

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**MEDICARE HOME HEALTH AGENCY
PROVIDER COMPLIANCE AUDIT:
TOTAL PATIENT CARE
HOME HEALTH, LLC**

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Office of Inspector General

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OFFICE OF AUDIT SERVICES FINDINGS AND OPINIONS

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Report in Brief

Date: December 2020

Report No. A-06-16-05005

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 Total Patient Care Home Health, LLC (TPC), 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: Total Patient Care Home Health, LLC

What OIG Found

TPC did not comply with Medicare billing requirements for 32 of the 100 home health claims that we reviewed. For these claims, TPC received overpayments of \$75,461 for services provided during our audit period, October 1, 2014, through September 30, 2016. Specifically, TPC incorrectly billed Medicare for services provided to beneficiaries who were not homebound or did not require skilled services. On the basis of our sample results, we estimated that TPC received overpayments of at least \$1.7 million for our audit period. All 100 claims within our sample are outside of the Medicare 4-year claim-reopening period.

What OIG Recommends and TPC Comments

We recommend that TPC exercise reasonable diligence to identify, report 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 TPC 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, TPC disagreed with our findings and recommendations and stated that it intends to contest our findings through the appeals process. To address TPC's concerns for all claims we originally found in error, we had our medical reviewer again review all 38 of the claims originally found in error. Based on the results of that review, we revised our determinations, reducing the total number of sampled claims incorrectly billed from 38 to 32, and adjusted the findings for 13 of the 32 claims. In addition, we eliminated one error category included in the draft report. We revised our related findings and recommendations accordingly. With these actions taken, we maintain that our remaining findings and recommendations, as revised, are valid. We acknowledge TPC's right to appeal the findings.

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INTRODUCTION

WHY WE DID THIS AUDIT

For calendar year (CY) 2016, Medicare paid home health agencies (HHAs) about \$18 billion for home health services. The Centers for Medicare & Medicaid Services (CMS) determined through its Comprehensive Error Rate Testing (CERT) program that the 2016 improper payment error rate for home health claims was 42 percent, or about \$7.7 billion. Although Medicare spending for home health care accounts for only about 5 percent of fee-for-service spending, improper payments to HHAs account for more than 18 percent of the total 2016 fee-for-service improper payments (\$41 billion). This audit is part of a series of audits of HHAs. Using computer matching, data mining, and data analysis techniques, we identified HHAs at risk for noncompliance with Medicare billing requirements. Total Patient Care Home Health, LLC (TPC), was one of those HHAs.

OBJECTIVE

Our objective was to determine whether TPC 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)

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

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

Home Health Agency Claims at Risk for Incorrect Billing

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

- beneficiaries did not always meet the definition of “confined to the home,”
- beneficiaries were not always in need of skilled services,
- HHAs did not always submit OASIS data 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 § 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, needs physical therapy or speech-language pathology, or has a continuing need for occupational therapy;
- under the care of a physician; and

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

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

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

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

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

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

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

Medicare Requirements for Providers To Identify and Return Overpayments

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

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

Total Patient Care Home Health, LLC

TPC is a proprietary home health care provider located in Richardson, Texas. Palmetto GBA, its Medicare contractor, paid TPC over \$15 million for approximately 4,000 claims for services

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

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

provided from October 1, 2014, through September 30, 2016 (audit period),⁶ on the basis of CMS's National Claims History (NCH) data.

HOW WE CONDUCTED THIS AUDIT

Our audit covered \$15,114,365 in Medicare payments to TPC for 3,994 claims.⁷ These claims were for home health services provided during our audit period.⁸ We selected a stratified random sample of 100 claims with payments totaling \$426,008 for review. We evaluated compliance with selected billing requirements and submitted these claims to independent medical review to determine whether the services met coverage, medical necessity, and coding requirements.

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

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

FINDINGS

TPC did not comply with Medicare billing requirements for 32 of the 100 home health claims that we reviewed. For these claims, TPC received overpayments of \$75,461 for services provided during our audit period. Specifically, TPC incorrectly billed Medicare for:

- services provided to beneficiaries who were not homebound and
- services provided to beneficiaries who did not require skilled services.

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

⁶ These claims were for home health services provided during the most recent timeframe for which data was available at the start of the audit.

⁷ In developing this sampling frame, we excluded from our audit home health claim payments for low utilization payment adjustments, partial episode payments, and requests for anticipated payments.

⁸ The HHA claim "through" date of service is the last day on the billing statement covering services provided to the beneficiary.

⁹ One sample item had more than one type of error.

On the basis of our sample results, we estimated that TPC received overpayments of at least \$1,749,462 for the audit period.¹⁰ As of the publication of this report, all 100 claims within our sample are outside of the Medicare 4-year claim-reopening period.

TOTAL PATIENT CARE HOME HEALTH, LLC, BILLING ERRORS

TPC incorrectly billed Medicare for 32 of the 100 sampled claims, which resulted in overpayments of \$75,461.

Beneficiaries Were Not Homebound

Federal Requirements for Home Health Services

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

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

CMS provided further guidance and specific examples in the Manual (chapter 7, § 30.1.1). Revision 172 of section 30.1.1 (effective November 19, 2013) and revision 208 of section 30.1.1 (effective January 1, 2015) covered different parts of our audit period.¹¹

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

¹⁰ To be conservative, we recommend recovery of overpayments at the lower limit of a two-sided 90 percent confidence interval. Lower limits calculated in this manner are designed to be less than the actual overpayment total 95 percent of the time.

¹¹ Coverage guidance is identical in both versions of the Manual chapter 7 § 30.1.1 in effect during our audit period. The only difference are minor revisions to a few examples.

Criterion One

The patient must either:

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

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

Criterion Two

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

Total Patient Care Home Health, LLC, Did Not Always Meet Federal Requirements for Home Health Services

For 28 of the sampled claims, TPC incorrectly billed Medicare for home health episodes for beneficiaries who did not meet the above requirements for being homebound for the full episode (6 claims) or for a portion thereof (22 claims).¹²

Example 1: Beneficiary Not Homebound—Entire Episode

The physical therapy evaluation documentation for one beneficiary showed that, from the start of the episode, the patient was able to independently walk on even and uneven surfaces and negotiate stairs without requiring assistance. There were no ongoing medical contraindications to leaving the home or any structural or mobility barriers. For the entire episode, leaving home did not require a considerable or taxing effort, and the medical information provided did not support that the patient was homebound.

Example 2: Beneficiary Not Homebound—Partial Episode

For another beneficiary, records showed that the patient was initially homebound. She was being treated for a shoulder fracture and required a partial shoulder replacement. In addition, she had shortness of breath with

¹² Of these 28 claims with homebound errors, 1 claim was also billed with skilled services that were not medically necessary. Appendix E provides detail on the extent of errors, if any, per claim reviewed.

weakness and decreased endurance. By a later date in the episode, the beneficiary was able to ambulate 250 feet without an assistive device and no reported weakness, and she had been discharged from home-based physical therapy to attend outpatient therapy treatments. At this later date in the episode, leaving home did not require a considerable or taxing effort, and the medical information provided did not support that the patient remained homebound.

These errors occurred because TPC (1) did not have adequate oversight procedures to ensure that it verified and continually monitored the homebound status of Medicare beneficiaries under its care and (2) did not properly document the specific factors that qualified the beneficiaries as homebound.

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).¹³ Skilled therapy services must be reasonable and necessary to the treatment of the patient's illness or injury or to the restoration or maintenance of function affected by the patient's illness or injury within the context of the patient's unique medical condition (42 CFR § 409.44(c) and the Manual, chapter 7, § 40.2.1). Coverage of skilled nursing care or therapy does not turn on the presence or absence of a patient's potential for improvement, but rather on the patient's need for skilled care. Skilled care may be necessary to improve a patient's current condition, to maintain the patient's current condition, or to prevent or slow further deterioration of the patient's condition (the Manual, chapter 7, § 20.1.2).

¹³ Skilled nursing services may 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).

Total Patient Care Home Health, LLC, Did Not Always Meet Federal Requirements for Skilled Services

For five of the sampled claims, TPC incorrectly billed Medicare for a portion of the home health episode for beneficiaries who did not meet the Medicare requirements for coverage of skilled nursing or therapy services.¹⁴

Example 3: Beneficiary Did Not Require Skilled Services

A beneficiary with multiple co-morbid medical conditions affecting her mobility was homebound. A physical therapy evaluation was indicated to assess the patient's mobility and need for an assistive device and home exercise program. At that evaluation the patient had no pain, shortness of breath, fatigue, or weakness. Her memory deficit included a failure to recognize person, place, and lack of ability to recall events of the last 24 hours, with impaired decision making. The patient did not have capacity to respond to the cognitive aspect of physical therapy. She needed a repetitive exercise program, not continued physical therapy.

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

OVERALL ESTIMATE OF OVERPAYMENTS

On the basis of our sample results, we estimated that TPC received overpayments totaling at least \$1,749,462 for the audit period. As of the publication of this report, all 100 claims within our sample are outside of the Medicare 4-year claim-reopening period.

RECOMMENDATIONS

We recommend that Total Patient Care Home Health, LLC:¹⁵

- based on the results of this audit, exercise reasonable diligence to identify, report, and return any overpayments in accordance with the 60-day rule and identify any of those

¹⁴ Of these five claims with skilled-need services that were not medically necessary, one claim was also billed for a beneficiary with a homebound error. Appendix E provides detail on the extent of errors, if any, per claim reviewed.

¹⁵ Our draft report contained a recommendation that Total Patient Care refund to the Medicare program the portion of the estimated overpayment for claims incorrectly billed that were within the reopening period. As of the date of issuance of this final report, all estimated overpayments are beyond the reopening period, so we have removed the recommendation to refund them. We also consolidated the two 60-day rule recommendations in our draft report into one in this final report.

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.

TOTAL PATIENT CARE HOME HEALTH, LLC, COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

TOTAL PATIENT CARE HOME HEALTH, LLC, COMMENTS

In written comments on our draft report, TPC, through its attorney, disagreed with all four of our original recommendations. For the first recommendation, to refund overpayments for incorrectly billed claims,¹⁶ TPC disagreed with our medical review determinations and maintained that all the sample claims were billed correctly. TPC stated that our medical reviewers (1) impermissibly used ambulation distances as a “rule of thumb” and inappropriately considered the architectural or structural features of a beneficiary’s residence as relevant in determining beneficiary homebound status, (2) “seemingly” applied the wrong coverage standards when determining skilled services medically unnecessary (although TPC stated that it could not evaluate and fully respond because our medical reviewers’ determinations were conclusory in nature), and (3) misapplied CMS guidelines for the lone coding “error.”

