to VNA of Central Jersey that we would not consider sending claims to our independent medical review contractor for a second review until we received VNA of Central Jersey's written comments on our draft report.

Office of Inspector General Response

Regarding our first recommendation, based on the conclusions of our independent medical review contractor's additional medical review, we revised some findings related to homebound status and skilled services (and the associated recommended disallowance). We maintain that the remaining findings related to homebound status and skilled services are valid. In addition, we maintain that our statistical approach resulted in a legally valid and reasonably conservative estimate of the amount overpaid by Medicare to VNA of Central Jersey.

Regarding our second and third recommendations, we acknowledge VNA of Central Jersey's right to appeal the findings. Regarding our fourth recommendation, because VNA of Central Jersey 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 provided, (4) services that were reasonably necessary, and (5) claims that were assigned incorrect HIPPS payment codes, we maintain that it did not have adequate procedures to prevent the incorrect billing of Medicare claims.

OFFICE OF INSPECTOR GENERAL'S AUDIT PROCESS

Visiting Nursing Association of Central Jersey Comments

Under the heading, "The Selection of VNA Was Not Arbitrary," VNA of Central Jersey expressed concern about why it was selected for review, contending that the OIG informed VNA that it was selected in an arbitrary and neutral manner, whereas it appears to them that the OIG selected VNA of Central New Jersey because it is one of the largest home health providers in the nation based on volume of claims. VNA of Central New Jersey also stated that there is no data to suggest that it is an outlier and no evidence that it was at risk for noncompliance with Medicare billing requirements. Moreover, VNA of Central Jersey noted that the OIG audit encompassed services provided by two separate entities. Specifically, prior to January 1, 2016, Mega Care, Inc. provided home health services under its Medicare provider number. On January 1, 2016, Visiting Nurse Association Health Group, Inc., (VNA HG) and Mega Care, Inc. formed a joint venture, VNA of Central Jersey, which provided home health services under the Medicare provider number previously assigned to Mega Care, Inc.²¹ According to VNA of Central Jersey, the OIG "intentionally lumped the two together to validate its targeting of VNA and to amplify its audit findings."

VNA of Central Jersey stated that it had serious concerns about the qualifications of the OIG medical reviewer and that we did not provide any substantive information by which VNA of Central Jersey could assess the medical reviewer. VNA of Central Jersey also stated that, instead, each of the reviewer's medical determinations contains the same vague statement that the reviewer is a "physician who is duly licensed to practice medicine," "knowledgeable in the

²¹ VNA of Central New Jersey, through counsel, provided the Medicare number in correspondence to the OIG dated February 27, 2019.

treatment of the enrollee’s medical condition,” and “familiar with the guidelines and protocols in the area of treatment under review.” In addition, VNA of Central Jersey said that the reviewer’s “biography” does not reference home health and could be used for any licensed physician. Without receiving any information about the reviewer, VNA of Central Jersey stated that it can assess the reviewer only through his or her individual medical determinations of the audited claims.

Office of Inspector General Response

Conducting provider-specific audits is an essential part of OIG’s mission to fight fraud, waste, and abuse and promote efficiency, effectiveness, and economy in Medicare and other Department of Health and Human Services programs. Not only do these audits identify and return overpayments to the Medicare trust funds, they also provide a sentinel effect to encourage correct billing to the program. Further, these audits frequently identify broader vulnerabilities and lead to nationwide audits that are designed to inform CMS about potential issues and opportunities for strengthening Medicare.

We selected VNA of Central Jersey for audit using computer matching, data mining, and data analysis techniques. Specifically, our risk analysis for noncompliance with Medicare requirements enabled us to identify a high number of VNA of Central Jersey claims that fell into one or more compliance risk categories. Larger providers, such as VNA of Central Jersey, may be selected for audit because they have a higher volume of claims and Medicare payments in a given risk area or in several risk areas. However, smaller providers may also be selected for audit based on our assessment of high risk in one or more areas.

The OIG selection process for home health services audits were based on Medicare provider numbers. At the start of the audit, VNA of Central Jersey officials explained that the Medicare provider number specified by the OIG initially belonged to Mega Care, Inc., and was transferred to the resulting joint venture (VNA of Central Jersey). All home health services reviewed as part of this audit were claimed under the Medicare provider number associated with VNA of Central Jersey. We also note that we reviewed claims for home health services performed in CY 2015 that were provided by VNA HG as part of our sample. Overpayments made to Mega Care, Inc. or VNA HG are legal obligations of VNA of Central New Jersey (*Medicare Financial Management Manual*, ch. 3, § 130).

With respect to medical reviews, 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 were 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.

BENEFICIARIES WERE NOT HOMEBOUND

Visiting Nursing Association of Central Jersey Comments

VNA of Central Jersey disagreed with the medical reviewer's determinations related to sampled claims in which the beneficiary did not qualify as homebound under Medicare standards. VNA of Central Jersey stated that these determinations reveal that the medical reviewer consistently failed to apply the appropriate Medicare criteria for homebound status. VNA of Central Jersey stated that the medical reviewer consistently concluded that a beneficiary was not homebound if he or she could ambulate a certain distance in the home or had a family member or caregiver available to assist the beneficiary. VNA of Central Jersey also stated that the medical reviewer did not consider the entirety of the beneficiary's medical record and condition, as Medicare regulations require.

VNA of Central Jersey requested that the medical reviewer reconsider the claims for which the reviewer found that the beneficiary lacked homebound status and that we engage a different qualified medical reviewer to audit the claims at issue. VNA of Central Jersey stated that the medical reviewer's determinations reflect a fundamental lack of understanding of home health services and relevant Medicare regulations and guidance.

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 10, rather than 12, sampled claims were associated with beneficiaries who did not meet the criteria for being homebound (6 claims for the full episode of care and 4 claims for part of the episode of care).

Ambulation distance is one of many factors 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 was not noted in all of the medical reviewer's decisions, and when it was, it was 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 of Central Jersey's comments regarding caregiver assistance into consideration when performing its additional medical review and revised the determinations accordingly.

We disagree with VNA of Central Jersey's assertion that our medical reviewer allowed individual clinical factors to determine homebound status and, therefore, failed to consider the entire medical record. Our medical reviewer prepared detailed medical review determination reports that documented relevant facts and the results of the reviewer's analysis. We provided these reports to VNA of Central Jersey 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 homebound status in accordance with CMS's definition of homebound status.

As noted above, we revised the findings related to homebound status based on our independent medical review contractor's additional review of the sampled claims. We did not use a different medical reviewer. We maintain that our contractor is qualified and knowledgeable about Medicare regulations and guidance specific to home health services. Accordingly, having revised our findings and the associated recommendation with respect to 2 of the sampled claims identified in our draft report, we maintain that our findings for the remaining 10 claims, and the revised recommendation, are valid.

BENEFICIARIES DID NOT REQUIRE SKILLED SERVICES

Visiting Nursing Association of Central Jersey Comments

VNA of Central Jersey disagreed with all medical review determinations related to sampled claims with skilled services found to be not medically necessary. VNA of Central Jersey stated that the associated medical records clearly documented the beneficiaries' need for skilled services. VNA of Central Jersey stated that it disagreed with our finding that five claims were noncompliant as lacking "adequate controls to prevent the incorrect billing of Medicare claims."

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 (and the associated recommended disallowance) to specify that four, rather than five, 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, § 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, § 40.1.2.1.

Rather than disregarding the Manual's guidance related to the distinct disciplines of physical and occupational therapy or the 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 of Central Jersey and carefully considered this information to determine whether VNA of Central Jersey billed the claims in compliance with selected billing requirements. The contractor similarly evaluated VNA of Central Jersey's comments. For both the initial and subsequent medical reviews, the contractor reached carefully considered conclusions as to whether the services met coverage, medical necessity, and coding requirements.

Accordingly, having revised our finding and the associated recommendation with respect to one of the sampled claims identified in our draft report, we maintain that our finding for the remaining four claims in our final report, and the revised recommendation, is valid.

SERVICES NOT PROVIDED

Visiting Nursing Association of Central Jersey Comments

VNA of Central Jersey acknowledged that it billed one sampled claim for which the home health aide visit was not actually completed, and that the visit should have been made "non-billable" in its billing system. However, VNA of Central Jersey contended that the aide visit had no impact on reimbursement.

Office of Inspector General Response

We did not revise our finding related to the sampled claim and note that we fully disallowed the claim because it also did not meet homebound requirements. Accordingly, we maintain that inclusion of this finding in our report is appropriate. We contend that it is appropriate to include all deficiencies identified during an audit so that the provider may have the opportunity to develop corrective actions to ensure that it does not bill for services that do not comply with Medicare requirements.

SERVICES NOT REASONABLE AND NECESSARY

Visiting Nursing Association of Central Jersey Comments

VNA of Central Jersey disagreed with the medical review determination related to one sampled claim identified in our draft report as being incorrectly billed for home health aide services that were not reasonable and necessary. VNA of Central Jersey stated that all services were reasonable and necessary and that our medical reviewer failed to review the complete record and apply the appropriate Medicare regulation.

Office of Inspector General Response

Based on the conclusion of our independent medical review contractor's additional medical review, we did not revise our finding related to the claim for services that were not reasonable and necessary. The independent medical review contractor examined all the material in the beneficiary's medical records and carefully considered this information to determine whether VNA of Central Jersey billed the claim in compliance with selected billing requirements. For both the initial and subsequent medical reviews, the independent contractor reached carefully considered conclusions as to whether the services met coverage, medical necessity, and coding requirements.

Accordingly, we maintain that our finding for the one claim is valid. We maintain that this error occurred primarily because VNA of Central Jersey did not have adequate oversight procedures to ensure that services provided to the beneficiary complied with Medicare requirements for being reasonable and necessary.

INSUFFICIENT OUTCOME AND ASSESSMENT INFORMATION SET DOCUMENTATION

Visiting Nursing Association of Central Jersey Comments

For the one sampled claim identified in our draft report as having insufficient documentation, VNA of Central Jersey stated that it was able to locate documentation that OASIS data it submitted to CMS for the associated beneficiary was accepted and included the documentation with its comments. VNA of Central Jersey stated that it vehemently disagreed with our assertion that it did not have adequate procedures to always ensure that it complied with Medicare documentation requirements.

