

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**MEDICARE HOME HEALTH AGENCY
PROVIDER COMPLIANCE AUDIT:
SOUTHEASTERN HOME HEALTH
SERVICES**

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Office of Inspector General

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

Report in Brief

Date: January 2021

Report No. A-03-17-00004

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 part-time or intermittent skilled nursing care and home health aide visits, therapy (physical, occupational, and speech-language pathology), medical social services, and medical supplies.

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

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

How OIG Did This Audit

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

Medicare Home Health Agency Provider Compliance Audit: Southeastern Home Health Services

What OIG Found

Southeastern did not comply with Medicare billing requirements for 18 of the 100 home health claims that we reviewed. For these claims, Southeastern received overpayments of \$46,404 for services provided in calendar years 2015 and 2016. Specifically, Southeastern incorrectly billed Medicare for: (1) services provided to beneficiaries who were not homebound, (2) services provided to beneficiaries who did not require skilled services, and (3) claims that were assigned with incorrect Health Insurance Prospective Payment System (HIPPS) codes. On the basis of our sample results, we estimated that Southeastern received overpayments of at least \$1.8 million for our audit period. All 100 claims within our sample are outside of the Medicare 4-year claim-reopening period.

What OIG Recommends and Southeastern's Comments

We recommend that Southeastern 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. We also recommend that Southeastern 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, (2) beneficiaries are receiving only reasonable and necessary skilled services, and (3) the correct HIPPS payment codes are billed.

In written comments on our draft report, Southeastern stated that it did not agree with the findings of our independent medical review contractor and therefore did not concur with our recommendations. Specifically, Southeastern stated that our draft report contained numerous and significant legal and factual errors. Southeastern stated that the majority of those errors were related to the misapplication and misinterpretation of Medicare's homebound and skilled need requirements. To address these concerns, we had our independent medical review contractor review Southeastern's written comments as well as the claim-by-claim rebuttal and additional medical records. Based on the results of that review, we reduced the sampled claims incorrectly billed from 29 to 18 and revised the related findings and recommendations. We maintain that our remaining findings and recommendations, as revised, are valid.

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INTRODUCTION

WHY WE DID THIS AUDIT

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

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

OBJECTIVE

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

BACKGROUND

The Medicare Program and Payments for Home Health Services

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

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

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

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

Home Health Agency Claims at Risk for Incorrect Billing

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

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

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

Medicare Requirements for Home Health Agency Claims and Payments

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

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

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

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

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

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

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

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

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

Medicare Requirements for Providers To Identify and Return Overpayments

The Office of Inspector General (OIG) believes that this audit report constitutes credible information of potential overpayments. Upon receiving credible information of potential overpayments, providers must exercise reasonable diligence to identify overpayments (i.e., determine receipt of and quantify any overpayments) during a 6-year lookback period. Providers must report and return any identified overpayments by the later of: (1) 60 days after identifying those overpayments or (2) the date that any corresponding cost report is due (if applicable). This is known as the 60-day rule.⁴

The 6-year lookback period is not limited by OIG’s audit period or restrictions on the Government’s ability to reopen claims or cost reports. To report and return overpayments under the 60-day rule, providers can request the reopening of initial claims determinations, submit amended cost reports, or use any other appropriate reporting process.⁵

Southeastern Home Health Services

Southeastern is a home health care provider with 11 offices in Pennsylvania and 2 locations in Virginia. CGS Administrators, LLC, its Medicare contractor, paid this specific Southeastern provider located in Bristol, Pennsylvania, approximately \$34 million for 9,640 claims for services

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

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

provided in CYs 2015 and 2016 (audit period) on the basis of CMS’s National Claims History (NCH) data.

HOW WE CONDUCTED THIS AUDIT

Our audit covered \$33 million in Medicare payments to Southeastern for 8,411 claims.⁶ These claims were for home health services provided in CYs 2015 and 2016.⁷ We selected a stratified random sample of 100 claims with payments totaling \$452,436 for review. We evaluated these claims for compliance with selected billing requirements and submitted these claims to independent medical review to determine whether the services met coverage, medical necessity, and coding requirements.

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

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

FINDINGS

Southeastern did not comply with Medicare billing requirements for 18 of the 100 home health claims that we audited. For these claims, Southeastern received overpayments of \$46,404 for services provided in CYs 2015 and 2016. Specifically, Southeastern incorrectly billed Medicare for:

- services provided to beneficiaries who were not homebound,
- services provided to beneficiaries who did not require skilled services, and
- claims that were assigned incorrect HIPPS payment codes.

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

⁶ In developing this sampling frame, we excluded from our review home health claim payments for low utilization payment adjustments, claims less than \$1,000, partial episode payments associated with HHA transfers, claims that were excluded by another entity, and requests for anticipated payments.

⁷ CYs were determined by the HHA claim “through” date of service. The “through” date is the last day on the billing statement covering services provided to the beneficiary.

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

On the basis of our sample results, we estimated that Southeastern received overpayments of at least \$1.8 million for the audit period.⁹ As of the publication of this report, all 100 claims in our sample are outside of the Medicare 4-year claim-reopening period.

SOUTHEASTERN BILLING ERRORS

Southeastern incorrectly billed Medicare for 18 of the 100 sampled claims, which resulted in overpayments of \$46,404.

Beneficiaries Were Not Homebound

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

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

CMS provided further guidance and specific examples in the Manual (chapter 7, § 30.1.1).¹⁰ The Manual states that for a patient to be eligible to receive covered home health services under both Part A and B, the law requires that a physician certify in all cases that the patient is confined to his or her home and an individual will be considered “confined to the home” (homebound) if the following two criteria are met:

Criterion One

The patient must either:

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

⁹ Southeastern received overpayments of at least \$1,898,125. To be conservative, we estimated overpayments at the lower limit of a two-sided 90-percent confidence interval. Lower limits calculated in this manner will be less than the actual overpayment total 95 percent of the time.

¹⁰ Revision 208 of § 30.1.1 (effective January 1, 2015) covered all of our audit period.

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

Criterion Two

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

Southeastern Did Not Always Meet Federal Requirements for Home Health Services

For 10 of the sampled claims, Southeastern incorrectly billed Medicare for home health episodes for beneficiaries who did not meet the above requirement for being homebound for the full episode (6 claims) or for a portion thereof (4 claims).¹¹

Example 1: Beneficiary Not Homebound – Entire Episode

For one beneficiary, the medical record showed that, from the start of the episode, the beneficiary was able to ambulate 250 feet independently with a rolling walker and verbal instructions. Although the beneficiary ambulated slowly and with shortness of breath with moderate exertion, the beneficiary's oxygen saturation was maintained. The beneficiary remained independent in terms of transfers and ambulation. The beneficiary was alert and oriented and was residing in an accessible facility without mobility barriers. There were no medical contraindications to leaving the home. For the entire episode, leaving the home did not require a considerable or taxing effort.

Example 2: Beneficiary Not Homebound – Partial Episode

For another beneficiary, records showed that the beneficiary was initially homebound. The beneficiary had fallen and had a sacral fracture and left ankle sprain. The beneficiary's medical conditions included osteoporosis, increasing the risk of fall-related injuries. The beneficiary was limited by pain and fatigue at the start of care, and, at that point, leaving the home would have required a considerable and taxing effort for the beneficiary. By a later date in the episode, the beneficiary had made progress with mobility was able to ambulate 200 feet twice with a rolling walker and standby assistance. The beneficiary was living in an accessible residence without mobility barriers. At this point, leaving the home would no longer require a considerable and taxing effort.

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

¹¹ Of these 10 claims with homebound errors, 1 claim was also billed with an incorrect HIPPS code. Appendix E provides detail on the extent of errors, if any, per claim reviewed.

provide a reason why these errors occurred because Southeastern officials contended that these claims met Medicare requirements.

Beneficiaries Did Not Require Skilled Services

Federal Requirements for Skilled Services

A Medicare beneficiary must be in need of skilled nursing care on an intermittent basis, or physical therapy or speech-language pathology, or have a continuing need for occupational therapy (the Act §§ 1814(a)(2)(C) and 1835(a)(2)(A) and Federal regulations (42 CFR § 409.42(c)). In addition, skilled nursing services must require the skills of a registered nurse or a licensed practical nurse under the supervision of a registered nurse, must be reasonable and necessary to the treatment of the patient's illness or injury, and must be intermittent (42 CFR § 409.44(b) and the Manual, chapter 7, § 40.1).¹² 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).

Southeastern Did Not Always Meet Federal Requirements for Skilled Services

For 8 of the sampled claims, Southeastern incorrectly billed Medicare for an entire home health episode (5 claims) or a portion of an episode (3 claims) for beneficiaries who did not meet the Medicare requirements for coverage of skilled nursing or therapy services.^{13, 14}

Example 3: Beneficiary Did Not Require Skilled Services

A beneficiary with a medical history of cerebral vascular accident with right-sided weakness, aphasia, dysphagia, atrial fibrillation, and congestive heart failure was homebound. There were no signs or symptoms of aspiration and no history of pneumonia, and the beneficiary denied difficulty with swallowing. Speech therapy services were ordered for treatment of dysphagia. Southeastern

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

¹³ Of these 8 claims with skilled need services that were not medically necessary, 1 claim was also billed with an incorrect HIPPS code. Appendix E provides detail on the extent of errors, if any, per claim reviewed.

¹⁴ For all 8 claims that did not always meet Federal requirements for skilled services, skilled nursing services were necessary for either the entire home health episode or a portion of the episode. However, at least one of the billed skilled therapy services was not.

provided skilled nursing care, physical therapy, and speech therapy to the homebound beneficiary. However, there was no medical need for speech therapy—the beneficiary had aphasia, which is a long-term condition.

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

Incorrect Health Insurance Prospective Payment System Codes Were Assigned to Claims

Federal Requirements for Billing Health Insurance Prospective Payment System Codes

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

Southeastern Did Not Always Meet Federal Requirements for Billing Health Insurance Prospective Payment System Codes

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

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

OVERALL ESTIMATE OF OVERPAYMENTS

On the basis of our sample results, we estimated that Southeastern received overpayments totaling at least \$1.8 million for the audit period. As of the publication of this report, all 100 claims in our sample are outside of the Medicare 4-year claim-reopening period.

¹⁵ Of the two claims with incorrect HIPPS codes assigned, one claim was also billed for a beneficiary with a homebound error and one claim was also billed for skilled need services that were not medically necessary. Appendix E provides detail on the extent of errors, if any, per claim reviewed.

¹⁶ We also made adjustments to the claim amounts due to homebound and skilled need services errors.

RECOMMENDATIONS

We recommend that Southeastern Home Health Services:¹⁷

- 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; and
- strengthen its procedures to ensure that:
 - the homebound statuses of Medicare beneficiaries are verified and continually monitored and the specific factors qualifying beneficiaries as homebound are documented,
 - beneficiaries are receiving only reasonable and necessary skilled services, and
 - the correct HIPPS payment codes are billed.

SOUTHEASTERN COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, Southeastern stated that it did not agree with the findings of our independent medical review contractor and therefore did not concur with our recommendations. Specifically, Southeastern stated that our draft report contained numerous and significant legal and factual errors. Southeastern stated that the majority of those errors were related to the misapplication and misinterpretation of Medicare's homebound and skilled need requirements. Additionally, Southeastern expressed concern about the lack of an in-person exit conference and about related documentation requests. Southeastern's comments, from which we have removed two appendices, appear as Appendix F.¹⁸ We are providing Southeastern's comments in their entirety to CMS.

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

¹⁸ Southeastern included two appendices as part of its comments on our draft report. One appendix was prepared by Southeastern staff and contained a claim-by-claim rebuttal of the findings in our draft report, as well as additional medical records not previously provided. We provided the rebuttal and medical records to our independent medical review contractor as part of our request for an additional review of claims identified as having errors. However, because this appendix was long and contained a considerable amount of personally identifiable information, we excluded it from this report. In addition, Southeastern hired an external statistical expert and included his opinions in another appendix. Because Southeastern included its concerns regarding our statistical sampling and estimation methodology in the body of its comments, we excluded this appendix from this report.

To address Southeastern's concerns related to the medical review decisions, we had our independent medical review contractor review Southeastern's written comments on our draft report as well as the claim-by-claim rebuttal and additional medical records. Based on the results of that review, we revised our determinations, reducing the total number of sampled claims incorrectly billed from 29 to 18, and revised our related findings and recommendations accordingly. We also adjusted the finding for 5 of the 18 claims. With these actions taken, we maintain that our remaining findings and recommendations are valid. Below is a summary of the reasons that Southeastern did not concur with our recommendations and disputed our findings, as well as our responses.

We conducted a telephonic exit conference as a timely response to the two separate letters we received from Southeastern in response to our preliminary audit findings. Before the teleconference, we communicated with Southeastern, and Southeastern acknowledged that an in-person exit conference would be duplicative. During this teleconference, we thoroughly discussed the audit findings and the concerns Southeastern raised in its letters and agreed to provide the statistical information at the time of the draft report. As described below, we provided Southeastern with the information necessary to recreate our statistical projections.

RECOMMENDATION REGARDING STRENGTHENING PROCEDURES

Southeastern Comments

Southeastern did not concur with our recommendation that it 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, (2) beneficiaries are receiving only reasonable and necessary skilled services, and (3) the correct HIPPS payment codes are billed. Southeastern stated that it already has strong procedures in place to ensure patients are homebound and receiving reasonable and necessary skilled services in accordance with Medicare coverage criteria and to ensure HIPPS billing codes are correctly assigned.

Office of Inspector General Response

Because Southeastern incorrectly billed Medicare for: (1) services provided to beneficiaries who were not homebound, (2) services provided to beneficiaries who did not require skilled services, and (3) claims that were assigned incorrect HIPPS payment codes, we maintain that Southeastern did not have adequate procedures to prevent the incorrect billing of Medicare claims.

OFFICE OF INSPECTOR GENERAL'S SAMPLING METHODOLOGY

Southeastern Comments

Southeastern's statistician concluded that our sampling methodology was not statistically valid. Southeastern's statistician contended that we:

- violated the United States Government Accountability Office Government Auditing Standards section 7.13 because we did not explain how the extrapolated overpayment calculation was determined;
- did not perform a probe audit or a discovery sample as mandated by OIG's own Corporate Integrity Agreement guidelines;
- used an incorrect variable of interest in calculating sample size, which resulted in a significant underestimate of the number of samples necessary for the extrapolation;
- did not properly manage the stratification plan for the sample frame and thus the sample because of reliance upon an incorrect variable of interest for conducting the stratification analysis and inclusion of high outliers;¹⁹
- relied upon incorrect metrics to calculate the extrapolated overpayment estimate for each stratum and for the audit overall; and
- significantly exceeded the maximum precision amount, rendering the overpayment results nonreplicable and not valid for extrapolation.

Office of Inspector General Response

We carefully considered Southeastern's comments on our sampling methodology, and we maintain that our statistical approach resulted in a legally valid and reasonably conservative estimate of the overpayment received by Southeastern during our audit period. The overpayment of \$1,898,125 is based on the claim errors identified in the sample and is a conservative estimate of the overpayments that exist within the sampling frame.

Federal courts have consistently upheld statistical sampling and extrapolation as a valid means to determine overpayment amounts in Medicare and Medicaid.²⁰ The legal standard for use of

¹⁹ Southeastern performed a t-test that, according to Southeastern, shows that the sample paid amounts differ significantly from the frame paid amounts.

