

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**MEDICARE HOME HEALTH
AGENCY PROVIDER COMPLIANCE
AUDIT: GEM CITY HOME CARE,
LLC**

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Office of Inspector General

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OFFICE OF AUDIT SERVICES FINDINGS AND OPINIONS

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

Report in Brief

Date: October 2020

Report No. A-05-18-00011

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



Why OIG Did This Audit

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

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

Our objective was to determine whether Gem City Home Care, LLC, (Gem City) 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 medical review.

Medicare Home Health Agency Provider Compliance Audit: Gem City Home Care, LLC

What OIG Found

Gem City did not comply with Medicare billing requirements for 25 of the 100 home health claims that we reviewed. For these claims, Gem City received overpayments of \$40,621 for services provided in fiscal years (FYs) 2016 and 2017. Specifically, Gem City incorrectly billed Medicare for services provided to beneficiaries who: (1) were not homebound or (2) did not require skilled services. On the basis of our sample results, we estimated that Gem City received overpayments of at least \$2.67 million during this period.

What OIG Recommends and Gem City Comments

We made several recommendations to Gem City, including that it: (1) refund to the Medicare program the portion of the estimated \$2.67 million in overpayments for incorrectly billed claims that are within the 4-year reopening period; (2) for the remaining portion of the estimated \$2.67 million overpayment for claims that are outside of the reopening period, exercise reasonable diligence to identify and return overpayments in accordance with the 60-day rule, and identify any returned overpayments as having been made in accordance with this recommendation; (3) exercise reasonable diligence to identify and return any additional similar overpayments outside of our audit period; and (4) strengthen its procedures to ensure that the homebound statuses of Medicare beneficiaries are verified and continually monitored and the specific factors qualifying beneficiaries as homebound are documented, and beneficiaries are receiving only reasonable and necessary skilled services.

In written comments on our draft report, Gem City stated that it takes significant exception with our findings and conclusions and did not concur with our recommendations. Gem City retained a health care consultant to review all of the claims we questioned and challenged our independent medical review contractor's application of Medicare requirements. Gem City stated that nearly all of the sampled claims were in compliance with CMS regulations and billing requirements. To address the concerns, we had our independent medical review contractor review Gem City's comments and reconsider each of the claims that we questioned in our draft report. On the basis of the results of that review, we reduced the sampled claims incorrectly billed from 36 to 25 and revised the related findings and recommendations. We maintain that our remaining findings and recommendations are valid, although we acknowledge Gem City's right to appeal the findings.

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INTRODUCTION

WHY WE DID THIS AUDIT

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

OBJECTIVE

Our objective was to determine whether Gem City 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 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 home health agencies.

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

³ 42 CFR §§ 484.20, 484.55, 484.210(e), and 484.250(a)(1); 74 Fed. Reg. 58077, 58110-58111 (Nov. 10, 2009); and CMS’s *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)).

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

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

Gem City Home Care, LLC

Gem City is a for-profit limited liability company located in Dayton, Ohio. Palmetto GBA, LLC, its Medicare administrative contractor, paid Gem City approximately \$41 million for 14,130 claims for services in fiscal years (FYs) 2016 and 2017 (audit period) on the basis of CMS’s National Claims History (NCH) data.

HOW WE CONDUCTED THIS AUDIT

Our audit covered \$35,689,451 in Medicare payments to Gem City for 10,417 claims.⁵ These

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

⁵ In developing this sampling frame, we excluded from our review home health claim payments for low utilization payment adjustments, partial episode payments, and requests for anticipated payments.

claims were for home health services provided in FYs 2016 and 2017.⁶ We selected a stratified random sample of 100 claims with payments totaling \$385,724 for review. We evaluated compliance with selected billing requirements and submitted these claims to an independent medical review contractor to determine whether the services met coverage, medical necessity, and coding requirements.

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

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

FINDINGS

Gem City did not comply with Medicare billing requirements for 25 of the 100 home health claims that we audited. For these claims, Gem City received overpayments of \$40,621 for services provided in FYs 2016 and 2017. Specifically, Gem City incorrectly billed Medicare for services provided to beneficiaries who:

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

These errors occurred primarily because Gem City did not have adequate controls to prevent the incorrect billing of Medicare claims within selected risk areas. On the basis of our sample results, we estimated that Gem City received overpayments of at least \$2.67 million⁸ for the audit period.⁹ As of the publication of this report, this amount included claims outside of the 4-year claim-reopening period.

⁶ FYs were determined by the HHA claim “through” date of service. The through date is the last day on the billing statement covering services provided to the beneficiary.

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

⁸ Rounded to the nearest whole dollar, the amount is \$2,667,849.

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

GEM CITY BILLING ERRORS

Gem City incorrectly billed Medicare for 25 of the 100 sampled claims, which resulted in overpayments of \$40,621.

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 208 of section 30.1.1 (effective January 1, 2015) and Revision 233 of section 30.1.1 (effective January 1, 2017) covered different parts of our audit period.¹⁰

Revisions 208 and 233 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 and that an individual will be considered “confined to the home” (homebound) if the following two criteria are met:

Criteria One

The patient must either:

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

¹⁰ Coverage guidance is substantively identical in both versions of § 30.1.1 in effect during our audit period. The only difference is Revision 233, effective January 1, 2017, provides further clarification of existing policies for clinicians who must decide whether to certify that a patient is homebound.

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

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

Criteria Two

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

Gem City Did Not Always Meet Federal Requirements for Home Health Services

For 18 of the sampled claims, Gem City incorrectly billed Medicare for home health episodes for beneficiaries who did not meet the above requirements for being homebound for the full episode (4 claims) or for a portion thereof (14 claims).

Example 1: Beneficiary Not Homebound – Entire Episode

The beneficiary was not homebound at the start of care. He had been hospitalized for falling down the stairs and received the treatment needed at an assisted living facility before being discharged to his home. During the first visit, it was noted that he was carrying boxes out to his car to take them to his wife in the nursing home. No gait deficiencies or barriers to leaving the home were documented. Leaving the home did not require a considerable or taxing effort at the start of care.

Example 2: Beneficiary Not Homebound – Partial Episode

For another beneficiary, records showed that the patient was initially homebound after having a total knee replacement. He had limited knee range of motion and was ambulating 75 feet with a rolling walker. Leaving the home would have required a considerable and taxing effort at the start of care. After several physical therapy visits he progressed from ambulating with a rolling walker to ambulating with a straight cane up and down stairs and for 150 feet multiple times on even and uneven surfaces. At that point, leaving the home did not require a considerable or taxing effort.

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

Beneficiaries Did Not Require Skilled Services

Federal Requirements for Skilled Services

A Medicare beneficiary must need skilled nursing care intermittently, 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 for 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).¹¹ Skilled therapy services must be reasonable and necessary for the treatment of the patient's illness or injury or for 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).

Gem City Did Not Always Meet Federal Requirements for Skilled Services

Gem City incorrectly billed Medicare for a portion of an episode (7 claims) for beneficiaries who did not meet the above Medicare requirements for coverage of skilled therapy services.

Example 3: Beneficiary Did Not Require Skilled Services

A beneficiary received an evaluation for speech therapy for a speech disorder caused by a chronic neurological condition. Two additional visits were needed to reassess the patient's condition, evaluate the caregiver's understanding of the information provided, and make any further recommendations. Ongoing speech therapy services after the third visit were excessive and could have been discontinued.

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

¹¹ Skilled nursing services can include observation and assessment of a patient's condition, management and evaluation of a patient plan of care, teaching and training activities, and administration of medications, among other things (the Manual, chapter 7, § 40.1.2).

OVERALL ESTIMATE OF OVERPAYMENTS

On the basis of our sample results, we estimated that Gem City received overpayments totaling at least \$2.67 million for the audit period. As of the publication of this report, this amount included claims outside of the 4-year claim-reopening period.

RECOMMENDATIONS

We recommend that Gem City:

- refund to the Medicare program the portion of the estimated \$2,667,849 in overpayments for incorrectly billed claims that are within the 4-year reopening period;¹²
- for the remaining portion of the estimated \$2,667,849 overpayment for claims that are outside of the reopening period, exercise reasonable diligence to identify and return overpayments in accordance with the 60-day rule, and identify any returned overpayments as having been made in accordance with this recommendation;
- exercise reasonable diligence to identify and return any additional similar overpayments outside of our audit period, in accordance with the 60-day rule, and identify any returned overpayments as having been made in accordance with this recommendation; and
- strengthen its procedures to ensure that:
 - the homebound statuses of Medicare beneficiaries are verified and continually monitored and the specific factors qualifying beneficiaries as homebound are documented and
 - beneficiaries are receiving only reasonable and necessary skilled services.

