

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**MEDICARE HOME HEALTH AGENCY
PROVIDER COMPLIANCE AUDIT:
RESIDENTIAL HOME HEALTH**

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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: April 2020

Report No. A-05-16-00063

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



Why OIG Did This Audit

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

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

Our objective was to determine whether Residential Home Health (Residential) 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 independent medical review.

Medicare Home Health Agency Provider Compliance Audit: Residential Home Health

What OIG Found

Residential did not comply with Medicare billing requirements for 11 of the 100 home health claims that we reviewed. For these claims, Residential received overpayments of \$16,927 for services provided in calendar years (CYs) 2014 and 2015. Specifically, Residential incorrectly billed Medicare for beneficiaries who (1) were not homebound or (2) did not require skilled services. On the basis of our sample results, we estimated that Residential received overpayments of at least \$2 million in CYs 2014 and 2015. All of the incorrectly billed claims are now outside of the Medicare reopening period.

What OIG Recommends

We recommend that Residential 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 our recommendations. We also recommend that Residential strengthen its procedures to ensure that (1) the homebound statuses of Medicare beneficiaries are verified and continually monitored and the specific factors qualifying beneficiaries as homebound are documented and (2) beneficiaries are receiving only reasonable and necessary skilled services.

In written comments on our draft report, Residential disagreed with our findings and recommendations and stated that it plans to contest our findings through the appeals process. After reviewing the response we received from Residential and further considering our medical review results, we maintain that our findings and recommendations 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) Comprehensive Error Rate Testing program determined 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. Residential Home Health (Residential) was one of these HHAs.

OBJECTIVE

Our objective was to determine whether Residential 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 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 home health agencies.

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)).

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 may request the reopening of initial claims determinations, submit amended cost reports, or use any other appropriate reporting process.⁵

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

Residential Home Health

Residential is a for-profit home healthcare provider with locations throughout the Midwest, including a provider office in Troy, Michigan. Residential’s MAC, National Government Services, paid Residential approximately \$83 million for 26,075 claims for services provided in CYs 2014 and 2015 (audit period) on the basis of CMS’s National Claims History (NCH) data.

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.

HOW WE CONDUCTED THIS AUDIT

Our audit covered \$79,443,274 in Medicare payments to Residential for 22,609 claims.⁶ These claims were for home health services provided during the most recent timeframe for which data were available at the start of the audit (CYs 2014 and 2015).⁷ We selected a stratified random sample of 100 claims with payments totaling \$377,485 for review. We evaluated compliance with selected billing requirements and sent the claims to an independent medical review contractor to determine whether the services met coverage, medical necessity, and coding requirements.

We conducted this performance audit in accordance with generally accepted government auditing standards (GAGAS). 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

Residential did not comply with Medicare billing requirements for 11 of the 100 home health claims that we reviewed. For these claims, Residential received overpayments of \$16,927 for services provided in CYs 2014 and 2015. Specifically, Residential incorrectly billed Medicare for services provided to beneficiaries who:

- were not homebound and
- did not require skilled services.

These errors occurred primarily because Residential 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, partial episode payments, and requests for anticipated payments.

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

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

On the basis of our sample results, we estimated that Residential received overpayments of at least \$2,068,902 for the audit period.⁹ As of the publication of this report, all incorrectly billed claims in the sample are outside of the reopening period.

RESIDENTIAL HOME HEALTH BILLING ERRORS

Residential incorrectly billed Medicare for 11 of the 100 sampled claims, which resulted in overpayments of \$16,927.

Beneficiaries Were Not Homebound

Federal Requirements for Home Health Services

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

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

CMS provided further guidance and specific examples in the Manual (chapter 7, § 30.1.1). Revision 172 of § 30.1.1 (effective Nov. 19, 2013) and Revision 208 of § 30.1.1 (effective Jan. 1, 2015) covered different parts of our audit period.¹⁰

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

⁹ To be conservative, we recommend recovery of overpayments at the lower limit of a two-sided 90-percent confidence interval. Lower limits calculated in this manner are designed to be less than the actual overpayment total 95 percent of the time.

¹⁰ Coverage guidance is identical in both versions of § 30.1.1 in effect during our audit period. The only difference are minor revisions to a few examples.

Criteria One

The patient must either:

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

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

Criteria Two

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

Residential Did Not Always Meet Federal Requirements for Home Health Services

For six of the sampled claims, Residential incorrectly billed Medicare for home health episodes for beneficiaries who did not meet the above requirements for being homebound for the full episode (one claim) or for a portion thereof (five claims).¹¹

Example 1: Beneficiary Not Homebound – Entire Episode

The medical record for one beneficiary showed that, upon release from inpatient physical therapy, the patient was able to ambulate 300 feet with a four-wheeled walker, had a steady gait with no loss of balance, and was modified independent with transfers. The patient was living in a home with ramp access and no stairs, and 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 patient was initially homebound. She required care in a home setting because she needed a rolling walker and the assistance of another person to ambulate and because she had pneumonia and chronic obstructive pulmonary disease, which caused shortness of breath. By a later date in the episode, her condition had improved and she was ambulating 150 feet with a rolling walker, was modified independent for all

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

transfers, was able to ascend and descend her ramp without difficulty or shortness of breath, and demonstrated improved balance and a decreased risk of falls. Leaving the home no longer required a considerable or taxing effort.

Residential disagreed with the errors and maintains that the medical record supports the beneficiary's homebound status.

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).

Residential Did Not Always Meet Federal Requirements for Skilled Services

For six of the sampled claims, Residential incorrectly billed Medicare for an entire home health episode (two claims) or a portion of an episode (four claims) for beneficiaries who did not meet the Medicare requirements for coverage of skilled nursing or therapy services.¹³

Example 3: Beneficiary Did Not Require Skilled Services

A beneficiary with severe osteoarthritis and advanced dementia was homebound throughout the episode. However, the beneficiary did not have

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 six claims with skilled services that were not medically necessary, one of the claims was also billed for a beneficiary with homebound errors. Appendix E provides detail on the extent of the errors, if any, per claim reviewed.

skilled needs. The beneficiary's conditions were chronic and stable without exacerbation and there was no history of recent injury or new impairing condition. She had caregiver assistance for processing information regarding her medical conditions and for providing assistance with activities of daily living. The beneficiary did not require skilled nursing.¹⁴

Residential disagreed with the errors and maintains that the medical record supports the beneficiary's need for skilled services.

OVERALL ESTIMATE OF OVERPAYMENTS

On the basis of our sample results, we estimated that Residential received overpayments totaling at least \$2,068,902 for the audit period. As of the publication of this report, all incorrectly billed claims in the sample are outside of the reopening period.

RECOMMENDATIONS

We recommend that Residential Home Health:

- for the estimated \$2,068,902 overpayment for claims that are outside of the Medicare reopening period, exercise reasonable diligence in identifying and returning overpayments in accordance with the 60-day rule, and identify any returned overpayments as having been made in accordance with this recommendation;
- exercise reasonable diligence to identify and return any additional similar overpayments outside of our audit period, in accordance with the 60-day rule, and identify any returned overpayments as having been made in accordance with this recommendation; and
- strengthen its procedures to ensure that:
 - the homebound statuses of Medicare beneficiaries are verified and continually monitored and the specific factors qualifying beneficiaries as homebound are documented and
 - beneficiaries are receiving only reasonable and necessary skilled services.

¹⁴ During our audit, Residential elected to voluntarily refund the Medicare payment for this claim. Residential initiated the refund, and its MAC processed the refund before we issued this report.

RESIDENTIAL HOME HEALTH COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

RESIDENTIAL STATEMENTS OF NONCONCURRENCE

In written comments on our draft report, Residential disagreed with all four of our recommendations. For the first recommendation, to refund overpayments for incorrectly billed claims that are within the reopening period,¹⁵ Residential disagreed with our medical review determinations and maintained that all of the sample claims were billed correctly. Residential stated that medical reviewers (1) applied the wrong coverage standards, (2) failed to adhere to or account for CMS guidelines, and (3) ignored relevant clinical evidence. In addition, Residential stated that we withheld critical audit-related materials and that our projected overpayment amount is misleading. Moreover, Residential stated that the sampling methodology used to extrapolate our overpayment was inherently flawed and unreliable.

Regarding our second and third recommendations, to exercise reasonable diligence to identify and return overpayments in accordance with the 60-day rule, Residential did not concur and plans to appeal our overpayment assessment through the Medicare appeals process for reasons described above. For our fourth recommendation, to strengthen its procedures to ensure that (1) the homebound statuses of Medicare beneficiaries are verified and continually monitored and the specific factors qualifying beneficiaries as homebound are documented and (2) beneficiaries are receiving only reasonable and necessary skilled services, Residential did not concur. Residential maintains that it is committed to strict adherence with all pertinent laws, rules, and regulations in general as well as applicable Medicare coverage, documentation, and coding and billing requirements. Residential further stated that it has detailed policies and procedures in place, including a compliance program and internal controls, to ensure that only reasonable and necessary home health services are provided to homebound beneficiaries.

We have included Residential's comments in their entirety as Appendix F.¹⁶

OFFICE OF INSPECTOR GENERAL RESPONSE

After reviewing the response we received from Residential and further considering our medical review results, we maintain that our findings and recommendations are valid. Below is a summary of the reasons Residential did not agree with our findings and recommendations and our responses.

¹⁵ The first recommendation in the draft report was to refund to the Medicare program the portion of the estimated overpayment for claims incorrectly billed that are within the reopening period. We removed this recommendation because all of the incorrectly billed claims are now outside of the reopening period.

¹⁶ Residential also included an appendix to its comments that contained a summary of its compliance program and a claim-by-claim rebuttal to the medical review findings in our draft report. However, these documents contain proprietary and personally identifiable information and are excluded from this report.

AUDIT-RELATED MATERIALS

Residential Comments

Residential expressed concerns that certain documents requested under the Freedom of Information Act (FOIA) were not provided, which impeded its ability to fully and effectively respond to our findings. Residential stated that it had requested (1) OIG's data analysis techniques that led OIG to conclude Residential was at risk for noncompliance with Medicare billing requirements, (2) the curricula vitae (CVs) of OIG's medical review contractors, and (3) OIG's policies and procedures for statistical sampling. Residential stated that without reviewing the policies for overpayment projection, it is unable to meaningfully opine on OIG's extrapolation methodology. Residential further stated that not disclosing the credentials of the medical reviewers represents a lack of transparency and calls into question whether GAGAS requirements for sufficient competence, expertise, and technical knowledge on the part of auditors and specialists were met.

Office of Inspector General Response

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

As part of our oversight responsibility, OIG has statutory authority to conduct reviews of any provider that receives Medicare funds. For provider-specific reviews, OIG generally selects providers on the basis of risk factors or patterns of questionable billing. Risk factors are identified by prior work done by OIG, the Government Accountability Office, CMS, and others. Questionable billing analysis identifies providers whose billing patterns exceed certain thresholds compared to their peers. Using OIG's oversight and enforcement expertise, and sometimes in consultation with others (e.g., CMS program officials or contractors), we identify the risk factors and indicators of questionable billing that are most relevant to the Medicare area or service we are auditing. Then, we analyze claims and other data to identify which providers are most strongly associated with our risk factors or questionable billing indicators. We may also consider other factors in selecting providers for review, such as the volume of Medicare claims or patients associated with a provider. Larger providers may be selected for review because they may have a higher volume of claims and Medicare payments in a given risk area or in several risk areas. We selected Residential for audit based on a risk analysis that

considered geographic areas identified as high risk for questionable billing by HHAs,¹⁷ amount of claims that fell into one or more risk categories for compliance with home health billing, volume of claims and Medicare payments compared with its peers, and input from other OIG components.

Residential stated that they were unable to opine on our extrapolation methodology without reviewing OIG's policies for overpayment projection. In the draft report shared with Residential, we described our sampling and estimation methodology, which is also included in this report as Appendix C. Further, we provided Residential with all the information necessary to replicate the sample from the sampling frame and recalculate the overpayment estimate amount included in the report. The items provided to Residential included, but were not limited to, a list of the claims in the sampling frame, a list of the random numbers used to select the sample, a summary of the sample findings with overpayment amounts, and the software output from the extrapolation process. Additionally, Residential has direct access to the claim information necessary to validate the sampling frame.

We do not agree with Residential's contention that we did not adhere to GAGAS requirements regarding the use of specialists. We have verified and documented that our medical reviewers have sufficient competence, expertise, and technical knowledge. The medical review determination letter for each claim indicates that the reviewer is licensed and has expertise and board certification in the area under review. The physician who completed the reviews for the 11 claims in error is board certified in Physical Medicine & Rehabilitation and Neuromuscular Medicine with expertise in Inpatient & Outpatient Physiatry, Pain Management, and Electrodiagnostic Testing. OIG ensures that our contracted medical reviewers are medical professionals who have the appropriate training and medical expertise to review the claims that are selected for review. OIG conducts a full and open competitive selection process in accordance with the Federal Acquisition Regulations to ensure that contracted medical reviewers have the appropriate experience, medical expertise, and technical ability to review Medicare Part A and Part B claims. Bidders submit the resumes and qualifications of key personnel, such as the medical director, who oversee the medical reviewers.¹⁸ OIG works with the medical reviewers to ensure that they apply the correct Medicare criteria, including coverage, medical necessity, and coding requirements. OIG-contracted medical reviewers assess the medical documentation to determine whether Medicare payments comply with Medicare requirements (e.g., medical necessity). Two clinicians review all claims that need a medical necessity determination before giving them to OIG. Second-level reviews are conducted by the medical director or a physician with appropriate qualifications and experience. All reviewers are required to be free of any conflict of interest.

