

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**MEDICARE HOME HEALTH AGENCY
PROVIDER COMPLIANCE AUDIT:
BROOKDALE HOME HEALTH, LLC**

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Office of Inspector General

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Report in Brief

Date: February 2021

Report No. A-04-18-06221

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



Why OIG Did This Audit

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

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

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

How OIG Did This Audit

Our audit covered over \$13.9 million in Medicare payments to Brookdale for 3,512 claims for home health services provided in calendar years 2016 and 2017 (audit period). We selected a stratified random sample of 100 claims and submitted those claims to independent medical review to determine whether the services met coverage, medical necessity, and coding requirements.

Medicare Home Health Agency Provider Compliance Audit: Brookdale Home Health, LLC

What OIG Found

Brookdale did not comply with Medicare billing requirements for 46 of the 100 home health claims that we reviewed. For these claims, Brookdale received overpayments of \$132,500 for services provided during our audit period. Specifically, Brookdale incorrectly billed Medicare for services provided to beneficiaries who were not homebound or did not require skilled services. These errors occurred primarily because Brookdale did not have adequate controls to prevent the incorrect billing of Medicare claims within the selected risk areas. On the basis of our sample results, we estimated that Brookdale received overpayments of approximately \$3.3 million for the audit period.

What OIG Recommends and Brookdale Comments

We recommend that Brookdale: (1) refund to the Medicare program the portion of the estimated \$3.3 million overpayment for claims incorrectly billed that are within the reopening period; (2) exercise reasonable diligence to identify, report, and return any overpayments in accordance with the 60-day rule and identify any of those returned overpayments as having been made in accordance with this recommendation; and (3) strengthen some of its procedures. The detailed recommendations are listed in the body of the report.

In written comments on our draft report, Brookdale agreed that 16 of the 46 claims we found to have been improperly billed were paid in error and stated that it had repaid those 16 claims. Brookdale disagreed with our remaining findings and all three of our recommendations. Brookdale used its medical review team to review the claims we questioned and challenged our independent medical review contractor's decisions, maintaining that nearly all of the sampled claims were billed correctly. To address its concerns, we reviewed Brookdale's claim rebuttals and considered the opinions of its medical review team. However, we maintain that our findings and recommendations are valid, although we acknowledge Brookdale'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 account for more than 18 percent of the total 2016 fee-for-service improper payments (\$41 billion). This audit is part of a series of audits of HHAs. Using computer matching, data mining, and data analysis techniques, we identified HHAs at risk of noncompliance with Medicare billing requirements. Brookdale Home Health, LLC (Brookdale), was one of those HHAs.

OBJECTIVE

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

BACKGROUND

The Medicare Program and Payments for Home Health Services

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

CMS adjusts the 60-day episode payments using a case-mix methodology based on data elements from the Outcome and Assessment Information Set (OASIS). The OASIS is a standard set of data elements that HHA clinicians use to assess the clinical severity, functional status, and service utilization of a beneficiary receiving home health services. CMS uses OASIS data to assign beneficiaries to the appropriate categories, called case-mix groups,¹ 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)

¹ A case-mix group is used in a patient classification system to group together patients with similar characteristics. These groups provide a basis for describing the types of patients to which a provider renders service.

codes² and represent specific sets of patient characteristics.³ CMS requires HHAs to submit OASIS data as a condition of payment.⁴

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

Home Health Agency Claims at Risk for Incorrect Billing

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

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

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

Medicare Requirements for Home Health Agency Claims and Payments

Medicare payments may not be made for items and services that “are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member” (Social Security Act (the Act) § 1862(a)(1)(A)). Sections 1814(a)(2)(C) and 1835(a)(2)(A) of the Act and 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;
- under the care of a physician; and

² HIPPS 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 home health agencies.

³ 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.

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

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

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

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

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

Medicare Requirements for Providers To Identify and Return Overpayments

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

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

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

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

Brookdale Home Health, LLC

Brookdale is a limited liability home health care provider with headquarters in Tennessee and a local provider office in Lake Worth, Florida. Palmetto Government Benefits Administrator, LLC, its Medicare contractor, paid this specific Brookdale provider approximately \$15 million for 4,074 claims for services provided in CYs 2016 and 2017 (audit period) on the basis of CMS's National Claims History (NCH) data.

HOW WE CONDUCTED THIS AUDIT

Our audit covered \$13,902,692 in Medicare payments to Brookdale for 3,512 claims.⁷ These claims were for home health services provided in CYs 2016 and 2017.⁸ We selected a stratified random sample of 100 claims with payments totaling \$421,348 for review. We evaluated compliance with selected billing requirements and submitted these claims to independent medical review to determine whether the services met coverage, medical necessity, and coding requirements.

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

Appendix A contains the details of our scope and methodology, Appendix C contains our statistical sampling methodology, Appendix D contains our sample results and estimates, and Appendix E contains the types of errors by sample item.⁹

FINDINGS

Brookdale did not comply with Medicare billing requirements for 46 of the 100 home health claims that we reviewed. For these claims, Brookdale received overpayments of \$132,500 for services provided during the audit period. Specifically, Brookdale incorrectly billed Medicare for:

- services provided to beneficiaries who were not homebound and

⁷ In developing this sampling frame, we excluded from our audit home health claim payments for low utilization payment adjustments, partial episode payments, and requests for anticipated payments. We also excluded paid claims less than \$1,000 and claims that had previously been reviewed by a Recovery Audit Contractor (RAC).

⁸ CY's were determined by the HHA claim "through" date of service. The "through" date is the last day on the billing statement covering services provided to the beneficiary.

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

- services provided to beneficiaries who did not require skilled services.

These errors occurred primarily because Brookdale did not have adequate controls to prevent the incorrect billing of Medicare claims within the selected risk areas. On the basis of our sample results, we estimated that Brookdale received overpayments of at least \$3,286,869 for the audit period.¹⁰ As of the publication of this report, this amount included claims outside of the 4-year claim reopening period.

BROOKDALE DID NOT ALWAYS COMPLY WITH MEDICARE BILLING REQUIREMENTS

Brookdale did not comply with Medicare billing requirements for 46 of the 100 sampled claims, which resulted in overpayments of \$132,500.

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” (sections 1814(a)(2)(C) and 1835(a)(2)(A) of the Act and 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 208 of section 30.1.1 (effective January 1, 2015) and Revision 233 of section 30.1.1 (effective January 1, 2017) covered different parts of our audit period.¹¹ Revisions 208 and 233 state that, for a patient to be eligible to receive covered home health services under both Part A and B, the law requires that a physician certify in all cases that the 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:

¹⁰ 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. (See Appendix D.)

¹¹ Coverage guidance is substantively identical in both versions of § 30.1.1 in effect during our audit period. The only difference is Revision 233, effective January 1, 2017, provides further clarification of existing policies for clinicians who must decide whether to certify that a patient is homebound.

Criteria One

The patient must:

- need, because of illness or injury, 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 places of residence or
- have a condition such that leaving his or her home is medically contraindicated.

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

Criteria Two

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

Brookdale Did Not Always Meet Federal Requirements for Being Homebound

For 26 of the sampled claims, Brookdale incorrectly billed Medicare for home health episodes for beneficiaries who did not meet the above requirements for being homebound for the full episode (14 claims) or for a portion thereof (12 claims).¹²

Example 1: Beneficiary Not Homebound—Entire Episode

The patient had recently been discharged from physical therapy 4 days before the episode of care. He was able to ambulate independently without an assistive device on level and non-level surfaces at a distance of 1,000 feet and had exceeded his long-term therapy goals. The medical information does not support that he was homebound during this certification period.

¹² Of these 26 claims with homebound errors, 11 claims were also billed with skilled services that were not medically necessary. Appendix E provides details on the extent of errors, if any, per claim reviewed.

Example 2: Beneficiary Not Homebound—Partial Episode

The patient was homebound at the start of care. The patient had a history of ataxia and had fallen, injuring her right foot. She had an unsteady gait and refused to use an assistive device. The patient's caregiver pushed her transport chair for long distance mobility. Leaving the home would have required a considerable and taxing effort. However, later in the episode, the patient was able to transfer and ambulate 480 feet and was also able to ambulate on unlevel surfaces. She had met higher level balance goals of being able to perform single leg stance. She had caregiver assistance available as well as a supportive family. Leaving the home no longer would have required a considerable and taxing effort.

These errors occurred because Brookdale did not have adequate oversight 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

Federal Requirements for Skilled Services

A Medicare beneficiary must need skilled nursing care on an intermittent basis, physical therapy, or speech-language pathology; or the beneficiary must have a continuing need for occupational therapy (sections 1814(a)(2)(C) and 1835(a)(2)(A) of the Act and 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).¹³ Skilled therapy services must be reasonable and necessary to the treatment of the patient's illness or injury or to the restoration or maintenance of function affected by the patient's illness or injury within the context of the patient's unique medical condition (42 CFR § 409.44(c) and the Manual, chapter 7, § 40.2.1). Coverage of skilled nursing care or therapy does not turn on the presence or absence of a patient's potential for improvement, but rather on the patient's need for skilled care. Skilled care may be necessary to improve a patient's current condition, to maintain the patient's current condition, or to prevent or slow further deterioration of the patient's condition (the Manual, chapter 7, § 20.1.2).

¹³ Skilled nursing services can include, among other things, observation and assessment of a patient's condition, management and evaluation of a patient plan of care, teaching and training activities, or administration of medications (the Manual, chapter 7, § 40.1.2).

Brookdale Did Not Always Meet Federal Requirements for Skilled Services

For 31 of the sampled claims, Brookdale incorrectly billed Medicare for an entire home health episode (4 claims) or a portion of an episode (27 claims) for beneficiaries who did not meet the Medicare requirements for coverage of skilled nursing or therapy services.¹⁴

Example 3: Beneficiary Did Not Require Skilled Services

The patient was being treated for cerebral palsy, which is a non-progressive neurological condition. There was no recent injury or hospitalization. During this episode of care, the patient was not prescribed skilled nursing services by his physician. He had caregiver assistance available for his mobility and activities of daily living. In terms of physical and occupational therapy, the patient presented with unstable gait, impaired balance, and spastic tone. In addition, he had decreased endurance, strength, and balance. However, because of the patient's non-progressive condition there was no clear need for either physical therapy or occupational therapy. In terms of speech therapy, the patient showed no impairment in language, movement of the mouth and throat, or understanding of verbal content. Also, there was no history of aspiration pneumonia. Speech therapy was also medically unnecessary.

These errors occurred because Brookdale did not always provide sufficient clinical review to verify that beneficiaries initially required skilled services or continued to require skilled services.

OVERALL ESTIMATE OF OVERPAYMENTS

On the basis of our sample results, we estimated that Brookdale received overpayments totaling at least \$3,286,869 for the audit period. As of the publication of this report, this amount included claims outside the 4-year claim reopening period.

¹⁴ Of these 31 claims with skilled services that were not medically necessary, 11 claims were also billed for beneficiaries with homebound errors. Appendix E provides details on the extent of errors, if any, per claim reviewed.

RECOMMENDATIONS

We recommend that Brookdale Home Health, LLC:

- refund to the Medicare program the portion of the estimated \$3,286,869 overpayment for claims incorrectly billed that are within the 4-year reopening period;¹⁵
- based on the results of this audit, exercise reasonable diligence to identify, report, and return any overpayments in accordance with the 60-day rule¹⁶ and identify any of those returned overpayments as having been made in accordance with this recommendation;
- 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 and
 - beneficiaries are receiving only reasonable and necessary skilled services.