²⁰ 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).

sampling and extrapolation is that it must be based on a statistically valid methodology, not the most precise methodology.²¹ We properly executed our statistical sampling methodology in that we defined our sampling frame and sampling unit, randomly selected our sample, applied relevant criteria in evaluating the sample, and used statistical software (i.e., RAT-STATS) to apply the correct formulas for the extrapolation.

To account for our design choices, the precision of our estimate, and the potential differences between our sample and sampling frame, we estimated the overpayment amount using the lower limit of a two-sided 90-percent confidence interval. Lower limits calculated in this manner are designed to be less than the actual overpayment in the sampling frame 95 percent of the time. The use of the lower limit accounts for the design choices, the precision of our estimate, and the potential differences between our sample and sampling frame in a manner that generally favors the auditee.²²

We do not believe that t-tests are necessary to assess the reasonableness of an estimate, as such tests are not recommended in the survey sampling literature. For the t-tests that Southeastern did perform, Southeastern failed to properly adjust for the multiple comparisons it made between the sample and the sampling frame. When such adjustments are performed, the t-test result noted by Southeastern is no longer significant.

With respect to Southeastern's comments about the need for a probe audit to be compliant with OIG Corporate Integrity Agreement guidance, this guidance is not relevant to this audit because the guidance is for recovery using the point estimate rather than the lower limit. Moreover, the guidance does not represent the only way to calculate a valid statistical estimate.

With regard to Southeastern's statement that we used incorrect metrics to calculate the estimate, Southeastern incorrectly assumed that we used parametric methods that make assumptions about the underlying distribution of the errors in the sampling frame. The point estimates we calculated are unbiased regardless of the distribution of error amounts in the sampling frame, and the lower limit is known to be overly conservative for cases in which data is positively skewed, as it was in this case.

We provided Southeastern with all the information necessary to replicate the sample from the sampling frame and recalculate the overpayment estimate amount included in the report. In addition, Southeastern has direct access to the claim information necessary to validate the sampling frame. Our sample was selected from and our estimate applies only to the sampling

²¹ 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).

²² E.g., see *Puerto Rico Dep't of Health*, DAB No. 2385, at 10 (2011); *Oklahoma Dep't of Human Servs.*, DAB No. 1436, at 8 (1993) (stating that the calculation of the disallowance using the lower limit of the confidence interval gave the State the "benefit of any doubt" raised by use of a smaller sample size).

frame. As a result, the sampling frame, which we provided to Southeastern, is the same as the universe for our audit.

OFFICE OF INSPECTOR GENERAL'S MEDICAL REVIEW DETERMINATIONS

Southeastern Comments

Southeastern disagreed with our medical review contractor's determinations related to sampled claims in which the beneficiary did not qualify as homebound under Medicare standards and sampled claims with skilled services found to be not medically necessary. Specifically, Southeastern disagreed with the application of Medicare coverage criteria for the homebound and skilled need requirements.

Regarding homebound status, Southeastern stated that our medical review contractor did not consider the medical records as a whole or base determinations on objective, clinical evidence regarding each beneficiary's individual need for care. Southeastern also stated that our medical review contractor applied an illegal "rule of thumb" with respect to ambulation distance, considered clinical evidence differently from one claim to the next, and made inappropriate assumptions regarding beneficiary residences.

Regarding skilled need requirements, Southeastern also stated that our medical review contractor did not consider the medical records as a whole or base determinations on objective, clinical evidence regarding each beneficiary's individual need for care. Southeastern stated that our medical review contractor applied an illegal "rule of thumb" and "numerical utilization screen" by arbitrarily only allowing three services for the claims for which the medical reviewer determined that beneficiaries only had a skilled need for a portion of the home health episode. Southeastern added that our medical review contractor did not defer to the treating physicians despite finding that all home health certification and plan of care documentation was valid and that all home health services were rendered in accordance with the certifications and plans of care.

Southeastern requested that the sampled claims in which the beneficiary did not qualify as homebound under Medicare standards and the sampled claims with skilled services found to be not medically necessary be re-reviewed in accordance with Medicare coverage criteria by a qualified reviewer and in consideration of the objective, clinical evidence contained in the medical records as a whole.

Office of Inspector General Response

Based on the conclusions of our independent medical review contractor's additional medical review, we revised the findings related to homebound status and skilled need requirements (and the associated recommended disallowances). We revised the homebound findings to specify that 10, rather than 24, sampled claims were associated with beneficiaries who did not meet the criteria for being homebound (6 claims for the full episode of care and 4 claims for part of the episode of care). We revised the skilled need findings to specify that 8, rather than

14, sampled claims were associated with beneficiaries who did not meet Medicare requirements for coverage of skilled nursing or therapy services (5 claims for the full episode of care and 3 claims for part of the episode of care).

In determining beneficiaries' homebound status, our medical review contractor prepared detailed medical review determination reports that documented relevant facts and the results of the reviewer's analysis. We provided these reports to Southeastern after issuing our draft report. Each determination report included a detailed set of facts based on a thorough review of the entire medical record for the beneficiary associated with the sampled claim. Our medical review contractor reviewed and documented in detail the beneficiary's relevant medical history, including diagnoses, skilled nursing or therapy assessments, cognitive function, and mobility. The determination of homebound status and whether claims meet Medicare requirements must be based on each beneficiary's individual characteristics as reflected in the available medical record. Our medical review contractor carefully considered ability to ambulate in conjunction with the individual characteristics noted in each beneficiary's medical record. Ambulation distance was not noted in all of the decisions, and when it was, it was simply one factor the reviewer considered in making the homebound status determination. This is evident from the relevant facts and discussion included in the individual decisions.

We disagree with Southeastern's assertion that our medical review contractor did not consider the medical records as a whole or did not base determinations on objective, clinical evidence regarding each beneficiary's individual need for care when determining homebound status. For all sampled claims, our medical review contractor considered the entire medical record and relied on the relevant and salient facts necessary to determine homebound status in accordance with CMS's definition of homebound status.

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

Accordingly, having revised our findings and the associated recommendation with respect to 14 of the sampled claims identified in our draft report as having homebound errors, we maintain that our findings for the remaining 10 claims in our final report, and the revised recommendation, are valid.

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

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

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

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

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

RECALCULATION OF PARTIALLY DENIED CLAIMS

Southeastern Comments

Southeastern stated that some of the recalculations for partially denied claims were incorrect. Specifically, Southeastern listed four partially denied claims for which there were discrepancies between the amount we recalculated and the amount Southeastern recalculated. Southeastern requested that we review and correct these payment amounts.

Office of Inspector General Response

Based on the conclusions of our independent medical review contractor's additional medical review, two of the four partially denied claims that Southeastern requested we review are no longer errors. We reviewed the remaining two recalculated payment amounts and maintain that our recalculated amounts are correct. For one of the claims, the amount Southeastern stated would be correct included a low-utilization payment adjustment add-on payment. However, when we recalculated the payment amount, the CMS Home Health PPS PC Pricer returned a code that indicated that no add-on payment applied to this claim. For the other claim, the amount Southeastern stated would be correct was the original amount returned by the CMS Home Health PPS PC Pricer. However, the Budget Control Act of 2011 required, among other things, mandatory across-the-board reductions in Federal spending, also known as

sequestration. Medicare fee-for-service claims with dates of service or dates of discharge on or after April 1, 2013, incurred a two percent reduction in Medicare payment. After we removed the required two percent sequestration adjustment from the payment amount calculated by the Pricer, the final revised overpayment amount is the amount stated in the report.

REQUEST FOR REDACTION

Southeastern Comments

Southeastern requested that its name be redacted in the final report, stating that the publication of the final report with Southeastern's name identified would cause both serious harm to Southeastern's reputation and serious financial losses. Southeastern added that there is no reason to publish its name and that Southeastern does not consent to its name being published.

Office of Inspector General Response

We will issue the final report unredacted. The treatment of the auditee name in this report is consistent with both the treatment of other auditees of similar organizational size whose names do not contain personally identifiable information and the treatment of the names of other audited home health agencies.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

Our audit covered \$33,004,302 in Medicare payments to Southeastern for 8,411 home health claims with episode-of-care through dates in CYs 2015 and 2016. From this sampling frame, we selected for review a stratified random sample of 100 home health claims with payments totaling \$452,436.

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

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

We conducted our audit from January 2017 through October 2020, and our audit work included: (1) fieldwork performed at Southeastern's office in Bristol, Pennsylvania; (2) medical review, the results of which were included in our draft report, performed by the independent medical review contractor; and (3) additional medical review, the results of which were included in our final report, performed by the independent medical review contractor after we received Southeastern's written comments on our draft report.

METHODOLOGY

To accomplish our objective, we:

- reviewed applicable Federal laws, regulations, and guidance;
- extracted Southeastern's paid claim data from CMS's NCH file for the audit period;
- removed payments for low utilization payment adjustments, claims less than \$1,000, partial episode payments associated with HHA transfers, claims that were excluded by another entity, and requests for anticipated payments from the population to develop our sampling frame;
- selected a stratified random sample of 100 home health claims totaling \$452,436 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 Southeastern 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 Southeastern'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 Southeastern for our audit period (Appendix D);
- discussed the results of our audit with Southeastern officials; and
- after receiving Southeastern's written comments on our draft report, had our independent medical review contractor perform an additional medical review of all of the claims questioned in our draft report and incorporated the results of that additional medical review into our own analysis and determination of the allowability of the claims in light of Southeastern's comments.

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

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

GENERAL MEDICARE REQUIREMENTS

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

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

OUTCOME AND ASSESSMENT INFORMATION SET DATA

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

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

COVERAGE AND PAYMENT REQUIREMENTS

To qualify for home health services, Medicare beneficiaries must: (1) be homebound; (2) need intermittent skilled nursing care (other than solely for venipuncture for the purpose of obtaining a blood sample) or physical therapy, speech-language pathology, or occupational therapy;²³ (3) be under the care of a physician; and (4) be under a plan of care that has been established and periodically reviewed by a physician (the Act §§ 1814(a)(2)(C) and 1835(a)(2)(A), 42 CFR § 409.42, and the Manual, chapter 7, § 30).

²³ Effective January 1, 2012, CMS clarified the status of occupational therapy to reflect when it becomes a qualifying service rather than a dependent service. Specifically, the first occupational therapy service, which is a dependent service, is covered only when followed by an intermittent skilled nursing care service, a physical therapy service, or a speech language pathology service as required by law. Once that requirement for covered occupational therapy has been met, however, all subsequent occupational therapy services that continue to meet the reasonable and necessary statutory requirements are considered qualifying services in both the current and subsequent certification periods (subsequent adjacent episodes) (76 Fed. Reg. 68526, 68590 (Nov. 4, 2011)).

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

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

Section 6407(a) of the Affordable Care Act²⁴ 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.²⁵

Confined to the Home

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

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

CMS provided further guidance and specific examples in the Manual (chapter 7, § 30.1.1).²⁶ 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

²⁴ The Patient Protection and Affordable Care Act, P.L. No. 111-148 (Mar. 23, 2010), as amended by the Health Care and Education Reconciliation Act of 2010, P.L. No. 111-152 (Mar. 30, 2010), collectively known as the Affordable Care Act.

²⁵ See 42 CFR § 424.22(a)(1)(v) and the Manual, chapter 7, § 30.5. The initial effective date for the face-to-face requirement was January 1, 2011. However, on December 23, 2010, CMS granted HHAs additional time to establish protocols for newly required face-to-face encounters. Therefore, documentation regarding these encounters must be present on certifications for patients with starts of care on or after April 1, 2011.

²⁶ Revision 208 of § 30.1.1 (effective January 1, 2015) covered all of our audit period.

patient is 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:

Criterion One

The patient must either:

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

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

Criterion Two

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

Need for Skilled Services

Intermittent Skilled Nursing Care

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

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

Requiring Skills of a Licensed Nurse

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

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

General Principles Governing Reasonable and Necessary Skilled Nursing Care

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

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

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

Reasonable and Necessary Therapy Services

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

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

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

Documentation Requirements

Face-to-Face Encounter

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

Plan of Care

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

APPENDIX C: SAMPLE DESIGN AND METHODOLOGY

TARGET POPULATION

The target population consisted of Southeastern’s claims for home health services²⁷ that it provided to Medicare beneficiaries with episodes of care that ended in CYs 2015 and 2016.

SAMPLING FRAME

The sampling frame, consisted of a database of 8,411 home health claims, valued at \$33,004,302, from CMS’s NCH file.

SAMPLE UNIT

The sample unit was a home health claim.

SAMPLE DESIGN

We used a stratified random sample.

Stratum	Payment Range of Claims	Number of Claims	Total Dollar Value of Claims
1	\$1,295.97 to \$3,664.11	4,172	\$10,381,691.57
2	\$3,669.38 to \$5,632.12	2,433	\$11,250,165.66
3	\$5,638.92 to \$10,624.62	1,806	\$11,372,444.52
Total		8,411	\$33,004,301.75

SAMPLE SIZE

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

SOURCE OF RANDOM NUMBERS

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

²⁷ Our sampling frame excluded home health claim payments for low utilization payment adjustments, claims less than \$1,000, partial episode payments associated with HHA transfers, claims that were excluded by another entity, and requests for anticipated payments.

METHOD OF SELECTING SAMPLE ITEMS

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

ESTIMATION METHODOLOGY

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

APPENDIX D: SAMPLE RESULTS AND ESTIMATES

Stratum	Frame Size	Value of Frame	Sample Size	Total Value of Sample	Incorrectly Billed Sample Items	Value of Overpayments In Sample
1	4,172	\$10,381,692	34	\$85,930	4	\$6,468
2	2,433	11,250,166	33	158,154	8	20,357
3	1,806	11,372,444	33	208,352	6	19,579
Total	8,411	\$33,004,302	100	\$452,436	18	\$46,404

ESTIMATES

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

Point estimate	\$3,366,001
Lower limit	1,898,125
Upper limit	4,833,877

APPENDIX E: TYPES OF ERRORS BY SAMPLE ITEM

STRATUM 1 (Samples 1–34)

Sample Number	Not Homebound	Did Not Require Skilled Services	Incorrect HIPPS Code	Overpayment
1	-	-	-	-
2	X	-	X	175
3	-	-	-	-
4	-	-	-	-
5	-	-	-	-
6	X	-	-	1,997
7	-	-	-	-
8	-	-	-	-
9	-	-	-	-
10	-	-	-	-
11	-	-	-	-
12	-	-	-	-
13	-	-	-	-
14	-	-	-	-
15	-	-	-	-
16	-	-	-	-
17	-	-	-	-
18	-	-	-	-
19	-	-	-	-
20	-	-	-	-
21	-	-	-	-
22	-	-	-	-
23	-	-	-	-
24	-	-	-	-
25	-	-	-	-
26	-	-	-	-
27	-	-	-	-
28	-	-	-	-
29	-	-	-	-
30	X	-	-	3,174
31	-	-	-	-
32	-	-	-	-
33	-	X	X	1,122
34	-	-	-	-

STRATUM 2 (Samples 35–67)

Sample Number	Not Homebound	Did Not Require Skilled Services	Incorrect HIPPS Code	Overpayment
35	-	-	-	-
36	-	-	-	-
37	X	-	-	1,251
38	-	-	-	-
39	-	-	-	-
40	-	-	-	-
41	-	-	-	-
42	-	-	-	-
43	-	-	-	-
44	-	-	-	-
45	-	-	-	-
46	-	-	-	-
47	-	-	-	-
48	-	-	-	-
49	-	X	-	509
50	X	-	-	4,040
51	-	-	-	-
52	-	-	-	-
53	-	X	-	1,307
54	-	-	-	-
55	-	-	-	-
56	-	-	-	-
57	-	-	-	-
58	-	-	-	-
59	-	-	-	-
60	X	-	-	1,248
61	-	-	-	-
62	-	-	-	-
63	X	-	-	4,302
64	-	-	-	-
65	-	X	-	3,424
66	-	X	-	4,278
67	-	-	-	-

STRATUM 3 (Samples 68–100)

Sample Number	Not Homebound	Did Not Require Skilled Services	Incorrect HIPPS Code	Overpayment
68	X	-	-	7,329
69	-	-	-	-
70	-	-	-	-
71	-	-	-	-
72	-	-	-	-
73	-	-	-	-
74	-	-	-	-
75	-	-	-	-
76	-	-	-	-
77	-	-	-	-
78	-	-	-	-
79	-	-	-	-
80	-	-	-	-
81	-	-	-	-
82	-	-	-	-
83	X	-	-	2,267
84	-	-	-	-
85	-	-	-	-
86	-	X	-	1,705
87	-	X	-	872
88	-	-	-	-
89	-	-	-	-
90	-	-	-	-
91	-	-	-	-
92	-	-	-	-
93	-	-	-	-
94	-	-	-	-
95	-	X	-	1,698
96	-	-	-	-
97	-	-	-	-
98	X	-	-	5,708
99	-	-	-	-
100	-	-	-	-
Total	10	8	2	\$46,406*

*Amounts do not add up exactly due to rounding.