¹⁷ Geographic areas identified in our August 2012 report *Inappropriate and Questionable Billing by Medicare Home Health Agencies* (OEI-04-11-00240). This report identified HHAs that billed unusually high amounts according to at least one of six measures of questionable billing.

¹⁸ OIG does not receive resumes of medical reviewers assigned to a particular audit.

PROJECTED OVERPAYMENT

Residential Comments

Residential said that it believes the estimated overpayment amount is misleading because 6 of the 11 claims in error fall outside of the reopening period at the time of Residential's review of the draft report. Residential calculates that an extrapolation based on the 5 claims subject to recovery would yield an overpayment estimate of \$514,319. In addition, Residential stated that 2 of the 11 claims in error were refunded prior to the audit and that OIG should not and cannot recover the same overpayment twice.

Office of Inspector General Response

We disagree with Residential's assertion that our estimated overpayment amount is misleading. The estimated overpayment of \$2,068,902 is based on the claim errors discovered in the sample and thus is an accurate statistical projection of the overpayments that exist within the sampling frame.

Additional claims have fallen outside the reopening period since Residential reviewed our draft report. Given these changes, we have attributed the full overpayment estimate to outside the reopening period. Federal regulations permit providers to request that a Medicare contractor reopen claims for the purpose of reporting and returning overpayments under the 60-day rule. Therefore, the Medicare contractor, with Residential's cooperation, has the ability to reopen all claims found in error and collect the entire estimated overpayment. For that reason, it would be inappropriate for OIG to report only a portion of the claim errors and estimated overpayment.

Residential stated that 2 of the 11 claims in error (S1-8 and S1-28) were refunded prior to our audit and therefore should not be included in our estimated overpayment. However, these 2 sample items and one other were refunded or adjusted subsequent to our audit notification letter and request for medical records. On September 12, 2016, Residential was notified of our audit and given a detailed list of the specific sample items under review. Residential cancelled and rebilled the claim for sample S1-8 on November 9, 2016, which reduced the claim payment by \$1,103. Residential cancelled the claim for sample S1-28 on October 25, 2016, which refunded the full claim payment of \$2,165. Additionally, Residential adjusted the claim for sample S2-45 on May 23, 2017, which reduced the claim payment by \$1,065. An adjustment or refund made by the provider after a statistical sample is pulled does not render a sample item ineligible for extrapolation. In fact, any adjustments or refunds made subsequent to pulling the sample are accounted for after extrapolation. This approach is used because the errors found in the sample are representative of the errors in the sampling frame. Action officials at CMS, acting through a Medicare contractor, will then determine the amount of the estimated overpayment (if any) that will be recouped, and they will take into account any amount the provider has already refunded.

BENEFICIARY HOMEBOUND STATUS

Residential Comments

Residential stated that determinations pertaining to noncompliance with homebound requirements were flawed because medical reviewers did not correctly apply Medicare coverage criteria or failed to account for relevant clinical evidence when determining homebound status, or both. Residential cited examples it believes showed that our medical reviewer impermissibly used ambulation distance as a “rule of thumb” or considered irrelevant factors such as architectural features of beneficiaries’ homes when determining homebound status.

Office of Inspector General Response

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

Ambulation distance is one factor among others that our medical reviewer considered in making homebound determinations. As shown in each medical review determination report, our medical reviewer documented in detail and reviewed the relevant medical history, including diagnoses, skilled nursing or therapy assessments, cognitive function, and mobility for each beneficiary. In terms of meeting CMS homebound criteria, medical review determinations must be based on each patient’s individual characteristics as reflected in the available record. Our medical reviewer carefully considered ability to ambulate in conjunction with the individual characteristics noted in each patient’s medical record. Ambulation distance was not noted in all decisions, and when it was, it was simply one factor the reviewer considered in making the homebound determination. This is evident from the relevant facts and discussion included in the individual decisions.

Architectural features of a patient’s home may also be relevant in determining homebound status. Residential stated that “there is no support in CMS regulations or coverage guidelines for the notion that a beneficiary should lose his or her eligibility for the Medicare home health benefit or become presumptively ineligible for home care if he or she lives in a home with a ramp or an assisted living facility (ALF).” However, Residential does not cite to any law, regulation, or CMS guidance directing that the physical characteristics of a patient’s home may not be considered in making a determination of homebound status. Moreover, our medical reviewer did not consider beneficiaries’ residences to be a dispositive factor, but one of many it deliberated upon when analyzing the unique circumstances of each beneficiary.

As set forth in the Manual, chapter 7, section 30.1.1, the second requirement for being homebound is that there must exist a normal inability to leave home and that leaving the home must require a considerable and taxing effort. CMS guidance provides the following example of a homebound patient, which references the physical characteristics of the living environment:

Some examples of homebound patients that illustrate the factors used to determine whether a homebound condition exists [would be] . . . A patient who has lost the use of their upper extremities and, therefore, is unable to open doors, use handrails on stairways, etc., and requires the assistance of another individual to leave their place of residence (the Manual, chapter 7, § 30.1.1).

Physical barriers in the home environment are relevant to the homebound assessment under the “normal inability” and “considerable and taxing effort” requirement (Criteria Two). Although the patient is the focus of the homebound requirement, the lack of physical access barriers in an ALF, as in a private residence, is a factor in determining whether a beneficiary is homebound under Criteria Two. For example, a patient residing in a walk-up but who no longer can negotiate steps or stairs has a “normal inability” to leave home, and leaving a home with that physical characteristic would require a “considerable and taxing effort.” This may not be the case for the same patient in a residence without steps or stairs. The physical characteristics of the home environment, however, are always considered along with the patient’s condition.¹⁹

CMS guidance mentions that a patient may have multiple residences and states that homebound status must be met at each residence (the Manual, chapter 7, § 30.1.2). CMS states the following (emphasis added):

A patient may have more than one home and the Medicare rules do not prohibit a patient from having one or more places of residence. A patient, under a Medicare home health plan of care, who resides in more than one place of residence during an episode of Medicare covered home health services will not disqualify the patient’s homebound status for purposes of eligibility. For example, a person may reside in a principal home and also a second vacation home, mobile home, or the home of a caretaker relative. The fact that the patient resides in more than one home and, as a result, must transit from one to the other, is not in itself, an indication that the patient is not homebound. **The**

¹⁹ Regarding physical environment characteristics beneficiaries may encounter once they leave the home, Title III of the Americans with Disabilities Act of 1990 (ADA), as amended (codified at 42 U.S.C. §§ 12181-12189), and its implementing regulations (28 CFR part 36), prohibits discrimination on the basis of disability in the activities of places of public accommodation (businesses that are generally open to the public and that fall into one of 12 categories listed in the ADA, such as restaurants, movie theaters, schools, day care facilities, recreation facilities, and doctors’ offices) and requires newly constructed or altered places of public accommodation—as well as commercial facilities (privately owned, nonresidential facilities)—to comply with the ADA standards.

requirements of homebound must be met at each location (e.g., considerable taxing effort, etc).

CMS anticipated that the physical characteristics of a patient's residence could impact the homebound determination under Criteria Two. Accordingly, it can be reasonably inferred that CMS expects the physical characteristics of a given residence to impact the homebound analysis under Criteria Two. Thus, contrary to Residential's assertions, it was not an error for our medical reviewer to consider the physical characteristics of the home environment as one of many factors in making homebound determinations.

MEDICAL NECESSITY

Residential Comments

Residential stated that medical review decisions related to medical necessity of skilled services were based on an inaccurate understanding of Medicare coverage criteria for home health services. Residential cited examples of determination letters in which beneficiaries were described as having "chronic," "longstanding," or "stable" conditions, which it believes demonstrates that our medical reviewer applied improper coverage standards.

Office of Inspector General Response

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

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

OFFICE OF INSPECTOR GENERAL'S OVERPAYMENT PROJECTION

Residential Comments

Residential said that it objected to our use of extrapolation to estimate our overpayment amount because OIG's sampling methodology is both substantively and procedurally flawed. Specifically, Residential claimed that we did not sign a sampling plan before pulling the sample. Residential stated that our audit did not follow OIG guidance for the use of extrapolation in claim reviews performed by independent review organizations (IROs) of providers who are subject to corporate integrity agreements (CIAs). Residential also asserted that "by extrapolating the audit results in this case despite the exceedingly low error rate," we failed to consider CMS's guidance from the Medicare *Program Integrity Manual* (PIM). Residential further stated that our audit report did not identify the sampling policy or guidelines followed during the review, in contravention of GAGAS. Residential contended that the overpayment projection is fundamentally unreliable because the precision value of the estimated overpayment is too high.

Office of Inspector General Response

We disagree that our sampling methodology and overpayment projection is unreliable and flawed. While we do not believe that a particular signature date is required for a valid sample, the sampling plan for this audit was signed a week before the sample was drawn. We performed our statistical sampling in a standard, widely accepted, and legally supportable manner based on considerable institutional knowledge and experience that can be replicated by any professional statistician. OIG audits use sampling and extrapolation methodologies, which have been consistently upheld by administrative appeal boards and Federal courts, to estimate the loss to Medicare from misspent funds.²⁰ We define our sampling population and sampling unit, randomly select our sample, apply relevant criteria when evaluating the sample, and use statistical sampling software to apply the correct formulas for the extrapolation.

Residential believes that our use of extrapolation in this audit is inconsistent with the application of a 5-percent threshold used in CIAs. However, OIG no longer uses the 5-percent error rate threshold in its CIAs. In addition, even in prior CIAs that used the 5-percent error rate threshold, the threshold was used to determine when a probe sample showed that a provider under a CIA required additional scrutiny by means of taking a full claims sample, not for when extrapolation of a full claims sample was permissible. The entity under the CIA was required to

²⁰ See, e.g., *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); *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); *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).

extrapolate the results of the full sample,²¹ regardless of the error rate.

Residential said that our extrapolation was inappropriate because the error rate was lower than PIM guidelines. However, Residential conceded that OIG audits are not subject to PIM guidelines, which are prescribed for CMS contractors.²² Further, the PIM guidelines and statutory provisions upon which the guidelines are based do not prohibit CMS from accepting and acting upon our monetary recommendation. When using a statistically valid sample, it is appropriate to extrapolate the error rate found in the sample to the entire sample frame, regardless of the overall error rate. The errors, and their associated overpayments, result in misspent Government funds. Although Residential contends that OIG should not extrapolate its sample results, we believe that it is not appropriate to forgo the reporting of Medicare overpayments simply because the error rate is low. Additionally, providers with lower error rates receive the benefit of lower recommended recoveries.

Residential claimed that our audit report did not identify the criteria for our statistical sampling methodology. We conducted and reported our audit in accordance with GAGAS. Section 7.13 of GAGAS (2011 Revision) states that when sampling significantly supports the auditor's findings, conclusions, or recommendations, the report should describe the sample design and state why the design was chosen, including whether the results can be projected to the intended population. The sampling and estimation methodology are included in Appendix C of our report.²³

While Residential contends that the precision value of the estimated overpayment is too high, the legal standard for use of sampling and extrapolation is that it must be based on a statistically valid methodology, not the most precise methodology.²⁴ Further, OIG has designed our extrapolation methodology so that, on average, less precise sample designs result in lower estimated overpayment amounts.²⁵ Factors that increase the uncertainty in the sample (e.g., smaller sample sizes, less precise design, highly variable claims) will tend to reduce the lower limit and lead to a lower estimated overpayment amount. This process gives the provider the

²¹ Whereas we extrapolate based on the lower limit, providers under a CIA were required to extrapolate using the point estimate.

²² The Act § 1893(f)(3); CMS *Medicare Program Integrity Manual*, chapter 8.4.1.4 (effective June 28, 2011).

²³ We previously described our sampling and estimation methodology in the draft report shared with Residential.

²⁴ See *John Balko & Assoc. v. Sebelius*, 2012 WL 6738246 at *12 (W.D. Pa. 2012), *aff'd* 555 F. App'x 188 (3d Cir. 2014); *Maxmed Healthcare, Inc., v. Burwell*, 152 F. Supp. 3d 619, 634–37 (W.D. Tex. 2016), *aff'd*, 860 F.3d 335 (5th Cir. 2017); *Anghel v. Sebelius*, 912 F. Supp. 2d 4, 18 (E.D.N.Y. 2012); *Transyd Enter., LLC, v. Sebelius*, 2012 U.S. Dist. LEXIS 42491 at *13 (S.D. Tex. 2012).

²⁵ The use of a less precise design can substantially reduce the lower limit that we use to calculate the estimated overpayment amount. For example, in the current audit the lower limit is almost 2.5 million less than the unbiased point estimate. Residential argues that a provider may sometimes benefit from a more precise design. This statement applies only a small percent of the potential outcomes of a given sample. When all potential outcomes are considered, the less precise design is always more advantageous for the provider.

benefit of the doubt for any uncertainty in the sampling process. The specific lower limit that we use is designed to produce an estimate that is less than the actual overpayment about 95 percent of the time.

