

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**MEDICARE HOME HEALTH AGENCY
PROVIDER COMPLIANCE AUDIT:
MISSION HOME HEALTH
OF SAN DIEGO, INC.**

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**August 2020
A-09-18-03008**

Office of Inspector General

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Report in Brief

Date: August 2020

Report No. A-09-18-03008

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



Why OIG Did This Audit

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

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

Our objective was to determine whether Mission Home Health of San Diego, Inc. (Mission Home Health) complied with Medicare requirements for billing home health services on selected types of claims.

How OIG Did This Audit

Our audit covered approximately \$59 million in Medicare payments to Mission Home Health for 16,113 claims. These claims were for home health services provided in calendar years 2015 and 2016 (audit period). We selected a stratified random sample of 100 claims and submitted these claims to independent medical review to determine whether the services met coverage, medical necessity, and coding requirements.

Medicare Home Health Agency Provider Compliance Audit: Mission Home Health of San Diego, Inc.

What OIG Found

Mission Home Health did not comply with Medicare billing requirements for 32 of the 100 home health claims that we audited. For these claims, Mission Home Health received overpayments of \$61,718 for services provided during our audit period. Specifically, Mission Home Health incorrectly billed Medicare for: (1) services provided to beneficiaries who were not homebound, (2) services provided to beneficiaries who did not require skilled services, (3) claims that were assigned incorrect payment codes, and (4) claims for which documentation was inadequate to support the services provided. These errors occurred primarily because Mission Home Health did not have adequate procedures to prevent the incorrect billing of Medicare claims. On the basis of our sample results, we estimated that Mission Home Health received overpayments of at least \$5.9 million for our audit period.

What OIG Recommends and Mission Home Health Comments

We recommend that Mission Home Health: (1) refund to the Medicare program the portion of the estimated \$5.9 million overpayment for claims incorrectly billed that are within the reopening period; (2) for the remaining portion of the estimated \$5.9 million overpayment for claims that are outside of the reopening period, exercise reasonable diligence to identify and return overpayments in accordance with the 60-day rule, and identify any returned overpayments as having been made in accordance with this recommendation; (3) exercise reasonable diligence to identify and return any additional similar overpayments outside of our audit period, in accordance with the 60-day rule, and identify any returned overpayments as having been made in accordance with this recommendation; and (4) strengthen its procedures to ensure the correct billing of Medicare claims. The detailed procedural recommendations are listed in the report.

Mission Home Health stated that it disputed nearly all of our findings and did not concur with our recommendations. Mission Home Health retained a health care consultant to review most of the claims we questioned and challenged our independent medical review contractor's decisions, maintaining that nearly all of the sampled claims were billed correctly. To address the concerns, we had our medical reviewer review Mission Home Health's written comments and its consultant's report. Based on the results of that review, we reduced the sampled claims incorrectly billed from 38 to 32 and revised the related findings and recommendations. We maintain that our remaining findings and recommendations are valid, although we acknowledge Mission Home Health's right to appeal the findings.

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INTRODUCTION

WHY WE DID THIS AUDIT

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

This audit is part of a series of audits of HHAs. Using computer matching, data mining, and data analysis techniques, we identified HHAs at risk for noncompliance with Medicare billing requirements. Mission Home Health of San Diego, Inc. (Mission Home Health) was one of those HHAs.

OBJECTIVE

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

BACKGROUND

The Medicare Program and Payments for Home Health Services

Medicare Parts A and B cover eligible home health services under a prospective payment system (PPS). The PPS covers part-time or intermittent skilled nursing care and home health aide visits, therapy (physical, occupational, and speech-language pathology), medical social services, and medical supplies. Under the home health PPS, CMS pays HHAs for each episode of care (e.g., a 60-day episode of care in CYs 2015 and 2016) that a beneficiary receives.

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

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

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

Home Health Agency Claims at Risk for Incorrect Billing

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

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

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

Medicare Requirements for Home Health Agency Claims and Payments

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

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

¹ HIPPS payment codes represent specific sets of patient characteristics (or case-mix groups) on which payment determinations are made under several Medicare prospective payment systems, including those for skilled nursing facilities, inpatient rehabilitation facilities, and HHAs.

² The final payment is determined at the conclusion of the episode of care using the OASIS information but also factoring in the number and type of home health services provided during the episode of care.

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

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

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

The Office of Inspector General (OIG) believes that this audit report constitutes credible information of potential overpayments. Providers that receive credible information of a potential overpayment must: (1) exercise reasonable diligence to investigate the potential overpayment, (2) quantify any overpayment amount over a 6-year lookback period, and (3) report and return any overpayments within 60 days of identifying those overpayments (60-day rule).⁴

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

Mission Home Health of San Diego, Inc.

Mission Home Health is a home health care provider located in San Diego, California. National Government Services, its MAC, paid Mission Home Health approximately \$62.1 million for 19,563 claims for services provided to Medicare beneficiaries in CYs 2015 and 2016 on the basis of CMS’s National Claims History (NCH) data.

⁴ The Act § 1128J(d); 42 CFR part 401, subpart D; 42 CFR §§ 401.305(a)(2) and (f); and 81 Fed. Reg. 7654, 7663 (Feb. 12, 2016).

HOW WE CONDUCTED THIS AUDIT

Our audit covered approximately \$59 million in Medicare payments to Mission Home Health for 16,113 claims.⁵ These claims were for home health services provided in CYs 2015 and 2016 (audit period).⁶ We selected a stratified random sample of 100 claims with payments totaling \$415,271. We evaluated compliance with selected billing requirements and submitted these claims to an independent medical review contractor to determine whether the services met coverage, medical necessity, and coding requirements.

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

Appendix A contains the details of our audit scope and methodology, Appendix C describes our statistical sampling methodology, Appendix D contains our sample results and estimates, and Appendix E contains the types of errors by sample item.⁷

FINDINGS

Mission Home Health did not comply with Medicare billing requirements for 32 of the 100 home health claims that we audited. For these claims, Mission Home Health received overpayments of \$61,718 for services provided in CYs 2015 and 2016. Specifically, Mission Home Health incorrectly billed Medicare for:

- services provided to beneficiaries who were not homebound,
- services provided to beneficiaries who did not require skilled services,
- claims that were assigned incorrect HIPPS payment codes, and
- claims for which documentation was inadequate to support the services provided.

⁵ In developing this sampling frame, we excluded home health payments that were: (1) for services provided in CY 2017, (2) less than \$1,000, (3) low-utilization payment adjustments, (4) partial episode payments, (5) requests for anticipated payments, and (6) identified in the Recovery Audit Contractor data warehouse as having been previously excluded by other entities.

⁶ The CYs were determined by the home health claims with episode-of-care “through” dates of service. The “through” date is the last day on the billing statement covering services provided to the beneficiary.

⁷ Sample items may have more than one type of error.

These errors occurred primarily because Mission Home Health did not have adequate procedures to prevent the incorrect billing of Medicare claims within the selected risk areas.

On the basis of our sample results, we estimated that Mission Home Health received overpayments of at least \$5.9 million for our audit period.⁸ As of the publication of this report, this amount included claims outside of the 4-year claim-reopening period.

MISSION HOME HEALTH’S BILLING ERRORS

Mission Home Health incorrectly billed Medicare for 32 of the 100 sampled claims, which resulted in overpayments of \$61,718.

Beneficiaries Were Not Homebound

Federal Requirements for Home Health Services

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

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

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

Revisions 172 and 208 state that for a patient to be eligible to receive covered home health services under both Medicare Parts A and B, the law requires that a physician certify in all cases that the patient is confined to his or her home and an individual will be considered “confined to the home” (homebound) if the following two criteria are met:

⁸ Mission Home Health received overpayments of at least \$5,969,826. To be conservative, we recommend recovery of overpayments at the lower limit of a two-sided 90-percent confidence interval. Lower limits calculated in this manner are designed to be less than the actual overpayment total 95 percent of the time.

Criterion One

The patient must either:

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

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

Criterion Two

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

Mission Home Health Did Not Always Meet Federal Requirements for Home Health Services

For 26 sampled claims, Mission Home Health incorrectly billed Medicare for home health episodes for beneficiaries who did not meet the above requirements for being homebound for the full episode (5 claims) or for a portion thereof (21 claims).⁹

Example 1: A Beneficiary Was Not Homebound—Entire Episode

For one beneficiary, the medical records showed that the beneficiary was independent in activities of daily living (e.g., grooming, dressing, bathing, toileting, meal preparation, and eating). The beneficiary was able to walk more than 1,000 feet without an assistive device. There was no history of recent or recurrent falls. Leaving the home would not have required a considerable and taxing effort for this patient at the start of care. The medical records did not support that the beneficiary was homebound for the entire episode.

⁹ Of these 26 claims with homebound errors, 1 claim was also billed with inadequate documentation, and 2 claims were also billed with incorrect HIPPS codes. Appendix E provides detail on the extent of errors, if any, for each claim reviewed.

Example 2: A Beneficiary Was Not Homebound—Partial Episode

For another beneficiary, the medical records showed that the patient was initially homebound because the beneficiary had a history of lower extremity impairment with bilateral knee replacements and was limited to walking 75 feet. By a later date in the episode, the beneficiary had increased activity and was able to go to a grocery store and ride a scooter. At that point, the beneficiary did not meet the requirements for being considered homebound.

These errors occurred because Mission Home Health did not have adequate procedures to ensure that it verified and continually monitored the homebound status of Medicare beneficiaries under its care and properly documented the specific factors that qualified the beneficiaries as homebound.

Beneficiaries Did Not Require Skilled Services

A Medicare beneficiary must be: (1) in need of skilled nursing care on an intermittent basis or (2) in need of physical therapy or speech-language pathology or (3) have a continuing need for occupational therapy (the Act §§ 1814(a)(2)(C) and 1835(a)(2)(A) and Federal regulations (42 CFR § 409.42(c))). In addition, skilled nursing services must require the skills of a registered nurse or a licensed practical nurse under the supervision of a registered nurse, must be reasonable and necessary to the treatment of the patient's illness or injury, and must be intermittent (42 CFR § 409.44(b) and the Manual, chapter 7, § 40.1).¹⁰ Skilled therapy services must be reasonable and necessary to the treatment of the patient's illness or injury or to the restoration or maintenance of function affected by the patient's illness or injury within the context of the patient's unique medical condition (42 CFR § 409.44(c) and the Manual, chapter 7, § 40.2.1). Coverage of skilled therapy does not turn on the presence or absence of a patient's potential for improvement, but rather on the patient's need for skilled care. Skilled care may be necessary to improve a patient's current condition, to maintain the patient's current condition, or to prevent or slow further deterioration of the patient's condition (the Manual, chapter 7, § 20.1.2).

For four sampled claims, Mission Home Health incorrectly billed Medicare for an entire home health episode or a portion of an episode for beneficiaries who did not meet the Medicare requirements for coverage of skilled therapy services.¹¹

¹⁰ Skilled nursing services can include observation and assessment of a patient's condition, management and evaluation of a patient plan of care, teaching and training activities, and administration of medications, among other things (the Manual, chapter 7, § 40.1.2).