¹² OIG audit recommendations do not represent final determinations by the Medicare program but are recommendations to U.S. Department of Health and Human Services action officials. Action officials at CMS, acting through a Medicare administrative contractor or other contractor, will determine whether a potential overpayment exists and will recoup any overpayments consistent with its policies and procedures. If a disallowance is taken, providers have the right to appeal the determination that a payment for a claim was improper (42 CFR § 405.904(a)(2)). The Medicare Part A/B appeals process has five levels, including a contractor redetermination, a reconsideration by a Qualified Independent Contractor, and a hearing before an Administrative Law Judge. If a provider exercises its right to an appeal, it does not need to return funds paid by Medicare until after the second level of appeal. An overpayment based on extrapolation is re-estimated depending on the result of the appeal.

GEM CITY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, Gem City stated that it takes significant exception with our findings and conclusions and did not concur with the recommendations in the draft report. Gem City retained a health care consultant to review all of the claims we questioned and submitted to us a report prepared by the consultant. Gem City challenged our independent medical review contractor's application of Medicare requirements, stating that nearly all of the sampled claims were in compliance with CMS regulations and billing requirements. Gem City's comments, from which we have removed two appendices, appear as Appendix F.¹³ We will provide Gem City's comments in their entirety to CMS.

To address Gem City's concerns related to the medical review decisions, we requested that our independent medical review contractor review Gem City's comments, including both appendices, and reconsider each of the 36 claims that we questioned in our draft report. On the basis of the results of that review, we revised our determinations, reducing the total number of sampled claims incorrectly billed from 36 to 25, and revised the related findings and recommendations accordingly. We also adjusted the finding for 12 of the 25 claims. (The overpayment amount decreased for nine claims, increased for two claims, and did not change for one claim.) With these actions taken, we maintain that our remaining findings and recommendations are valid, although we acknowledge Gem City's right to appeal the findings. Below is a summary of the reasons that Gem City did not concur with our recommendations and disputed our findings, followed by our responses.

STATEMENTS OF NONCONCURRENCE WITH RECOMMENDATIONS

Gem City Comments

Gem City did not concur with our recommendations.¹⁴ Regarding our first recommendation, Gem City did not concur with the conclusions in the draft report and, therefore, does not believe that a repayment of the amount recommended is required. Gem City's health care consultants agreed with the findings and overpayments related to five claims. In addition, Gem City's health care consultants disagreed with the findings but identified potential overpayments related to two claims. As a result, Gem City stated that it has refunded overpayments totaling \$11,037 (2.86 percent of sampled claim payments) to its Medicare administrative contractor,

¹³ Gem City included two appendices as part of its comments on our draft report. The first appendix contained a letter from Gem City's Director of Compliance to the OIG requesting clarification from our independent medical review contractor on the application of Medicare's requirements during its third-party review. In addition, the second appendix, prepared by the health care consultant, contained a claim-by-claim rebuttal of the findings in our draft report. However, because of the length of the appendices and one of the appendices containing personally identifiable information, we excluded these appendices from this report.

¹⁴ We added the second recommendation to the final report after the draft was issued. The second recommendation was not applicable because all sampled claims were within the reopening period at the time the draft was issued to Gem City. Therefore, Gem City only responded to the first, third, and fourth recommendations in its comments.

Palmetto GBA. In addition, Gem City stated that the error rate they agree with (2.86 percent) is below 3 percent; therefore, Gem City did not agree that the findings need to be extrapolated across the population of claims.

Regarding our third recommendation, Gem City did not specifically concur but stated that it refunds overpayments consistent with the 60-day rule and that it goes to great lengths to identify errors before they are billed.

Regarding our fourth recommendation, Gem City did not concur and stated that it routinely assesses and monitors each patient's status and constantly communicates with the field clinicians and clinical manager. Gem City stated that the patients are discharged if the documentation does not support homebound status or the ongoing need for medically necessary skilled care. In addition, Gem City stated that its compliance department develops and updates the billing and operational compliance policies to meet Federal and State requirements, reviews and interprets changes to healthcare regulations, and provides further guidance regarding regulatory oversight and internal compliance policies. Gem City stated that annual training is conducted for all associates to ensure knowledge of, and compliance with, its policies and current regulations. In addition, Gem City stated that its compliance department investigates any allegations of compliance violations and oversees the implementation of corrective actions for any detected deficiencies.

Office of Inspector General Response

Regarding our first recommendation, based on the conclusions of our independent medical review contractor's additional medical review, we revised some of the findings related to homebound status and skilled services (and the associated recommended disallowance). We maintain that the other findings related to homebound status and skilled services are valid. In addition, we maintain that our statistical approach resulted in a legally valid and reasonably conservative estimate of the amount overpaid by Medicare to Gem City.

Regarding our third recommendation, we acknowledge the corrective actions that Gem City described in its comments. We maintain that all of our findings, as revised, are valid for the reasons given above, and we, therefore, maintain that our second recommendation, regarding the identification and return of similar overpayments outside of our audit period, remains valid as well.

Regarding our fourth recommendation, we acknowledge the procedures and policies that Gem City stated were in place, as described in its comments and as summarized above. Based on our findings, as revised, we maintain that Gem City did not have adequate procedures to prevent the incorrect billing of Medicare claims.

BENEFICIARY HOMEBOUND STATUS

Gem City Comments

Gem City disagreed with 23 of the 26 sampled claims for beneficiaries who did not meet the Medicare requirements for being homebound as determined by our independent medical reviewer and identified in our draft report. Gem City stated that nearly all of the medical reviewer's determinations were solely based on an isolated event in which the patient ambulated rather than basing the determinations on longitudinal clinical information about the patient's overall health status. In addition, Gem City stated that all of the preliminary findings related to homebound status appear to be based on a determination that leaving the home did not require a considerable and taxing effort.

Gem City stated that our independent medical reviewer adopted an extremely narrow interpretation of the term "homebound," failed to apply the rules to each individual patient, and based the denials on simple ambulation as the primary criteria for the patient's homebound status. Gem City stated that the misapplication of the homebound standard by the medical reviewer is inconsistent with the requirements, which compromises the conclusions and renders them unreliable and incorrect. In addition, Gem City requested that our independent medical reviewer reconsider the homebound status for the 23 claims.

Office of Inspector General Response

On the basis of 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 18, rather than 26, sampled claims were associated with beneficiaries who did not meet the criteria for being homebound (4 claims for the full episode of care and 14 claims for part of the episode of care).

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

We disagree with Gem City's assertion that our medical reviewer failed to apply the rules to each individual patient and based the denials on ambulation as the primary criteria for the

patient's homebound status. Our medical reviewer prepared detailed medical review determination reports that documented relevant facts and the results of the reviewer's analysis. We provided these reports to Gem City before issuing our draft report. Each determination report included a detailed set of facts based on a thorough review of the entire medical record for the beneficiary associated with the sampled claim. For all sampled claims, our medical reviewer considered the entire medical record and relied on the relevant and salient facts necessary to determine homebound status in accordance with CMS's definition of homebound status.

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

Accordingly, having revised our findings and the associated recommendation with respect to 8 of the sampled claims identified in our draft report, we maintain that our findings for the remaining 18 claims, and the revised recommendation, are valid.

SKILLED SERVICES

Gem City Comments

Gem City disagreed with 10 of the 13 medical review determinations for the sampled claims with skilled services that were determined not to be medically necessary in our draft report. Gem City stated that the independent medical reviewer used the absence of a new condition as a basis for the denial of claims; however, CMS makes no distinction on the timing of the conditions for which skilled services can be applied. In addition, Gem City stated that the medical reviewer determined that some patients did not qualify for skilled services on the grounds that the caregiver could perform the same role. Finally, Gem City stated that the three-visit rule applied by the medical review had no basis in CMS laws or regulations.

Office of Inspector General Response

On the basis of 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 7, rather than 13, sampled claims were associated with beneficiaries who did not meet Medicare requirements for coverage of skilled nursing or therapy services.

Our medical review contractor's determinations of the medical necessity of skilled therapy services were made in accordance with the Manual, chapter 7, section 40.2. In accordance with these CMS guidelines, it is necessary to determine whether individual therapy services are skilled and whether, in view of the beneficiary's overall condition, skilled management of the services provided is needed. The guidelines also state that although a beneficiary's particular

medical condition is a valid factor in deciding whether skilled therapy services are needed, a beneficiary's diagnosis or prognosis should never be the sole factor in deciding whether a service is or is not skilled. The key issue is whether the skills of a therapist are needed to treat the illness or injury or whether the services can be carried out by nonskilled personnel. The skilled therapy services must be reasonable and necessary for the treatment of the beneficiary's illness or injury within the context of the beneficiary's unique medical condition.

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

Rather than disregarding the Manual's guidance related to the distinct disciplines of physical and occupational therapy or the guidance related to the medical necessity of home health skilled nursing, the medical review contractor examined all of the material in the records and documentation submitted by Gem City and carefully considered this information to determine whether Gem City billed the claims in compliance with selected billing requirements. For all of the medical reviews performed, the independent medical review contractor carefully considered conclusions as to whether the services met coverage, medical necessity, and coding requirements.