Our extrapolation approach results in a conservative estimate that is almost always less than what we would have obtained from reviewing all the claims in our sampling population. Using extrapolation rather than reviewing all population claims drastically reduces the burden on both the provider and the Government.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

Our audit covered \$79,443,274 in Medicare payments to Residential for 22,609 home health claims with episodes of care through dates in CYs 2014 and 2015. From this sample frame, we selected for review a stratified random sample of 100 home health claims with payments totaling \$377,485.

We evaluated compliance with selected coverage and billing requirements and submitted the sampled claims to independent medical review.

We limited our review of Residential'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 December 2016 through February 2020.

METHODOLOGY

To accomplish our objective, we:

- reviewed applicable Federal laws, regulations, and guidance;
- extracted Residential's paid claim data from CMS's NCH file for the audit period;
- removed payments for low utilization payment adjustments,²⁶ partial episode payments,²⁷ and requests for anticipated payments²⁸ from the population to develop our sampling frame;
- selected a stratified random sample of 100 claims totaling \$377,485 for detailed review (Appendix C);

²⁶ If fewer than five visits are delivered during a 60-day episode, the home health agency is paid per visit, by visit type, with a low utilization payment adjustment, rather than by the episode payment method.

²⁷ A partial episode payment is made when a beneficiary elects to transfer to another home health agency or is discharged and readmitted to the same home health agency during the 60-day episode.

²⁸ Episode payments are split between a request for anticipated payment (RAP), submitted by the home health agency as soon as an episode begins, and a home health claim, submitted after the end of the episode. For all episode payments, the home health claim payment amount will show the total payment for the episode, and the RAP will be canceled.

- 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 Residential to support the sampled claims;
- 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 Residential'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 Residential for our audit period (Appendix D);
- discussed the results of our audit with Residential officials; and
- requested that our medical reviewer review the additional documentation provided by Residential in response to our findings.

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 may 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. 58077, 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;²⁹ (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).

²⁹ Effective January 1, 2012, CMS clarified the status of occupational therapy to reflect when it becomes a qualifying service rather than a dependent service. Specifically, the first occupational therapy service, which is a dependent service, is covered only when followed by an intermittent skilled nursing care service, physical therapy service, or speech language pathology service as required by law. Once that requirement for covered occupational therapy has been met, however, all subsequent occupational therapy services that continue to meet the reasonable and necessary statutory requirements are considered qualifying services in both the current and subsequent certification periods (subsequent adjacent episodes) (76 Fed. Reg. 68525, 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 Act³⁰ added a requirement to sections 1814(a)(2)(C) and 1835(a)(2)(A) of the Act that the physician must have a face-to-face encounter with the beneficiary. In addition, the physician responsible for performing the initial certification must document that the face-to-face patient encounter, which is related to the primary reason the patient requires home health services, occurred no more than 90 days prior to the home health start-of-care date or within 30 days of the start of the home health care by including the date of the encounter.³¹

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.

³⁰ 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.

³¹ 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.

CMS provided further guidance and specific examples in the Manual (chapter 7, § 30.1.1). Revision 172 of § 30.1.1 (effective Nov. 19, 2013) and Revision 208 of § 30.1.1 (effective Jan. 1, 2015) covered different parts of our audit period.³²

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

Criteria One

The patient must either:

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

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

Criteria Two

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

Need for Skilled Services

Intermittent Skilled Nursing Care

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

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

³² Coverage guidance is identical in both versions of § 30.1.1 in effect during our audit period. The only difference are minor revisions to a few examples.

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, which 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 population consisted of Residential's claims for home health services that it provided to Medicare beneficiaries with episodes of care that ended in CYs 2014 and 2015.

SAMPLING FRAME

The sampling frame consisted of an Excel spreadsheet containing 22,609 home health claims, valued at \$79,443,274, from CMS's NCH file.³³

SAMPLE UNIT

The sample unit was a home health claim.

SAMPLE DESIGN AND SAMPLE SIZE

We used the following stratified random sample:

Table 1: Sample Design Information

Stratum	Frame Information			Sample Size
	Payment Range	Count Total	Dollar Total	
1	<=\$3,818	14,594	\$38,853,682	50
2	>\$3,818	8,015	40,589,592	50
Total		22,609	\$79,443,274	100

SOURCE OF RANDOM NUMBERS

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

METHOD FOR SELECTING SAMPLE UNITS

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

³³ Our sampling frame excluded home health claim payments for low utilization payment adjustments, partial episode payments, and requests for anticipated payments. We also excluded claims that resulted in error code 534 when matched against the Recovery Audit Contractor Data Warehouse. This code represents claims that have already been marked for exclusion by an OIG audit, investigation, or similar review.

ESTIMATION METHODOLOGY

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

APPENDIX D: SAMPLE RESULTS AND ESTIMATES

Table 2: Sample Results

Stratum	Frame Size	Value of Frame	Sample Size	Total Value of Sample	Incorrectly Billed Sample Items	Value of Over-payments in Sample
1	14,594	\$38,853,682	50	\$132,933	8	\$13,611
2	8,015	40,589,592	50	244,552	3	3,316
Total	22,609	\$79,443,274	100	\$377,485	11	\$16,927

Table 3: Estimates

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

Point estimate	\$4,504,397
Lower limit	2,068,902
Upper limit	6,939,892

APPENDIX E: TYPES OF ERRORS BY SAMPLE ITEM

STRATUM 1 (Samples 1-25)

Stratum and Sample Number	Not Homebound	Did Not Require Skilled Services	Overpayment
S1-1	-	-	-
S1-2	-	-	-
S1-3	-	-	-
S1-4	-	-	-
S1-5	-	-	-
S1-6	-	X	\$2,760
S1-7	-	-	-
S1-8	X	-	1,103
S1-9	-	-	-
S1-10	-	-	-
S1-11	-	-	-
S1-12	-	-	-
S1-13	-	-	-
S1-14	-	-	-
S1-15	X	-	693
S1-16	-	-	-
S1-17	-	-	-
S1-18	-	-	-
S1-19	-	-	-
S1-20	-	-	-
S1-21	-	-	-
S1-22	-	-	-
S1-23	-	-	-
S1-24	-	-	-
S1-25	-	-	-

STRATUM 1 (Samples 26-50)

Stratum and Sample Number	Not Homebound	Did Not Require Skilled Services	Overpayment
S1-26	-	-	-
S1-27	-	-	-
S1-28	-	X	\$2,165
S1-29	-	-	-
S1-30	-	-	-
S1-31	-	-	-
S1-32	-	-	-
S1-33	-	-	-
S1-34	-	-	-
S1-35	-	-	-
S1-36	-	-	-
S1-37	-	-	-
S1-38	-	-	-
S1-39	X	-	2,411
S1-40	-	X	2,191
S1-41	-	X	1,604
S1-42	-	-	-
S1-43	-	-	-
S1-44	-	-	-
S1-45	-	-	-
S1-46	-	-	-
S1-47	-	-	-
S1-48	-	-	-
S1-49	-	-	-
S1-50	X	X	684

STRATUM 2 (Samples 1-25)

Stratum and Sample Number	Not Homebound	Did Not Require Skilled Services	Overpayment
S2-1	-	-	-
S2-2	-	-	-
S2-3	-	-	-
S2-4	-	-	-
S2-5	-	-	-
S2-6	-	-	-
S2-7	X	-	\$1,080
S2-8	-	-	-
S2-9	-	-	-
S2-10	-	-	-
S2-11	-	-	-
S2-12	-	-	-
S2-13	-	-	-
S2-14	-	-	-
S2-15	-	-	-
S2-16	-	-	-
S2-17	-	-	-
S2-18	-	-	-
S2-19	-	-	-
S2-20	-	-	-
S2-21	-	-	-
S2-22	-	-	-
S2-23	-	-	-
S2-24	-	-	-
S2-25	-	-	-

STRATUM 2 (Samples 26-50)

Stratum and Sample Number	Not Homebound	Did Not Require Skilled Services	Overpayment
S2-26	-	-	-
S2-27	-	-	-
S2-28	-	-	-
S2-29	-	-	-
S2-30	-	-	-
S2-31	-	-	-
S2-32	-	-	-
S2-33	X	-	\$390
S2-34	-	-	-
S2-35	-	-	-
S2-36	-	-	-
S2-37	-	-	-
S2-38	-	-	-
S2-39	-	-	-
S2-40	-	-	-
S2-41	-	-	-
S2-42	-	-	-
S2-43	-	-	-
S2-44	-	-	-
S2-45	-	X	1,846
S2-46	-	-	-
S2-47	-	-	-
S2-48	-	-	-
S2-49	-	-	-
S2-50	-	-	-
Total	6	6	\$16,927

APPENDIX F: RESIDENTIAL HOME HEALTH COMMENTS



October 29, 2019

VIA ELECTRONIC DELIVERY

Sheri L. Fulcher, Regional Inspector General
Office of Audit Services – Region V
HHS – Office of Inspector General
233 North Michigan Street, Suite 1360
Chicago, IL 60601

Re: Response to Draft Report

Dear Ms. Fulcher:

This letter replaces the cover letter previously sent to your office dated October 23, 2019.

Our firm represents Residential Home Health LLC (“Residential”). Residential, through counsel, previously submitted its response to draft report number A-05-16-00063, which was issued by your office on September 4, 2019. Per your request, we enclosed one version of the response with digital signatures and one version with electronic signatures. The documents are otherwise identical.

We would like to take this opportunity to extend our gratitude to you and your staff for your professionalism and courtesy. We sincerely appreciate your flexibility and assistance throughout the audit process.

Thank you for your attention to this matter. Please direct any inquiries or concerns regarding this submission to the attention of the undersigned attorney.

Very Truly Yours,

CALHOUN BHELLA & SECHREST LLP

By: Adam L. Bird

ADAM L. BIRD
PARTNER



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RESIDENTIAL HOME HEALTH LLC

Response to Draft OIG Report No. A-05-16-00063

Prepared by:

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Attorney for Residential Home Health LLC

I. INTRODUCTION

Residential Home Health LLC (“Residential”) hereby submits this response to the draft report (“Report”) issued by the Office of Inspector General (OIG) as to report number A-05-16-00063. For the reasons discussed below, Residential disputes the findings set forth in the Report and does not concur with OIG’s related recommendations.

According to the Report, OIG initiated this Medicare compliance review because, “...the 2016 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 [home health agencies] account for more than 18 percent of the total 2016 fee-for-service improper payments (\$41 billion).”¹

Even though Residential disputes OIG’s findings, it is critical to view those findings in context and consider the extent to which Residential stands out among its peer providers in terms of compliance with Medicare coverage and documentation rules. First, according to the Comprehensive Error Rate Testing (CERT) reports released by the Centers for Medicare and Medicaid Services (CMS), the average home health payment error rate in 2014 and 2015 was 55.2%.² OIG’s findings in this Medicare compliance review, by contrast, revealed a payment error rate of only 4.4%.³ Figures 1 and 2 below represent the payment error rates by calendar year.

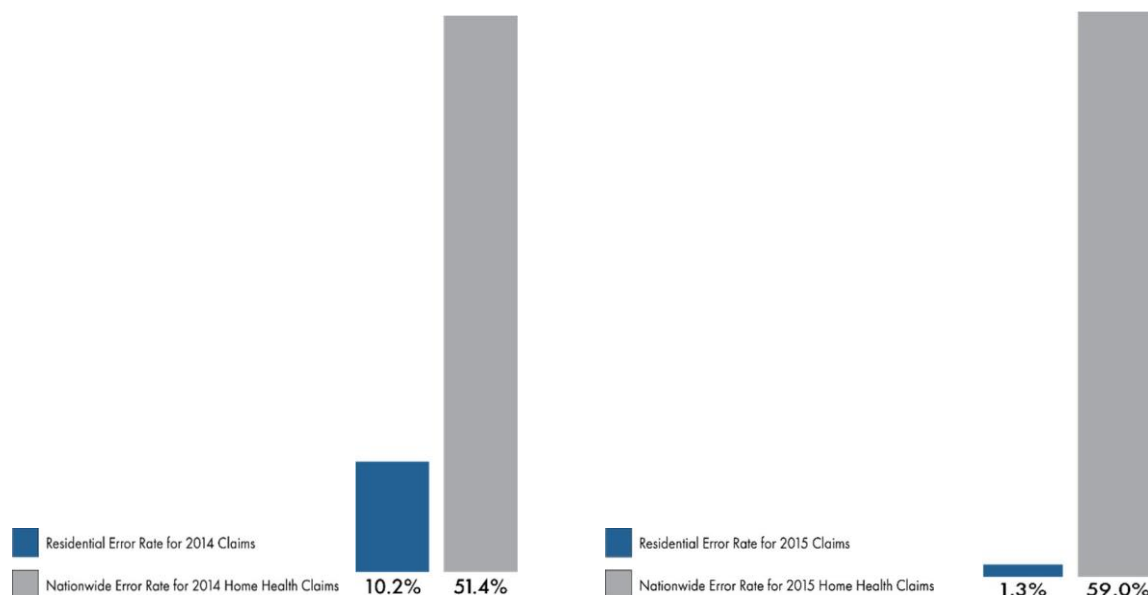


Figure 1

Figure 2

¹ Report at 1. OIG’s statement here is technically inaccurate; this Medicare compliance review, which was initiated in the third quarter of 2016, could not have been based on the nationwide error rate for home health services in 2016.