APPENDIX F: SOUTHEASTERN COMMENTS²⁸



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November 21, 2019

Nicole Freda, Regional Inspector General for Audit Services
Department of Health and Human Services
Office of Inspector General, Office of Audit Services, Region III
801 Market Street, Suite 8500
Philadelphia, PA 19107

RE: Response to Draft Report
Report Number: A-03-17-00004

Liles Parker PLLC represents Southeastern Home Health Services (“Southeastern” or “Agency”). This letter constitutes Southeastern’s response to the Department of Health and Human Services (HHS), Office of Inspector General’s (OIG) draft report entitled *Medicare Home Health Agency Provider Compliance Review: Southeastern Home Health Services*. As set out herein, Southeastern does not agree with the findings of OIG’s independent medical review contractor, MAXIMUS Federal Services, Inc., and therefore does not concur with OIG’s associated recommendations. Southeastern is submitting this response to OIG’s draft report in the spirit of cooperation and with the understanding that OIG will work with the Agency to address the identified deficiencies. Southeastern would appreciate OIG’s careful consideration of the issues in this audit which are important to both Southeastern and the home health community at large. Southeastern would like to meet with the OIG Region III team to discuss its concerns.

Specifically, it is Southeastern’s contention that the draft report contains numerous and significant legal and factual errors. Southeastern believes that the overwhelming majority of these errors are related to the misapplication and misinterpretation of Medicare’s homebound and skilled need requirements by OIG’s independent medical review contractor. Southeastern is respectfully requesting that the claims in question be sent back to the independent medical review contractor for re-review based upon the additional information contained in this response. In the most recently published reports by OIG, the subject home health agencies were afforded this courtesy. Specifically, in *Mederi Caretenders Home Health Billed for Home Health Services That Did Not Comply With Medicare Billing Requirements* (A-07-16-05092) (2019), OIG’s reviewer reversed

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²⁸ **OIG Note:** We redacted text in several places in this appendix because it is personally identifiable information.

twenty-one out of the forty-two claims initially found to be in error. In fact, thirty-three of the claims that were initially found to be in error for homebound status were reduced down to fifteen errors. In *Great Lakes Home Health Services, Inc., Billed for Home Health Services That Did Not Comply with Medicare Coverage and Payment Requirements (A-05-16-00057)* (2019), OIG's reviewer reversed, in whole or in part, thirty of the fifty-nine claims initially found to be in error. In *Excella HomeCare Billed for Home Health Services That Did Not Comply with Medicare Coverage and Payment Requirements (A-01-16-00500)* (2019), 35 claims of the initial 70 claims found to be in error were overturned in part or full. In each of these three recent cases, OIG's independent medical review contractor reversed approximately 50% of its own initial findings. Clearly such a high level of reversal demonstrates a fundamental flaw in its review process and its initial findings. Southeastern believes its fact pattern is very similar to each of the three cases cited above and requests that it be afforded the same courtesy as was afforded to these other home health agencies.

I. Background on Southeastern

Southeastern was founded in 1987 by two Registered Nurses. The Agency began providing home health care services to the elderly from a single location in lower Bucks County Pennsylvania. Since that time, the Agency has grown to cover most of southeastern Pennsylvania and has become one of the largest independent providers of home care services in the area. Southeastern has been accredited by the Joint Commission since 1992. The Agency is committed to its employees and to its clients. They service patients residing in some of the most impoverished areas of the Philadelphia region. The Agency's growth has been fostered by its dedication to the care of its patients. Southeastern does this by attracting superior talented employees and offering a work culture of integrity, clinical excellence, respect, and empowerment. The Agency's employees are offered ongoing education, training, and opportunities for growth and professional development.

II. Overview of OIG's Audit

By letter dated March 9, 2017, OIG notified Southeastern of its intention to audit Medicare payments made to Southeastern for home health services. OIG indicated that its audit would cover selected claims for Calendar Years 2015 and 2016. OIG stated that its objective was to determine whether Southeastern complied with Medicare requirements for billing home health services. It is Southeastern's understanding that this audit was part of a series of reviews of home health agencies and that Southeastern was selected for review based on computer matching, data mining, and data analysis, and not any specific compliance concern or issue. On March 9, 2017, OIG also electronically transmitted an excel file titled A-03-17-00004 Sample Selection.xlsx to Southeastern. This document requested the following materials for 100 claims:

- Itemized billing statements
- State OASIS validation reports
- Complete medical records

OIG requested that the documentation for 10 specific claims be provided by March 16, 2017, that the documentation for another 45 claims be provided by May 1, 2017, and that the documentation

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for the remaining 45 claims be provided by May 30, 2017. Southeastern timely produced the requested documentation. OIG commented to Southeastern representatives how much they appreciated the timely responses and cooperation with their requests.

An Entrance Conference was held by OIG on March 21, 2017. Over two years after OIG notified Southeastern of its audit and requested records, on May 1, 2019, OIG electronically transmitted an excel file titled A-03-17-00004 Audit Results.xlsx to Southeastern, as well as 29 PDF files constituting OIG's independent medical review contractor's claim determination reports. At both the Entrance conference and with the transmission of the May file, Southeastern was informed that it would be afforded an "in person" Exit Conference at our location. This never occurred and instead we were only afforded a telephonic Exit Conference. This telephonic Exit Conference was held on Tuesday, June 25, 2019.¹ During the Exit Conference, ██████████, the Assistant Regional Inspector General for Audit Services, indicated that the Agency would receive one week's advance notice before OIG transmitted the draft report to Southeastern. During the Exit Conference, we also specifically requested and itemized all materials relating to the sampling methodology that the Agency would need to assess the validity of the sampling methodology. ██████████ rejected our request and stated that we could only request those materials at the time OIG notified us of their intention to transmit the draft report.

Southeastern immediately began reviewing OIG's independent medical review contractor's findings and identified numerous fundamental errors. Southeastern sent a letter to OIG on May 10, 2019 detailing some of the identified issues and Southeastern attempted to raise these issues during the Exit Conference as well. Regrettably, while Southeastern tried to have an open dialog to resolve these errors, these efforts did not prove successful as OIG's independent medical review contractor's errors persist in the draft report.

On October 2, 2019, over three months after the Exit Conference, the draft report was electronically transmitted to us (A031700004_signed_draft_report.pdf). OIG did not provide one week's advance notice as stated in the Exit Conference. OIG requested that Southeastern provide its written comments within 30 days from the date of the letter. The draft report did not include, and we thus again requested, the following materials on October 3, 2019: the universe file; the sampling frame; information needed to recreate the sampling frame from the universe, including the sort order and strata definitions; identification of the random number generator used; the random number seeds, one for each stratum; the steps taken in calculating the overpayment; and a sampling plan that pre-dates the selection of the sample and the medical review. On October 8, 2019, five days later (despite that the materials the Agency needed with respect to the sampling methodology had been previously requested and itemized for OIG), OIG transmitted the following files to us electronically:

- A-03-17-00004 Sampling Plan - Stratified - Final.pdf
- A031700004 Southeastern Sample Frame.xlsx
- Calculation of Overpayment Amounts.xlsx

¹ Please see section VI. of this letter for ██████████'s statements during the Exit Conference relating to the Agency's redaction request.

- RandomNumbers.xlsx

OIG did not produce all of the requested materials. We sent a Freedom of Information Act (FOIA) request to OIG on October 8, 2019 for the universe file and all information needed to recreate the sampling frame from the universe, including the sort order and strata definitions, but have not received the requested materials to date.

III. Statement of Nonconurrence

The draft report includes recommendations for refunding an alleged overpayment and ongoing compliance. Southeastern takes its compliance obligations very seriously and addresses each of OIG's recommendations as follows:

- 1) OIG recommends that Southeastern *"refund to the Medicare program the portion of the estimated \$4,220,429 overpayment within the reopening period"*.

Southeastern does not concur with this recommendation because the claims selected for review were not billed incorrectly. As established *infra*, OIG's independent medical review contractor's medical review determinations are fundamentally flawed. OIG's reviewer engaged in misapplication of Medicare coverage criteria and disregarded information expressly detailed in the medical records provided by Southeastern. Furthermore, OIG's sampling methodology is statistically invalid as established in greater detail below. Southeastern thus does not owe \$4,220,429 to the Medicare program.

- 2) OIG recommends that Southeastern *"for the portion of the estimated \$4,220,429 overpayment for claims outside of the Medicare reopening period, exercise reasonable diligence to identify and return overpayments in accordance with the 60-day rule, and identify any returned overpayments as having been made in accordance with this recommendation"*.

Again, Southeastern does not concur with this recommendation because the claims selected for review were not billed incorrectly. As established below, OIG's independent medical review contractor's medical review determinations are fundamentally flawed. OIG's reviewer engaged in misapplication of Medicare coverage criteria and disregarded information expressly detailed in the medical records provided by Southeastern. Furthermore, OIG's sampling methodology is statistically invalid as established in greater detail below. Southeastern thus does not owe \$4,220,429 to the Medicare program regardless of whether portions of this alleged overpayment fall within or outside of the reopening period.

- 3) OIG recommends that Southeastern *"exercise reasonable diligence to identify and return any additional similar overpayments outside of our audit period, in accordance with the 60-day rule, and identify any returned overpayments as having been made in accordance with this recommendation"*.

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Southeastern does not concur with this recommendation because the alleged overpayments identified by OIG's independent medical review contractor are in error and there are thus no "additional similar overpayments" outside of OIG's audit period. Southeastern is fully aware of and committed to its legal obligation to report any overpayments within 60 days pursuant to 42 C.F.R. § 401.305. The Centers for Medicare and Medicaid Services (CMS) has expressly stated that a provider may reasonably assess that it is premature to initiate an investigation into similar claims based on receipt of notice of an overpayment until it has worked the overpayment through the administrative appeals process.² Southeastern reasonably believes that it is premature to initiate a review of similar claims based on OIG's draft report as it intends to vigorously contest the adverse claim determinations and the validity of OIG's sampling methodology in the Medicare administrative appeals process and anticipates that the adverse claim determinations will be reversed on appeal.

- 4) OIG recommends that Southeastern "*strengthen its procedures to ensure that: the homebound statuses of Medicare beneficiaries are verified and continually monitored and the specific factors qualifying beneficiaries as homebound are documented, beneficiaries are receiving only reasonable and necessary skilled services, and HIPPS billing codes are correctly assigned.*"

Southeastern does not concur with this recommendation because it already has strong procedures in place to ensure patients are homebound and receiving reasonable and necessary skilled services in accordance with Medicare coverage criteria, and to ensure HIPPS billing codes are correctly assigned.³ As established herein, OIG's reviewer misapplied Medicare coverage criteria and disregarded evidence documented in the Agency's records.

IV. OIG's Sampling Methodology is Not Statistically Valid

In its draft report, OIG states that it selected a stratified random sample of 100 claims. OIG refers to several appendices enclosed with its draft report as follows: "*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.*" As noted above, we had to follow-up with OIG for many documents relating to its sampling methodology that were not provided with the draft report, and OIG released some of the requested materials to us on October 8, 2019, though not the universe or a statement of the sort order for the sampling frame. Southeastern's statistician, [REDACTED], reviewed all materials released by OIG to date and concluded that OIG's sampling methodology is not statistically valid. [REDACTED]'s report is enclosed as **Appendix A**. [REDACTED] findings are briefly summarized as follows:

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

³ OIG requested and received Southeastern's claims processing policies and procedures as part of its initial records request.

- 1) OIG violated the United States Government Accountability Office Government Auditing Standards (GAGAS). Section 7.13 of GAGAS states, in part: *“In reporting audit methodology, auditors should explain how the completed audit work supports the audit objectives, including the evidence gathering and analysis techniques, in sufficient detail to allow knowledgeable users of their reports to understand how the auditors addressed the audit objectives.”* OIG did not explain how the extrapolated overpayment calculation was determined. OIG did not provide samples of calculations nor any other details that would allow a third party to be able to replicate their findings, conclusions, and / or recommendations. OIG did not identify the specific parameters that were used to calculate sample size, estimate overpayment data by strata, or calculate the extrapolated overpayment estimate, for example.
- 2) OIG failed to perform a probe audit or a discovery sample as mandated by OIG’s own Corporate Integrity Agreement (CIA) guidelines. In describing the process for selecting a sample using RAT-STATS, OIG’s guidelines provide: *“After creating the text file of overpayments based on the results of the discovery sample, select the Variable Appraisals component of RAT-STATS to calculate the mean and standard deviation of the overpayment amount in the sample.”* There is no evidence in OIG’s Sampling Plan or any other documentation released by OIG that indicates that OIG relied upon the use of a probe audit or discovery sample. OIG’s failure to use a probe audit or discovery sample was a fatal flaw. ██████████ was able to confirm as much using a common metric called the Pearson Correlation Coefficient which established a correlation coefficient of only 0.1, which is neither high or low enough to support the theory that there was a high correlation between the paid and overpaid amounts.
- 3) OIG used the wrong variable of interest in calculating sample size, resulting in a significant underestimate of the number of samples necessary for use in this extrapolation. OIG’s CIA guidelines provide that a full sample size cannot be estimated based on paid amounts rather than overpayment; it must be based on overpayment amounts. However, OIG used the paid amounts in this case. ██████████ conducted a sample size calculation for a stratified sample using RAT-STATS, the breakpoints identified by OIG in its Sampling Plan, and the results provided by OIG. RAT-STATS reported a significantly larger sample size than that used by OIG. Specifically, to achieve a confidence level of 90% and a precision level of 25%, the total sample size should have been 155, or more than 50% larger than what was used for this audit. Additionally, RAT-STATS relies upon the data being normally or near-normally distributed to ensure that the calculations are accurate and reliable in order to ensure a fair and reliable sample size. ██████████ tested the data against 12 different distributions and none of them accurately associated to the distribution of the data found within the sample frame. Testing against a normal distribution the p-value is less than 0.005, indicating that the data do not fit the normal distribution.
- 4) OIG failed to properly manage the stratification plan for the sample frame and thus the sample by relying upon the wrong variable of interest to conduct the stratification analysis and including high outliers that were both part of both the sample frame and the sample.