Accordingly, having revised our finding and the associated recommendation with respect to six of the sampled claims identified in our draft report, we maintain that our findings for seven claims in our final report, and the revised recommendation, are valid.

ESTIMATION OF OVERPAYMENTS

Gem City Comments

Gem City objects to our use of extrapolation to estimate our overpayment amount. Specifically, it stated that extrapolation is inappropriate unless there exists a "sustained or high level of payment error."

Office of Inspector General Response

Gem City's statement that our extrapolation was inappropriate because our error rate did not support a "sustained or high level of payment error" (according to guidelines prescribed for CMS and its contractors) is not applicable because OIG is not a Medicare contractor.¹⁵

¹⁵ The Act § 1893(f)(3); CMS *Medicare Program Integrity Manual*, Pub. No. 100-08, chapter 8.4 (effective Jan. 2, 2019).

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

Our audit covered \$35,689,451 in Medicare payments to Gem City for 10,417 home health claims with episode-of-care through dates in FYs 2016 and 2017. From this sampling frame, we selected for review a stratified random sample of 100 home health claims with payments totaling \$385,724.

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

We limited our review of Gem City'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 February 2018 through August 2020.

METHODOLOGY

To accomplish our objective, we:

- reviewed applicable Federal laws, regulations, and guidance;
- extracted Gem City's paid claims data from CMS's NCH file for the audit period;
- removed payments for low utilization payment adjustments, partial episode payments, and requests for anticipated payments from the population to develop our sampling frame;
- selected a stratified random sample of 100 claims totaling \$385,724 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 Gem City 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 Gem City's procedures for billing and submitting Medicare claims;
- verified State licensure information for selected medical personnel providing services to the beneficiaries in our sample;
- calculated the correct payments for those claims requiring adjustments;
- used the results of the sample to estimate the total Medicare overpayments to Gem City for our audit period (Appendix D); and
- discussed the results of our audit with Gem City officials.

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

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

GENERAL MEDICARE REQUIREMENTS

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

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

OUTCOME AND ASSESSMENT INFORMATION SET DATA

The OASIS is a standard set of data elements that HHA clinicians use to assess the clinical needs, functional status, and service utilization of a beneficiary receiving home health services. CMS uses OASIS data to assign beneficiaries to 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. HHA beneficiaries may be classified into 153 case-mix groups that are used as the basis for the HIPPS rate codes used by Medicare 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 Fed. Reg. 58077, 58110 (Nov. 10, 2009); and *CMS’s Medicare Program Integrity Manual*, Pub. No. 100-08, chapter 3, § 3.2.3.1).

COVERAGE AND PAYMENT REQUIREMENTS

To qualify for home health services, Medicare beneficiaries must (1) be homebound; (2) need intermittent skilled nursing care (other than solely for venipuncture for the purpose of obtaining a blood sample) or physical therapy or speech-language pathology, or occupational therapy;¹⁶ (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).

¹⁶ 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 the requirement for covered occupational therapy has been met, however, all subsequent occupational therapy services that continue to meet the reasonable and necessary statutory requirements are considered qualifying services in both the current and subsequent certification periods (subsequent adjacent episodes) (76 Fed. Reg. 68525, 68590 (Nov. 4, 2011)).

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

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

Section 6407(a) of the Affordable Care Act¹⁷ added a requirement to sections 1814(a)(2)(C) and 1835(a)(2)(A) of the Act that the physician have a face-to-face encounter with the beneficiary. In addition, the physician responsible for performing the initial certification must document that the face-to-face patient encounter, which is related to the primary reason the patient requires home health services, has occurred no more than 90 days prior to the home health start-of-care date or within 30 days of the start of the home health care by including the date of the encounter.¹⁸

Confined to the Home

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

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

¹⁷ The Patient Protection and Affordable Care Act, P.L. No. 111-148 (Mar. 23, 2010), as amended by the Health Care and Education Reconciliation Act of 2010, P.L. No. 111-152 (Mar. 30, 2010), collectively known as the Affordable Care Act.

¹⁸ See 42 CFR § 424.22(a)(1)(v) and the Manual, chapter 7, § 30.5. The initial effective date for the face-to-face requirement was January 1, 2011. However, on December 23, 2010, CMS granted HHAs additional time to establish protocols for newly required face-to-face encounters. Therefore, documentation regarding these encounters must be present on certifications for patients with starts-of-care on or after April 1, 2011.

CMS provided further guidance and specific examples in the Manual (chapter 7 § 30.1.1). Revision 208 of section 30.1.1 (effective January 1, 2015) and Revision 233 of section 30.1.1 (effective January 1, 2017) covered different parts of our audit period.¹⁹

Revisions 208 and 233 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 must be considered “confined to the home” (homebound) if the following two criteria are met:

Criteria One

The patient must either:

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

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

Criteria Two

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

Need for Skilled Services

Intermittent Skilled Nursing Care

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

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

¹⁹ Coverage guidance is substantively identical in both versions of § 30.1.1 in effect during our audit period. The only difference is Revision 233, effective January 1, 2017, provides further clarification of existing policies for clinicians who must decide whether to certify that a patient is homebound.

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

Requiring Skills of a Licensed Nurse

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

General Principles Governing Reasonable and Necessary Skilled Nursing Care

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

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

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

Reasonable and Necessary Therapy Services

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

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

Documentation Requirements

Face-to-Face Encounter

Federal regulations (42 CFR § 424.22(a)(1)(v)) and the Manual (chapter 7 § 30.5.1) state that, prior to initially certifying the home health patient's eligibility, the certifying physician must document that he or she, or an allowed nonphysician practitioner, had a face-to-face encounter with the patient, which is related to the primary reason the patient requires home health services. In addition, the Manual (chapter 7 § 30.5.1.1) 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 in the plan of care must indicate the type of services to be provided to the patient, both with respect to the professional who will provide them and the nature of the individual services, as well as the frequency of the services (the Manual, chapter 7, § 30.2.2). The plan of care must be reviewed and signed by the physician who established the plan of care, in consultation with HHA professional personnel, at least every 60 days. Each review of a patient's plan of care must contain the signature of the physician and the date of review (42 CFR § 409.43(e) and the Manual, chapter 7, § 30.2.6).

APPENDIX C: SAMPLE DESIGN AND METHODOLOGY

TARGET POPULATION

The target population consisted of Gem City’s claims for home health services²⁰ that it provided to Medicare beneficiaries with episodes of care that ended in FYs 2016 and 2017.

SAMPLE FRAME

The sampling frame consisted of a database of 10,417 home health claims, valued at \$35,689,451, from CMS’s NCH file.

SAMPLE UNIT

The sample unit was a Medicare home health paid claim.

SAMPLE DESIGN

We used a stratified random sample.

Stratum	Frame Information			Sample Size
	Payment Range	Count Total	Dollar Total	
1	<=\$3,996	6,931	\$16,925,461	50
2	>\$3,996	3,486	18,763,990	50
Total		10,417	\$35,689,451	100

SAMPLE SIZE

We randomly selected 50 sample units from each stratum for a total sample size of 100.

SOURCE OF RANDOM NUMBERS

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

METHOD FOR SELECTING SAMPLE UNITS

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

²⁰ We excluded home health payments for low utilization adjustments, partial episode payments, and requests for anticipated payments. We also excluded claims that resulted in error code 540 when matched against the Recovery Audit Contractor Data Warehouse. This code represents claims that have already been marked for exclusion by an OIG audit, investigation, or similar review.