² See CMS, *Medicare Fee-for-Service 2015 Improper Payments Report* (“2015 CERT Report”), at 17 (Sept. 12, 2016); CMS, *Medicare Fee-for-Service 2014 Improper Payments Report* (“2014 CERT Report”), at 17 (July 7, 2015).

³ A payment error rate is calculated by dividing the alleged overpayment amount by the aggregate payment amount in the sample. In this case, the payments in the sample totaled \$377,485. OIG alleges that Residential was overpaid in connection with 11 claims in the amount of \$16,927. Report at 19.

Second, the CERT reports make clear that one of the principal drivers of the spike in home health claim errors was the face-to-face requirement implemented by CMS in 2011.⁴ In this case, it is notable that OIG’s auditors did not identify a single invalid or non-compliant face-to-face record.

Third, the Report notes that this audit was part of a nationwide series of Medicare compliance reviews of home health providers. Residential’s payment error rate of only 4.4% is significantly lower than the error rates from other reports published to date by OIG as part of this series.⁵

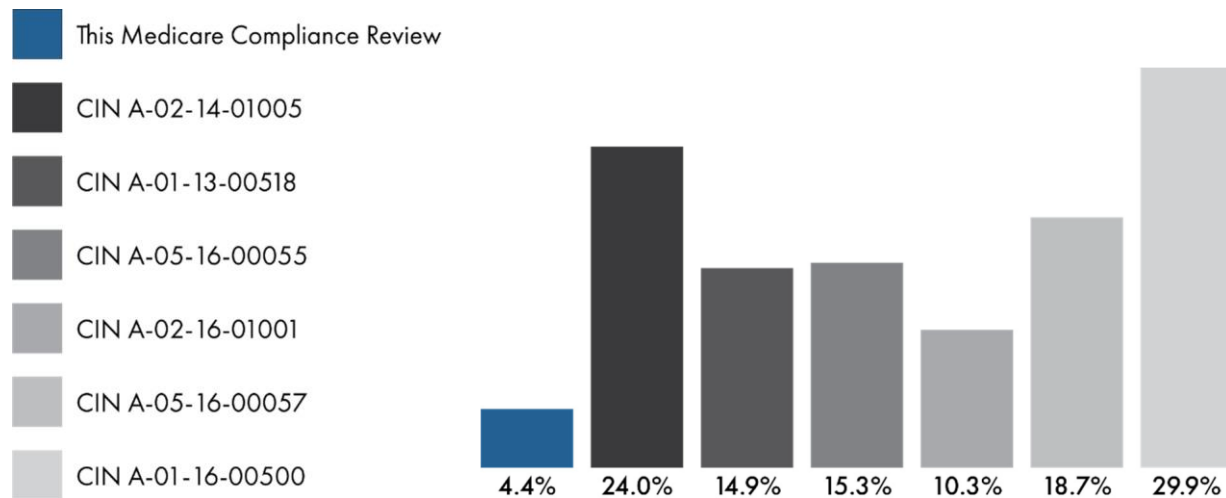


Figure 3

II. OVERVIEW OF RESIDENTIAL HOME HEALTH

Residential has provided high quality home health services to the elderly and medically fragile residents of eastern Michigan for almost 20 years. Residential employs a dedicated staff of more than 500 clinical and administrative professionals. Many of Residential’s clinicians hold special certifications, such as:

- More than 100 therapists are LSVT BIG®-certified or LSVT LOUD®-certified. These credentials enable therapists to apply evidence-based treatment protocols when caring for patients with Parkinson’s Disease or other neurological conditions.
- 2 clinicians are certified lymphedema specialists.
- 2 clinicians are certified by the Neuro-Developmental Treatment (NDTA) Association. This credential enables Residential’s clinicians to plan and oversee multi-disciplinary treatment regimens for patients with neuromuscular dysfunction.
- 12 nurses are certified by the Wound, Ostomy, and Continence Nursing Certification Board.

⁴ See 2015 CERT Report at 18; 2014 CERT Report at 9; see also OIG, *Limited Compliance With Medicare’s Home Health Face-to-Face Documentation Requirements*, Report No. OEI-01-12-00390 (April 2014).

⁵ The payment error rates from the other Medicare compliance reviews were calculated based on the information available in the reports published on OIG’s website.

- More than 20 speech therapists hold certification of clinical competence (CCC) credentials from the American Speech-Language-Hearing Association (ASHA). Speech language pathologists who hold CCC credentials possess over 1,600 hours of supervised clinical experience and have passed a rigorous national examination administered by the ASHA.

These certifications and credentials enable Residential's clinicians to provide high quality and specialized care to Residential's patients.

In addition to the CMS-mandated Outcome and Assessment Information Set (OASIS), Residential's clinicians routinely administer numerous individually-tailored assessments to better address the unique clinical needs and functional deficits of patients. These assessments include, but are not limited to, the Allen Cognitive Levels Scale, the Berg Balance Test, the Tinetti Assessment, the Missouri Alliance for Home Care (MAHC-10) Fall Risk Assessment, the Timed Up and Go (TUG) test, and the Braden Scale for Predicting Pressure Sore Risk. Residential has also developed a Dementia Care Program for specialized treatment of patients suffering from Alzheimer's disease and all types of dementia.

Approximately 80% of Residential's patients are admitted to home health following treatment in a hospital or post-acute facility, such as an inpatient rehabilitation facility or a skilled nursing facility.⁶ The most common diagnoses for Residential's patients involve the endocrine system, the nervous system, the circulatory system, the musculoskeletal system, and the respiratory system. Residential's patients present with a higher risk of re-hospitalization than the average home health patient, as indicated by a history of previous hospitalizations, a history of falls, polypharmacy, and documented frailty factors. The majority of Residential's patients have impaired functional mobility and are dependent on others for personal care, such as bathing, grooming, dressing, and toileting hygiene. Residential also treats a higher percentage of patients with cognitive, mental, or behavioral impairments than the nationwide average. Residential's patients are more likely to be incontinent of urine than the typical home health patient, which places them at greater risk for skin breakdown.

Residential's CASPER report data reflects that, on the whole, it achieves better patient outcomes in a variety of areas relative to the average home health provider nationwide. Our patients more often improve with performance of their activities of daily living (ADLs), such as bathing, bed transferring, and ambulation/locomotion. With respect to clinical outcomes, Residential's patients also demonstrate higher-than-average improvement in administering their oral medications and managing conditions such as shortness of breath and pain. Patients with surgical wounds also improve at better rates than their peers nationwide. This data underscores the quality of home health services furnished by Residential. This high-quality care, in turn, reduces the need for additional, more costly healthcare services – such as hospital admissions – and enables patients to remain as safely and independently as possible in their own homes.

⁶ The patient demographic data summarized here was gleaned from Residential's CASPER reports from 2014 and 2015, which overlaps with the audit period. *See generally* 42 C.F.R. § 484.225.

III. SUMMARY OF RESIDENTIAL'S EFFECTIVE COMPLIANCE PROGRAM AND INTERNAL CONTROLS.

In addition to clinical excellence, Residential is committed to maintaining robust compliance with applicable federal and state laws.⁷ To that end, Residential has implemented an effective compliance program that adheres to the Compliance Program Guidance for Home Health Agencies promulgated by OIG.⁸ This guidance recommends, and Residential has adopted and maintained, a compliance program consisting of the following seven elements:

Element 1: The development and distribution of written standards of conduct, as well as written policies and procedures that promote the home health agency's commitment to compliance and address potential risk areas. These policies are regularly reviewed and updated, and Residential's employees receive thorough training on the policies applicable to their areas of practice.

Summary of Residential's Implementation: Residential has developed a mission / vision statement, employee handbook (which contains, among other things, an employee code of conduct), as well as policies and procedures governing administrative operations, service delivery, clinical issues, and matters arising under the Health Insurance Portability and Accountability Act (HIPAA). These policies and procedures are regularly updated by leadership and reviewed with employees on at least an annual basis.

Element 2: The designation of a compliance officer and other appropriate bodies charged with operating and monitoring the compliance program.

Summary Residential's Implementation: Residential's compliance officer is also the company's general counsel. He holds a certification in healthcare compliance (CHC) credential from the Compliance Certification Board. The compliance officer reports directly to the chief executive officers of the company. Residential also has a compliance committee that is comprised of the corporate officers of the agency, the human resources director, and the compliance officer. Among other tasks, the compliance committee is responsible for updating Residential's compliance plan to ensure it remains effective. These updates include, but are not limited to, revisions to address known compliance risk areas as identified by OIG in its annual Work Plan.

Element 3: The development of regular and effective education and training programs for employees.

Summary of Residential's Implementation: All new clinical employees undergo a comprehensive orientation that includes instruction on policies and procedures and the processes in place for clinical chart reviews and compliance with applicable documentation rules, Medicare regulations, and Medicaid requirements.⁹ Following orientation, employees are administered tests

⁷ Attached and marked as **Appendix A** is a booklet summarizing the features of Residential's compliance program.

⁸ Publication of the OIG Compliance Program Guidance for Home Health Agencies, 63 Fed. Reg. 42410 (Aug. 7, 1998).

⁹ These orientation programs may include additional information that is relevant to the employee's job responsibilities. For example, clinical employees who will complete OASIS assessments receive, in addition to standard compliance training during orientation, two four-hour classes on the fundamentals of OASIS documentation and coding. *See generally* 42 C.F.R. § 484.55.

to ensure their understanding of the materials and must attest to their compliance with same. Employees subsequently undergo annual compliance retraining and must demonstrate their understanding of Residential's compliance policies by passing a written examination. Additional education on selected topics, such as coding or OASIS documentation, is conducted quarterly, weekly, daily, or on an "as needed" basis. Residential also maintains a robust library of educational materials on its intranet and provides extensive opportunities for specialized training on a wide variety of clinical and compliance topics.

Element 4: The creation and maintenance of a process, such as a hotline or other reporting system, to receive complaints in a manner that protects potential whistleblowers from retaliation.

Summary of Residential's Implementation: Residential strongly encourages all employees to report potential non-compliance to their supervisors. In addition, it publicizes a hotline phone number that employees can use to report, either directly or anonymously, suspected instances of non-compliance. Residential explicitly communicates to all employees, through the employee handbook and related educational presentation, that utilization of the hotline or any other reporting mechanism will not result in any retaliation or adverse actions taken against the employee. All complaints are thoroughly investigated through the compliance department and appropriate actions taken based upon the results / lessons learned. Complaints are logged and tracked through an electronic system that allows for efficient organization, archival, and reporting.

Element 5: The development of a system to respond to allegations of improper or illegal activities and the enforcement of appropriate disciplinary action against employees who have violated internal compliance protocols, laws, or federal / state healthcare program requirements.

Summary of Residential's Implementation: Residential's code of employee conduct clearly outlines the disciplinary process available for violations. The compliance officer works closely with the human resources department to resolve all compliance-related personnel matters.

Element 6: The use of audits and / or other evaluation techniques to monitor compliance and assist in the reduction of identified problem areas.

Summary of Residential's Implementation: Residential engages external resources to perform regular audits and reviews of company operations, including but not limited to, those related to documentation, coding and billing.¹⁰ It also maintains an in-house clinical quality committee, a clinical quality educator, and dedicated clinical "teams" responsible for ensuring compliance in certain areas or with specific rules. For example, one such team is responsible entirely for obtaining and reviewing physician face-to-face encounter documentation.¹¹ In addition, Residential has partnered with a data analytics firm to closely monitor its OASIS assessment data in real time which, in turn, enables Residential to flag potential problem areas for further review and verify that remedial compliance measures are effective.

¹⁰ Prior to submission, all OASIS assessment data is reviewed by an external consultant who holds an appropriate coding certification. In addition, Residential regularly engages reputable, third-party consulting firms to perform independent audits and medical record reviews.

¹¹ See generally 42 C.F.R. § 424.22(a)(v).

Element 7: The investigation and remediation of identified systemic problems and the development of policies addressing the non-employment or retention of sanctioned individuals.

Summary of Residential's Implementation: As noted above, Residential maintains a dedicated compliance hotline and has processes in place for employees to report compliance concerns. All such reports are directed to the compliance officer for resolution. The compliance officer, working with the compliance committee, takes prompt remedial action that is commensurate with the nature and severity of the report or allegations. The compliance officer, in conjunction with senior leadership as appropriate, also provides regular updates on any issues to the compliance committee that may be systematic in nature.¹²

Residential has also instituted a series of specific internal controls to ensure that services are medically reasonable and necessary for the entire duration of an episode and that services are only provided to homebound beneficiaries. For example, OIG's compliance guidance for home health agencies recommends the following with respect to verification of beneficiary homebound status:

One means by which home health agencies may verify the homebound status of a Medicare beneficiary is the inclusion of written prompts on nursing note forms. These prompts can direct the home health agency's clinicians...to adequately assess and document the homebound status of a Medicare beneficiary based upon clinical expertise, consultation with the beneficiary, and orders of the attending physician. Carefully designed prompts on nursing note forms may help ensure the complete and appropriate documentation necessary to substantiate the homebound status of a Medicare beneficiary for reimbursement purposes.¹³

Consistent with this recommendation, Residential's electronic medical record (EMR) system prompts every treating clinician to provide detailed information regarding the beneficiary's homebound status. Several examples are reproduced below for illustration purposes.