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OIG chose to use a stratified sample, selecting three strata and sampling using a simple random sample strategy from within each stratum based, from what [REDACTED] can infer, on the paid amount to the Agency. The goal of stratification is to separate the universe into sample frames when the universe consists of data points with *unlike* characteristics that can be organized into subsets with *like* characteristics. However, OIG's breakpoints were so close to each other as to render the stratification logic useless.⁴ After stratification, strata 3 includes dozens of high outliers, none of which should have been included in the extrapolation calculations. To ensure that the samples are representative of the sample frames from which they were drawn, statisticians will often perform a hypothesis test, one such test being the 2-sample t-test which was used by [REDACTED]. Using this test, [REDACTED] found that stratum 2's p-value was 0.088 (0.1 or greater indicates the sample is representative). [REDACTED] also found that there was a great deal of variance between the distribution of frequency between the sample and the sample frame. For example, the frequency for claims in stratum 1 for the sample frame was almost 50%, yet the OIG chose only 34% of claims in this stratum for the sample. For stratum 3, the frame reported a frequency of 21.47%, or about a fifth of all claims, yet, for the sample, fully a third of the claims were included in stratum 3. The person who creates the sample must decide how to allocate a sample of a certain total size to individual strata. This can be done through a method called "optimal allocation" if the values of variances within each stratum are known; however, without this knowledge, a safe approach is to allocate proportionally. The failure of OIG to utilize a valid allocation method resulted in under-sampling of the lowest paid claims and oversampling of the highest paid claims.⁵ [REDACTED] thus concluded that the sample would have been more representative of the universe if OIG had not stratified the sample frame and instead performed the audit without the use of stratification; and that this would have also likely resulted in a better precision ratio and a smaller sample error.

- 5) OIG relied upon the wrong metrics (mean and standard deviation) to calculate the extrapolated overpayment estimate for each stratum and for the audit itself. As with the sampling frame, [REDACTED] tested the overpayment amounts against 12 different distributions and found that none of them accurately associated to the distribution of the data found within the sample frame. The p-value was again less than 0.005. OIG relied upon the mean value per overpaid claim as the basis for their calculations, but this is only appropriate when the distribution of the data is either normal or at least near-normal, which is not the case here with the data bounded on the left by zero. The use of mean thus

⁴ For example, stratum 1 represented claims with paid amounts of \$1,295.97 to \$3,664.11 while stratum 2 began with claims paid at \$3,669.38; a difference between the two strata of only \$4.27. The same held true for stratum 2 and stratum 3, which showed a difference between the breakpoints of only \$6.80.

⁵ For example, for stratum 1, the mean paid amount was \$2,488.40 while for stratum 3, the mean paid amount was \$6,297. Using this non-proportional method, the Auditor sampled 31.5% fewer of the lowest paid claims while sampling 54% more of the highest paid claims.

misrepresented the value of the variable being measured. The differences between the mean and median value were also found to be quite significant.⁶

- 6) OIG significantly exceeded the maximum precision amount, rendering the overpayment results non-replicable and not valid for extrapolation. As noted previously, OIG did not provide any documentation or explanation as to how the extrapolation was actually conducted, other than to say that they used RAT-STATS. This forced ██████ to reconstitute the overpayment data and calculate the precision himself. To calculate the precision, ██████ took \$261.22 – which represents the difference between the average overpayment of all three strata (\$803.81) and the lower bound of the 90% confidence interval around the mean (\$542.59) – and divided it by the mean which resulted in a precision ratio of 32.5%, significantly higher than even the most conservative ratio required by OIG to extrapolate. Under OIG’s CIA guidelines, the number of paid claims to be selected for the full sample should correspond to 90 percent confidence and 25 percent precision levels.

It is ██████’s expert opinion that any one of these many flaws and errors introduced by OIG would be reason enough to exclude the extrapolation from consideration. Therefore, we request that the overpayment projection be removed and that the alleged overpayment be reduced to the actual payment amounts for the denied claims, which total **\$80,381**.

Southeastern would also like to point out that under federal law, Medicare contractors are only permitted to extrapolate if the Secretary of HSS has determined there is a sustained or high level of payment error or documented educational intervention has failed to correct the payment error.⁷ Southeastern does not have and has never had a sustained or high level of payment error with respect to Medicare claims nor has any documented education ever occurred which failed to correct the payment error. Therefore, extrapolation was not appropriate in this audit.

V. OIG’s Medical Review Determinations are Incorrect

Based on the audit results released by OIG in its draft report, Southeastern’s error rate is 17.77%.⁸ Even though Southeastern disputes this error rate, this is nonetheless substantially below the industry average. Southeastern’s response to the draft report is intended to demonstrate that Southeastern has an excellent record of compliance and makes far fewer errors than most home health agencies. Furthermore, when Southeastern identifies an error, it works diligently to correct the error. Despite that there are fundamental errors in the draft report, Southeastern appreciates that OIG has qualified its findings by providing that its “*recommendations do not represent final determinations by the Medicare program, but are recommendations to HHS action officials*”.

⁶ For stratum 1, the mean overpayment is \$435.62 yet the median overpayment is zero. This is clear compelling evidence that no extrapolation should have occurred for stratum 1. For stratum 2, the mean overpayment is \$1,202.7 while the median overpayment is again \$0. We see the same for stratum 3; a mean overpayment of \$784.25 and a median overpayment of \$0, again, indicating that no extrapolation should have been performed.

⁷ 42 U.S.C. 1395ddd(f)(3).

⁸ The error rate was calculated by dividing the value of overpayments in the sample (\$80,381) by the total value of the sample (\$452,436), and multiplying by 100.

OIG audited 100 claims. According to OIG, the medical review function was delegated to an independent medical review contractor. OIG's independent medical review contractor assessed several clinical factors when reviewing the Agency's records, including whether:

- Patient is homebound
- Patient has skilled need
- Skilled need supports medical necessity of services on home health certification and plan of care
- Home health certification and plan of care documentation is sufficient
- Home health care delivered in accord with home health certification and plan of care
- Documentation of home health care delivery is sufficient
- Home health care billed appropriately⁹

OIG's reviewer identified 29 claims with errors. The primary error alleged by the OIG reviewer in this audit is that the beneficiary is not homebound. In only five of the 29 cases at issue, the OIG reviewer agreed the beneficiary was homebound.¹⁰ In the other 24 cases, the OIG reviewer determined that the beneficiary was not homebound for part or all of the home health episode under review. In 18 of those 24 cases where the OIG reviewer disputed that the beneficiary was homebound for all or part of the episode, the OIG reviewer simultaneously determined the beneficiary had skilled need for all of the home health services received (i.e., skilled nursing, skilled physical therapy, skilled occupational therapy, and / or skilled speech therapy).¹¹ In the remaining six cases, the OIG reviewer determined that the beneficiary had skilled need for some disciplines and / or for a certain period of time during the home health episode under review. There were no instances where the OIG reviewer determined that the beneficiary was both not homebound for the duration of the home health episode and did not have skilled need for any of the home health services received. Notably, there were no errors associated with the home health certifications and plans of care or home health care delivery documentation. OIG's reviewer alleged that the home health care was not billed appropriately with respect to one claim only.¹²

⁹ These are the clinical factors identified in OIG's reviewer's claim review determination reports. In its initial records request letter dated March 9, 2017, OIG stated that its initial review areas included: verification of homebound requirements; review of transfers and readmissions that could result in partial episode payments; review of outcome and assessment information set reporting; verification of therapy coverage and reassessments procedures; review of full episodes that could be billed as low utilization payment adjustments; review of primary diagnosis codes that result in high payments; review of physician plan of care and services billed for selected claims; review of outlier payments made due to excessive visits; review of physician reassessment after the 90 days period; review of consolidated billing procedures; verification of duplicate HHA payments; verification of the Core Based Statistical Area (CBSA) rates; verification of skilled and home aide services; and review of other billing that could result in high payments. Notably, there is no 90 day physician reassessment requirement related to home health; this appears to be a non-applicable hospice reference.

¹⁰ The five cases where the OIG reviewer agreed the beneficiary was homebound are: S2-32, S3-19, S3-28, S3-20, and S3-23.

¹¹ The OIG reviewer's determination in these 18 cases appears to acknowledge that the functional deficits were significant enough to warrant skilled home health services but expressly disagrees that they were significant enough to render the beneficiaries homebound.

¹² The claim is S1-2.

Southeastern disagrees with the medical review findings of OIG's independent medical review contractor. Southeastern would like the opportunity to meet in person to review its concerns and discuss OIG's steps to address them. Given that OIG's October 2, 2019 correspondence indicates that the draft report is subject to further review and revision, it is Southeastern's understanding that OIG will carefully consider its concerns as detailed herein and not simply issue a final report mirroring the draft report. Southeastern understands this draft report response opportunity to be an integral component of a fair process where all information will be assessed in more detail by both parties, and potentially with additional qualified reviewers to ensure that OIG's independent medical review contractor's medical review findings are accurate and reasonable. To the extent that OIG opts to review the work of its independent medical review contractor and redraft the draft report, Southeastern respectfully requests the opportunity to review the revised findings and supplement this response.

Surely OIG can agree that flawed medical review impedes rather than assists OIG with conducting independent assessments of HHS programs and operations. Unfortunately, it appears that many of the issues identified by other home health agencies in other OIG audits persist and that OIG's independent medical review contractor has not updated its medical review processes to reflect correct application of Medicare coverage criteria.¹³ Notably, in those other cases, OIG had the independent medical review contractor re-review their findings and the errors were reduced significantly.

1) Homebound Requirement

As noted *supra*, the biggest alleged issue is that 24 beneficiaries were not homebound for all or part of the home health episodes under review. One of our primary concerns is OIG's reviewer's misapplication of the homebound requirement, which we also articulated in a comprehensive letter to OIG dated May 10, 2019.¹⁴ Under Medicare guidelines, a Medicare beneficiary is considered "confined to the home" or homebound if the following two criteria are met:

1. Criteria-One:

The patient must either:

- Because of illness or injury, need the aid of supportive devices such as crutches, canes, wheelchairs, and walkers; the use of special transportation; or the assistance of another person in order to leave their place of residence

OR

- Have a condition such that leaving his or her home is medically contraindicated.

¹³ See, e.g., A-01-16-00500 (May 2019) and A-05-16-00057 (May 2019).

¹⁴ OIG did not respond.

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

2. Criteria-Two:

- There must exist a normal inability to leave home;

AND

- Leaving home must require a considerable and taxing effort.¹⁵

These are the homebound guidelines that have been effective since November 2013. CMS had revised the homebound guidelines on account of significant confusion to better mirror the verbiage in the Social Security Act, which provides:

“an individual shall be considered to be “confined to his home” if the individual has a condition, due to an illness or injury, that restricts the ability of the individual to leave his or her home except with the assistance of another individual or the aid of a supportive device (such as crutches, a cane, a wheelchair, or a walker), or if the individual has a condition such that leaving his or her home is medically contraindicated. While an individual does not have to be bedridden to be considered “confined to his home”, the condition of the individual should be such that there exists a normal inability to leave home and that leaving home requires a considerable and taxing effort by the individual. Any absence of an individual from the home attributable to the need to receive health care treatment, including regular absences for the purpose of participating in therapeutic, psychosocial, or medical treatment in an adult day-care program that is licensed or certified by a State, or accredited, to furnish adult day-care services in the State shall not disqualify an individual from being considered to be “confined to his home”. Any other absence of an individual from the home shall not so disqualify an individual if the absence is of infrequent or of relatively short duration. For purposes of the preceding sentence, any absence for the purpose of attending a religious service shall be deemed to be an absence of infrequent or short duration.”¹⁶

The regulation provides that the patient need not be bedridden and that a patient can leave the home and still be considered homebound so long as absences from the home are for receiving health care treatment or when absences are infrequent or of relatively short duration. OIG’s reviewer acknowledges that the beneficiaries relied on supportive devices to ambulate, and thus that criterion one was met.¹⁷ In terms of the homebound determination, the only remaining issue

¹⁵ Medicare Benefit Policy Manual Ch. 7 § 30.1.1 (Pub. 100-02, Rev. 208) (2015).

¹⁶ 42 U.S.C. 1395n(a)(2)(F).

¹⁷ For purposes of establishing that OIG’s reviewer acknowledges that the beneficiaries relied on supportive devices to ambulate, and thus that criteria-one was met, we have identified the supportive device(s) as acknowledged by OIG’s reviewer in the 10 highest dollar value cases where homebound is a purported error in the following table:

is thus whether the beneficiaries met criterion two as well (i.e., had a normal inability to leave home and leaving home required a considerable and taxing effort). In regard to criterion two, Medicare guidelines specifically provide:

“To clarify, in determining whether the patient meets criterion two of the homebound definition, the clinician needs to take into account the illness or injury for which the patient met criterion one and consider the illness or injury in the context of the patient’s overall condition. The clinician is not required to include standardized phrases reflecting the patient’s condition (e.g., repeating the words “taxing effort to leave the home”) in the patient’s chart, nor are such phrases sufficient, by themselves, to demonstrate that criterion two has been met. For example, longitudinal clinical information about the patient’s health status is typically needed to sufficiently demonstrate a normal inability to leave the home and that leaving home requires a considerable and taxing effort. Such clinical 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 (worsening or improvement), prognosis, nature and extent of functional limitations, other therapeutic interventions and results, etc.”¹⁸

OIG cites two examples in its draft report of claims where its reviewer found that the beneficiary was not homebound, one for the entire episode and one for part of the episode: S1-4 and S2-2. We will address each of OIG’s examples in turn. These examples highlight that OIG’s independent medical review contractor did not conduct the requisite multi-factor assessment, including consideration of factors such as the patient’s diagnosis, duration of the patient’s condition, clinical course, prognosis, nature and extent of functional limitations, or other therapeutic interventions and results. OIG’s reviewer’s denial rationale exclusively considered ambulation distance, whether the patient required hands-on assistance for ambulation and transfers, and whether the patient resided in an assisted living facility (ALF). OIG’s reviewer evidently does not understand the homebound requirement and appears to have created its own standard for homebound which is not founded in Medicare regulations or guidelines.

Example 1

OIG Sample No.	Dates of Service	Alleged Overpayment Amount	Supportive Device(s) Acknowledged by OIG Reviewer
3-9	08/14/15-10/12/15	\$6,205.36	Rolling walker
3-31	01/13/16-03/12/16	\$5,708.22	Rollator walker, power wheelchair
2-31	06/24/15-08/22/15	\$5,632.12	Walker
2-33	01/09/16-02/16/16	\$5,438.60	Roller walker, wheelchair
2-19	03/12/15-04/07/15	\$4,738.88	Cane
3-1	12/30/14-02/27/15	\$4,607.75	Rolling walker / wheeled walker
2-29	07/19/15-09/11/15	\$4,302.01	Cane
2-3	11/27/15-01/25/16	\$4,230.15	Wheelchair, walker
2-16	01/22/16-03/15/16	\$4,039.66	Walker
1-30	02/18/16-03/15/16	\$3,173.56	Walker

¹⁸ Medicare Benefit Policy Manual Ch. 7 § 30.1.1 (Pub. 100-02, Rev. 208) (2015).

Beneficiary S1-4
DOS 11/05/15-01/03/16

In the draft report, OIG states that the entire episode was denied because this beneficiary was not homebound as follows:

“For one beneficiary, the medical record showed that, from the start of the episode, the patient was able to ambulate 200 feet and perform transfers without hands-on assistance, and the initial treatment session included higher level gait activities, such as negotiating obstacles. For the entire episode, leaving the home did not require a considerable or taxing effort.”