OTHER MATTERS

The Medicare program will pay a request for anticipated payment even though the physician has not signed the plan of care (42 CFR § 409.43(c)).¹⁷ Moreover, the Medicare program will make the final percentage payment as long as the physician signs and dates the plan of care before the claim for the episode of service is submitted, even if the physician does not sign and date the plan of care during the episode of service (42 CFR § 409.43(c)(3)). Nevertheless, Federal law and regulations require, as conditions of payment, coverage, and participation, that physicians *establish* plans of care for home health services.

¹⁵ OIG audit recommendations do not represent final determinations by the Medicare program. CMS, acting through a MAC or other contractor, will determine whether overpayments exist and will recoup any overpayments consistent with its policies and procedures. Providers have the right to appeal those determinations and should familiarize themselves with the rules pertaining to when overpayments must be returned or are subject to offset while an appeal is pending. The Medicare Part A and Part B appeals process has five levels (42 CFR § 405.904(a)(2)), and if a provider exercises its right to an appeal, the provider does not need to return overpayments until after the second level of appeal. Potential overpayments identified in OIG reports that are based on extrapolation may be re-estimated depending on CMS determinations and the outcome of appeals.

¹⁶ This recommendation does not apply to any overpayments that are both within our sampling frame (i.e., the population from which we selected our statistical sample) and refunded based upon the extrapolated overpayment amount. Those overpayments are already covered in the previous recommendation.

¹⁷ Federal regulations (42 CFR § 409.43(c)(1)(i)(D)) require that, as a condition of payment for a RAP, if the physician has not signed the plan of care by the time the home health agency submits the RAP, the physician verbal order be copied into the plan of care, which is *immediately* submitted to the physician. This suggests the urgency of physician involvement in reviewing and establishing the plan of care.

Sections 1814(a)(2)(C) and 1835(a)(2)(A) of the Act require, as a condition of payment for home health services, that a physician certify and recertify that the Medicare beneficiary is receiving services under a plan of care that has been *established* and periodically reviewed by a physician. Federal regulations (42 CFR § 409.42(b)) require, as a condition of coverage for home health services, that a beneficiary be under the care of a physician who *establishes* the plan of care. Moreover, 42 CFR § 484.18¹⁸ requires, as a condition of participation, that a plan of care be *established* and periodically reviewed by a physician at least once every 60 days.

Twelve of the one hundred claims in our sample had plans of care that were signed by a physician after the 60-day certification period but prior to submission of claims for final percentage payment. These plans of care documented the verbal start of care orders signed by a nurse or other medical professional, not by a physician, and they were dated on the first day of the 60-day episode.

The physicians' signatures on plans of care after the 60-day certification period may indicate an absence of physician participation in establishing and reviewing plans of care. Without a physician signature, contemporaneous with the establishment of the plan of care, it may not be clear from the medical record that the Medicare requirements listed above were met. Although there is no specific requirement that the plan of care be signed by the physician at the time it was established, such a signature may be an effective way to document that the Medicare requirements were met.

BROOKDALE HOME HEALTH COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, Brookdale¹⁹ agreed that 16 of the 46 claims that we found to have been improperly billed were paid in error and stated that it had repaid those 16 claims. Brookdale disagreed with our remaining findings and all three of our recommendations. With respect to our first recommendation, to refund estimated overpayments, Brookdale alleged that our medical review contractor erroneously found that beneficiaries were not homebound or did not require skilled services. Brookdale claimed that our independent medical review contractor (1) relied upon irrelevant and out-of-context facts instead of patient's medical records as a whole; (2) applied erroneous readings of regulations or non-existent standards; (3) made repeated factual errors; and (4) denied claims in contravention of OIG policy. Brookdale also stated that it had serious concerns about its selection for audit and the qualifications of our medical reviewers. Brookdale stated that rebuttals prepared by its medical experts support 30 of the 46 claims that we found to have been billed in error. Further, Brookdale stated that our sampling methodology was not statistically valid or reliable. Moreover, Brookdale stated that we could not extrapolate overpayments absent a sustained or high level of payment error or include claims outside the 4-year reopening period.

¹⁸ This requirement was moved to 42 CFR § 484.60(a) effective July 13, 2017 (82 Fed. Reg. 4504 (Jan. 13, 2017)).

¹⁹ During our audit period, Brookdale Home Health, LLC, was owned and operated by Brookdale Senior Living, Inc. Prior to our audit period, Brookdale had merged with another agency, Nurse on Call – Lake Worth, and has been operating under the name “Nurse on Call” since that time. In Brookdale's response, NOC stands for Nurse on Call.

With respect to our second recommendation to exercise reasonable diligence in accordance with the 60-day rule, Brookdale stated that it disagreed with all but 16 of our medical necessity errors and intended to appeal all adverse findings. Finally, with respect to our third recommendation to strengthen its procedures, Brookdale contended that there was no systemic issue with its policies and procedures and that they were effective in ensuring compliance with Medicare coverage, documentation, coding, and billing requirements.

Brookdale's comments, from which we removed in excess of 300 pages of exhibits because of their volume and content (namely personally identifiable information), are attached as Appendix F. We are providing Brookdale's comments in their entirety to CMS.

After reviewing Brookdale's comments and further considering the opinions of its medical review experts we maintain that our findings and recommendations are valid. Below is a summary of the reasons Brookdale did not agree with our recommendations and our responses to that disagreement.

BENEFICIARY HOMEBOUND STATUS

Brookdale Comments

Brookdale stated that we did not provide our medical reviewers with its rebuttals to medical review findings that Brookdale presented on March 12, 2019, and June 21, 2019, and that information gathered by its Freedom of Information Act (FOIA) request indicated that we also questioned the quality of our medical review contractor's findings.

Brookdale also stated that our determinations pertaining to noncompliance with homebound requirements were flawed because medical reviewers did not correctly apply Medicare coverage criteria or did not account for relevant clinical evidence. Brookdale further stated that our medical reviewers did not view the medical record as a whole but, instead, allowed isolated clinical notes to drive the conclusion that the beneficiaries were not homebound. Brookdale cited examples that it believed showed that our medical reviewer incorrectly used ambulation distance as a "rule of thumb" or considered other irrelevant factors, such as size of independent facility, when determining homebound status.

Office of Inspector General Response

We considered the rebuttals that Brookdale provided on March 12, 2019, and June 21, 2019, when making our final determinations of overpayments. We did not provide the rebuttals to our medical reviewers because the only additional information Brookdale provided was its medical reviewer's opinion on the medical record. Brookdale's rebuttals contained no additional medical documentation. Because our medical reviewers had already reviewed the medical record in its entirety and had made its determination, there was no reason to provide

the rebuttals for its review.²⁰ The information gathered by Brookdale’s FOIA request documents was nothing more than the process of our auditors corresponding with the medical reviewers to ensure that a quality medical review was performed. As part of the medical review process, our medical reviewers will make initial determinations based on the medical records and send them to us for comments or inquiries. It is not uncommon for us to question our medical reviewers about its determinations or to seek clarification on language used in those determinations.

We disagree with Brookdale’s assertion that our medical reviewers did not correctly apply Medicare coverage criteria or did not account for relevant clinical evidence when determining homebound status. Our medical reviewer prepared detailed medical review determination reports documenting its thorough analysis of relevant clinical evidence. We provided these reports to Brookdale before we issued our draft report. Each determination letter included a detailed set of facts based on a thorough review of the entire medical record. *In all cases, our medical reviewer considered the entire record as provided* and relied upon the relevant and salient facts necessary to determine homebound status in accordance with CMS’s homebound definition.

Ambulation distance is one factor among others that our medical reviewer considered in making homebound determinations. As shown in each medical review determination report, our medical reviewer documented in detail the relevant medical history, including diagnoses, skilled nursing or therapy assessments, cognitive function, and mobility for each beneficiary. Regarding meeting CMS homebound criteria, medical review determinations must be based on each patient’s individual characteristics as reflected in the available record. Our medical reviewer carefully considered ability to ambulate in conjunction with other individual characteristics noted in each patient’s medical record. Ambulation distance, when noted in the determination letter, was simply one factor the reviewer considered in making the homebound determination. The facts the reviewer considered are evident from the discussion included with each individual determination.

BENEFICIARY NEED FOR SKILLED NURSING SERVICES

Brookdale Comments

Brookdale stated that our medical reviewers failed to evaluate the need for skilled services appropriately and made the following four primary errors when evaluating skilled nursing services: (1) relied on unfounded expectations that a patient “could reasonably have been expected to improve spontaneously” or lacked “restorative potential”; (2) stated without evidence that available unskilled caregivers could provide the skilled services as a substitute for trained professionals; (3) incorrectly equated PT and OT services and concluded that one was duplicative of the other; and (4) denied services prior to reassessment and, therefore, ignored crucial information on the need for additional skilled services. Brookdale cited examples of

²⁰ Audit teams make audit specific (i.e., audit-by-audit) decisions whether to send auditee rebuttals to our medical reviewers for review.

determination letters in which beneficiaries were described as not having the ability to show spontaneous improvement and attributed their improvement to skilled caregivers. Brookdale believes these examples demonstrate that our medical reviewer applied improper coverage standards.

Office of Inspector General Response

Our medical reviewer determined the medical necessity of skilled therapy services in accordance with the Manual, chapter 7, section 40.2. Per these CMS guidelines, it is necessary to determine whether individual therapy services are skilled and whether, in view of the patient's overall condition, skilled management of the services provided is needed. The guidelines also state: "While a patient's particular medical condition is a valid factor in deciding if skilled therapy services are needed, a patient's diagnosis or prognosis should never be the sole factor in deciding that a service is or is not skilled." The key issues are whether the skills of a therapist are needed to treat the illness or injury and whether the services can be carried out by unskilled personnel. The skilled therapy services must be reasonable and necessary for the treatment of a patient's illness or injury within the context of a patient's unique medical condition.

In determining the medical necessity of skilled nursing services, our medical reviewer considered the patient's clinical condition and whether skilled services were necessary to safely and effectively maintain the patient's current condition or to slow further deterioration in accordance with the Manual, chapter 7, section 40.1.1. Per these CMS guidelines, when the services provided could be safely and effectively performed by the patient or unskilled caregivers, such services will not be covered under the home health benefit.

OFFICE OF INSPECTOR GENERAL AUDIT PROCESS

Brookdale Comments

Brookdale stated that we did not explain why it was selected for audit and instead cited statistics on how much Medicare paid home health agencies in general and the estimated error rate for all home health billing claims. Brookdale believed that our selection process was divorced from the intended purpose of the audits, which was to review outliers in billing non-compliance. Brookdale suggested that large providers like it were unfairly and unnecessarily targeted and publicly scrutinized. Brookdale also stated that it had serious concerns about the qualifications of our contracted medical reviewers because the OIG has provided no substantive information to validate their qualifications.

Office of Inspector General Response

Prior to conducting this audit, we conducted a risk assessment at four Brookdale facilities in Florida based on our claim data analysis incorporating case mix. This analysis determined that Brookdale had one of the highest case-mix group paid rankings. Our research of the Medicare HHA reimbursement system determined that case mix is the largest single factor in increasing

reimbursements for an HHA. Also, we noted during our claim data analysis that Brookdale had a pattern of reporting a case mix that CMS later reduced significantly upon re-grouping, which could signify internal control problems. During our risk assessment, we reviewed 30 claims and, using auditor experience from prior HHA compliance reviews, determined the potential for a high error rate. We selected Brookdale for audit based on the case mix paid rankings and our risk assessment determinations and did not target it solely because it is a large Medicare biller.