<p>HOMEBOUND STATUS</p> <p><u>HAS THE PATIENT'S HOMEBOUND STATUS CHANGED SINCE THE LAST VISIT?</u></p> <p>NO</p>
<p>HOMEBOUND STATUS</p> <p><u>IS THE PATIENT HOMEBOUND?</u></p> <p>YES</p> <p><u>THE PATIENT IS HOMEBOUND BECAUSE: (MARK ALL THAT APPLY)</u></p> <p>ILLNESS OR INJURY, PATIENT NEEDS THE AID OF A WALKER</p> <p>REQUIRES THE ASSISTANCE OF ANOTHER PERSON</p> <p><u>DOES THE PATIENT HAVE A NORMAL INABILITY TO LEAVE HOME AND LEAVING HOME REQUIRES SIGNIFICANT AND TAXING EFFORT?</u></p> <p>YES</p> <p><u>DESCRIBE CLINICAL PICTURE WITH UNIQUE FUNCTIONAL REASONS FOR HOMEBOUND STATUS:</u></p> <p>PATIENT RECOVERING FROM FEMUR NECK FX WITH HEMIARTHROPLASTY RESULTING IN PTNT WALKER BOUND AND HAVING STEPS TO ENTER/EXIT NECESSITATING ASSIST OF ANOTHER PERSON TO LEAVE THE HOME. SHE HAS INHERENT POST SURGICAL WEAKNESS, PAIN AND DECREASED BALANCE THAT ALSO DECREASE HER SAFETY AND EASY OF FUNCTIONAL MOBILITY.</p>

¹² Hotline reports that do not involve compliance issues are referred to the appropriate department for follow-up and resolution. For example, if an employee anonymously reports a clinical issue to the hotline, this matter would be referred to Residential's Quality Assessment and Performance Improvement (QAPI) Committee for review. See generally 42 C.F.R. § 484.65.

¹³ 63 Fed. Reg. at 42416.

HOMEBOUND STATUS

IS THE PATIENT HOMEBOUND?

YES

THE PATIENT IS HOMEBOUND BECAUSE: (MARK ALL THAT APPLY)

ILLNESS OR INJURY, PATIENT NEEDS THE AID OF A WALKER

ILLNESS OR INJURY, PATIENT NEEDS THE AID OF A WHEELCHAIR

REQUIRES THE ASSISTANCE OF ANOTHER PERSON

REQUIRES ASSISTANCE DUE TO COGNITIVE DEFICITS

DOES THE PATIENT HAVE A NORMAL INABILITY TO LEAVE HOME SUCH THAT LEAVING HOME REQUIRES CONSIDERABLE AND TAXING EFFORT? (CHECK ALL CONDITIONS THAT IMPACT THE PATIENT'S ABILITY TO SAFELY LEAVE THE HOME)

YES, IMPAIRED MEMORY, COGNITION OR PSYCHIATRIC CONDITION

YES, SIGNIFICANT WEAKNESS OR PAIN IMPAIR FUNCTIONAL TRANSFERS

YES, AMBULATION OR MOBILITY SKILLS ARE IMPAIRED PRODUCING AN INCREASED FALL RISK OUTSIDE OF THE HOME

YES, REQUIRES PROLONGED REST AND RECOVERY TIME AFTER RETURNING FROM LEAVING HOME

MEDICARE GUIDELINES ALLOW ABSENCES FROM THE HOME FOR ANY MEDICAL TREATMENT (INCLUDING STATE-CERTIFIED ADULT DAYCARE) AND TO ATTEND ANY RELIGIOUS SERVICES. OTHER ABSENCES ARE REQUIRED TO BE INFREQUENT OR OF SHORT DURATION. THE PATIENT AND CLINICIAN AGREE THAT THE PATIENT IS HOMEBOUND AND WILL NOTIFY SUPERVISION IMMEDIATELY IF THE STATUS CHANGES.

YES

HOMEBOUND STATUS

I ATTEST THAT THE PATIENT HAS BEEN EDUCATED ON HOMEBOUND CRITERIA, MEETS HOMEBOUND CRITERIA, HAS BEEN INSTRUCTED TO CONTACT RESIDENTIAL HOME HEALTH IMMEDIATELY IF THEIR HOMEBOUND STATUS CHANGES AND A SUPERVISOR WILL BE NOTIFIED IMMEDIATELY IF THE PATIENT IS NO LONGER HOMEBOUND.

YES

I ATTEST THAT THE PATIENT ACKNOWLEDGES THAT THEY HAVE BEEN EDUCATED ON HOMEBOUND CRITERIA, MEETS HOMEBOUND CRITERIA, AND AGREES TO NOTIFY RESIDENTIAL HOME HEALTH IMMEDIATELY IF THEIR HOMEBOUND STATUS CHANGES OR ARE NO LONGER HOMEBOUND.

YES

More generally, the following internal controls exist to ensure that all services furnished by Residential satisfy Medicare coverage and documentation criteria:

- Supervisory clinical staff reviews clinical documentation at the OASIS timepoints (i.e., start-of-care, transfer to an inpatient facility, resumption of care, recertification, and discharge) to, among other things, validate that the documentation supports the beneficiary's homebound status and medical necessity of the services.
- As noted in section II, Residential's clinicians utilize evidence-based tests and measurements, such as the MAHC-10 fall risk assessment and the TUG test, that are highly relevant to patients' homebound statuses.
- Beneficiaries can only be recertified for a subsequent episode or discharged with supervisory approval following review of the chart.
- Supervisory clinical staff reviews charts involving high utilization of services to determine that the amount, frequency, and duration of services are medically reasonable and necessary. To this end, Residential employs a dedicated Director of Utilization Management to oversee cases with atypical service utilization.
- Supervisory clinical staff utilizes evidence-based best practices for recommendation of visit frequencies and identification of service needs. Some of these evidence-based practices, such as the MAHC-10 fall risk assessment tool, the Braden Scale for Predicting Pressure Sore Risk, and the TUG test, are incorporated into Residential's OASIS assessment templates. Our clinicians also utilize evidence-based treatment protocols, such as LSVT BIG® and LSVT LOUD®, where appropriate.

- Beneficiary or caregiver signatures are obtained for all visit notes to corroborate that the services were provided as ordered.¹⁴

IV. STATEMENT OF NONCONCURRENCE

For the reasons given below and as discussed herein, Residential does not concur with OIG's recommendations as stated in the Report.

OIG Recommendation No. 1: “We recommend that Residential Home Health refund to the Medicare program the portion of the estimated \$2,068,902 in overpayments for incorrectly billed claims that are within the reopening period.”

Residential Response: Residential does not concur with this recommendation because none of the sample claims were billed incorrectly. As explained in greater detail below, Residential disagrees with OIG's claim determinations because the auditors applied the wrong coverage standards during the course of their review, failed to adhere to or account for CMS guidelines, and ignored relevant clinical evidence. Residential also believes that the sampling methodology used by OIG to extrapolate the alleged overpayment is inherently flawed and unreliable.

OIG Recommendation No. 2: “We recommend that Residential Home Health, for the remaining portion of the estimated \$2,068,902 in overpayments for claims that are outside the Medicare reopening period, exercise reasonable diligence in identifying and returning overpayments in accordance with the 60-day rule, and identify any returned overpayments as having been made in accordance with this recommendation.”

Residential Response: Residential acknowledges its obligation to exercise reasonable diligence to identify potential overpayments upon receipt of credible information that an overpayment exists.¹⁵ However, Residential does not concur with OIG's recommendation because it intends to challenge the alleged overpayment assessment through the Medicare administrative appeals process.¹⁶ As CMS explained when implementing the 60-day rule, a provider may, upon receipt of adverse audit results, reasonably determine that it is premature to conduct an additional investigation while it appeals the audit findings:

[W]e recognize that in certain cases, the conduct that serves as the basis for [a] contractor identified overpayment may be nearly identical to conduct in some additional time period not covered by the contractor audit. If the provider appeals the contractor identified overpayment, the provider may reasonably assess that it is premature to initiate a reasonably diligent investigation into the nearly identical conduct in an additional time period until such time as the contractor identified overpayment has worked its way through the administrative appeals process.¹⁷

¹⁴ This corresponds with the following recommendation from OIG's compliance guidance: “A home health agency may consider including attestations on nursing note forms to be signed by caregivers for the purpose of reinforcing the importance of accurate documentation of services performed and billed.” 63 Fed. Reg. at 42416.

¹⁵ See generally 42 U.S.C. § 1320a-7k(d); 42 C.F.R. § 401.305.

¹⁶ See generally 42 C.F.R. § 405.940 *et seq.*

¹⁷ Medicare Program; Reporting and Returning Overpayments, 81 Fed. Reg. 7654, 7667 (Feb. 12, 2016).

In this case, Residential strongly believes that an investigation to identify other potential overpayments is not warranted at this time since the OIG's medical review decisions are incorrect and likely to be reversed on appeal.

OIG Recommendation No. 3: “We recommend that Residential Home Health 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.”

Residential Response: Residential respectfully disagrees with this recommendation for the same reason it does not concur with the OIG's second recommendation. Residential further notes that it exercises reasonable diligence to audit and monitor payments and return any overpayments on a regular basis. As explained in section III, Residential maintains strict controls processes related to auditing and monitoring payments, and it promptly refunds any monies determined to be overpayments. However, Residential does not believe that any of the payments identified in the Report are improper or should be considered overpayments.

OIG Recommendation No. 4: “We recommend that Residential Home Health strengthen its procedures to ensure that: the homebound statuses of Medicare beneficiaries are verified and continually monitored and the specific factors qualifying beneficiaries as homebound are documented; and beneficiaries are receiving only reasonable and necessary skilled services.”

Residential Response: As discussed at length in the preceding section, Residential is committed to strict adherence with all pertinent laws, rules, and regulations in general as well as Medicare coverage, documentation, coding, and billing requirements in particular. Residential has detailed policies and procedures in place to ensure that only reasonable and necessary home health services are rendered to homebound beneficiaries. As discussed in section III, Residential's effective compliance program and internal controls are based on and align with the compliance guidance for home health agencies promulgated by OIG.¹⁸ Because we disagree with OIG's medical review determinations and OIG has not identified any flaws or gaps in Residential's compliance program, we respectfully do not concur with this recommendation.¹⁹

V. OIG'S AUDIT WAS MARRED BY A LACK OF TRANSPARENCY, AND THE REPORT CONTAINS MISLEADING CONCLUSIONS.

Residential has general concerns regarding the manner in which OIG has conducted this audit. Although forthcoming with some case documents, OIG has withheld other materials that would be critical to Residential's ability to meaningfully comment on some of the contents of the Report. Residential also believes that some aspects of the Report are misleading and, consequently, should be corrected.

¹⁸ See 63 Fed. Reg. at 42410.

¹⁹ OIG followed Generally Accepted Government Auditing Standards in this case. Report at 4. *Government Auditing Standards*, promulgated by the Government Accountability Office (GAO), defines both design control deficiencies and operation control deficiencies in the context of field work standards for performance audits. GAO, *Government Auditing Standards*, Ch. 6 § 6.21 (2011). Neither type of deficiency is present in this case, so OIG should withdraw its fourth recommendation.

A. OIG Has Withheld Critical Audit-Related Materials Despite Residential’s Formal Requests Under the Freedom of Information Act.

At various stages of the audit process, Residential has submitted Freedom of Information Act (FOIA) requests to OIG for the following information:

- Materials related to the “computer matching, data mining, and data analysis techniques” that led OIG to conclude Residential was “at risk for noncompliance with Medicare billing requirements.”²⁰
- The curricula vitae (CVs) of OIG’s medical review contractors.²¹
- Any and all policies and procedures OIG followed when selecting the sample of claims and extrapolating the alleged overpayment.²²

Even though Residential submitted official FOIA requests seeking this information, it has not been permitted to receive or review any of these materials.²³ This lack of transparency has impeded Residential’s ability to fully and effectively respond to OIG’s findings.²⁴ For example, Residential is unable to meaningfully opine on OIG’s extrapolation methodology without first reviewing the guidelines that OIG purportedly followed when projecting the alleged overpayment. As of the date of this response, OIG has provided no reason for withholding this information from Residential.

There is, moreover, no legitimate basis for OIG to not disclose the credentials of its medical reviewers.²⁵ Generally Accepted Government Auditing Standards, to which the OIG claims to have adhered in this case, require sufficient competence, expertise, and technical knowledge on the part of auditors and specialists.²⁶ In the absence of the previously-requested CVs, neither Residential nor any third party is in a position to validate that this requirement has been met. Such a lack of transparency is deeply disturbing, particularly because OIG has alleged the existence of a Medicare overpayment of more than \$2 million based on these reviewers’ decisions.

B. OIG’s Projected Overpayment Amount is Misleading.

The alleged overpayment amount of \$2,068,902 is fundamentally misleading for two reasons. As OIG readily acknowledges, 6 of the 11 claim overpayments fall outside of the reopening period.²⁷ Removing these claims from the aggregate sample overpayment reduces the calculated amount by approximately 50%. This downward adjustment to the sample overpayment amount would dramatically reduce the projected overpayment. Residential has calculated that an

²⁰ Report at 1.

²¹ See Report at 4.

²² See Report at 17-18.