In addition, TPC stated that it intends to challenge the validity and reliability of our statistical sampling methodology and contest all aspects of our report in the Medicare administrative appeals process.

Regarding our second and third recommendations, to exercise reasonable diligence to identify and return overpayments in accordance with the 60-day rule,¹⁷ TPC did not concur and plans to appeal our overpayment assessment through the Medicare appeals process for reasons

¹⁶ 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 the incorrectly billed claims are now outside of the reopening period.

¹⁷ The second and third recommendations in the draft report were as follows: (1) for the remaining portion of the estimated overpayments for claims that are outside of the Medicare reopening period, exercise reasonable diligence to identify and return any overpayments in accordance with the 60-day rule and (2) exercise reasonable diligence to identify and return any additional similar overpayments outside of our audit period, in accordance with the 60-day rule.

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, TPC did not concur. TPC maintains that its existing compliance plan adheres to OIG's Compliance Program Guidance for Home Health Agencies. TPC concluded that it cannot strengthen its documentation processes and procedures based on OIG's medical determinations that are conclusory in nature and are absent of clear, publicly available guidelines.

TPC also stated that it had concerns about the qualifications of the OIG medical reviewers and that we did not provide any substantive information by which TPC could assess them. We have included TPC's comments in their entirety as Appendix F.¹⁸

OFFICE OF INSPECTOR GENERAL RESPONSE

To address TPC's concerns related to the medical reviewers' decisions, we had our independent medical review contractor again review the claims originally found in error along with the original records provided by TPC and supplemental information TPC provided with its comments on our draft report. Based on the results of that review, we revised our determinations, reducing the total number of sampled claims incorrectly billed from 38 to 32, and revised our related findings and recommendations accordingly. We also adjusted the findings for 13 of the 32 claims. (The overpayment amount decreased for eight claims and did not change for five claims.) In addition, we eliminated one error category included in the draft report. With these actions taken, we maintain that our remaining findings and recommendations, as revised, are valid. In addition, we maintain that our statistical approach resulted in a legally valid and reasonably conservative estimate of the amount overpaid by TPC. We acknowledge TPC's right to appeal the findings. With respect to the qualifications of the medical reviewers, all medical necessity determinations were made by licensed physicians who were board certified in an area appropriate to the treatment under review. All reviewers were also required to be free of any conflict of interest. We describe below the reasons that TPC did not concur with our recommendations and disputed our findings, as well as our responses.

BENEFICIARY HOMEBOUND STATUS

Total Patient Care Home Health, LLC, Comments

TPC stated that medical reviewers' determinations pertaining to noncompliance with homebound requirements were flawed because medical reviewers did not properly apply Medicare coverage criteria, impermissibly used ambulation distances as a "rule of thumb," and

¹⁸ TPC also included a comprehensive appendix to its comments. This document includes a claim-by-claim rebuttal to the claim findings in our draft report. However, this document contains personally identifiable information, so we excluded it from this report.

inappropriately considered the architectural or structural features of a beneficiary's residence as relevant in determining beneficiary homebound status.

Office of Inspector General Response

Based on the conclusions of our independent medical review contractor's additional medical review, we revised the findings related to homebound status (and the associated recommended disallowance) to specify that 28 rather than 31 sampled claims were associated with beneficiaries who did not meet the criteria for being homebound.¹⁹ We maintain that the other findings related to homebound status are valid.

Our medical reviewers prepared detailed medical review determination reports documenting relevant clinical evidence and its analysis. Each determination letter included a detailed set of facts based on a thorough review of the entire medical record. In all cases, our medical reviewers 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 reviewers considered in making homebound determinations. As shown in each medical review determination report, our medical reviewers 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 reviewers carefully considered ability to ambulate in conjunction with the individual characteristics noted in each patient's medical record. Ambulation distance, when noted, was simply one factor the reviewers 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. TPC stated that "there is no support in the law for the notion that the architectural features of a beneficiary's residence are dispositive as to homebound status." However, TPC 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 reviewers 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:

¹⁹ Of these 28 claims with homebound errors, 1 claim was also billed with skilled services that were not medically necessary. Appendix E provides detail on the extent of errors, if any, per claim reviewed.

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 (Criterion 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 Criterion 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.²⁰

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 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 Criterion Two. Accordingly, it can be reasonably inferred that CMS expects the physical characteristics of a given residence to impact the homebound analysis under Criterion Two. Thus, contrary to TPC’s assertions, it was not an error for our medical

²⁰ 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.

reviewers to consider the physical characteristics of the home environment as one of many factors in making homebound determinations.

SKILLED SERVICES

Total Patient Care Home Health, LLC, Comments

TPC disagreed with the medical review determinations related to claims with skilled therapy services found to be not medically necessary. TPC stated that our medical reviewers' decisions failed to furnish any medical or clinical rationale as to why skilled services were deemed medically unnecessary. TPC stated that it is unable to evaluate and fully respond to the reviewers' determinations because they are conclusory in nature. In addition, TPC asserted that our medical reviewers "seemingly" applied the wrong coverage Medicare guidelines for certain skilled services. TPC set forth several examples that it said illustrate this.

Office of Inspector General Response

Based on the conclusions of our independent medical review contractor's additional medical review, we revised our findings related to skilled services (and the associated recommended disallowance) to specify that 5 rather than 10 sampled claims were associated with beneficiaries who did not meet Medicare requirements for coverage of skilled nursing or therapy services.²¹ We maintain that the other findings related to skilled services are valid.

Our medical reviewers 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 reviewers 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, section 40.1.1. Per these CMS guidelines, when the services provided could be safely and effectively performed by the patient or unskilled caregivers, such services will not be covered under the home health benefit.

²¹ Appendix E provides detail on the extent of errors, if any, per claim reviewed.

HEALTH INSURANCE PROSPECTIVE PAYMENT SYSTEM CODING

Total Patient Care Home Health, LLC, Comments

TPC stated that the medical reviewers incorrectly concluded in our draft report that one claim contains a HIPPS coding error. TPC stated that the medical reviewer's decision was the result of a misapplication of Medicare coding guidelines for home health services. According to TPC, this non-routine supply was thus appropriately included on the claim form.

Office of Inspector General Response

Based on the conclusions of our independent medical review contractor's additional medical review, the HIPPS coding error originally identified in our draft report was reversed and we eliminated that error category that was included in the draft report. Since the claim was also billed for a beneficiary with a homebound error, it remains in the 32 claims that were incorrectly billed.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

Our audit covered \$15,114,365 in Medicare payments to TPC for 3,994 home health claims with dates of service from October 1, 2014, through September 30, 2016. From this sample frame we selected for review a stratified random sample of 100 home health claims with payments totaling \$426,008.

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

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

We conducted our fieldwork from January 2017 through July 2020.

METHODOLOGY

To accomplish our objective, we:

- reviewed applicable Federal laws, regulations, and guidance;
- extracted TPC's paid claim data from CMS's NCH file for the audit period;
- removed payments for low utilization payment adjustments,²² partial episode payments,²³ and requests for anticipated payments²⁴ from the population to develop our sampling frame;

²² 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.

²³ 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.

²⁴ 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.

- selected a stratified random sample of 100 home health claims totaling \$426,008 for detailed review (Appendix C);
- reviewed available data from CMS's Common Working File for the sampled claims to determine whether the claims had been canceled or adjusted;
- obtained and reviewed billing and medical record documentation provided by TPC to support the claims sampled;
- reviewed sampled claims for compliance with known risk areas;
- used an independent medical review contractor to determine whether the 100 claims contained in the sample were reasonable and necessary and met Medicare coverage and coding requirements;
- reviewed TPC'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 TPC for our audit period (Appendix D);
- discussed the results of our audit with TPC officials; and
- after receiving TPC's written comments on our draft report, had the independent medical review contractor perform an additional medical review of all of the claims that our draft had questioned and incorporated those results into our own analysis and determination of the allowability of the claims based on TPC's comments.

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

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

GENERAL MEDICARE REQUIREMENTS

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

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

OUTCOME AND ASSESSMENT INFORMATION SET DATA

The OASIS is a standard set of data elements that HHA clinicians use to assess the clinical needs, functional status, and service utilization of a beneficiary receiving home health services. CMS uses OASIS data to assign beneficiaries to the appropriate categories, called case-mix groups; to monitor the effects of treatment on patient care and outcome; and to determine whether adjustments to the case-mix groups are warranted. HHA beneficiaries can be classified into 153 case-mix groups that are used as the basis for the HIPPS rate codes Medicare uses in its PPSs. 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 Federal Register 58078, 58110 (Nov. 10, 2009); and the 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, or speech-language pathology, or occupational therapy;²⁵ (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).

²⁵ 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. 68526, 68590 (Nov. 4, 2011)).

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

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

Section 6407(a) of the Affordable Care Act²⁶ added a requirement to sections 1814(a)(2)(C) and 1835(a)(2)(A) of the Act, stating 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.²⁷

Confined to the Home

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.

²⁶ The Patient Protection and Affordable Care Act, P.L. 111-148 (Mar. 23, 2010), as amended by the Health Care and Education Reconciliation Act of 2010, P.L. 111-152 (Mar. 30, 2010), collectively known as the Affordable Care Act.

²⁷ See 42 CFR § 424.22(a) and the Manual, chapter 7, § 30.5. The initial effective date for the face-to-face requirement was January 1, 2011. However, on December 23, 2010, CMS granted HHAs additional time to establish protocols for newly required face-to-face encounters. Therefore, documentation regarding these encounters must be present on certifications for patients with starts of care on or after April 1, 2011.