¹¹ For one of these four claims, Mission Home Health incorrectly billed Medicare for speech therapy for the entire episode and physical therapy for a portion of the episode. For another claim, Mission Home Health incorrectly billed Medicare for occupational therapy and physical therapy for the entire episode and skilled nursing for a portion of the episode. For the remaining two claims, Mission Home Health incorrectly billed Medicare for all skilled services for a portion of the episodes.

Example 3: A Beneficiary Did Not Require Skilled Therapy Services

A beneficiary with a history of Alzheimer’s disease, dementia, myopia, and generalized muscle weakness was homebound. Mission Home Health provided physical therapy to the homebound beneficiary. At the start of care, the beneficiary was ambulating 50 feet. Gait and balance training were provided, and a home exercise program was developed and taught. At a later date, the beneficiary was able to perform transfers with standby assistance (the supervision of a caregiver close by for safety). The beneficiary had responded well to physical therapy and had improved gait and strength and maintained fair balance. At that point, physical therapy services were not medically necessary. The medical records did not support that the beneficiary required physical therapy services for a portion of the episode.

These errors occurred because Mission Home Health did not have adequate procedures to ensure that clinical review was sufficient to verify that beneficiaries initially required or continued to require skilled services.

Incorrect Health Insurance Prospective Payment System Codes Were Assigned to Claims

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 three sampled claims, Mission Home Health assigned incorrect HIPPS payment codes to the claims.¹² The OASIS and the medical records did not support the payment codes that Mission Home Health used. The incorrect HIPPS payment codes resulted in higher HHA payments for two claims and a lower HHA payment for one claim. Using the correct HIPPS payment code, we computed the payment amount in error for each claim by subtracting the correct payment amount from the original payment.

These errors occurred primarily because Mission Home Health did not have adequate procedures to ensure that the correct HIPPS payment codes were billed.

Documentation Was Inadequate To Support the Services Provided

Medicare pays for home health services only if a physician certifies that the beneficiary meets the coverage requirements specified in Federal law and regulations (the Act §§ 1814(a)(2) and 1835(a)(2)(A); 42 CFR § 424.22(a)). Before certifying a beneficiary’s eligibility for home health

¹² Two of these three claims were also billed for beneficiaries with homebound errors.

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 that the beneficiary 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 physician's orders on a beneficiary's home health certification and plan of care must indicate the type of services to be provided, 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). 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)).

For two sampled claims, Mission Home Health incorrectly billed Medicare for home health episodes that did not meet Medicare documentation requirements.¹³ Specifically, these claims did not have documentation of beneficiary's home health certification and plan of care.

These errors occurred primarily because Mission Home Health did not have adequate procedures to always ensure that it had documentation of a beneficiary's home health certification and plan of care to support the services provided.

OVERALL ESTIMATE OF OVERPAYMENTS

On the basis of our sample results, we estimated that Mission Home Health received overpayments of at least \$5.9 million for our audit period. As of the publication of this report, this amount included claims outside of the 4-year claim-reopening period.

RECOMMENDATIONS

We recommend that Mission Home Health of San Diego, Inc.:

- refund to the Medicare program the portion of the estimated \$5,969,826 overpayment for claims incorrectly billed that are within the reopening period;¹⁴

¹³ One of these claims was also billed for a beneficiary who was not homebound.

¹⁴ OIG audit recommendations do not represent final determinations by the Medicare program but are recommendations to Department of Health and Human Services action officials. Action officials at CMS, acting through a MAC or other contractor, will determine whether a potential overpayment exists and will recoup any overpayments consistent with CMS's policies and procedures. If a disallowance is taken, a provider has the right to appeal the determination that a payment for a claim was improper (42 CFR § 405.904(a)(2)). The Medicare Part A/B appeals process has five levels, including a contractor redetermination, a reconsideration by a Qualified Independent Contractor, and a decision by the Office of Medicare Hearings and Appeals. If a provider exercises its right to an appeal, it does not need to return funds paid by Medicare until after the second level of appeal. An overpayment based on extrapolation is re-estimated depending on the result of the appeal.

- for the remaining portion of the estimated \$5,969,826 overpayment for claims that are outside of the reopening period, exercise reasonable diligence to identify and return overpayments in accordance with the 60-day rule, and identify any returned overpayments as having been made in accordance with this recommendation;
- exercise reasonable diligence to identify and return any additional similar overpayments outside of our audit period, in accordance with the 60-day rule, and identify any returned overpayments as having been made in accordance with this recommendation; and
- strengthen its procedures to ensure that:
 - the homebound statuses of Medicare beneficiaries are verified and continually monitored and the specific factors qualifying beneficiaries as homebound are documented,
 - beneficiaries are receiving only reasonable and necessary skilled services,
 - the correct HIPPS payment codes are billed, and
 - documentation is maintained for beneficiaries' home health certifications and plans of care.

MISSION HOME HEALTH COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, Mission Home Health stated that it disputed nearly all of our findings and did not concur with any of our four recommendations. Mission Home Health retained a health care consultant to review most of the claims we questioned and submitted to us a report prepared by the consultant. Mission Home Health challenged our selection of Mission Home Health for audit as well as the independent medical review contractor's decisions, maintaining that nearly all of the sampled claims were billed correctly. Mission Home Health's comments, from which we have removed three appendices, appear as Appendix F.¹⁵ We are providing Mission Home Health's comments in their entirety to CMS.

¹⁵ Mission Home Health included a comprehensive appendix as part of its comments on our draft report. This appendix, prepared by the health care consultant, contained a claim-by-claim rebuttal of the findings in our draft report. We provided this appendix to the independent medical review contractor as part of our request for an additional review of claims identified as having errors. However, because this appendix was long and contained a considerable amount of personally identifiable information, we excluded it from this report. In addition, Mission Home Health hired an external statistical expert and included his opinions in another appendix. Because Mission Home Health included its concerns regarding our statistical sampling and estimation methodology in the body of its comments, we excluded this appendix from this report. Lastly, we also excluded an appendix that included resumes of individuals who worked for the health care consultant.

To address Mission Home Health's concerns related to the medical review decisions, we requested that our independent medical review contractor review Mission Home Health's written comments on our draft report as well as the report by Mission Home Health's consultant. Based on the results of that review, we revised our determinations, reducing the total number of sampled claims incorrectly billed from 38 to 32, and revised our related findings and recommendations accordingly. We also adjusted the finding for 7 of the 32 claims. (The overpayment amount decreased for four claims, increased for one claim, and did not change for two claims. Footnote 16 on page 15 explains why the overpayment did not change for the two claims). With these actions taken, we maintain that our remaining findings and recommendations are valid, although we acknowledge Mission Home Health's right to appeal the findings. Below is a summary of the reasons that Mission Home Health did not concur with our recommendations and disputed our findings, as well as our responses.

STATEMENTS OF NONCONCURRENCE WITH RECOMMENDATIONS

Mission Home Health Comments

Mission Home Health did not concur with our recommendations. Regarding our first recommendation, Mission Home Health disagreed with our medical review findings and maintained that nearly all of the sampled claims were billed correctly. Mission Home Health stated that: (1) the medical reviewer impermissibly fixated on the distance beneficiaries could walk to determine homebound status and did not consider the entirety of a beneficiary's medical record and condition; (2) both the homebound status of the beneficiary and the medical necessity of skilled services provided were supported by the medical records and were billed correctly; and (3) our sampling methodology was not statistically valid and should not be used as a basis to calculate an extrapolated overpayment. Mission Home Health acknowledged that four sampled claims were in error (two of three claims with incorrect HIPPS payment codes and two of two claims with missing documentation) and stated that it would refund any overpayments associated with these four individual claims but not the extrapolated amount.

Regarding our second and third recommendations, Mission Home Health did not concur and stated that it plans to appeal our overpayment assessment through the Medicare appeals process for the reasons described above. Regarding our fourth recommendation, Mission Home Health did not concur and stated that it disagrees that its procedures allowed any systemic issues to occur. It also stated that we had not identified any particular policies or procedures that we believed to be lacking or insufficient and that our findings reflect an effective compliance program.

Office of Inspector General Response

Regarding our first recommendation, based on the conclusions of our independent medical review contractor's additional medical review, we revised some findings related to homebound status and skilled services (and the associated recommended disallowance). We maintain that the other findings related to homebound status and skilled services are valid. In addition, we

maintain that our statistical approach resulted in a legally valid and reasonably conservative estimate of the amount overpaid by Medicare to Mission Home Health.

Regarding our second and third recommendations, we acknowledge Mission Home Health's right to appeal the findings.

Regarding our fourth recommendation, because Mission Home Health incorrectly billed Medicare for (1) services provided to beneficiaries who were not homebound, (2) services provided to beneficiaries who did not require skilled services, (3) claims that were assigned incorrect HIPPS payment codes, and (4) claims for which documentation was inadequate to support the services provided, we maintain that Mission Home Health did not have adequate procedures to prevent the incorrect billing of Medicare claims.

OFFICE OF INSPECTOR GENERAL'S AUDIT PROCESS

Mission Home Health Comments

Mission Home Health expressed concerns about why it was selected for review, stating that the only data that OIG used to identify Mission Home Health for audit were the number of dollars it bills to Medicare for home health services.

Mission Home Health stated that it had serious concerns about the qualifications of the medical reviewer and that we did not provide any substantive information by which Mission Home Health can assess the medical reviewer. Mission Home Health also stated that each of the reviewer's medical determinations contains the same vague statement that the reviewer is a "physician who is duly licensed to practice medicine," "knowledgeable in the treatment of the enrollee's medical condition," and "familiar with the guidelines and protocols in the area of treatment under review." In addition, Mission Home Health said that the reviewer's "biography" does not even reference home health and could be used—and presumably has been used—for any licensed physician of any training or qualification whatsoever. Without receiving any information about the reviewer, Mission Home Health stated that it can assess the reviewer only through his or her individual medical determinations of the audited claims.

Mission Home Health stated that our statistical sampling and extrapolation methodology was flawed. It stated the sample size was too small and failed to account for variations in the broader universe of claims. Mission Home Health also stated that our sample was not representative of the universe of claims because we failed to stratify the sample.

Office of Inspector General Response

Conducting provider-specific audits is an essential part of OIG's mission to fight fraud, waste, and abuse and promote efficiency, effectiveness, and economy in Medicare and other Department of Health and Human Services programs. Not only do these audits identify and return overpayments to the Medicare trust funds, they also provide a sentinel effect to

encourage correct billing to the program. Further, these audits frequently identify broader vulnerabilities and lead to nationwide audits that are designed to inform CMS about potential issues and opportunities for strengthening Medicare.