²³ See 5 U.S.C. § 552 *et seq.*; 45 C.F.R. § 5.1.

²⁴ Cf. 45 C.F.R. § 5.2(a) (HHS commenting that it will “administer the FOIA with a presumption of openness.”).

²⁵ Residential understands that it would be inappropriate for OIG to disclose documents containing the reviewers’ personally identifiable information, such as names, addresses, or telephone numbers. This is why Residential preemptively agreed to the redaction of all such sensitive information as part of its FOIA request. See 45 C.F.R. § 5.31(f).

²⁶ See *Government Auditing Standards*, Ch. 3 § 3.72, Ch. 6 §§ 6.42 and 6.43.

²⁷ See Report at 4. The 5 sample items within the reopening period as of the date of this response are S1-39, S1-40, S1-41, S1-50, and S2-45. The alleged overpayments for these claims amount to \$8,736.

extrapolation based only on the 5 claims subject to recovery would yield an overpayment estimate of only \$514,319. This is barely 25% of the alleged overpayment amount stated in the Report. Residential therefore requests that, upon final publication, OIG reduce the alleged overpayment figure based on the claims available for recovery inside the reopening period.

In addition, the alleged sample overpayment amount includes two claims that were refunded by Residential prior to the audit.²⁸ OIG should not and cannot effectively recover the same overpayment twice.²⁹ In fact, OIG has previously allowed providers subject to Medicare compliance reviews to initiate limited, preemptive refunds prior to completion of the audits without penalizing those providers with overpayment assessments for the same claims.³⁰ There is no reason to depart from that practice in this case. Although this issue only affects two sample items, OIG's effort to essentially recover the same two overpayments twice has a material impact on the extrapolated amount. Residential calculates that, upon removal of S1-8 and S1-28 from the list of improperly paid sample items, the projection amount will decrease by approximately \$700,000 to \$1,333,538.³¹

For these reasons, OIG should substantially revise the Report to ensure that the alleged overpayment amount stated, if any, is factually accurate and consistent with applicable rules and OIG's past practices in similar cases.

VI. OIG'S CLAIM DETERMINATIONS ARE INCORRECT BECAUSE THEY ARE INCONSISTENT WITH THE APPLICABLE COVERAGE STANDARDS AND FAILED TO ACCOUNT FOR RELEVANT CLINICAL EVIDENCE.

Residential's general responses to the OIG's medical review decisions are set forth below. Residential has also composed beneficiary-specific summaries for each of the denied or repriced claims explaining why the applicable coverage criteria have been met. Those summaries are marked as **Appendix B**.

A. Beneficiary Homebound Status.

The Medicare statute states the following with respect to beneficiary homebound status:

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

²⁸ These two claims are sample items S1-8 and S1-28.

²⁹ CMS has also stated as much. When implementing the final version of the 60-day rule, CMS observed in the Federal Register that it "will not recover an overpayment twice..." 81 Fed. Reg. at 7667.

³⁰ See *Medicare Compliance Review of Memorial University Medical Center*, Report No. A-04-17-08055, at 5-6 (Feb. 2018); *Medicare Payments to New York Rehabilitative Services LLC for Lower Limb Prosthetic Services Generally Complied with Certain Federal Requirements*, Report No. A-02-12-01002, at 3 (Jan. 2013).

³¹ This extrapolated amount includes claims that are outside of the reopening period and therefore not recoverable.

be such that there exists a normal inability to leave home and that leaving home requires a considerable and taxing effort by the individual.³²

CMS has interpreted this statute through Medicare Benefit Policy Manual (MBPM), which contains additional guidance regarding the conditions under which beneficiaries will be considered homebound.³³ The MBPM states in relevant part:

For purposes of the statute, an individual shall be considered ‘confined to the home’ (homebound) if the following two criteria are met:

1. 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.

2. Criterion Two

- There must exist a normal inability to leave home;

AND

- Leaving home must require a considerable and taxing effort.³⁴

The MBPM also contains several examples of beneficiaries who CMS would consider to be homebound.³⁵

For 6 of the 11 claims at issue, OIG’s reviewers concluded that the beneficiaries were not confined to their homes. In one case, the reviewer determined that the beneficiary was not homebound for the duration of the episode. In all other cases, the auditors found that the beneficiaries ceased being homebound at a seemingly arbitrary point during the certification period. All such determinations are flawed because they did not correctly apply Medicare coverage criteria and / or failed to account for relevant clinical evidence.

³² 42 U.S.C. § 1395f(a)(8).

³³ *See, e.g., Shalala v. Guernsey Mem’l. Hosp.*, 514 U.S. 87, 101 (1995) (describing a Medicare manual as a set of “interpretative rules...that advise providers how [CMS] will apply the Medicare statute and regulations...”).

³⁴ MBPM Ch. 7 § 30.1.1.

³⁵ *Id.*

1. Incorrect Coverage Standards.

OIG has applied improper coverage standards in that the reviewers have impermissibly used ambulation distance as a “rule of thumb” for determining beneficiary homebound status. The reviewers have also considered irrelevant factors, such as the structural or architectural features of beneficiaries’ homes, in reaching their decisions.

(a). Improper Standard: Ambulation Distance as a Rule of Thumb.

In some cases, the auditors found that beneficiaries were no longer homebound because they could ambulate for a certain distance during therapy visits. For example, the reviewers determined that beneficiary S1-39 was not homebound at the start of care because:

The patient was seen for physical therapy on 11/12/2014. She had used a walker since a prior hospitalization and was able to transfer and ambulate 300 feet with a steady gait and no loss of balance.

Similarly, the auditor found that S1-50 was no longer homebound at a specific point in the certification period because:

She improved with care and by 10/17/2015, she had progressed to ambulating 150 feet with a four-wheeled walker and standby assistance / moderate independence with verbal cues to slow stride. This is community level ambulation.

As these examples readily illustrate, the reviewer treated ambulation distance as dispositive of the beneficiary’s homebound status. This is both clinically inappropriate and contrary to Medicare coverage guidelines.

CMS regulations state that home health coverage decisions must be predicated on objective, clinical evidence regarding the beneficiary’s individual need for care.³⁶ For this reason, the MBPM explicitly disallows the use of “rules of thumb” when rendering coverage decisions:

Medicare recognizes that determinations of whether home health services are reasonable and necessary must be based on an assessment of each beneficiary’s individual care needs. Therefore, denial of services based on numerical utilization screens, diagnostic screens, or specific treatment norms is not appropriate.³⁷

Any presumption or general precondition that fails to account for a beneficiary’s individual care needs, therefore, constitutes an improper “rule of thumb.”³⁸ A decision that a beneficiary is not homebound because he or she can ambulate for a certain distance would thus qualify as a “rule of thumb” because it constitutes a presumption unrelated to the beneficiary’s unique clinical

³⁶ 42 C.F.R. § 409.44(a).

³⁷ MBPM Ch. 7 § 20.3.

³⁸ See, e.g., *Jimmo v. Sebelius*, 2011 WL 5104355, at *4-6 (D. Vt. 2011) (discussing the plaintiffs’ allegation that the “improvement standard” was an impermissible rule of thumb on which Medicare coverage of therapy services was conditioned).

condition as a whole and effectively creates a new coverage requirement for home health eligibility.³⁹

Even assuming that OIG's reviewers have not applied a "rule of thumb" in the form of ambulation distance, all such decisions are nevertheless clinically flawed because they were not based on objective, clinical evidence and failed to account for the beneficiaries' individual care needs.⁴⁰ The fact that a beneficiary may be able to ambulate for 100 or 200 feet during a therapy session inside his or her home (or in a facility with wide hallways, level surfaces, and handrails) with supervision or assistance from a licensed therapist and use of an assistive device does not demonstrate that the beneficiary would possess sufficient functional mobility to leave home safely, independently, and on a regular basis. The Medicare Appeals Council, which is the administrative appellate body responsible for issuing final administrative decisions as to Medicare claim appeals on behalf of the Secretary of Health and Human Services, has previously considered and rejected a similar approach to assessing beneficiary homebound status:

Turning to the factors which the [Administrative Law Judge] did discuss in determining that beneficiaries were not homebound, we find that, in many cases, the ALJ appears to have given decisive weight to aspects of the beneficiaries' condition that do not necessarily evidence that they were able to leave home safely at all or without considerable and taxing effort. For example, the ALJ relied on findings in OASIS reports that a beneficiary was independent with some or all basic activities of daily living (ADLs), without acknowledging that an ability to eat, dress, toilet, or bathe oneself is not equivalent to the ability to leave the house safely and without considerable effort. Nor does the ability to independently transfer from bed to chair or on to and off of a toilet imply sufficient independent mobility outside the home.⁴¹

The Council's point here is that any analysis of a beneficiary's homebound status must consider the safety with which the beneficiary would be able to leave home and / or the degree of effort that would be required for the beneficiary to leave his or her residence. Many of the OIG's adverse homebound determinations in this case fail that test. The singular focus on beneficiary ambulation distance inside of the home thus cannot and should not serve as a basis to conclude that the beneficiary is not homebound. OIG should withdraw all such determinations.

(b). Improper Standard: Structural or Architectural Features of Beneficiary's Residence.

In some instances, OIG's reviewers opined that beneficiaries were not homebound because of certain structural or architectural features of their residences. For example, the auditor commented in the case of S1-8 that the beneficiary "was residing in an accessible first floor apartment." For S1-39, the reviewer made mention of the fact that the beneficiary "was living in a home with ramp access and no stairs." There is no support in CMS regulations or coverage guidelines for the notion that a beneficiary should lose his or her eligibility for the Medicare home

³⁹ Cf. *id.*

⁴⁰ Cf. 42 C.F.R. § 409.44(a); MBPM Ch. 7 § 20.3.

⁴¹ *In the case of Quality Home Health Services, Inc.*, 2009 WL 10487060, at *6 (HHS 2009). Residential recognizes that Council decisions are not binding on the OIG. Such decisions are, however, exceedingly relevant insofar as they represent the Secretary's interpretation of Medicare coverage guidelines as applied to a particular fact pattern or claim.

health benefit or become presumptively ineligible for home care if he or she lives in a home with a ramp or an assisted living facility (ALF).⁴² The reviewers therefore reached the corresponding decisions in error.

2. Several Beneficiaries' Cases Align with Examples of Homebound Beneficiaries in the MBPM.

In some cases, the reviewers have ignored analogous examples of homebound beneficiaries given by CMS in the MBPM. This information would clearly be relevant to a homebound determination, yet it was not mentioned in any of the medical review determinations.⁴³

Beneficiary S1-50, for example, was admitted to home health services with Residential after being hospitalized for treatment of pneumonia. Her medical history was significant for diabetes, hypokalemia, dementia, encephalopathy, hypertension, tremors, coronary artery disease, osteopenia, and severe ataxia. The beneficiary was very hard of hearing, had poor endurance, became dyspneic with moderate exertion, depended on a walker to ambulate safely, and required 24-hour supervision due to her cognitive deficits. S1-50's physician appropriately certified that she was confined to her home.

As noted in the preceding section, the OIG reviewer concluded that S1-50 was no longer homebound less than 3 weeks into the episode because, "...she had progressed to ambulating 150 feet with a four-wheeled walker and standby assistance / moderate independence and verbal cues to slow stride." This rationale does not address the beneficiary's dementia and related cognitive impairment, which were highly relevant to her homebound status.

During the initial start of care assessment, the registered nurse described S1-50's cognitive functioning as follows: "Requires considerable assistance in routine situations. Is not alert and oriented or is unable to shift attention and recall directions more than half the time." The beneficiary was "constantly" confused, and she exhibited forgetfulness, impulsive behavior, and unsafe decision-making on a daily basis. Similarly, the physical therapist documented the following on the same date OIG found the beneficiary was no longer homebound: "Patient has dementia and requires frequent verbal cues to stay on task and for safety with walking and transfers to minimize fall risk."

S1-50's cognitive deficits were consistently documented by the home health clinicians throughout the episode. For example, the therapist stated the following upon the beneficiary's discharge on 11/02/15: "With dementia, [she] will require continued assistance for all ADLs to maximize her safety, especially cues to slow her gait pattern and properly performing transfers." These facts thus align closely with two examples of homebound beneficiaries in the Medicare Benefit Policy Manual:

⁴² See MBPM Ch. 7 § 30.1.2(A) (ALF can serve as a beneficiary's residence for home health purposes).

⁴³ See *Morris v. North Haw. Cmty. Hosp.*, 37 F.Supp.2d 1181, 1188 (D. Haw. 1999) (beneficiary homebound in part because the facts of his case "closely match[] the conditions of those identified in [CMS'] guidelines as being homebound.").

CMS Example of Homebound Beneficiary: “A patient who is...senile and requires the assistance of another person in leaving their place of residence.”⁴⁴

Although the term “senile” does not have a precise clinical definition, S1-50 indisputably suffered extensive cognitive and memory deficits, as described above, such that she required 24-hour supervision for safety. There also appears to be no dispute that the beneficiary required assistance from another person when leaving her home for the duration of the episode.

CMS Example of Homebound Beneficiary: “A patient with a psychiatric illness that is manifested in part by a refusal to leave home or is of such a nature that it would not be considered safe for the patient to leave home unattended, even if they have no physical limitations.”⁴⁵

While dementia is not a “psychiatric illness,” the record is clear that, because of her cognitive limitations, it would have been unsafe for S1-50 to leave her home unattended.