ESTIMATION METHODOLOGY

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

APPENDIX D: SAMPLE RESULTS AND ESTIMATES

SAMPLE RESULTS

Stratum	Frame Size	Value of Frame	Sample Size	Total Value of Sample	Incorrectly Billed Sample Items	Value of Over-payments in Sample
1	6,931	\$16,925,461	50	\$124,186	12	\$20,013
2	3,486	18,763,990	50	261,538	13	20,608
Total	10,417	\$35,689,451	100	\$385,724	25	\$40,621

ESTIMATES

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

Point estimate	\$4,210,967
Lower limit	2,667,849
Upper limit	5,754,085

APPENDIX E: TYPES OF ERRORS BY SAMPLE ITEM

STRATUM 1 (Samples 1-25)

Sample	Not Homebound	Did Not Require Skilled Services	Overpayment
1	-	-	-
2	-	-	-
3	-	-	-
4	-	-	-
5	X	-	\$1,918
6	-	-	-
7	-	-	-
8	-	-	-
9	-	-	-
10	-	-	-
11	-	-	-
12	X	-	1,481
13	-	-	-
14	-	-	-
15	X	-	3,164
16	-	-	-
17	-	-	-
18	-	-	-
19	-	-	-
20	-	-	-
21	-	-	-
22	X	-	534
23	-	-	-
24	-	-	-
25	-	-	-

STRATUM 1 (Samples 26–50)

Sample	Not Homebound	Did Not Require Skilled Services	Overpayment
26	-	-	-
27	-	X	\$1,908
28	-	-	-
29	X	-	744
30	X	-	2,237
31	X	-	2,214
32	-	-	-
33	X	-	897
34	-	X	225
35	X	-	2,041
36	-	-	-
37	-	-	-
38	-	-	-
39	-	-	-
40	-	-	-
41	-	-	-
42	-	-	-
43	-	-	-
44	-	-	-
45	-	-	-
46	-	-	-
47	X	-	2,650
48	-	-	-
49	-	-	-
50	-	-	-

STRATUM 2 (Samples 51–75)

Sample	Not Homebound	Did Not Require Skilled Services	Overpayment
51	-	-	-
52	-	-	-
53	-	-	-
54	-	-	-
55	X	-	1,253
56	-	-	-
57	X	-	1,830
58	-	-	-
59	-	-	-
60	X	-	1,813
61	-	-	-
62	-	-	-
63	-	-	-
64	-	-	-
65	-	-	-
66	-	X	1,013
67	-	-	-
68	-	-	-
69	-	-	-
70	-	-	-
71	-	-	-
72	-	-	-
73	-	X	478
74	-	-	-
75	-	-	-

STRATUM 2 (Samples 76–100)

Sample	Not Homebound	Did Not Require Skilled Services	Overpayment
76	-	-	-
77	-	-	-
78	-	-	-
79	-	-	-
80	X	-	\$1,921
81	X	-	5,088
82	-	-	-
83	X	-	2,710
84	-	-	-
85	-	X	233
86	-	-	-
87	-	-	-
88	-	-	-
89	-	-	-
90	-	-	-
91	-	-	-
92	-	-	-
93	-	-	-
94	-	-	-
95	X	-	1,015
96	-	-	-
97	-	X	1,227
98	-	-	-
99	X	-	1,692
100	-	X	335
Total	18	7	\$40,621

APPENDIX F: GEM CITY COMMENTS²¹



October 31, 2019

Sheri L. Fulcher
Regional Inspector General of Audit Services
Office of the Inspector General Department of Health and Human Services
Office of Audit Services, Region V
233 North Michigan, Suite 1360
Chicago, Illinois 60601

Re: RESPONSE TO DHHS, OIG DRAFT AUDIT REPORT A-05-18-00011

Dear Ms. Fulcher:

Gem City Home Health Care, LLC ("Gem City") submits this response to the U.S. Department of Health and Human Services ("HHS"), Office of Inspector General ("OIG") Office of Audit Services ("OAS") in connection with the draft audit report A-05-18-00011 dated October 1, 2019 (the "Draft Report"). The purpose of this letter is to set forth Gem City's formal, detailed response outlining our concerns and disagreements with the Draft Report's findings and with the audit process as a whole.

At the outset, we believe that the Draft Report contains numerous regulatory and factual errors that we believe should be corrected prior to issuance of a Final Report. Specifically, the OIG's outside contractor who reviewed these records ("OIG Reviewer") did not correctly apply Medicare's homebound requirements appropriately. Additionally, it appears the OIG Reviewer failed to perform a complete review of the medical records as they did not take into account appropriate regulatory requirements and failed to address complete patient information that demonstrated homebound status. In addition, the OIG Reviewer misapplied the "skilled services" requirements and failed to appreciate the professional expertise required to perform these services. For example, the OIG Reviewer improperly concluded that certain physical or occupational therapy services could be provided by "home caregivers" when, in fact, such services can only be provided by professionals who are licensed by the State of Ohio to do so. Despite these concerns, and others, which were raised both during the exit conference on April 8, 2018 and then again in our request for clarification, dated May 15, 2019 (a copy of which is attached to this letter as [Appendix A](#)), but your office has declined to respond.

Gem City submits this response with the expectation that, since the Draft Report is "subject to further review and revision," the OIG will judiciously evaluate the concerns raised herein and will not issue a final report identical to the Draft Report. While we understand that Draft the Report's "recommendations do not represent final determinations by the Medicare program, but are recommendations to HHS action officials," we believe it is in the best interests of all affected parties to resolve the errors contained in the Draft Report, especially as a flawed and inaccurate report could have collateral consequences (i.e., reputation damage) to Gem City. Moreover, we believe that if afforded the opportunity to clarify the standards applied by the OIG's third-party reviewer, we can establish that the concerns raised in the Draft Report are without foundation and that the care provided by Gem City is compliant with Medicare billing requirements. If the OIG elects to re-review

[REDACTED]

²¹ **OIG Note:** We redacted text in several places in this appendix because it is personally identifiable information.

the work of the OIG Reviewer and redraft the Draft Report, Gem City hereby requests the opportunity to supplement this response.

As set forth in greater detail below, after an intensive review of the claims in question by Gem City's third-party reviewer, we take significant exception to the OIG's findings, conclusions and recommendations. In fact, of the thirty-six (36) claims that the OIG Reviewer identified as being in error, our third party reviewer found all but seven (7) to be in full compliance with CMS regulations and billing requirements resulting in a billing accuracy rate of 97.14% (i.e., a billing error rate of only 2.86%).¹

OVERVIEW OF GEM CITY AND ITS COMMITMENT TO COMPLIANCE

For over thirty (30) years, Gem City has been a respected provider of home health services in the Ohio market. Gem City is not only committed to upholding the highest standards of care for its patients, it is also dedicated to ensuring full compliance with the myriad of laws and regulations that govern its operations. Understanding that we operate in a heavily regulated industry, dedication to adherence with Medicare rules and regulations is of utmost importance. Gem City has been devoted to maintaining a culture of compliance and our clinicians, leadership team, and support staff are committed to ensuring we operate within the guidelines set forth by the government. Gem City's commitment to business ethics and regulatory compliance is evidenced through its Ethics and Compliance Program ("Compliance Program"), which is designed to ensure that associates, contractors, and third parties comply with regulatory guidelines, adhere to appropriate standards of business conduct, and follow the applicable billing guidelines. Included among the other elements of the compliance program are internal and external reviews to ensure compliance with company policies and federal and state laws.

As part of the Compliance Program, Gem City conducts scheduled and ad hoc internal reviews to ensure that claims are coded and billed in accordance with compliance policies and federal and state reimbursement requirements. This includes prospective audits on a scheduled basis, tailored to claim volume and relative risk associated with the type of claims, and performed by an independent, third-party auditor - [REDACTED], a leading expert in home health auditing and compliance. These audits are subject to modification based on the completed audit results and any identified areas of improvement. In addition, Gem City conducts retrospective ad hoc audits on an as-needed basis to address potential risk areas identified in scheduled audits or via any other reporting or risk evaluation mechanism.

We also wish to highlight for the OIG that physicians serve an essential role in the ordering and provision of home health services. The threshold for qualification of home health services requires a physician to (1) certify the need for skilled services; (2) certify the patient is homebound; and (3) conduct a face-to-face evaluation of the patient. This means that home health services cannot be initiated until a physician makes a medical determination that the patient is eligible and that the services are necessary. Only then can the home health agency, after reviewing the physician's order,

¹ Please note, that with respect to the errors identified during our review, Gem City has taken the necessary steps to remit the appropriate refunds to the applicable Medicare contractor in accordance with the effective policies and procedures we have in place.

conduct an assessment to ensure that the patient is, in fact, eligible for the Medicare benefit, and verify that the plan of care is consistent with what the physician has ordered. If the home health agency determines that their assessment is different, or that alternative services must be ordered, the physician must agree to any changes made to the plan of care or considerations of patient eligibility.

OVERVIEW OF DRAFT REPORT FINDINGS

The Draft Report was based upon a review of one hundred (100) claims from fiscal years 2016 and 2017 with payments totaling \$385,724 for review. The sample was stratified into two (2) categories (claims less than \$3,996 and claims above \$3,996) with half of the claims selected from each category. The OIG then sent the claims to an OIG Reviewer for review and determination of whether the services met coverage, medical necessity, and coding requirements.

The OIG Reviewer identified thirty-six (36) claims, in whole or in part, that did not comply with the Medicare payment requirements. According to the OIG and the OIG Reviewer, the alleged overpayment amount on the thirty-six (36) claims was \$64,590.19 out of the \$385,724 in total claims paid to Gem City for the entire sample. The Draft Report then seeks to extrapolate the findings to the entire universe of Gem City claims paid by Medicare over the audit years of 2016 and 2017 (\$35,689,451) and determines that based on the lower limit of a 90% confidence level, the total amount of the alleged overpayment is \$4,326,995.