We selected Mission Home Health for audit using computer matching, data mining, and data analysis techniques. Specifically, we selected Mission Home Health for audit based on a risk analysis that considered the amount of claims that fell into one or more risk categories for compliance with home health billing, the volume of claims and Medicare payments compared with Mission Home Health's peers, and input from OIG components. Larger providers, such as Mission Home Health, may be selected for audit because they have a higher volume of claims and Medicare payments in a given risk area or in several risk areas. However, smaller providers may also be selected for audit based on our assessment of high risk in one or more areas.

With respect to the qualifications of OIG's medical reviewers, OIG conducted a full and open competition when it signed the contract under which these reviews are conducted. As part of that competition, OIG evaluated the offeror's understanding of the project and its technical approach, the qualifications of its personnel and its ability to assemble an appropriately skilled team, and the quality assurance and project management plans it submitted. OIG determined that the awardee was a responsive and responsible bidder and represented the best value to the Federal Government. The Request for Proposal also included a description of the review process and the oversight provided by the contractor's medical director or physician, OIG contracting officer representative, and other OIG representatives. For example, the contract required that all claims with a medical necessity determination be reviewed by two clinicians before being provided to OIG. The second-level reviews were to be conducted by the medical director or a physician with the same qualifications who had experience in the appropriate specialty under review. All reviewers were also required to be free of any conflict of interest.

We properly executed our statistical sampling methodology in that we defined our sampling frame and sampling unit, randomly selected our sample, applied relevant criteria in evaluating the sample, and used statistical sampling software (i.e., RAT-STATS) to apply the correct formulas for the extrapolation. The "Estimation of Overpayments" section of this report contains our expanded response related to our statistical sampling methodology and estimation methods.

BENEFICIARY HOMEBOUND STATUS

Mission Home Health Comments

Mission Home Health disagreed with the medical reviewer's determinations that the beneficiary did not qualify as homebound under Medicare standards (1) for the entire episode of care for 6 sampled claims and (2) for part of the episode of care for 28 sampled claims. Mission Home Health stated that these determinations reveal that the medical reviewer consistently failed to apply the appropriate Medicare criteria for homebound status. Mission Home Health stated that the medical reviewer consistently concluded that a beneficiary was

not homebound if he or she could ambulate a certain distance in the home or had a family member or caregiver available to assist the beneficiary. Mission Home Health also stated that the medical reviewer did not consider the entirety of the beneficiary's medical record and condition, as Medicare regulations require.

Mission Home Health requested that the medical reviewer reconsider the claims that the reviewer found lacked homebound status and also requested that we engage a different, qualified medical reviewer to audit the claims at issue. Mission Home Health stated that the initial reviewer's medical determinations reflect a fundamental lack of understanding of home health services and relevant Medicare regulations and guidance.

Office of Inspector General Response

Based on the conclusions of our independent medical review contractor's additional medical review, we revised the findings related to homebound status (and the associated recommended disallowance) to specify that 26, rather than 34, sampled claims were associated with beneficiaries who did not meet the criteria for being homebound (5 claims for the full episode of care and 21 claims for part of the episode of care).

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

Our independent medical review contractor took Mission Home Health's comments regarding caregiver assistance into consideration when performing its additional medical review and revised the determinations accordingly.

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

As noted above, we revised the findings related to homebound status based on our independent medical review contractor's additional review of the sampled claims. We did not use a different medical reviewer. We maintain that our contractor is qualified and knowledgeable about Medicare regulations and guidance specific to home health services.

Accordingly, having revised our findings and the associated recommendation with respect to 8 of the sampled claims identified in our draft report, we maintain that our findings for the remaining 26 claims, and the revised recommendation, are valid.

SKILLED SERVICES

Mission Home Health Comments

Mission Home Health disagreed with all medical review determinations related to sampled claims with skilled services found to be not medically necessary. Mission Home Health stated that the medical records clearly documented the beneficiaries' need for skilled services. Mission Home Health stated that it disagreed with our finding that three claims were noncompliant "for lack of requiring skilled services."

Office of Inspector General Response

Based on the conclusions of our independent medical review contractor's additional medical review, we revised our findings related to skilled services (and the associated recommended disallowance) to specify that four, rather than three, sampled claims were associated with beneficiaries who did not meet Medicare requirements for coverage of skilled nursing or therapy services. Specifically, we revised our finding to indicate that one claim we had identified as an error in our draft report was not an error and identified an additional two claims as errors.¹⁶

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

¹⁶ In our draft report, these two claims were associated with beneficiaries who did not meet Medicare requirements for homebound status. Our independent medical review contractor's additional medical review determined that, for a portion of the episode, these beneficiaries did not require skilled services. However, the overpayment amount for these claims did not change.

skilled therapy services must be reasonable and necessary for the treatment of the beneficiary's illness or injury within the context of the beneficiary's unique medical condition.

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

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

Accordingly, having revised our finding and the associated recommendation with respect to one of the sampled claims identified in our draft report and the additional two claims found in error by the additional review, we maintain that our findings for four claims in our final report, and the revised recommendation, are valid.

ASSIGNMENT OF HEALTH INSURANCE PROSPECTIVE PAYMENT SYSTEM CODES

Mission Home Health Comments

Mission Home Health agreed that an incorrect HIPPS payment code was assigned to each of the three sampled claims identified in our draft report. However, Mission Home Health stated that, for one claim, submitting the incorrect code caused Mission Home Health to receive a lower amount of reimbursement than it would have received if it had submitted the correct code. Mission Home Health agreed that the other two claims were billed with incorrect HIPPS payment codes that caused an increase in the amount of reimbursement for the claims. Mission Home Health vehemently disagreed with our assertion that it did not have adequate procedures to ensure that the correct HIPPS payment codes were billed.

Office of Inspector General Response

Based on the conclusions of our independent medical review contractor's additional medical review, we revised our findings related to the HIPPS payment code errors (and the associated recommended disallowance) to specify that the incorrect HIPPS payment codes resulted in higher HHA payments for two, rather than three, sampled claims.

Regarding the one sampled claim for which Mission Home Health identified that the incorrect HIPPS payment code resulted in a lower HHA payment, this claim was identified as an overpayment in our draft report because it was billed for a beneficiary who also had a homebound error. Based on the medical review contractor's additional medical review, we reversed the homebound error for this claim. Therefore, the incorrect HIPPS payment code for this claim resulted in a lower HHA payment.

The independent medical review contractor examined all the material in the beneficiaries' medical records and carefully considered this information to determine whether Mission Home Health billed the claims in compliance with selected billing requirements. For all medical review, the contractor reached carefully considered conclusions as to whether the services met coverage, medical necessity, and coding requirements.

Accordingly, having revised our finding and the associated recommendation with respect to one of the sampled claims identified in our draft report, we maintain that our findings for the remaining two claims, and the revised recommendation, are valid. We maintain that these errors occurred primarily because Mission Home Health did not have adequate procedures to ensure that the correct HIPPS payment codes were billed.

DOCUMENTATION TO SUPPORT SERVICES

Mission Home Health Comments

For the two sampled claims we identified as having inadequate documentation, Mission Home Health stated that it was able to locate documentation that supported the services provided; however, Mission Home Health acknowledged that a physician did not sign the plans of care. Mission Home Health vehemently disagreed with our assertion that it did not have adequate procedures to always ensure that it had documentation of a beneficiary's home health certification and plan of care to support the services provided.

Office of Inspector General Response

Although Mission Home Health indicated that documentation for the two sampled claims existed, it did not provide the documentation to us. In addition, Mission Home Health acknowledged that the plans of care were not signed by a physician who established the plan of care, in consultation with HHA professional personnel.

The independent medical review contractor examined all the material in the medical records and carefully considered this information to determine whether Mission Home Health billed the claims in compliance with selected billing requirements. For all medical review, the contractor reached carefully considered conclusions as to whether the services met coverage, medical necessity, and coding requirements.

We maintain that for the two sampled claims, Mission Home Health incorrectly billed Medicare for home health episodes that did not meet Medicare documentation requirements. We maintain that these errors occurred primarily because Mission Home Health did not have adequate procedures to always ensure that it had documentation of a beneficiary's home health certification and plan of care to support the services provided.

ESTIMATION OF OVERPAYMENTS

Mission Home Health Comments

Mission Home Health stated that it objected to our use of extrapolation to estimate our overpayment amount. Specifically, it stated that extrapolation is inappropriate unless there exists a "sustained or high level of payment error." Mission Home Health also stated that the statistical sampling and extrapolation methodology was flawed because the sample size was too small and failed to account for variations in the broader universe of claims, such as the complexity of the health conditions of beneficiaries in the universe of claims. Mission Home Health further stated that we did not provide additional key data points that would allow Mission Home Health to analyze conclusively whether the OIG sample is representative of the relevant universe of claims.

Office of Inspector General Response

We carefully considered Mission Home Health's comments on our sampling and estimation methods, and we maintain that our statistical approach resulted in a legally valid and reasonably conservative estimate of the amount overpaid by Medicare to Mission Home Health. Federal courts have consistently upheld statistical sampling and extrapolation as a valid means to determine overpayment amounts in Medicare and Medicaid. See *Yorktown Med. Lab., Inc. v. Perales*, 948 F.2d 84 (2d Cir. 1991); *Illinois Physicians Union v. Miller*, 675 F.2d 151 (7th Cir. 1982); *Momentum EMS, Inc. v. Sebelius*, 2013 U.S. Dist. LEXIS 183591 at *26-28 (S.D. Tex. 2013), *adopted by* 2014 U.S. Dist. LEXIS 4474 (S.D. Tex. 2014); *Anghel v. Sebelius*, 912 F. Supp. 2d 4 (E.D.N.Y. 2012); *Miniet v. Sebelius*, 2012 U.S. Dist. LEXIS 99517 (S.D. Fla. 2012); *Bend v. Sebelius*, 2010 U.S. Dist. LEXIS 127673 (C.D. Cal. 2010).

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. See *John Balko & Assoc. v. Sebelius*, 2012 WL 6738246 at *12 (W.D. Pa. 2012), *aff'd* 555 F. App'x 188 (3d Cir. 2014); *Maxmed Healthcare, Inc. v. Burwell*, 152 F. Supp. 3d 619, 634–37 (W.D. Tex. 2016), *aff'd*, 860 F.3d 335 (5th Cir. 2017); *Anghel v. Sebelius*, 912 F. Supp. 2d 4, 18 (E.D.N.Y. 2012); *Transyd Enters., LLC v. Sebelius*, 2012 U.S. Dist. LEXIS 42491 at *13 (S.D. Tex. 2012). We properly executed our statistical sampling methodology in that we defined our sampling frame and sampling unit, randomly selected our sample, applied relevant criteria in evaluating the sample, and used statistical software (i.e., RAT-STATS) to apply the correct formulas for the extrapolation. Our methodology accounts for the difference between the sample and the sampling frame and for the potential non-normal distribution of the sample mean.

