Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

MEDICARE COMPLIANCE REVIEW OF HOME HEALTH VNA FOR 2011 AND 2012

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August 2016
A-01-13-00518

Office of Inspector General

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EXECUTIVE SUMMARY

Home Health VNA did not fully comply with Medicare requirements for billing home health services, resulting in overpayments of at least $15.48 million over 2 years.

WHY WE DID THIS REVIEW

This review is part of a series of reviews of home health agencies (HHAs). Using computer matching, data mining, and data analysis techniques, we identified certain types of home health claims that are at risk for noncompliance with Medicare billing requirements. For calendar year (CY) 2014, Medicare paid HHAs about $18 billion for home health services. The Centers for Medicare & Medicaid Services' (CMS) Comprehensive Error Rate Testing (CERT) program determined that the 2014 improper payment error rate for home health claims was 51.4 percent, or about $9.4 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 20 percent of the total 2014 fee-for-service improper payments ($46 billion).

The objective of this review was to determine whether Home Health VNA (the Agency) complied with Medicare requirements for billing home health services on selected types of claims.

BACKGROUND

Under the home health prospective payment system (PPS), CMS pays 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. CMS adjusts the 60-day episode payment 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 outcome and to determine whether adjustments to the case-mix groups are warranted.

The Agency is a home health care agency located in Lawrence, Massachusetts. National Government Services, its Medicare contractor, paid the Agency approximately $50 million for 17,800 home health claims for services provided to beneficiaries whose final episode of care ended in CYs 2011 or 2012 on the basis of CMS's National Claims History data.

Our audit covered $48.9 million in Medicare payments to the Agency for 17,216 claims for home health services that had dates of service primarily in CYs 2011 or 2012 (audit period). We selected for review a stratified random sample that included 497 home health claims with payments totaling $2.1 million.

WHAT WE FOUND

The Agency did not comply with Medicare billing requirements for 105 of the 497 home health claims that we reviewed. For these claims, the Agency received net overpayments of $314,406 for services provided to beneficiaries whose final episode of care ended in CYs 2011 and 2012. Specifically, the Agency incorrectly billed Medicare because beneficiaries were not homebound; beneficiaries did not require skilled services; documentation from the certifying physicians was missing or insufficient to support the services the Agency provided; or, in one instance, a claim contained an incorrect Health Insurance Prospective Payment System payment code. These errors occurred primarily because the Agency did not have adequate controls to prevent the incorrect billing of Medicare claims within selected risk areas.

On the basis of our sample results, we estimated that the Agency received overpayments of at least $15,483,448 for the audit period. This amount includes claims with payment dates outside of the 3-year recovery period. Of the total estimated overpayments, we estimated that at least $6,348,971 was within the 3-year recovery period, and as much as $9,134,477 was outside the 3-year recovery period. (The Patient Protection and Affordable Care Act established a 60-day repayment rule, under which Medicare overpayments must be reported and returned within 60 days after being identified.)

WHAT WE RECOMMEND

We recommend that the Agency:

- refund to the Medicare contractor $6,348,971 in estimated overpayments for claims incorrectly billed that are within the 3-year recovery period;

- work with the contractor to refund net overpayments outside of the 3-year recovery period, which we estimate to be $9,134,477 for our audit period, in accordance with the 60-day repayment rule;

- identify claims in subsequent years that did not meet Medicare payment requirements and refund any associated overpayments; 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 services, and

    - the physicians' certification and plan of care comply with Medicare documentation requirements and support the services the Agency provided.

HOME HEALTH VNA COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, the Agency disagreed with our findings and our first, second, and fourth recommendations. Although the Agency responded to our third recommendation, it said it had reviewed claims related to care provided in 2010, not claims in years subsequent to our audit period. The Agency commented that the high HHA CERT error rate we cited in our report was a condemnation of the systems and processes involved, rather than individual providers. Further, the Agency challenged our statistical methods and stated that our extrapolation of our audit results was invalid. The Agency challenged the independence of our contracted medical reviewer and the accuracy of its medical review work. The Agency asserted that it has no meaningful appeals process for our findings, as the appeal system is overloaded and not functioning consistent with requirements. Lastly, the Agency stated that we rushed the process to issue our draft report and did not give it sufficient time to respond to our findings.

We disagree with the Agency's assertions and maintain the validity of our findings and recommendations. For reasons we explain in more detail in the report, we stand by our audit methodology, procedures, findings, and recommendations.

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INTRODUCTION

WHY WE DID THIS REVIEW

This review is part of a series of reviews of home health agencies (HHAs). Using computer matching, data mining, and data analysis techniques, we identified certain types of home health claims that are at risk for noncompliance with Medicare billing requirements. For calendar year (CY) 2014, Medicare paid HHAs about $18 billion for home health services. The Centers for Medicare & Medicaid Services' (CMS) Comprehensive Error Rate Testing (CERT) program determined that the 2014 improper payment error rate for home health claims was 51.4 percent, or about $9.4 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 20 percent of the total 2014 fee-for-service improper payments ($46 billion).

OBJECTIVE

Our objective was to determine whether Home Health VNA (the Agency) 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) covers eligible home health services under a prospective payment system (PPS) that covers 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 a standardized payment 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 outcome 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 codes and represent specific sets of patient characteristics. CMS requires the submission of OASIS data as a condition of payment.[1]

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

[1] 42 CFR 484.210(e); 74 Federal Register 58110 (Nov. 10, 2009) and CMS's *Program Integrity Manual*, chapter 3, § 3.2.3.1.

Home Health Agency Claims at Risk for Incorrect Billing

In prior years, our reviews 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,
- some home health visits overlapped institutional stays, and
- billed services were not always adequately documented.

For the purposes of this report, we refer to these areas of incorrect billing as "risk areas." We reviewed these and other risk areas as part of this review.

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 establish, and regulations at 42 CFR § 409.42 implement, as a condition of payment for home health services, the requirement that a physician certify and recertify that the Medicare beneficiary is:

- confined to the home (homebound);
- in need of skilled nursing care on an intermittent basis, or physical therapy or speech-language pathology, or has a continuing need for occupational therapy;
- under the care of a physician; and
- receiving services under a plan of care that has been established and periodically reviewed by a physician.

Furthermore, sections 1814(a)(2)(C) and 1835(a)(2)(a) of the Act require that the physician document a face-to-face encounter between the physician (or other allowable practitioner) and the Medicare beneficiary during the 6 months preceding the certification or at another reasonable timeframe as determined by the Secretary of Health and Human Services.[2] In addition, the Act

[2] CMS's *Medicare Benefit Policy Manual* (the Manual), Pub. No. 100-02, chapter 7, § 30.5.1.1.3, requires the face-to-face encounter to occur no more than 90 days prior to the home health start of care date or within 30 days after the start of care.

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" (the Manual, chapter 7, § 20.1.2).

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

Home Health VNA

The Agency is a not-for-profit HHA located in Lawrence, Massachusetts, and licensed in both Massachusetts and New Hampshire. National Government Services, its Medicare contractor, paid the Agency approximately $50 million for 17,800 claims for services provided to beneficiaries during calendar years[3] (CYs) 2011 or 2012 (audit period) based on CMS's National Claims History (NCH) data.

HOW WE CONDUCTED THIS REVIEW

Our audit covered $48,938,413 in Medicare payments to the Agency for 13,579 beneficiary starts-of-care.[4] These beneficiary starts-of-care included 17,216 claims for home health services that had dates of service primarily in CY 2011 or CY 2012. We selected a stratified random sample of 125 beneficiary starts-of-care (including 497 claims) with payments totaling $2,096,982 for review. We evaluated compliance with selected billing requirements and subjected 204 of the 497 claims to focused medical review to determine whether the services met coverage, medical necessity, and coding requirements.

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

[3] Calendar years were determined by the home health agency claim "through" date of service. The "through" date is the last day on the billing statement covering services provided to the beneficiary.

[4] A beneficiary start-of-care represents all contiguous home health episodes of care during the audit period for the same beneficiary. A beneficiary start-of-care series could range from one to several individual 60-day episodes of care. A home health agency submits a claim for Medicare payment for each episode of care. For purposes of defining our audit period, we selected beneficiary starts-of-care as our sample unit on the basis of the final episode "through" date for each beneficiary start-of-care unit. Accordingly, we selected these "through" dates falling within CY 2011 and 2012. Because some beneficiary starts of care contain multiple episodes, claims subjected to audit could include dates of service prior to CY 2011.

FINDINGS

The Agency did not comply with Medicare billing requirements for 105 of the 497 home health claims that we reviewed.[5] For these claims, the Agency received net overpayments of $314,406 for services primarily in CYs 2011 or 2012. Specifically, the Agency incorrectly billed Medicare because:

- beneficiaries were not homebound,
- beneficiaries did not require skilled services,
- documentation from the certifying physicians was missing or insufficient to support the services the Agency provided, or
- one claim contained an incorrect HIPPS payment code.

