

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**GREAT LAKES HOME HEALTH
SERVICES, INC., BILLED FOR
HOME HEALTH SERVICES THAT
DID NOT COMPLY WITH
MEDICARE COVERAGE AND
PAYMENT REQUIREMENTS**

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Office of Inspector General

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operating divisions will make final determination on these matters.

Report in Brief

Date: May 2019

Report No. A-05-16-00057

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



Why OIG Did This Review

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

Our prior reviews 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 Great Lakes Home Health Services, Inc. (Great Lakes), complied with Medicare requirements for billing home health services on selected types of claims.

How OIG Did This Review

We selected a stratified random sample of 100 home health claims and submitted these claims to independent medical review.

Great Lakes Home Health Services, Inc., Billed for Home Health Services That Did Not Comply With Medicare Coverage and Payment Requirements

What OIG Found

Great Lakes did not comply with Medicare billing requirements for 38 of the 100 home health claims that we reviewed. For these claims, Great Lakes received overpayments of \$64,114 for services provided in calendar years (CYs) 2014 and 2015. Specifically, Great Lakes incorrectly billed Medicare for beneficiaries who (1) were not homebound and (2) did not require skilled services. On the basis of our sample results, we estimated that Great Lakes received overpayments of \$10.5 million in CYs 2014 and 2015.

What OIG Recommends and Great Lakes Comments

We made several recommendations to Great Lakes, including that it (1) refund to the Medicare program the portion of the estimated \$10.5 million in overpayments for claims incorrectly billed for the reopening period; (2) exercise reasonable diligence to identify and return overpayments, in accordance with the 60-day rule, for claims that are outside the reopening period; (3) exercise reasonable diligence to identify and return any additional similar overpayments outside of our audit period; and (4) strengthen its procedures.

In written comments on our draft report, Great Lakes generally disagreed with all of our findings and recommendations. Great Lakes challenged OIG's medical review decisions and maintained that most of the sample claims were billed correctly. To address Great Lakes' concerns, we requested that our medical reviewer review Great Lakes' written comments on our draft report as well as Great Lakes' health care consultant audit report. On the basis of the results of this review, we removed 21 of the 59 claims originally found to be in error in our draft report and adjusted the finding for an additional 9 claims. With these actions taken, we maintain that our remaining findings and recommendations are valid, although we acknowledge Great Lakes' rights to appeal the findings.

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INTRODUCTION

WHY WE DID THIS REVIEW

For calendar year (CY) 2016, Medicare paid home health agencies (HHAs) about \$18 billion for home health services. The Centers for Medicare & Medicaid Services' (CMS) Comprehensive Error Rate Testing (CERT) program determined that the 2016 improper payment error rate for home health claims was 42 percent, or about \$7.7 billion. Although Medicare spending for home health care accounts 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 review is part of a series of reviews of HHAs. Using computer matching, data mining, and data analysis techniques, we identified HHAs at risk for noncompliance with Medicare billing requirements.

OBJECTIVE

Our objective was to determine whether Great Lakes Home Health Services, Inc. (Great Lakes) 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 (MACs) to process and pay claims submitted by HHAs.

Home Health Agency Claims at Risk for Incorrect Billing

In prior years, our reviews at other HHAs identified significant overpayments and included 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;

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.

- under the care of a physician; and
- 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 notification of these potential overpayments must (1) exercise reasonable diligence to investigate the potential overpayment, (2) quantify any 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.

Great Lakes Home Health Services, Inc.

Great Lakes is a proprietary for-profit home health care provider located in Jackson, Michigan. National Government Services, its Medicare contractor, paid Great Lakes approximately \$73 million for 26,902 claims for services provided in CYs 2014 and 2015 (audit period) on the basis of CMS's National Claims History (NCH) data.