CMS provided further guidance and specific examples in the Manual (chapter 7, § 30.1.1). Revision 172 of section 30.1.1 (effective November 19, 2013) and Revision 208 of section 30.1.1 (effective January 1, 2015) covered different parts of our audit period.²⁸

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:

Criterion One

The patient must either:

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

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

Criterion Two

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

Need for Skilled Services

Intermittent Skilled Nursing Care

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

The Act defines “part-time or intermittent services” as skilled nursing and home health aide services furnished any number of days per week as long as they are furnished (combined) less than 8 hours each day and 28 or fewer hours each week (or, subject to review on a case-by-

²⁸ Coverage guidance is identical in both versions of the Manual chapter 7 § 30.1.1 in effect during our audit period. The only differences are minor revisions to a few examples.

case basis as to the need for care, less than 8 hours each day and 35 or fewer hours each week) (the Act § 1861(m) and the Manual, chapter 7, § 50.7).

Requiring Skills of a Licensed Nurse

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

General Principles Governing Reasonable and Necessary Skilled Nursing Care

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

Some services may be classified as a skilled nursing service on the basis of complexity alone (e.g., intravenous and intramuscular injections or insertion of catheters) and, if reasonable and necessary to the patient's illness or injury, would be covered on that basis. If a service can be safely and effectively performed (or self-administered) by an unskilled person, without the direct supervision of a nurse, the service cannot be regarded as a skilled nursing service even though a nurse actually provides the service. However, in some cases, the condition of the patient may cause a service that would ordinarily be considered unskilled to be considered a skilled nursing service. This would occur when the patient's condition is such that the service can only be safely and effectively provided 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 only be performed safely and effectively by or under the general supervision of a skilled therapist;
- consistent with the nature and severity of the illness or injury and the patient's particular medical needs, which include services that are reasonable in amount, frequency, and duration; and
- considered specific, safe, and effective treatment for the patient's condition under accepted standards of medical practice.

Documentation Requirements

Face-to-Face Encounter

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

Plan of Care

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

APPENDIX C: SAMPLE DESIGN AND METHODOLOGY

POPULATION

The population consisted of TPC's claims for home health services that it provided to Medicare beneficiaries with episode dates of service from October 1, 2014, through September 30, 2016.

SAMPLING FRAME

The sampling frame consisted of a database of 3,994 home health claims, valued at \$15,114,365, from CMS's NCH file.²⁹

SAMPLE UNIT

The sample unit was a Medicare home health claim.

SAMPLE DESIGN

We used a stratified random sample.

Stratum	Amount Range of Claims Paid	Number of Claims	Total Dollar Value of Claims
1	<= \$4,354.06	2,785	\$7,742,142
2	> \$4,354.06	1,209	7,372,223
Total		3,994	\$15,114,365

SAMPLE SIZE

We randomly selected 50 claims from stratum 1 and 50 claims from stratum 2. Our total sample size was 100 claims.

SOURCE OF RANDOM NUMBERS

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

²⁹ Our sampling frame excluded home health claim payments for low utilization payment adjustments, partial episode payments, and requests for anticipated payments.

METHOD OF SELECTING SAMPLE ITEMS

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

ESTIMATION METHODOLOGY

We used the OAS statistical software to estimate the total amount of overpayments paid to TPC 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 will be less than the actual overpayment total in the sampling frame 95 percent of the time.

APPENDIX D: SAMPLE RESULTS AND ESTIMATES

Stratum	Frame Size	Value of Frame	Sample Size	Total Value of Sample	Incorrectly Billed Sample Items	Value of Over-Payments in Sample
1	2,785	\$7,742,142	50	\$139,308	13	\$22,068
2	1,209	7,372,223	50	286,700	19	53,393
Total	3,994	\$15,114,365	100	\$426,008	32	\$75,461

ESTIMATES

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

Point estimate	\$2,520,247
Lower limit	1,749,462
Upper limit	3,291,032

APPENDIX E: TYPES OF ERRORS BY SAMPLE ITEM

STRATUM 1 (Samples 1–25)

Sample	Not Homebound	Did Not Require Skilled Services	Overpayment
1			
2	X		\$1,397
3			
4	X		\$1,851
5			
6			
7			
8			
9	X		\$1,470
10			
11			
12			
13			
14			
15			
16			
17			
18			
19			
20			
21			
22			
23			
24			
25			

STRATUM 1 (Samples 26–50)

Sample	Not Homebound	Did Not Require Skilled Services	Overpayment
26			
27			
28			
29			
30			
31	X		\$716
32			
33		X	\$1,351
34	X	X	\$331
35			
36	X		\$3,246
37			
38			
39			
40	X		\$3,509
41	X		\$679
42	X		\$716
43			
44			
45			
46	X		\$1,694
47			
48			
49	X		\$3,856
50	X		\$1,252

STRATUM 2 (Samples 51–75)

Sample	Not Homebound	Did Not Require Skilled Services	Overpayment
51			
52	X		\$689
53			
54			
55	X		\$2,412
56			
57	X		\$2,159
58			
59			
60	X		\$1,636
61			
62			
63			
64	X		\$2,614
65			
66		X	\$2,022
67			
68	X		\$2,045
69			
70	X		\$1,003
71			
72			
73		X	\$2,462
74			
75			

STRATUM 2 (Samples 76–100)

Sample	Not Homebound	Did Not Require Skilled Services	Overpayment
76			
77	X		\$1,708
78			
79		X	\$3,740
80			
81			
82	X		\$581
83			
84			
85			
86	X		\$2,282
87			
88	X		\$5,838
89	X		\$2,349
90			
91			
92			
93	X		\$3,794
94	X		\$6,337
95	X		\$3,205
96			
97	X		\$6,519
98			
99			
100			
Total	28	5	\$75,461

APPENDIX F: TOTAL PATIENT CARE HOME HEALTH, LLC, COMMENTS



July 15, 2019

VIA ELECTRONIC DELIVERY

Eurika Ramdas, Senior Auditor
Office of Audit Services – Region VI
HHS – Office of Inspector General
1100 Commerce Street, Room 632
Dallas, TX 75242

Re: Response to Draft OIG Report

Dear Ms. Ramdas:

Our firm represents Total Patient Care Home Health, LLC (“TPC”). Enclosed you will find TPC’s response to draft report number A-06-16-05005, which was issued by your office on June 4, 2019. We ask that you please give appropriate consideration to TPC’s arguments as set forth herein.

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 prompt assistance with our inquiries throughout the audit process.

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

Very Truly Yours,

CALHOUN BHELLA & SECHREST LLP

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Encl.

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TOTAL PATIENT CARE HOME HEALTH, LLC

Response to Draft OIG Report No. A-06-16-05005

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I. INTRODUCTION

Total Patient Care Home Health, LLC (“TPC” or “provider”) hereby submits this response to the draft report (“Report”) issued by the Office of Inspector General (OIG) under report number A-06-16-05005. As explained herein, TPC disputes OIG’s conclusions as stated in the Report and does not concur with OIG’s recommendations.

II. BACKGROUND ON TPC

TPC is a Medicare-certified home health agency that has furnished high quality services to the residents of northeast Texas since 2004. TPC currently provides services to 300 elderly, medically fragile, and homebound patients. According to the Medicare Home Health Compare tool available on the website of the Centers for Medicare and Medicaid Services (CMS), TPC currently exceeds the Texas state and national averages for numerous quality-of-care metrics.¹ These include, but are not limited to, the following areas:

- How often patients had less pain when moving around.
- How often patients’ breathing improved.
- How often patients’ wounds healed after an operation.
- How often patient compliance with oral medications improved.
- How often patients were admitted to the hospital or required unplanned emergency care.

TPC’s commitment to high quality care is also reflected in its survey results, which have never included citations for “condition-level” deficiencies or findings of immediate jeopardy.²

In addition to clinical excellence, TPC is committed to maintaining robust compliance with applicable federal and state laws.³ To that end, TPC has implemented an effective compliance program that adheres to the Compliance Program Guidance for Home Health Agencies promulgated by OIG.⁴ This guidance recommends, and TPC 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.
- **TPC Implementation:** TPC 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, clinical issues, documentation, and quality of care. These policies and procedures are updated on an annual basis and communicated to employees during employee training events (i.e., new employee orientation, quarterly in-services, annual agency-wide in-service).

¹ TPC’s current Medicare “Star Rating” is 4/5 stars. See CMS, *Quality of Patient Care Star Ratings Methodology* (April 2019).

² See Medicare State Operations Manual, Appendix Q (Pub. 100-07, Rev. 187) (2019).

³ TPC furnished OIG with a copy of its compliance plan at the outset of this Medicare compliance review.

⁴ HHS Office of Inspector General, *Publication of the OIG Compliance Program Guidance for Home Health Agencies*, 63 Fed. Reg. 42,410 (Aug. 7, 1998).

- **Element 2:** The designation of a compliance officer and other appropriate bodies charged with operating and monitoring the compliance program.
- **TPC Implementation:** TPC has a designated Compliance Officer who is responsible for overseeing all aspects of regulatory compliance. The Compliance Officer reports directly to the provider's Compliance Committee and governing body.

- **Element 3:** The development of regular and effective education and training programs for employees.
- **TPC Implementation:** All new clinical employees participate in a one-on-one orientation with a clinical manager for training related to patient care, documentation, and use of the agency's electronic medical record (EMR) system. New clinical employees are then assigned to a preceptor during a 90-day orientation period. All employees undergo retraining on a variety of topics (including issues related to Outcome and Assessment Information Set (OASIS) coding and documentation) on an annual, quarterly, or "as needed" basis. In-services and employee training are conducted by the provider's senior clinical leadership (all of whom possess more than a decade of experience in the home health industry) or reputable, experienced third-party vendors.

- **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.
- **TPC Implementation:** TPC strongly encourages all employees to report potential instances of non-compliance to their supervisors. In addition, the provider has policies and procedures in place for promptly responding to both patient and employee complaints. TPC explicitly communicates to all employees that the submission of any complaints will not result in any retaliation or adverse actions taken against the employee.

- **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.
- **TPC Implementation:** TPC's employee code of conduct clearly outlines the progressive disciplinary process available for violations. The Compliance Officer works closely with human resources personnel 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.
- **TPC Implementation:** At the time of the audit period, TPC employed a quality assurance nurse who audited and reviewed clinical documentation on a full-time basis. The quality assurance coordinator was available to staff for questions related to documentation, coding, and home health eligibility criteria. In addition, TPC's clinical management reviews all OASIS assessments for accuracy and completeness. The provider utilizes a special software system to track OASIS item responses by individual clinician and on a provider-wide basis to monitor the accuracy and consistency of all assessment documentation. TPC also works with an external, independent consulting company to verify and review the accuracy of all OASIS coding before assessments are submitted to the state repository and

claims are submitted to the responsible payor(s). The provider’s Quality Assurance and Performance Improvement (QAPI) Committee also performs chart audits on a biannual basis.