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

On the basis of our sample results, we estimated that the Agency received overpayments of at least $15,483,448 for the audit period.[6] This overpayment amount includes claims with payment dates outside the 3-year recovery period. Of the total estimated overpayments, we estimated that at least $6,348,971 was within the 3-year recovery period, and as much as $9,134,477 was outside the 3-year recovery period.[7]

Appendix C contains our statistical sampling methodology, Appendix D contains our sample results and estimates, and Appendix E contains the types of errors by sample item.[8]

[5] The billing errors for 105 of the 497 claims correspond to errors for 71 of the sample of 125 beneficiary starts-of-care.

[6] 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 will be less than the actual overpayment total 95 percent of the time.

[7] Our audit report represents the results for all claims within our audit period. Section 1870(b) of the Act governs the recovery of excess payments. This section provides that excess payments identified are barred from recovery 3 years after the year in which the original payment was made. In addition, the Agency is responsible for reporting and returning overpayments they identified to their MAC. The 2010 Patient Protection and Affordable Care Act requires the reporting and return of Medicare overpayments along with a written notice of the reason for the overpayment within 60 days after the overpayment was identified (60-day repayment rule). Failure to meet this deadline subjects providers to potential False Claims Act and Civil Monetary Penalty Law liability.

[8] Sample items may have more than one type of error.

AGENCY BILLING ERRORS

The Agency incorrectly billed Medicare for 105 of the 497 sampled claims, which resulted in net overpayments of $314,406.

Beneficiaries Were Not Homebound

For the reimbursement of home health services, the beneficiary must be "confined to the home" (sections 1814(a)(2)(C) and 1835(a)(2)(A) of the Act and Federal regulations (42 CFR § 409.42)). The Manual (chapter 7, § 30.1.1, revised October 1, 2003) states that a beneficiary qualifies as "confined to the 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. Even though 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. Any other absence of an individual from the home shall not so disqualify an individual if the absence is of infrequent or of relatively short duration.

For 62 of the sampled claims, the Agency incorrectly billed Medicare for home health episodes for beneficiaries who did not meet the above criteria for being homebound.[9] For example, documentation for one beneficiary did not support that the patient was homebound as the patient was able to walk 400 feet, and documentation did not substantiate that it would require significant and taxing effort to leave the home for further therapy or treatment. These errors occurred because the Agency did not have adequate oversight procedures to ensure that it verified the homebound status of Medicare beneficiaries and did not properly document the specific factors that qualify the beneficiaries as homebound.

As a result of these errors, the Agency received overpayments of $200,507.

Beneficiaries Did Not Require 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 (section 1395n(a)(2)(A) of the Act and Federal regulations (42 CFR § 409.42(c))). In addition, skilled nursing services must require the skills of a registered nurse or a licensed practical nurse under the supervision of a registered nurse, must be reasonable and necessary to the treatment of the patient's illness or injury, and must be intermittent (42 CFR §§§ 409.42(c) and 409.44(b) and the Manual, chapter 7, § 40.1). Skilled therapy services must be reasonable and necessary to the treatment of the patient's illness or injury or to the restoration or

[9] Additionally, 43 of these claims had other errors. In these cases, the beneficiary also did not require skilled services in addition to not being homebound. Appendix E provides detail on the extent of errors, if any, per sample item reviewed.

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).

For 36 of the sampled claims, the Agency incorrectly billed Medicare for an entire home health episode (18 claims) or part of the episode (18 claims) for beneficiaries who did not meet the Medicare requirements for coverage of skilled nursing or therapy services. For example, the Agency provided skilled nursing care to a beneficiary who required only simple bandage changes. As a result, skilled nursing services on the entire claim were not considered reasonable and necessary. On another claim, the Agency provided both skilled nursing and physical therapy as part of the beneficiary's plan of care. Even though the skilled nursing services were appropriate, the services of a licensed physical therapist were not necessary for repetitive stretching and range-of-motion exercises. If the claim did not include these unnecessary services, the HIPPS coding on the claim would have changed, and the payment would have been reduced. These errors occurred because the Agency did not always provide sufficient clinical review to verify that beneficiaries required skilled services.

As a result of these errors, the Agency received overpayments of $88,178.

Missing or Insufficient Documentation

Medicare pays for home health services only if a physician certifies that the beneficiary meets the coverage requirements specified in the statute and regulations (sections 1814(a)(2) and 1835(a)(2)(A) of the Act and 42 CFR § 424.22(a)). Prior to certifying a patient's eligibility for home health services, the certifying physician must document that he or she (or an allowed nonphysician practitioner) had a face-to-face patient encounter related to the primary reason the patient requires home health services. In addition, the certifying physician must document the encounter either on the certification, which the physician signs and dates, or in a signed addendum to the certification (42 CFR § 424.22(a)) and the Manual (chapter 7, § 30.5.1.1).

The orders on the patient's 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 (42 CFR § 409.43(e) and the Manual, chapter 7, § 30.2.6). Each review of a patient's plan of care must contain the signature of the physician and the date of review.

For six of the sampled claims, the Agency incorrectly billed Medicare for home health episodes that did not meet the Medicare documentation requirements for the physician certification or the plan of care. These claims contained the following types of errors:

- the plan of care was missing or unsigned by the physician (two claims),

- face-to-face encounter documentation was missing (two claims) or unrelated to the beneficiary's condition at the time of admission (one claim), and

- skilled nursing visit notes failed to include the required wound measurements (one claim).

These errors occurred primarily because the Agency did not have sufficient procedures to always ensure that the physician's certification and plan of care complied with Medicare documentation requirements and supported the services the Agency provided.

As a result of these errors, the Agency received overpayments of $25,811.

Incorrectly Billed Health Insurance Prospective Payment System Code

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).

For one sampled claim, the Agency assigned an incorrect HIPPS billing code to the Medicare claim. The OASIS and other supporting medical records did not support the billing code that the Agency used. The error resulted in the amount of supplies provided to the patient being understated in the payment computation. We attributed this error in HIPPS coding to a clerical error.

As a result of this error, the Agency received an underpayment of $90.

OVERALL ESTIMATE OF NET OVERPAYMENTS

On the basis of our sample results, we estimated that the Agency received net overpayments totaling at least $15,483,448 for the audit period. This overpayment amount includes claims with payment dates outside of the 3-year recovery period. Of the total estimated overpayments, at least $6,348,971 was within the 3-year recovery period, and as much as $9,134,477 was outside the 3-year recovery period.

RECOMMENDATIONS

We recommend that the Agency:

- refund to the Medicare contractor $6,348,971 in estimated overpayments for claims incorrectly billed that are within the 3-year recovery period;

- work with the contractor to refund net overpayments outside of the 3-year recovery period, which we estimate to be $9,134,477 for our audit period, in accordance with the 60-day repayment rule;

- identify claims in subsequent years that did not meet Medicare payment requirements and refund any associated overpayments; 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 services, and

    - the physicians' certification and plan of care comply with Medicare documentation requirements and support the services the Agency provided.

HOME HEALTH VNA COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, the Agency disagreed with our findings and our first, second, and fourth recommendations. Although the Agency responded to our third recommendation, it said it had reviewed claims related to care provided in 2010, not claims in years subsequent to our audit period. Regarding our first and second recommendations, the Agency did not agree with our estimates of overpayments for claims that were within and outside of the 3-year recovery period. The Agency maintained that only seven claims in our sample were overpayments, and it has refunded $22,155 to CMS for these claims. Although the Agency disagreed with our fourth recommendation to strengthen its procedures to ensure compliance with Medicare requirements, it stated that its extensive dialog with OIG throughout the process enabled the Agency to view its processes from another perspective and facilitated the strengthening of many of its processes.

The Agency questioned why we pursued this audit despite the Agency's perception of serious system problems, as evidenced by the high national error rate for home health providers. The Agency also stated concerns it had regarding our statistical methods, the third-party medical review, its inability to challenge the audit process, and premature audit findings.

In concluding its comments, the Agency stated that not one finding in the report reflected negatively on the quality of care it provided.

As we informed the Agency, our draft report was subject to revision. After considering the Agency's comments and additional supporting documentation it provided, we adjusted our sample results to reduce the total number of errors originally reported in our draft report from 114 to 105. We also removed a related recommendation that addressed strengthening procedures

for billing correct HIPPS codes. We calculated a new statistical estimation and recommended that the Agency repay the estimated amount of $15,483,448 for our CYs 2011 and 2012 audit period. We also calculated a new statistical projection for overpayments within the 3-year recovery period of $6,348,971. This finding increased mainly because of two claims identified as errors that were inadvertently excluded from the 3-year recovery period category in the draft report.