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

ESTIMATION OF OVERPAYMENTS

Brookdale Comments

Brookdale stated that our statistical sampling methodology was unreliable and fundamentally flawed, thereby calling into question the statistical validity of the extrapolated overpayment. Brookdale believes that we used a faulty sampling methodology that necessarily inflated its estimated error rate, resulting in an inaccurate extrapolated overpayment. Specifically, Brookdale argues that our sample was not representative of the sampling frame and our results were biased due to the probability each beneficiary had of being included in the sample. Brookdale also stated that our estimation of overpayments was inappropriate in the absence of a sustained or high level of payment error that constitutes an error rate greater than or equal to a 50 percent error rate pursuant to 42 U.S.C. section 1395ddd(f)(3)(A) and the PIM, chapter 8, section 8.4.1.4. Brookdale also stated that the estimated overpayment amount was misleading because some erroneous claims occurred outside of the reopening period, and we were attempting to circumvent Medicare regulations by using extrapolation to reopen claims beyond that 4-year period.

Office of Inspector General Response

Brookdale'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) was not applicable because OIG is not a Medicare contractor.²¹ We maintain that our statistical approach resulted in a legally valid and reasonably conservative estimate of overpayments Brookdale received. The estimated overpayment of \$3,286,869 is

²¹ The Act § 1893(f)(3); CMS *Medicare Program Integrity Manual*, Pub. No. 100-08, chapter 8.4 (effective Jan. 2, 2019).

based on the claim errors discovered in the sample and thus is a conservative measure of the overpayments that exist within the sampling frame.

We disagree that we are using our extrapolation to recommend the recoupment of funds outside the 4-year reopening period. We calculated and accurately reported a conservative estimate of the amount overpaid to Brookdale for the claims within our sampling frame. We recommend that Brookdale refund the portion of the estimated overpayment that arises from claims within the 4-year reopening period. We did not separately estimate the portion of the overpayment within the 4-year reopening period because the amount cannot be calculated until the claims are reopened, which will occur after the report is published.

Federal courts have consistently upheld statistical sampling and extrapolation as a valid means to determine overpayment amounts in Medicare and Medicaid.²² 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.²³ 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.

The differences between the sample and the sampling frame that were identified by Brookdale are an expected part of the sampling process and are accounted for through our use of the lower limit to calculate the recommended recovery. The statistical lower limit represents a conservative estimate of the overpayment that we would have identified if we had reviewed every claim in the sampling frame. We use the lower limit of a two-sided 90-percent confidence interval, which is designed to be less than the actual overpayment amount 95 percent of the time. This conservative approach gives the provider the benefit of the doubt for the uncertainty in the sampling process, including uncertainty due to the number of unique diagnosis codes appearing in the sample as compared with the sampling frame.

Brookdale also argues that the sample was biased due to the probability each beneficiary had of being included in the sample. The sample unit for this audit is a claim, not a beneficiary. The proofs for the unbiased nature of our estimate and the conservative nature of the lower limit require random selection of the sample units (here claims) from each stratum. We performed this selection using a valid random number generator. The proofs underlying our methods do

²² 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).

²³ 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).

not make any assumptions about the distribution of beneficiaries in the sampling frame or in the sample.

60-DAY RULE RECOMMENDATION

Brookdale Comments

Brookdale disagreed with our second recommendation to exercise reasonable diligence to identify and return overpayments in accordance with the 60-day rule. It plans to appeal our overpayment assessment through the Medicare administrative appeals process and does not intend to refund any overpayments until that process is complete.

Office of Inspector General Response

We maintain that our findings are valid, for the reasons stated above, and we therefore maintain our belief that this audit report constitutes credible information of potential overpayments and maintain that our second recommendation, to exercise reasonable diligence in accordance with the 60-day rule, is valid.

STRENGTHEN PROCEDURES RECOMMENDATION

Brookdale Comments

Brookdale disagreed with our third recommendation to strengthen its procedures to ensure that (1) the homebound statuses of Medicare beneficiaries are verified and continually monitored and the specific factors qualifying beneficiaries as homebound are documented and (2) beneficiaries are receiving only reasonable and necessary skilled services. Brookdale disagreed because it believes it has strong controls that ensure full compliance with Medicare requirements.

Office of Inspector General Response

Brookdale has agreed that 16 of the 100 sampled claims were overpayments and stated that it repaid them. We believe 16 percent of the sampled claims material is evidence that the compliance procedures at Brookdale are not sufficient to prevent overpayments, regardless of Brookdale's non-concurrence and appeal of the other 30 potential overpayments.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

Our audit covered \$13,902,692 in Medicare payments to Brookdale for 3,512 home health claims with episode-of-care through dates in CYs 2016 and 2017 (audit period). From this sampling frame, we selected for review a stratified random sample of 100 home health claims with payments totaling \$421,348.

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

We limited our audit of Brookdale'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 at Brookdale from June 2018 through March 2020.

METHODOLOGY

To accomplish our objective, we:

- reviewed applicable Federal laws, regulations, and guidance;
- extracted Brookdale's paid claims data from CMS's NCH file for the audit period;
- removed payments for low utilization payment adjustments, partial episode payments, RAC reviewed claims, claims less than \$1,000 and requests for anticipated payments from the population to develop our sampling frame;
- selected a stratified random sample of 100 home health claims totaling \$421,348 for detailed review (Appendix C);
- reviewed available data from CMS's Common Working File for the sampled claims to determine whether the claims had been canceled or adjusted;
- obtained and reviewed billing and medical record documentation provided by Brookdale to support the claims sampled;
- reviewed sampled claims for compliance with known risk areas;

- used an independent medical review contractor to determine whether the 100 claims contained in the sample were reasonable and necessary and met Medicare coverage and coding requirements;
- reviewed Brookdale’s procedures for billing and submitting Medicare claims;
- verified State licensure information for selected medical personnel providing services to the patients in our sample;
- calculated the correct payments for those claims requiring adjustments;
- used the results of the sample to estimate the total Medicare overpayments to Brookdale for our audit period (Appendix D); and
- discussed the results of our audit with Brookdale officials.

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

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

GENERAL MEDICARE REQUIREMENTS

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

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

OUTCOME AND ASSESSMENT INFORMATION SET DATA

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

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

COVERAGE AND PAYMENT REQUIREMENTS

To qualify for home health services, Medicare beneficiaries must (1) be homebound; (2) need intermittent skilled nursing care (other than solely for venipuncture for the purpose of obtaining a blood sample) or physical therapy or speech-language pathology, or occupational therapy;²⁴ (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 (sections 1814(a)(2)(C) and 1835(a)(2)(A) of the Act; 42 CFR § 409.42; and the Manual, chapter 7, § 30).

²⁴ 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, Medicare covers the first occupational therapy service, which is a dependent service, only when followed by an intermittent skilled nursing care service, physical therapy service, or speech language pathology service as required by law. Once that requirement for covered occupational therapy has been met, however, all subsequent occupational therapy services that continue to meet the reasonable and necessary statutory requirements are considered qualifying services in both the current and subsequent certification periods (subsequent adjacent episodes) (76 Fed. Reg. 68526, 68590 (Nov. 4, 2011)).

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

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

Section 6407(a) of the Affordable Care Act²⁵ added a requirement to sections 1814(a)(2)(C) and 1835(a)(2)(A) of the Act that the physician have a face-to-face encounter with the beneficiary. In addition, the physician responsible for performing the initial certification must document that the face-to-face patient encounter, which is related to the primary reason the patient requires home health services, has occurred no more than 90 days prior to the home health start-of-care date or within 30 days of the start of the home health care by including the date of the encounter.²⁶

Confined to the Home

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

[A]n individual shall be considered “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 the home,” the condition of the individual should be such that there exists a normal inability to leave home and that leaving home requires a considerable and taxing effort by the individual.

CMS provided further guidance and specific examples in the Manual (chapter 7, § 30.1.1). The Manual states that, for a patient to be eligible to receive covered home health services under both Part A and Part B, the law requires that a physician certify in all cases that the patient is

²⁵ The Patient Protection and Affordable Care Act, P.L. 111-148 (Mar. 23, 2010), as amended by the Health Care and Education Reconciliation Act of 2010, P.L. 111-152 (Mar. 30, 2010), collectively known as the Affordable Care Act.

²⁶ See 42 CFR § 424.22(a) and the Manual, chapter 7, § 30.5. The initial effective date for the face-to-face requirement was January 1, 2011. However, on December 23, 2010, CMS granted HHAs additional time to establish protocols for newly required face-to-face encounters. Therefore, documentation regarding these encounters must be present on certifications for patients with starts of care on or after April 1, 2011.

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

Criteria One

The patient must:

- need, because of illness or injury, 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 (the Manual, chapter 7, § 30.1.1).

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

Criteria Two

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

Need for Skilled Services

Intermittent Skilled Nursing Care

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

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

Requiring Skills of a Licensed Nurse

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

General Principles Governing Reasonable and Necessary Skilled Nursing Care

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

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

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

Reasonable and Necessary Therapy Services

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

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

Documentation Requirements

Face-to-Face Encounter

Federal regulations (42 CFR § 424.22(a)) and the Manual (chapter 7, § 30.5.1.1) state that, prior to initially certifying the home health patient's eligibility, the certifying physician must document that he or she, or an allowed nonphysician practitioner, had a face-to-face encounter with the patient that is related to the primary reason the patient requires home health services. In addition, the Manual (chapter 7, § 30.5.1) states that the certifying physician must document the encounter either on the certification, which the physician signs and dates, or a signed addendum to the certification.

Plan of Care

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

APPENDIX C: SAMPLE DESIGN AND METHODOLOGY

SAMPLING FRAME

The sampling frame consisted of a database of 3,512 home health claims, valued at \$13,902,692.29, from CMS's NCH file. These claims were for select home health services²⁷ that Brookdale provided to Medicare beneficiaries with episodes of care that ended in CYs 2016 and 2017.

SAMPLE UNIT

The sample unit was a home health claim.

SAMPLE DESIGN AND SAMPLE SIZE

We used the following stratified random sample:

Table 1: Claims by Stratum

Stratum	Frame Information			Sample Size
	Payment Range	Claims in Sample Frame	Total Value of Frame	
1	\$1,328.20 to \$3,838.74	1,622	\$4,488,180.11	34
2	\$3,838.75 to \$5,119.56	1,011	4,603,972.31	33
3	\$5,119.57 to \$10,629.35	879	4,810,539.87	33
Total		3,512	\$13,902,692.29	100

SOURCE OF RANDOM NUMBERS

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

METHOD OF SELECTING SAMPLE ITEMS

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

²⁷ We excluded home health payments for low utilization adjustments, partial episode payments, and requests for anticipated payments. We also excluded paid claims less than \$1,000 and claims that had previously been reviewed by a RAC.