- **Element 7:** The investigation and remediation of identified systemic problems and the development of policies addressing the non-employment or retention of sanctioned individuals.
- **TPC Implementation:** As noted above, TPC 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 and / or the governing body, takes prompt remedial action that is commensurate with the nature and severity of the report or allegation along with the processes outlined in the applicable policies and procedures.

Please note that the foregoing summary of TPC’s compliance efforts is by no means exhaustive but instead intended to illustrate the extent to which TPC’s compliance program conforms to OIG’s guidelines.

TPC’s commitment to regulatory compliance in the areas of documentation, coding, and billing has been validated by the results of prior Medicare claim audits, the results of which are summarized below.

Auditor	DOS for Claims	Result
Zone Program Integrity Contractor	2009	23 of 25 (92%) claims approved
Zone Program Integrity Contractor	2016	23 of 25 (92%) claims approved
Medicare Administrative Contractor	2016	5 of 5 (100%) claims approved

Notably, claims from two of these audits overlapped with OIG’s audit period in this case. In more than 15 years of operating, TPC has *never* received audit results or adverse claim determinations even remotely similar to those outlined in the Report.

III. BACKGROUND ON OIG’S RECENT MEDICARE COMPLIANCE REVIEWS OF HOME HEALTH AGENCIES

As OIG noted in the Report, this audit was part of a series of Medicare compliance reviews for home health agencies around the country. OIG initiated these reviews because “...the 2016 improper payment error rate for home health claims was 42 percent, or about \$7.7 billion.”⁵ According to the 2016 Comprehensive Error Rate Testing (CERT) Report, “[i]nsufficient documentation caused a large proportion of improper payments for home health services.”⁶ The largest single contributing factor to the high error rate for home health services is the face-to-face encounter rule.⁷ According to the Government Accountability Office, the spike in the Medicare payment error rate for home health services coincides almost entirely with the implementation of

⁵ Report at 1.

⁶ CMS, *Medicare-Fee-For-Service 2016 Improper Payments Report*, at 17 (July 27, 2017).

⁷ See 42 C.F.R. § 424.22(a)(v).

the face-to-face encounter rule.⁸ In this case, it is thus noteworthy that OIG’s reviewers did not identify *any* alleged errors in TPC’s claims involving face-to-face issues.

It is critical to view the Report in the appropriate context. As of the date of this response, OIG has issued several reports on Medicare compliance audits of home health agencies around the country. Upon information and belief, OIG has used the same contractor for the medical review portion of these audits. In our view, OIG’s prior reports suggest that its contractor has incorrectly applied Medicare coverage guidelines for home health services. For example, in one report OIG was forced to concede that “[O]ur medical reviewer incorrectly applied Medicare coverage criteria...”⁹ In at least one other case, OIG had to re-submit claims for additional medical review based on the providers’ comments in response to the draft report.¹⁰

A review of all of the aforementioned OIG reports further demonstrates that the medical reviewers’ findings are remarkably similar across all home health providers, despite differences in, among other areas, the providers’ sizes, geographic areas, and patient populations. In almost every case, the lion’s share of the claim denials was based on beneficiary homebound status. And a review of the providers’ comments in those cases suggests that the reviewers determined beneficiaries were not homebound largely because they could ambulate for certain distances or resided in “accessible assisted living facilities.” The results of these other reports are summarized below.

CIN	Homebound “Errors”	Medical Necessity “Errors”	Other “Errors”
A-05-16-00057	30/100	14/100	0/100
A-02-16-01001	2/100	3/100	7/100
A-05-16-00055	31/100	7/100	0/100
A-01-16-00500	28/100	23/100	0/100
A-06-16-05005	31/100	10/100	1/100

The entries in bold typeface represent the data from OIG’s Report in this case. This evidence persuasively suggests that the medical review contractor was largely predisposed to identifying certain types of errors – particularly as they related to beneficiary homebound status – in home health reviews.

IV. BACKGROUND ON THIS MEDICARE COMPLIANCE REVIEW

OIG initiated this review in November 2016 and, shortly thereafter, requested documentation in support of 100 Medicare claims billed by TPC between 2014 and 2016. TPC produced this documentation in April and May of 2017. In March of 2018, OIG delivered to TPC medical review decisions that identified 61 claims with alleged homebound, medical necessity, and coding “errors.” These decisions were themselves rife with mistakes. For example,

⁸ Government Accountability Office, *Medicare and Medicaid – CMS Should Assess Documentation Necessary to Identify Improper Payments*, at 21 (March 2019).

⁹ OIG, *Excella HomeCare Billed for Home Health Services That Did Not Comply With Medicare Coverage and Payment Requirements*, at 11 (May 2019).

¹⁰ OIG, *Metropolitan Jewish Home Care, Inc. Billed for Home Health Services That Did Not Comply With Medicare Requirements*, at 9-10 (2019).

approximately *one third* of those determinations contained the wrong provider's name. There were also numerous substantive deficiencies that, in our opinion, resulted in flawed decisions related to beneficiary homebound status, coverage criteria for nursing and therapy services, and home health coding conventions. TPC devoted a significant amount of time and resources to preparation of a preliminary response to bring these errors to OIG's attention. As a result, OIG subsequently withdrew 23 adverse medical review decisions. Unfortunately, however, the same errors persist with the remaining 38 medical review decisions, which are flawed for the reasons discussed below in section VI.

In order to more fully evaluate the merits of OIG's claim determinations, TPC previously requested copies of the curricula vitae of the medical reviewers. As part of this request, TPC pre-emptively agreed to the redaction of all sensitive and personally identifiable information in the CVs. OIG subsequently refused to produce this information. There is, however, no legitimate basis for OIG to withhold information regarding the credentials of its reviewers – particularly where, as here, there is an eminently reasonable basis on which to question those reviewers' qualifications. Generally Accepted Government Auditing Standards (GAGAS), 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.¹¹ In the absence of the previously-requested CVs, neither TPC nor any third party is in a position to validate that this requirement has been met. Such a lack of transparency is deeply disturbing, especially in a case such as this involving an alleged Medicare overpayment of more than \$2 million.

V. STATEMENT OF NONCONCURRENCE

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

OIG Recommendation #1: We recommend that TPC refund to the Medicare program the portion of the estimated \$2,490,795 overpayment for claims incorrectly billed that are within the reopening period.

TPC Response: TPC does not concur with this recommendation because none of the sample claims was billed incorrectly. Instead, OIG's medical review determinations are flawed for several reasons. For example, even a cursory review of the adverse claim determinations shows that most of them impermissibly used ambulation distance as a "rule of thumb" for assessing beneficiary homebound status. There is also no law, rule, or regulation which states that the architectural features of a patient's residence are relevant to a homebound determination. OIG has, moreover, failed to furnish TPC with any medical or clinical rationale as to why skilled services were deemed medically unnecessary in 10 cases. The lone coding "error" is predicated on a misapplication of CMS guidelines. TPC also intends to challenge the validity and reliability of OIG's statistical sampling methodology. For these reasons and others, TPC will vigorously contest all aspects of OIG's Report in the Medicare administrative appeals process. As such, any refund by TPC to the Medicare program would be premature.

¹¹ See Government Accountability Office, *Government Auditing Standards*, Ch. 3 § 3.72, Ch. 6 §§ 6.42 and 6.43 (2011).

When TPC is able to secure reversal of OIG's adverse claim determinations on appeal, TPC respectfully requests that OIG update and revise the final, public draft of the Report to reflect the results of the appeals process.

OIG Recommendation #2: We recommend that TPC, for the remaining portion of the estimated \$2,490,795 overpayment for claims that are outside of the Medicare reopening period, exercise reasonable diligence to identify and return overpayments in accordance with the 60-day rule, and identify any returned overpayments as having been made in accordance with this recommendation.

TPC Response: TPC does not concur with this recommendation because it intends to contest OIG's medical review findings through the available appeals process. In cases where a provider receives notice of adverse audit results, CMS recognizes that a provider's obligation to exercise reasonable diligence under the 60-day rule is not triggered until after the provider has exercised its appeal rights. CMS has stated:

[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.¹²

OIG Recommendation #3: We recommend that TPC 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.

TPC Response: TPC does not concur with this recommendation for the same reason it does not concur with OIG's second recommendation.

OIG Recommendation #4: We recommend that TPC 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.

TPC Response: TPC does not concur with this recommendation because, as summarized in section II, its existing compliance plan already adheres to OIG's Compliance Program Guidance for Home Health Agencies. For example, the OIG guidance 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

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

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

TPC's EMR system requires each treating clinician or other staff member to evaluate and document the beneficiary's homebound status during every visit. Examples of these verifications are reproduced below.

HOMEBOUND STATUS

INDICATE REASONS CLIENT IS HOMEBOUND: (MARK ALL THAT APPLY)

DIFFICULTY TRANSFERRING

AMBULATION DIFFICULTIES

LEAVING HOME REQUIRES SIGNIFICANT AND TAXING EFFORT

POST OP WEAKNESS

POOR ENDURANCE/COORDINATION

UNABLE TO LEAVE HOME WITHOUT ASSISTANCE OF ONE OR MORE PERSONS

UNABLE TO LEAVE HOME WITHOUT ASSISTANCE OF ASSISTIVE DEVICES

HOMEBOUND STATUS

INDICATE REASONS CLIENT IS HOMEBOUND: (MARK ALL THAT APPLY)

SHORTNESS OF BREATH

LEAVING HOME REQUIRES SIGNIFICANT AND TAXING EFFORT

POOR ENDURANCE/COORDINATION

DISORIENTATION/CONFUSION

UNABLE TO LEAVE HOME WITHOUT ASSISTANCE OF ONE OR MORE PERSONS

UNABLE TO LEAVE HOME WITHOUT ASSISTANCE OF ASSISTIVE DEVICES

Despite the inclusion of this assessment information in *every clinical visit note* revalidating the beneficiaries' homebound statuses, many claims were still denied. In fact, the claims from which the examples reproduced above were taken were both denied because the beneficiaries were allegedly not homebound.