HOW WE CONDUCTED THIS REVIEW

Our audit covered \$69,745,515 in Medicare payments to Great Lakes for 22,511 claims.⁵ These claims were for home health services provided during the most recent timeframe for which

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.

data was available at the start of the audit (CYs 2014 and 2015).⁶ We selected a stratified random sample of 100 claims with payments totaling \$341,150 for review. We evaluated compliance with selected billing requirements and sent the claims to an independent medical review contractor to determine whether the services met coverage, medical necessity, and coding requirements.

We conducted this performance audit in accordance with generally accepted government auditing standards. 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 for each sample item.⁷

FINDINGS

Great Lakes did not comply with Medicare billing requirements for 38 of the 100 home health claims that we reviewed. For these claims, Great Lakes received overpayments of \$64,114 for services provided in CYs 2014 and 2015. Specifically, Great Lakes incorrectly billed Medicare for services provided to beneficiaries who:

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

These errors occurred primarily because Great Lakes 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 Great Lakes received overpayments of at least \$10,486,922 for the audit period.⁸

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

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

⁸ To be conservative, we recommend recovery of overpayments at the lower limit of a two-sided 90-percent confidence interval. Lower limits calculated in this manner will be less than the actual overpayment total 95 percent of the time.

GREAT LAKES BILLING ERRORS

Great Lakes incorrectly billed Medicare for 38 of the 100 sampled claims, which resulted in overpayments of \$64,114.

Beneficiaries Were Not Homebound

Federal Requirements for Home Health Services

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

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

CMS provided further guidance and specific examples in the Manual (chapter 7, § 30.1.1). Revision 172 of § 30.1.1 (effective November 19, 2013) and Revision 208 of § 30.1.1 (effective January 1, 2015) covered different parts of our audit period.⁹

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

Criteria One

The patient must either:

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

⁹ Coverage guidance is identical in both versions of § 30.1.1 in effect during our audit period. The only difference are minor revisions to a few examples.

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.

Great Lakes Did Not Always Meet Federal Requirements for Home Health Services

For 30 of the sampled claims, Great Lakes incorrectly billed Medicare for home health episodes for beneficiaries who did not meet the above requirements for being homebound for the full episode (8 claims) or for a portion thereof (22 claims).¹⁰

Example 1: Beneficiary Not Homebound – Entire Episode

Documentation for one beneficiary showed that, from the start of the episode of care, the patient was able to ambulate more than 300 feet without an assistive device and could enter and exit her residence independently. She had no functional deficits and was able to perform a home exercise program. For the entire episode, leaving the home did not require a considerable or taxing effort.

Example 2: Beneficiary Not Homebound – Partial Episode

For another beneficiary, records showed that the patient was initially homebound because she had a right heel wound with a surgical incision and a history of diabetes. She had a suture removed from her foot wound and required an ambulation boot and an assistive device to ambulate. Later in the episode, the wound healed without complication, and the patient was noted to walk briskly down stairs without signs or symptoms of decreased strength. At that point, the beneficiary did not meet the requirements for being considered homebound; leaving the home no longer required a considerable or taxing effort.

These errors occurred because Great Lakes did not have adequate oversight procedures to ensure that it verified and continually monitored the homebound status of Medicare beneficiaries under its care and properly documented the specific factors that qualified the beneficiaries as homebound.

¹⁰ Of these 30 claims with homebound errors, 6 claims were also billed with skilled services that were not medically necessary. Appendix E provides detail on the extent of errors, if any, per claim reviewed.