We maintain that the remainder of our findings and recommendations are valid, although we acknowledge the Agency's rights to appeal the findings. We used an independent and qualified medical review contractor to determine whether 204 claims contained in the sample were reasonable and necessary and met Medicare coverage and coding requirements. The contractor examined all of the medical records and documentation submitted and carefully considered this information to determine whether the Agency billed the claims in compliance with Medicare requirements. Primarily on the basis of the contractor's conclusions, we determined that the Agency incorrectly billed Medicare for 105 of the 497 sampled claims, many of which had multiple types of billing errors.

We received the Agency's initial comments to our draft report on March 17, 2016. We found inaccuracies in the initial comments, and the Agency agreed to revise its comments. The Agency submitted revised comments on April 26, 2016. We have included the Agency's revised comments in their entirety as Appendix F. Below is a summary of the reasons the Agency did not agree with our findings and recommendations and our responses.

HIGH NATIONAL ERROR RATE FOR HOME HEALTH PROVIDERS

Agency Comments

The Agency stated that the high CERT error rate for home health claims cited in our report "is a condemnation of the systems and processes involved more than of the individual providers." It also stated that this error rate far exceeds the rates for other provider types, which "indicates a pervasive level of noncompliance consistent with unclear rules, procedures, and guidelines." Further, the Agency stated, "it is of significant concern that the OIG pursued its initiative to audit home health agencies and assess financial liability to such providers knowing this error rate existed." The Agency noted that "this error rate assures that there is very little probability of providers successfully 'passing' such an audit ...."

Office of Inspector General Response

The CERT national error rate for home health agencies has been high for several years. Part of OIG's mission is to protect the integrity of the Department of Health and Human Services' programs and, by extension, the Medicare trust funds. Therefore, OIG reviews providers that are at high risk for submitting incorrect claims to Medicare for reimbursement.

STATISTICAL METHODS

Agency Comments

The Agency stated that it consulted with a statistical consultant familiar with Medicare statistical sampling and extrapolation requirements as set forth in various Medicare manuals, including the *Medicare Program Integrity Manual*, and as established in legal proceedings. The Agency's statistical consultant concluded that our extrapolation was invalid because it failed to meet established requirements. Specifically, the Agency stated that we did not provide it with the universe of claims, and the sampling frame that we provided did not include any dates when a claim was paid, which prevented the consultant from replicating our results. Further, the Agency said that we used a confidence interval method to estimate, which requires that the stratified average overpayments be normally distributed. However, according to the Agency, the statistical tests we performed proved that the stratified average overpayments were not normally distributed. Thus, the Agency maintained that our "extrapolation of the audit results is invalid and the repayments amounts were not properly calculated because incorrect formulas were used."

The Agency said that although our report stated that our audit was of services provided in 2011 and 2012, there were also 2010 claims in the audit.

Office of Inspector General Response

We disagree with the Agency that without the universe of claims, the Agency could not reproduce the audit results. Our overpayment estimate applies only to the sampling frame. Any overpayments in claims outside of our sampling frame are not covered within this report. We provided the sampling frame to the Agency. The requirements regarding statistical sampling and extrapolation as set forth in the *Medicare Program Integrity Manual* apply only to Medicare contractors. (*See* CMS *Medicare Program Integrity Manual*, chapter 8.4.1.1 (effective June 28, 2011)). Furthermore, no statutory or other authority limits OIG's ability to recommend to CMS a recovery based upon sampling and extrapolation.

Regarding our statistical methods, Federal courts have consistently upheld statistical sampling and extrapolation as a valid means to determine overpayments in Medicare.[10] Additionally, 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.[11] We properly executed our statistical sampling methodology in that we defined our sampling frame and sampling unit, randomly

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

[11] 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*, 2016 U.S. Dist. LEXIS 6816 at *31-33, 37-39 (W.D. Tex. 2016); *Anghel v. Sebelius*, 912 F. Supp. 2d 4, 18 (E.D.N.Y. 2012); *Transyd Enter., LLC v. Sebelius*, 2012 U.S. Dist. LEXIS 42491 at *13 (S.D. Tex. 2012).

selected our sample, applied relevant criteria in evaluating the sample, and used statistical sampling software (i.e., RAT-STATS) to apply the correct formulas for the extrapolation. These formulas accurately account for the number of claims selected from each of the strata.

It is also important to note that we recommended recovery of overpayments at the lower limit of a two-sided 90-percent confidence interval. Lower limits calculated in this manner will be less than the actual overpayment amount 95 percent of the time. In addition, we checked our statistical lower limits against limits calculated using the empirical likelihood method which does not assume normality of the stratified averages. The limits calculated using the empirical likelihood were found to be higher for both the overall overpayment and for the overpayment amount within the 3 year recovery period.[12] These results are not surprising since the normal approximation is known to be overly conservative in situations like the current one where the overpayment amounts are positively skewed.

Regarding the Agency's comment that 2010 claims were included in our sample, we selected beneficiary starts-of-care as our sample unit based on the final episode "through" date for each beneficiary start-of-care unit. Accordingly, we selected these "through" dates falling within CYs 2011 and 2012. Because some beneficiary starts-of-care contain multiple episodes, claims subjected to audit could include dates of service prior to CY 2011.

THIRD-PARTY MEDICAL REVIEW

Agency Comments

The Agency stated that our audit was essentially a Recovery Audit Contractor (RAC) audit and contained all the inherent flaws of the RAC audit process. The Agency speculated that our contracted medical reviewers had their contracts terminated by CMS and that this audit was one of their last efforts. The Agency also asserted that the method of the contracted medical reviewers' compensation calls into question their objectivity because many of these reviewers are paid on a contingency and, regardless, such reviewers have an incentive to "find" errors.

The Agency noted that most of the errors were identified by third-party medical review and not OIG and are issues of clinical dispute. The Agency asserted that there were numerous problems with the quality and accuracy of the third-party medical reviews performed as part of this audit, and it is clear that the high reliance on contracted clinical reviewers calls into question virtually all of the findings in the report. The Agency also stated that no work papers could be produced that showed how the medical reviewers made their decisions; all that was produced were reviewer summaries, which did not always clearly state the basis for the reviewers' determinations. Further, the Agency noted that the high rate of reversal of these types of third-party auditors' findings by administrative law judges "further challenges the validity of such reviewers' findings."

[12] Using the empirical likelihood approach, the two-sided 90-percent lower limit was $6,787,113 for the estimated overpayment within the 3-year recovery period and $15,766,878 for the overall estimated overpayment amount.

Office of Inspector General Response

We previously informed the Agency that our medical review contractor was not a terminated RAC contractor, nor did it work on a contingency basis for OIG.

Our audit required the use of medical review specialists. As auditors, we are not qualified to render clinical determinations. However, government auditing standards permit us to engage specialists, when necessary, provided we obtain reasonable assurance as to their professional qualifications and independence, which we did. This specific medical review contractor has considerable experience in reviewing Medicare claims. The contractor maintains an internal quality control system to ensure that its medical review determinations are clearly presented and consistent with Medicare criteria. Also, our contract requires that individual medical reviewers possess professional competence and meet the work experience requirements to conduct medical review of home health claims.

We used this independent medical review contractor to determine whether 204 claims contained in the sample were reasonable and necessary and met Medicare coverage and coding requirements. The contractor examined all of the medical records and documentation submitted and carefully considered this information to determine whether the Agency billed the claims in compliance with Medicare requirements. Each claim that was denied was reviewed by qualified personnel, including a licensed physician who was board certified in physical medicine and rehabilitation.

We provided the Agency with the determination reports from our contracted medical reviewer to support the reasons for each claim found in error. Each report contained a comprehensive summary of the facts as presented in the medical record, the reviewer's analysis and findings, and the reviewer's determination. We will provide these medical review determination reports to the appropriate parties upon request if the Agency decides to appeal these findings.

APPEALING AUDIT FINDINGS

Agency Comments

The Agency asserted that there is no meaningful appeals process for our findings, as the appeal system is overloaded and not functioning consistent with requirements, and it maintained that its comments on our draft report are its only means to challenge the findings in our report. The Agency stated that it had no choice but to pursue numerous individual claim appeals, as the findings of the medical review contractors are not supported by the clinical record. The Agency noted that these multiple appeals will be costly, but more importantly it will result in at least a 3- to 5-year delay, owing to the proliferation of appeals, before the Agency would be able to prove that the vast majority of findings are incorrect. During that time, the Agency contends it must repay the amounts Medicare has allegedly overpaid, and it will only be able to secure the return of such funds over time on a case-by-case basis. The Agency stated that OIG should consider this lack of meaningful due process as it pursues such efforts as this audit.

Office of Inspector General Response

We informed the Agency that it could dispute the findings when commenting on our draft report. We also informed the Agency that, after we issue our final report, it would have the opportunity to present to a CMS action official any comments or additional information that the Agency believes may have a bearing on the action official's final determination. Further, subsequent to that final determination, the Agency has five levels of appeal to challenge our findings.