OIG's compliance guidance also suggests that home health providers "distribute written notices to Medicare beneficiaries reminding them that they must satisfy the regulatory requirement for homebound status to be eligible for Medicare coverage."¹⁴ TPC has implemented this recommendation and provides every newly-admitted Medicare beneficiary with written admission materials that address, among other issues, the homebound requirement. This fact is also documented frequently in the comprehensive start of care assessments. For example, in the case of S1-4, the nurse documented the following as part of the admission assessment:

¹³ 63 Fed. Reg. at 42,416.

¹⁴ *Id.*

[Nurse] reviewed patient information booklet with patient and caregiver. Instructed on patient's rights and responsibilities, confidentiality and privacy practices, abuse, neglect and exploitation policies; substance abuse policies; emergency procedures; how to contact nurse at all times, when to call 911; emergency preparedness, when to call 211, advance directives; infection control, and hand-washing. *Discussed [plan of care] with patient, homebound requirement, and ordered services for next 60 days and provided answers to questions.* (emphasis added).

Despite TPC's implementation of OIG's own guidance, however, this claim was still denied.

As explained below in section VI, the reasons for most of OIG's adverse medical decisions are not explicitly spelled out in any published Medicare guidance. For example, there are no laws, rules, or regulations that state beneficiaries must suffer a "recent injury or new impairing condition" to be considered homebound. Similarly, there is no way for TPC to "strengthen" its documentation processes based on OIG's medical necessity determinations because those decisions are conclusory in nature; neither TPC nor any Medicare provider can meaningfully change its internal practices based on bald and vague statements by anonymous reviewers that a service is "excessive" or "not medically necessary." Consequently, TPC does not concur with OIG's recommendation because it cannot "strengthen its procedures" in the absence of clear, publicly available guidelines.

VI. OIG SHOULD WITHDRAW ITS MEDICAL REVIEW DETERMINATIONS BECAUSE THEY ARE INCONSISTENT WITH EXISTING MEDICARE REGULATIONS AND FAILED TO PROPERLY ACCOUNT FOR THE INFORMATION IN THE MEDICAL RECORDS

OIG's medical review decisions fall into three categories: (1) medical necessity; (2) homebound status; and (3) Health Insurance Prospective Payment System (HIPPS) coding. These determinations contain consistent themes and trends that illustrate the reviewers have not properly applied Medicare coverage guidelines. The discussion that follows is intended to address these thematic issues. TPC has also prepared individual, claim-specific summaries addressing the clinical facts and circumstances unique to each beneficiary / claim. Those summaries are marked as **Appendix A**.

Medicare covers home health services provided to beneficiaries who meet the following conditions: (a) the beneficiary is under the care of a physician who certifies that his or her patient is eligible for the Medicare home health benefit and establishes a plan of care under which the beneficiary will receive treatment; (b) the services are medically reasonable and necessary; and (c) the beneficiary is confined to the home.¹⁵ All of the claims examined by OIG as part of this Medicare compliance review satisfied those criteria.

1. Medical Necessity

The medical reviewers purportedly identified 10 claims where beneficiaries did not require

¹⁵ 42 U.S.C. § 1395f(a)(2)(C).

skilled services for parts of the episodes at issue.¹⁶ These claims all involve physical, occupational, and / or speech therapy services. As noted in section V, TPC is unable to evaluate and fully respond to the reviewers' determinations because they are conclusory in nature.¹⁷ In each case, the reviewer simply opined that therapy services were "excessive" and "not medically necessary" as of a certain date. Without a more detailed clinical rationale, TPC is left guessing as to the bases for the reviewers' decisions.

For example, in the case of S2-53, the reviewer merely opined:

A speech therapy evaluation was indicated for dysphagia. The patient was at risk for aspiration pneumonia and speech therapy was needed to modify her diet and provide education in a home management program including developing compensatory swallowing strategies. A second skilled speech therapy visit was needed to reassess the patient's condition and to evaluate the patient's caregiver's understanding of the information provided and to answer any questions. A third visit was reasonable for a final reassessment and to make any further recommendations if needed. However, the speech therapy services provided were excessive and could have been discontinued after the third session on [date] as ongoing speech therapy services were not medically necessary.

This rationale contains absolutely no clinical facts to support the reviewer's tautology that speech therapy services were "excessive...as ongoing speech therapy services were not medically necessary." As such, TPC is unable to ascertain the basis for the reviewer's determination and respond in detail and with particularity.¹⁸

A. OIG has seemingly applied the wrong coverage standards for therapy services in many cases.

There are several cases where the reviewers included comments in their determinations that suggest they applied the wrong coverage standards.¹⁹ According to Medicare coverage rules, therapy services are covered under the home health benefit when the following conditions are met:

To be covered as skilled therapy, the services must require the skills of a qualified therapist and must be reasonable and necessary for the treatment of the patient's illness or injury as discussed below. Coverage does not turn on the presence or absence of an individual's potential for improvement, but rather on the beneficiary's need for skilled care.

...

¹⁶ The sample items in question are: S1-33, S2-53, S2-65, S2-66, S2-73, S2-79, S2-84, S2-94, S2-97, and S2-100.

¹⁷ A government agency acts in an arbitrary and capricious manner where it fails to articulate a satisfactory explanation for its decision that includes a rational connection between the facts found and the choice made. *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

¹⁸ This issue is also apparent from example 3 provided in the Report, where the only reason given for the partially unfavorable decision is that, "[o]ngoing skilled physical therapy services after the third visit were not medically necessary and were excessive." Report at 8.

¹⁹ Use of the incorrect coverage standards when evaluating a Medicare claim constitutes reversible error. *See, e.g., Caring Hearts Pers. Home Servs. v. Burwell*, 824 F.3d 968 (10th Cir. 2016) (Gorsuch, J.); *Albert v. Burwell*, 118 F.Supp.3d 505 (E.D.N.Y. 2015).

The service of a physical therapist, speech-language pathologist, or occupational therapist is a skilled therapy service if the inherent complexity of the service is such that it can be performed safely and / or effectively 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 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.

...

While a patient's particular medical condition is a valid factor in deciding if skilled therapy services are needed, a patient's diagnosis or prognosis should never be the sole factor in deciding that a service is or is not skilled. The key issue is whether the skills of a therapist are needed to treat the illness or injury, or whether the services can be carried out by unskilled personnel.²⁰

As illustrated by the examples below, OIG's reviewers have not properly applied these standards.

Sample ID: S2-84
Service(s): Speech Therapy

In this case, the reviewer determined that 3 speech therapy visits did not meet Medicare criteria for coverage because, "[T]here was no medical necessity found for speech therapy. There was no history of recent aspiration of pneumonia or neurological injury." This is the entirety of the reviewer's reasoning. Contrary to this determination, CMS does not require that beneficiaries have a history of aspiration pneumonia or neurological injury in order to qualify for speech therapy services. In fact, the Medicare Benefit Policy Manual explicitly states that a patient's diagnosis should *never* be the sole factor in deciding whether skilled therapy is warranted.²¹ Instead, the review must focus on the "beneficiary's need for skilled care."²² There is no evidence on the face of OIG's determination that the reviewer applied or was even aware of this standard.

Around the time of the episode in question, S2-84 was an 83 year-old female who had sustained a fall resulting in a fracture to her left tibia and fibula. She was treated in the hospital with a leg brace and subsequently transferred to the skilled nursing facility for rehabilitation. After she returned home, S2-84's physician ordered that she be admitted to TPC for skilled nursing services, physical therapy, occupational therapy, and speech therapy. The patient's medical history was significant for osteoporosis, hypertension, dementia, neuropathy, symbolic dysfunction, generalized weakness, and recurrent falls. She was incontinent of bladder, forgetful, had poor endurance, and generally used a wheelchair for mobility or a walker for ambulation. S2-84 was discharged at the conclusion of the episode upon reaching her maximum rehabilitation potential.

²⁰ Medicare Benefit Policy Manual (MBPM) Ch. 7 §§ 40.2 and 40.2.1 (Pub. 100-02, Rev. 208) (2015).

²¹ MBPM Ch. 7 § 40.2.1 (Pub. 100-02, Rev. 144) (2014).

²² MBPM Ch. 7 § 40.2 (Pub. 100-02, Rev. 179) (2014).

In compliance with the physician's orders, S2-84 was evaluated by a licensed speech therapist. The therapist identified cognitive-linguistic deficits requiring skilled treatment and documented that:

Patient reports difficulty with her short-term memory. Patient reported that she worked on high problem-solving skills (e.g. banking) while in rehabilitation.

...

Patient presents with moderate cognitive deficits including decreased short-term memory, decreased divided attention, decreased complex reasoning and problem-solving, and decreased insight into deficits. Patient's immediate memory and retention are functional. Language skills are functionally intact, although patient reports mild word-finding difficulties.

Based on S2-84's deficits and unique needs, the speech therapist created a treatment plan consisting of goals to address the patient's memory, attention, problem-solving, organization, and concentration. The therapist summarized:

Speech therapy targeting cognitive-linguistic skills via structured activities, [speech language pathology] instruction, and use of compensatory strategies. Goals: given a hypothetical situation, patient will devise 1-2 compensatory memory strategies to improve carryover of memory skills. Patient will use 1-2 new memory strategies in her current environment. Patient will complete complex problem-solving tasks to improve reasoning skills with 90% accuracy with minimal cues.

All of these facts amply support that S2-84 required a brief period of skilled treatment to address her cognitive-linguistic deficits. The fact that the beneficiary did not suffer from aspiration pneumonia or a recent neurological injury is irrelevant. As such, OIG's determination was reached in error.

Sample ID: S2-79

Service(s): Occupational Therapy

S2-79 was an 82 year-old female who resided in the memory care unit of an assisted living facility (ALF). She was originally admitted to home health services on 06/04/14 for right lower extremity pain and increased confusion and agitation. Immediately prior to the episode at issue, S2-79 exhibited signs and symptoms of a transient ischemic attack along with a "significant decline" in her functional status. She also sustained a fall and was found to have suffered an L2 compression fracture. Her medical history was significant for dementia, depressive psychosis, anxiety, and hypertension. S2-79 was confused, disoriented, incontinent of bladder, hard of hearing, had poor endurance, and used a walker to ambulate.

S2-79's physician ordered, among other services, occupational therapy services due to the beneficiary's overall decline in function. The occupational therapy assessment revealed that the beneficiary required standby to maximum assistance to perform activities of daily living (ADLs),

such as toileting, lower body dressing, and ADL transfers. The therapist graded her upper extremity strength as 3+/5. These deficits clearly established a need for skilled occupational therapy intervention, and OIG has provided no explanation as to how these deficits could have been addressed in the absence of skilled care.