The OIG Reviewer concluded that Gem City incorrectly billed Medicare because (1) beneficiaries were not homebound (26 claims; 7 full denial, 19 partial denial); and (2) beneficiaries did not require skilled services (13 claims; 13 partial denial)². Gem City firmly disagrees with the conclusions of the OIG Reviewer and believes these findings reflect a lack of understanding and a misapplication of the Medicare regulations and billing requirements for home health services. Additionally, it appears that the OIG Reviewer failed to examine the complete medical record in the review of the file, a clear contradiction of Medicare guidance. In fact, Gem City notes that references to OASIS assessments, documentation associated with face-to-face encounters, and the certifying physician's medical record are conspicuously absent in the Draft Report even though all of these sources can be used as a basis to establish beneficiary eligibility.

After receiving the results of the OIG audit, Gem City retained its consultant expert [REDACTED], to conduct a full audit of the claims with which the OIG took issue. The record reviews were completed by [REDACTED]³ Significantly [REDACTED] agreed

² Because three (3) of the claims were considered errors by the OIG Reviewer in both the homebound category and the skilled need category, the number of beneficiary claims in which there was an error equaled thirty-six (36) instead of thirty-nine (39).

[REDACTED]

with only five (5) of the OIG Reviewer's conclusions and that the overpayments related to these claims, which have been repaid, totaled \$10,431.79. There were also two (2) claims for which [REDACTED] disagreed with the OIG Reviewer's conclusions but at the same time still identified some potential overpayments (an additional amount of \$605.14) which was also repaid.

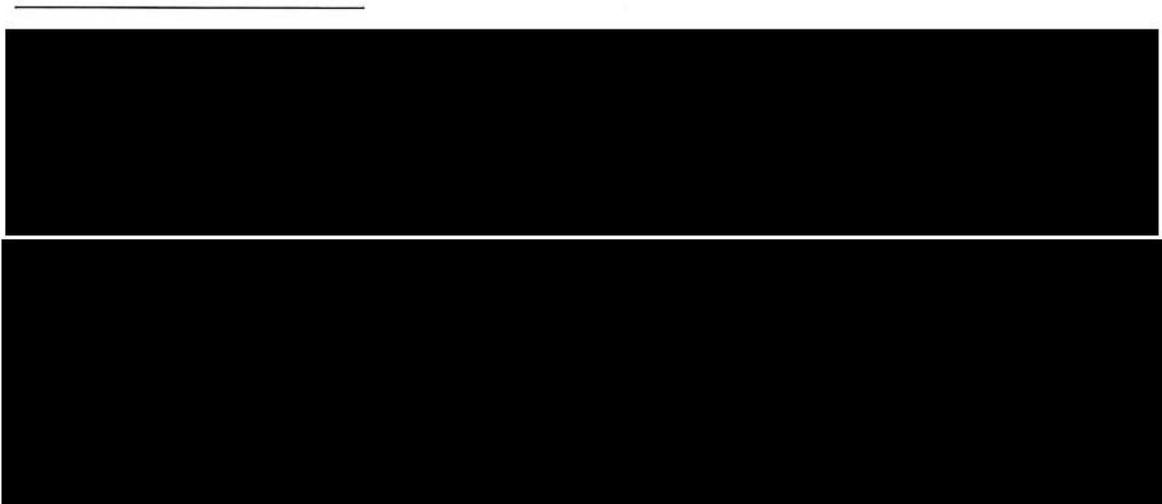
Based upon the total amounts repaid for the sample claims, Gem City's billing error rate is only 2.86%, which is *well* below the industry average.

The OIG Reviewer's Conclusions of Homebound Status are Erroneous

The OIG Reviewer alleged that Gem City billed claims in error for beneficiaries who were not "homebound". The determination of whether a beneficiary meets eligibility requirements for home health services is based on the clinical conditions and presentation of the beneficiary as assessed by a qualified clinician. However, the OIG Reviewer concluded that patients were not homebound based upon their creation of a standard on how far a patient could ambulate at single point in time; such a standard has no basis in law, regulation, or CMS guidance, nor is it medically sound.

1. Rules and Regulations for Determining Homebound Status

CMS requires that a physician certify homebound status and the need for skilled services based on a clinical evaluation of a totality of the patient's condition and the ability to review and consider the entire medical record.⁴ The definition of "homebound" is essential to ensuring patients, providers, Medicare contractors, and CMS have a definitive criterion for determining patient eligibility. It must be noted that a plain reading of the language permits a person to be "homebound" without necessitating the person be bedridden or require the assistance of another to move around. Title XVIII of the Social Security Act (the "Statute") sets forth the criteria that must be met in order for a patient to be considered "homebound:"



⁴ See 76 Fed. Reg. 68526, 68596 (November 4, 2011).

A condition, due to an illness or injury, that restricts the ability of the individual to leave his or her home except with the assistance of another individual or the aid or a supportive device (such as crutches, a cane, a wheelchair, or a walker), or if the individual has a condition such that leaving his or her home is medically contraindicated. While an individual does not have to be bedridden to be considered “confined to his home”, the condition of the individual should be such that there exists a normal inability to leave home and that leaving home requires a considerable and taxing effort by the individual. Any absence of an individual from the home attributable to the need to receive healthcare treatment, including regular absences for the purpose of participating in therapeutic, psychosocial, or medical treatment in an adult day-care program that is licensed or certified by a State, or accredited, to furnish adult day-care services in the State shall not disqualify an individual from being considered to be “confined to his home.” Any other absence of an individual from the home shall not so disqualify an individual if the absence is of infrequent or of relatively short duration. For purposes of the preceding sentence, any absence for the purpose of attending a religious service shall be deemed to be an absence of infrequent or short duration.⁵

Guidance on how physicians, home health agencies, and Medicare contractors assess “homebound” eligibility has evolved and the Medicare Benefit Policy Manual requires Medicare beneficiaries meet two sets of criteria to determine whether the patient has the ordinary ability to leave the home:

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 conditions of the first criterion, 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 effort⁶

⁵ 42 U.S.C. § 1395n (a)(2), as amended by the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA), Pub. L. No. 106-554 (Dec. 21, 2000) (emphasis added).

⁶ Medicare Benefit Policy Manual, Pub. 100-02, Ch. 7, § 30.1.1.

In interpreting CMS requirements, OIG has stated that “[h]omebound beneficiaries do not have to be bedridden but should be able to leave their residences only infrequently with “considerable and taxing effort” for short durations or for health care treatments.”⁷

All twenty-six (26) of the preliminary findings citing a beneficiary eligibility deficiency related to homebound status appear to be based on a determination that for the patients in question, leaving the home did not require a considerable and taxing effort. The OIG Reviewer appeared to base twenty-four (24) of these determinations solely on an isolated event in which the patient ambulated rather than longitudinal clinical information about the patient’s overall health status. Many of these findings also state that the patients in question had caregiver assistance available even though the statute nor the regulatory guidance require a patient to be bedridden nor be without any caregiver assistance to be considered homebound as it relates to Medicare home health eligibility. Additionally, there are numerous contradictions between information listed in the “Facts” section of the OIG Reviewer’s determinations and the conclusions reached in the “Rationale” section. By way of example, for Sample S1-5, the “Facts” section states: “The patient’s weakness, gait abnormalities, and lack of strength would make leaving the home require physical assistance and considerable and taxing effort” and that “The patient was short of breath (SOB) with moderate exertion.” The “Rationale” section concludes, however, that “Leaving the home would not have required a considerable and taxing effort for this patient at the start of care” without addressing the weakness, gait abnormalities, or shortness of breath previously noted. The clear majority of the determination letters contain similar contradictions which hinder our ability to effectively respond.

It is also important to note that CMS guidance is very explicit that being bedridden or confined to the home is not tantamount to qualifying for homebound status. As previously illustrated, the first tier of the test is quite unambiguous. Either the patient needs a supportive device or the assistance of another individual, or he doesn’t. If either of those two qualifications is met, then the first criterion of the Medicare eligibility test is met. As such, none of the twenty-six (26) considered to lack homebound status failed to meet this first criterion of the test.

The second tier of the test is more subjective in nature as CMS does not define what is considered a “normal inability” to leave the home or what constitutes a “considerable and taxing effort.” In making the determination of homebound status, CMS clarifies that one should contemplate the illness or injury in the context of the patient’s overall condition and can consider “such factors as the patient’s diagnosis, duration of the patient’s condition, clinical course (worsening or improvement), prognosis, nature and extent of functional limitations, and other therapeutic interventions and results, etc.”⁸ CMS acknowledges that a patient who can ambulate can still be considered homebound, explaining that “occasional absences from the home for nonmedical purposes, e.g., an occasional trip to the barber, a walk around the block or a drive, . . . or other

⁷ See U.S. Dep’t of Health and Human Services, Office of Inspector General (OIG), Documentation Coverage Requirements for Medicare Home Health Claims, OEI-01-08-00390 (March 2012) referencing Medicare Benefit Policy Manual, Pub. 100-02, Ch. 7, § 30.1.1.