ESTIMATION METHODOLOGY

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

APPENDIX D: SAMPLE RESULTS AND ESTIMATES

Table 2: Sample Results

Stratum	Frame Size	Total Value of Frame	Sample Size	Total Value of Sample	Incorrectly Billed Sample Items	Value of Overpayments In Sample
1	1,622	\$4,488,180.11	34	\$89,249	10	\$20,719
2	1,011	4,603,972.31	33	151,674	20	59,815
3	879	4,810,539.87	33	180,425	16	51,966
Total	3,512	\$13,902,692.29	100	\$421,348	46	\$132,500

ESTIMATES

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

Point estimate	\$4,205,096
Lower limit	3,286,869
Upper limit	5,123,323

APPENDIX E: TYPES OF ERRORS BY SAMPLE ITEM

Table 4: Stratum 1 (Samples 1–25)

Sample	Not Homebound	Did Not Require Skilled Services	Overpayment
1			
2			
3			
4			
5			
6			
7			
8			
9			
10			
11			
12			
13			
14	X		\$1,447
15		X	1,534
16			
17		X	2,565
18			
19			
20			
21	X		3,617
22		X	623
23	X		3,212
24			
25			

Table 5: Stratum 1 (Samples 26-34)

Sample	Not Homebound	Did Not Require Skilled Services	Overpayment
26		X	780
27	X	X	(293)
28	X		3,812
29			
30			
31			
32			
33			
34	X		3,423

Table 6: Stratum 2 (Samples 35-67)

Sample	Not Homebound	Did Not Require Skilled Services	Overpayment
35			
36			
37			
38	X		1,129
39		X	2,602
40			
41			
42	X		4,032
43			
44	X	X	1,203
45	X		5,051
46	X		4,158
47		X	3,058
48	X	X	620
49	X		4,592
50		X	4,462
51	X	X	4,561
52			
53		X	4,548
54			
55			
56	X		817
57	X		3,894
58	X		4,966
59	X		1,649
60		X	3,734
61			
62	X		1,138
63			
64		X	1,950
65			
66			
67	X	X	1,649

Table 7: Stratum 3 (Samples 68–99)

Sample	Not Homebound	Did Not Require Skilled Services	Overpayment
68		X	5,136
69			
70		X	1,335
71			
72			
73			
74			
75			
76	X	X	1,980
77			
78			
79	X	X	5,421
80			
81			
82	X	X	5,313
83		X	1,214
84		X	2,361
85		X	3,212
86		X	1,181
87			
88	X	X	5,399
89		X	3,261
90			
91			
92			
93			
94	X	X	5,313
95			
96		X	2,272
97		X	2,850
98		X	3,887
99	X	X	1,832

Table 8: Stratum 3 (Sample 100)

Sample	Not Homebound	Did Not Require Skilled Services	Overpayment
100			
Totals	26	31	\$132,500

APPENDIX F: BROOKDALE HOME HEALTH, LLC, COMMENTS

BASS BERRY + SIMS_{PC}

Brian D. Roark
[REDACTED]

August 6, 2020

Via Kiteworks & FedEx

Attn: Lori S. Pilcher, Regional Inspector General for Audit Services
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61 Forsyth Street, SW, Suite 3T41
Atlanta, GA 30303

**Re: Brookdale Senior Living, Inc. d/b/a Nurse on Call
Response to Office of Audit Services Draft Report No. A-04-18-06221**

Dear Ms. Pilcher,

I am writing on behalf of my client, Brookdale Home Health, LLC d/b/a Nurse on Call (“NOC”)¹ in response to the Office of Inspector General, Office of Audit Services’ (“OIG”) May 12, 2020 Draft Report: *Medicare Home Health Agency Provider Compliance Audit: Brookdale Home Health, LLC* (“Draft Report”).

OIG focused this audit on home health services provided by NOC’s Lake Worth agency between 2016 and 2017. We understand that OIG selected NOC for this audit as part of its home health reviews as noted in OIG work plans, and in large part simply because NOC is a large provider that bills Medicare for home health services. In the section of the Draft Report explaining “Why We Did This Audit,” OIG does not explain why it selected NOC for this audit, instead citing statistics on how much Medicare paid home health agencies generally and the estimated error rate for all home health billing claims. The selection process is divorced from the intended purpose of the audits, which is to review outliers in billing non-compliance. Instead, it suggests that large providers like NOC are unfairly and unnecessarily targeted, and publicly scrutinized.

The Draft Report further relies on the opinions of the contracted medical reviewers at Maximus, OIG’s qualified independent contractor (“QIC”), who consistently failed to analyze the records under the appropriate standards. Instead Maximus opted to apply arbitrary rules based on isolated instances in the medical record, leading to necessarily erroneous results. After OIG sent NOC the preliminary medical determinations, NOC responded and identified various errors as set forth in two rebuttal letters, dated March 12, 2019 and June 21, 2019. These rebuttal letters detailed the deficiencies in the medical reviewers’ conclusions, including that the medical reviewers had analyzed the wrong medical record entirely for at least one patient. However, despite having NOC submit these rebuttals more than one year ago, OIG has ignored the rebuttals and not considered them in issuing this Draft Report. NOC respectfully submits that the Draft Report should not be

¹ At all times, the agency has been owned and operated by Brookdale Senior Living, Inc. However, in 2015, the Brookdale agency merged with another agency, Nurse on Call – Lake Worth, and has been operating under the name “Nurse on Call” since that time.

Office of Inspector General Note -- The deleted text has been redacted because it is personally identifiable information.

finalized until OIG has reviewed – or had its contracted medical reviewer consider – the rebuttals submitted by NOC.

This is especially the case given that OIG itself expressed concerns about the adequacy of the medical review and noted significant disagreement with its own medical reviewer’s findings. As set forth in documents produced by OIG in response to NOC’s FOIA request, OIG questioned the “quality” of Maximus’s initial review, raised concerns about factual errors, disagreed with clinical assessments made in the review, and questioned Maximus’s understanding and application of the laws, regulations, and policies relating to home health billing. NOC shares these same concerns. The claims determinations in this matter reflect a failure to understand and apply the relevant regulations, factual errors, and policy determinations that neither reflect the stated positions of CMS nor the best interest of patients.

For OIG to issue the Report without having taken into account obvious errors in the medical review pointed by NOC – and often echoed by OIG’s own review – raises serious questions about the accuracy of the Report. **As such, NOC renews its request for OIG to direct its medical reviewers to reconsider their denials and partial denials in light of these comments and enclosed rebuttal statements, and reissue their medical determinations based on an accurate application of Medicare statutes, regulations, and guidance. Following this reconsideration, NOC requests the opportunity to review and comment on a revised draft report before the issuance of a Final Report.** A public report based on potentially incorrect findings, and without an opportunity to truly engage with OIG’s medical review contractors, will unnecessarily harm the reputation of NOC.

I. Executive Summary of the Response

During the course of this audit, OIG reviewed one hundred (100) claims and found that NOC did not comply with billing requirements for forty-six (46) claims. OIG alleged that NOC received overpayments of \$132,500 in connection with these claims and estimated that NOC received extrapolated overpayments of approximately \$3.3 million for the audit period of calendar years 2016 and 2017. As discussed further below, NOC disagrees with each of the conclusions reached by OIG in the Draft Report.

First, the audit suffers from significant structural and analytical errors. OIG engaged Maximus to serve as its QIC. A review of the analysis indicates that in its claim denials, Maximus:

- Relied on irrelevant and out-of-context facts to support its conclusions, instead of relying on the patients’ medical records as a whole;
- Applied erroneous readings of the regulations, or relied on standards that are nowhere to be found in the laws and regulations surrounding home health billing, in support of its claim denials;
- Made repeated factual errors in its analysis, including in at least one case analyzing the wrong patient record; and

- Denied claims in contravention of OIG policy and in such circumstances where denial of services would have seriously endangered beneficiaries.

The patients' medical records support the overwhelming majority of the audit claims. NOC has summarized the major deficiencies in the review below and submitted rebuttals challenging these determinations in Exhibit 1. It also appears that OIG agrees with NOC on a significant number of these issues.²

In addition, as explained in the attached report from FTI Consulting in Exhibit 2, the sampling methodology used by OIG is not statistically valid or reliable. The design of the sampling methodology and analysis of the sample used by OIG in the extrapolation foreclose any possibility that it was representative of the universe of claims as a whole. As such, any extrapolation is unreliable and cannot fairly represent any potential overpayment. OIG also appears to be using the extrapolation to attempt to recoup payment for claims that it has no power to recover directly under relevant regulations.

NOC understands and takes seriously its obligations to bill Medicare appropriately for home health services rendered to program beneficiaries and acknowledges the important role OIG plays in enforcing these obligations. NOC also understands the importance of ensuring OIG's Final Report accurately reflects correct conclusions based upon the records being reviewed. However, NOC disagrees with the methodology and findings of the Draft Report, and each of OIG's recommendations.

II. Background on Nurse on Call

NOC's experience, provision of quality care, and culture of compliance has contributed to making NOC a leading provider in the home health industry at large. Since 1989, NOC has provided quality skilled nursing and other therapeutic services to Medicare beneficiaries, in compliance with Medicare coverage criteria and leading industry standards. NOC is professionally managed and operated. As a subsidiary of Brookdale Senior Living, it receives the support and resources of one of the nation's leading and largest senior care providers. NOC has a long-standing reputation for caring for Medicare beneficiaries with high quality home health services in compliance with applicable professional and payor standards and rules. NOC has in place an effective compliance program, designed to ensure that all applicable statutory and regulatory provisions are followed. The program includes effective disciplinary and corrective action policies, as well as appropriate anonymous reporting channels and non-retaliation policies to ensure that non-compliant behavior is reported and responded to as necessary. Further, NOC has adopted policies and procedures specifically addressing compliance with applicable laws, ethical billing practices, utilization review, and other areas of concern. Risk assessments are conducted annually and all necessary changes are implemented to meet the compliance objectives. The strength of NOC's compliance program is evident.

NOC understands that Medicare payment and coverage criteria are more than broad compliance concerns, but contain essential technical components that must be met prior to

² On March 10, 2020, NOC submitted a FOIA request at the direction of OIG for certain categories of documents. The response to the FOIA request was received on July 30, 2020. Selections from the voluminous FOIA response have been attached as Exhibit 3A-H.

submitting claims for final Medicare payment. NOC reviews all home health claims prior to submitting a claim to Medicare for payment. Claims lacking necessary supporting documentation are held unless and until such documentation is obtained and compliance with all Medicare coverage criteria can be substantiated.

In addition to its detailed and evolving compliance plan, NOC staff and administration routinely attend educational seminars that cover issues of compliance, such as training on homebound status, skilled services, face-to-face encounters, and documentation requirements. NOC has created a culture of compliance and provided its staff with the appropriate tools and education to achieve its compliance objectives.

III. NOC Does Not Concur with OIG's Recommendations

a. OIG Recommendation 1

Refund to the Medicare program the portion of the estimated \$3,286,869 overpayment for claims incorrectly billed that are within the reopening period.

NOC's Response: NOC does not concur with this recommendation. The conclusions of OIG's contracted medical reviewers and the methodology used to reach them are fundamentally flawed. As detailed in the attached rebuttal statements prepared by NOC's qualified medical experts, the patients' medical records support the overwhelming majority of the audit claims. These claims were billed appropriately and do not merit repayment. In addition, as explained in the attached report from FTI Consulting, the sampling methodology used by OIG is not statistically valid or reliable. The sampling methodology used did not result in a representative sample of claims and, therefore, OIG cannot use this methodology as a basis to calculate an extrapolated overpayment. In addition to the unreliable extrapolation, NOC intends to vigorously challenge negative claims findings and any sampling methodology used to calculate and extrapolate overpayments following the issuance of a Final Report by exercising its right to appeal any adverse findings through the Medicare administrative appeals process. NOC anticipates that any alleged overpayment will be overturned. Therefore, any refund to the Medicare program is inappropriate and premature.

b. OIG Recommendation 2

Based on the results of this audit, exercise reasonable diligence to identify, report, and return any overpayments in accordance with the 60-day rule, and identify any of those returned overpayments as having been made in accordance with this recommendation.