Office of Inspector General Response

Based on the additional documentation provided by VNA of Central Jersey, we revised our determination for this sampled claim and removed this error category from our report accordingly.

INCORRECTLY BILLED HEALTH INSURANCE PROSPECTIVE PAYMENT SYSTEM CODE

Visiting Nursing Association of Central Jersey Comments

VNA of Central Jersey disagreed that it assigned an incorrect HIPPS payment code to one sampled claim identified in our draft report. VNA of Central Jersey stated that our medical reviewer made a conclusory statement with limited supporting documentation and vehemently disagreed with our assertion that it did not have adequate procedures to ensure that the correct HIPPS payment code was billed.

Office of Inspector General Response

Based on the conclusion of our independent medical review contractor's additional medical review, we did not revise our finding related to the HIPPS payment code error (and the associated recommended disallowance) to specify that the incorrect HIPPS payment codes resulted in higher HHA payments for the one sampled claim.²²

The independent medical review contractor examined all the material in the beneficiary's medical records and carefully considered this information to determine whether VNA of Central Jersey billed the claim in compliance with selected billing requirements. For both the initial and subsequent medical reviews, the independent contractor reached carefully considered conclusions as to whether the services met coverage, medical necessity, and coding requirements.

Accordingly, we maintain that our finding for the one claim is valid. We maintain that this error occurred primarily because VNA of Central Jersey did not have adequate procedures to ensure that the correct HIPPS payment code was billed.

ESTIMATION OF OVERPAYMENTS

Visiting Nursing Association of Central Jersey Comments

VNA of Central Jersey stated that it objected to our use of extrapolation to estimate our overpayment amount. Specifically, it stated that extrapolation is inappropriate unless there exists a "sustained or high level of payment error." VNA of Central Jersey also stated that the statistical sampling and extrapolation methodology was flawed because the sample size was too small and failed to account for variations in the broader universe of claims, such as the complexity of the health conditions of beneficiaries in the universe of claims.

²² In our draft report, the claim was associated with beneficiaries who did not meet Medicare requirements for skilled need. However, our independent medical review contractor's additional medical review determined that this beneficiary required skilled services.

Office of Inspector General Response

We carefully considered VNA of Central Jersey'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 of Central Jersey. Federal courts have consistently upheld statistical sampling and extrapolation as a valid means to determine overpayment amounts in Medicare and Medicaid.²³ 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.²⁴ 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. To account for the potential differences between the sample and the sampling frame, we recommend recovery at the statistical lower limit of a two-sided 90-percent confidence interval.²⁵ 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, sample size, and differences between the sample and the sampling frame in a manner that favors the auditee.²⁶

VNA of Central Jersey contended that the validity of the lower limit could be impacted by the potential non-normality of the sample mean. To address this point, we compared our original approach against an alternative, known as the empirical likelihood method, that does not assume normality. The lower limit calculated using the empirical likelihood method was higher

²³ 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).

²⁴ 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).

²⁵ VNA of Central Jersey performed tests whose stated purpose was to show that the sample was not representative of the universe. Samples are not expected to match the sampling frame from which they are drawn. A key goal of statistics is to measure the differences between the sample and population and account for them in a reasonable manner. One well-supported approach for handling the potential differences between the sample and the sampling frame is to rely on the confidence interval, as was done here, rather than the point estimate obtained from the sample. The confidence interval is designed to reliably cover the sampling frame total of interest even though the sample itself may not match the population.

²⁶ See *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).

than our original calculation.²⁷ This result is not surprising given that the normal approximation is known to be conservative in situations like the current one where the overpayment amounts are positively skewed.

VNA of Central Jersey's statement that our extrapolation was inappropriate because our error rate did 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.²⁸

²⁷ The empirical likelihood approach resulted in a lower limit of \$2,428,694, which was higher than the \$2,015,925 that we calculated using RAT-STATS.

²⁸ The Act § 1893(f)(3); CMS *Medicare Program Integrity Manual*, Pub. No. 100-08, chapter 8.4 (effective Jan. 2, 2019).

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

Our audit covered \$66,010,746 in Medicare payments to VNA of Central Jersey for 19,603 home health claims with episode-of-care through dates in CYs 2015 and 2016. From this sampling frame, we selected for review a simple random sample of 100 claims with payments totaling \$333,971.

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

We limited our review of VNA of Central Jersey'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 fieldwork at VNA of Central Jersey.

METHODOLOGY

To accomplish our objective, we:

- reviewed applicable Federal laws, regulations, and guidance;
- extracted VNA of Central Jersey's paid claims data from CMS's NCH file for the audit period;
- removed payments for LUPAs and PEPs from the population to develop our sampling frame;²⁹
- created a sample frame of 19,603 claims totaling \$66,010,746;
- selected a simple random sample of 100 claims for detailed review (Appendix C: Statistical Sampling Methodology);
- reviewed available data from CMS's Common Working File for the sampled claims to determine whether the claims had been canceled or adjusted;

²⁹ We also removed payments for claims that were identified in the RAC Data Warehouse as previously excluded or under review, were duplicate claim numbers, and had the same "From" and "Through" dates of service.

- obtained and reviewed billing and medical record documentation provided by VNA of Central Jersey to support the claims sampled;
- 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 of Central Jersey's procedures for billing and submitting Medicare claims;
- verified State licensure information for medical personnel providing services to the patients in our sample;
- calculated the correct payments for those claims requiring adjustments;
- used the results of the sample to estimate the total Medicare overpayments to VNA of Central Jersey for our audit period (Appendix D: Sample Results and Estimates);
- discussed the results of our audit with VNA of Central Jersey officials; and
- after receiving VNA of Central Jersey's written comments on our draft report, had the independent medical review contractor perform an additional medical review of all of the claims that we questioned in our draft report, and incorporated those results into our own analysis and determination of the allowability of the claims in light of VNA of Central Jersey'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 outcomes; and to determine whether adjustments to the case-mix groups are warranted. HHA beneficiaries may be classified into 153 case-mix groups that are used as the basis for the HIPPS rate codes used by Medicare 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 or speech-language pathology, or occupational therapy;³⁰ (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

³⁰ 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, physical therapy service, or speech language pathology service as required by law. Once the 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)).

1835(a)(2)(A), 42 CFR § 409.42, and the Manual, chapter 7, § 30). 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 Act³¹ added a requirement to §§ 1814(a)(2)(C) and 1835(a)(2)(A) of the Act stating that the physician must 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, 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.³²

Confined to the Home

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 he or she has a condition, due to an 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). The Manual states that for a patient to be eligible to receive covered home health services under both Part A and Part B, the law requires that a physician certify in all cases that the patient is

³¹ The Patient Protection and Affordable Care Act, P.L. 111-148 (Mar. 23, 2010), as amended by the Health Care and Education Reconciliation Act of 2010, P.L. 111-152 (Mar. 30, 2010), collectively known as the Affordable Care Act.

³² 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.

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

Criteria 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 Criteria One conditions, then the patient must also meet two additional requirements defined in Criteria Two below.

Criteria 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: STATISTICAL SAMPLING METHODOLOGY

POPULATION

The population consisted of the VNA of Central Jersey's claims for home health services that it provided to Medicare beneficiaries whose final episode of care ended in CYs 2015 and 2016.

SAMPLING FRAME

The sampling frame consisted of an Access database of 19,603 home health claims from CMS's NCH file, for services provided by VNA of Central Jersey during CYs 2015 and 2016, totaling \$66,010,746.³³

SAMPLE UNIT

The sample unit was a home health claim.

SAMPLE DESIGN

We used a simple random sample

SAMPLE SIZE

We selected a sample of 100 claims.

SOURCE OF RANDOM NUMBERS

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

METHOD OF SELECTING SAMPLE ITEMS

We consecutively numbered the sample units in the sampling frame from 1 to 19,603. After generating 100 random numbers, we selected the corresponding frame items.

³³ We excluded from the frame claims that: (a) were identified in the RAC Data Warehouse as previously excluded or under review, (b) were duplicate claim numbers, (c) had the same From and Through dates of service, and (d) were LUPA claims or PEP claims.

ESTIMATION METHODOLOGY

We used the OAS statistical software to estimate the total amount of overpayments made to VNA of Central Jersey during the audit period at the lower limit of the two-sided 90-percent confidence interval. 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 95-percent of the time. We also used this software to calculate the corresponding point estimate and upper limit of the 90-percent confidence interval.