We disagree with the Agency's assertion that it will take from 3 to 5 years before it can prove through the appeals process that the vast majority of findings are incorrect. Although it is correct that there is a significant number of cases awaiting the third level of appeal before an administrative law judge, the Agency has ample opportunity to obtain a prompt appeal by filing a request for redetermination with its MAC, which generally renders a decision within 60 days of receipt of the request. If the Agency disagrees with the redetermination decision, it may request a reconsideration by a Qualified Independent Contractor, which generally renders a decision within 60 days of the receipt of the request.

Further, contrary to its comments, if the Agency decides to file a valid and timely appeal, it does not have to repay Medicare until after the second level of appeal. Specifically, Medicare will permit the Agency to stop the recoupment process if it receives a valid and timely request for reconsideration within 30 days from the date of the demand letter. Medicare will again stop recoupment if, following an unfavorable or partially favorable redetermination decision, the Agency files a valid and timely request for a reconsideration.[13] Following any unfavorable decision by the Qualified Independent Contractor, Medicare will begin or resume recoupment whether or not the Agency appeals to any further level.

If the Agency still has concerns about delays in CMS's hearing of appeals, it should direct them to CMS or the HHS Office of Medicare Hearings and Appeals, as appropriate.

TIMING OF AUDIT ISSUANCE

Agency Comments

The Agency stated that it was given only a summary spreadsheet identifying the alleged errors and calculating the overpayment estimate the day before the exit conference. Further, the Agency stated that our release of the draft report to CMS before its finalization and formal publication was premature, not consistent with routine procedures used by OIG in other audits, and done to recoup overpayments. According to the Agency, it "was forced to endure a procedural nightmare until this premature recoupment process was stopped by CMS …." Lastly, the Agency stated that OIG agreed to review errors that were strictly technical in nature and, as a result, overturned 9 of 10 payment errors. Additionally, the Agency believed "that the vast majority of the audit results based on clinical judgement by third party reviewers are in error" and that it will prevail when it has the chance to appeal those findings.

[13] CMS *Medicare Financial Management Manual*, chapter 3, § 200.2.1(IV)

Office of Inspector General Response

We provided the Agency with sufficient documentation from our contracted medical reviewer to support the reasons for each denied claim in advance of our exit conference. Specifically, 3 weeks prior to the exit conference, we sent the Agency copies of each medical review determination report for those claims in error along with the summary spreadsheet to which the Agency referred above. We believe this was sufficient time to disclose the extent of our findings to allow the Agency to prepare for the exit conference.

In response to the Agency's concerns about premature recoupment efforts, it is our understanding that the Agency's MAC canceled the initial demand letter for repayment and will issue a new demand letter after we issue our final report.

At the Agency's request, we agreed to follow up with the medical review contractor for those 10 claims, including 9 for which the medical review contractor was unable to reconcile the assigned HIPPS code to the supporting documentation.[14] The contractor responded that it had computed a different HIPPS code than the Agency had determined but could not pinpoint the reason for the difference. We agree with the Agency's comment that generating a HIPPS code is a complex process. After obtaining the assistance of the MAC on this technical issue, we determined eight of the nine claims in the Agency's favor because the MAC computed HIPPS codes that were either the same as, or similar to, the codes used by the Agency. However, because most of these claims were initially determined to be partial payment errors, our reversal of 9 of 10 determinations had only a minimal impact on our overall error estimate. Further, only four of the overturned claims fell within the 3-year recovery period.

[14] The remaining claim was initially denied for missing documentation. We were subsequently able to locate the missing document and overturn the finding.

APPENDIX A: MEDICARE REQUIREMENTS FOR COVERAGE AND PAYMENT OF CLAIMS FOR HOME HEALTH SERVICES

GENERAL MEDICARE REQUIREMENTS

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

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

OUTCOME AND ASSESSMENT INFORMATION SET DATA

The OASIS is a standard set of data elements that HHA clinicians use to assess the clinical needs, functional status, and service utilization of a beneficiary receiving home health services. CMS uses OASIS data to assign beneficiaries to the appropriate categories, called case-mix groups; to monitor the effects of treatment on patient care and outcome; and to determine whether adjustments to the case-mix groups are warranted. HHA beneficiaries can be classified into 153 case-mix groups that are used as the basis for the HIPPS rate codes used by Medicare in its prospective payment systems. Case-mix groups represent specific sets of patient characteristics and are designed to classify acute care inpatients 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 Federal Register 58110 (Nov. 10, 2009); and CMS's *Medicare Program Integrity Manual*, 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;[15] (3) be under the care of a physician; and (4) be under a plan of care that has been established and periodically reviewed by a physician (the Act §§ 1814(a)(2)(C) and 1835(a)(2)(A), 42 CFR § 409.42, and the Manual, chapter 7, § 30).

[15] 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 that requirement for covered occupational therapy has been met, however, all subsequent occupational therapy services that continue to meet the reasonable and necessary statutory requirements are considered qualifying services in both the current and subsequent certification periods (subsequent adjacent episodes).

Per the Manual, chapter 7, section 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)).

The Affordable Care Act added an additional requirement to §§ 1814(a)(2)(C) and 1835(a)(2)(A) of the Act that the physician have a face-to-face encounter with the beneficiary. In addition, the physician responsible for performing the initial certification must document that the face-to-face patient encounter, which is related to the primary reason the patient requires home health services, has occurred no more than 90 days prior to the home health start of care date or within 30 days of the start of the home health care by including the date of the encounter.[16]

Confined to the Home

Sections 1814(a)(2)(C) and 1835(a)(2)(A) of the Act and Federal regulations (42 CFR § 409.42) require for reimbursement of home health services that the beneficiary is "confined to the home." The Manual (chapter 7, § 30.1.1, revised 10/1/03) states that a beneficiary qualifies as "confined to the 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. Although 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. Any other absence of an individual from the home shall not so disqualify an individual if the absence is of infrequent or of relatively short duration.

Need for Skilled Services

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

[16] See 42 CFR § 424.22(a) 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.

Intermittent Skilled Nursing Care

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 cannot 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 although 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)) 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, which is related to the primary reason the patient requires home health services. In addition, the Manual (chapter 7, § 30.5.1.1) 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 B: AUDIT SCOPE AND METHODOLOGY

SCOPE

Our audit covered $48,938,413 in Medicare payments to the Agency for 13,579 beneficiary starts-of-care. We selected for review a stratified random sample of 125 beneficiary starts-of-care[17] with payments totaling $2,096,982. These beneficiary starts-of-care included 497 claims for home health services that the Agency provided to Medicare beneficiaries where the final episode of care ended in CYs 2011 or 2012 (audit period).

We evaluated compliance with selected coverage and billing requirements and subjected 204 claims to focused medical review.

We limited our review of the Agency'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 the Agency from January 2014 through December 2015.

METHODOLOGY

To accomplish our objective, we:

- reviewed applicable Federal laws, regulations, and guidance;
- extracted the Agency's paid claims data from CMS's NCH file for the audit period;
- used computer matching, data mining, and analysis techniques to identify claims at risk for noncompliance with selected Medicare billing requirements;
- selected a stratified random sample of 125 beneficiary starts-of-care that included 497 claims totaling $2,096,982 for detailed review (Appendix C);
- reviewed available data from CMS's Common Working File for the sampled claims to determine whether the claims had been canceled or adjusted;
- obtained and reviewed billing and medical record documentation provided by the Agency to support the claims contained in the sampled beneficiary starts-of-care;

[17] A beneficiary start-of-care may include more than one claim.

- used an independent medical review contractor to determine whether 204 claims contained in the sample were reasonable and necessary and met Medicare coverage and coding requirements;

- reviewed the Agency's procedures for billing and submitting Medicare claims;

- verified State licensure information for selected nurses and therapists 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 the Agency for our audit period (Appendix D);

- used the results of the sample to estimate the Medicare overpayments to the Agency for our audit period that are within the 3-year recovery period (Appendix D);

- calculated a non-statistical estimate of the Medicare overpayments to the Agency for our audit period that are outside the 3-year recovery period (Appendix D); and

- discussed the results of our review with Agency officials.

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 C: SAMPLE DESIGN AND METHODOLOGY

POPULATION

The population consisted of the Agency's claims for home health services that it provided to Medicare beneficiaries whose final episode of care ended in CYs 2011 and 2012.

SAMPLING FRAME

We developed a database of 17,216 home health claims from CMS's NCH file. We grouped these claims by beneficiary Health Insurance Claim Number and start-of-care. We defined the grouping of claims or frame unit as a beneficiary start-of-care. The grouping resulted in 13,579 frame units (beneficiary starts-of-care) valued at $48,938,413.

SAMPLE UNIT

The sample unit was a beneficiary start-of-care.