OIG’s reviewer otherwise found that the Agency satisfied all other clinical factors for home health. OIG’s determination regarding this beneficiary’s homebound status is in error. Leaving home did require a considerable and taxing effort for S1-4.

By way of background, S1-4 was an 86-year-old beneficiary during the November 5, 2015 through January 3, 2016 home health episode at issue. S1-4 resided in an ALF. S1-4 had previously been on palliative care due to a decline in function. S1-4’s underlying medical history was significant for heart failure, chronic obstructive pulmonary disease (COPD), type II diabetes mellitus, enlarged prostate with lower urinary tract symptoms, retention of urine, and long-term use of insulin. He had blurred vision and mild bilateral hearing loss. He was taking approximately 23 medications. S1-4 consumed a pureed diabetic diet that was prepared and administered by his facility. Due to incontinence and benign prostatic hyperplasia, S1-4 required a Foley catheter. He was hospitalized August 5, 2015 through August 9, 2015 with urosepsis, acute kidney injury, and troponinemia.¹⁹ During the episode at issue, S1-4 was diagnosed with a urinary tract infection (UTI). S1-4 utilized a walker and wheelchair for mobility. He received skilled nursing and skilled physical therapy services during the episode at issue.

¹⁹ The hospital discharge summary provides in part,

“The patient is an 86-year-old male with past medical history of CAD, hypertension, AFib, CKD, hyperlipidemia, diabetes, DVT, PE not anticoagulation, multiple recurrent UTIs, urinary obstruction presented from nursing home with shortness of breath. Per the nursing home, the patient has poor p.o. intake and was recently treated for left lower extremity cellulitis. The patient has had chronic Foley since 1 year for urinary retention, which was changed 3 days prior to admission at the nursing home secondary to being clogged. In the ED, the patient was found to be hypotensive with systolic blood pressure in 80s, was given 2 L normal saline boluses. The patient’s O2 sats were in the 80s, which improved with DuoNeb treatment, Foley catheter was changed in the ER, and the patient also received 1 dose of vancomycin and cefepime for positive UA. At this point, there was suspicion of sepsis secondary to UTI. [...] transferred to the ICU [...] and] was aggressively resuscitated with normal saline. [...] Aggressive resuscitation improved urinary output and the worsening kidney function. [...] urine cultures that were drawn on 08/04 came back positive for E. coli. [...] Cardiology was consulted as the patient had a troponin leak. [...] During the admission, the patient had an episode of shortness of breath while he was eating that was accompanied with cough and choking. Hence, the patient was evaluated by speech and swallow therapist who recommended ground diet.”

(S1-4, pp. 128-131).

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The recertification OASIS dated November 3, 2015 provides that S1-4 was at risk for falls. He scored “7” on the fall risk assessment. Factors that contributed to his fall risk included age, number of co-existing diagnoses, incontinence, impaired functional mobility, poly pharmacy, pain affecting level of function, and cognitive impairment. S1-4’s musculoskeletal assessment was significant for decreased mobility, poor endurance, and poor conditioning, as well as dependence on walker, wheelchair, and one-person assist. S1-4 required assistance with all of his activities of daily living (ADLs) including upper / lower body dressing, bathing, and transferring. S1-4 was only able to walk with supervision or assistance of another person at all times and required a wheelchair or walker for mobility. S1-4 was also noted to become dyspneic or noticeably short of breath when walking more than 20 feet and when climbing stairs. (S1-4, pp. 27-36).

In describing the first physical therapy session of the episode, OIG’s reviewer wrote,

“PT saw the patient on 11/5/2015 and the patient was gait training 150 feet times one with standby assist plus carryover for upright posture, step height for foot clearance and step length, turning while walking, turning while walking 180 degrees with rolling walker, and lower extremity sequencing with correct weight shifting. Transfer training was reported as sit to/from stand times six trials with standby assist, stand pivot to/from the wheelchair and bed with standby assist with carryover for direction of navigation to bed.”

See A-03-17-00004A, S1-4, p. 2.²⁰ The degree of assistance S1-4 required and his overall safety while ambulating would be material to the question of whether a considerable and taxing effort would be required for him to leave home. OIG’s reviewer expressly concedes in its claim review report that S1-4 required standby assist for both ambulation and transfers. While there is no physical contact from the skilled physical therapist with standby assist, the skilled physical therapist must be close to the beneficiary to maximize safety for a beneficiary who requires standby assist. The physical therapy note also provides that S1-4 required ongoing teaching for safety carryover. Additionally, the note provides that S1-4 was lethargic on this date and that he reported daily (though not constant) right shoulder pain.

CMS regulations state that home health coverage decisions must be predicated on a review of the medical record as a whole and based on objective, clinical evidence regarding a beneficiary’s individual need for care.²¹ It is therefore not appropriate for OIG’s reviewer to focus only on the beneficiary’s performance during the first physical therapy session of the episode. Additionally, medical reviewers may not base their decisions on a “rule of thumb.”²² The determination that S1-4 was not homebound because he could walk a certain distance – without regard for any of the patient’s other limitations – constitutes an inappropriate “rule of thumb” that is expressly contrary to CMS guidelines. In terms of ambulation distance, the Medicare guidelines actually expressly state that an occasional “walk around the block” for nonmedical purposes would not necessitate a finding that the patient is not homebound.²³ A small city block measures 200 feet per side, which

²⁰ This represents a reference to OIG’s reviewer’s claim review determination report; the format is OIG’s CIN, OIG’s Sample ID, and the specific page number of the report.

²¹ 42 C.F.R. § 409.44(a) (2016).

²² Medicare Benefit Policy Manual Ch. 7 § 20.3 (Pub. 100-02, Rev. 208) (2015).

²³ Medicare Benefit Policy Manual Ch. 7 § 30.1.1 (Pub. 100-02, Rev. 208) (2015).

would mean walking around a small block is approximately 800 feet. The Medicare guidelines therefore suggest a beneficiary's ability to ambulate 800 feet would not negate their homebound eligibility.

The reviewer's one-dimensional analysis of S1-4's homebound status ignores the extensive functional limitations documented by the clinicians before and throughout the episode, including:²⁴

- S1-4 was first evaluated by a physical therapist status post hospitalization on September 4, 2015. His prior level of function was noted to be independent with transfers and standby assist with rolling walker. The skilled physical therapist noted that S1-4 had had a significant decline in function as a result of his hospitalization such that he now required total assist for ADLs, transfers, and gait. S1-4 exhibited bilateral lower extremity weakness and balance deficits on evaluation. The skilled physical therapist developed goals for S1-4 to accomplish over the course of physical therapy, including to become independent with transfers and to ambulate more than 100 feet with rolling walker and standby assist for decreased fall risk, improved safety, and decreased caregiver burden. (S1-4, pp. 88-91).
- On November 9, 2015, S1-4 reported minor pain to the lumbar region to the skilled nurse. The pain was described as aching / nagging and was precipitated by moving. The skilled nurse assessed S1-4's respiratory system and noted wheezing and that S1-4 had an occasional cough. The skilled nurse also assessed the beneficiary's musculoskeletal system and noted that he presented with decreased mobility, poor endurance, poor balance, poor conditioning, and altered fine motor skills, and that S1-4 required human assistance times one. (S1-4, pp. 47-50).
- On November 10, 2015, S1-4 missed physical therapy because he was too fatigued. (S1-4, p. 77).
- On November 12, 2015, the skilled physical therapist documented that S1-4 ambulated 175 feet with a rolling walker while the skilled physical therapist followed behind the beneficiary with a wheelchair. The therapist noted that S1-4 continued to hike his shoulders and placed increased pressure through his bilateral upper extremities. The therapist provided verbal and tactile cues for scapular depression and retraction. (S1-4, p. 78).
- On November 12, 2015, S1-4 was also seen by skilled nursing. S1-4 was again noted with wheezing breath sounds and an occasional cough. He also continued to suffer from minor lumbar back pain. S1-4 was diagnosed with a UTI, for which he was prescribed antibiotics (i.e., Keflex). (S1-4, pp. 51-54).
- A physical therapist reassessed S1-4 on November 17, 2015 and documented that he ambulated 100 feet two times with a rolling walker and required minimum²⁵ to standby assistance and a wheelchair to follow. The skilled therapist observed that S1-4 was

²⁴ Notably, the reviewer's determination appears to acknowledge that the beneficiary's deficits were significant enough to warrant skilled nursing and skilled physical therapy but expressly disagrees that they were significant enough to render S1-4 homebound.

²⁵ Minimal assist means the patient requires approximately 25% physical assistance or support to safely complete a task.

progressing toward his goals in that his rating of perceived exertion (RPE)²⁶ had been decreasing with increased ambulation distance when he used a rolling walker with wheelchair following. However, S1-4 was also noted to become short of breath when hurrying on level surfaces and walking up a slight hill. During the reassessment, S1-4 required standby assistance for transfers. Additionally, the therapist noted that the patient had an altered gait, impaired balance, and required an assistive device to navigate level surfaces. S1-4 was assessed with decreased strength in his bilateral lower extremities, which was graded 4/5. (S1-4, pp. 80-81).

- During the skilled nursing visit on November 17, 2015, S1-4's respiratory system was positive for a slight posterior wheeze. S1-4 was also noted to have bilateral lower extremity weakness and moderate / poor cognitive performance. (S1-4, pp. 55-58).
- On November 20, 2015, S1-4 ambulated 150 feet with a rolling walker and required standby assistance and a wheelchair to follow. The skilled physical therapist provided carryover instruction for gait mechanics and decreased RPE; dual task walk and talk; and obstacle navigation with quarter / half turns while walking. The skilled physical therapist also provided cuing to assist S1-4 with navigating around dynamic obstacles, weight shifting, and safety while ambulating in an open environment with visual / physical dual tasking. Additionally, S1-4 required standby assist with transfers from wheelchair and bed while utilizing a rolling walker. (S1-4, p. 82).
- On December 7, 2015, a skilled nurse noted that S1-4 continued to present with posterior wheezes. The skilled nurse removed S1-4's Foley catheter and placed a new Foley catheter. S1-4 presented with a scaly facial rash and Hydrocortisone 2% ointment was ordered. (S1-4, pp. 59-62).
- S1-4 presented with posterior wheezes on December 9, 2015. A skilled nurse noted that S1-4 also presented with a rash on his face and that the facility staff was concerned that he had cellulitis (recall S1-4 had been recently treated for left lower extremity cellulitis). S1-4 had an elevated blood pressure of 146/86 mmHg. (S1-4, p. 63-66).
- On December 14, 2015, S1-4 was assessed with an elevated blood pressure of 142/78 mmHg and an oxygen saturation of 96%. He continued to present with posterior wheezes. His musculoskeletal system was positive for decreased mobility, poor endurance, poor balance, poor coordination, altered fine motor skills, and need for human assistance times one. (S1-4, pp. 67-70).
- On December 17, 2015, a skilled nurse documented that S1-4's blood pressure was elevated at 142/78 mmHg. His oxygen saturation had decreased to 95%. S1-4's respiratory system remained positive for posterior wheezes. (S1-4, pp. 71-74).
- A recertification assessment was conducted by a registered nurse on December 31, 2015. The nurse documented that S1-4 remained at high risk for falls. His oxygen saturation was 96% and his blood pressure was recorded as 138/78 mmHg. S1-4 continued to present with decreased mobility, poor endurance, and poor conditioning; be dependent on both a walker and wheelchair; and require supervision or assistance of another person at all times to walk. (S1-4, pp. 37-46).

²⁶ The RPE scale allows individuals to subjectively rate their level of exertion during exercise or exercise testing. It is a widely used and reliable indicator to monitor and guide exercise intensity.

Based on a review of the medical record as a whole and the objective, clinical evidence, S1-4 was homebound. S1-4 relied on a rolling walker to ambulate, as well as a wheelchair for mobility. A beneficiary who was physically deconditioned after a five day hospitalization; resided in an ALF; depended on a device to walk safely; required standby assist (and even minimal assist at times) to ambulate and transfer; required instruction for safety while ambulating; could only ambulate a distance of 200 feet at one time on his best day; exhibited impaired balance; became short of breath while ambulating more than 20 feet, when hurrying on level surfaces, and walking up a slight hill secondary to heart failure and COPD; presented with wheezing, coughing, and elevated blood pressure readings; took 23 different medications; and was at a high risk for falls would require a considerable and taxing effort to leave home.

Example 2
Beneficiary S2-2
DOS 11/05/15-01/03/16

In the draft report, OIG states that the episode was partially denied because this beneficiary was not homebound as follows:

“For another beneficiary, records showed that the patient was initially homebound. The patient was limited by debility and required assistance when using her rolling walker and was ambulating less than household distances.²⁷ At the start of care, leaving the home would have required a considerable and taxing effort for this patient. By a later date in the episode, she was able to transfer and ambulate 200 feet with a rolling walker without hands-on assistance. She was living in an accessible residence without mobility barriers. Leaving the home would no longer require a considerable and taxing effort.”²⁸

OIG’s reviewer otherwise found that the Agency satisfied all other clinical factors for home health. OIG’s determination regarding this beneficiary’s homebound status is in error. Leaving home did require a considerable and taxing effort for S2-2.

By way of background, S2-2 was an 88-year-old female when she was admitted to home health on April 30, 2015. S2-2 resided at [REDACTED] continuing care retirement community. On admission to home health, S2-2’s primary issues were physical deconditioning, generalized weakness, and gait dysfunction. Her functional limitations included poor endurance and difficulty ambulating. She had last sustained a fall on February 19, 2015. S2-2 relied on a walker and wheelchair for mobility. Her medical condition was otherwise significant for hypertension, hyperlipidemia, depression, hypothyroidism, type 2 diabetes mellitus, and Vitamin D deficiency. She was taking approximately nine medications. She received skilled physical therapy during the episode under review.

Not only does OIG’s reviewer fail to consider the record as a whole as well as apply an illegal rule

²⁷ OIG’s reviewer does not define “household distances”. This is not a phrase used or defined in Medicare guidelines.
²⁸ In OIG reviewer’s claim review report, the reviewer more specifically asserted the Rationale section that “Her condition improved, and by 5/15/2015 she was able to transfer and ambulate 200 feet without hands on assistance.” See A-03-17-00004B, S2-2, p. 3.

of thumb with respect to ambulation distance, the assertion that S2-2 was able to “transfer and ambulate 200 feet without hands on assistance” by May 15, 2015 is materially inaccurate. *See* A-03-17-00004 Sample 2-2, p. 3. On May 15, 2015, S2-2 ambulated 150 feet with contact guard assist, not 200 feet without hands on assist. With contact guard assist, the skilled physical therapist places one or two hands on the patient’s body to help steady the patient or help with balance. Therefore, OIG’s reviewer’s assertion that S2-2 ambulated “without hands on assistance” is a mischaracterization of the level of assistance she required. Additionally, the physical therapist noted that S2-2 exhibited decreased step length, forward flexed trunk, narrow base of support, decreased cadence, and decreased heel-to-toe sequencing with ambulation on May 15, 2015. S2-2 also required minimal assist and cues for hand placement during transfer training. (S2-2, pp. 67-68). Minimal assist means the patient requires approximately 25% physical assistance or support to safely complete a task. OIG’s reviewer doesn’t acknowledge any of these other functional circumstances, such as specific gait attributes and transfer abilities, related to the May 15, 2015 date of service in its claim review report, thus not only making a materially inaccurate assertion but also taking ambulation distance and level of assistance required by the beneficiary out of context such that objective clinical evidence is clearly overlooked if not expressly disregarded. OIG also appears to fail to understand that in order for a patient to ambulate, they have to be able to get up. If they require minimal assist to transfer, as S2-2 did, this is extremely important context for any discussion of ambulation abilities. Of note, the skilled physical therapist established the following long-term goals for S2-2 to accomplish through skilled physical therapy at the time of initial evaluation: S2-2 would be able to ambulate 250 feet with rolling walker with distant supervision and transfer independently with rolling walker. (S2-2, p. 64). These goals were developed based on the beneficiary’s prior level of function. S2-2 had not achieved these goals by May 15, 2015 (nor by June 2, 2015, the 30-day reassessment mark). (S2-2, p. 71).