APPENIX D: SAMPLE RESULTS AND ESTIMATES

Sample Details and Results

Frame Size	Total Value of Frame	Sample Size	Total Value of Sample	Incorrectly Billed Sample Items	Value of Overpayments in Sample
19,603	\$66,010,746	100	\$333,971	14	\$21,553

Estimated Overpayments for the Audit Period
(Limits Calculated for a 90-Percent Confidence Interval)

Point estimate	\$4,224,962
Lower limit	2,015,925
Upper limit	6,433,999

APPENDIX E: TYPES OF ERRORS BY SAMPLE ITEM

Sample Number	Beneficiary Not Homebound	Beneficiary Did Not Require Skilled Services	Service Not Provided	Service Not Reasonable and Necessary	Home Health Care Billed Inappropriately	Overpayment
1						-
2						-
3						-
4						-
5	X					\$2,148
6					X	37
7						-
8						-
9						-
10						-
11						-
12						-
13						-
14						-
15						-
16	X		X			2,543
17						-
18						-
19						-
20	X					2,572
21						-
22						-
23						-
24						-
25						-
26						-
27						-
28						-
29						-
30						-

Sample Number	Beneficiary Not Homebound	Beneficiary Did Not Require Skilled Services	Service Not Provided	Service Not Reasonable and Necessary	Home Health Care Billed Inappropriately	Overpayment
31						-
32						-
33						-
34						-
35						-
36						-
37						-
38						-
39						-
40						-
41	X					2,885
42						-
43						-
44	X					414
45						-
46						-
47						-
48						-
49	X					3,057
50						-
51						-
52						-
53						-
54						-
55						-
56						-
57						-
58						-
59						-
60						-
61	X					3,351

Sample Number	Beneficiary Not Homebound	Beneficiary Did Not Require Skilled Services	Service Not Provided	Service Not Reasonable and Necessary	Home Health Care Billed Inappropriately	Overpayment
62						-
63						-
64						-
65						-
66						-
67						-
68						-
69	X					913
70	X					520
71						-
72						-
73						-
74		X		X		937
75						-
76	X	X				937
77						-
78						-
79		X				412
80						-
81						-
82						-
83						-
84		X				827
85						-
86						-
87						-
88						-
89						-
90						-
91						-
92						-

Sample Number	Beneficiary Not Homebound	Beneficiary Did Not Require Skilled Services	Service Not Provided	Service Not Reasonable and Necessary	Home Health Care Billed Inappropriately	Overpayment
93						-
94						-
95						-
96						-
97						-
98						-
99						-
100						-
Totals:	10	4	1	1	1	\$21,553

APPENDIX F: VISITING NURSE ASSOCIATION OF CENTRAL JERSEY COMMENTS

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July 26, 2019

SENT VIA KITEWORKS & FEDEX

OFFICE OF AUDIT SERVICES, REGION II
ATTN: MS. BRENDA M. TIERNEY
REGIONAL INSPECTOR GENERAL FOR AUDIT SERVICES
DEPARTMENT OF HEALTH AND HUMAN SERVICES
OFFICE OF INSPECTOR GENERAL
JACOB K. JAVITS FEDERAL BUILDINGS
26 FEDERAL PLAZA, ROOM 3900
NEW YORK, NY 10278

Re: Office of Audit Services Draft Report Number A-02-17-01025

Dear Ms. Tierney:

I am writing on behalf of my client, Visiting Nurse Association of Central Jersey Home Care and Hospice, Inc. ("VNA") in response to the US Department of Health and Human Services ("HHS"), Office of Inspector General's ("OIG") draft audit report A-02-17-01025, dated June 14, 2019 (the "Draft Report").¹

The Draft Report contains significant legal errors and mischaracterizes the facts to support findings where there are none. Many of these errors result from the OIG's reliance on outside contractors to review the medical and technical requirements of home health eligibility and billing. Within several weeks of VNA receiving copies of the medical determinations drafted by the OIG's outside contractors, VNA submitted a lengthy response including rebuttals to each of the denied claims from a highly qualified home health specialized physician and independent, third-party nurse and therapist reviewers. These rebuttals contested the findings of the OIG's medical reviewers and highlighted the faulty legal, clinical and factual findings in the medical determinations.

Despite receiving assurances from the OIG that it would consider providing VNA's response to its medical reviewers to allow them to re-review the claims, VNA was told by the OIG it was received, but that it did not consider VNA's submission. Instead, the OIG waited four additional months and issued the Draft Report with no consideration of VNA's response. **VNA renews its request for the OIG to submit VNA's response to the Draft Report to its contracted medical reviewers for reconsideration of the sixteen claims based on sound medical reasoning and an accurate application of Medicare statutes, regulations and guidance. Following this reconsideration, VNA requests the opportunity to review and comment on a**

¹ In accordance with our prior communication with Brenda Tierney, Regional Inspector General for Audit Services, this response is timely submitted by the July 29, 2019, extended submission deadline. Note that VNA is not currently, and has never been, affiliated with "Home Health VNA" which was subject to an OIG OAS Audit in August 2016 (A-01-13-00518).

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revised draft report before the issuance of the Final Report. VNA has, and will continue to, fully cooperate and provide timely responses.

Although VNA strongly disagrees with the findings, the Draft Report reflects that VNA had a compliance rate of 95 percent or higher in five out of the six areas addressed. The one area VNA was below 95 percent was homebound status (88 percent compliance), but the OIG's conclusions related to homebound status are flawed as they rely on an outside medical reviewer who consistently misapplied Medicare billing requirements.

VNA strongly disagrees with both the methodology and the findings of the Draft Report and does not concur with any of the OIG's recommendations. The majority of the outside reviewer's findings reflect no more than a difference in medical opinion about an individual patient's condition, and thus do not constitute systemic "error" supporting extrapolation.

I. VNA DOES NOT CONCUR WITH OIG RECOMMENDATIONS

For the reasons set forth below, VNA does not concur with any of the four recommendations in the Draft Report.

A. OIG RECOMMENDATION NUMBER ONE

Refund to the Medicare program the portion of the estimated \$3,443,941 overpayment for claims incorrectly billed that are within the reopening period.

VNA Response: VNA DOES NOT CONCUR WITH THIS RECOMMENDATION.

All of the OIG's findings regarding the audited claims are flawed. Based upon a review by a third party expert, which is detailed in the rebuttal statements submitted with this response, the audited claims are supported by the patient's medical records and were billed appropriately. The sampling methodology is not statistically valid and should not be used as a basis to calculate an extrapolated overpayment. VNA intends to vigorously challenge negative claims findings and any sampling methodology used to calculate and extrapolate overpayments following the issuance of a final report by exercising its right to appeal any adverse findings through the Medicare administrative appeals process. VNA anticipates that any alleged overpayment will be eliminated. Therefore, any refund to the Medicare program is inappropriate.

B. OIG RECOMMENDATION NUMBER TWO

For the remaining portion of the estimated \$3,443,941 overpayment for claims that are outside of the Medicare reopening period, exercise reasonable diligence to identify and return overpayments in accordance with the 60-day rule, and identify any returned overpayments as having been made in accordance with this recommendation.

VNA Response: VNA DOES NOT CONCUR WITH THIS RECOMMENDATION.

VNA acknowledges its legal obligation to exercise reasonable diligence to identify potential overpayments within the preceding six years based upon receipt of credible information

that an overpayment may exist.² The Centers for Medicare & Medicaid Services (“CMS”) has acknowledged, however, that a provider that receives notice of a potential overpayment through an audit may reasonably determine that additional investigation of potential additional overpayments is premature during the audit appeals process.³ As noted above, VNA disagrees with the OIG’s findings and believes each of the audited claims is supported by the patient’s medical records and was billed appropriately.

C. OIG RECOMMENDATION NUMBER THREE

Exercise reasonable diligence to identify and return any additional similar overpayments outside of our audit period, in accordance with the 60-day rule, and identify any returned overpayments as having been made in accordance with this recommendation.

VNA Response: VNA DOES NOT CONCUR WITH THIS RECOMMENDATION.

VNA does not concur with this recommendation for the same reasons that it does not concur with Recommendations #1 and # 2, as described above.

D. OIG RECOMMENDATION NUMBER FOUR

Strengthen its procedures to ensure that:

- *The homebound statuses of Medicare beneficiaries are verified and the specific factors qualifying beneficiaries as homebound are documented,*
- *Beneficiaries are receiving only reasonable and necessary skilled and home health aide services,*
- *Claims for Medicare reimbursement are only made for services that are provided,*
- *Proper documentation is maintained to support services provided, and*
- *Appropriate billing codes are assigned when submitting claims for Medicare reimbursement.*

VNA Response: VNA DOES NOT CONCUR WITH THIS RECOMMENDATION.

Even assuming that the audit results are valid – which they are not – VNA has a compliance rate of 88-95 percent in all six of the areas identified by the OIG. For 2016, CMS determined through its Comprehensive Error Rate Testing program that the improper payment error rate for home health claims industry-wide was 42 percent. Here, even if you accept as valid all of the OIG’s findings, VNA has an error rate of roughly 9 percent. This means that VNA’s compliance, when measured against other providers, is exemplary.

² 42 C.F.R. § 401.305.

³ See Medicare Program; Reporting and Returning Overpayments, 81 Fed. Reg. 7,654, 7,667 (Feb. 12, 2016).

Nevertheless, the OIG has attempted to mischaracterize and overstate its findings. Rather than recognizing that VNA has done exceptionally well in a complex and ever-changing regulatory environment where compliance takes considerable resources and attention, the OIG has attempted to portray VNA as a bad actor. A close look at the OIG's findings, together with this response, reveals that there is no systemic issue and that VNA is a model for how home health care should be provided, how claims should be reviewed and billed and how a robust compliance program will ensure that a provider continues to evolve with the ever-changing regulatory landscape. Implementation of further policies and procedures is unnecessary, as this audit proves that VNA's compliance program has been, and will continue to be, successful.

II. INTRODUCTION & BACKGROUND

VNA is a 107-year-old non-profit organization with a rich history dedicated to helping individuals and families achieve their best well-being by providing compassionate, coordinated and innovative care.⁴ VNA started as a local, charity-based, mission-driven nursing service that brought care into the homes of people most in need. Since that very humble beginning, VNA has grown (both organically and through ventures with other not-for-profit partners) into one of the largest not-for-profit home health enterprises in the country. It fully embraced the Medicare home health program from its inception, appreciating those Medicare dollars would allow it to continue its charitable mission and serve a rapidly growing frail elderly population. VNA's vision is to lead the transformation of home and community health care to achieve the highest level of quality, access and value by providing home health care, hospice, palliative, and community-based care. VNA is physician-led and provides quality services and favorable outcomes.

VNA has developed and implemented a robust compliance program. The program includes each of the seven fundamental elements of an effective compliance program in the OIG's compliance guidance for home health agencies. VNA employs a full-time compliance officer who holds a certificate in health care compliance through the Compliance Certification Board affiliated with the Health Care Compliance Association. VNA also conducts comprehensive internal and external, targeted and routine, compliance, quality assurance and clinical documentation audits. Further, VNA uses one of the most advanced EMR systems available to allow it to review and approve claims before submission to ensure compliance with billing and coding regulations. VNA provides regular training for its home health providers and billing department, including annual compliance training and has an established policy addressing identification and refund of overpayments.