NOC's Response: NOC does not concur with this recommendation. NOC 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.³ 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

³ 42 C.F.R. § 401.305.

overpayments is premature during the audit appeals process.⁴ Rather than automatically contest every denial, NOC, after a careful review of the claims, determined that sixteen (16) of these claims were properly denied, and has since repaid those claims.⁵ As noted in this response and as detailed in the attached rebuttals, NOC disagrees with OIG's remaining findings and believes the audited claims are supported by the patient's medical records and were billed appropriately.

c. **OIG Recommendation 3**

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; and*
- *Beneficiaries are receiving only reasonable and necessary skilled services*

NOC's Response: NOC does not concur with this recommendation. NOC is committed to maintaining and improving its compliance efforts notwithstanding the complex and ever-evolving regulatory landscape. OIG attempts to characterize NOC as a bad actor by insisting its compliance policies and procedures are insufficient. To the contrary, there is no systemic issue with NOC's policies and procedures. The records for these patients, when viewed by a qualified medical expert applying the appropriate medical standards, demonstrate that NOC's policies and procedures are effective in their aim to ensure compliance with applicable Medicare coverage, documentation, coding, and billing requirements. NOC regularly evaluates whether opportunities exist to improve its policies and procedures, and will continue to do so; however, implementation of further policies and procedures at this time is unnecessary because this audit demonstrates that NOC's compliance efforts have been, and will continue to be, successful.

IV. **Overview of Issues in OIG's Audit Process**

a. **The Medical Reviewers Repeatedly Relied on Irrelevant and Out-of-Context Facts to Support their Conclusions**

OIG's contracted medical reviewers failed to review the patients' medical records as a whole and analyze their eligibility for home health services based on relevant criteria. Instead, throughout OIG medical determinations, the reviewers relied upon isolated chart notes made by a physical or occupational therapist who was evaluating the patient not for homebound eligibility, but for that patient's progress relative to the individual therapy service being provided at that time. In other words, the external medical reviewers ignored the medical opinion of the home health "gatekeeper" (i.e., the certifying physician), in favor of what was usually a single observational note by a physical or occupation therapist who, notably, lacked the authority to even order home health services.

For example, the contracted medical reviewers often relied on a patient's ability to ambulate for a certain number of feet to determine homebound status, as opposed to recognizing:

⁴ See Medicare Program; Reporting and Returning Overpayments, 81 Fed. Reg. 7654, 7667 (Feb. 12, 2016).

⁵ One of these claims did not result in any change in reimbursement, so there was no repayment.

(1) the distances required in order for the patient to safely and independently leave home and the varying needs for each patient based on their actual living environment; (2) the comorbidities and disease processes that critically impact the patient's safety and ability to leave the home; or (3) the physician's initial determinations that the patient was in fact homebound.

The home health certifications require that physicians certify that beneficiaries are: confined to the home; need skilled services; under the care of a physician; receive services under a plan of care established and reviewed by a physician; and have had an appropriate face-to-face encounter. The certifying physicians, in their expert medical judgment, determined the patients were eligible for home health services. The records indicate that NOC provided care that was ordered by, certified by, and at the direction of physicians, and reflect clear collaboration with physicians throughout the patients' admission.⁶

For these reasons, as well as those set forth below, we request OIG have its medical reviewers consider the enclosed analyses and reconsider their initial determinations.

b. The Medical Reviewers Reach Conclusions on Eligibility for Services Based on Erroneous Readings of the Regulations

The analysis of OIG's contracted medical reviewers also reveals a consistent and problematic theme: those reviewers failed to apply the appropriate Medicare criteria for determining a patient's eligibility for Medicare home health services. From its FOIA response, OIG shared the same concern. Specifically, OIG expressed concerns that Maximus repeatedly failed to view the medical record as a whole. Instead, they relied on shorthand metrics regarding the capabilities of the patient or assumptions regarding the availability of assistance to those patients. These standards appear nowhere in the laws and regulations surrounding home health care billing and raise serious concerns about the reliability of this review.

Significantly, observations made by Maximus do not apply the standards set forth by the regulations at issue regarding homebound status or skilled services. In its FOIA request, NOC requested the "matrix" used by Maximus. OIG provided this document, the notes of the entrance meeting, and correspondence relating to Maximus's claims review in its response. OIG's comments to Maximus on their initial claims reviews reflect that Maximus failed to understand and apply the correct regulations and policies:

- Regarding Patients 15, 19, 26, 44, and 49, OIG questioned whether Maximus could provide "some criteria or language that states therapy is not reasonable or necessary if a patient resides in an ALF? Does living in an ALF disqualify a patient from receiving therapy?" Ex. 3-E, 3-G, 3-H. In its claim determinations, Maximus was unable to provide a citation to any regulation or guidance supporting such denials,

⁶ While start of care orders for some patients may have been signed by nurses or other medical professionals rather than a physician, as the OIG Draft Report acknowledges, "there is no specific requirement that the plan of care be signed by the physician at the time it was established." A physician may appropriately give verbal orders to start care and be involved throughout the provision of care. The fact that for certain patients, the physician did not physically sign the plan of care until after the certification period is insufficient to overcome indications in the record that the physicians were actively involved in the patients' care, including establishing the plan of care.

because none exists. Nonetheless, Maximus declined to reverse its denial of these claims.

- Regarding Patients 19, 26, 44, 49, and 83, OIG raised concerns that Maximus denied claims contrary to OIG policy: “[f]or previous HHA reviews OIG supervisory management has decided that Occupational Therapy Being Duplicative of Other Therapy/Services claims are non-errors.” Ex. 3-E, 3-F. Again, Maximus declined to reverse its denial of these claims.
- Regarding Patients 97 and 98, OIG raised concerns that Maximus was applying the “improvement standard,” which was previously disallowed by the settlement agreement in *Jimmo v. Sebelius*. Ex. 3-F

Maximus had no substantive response to these concerns regarding the regulations. Maximus was unable to point to any regulatory provision that required consideration of “available caregivers,” that disallowed “duplicative” OT and PT services, or that validated the “improvement standard.” Instead, Maximus largely responded by adding alternative language to its denials, masking its true reason for denial in some cases. Because Maximus failed to apply the appropriate regulatory standard, the Draft Report should be revised to reflect the correct standard prior to being finalized.

c. The Medical Reviewers Reached Conclusions on Eligibility for Services Based on Factually Inaccurate Statements

The medical reviewers also relied on incorrect information in making their determinations, presumably by reviewing the wrong record in at least one instance. In the preliminary medical determination, the medical reviewers determined the claim for services provided to Patient 19 to be partially erroneous on the grounds that there was no clear need for occupational therapy. The reviewers supported these findings in a determination letter, which states in relevant part:

- “The patient ... required meal set-up and spoon feeding for meals.”
- “The patient’s independent caregiver was able to manage the colostomy appliance by herself.”
- Under the heading “Rationale”: “There was no clear need for occupational therapy. She was residing in an assisted living facility and had an aide to assist with dressing and bathing. The patient had a caretaker who was independent with the patient’s colostomy care. Her meals required set-up and she was hand fed by the staff. The patient was dependent on staff to propel the wheelchair around the facility.”

Each of the aforementioned items is factually inaccurate and absent from the record, and, therefore, should clearly not preclude billing for occupational therapy services.

The medical chart for Patient 19 does not indicate that this patient required meal set-up or was spoon-fed. This patient did not have a colostomy appliance at all, much less an independent caregiver to manage a colostomy appliance. This patient did not have a wheelchair and was not

dependent on staff to “propel the wheelchair around the facility.” All of these “facts,” used to support the denial, are wrong, cast doubt on this finding, and also undermine the findings made for other patients. **It appears that the medical review contractor has reviewed the wrong record in this case and then used that erroneous information to make a determination regarding the medical necessity of services.** The fact that the medical reviewers reached conclusions about this patient’s eligibility for services based on these blatantly erroneous “facts” highlights the inability of the reviewers to render a correct decision based on relevant regulatory criteria and accurate information, and undercuts the reliability of each of the medical reviewers’ findings underlying the Draft Report.

OIG also identified numerous instances of factual errors in the medical reviewers’ determinations. For example, in response to NOC’s FOIA request, OIG produced an email to Maximus identifying another instance of the reviewers including information about the wrong patient in their analysis: “When going through the determination letter revisions we determined that the file ‘AS18-003252 [(Patient 23)] . . .’ contains incorrect information for another case number.” Ex. 3-A at OIG-000452. OIG again identified that the medical reviewers used the wrong case number for Patient 42. Ex. 3-E. And for yet another patient, Patient 17, OIG notified the medical reviewer that it had made an error in the date of the plan of care. Ex. 3-E. That the medical reviewers made frequent errors in even the most basic factual determinations illustrates the inherent unreliability of Maximus’s findings. These errors should be corrected prior to issuance of a final report.

d. The Qualifications of the Unidentified Medical Reviewers are Questionable

NOC also has serious concerns about the qualifications of OIG’s contracted medical reviewer(s). OIG has provided no substantive information to validate the reviewers’ qualifications. Instead, each of the 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 guidelines and protocols in the area of treatment under review.” The reviewer’s “biography,” does not reference any home health experience. This “biography” could be used, and presumably has been used, for any licensed physician regardless of whether he/she has relevant training and qualifications. Additionally, at the Exit Conference, OIG was unwilling to provide the names or relevant qualifications of the medical reviewers, and would not even identify whether the reviews were conducted by one, or multiple, physicians. Having been provided no relevant information about the medical reviewers other than the fact they were licensed, had “knowledge” about the patient’s condition, and were “familiar” with unspecified Medicare standards, NOC can assess the reviewers only through the individual medical determinations of the audited claims.

As detailed below, we raise this concern because Maximus’s findings regarding homebound status and the need for skilled services were flawed, and appeared to be the opinion of someone unfamiliar with Medicare home health guidelines. For instance, the reviewers consistently concluded that a beneficiary was not homebound based on irrelevant criteria such as whether he or she could ambulate an arbitrary distance in the home. The reviewers concluded beneficiaries did not need skilled services if certain immaterial factors were present, such as if the beneficiary had a family member or caregiver available for assistance. These contrived standards are far removed from the criteria for determining homebound status and eligibility for skilled

services under applicable federal regulations and guidance. The inability or unwillingness to apply the appropriate standards would suggest that the reviewers are *not* qualified to accurately assess the home health services that NOC provided to its Medicare beneficiaries.

e. OIG Refused to Consider NOC's Rebuttal Responses to OIG's Preliminary Findings, So NOC Renews its Request for Medical Reconsideration

Pursuant to its protocol, OIG conducted an Exit Conference with NOC on February 18, 2020, where NOC again asked if OIG would take into consideration NOC's response to OIG's medical reviewers' claim denials. Prior to the Exit Conference, NOC had submitted responses to the medical reviewers' preliminary determinations on March 12, 2019 and June 21, 2019. Each submission included rebuttals from highly qualified experts, who contested the vast majority of the OIG medical reviewers' findings and highlighted the faulty legal, clinical, and factual findings in Maximus's medical determinations. Because of its substantial disagreement with the reviewers' initial findings, NOC requested in both of its rebuttal responses that OIG have its medical reviewers reconsider their decisions in light of NOC's rebuttals to correct their errors before issuance of the Draft Report. Notwithstanding NOC identifying pervasive errors in the medical reviewers' analysis, OIG confirmed that, despite having received fulsome responses from NOC and having nearly one year from the second response to consider the responses, OIG opted not to take a single claim back to its medical reviewer for reconsideration.