Mission Home Health’s statement that our extrapolation was inappropriate because our error rate did not support a “sustained or high level of payment error” (according to guidelines prescribed for CMS and its contractors) is not applicable because OIG is not a Medicare contractor.¹⁷

To account for the potential differences between the sample and the sampling frame, we recommend recovery at the statistical lower limit of a two-sided 90-percent confidence interval. Lower limits calculated in this manner are designed to be less than the actual overpayment in the sampling frame 95 percent of the time. The use of the lower limit accounts for both the sample design and sample size in a manner that favors the auditee. See *Puerto Rico Dep’t of Health*, DAB No. 2385, at 10 (2011); *Oklahoma Dep’t of Human Servs.*, DAB No. 1436, at 8 (1993) (stating that the calculation of the disallowance using the lower limit of the confidence interval gave the State the “benefit of any doubt” raised by use of a smaller sample size).

We provided Mission Home Health with all the information necessary to replicate the sample from the sampling frame and recalculate the overpayment estimate amount included in the report. In addition, Mission Home Health has direct access to the claim information necessary to validate the sampling frame, and we provided Mission Home Health with a listing of the claims in the sampling frame, which matched our population. With knowledge of our methodology and the actual data used to perform our sampling and extrapolation, Mission Home Health offered no specific objections to our stated methodology.

¹⁷ The Act § 1893(f)(3); CMS *Medicare Program Integrity Manual*, Pub. No. 100-08, chapter 8.4 (effective Jan. 2, 2019).

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

Our audit covered \$59,004,978 in Medicare payments to Mission Home Health for 16,113 home health claims with episode-of-care “through” dates in CYs 2015 and 2016. We selected a stratified random sample of 100 home health claims with payments totaling \$415,271. We evaluated compliance with selected billing requirements and submitted these claims to an independent medical review contractor to determine whether the services met coverage, medical necessity, and coding requirements.

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

We conducted our audit from September 2017 through June 2020, which included:

- (1) fieldwork performed at Mission Home Health’s headquarters in San Diego, California;
- (2) medical review performed by the independent medical review contractor, the results of which were included in our draft report; and
- (3) additional medical review performed by the independent medical review contractor after we had received Mission Home Health’s written comments on our draft report, the results of which were included in our final report.

METHODOLOGY

To accomplish our objective, we:

- reviewed applicable Federal laws, regulations, and guidance;
- extracted Mission Home Health’s paid claim data from CMS’s NCH file for our audit period;
- to develop our sampling frame, removed home health payments from the population that were: (1) for services provided in CY 2017, (2) less than \$1,000, (3) low-utilization payment adjustments, (4) partial episode payments, (5) requests for anticipated payments, and (6) identified in the Recovery Audit Contractor data warehouse as having been previously excluded by other entities;
- selected for detailed review a stratified random sample of 100 home health claims totaling \$415,271 (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 Mission Home Health to support the claims sampled;
- reviewed the sampled claims for compliance with selected risk areas;
- used an independent medical review contractor to determine whether the 100 sampled claims were for services that were reasonable and necessary and met Medicare coverage and coding requirements;
- reviewed Mission Home Health's procedures for billing and submitting Medicare claims;
- verified State licensure information for selected medical personnel providing services to the beneficiaries in our sample;
- calculated the correct payments for those claims requiring adjustments;
- used the results of our sample to estimate the total Medicare overpayments to Mission Home Health for our audit period (Appendix D);
- discussed the results of our audit with Mission Home Health officials; and
- after receiving Mission Home Health's written comments on our draft report, asked the independent medical review contractor to perform an additional medical review of all of the claims that our draft had questioned, and incorporated those results into our own analysis and determination of the allowability of the claims in light of Mission Home Health's comments.

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

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

GENERAL MEDICARE REQUIREMENTS

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

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

OUTCOME AND ASSESSMENT INFORMATION SET DATA

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

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

COVERAGE AND PAYMENT REQUIREMENTS

To qualify for home health services, Medicare beneficiaries must: (1) be homebound; (2) need intermittent skilled nursing care (other than solely for venipuncture for the purpose of obtaining a blood sample) or physical therapy, speech-language pathology, or occupational therapy;¹⁸ (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).

¹⁸ Effective January 1, 2012, CMS clarified the status of occupational therapy to reflect when it becomes a qualifying service rather than a dependent service. Specifically, the first occupational therapy service, which is a dependent service, is covered only when followed by an intermittent skilled nursing care service, a physical therapy service, or a speech-language pathology service as required by law. Once that requirement for covered occupational therapy has been met, however, all subsequent occupational therapy services that continue to meet the reasonable and necessary statutory requirements are considered qualifying services in both the current and subsequent certification periods (subsequent adjacent episodes) (76 Fed. Reg. 68525, 68590 (Nov. 4, 2011)).

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

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

Section 6407(a) of the Affordable Care Act¹⁹ added a requirement to sections 1814(a)(2)(C) and 1835(a)(2)(A) of the Act that the physician have a face-to-face encounter with the beneficiary. In addition, the physician responsible for performing the initial certification must document that the face-to-face patient encounter, which is related to the primary reason the patient requires home health services, has occurred no more than 90 days before 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.²⁰

Confined to the Home

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

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

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

¹⁹ The Patient Protection and Affordable Care Act, P.L. No. 111-148 (Mar. 23, 2010), as amended by the Health Care and Education Reconciliation Act of 2010, P.L. No. 111-152 (Mar. 30, 2010), is collectively known as the Affordable Care Act.

²⁰ See 42 CFR § 424.22(a)(1)(v) and the Manual, chapter 7, § 30.5. The initial effective date for the face-to-face requirement was January 1, 2011. However, on December 23, 2010, CMS granted HHAs additional time to establish protocols for newly required face-to-face encounters. Therefore, documentation regarding these encounters must be present on certifications for patients with starts of care on or after April 1, 2011.

Revisions 172 and 208 state that for a patient to be eligible to receive covered home health services under both Medicare Parts A and B, the law requires that a physician certify in all cases that the patient is confined to his or her home. For purposes of the statute, an individual will be considered “confined to the home” (homebound) if the following two criteria are met:

Criterion One

The patient must either:

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

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

Criterion Two

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

Revision 172 and Revision 208 (the Manual, chapter 7, § 40.2.1) state that for each therapy discipline for which services are provided, a qualified therapist (instead of an assistant) must assess the patient’s function using a method that objectively measures activities of daily living, such as, but not limited to, eating, swallowing, bathing, dressing, toileting, walking, climbing stairs, using assistive devices, and mental and cognitive factors. It states that the measurement results must be documented in the clinical record.

Need for Skilled Services

Intermittent Skilled Nursing Care

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

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

Requiring Skills of a Licensed Nurse

Federal regulations (42 CFR § 409.44(b)(1)) state that in determining whether a service requires the skill of a licensed nurse, consideration must be given to the inherent complexity of the service, the condition of the beneficiary, and accepted standards of medical and nursing practice. If the nature of a service is such that it can be safely and effectively performed by the average nonmedical person without direct supervision of a licensed nurse, the service may not be regarded as a skilled nursing service. The fact that a skilled nursing service can be or is taught to the beneficiary or to the beneficiary's family or friends does not negate the skilled aspect of the service when performed by the nurse. If the service could be performed by the average nonmedical person, the absence of a competent person to perform it does not cause it to be a skilled nursing service.

General Principles Governing Reasonable and Necessary Skilled Nursing Care

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

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

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

Reasonable and Necessary Therapy Services

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

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

Documentation Requirements

Face-to-Face Encounter

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

Plan of Care

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

APPENDIX C: STATISTICAL SAMPLING METHODOLOGY

TARGET POPULATION

The target population consisted of Mission Home Health's claims for home health services that Mission Home Health provided to Medicare beneficiaries with episodes of care that ended in CYs 2015 and 2016.

SAMPLING FRAME

The sampling frame consisted of a database of 16,113 home health claims, valued at \$59,004,978, from CMS's NCH file.²¹

SAMPLE UNIT

The sample unit was a home health claim.

SAMPLE DESIGN

We used a stratified random sample (Table 1).

Table 1: Strata for Our Sample

Stratum	Payment Range of Claims	No. of Claims	Dollar Value of Claims
1	\$1,561.06 to \$3,256.63	7,663	\$20,052,737
2	\$3,260.78 to \$4,563.75	5,188	19,969,248
3	\$4,564.74 to \$10,082.14	3,262	18,982,993
Total		16,113	\$59,004,978

SAMPLE SIZE

We randomly selected 34 claims from stratum 1, 33 claims from stratum 2, and 33 claims from stratum 3. Our total sample size was 100 claims.

²¹ Our sampling frame excluded home health claim payments that were: (1) for services provided in CY 2017, (2) less than \$1,000, (3) low-utilization payment adjustments, (4) partial episode payments, (5) requests for anticipated payments, and (6) identified in the Recovery Audit Contractor data warehouse as having been previously excluded by other entities.

SOURCE OF RANDOM NUMBERS

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

METHOD OF SELECTING SAMPLE ITEMS

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

ESTIMATION METHODOLOGY

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

APPENDIX D: SAMPLE RESULTS AND ESTIMATES

Table 2: Sample Results

Stratum	No. of Items in Sampling Frame	Value of Frame	Sample Size	Value of Sample	No. of Incorrectly Billed Sample Items	Value of Overpayments
1	7,663	\$20,052,737	34	\$89,838	5	\$12,875
2	5,188	19,969,248	33	125,439	18	20,322
3	3,262	18,982,993	33	199,994	9	28,521
Total	16,113	\$59,004,978	100	\$415,271	32	\$61,718

**Table 3: Estimated Overpayments for Our Audit Period
(Limits Calculated for a 90-Percent Confidence Interval)**

Point estimate	\$8,915,953
Lower limit	5,969,826
Upper limit	11,862,079

APPENDIX E: TYPES OF ERRORS BY SAMPLE ITEM

STRATUM 1 (Sample Items 1–34)

Sample Item	Not Homebound	Did Not Require Skilled Services	Incorrect HIPPS Code	Inadequate Documentation	Overpayment
1	-	-	-	-	-
2	-	-	-	-	-
3	-	-	-	-	-
4	-	-	-	-	-
5	-	-	-	-	-
6	X	-	-	-	\$2,966
7	-	-	-	-	-
8	-	-	-	-	-
9	-	-	-	-	-
10	-	-	-	-	-
11	X	-	-	X	2,372
12	-	-	-	-	-
13	-	-	-	-	-
14	-	-	-	-	-
15	-	-	-	-	-
16	-	-	-	-	-
17	X	-	-	-	2,757
18	-	-	-	-	-
19	-	-	-	-	-
20	-	-	-	-	-
21	X	-	X	-	2,129
22	-	-	-	-	-
23	-	-	-	-	-
24	-	-	-	-	-
25	-	-	-	-	-
26	-	-	-	-	-
27	-	-	-	-	-
28	-	-	-	-	-
29	-	-	-	-	-
30	-	-	-	-	-
31	X	-	-	-	2,651
32	-	-	-	-	-
33	-	-	-	-	-
34	-	-	-	-	-