The compliance rate found in this audit is even more remarkable given the fact that this is really an audit of two separate home health providers. The OIG reviewed claims submitted between CY 2015 and CY 2016. On January 1, 2016, Visiting Nurse Association Health Group, Inc. ("VNA HG") and Mega Care, Inc. combined to create a new joint venture, the VNA, which from that date forward used VNA HG's systems, records, policies and procedures. Therefore, every OIG inquiry and finding about billing, medical records, policies and manuals (or anything related) in 2015, is a finding related solely to Mega Care, Inc. Despite requests to the OIG to recognize and incorporate this significant distinction into this audit, the OIG lumped the two agencies together for its analysis and has extrapolated a total damages figure far larger than either

⁴ VNA's 107-year history includes former predecessor organizations. For ease of reading, we will refer to all predecessor organizations as "VNA."

agency would have been singly accountable. VNA submits this combined reporting unfairly and unfavorably impacts the audit results.

VNA's commitment to ongoing compliance is reflected in its PEPPER reports. The Program for Evaluating Payment Patterns Electronic Report ("PEPPER") is an educational tool developed by TMF Health Quality Institute under contract with the CMS that summarizes a home health agency's claims data for services in areas identified as high risk for improper payments. The PEPPER report explains that any score above an 80 percent indicates that the home health agency may be a higher risk for improper payment. VNA ranks well below this benchmark. In its most recent PEPPER report, VNA ranks in the 26th percentile nationally for the average number of episodes per beneficiary, the 2nd percentile nationally for the proportion of high therapy utilization episodes and the 33rd percentile nationally for proportion of outlier payments by Medicare. In the previous PEPPER report, with claims data overlapping the audit period, VNA ranked in the 24th percentile nationally for the average number of episodes per beneficiary, the 1st percentile nationally for the proportion of high therapy utilization episodes and the 14th percentile nationally for proportion of outlier payments by Medicare.

III. CONCERNS RELATED TO THE OIG'S AUDIT PROCESS

A. THE SELECTION OF VNA WAS NOT ARBITRARY

VNA has numerous concerns with the OIG's audit process. First, the OIG originally conveyed that selection of VNA for this audit was arbitrary and neutral. In the OIG's Draft Report, however, it appears the OIG targeted VNA because it is one of the largest home health providers in the nation based on its volume of claims. There is no data to suggest that VNA is an outlier. To the contrary, as the PEPPER reports indicate, the data supports VNA's compliance with Medicare billing requirements. And, despite a claim in its Draft Report to the contrary, the OIG has presented no evidence that VNA was at risk for noncompliance with Medicare billing requirements. VNA renews its previous request that the OIG remove the language found on Page 3 of the Draft Report related to this issue because it is inaccurate and irrelevant.

Specifically, VNA has concerns with this language because (1) the sentence is factually inaccurate, and (2) where VNA falls regarding volume of claims is irrelevant - especially where the results of the audit show that VNA has good compliance safeguards in place. And, this audit period covers two separate providers. The 2015 claims were Mega Care's; the 2016 claims are VNA's. Nonetheless, the audit treats the two as though they were the same agency throughout the audit period. VNA again submits that the OIG has intentionally lumped the two together to validate its targeting of VNA and to amplify its audit findings.

B. OIG MISCHARACTERIZED RESULTS & MEDICAL REVIEWER WAS NOT QUALIFIED

The OIG's mischaracterizations begin in the first sentence of its report when it alleges that VNA did not comply with Medicare billing requirements for 16 out of 100 home health claims it reviewed. In reality, according to the OIG's own findings, VNA is 95-99 percent compliant in five out of six areas in which the OIG purportedly discovered issues: whether beneficiaries required skilled services (95 percent compliant); whether services were provided (99 percent compliant);

whether services were reasonable and necessary (99 percent compliant); whether documentation supported the claim (99 percent compliant); and whether the claim contained the correct HIPPS code (99 percent compliant). For the sixth area addressed in the Draft Report (whether the beneficiaries were homebound), the OIG concluded that a beneficiary was not homebound for the full episode of care for only seven out of the 100 audited claims. Thus, even accepting the OIG's findings as accurate (which, they are not), 93 percent of VNA's beneficiaries were homebound and eligible for home health services for part or all of the audited episodes.

VNA also has serious concerns about the qualifications of the OIG's unidentified medical reviewer. The OIG has provided no substantive information to validate the reviewer's qualifications. Instead, each of the reviewer's medical determinations contains the same vague 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." The reviewer's "biography" does not even reference home health experience and could be used – and presumably has been used – for any licensed physician of any training or qualification. Additionally, the OIG was unwilling to verify whether the physician reviewer wrote the medical determinations upon which it relied, or whether these were written by a non-physician clinician (with a physician presumably later signing off on them). Receiving no information about the reviewer or the actual author of the medical determinations, VNA can assess the reviewer only through his or her individual medical determinations of the audited claims.

As discussed in additional detail below, we raise this concern because each of the reviewer's findings regarding homebound status and the need for skilled services was flawed, and appeared to be the opinion of someone unfamiliar with Medicare home health guidelines. Specifically, the reviewer consistently concluded that a beneficiary was not homebound if he or she could ambulate in the home or if the beneficiary had a family member or caregiver available for assistance. Those simply are not the standards for determining homebound status under applicable federal regulations. These statements would likewise not provide a basis for determining that a beneficiary is not homebound for purposes of eligibility for home health services. Given the reviewer consistently concluded the beneficiaries were not homebound on such grounds establishes that the reviewer is *not* qualified to accurately assess the home health services that VNA provided to Medicare beneficiaries.

Besides the clinical errors underlying the Draft Report, the OIG's statistical sampling and extrapolation methodology also was flawed. The OIG's sample was flawed because the sample size was too small, arbitrarily chosen and failed to account for variations in the broader universe of claims. In addition, the distribution of the overpayment averages derived from the OIG's sample was skewed, making the lower bound of the OIG's confidence interval incorrect. For all of these reasons, extrapolation of purported overpayments across the universe of VNA's claims is inappropriate.

Finally, as VNA has discussed with the OIG, the title of the Draft Report differs from the previous final reports issued by the OIG and is a misleading summation of the OIG's findings. And, although VNA disagrees with the OIG's conclusions, VNA requests that if the OIG is unwilling to change its ultimate finding(s), the title of the final report be identical to the other similar audit final reports issued by the OIG in 2019.⁵

C. THE OIG REFUSED TO CONSIDER VNA'S INTERIM RESPONSE TO MEDICAL DETERMINATIONS & VNA RENEWS ITS REQUEST FOR MEDICAL RECONSIDERATION

Pursuant to its protocol, the OIG conducted an Exit Conference with VNA in late-January 2019 where it presented VNA with its preliminary results. During the Exit Conference, VNA requested additional details about the findings and requested copies of the medical determinations. VNA also asked if it could have an opportunity to respond to the medical determinations before the issuance of the Draft Report. Specifically, VNA asked if the OIG would take VNA's response to the OIG's medical reviewers for reconsideration. The OIG stated that it would consider taking a response to the medical reviewers for reconsideration. Following the Exit Conference, the OIG provided copies of the medical determinations to VNA. Less than a month later, VNA submitted a detailed, thoughtful response to every one of the OIG's Exit Conference medical determinations. Each submittal included rebuttals from a highly-qualified home health physician and also independent, third-party nurse and therapist reviewers. These expert rebuttals contested every finding by the medical reviewer and highlighted the faulty legal, clinical and factual findings in the OIG's medical determinations. Because of its substantial disagreement with the reviewer's initial findings, VNA requested on multiple occasions that its responsive submission either be reconsidered by that external reviewer or be presented to a new reviewer, before the issuance of the Draft Report, to correct the issues identified by VNA.

The OIG did neither. When the OIG issued the Draft Report four months after VNA's submission, VNA was disappointed to see that the OIG's findings in the Draft Report were identical to those from the Exit Conference. The OIG confirmed that, despite having a fulsome response from VNA and four months in which to consider it, the OIG decided not to take a single claim back to its medical reviewer for reconsideration. Citing to a "new policy," the OIG instead continued those initial determinations right into the Draft Report.

In this response, VNA renews its request that the OIG take the Draft Report, including the expert rebuttals, back to its medical reviewers for reconsideration. Because its rebuttals are based on reviews done by licensed medical experts with knowledge of home health, VNA also asks that the OIG have a physician with home health experience review them and have that physician make the determination whether reconsideration is warranted. VNA is very concerned that the OIG has stated non-clinicians will determine whether additional outside medical review is warranted, and submits that a review by a non-clinician would be meaningless. The clinical issues raised by VNA must be considered by clinicians qualified to review the issues for a fair determination to be made.

⁵ The titles of the Final Reports issued by the OIG in 2019 are: (1) Great Lakes Home Health Services, Inc. Billed for Home Health Services That Did Not Comply With Medicare Coverage And Payment Requirements; (2) Metropolitan Jewish Home Care, Inc. Billed For Home Health Care Services That Did Not Comply With Medicare Requirements; (3) EHS Home Health Care Service, Inc. Billed For Home Health Services That Did Not Comply With Medicare Coverage And Payment Requirements; and (4) Excella Homecare Billed For Home Health Services That Did Not Comply With Medicare Coverage And Payment Requirements.

VNA again requests the opportunity to review and comment on a revised draft report before the issuance of the Final Report.

IV. RESPONSE TO THE OIG'S FINDINGS

The Draft Report alleges that VNA did not comply with Medicare billing requirements for 16 out of the 100 home health claims that the OIG audited, resulting in an alleged overpayment of \$31,306. The OIG concluded that VNA improperly billed claims in these five ways: (1) beneficiaries did not meet homebound criteria (12 claims; 7 full-episode, 5 part-episode); (2) beneficiaries did not require skilled services (5 claims; 5 part-episode); (3) services were not provided (1 claim); (4) services were not reasonable or necessary (1 claim); (5) documentation was inadequate to support the services provided (1 claim); and (6) incorrect Health Insurance Prospective Payment System Code was assigned to a claim (1 claim).