In this response, NOC renews its requests that OIG take NOC's response to the Draft Report, including the expert rebuttals, back to Maximus for reconsideration. Because NOC's rebuttals are based on reviews by licensed medical experts with knowledge and experience in home health, NOC also asks that OIG have a provider with home health knowledge and experience review the rebuttals. The clinical issues raised by NOC must be considered by clinicians qualified to review the issues for a fair determination to be made. NOC again requests the opportunity to review and comment on a revised draft report before the issuance of the Final Report.

f. OIG's Statistical Sampling and Extrapolation Methodology Was Flawed

Besides the clinical errors underlying the Draft Report, OIG's statistical sampling and extrapolation methodology was fundamentally flawed. As detailed below and in the attached report from FTI Consulting, extrapolation of purported overpayments across the universe of NOC's claims is inappropriate where the sampling methodology made it impossible for OIG to create a representative sample of claims.

The most significant problem is that OIG erroneously sampled by claim as opposed to sampling by patient, which led to a sample average overpayment amount that is higher than would be found in the overall population. As each beneficiary can have multiple claims, beneficiaries with more claims (i.e. longer lengths of stay, or multiple recertifications) are more likely to be sampled using this methodology. By sampling by claim, OIG oversampled patients with longer length of stays by a statistically significant amount. Sampled beneficiaries had nearly twice the length of stay as non-sampled beneficiaries.

of the appeals team for nine years. [REDACTED] has twenty-one years of previous home health experience and has been part of the appeals team for twelve years. [REDACTED] has eleven years of previous home health experience and has been part of the appeals team for twenty years, with the last six as the Senior Director of Appeals. As explained in more detail in the rebuttal statements, NOC has concluded that OIG's Draft Report findings in thirty six (36) of the claims are in error and not supported by the patients' medical records. While the rebuttal statements at Exhibit 1 address each claim in detail, we have addressed several of the primary deficiencies below.

a. The Draft Report Alleges Beneficiaries in the Audited Sample Were Not Homebound

OIG alleges that twenty-six (26) claims were non-compliant because the beneficiary did not qualify as homebound under the Medicare standards discussed below for all or a portion of the episode of care. As set forth in the attached rebuttals, OIG's medical reviewers failed to view the medical record as a whole, but instead allowed isolated clinical notes to drive the conclusion that the beneficiaries were not homebound.

To receive payment for home health services, the beneficiary must be homebound.⁸ A beneficiary qualifies as homebound if he or she satisfies two conditions: First, the patient must either, because of illness or injury, need the aid of supportive devices such as crutches, canes, wheelchairs, and walkers; the use of special transportation; or the assistance of another person in order to leave his or her place of residence or have a condition such that leaving his or her home is medically contraindicated. Second, there must exist a normal inability to leave home and leaving home must require a considerable and taxing effort.⁹ Homebound status is not contingent upon a single clinical factor; in fact, Medicare guidance acknowledges that "longitudinal clinical information about the patient's health status" is typically necessary to evaluate and categorize a patient as homebound.¹⁰ 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."

Fatal to their analyses, the reviewers did not evaluate homebound status using the aforementioned two-step criteria. In doing so, OIG's reviewers applied—and appeared to rely exclusively on—criteria for evaluating homebound status simply not present in the Medicare regulations and ignored "longitudinal clinical information" that supported the level of care rendered by NOC. The Draft Report identified just two sample claims to illustrate its argument that NOC improperly billed for patients who were not homebound. NOC agrees these claims did not meet the criteria for determining homebound status.¹¹ Nevertheless, the medical reviewers' remaining preliminary medical determinations are rife with flawed analyses. For example, the medical reviewers routinely used arbitrary ambulation distances as a proxy for homebound status without regard to the complete medical picture of the patient:

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

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

¹⁰ *Id.*

¹¹ OIG failed to identify which patients these examples were based on, but NOC was able to determine that the examples were for OIG Patients # 21 and 62.

- **OIG Patient # 14:** OIG’s reviewers contend that as of 6/30/2016, this beneficiary “was able to ambulate 350 feet at a modified independent level with a rolling walker” and that “[l]eaving the home no longer would have required a considerable and taxing effort.” The reviewers concluded that the beneficiary “was residing in an independent living facility and had transportation available.” Determining homebound status based on these factors alone is wholly incongruous with the Medicare regulations and manual guidance. For example, nothing in the Medicare rules suggests it is permissible to discount homebound status based on the technical measurements such as the number of feet a patient can ambulate. It cannot be viewed in a vacuum without considering the beneficiary’s complete medical record.

Here, had OIG reviewers considered the complete record, they would have seen an 86-year-old woman who was admitted to the agency due to an exacerbation of Parkinson’s disease, which resulted in increased difficulty with ambulation and functional mobility. The patient required a four-wheeled walker for safe ambulation, demonstrated difficulty maneuvering on uneven surfaces, and was at a high risk for falls. Further, the **patient resided in a large-scale independent living community that spanned over 30 acres**. OIG reviewers did not recognize that even if the beneficiary could ambulate 350 feet on 6/30/2016, it was only on **level ground**. Her capabilities at that time did not include common obstacles that she would encounter in the general community such as ramps, curbs, thresholds, or uneven surfaces. During the dates in question, she continued to require an assistive device and the assistance of another person for ambulation (Criterion 1). As reflected in the documentation, poor cardiovascular stamina, visual deficits, incontinence, Timed Up and Go scores, and an inability to negotiate uneven surfaces including ramps, curbs, and stairs created a considerable and taxing effort; she remained a high fall risk and required constant supervision or assistance (Criterion 2). This patient clearly remained homebound after 6/30/2016.

- **OIG Patient #27:** OIG reviewers contend that as of 7/14/2017, this beneficiary “was able to ambulate 150 feet and transfer without hands-on assistance. He was residing in an assisted living facility and had caregiver assistance available.” The reviewers concluded that “[t]here were no medical contraindications to leaving his residence” and that he was no longer homebound.

OIG reviewers could only reach this conclusion by completely ignoring the medical status of the beneficiary. The beneficiary is a 63-year-old male residing in a locked memory care unit who was admitted to home health following a hospice discharge. The patient had been admitted to the hospice agency due to multiple hospitalizations associated with multiple co-morbidities including a cerebrovascular accident, type II diabetes mellitus, neuropathy with chronic kidney disease, Alzheimer’s dementia, coronary artery disease, atrial fibrillation, and traumatic brain injury. This patient suffered from significant cognitive limitations **requiring constant supervision in a locked memory care unit**. This is textbook homebound status. So much so that the Medicare Benefit Policy Manual, Chapter 7, § 30.1, uses this as an example of homebound status – “a patient who is blind or

senile and requires the assistance of another person in leaving their place of residence is eligible for Medicare home health services.”

- **OIG Patient # 56:** According to OIG reviewers, as of 12/9/2016, this beneficiary was able to ambulate 350 feet, and “[l]eaving the home no longer would have required a considerable and taxing effort.” The reviewers note that the patient received an epidural injection on 12/8/2016, which they concluded “improved his back pain significantly,” allowing him to walk further distances.

Rather than consider the record as a whole, OIG reviewers reached the conclusion that the patient was not homebound based on this small window of pain relief. The reviewers neglected to consider that it is common for epidurals to initially have a substantial pain relieving effect, only to wear off over time. This was not a permanent solution to the patient’s pain; had the reviewers considered the entire record, rather than just the day after the patient received a dose of potent pain medication, they would have realized that the patient’s pain increased at *every visit* after the epidural, and had increased to a level 6 of 10 by 12/16/2016, a mere week after the injection. Furthermore, though he could ambulate 350 feet, the patient lived in an assisted living facility, which required him to **ambulate 600 feet just to reach the dining room or the parking lot**; so the conclusion that the patient could leave the home without a considerable and taxing effort, even when considered in the light of the reviewers’ own inappropriate short-hand metrics, is nonsensical. During the dates in question, the patient continued to require an assistive device and the assistance of another person for ambulation (Criterion 1). As reflected in the documentation, poor cardiovascular stamina with shortness of breath, poor renal status with need for dialysis, severe back pain with need for epidural injection, and an inability to negotiate uneven surfaces including ramps, curbs, and stairs created a considerable and taxing effort as he remained a high fall risk and required constant supervision or assistance (Criterion 2). This patient clearly remained homebound after 12/8/2016.

- **OIG Patient # 94:** OIG reviewers argue that the beneficiary was not homebound because she had already received eleven sessions of physical therapy “and was able to transfer and ambulate 200 feet without hands-on assistance.” The reviewers reason that leaving the home was not medically contraindicated, and would not require a considerable and taxing effort.

Again, to reach this conclusion, OIG reviewers rely on fixed metrics wholly divorced from the patient’s complete medical record. Though the patient was previously able to function independently with the help of assistive devices, upon admission to home health, the patient’s functional mobility was limited due to recent falls associated with gait disturbance, weakness, and dizziness. While the patient may have been able to ambulate 200 feet, the reviewers failed to consider that **doing so caused her fatigue and dyspnea, necessitating frequent rest breaks**. She lacked adequate strength, balance, and endurance to leave the home without a considerable and taxing effort. And while OIG reviewers inexplicably reason that the patient was no longer homebound because she underwent eleven

physical therapy sessions, it took her approximately thirteen sessions after admission simply to ambulate 400 feet, the distance needed to reach the dining room in her assisted living facility. No consideration was given to the patient's complicating factors and the distances required to interact in her large senior living community including uneven surfaces, ramps, stairs, and curbs. Considering the entire record rather than arbitrary metrics divorced from the patient's actual living conditions, the documentation demonstrates that this patient meets the criteria for homebound status because she required a four-wheeled walker and contact guard assist for ambulation (Criterion 1). Also, given her high risk of falls, unstable gait, left knee pain, and decreased cardiovascular stamina, it was clearly a considerable and taxing effort to leave home (Criterion 2).

These are only four examples among the claims with which NOC wholly disagreed with OIG's medical reviewers. OIG reviewers' persistent use of overly narrow and patently inapplicable criteria for Medicare home health payment resulted in denials that tremendously distort reality. The reviewers did not take into account the actual living environment of the beneficiaries, clear deficits of the beneficiaries during the course of care, and significant comorbid conditions that limited the beneficiaries' ability to safely and independently leave the home. The reviewers did not look at the gait pattern of the beneficiary, assistance required to ambulate safely, use of assistive devices, visual impairments, or cardiovascular status.