STRATUM 2 (Sample Items 35–67)

Sample Item	Not Homebound	Did Not Require Skilled Services	Incorrect HIPPS Code	Inadequate Documentation	Overpayment
35	X	-	-	-	\$860
36	-	-	-	-	-
37	-	-	-	-	-
38	X	-	-	-	803
39	-	-	-	-	-
40	X	-	-	-	2,183
41	-	X	-	-	591
42	X	-	-	-	896
43	-	X	-	-	370
44	X	-	-	-	135
45	X	-	-	-	4,078
46	-	-	-	-	-
47	-	-	X	-	(347)
48	X	-	-	-	1,291
49	-	-	-	-	-
50	X	-	-	-	803
51	-	-	-	-	-
52	-	-	-	-	-
53	-	-	-	-	-
54	-	-	-	-	-
55	-	-	-	-	-
56	-	-	-	-	-
57	-	-	-	-	-
58	X	-	-	-	478
59	X	-	-	-	616
60	X	-	-	-	787
61	-	-	-	-	-
62	-	-	-	-	-
63	-	-	-	-	-
64	X	-	-	-	3,765
65	X	-	-	-	803
66	X	-	-	-	401
67	X	-	-	-	1,809

STRATUM 3 (Sample Items 68–100)

Sample Item	Not Homebound	Did Not Require Skilled Services	Incorrect HIPPS Code	Inadequate Documentation	Overpayment
68	-	-	-	-	-
69	-	-	-	-	-
70	-	-	-	X	\$4,787
71	-	X	-	-	6,185
72	-	-	-	-	-
73	-	X	-	-	2,988
74	-	-	-	-	-
75	-	-	-	-	-
76	-	-	-	-	-
77	-	-	-	-	-
78	X	-	-	-	2,692
79	X	-	-	-	2,268
80	X	-	-	-	4,174
81	-	-	-	-	-
82	X	-	X	-	2,583
83	-	-	-	-	-
84	-	-	-	-	-
85	-	-	-	-	-
86	-	-	-	-	-
87	-	-	-	-	-
88	-	-	-	-	-
89	-	-	-	-	-
90	-	-	-	-	-
91	-	-	-	-	-
92	-	-	-	-	-
93	-	-	-	-	-
94	-	-	-	-	-
95	X	-	-	-	846
96	-	-	-	-	-
97	X	-	-	-	1,998
98	-	-	-	-	-
99	-	-	-	-	-
100	-	-	-	-	-
Total	26	4	3	2	\$61,718

APPENDIX F: MISSION HOME HEALTH COMMENTS²²

BASS BERRY + SIMS_{PC}



June 21, 2019

VIA KITEWORKS

Ms. Lori Ahlstrand
Regional Inspector General for Audit Services
Department of Health and Human Services
Office of Inspector General
Office of Audit Services, Region IX
90 7th Street, Suite 3-650
San Francisco, CA 94103

Re: Office of Audit Services Draft Report Number A-09-18-03008

Dear Ms. Ahlstrand:

Mission Home Health of San Diego, Inc. (“Mission”) submits this response to the draft Report Number A-09-18-03008 that the Office of Inspector General, Office of Audit Services (the “OIG”) issued to Mission on May 22, 2019 (the “Report”).

Because the OIG found that Mission’s compliance rate was at least 97 percent with respect to three of the four areas addressed by the Report, no response is warranted with respect to the vast majority of the audited claims and issues. With respect to the one area in which the OIG found Mission to be less than 97 percent compliant – the homebound status of beneficiaries – the OIG’s Report is demonstrably flawed. The OIG’s medical reviewer consistently fixated on the distance that beneficiaries could walk to determine homebound status, which is not only clinically inappropriate but also directly contrary to Medicare guidance. For the reasons discussed below, Mission disputes nearly all of the findings contained in the Report and does not concur with any of the OIG’s four recommendations.

I. Mission Does Not Concur with OIG Recommendations

For the reasons set forth below and as discussed in more detail herein, Mission does not concur with any of the four recommendations set forth in the Report.

OIG Recommendation #1: Refund to the Medicare program the portion of the estimated \$7,508,212 overpayment for claims incorrectly billed that are within the reopening period.

Mission Response: Mission does not concur with this recommendation. The vast majority of the OIG’s findings with respect to the audited claims are flawed, including *all* of the findings that Mission provided services to beneficiaries who were not homebound or provided medically unnecessary skilled services. Based upon a review by a third party expert engaged by Mission, which is detailed in the rebuttal statements submitted with this response, each of the



²² **OIG Note:** We redacted text in several places in this appendix because it is personally identifiable information.

audited claims relating to homebound status or the medical necessity of skilled services is supported by the patient's medical records and was billed appropriately. Moreover, the sampling methodology is not statistically valid and should not be used as a basis to calculate an extrapolated overpayment. As such, Mission intends to vigorously challenge negative claims findings and any sampling methodology used to calculate and extrapolate overpayments following the issuance of a final report by exercising its rights to appeal any adverse findings through the Medicare administrative appeals process. Mission anticipates that any alleged overpayment related to homebound status or medical necessity will be eliminated entirely through the appeals process. Therefore, any refund to the Medicare program on those grounds at this juncture would be premature.

Mission acknowledges that two of the 100 audited claims included a plan of care that lacked a physician signature and that two of the 100 audited claims were submitted with an incorrect Health Insurance Prospective Payment System ("HIPPS") code assigned to the claims that increased the amount of reimbursement paid on the claims. As described herein, the two claims with an unsigned plan of care pre-date a systems change at Mission, and Mission is confident that those plans of care were signed in advance of billing and is working diligently to recover copies of the signed documentation. Nonetheless, Mission will refund or repay any overpayments associated with these individual four claims. Because those instances were isolated and not sustained or systemic, however, any extrapolated overpayment based upon these four claims to a broader universe of claims is inappropriate.

OIG Recommendation #2: For the remaining portion of the estimated \$7,508,212 overpayment for claims that are outside of the reopening period, exercise reasonable diligence to identify and return overpayments in accordance with the 60-day rule, and identify any returned overpayments as having been made in accordance with this recommendation.

Mission Response: **Mission does not concur with this recommendation.** Mission acknowledges its legal obligation to exercise reasonable diligence to identify potential overpayments within the preceding six years based upon receipt of credible information that an overpayment may exist.¹ The Centers for Medicare & Medicaid Services ("CMS") has acknowledged, however, that a provider that receives notice of a potential overpayment through an audit may reasonably determine that additional investigation of potential additional overpayments is premature during the audit appeals process.² As noted above, Mission disagrees with the OIG's findings and believes each of the audited claims is supported by the patient's medical directors and was billed appropriately.

OIG Recommendation #3: Exercise reasonable diligence to identify and return any additional similar overpayments outside of our audit period, in accordance with the 60-day rule, and identify any returned overpayments as having been made in accordance with this recommendation.

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

¹ See 42 C.F.R. § 401.305.

² See Medicare Program; Reporting and Returning Overpayments, 81 Fed. Reg. 7,654, 7,667 (Feb. 12, 2016).

OIG Recommendation #4: Strengthen its procedures to ensure that:

- the homebound statuses of Medicare beneficiaries are verified and continually monitored and the specific factors qualifying beneficiaries as homebound are documented,
- beneficiaries are receiving only reasonable and necessary skilled services,
- the correct HIPPS payment codes are billed, and
- documentation is maintained for beneficiaries' home health certifications and plans of care.

Mission Response: Mission does not concur with this recommendation. Mission disagrees that its procedures allowed any systemic issues to occur. The OIG's audit findings illustrate that Mission already employs effective procedures to ensure compliance with applicable Medicare coverage, documentation, coding, and billing requirements. The OIG has not identified any particular policies or procedures that it believes to be lacking or insufficient, and the OIG's findings reflect an effective compliance program. Mission constantly evaluates whether opportunities exist to improve its procedures and processes and will continue to do so.

II. Background

Mission is a clinically owned and operated leading provider of home health services in San Diego. Mission provides a compassionate team of licensed nurses, therapists, and social workers focused on addressing the specific clinical and emotional needs of each individual patient. Mission believes that the home presents the optimal healing environment for the patient and reduces healthcare expenditures by costing a fraction of what comparable care in a traditional, institutionalized setting would cost.

Mission has developed and implemented a robust compliance program to ensure compliance with applicable Medicare coverage, documentation, coding, and billing requirements. That program specifically includes each of the seven fundamental elements of an effective compliance program set forth in the OIG's compliance program guidance for home health agencies, including:

- Implementing written policies, procedures and standards of conduct;
- Designating a compliance officer and compliance committee;
- Conducting effective training and education;
- Developing effective lines of communication;
- Enforcing standards through well-publicized disciplinary guidelines;
- Conducting internal monitoring and auditing; and

- Responding promptly to detected offenses and developing corrective action.³

In particular, Mission employs a large team of individuals to participate in each aspect of its compliance efforts, including positions for a full-time Compliance Officer, Director of Education, and Educator. Each Mission location employs a Quality Care Manager who reviews every patient admission, including all Home Health Outcome and Assessment Information Set (“OASIS”) data. Each location’s Director is a registered nurse trained to focus on Mission’s clinical, quality, and compliance efforts. In addition to those Directors, Mission employs seven additional registered nurses as field staff supervisors. Mission regularly reviews and scores its individual clinicians based the accuracy and completeness of OASIS data and provides both group and individualized training to its clinicians that is tailored to any specific issues that are identified.

Mission also has robust audit processes in place to ensure that its claims are billed appropriately. Mission screens all referrals from the moment they are received prior to admission to confirm that the patient is eligible to receive home health services and that all required documentation is in place. Following admission but before billing, Mission conducts a pre-bill audit of 100 percent of its Medicare claims to confirm compliance with Medicare regulations. Any claim deemed not to be compliant and that cannot be corrected is written off and not billed. In addition to its pre-bill audit, Mission regularly audits randomly-selected billed charts from each of its home health locations.

Mission’s commitment to compliance is demonstrated by its results. According to its most recent PEPPER report, Mission ranks in the 19th percentile nationally for the average number of episodes per beneficiary, the 16th percentile nationally for the proportion of high therapy utilization episodes, and the 8th percentile nationally for proportion of outlier payments by Medicare. Mission’s previous PEPPER report reflects even better percentages in relation to other home health providers. Since its founding in 2009, Mission has not been the subject of any other audit, investigation, or enforcement action related to potential billing or reimbursement issues conducted by the OIG, United States Department of Justice, or any other government enforcement authority.