Furthermore, the reviewer’s one-dimensional analysis of S2-2’s homebound status ignores the extensive functional limitations documented by the skilled physical therapists after May 15, 2015, including:²⁹

- On May 19, 2015, the skilled physical therapist documented that S2-2 required close supervision and cues for hand placement with transfers. She was able to ambulate 175 feet times two with a rolling walker but exhibited a narrow base of support, decreased step length, shuffling gait, and decreased cadence. (S2-2, p. 69).
- On May 29, 2015, S2-2 ambulated 300 feet with close supervision though required minimal assist to navigate obstacles. She also required contact guard assist for transfers. (S2-2, p. 70).
- On June 2, 2015, the skilled physical therapist performed a 30-day reassessment. S2-2 required contact guard assist for transfers and could ambulate 300 feet with rolling walker and close supervision. Again, her goals as established at the outset of therapy were to be independent with transfers with rolling walker and to be able to ambulate 250 feet with rolling walker and distant supervision. She had not achieved her goals by this date. The

²⁹ Notably, the OIG reviewer’s determination appears to acknowledge that the beneficiary’s deficits were significant enough to warrant skilled physical therapy but expressly disagrees that they were significant enough to render S2-2 homebound.

- skilled physical therapist determined that S2-2 required further skilled physical therapy services to progress to all goals on her plan of care. (S2-2, p. 71).
- On June 10, 2015, S2-2 continued to demonstrate ambulation ability of 300 feet with rolling walker and close supervision. She also continued to exhibit gait deficits, including decreased cadence, narrow base of support, and decreased step length. In terms of transfers, she required cues for hand placement. (S2-2, p. 72).
 - On June 11, 2015, S2-2 was able to increase her ambulation distance to 350 feet, though she continued to require close supervision due to decreased step length and cadence, narrow base of support, and forward flexed trunk. (S2-2, p. 72).
 - On June 16, 2015, the skilled physical therapist discussed with the nursing and care manager S2-2's need to ambulate to at least one meal per day. During this session, she ambulated 300 feet with close supervision and decreased step length and cadence, as well as narrow base of support. She also transferred with close supervision and required cues for hand placement. S2-2 was encouraged to ambulate to meals. (S2-2, p. 73).
 - On June 18, 2015, S2-2 ambulated 250 feet times two with close supervision, as well as contact guard assist for turns and obstacles. She exhibited decreased cadence and step length, as well as narrow base of support with ambulation. She continued to require close supervision for transfers, as well as cues for hand placement and weight shifting. She was noted to have ambulated to breakfast this morning with facility staff. (S2-2, p. 73).
 - On June 23, 2015, S2-2 was discharged from skilled physical therapy. She had met the distance portion of her long-term ambulation goal, though not the assistance level as she could ambulate 300 feet with rolling walker but required close supervision and cues for increased step length and speed. She met her short-term goal for transfers though not her long-term goal as she required supervision with cues for hand placement. S2-2 was discharged from skilled physical therapy due to having reached a functional plateau. (S2-2, p. 74).

Based on a review of the medical record as a whole and the objective, clinical evidence, S2-2 was homebound for the duration of the home health episode. Leaving home required a considerable and taxing effort for S2-2. An 88-year-old beneficiary who was experiencing physical deconditioning and generalized weakness as evidenced by a fall and increased time in a wheelchair, depended on human assistance and a rolling walker to walk and transfer safely, took at least nine different medications, and was at ongoing risk for falls would require a considerable and taxing effort to leave home.

OIG's reviewer also asserts that S2-2 resided in an accessible residence without mobility barriers. While it may be reasonable for OIG to infer that CMS expects the physical characteristics of a given residence to impact the homebound analysis under Criterion Two of the homebound criteria,³⁰ OIG's reviewer provides absolutely no analysis of the beneficiary's residence to support its conclusions that the residence is both accessible and without mobility barriers. In fact, with respect to all claims where OIG's reviewer makes this assertion in support of its denial rationale, OIG's reviewer does not provide any evidence that it evaluated the physical characteristics of a given residence as relate to a specific beneficiary (e.g., assess the floor plans of the buildings and

³⁰ This is the position OIG takes in OIG OAS report A-01-1-600500 (May 2019).

/ or grounds or measure distances between the beneficiaries' rooms and facilities, such as the dining hall). OIG's reviewer appears to have simply assumed that ALFs and other senior living accommodations are automatically accessible and without mobility barriers, which is egregious and not founded in Medicare coverage criteria or any regulations pertaining to homebound status. ALFs and other senior living accommodations often have multiple floors or wings and every patient resides in a specific room which may be closer or further from certain facilities. Every residence is different. CMS guidelines perhaps suggest that the physical characteristics of a given residence may be relevant to a beneficiary's homebound status, but in order to determine the impact of the physical characteristics of a given residence on a specific beneficiary's homebound status, the physical characteristics of a given residence as relate to a specific beneficiary must actually be evaluated, and OIG has provided absolutely no evidence of this.

Furthermore, the Agency's medical records (which were provided to OIG) provide specific evidence that the beneficiaries' homes were not accessible to the beneficiaries and / or that their homes had mobility barriers specific to the beneficiaries, contrary to the reviewer's contention. For example, in regard to S2-33, the OIG reviewer asserted in its rationale as to why the beneficiary was not homebound that "[s]he was residing in an accessible assisted living facility" and "she was able to ambulate 145 feet with a rolling walker without hands on assistance". See A-03-17-00004 Sample 2-33, pp. 2-3. By way of background, beneficiary S2-33 was 84 years old and resided in an ALF called [REDACTED]. She sustained a transient ischemic attack on November 1, 2015 with resultant left-sided weakness. She was admitted to home health on November 9, 2015. Her underlying medical history was also significant for dementia, hypothyroidism, hypertension, anxiety, overactive bladder, glaucoma, back pain, and headaches. She was taking 11 prescription medications. Beneficiary S2-33 utilized a rolling walker and wheelchair for mobility. She received skilled occupational and physical therapy during the episode at issue. The documentation supports that it was 400 feet between beneficiary S2-33's room in the ALF and the dining room where meals were served. (S2-33, p. 36). As acknowledged by OIG's reviewer, beneficiary S2-33 could only ambulate 145 feet with rolling walker at the beginning of this episode, meaning that beneficiary S2-33 could not access critical amenities in the ALF with her state of function at the time. (S2-33, p. 56). Therefore, the ALF was not accessible to S2-33 as OIG's reviewer contends.³¹

OIG's reviewer also makes mistakes and asserts that beneficiaries lived in certain kinds of residences when they didn't. This appears to be a result of OIG's reviewer copying and pasting templated denial rationale. For example, in regard to S3-31, the reviewer stated the beneficiary "was residing in an accessible assisted living facility without mobility barriers." See A-03-17-00004 Sample 3-31, p. 3. This is false. Beneficiary S3-31 resided in an apartment in an independent living facility, which is not the same thing as an ALF. (S3-31, pp. 87-88, 120).³²

³¹ Another example where OIG's reviewer makes this assertion and the record directly conflicts with their conclusion is S2-3. The physical therapy initial evaluation indicates that S-3 needed to be able to ambulate 400 feet to manage navigating the ALF. (S2-3, p. 71). However, she was only able to ambulate 210 feet (with rolling walker and standby assist on level surface only) at the start of care. (S2-3, p. 69).

³² Another example is S1-30. OIG's reviewer states beneficiary resided in "an assisted living facility." See A-03-17-00004A, S1-30, p. 2. However, the beneficiary resided in an Independent Living Facility. (S1-30, p. 12).

OIG's reviewer provided the reasoning for its Medicare coverage determinations in the "Rationale" section of its claim review reports. Ambulation distance is noted in almost all the decisions as the primary factor OIG's reviewer considered in making the homebound determination. In fact, references to level of assistance needed by the beneficiary (which are almost always mischaracterized) and use on an assistive device are only in the context of ambulation distance. For example, in the rationale section for S1-4, OIG's reviewer wrote:

"At the start of care, the patient was able to ambulate 150 feet and perform transfers without hands on assistance. During his initial treatment on 11/05/2015, he was able to ambulate 200 feet, also without hands on assistance and the session included higher level gait activities such as negotiating obstacles."

See A-03-17-00004A, S1-4, p. 3. In the rationale section for S2-2, OIG's reviewer wrote:

"The medical information supports that the patient was homebound at the start of care. The patient was limited by debility and required assistance when using her rolling walker and was ambulating less than household distances. Leaving the home would have required a considerable and taxing effort for this patient at the start of care. Her condition improved, and by 5/15/2015 she was able to transfer and ambulate 200 feet without hands on assistance. She was residing in an accessible assisted living facility without mobility barriers."

See A-03-17-00004B, S2-2, p. 3. These are examples of OIG's reviewer's "complete" denial rationale; nothing more is said to support the denial. OIG's reviewer fails to acknowledge the level of assistance required by the beneficiaries to ambulate. They often use the phrase "without hands on assistance" (and sometimes in error) rather than describing the level of assistance the patient actually needed, such as supervision and / or cues (e.g., verbal or tactile). They never describe the patient's gait characteristics in their rationale, which are often abnormal; or problems with respiratory effort associated with ambulation or other functional tasks, such as shortness of breath, decreased oxygen saturation, or elevated blood pressure. They often disregard other functional deficits, like transfer abilities, or characterize transfer and ambulation abilities as being the same when they are not.

The OIG reviewer also uses clinical details inconsistently in an effort to make a determination that the beneficiary was not homebound. For example, in the rationale section for beneficiary S2-3, the reviewer states that the beneficiary "was without a history of recent fall". See A-03-17-00004, S2-3, p. 3. However, in cases where there was history of recent fall, the OIG reviewer does not acknowledge "a history of recent fall" or make any mention of falls in the rationale section at all. See, e.g., S2-29 (documented fall immediately prior to home health episode resulting in emergency room admission and fractures to left shoulder and nose) and S3-9 (numerous documented falls immediately prior to and during the home health episode under review).

Additionally, OIG's reviewer overlooks or intentionally disregards relevant clinical information. For example, in regard to S2-29, OIG's reviewer writes that there were "no weight-bearing precautions" in the rationale section of its claim review report. See A-03-17-00004, S2-29, p. 2.

This statement is misleading because all physician-mandated precautions related to functional status post fracture would be material to the question of whether beneficiary S2-29 had a normal inability to leave her home and a considerable and taxing effort would be required for her to leave home, not just “weight-bearing precautions”. By way of background, beneficiary S2-29 was an 82-year-old elderly female when she was admitted to home health on July 19, 2015. Beneficiary S2-29 resided alone in a private residence. Prior to her admission to home health, beneficiary S2-29 sustained a fall when she was taking out the garbage. She was taken to the emergency room and assessed with left humerus and nasal fractures. She was discharged home with home care. Her medical history was significant for another fall in 2013 which resulted in a right hip fracture which required open reduction and internal fixation (ORIF). Beneficiary S2-29’s medical history was also significant for depression, osteoarthritis, B12 deficiency, gastrointestinal reflux disease (GERD), and degenerative joint disease (DJD). Beneficiary S2-29 utilized a cane during ambulation. She received skilled nursing, skilled physical therapy, skilled occupational therapy, and home health aide services during the episode at issue.

OIG’s reviewer only references weight-bearing precautions. However, as per the July 21, 2015 physical therapy assessment, beneficiary S2-29 was required to wear a sling for her left shoulder at all times (except during showers) to immobilize her left upper extremity.³³ (S2-29, p. 82). Notably, beneficiary S2-29 had a history of multiple falls that resulted in fractures; the latest fall—immediately prior to this home health admission—occurred when beneficiary S2-29 was taking out the garbage. She was, of course, not wearing a sling to her left shoulder at that time. Beneficiary S2-29 was at risk of falls *without* a mandated sling, let alone with a sling immobilizing her left upper extremity as was the case upon admission to home health. Beneficiary S2-29’s physician also ordered that active range of motion (AROM) of left shoulder could begin on August 19, 2015 (one month into the home health episode under review), but she remained restricted to AROM only at this time. (S2-29, p. 120). OIG’s reviewer does not acknowledge this anywhere in their claim review report. There were numerous precautions maintained by her orthopedic physician that affected this beneficiary’s functional abilities which OIG’s reviewer either overlooked or intentionally disregarded and are certainly relevant to the homebound analysis.

Based on the foregoing, it is incontrovertible that OIG’s reviewer misapplied Medicare coverage criteria with regard to homebound status. OIG’s reviewer clearly did not consider the medical records as a whole or base their determinations on objective, clinical evidence regarding each beneficiaries’ individual need for care. OIG’s reviewer also applied an illegal rule of thumb with respect to ambulation distance, considered clinical evidence differently from one claim to the next, and made inappropriate assumptions regarding beneficiary residences. We respectfully request that the claims at issue be re-reviewed in accordance with Medicare coverage criteria by a qualified reviewer and in consideration of the objective, clinical evidence contained in the medical records as a whole.

³³ OIG’s reviewer acknowledges in the Facts section of its claim review report that S2-29 was wearing a sling to her left arm, but OIG’s reviewer does not acknowledge that this was expressly mandated by her orthopedic physician or discuss this requirement in the context of the beneficiary’s ambulation abilities where the reviewer takes the time to state there were no weight-bearing precautions (but then conveniently fails to acknowledge the relevant precautions that actually were in place). See A -03-17-00004A, S2-29, pp. 1-2.

2) Skilled Need Requirement

OIG's reviewer has alleged that 12 of the audited claims did not meet Medicare requirements for coverage of skilled nursing or therapy services. However, OIG's reviewer misapplied Medicare coverage criteria. Federal regulations clearly provide that homebound Medicare beneficiaries are entitled to receive home health if they are in need of skilled nursing care on an intermittent basis or physical therapy or speech-language pathology, or have a continuing need for occupational therapy, so long as all other conditions of payment are met.³⁴ The determination of whether care is reasonable and necessary must be "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."³⁵ Medicare guidelines require that medical necessity determinations be based upon objective clinical evidence regarding the beneficiary's individual need for care.³⁶ Southeastern disputes all of OIG's adverse determinations for its failure to evaluate the Agency's medical records in accordance with federal regulations and Medicare guidelines.

OIG cites one example in its draft report of a claim where its reviewer found that the home health services received by the beneficiary, specifically the speech therapy services, were purportedly not medically reasonable and necessary. We address OIG's example as follows:

Example 3
Beneficiary S3-20
DOS 03/17/16-04/29/16

In the draft report, OIG states that all of the skilled speech therapy services were denied because:

"A beneficiary with a medical history of cerebral vascular accident with right-sided weakness, aphasia, dysphagia, atrial fibrillation, and congestive heart failure was homebound. There were no signs or symptoms of aspiration and no history of pneumonia, and the patient denied difficulty with swallowing. Speech therapy services were ordered for treatment of dysphagia. Southeastern provided skilled nursing care, physical therapy, and speech therapy to the homebound beneficiary. However, there was no medical need for speech therapy—the patient had aphasia, which is a long-term condition."