OIG appeared to recognize these deficient findings, noting in several places that it disagreed with the clinical findings of the medical reviewer. For example, regarding Patient 45, OIG noted to Maximus that "[t]he patient required a walker to ambulate and suffered from dementia and Parkinson's disease. Even though they were able to ambulate without hands-on assistance we believe leaving the home would have required a considerable and taxing effort." Ex. 3-E. The medical reviewer continued to deny the claim. OIG also commented on Patient 56, stating "[a]fter 12/9/2016, the patient was still using a walker and it is unclear whether the patient's back was better because of healing or if it was strictly just the epidural injection. Was the absence of pain temporary because of the injection or permanent due to natural healing?" Maximus admitted in its response that "the epidural injection was the direct cause of decreased pain. . . The patient may still require something to stabilize them until they get stronger and learn correct body mechanics." Ex. 3-D. The medical reviewer acknowledged that OT was required to correct systemic problems and yet continued to deny payment due to temporary pain relief. This shorthand not only distorts or ignores the applicable regulations, but also would put patients in danger if actually used by clinicians to make discharging decisions. Discharging a patient due to temporary pain relief from an epidural, rather than continuing to treat the underlying cause of pain, could result in significant over-medication of senior populations. Or discharging a patient when they could ambulate a distance of 150 feet, when that clinician knows the dining room is more than 300 feet away, could result in unnecessary falls or hospitalizations. NOC respectfully requests that OIG medical reviewers assess the documentation in light of this submission and reverse these claim denials.

b. The Draft Report Alleges Beneficiaries in the Audited Sample Did Not Require 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: (1) 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; (2) physical therapy (“PT”); (3) speech-language pathology (“SLP”); or (4) occupational therapy (“OT”).¹² Each individual therapy service must comply with certain additional requirements to be covered.¹³

OIG found that thirty-one (31) of the claims were non-compliant because the beneficiary did not require medically necessary skilled nursing or skilled therapy services. OIG medical reviewers failed to evaluate the need for skilled services appropriately and made four primary errors in this category: (1) relying on unfounded expectations that a patient “could reasonably have been expected to improve spontaneously” or lacked “restorative potential”; (2) stating without evidence that available caregivers could substitute for the skilled services being provided by trained professionals; (3) incorrectly equating PT and OT services and concluding that one was duplicative of the other; and (4) denying services prior to the reassessment, and therefore, ignoring crucial information on the need for additional skilled services. In OIG’s comments to Maximus regarding the medical reviewers’ findings, OIG disagreed with many of its own reviewers’ determinations, identifying various instances where the medical reviewers’ conclusions were inconsistent with regulatory requirements.

First, OIG reviewers made unfounded assumptions that several patients “could reasonably have been expected to improve spontaneously.”¹⁴ While CMS does recognize that spontaneous improvement may be expected in certain cases, this is generally considered only for a “transient or easily reversible loss of function.”¹⁵ OIG reviewers applied this standard far more expansively and erroneously. For example:

- **OIG Patient #27:** OIG reviewers stated, “[p]hysical therapy was needed to progress the patient’s mobility and to establish a maintenance home exercise program. However, as of 7/14/2017, he was able to transfer and ambulate without hands-on assistance. The patient could reasonably have been expected to improve spontaneously by gradually resuming normal activities.”

The reviewers’ final conclusion finds no support in the record. Medical necessity for these services is evident throughout the documentation. Goals were established so the patient could reach the dining room for meals with safety and supervision. Skilled interventions included gait training for device placement, gait pattern, obstacle negotiation, and safety; facilitation of balance strategies to improve righting reactions and limits of stability; progressions of a lower extremity progressive exercise program for strength and coordination; and skilled training with graded cueing for transfer safety and performance. Upon discharge,

¹² See 42 C.F.R. § 409.42(c).

¹³ See 42 C.F.R. § 409.44(c).

¹⁴ OIG reviewers made this or a nearly identical finding for **OIG Patients 27, 47, and 48**.

¹⁵ Medicare Benefit Policy Manual, Ch. 7, § 40.2.1(d).

documentation demonstrates he was independent with use of a four-wheeled walker for transfers and bed mobility, and he could ambulate with remote supervision and a walker for 200 feet, which allowed him to reach the dining room safely. His balance improved from poor to good, and his strength improved from 3+/5 to 4+/5. This progress is a direct result of skilled intervention and cannot be attributed to spontaneous improvement as suggested by the reviewers. Non-skilled caregivers would not have the unique skills and education that only a licensed therapist possesses.

Similarly, several of the medical reviewers' conclusions were improperly predicated on the "improvement standard," under which a claim is erroneously denied due to the beneficiary's lack of "restoration potential" even though the patient did in fact need skilled services to prevent or slow further deterioration of his or her clinical condition, as noted above.¹⁶ OIG disagreed with the medical reviewers' conclusions based on this standard. For instance:

- **OIG Patient #97:** OIG reviewers determined that physical therapy was "excessive" because "[t]he patient's expected restorative potential was not significant in relation to the extent and duration of therapy services expected to be required to reach that potential." OIG disagreed with the medical reviewers' determination based on this standard, stating: "In the rationale it is mentioned that PT services should be discontinued due to the lack of functional improvement. We want to ensure the determination is not predicated on the Improvement Standard[,] which would be contrary to the *Jimmo vs. Sebulious* [sic] settlement agreement."

The patient was a 90-year old male residing in an apartment in an assisted living facility. He was recertified for physical therapy on 1/5/16 due to continued deficits in bilateral lower extremity strength, dynamic standing balance, and safety with transfers and ambulation. After only three physical therapy visits, the patient was hospitalized on 1/22/16. OIG's inappropriate decision to deny services based on the beneficiary's apparent lack of "restorative potential" belies the beneficiary's medical record, which indicates the beneficiary's hospitalization interrupted his therapy services and caused further functional decline. Specifically, after the hospitalization this beneficiary had a significant decline in his transfers, ambulation, and bilateral lower extremity strength. He was then diagnosed with

¹⁶ According to a CMS [Fact Sheet](#) for the *Jimmo v. Sebelius* Settlement Agreement:

The Medicare statute and regulations have never supported the imposition of an "Improvement Standard" rule-of-thumb in determining whether skilled care is required to prevent or slow deterioration in a patient's condition. A beneficiary's lack of restoration potential cannot, in itself, serve as the basis for denying coverage, without regard to an individualized assessment of the beneficiary's medical condition and the reasonableness and necessity of the treatment, care, or services in question. . . . The settlement agreement is intended to clarify that when skilled services are required in order to provide care that is reasonable and necessary to prevent or slow further deterioration, coverage cannot be denied based on the absence of potential for improvement or restoration.

See also 42 C.F.R. § 409.32(c) ("The restoration potential of a patient is not the deciding factor in determining whether skilled services are needed. Even if full recovery or medical improvement is not possible, a patient may need skilled services to prevent further deterioration or preserve current capabilities.").

adult failure to thrive and depression and was prescribed three new medications for the depression and dementia symptoms. These severe deficits notwithstanding, upon resuming physical therapy services, the patient increased participation in therapy and began to make functional gains; continued progress was expected due to his improving medical status. Had the medical reviewers focused on the relevant inquiry—the patient’s need for skilled services—rather than incorrectly and arbitrarily focusing on the patient’s potential for improvement, they would have concluded that continued physical therapy services were medically reasonable and necessary.¹⁷

Second, OIG reviewers relied erroneously on the assistance of “available caregivers” in determining that skilled services were not reasonable and necessary.¹⁸ Beneficiaries are entitled to reimbursement of reasonable and necessary services regardless of whether someone is available to furnish those services.¹⁹ OIG appears to agree that availability of caregivers is an insufficient ground to deny skilled services. In disagreeing with the medical reviewers’ conclusion for Patient 15 for example, OIG questions the reviewers’ basis for the denial, asking that the reviewers “provide some criteria or language that states therapy is not reasonable and necessary if a patient resides in an ALF” and whether “living in an ALF disqualif[ies] a patient from receiving therapy.” Ex. 3-E. Despite these comments, Maximus continued to rely on this extra-regulatory standard to deny claims.

Notwithstanding the presumption that there is no able and willing person in the patient’s home to provide the services,²⁰ the reviewers appeared to make assumptions about the caregivers (either in their availability or capabilities) that were unwarranted by the record. In determining whether services are reasonable and necessary, the primary questions are “whether the beneficiary needs skilled care” and whether “the inherent complexity of the service is such that it can be performed safely and/or effectively only by or under the general supervision of a skilled therapist.”²¹ OIG reviewers did not answer these fundamental questions and necessarily reached incorrect conclusions on the necessity of services. For example:

- **OIG Patient #47:** OIG reviewers indicated, “[t]here was no clear need for occupational therapy.” The only justification for this conclusion was that “[t]he patient was living with his spouse and had assistance available if needed.”

The beneficiary is an 85-year-old morbidly obese male with multiple chronic medical conditions who was most recently hospitalized due to an intestinal virus and heart failure. His wife, the individual that OIG reviewers assumed could assist

¹⁷ OIG reviewers made this or a nearly identical finding for **OIG Patients 15, 50, and 98**.

¹⁸ OIG reviewers made this or a nearly identical finding for **OIG Patients 15, 17, 19, 44, 47, 51, 67, 71, 79, 80, 85, and 93**.

¹⁹ Medicare Benefit Policy Manual, Ch. 7, § 20.2.

²⁰ “Ordinarily it can be presumed that there is no able and willing person in the home to provide the services being rendered by the HHA unless the patient or family indicates otherwise and objects to the provision of the services by the HHA, or unless the HHA has first hand knowledge to the contrary.” Medicare Benefit Policy Manual, Ch. 7, § 20.2.

²¹ Medicare Benefit Policy Manual, Ch. 7, § 40.2.1. Further, these services may still be reasonable and necessary if the criteria for maintenance therapy is met.

with activities of daily living, was an **elderly and frail woman herself**. There is no way that she could reasonably be expected to assist her morbidly obese husband with dressing, toileting, toilet transfers, and bathing. Instead, the occupational therapist created a skilled plan of care that included activities of daily living retraining such as self-care techniques, progressive resistive therapeutic exercises, pain management techniques for shoulder pain, skilled training and education in ADL transfers, positioning, proper body mechanics, postural control, safety techniques, fall prevention, and energy conservation techniques including pacing and breathing strategies. The occupational therapist was instrumental in providing the skilled interventions. This returned the beneficiary to an independent level of function, as he was before the onset of his illness. A non-skilled person would not have had the specialized training and education to provide the assessment and interventions necessary for improved independence in self-care.

- **OIG Patient #51:** As the sole support for OIG reviewers' finding that there was no clear need for physical or occupational therapy, they assert in perfunctory fashion that this beneficiary "was living in an assisted living facility and would be expected to have caregiver assistance available if needed."

The beneficiary, a 94-year-old female, had a fall shortly before the start of this episode while attempting to transfer off the toilet. The fall caused increased shoulder pain limiting mobility and the ability to safely perform self-care and homemaking tasks. She experienced continued balance deficits that also affected her ability to safely and effectively complete self-care tasks. The patient was unable to safely negotiate stairs, curbs, and uneven surfaces. Furthermore, her progress in therapy was hindered by various diagnoses that developed throughout the episode, including two buttock wounds and multiple urinary tract infections, which underscore the need for skilled services by an individual with specialized training and education. Essential skilled interventions included obstacle negotiation; progressive balance strategies to improve ankle and hip strategies; energy conservation techniques; and compensatory techniques to compensate for essential tremors. The patient demonstrated improvement throughout the course of therapy; this improvement cannot be attributed to spontaneous recovery and could not have been achieved with only the assistance of an unlicensed caregiver.

Next, OIG reviewers incorrectly equated PT and OT services, denying a number of claims on the grounds that the occupational therapy services provided were duplicative of the physical therapy services.²² OIG agreed, noting that "OIG supervisory management has decided that Occupational Therapy Being Duplicative of Other Therapy/Services claims are non-errors."²³

Medicare guidance makes clear that physical and occupational therapy are independent disciplines with differing goals.²⁴ The proper inquiry here is "whether individual therapy services

²² OIG reviewers made similar findings for OIG Patients 70, 80, 82, and 94.

²³ OIG raised concerns that the medical reviewers improperly denied services based on physical and occupational therapy services being "duplicative" for **OIG Patients 19, 26, 44, 49, and 83**.

²⁴ Medicare Benefit Policy Manual, Ch. 7, §§ 40.2.2, 40.2.4.

are skilled and whether, in view of the patient's overall condition, skilled management of the services provided is needed."²⁵ Instead, OIG reviewers again rely on their own misguided concept of what makes a beneficiary eligible for home care, leading to additional erroneous determinations. Take for example the following:

- **OIG Patient #84:** OIG reviewers determined occupational therapy services were not warranted after 9/7/2016. In reaching this conclusion, they reasoned that this patient's "rehabilitation needs were being addressed through the physical therapy being provided."