OIG's reviewer decided that the occupational therapy services provided to S2-79 were not medically necessary after the second visit. The determination states:

An occupational therapy evaluation was indicated to assess the patient's activities of daily living and need for adaptive equipment or a home exercise program. A second skilled visit was needed to reassess her condition and to evaluate her caregiver's understanding of the information provided in to answer any questions. There was no new impairing upper extremity condition. The patient had caregivers available who were familiar with her condition and with providing care for individuals with severe cognitive impairments.

Medicare coverage for occupational therapy is not contingent upon the presence of a "new impairing upper extremity condition."²³ The reviewer's determination is thus flawed insofar as it contains no findings as to whether the occupational therapy services rendered to S2-79 met the standards set forth in the Medicare Benefit Policy Manual in that they could only be safely and effectively furnished by a therapist and whether, in view of S2-79's overall condition, skilled services were needed.²⁴

The availability of custodial care is also completely irrelevant to a decision regarding the medical necessity of skilled therapy services. The Medicare Benefit Policy Manual states:

Where the Medicare criteria for coverage of home health services are met, patients are entitled by law to coverage of reasonable and necessary home health services. Therefore, a patient is entitled to have the costs of reasonable and necessary services reimbursed by Medicare without regard as to whether there is someone available to furnish the services. However, where a family member or other person is or will be providing services that adequately meet the patient's needs, it would not be reasonable and necessary for [home health agency] personnel to furnish such services. Ordinarily it can be presumed that there is no able and willing person in the home to provide the services being rendered by the [home health agency] unless the patient or family indicates otherwise and objects to the provision of the services by the [home health agency], or unless the [home health agency] has firsthand knowledge to the contrary.²⁵

In this case, the record does not support that S2-79's caregivers possessed the knowledge, skills, training, or experience of a licensed occupational therapist. There is likewise no information in the record to show that a non-skilled caregiver was capable of addressing the deficits identified during the occupational therapist's evaluation. Custodial care is not a substitute for skilled therapy intervention. The fact that a caregiver may have been able to help S2-79 use the restroom or take a bath, for example, does not mean that the beneficiary did not deserve a chance to improve her

²³ A similar determination was issued for the occupational therapy services provided to S2-65.

²⁴ See MBPM Ch. 7 §§ 40.2 and 40.2.1 (Pub. 100-02, Rev. 208) (2015).

²⁵ MBPM Ch. 7 § 20.2 (Pub. 100-02, Rev. 208) (2015).

ability to safely and independently perform those same tasks. OIG’s determination was made using the incorrect coverage standard.

B. The lone claim example in the Report of a case where the beneficiary allegedly did not require skilled services does not represent an overpayment.

Example 3 in the Report is a claim where OIG’s reviewers apparently determined a beneficiary did not require physical therapy services after the third visit. This is sample item S2-100. Because the Report lacks any context whatsoever regarding this claim, TPC will provide it to show that the reviewer’s decision is incorrect.

S2-100 was an 89 year-old male beneficiary who suffered from Alzheimer’s Disease and dementia. The patient’s cognitive condition began to decline, and he subsequently moved to an ALF. At the same time, S2-100’s physician referred him to TPC for home health care. The physician ordered that, among other services, S2-100 should receive physical therapy due to an onset of increasing right hip pain that rendered his gait unstable and analgic.

The initial physical therapy evaluation revealed deficits related to functional mobility, balance, and lower extremity strength. These deficits are summarized below:

Functional Area	Evaluation Status
Bed Mobility	Contact Guard Assistance
Sit-to-Stand Transfers	Contact Guard Assistance
Dynamic Sitting Balance	Fair
Timed Up and Go Score	24 seconds
Gait Distance – Level Surfaces	75 feet
Gait Assistance – Level Surfaces	Contact Guard Assistance
HEP Performance	Contact Guard Assistance
Right Lower Extremity Strength	4-/5
Left Lower Extremity Strength	4-/5

The therapist generally assessed S2-100 with “progressive weakening” due to inactivity. A plan of care with treatment goals was developed, and the therapist implemented a home exercise program (HEP). The therapist also recommended that S2-100 obtain a multi-wheeled walker due to his unstable standing balance.

The record reflects that S2-100 had not met his goals for treatment as of the date of disallowance and continued to exhibit deficits across numerous functional areas. There was thus no basis for the reviewer to conclude that physical therapy was “excessive” after the third visit. S2-100 actively participated in treatment, and it was thus reasonable for the physician and therapist to expect that the beneficiary’s condition would improve materially and in a reasonable predictable period of time. For example, after the date of disallowance, S2-100 received a new multi-wheeled walker as per the therapist’s recommendation. The therapist implemented gait training with the new device, and the beneficiary did “significantly better with his gait task” using the rollator. S2-100’s balance was steadier, he exhibited fewer gait deviations, and he was able to tolerate gait training for longer distances over the course of the episode. None of this would have been possible

if physical therapy had been prematurely discontinued after the third visit. OIG should accordingly rescind its conclusory decision in this and all similar cases.

2. Homebound Status

The Medicare Benefit Policy Manual contains the following guidelines for assessing beneficiary homebound status:

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.²⁶

The vast majority of the adverse claim decisions reached by OIG – 31 out of 38 – are predicated in whole or in part on beneficiary homebound status. Among these 31 determinations, the reviewers found that 9 beneficiaries were not homebound at the start of care. For the remaining 22 beneficiaries, OIG concluded that they ceased being homebound at an arbitrary date during the episode. For the reasons explained below, TPC vigorously disputes these decisions because they did not properly apply CMS coverage criteria, were the product of an improper and illegal “rule of thumb,” the reviewers inappropriately considered the architectural or structural features of a beneficiary’s residence as relevant to the homebound analysis, and many beneficiaries’ conditions were similar to those that CMS would consider homebound as per the Medicare Benefit Policy Manual.

²⁶ MBPM Ch. 7 § 30.1.1 (Pub. 100-02, Rev. 172) (2013) (emphasis added).

A. OIG’s reviewers have used ambulation distance as an illegal “rule of thumb” to conclude that virtually all of the claims at issue did not meet Medicare homebound criteria.

Home health coverage determinations must be predicated on objective, clinical evidence.²⁷ The Medicare Benefit Policy Manual further explains that:

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, diagnoses, or specific treatment norms is not appropriate.²⁸

Any presumption or general precondition that fails to consider a beneficiary’s individual condition and unique needs thus constitutes an improper “rule of thumb.”²⁹ OIG’s medical review determinations in this case, taken as a whole, clearly show that ambulation distance has been used as a “rule of thumb” to decide that many beneficiaries were not homebound.

Among the 31 claim denials predicated on homebound status, 26 out of 31 (or 84%) explicitly referenced ambulation distance.³⁰ In many cases, this is the *only* fact from the record mentioned by the reviewer in support of the decision. With respect to S1-31, for example, the reviewer determined:

The medical information supports that the patient was homebound at the start of care. The patient had been treated for sepsis and was limited by debility at the start of care. She was able to ambulate only short distances. Leaving the home would have been a considerable and taxing effort for this patient. However, the patient gained function and as of 9/4/2016 she was ambulating 150 feet. Her physical therapy was interrupted when she had diarrhea. When treatments resumed on 9/16/2016, she was now able to ambulate 200 feet. Leaving the home no longer would have required a considerable and taxing effort for this patient. She patient [sic] was no longer homebound after 9/16/2016.

Similarly, the reviewer decided S2-55 was not homebound for part of the episode based on the following:

The medical information supports that the patient was homebound at the start of care. The patient had undergone a right total hip [sic]³¹ replacement and was limited to ambulating 20 feet at the start of care. She had pain and shortness of breath and was obese with a body mass index of nearly 44. Leaving the home would have required considerable and taxing effort for the patient at the start of care. However, she made good progress with her mobility

²⁷ 42 C.F.R. § 409.44(a); *see also* MBPM Ch. 7 § 20.1.2 (Pub. 100-02, Rev. 208) (2015).

²⁸ MBPM Ch. 7 § 20.3 (Pub. 100-02, Rev. 1) (2003).

²⁹ *See Jimmo v. Sebelius*, 2011 WL 5104355, at *4-6 (D. Vt. 2011).

³⁰ This error applies to S1-2, S1-9, S1-31, S1-34, S1-36, S1-40, S1-41, S1-42, S1-46, S1-49, S1-50, S2-52, S2-55, S2-57, S2-64, S2-68, S2-70, S2-77, S2-81, S2-82, S2-84, S2-86, S2-88, S2-89, S2-94, and S2-97.

³¹ The reviewer incorrectly stated that S2-55’s hip had been replaced whereas she had actually undergone a knee replacement procedure.

status and as of [date] she was ambulating 450 feet. There were no medical contraindications to leaving the home.

This decision is based exclusively on the beneficiary's ambulation distance because the limitations that rendered S2-55 homebound at the start of care – morbid obesity, shortness of breath on exertion, and pain affecting her activities and movement – had not changed as of the date of disallowance; the *only* change was the fact that the beneficiary could tolerate gait training for a distance of 450 feet instead of 20 feet.

We anticipate OIG will respond by denying the obvious and asserting that ambulation distance was simply one factor among many considered by the medical reviewers. But this is belied by cases, such as the two preceding examples, where ambulation distance was the *only* fact mentioned by the reviewers in their determination rationales. Moreover, the data reveals a clear and consistent pattern: the reviewers were overwhelmingly more likely to deny claims for homebound reasons where those claims involved physical therapy services and the beneficiaries could, at some point during the episode, tolerate gait training for at least 125 feet.³² Among the 50 claims comprising the first stratum of claims, 31 of them (or 62%) involved at least one physical therapy service. Yet the reviewers only denied 12 of the 50 claims (or 24%) in the first stratum for homebound reasons. The second stratum, by contrast, contains 45 of 50 claims (or 90%) involving at least one physical therapy service, and the reviewers were much more inclined to deny stratum two claims in that 19 of those claims (or 38%) were denied. This data supports that ambulation distance was much more than one factor among many used in the reviewers' decisions; it was often the determinative factor.