SAMPLE DESIGN

We used a stratified random sample. We stratified the sampling frame into four strata based on total payments for all claims within an individual beneficiary start-of-care.

Stratum	Dollar Range of Frame Units	Number of Frame Units	Dollar Value of Frame Units
1	$111.54 to $3,081.99	7,981	$14,959,893.90
2	$3,082 to $6,645.99	4,257	18,784,980.74
3	$6,646 to $29,807.20	1,306	13,569,845.96
4 (100% review)	$29,807.21 to $111,261.03	35	1,623,692.45
Totals		**13,579**	**$48,938,413.05**

SAMPLE SIZE

We randomly selected 30 beneficiary starts-of-care from stratum one, 30 from stratum two, and 30 from stratum three. We selected all 35 beneficiary starts-of-care in stratum four. Our total sample size was 125 beneficiary starts-of-care.

SOURCE OF RANDOM NUMBERS

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

METHOD OF SELECTING SAMPLE ITEMS

We consecutively numbered the sample units within strata one through three. After generating the random numbers for strata one through three, we selected the corresponding beneficiary starts-of-care in each stratum. We selected all beneficiary starts-of-care from stratum four.

ESTIMATION METHODOLOGY

We used the OAS statistical software to estimate the total amount of Medicare overpayments made to the Agency during our audit period and to estimate the amount of Medicare overpayments made to the Agency within the 3-year recovery period. We also calculated a nonstatistical estimate of the overpayments made outside the 3-year recovery period. To obtain this amount, we subtracted our estimate of the overpayments within the 3-year recovery period at the lower limit of the 90-percent confidence interval from our estimate of the total overpayments at the lower limit of the 90-percent confidence interval.

APPENDIX D: SAMPLE RESULTS AND ESTIMATES

OVERALL SAMPLE RESULTS[18]

Stratum	Frame Size	Value of Frame	Sample Size	Total Value of Sample	Incorrectly Billed Sample Items	Value of Net Overpayments In Sample
1	7,981	$14,959,894	30	$53,636	13	$19,576
2	4,257	18,784,981	30	131,328	19	60,315
3	1,306	13,569,846	30	288,325	20	130,870
4*	35	1,623,692	35	1,623,693	19	103,646
Total	**13,579**	**$48,938,413**	**125**	**$2,096,982**	**71**	**$314,406**

***** We reviewed all sample items in this stratum.

ESTIMATES

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

Point estimate	$19,567,281
Lower limit	15,483,448
Upper limit	23,651,114

[18] The sample of 125 beneficiary starts-of-care included 497 claims. Seventy-one of the sample of 125 starts-of-care contained billing errors, which correspond to 105 of 497 claims.

SAMPLE RESULTS WITHIN THE 3-YEAR RECOVERY PERIOD

Stratum	Frame Size	Value of Frame	Sample Size	Total Value of Sample	Incorrectly Billed Sample Items	Value of Net Overpayments In Sample
1	7,981	$14,959,894	30	$53,636	7	$8,955
2	4,257	18,784,981	30	131,328	9	32,684
3	1,306	13,569,846	30	288,325	10	63,042
4*	35	1,623,692	35	1,623,693	16	80,882
Total	**13,579**	**$48,938,413**	**125**	**$2,096,982**	**42**	**$185,562**

***** We reviewed all sample items in this stratum.

ESTIMATES

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

Point estimate	$9,845,444
Lower limit	6,348,971
Upper limit	13,341,918

MATHEMATICAL CALCULATION OF OVERPAYMENTS OUTSIDE THE 3-YEAR RECOVERY PERIOD

1. **Description of Mathematical Calculation:** We calculated the amount of Medicare overpayments made for claims paid to the Agency outside the 3-year recovery period. Section 1870(b) of the Social Security Act governs the recovery of excess payments and provides that excess payments identified are barred from recovery 3 years after the year in which the original payment was made.

2. **Mathematical Calculation Methodology:** To calculate the amount of Medicare overpayments made for home health claims paid to the Agency outside the 3-year recovery period, we estimated (1) the total amount of improper Medicare payments for unallowable home health during our audit period and (2) the amount of overpayments for home health claims paid to the Agency within the 3-year recovery period. Both of these estimates are calculated at the lower limit of the 90-percent confidence interval. The amount of Medicare overpayments made for claims outside the 3-year recovery period is calculated as the difference between the total overall estimate and the estimate for claims within the 3-year recovery period.

Total overall estimate	$15,483,448
Less: estimated overpayment for claims within 3-year recovery period	$6,348,971
Difference: estimated overpayments for claims outside 3-year recovery period	$9,134,477

APPENDIX E: TYPES OF ERRORS BY SAMPLE ITEM

STRATUM 1

Sample	No. of Claims	Not Homebound	Did Not Require Skilled Services	Missing or Insufficient Documentation	Incorrect HIPPS Code	Overpayment
1	1	-	1	-	-	$2,885
2	1	1	1	-	-	351
3	1	-	-	-	-	-
4	1	1	1	-	-	1,625
5	1	-	-	-	-	-
6	1	-	-	-	-	-
7	1	1	1	-	-	399
8	1	1	1	-	-	238
9	1	-	-	-	-	-
10	1	-	-	-	-	-
11	1	-	1	-	-	346
12	1	-	-	-	-	-
13	1	1	-	-	-	2,263
14	1	-	-	-	-	-
15	1	-	-	-	-	-
16	1	-	-	-	-	-
17	1	-	-	-	1	(90)
18	1	-	-	-	-	-
19	1	-	-	-	-	-
20	1	-	-	-	-	-
21	1	1	-	-	-	439
22	1	-	1	-	-	2,700
23	1	1	1	-	-	2,868
24	1	-	-	-	-	-
25	1	-	-	-	-	-
26	1	-	-	-	-	-
27	1	1	-	-	-	3,077
28	1	-	-	-	-	-
29	1	1	1	-	-	2,473
30	1	-	-	-	-	-

STRATUM 2

Sample	No. of Claims	Not Homebound	Did Not Require Skilled Services	Missing or Insufficient Documentation	Incorrect HIPPS Code	Overpayment
31	1	-	-	-	-	-
32	1	1	1	-	-	$6,485
33	1	-	-	-	-	-
34	2	-	-	-	-	-
35	1	-	-	-	-	-
36	2	-	-	-	-	-
37	1	1	1	-	-	5,362
38	1	-	1	1	-	5,021
39	1	-	1	-	-	1,033
40	1	1	1	-	-	1,097
41	1	-	1	-	-	870
42	2	2	2	-	-	4,524
43	1	1	-	-	-	3,998
44	1	1	-	-	-	3,978
45	1	-	-	-	-	-
46	1	-	1	-	-	3,947
47	1	-	-	-	-	-
48	1	-	-	-	-	-
49	1	-	1	-	-	756
50	1	-	1	-	-	921
51	1	-	-	-	-	-
52	1	1	1	-	-	3,643
53	1	-	-	-	-	-
54	1	-	-	-	-	-
55	1	1	-	-	-	3,472
56	1	1	1	-	-	3,454
57	1	-	1	-	-	2,772
58	1	-	1	-	-	2,748
59	1	1	1	-	-	3,120
60	1	1	1	-	-	3,114

STRATUM 3

Sample	No. of Claims	Not Homebound	Did Not Require Skilled Services	Missing or Insufficient Documentation	Incorrect HIPPS Code	Overpayment
61	1	-	-	-	-	-
62	1	-	-	-	-	-
63	2	1	2	-	-	$5,076
64	2	-	1	-	-	2,841
65	1	-	-	-	-	-
66	3	2	2	1	-	4,855
67	4	4	-	-	-	8,377
68	3	-	1	-	-	5,888
69	2	1	1	-	-	6,792
70	2	-	1	-	-	2,584
71	3	1	3	-	-	9,013
72	3	-	-	-	-	-
73	2	-	-	-	-	-
74	5	5	2	-	-	10,205
75	3	-	-	-	-	-
76	1	1	1	-	-	7,880
77	4	3	4	-	-	6,784
78	2	-	-	2	-	8,287
79	4	-	4	-	-	3,906
80	2	-	2	-	-	3,298
81	2	-	1	-	-	260
82	2	-	-	-	-	-
83	1	-	-	-	-	-
84	2	1	1	-	-	3,978
85	6	5	2	-	-	19,302
86	2	-	-	-	-	-
87	3	-	2	-	-	4,161
88	1	-	-	1	-	6,649
89	2	-	-	-	-	-
90	6	4	4	-	-	10,735

STRATUM 4

Sample	No. of Claims	Not Homebound	Did Not Require Skilled Services	Missing or Insufficient Documentation	Incorrect HIPPS Code	Overpayment
91	11	-	-	-	-	-
92	10	-	-	-	-	-
93	9	1	1	-	-	$9,686
94	12	-	-	-	-	-
95	12	1	1	-	-	4,904
96	12	-	-	-	-	-
97	12	1	1	-	-	4,819
98	12	-	-	-	-	-
99	13	-	1	-	-	3,629
100	8	-	1	1	-	4,823
101	13	-	-	-	-	-
102	10	-	1	-	-	1,564
103	10	2	2	-	-	11,925
104	12	-	-	1	-	2,910
105	12	-	1	-	-	2,465
106	12	-	1	-	-	4,040
107	7	-	-	-	-	-
108	12	-	-	-	-	-
109	7	-	1	-	-	1,336
110	13	-	-	1	-	2,944
111	9	-	-	-	-	-
112	12	-	-	-	-	-
113	8	-	1	-	-	4,923
114	8	-	-	-	-	-
115	12	2	-	-	-	5,296
116	13	-	-	-	-	-
117	8	-	-	-	-	-
118	7	-	-	-	-	-
119	11	2	2	-	-	5,597
120	4	2	2	-	-	16,597
121	7	-	-	-	-	-
122	10	-	2	-	-	7,068
123	12	-	2	-	-	3,784
124	11	2	2	-	-	5,336
125	6	-	-	-	-	-
Total	**497**	**62**	**82**	**8**	**1**	**$314,406**

Home Health VNA
Merrimack Valley Hospice
HomeCare, Inc.