Overall, the analysis of the OIG's reviewers reveals a consistent and problematic theme: the OIG's reviewers failed to apply the appropriate Medicare criteria for determining a patient's eligibility for Medicare home health services.⁶ Specifically, the OIG's reviewers repeatedly failed to view the medical record as a whole. Instead, they appeared to allow individual clinical comments made by non-physicians to drive the conclusion that a particular beneficiary was not eligible for home health services. In doing so, the OIG's reviewers applied – and appeared to rely exclusively or primarily on – criteria for evaluating eligibility not contained in the Medicare regulations, and often failed to “*apply the review process to the entire patient's medical record*” as required by CMS regulations and guidance.⁷ When considering the entire record, particularly the documents by the physicians who actually physically evaluated the patients, the OIG's reasons to issue partial or full denials in its preliminary report are not supported.

Perhaps the most telling evidence is that the OIG medical reviewers did not contradict the certifying physician's attested medical opinion that a patient was eligible for home health services. Instead, throughout the OIG medical determinations, its reviewers cherry-picked and relied upon isolated chart notes made by a physical or occupational therapist evaluating the patient not for homebound eligibility, but for that patient's progress relative to the individual therapy service being provided at that time. In other words, the external medical reviewers ignored the medical opinion of the home health “gatekeeper” (*i.e.*, the certifying physician), in favor of what was usually a single observation documented within a note by a physical therapist (“PT”) or occupational therapist (“OT”), often outside of the home health episode. These PTs and OTs, it should be noted, lack the authority to order home health services. For this reason, as well as those set forth below, the OIG should have its medical reviewers consider the enclosed analyses and reconsider their initial determinations.

VNA takes these allegations seriously and disputes all of the findings. To evaluate the OIG's findings objectively, VNA engaged LW Consulting, Inc., a reputable third-party auditor with substantial experience in home health care, to review the allegedly improper claims. LW auditors come from multiple clinical disciplines, including nursing and therapy, and each has over twenty years of experience in home health clinical operations and Medicare reimbursement

⁶ Medicare Program Integrity Manual, Ch. 6, § 6.2.3.

⁷ *Id.*

criteria. Patty Klinefelter is a registered nurse and the Director of LW's Home Health and Clinical division. She has over thirty years of experience in home health performing compliance audits, developing policies and procedures and conducting survey readiness. Cathy Trescott is a registered nurse with thirty-five years of experience in home health, including providing quality and compliance review of coverage criteria, OASIS data, ICD-10-CM coding, documentation, quality improvement measures, Medicare compliance and patient safety. Attached as Exhibit 1 are the curricula vitae of the LW auditors.

VNA also is uniquely resourced for reviewing the OIG's findings in that its President and CEO is a Cleveland Clinic-trained, nationally recognized geriatrician who has spent his career in the home health field. Steven Landers, MD, MPH has been routinely consulted by Congress and CMS to advise on home health policy, and was a Trustee on the Board of the Visiting Nurse Associations of America (VNAA). Attached as Exhibit 2 is Dr. Landers' curriculum vitae. Dr. Landers also completed an in-depth clinical review of each claim at issue in this audit.

As explained in more detail in the individual rebuttal statements prepared by Dr. Landers and the individual rebuttal statements prepared by LW Consultants, which are attached as collective Exhibit 3 (organized by patient), both experts independently concluded the OIG's Preliminary Findings in all of the sixteen claims are in error and not supported by the patients' medical records. We highlight the gross disparity between the OIG's external reviewers and the VNA experts by presenting their analyses of certain of the specific audited claims, and of the examples set forth in the OIG's Draft Report, below.

A. ALL OF THE BENEFICIARIES IN THE AUDITED SAMPLE WERE HOMEBOUND

A home health provider may only receive payment for home health services provided to a beneficiary who is homebound.⁸ To be homebound, a beneficiary must satisfy two criteria. First, the beneficiary either must have 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, the use of special transportation, or the aid of a supportive device (e.g., crutches, cane, wheelchair, or walker), or must have a condition such that leaving the home is medically contraindicated.⁹ Second, the beneficiary must have a normal inability to leave home and doing so must require a considerable and taxing effort and expense.¹⁰ An individual need not be bedridden to be homebound. In fact, a beneficiary can leave the home and nevertheless be considered homebound if the absences from the home are infrequent or for periods of relatively short duration, or are attributable to the need to receive health care treatment.¹¹ Homebound status is not contingent upon a single clinical factor; rather, Medicare guidance acknowledges that "longitudinal clinical information about the patient's health status" is typically necessary to evaluate and categorize a patient as homebound.¹² Such information "about the patient's overall health status may include, but is not limited to, such factors as the patient's diagnosis, duration of the patient's condition,

⁸ 42 U.S.C. § 1395f(a)(2)(C); 42 C.F.R. § 409.42.

⁹ Medicare Benefit Policy Manual, Ch. 7, § 30.1.1.

¹⁰ *Id.*

¹¹ *Id.*

¹² *Id.*

clinical course..., prognosis, nature and extent of functional limitations, other therapeutic interventions and results, etc.”¹³

In this audit, the OIG alleges that seven out of 100 beneficiaries did not qualify as homebound for the entire home health episode and five out of 100 did not qualify as homebound for part of an episode when reviewed under Medicare’s standards. The medical determination letters provided by the OIG reveal that the OIG’s medical reviewer consistently misapplied Medicare’s homebound requirements. The OIG’s medical reviewer also ignored or missed clinically significant data in the medical records, failed to apply appropriate legal requirements and/or disregarded the complete patient information in favor of select excerpts.

The OIG Draft Report highlights two specific examples of beneficiaries it claimed failed to meet homebound criteria. These two examples instead show exactly how the OIG misapplied Medicare guidance:

- **Response to Example 1, Sample Patient No. 16 (Full-Episode Denial):** The Draft Report and external reviewer characterize the care of this beneficiary in a way that is both misleading and factually incorrect. Specifically, the OIG concluded this beneficiary was not homebound because he was “being treated on an outpatient basis for chronic pulmonary disease.” That outpatient treatment, however, was provided by the beneficiary’s own physician in the patient’s home. The physician traveled there precisely because the patient was too weak to leave the home. Outpatient care does not disqualify a patient from home health eligibility. In fact, Medicare guidance expressly permits it, provided the other eligibility criteria are met – as they clearly are in this case.

When the patient’s condition is reviewed in light of his entire clinical record, it is almost inconceivable that the OIG could conclude this beneficiary was not homebound. This 90-year-old patient—with severe co-morbidities including atrial fibrillation, suspected cancer with a documented lung mass, and aortic aneurysm repair—began home care shortly after a three-day inpatient hospitalization for an acute respiratory infection and heart failure.

The patient had lost 40 pounds within the past year, and was cachectic, thin, and frail with temporal wasting. His physical decline continued after his return home, with the record noting that he was too weak to make it to the medical office, suffered from low albumin levels and low kidney function, and had worsening bronchitis and respiratory symptoms. About a week out from this hospitalization, this beneficiary was seen *at home* by *his internal medicine physician because he was too weak to make it to the medical office per the physician note*. This beneficiary continued to be seen at home by his own physician until that physician decided the patient was appropriate for home health care and referred the patient to VNA.

¹³ *Id.*

The OIG reviewer acknowledged that at admission, the patient had dyspnea with minimal exertion, was at a high risk for falls, and suffered from decreased strength in his lower extremities. That reviewer noted the patient experienced shortness of breath when ambulating only 20 feet, had low endurance, had difficulty breathing, and required the assistance of another person to leave the home, and even within the home for basic activities of daily living, like bathing, toileting, and dressing. Nonetheless, that same reviewer concluded the patient was not homebound because a single PT note, made three days after admission and in stark contrast to all other documentation, opines the patient was functionally independent and did not need assistance to ambulate in the home.

That single PT note was based on an observation of the patient's gait only indoors and only on level surfaces, and which failed to assess all activities of daily living. On that very same day, a social worker documented the patient's severe depression, which was related to the patient's inability to care for himself and perform activities of daily living. Throughout the rest of the episode, the patient's record consistently documented the patient's homebound status and need for assistance with personal care. In fact, when the patient's daughter—his caregiver—had to leave for a month, she planned to arrange for alternate care for the patient, and ultimately opted take the patient with her, leading to his discharge from homecare; this further illustrates his lack of functionality in the home. The patient was demonstrably homebound throughout the entire episode. The reviewer ignored all of this other documentation to the contrary and rested its conclusion on a single unsupported therapy note.

Additionally, PTs may not order home health services. It was an error for the reviewer to rely on this isolated comment rather than the certifying physician's judgment based on a more robust review of the patient's entire record.

- **Response to Example 2, Sample Patient No. 44 (Partial-Episode Denial):** The OIG acknowledged this patient was initially homebound at the beginning of the episode of care. The medical reviewer contended this 86-year-old patient was not homebound as of July 26, 2016. The reviewer so reasoned because the patient was performing all of her exercises and was able to ambulate with a cane both indoors and outdoors, including on uneven ground such as grass, gravel, and an asphalt driveway. The medical reviewer further contended that the patient's wound from her recent hysterectomy had healed and that she had no other medical contraindications.

However, the reasons the OIG reviewer gave in support of the patient not being homebound do not support, and actually undermine, the reviewer's conclusion. First, the reviewer established that the first homebound criteria was met by acknowledging the patient needed an assistive device—a cane—to ambulate outside of the home. As the reviewer also noted, the patient continued to require stand-by assistance *in addition to her cane* to leave the home; her continued need for stand-by assistance or supervision when ambulating with her cane was well documented even after July 26. As for the second criteria, the patient was referred to home health after hospitalization for a total abdominal hysterectomy performed

due to the patient's endometrial cancer and vaginal bleeding, which likely resulted in anemia. The patient's post-operative weakness required her to take frequent rests because she tired easily; this contributed to the considerable and taxing effort for her to leave the home. The patient's continued homebound status was documented throughout the record. Neither the fact that she performed her exercises as prescribed, nor that her wound had healed, undermines this determination on her homebound status throughout the entire episode.