More generally, the reviewers' findings that beneficiaries were ambulating a certain distance at the start of care or as of a certain date in the episode are also devoid of any context.³³ The beneficiaries were only able to ambulate for those distances when performing gait training with licensed physical therapists. The beneficiaries almost universally required devices to ambulate safely, standby or hands-on assistance from the therapists, exhibited gait deviations requiring verbal and tactile cues from the therapist for correction, and were short of breath or exhausted after gait training such that rest breaks were required for recovery. In addition, the reviewers failed to mention that these gait training activities most often took place in the beneficiaries' homes on level surfaces. The fact that a patient is able to walk on even surfaces in a familiar environment and with assistance from a licensed therapist does not imply sufficient functional mobility for community ambulation.³⁴ OIG should accordingly withdraw the 26 claim decisions where its reviewers relied on ambulation distance as the primary basis for their decisions.

³² There are *no* other clinical similarities across these decisions with respect to the beneficiaries' functional mobility aside from the fact that they were all able to tolerate gait training for at least 125 feet. For example, some patients could perform gait training on uneven surfaces while others could not; some beneficiaries needed hands-on assistance from the therapist to walk or transfer, while others needed standby assistance; and some beneficiaries used assistive devices to ambulate, whereas others relied on assistance from another person to do so.

³³ A government agency's failure to properly resolve conflicts in the medical evidence when rendering a homebound determination constitutes reversible error. See *Russell v. Sebelius*, 686 F.Supp.2d 386 (D. Vt. 2010); *Burgess v. Shalala*, 1993 WL 327764 (D. Vt. 1993).

³⁴ The Medicare Appeals Council, the administrative adjudicative body responsible for issuing final agency decisions with respect to Medicare claim appeals, has echoed this sentiment. See *In the case of Quality Home Health Services*,

B. The reviewers inappropriately determined some beneficiaries were not homebound because they had not suffered a “recent injury or new impairing condition.”

In some cases, the reviewers incorrectly found that beneficiaries were not homebound because they had not suffered any recent injuries or new impairing conditions.³⁵ However, there is no law, rule, or regulation that states a beneficiary cannot be rendered homebound by limitations stemming from chronic conditions. In fact, the Medicare Benefit Policy Manual contains several examples of beneficiaries rendered homebound by chronic or permanent conditions:

- A patient who is blind or senile and requires the assistance of another person in leaving his or her place of residence.
- A patient in the late stages of amyotrophic lateral sclerosis or neurodegenerative disabilities.
- A patient with arteriosclerotic heart disease of such severity that he or she must avoid all stress and physical activity.
- 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 he or she does not have any physical limitations.³⁶

In each of the preceding examples, CMS would consider the beneficiary homebound in spite of the absence of a “recent injury or new impairing condition.” This illustrates that the reviewers have applied the wrong coverage criteria when evaluating the relevant claims, and OIG should rescind these determinations.

C. The architectural or structural features of a beneficiary’s residence are not relevant to the question of whether the beneficiary is confined to the home.

In many cases, the reviewers decided that beneficiaries were not homebound because they resided in “accessible” assisted or independent living facilities without “mobility barriers.”³⁷ There is no support in the law for the notion that the architectural features of a beneficiary’s residence are dispositive as to homebound status. Instead, Medicare regulations and guidelines require an analysis of the beneficiary’s ability to leave his or her residence safely and independently.³⁸ The reviewers have failed to properly apply this standard.

A beneficiary does not cease being homebound simply because he or she is able to take one step out of the house. The purpose of the homebound rule is to limit the availability of home health services to beneficiaries who do not have the ability to regularly obtain the types of services

Inc., 2009 WL 10487060, at *6 (H.H.S. 2009) (commenting that a beneficiary’s ability to perform ADLs inside the home is not tantamount to the ability to leave home safely or without taxing effort).

³⁵ This error applies to sample items S1-40, S2-95, S2-95, and S2-97.

³⁶ MBPM Ch. 7 § 30.1.1 (Pub. 100-02, Rev. 172) (2013).

³⁷ The reviewers improperly considered this with respect to sample items S2-52, S2-56, S2-57, S2-82, S2-94, and S2-95.

³⁸ See 42 C.F.R. § 409.44(a); MBPM Ch. 7 § 30.1.1 (Pub. 100-02, Rev. 172) (2013) (emphasis added).

available under the home health benefit outside of the home.³⁹ The fact that a beneficiary's residence does not contain "mobility barriers" is thus irrelevant to a homebound determination because a beneficiary who is able to set foot out of the home to, for example, sit on the front porch could very well still be unable to regularly obtain healthcare treatment outside of the home.

All states, including the state where TPC is located, strictly regulate congregate living facilities. These regulations almost always include rules mandating certain architectural features for accessibility purposes. If residing in such a facility is a substantial consideration (or even relevant factor) to a homebound determination, then, under OIG's reasoning, all residents of such facilities would be presumptively *not* homebound and ineligible for the Medicare home health benefit.

We anticipate OIG's response will reference the following section of the Medicare Benefit Policy Manual:

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... 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 requirements of homebound must be met at each location (i.e., the patient must meet both criteria listed in section 30.1.1).⁴⁰

This is hardly clear and explicit guidance to home health providers that the architectural and structural features of their patients' residences will be used as a basis for determining homebound status. Neither TPC nor any reasonable home health provider could be expected to draw the same inference from the last sentence of the passage cited above.⁴¹ It is therefore not "clear and obvious" that such patients received non-covered services, and TPC's liability for any alleged overpayment should be waived under section 1879 of the Medicare statute.⁴²

D. Many beneficiaries' conditions closely mirrored examples of homebound beneficiaries supplied by CMS in the Medicare Benefit Policy Manual.

In many cases, the beneficiaries' overall conditions were similar or even identical to examples of homebound beneficiaries in the Medicare Benefit Policy Manual. The medical review determinations contain no indication that the reviewers were aware of this guidance, much less any reasons for departing from it. The fact that a beneficiary's condition aligns with an example

³⁹ See MBPM Ch. 7 § 30.1.1 (Pub. 100-02, Rev. 172) (2013) (commenting that a beneficiary cannot qualify for home health services if he or she has the "capacity to obtain the healthcare provided outside rather than in the home.").

⁴⁰ *Id.* at § 30.1.2 (Pub. 100-02, Rev. 208) (2015).

⁴¹ This is also an extraordinarily flimsy basis on which to base a significant portion of the overpayment. The affected sample items collectively represent an alleged actual overpayment of \$17,151. This accounts for approximately 16% of the aggregate overpayment, which equals \$404,511 of the alleged extrapolated overpayment.

⁴² See 42 U.S.C. § 13955pp; Medicare Claims Processing Manual (MCPM) Ch. 30 § 40.1.2 (Pub. 100-04, Rev. 1186) (2006).

of a homebound patient in the policy manual constitutes persuasive evidence that the beneficiary is confined to the home.⁴³ The following claim example is illustrative.⁴⁴

Around the time of the episode in question, S2-60 was a 77 year-old beneficiary who underwent a procedure to repair a left rotator cuff tear as well as a total shoulder arthroplasty (TSA). After she was discharged home, S2-60 was admitted to TPC for in-home physical therapy. Her medical history was significant for generalized osteoporosis, hypertension, asthma, and gait abnormality. S2-60 was incontinent of bladder, had low endurance, exhibited an unsteady gait and balance, and was at risk for falls. S2-60's physician ordered limitations on the use of her left shoulder and restricted her general activities during the recovery period. Approximately one month after the episode started, S2-60 was discharged from home health services to transition to an outpatient rehabilitation program.

The reviewer determined S2-60 was only homebound for two weeks until she was able to commence gait training outdoors with the physical therapist:

Her mobility improved, and as of [date], she was able to ambulate distances without hands on assistance and at the next visit on [date], she had been progressed to ambulating outdoors. There were no medical contraindications to leaving the home. Leaving the home no longer would have required a considerable and taxing effort after [date].

This decision ignores the following example of a homebound beneficiary given by CMS:

A patient who has just returned from a hospital stay involving surgery, who may be suffering from resultant weakness and pain because of the surgery and, therefore, their actions may be restricted by their physician to certain specified and limited activities (such as getting out of bed only for a specified period of time, walking stairs only once a day, etc.).⁴⁵

S2-60's case aligns with this example because the physical therapist regularly assessed S2-60 with post-operative weakness and constant pain precipitated by activities and movement – including after the date of disallowance. Moreover, the physician ordered restrictions on S2-60's activities as part of the initial plan of care and then later medically restricted S2-60 to home for two weeks because she was at risk for serious fall-related injury. These facts are not even mentioned – much less analyzed – in the reviewer's determination, and there is no basis on which to distinguish S2-60's case with the preceding example of a homebound beneficiary from CMS. OIG should withdraw this and all similar determinations.

⁴³ See *Morris v. N. Haw. Cmty. Hosp.*, 37 F.Supp.2d 1181, 1188 (D. Haw. 1999).

⁴⁴ This error applies to the following sample items: S1-34, S1-41, S1-50, S2-56, S2-60, S2-77, S2-81, S2-82, and S2-95.

⁴⁵ MBPM Ch. 7 § 30.1.1 (Pub. 100-02, Rev. 172) (2013).

E. The claim examples provided by OIG in the Report of beneficiaries who were allegedly not homebound do not constitute overpayments.

The Report contains two examples of beneficiaries who were allegedly not homebound.⁴⁶ Because the descriptions of those beneficiaries' functional statuses are inaccurate and incomplete, TPC will address them here.

The first example given in the Report is the claim for S1-4. In that case, OIG has concluded:

The physical therapy evaluation documentation for one beneficiary showed that, from the start of the episode, the patient was able to independently walk on even and uneven surfaces and negotiate stairs without requiring assistance. There were no ongoing medical contraindications to leaving the home or any structural or mobility barriers. For the entire episode, leaving home did not require a considerable or taxing effort and the medical information provided did not support the patient was homebound.

Around the time of the episode in question, S1-4 was a 66 year-old beneficiary who had undergone a procedure to remove an implanted cardiac device because it had become infected. The patient was discharged home with antibiotics, but the infection had still not resolved. S1-4 later returned to the hospital for treatment due to increasing drainage, pain, and erythema to the surgical site. The beneficiary was then discharged home again with orders to be admitted to TPC for skilled nursing care.⁴⁷ S1-4's medical history included chronic obstructive pulmonary disease, coronary artery disease, depressive disorder, gastroesophageal reflux disease, hypothyroidism, and diabetes.