⁸ Medicare Benefit Policy Manual, Pub 100-02, Ch. 7, § 30.1.1.

infrequent or unique event would not necessitate a finding that the patient is not homebound if the absences are undertaken on an infrequent basis or are of relatively short duration . . .”

The OIG Reviewer adopted an extremely narrow interpretation of “homebound” and failed to appreciate the complexities of the rule as applied to each individual patient’s situation. Based on the denial patterns of the OIG Reviewer, simple ambulation is the primary criterion by which to identify homebound status. There were no records for which the OIG Reviewer referred to the existence of any measure other than ambulation distance to determine a patient’s ability to leave the home. Such misapplication of the homebound standard is inconsistent with the law’s requirement, compromising the OIG Reviewer’s conclusions and rendering them unreliable and incorrect.

2. Examples of Misappropriation of Homebound Status Rules and Response

Set forth below are five (5) examples of the OIG Reviewer’s failure to take the entirety of the record into consideration and/or misapplying the rules when evaluating homebound status. In addition to the below summaries, please refer to [Appendix B](#) to this letter which sets forth full details of our Chart Reviews of all of the medical records.

Record S2-5

Summary of OIG Findings:

The OIG Reviewer determined that as of 7/12/16, this patient was no longer homebound due to her ability to ambulate on her gravel driveway and yard and exit her residence with a cane during two physical therapy visits.

Response:

In this record, the OIG Reviewer noted a post-operative patient with a new right knee replacement to be no longer homebound on the second day of the episode of care because the patient was able, on that day, to ambulate for an unknown distance on her driveway, with assistance provided by the therapist and while making use of a walker. Therefore, in the OIG Reviewer’s opinion, leaving home “no longer would have required a considerable and taxing effort” even though the OIG Reviewer acknowledges in his/her recitation of the facts that the patient had decreased range of motion in the right knee from 15 to 85° at that visit (normal flexion ROM would be 0 to 130°).

The OIG Reviewer gave no consideration to the fact that this patient was documented to be living alone and that this was a right knee replacement which would have precluded her ability to safely drive for several weeks following her surgery. Nonetheless, the OIG Reviewer found that the patient should have been able to avail herself of outpatient therapy services irrespective of her extenuating circumstances and also irrespective of the fact that her orthopedic surgeon certified the Plan of Care which was consistent with his standard post-operative protocols for a total knee arthroplasty. The OIG Reviewer simply failed to consider the totality of the information in the record or the judgment of the physician who performed the surgery and ordered home health care.

Record S2-7

Summary of OIG Findings:

The OIG Reviewer determined that as of 4/1/16, this patient was no longer homebound due to her ability to ambulate 300 feet during a physical therapy visit. The patient was residing with family members and had caregiver assistance available.

Response:

In this record, the OIG Reviewer predicated a finding that the patient was no longer homebound based on the fact that the patient was able to ambulate for a distance of 300 feet within her home, on a level surface only, without an assistive device. The rest of the record shows that this 92-year-old, living alone, was admitted for home health following a fall at home and she had a long history of falls. She had a walker that she did not use for ambulation support.

The OIG Reviewer noted that the patient lived with family members; however, an accurate account of the record shows that the patient had a friend who was present some, but not all, of the time and available only "inconsistently." After the date on which the OIG Reviewer pronounced this patient no longer homebound, the record shows that she experienced back pain and lower extremity weakness that contributed to difficulty in completion of activities of daily living ("ADL"). She experienced a decline in functional status, observed by the occupational therapist, due to postural imbalance, pain at an intensity of 8/10 during standing exercises and decreased range of motion in her shoulder. Nineteen (19) days later, this patient required human assistance with the walker for home access and management of the steps at the front door of the house with indications of loss of balance, elevated blood pressure and heart rate with visual disturbance. The patient required frequent rest breaks when performing standing activities with only limited mobility tolerance. Her normal ability to leave home with anything other than a taxing effort was practically non-existent but the OIG Reviewer considered none of these factors and relied solely on the fact that she was able, unsafely, to ambulate indoors for 300 feet without the use of an assistive device.

Record S2-10

Summary of OIG Findings:

The OIG Reviewer determined that as of 4/4/17, the patient (a 50-year-old with HIV and a recent hospitalization due to respiratory failure, followed by a rehab stay) was no longer homebound due to his ability to ambulate, including outdoors, with a straight cane approximately 250 feet.

Response:

The OIG Reviewer acknowledges in his/her recitation of the facts that this patient had a current diagnosis of critical illness myopathy which is a condition affecting the muscles of the limbs and respiratory system observed most often following mechanical ventilation

associated with inpatient intensive care. The result is significant systemic weakness. On the date that the OIG Reviewer concluded the patient was no longer homebound, the patient walked with the cane but while doing so required two rest breaks as his oxygen saturation level dropped to 89% with an elevated heart rate of 104 BPM.

In the case of this patient, a complete reading of the record shows that he was not independent with any ADLs except toileting, had a history of frequent pneumonia and longstanding HIV, diagnosed in 2005. He was dependent on the use of an assistive device for the duration of his home health care. He was extremely short of breath to the point of needing supplemental oxygen at 3/LPM and fatigued. He was weak. He lived in a ground floor apartment with 18 steps to the front entrance and a back entrance that was level with the ground. This was a large apartment complex, a fact that the OIG Reviewer apparently failed to consider. As a result, the distance from the front of the building, around the corner to the level ground back entrance is unknown but would require traversing a fairly significant distance on uneven terrain with a substantial slope (given the number of steps at the front entrance). This would have been very difficult for a person carrying oxygen and using a cane with the added dimension of pervasive physical weakness. The OIG Reviewer simply failed to take into account the totality of the record.

Record S2-21

Summary of OIG Findings:

The OIG Reviewer determined that as of 12/21/15, the patient was no longer homebound due to her ability to ambulate 250 feet at a modified independent level.

Response:

In this record, the OIG Reviewer did not consider that this 82-year-old with multiple rib fractures and pain was also dealing with bouts of dizziness, falls times three, a new diagnosis of supranuclear palsy (a brain disorder that affects movement, gait, balance, speech, swallowing, vision, mood, behavior and thinking) along with medication changes. She relied on the use of the walker for the entirety of the episode of care and, under the circumstances considering her other physical limitations, leaving home would have been a significant, taxing and likely very unsafe exercise.

Record S2-33

Summary of OIG Findings:

The OIG Reviewer determined that as of 3/24/17, two days after the home health start of care, the patient (a 90-year-old woman) was no longer homebound due to her ability to ambulate 230 feet at a modified independent level. The patient was residing in an assisted living facility and had caregiver assistance available.

Response:

As noted, this patient was elderly and living in a new assisted living facility, having been transferred from her independent living apartment following significant functional decline and a fall at home while trying to reach the telephone. The result of the fall was a closed wedge compression fracture at the thoracic vertebrae that required hospitalization. As she was discharged to home health, she was noted to require the use of a walker at all times and human assistance to ambulate due to weakness, fatigue, reduced endurance, decreased balance and gait abnormalities related to walking speed, step height and step length.

On the third day of her home health episode, the OIG Reviewer notes the patient to no longer be homebound, even though the record shows that she continued to exhibit gait abnormalities, had not yet ambulated outdoors and had a need for frequent rest breaks due to weakness and fatigue. At each of the physical therapy visits after that date, this patient ambulated only for short distances and always with both her walker and the benefit of supervision. The first time she was able to go outdoors she lost her balance and nearly fell. It was month and a half after the OIG Reviewer notes the patient to be no longer homebound that she was able to ambulate with her walker at a modified independent level of function.

Meanwhile, the occupational therapist's notes show the patient at the initial evaluation visit to be weak and without sufficient endurance. On 3/30, the patient was only able to stand for a total of nine (9) minutes at a time (which was eight (8) days after she was supposedly no longer homebound and able to leave home without difficulty). Her upper extremity strength, both right and left, was documented as -4. By 4/6, the occupational therapist was ready to try showering, but the patient was noted to be "shaky" and very fearful of another fall.

The content of this record depicts a patient who depended on the use of her walker and human assistance to move around. Added to that, she had both upper and lower extremity weakness, was unable to sustain standing balance for more than a few minutes and unable to independently complete most activities of daily living due to pain and weakness. This would have made it very difficult for her to leave home.

A review of the above-referenced examples illustrates a systematic misunderstanding of Medicare homebound status requirements that appears to require patients to be bedridden or confined to the home. When the proper standards are applied, as we believe they were in ■■■'s review, it was determined that twenty-three (23) out of twenty-six (26) did, in fact, qualify for homebound status. Gem City respectfully requests that the OIG and/or the OIG Reviewer reconsider the remaining twenty-three (23).