Although the OIG intended these two examples to illustrate that VNA treated patients who did not meet homebound criteria, the voluminous medical records (including the notes of one of the patient's own physician) illustrate the opposite—especially when reviewed under correct application of Medicare guidelines.

The OIG's other medical determinations throughout the audit also were riddled with the medical reviewer's misapplication and misunderstanding of the Medicare guidance. Specifically, the reviewer applied impermissible standards to determine homebound status. The reviewer consistently concluded that a beneficiary was not homebound if he or she could ambulate a certain distance even with assistance in the home or at an acute or post-acute facility predating the home health episode. Over 60% of the medical reviewer's denials cited a specific distance as its rationale for finding the beneficiary was not homebound.

According to the medical reviewer, the ability to ambulate between twenty steps and 500 feet disqualifies a beneficiary from being homebound. Most frequently, the medical reviewer relied on a distance of 200-250 feet to determine that a beneficiary was no longer homebound. This is contrary to Medicare guidance and is not appropriate criteria for evaluating homebound status under Medicare regulations. A beneficiary can absolutely ambulate in the home while being considered homebound because that ability has no bearing on his or her ability to leave the home. Similarly, Medicare regulations specifically contemplate that a homebound beneficiary may only be able to leave the home with the assistance of another individual. Requiring the assistance of another to leave the home is the very essence of being homebound, yet the OIG reviewer turned that on its head and concluded (in five of 12 denials) that having available the assistance of another meant the beneficiary was not homebound.

The Medicare Benefits Policy Manual ("MBPM") explicitly prohibits using a bright-line standard such as ambulation distance to determine homebound status. Homebound status must be based on each individual beneficiary's unique medical condition as determined through a comprehensive assessment of the patient's overall health and circumstances. Measurements such as ambulation distance cannot be dispositive of homebound status. The MBPM states 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 screens, diagnostic screens, or specific treatment norms is not appropriate."¹⁴ Thus, using a numerical standard such as ambulation distance to determine homebound status directly contradicts Medicare guidance.

¹⁴ MBPM, Ch. 7 § 20.3.

- **Sample Patient No. 20 (Full-Episode Denial):** The OIG reviewer concludes this patient was not homebound. In reaching this decision, the reviewer notes that ten days before her admission, the patient ambulated 245 feet times two *with a rolling walker* and perform transfers *with supervision*; the reviewer also acknowledges that the patient was limited by endurance and shortness of breath on this day.

While a patient's need for an assistive device and supervision, together with poor endurance and difficulty breathing, are typically the hallmarks of homebound status, the OIG reviewer inexplicably cited them to conclude that the patient was not homebound. The reviewer's singular focus on distance (245 feet) meant the reviewer missed and/or ignored the rest of the patient's serious and complex medical condition, instead relying on a single measure in the record.

Had the reviewer considered the patient's record as a whole, her homebound status would have been self-evident. Weeks before her admission, the patient was hospitalized for dizziness, urinary tract infection, pleural effusion, shortness of breath, and hypoxia; the hospital's clinical team stated the patient would need rehabilitation and nursing services before she could safely return home. She also required close supervision to ambulate safely. Throughout the episode, the patient's clinical notes indicated that the patient took medications that increased her risks of falling and having severe bleeding complications in the event of a fall. The record illustrated that the patient was often weak, short of breath, and became delirious with new medical conditions or exacerbations of existing conditions which, unfortunately for this 90-year-old patient, occurred frequently. She had unsteady gait, poor balance, impaired functional mobility, and needed assistance with activities of daily living and for safe ambulation. The patient was clearly homebound throughout this entire episode. The OIG reviewer literally took a fraction of one single data piece—"ambulate 245 feet"—and, to the exclusion of the rest of the record, concluded the patient was not homebound.

- **Sample Patient No. 49 (Full-Episode Denial):** This 67-year-old patient was in a head-on vehicle collision that caused internal bleeding and crushed organs and left her in a coma for one month. She was hospitalized for multiple injuries including a colon injury necessitating a colostomy, a liver laceration, and a splenic fracture with splenectomy, among other severe conditions. Astonishingly, the OIG reviewer nonetheless concluded that the patient was not homebound because the patient was able to ambulate a mere 20 *steps*-provided she had a cane to do so.

This conclusion is wholly divorced from the applicable guidance for determining homebound status. The patient's need for a cane to walk only 20 steps indoors supports rather than contradicts the patient's need for assistance to leave the home. The record showed she had a need for caregivers within the home, which bolsters rather than undermines her lack of functional independence and inability to leave the home without a considerable and taxing effort. The patient's extensive injuries and lengthy hospitalization with subsequent deconditioning caused the patient to be homebound during this episode. The patient's need for assistance was well documented in the record: her generalized weakness and decreased strength

following her traumatic injuries placed her at risk of falls or additional injury if she were to ambulate in the community without assistance. The claim for home care should have been allowed in full.

- **Sample Patient No. 70 (Partial-Episode Denial):** Although agreeing that the patient was homebound at the start of care, the OIG reviewer concludes that the patient lost that status once he could ambulate 175 feet, albeit with a cane and with the assistance of family and friends as caregivers. Again, the OIG reviewer disregarded the appropriate guidance for assessing homebound status, instead choosing arbitrary—and inappropriate—“rules of thumb” and other factors unrelated to the patient’s ability to leave the home. The patient suffered multiple severe co-morbidities, including end-stage renal disease requiring dialysis, a recent stroke, and coronary artery disease requiring coronary artery bypass surgery.

But for that note about ambulating 175 feet, the rest of the patient’s record for the entire episode of care illustrated the patient’s need for assistive devices to leave the home, and the considerable and taxing effort it took the patient to do so. For instance, the patient needed a supportive device, and assistance and verbal cuing from another person for safe ambulation. A caregiver needed to accompany the patient in order to assist the patient in and out of a car. The record also indicated that the patient had a history of falls, dyspnea with ambulating short distances and dressing, shortness of breath, fatigue, and lower extremity weeping edema. The patient’s need for assistance and difficulty leaving the home was very well documented. That he could ambulate at a modified independent level with assistive devices in the comfort and familiarity of his home, does not call into question the patient’s inability to leave the home without assistance. Nor does the availability of caregivers decrease the taxing and considerable effort required. Had the OIG reviewer appropriately considered all of the criteria, rather than focusing on one measured gait distance, the patient’s homebound status would have been upheld for the entire episode.

These examples confirm that the OIG’s medical reviewers did an incomplete review of the records using standards inconsistent with Medicare regulations and guidance. For all 12 claims the Draft Report alleges fail to meet homebound criteria, the complete medical records, properly assessed against Medicare guidance establish that each beneficiary was and remained homebound for the entire episode of care. Indeed, the OIG’s reviewer acknowledged that five of those 12 beneficiaries were homebound at the start of care.

Accordingly, VNA requests that the OIG’s medical reviewer reconsider each of those twelve claims, particularly in light of the rebuttal statements that VNA is submitting with this response. Alternatively, VNA requests that the OIG engage a different, qualified medical reviewer to audit the claims at issue, as the initial reviewer’s medical determinations reflect a fundamental lack of understanding of home health services generally and relevant Medicare regulations and guidance specifically.

B. ALL OF THE BENEFICIARIES IN THE AUDITED SAMPLE REQUIRED SKILLED SERVICES & THE OUTSIDE CONTRACTOR'S CONCLUSIONS OF SKILLED SERVICES ARE ERRONEOUS.

In addition to homebound status, Medicare payment for home health services is contingent upon the beneficiary requiring at least one of these skilled services: (i) intermittent skilled nursing services, which must demand the skills of a registered nurse ("RN"), or licensed practical nurse under RN supervision, and which must be reasonable and necessary; (ii) physical therapy; (iii) speech-language pathology; or (iv) occupational therapy.¹⁵ Each individual therapy service must comply with certain additional requirements to be covered.¹⁶

OIG found that five of the 100 claims were non-compliant because the beneficiary did not require medically necessary skilled nursing or skilled therapy services. Even if VNA agreed with these findings, which it does not, such finding means that the OIG agrees with VNA's determination that the beneficiary required skilled services for 95 percent of the audited claims – which by any measure is exemplary. All five of these denials are for a portion of the episode, not the entirety. This statistic is emphasized not to suggest that VNA should get a "pass" on any inappropriate claim, but rather that the OIG's characterization of VNA as lacking "adequate controls to prevent the incorrect billing of Medicare claims" does not comport with the VNA's laudatory compliance efforts.

In any event, VNA does not agree with the medical reviewer's findings regarding the five claims that the OIG contends were non-compliant with the Medicare requirements for coverage of skilled nursing or therapy visits. Again, the example claim used by the OIG in its Draft Report highlights the opposite of what the OIG intended; it, as in the homebound examples, shows that the medical reviewers have a faulty understanding of Medicare criteria and the important clinical distinctions necessary to correctly apply them.

- **Response to Example 3, Sample Patient No. 6 (Partial-Episode):** The OIG reviewer concluded this patient did not require skilled nursing services for the second half of his short six-day home care episode. Specifically, the reviewer concluded that although skilled nursing was initially indicated for catheter care and assessing the patient's pain response on the start of home care, two days later that same patient no longer required these services because his catheter was removed without complication.

However, this conclusion grossly underestimates the complexity and severity of the patient's condition. When taken as a whole, the patient's record "tell[s] the story of the patient's achievement towards his/her goals," and therefore "demonstrate[s] why a skilled service is needed."¹⁷ The OIG reviewer's failure to account for the patient's entire record led to the faulty conclusion that the skilled services were not medically necessary. Just before this episode, the patient had undergone urology surgery for an enlarged prostate with other abnormal diagnostic tests suggestive of

¹⁵ 42 C.F.R. § 409.42(c).

¹⁶ See, 42 C.F.R. § 409.44(c).

¹⁷ Medicare Benefit Policy Manual, Ch. 7, § 40.2.1.

a potential prostate malignancy; this procedure consisted of 30 biopsies and insertion of a catheter.