The Leaders in Home Health and Hospice Care

March 17, 2016

John G. Albert
President and CEO

David Lamir, Regional Inspector General for Audit Services
Department of Health and Human Services
Office of Inspector General, Audit Services Region I
JFK Federal Building
15 New Sudbury Street, Room 2425
Boston, MA 02203

Dear Mr. Lamir:

We appreciate the opportunity to provide our views on the validity of the facts and the reasonableness of the recommendations in your draft report dated December 17, 2015 (Report) prior to its finalization and publication. Your efforts addressing our concerns regarding errors and inaccuracies in this Report and addressing our questions also were most appreciated. Lastly, the assistance provided by your office in dealing with the premature recoupment efforts by the Centers for Medicare and Medicaid Services (CMS) and the various challenges and problems such efforts created for Home Health VNA, was invaluable.

As a highly respected, not-for-profit agency, Home Health VNA has a 120 year distinguished history of providing comprehensive medical care and support services to patients and families throughout our region. We are proud of the high quality care we provide to the communities and patients we serve. Moreover, we believe the care we provide is in full compliance with the many and varied complex laws that govern such services. Home Health VNA's management and dedicated lay Board of Directors devote extensive efforts and resources to assure the provision of high quality of care in full compliance with all laws. We believe this Report presents an unfair and inaccurate assessment of our efforts and success.

This opportunity to provide our comments on this Report and the allegations contained in it is extremely critical to Home Health VNA. As we have no ability to formally challenge this OIG audit process and the alleged findings, these comments are the only means of addressing what we believe are an unfair and inaccurate assessment of our services. If Home Health VNA were able to directly appeal the findings in this Report with the Office of Inspector General ("OIG"), we believe the outcome would significantly alter the findings in this Report. As a result, Home Health VNA desires the public record to reflect its concerns and disagreements with many of the findings and with the audit process in general.

Summary of Concerns

Compliance with all the applicable requirements of Medicare is one of the highest priorities for Home Health VNA. We appreciated your verification that there was no indication of fraud on the part of Home Health VNA. We also recognize that not one of your findings challenges the high level of quality of care provided by Home Health VNA, but is instead intended as commentary on technical compliance with billing requirements. However, as Home Health VNA expends significant efforts and resources to provide its care and perform the related billing in full compliance with Medicare's many requirements, the findings of the audit raise material concerns for us.

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Home Health VNA has numerous concerns with the processes associated with this audit, the methods used, the ultimate cost and benefit to the Medicare Program, and its lack of inherent fairness. We recognize that this response letter is not the place to express all of our concerns and that legislative and other efforts are required to restore the rational nature of these processes. In this letter, we are merely attempting to assure that the OIG understands our primary concerns with this process as experienced by Home Health VNA.

1. Alleged Industry Error Rate Indicates Serious System Problems

The background or basis for this audit is referenced in the Report as being driven by findings of high levels of error rates in home health billing activities. Specifically, you state that CMS determined through CERT reviews that home health billing claims have an error rate of 51.4%. This fact, or rate, is a significant finding and requires further consideration as it relates to the audit done on Home Health VNA for several reasons and needs to be analyzed further.

The primary concern such a high error rate raises is that it is a condemnation of the systems and processes involved, more than of the individual providers. A further evaluation of CMS CERT data indicates that the home health rate far exceeds the error rate of other providers, which is again another indicator that there is something wrong with the system. It is notable that the range of improper payment rates for other provider types ranges from 6.2% to 39.9%. Clearly a national rate of 51.4% indicates that further evaluation is required as that level of error is not consistent with other providers and indicates a pervasive level of noncompliance consistent with unclear rules, procedures and guidelines.

There are two key components in the calculation of an error rate: the system itself and the person/provider who is using the system. In circumstances such as this, where there is no allegation of willful or deliberate improper actions, the error rate is a combination of (i) system problems and (ii) user errors. It is inappropriate to use or attribute the error solely to Home Health VNA. Practically speaking, it is very hard to be wrong more than 50% of the time without other factors influencing such errors.

One of the tenets of quality improvement processes and systems is that error rates are not appropriately used to attribute fault to an individual without first considering the system. Quality improvement literature indicates that when we fall into this trap the system is not improved, and that such data should be used primarily to determine how the system can be improved. Additionally, use of such numbers to infer individual responsibility is reported to have low and even negative results.

It is of significant concern that the OIG pursued its initiative to audit home health agencies and assess financial liability to such providers knowing this error rate existed. This error rate assures that there is very little probability of providers successfully "passing" such an audit as providers will be measured to a clearly flawed system and statistically demonstrated flawed or problematic standards. Prior to measuring an individual home health agency, the directions and guidelines with which a home health agency must comply when billing for services should be fully evaluated for adequacy as they clearly are not adequate based on this error rate.

The OIG's initial audit data indicated the error rate for Home Health VNA was 44.55% (later adjusted to 44.53%) based on amount billed. This rate is important to examine for at least two reasons. First, it is the most negative way to state the finding. To be more accurate, the error rate should be based on claims billed as that is where the alleged errors occurred. The initial finding was that 114 of the 497 claims reviewed failed to meet the multiple Medicare billing requirements. This is a 22.9% error rate based on number of claims (21.1% after adjustment for corrections in the draft Report). More importantly, regardless of how the error rate was calculated and the accuracy of the underlying calculations, it is important to recognize that Home Health VNA compares very positively to the CMS reported national average error rate of 51.4%. Its error rate clearly indicates that it has one of the highest levels of accuracy in billing by CMS standards, despite the evidence that CMS has failed to provide clear billing compliance standards for home health agencies.

2. Statistical Processes Flawed

Home Health VNA does not intend to present a detailed review of its concerns relative to the statistical processes used by the OIG in this Report. The detailed analyses from its consultants is too lengthy for this response; however, it does want to provide the OIG with feedback regarding critical issues related to this aspect of the Report as the use of statistical methods and extrapolation to determine overpayments must be correctly done or extreme unfairness to the provider can occur. Moreover, these are sophisticated areas where there is great reliance on experts and it is important to make sure the areas of professional disagreement are recognized.

Home Health VNA consulted a qualified statistical consultant, familiar with Medicare statistical sampling and extrapolation requirements as set forth in various Medicare manuals, including the Medicare Program Integrity Manual ("MPIM"), and as established in legal proceedings. Our consultant concluded that the extrapolation performed in this audit is invalid because it fails to meet established requirements. More specifically, the consultant concluded that the following errors and/or deficiencies existed in the statistical process used by the OIG.

(a) The documentation required per §8.4.4.4.1 and §8.4.2 of the MPIM was not provided to Home Health VNA.

The OIG did not produce the universe of all pertinent claim line data from which the sample frame was created for both the 2011 and 2012 portions of the audit. Specifically, the 2012 portion of the universe data is critical because this is the only calendar year for which extrapolation is permitted based on Section 1870 (b) of the Social Security Act. What the OIG did produce was the *Sampling Frame.xls* file of claim numbers, patient numbers (HICNs), claim start date, claim treatment authorization number, claim from date, and claim through date for each claim in the frame. But there are no "dates when claim was paid", which is part of the sampling unit's operational definition. Thus, when the consultant attempted to replicate the OIG's results, he was unable to reach the same results as the OIG based on the information he was provided. This is in violation of the requirement that sufficient documentation shall be kept so that the sampling frame can be re-created, should the methodology be challenged.

(b) Incorrect formulas for estimation and extrapolation were used that did not meet this mandatory requirement of §8.4.2 of the MPIM.