This 86-year-old patient was admitted due to pain in her back and lower extremities, with gait deviations and decreased functional mobility. Although she lived in an assisted living facility, she was having difficulties navigating through the building and performing self-care tasks safely, which required physical and occupational therapy services to remedy. The record reflects the focus of physical therapy was to address the patient's balance, gait, strength, and transfers through interventions like bilateral strengthening and therapeutic exercises, and instruction of gait strategies, postural training, and energy conservation techniques. In contrast, the patient required occupational therapy due to her need for assistance with *all* self-care tasks; accordingly, the occupational therapist focused on instruction on the use of assistive devices for safe performance of self-care tasks, body mechanics including transfer techniques, and compensatory strategies to assist with performance and safety for self-care tasks. The record clearly indicates the patient had separate skilled needs, which required specialized skill sets to meet. The reviewers erred in believing physical therapy was sufficient to compensate for the patient's severe self-care deficits.

Lastly, OIG reviewers denied skilled services as not medically necessary prior to reassessments showing a comprehensive picture of the extent of the patients' progress towards their goals. During the reassessment process, the therapist functionally reassesses the patient, comparing the resultant measure to prior assessment measurements to determine the effectiveness of therapy based on the patient's medical record to date.²⁶ This process is essential because a patient's performance may vary widely from day to day. When taken as a whole, the patient's record "tell[s] the story of the patient's achievement towards his/her goals," and therefore "demonstrate[s] why a skilled service is needed."²⁷ By denying services prior to the reassessment, OIG reviewers failed to fully appreciate the patient's full clinical story, instead opting to make a determination of medical necessity based on a mere snapshot that could not possibly capture the extent of the patient's condition. For instance:

- **OIG Patient # 80:** OIG reviewers concluded that after 1/5/2017, the patient no longer needed occupational therapy because she only needed minimum assistance for lower body dressing, and had assistance available from an assisted living facility.

²⁵ Medicare Benefit Policy Manual, Ch. 7, § 40.2.1.

²⁶ Medicare Benefit Policy Manual, Ch. 7, § 40.2.1(b)(ii).

²⁷ Medicare Benefit Policy Manual, Ch. 7, § 40.2.1.

The patient is a 92-year old female who was admitted due to a recent hospitalization for pneumonia, which resulted in increased weakness and decreased ability to perform self-care and homemaking tasks, limited mobility, and a high risk of falls. Though she may have required only minimum assistance for lower body dressing, her plan for therapy was to increase transfer and safety in other activities of daily living, like toileting and bathing. OIG reviewers also neglected to consider that the patient had a recent inpatient stay, which impacted the rate at which she could recover. Moreover, after her hospitalization, the patient moved into a new facility; therefore, all of her surroundings were unfamiliar, which caused increased challenges to reversing her functional decline. Crucially, OIG reviewers determined occupational therapy services were not necessary a mere five days prior to a reassessment visit performed on 1/10/2017. Had they taken this reassessment into account, the reviewers would have realized that the patient had not yet achieved her goal progression for short and long-term goals; rather, her progress was inhibited by dyspnea, cognitive deficits, and her new living environment. The additional four visits between the reassessment and the final visit focused on skilled interventions such as compensatory strategies for self-care and homemaking tasks including energy conservation techniques and joint protection techniques; proper body mechanics; environmental adaptations to increase safety and functional independence within her new environment; and safety and balance strategies to facilitate safe reaching and bending during self-care and homemaking tasks. If OIG reviewers had considered the patient's full clinical picture, rather than just a snapshot before a reassessment of the patient's condition, the patient's eligibility for occupational therapy after 1/5/2017 would have been evident.

- **OIG Patient # 56:** According to OIG medical reviewers, this patient was no longer homebound as of 12/9/2016. However, this determination fails to appropriately take into account physical and occupational therapy reassessments performed days later on 12/12/2016 and 12/14/2016, respectively. Had the reviewers considered these reassessments, they would have realized that though the patient had improved, making progress towards short-term goals, the patient still had a number of physical and functional struggles, limiting his ability to improve on long-term goals. For instance, the patient experienced pain so severe that he required an epidural injection on 12/8/2016, the day before OIG's reviewers determined the patient was no longer homebound. He also demonstrated poor carryover with energy conservation techniques, poor postural awareness with all functional activities, mild safety impairment, and deficits in upper body strengthening, grip strength, mobility, and dressing skills. These reassessments illustrate that even after 12/9/2016, the patient continued to require assistance to leave the home, and it was still a considerable and taxing effort to do so.

Fundamentally, OIG reviewers relied on assumptions not supported by the record and criteria not indicated in CMS guidance in making their determinations regarding the medical necessity of services. More detailed discussions of each of these errors can be found in the individual rebuttal letters attached in [Exhibit 1](#). NOC respectfully requests that OIG medical reviewers re-assess the documentation under the proper standards and reverse these claim denials.

VI. OIG's Extrapolation of NOC's Overpayment Obligation is Flawed

As detailed above, NOC disagrees with the flawed review undertaken by OIG medical reviewers. NOC further objects to OIG's use of extrapolation to arrive at an estimated overpayment amount. Any statistical analysis conducted now is premature and inevitably leads to incorrect and inflated claim and financial error rates. Extrapolation of Medicare overpayments is inappropriate unless there is a "sustained or high level of payment error."²⁸ 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.²⁹ Even if OIG's initial determinations were correct, which they are not, NOC's "error rate" would be well below the 50 percent threshold and would not merit any extrapolation.

In addition, statistical sampling and extrapolation may be used as valid means to determine overpayments only when based on a statistically valid method. Here, however, OIG's sampling and extrapolation methodology was fundamentally flawed. OIG used a faulty sampling methodology that necessarily inflated its estimated error rate, resulting in an inaccurate extrapolated overpayment. NOC engaged FTI Consulting ("FTI") to evaluate this sampling and extrapolation methodology. [REDACTED] FTI's Senior Director of Economic Consulting, and [REDACTED] prepared a report ("FTI Report") analyzing OIG's methodology. [REDACTED] is an applied economist with more than 20 years of experience in advanced statistical sampling methods, statistical studies, and healthcare claims sampling and audits. A copy of the FTI Report is attached as Exhibit 2.

As discussed more fully in the FTI Report, OIG's sampling and extrapolation methodology was flawed in various respects. First, OIG created a "random" sample based on the home health *claims*, not the home health beneficiaries themselves, which yielded a sample average overpayment amount that is higher than what would be found in the overall population. Rather than obtain a random sample of patients, OIG's sampling methodology necessarily resulted in an oversampling of patients with longer lengths of stay because patients with longer stays have more claims. This, combined with the fact that home health patients with longer stays were more likely to have claims with OIG-determined overpayments, yielded biased sample results that cannot be reliably extrapolated to the population of claims.

From a clinical standpoint, OIG frequently found errors at the end of an episode after the patient had progressed, concluding that the patient should have been discharged several days or weeks earlier. For example:

- The medical reviewers found **OIG Patient # 27** was no longer homebound after July 14, 2017, **eleven days** before he was discharged on July 25, 2017. The patient was admitted for home health services on March 30, 2017, and was on his **second episode of care**. The reviewers incorrectly determined the patient "could reasonably have been expected to improve spontaneously by gradually resuming normal activities" when in fact he remained homebound due to his severe cognitive

²⁸ 42 U.S.C. § 1395ddd(f)(3)(A).

²⁹ See Medicare Program Integrity Manual, Chapter 8, § 8.4.1.4. Although NOC recognizes that the Medicare Program Integrity Manual is not binding on OIG, the purported overpayments identified in the Draft Report would be overpayments from Medicare, and extrapolation of Medicare overpayments absent a sustained or high level of payment error is inappropriate.

limitations and need for an assistive device. Additional skilled intervention was required to improve his balance, strength, and mobility so that he could be safely discharged.

- The medical reviewers determined that **OIG Patient # 51**, who was on her **third episode of care**, was no longer homebound or eligible for skilled nursing services after April 28, 2016, almost five months after the start of care on December 5, 2015, and **one month** before her discharge on June 1, 2016. However, the medical reviewers failed to adequately consider that the patient experienced a fall just prior to this episode, had new diagnoses during this episode, and experienced frequent shortness of breath and had poor vision; all of these factors necessitated continued services after April 28.
- **OIG Patient # 97** was admitted for home health services on November 11, 2015 and was discharged on March 9, 2016 after **two episodes of care**. The medical reviewers found that physical therapy services were no longer reasonable or medically necessary after February 3, 2016, **one month** prior to discharge. However, the medical reviewers failed to consider that the patient was recently hospitalized, which interrupted his care and caused further functional decline.

These determinations erroneously concluded that patients should no longer receive services in the final days or weeks of treatment by relying on unfounded assumptions or arbitrary metrics that are absent from CMS regulations and guidance. OIG applied these arbitrary metrics more often at the end of longer lengths of stay, which in turn appeared more often in the sample due to their sampling methodology. Though we disagree that even these claims were erroneous, by oversampling the longer lengths of stay, OIG made it more likely that it would identify an “error,” thus resulting in an inherently unreliable error rate. Because the longer lengths of stay accounted for a significant portion of the errors and are not representative of the claims as a whole, the extrapolation is not statistically valid and inaccurately reflects any overpayments.

More critically, the sample drawn by OIG is *not* statistically representative of the population of claims from which it was drawn. Specifically, the patients represented in the OIG sample (1) have longer lengths of stay, (2) have higher aggregate reimbursements, (3) have higher aggregate charges, (4) have more claims, and (5) are older than the patients in the population. The result is that OIG’s sampling methodology has biased the beneficiaries associated with its sample of claims towards a larger overpayment extrapolation, which makes the extrapolation unreliable.

Finally, a review of OIG’s sampling methodology shows there are categories of specific claim codes that account for large shares of the total reimbursements in the claim population that either were not sampled or were sampled but did not have OIG-determined overpayments, which also calls into question the reliability of any extrapolation.

VII. OIG Should be Prohibited from Using Extrapolation to Recoup Funds for Claims Outside of the Four-Year Reopening Period

Based on its problematic extrapolation methodology, OIG estimated that NOC received \$3,286,869 in overpayments. These alleged overpayments, extrapolated over calendar years 2016

and 2017, included claims outside of the four-year reopening period. Medicare regulations allow a contractor to reopen a claim within four years from the date of the initial determination or redetermination for good cause.³⁰ Even assuming that the good cause standard is met here—and NOC does not concede it is—claims cannot be reopened beyond four years. Yet, OIG attempts to circumvent this rule by using extrapolation to indirectly do what it cannot do directly—reopen claims beyond the four-year period. This flouts the regulatory timeframe and, particularly in light of the flaws in its sampling and extrapolation methodology, is fundamentally unfair. Accordingly, OIG should be prohibited from using extrapolation to recoup funds for claims outside the four-year reopening period.

VIII. Conclusion

For the reasons set forth above, the audit process and results in the Draft Report are flawed. As OIG acknowledges, its medical reviewer applied incorrect criteria to determine the beneficiaries' homebound status and consistently failed to consider the complete record, which led to a grossly overstated error rate. The beneficiaries' medical records fully support both the homebound status and the medical necessity of skilled services for all of the audited beneficiaries.

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

On behalf of NOC, thank you for the opportunity to provide this response.

Sincerely,



Brian D. Roark

³⁰ 42 C.F.R. § 405.980(b)(2); 42 C.F.R. § 405.986(a).