The OIG reviewer did not explain how it would have been safe for this beneficiary to leave home independently and on a regular basis given her cognitive and memory limitations. The reviewer also failed to distinguish the two analogous examples of homebound beneficiaries supplied by CMS in the manual. OIG should rescind this and all similarly flawed determinations.

3. In Most Cases, OIG’s Reviewers Failed to Consider Highly Probative Clinical Evidence in the Records.

The auditors also failed to account for relevant clinical evidence that showed the beneficiaries were homebound or remained homebound for the duration of the certification periods under review. As a general matter, a government agency’s failure to consider relevant evidence renders the resulting decision susceptible to reversal.⁴⁶ In the context of Medicare claim determinations, a reviewer’s failure to properly resolve conflicts in the clinical evidence is grounds for reversal of the coverage determination.⁴⁷

S2-7 is a prime example of this type of error. At the time of the episode under review, S2-7 was an 82 year-old female who lived alone. Prior to her admission to Residential, the beneficiary was treated in the hospital for an exacerbation of chronic obstructive pulmonary disease along with pneumonia. Her medical history was significant for congestive heart failure, hypertension, depression, anxiety, and anemia. The beneficiary used supplemental oxygen at a rate of 3 liters per minute via nasal cannula. S2-7 had poor endurance, used a walker to ambulate safely, and became noticeably short of breath with only minimal exertion.

Despite her clear functional limitations, the OIG reviewer found that S2-7 was no longer homebound approximately one month into the episode because she had made some progress during

⁴⁴ MBPM Ch. 7 § 30.1.1.

⁴⁵ *Id.*

⁴⁶ See, e.g., *Motor Vehicle Mfrs. Ass’n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

⁴⁷ See *Russell v. Sebelius*, 686 F.Supp.2d 386, 396-97 (D. Vt. 2010); *Burgess v. Shalala*, 1993 WL 327764, at *6-7 (D. Vt. 1993).

physical therapy treatments. The reviewer stated:

Her condition improved with care, and...she was able to ambulate 150 feet with a walker and cuing. She was able to ascend and descend her ramp without difficulty or shortness of breath. The patient progressed to modified independent for all transfers, bed mobility, and household ambulation using her walker. She was taught a [home exercise program] and she purchased an upper / lower extremity bike which was incorporated into the HEP. The patient improved in endurance and demonstrated improved balance with ADLs and upper extremity strength during the episode. She was no longer home bound [sic].

This decision, which focuses almost exclusively on the amount of gait training S2-7 was able to tolerate during physical therapy, ignores the following probative evidence in the record:

- The physical therapy visit note dated the same day OIG determined S2-7 was no longer homebound reflects that the beneficiary reported slight effort on the cardiac rehabilitation breathing scale, and her time on task was limited to 8 minutes.
- S2-7 exhibited shortness of breath with balance activities performed during occupational therapy sessions and continued to use supplemental oxygen for the duration of the episode. For example, on 05/01/14, the occupational therapist documented: “Patient continues to demonstrate decreased pulmonary function requiring O2 via nasal cannula to complete basic ADLs / instrumental ADLs.”
- Around the conclusion of the episode on 05/20/14, the occupational therapist assessed S2-7’s standing tolerance as limited to 8 minutes. A patient would clearly need to tolerate standing for much longer durations in order to leave home safely, regularly, and without significant effort.
- The clinicians who treated the beneficiary for the duration of the episode assessed S2-7’s homebound status during each visit and explicitly documented that the beneficiary remained confined to her home.⁴⁸

These clinical facts strongly support that S2-7 was confined to her home for the entire certification period. Although her cardiopulmonary endurance had improved, the beneficiary continued to require supplemental oxygen at a rate of 3 liters via nasal cannula to complete basic ADLs such as dressing, grooming, and housekeeping. This, considered with S2-7’s limited standing tolerance, strongly suggests that the beneficiary would not have been able to leave home without a considerable and taxing effort. A complete review of all of the clinical evidence in the records for this and all other claims will substantiate that the beneficiaries met Medicare criteria for homebound status.

B. Medical Necessity.

In 6 of 11 cases, OIG’s reviewers found that the beneficiaries did not require skilled care. For 2 claims, the auditors alleged that none of the services provided to the beneficiaries were

⁴⁸ Cf. 63 Fed. Reg. at 42416.

medically reasonable and necessary. In the remaining 4 cases, the reviewers determined that skilled care should have terminated at an earlier date than the treating physicians and clinicians believed it would have been appropriate or safe to do so.⁴⁹ Once again, however, these decisions were based on an inaccurate understanding of Medicare coverage criteria for home health services.

According to CMS regulations, “skilled” services are those that can only be safely and effectively provided by licensed or technical personnel.⁵⁰ The policy manual elaborates:

A skilled nursing service is a service that must be provided by a registered nurse or a licensed practical (vocational) nurse under the supervision of a registered nurse to be safe and effective. In determining whether a service requires the skills of a nurse, the reviewer considers both the inherent complexity of the service, the condition of the patient, and accepted standards of medical and nursing practice.

Some services may be classified as a skilled nursing service on the basis of complexity alone...[h]owever, 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 by a nurse.⁵¹

With respect to general coverage requirements for skilled nursing services, the MBPM goes on to state that such services must be:

...reasonable and necessary to the diagnosis and treatment of the patient’s illness or injury within the context of the patient’s unique medical condition...A patient’s overall medical condition is a valid factor 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. The determination of whether the services are reasonable and necessary should be made in consideration that a physician has determined that the services are reasonable and necessary. ***The services must, therefore, be viewed from the perspective of the patient when the services were ordered and what was, at that time, reasonably expected to be appropriate treatment for the illness or injury throughout the certification period.***⁵²

Therapy services are also covered as part of the home health benefit under the following general conditions:

The service of a [licensed] therapist...is a skilled therapy service if the inherent complexity of the service is such that it can be performed safely and / or effectively only by or under the general supervision of a skilled therapist. To be covered, assuming all other eligibility and coverage criteria have been met, the skilled services must also be reasonable and

⁴⁹ Cf. MBPM Ch. 7 § 20.1.1 (“In enacting the Medicare program, Congress recognized that the physician would play an important role in determining utilization of services.”).

⁵⁰ See 42 C.F.R. § 409.44(b)(1).

⁵¹ MBPM Ch. 7 § 40.1.

⁵² MBPM Ch. 7 § 40.1.1 (emphasis added).

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. It is necessary to determine whether individual therapy services are skilled and whether, in view of the patient's overall condition, skilled management of the services provided is needed.⁵³

A reasonable review of the medical records for the applicable claims will support that, contrary to OIG's decisions, the coverage criteria summarized above have been met.

1. Incorrect Coverage Standards.

As with the claims denied for beneficiary homebound status, OIG has applied improper coverage standards in reaching the erroneous conclusions that some services were not medically necessary.

(a). Improper Standard: Denial of Services Due to Chronic Conditions.

In some cases, OIG's reviewers focused on the "chronic" or "longstanding" nature of the beneficiaries' conditions in reaching their unfavorable decisions. In the case of S1-50, for example, the auditor found that, "As of 10/16/2015, the patient's catheter had been removed. Her medical conditions were of long standing [sic] and she had caregiver assistance available for processing information with respect to education regarding her medical conditions." Similarly, the reviewer noted that S1-6's condition (muscular dystrophy) was "chronic" in denying the medically necessary speech therapy services provided to that beneficiary.

The issue of whether a beneficiary's condition or diagnosis is acute or chronic is totally irrelevant to the issue of whether the beneficiary qualifies for intermittent skilled care under the home health benefit. Medicare regulations provide that, "The determination of whether skilled nursing care is reasonable and necessary must be based solely upon the beneficiary's unique condition and individual needs, without regard to whether the illness or injury is acute, chronic, terminal, or expected to last a long time."⁵⁴ With respect to therapy services, the MBPM states that, "...a patient's diagnosis or prognosis should never be the sole factor in deciding that a service is or is not skilled."⁵⁵ There is simply no way to conclude that OIG's claim decisions were made in compliance with these principles.

(b). Improper Standard: Denial of Services Due to "Stable" Conditions.

In other instances, the auditors denied services because the beneficiaries' conditions were allegedly "stable." While Residential emphatically disputes those characterizations of the beneficiaries' disease processes, the stability of a beneficiary's condition alone would not be a valid basis on which to deny services. As one federal court has aptly observed:

The fact that skilled care has stabilized a claimant's health does not render that level of care unnecessary. An elderly claimant need not risk a deterioration of her fragile health to

⁵³ MBPM Ch. 7 § 40.2.1.

⁵⁴ 42 C.F.R. § 409.44(b)(3)(iii).

⁵⁵ MBPM Ch. 7 § 40.2.1.

validate the continuing requirement for skilled care.⁵⁶

This is precisely why CMS recognizes that skilled services are covered so long as a beneficiary presents with a reasonable potential for suffering an acute exacerbation in his or her condition.⁵⁷

S1-28 is an example of such an improperly denied claim. This beneficiary was a 92 year-old female who resided in an adult foster home. S1-28 suffered from dementia and, due to her resulting cognitive deficits, required around-the-clock supervision. The beneficiary's medical history was also significant for severe osteoarthritis, hypertension, hyperlipidemia, depression, arthropathy, chronic back pain, and recurrent falls. She was admitted to Residential for skilled care following a visit with her physician. During that encounter, the physician assessed S1-28 as "pleasantly confused" and with complaints of lower back and hip pain. The physician further noted that S1-28, "has lost a lot of weight since her last [office visit]...I asked her sister in law to be sure her home is getting her to all meals and she needs a supplement in between." Given the beneficiary's history of dementia, recent unexplained weight loss, and complaints of pain, a brief period of skilled care was warranted. In accordance with the policy manual, S1-28 was admitted to Residential for one month.⁵⁸ Once it became apparent that the beneficiary did not have skilled needs, she was discharged from home health services at that time. Because this beneficiary presented with a reasonable potential for an acute exacerbation in her condition, the skilled services provided to her are covered by Medicare. OIG should rescind its decision for this and similar cases.

The preceding discussion is intended to address the most prominent thematic issues in OIG's claim determinations. As summarized above, the reviewers applied incorrect coverage standards when auditing virtually all of the claims at issue. Moreover, a reasonable review of the relevant documentation will support that, in view of the proper coverage standards, the services under review were medically reasonable and necessary and the beneficiaries were confined to their homes. OIG should therefore reconsider and withdraw its adverse medical review decisions.

VII. OIG'S OVERPAYMENT PROJECTION IS ARBITRARY, CAPRICIOUS, UNRELIABLE, AND FLAWED.

OIG's sampling methodology is both substantively and procedurally flawed. As explained below, OIG has failed to follow its own guidelines for extrapolation in similar cases, maintain sufficient documentation in connection with its statistical methodology, and properly execute its chosen sample design.

A. OIG Has No Basis to Extrapolate in this Case.

As an initial matter, OIG is not required to extrapolate an overpayment identified during

⁵⁶ *Folland v. Sullivan*, 1992 WL 295230, at *7 (D. Conn. 1992).

⁵⁷ See MBPM Ch. 7 § 40.1.2.1 ("Where a patient was admitted to home health care for skilled observation because there was a reasonable potential of a complication or further acute episode but did not develop a further acute episode or complication, the skilled observation services are still covered for 3 weeks or so long as there remains a reasonable potential for such a complication or further acute episode.").

⁵⁸ The nurses also educated S1-28's caregivers regarding the disease process of dementia. Teaching and training constitute covered skilled services under the Medicare home health benefit. 42 C.F.R. § 409.33(a)(3); MBPM Ch. 7 § 40.1.2.3.

the course of a Medicare compliance review. In fact, OIG has published reports following similar reviews of other providers that did not result in extrapolated overpayments. For example, OIG completed an audit of a pharmacy in 2017 that found 3 out of 100 claims did not satisfy Medicare coverage rules. OIG did not extrapolate the alleged overpayment of \$48 to the pharmacy's universe of claims.⁵⁹ Similarly, OIG performed a review of certain Medicare claims submitted by a prosthetics supplier in 2013. In that case, OIG determined that 2 of the 100 claims at issue were billed incorrectly, resulting in overpayments of \$1,929 to the supplier.⁶⁰ These reports confirm that OIG has the discretion to determine when to extrapolate alleged overpayments based on Medicare compliance reviews of providers. OIG should accordingly exercise its discretion and withdraw the alleged extrapolated overpayment identified in the Report.

As discussed in section I, the payment error rate calculated from OIG's review is a miniscule 4.4%. In fact, the true payment error rate is even lower. As OIG acknowledges in the Report, several denied claims fall outside of the reopening period.⁶¹ As of the date of this response, only 6 claims with alleged overpayments totaling \$8,736 are still within the reopening window. The payment error rate among claims subject to recovery is therefore 2.3%. In either case, extrapolation of the sample results to the population is inappropriate – a conclusion that is confirmed by OIG's guidance for similar cases.⁶²

The limited public guidance available from OIG on the topic of statistical sampling relates to the performance of “systems reviews” by independent review organizations (IROs) of providers subject to corporate integrity agreements (CIAs).⁶³ There, OIG explains that the purpose of a systems review is to, “...identify problems and weaknesses that resulted in overpayments. A systems review is a walk-through of the system(s) and process(es) that generated the paid claim determined to be in error.” Similarly, OIG states in the Report that its objective with this Medicare compliance review was to, “...determine whether Residential complied with Medicare requirements for billing home health services on selected types of claims.” Many CIAs provide for review of “discovery samples,” the purpose of which is to probe for potential errors in the provider's claims. If the payment error rate from the discovery sample is less than 5%, OIG does not require the provider to proceed to review of a “full sample” and extrapolate the audit results to its universe of claims.