OIG's reviewer otherwise found that the Agency satisfied all other clinical factors for home health. OIG's determination regarding this beneficiary's lack of need for skilled speech therapy is in error.

CMS guidelines specifically provide that "skilled speech-language pathology services are covered when the individualized assessment of the patient's clinical condition demonstrates that the specialized judgment, knowledge, and skills of a qualified speech-language pathologist are necessary".³⁷ Skilled speech therapy services are covered to address cognitive communication

³⁴ See Social Security Act §§ 1814(a)(2)(C) and 1835(a)(2)(A); and 42 C.F.R. § 409.42.

³⁵ Medicare Benefit Policy Manual Ch. 7 § 20.1.2 (Pub. 100-02, Rev. 208) (2015).

³⁶ *Id.*

³⁷ Medicare Benefit Policy Manual Ch. 7 § 40.2.3 (Pub. 100-02, Rev. 208) (2015).

deficits and aphasia when the specialized judgment, knowledge, and skills of a qualified speech therapist are necessary.³⁸ The home health record clearly supports that the patient was in need of a complete speech program for dysphagia, aphasia, and cognitive communication deficits. Aspiration, history of pneumonia, and difficulty swallowing are not required in order for a beneficiary to be eligible to receive skilled speech therapy. Medicare coverage criteria also do not provide that speech therapy services only apply to short-term conditions (as opposed to “long-term conditions”) as OIG’s reviewer contends.³⁹ In fact, the Medicare guidelines provide that,

“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 issue is whether the skills of a therapist are needed to treat the illness or injury, or whether the services can be carried out by unskilled personnel.”⁴⁰

OIG’s reviewer provides no analysis as to whether the skills of a speech language pathologist were needed to treat S3-20’s documented dysphagia, aphasia, and cognitive communication deficits in its claim review report. OIG’s reviewer only assesses the beneficiary’s medical condition (and incorrectly at that).

By way of background, S3-20 was an 81-year-old beneficiary when she was admitted to home health on March 17, 2016. Prior to her admission to home health, S3-20 was hospitalized for congestive heart failure and dysphagia. She was discharged from inpatient care on March 15, 2016. S3-20 resided in an independent living apartment at [REDACTED] which she had just moved in to. On admission to home health, her primary diagnosis was heart failure and her other diagnoses included other sequelae of cerebral infarction, generalized muscle weakness, dysphagia, and severe expressive aphasia.

As acknowledged by the OIG reviewer, per the initial skilled nursing assessment on March 17, 2016, S3-20 had severe difficulty with speech, limited to single words or short phrases. See A-03-17-00004A, S3-20, p. 2. Per section M1230, S3-20 had severe difficulty expressing basic ideas or needs and required maximal assistance or guessing by listener (and speech was limited to single words or short phrases). (S3-20, pp. 20-33).

³⁸ *Id.* Medicare guidelines provide that speech language pathology services are covered “where a skilled service can only be provided by a speech-language pathologist and where it is reasonably expected that the skilled service will improve, maintain, or prevent or slow further deterioration in the patient’s ability to carry out communication”; “to establish a hierarchy of speech-voice-language communication tasks and cueing that directs a patient toward speech-language communication goals in the plan of care would be covered speech-language pathology”; and “to assist patients with aphasia in rehabilitation of speech and language skills are covered when needed by a patient”.

³⁹ Given OIG’s reviewer’s comment regarding a “long-term condition”, it is probably pertinent to mention the coverage of maintenance therapy in accordance with the Jimmo Settlement which provides,

“Skilled therapy services are covered when an individualized assessment of the patient’s clinical condition demonstrates that the specialized judgment, knowledge, and skills of a qualified therapist (“skilled care”) are necessary for the performance of a safe and effective maintenance program. Such a maintenance program to maintain the patient’s current condition or to prevent or slow further deterioration is covered so long as the beneficiary requires skilled care for the safe and effective performance of the program.”

⁴⁰ Medicare Benefit Policy Manual Ch. 7 § 40.2.1 (Pub. 100-02, Rev. 208) (2015).

Per the occupational therapy assessment dated March 18, 2016, one of S3-20's diagnoses was pneumonia, contrary to the OIG reviewer's assertion that S3-20 did not have a history of pneumonia. (S3-20, pp. 96-97). The occupational therapist also documented on March 18, 2016 that S3-20 was unable to express details of her expectations / goals for occupational therapy due to aphasia (aside from that she wanted to acclimate to her new facility). (S3-20, pp. 96-97). Per the April 6, 2016 occupational therapy note, the occupational therapist had communicated with the speech language pathologist who relayed that S3-20 had receptive / expressive aphasia; as such, she needed instructions broken down and simplified for increased understanding. (S3-20, p. 101).

The speech therapy evaluation on March 21, 2016 noted moderate/severe impairment of receptive language and expressive language skills, as acknowledged by the OIG reviewer. *See* A-03-17-00004A, S3-20, p. 2. Furthermore, on evaluation, S3-20 was unable to produce a few rote expressions with or without cues beyond "okay" and she was not attempting to use verbal communication resulting in risk of social isolation in her new residence. The speech therapist devised goals for S3-20 to accomplish over the course of skilled speech therapy (nine weeks), including to be able to produce five common phrases using strategies such as dynamic temporal and tactile cueing (DTTC) with prompts. (S3-20, pp. 107-108).

The home health record thus establishes that S3-20 was eligible for skilled speech therapy pursuant to Medicare coverage criteria to address her dysphagia, aphasia, and cognitive communication deficits, and that the skills of a skilled speech therapist were needed to treat S3-20's illness. The therapy notes demonstrate S3-20's skilled need and the specialized judgment, knowledge, and skills of the qualified speech therapist, including as follows:

- On March 2016, the skilled speech language pathologist utilized a picture description task during the session wherein the beneficiary was encouraged to use verbalization or gestures to communicate intent. Out of 12 opportunities, the beneficiary used gestures 75% of the time and did not provide a response 25% of the time. The skilled speech language pathologist also had the beneficiary work on two-step directions with one repetition allowed. The beneficiary was unable to complete two steps without cues. She was able to complete two of five opportunities with cues and prompts. Finally, the speech therapist had the beneficiary work with playing cards by naming the color (black or red) to work on articulation and motor transition. The beneficiary completed this task at 65%. She was noted to do well with phonemic placement cues. (S3-20, p. 109).
- On March 30, 2016, the speech language pathologist had the beneficiary attempt to count metronome beats (set at 40 beats per minute) to work on temporal processing and articulation precision. The beneficiary was only able to count four numbers in a row at the most over four trials. The therapist also had the beneficiary work on repetition with a metronome. She was able to do so with 27% success over two trials. Finally, the speech language pathologist utilized DTTC procedure with the phrase "How are you?". The beneficiary was able to produce with and without model and use in functional manner at 6 of 8 attempts with cues and 2 of 8 attempts without cues. The speech therapist introduced another phrase in a similar manner with similar results. The beneficiary was able to alternate between the

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- phrases with 50% accuracy. The therapist noted that the beneficiary was receptive to DTTC approach. (S3-20, p. 111).
- On April 1, 2016, the speech language pathologist reviewed the phrases with the beneficiary that were introduced during the March 30, 2016 visit. The beneficiary was able to produce one phrase at repetitive level and the other with modeling only. The beneficiary showed the therapist her Dynavox AAC program. She had two phrases that she used to use and these phrases were noted to be similar to those that were being addressed in therapy (e.g., "How are you?"). The beneficiary exhibited difficulty manipulating screen and finding phrases efficiently and the therapist was going to try and improve the efficiency of the AAC device. (S3-20, p. 112).
 - 04/06/16: The therapist noted that the beneficiary was unable to repeat the phrase "I am happy to see you" with two attempts. Using DTTC, however, the beneficiary was able to produce the phrase with 60% accuracy. The speech therapist noted that the beneficiary was moving through the DTTC hierarchical steps with increased ease and that they would continue with DTTC. (S3-20, p. 113).
 - During the April 11, 2016 skilled speech therapy session, the therapist had the beneficiary work on a label task with close approximation. She was able to complete the task at 10% without cues and 60% with phonemic cues; otherwise, she erred the other 30%. The therapist also had the beneficiary work on a sentence completion task with picture cues which she was able to successfully complete 80% of the time; she was also able to retell the sentence 60% of the time without cues. The speech therapist noted that the beneficiary had been completing her home practice exercises. (S3-20, p. 114).
 - The speech therapist had the beneficiary work on answering questions with linguistic cues on April 13, 2016, such as "What did you have for lunch?" The beneficiary had trouble with single word responses and was only successful 50% of the time. The beneficiary became fatigued and frustrated during this task. She was able to increase her success rate by 23% to 73% by reading printed cues for questions. (S3-20, p. 115).
 - During the April 18, 2016 session, the speech therapist reviewed the steps to review common phrases on the beneficiary's AAC program. There were many steps for the beneficiary to sequence and it was hard for her. The therapist had the beneficiary work on a target word repetition task which she was able to do with 90% success with picture and written word cues provided by the therapist. (S3-20, p. 116-117).
 - On April 29, 2016, the skilled speech therapist determined that the beneficiary had made modest gains over the course of therapy. During this session, the therapist had the beneficiary work on a functional phrase task, which she was able to complete with 30% accuracy. The therapist also had the beneficiary work on a two-step functional direction task. For example, the therapist set up a field of four items and then would instruct the beneficiary to "pick up the comb and hand it to me." The beneficiary was able to complete this task with 50% accuracy. Finally, the therapist had the beneficiary work on a naming task. She was able to complete 7 of 15 opportunities without cues, 3 of 15 with cues, and she was unable to respond for 5 of 15 opportunities. (S3-20, p. 118-119).

In regard to the speech therapy sessions, OIG's reviewer says only that the therapist used "*prompts to increase phrases and verbal communication*" and "*reading cues to assist were added to the goals*" during the April 18, 2016 reassessment. See A-03-17-00004, S3-20, p. 2. This grossly

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underrepresents and mischaracterizes the skilled speech therapy services provided to this beneficiary. Speech therapy was medically reasonable and necessary to treat S3-20's severe receptive / expressive aphasia and cognitive communication deficit, particularly since she had just moved into an independent living apartment and needed to be able to communicate with staff and other residents. Only a licensed skilled speech therapist could administer the therapy tasks that were utilized which involved specialized techniques, such as DTTC, including the hierarchical steps necessary to build a patient's abilities using DTTC.

We also observed a trend by OIG's reviewer in cases of partial denials for skilled services.⁴¹ OIG's reviewer applied an arbitrary rule of three in these cases, always allowing the first three visits and then denying the remaining visits. Medicare guidelines specifically prohibit "rules of thumb" and "numerical utilization screens". The application of this arbitrary rule is also clearly counter to the fundamental tenants of skilled care, which include that coverage for skilled services should be based on each patient's individual need for skilled care and their unique clinical condition.

To provide an example, OIG's reviewer allowed the first three skilled physical therapy visits for S2-32 but then denied the remaining 14 skilled physical therapy visits.⁴² In regard to physical therapy, the OIG reviewer alleged that the ongoing skilled physical therapy services were "excessive" after the third visit.⁴³ See A-03-17-00004B, S2-32, p. 3. However, CMS coverage guidelines state that therapy services are covered if they are 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. Skilled physical therapy services include gait training for a patient whose ability to walk has been impaired by neurological abnormality which requires the skills of a qualified physical therapist and constitute skilled physical therapy and are considered reasonable and necessary if they can be expected to materially improve or maintain the patient's ability to walk or prevent or slow further deterioration of the patient's ability to walk. Skilled physical therapy services also include therapeutic exercises and periodic reassessments.⁴⁴

By way of background, S2-32 was an 87-year-old beneficiary when she was admitted to home health on May 11, 2016. S2-32 resided in a memory unit at [REDACTED]. She suffered from repeated falls, gait and mobility abnormalities, hypertension, dementia, anemia, depression, and fibromyalgia. S2-32's functional limitations included severe memory loss (to the extent that

⁴¹ These claims included: S2-15, S2-19, S2-31, S2-32, S3-23, S3-28, and S3-29.

⁴² OIG's reviewer's determination to allow four visits (one skilled nurse visit and three skilled physical therapy visits) conveniently triggered a low utilization payment adjustment (LUPA) (i.e., an episode with four or fewer visits is paid the national per visit amount by discipline adjusted by the appropriate wage index based on the site of service of the beneficiary). OIG's payment amount for these four visits (\$576.11) appears to be in error because it does not appear that OIG increased the payment by an add-on amount as required since this LUPA occurred as the only episode. See Medicare Benefit Policy Manual Ch. 7 § 10.7. The correct payment amount would be \$703.96. As explained in this response document, the Agency does not agree with OIG's decision to deny 14 physical therapy visits.

⁴³ The OIG reviewer allowed the first three physical therapy episodes as follows: "A physical therapy evaluation was indicated to assess the patient's mobility and need for an assistive device or home exercise program. A second skilled visit reasonably was needed to reassess her condition and to evaluate her caregiver's understanding of the information provided and to answer any questions. A third visit was reasonable to reassess her condition and make any further recommendations if needed." See A-03-17-00004B, Sample 2-32, pp. 2-3.

⁴⁴ Medicare Benefit Policy Manual Ch. 7 § 40.2.2 (Pub. 100-02, Rev. 208) (2015).

supervision was required), constant confusion, unsteady gait, and history of falling. S2-32 had a face-to-face encounter with her physician on March 31, 2016 and the encounter note provides,

“She has been having episodes of anxiety and leaving her apartment in the middle of the night. She goes to the lobby and is confused and upset looking for her children. This occurs more after the patient has been with family members that day. She no longer goes out of her apartment and they are taking her meals to her. She is friendly and talkative with the aides when they come into her apartment. She gets anxiety and finds excuses not to leave for Doctor appts. Doesn’t recall ever being a patient here”.

(S2-32, p. 11). S2-32 was only able to walk with use of a rolling walker as well as the supervision or assistance of another person. S2-32 received skilled nursing and skilled physical therapy during the episode at issue.

The home health record clearly establishes that the skilled physical therapy services were medically reasonable and necessary for the May 17, 2016 through June 27, 2016 period (the period of disallowance) as follows:

- On May 11, 2016, S2-32 was evaluated by a skilled physical therapist. Her diagnoses were indicated to be a decrease in functional mobility and history of falls. S2-32 was noted to be modified independent in terms of her prior level of function. In terms of her functional status, she required supervision for tub transfers and ambulating with her rolling walker. Her static standing balance was Fair. S2-32’s endurance was graded Fair-. She ambulated 229 feet over the course of three minutes and 30 seconds with her rolling walker and needed to make stops due to fatigue / shortness of breath. She completed the Timed Up and Go (TUG) assessment in 27 seconds. She completed three chair raises. The skilled physical therapist determined that S2-32 would benefit from skilled physical therapy services and that her rehabilitation potential was good. The skilled physical therapist developed the following short- and long-term goals for S2-32 to accomplish over the course of nine weeks:

Goal	Timeframe
5 chair raises	Short-term
TUG in 26 seconds	Short-term
Ambulate 300 feet	Short-term
6 chair raises	Long-term
TUG in 24 seconds	Long-term
Ambulate 500 feet	Long-term

(S2-32, pp. 50-51).

- On May 13, 2016, the skilled physical therapist worked with S2-32 on completing therapeutic exercises involving active range of motion to her bilateral lower extremities, including seated hip flexion, long arc quad, hip adduction with pillow, and hip abduction with knees extended. She completed three sets of 10 repetitions each with rest breaks. S2-32 performed sit-to-stand exercises at two sets of five repetitions. She participated in gait

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training activities with rolling walker within secure memory unit to work on endurance and safety with ambulation. Notably, S2-32 reported “heaviness in chest” when ambulating and her blood pressure was very elevated at 160/80mmHg. (S2-32, p. 52).