The OIG Reviewer Incorrectly Concluded that "Skilled Services" Were Not Medically Necessary

The Draft Report identified thirteen (13) "errors" based upon the condition that the patients in question receiving skilled services that were not "medically necessary." Upon ■■■'s review, only three (3) of the thirteen (13) claims considered not "medically necessary" by the OIG constituted errors based on CMS regulations. Through the review of these claims, ■■■ concluded there were two

(2) prevailing themes in the OIG Reviewer's reports: (1) absence of a new condition as the basis for denial, and (2) a three-visit limit with transfer of care responsibility to a caregiver.

1. Absence of a New Condition as a Basis for Denial

With respect to the principles governing reasonable and necessary therapy services, CMS dictates that the 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."⁹ There is no prohibition of therapy treatment for a previously existing illness or injury. In fact, despite the OIG Reviewer's conclusions, 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. In referencing the patient's "condition," CMS makes no distinction on the timing of the condition for which skilled services can be applied.

2. Three-Visit Limit with Transfer of Care Responsibility to a Caregiver

The OIG Reviewer determined that some patients did not qualify for skilled services on the grounds that the caregiver could perform the same role, frequently referencing the availability of (unskilled) caregivers as adequate substitutes for professional therapists in the supervision of home exercise programs and therapeutic intervention. The position the OIG Reviewer seems to be taking is that an assessment visit and two additional visits to "evaluate the caregiver's understanding of the information provided and to answer any questions" or "to make any further recommendations if needed" is a sufficient level of professional intervention, especially if services from more than one therapy discipline are indicated.

Skilled Professional Versus Unskilled Caregiver

The OIG Reviewer determined that some patients did not qualify for skilled services on the grounds that the unskilled family or friend caregiver could perform the same role. In addition, the OIG Reviewer confused the legally distinct roles and requirements that different therapy service professionals provide.¹⁰ Each is a specific discipline with a specific scope of practice that is defined

⁹ See Medicare Benefit Policy Manual, Pub 100-02, Ch. 7, § 40.2.1.

¹⁰ See Medicare Benefit Policy Manual. Pub 100-02, Ch. 15, § 230.1 (outlining the qualifications of, and services provided by physical therapists, who are defined as those qualified to "diagnos[e] and treat [] impairments, functional limitations, disabilities or changes in physical function and health status, and offering examples of such services including) (cross referencing Pub. 100-03, the Medicare National Coverage Determinations Manual); *id.* at § 230.2 (outlining the qualifications of, and services provided by occupational therapists, who are defined as those trained at "improving or restoring functions which have been impaired by illness or injury or, where function has been permanently lost or reduced by illness or injury, to improve the individual's ability to perform those tasks required for independent functioning" and offering examples of such services including "teaching a stroke patient new techniques to enable the patient to perform feeding, dressing, and other activities as independently as possible" and teaching a patient who has lost the use of an arm how to pare potatoes and chop vegetables with one hand"); *id.* at § 230.3 (outlining the qualifications of, and services provided by speech-language pathologists, who are defined as those qualified to undertake "the diagnosis and treatment of speech and language disorders, which result in communication disabilities and for the diagnosis or treatment of swallowing disorders (dysphagia).").

by state licensure laws and professional standards and understanding these distinctions is critical in determining the medical necessity of skilled therapy services for a patient.

According to the regulations, skilled nursing services are covered "where such skilled nursing services are necessary to maintain the patient's current condition or to prevent or slow further deterioration so long as the beneficiary requires skilled care for the services to be safely effectively provided."¹¹ The OIG Reviewer takes a flawed (and unsafe) approach that every caregiver can, and should, be responsible for a patient's therapy once provided an exercise program by the therapist and confuses the significant distinctions between the services provided by physical therapists or occupational therapists and those provided by "home caregivers." This is contrary to CMS's view that "a service that, by its nature, requires the skills of a nurse to be provided safely and effectively continues to be a skilled service even if it is taught to the patient, the patient's family, or other caregivers" and that in some cases, "the condition of a patient may cause a service that would ordinarily be considered unskilled to be considered a skilled service" when the patient's condition is such that the services can be safely and effectively provided only by a nurse.

"Rules of Thumb" Have No Basis in the Law or Regulations

Eleven (11) of the thirteen (13) findings related to the provision of skilled services lacking medical necessity appear to be based on a manufactured three-step process for evaluation of the appropriateness of therapy services. This three-step, or three-visit, rule applied by the OIG Reviewer has no basis in the laws or CMS regulations. In these determinations, the OIG Reviewer considered the first visit appropriate in order to assess the patient's mobility level or activities of daily living and evaluate the need for assistive devices, adaptive equipment, or a home exercise program. The second visit is deemed to be necessary to reassess the patient's condition and to evaluate patient and/or caregiver understanding of the information provided. The third visit is also determined to be appropriate to reassess the patient's condition and to make any further elaboration.

Often, when the OIG Reviewer cited this apparent "three-visit rule," it was for the denial of occupational therapy services when a physical therapist was also providing care, rationalizing that "physical therapy was needed to . . . establish a maintenance home exercise program." In each case, the physical therapy documentation did not reference any transition to a therapy maintenance program and there were no orders to support establishment of such a program. Nonetheless, with the "three-visit minimum," the OIG Reviewer seems to be implying that the occupational therapy interventions were oriented to maintenance (and prevention of further decline) rather than restorative care and, therefore, unskilled caregivers could be instructed to deliver care that was being supervised by the physical therapist. ***There is absolutely no support for such rationale in the regulatory guidance offered by CMS.***

In fact, CMS specifically forbids use of a "rule of thumb," recognizing that "determinations of whether services are reasonable and necessary must be based on an assessment of each beneficiary's individual care needs" and prohibits a denial of services based on numerical utilization screens,

¹¹ See Medicare Benefit Policy Manual, Pub 100-02, § 40.1.1 (emphasis added).

diagnostic screens, diagnosis, or specific treatment norms.¹² The Medicare Benefit Policy Manual establishes a thirty (30) day timeline to evaluate the effectiveness, or lack thereof, of therapy services which contradicts the OIG Reviewer's belief that this determination can be made in three (3) visits.¹³ The evaluation of a patient's progress on a rehabilitative therapy care plan has the potential to influence the ongoing medical necessity of the skilled care provided. If a patient is no longer progressing towards a rehabilitative goal, it may be appropriate to discontinue skilled therapy services. Many of the patients determined to have received skilled therapy services without requisite medical necessity were eventually discharged from therapy with goals met or were discharged as a result of reaching maximum rehabilitative potential. Further, depending on the unique condition of the patient, skilled care may continue to be necessary the patients whose condition is stable.¹⁴ However, the OIG Reviewer does not appear to find this relevant to ongoing determinations of medical necessity for skilled therapy services.

3. Examples of Misappropriation of Medical Necessity of Skilled Need Services and Response

The deviations from accepted practice, as well as the regulatory guidance, are demonstrated by the medical necessity findings in the following record examples. Please see [Appendix B](#) for a more detailed description.

Record S1-10

Summary of OIG Findings:

The OIG Reviewer determined that occupational therapy services were no longer needed after the third visit as there was no new impairing upper extremity condition and the patient had assistance available if needed. Ongoing skilled occupational therapy services were excessive.

Response:

The OIG Reviewer noted that, for this patient, physical therapy was needed to progress the patient's mobility "and to establish a maintenance home exercise program." The OIG Reviewer went on to note that an occupational therapy evaluation performed in anticipation of this episode of service was indicated to assess the patient's activities of daily living and the 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 and to answer any questions. A third visit would have been reasonable to reassess her condition and make any further recommendations if needed. After that, the OIG Reviewer stated that ongoing occupational therapy services were excessive because

¹² *Id.* at § 20.3.

¹³ *Id.* at § 40.2.1(b)(ii).

¹⁴ *See id.* at § 40.1.1.

here was no new impairing upper extremity condition and the patient had caregiver assistance available.

Neither the physical therapy nor occupational therapy services are construed as maintenance. The physical therapist's recorded goals for this period address mobility, ambulation, and a home exercise program for lower extremity strengthening. The occupational therapist's recorded goals address optimization of ADLs/IADLs, transfers, increased functional mobility and upper extremity strength and function. The two do not overlap and there is no basis for a suggestion that the occupational therapist's care plan can be executed by non-skilled caregivers.

Record S1-27

Summary of OIG Findings:

The OIG Reviewer determined that occupational therapy services were no longer needed after the second visit as there was no new impairing upper extremity condition and the patient had assistance available if needed. Ongoing skilled occupational therapy services were excessive.

Response:

The OIG Reviewer denied four occupational therapy visits in this episode due to an apparent root finding that stemmed from a physical therapy visit at which the OIG Reviewer notes that the patient did not feel as though he needed therapy. The OIG Reviewer used this incident to deny all occupational therapy services after the physical therapy discharge noting that the second occupational therapy visit in this episode (which was the third in the series that began in the prior episode) was only necessary for the purpose of reassessing the patient's condition and to evaluate his caregiver's understanding of the information earlier provided. The OIG Reviewer went on to note that this patient had no new impairing upper extremity condition and that the patient had assistance from assisted living facility caregivers.