“It is axiomatic that [a government] agency must treat similar cases in a similar manner unless it can provide a legitimate reason for failing to do so...if an agency treats similarly situated

⁵⁹ *Lincare Pharmacy Services, Inc. Generally Complied with Medicare Requirements When Billing for Inhalation Drugs*, Report No. A-09-16-02037 (Dec. 2017).

⁶⁰ *Medicare Payments to New York Rehabilitative Services LLC for Lower Limb Prosthetic Services Generally Complied with Certain Federal Requirements*, Report No. A-02-12-01002 (Jan. 2013).

⁶¹ See generally 42 C.F.R. § 405.980.

⁶² Generally Accepted Government Auditing Standards also suggest that sample results should only be projected to the population in cases where “sampling significantly supports the auditors' findings.” *Government Auditing Standards*, Ch. 7 § 7.13. That is certainly not the case here. During the 2014-2015 audit period, Residential received \$82,672,273.59 in Medicare payments. The payment error amount of \$16,927 therefore represents only .00068% of Residential's Medicare revenue for the relevant timeframe.

⁶³ See Office of Inspector General, *Corporate Integrity Agreement FAQ*, available at <https://oig.hhs.gov/faqs/Corporate-Integrity-Agreements-faq.asp> (last accessed October 13, 2019).

parties differently, its action is arbitrary and capricious in violation of the [law].”⁶⁴ OIG’s guidance and the Report make clear that the purpose of a CIA systems review is virtually indistinguishable from the objective of this Medicare compliance review. OIG must therefore provide a legitimate reason for electing to use extrapolation in this case, where the payment error rate is only 4.4%, whereas it would not have required a similarly situated provider under a CIA to extrapolate its findings upon review of a discovery sample. The Report contains absolutely no reasoning to justify OIG’s use of extrapolation given the exceedingly low payment error rate in this case.

The Medicare statute provides that extrapolation, when used in the context of post-payment claim audits, should be reserved for cases where an audit reveals a “sustained or high level of payment error.”⁶⁵ Although the law and the implementing regulatory authority do not contain a threshold error rate, CMS has issued sub-regulatory guidance suggesting that a payment error rate should exceed 50% before audit results are eligible for extrapolation. The Medicare Program Integrity Manual (MPIM) states:

The contractor shall use statistical sampling when it has been determined that a sustained or high level of payment error exists. The use of statistical sampling may be used after documented educational intervention has failed to correct the payment error. For purposes of extrapolation, a sustained or high level of payment error shall be determined to exist through a variety of means, including, but not limited to: [h]igh error rate determinations by the contractor or by other medical reviews (i.e., ***greater than or equal to 50 percent from previous pre- or post-payment review***)...⁶⁶

Residential appreciates that this statutory provision and CMS’ related manual instructions are not binding on OIG. But these rules will directly bear on the question of whether CMS can even accept OIG’s findings as to the amount of the alleged overpayment in the first instance.⁶⁷ This principle is part of field work standards for performance audits contained in Generally Accepted Government Auditing Standards. There, GAO explains:

Auditors should obtain an understanding of the nature of the program or program component under audit and the potential use that will be made of the audit results or report as they plan a performance audit.⁶⁸

By extrapolating the audit results in this case despite the exceedingly low error rate, OIG has failed to consider CMS’ rules and regulations. Because OIG lacks a valid justification for extrapolating the alleged overpayment in this case, the recommendations in the Report should be updated to include only the actual amounts for claims that remain inside the reopening period as of the date of publication.

⁶⁴ *El Rio Santa Cruz Neighborhood Health Ctr., Inc. v. Dep’t. of Health & Human Servs.*, 300 F.Supp.2d 32, 42-43 (D.D.C. 2004) (citations and quotations omitted).

⁶⁵ 42 U.S.C. § 1395ddd(f)(3).

⁶⁶ MPIM Ch. 8 § 8.4.1.4 (emphasis added).

⁶⁷ See Report at 8, n.14 (“OIG audit recommendations do not represent final determinations by the Medicare program but are recommendations to HHS action officials.”).

⁶⁸ *Government Auditing Standards*, Ch. 6 § 6.13.

B. OIG Did Not Create a Sampling Plan that Was Finalized Before the Sample Was Selected and the Alleged Overpayment Was Extrapolated or Identify the Guidelines Followed During the Extrapolation Process.

The sampling materials produced by OIG included the seed value, the random numbers used to select the claims, the RAT-STATS variable appraisal output, the sampling frame, the sample, and the medical review findings. OIG also provided an undated Microsoft Word document entitled “READ ME FIRST” that summarized the sampling materials and contained a broad overview of the process OIG purportedly followed to extrapolate the overpayment.

There is no evidence among the documents produced to Residential that OIG designed and finalized its sampling plan prior to the selection of the sample of claims. This is necessary to ensure the integrity of any sampling process so that the statistician does not alter his or her sample design in an effort to affect the alleged overpayment amount. This is precisely why formal guidelines for statistical sampling often require the adoption of a sampling plan prior to the selection of the sample and the extrapolation of findings to the universe.⁶⁹

The Report also fails to identify the sampling policy or guidelines followed by OIG in this case. Generally Accepted Government Auditing Standards generally require that,

Auditors should identify criteria. Criteria represent the laws, regulations, contracts, grant agreements, standards, specific requirements, measures, expected performance, defined business practices, and benchmarks against which performance is compared or evaluated. Criteria identify the required or desired state or expectation with respect to the program or operation. Criteria provide a context for evaluating evidence and understanding the findings, conclusions, and recommendations included in the report. Auditors should use criteria that are relevant to the audit objectives and permit consistent assessment of the subject matter.⁷⁰

The criteria set forth in an audit report are important because they serve as the benchmarks against which the audit results are to be measured. Without such criteria, an independent auditor, reviewer, or even the auditee would be unable to meaningfully assess the results of the audit.⁷¹ OIG’s failure to identify the criteria for its statistical sampling methodology prejudices Residential insofar as it is unable to meaningfully assess OIG’s adherence to those criteria.

C. The Precision Value of OIG’s Estimate is Unacceptably High at 54.07%, Thereby Rendering the Overpayment Projection Fundamentally Unreliable.

The precision value and the confidence level are the two most important parameters characterizing a statistical estimate. Because of this, statisticians control the precision and

⁶⁹ See generally MPIM Ch. 8 §§ 8.4.4.4 (Medicare contractor shall maintain “complete documentation” of the sampling methodology followed), 8.4.4.4.1 (CMS requires an “explicit statement” of how the universe, sampling frame, and sampling units are defined), and 8.4.4.2 (Medicare requires a record of the random number selection used during the sampling process).

⁷⁰ *Government Auditing Standards*, Ch. 6 § 6.37.

⁷¹ *Government Auditing Standards*, Ch. 6 § 6.79.

confidence level by properly adjusting the size of their samples. This is typically done using statistical software, such as RAT-STATS. OIG's sampling documentation does not reflect that any effort was made to appropriately size the sample in order to control the precision of the resulting estimate.

OIG's overpayment estimate is situated at the lower bound of a 90% two-sided confidence interval. The precision for the estimate is 54.07%. This means that OIG is 95% certain that the overpayment amount is at least \$2,068,902. However, there is a 5% chance that this estimate may be more than what Residential allegedly owes. And if this case is among the 5% of cases where Residential would be required to repay more than what it allegedly owes, the difference between this amount and what it actually owes will be *more than double* what it would have otherwise been if OIG had achieved the 25% precision value contemplated by its own guidelines. This fundamentally undermines the reliability of OIG's overpayment projection.

Because the precision value and confidence levels are so important to generating a reliable and accurate overpayment estimate, OIG places limitations on those parameters for providers when performing systems reviews in the context of CIAs. Generally speaking, OIG requires that providers utilize statistical software, such as RAT-STATS, to appropriately size their samples to achieve a 25% precision level and a 90% confidence interval:

If the size of the full sample was determined by RAT-STATS or another statistical software package to reach a 90 percent confidence and 25 percent precision level, and if the actual precision level exceeds 25 percent at the 90 percent confidence level, the IRO does not need to review additional paid claims. The number of paid claims identified by statistical software for review is an estimate that is based on the results of the discovery sample. Because this is an estimate, some samples will achieve a precision better than 25 percent and some worse than 25 percent. (emphasis added).

In cases where a provider audits a "full sample" (i.e., a sample from which the results will be extrapolated to the population) based on a discovery sample, OIG states:

There is no set number of claims that the IRO is required to examine in the full sample. The full sample size is based on the mean and standard deviation of the overpayment amount as calculated in the discovery sample. As a result, the full sample must include a sufficient number of paid claims *to yield results that estimate the overpayment in the population to be within certain confidence and precision levels (e.g., 90 percent confidence and 25 percent precision)*. The sample size will vary according to the variability of the discovery sample and the size of the population. (emphasis added).

OIG's sample design in this case does not follow the guidelines for CIA systems reviews because (1) OIG failed to use statistical software to determine an adequate sample size; and (2) the precision value for the estimate is more than twice the 25% threshold.⁷²

⁷² As explained in section VII.A, the purposes of a CIA systems review and a Medicare compliance review are virtually identical. OIG is therefore required to treat such cases in a similar manner in the absence of a legitimate reason for doing otherwise. The Report contains no such justification.

Due to the unreliable nature of its estimate, there is little reason to believe that OIG's sampling methodology would be accepted as valid by an administrative or judicial tribunal. For example, one federal court recently held that an extrapolated Medicare overpayment assessed against a home health provider was fatally flawed due to a precision value of 32.4%.⁷³ The court concluded:

[The Medicare contractor's] poor precision level is indicative of the unreliability of its methodology and the results of its analysis. The 32.4% precision level affects the weight [the methodology] should be afforded in this Court. The statistical analysis is clearly too unreliable for it to constitute substantial evidence to support the [Medicare] Appeals Council's decision.⁷⁴

In the event Residential is forced to appeal OIG's audit findings, we believe a similar result would obtain in this case. Because OIG has not followed its own guidance and achieved such as remarkably poor precision for its estimate, the extrapolated overpayment determination should be withdrawn.

D. The Extrapolated Overpayment Calculation Does Not Appear to Give Residential Credit for the Underpayment Identified by the Medical Reviewers.

OIG's initial medical review results contained one case where the auditors concluded Residential was *underpaid*. In the case of S2-46, the reviewers found that the claim was not coded correctly, and Residential therefore entitled to an additional \$48.35 in reimbursement. This underpayment is not included in the "Summary of Findings" spreadsheet delivered with OIG's other sampling materials.

Any alleged overpayments identified during the course of a post-payment audit should fairly be offset by any underpayments that are also discovered. For example, CMS guidelines for statistical sampling state, "[s]ampling units that are found to be underpayments, in whole or in part, are recorded as negative overpayments and shall be used in calculating the estimated overpayment."⁷⁵ In the event OIG declines to withdraw its flawed extrapolation, it should, at a minimum, recompute the alleged overpayment amount to include the underpayment for S2-46.

VIII. CONCLUSION

Providers like Residential play a vital role in our nation's healthcare system in that they enable elderly patients to reside as safely and independently as possible in their own homes. This enhances patient quality of life and reduces the need for utilization of more costly healthcare services, such as hospital admissions.

⁷³ *Cent. La. Home Health Care, LLC v. Price*, 2018 WL 7888523 (W.D. La. 2018); *see also Duran v. U.S. Bank Nat'l. Ass'n.*, 172 Cal.Rptr.3d 371, 325 (2014) (characterizing a precision value of 43.3% as "intolerably high").

⁷⁴ *Cent. La. Home Health*, 2018 WL 7888523 at *20.

⁷⁵ MPIM Ch. 8 § 8.4.5.2. CMS restates this requirement frequently throughout the MPIM. *See* MPIM Ch. 8 §§ 8.4.3.2.2, 8.4.4.4.3, 8.4.4.4.4, 8.4.5.1, 8.4.6.3, and 8.4.7.1.

Residential maintains that OIG's coverage determinations are flawed in that they did not properly apply Medicare coverage guidelines for home health services or fully account for the clinical information available in the medical records. Residential believes that a reasonable and fair review of the documentation will substantiate that all of the services at issue were medically reasonable and necessary and furnished to beneficiaries who met the homebound criteria.

The extrapolated overpayment assessment is flawed insofar as OIG failed to adhere to its own guidelines and achieved a remarkably poor precision value for its estimate. Due to the inherently unreliable nature of OIG's projection, the final report should be revised to reference only the actual amount(s) of any remaining denied claim(s).

Although Residential intends to vigorously contest the findings summarized in the Report through the CMS administrative appeals process, it nonetheless appreciates the opportunity to comment on the Report. Residential would also like to extend its gratitude to the OIG auditors for their professionalism and many courtesies extended throughout the audit process.

Respectfully Submitted,

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