- When the skilled physical therapist presented for a visit on May 16, 2016, S2-32 complained of feeling tired. The therapist encouraged the patient / facility staff to increase the time she spent out of her bed during the day. The staff agreed to go back to meals in the facility dining room during the day (rather than bringing the meals to S2-32’s room). The skilled physical therapist worked with S2-32 on therapeutic exercises, gait training, and balance activities during this session. S2-32 ambulated distances up to 150 to 175 feet in secure memory unit with rolling walker and supervision. She completed seated therapeutic exercises (hip flexion, long arc quad, hip abduction with knees extended) at 30 repetitions each. (S2-32, p. 53).
- On May 18, 2016, S2-32’s daughter was present during the skilled physical therapy visit. The skilled physical therapist encouraged the patient’s family to ambulate with her and to attend activities outside of her room. S2-32 continued to ambulated distances up to 150 to 175 feet in secure memory unit with rolling walker and rest breaks as needed. She also participated in static standing balance exercises with emphasis on upright posture. (S2-32, p. 53).
- On May 24, 2016, the skilled physical therapist noted that the patient had gone to the emergency room the night before for diarrhea and black stool, as relayed by the facility staff. S2-32 was back in her room and able to participate in skilled physical therapy on this date. The skilled physical therapist worked on gait training, balance activities, and safety instruction during this session. The skilled physical therapist provided safety education to reduce falls. The skilled physical therapist incorporated balance challenges to reduce her fall risk by having S2-32 reach out of her base of support. (S2-32, p. 54).
- On May 25, 2016, the skilled physical therapist worked with S2-32 on therapeutic exercises and gait training on this date. S2-32 was able to perform seated bilateral lower extremity therapeutic exercises in her room to increase her muscle strength at three sets of 10 repetitions each, including long arc quad, marches, and ankle pumps. S2-32 worked on ambulation in the hallway with use of her rolling walker to improve gait pattern, increase safety with directional changes, improve posture, and improve heel strike. (S2-32, p. 55).
- The skilled physical therapist noted that S2-32 continued to require verbal encouragement from staff and family to get out of bed and perform activities outside of her room on May 27, 2016. On this date, the therapist worked with S2-32 on balance activities to challenge her balance and reduce her fall risk, as well as gait training with rolling walker in unit with supervision and verbal cues to improve gait pattern. (S2-32, p. 56).
- S2-32 complained of diarrhea symptoms on May 31, 2016. The skilled physical therapist worked with S2-32 on therapeutic exercise, gait training, safety instruction, and fall prevention activities. The skilled physical therapist worked with S2-32 on improving upright posture and endurance during ambulation. The therapist educated S2-32 and staff on fall prevention. S2-32 was advised to wear slippers when out of bed instead of walking around in her bare feet. S2-32 completed 30 repetitions of therapeutic exercises (hip flexion, long arc quads, and hip abduction with knee extended) and 10 repetitions of sit-to-stand. (S2-32, p. 57).

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- During gait training on June 1, 2016, S2-32 ambulated 200 to 225 feet with supervision and verbal cues from the skilled physical therapist for technique. (S2-32, p. 57).
- S2-32 complained of light headedness and nausea on June 7, 2016 and had skipped breakfast. The skilled physical therapist worked with S2-32 on balance challenges (dynamic balance) and gait training activities with rolling walker within secure memory unit (specifically negotiating obstacles). (S2-32, p. 58).
- S2-32 was feeling better on June 9, 2016. S2-32 participated in gait training activities but declined therapeutic exercises. She was able to ambulate 175 feet with verbal encouragement. (S2-32, p. 58).
- On June 10, 2016, he skilled physical therapist worked with S2-32 on balance activities to promote improved postural control and balance, as well as gait training, including negotiating obstacles. (S2-32, p. 58).
- The skilled physical therapist worked with S2-32 on gait training and balance activities (supported and unsupported) on June 13, 2016. S2-32 was able to ambulate 150 feet with rolling walker and supervision for improved endurance and safety. S2-32 was noted to have tolerated the session well. (S2-32, p. 59).
- The skilled physical therapist worked with S2-32 on gait training and balance activities on June 15, 2016. S2-32 was able to ambulate 170 to 200 feet with rolling walker and supervision. The skilled physical therapist provided verbal cues for safety to improve gait pattern and endurance. In terms of balance activities, S2-32 performed static standing balance activities unsupported with wide base of support, narrow base of support, and in semi-tandem stance with one-to-two minute holds each to improve her ability to right self and standing tolerance. (S2-32, p. 59).
- The skilled physical therapist reassessed S2-32 on June 20, 2016. She could complete TUG in 25 seconds, and she was able to complete seven chair raises. S2-32 participated in gait training and was able to ambulate 200 feet with brief standing rest periods. The therapist indicated discharge planning for the following week as S2-32 appeared to be reaching her maximum potential. (S2-32, p. 60).
- The skilled physical therapist worked with S2-32 on proper sit-to-stand techniques and gait training to improve her gait pattern and increase her endurance on June 23, 2016. S2-32 was able to ambulate 200 feet with use of rolling walker. The skilled physical therapist called S2-32's daughter in regard to the last covered day of therapy. (S2-32, p. 61).
- The skilled physical therapist performed a discharge assessment on June 27, 2016. S2-32 was discharged because she had achieved her maximum rehabilitation potential. The skilled physical therapist reviewed safety / fall prevention strategies. S2-32 was able to ambulate 250 to 275 feet with rolling walker. She required verbal cues to improve her upright posture. Her endurance was graded Good-. She completed TUG in 24 seconds. She could complete six chair raises. S2-32 continued to require cueing to encourage out of room activities. S2-32 was able to improve her functional abilities from the time of initial evaluation as follows:

Functional Area	Initial evaluation	Discharge
	05/11/16	06/27/16
Endurance	Fair-	Good-

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TUG	27 seconds	24 seconds
Ambulation	229 feet with rolling walker in 3 minutes, 30 seconds with supervision and rest periods due to fatigue / shortness of breath	250-275 feet with rolling walker and verbal cues to improve upright posture
Chair raises	3	6
Strength	3+/5	Within functional limits

(S2-32, pp. 34-48, 62-63).

S2-32's improvement is thus evidenced by objective successive measurements. Physical therapy focused on restoring S2-32's function which had declined as a result of her increased confinement to her bedroom. S2-32's prior level of function was modified independent. However, she had become increasingly confused and anxious secondary to disease progression of dementia prompting her to stay in her bedroom most of the time, including for meals. This resulted in physical deconditioning. During the initial physical therapy evaluation, S2-32 was observed to become short of breath and fatigued with ambulation and demonstrate decreased safety awareness as evidenced by stooped posture and leaning over her rolling walker. Skilled physical therapy focused on gait training to improve S2-32's endurance and safety, as well as on balance activities and therapeutic exercises. The skilled physical therapist encouraged the patient, family, and staff to have S2-32 engage in activities outside of her room and to ambulate with the patient. S2-32 demonstrated improvement in all functional areas through participation in skilled physical therapy and was discharged on June 27, 2016 by which time she achieved her maximum rehabilitation potential, a couple of weeks prior to the end of the home health episode (July 9, 2016). Skilled physical therapy was thus medically reasonable and necessary for S2-32 through June 27, 2016. OIG's reviewer's determination to allow the first three skilled physical therapy visits and deny the rest of the visits represents an improper numerical utilization screen.

Relative to the issue of medical necessity, it appears that OIG's reviewer failed to grant any deference to the treating providers who actually treated the patients and ordered the home health services for the patients. Medicare program regulations provide that a "physician has a major role in determining utilization of health services furnished by providers".⁴⁵ Additionally, courts have long acknowledged that the treating physician should be granted additional weight and deference in any dispute over medical necessity.⁴⁶ The reasoning underpinning these holdings is abundantly

⁴⁵ See 42 C.F.R. § 424.10(a).

⁴⁶ In *State of New York o/b/o Holland v. Sullivan*, the United States Court of Appeals for the Second Circuit concluded that,

"Though the considerations bearing on the weight to be accorded a treating physician's opinion are not necessarily identical in the [Social Security disability] and Medicare context, we would expect the Secretary to place significant reliance on the informed opinion of a treating physician and either to apply the treating physician rule, with its component of 'some extra weight' to be accorded that opinion, or to supply a reasoned basis, in conformity with statutory purposes, for declining to do so."

clear: a treating and ordering physician has a unique opportunity to personally examine and assess the clinical condition of a patient and subsequently prescribe a course of treatment. A third-party reviewer (such as OIG's independent medical review contractor), by contrast, must base its opinion on a cold record, often years after the treating physician evaluated the patient. OIG's reviewer failed to give the treating providers any deference even though they agree that in all cases, the home health certification and plan of care documentation was sufficient and home health care was delivered in accord with home health certifications and plans of care.

Based on the foregoing, it is incontrovertible that OIG's reviewer misapplied Medicare coverage criteria with regard to skilled need. OIG's reviewer clearly did not consider the medical records as a whole or base their determinations on objective, clinical evidence regarding each beneficiaries' individual need for care. OIG's reviewer also applied an illegal rule of thumb and numerical utilization screen by arbitrarily only allowing three services for the claims where OIG's reviewer determined that beneficiaries only had skilled need for a portion of the home health episode. Furthermore, OIG's reviewer didn't give any deference to the treating physicians despite that it found all home health certification and plan of care documentation to be valid and all home health services to have been rendered in accordance with the certifications and plans of care. We respectfully request that the claims at issue be re-reviewed in accordance with Medicare coverage criteria by a qualified reviewer and in consideration of the objective, clinical evidence contained in the medical records as a whole.

In regard to all of the denied claims at issue in the draft report, Southeastern does not agree with OIG's medical review determinations. Southeastern has prepared a claim response summary for each denied claim which addresses each of OIG's reviewer's denial reasons. While it is Southeastern's position that the records it provided to OIG support that home health services were ordered and rendered in accordance with Medicare coverage criteria, Southeastern has secured additional medical records for many of the denied claims to corroborate homebound status and skilled need. These materials are enclosed with Southeastern's claim response summaries in **Appendix B**.

VI. Incorrect "Correct" Payment Amount Recalculations

Some of the claims at issue were denied only in part such that OIG's reviewer recalculated the "correct" payment amount that the Agency should have been reimbursed. However, it appears that

927 F.2d 57, 60 (2d Cir. 1991); see also *Schiller v. Bowen*, 851 F.2d 43, 47 (2d Cir. 1988). Similarly, in *Marsh v. Bowen*, the United States District Court for the District of Connecticut observed that there is a "well-settled principle that the opinion of the treating [physician] is entitled to special deference unless it is contradicted by substantial evidence." 1985 WL 69272 (D. Conn. 1985) (emphasis added). The Court ultimately held that the opinion of a medical advisor representing the government was *not* sufficient to equal the substantial evidence necessary to overcome the opinion of treating physicians. *Id.* This principle, known as the "Treating Physician Rule", has been applied in a number of cases where courts have held that a treating physician's determination regarding the care of his or her patient is of paramount importance. See *Keefe v. Shalala*, 71 F.3d 1060, 1064 (2d Cir. 1995) (suggesting that the treating physician rule applies to Medicare cases); *Klementowski v. Sec'y of HHS*, 801 F. Supp. 1022 (W.D.N.Y. 1992) (holding that the treating physician rule applies in a case where a plaintiff sought reimbursement for air ambulance services under Medicare Part B); *Hirsh v. Bowen*, 655 F. Supp. 342 (S.D.N.Y. 1987); *Gartmann v. Sec'y of HHS*, 633 F. Supp. 671 (E.D.N.Y. 1986).

OIG's reviewer's recalculations are not always correct. To be perfectly clear, Southeastern does not agree with OIG's reviewer's denials. However, when calculating the "correct" payment amounts based on OIG's reviewer's denials, Southeastern found the following discrepancies:

Claim	OIG's Calculation of the Correct Payment Amount	Southeastern's Calculation of the Correct Payment Amount
S2-2	\$3,089.21	\$3,150.00
S2-32	\$576.11	\$703.96
S3-20	\$5,816.31	\$5,935.01
S3-29	\$4,340.18	\$4,428.75

We therefore respectfully request that OIG review and correct these payment amounts.

VII. Request for Redaction of Southeastern's Name in the Final Report

We hereby request that Southeastern's name be redacted in the final report published by OIG. The publication of the final report with Southeastern's name will cause serious harm to the Agency's reputation and serious financial loss. There is no purpose for publishing the Agency's name and Southeastern does not consent to OIG doing so.

██████████, the Assistant Regional Inspector General for Audit Services, instructed Southeastern that its request for redaction of the final report should be made in writing separately from its response to the draft report. Per these instructions, Southeastern requested that the final report be redacted in correspondence to OIG dated May 21, 2019. Southeastern did not receive a written response from OIG. When we followed-up on the redaction request during the Exit Conference, ██████████ indicated that the request had been forwarded to counsel and considered, and that OIG still intended to publish the final report unredacted as of that time. ██████████ also addressed the list of published redacted reports that were detailed in Southeastern's May 21, 2019 correspondence. ██████████ said that those particular reports were redacted because the provider names were names of individuals. However, we looked into this further and confirmed that this is not actually true. For example, in regard to OIG Audit No. A-07-14-01146 (August 2016), we spoke to counsel who represented the "Kansas Physical Therapy Practice" and he confirmed that, in fact, the provider's name is not an individual's name. We sent another letter to OIG on July 22, 2019, this time to the attention of OIG Senior Counsel ██████████⁴⁷. We relayed our findings with respect to OIG Audit No. A-07-14-01146 and renewed our request for redaction. ██████████ never responded to our letter or efforts to follow-up.

As an independent provider, the Agency's major competitors are either health system affiliated home health agencies or national, publicly traded agencies. These organizations already have an unfair advantage in restricting Southeastern's access to referral sources. The hospital systems try to control the market by keeping all hospital referrals for home health within their affiliated home care companies. Publishing the OIG report unredacted will cause reputational damage that will be used by the Agency's competitors to further restrict their referrals.

⁴⁷ ██████████ participated in the Exit Conference.

The damage of an unredacted final report to Southeastern's reputation will also significantly impact the Agency's ability to recruit and retain new employees in what is already a tight employment market. OIG's final reports are usually picked up by local news outlets. Once this occurs, the Agency's competitors are very likely to aggressively utilize the OIG report to gain a competitive advantage with its referral sources. The health care community almost certainly won't notice the actual 17.77% error rate or be privy to the fact that disallowed claims are being appealed; rather, the sensationalized \$4.2 million alleged overpayment will be what sticks with them.

VIII. Conclusion

As established herein, the claims selected for review were not billed incorrectly as OIG asserts. Additionally, OIG's sampling methodology is statistically invalid. We respectfully request that OIG direct its independent medical review contractor to re-review the denied claims in accordance with published Medicare guidelines in advance of finalizing its report and that any refund recommendation be based on the actual payment amounts. While Southeastern adamantly disagrees with OIG's reviewer's findings as summarized in its draft report and intends to vigorously contest OIG's reviewer's adverse determinations through the Medicare administrative appeals process, Southeastern does appreciate the opportunity to respond to the draft report.

Sincerely,
/s/ Lorraine A. Rosado
Liles Parker PLLC

Encl.
Appendix A (Statistical Expert Report)
Appendix B (29 Claim Response Summaries and Medical Records)

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