III. Concerns Related to the OIG’s Audit Process

Mission has numerous concerns with the OIG’s audit process. At the outset, it appears the OIG selected Mission for audit simply because Mission bills Medicare for home health services. Attempting to explain “why we did this review,” the Report does not provide a single reason why Mission specifically was selected for audit. Instead, the Report recites statistics about how much Medicare paid home health agencies in 2016 and what CMS believes the general error rate to be for all home health billing claims. The Report states that this audit was “part of a series of reviews of HHAs” and that Mission was identified as at risk for noncompliance through “data mining and data analysis techniques.” It appears, however, that the only data that the OIG used to identify Mission for audit is the number of dollars it bills Medicare for home health services. Not only do Mission’s PEPPER reports identify it as more conservative in its provision of home health services than the vast majority of its peers, but, as discussed below, the OIG’s own audit

³ Compliance Program Guidance for Home Health Agencies, 63 Fed. Reg. 42,410 (Aug. 7, 1998).

concluded that Mission is almost 100 percent compliant in each of the OIG's identified "selected risk areas" for HHAs.

Although the Report's first sentence asserts the OIG found that Mission was not compliant for 38 of the 100 claims reviewed, that 38 percent "error rate" is extremely misleading. **According to the OIG's own findings, Mission was either 97 percent or 98 percent compliant in three of the four areas in which the OIG purportedly discovered issues:** whether beneficiaries required skilled services, whether documentation was adequate to support the services provided, and whether the correct payment system codes were assigned to claims. For the fourth area addressed in the Report – whether the beneficiaries were homebound – the OIG concluded that a beneficiary was not homebound for the full episode of care for only 6 of the 100 audited claims. Thus, even accepting the OIG's findings as accurate – which, as discussed below, they are not – **94 percent of Mission's beneficiaries were homebound and eligible for home health services for part or all of the audited episodes of home health services.**

Mission also has serious concerns about the qualifications of the OIG's unidentified medical reviewer. The OIG has not provided any substantive information by which Mission can assess the medical reviewer. Instead, each of the reviewer's medical determinations contains the same vague statement that the reviewer is a "physician who is duly licensed to practice medicine," "knowledgeable in the treatment of the enrollee's medical condition," and "familiar with the guidelines and protocols in the area of treatment under review." The reviewer's "biography" does not even reference home health and could be used – and presumably has been used – for any licensed physician of any training or qualification whatsoever. Without receiving any information about the reviewer, Mission can only assess the reviewer through his or her individual medical determinations of the audited claims.

As discussed below, every single one of the reviewer's findings with respect to homebound status and the need for skilled services was flawed. Specifically, the reviewer consistently concluded that a beneficiary was not homebound if he or she could ambulate in the home or if the beneficiary had a family member or caregiver available to assist the beneficiary. Those simply are not the standards for determining homebound status under applicable federal regulations, nor does either of those facts provide a basis for determining that a beneficiary is not homebound for purposes of eligibility for home health services. That the reviewer consistently concluded that beneficiaries were not homebound on such grounds establishes that the reviewer is *not* qualified to accurately assess the home health services that Mission provided to Medicare beneficiaries.

In addition to the clinical errors underlying the Report, the OIG's statistical sampling and extrapolation methodology also was flawed. As discussed in more detail below, the OIG's sample is flawed because the sample size was too small and failed to account for variations in the broader universe of claims. In addition, the OIG's sample was not representative of the universe of claims because the OIG failed to stratify the sample and did not address the complexity of the universe of Mission's claims in designing its sample. For all of these reasons, extrapolation of purported overpayments across the universe of Mission's claims is inappropriate.

IV. Response to OIG's Findings

The OIG's Report alleges that Mission did not comply with Medicare billing requirements for 38 out of the 100 home health claims that the OIG audited, resulting in an alleged overpayment of \$72,386. Specifically, the OIG found that Mission billed claims improperly in four ways: (1) beneficiaries were not homebound; (2) beneficiaries did not require skilled services; (3) incorrect Health Insurance Prospective Payment System Codes were assigned to claims; and (4) documentation was inadequate to support the services provided.

Mission takes allegations of improper billing seriously. To evaluate the OIG's findings objectively, Mission engaged [REDACTED] a well-respected third-party auditor with substantial experience in home health care, to review the allegedly improper claims. [REDACTED] auditors come from multiple clinical disciplines, including nursing and therapy, and each has over twenty years of experience in home health clinical operations and Medicare reimbursement criteria. [REDACTED] is a registered nurse and the Director of [REDACTED] Home Health and Clinical division. She has over thirty years of experience in home health performing compliance audits, developing policies and procedures, and conducting survey readiness. [REDACTED] is a registered nurse with over forty years of experience in home health, including providing quality and compliance review of coverage criteria, OASIS data, ICD-10-CM coding, documentation, quality improvement measures, Medicare compliance, and patient safety. [REDACTED] F.A.A.F.P. has more than twenty years of experience as a physician who has been directing home health services for his patients for twenty-three years, including reviewing and signing home health orders. Attached as Exhibit A to this response are the [REDACTED] auditors' curriculum vitae.

The [REDACTED] auditors reviewed the 38 allegedly improper claims and prepared rebuttal statements for each claim. The [REDACTED] auditors concluded that the OIG's findings for 37 of those 38 claims are flawed and not supported by the patients' medical records.⁴ The rebuttal statements are attached as Exhibit B to this response. In addition, certain of the specific audited claims, including the examples set forth in the OIG's Report, are discussed in more detail below.

Mission previously requested that the OIG provide its medical determinations to Mission in advance of issuing its draft audit report to allow Mission to respond to the medical findings and resolve any disagreements in advance of the draft report, but the OIG declined to do so. Because of the significant number of inaccurate findings and the questionable qualifications of the OIG's medical reviewer, Mission submits that the OIG's medical findings must be reconsidered. Accordingly, Mission requests that the audited claims be resubmitted for medical review with the appropriate standards and criteria applied to that re-review. As discussed herein and in the accompanying rebuttal statements, the OIG's medical reviewer applied incorrect criteria during the audit and issued inaccurate findings.

⁴ The [REDACTED] auditors concluded that at least one finding for 37 of the 38 claims was incorrect. [REDACTED] and Mission agree that for one claim, Sample Patient No. 70, the OIG reviewer's sole finding related to the documentation in support of the code billed for the services provided is accurate.

A. All of the Beneficiaries in the Audited Sample Were Homebound.

A home health provider may only receive payment for home health services provided to a beneficiary who is homebound.⁵ To be homebound, a beneficiary must satisfy two criteria. First, the beneficiary either must have a condition, due to illness or injury, that restricts the ability of the individual to leave his or her home except with the assistance of another individual, the use of special transportation, or the aid of a supportive device (e.g., crutches, cane, wheelchair, or walker), or must have a condition such that leaving the home is medically contraindicated.⁶ Second, the beneficiary must have a normal inability to leave home and doing so must require a considerable and taxing effort.⁷ An individual need not be bedridden to be homebound. In fact, a beneficiary can leave the home and nevertheless be considered homebound if the absences from the home are infrequent or for periods of relatively short duration, or are attributable to the need to receive health care treatment.⁸ Homebound status is not contingent upon a single clinical factor; rather, Medicare guidance acknowledges that “longitudinal clinical information about the patient’s health status” is typically necessary to evaluate and categorize a patient as homebound.⁹ Such information “about the patient’s overall health status may include, but is not limited to, such factors as the patient’s diagnosis, duration of the patient’s condition, clinical course..., prognosis, nature and extent of functional limitations, other therapeutic interventions and results, etc.”¹⁰

The OIG alleges that the beneficiary did not qualify as homebound under Medicare standards for the entire episode of care for 6 of the 100 audited claims and did not qualify as homebound for part of the episode of care for 28 of the 100 audited claims. Mission disagrees with each of those determinations. The medical determinations provided by the OIG reveal that the OIG’s medical reviewer consistently failed to apply the appropriate Medicare criteria for homebound status.

In fact, the reviewer applied impermissible standards to determine homebound status. The reviewer consistently concluded that a beneficiary was not homebound if he or she could ambulate for a certain distance in the home or if the beneficiary had a family member or caregiver available to assist the beneficiary. Not only are those not criteria for evaluating homebound status under Medicare regulations, but those criteria are *entirely consistent* with a beneficiary being homebound. That a beneficiary can ambulate in the home has no bearing on that beneficiary’s ability – or lack thereof – to leave the home. Similarly, Medicare regulations specifically contemplate that a homebound beneficiary may only be able to leave the home with the assistance of another individual. Such assistance in no way establishes that a beneficiary is not homebound.

In addition, the Medicare Benefits Policy Manual (“MBPM”) explicitly prohibits using a bright-line standard such as ambulation distance to determine homebound status. Homebound status must be based on each individual beneficiary’s unique medical condition as determined through a comprehensive assessment of the patient’s overall health and circumstances.

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

⁶ Medicare Benefit Policy Manual, Ch. 7, § 30.1.1.

⁷ *Id.*

⁸ *Id.*

⁹ *Id.*

¹⁰ *Id.*

Measurements such as ambulation distance cannot be dispositive of homebound status. The MBPM states that “determinations of whether home health services are reasonable and necessary must be based on an assessment of each beneficiary’s individual care needs. Therefore, denial of services based on numerical screens, diagnostic screens, or specific treatment norms is not appropriate.”¹¹ Thus, using a numerical standard such as ambulation distance to determine homebound status directly contradicts Medicare guidance.

The OIG’s medical reviewer’s consistently flawed analysis is evident in the two examples of allegedly non-homebound beneficiaries set forth in the Report.

- **Example 1, Sample Patient No. 6.** The OIG contends that this 85-year-old patient was not homebound because she was able to walk more than 1,000 feet without an assistive device and because there was no history of recent or recurrent falls. Based primarily on those two factors, and also noting that the patient’s daughter “lived nearby and was available in terms of providing assistance,” the OIG found that the patient was not homebound for the entire episode of care from 4/15/2015 to 5/8/2015.

Determining homebound status based on the factors provided by the OIG directly contradicts Medicare regulations and manual guidance. Being able to walk 1,000 feet and having no history of recent or recurrent falls in no way disqualifies a beneficiary from being homebound. Nothing in the Medicare rules even suggests that homebound status can be discounted based on a technical measurement such as the number of feet a patient can ambulate. Instead, the beneficiary’s complete medical record and condition must be considered in totality. For this episode of care, although the patient’s medical record indicates that the patient was able to ambulate 1,000 feet without an assistive device, the record further states *on the same date* that the patient was *unsafe* when ambulating without assistance. Thus, the patient required assistance to ambulate safely and in order to leave the home, entirely consistent with Medicare regulations. In addition, the patient’s medical record further documents that the patient had poor balance, intermittent dizziness, limited right shoulder range of motion, and a risk for falls. Medicare regulations do not require a documented history of recent or recurrent falls to establish homebound status. Limitations such as those documented in the patient’s record directly affect the safety of ambulation and the patient’s ability to be out of the home.

- **Example 2, Sample Patient No. 21.** The OIG acknowledges that this patient initially was homebound at the beginning of the episode of care because she had a history of lower extremity impairment with bilateral knee replacements and was limited to walking 75 feet. The OIG contends, however, that the beneficiary was not homebound for a portion of the episode of care from 4/9/2015 to 4/16/2015 because she had “increased activity” and was able to go to a grocery store and ride a scooter.