The comprehensive recertification assessment performed prior to the episode under review revealed that S1-4 suffered intermittent pain that interfered with his activities and movement. The nurse assessed the patient as becoming noticeably short of breath when performing activities such as getting dressed, using the restroom, or walking less than 20 feet. His endurance was poor.⁴⁸ He required setup assistance or a device to safely perform ADLs such as dressing and bathing. S1-4 remained on oral antibiotics for the infection to his surgical wound, and the nurse assessed him with a still-open wound to his left chest wall. During the episode, S1-4 underwent a procedure to implant another pacemaker. After he returned home, the nurse assessed the patient with daily pain to the surgical site that was precipitated by transitional movement and interfered with his activities. His arm was in a sling. All of this information, considered as a whole, supports that S1-4 was homebound.

The second example furnished in the Report is S1-2, where OIG has determined:

[R]ecords showed that the patient was initially homebound, as she was being treated for a shoulder fracture and required a partial shoulder replacement. In addition, she had shortness of breath with weakness and decreased endurance. By [a later date in the

⁴⁶ Report at 6-7.

⁴⁷ The Report incorrectly notes that S1-4 received physical therapy services, but skilled nursing care was the only service rendered during the episode in question.

⁴⁸ Around the time his first pacemaker was implanted, S1-4's ejection fraction was only 35%.

episode], the beneficiary was able to ambulate 250 feet without an assistive device and had been discharged from home based physical therapy to attend outpatient therapy treatments. At this later date in the episode, leaving home did not require a considerable and taxing effort and the medical information provided did not support that the patient remained homebound.

S1-2 was an 87 year-old beneficiary who lived alone. Her medical history was significant for hypertension, bladder cancer, orthostatic hypotension, dehydration, monoarthritis, hypothyroidism, and hyperlipidemia. She was hard of hearing, used supplemental oxygen, had poor endurance, and experienced difficulty ambulating. Approximately one week prior to the episode at issue, S1-2 suffered a syncopal episode and fell to the floor of her home. She was unable to stand up and used an emergency alert system to summon assistance. S1-2 was transported to the hospital where she stayed until the following day when she was discharged home with a new prescription for Amlodipine. Her physician ordered that she should be admitted to TPC for a brief period of skilled nursing and physical therapy services. S1-2 was discharged from home health services after approximately three weeks upon meeting her goals for treatment.

OIG concluded that S1-2 was homebound at the start of care secondary to shortness of breath, weakness, and low endurance. Notably, the patient continued to exhibit these deficits after the date of disallowance. It is thus clear that, as discussed in section VI.2.A, the only basis for the reviewer's decision was the fact that, at the time of the physical therapy evaluation, S1-2 was able to tolerate gait training for approximately 200 feet. But this fact is presented without context, which is critical to an accurate determination in this case. The evaluation showed in relevant part:

Gait: The patient is safe to ambulate 200 feet without an assistive device. She does have a flexed posture. She can safely ambulate on level surfaces *throughout her home*. Outside the [therapist] recommend[s] [standby assistance] to [contact guard assistance] for safety as she refuses to use an assisted device. (emphasis added).

The reviewer's description of S1-2's functional status also ignores several clinical facts that are highly relevant to the question of whether she was homebound. For example, the following facts were documented by the treating clinicians after the date of disallowance and support that S1-2 remained homebound:

- The patient reported daily pain to her right shoulder (often rated 6/10 or 7/10) that was precipitated by activities and movement.
- The nurses regularly evaluated S1-2 with generalized weakness, muscle atrophy, and a limited range of motion to her upper and lower extremities.
- S1-2 had a history of orthostatic hypotension and syncopal episodes, placing her at increased risk for fall-related injury.
- The nurses assessed the patient with breathlessness on the functional dyspnea scale, and S1-2 used supplemental oxygen at a rate of 3 liters per nasal cannula. The patient also became noticeably dyspneic when walking more than 20 feet or climbing stairs.

The Report also implies that S1-2 had transitioned to an outpatient therapy program *during* the home health episode. This is misleading. The record states:

She was discharged from home health [approximately 3 months prior to the episode at issue] and attended outpatient physical therapy appointments *before falling out of bed [later] and refracturing her left shoulder / arm* requiring a partial total shoulder replacement that was performed [approximately six weeks prior to the episode at issue]. (emphasis added).

The fact that S1-2 was able to participate in an outpatient therapy program three months *prior to* the episode under review and *before* she suffered two additional syncopal episodes and fractured her shoulder is irrelevant to the question of whether she was homebound during the dates of service in question.

For these reasons, OIG should withdraw its determinations that S1-2 and S1-4 were not homebound for all or part of the episodes under review.

3. HIPPS Coding

For one of the sample items, OIG incorrectly concluded that the claim contains a HIPPS coding error. The Report states: “For one sampled claim, TPC assigned an incorrect HIPPS payment code to the Medicare claim. The OASIS and other supporting medical records did not support the payment code that TPC used...We attributed this error in HIPPS coding to clerical error.”⁴⁹ The medical reviewer’s determination elaborates: “Although a supply charge was noted on the claim form, the case file does not substantiate that additional supplies were medically necessary. The supplies charged on the claim were not substantiated.” This decision was the result of a misapplication of Medicare coding guidelines for home health services.

The Medicare Benefit Policy Manual explains the role of supplies in the home health coding system as follows:

The Medicare law governing the home health PPS is specific to the type of items and services bundled to the HHA and the time the services are bundled. Medical supplies are bundled while the patient is under a home health plan of care. If a patient is admitted for a condition which is related to a chronic condition that requires a medical supply (e.g., ostomy patient) the HHA is required to provide the medical supply while the patient is under a home health plan of care during an open episode. The physician orders in the plan of care must reflect all nonroutine medical supplies provided and used while the patient is under a home health plan of care during an open 60-day episode. The consolidated billing requirement is not superseded by the exclusion of certain medical supplies from the plan of care and then distinguishing between medical supplies that are related and unrelated to the plan of care. Failure to include medical supplies on the plan of care does not relieve HHAs from the obligation to comply with the consolidated billing requirements. The comprehensive nature of the current patient assessment and plan of care requirements looks at the totality of patient needs. However, there could be a circumstance where a physician could be uncomfortable with writing orders for a preexisting condition unrelated to the

⁴⁹ Report at 8.

reason for home health care. In those circumstances, PRN orders for such supplies may be used in the plan of care by a physician.⁵⁰

The manual goes on to provide several examples of routine supplies, which are not reportable with home health claims, as well as non-routine supplies, which are reportable.⁵¹

The sample item at issue is S1-46. In this case, the beneficiary was admitted to home health services for treatment of worsening lower back pain and an onset of confusion. His medical history was significant for a spinal compression fracture, spinal stenosis, hypertension, diabetes, coronary atherosclerosis, dementia, atrial fibrillation, and a urinary tract infection. Relevant here, the patient received skilled nursing care during the episode at issue.

During the episode, the physician ordered the nurse to perform a lab draw for a complete blood count, a complete metabolic panel, and to assess the patient's vitamin B-12, thyroid stimulating hormone, and lipid levels. The nursing documentation reflects that the nurse performed this service: "Per MD orders, SN obtained CBC, CMP, TSH, LPP, and VIT B12 using 25 gauge butterfly and bilateral antecubital spaces, as left antecubital blew during procedure." The lab results are available in the file and were reported to the physician.

The Medicare Benefit Policy Manual contains several examples of non-routine supplies that are reportable on home health claims, and one such example is syringes or needles.⁵² In the case of S1-46, the nurse documented use of a butterfly needle to perform the lab draw ordered by the physician. This non-routine supply was thus appropriately included on the claim form.

The medical reviewer stated that the record does not support that the supplies were medically reasonable and necessary. The reviewer also determined that the skilled nursing services provided to S1-46 were medically necessary and met Medicare coverage criteria. CMS coding guidelines do not contemplate that a separate medical necessity determination will be made for non-routine supplies when the skilled service with which those supplies were used was considered medically necessary.⁵³ OIG's coding determination was thus reached in error, and the Report should be revised to reflect as much.

VII. TPC WILL CHALLENGE THE VALIDITY OF OIG'S SAMPLING METHODOLOGY

The use of extrapolation is inappropriate in this case because, for the reasons explained above, the claims reviewed by OIG do not represent overpayments to TPC. To the extent any overpayments do exist upon reconsideration of the claims by OIG's medical reviewers, such overpayments would not support an error rate significant enough to justify the use of extrapolation.

TPC intends to retain the services of a qualified, independent statistician to assess the

⁵⁰ MBPM Ch. 7 § 50.4.1.1(A) (Pub. 100-02, Rev. 1) (2003).

⁵¹ *Id.* at §§ 50.4.1.2 and 50.4.1.3 (Pub. 100-02, Rev. 1) (2003).

⁵² *Id.* at § 50.4.1.3(6) (Pub. 100-02, Rev. 1) (2003).

⁵³ See MCPM Ch. 10 § 40.2 (Pub. 100-04, Rev. 3151) (2014) ("If non-routine supplies were provided, the supply charges *must* be added to the claim using the appropriate supply revenue code." (emphasis added)).

validity of OIG's sampling methodology. As such, TPC reserves the right to assert any and all arguments regarding OIG's overpayment projection in the Medicare appeals process.

VIII. CONCLUSION

TPC maintains that OIG's claim determinations are flawed because they do not account for all of the relevant clinical information in the records and resulted from application of the wrong coverage standards. For example, the reviewers have clearly applied an improper "rule of thumb" to determine many beneficiaries were not homebound, seemingly created a presumption that beneficiaries residing in congregate living facilities do not qualify for the Medicare home health benefit, and failed to consider examples of homebound beneficiaries given in CMS guidance. In other cases, OIG's reviewers simply stated in conclusory fashion that services were "excessive" or "not medically necessary."

As a Medicare-certified home health agency, TPC is committed to strict compliance with all applicable laws, rules, and regulations. In the case of documentation and billing rules, TPC's compliance has been borne out by the results of its previous Medicare audits. Further, OIG has received and reviewed a copy of TPC's compliance plan but not identified any deficiencies or ways in which that compliance program departs from OIG's own guidance.

TPC appreciates the opportunity to comment on the Report.

Respectfully Submitted,

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