Beneficiaries Did Not Require Skilled Services

Federal Requirements for Skilled Services

A Medicare beneficiary must be in need of skilled nursing care on an intermittent basis, or physical therapy or speech-language pathology, or have a continuing need for occupational therapy (the Act §§ 1814(a)(2)(C) and 1835(a)(2)(A) and Federal regulations (42 CFR § 409.42(c))). In addition, skilled nursing services must require the skills of a registered nurse or a licensed practical nurse under the supervision of a registered nurse, must be reasonable and necessary to the treatment of the patient's illness or injury, and must be intermittent (42 CFR § 409.44(b) and the Manual, chapter 7, § 40.1).¹¹ Skilled therapy services must be reasonable and necessary to the treatment of the patient's illness or injury or to the restoration or maintenance of function affected by the patient's illness or injury within the context of the patient's unique medical condition (42 CFR § 409.44(c)) and the Manual, chapter 7, § 40.2.1). Coverage of skilled nursing care or therapy does not turn on the presence or absence of a patient's potential for improvement, but rather on the patient's need for skilled care. Skilled care may be necessary to improve a patient's current condition, to maintain the patient's current condition, or to prevent or slow further deterioration of the patient's condition (the Manual, chapter 7, § 20.1.2).

Great Lakes Did Not Always Meet Federal Requirements for Skilled Services

For 14 of the sampled claims, Great Lakes incorrectly billed Medicare for an entire home health episode (5 claims) or a portion of an episode (9 claims) for beneficiaries who did not meet the Medicare requirements for coverage of skilled nursing or therapy services.¹²

Example 3: Beneficiary Did Not Require Skilled Services

A beneficiary received home health services for the treatment of diabetes and a neurotrophic foot ulcer in a prior episode of care. During that episode of care, a skilled nurse provided the beneficiary with services that included educating the beneficiary about preventing ulcers. The foot ulcer healed and the beneficiary's other medical conditions were brought under control before a new episode of care began. During this episode, a skilled nurse continued to report that she provided wound care, and dressing supplies continued to be delivered, despite stating that the wound had healed and was left open to the air. The skilled nurse also reported that she continued to educate the beneficiary about preventing

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, administration of medications, among other things. Manual, chapter 7, § 40.1.2.

¹² Of these 14 claims with skilled need services that were not medically necessary, Great Lakes billed 6 of the claims for beneficiaries with homebound errors. Appendix E provides detail on the extent of errors, if any, per claim reviewed.

ulcers. Because the wound had healed before the start of this episode of care, the beneficiary did not require skilled nursing.

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

OVERALL ESTIMATE OF OVERPAYMENTS

On the basis of our sample results, we estimated that Great Lakes received overpayments totaling at least \$10,486,922 for the audit period.

RECOMMENDATIONS

We recommend that Great Lakes:

- refund to the Medicare program the portion of the estimated \$10,486,922 overpayment for claims incorrectly billed that are within the reopening period;¹³
- for the remaining portion of the estimated \$10,486,922 overpayment for claims that are outside of the Medicare reopening period, exercise reasonable diligence to identify and return overpayments in accordance with the 60-day rule, and identify any returned overpayments as having been made in accordance with this recommendation;
- 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

¹³ OIG audit recommendations do not represent final determinations by the Medicare program but are recommendations to HHS action officials. Action officials at CMS, acting through a MAC 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.

- beneficiaries are receiving only reasonable and necessary skilled services.

GREAT LAKES HOME HEALTH SERVICES, INC. COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, Great Lakes generally disagreed with all of our findings and recommendations. Great Lakes retained a health care consultant to review all claims we questioned and submitted to us a report prepared by their consultant. Great Lakes challenged the Office of Inspector General's (OIG's) "target[ing]" of home care as well as the medical review decisions maintaining that most of the sample claims were billed correctly. To address Great Lakes' concerns related to the medical review decisions, we requested that our medical reviewer review Great Lakes' written comments on our draft report as well as the report by Great Lakes' consultant. We have included Great Lakes' comments in their entirety as Appendix F.¹⁴

Based on the results of this review, we removed 21 of the 59 claims originally found to be in error in our draft report and adjusted the finding for an additional 9 claims.¹⁵ With these actions taken, we maintain that our remaining findings and recommendations are valid, although we acknowledge Great Lakes' rights to appeal the findings. Below is a summary of the reasons Great Lakes did not agree with our findings and recommendations and our responses.