The calculations in the Report used a confidence interval method to estimate a recoupment amount that requires the stratified average overpayments to be normally distributed. The tests performed by our statistical consultant proved the stratified average overpayments from the audit of Home Health VNA are not normally distributed. Thus the OIG's extrapolation of the audit results is invalid and the repayments amounts were not properly calculated because incorrect formulas were used.

3. Audit Was Effectively a RAC Audit.

A primary flaw in this audit of billing compliance is that in the end, it was no different than a RAC audit and, as a result, has all the inherent flaws of the RAC audit process. As you stated in the exit conference, the OIG audit staff itself found very few errors or deficiencies in Home Health VNA's Medicare billing or documentation related processes. Virtually all of the errors identified arose as a result of medical reviews done by a third party contractor and not the OIG, and are issues of clinical or professional dispute. There are numerous problems with the third party medical/clinical reviews performed as part of this audit.

In response to its identification of obvious errors in the clinical findings, Home Health VNA was told that such errors could not be addressed as the OIG no longer had access to the contractor that performed the clinical review. It appears that these reviewers were contracted reviewers who had their contracts terminated by CMS as of December, 2015 and this audit was one of their last efforts. In addition to being rushed to complete their reviews, it is clear the OIG performed little or no review of the accuracy of these findings, as it does not have that capability. Moreover, the method of compensation used with such reviewers calls into question their objectivity. Many of these auditors are paid on a contingency basis, but regardless, such auditors have a built in incentive to "find" errors as contracts are not likely to be renewed if low error rates are found.

Lastly, the high rate of reversal of findings by these third party auditors by administrative law judges further challenges the validity of such reviewers' findings. This is a critical factor as it is this aspect of the process that is intended to provide an impartial review, free from influence by CMS, such as the direct and indirect influence for denials experienced by third party contractors. One OIG report indicated that in 2010, 56% (62% when partial reversals are included) of all appeals were in the provider's favor. Hospices and home health agencies were reported to have an appeal success rate of 62% and hospitals had a 72% success rate.

Further complicating the review of these clinical denials, no work papers could be produced that showed the analytic process used by the reviewers in making their decisions, despite our requests to be given these work papers. All that was produced was a summary of the review by the reviewer which frequently contained contradictory information or information for which the source could not be identified. Moreover, the documentation did not always clearly state the basis for the medical reviewer's determination, making it impossible for Home Health VNA to replicate the decision making and review process.

Based on the issues identified by Home Health VNA relative to the quality and accuracy of the clinical reviews performed, it is clear that this high reliance on contracted clinical reviewers calls into question virtually all of findings in this Report. It appears that the use of these contractors resulted in many of

the same issues that were identified in the RAC audit process. The OIG's use of contractors who were being phased out due to the numerous concerns about their work and who could not provide responses regarding the work they performed, only adds to the underlying concerns regarding the accuracy of this material aspect of the Report.

The inadequate reviews by such contractors in the RAC audit and similar other audits resulted in a proliferation of appeals that CMS has not been able to handle. These virtual explosions in the number of appeals providers are pursuing has resulted in a backlog of over 350,000 appeals and created delays measured in years, not months, before a provider can obtain a fair hearing on these flawed audit findings. This is one of the primary reasons RAC audits were suspended; however, if the OIG uses the same auditors with the same results (inaccurate findings resulting in numerous appeals), it is unlikely this problem can ever be effectively addressed, continuing the high level of expenditures on appeals. This is a waste of critical funds for both providers and CMS and benefits no one.

Home Health VNA has no choice but to pursue numerous individual claim appeals as a result of this Report as the findings of these contractors are not supported by the clinical record. These multiple appeals will be costly for both Home Health VNA and CMS, but more importantly, it will result in at least a three to five year delay before Home Health VNA can vindicate itself and finally be able to prove that the vast majority of findings in this report are incorrect. During that time, Home Health VNA must repay the amounts Medicare has allegedly overpaid it and will only be able to secure the return of such funds over time, on a case by case basis.

This is an extremely unfair and inequitable situation. Practically speaking the effect is that Home Health VNA has no meaningful appeals process for the findings in this Report as the only appeal option is an appeal system that is overloaded and not functioning consistent with statutory requirements. As a result of RAC and other audits, the appeal system is in crisis. Appellants are not receiving timely access to this process as required by law, and at this point in time, it is unclear if current appellants will ever secure meaningful access to these required appeals processes. This lack of meaningful procedural due process should be considered as the OIG pursues such auditing efforts such as its audit of Home Health VNA.

4. Premature Audit Findings Result in Errors and Problems.

Thus far, the more than two and a half years Home Health VNA has been involved in this audit process have been challenging at best. We believe that we went above and beyond in our cooperation with and assistance to, the auditors. As was explained to us on more than one occasion, the OIG staff lacked familiarity with home health billing and related provider requirements. We provided answers and references to your numerous inquiries and our staff spent hours supporting your efforts as we desired a fair review. We even involved our software vendor in providing explanations to industry standard processes to your auditors.

In July of 2015, we were told that the audit was essentially concluded and that Home Health VNA had a significant error rate of approximately 44%. You further stated that you were waiting for the final results from medical review to finalize the audit and that it should be finalized in September or October at the latest. October came and went. Late in November, we were told the audit was nearing

completion and that you wanted to schedule an exit conference with us. This was scheduled for December 16, 2015; however, all we were provided prior to the exit conference was a summary spread sheet identifying the alleged errors and calculating the overpayment estimate the day before the exit conference. Needless to say, it was difficult, if not impossible for us to ask any meaningful questions during the exit conference without the benefit of reviewing the report.

Two days after the exit conference, December 18, 2015, we received a copy of the draft Report. We immediately began reviewing it and it was soon clear to us that there were several obvious errors in the findings. This level of obvious error raised the concern that the finalization of the audit was rushed solely so that CMS would be able to recoup 2012 alleged overpayments as the protracted audit period and delay in finalizing the audit had already prevented the recoupment of 2011 alleged overpayments.

This "rush" was confirmed when on January 8, 2016, we received a demand letter from CMS for repayment of $5,909,882 by January 29, 2016 or recoupment and interest assessments would commence. The letter was dated December 30, 2015 and obviously was the result of the OIG's release of its draft Report to CMS. It was disheartening at best that the OIG's priority was trying to meet the December 31st deadline and not providing Home Health VNA an accurate report or a meaningful opportunity to respond to the allegations.

As you know from our numerous discussions with you, the OIG's release of this draft Report to CMS prior to our review, comments, finalization by your office and its formal release or publication, consistent with routine procedures used by the OIG in other audits, resulted in numerous issues and problems for Home Health VNA. We could detail them here; however, the list is too lengthy. The most telling facts are that the administrative contractor had no idea how to handle a recoupment on a draft report and told us on various occasions that the demand should not have been issued until the report was final. Clearly Home Health VNA was forced to endure a procedural nightmare until this premature recoupment process was stopped by CMS on January 27, 2016. At that time, CMS informed us it had "voided" the December 30th demand letter. This only verified that the provision of a draft report to CMS prior to its finalization was inconsistent with routine procedures and requirements in order to attempt premature recoupment.

Another indication of the fact this draft Report was rushed and prematurely released solely in order to prematurely recoup payments is that we were readily able to identify obvious technical errors made by the third party auditors. Although the bulk of the denial rationales provided by the third party auditors were clinical in nature, the OIG did agree to review those errors that they deemed strictly technical in nature. This resulted in Home Health VNA providing the OIG with technical arguments on 10 separate denials, 9 of which the OIG agreed should be overturned, resulting in a 90% overturn rate on these technical denials. In addition to these technical errors, we believe that the vast majority of the audit results based on clinical judgment by third party reviewers are in error, and we will similarly prevail when we are provided a meaningful opportunity to challenge those findings.

The rush to complete this audit process is also reflected in the draft Report. The report indicates that this was an audit of "services provided" in 2011 and 2012. Based on our understanding of this Report from our various discussions, we believe that is incorrect. There are services included in this audit which were provided in 2010. In response to multiple inquiries, the audit team confirmed the basis of the

audit sample was claims paid in the 2011 and 2012 timeframe. This sampling method does not directly reflect when services were provided. This is a critical distinction as it affects how the results are analyzed.

Additionally, just within this past week, there have been multiple new adjustments made to the OIG's summary report and the alleged overpayment liability which we believe are further indications of the rush to complete this audit. On Wednesday, March 9, 2016 Home Health VNA requested that the OIG issue a revised summary report based on the fact that the OIG had reversed its decision on 9 claims. Later that day, your office emailed us new projected overpayment amounts which took into account the claims reversals, resulting in a slight increase in the overpayment which we found questionable considering the corrections made to the nine files. This was followed on Friday, March 11, 2016 by a new summary report which added an additional $400,000 to the extrapolated, projected overpayment.