After the physical therapist's discharge of the patient due to his refusal of the second visit, the occupational therapist continued providing services that were focused on safe transfers, functional endurance and upper extremity strengthening. All the services performed by the occupational therapist constituted skilled care that could not have been safely delivered by unskilled caregivers at the assisted living facility. As a result, they were reasonable and necessary and there is no basis for the OIG Reviewer's denial based on an entirely artificial rule of thumb related to visit volume limits.

Record S1-34

Summary of OIG Findings:

The OIG Reviewer determined that physical therapy services were no longer medically necessary after the third visit as the three visits are sufficient to assess the patient and

evaluate caregivers understanding of the information provided. Ongoing physical therapy services were excessive.

Response:

This patient started with a Tinetti score of 17/28, significant gait deviations and an assessment of poor dynamic standing balance. She was a high fall risk and had already fallen twice, the last time with injury. This patient's therapy needs could not have been adequately addressed by non-professional caregivers. Gait distances align with the patient's progression toward goals, as written, including achievement of a Tinetti score of 22/28, ambulation for a distance of 500 feet with the use of the four-wheeled walker and an increase in BLE equal to a half grade. The OIG Reviewer's decision implies that ambulation of 300 feet and the need for verbal cues due to this patient's cognitive and behavioral issues that will never fully resolve means that additional physical therapy is not supported; however, the OIG Reviewer admits that ongoing balance issues do indicate than an increase in ambulation distance would warrant continued skilled follow up. The decision to limit visits to three (3) is arbitrary and unfounded in applicable regulatory guidance.

Record S2-1

Summary of OIG Findings:

The OIG Reviewer concluded that the patient was not entitled to occupational skilled therapy services as prescribed by a physician because the patient's rehabilitation needs were being addressed through the physical therapy being provided. Additionally, the OIG Reviewer determined that speech language pathology ("SLP") services provided were excessive and could have been discontinued after the third (3rd) session as the patient had chronic, stable impairing conditions without new injury or neurological event.

Response:

In this record, there were six (6) occupational therapy visits, all of which were directed at improving this patient's endurance, daily task completion. At the beginning, the patient exhibited fatigue while performing ADL tasks. She also showed signs of confusion and memory deficit. The occupational therapist worked with the patient on performance of dressing and bathing activities, development of a home exercise program and safety with transfers. After merely three weeks of occupational therapy intervention, the patient was able to be discharged having met her goals.

The SLP services were also reasonable and necessary for this patient. Once again, by virtue of the OIG Reviewer's own recitation of the pertinent facts, this patient was having difficulty with memory. She could not remember visual renaming tasks nor the physical therapy and occupational therapy visits from the day before. She had a clear need for memory support and reinforcement of short-term memory skills. Even though the root cause of this patient's memory deficit was not new, the skills of the SLP were required and did result in improvement that could not have been achieved by an unskilled caregiver.

Record S2-38

Summary of OIG Findings:

The OIG Reviewer determined that the SLP services provided were excessive and could have been discontinued after the third session as the patient had chronic, stable impairing conditions without new injury or neurological event.

Response:

The OIG Reviewer noted that this 78-year-old patient with advancing Parkinson's disease had no need for SLP services beyond a three-visit limit because the patient's condition was chronic and there was no evidence of a new injury or neurological impairment.

Once again, the OIG Reviewer took the position that an assessment visit and two additional visits for the purpose of communicating findings to unskilled caregivers regarding additional care was sufficient to address any ongoing issues this patient had. It should be noted that the OIG Reviewer did not suggest that the services were unskilled, only that they were unnecessary even though they produced measurable benefit for this patient. At the time that SLP services were started, this patient had identified issues related to following directions, reading, reliability, and problem-solving ability. These deficits impacted his ability to communicate and his safety awareness. He had reduced speech intelligibility and required training and therapeutic exercises in compensatory strategies that could not have been delivered by an unskilled caregiver. As a result of the therapy that was provided, the patient was able to move the percentage of speech intelligibility to 100% and word finding skills to 95% by the end of the episode. We believe there is ample evidence that the services were necessary and that they required the skills of a professional therapist.

There is No Legal or Factual Basis to Justify Extrapolation

The Draft Report extrapolates erroneous findings to the entire universe of claims billed by Gem City during the review time period. Gem City objects to the OIG's use of extrapolation in determining an estimated overpayment amount. In accordance with the statute, extrapolation of Medicare payments is inappropriate unless there is a "sustained or high level of payment error."¹⁵ Despite the OIG Reviewer alleging potential errors in thirty-six (36) of the one hundred (100) claims reviewed, a reliable review substantiated by medical record documentation, suggests that the error rate is nominal (less than 3%), not a "sustained or high level of payment error," and not suggestive of a systematic error warranting extrapolation or further investigation.

¹⁵ 42 U.S.C. §1395ddd(f)(3). Gem City acknowledges that the OIG is not bound by this statute as it is not a "Medicare contractor," per se. However, the alleged overpayments are Medicare overpayments, and the Medicare contractor that processes and associated overpayment demand letter is subject to this provision.

RESPONSE TO OIG RECOMMENDATIONS

The Draft Report makes three (3) recommendations regarding ongoing compliance, each of which we have addressed below:

OIG Recommendation 1: Refund to the Medicare program the estimated \$4,326,995 in overpayments for incorrectly billed claims.

Gem City Response to Recommendation 1: *For the reasons detailed above, Gem City takes exception with the conclusions in the Draft Report and therefore, does not believe that a repayment of this magnitude is required. Moreover, given that the error rate with which we agree is below 3%, we do not believe that it is necessary that any of these findings be extrapolated across the larger population of claims. At the same time, in connection with the errors that were identified, we have refunded \$11,036.93 to the appropriate MAC, Palmetto GBA, accordingly.*

OIG Recommendation 2: Exercise reasonable diligence to identify and return any additional similar overpayments outside of the audit period, in accordance with the 60-day rule, and identify any returned overpayments as having been made in accordance with this recommendation.

Gem City Response to Recommendation 2: *Consistent with the Company's robust compliance and internal audit program, Gem City understands its obligations and does, in fact, affirmatively refund overpayments consistent with the 60-day rule. Moreover, as a result of Gem City's prospective audit program, one will find a lower percentage of refunds owed and paid to Medicare by Gem City as the Company goes to great lengths to identify errors before they are billed.*

OIG Recommendation 3: 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.

Gem City Response to Recommendation 3: *As set forth above, Gem City disagrees with the finding that its procedures failed to assure that the Medicare beneficiaries in the sample were, in fact, homebound and that they receive only reasonable and necessary skilled services. Nevertheless, Gem City takes its compliance obligations seriously and routinely assesses and monitors each patient's status via constant communication between the field clinicians and the clinical manager. It is only after reviewing the entirety of the patient's available medical record, including but not limited to, the OASIS assessment, face-to-face encounter, and any other relevant documentation contained in the certifying physician's medical record or that of the home health agency that a physician makes a determination and certifies homebound status and eligibility. If the documentation does not support homebound status or the ongoing need for medically necessary skilled care, those patients are appropriately discharged.*

As a result, Gem City's Compliance Department has developed, and regularly updates, billing and operational compliance policies to meet federal and state requirements. Annual training is conducted for all associates to ensure knowledge of, and compliance with, Company policies and current regulations. The Compliance Department also reviews and interprets changes to healthcare regulations to ensure the Company and its associates comply with regulations. Management is informed if the Company needs to change or revise policies to comply with new or updated regulations. Further guidance is provided to associates and other affiliated clinical personnel at all levels in the organization regarding regulatory oversight and internal compliance policies and the department investigates any allegations of compliance violations and oversees the implementation of corrective action for any detected deficiencies.

Notwithstanding the above, Gem City and its Compliance Department are consistently seeking opportunities to strengthen its existing policies, procedures and assessing ways to improve, and will continue to monitor compliance with Medicare regulations as it strives for excellence.

CONCLUSION

While Gem City recognizes the OIG's oversight authority and the need to ensure Medicare services are properly furnished and billed, from Gem City's perspective, the audit process undertaken by the OIG was flawed. The Gem City billing error rate, based on an expert audit, was 2.86%, validating the diligent billing practices, dedicated compliance program, and robust audit process of the agency. The OIG Reviewer utilized by the OIG repeatedly misapplied CMS standards which resulted in misidentified errors and a grossly overstated error rate.

As stated previously, we would welcome the opportunity to, again, meet with your team to discuss our concerns, and we appreciate your willingness to consider these issues which are not only important to Gem City, but also to the accuracy and integrity of any similar reviews.

Respectfully,

[Redacted signature block]

Attachments:

Appendix A – May 15, 2019 Letter from [Redacted]

Appendix B – Detailed Chart Review Responses