BENEFICIARY HOMEBOUND STATUS

Great Lakes Comments

Great Lakes stated that the medical reviewer did not apply Medicare's homebound requirements correctly. In addition, Great Lakes stated that the medical reviewer did an incomplete review of medical records, failing to take into account appropriate legal requirements or disregarding the complete patient information that demonstrated homebound status. Great Lakes stated that the medical reviewer applied a standard for homebound inconsistent with the Medicare law's requirements and used ambulation as the only criteria by which to identify homebound status. Great Lakes provided examples in which the medical reviewer cited a patient's ability to ambulate a defined distance within the home, a patient's access to assistive devices such as rolling walkers and transport chairs, and an analysis of

¹⁴ Great Lakes also included a comprehensive appendix to its comments on our draft report. This appendix includes a claim-by-claim rebuttal of the claim findings in our draft report. We provided this appendix to our medical reviewer as part of our request for an additional review of claims identified as having errors. However, this appendix contains a considerable amount of personally identifiable information, so we excluded it from this report. In addition, Great Lakes hired an external statistical expert and included his opinions in another appendix to its comments on our draft report. Because Great Lakes includes its concerns regarding our statistical sampling and extrapolation in the body of its response, we excluded the additional appendix from this report.

¹⁵ The overpayment amount for nine claims decreased.

architectural features of a patient's home as reasons patients did not qualify as homebound. Great Lakes asserted that these factors are inappropriate in making a homebound determination.

Office of Inspector General Response

We disagree with Great Lakes' assertions that our medical reviewer used ambulation as the only criteria in determining homebound status and did not consider the entire medical record in making homebound determinations. Our medical reviewer prepared detailed medical review determination reports documenting relevant facts and their analysis. These were provided to Great Lakes prior to issuing our draft report. Each determination letter included a detailed set of facts based on a thorough review of the entire medical record. In all cases, our medical reviewer considered the entire record and relied upon the relevant and salient facts necessary to determine homebound status in accordance with the CMS's homebound definition.

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

Architectural features of a patient's home may also be relevant in determining homebound status. Although Great Lakes asserts that consideration of architectural features is inappropriate in making a homebound determination, Great Lakes does not cite to any law, regulation, or CMS guidance directing that the physical characteristics of a patient's home may not be considered in determining homebound status. Moreover, our medical reviewer did not consider beneficiaries' residences to be a dispositive factor, but one of many they deliberated upon when analyzing the unique circumstances of each beneficiary.

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

Some examples of homebound patients that illustrate the factors used to determine whether a homebound condition exists [would be] A patient who has lost the use of their upper extremities and, therefore, is unable to open

doors, use handrails on stairways, etc., and requires the assistance of another individual to leave their place of residence (the Manual, chapter 7, § 30.1.1).

Physical barriers in the home environment are relevant to the homebound assessment under the “normal inability” and “considerable and taxing effort” requirement (“Criteria Two”). Although the patient is the focus of the homebound requirement, the lack of physical access barriers of a beneficiary’s residence, is a factor in determining whether a beneficiary is homebound under Criteria Two. For example, a patient residing in a walk-up but who no longer can negotiate steps or stairs has a “normal inability” to leave home and leaving a home with that physical characteristic would require a “considerable and taxing effort.” This may not be the case for the same patient in a residence without steps or stairs. The physical characteristics of the home environment, however, are always considered along with the patient's condition.¹⁶

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

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

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

¹⁶ Regarding physical environment characteristics beneficiaries may encounter once they leave the home, Title III of the Americans with Disabilities Act of 1990 (ADA), as amended (codified at 42 U.S.C. §§ 12181-12189), and its implementing regulations (28 CFR part 36), prohibits discrimination on the basis of disability in the activities of places of public accommodation (businesses that are generally open to the public and that fall into one of 12 categories listed in the ADA, such as restaurants, movie theaters, schools, day care facilities, recreation facilities, and doctors’ offices) and requires newly constructed or altered places of public accommodation—as well as commercial facilities (privately owned, nonresidential facilities)—to comply with the ADA Standards.