¹¹ MBPM, Ch. 7 § 20.3.

Not only does the OIG's medical determination fail to contradict that the patient was homebound for the entire episode, but the patient's complete medical record establishes without question that she remained homebound for the entire episode. The Report states that the patient was able to go to the grocery store but acknowledges that she rode a scooter while there. The Report ignores documentation in the medical record that the patient continued to ambulate with a walker and needed standby assistance for safety on 4/8/2015, that the patient's gait was only fair when using the rolling walker with standby assistance on 4/10/2015, and that the patient ambulated with a walker and the assistance of another person on 4/16/2015. The patient's record indicates that she was instructed to use a walker or cane when walking out of the home. All of those well-documented limitations support homebound status, particularly where the patient was admitted to home health after a hospitalization for hypertension and dizziness, with impaired balance, abnormal gait, mobility and cognitive deficits, generalized weakness, and knee pain. To the contrary, nothing in the OIG's medical determination discounts homebound status for any portion of the episode. The OIG's reviewer considers going to the grocery store and riding a scooter as "increased activity" that obviated homebound status, but that is flatly incorrect, particularly where the patient's record unquestionably illustrates that the patient could not conduct such activity without supportive devices or assistance and without considerable and taxing effort. This patient was homebound for the entire episode of care.

Not only was the OIG's analysis with respect to the Report's two example beneficiaries substantially flawed, but the OIG's other medical determinations are rife with similarly egregious findings. For example:

- **Sample Patient No. 51.** This 78-year-old patient was profoundly impacted by Parkinson's disease. On 11/14/2014, a physician described the patient's condition as severe Parkinson's with abnormal gait, severe drooling, memory loss, increasing tremors, and declining gait requiring constant care by his exhausted wife. The patient had fallen the day prior to the physician visit and had increased pain in his flank area. The physician noted the patient had basically no response to Sinemet and recommended a wheelchair, noting that even when the patient used a walker, he was so slow and impaired that his wife was exhausted and expressed that the walker may not be safe enough.

The OIG contends that the patient was not homebound from 1/21/2015 to 1/24/2015 because as of 1/20/2015, the patient was able to ambulate 300 feet without hands on assistance. As with other claims, the OIG's medical reviewer appears to believe that homebound status can be preempted based on a patient's ability to ambulate a certain, arbitrary number of feet on a given day. Nothing in Medicare regulations or guidance support that conclusion. In addition, the OIG's medical determination for this patient acknowledges that on 1/20/2015 the patient ambulated 300 feet "with the wheeled walker with standby assistance." Rather than defeat homebound status, requiring both a supportive device and oversight by a caregiver to ambulate *supports* homebound status under the Medicare regulations. The OIG's finding that this

patient was homebound for the first 56 days of the episode of care but somehow not homebound for the final 4 days of the episode based on his ability to ambulate 300 feet with a walker and standby assistance is wholly unsupported by Medicare regulations and guidance.

- **Sample Patient No. 65.** This 92-year-old patient was referred to home health after receiving care in the emergency department for syncope, collapse, and a fall for the second time within a month. He had fractured a finger during a previous fall approximately three weeks prior. Comorbidities included coronary artery disease, chronic kidney disease, diabetes, hypertension, and depression. His wife of 72 years had died two months prior. In the emergency department, the patient was found to have orthostatic blood pressure changes.

The OIG contends that the patient was not homebound from 3/12/2015 to 3/19/2015 because the patient ambulated 170 feet and transferred with supervision but without assistance on 3/11/2015. The OIG's medical determination also notes that the patient ambulated 220 feet with a walker and standby assistance on 3/13/2015. Once again, the OIG's medical reviewer incorrectly concludes that a patient is not homebound because he can ambulate a certain, arbitrary distance with a walker and caregiver oversight. The OIG's medical determination for this patient reveals why that is not only an unsupported but also an unworkable standard to apply. The determination recognizes that by 3/4/2015, the patient walked "140 feet times two with walker and standby assist." Despite that ability, the OIG's reviewer acknowledges that the patient remained homebound until 3/12/2015, when he was able to walk 170 feet with caregiver supervision. Thus, the OIG's reviewer believes that the line between homebound and non-homebound status lies somewhere between walking 140 feet times two with a walker and walking 170 feet with caregiver supervision. The former purportedly supports homebound status, while the latter does not. Nothing in the Medicare regulations or guidance supports such an arbitrary and technical standard for determining homebound status.

- **Sample Patient No. 67.** This 77-year-old patient with Parkinson's disease and diabetic neuropathy, an unspecified autoimmune disorder, had a history of recent falls and was admitted to home health when she had a decline in function and self-care management with increased tremors, declining balance, and unsteady gait. The patient's physician noted those problems upon examination after the patient's daughter, also a physician, expressed concern for the patient's well-being. The patient had moved to a new living situation within two weeks prior to admission following falls at home and recent failure to perform activities of daily living or take her medications correctly. She also had a history of recurrent depression.

The OIG contends that the patient was not homebound from 6/24/2016 to 7/22/2016 because she walked 250 feet in the hallway with her walker on 6/23/2016, and because she was living in an assisted living facility and had caregiver assistance available. It is difficult to understand from the OIG's own

medical determination how the reviewer concluded that the patient was not homebound as of 6/23/2016. The determination states that on that date a physical therapist described the patient's "festinating gait," that "the patient needed cueing to slow down," and that the patient experienced "gait deviations [that] included short step length and inconsistent rhythm." During a subsequent evaluation on 6/27/2016, the patient reported multiple falls that caused her to have difficulty with her lower extremities and to need help with activities of daily living. Those descriptions within the OIG's medical determination simply do not support a finding that after 6/23/2016, leaving the home no longer would have required a considerable and taxing effort. To the contrary, the patient could not walk within her assisted living facility without her walker and without falling, much less could she leave her home without considerable and taxing effort.

- **Sample Patient No. 95.** This 93-year-old patient was admitted to home health following re-hospitalization for heart failure and then a fall. Her weakness and gait abnormality caused an unsteady and unsafe gait, and she lived alone. Comorbidities included heart failure, chronic kidney disease, atrial fibrillation, and a history of recent respiratory failure, anemia, and transient ischemic attack.

The OIG contends that the patient was not homebound from 10/15/2015 to 10/28/2015 because by 10/14/2015 she was able to walk at least 150 feet at a time with a rolling walker and without hands-on assistance. She did require contact guard assistance for transfers from sitting to standing and ambulation. In addition, the OIG's reviewer acknowledged that the patient was homebound from the start of the episode until 10/14/2015 and that during that time she could walk 200 feet "with minimal assistance." There is absolutely no basis – and the OIG provides none – to conclude that a patient is homebound when she walks 200 feet with minimal assistance but is not homebound when she walks 150 feet with a rolling walker and requires contact guard assistance for transfers from sitting to standing and ambulation. The OIG provides no other basis for finding that the patient no longer was homebound as of 10/15/2015. Like the OIG's other findings based solely on the distance that the patient was able to walk on a particular day, this finding flatly contradicts Medicare guidance.

As these examples demonstrate, the OIG's medical reviewer's findings with respect to homebound status are demonstrably flawed. Throughout the review of audited claims, the OIG's reviewer applied an arbitrary and unsupported standard to find that beneficiaries were not homebound based solely on the distance that the patient could walk in a particular setting on a particular day, settings which varied significantly over time and from patient to patient. The OIG's reviewer impermissibly based homebound status on the distance that the beneficiary could walk and did not consider the entirety of the patient's medical record and condition, as Medicare regulations require. In addition, the vast majority of the "errors" identified with respect to homebound status are partial errors, findings that the beneficiary lost homebound status during the episode of care, often near the end of the episode of care. The beneficiaries' medical records do not support those findings. For all 34 claims identified in the Report as not homebound, the

medical records establish that each beneficiary was and remained homebound for the entire episode of care. Indeed, the OIG's reviewer acknowledged that 28 of those 34 beneficiaries were homebound at the start of care.

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

B. All of the Beneficiaries in the Audited Sample Required Skilled Services.

In addition to homebound status, Medicare payment for home health services is contingent upon the beneficiary requiring at least one of the following skilled services: (i) intermittent skilled nursing services, which must demand the skills of a registered nurse ("RN"), or licensed practical nurse under RN supervision, and must be reasonable and necessary; (ii) physical therapy; (iii) speech-language pathology; or (iv) occupational therapy.¹² Each individual therapy service must comply with certain additional requirements to be covered.¹³

The OIG contends that 3 of the 100 sampled claims were non-compliant because the beneficiary did not require medically necessary skilled nursing or skilled therapy services. Thus, the OIG agrees with Mission's determination that the beneficiary required skilled services for 97 out of the 100 audited claims. Mission appreciates that agreement and believes that a 97 percent compliance rate – which, at a minimum, the OIG acknowledges – would be exemplary.

Nonetheless, Mission disagrees with the OIG's findings with respect to the 3 claims that the OIG contends were non-compliant for lack of requiring skilled services. The beneficiary in each of those 3 claims required skilled services, as illustrated in the example set forth in the Report.

- **Example 3, Sample Patient No. 49.** The OIG acknowledges that this 84-year-old wheelchair-bound patient required skilled services at the outset of the episode of care for monitoring the patient's medical conditions and for medication oversight and education and subsequently for assessing and reassessing the patient's condition, activities of daily living, need for adaptive equipment or a home exercise program, and caregiver's understanding of the information provided. The OIG contends, however, that skilled services were not required after 8/25/2015 because the patient lived in an assisted living facility and had caregiver assistance available.

The OIG's findings contradict clear documentation of the need for skilled services in the patient's medical record. This patient lived in a facility away from any family or friends and required occupational therapy visits due to her decline in functional activities of daily living and difficulty managing in her

¹² 42 C.F.R. § 409.42(c).

¹³ See 42 C.F.R. § 409.44(c).

apartment, as evidenced by her falling out of her wheelchair *after* the date on which the OIG contends skilled services no longer were necessary. The patient had peripheral vascular disease, back pain, paraparesis, depression, hypertension, chronic obstructive pulmonary disease, and coronary artery disease. She also suffered from muscle weakness and osteoarthritis, and her back and lower extremity pain continued to affect her ability to manage activities of daily living. All of these diagnoses and conditions are documented in the patient's record, clearly establishing that occupational therapy visits were necessary to improve her functional activities of daily living and her safety within her home.

The medical records for the other two beneficiaries to whom the OIG contends Mission provided unnecessary skilled services similarly support the need for those services. The OIG's medical reviewer found that skilled therapy services were not necessary for Patient No. 71 because the patient's progression "would have been limited by dementia," and the patient had "no new injury or neurological event." Neither of those facts, even if true, establishes that skilled services were not necessary. In addition, the patient's medical record clearly indicates that physical therapy and speech therapy improved the patient's safety, speech, and orientation but that the patient remained impaired and in need of skilled services throughout the episode of care.