Twice during this brief admission the catheter clogged due to postoperative bleeding/clotting, which on one occasion required the skilled nurse to make an urgent home visit to irrigate and prevent the need for hospitalization and emergent care. While the OIG reviewer acknowledged that the patient was at risk of infection and post-operative bleeding, the reviewer apparently concluded those risks were eliminated when the patient's catheter was removed; however, this could not be further from the truth. To be sure, just one day before the home care admission when the patient's catheter was removed, the patient could not void, passing only clots and developing bladder pressure, thus necessitating re-catheterization. On the day the catheter was removed, the patient again reported clotting and bladder spasms. It would have been careless to discharge the patient at that time, ignoring the patient's risks of bleeding, clotting, infection, obstruction, and incontinence, and disregarding symptoms of a complication that occurred merely three days prior. Instead, VNA took the reasonable and necessary actions of assessing the patient over the next few days for further signs of complications and training the patient on signs and symptoms he could be in danger again. Concluding that skilled nursing was not reasonable and necessary, given these extreme circumstances, is not only erroneous, but also illogical, given the patient's full clinical presentation.

In addition to the medical reviewer's misapplication of the Medicare guidelines in this example, the OIG's other medical determinations also reflected the medical reviewer's misunderstanding and misapplication of the Medicare guidance. For example:

- **Sample Patient No. 74 (Partial-Episode):** Without an effort at explanation, the OIG reviewer concluded that physical therapy and occupational therapy services delivered to this 94-year-old patient were "excessive" on two days during his episode. In determining whether services are reasonable and necessary, the reviewer's focus should be on whether the beneficiary needs skilled care and whether "the inherent complexity of the service is such that it can be performed safely and/or effectively only by or under the general supervision of a skilled therapist."¹⁸

Rather than answer these fundamental questions, the reviewer skipped the analysis entirely and concluded the patient did not require these skilled services.

Had the reviewer performed the requisite analysis, however, the need for these services would have been obvious. Physical therapy was initiated for this patient due to concerns surrounding his gait, mobility, and safety when navigating in his home. The patient had recently experienced a significant decline in function, which threatened his safety, ability to live independently in the community, and his overall quality of life. Physical therapy on one of those days focused on issues like the

¹⁸ Medicare Benefit Policy Manual, Ch. 7, § 40.2.1. Further, these services may still be reasonable and necessary if the criteria for maintenance therapy is met.

patient's increasing bowel urgency, balance, and strengthening. The addition of a new symptom—lightheadedness—necessitated instruction in safety management, which was further exacerbated by the patient's continued fatigue at ambulating even short distances. Physical therapy was not excessive given the patient's condition, and was needed to maintain his current condition, prevent or slow his decline and deterioration, and improve his function where possible.

As for occupational therapy services, the OIG reviewer seemed to disregard therapist notes indicating that the patient did not yet have grab bars installed, was still unsafe in transfers from chairs, and needed more improvement in posture and neck positioning while walking. Additional therapy was needed to meet his goals, and with further services, the patient demonstrated improvement in his shoulder range of motion, upper body strength, and independence in the home. Skilled services were medically reasonable and necessary, and the OIG reviewer erred by concluding otherwise.

- **Sample Patient No. 79 (Partial-Episode):** In addition to opining that the patient received “excessive” skilled physical therapy services during his episode, the OIG reviewer reasoned that occupational therapy services were not medically necessary because “[t]he patient’s rehabilitation needs were being addressed through the physical therapy being provided. The occupational therapy services provided were duplicative.” Before this episode, the patient endured a number of medical setbacks, including multiple emergency room visits and hospitalization for urinary tract infection, pneumonia, and mental status changes; the resulting decline in function is unsurprising. The patient’s weakness, immobility, and high risk of falls led to the initiation of physical therapy. Documentation of these functional deficiencies continued through discharge. Furthermore, the patient suffered from mental deficits, which required the physical therapist to assess and instruct the patient’s caregiver on the need for continued assistance for safe ambulation, and assess the patient’s ability to respond to various instructions with repetition and practice for a quality outcome. Therefore, the OIG reviewer erred in concluding the skilled physical therapy services were not reasonable and necessary. Confusing physical therapy and occupational therapy services, the OIG reviewer erroneously concludes that the occupational therapy services were duplicative of the physical therapy services.

Medicare guidance makes clear that physical and occupational therapy are separate disciplines with different goals.¹⁹ Concluding the occupational therapy services were not medically necessary on this ground is directly contrary to the applicable guidance. In fact, the patient required the specialized services of an occupational therapist to manage her deficits in activities of daily living and instrumental activities of daily living and strengthen her upper extremities to improve safe transfer, among other functions; a physical therapist would not be equipped handle such services. All skilled services provided to the patient during this episode were reasonable and necessary for her to reach her optimal safe level of mobility in her

¹⁹ Medicare Benefit Policy Manual, Ch. 7, §§ 40.2.2, 40.2.4.

home following deconditioning due to her illness, and to clinically evaluate and assess the patient's safety status due to her cognitive and memory deficits.

VNA strongly disagrees with the OIG's assertion these alleged billing errors occurred because VNA "did not always provide sufficient clinical review to verify that beneficiaries required skilled services." To the contrary, VNA's robust compliance program and clinical review process ensured, at a minimum, a 95 percent compliance rate. Because the medical records for the five beneficiaries identified in the Draft Report clearly establish that the beneficiaries required skilled services, VNA's actual compliance rate is 100 percent. With this submission and the accompanying rebuttals, VNA again asks the medical reviewer to re-review the five claims at issue and reverse the previous findings that five beneficiaries received skilled services that were not medically necessary.

C. VNA WAS NOT REIMBURSED FOR A HOME HEALTH AIDE VISIT THAT WAS NOT COMPLETED

The OIG mischaracterizes this finding by claiming in its Draft Report that VNA "received reimbursement for claims for some services that were not provided." VNA acknowledges that the OIG is correct that one home health aide visit was billed where that visit was not actually completed. However, this aide visit had no impact on reimbursement.

The home health aide visit at issue was scheduled, and the aide went to the home as planned. However, the patient was not home, and the visit note therefore did not include personal care. The visit note was submitted correctly stating the patient was not home and care was not provided. Although this visit should have been made non-billable in the billing system, this aide visit did not affect reimbursement because it did not change this claim to a LUPA. The claim included 10 visits: 4 skilled nursing, 4 aide, 1 physical therapy and 1 MSW. Removing this aide visit leaves 9 billable visits, and because this does not create a LUPA, it does not impact reimbursement for this claim.

As such, the OIG's conclusion that VNA received payment or reimbursement for claims for services not provided – is demonstrably false. There is one home aide visit at issue, so it is inaccurate for the OIG to characterize this as anything other than the improper submission of one aide visit. Because it received no reimbursement due to this singular and isolated error, VNA requests that the OIG remove this finding. If the OIG will not remove this finding, VNA requests it be revised to state that VNA erroneously billed for one home health aide visit, but received no reimbursement because of this error.

VNA also disputes the OIG's conclusion that this alleged billing error occurred because VNA "did not have adequate oversight procedures to ensure that it did not bill Medicare for services not provided." To the contrary, VNA's robust compliance program and clinical review process ensured, at a minimum, a 99 percent compliance rate. Additionally, in 2018, the VNA Billing and Revenue Cycle began an audit process to include a review of randomly selected claims to ensure the proper billing of home health visits such as this one.

D. ALL SERVICES WERE REASONABLE AND NECESSARY

The OIG again relies on one erroneously denied claim to make a broad accusation that VNA “Did Not Always Meet Federal Requirements for Providing Reasonable and Necessary Services.” This finding is unfounded and the OIG’s medical reviewer again failed to review the complete record and apply the appropriate Medicare regulations. The OIG is alleging that for one of the sampled claims, VNA billed Medicare for home health aide services that were not reasonable and necessary.

The claim in question is for a home health date of 2/20/2016 through 3/16/2016. The home health services in this episode were partially disallowed. While the OIG reviewer agreed that the initial services at the start of the episode were allowable, the reviewer alleged that certain services were not allowable, stating, in part, that, there “was no clear need for home health aide services as the patient was receiving assistance from his family and was able to bathe independently.”

As noted in PT, OT and MSW visit notes, the patient’s wife who was the caregiver could not always be present in the home and also was caring for her elderly mother in another town where she stayed overnight one night per week. The physician initially ordered the home health assessment when the family requested a patient evaluation and help, because they were concerned about the patient’s mobility, walking and safety in the home and their ability to care for him in the home. This was the reason they contacted his primary care physician and home health for help.

VNA also disputes the OIG’s conclusion this error occurred because VNA “did not have adequate oversight procedures to ensure that services provided to the beneficiary complied with Medicare requirements for being reasonable and necessary.” To the contrary, VNA’s robust compliance program and clinical review process ensured, at a minimum, a 99 percent compliance rate.

E. ALL DOCUMENTATION SUPPORTING THE SERVICES PROVIDED WAS PROVIDED

The OIG Draft Report states that for one claim, “CMS records indicated that the OASIS data submitted by VNA for the associated beneficiary was not accepted; therefore, there was no OASIS data available for the beneficiary.” The Draft Report further claims this “error occurred because VNA of Central Jersey did not have sufficient procedures to always ensure that it complied with Medicare documentation requirements.” VNA asserts this claim was denied by the OIG in error and has made numerous attempts to resolve the matter prior to and following the issuance of the Draft Report. Despite these efforts, and overwhelming evidence that OIG has erroneously denied this claim, the OIG has inexplicably refused to reverse its claim decision. VNA is confident this issue will be overturned on appeal.

In preliminary conversations, the OIG explained that, for Patient Number 52, its internal data received from CMS showed that the 2014-2015 episode was disallowed because “OASIS Not Accepted.” The records show this finding is in error. The submission validation form in CMS CASPER reflects the completed OASIS for December 11, 2014 and January 7, 2015 were accepted. The relevant part of this report – including direct verification from CMS – was provided to the OIG multiple times, including: (1) in October 2017 during its initial records request process,

(2) at the January 28, 2019 exit conference, and (3) in a January 28, 2019 letter to the Office of Audit Services, Region II.