The last minute corrections in the Report have continued. The rationale given for this increase was that the OIG had identified two claims that it had failed to include in the extrapolation calculation. Upon further analysis by Home Health VNA, one of the two claims cited by the OIG was included in the unrecoverable Stratum 4 and should never have been included in the extrapolation. Yesterday, this was confirmed to be another error and that the $400,000 increase in the alleged overpayments was due to only one claim, not two as indicated last week. The fact that this oversight was identified after months and months of opportunity to finalize the Report, in combination with errors we have identified in the audit and the statistical methodology used call into question this entire process, its validity and its fairness.

Another example of the errors permeating this process, relates to the voided recoupment effort by CMS. There was significant confusion within the MAC relative to how to handle this matter since the audit was not final. Not only did we have to deal with the fact that claims were prematurely marked for recoupment prior before to CMS instructing the MAC to rescind the demand letter of December 30, 2015, CMS recouped funds for at least one patient that was not in the audit sample. This appeared to indicate errors in transmitting the claim or recoupment data.

This audit was about Home Health VNA's billing compliance with what are often very unclear rules. It is not about patient care. Its results are based on third party reviews that have no clear standards and permit wide variation in judgments. It is ironic at best that Home Health VNA then is the victim of government agencies' rush to recoup funds, resulting in audit inaccuracies and bending of procedures and processes just so such recoupment can occur. Such procedural unfairness has unfortunately been the hallmark of virtually every aspect of this extremely lengthy and protracted audit process. Moreover, it is clear that this process is not over, as Home Health VNA's fight to vindicate itself from these findings will easily take another three to five years or more as a result of CMS's inability to comply with its own statutory requirements.

Concurrence or Non-concurrence with Recommendations

As clearly indicated in this letter, Home Health VNA takes the OIG's allegations and related recommendations very seriously. Also as clearly indicated, Home Health VNA disagrees with the majority of the findings in the Report. It is important to note that Home Health VNA has not yet had an

opportunity to adjudicate or appeal the allegations in this Report. As a result, Home Health VNA reserves all rights to defend itself from the claims that it did not comply with the applicable billing requirements, and that it did not have adequate controls to prevent incorrect billing. In addition, as Home Health VNA will be forced to fight these audit findings through a broken and nonfunctioning appeals system, it reserves its right to seek relief in the nature of mandamus under 28 U.S.C. §1361.

In compliance with the requirements of your letter, we offer the following more specific, summary comments for each recommendation made by the OIG. Please note that all amounts referenced in this section are based on what was presented in the report. We acknowledge that your office provided us with a recalculation of the overall alleged liability, reducing it; however, these communications increased the 2012 overpayment liability. On March 9, 2016, your office indicated that such liability was $5,926,424 and then a further revised calculation on March 11, 2016 that it was $6,348,971, an even higher amount as discussed above. As the draft audit report we were provided was not updated with these numbers, we are responding to the draft report as provided to us.

- Refund to the Medicare contractor $5,909,882 in estimated overpayments for claims incorrectly billed that are within the 3-year recovery period;

As required by applicable law, Home Health VNA will respond to any lawful and appropriate demand made by CMS for repayment based on the findings of the OIG's audit. Based on our detailed review of the OIG's allegations, we will appeal all of the findings, except the limited number referenced below for which repayment has already been made to CMS. We believe that these findings were inappropriately made and that our historic 83% success rate on such appeals will result in the reversal of most if not all of these claims. Please note that of the 197 claims in the 2012 period that is the basis of the claim that $5,909,882 should be repaid, we concur that 4 claims were correctly categorized as overpayments and $17,879 has been refunded to CMS.

- Work with the contractor to refund net overpayments outside of the 3-year recovery period, which we estimate to be at least $9,748,225 for our audit period, in accordance with the 60-day repayment rule.

We conducted a detailed review of the 270 claims in the 2011 period. We concur that of those claims, 3 were overpayments and $4,276 was refunded to CMS within the required 60-day period. Based on our review of the remaining claims, we could not identify any basis to support the allegation of overpayment.

- Identify claims in subsequent years that did not meet Medicare payment requirements and refund any associated overpayments;

Please note that for the 30 additional claims in this audit that related to care provided in 2010, we also reviewed these claims consistent with the reviews of claims related to services provided in 2011 and 2012. There were no additional claims identified for which we determined the repayment requirements were met and refunds appropriate.

Home Health VNA has ongoing, robust systems in place to assure compliance with all Medicare payment requirements and to identify overpayments and make repayments to CMS when indicated. It is in the process of further reviewing prior years within the required timeframes applicable to the 60-day rule to determine if there are any incidents of overpayment not previous identified by its standard review processes.

- Strengthen its procedures to ensure that:
    - The homebound status of Medicare beneficiaries are verified and the specific factors qualifying beneficiaries as homebound are documented,
    - Beneficiaries are receiving only reasonable and necessary services,
    - The physician's certification and plan of care comply with Medicare documentation requirements and support the services the agency provided, and
    - The correct HIPPS code is billed.

Home Health VNA disagrees that its procedures materially failed to assure (i) homebound status was correctly verified, (ii) beneficiaries received only reasonable and necessary services, (iii) physician certification and plans of care complied with Medicare requirements, and (iv) it billed the correct HIPPS code. Notwithstanding the foregoing, Home Health VNA consistently seeks opportunities for improvement of its processes. The extensive dialog with the OIG auditors throughout this process enabled Home Health VNA to view its processes from another perspective and facilitated the strengthening of many of its processes. Home Health VNA will continue to strengthen its processes in the future.

In reference to items (i), (ii) and (iii) above and as stated previously, these are essentially disagreements of professional opinion with the review by the contracted auditors. We strongly believe once we are given the opportunity to challenge those findings, we will be successful and those findings will be overturned. We understand that the OIG does not have the capability to review or verify the accuracy of that aspect of the audit process, but believe that if it had been performed by OIG staff there would be a higher level of accuracy in such results, similar to other aspects of this audit.

Lastly, in regards to (iv), in working with your office, we were able to demonstrate that the finding that 8 of 9 claims were coded incorrectly was an error. After working with you, this error rate was reduced to 1 out of 9. Moreover, due to the complexity of the process related to generating the HIPPS code, we still question whether this one claim is an error and plan to pursue it further.

Regardless of our disagreement with the findings of the Report, Home Health VNA is committed to improving its processes and strengthening its various compliance procedures. Furthermore, it is committed to investing resources in these ongoing process improvement efforts. While this audit process has at best been a difficult process for Home Health VNA, it is determined to take what it has learned and further strengthen its compliance efforts.

We hope our response provides clear indication that we take our responsibility as a Medicare provider very seriously. Our procedures are constantly evolving and improving. We will continue to examine and improve these processes in the future. We are committed to ensuring continued compliance with

Medicare billing and related requirements. We will continue to devote significant resources to assuring ongoing compliance with all Medicare requirements.

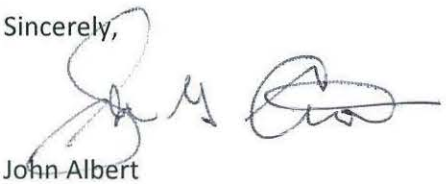
Conclusion

It is difficult for anyone to fully understand the magnitude and impact of this audit process, unless they experience it firsthand. I look back on all the time, resources and efforts expended with your office since we were first notified of this audit in August of 2013 to now, 32 months later. To date, Home Health VNA has expended uncountable hours working with the OIG in this audit process and in the review of these findings. The fact that we will need to expend further resources over the next three to five years in a claim by claim process just to prove the inaccuracy of these findings is more than disheartening. At the end of this potentially eight year process, both Home Health VNA and the government will spend hundreds of thousands of dollars in administrative processes and not in furtherance of care to patients. This is a sad commentary on this process.

We note that there was not one finding in this Report that reflected negatively on the quality of care provided by Home Health VNA. Moreover, there was not one finding indicating that Home Health VNA failed to provide necessary and needed services. There was no finding that Home Health VNA was not highly qualified to provide the services it proudly provides to its patients. This report is primarily about the disagreement between Home Health VNA's professional staff's determination of the care its patients need and those of a third party reviewer who has only the benefit of a paper record on which to base its findings.

We do not believe that it is the objective of the Medicare program or the OIG that providers spend more resources on its administrative processes than the delivery of care. Providers will have no choice but to do so if they are at risk of audits such as the one Home Health VNA experienced. A demand of repayment of $6M is crippling and would force most home health agencies into bankruptcy and closure. This roulette type risk of financial disaster where the certainty of adverse findings is 100% is an unacceptable environment in which to provide services and is not something most home health agencies can survive. Just as the RAC audit process has had to be seriously reconsidered and evaluated, we hope that the OIG will consider our comments in its ongoing review and improvement of its processes as it does not benefit the Medicare program.

Sincerely,



John Albert
President/CEO