The OIG's medical reviewer found that occupational therapy services were not necessary for Patient No. 73 because the patient was "not motivated" to perform activities of daily living and was noncompliant with home exercises. The patient's medical record, however, establishes the opposite: the patient's occupational therapist documented that the patient was motivated and making good progress in numerous ways, including implementing a home exercise program and adaptive aids for feeding and improving his participation in dressing activities.

Even accepting the OIG's findings as accurate – which they are not – the OIG's audit establishes that Mission has a 97 percent compliance rate with respect to the medical necessity of skilled services that it provides. Mission vehemently disagrees with the OIG's assertion that Mission did not have "adequate procedures to ensure that clinical review was sufficient to verify that beneficiaries initially required or continued to require skilled services." Mission's robust procedures ensured, at a minimum, a 97 percent compliance rate. In fact, because the medical records for the three beneficiaries identified in the Report clearly establish that those beneficiaries required skilled services, Mission's actual compliance rate is 100 percent. Mission requests that the OIG medical reviewer re-review the three claims at issue in light of this submission and the accompanying rebuttal statements and reverse the previous findings that three beneficiaries received skilled services that were not medically necessary.

C. Health Insurance Prospective Payment System Codes Assigned to Claims

Medicare pays for home health services based on a case-mix adjusted payment for each 60-day episode of care. Each episode is assigned to a home health resource group ("HHRG") that is represented on a home health claim using a HIPPS code, which ultimately drives the Medicare payment amount. A bill must be "completed accurately" to be processed and paid correctly, and, therefore, a home health agency must use proper HIPPS codes on its claims.

The OIG contends that Mission assigned incorrect HIPPS payment codes to three of the audited claims because the OASIS and medical records did not support the payment codes that Mission used for those claims. Thus, the Report establishes that Mission had a 97 percent compliance rate with respect to the HIPPS payment codes that it submitted with its claims. After reviewing the three claims identified in the Report, Mission agrees that an incorrect HIPPS payment code was assigned to each of those claims. For Sample Patient No. 47, however, submitting the incorrect code caused Mission to receive a *lower* amount of reimbursement than it would have received if it had submitted the correct code. Mission agrees that the claims for Sample Patient Nos. 21 and 82 were billed with an incorrect HIPPS payment code that caused an increase in the amount of reimbursement paid on the claims.

Mission vehemently disagrees with the OIG's assertion that Mission did not have "adequate procedures to ensure that the correct HIPPS payment codes were billed." Mission's robust procedures ensured, at a minimum, a 97 percent compliance rate. Mission received a higher amount of reimbursement based on an incorrect HIPPS code for only two out of the 100 audited claims. Whether assessing Mission's HIPPS coding from the perspective of a 97 percent coding accuracy rate or a 98 percent reimbursement accuracy rate, the OIG's audit unquestionably did not reveal any systemic issue related to Mission's HIPPS coding, particularly considering the two-year time period at issue in the audit. Moreover, since the audit time period of 2015 – 2016, Mission has transitioned to a new electronic medical record ("EMR") maintenance and billing system that includes additional safeguards to ensure accurate coding and billing. Although Mission acknowledges that two of the 100 audited claims included a coding error that caused a higher rate of reimbursement, the amount of the difference in that reimbursement is extremely small. In addition, given the lack of any recurring issue or high level of payment error, Mission disagrees that it is appropriate to extrapolate the effect of that coding error to a broader universe of claims.

D. Documentation Supporting the Services Provided

The OIG contends that documentation was inadequate to support services provided with respect to two of the audited claims because those claims lacked documentation of the beneficiary's home health certification and plan of care. By identifying only two documentation issues, the Report establishes that Mission had at least a 98 percent compliance rate with respect to documentation adequately supporting the services provided to Medicare beneficiaries. Reviewing the two claims identified in the Report, Mission was able to locate documentation for those two claims that supports the services provided to those two beneficiaries. Mission acknowledges, however, that the plans of care that it has been able to locate to date were not signed by a physician. Notably, the Report does not identify documentation that was missing from any of the 100 audited claims.

In addition, the two claims that the OIG identified that contain unsigned plans of care were billed under Mission's former EMR system, before the transition in systems referenced above. Mission made a significant financial investment to transition to its current system and also invested in an integrated software product, which together are equipped with automated safeguards that prevent billing claims that do not include all the necessary signatures within the documentation, thereby minimizing or removing human error from the process. Thus, it is virtually impossible that claims with unsigned plans of care were billed to Medicare after Mission changed to its current system. Mission is confident that the plans of care in the two

claims that the OIG identified were signed in advance of billing and continues to work diligently to recover copies of the signed documentation.

Mission vehemently disagrees with the OIG's assertion that Mission did not have "adequate procedures to always ensure that it had documentation of a beneficiary's home health certification and plan of care to support the services provided." Mission's procedures ensured, at a minimum, a 98 percent compliance rate with respect to the adequacy of its documentation. Not only was Mission almost entirely compliant during the audit time period of 2015 – 2016, but Mission's transition to a new EMR system since the audit period has addressed any issue with respect to missing physician signatures and prevents claims without signed plans of care from being billed. Moreover, given the lack of any recurring issue or high level of payment error, coupled with the fact that Mission's new EMR system prevents billing claims with unsigned plans of care, Mission disagrees that it is appropriate to extrapolate the effect of the two unsigned plans of care to a broader universe of claims.

E. Extrapolation of Overpayment Obligations is Inappropriate.

Mission objects to the OIG's use of extrapolation to arrive at an estimated overpayment amount. Extrapolation of Medicare overpayments is inappropriate unless there exists a "sustained or high level of payment error."¹⁴ For purposes of extrapolation, a sustained or high level of payment error constitutes an error rate greater than or equal to a 50 percent error rate.¹⁵ That is not the case here. Even accepting the OIG's initial audit results, 94 percent of Mission's beneficiaries were homebound for part or all of the episode of care, 97 percent of the beneficiaries to whom Mission provided skilled services required those services, Mission's documentation supported the services provided to 98 percent of its beneficiaries, Mission utilized accurate HIPPS payment codes for 97 percent of its claims, and Mission submitted the OASIS in a timely fashion for 100 percent of its claims. In addition, even those remarkable compliance rates are conservative, as the OIG's medical reviewer erred in almost all of his findings that were adverse to Mission. A comprehensive review of the beneficiaries' complete medical records establishes that Mission provided home health services only to beneficiaries who were homebound and provided skilled services only to beneficiaries who required such services. Because no "sustained or high level of payment error" exists – even under the OIG's initial, un rebutted findings – extrapolation is inappropriate.

Extrapolation of the audit results across a broader set of claims also is inappropriate because the OIG's sampling and extrapolation methodology was flawed. Mission engaged [REDACTED] to evaluate the OIG's statistical sampling and extrapolation methodology. [REDACTED] is a leading consulting firm that provides independent assessment and data analytics and has substantial experience in home health care. Specifically, [REDACTED] has a Masters of Science degree in Statistics from the University of Dortmund/Germany and a Masters of Arts degree in Economics from the University of California, San Diego. [REDACTED] work focuses on applying economic, statistical, and financial models to address various business issues and study economic impacts. He has over twenty-five years of experience in the healthcare

¹⁴ 42 U.S.C. § 1395ddd(f)(3).

¹⁵ See Medicare Program Integrity Manual, § 8.4.1.4. Although Mission recognizes that the Medicare Program Integrity Manual is not binding on the OIG, the purported overpayments identified in the Report would be overpayments from Medicare, and extrapolation of Medicare overpayments absent a sustained or high level of payment error is inappropriate.

industry providing statistical and economic consulting to a variety of healthcare-related entities, including providers, payors, and federal, state, and local government agencies. Attached as Exhibit C to this response is the Expert Report of [REDACTED], which addresses whether the statistical sampling methodology underlying the OIG's audit warrants the extrapolation of the sample findings to a broader universe of Mission's claims.

As discussed more fully in the [REDACTED] Report, the OIG's sample is flawed in numerous respects. First, the OIG's sample size was too small and was arbitrarily chosen without taking into account the variation in the broader universe. Beyond citing the minimum sample size required by OAS, the OIG provided no indication of how it calculated its sample size. In fact, it appears that the OIG's sample size is in no way based on the universe of Mission's claims but rather that the OIG simply adopted the minimum recommended sample size of 100. Because the OIG's sample was skewed and not symmetric, or normally distributed, the sample size was too small to use the normal approximation to draw inferences about the underlying universe, as the OIG did here.

The [REDACTED] Report also explains that the OIG's sample is not representative of the broader universe of claims, yielding unreliable results not suitable for extrapolation. The OIG's sample did not adequately represent the complexity of the health conditions of patients in the universe of claims. The complexity of patients' health conditions is expressed through diagnosis codes that the patients receive upon admission; the OIG failed to incorporate diagnosis codes into its sampling design, thereby creating a large degree of misrepresentation of health conditions in the sample as compared to the universe. In addition, statistical hypothesis tests illustrate that the OIG's sample is not representative of the underlying universe because the sample and the universe do not have the same distribution.

Moreover, in addition to the flaws noted above, the OIG did not provide additional key data points that allow Mission to analyze conclusively whether the OIG's sample is representative of the relevant universe of claims. Without fully conducting that analysis, it is impossible to conclude that the sample correctly addresses the underlying universe of claims. Extrapolation of audit results to conclude that an overpayment existed across a broader universe of claims is only appropriate where the extrapolation was made from a *representative* sample and was statistically significant.¹⁶ The OIG has not established that its sample is representative of the universe of Mission's claims, and, for the reasons discussed above, the sample is *not* representative of the broader universe. As such, the audit results cannot be extrapolated to those claims.

F. Conclusion

For the reasons discussed herein, the OIG's findings as set forth in the Report are flawed. With respect to homebound status – the one area in which the Report identified Mission as less than 97 percent compliant – the OIG's medical reviewer did not apply the correct criteria to determine the beneficiaries' homebound status and consistently failed to consider each beneficiary's individualized clinical condition and needs. The beneficiaries' medical records fully support both the homebound status and the medical necessity of skilled services for all of the audited patients.

¹⁶ See *Chaves County Home Health Serv., Inc. v. Sullivan*, 931 F.2d 914, 921-22 (D.C. Cir. 1991).

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Mission understands that it will have the opportunity to challenge the Report's findings on appeal and is confident that those findings will be overturned. Nonetheless, Mission hopes that that appeal will not be necessary and requests that the OIG review and withdraw those findings without the need for an appeal. Mission is committed to providing only the highest quality home health services to its patients while maintaining strict compliance with all applicable laws, rules, and regulations, and it appreciates the opportunity to comment on the OIG's findings before the Report is finalized.

Sincerely,

A large black rectangular redaction box covering the signature area.

Enclosures

cc:  DHHS/OIG/OAS (via FedEx)