Despite having verification from CMS, the OIG inexplicably continues to deny the claim and told VNA it would need something more from CMS – without explaining what it would accept from CMS as dispositive. The OIG suggested that VNA contact CMS directly. As a result, VNA reached out to:

- ***The New Jersey OASIS Automation Coordinator, NJ Department of Health:***

The New Jersey OASIS Automation Coordinator reviewed all documents related to the beneficiary and concluded that the OASIS (SOC and D/C) was completed properly, however it remained unclear to her as to why the CMS data file provided to the OIG reflected no account of the timely OASIS submissions. Follow-up calls to the New Jersey OASIS Automation Coordinator went unanswered because she is out of the office indefinitely.

- ***New Jersey Department of Health:***

VNA was referred to another person at the New Jersey Department of Health following the leave of absence by the OASIS Automation Coordinator. This contact indicated that she was not the correct person to help. VNA was told that her supervisor would call, but we never received a follow-up call. This person indicated that they could not release any CMS documentation and that VNA would need to go back to CMS for verification.

- ***Acting Division Director of the Division of Continuing Care Providers, Quality, Safety & Oversight Group at CMS:***

VNA contacted the Acting Division Director of the Division of Continuing Care Providers, Quality, Safety & Oversight Group, but was told this issue was outside of the Division's scope. VNA was told that the best source was the Quality Improvement and Evaluation System (QIES) Technical Support Office Help Desk (QTSO).

- ***CMS Technical Help Desk (QTSO):***

The help desk looked up both validation reports for the beneficiary in question and verified that both reports were in the system and were accepted. The help desk stated that they could not email a screenshot or other proof of the validation. The help desk told us to reach out directly to the New Jersey OASIS Automation Coordinator, as that would be the person who could provide documentation.

- ***Principal Deputy Administrator for Operations of CMS:***

Because CMS was directing VNA to state officials in New Jersey and the state officials were sending VNA back to CMS, VNA contacted the Technical Director

for CMS. VNA had a call with the Technical Director who reached out directly to the OIG to ask for the data files that OIG received from CMS. OIG sent the files, and they are under review by CMS.

When extrapolated, the financial impact of this erroneous claim is almost \$450,000. Because VNA has verification from CMS that the OASIS was both submitted and accepted, and because all required documentation was timely submitted, this claim should be reversed and in no event should this claim be extrapolated. It is especially disappointing that, despite having verification this claim was properly submitted and accepted, the OIG included this claim in its Draft Report and concluded that the error resulted because VNA did not have sufficient procedures to always ensure that it complied with Medicare documentation requirements. This was not an error by VNA, so VNA strongly disagrees with the OIG's statement that VNA did not have sufficient procedures in place.

F. ALL HEALTH INSURANCE PROSPECTIVE PAYMENT SYSTEM CODES ASSIGNED TO CLAIMS WERE CORRECT

Medicare pays for home health services based on a case-mix adjusted payment for each 60-day episode of care. Each episode is assigned to a home health resource group ("HHRG") that is represented on a home health claim using a HIPPS code, which ultimately drives the Medicare payment amount. A bill must be "completed accurately" to be processed and paid correctly, and, therefore, a home health agency must use proper HIPPS codes on its claims. The OIG alleges that VNA failed to use the proper HIPPS code on one claim, which resulted in higher reimbursement. Specifically, the medical reviewer stated that VNA used 1BFK2 rather than 1BFK1. VNA disagrees with this result and using the Home Health Prospective Payment System (HH PPS) Grouper (the "Grouper") cannot replicate the medical reviewer's finding. Even assuming the medical reviewer is correct – which again is not the case – the difference in reimbursement between the two levels is \$38.62.²⁰

As far as VNA can discern, the OIG medical reviewers essentially made a conclusory statement with limited supporting documentation. VNA and LW disagree with this finding; the proper HIPPS code on the original claim was submitted based upon the patient's Pertinent Diagnoses and OASIS responses applying the relevant standards from the CMS OASIS Guidance Manual. A copy of VNA's Grouper confirming the accuracy of 1BFK1 is attached as [Exhibit 4](#). VNA requests that the OIG rerun the grouper and reverse its finding. The error in the Grouper run by the medical reviewer also disproportionately affects the extrapolated overpayment calculation.

Further, VNA objects to the way the OIG characterizes the issue. In the OIG Draft Report, the OIG states this error "occurred due to a clerical error made by [VNA]." However, in the heading of the same section, the OIG states that VNA "Incorrectly Billed Health Insurance Prospective Payment System Code." The OIG again seeks to mischaracterize and sensationalize its findings rather than highlighting VNA's strong and successful commitment to compliance. VNA's robust procedures ensured, at a minimum, a 99 percent compliance rate. The OIG's audit unquestionably revealed no systemic issue related to VNA's HIPPS coding, particularly considering the two-year time period at issue in the audit.

²⁰ \$2480.89 versus \$2442.27.

V. EXTRAPOLATION OF OVERPAYMENT OBLIGATIONS IS INAPPROPRIATE

VNA strongly disagrees with the OIG's use of extrapolation to arrive at an estimated overpayment amount. As discussed at length in this response, the medical review conducted by the OIG medical reviewers is fundamentally flawed. Any statistical analysis of the OIG's results at this juncture is premature and inevitably leads to incorrect and inflated claim and financial error rates.

Additionally, extrapolation of Medicare overpayments is inappropriate unless there exists a "sustained or high level of payment error."²¹ For purposes of extrapolation, a sustained or high level of payment error constitutes an error rate greater than or equal to a 50 percent error rate.²² That is not the case here. Even assuming the OIG's findings are all valid (which they are not), the financial payment error rate is 9.4 percent, significantly below 50 percent. The comprehensive reviews conducted of the beneficiaries' complete medical records by LW and by Dr. Landers establish that VNA provided home health services only to beneficiaries who were homebound and provided skilled services only to beneficiaries who required such services.

Although federal courts have upheld statistical sampling and extrapolation as a valid means to determine overpayment amounts in Medicare, the courts only do so when it is based on a statistically valid method. Here, the OIG has not properly executed its statistical sampling or applied the correct formulas for the extrapolation. Indeed, Stefan Boedeker, a leading statistician with Berkeley Research Group ("BRG") who has over twenty-five years of experience applying economic, statistical, and financial models to address various business issues and study economic impacts, reviewed the OIG's work in this audit and concluded that:

While statistical sampling may be appropriate if applied correctly, the OIG's extrapolation method for alleged overpayment is unreliable and statistically invalid because it was based on a flawed sample design. OIG's extrapolations are no more than speculative guess work because it failed to conduct a statistically valid sample. Therefore, the findings from the OIG Audit cannot reasonably be extrapolated to a broader universe.

A copy of Mr. Boedeker's curriculum vitae is attached as Exhibit 5, and a copy of Mr. Boedeker's full analysis and report is attached as Exhibit 6 the "Boedeker Report"). The OIG will almost certainly claim it properly executed its statistical sampling methodology in that it defined a sampling frame, sampling unit, randomly selected its sample, applied relevant criteria in evaluating the sample and used its statistical sampling software (*i.e.*, RAT-STATS) to apply the correct formulas for the extrapolation. As set forth in the Boedeker Report, however, this is not the case. Specifically:

- (1) The OIG's sample size was too small and arbitrarily chosen without considering the variation in the universe. The OIG's sample size was not based on the universe of VNA's claims but rather the OIG simply adopted the minimum recommended sample

²¹ 42 U.S.C. § 1395ddd(f)(3).

²² See Medicare Program Integrity Manual, § 8.4.1.4. Although VNA recognizes that the Medicare Program Integrity Manual is not binding on the OIG, the purported overpayments identified in the Draft Report would be overpayments from Medicare, and extrapolation of Medicare overpayments absent a sustained or high level of payment error is inappropriate.

size of 100. At the Exit Conference with VNA, the OIG acknowledged that it used the minimum recommended sample size because a larger sample proved too burdensome for the OIG in the Excellent Home Care Audit in 2016.²³ As a result, and seemingly without justification other than convenience and simplicity, the OIG now uses only the minimum recommended and arbitrarily chosen sample size of 100 nationwide. The sample was not appropriate for extrapolation.

- (2) The OIG's sample is not representative of the broader universe of claims, yielding unreliable results not suitable for extrapolation.
- (3) The lower bound of the 90% two-sided confidence intervals typically required by the OIG was incorrect.

Extrapolation of audit results to conclude that an overpayment existed across a broader universe of claims is only appropriate where the extrapolation was made from a *representative* sample and was statistically significant.²⁴ The OIG has not established that its sample is representative of the universe of VNA's claims, and, for the reasons discussed above, the sample is *not* representative of the broader universe. The audit results cannot be extrapolated to those claims.

VI. CONCLUSION

The OIG's findings in the Draft Report are flawed. Regarding homebound status – the one area in which the Draft Report identified VNA as less than 95 percent compliant – the OIG's medical reviewer applied incorrect criteria to determine the beneficiaries' homebound status and consistently failed to consider the complete record reflecting each beneficiary's individualized clinical condition and needs. The beneficiaries' medical records fully support both the homebound status and the medical necessity of skilled services for all of the audited beneficiaries.

VNA understands that it can challenge the Report's findings on appeal and is confident those findings will be overturned. But VNA hopes that that appeal will not be necessary and requests that the OIG submit this response to the Draft Report to its medical reviewers for reconsideration. VNA is confident that upon reconsideration using the appropriate Medicare guidelines, the OIG's findings will be overturned and withdrawn without the need for a costly appeal. VNA remains committed to providing only the highest quality home health services to its patients while maintaining strict compliance with all applicable laws, rules, and regulations, and it appreciates the opportunity to comment on the OIG's findings before the Report is finalized.

Sincerely,

//Anna M. Grizzle//

Anna M. Grizzle

²³ See OIG Audit A-02-14-01005 (July 2016).

²⁴ See *Chaves County Home Health Serv., Inc. v. Sullivan*, 931 F.2d 914, 921-22 (D.C. Cir. 1991).

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