MEDICAL NECESSITY

Great Lakes Comments

Great Lakes stated that the draft report confused the significant distinctions between the services provided by physical and occupational therapists and those provided by “home caregivers.” Great Lakes also asserted that it is important to note that home health agencies receive physician orders that document that the patient needs skilled home health services and is eligible for the home health benefit; home health agencies then must use the tools required to assess whether the patient meets the eligibility criteria and the skilled services, including therapy services that have been ordered. Great Lakes claimed that the medical reviewer ignored the law’s requirements in qualifying patients for skilled services from a physical therapist or occupational therapist because it determined that the patient’s caregiver could perform the same role. In addition, Great Lakes claimed that the medical reviewer confused the legally distinct roles and requirements that different therapy services professionals provide.

To illustrate Great Lake’s concern about its claims that the draft report confused the distinctions between the services provided by physical and occupational therapists, Great Lakes cited two sample items as being partially denied because physical therapy or occupational therapy services were deemed to be duplicative.

Office of Inspector General Response

CMS addresses Medicare coverage of skilled physical therapy services and skilled occupational therapy services in the Manual, chapter 7, §§ 40.2.1, 40.2.2 and 40.2.4. We agree that physical therapy and occupational therapy are individual disciplines with differing goals. Upon further consideration of the two sample items Great Lakes specifically cited in its comments as duplicative, our medical reviewers reversed both of these decisions, and we adjusted our findings accordingly.

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

Skilled nursing services can include observation and assessment of a patient’s condition (the Manual, chapter 7, § 40.1.2). In determining the medical necessity of skilled nursing for

observation and assessment, our medical reviewer considered the reasonable potential of a change in condition, complication, or further acute episode (e.g., high risk of complications) pursuant to the Manual, chapter 7, § 40.1.2.1.

HEALTH INSURANCE PROSPECTIVE PAYMENT SYSTEM CODING

Great Lakes Comments

Great Lakes stated that the six claims identified by the medical reviewer as having incorrect HIPPS codes had the accurate HIPPS codes assigned. Great Lakes also stated that the medical reviewer did not use the correct tools and processes in arriving at its conclusions.

Office of Inspector General Response

We requested that our medical reviewer review its determinations for claims identified in our draft report with HIPPS coding errors. Our medical reviewer identified a software error in its home health grouper program and we reversed all six HIPPS coding errors originally identified in our draft report.

FOCUS ON HOMECARE

Great Lakes Comments

Great Lakes commented that homecare has been improperly targeted because of “alleged” error rates that were due in part to ambiguous requirements. Great Lakes said that, according to CMS, the home health industry’s error rate demonstrates that the industry has struggled to comply with Medicare program requirements. Great Lakes said that the error rates cited by CMS generally point to a lack of uniformity and consistency regarding complying with home health documentation requirements, is the result of a subjective and overly complicated system for physicians, home health agencies, and Medicare contractors.

Office of Inspector General Response

We disagree with Great Lakes’ contention that ambiguous requirements caused or contributed to the historical pattern of high error rates in Medicare home health services. The error rates that garnered our attention and led to our focus on home health services were found by the CERT program and reported by CMS. Our mission is to provide reasonable assurance that applicable laws, regulations, policies, procedures, and standards are followed. We identify and report ways to improve the economy, efficiency, and effectiveness of operations and services to beneficiaries of HHS programs. The Medicare home health benefit has long been recognized as a program area vulnerable to fraud, waste, and abuse; therefore, OIG believes conducting home health provider specific reviews is an essential part of its roll in conducting oversight of the Medicare program. Our provider specific reviews frequently identify broader vulnerabilities

and lead to nationwide reviews which are designed to inform CMS about potential issues and opportunities for strengthening the Medicare program.

BASIS TO JUSTIFY EXTRAPOLATION

Great Lakes Comments

Great Lakes stated that current law permits extrapolation by a Medicare contractor if the Secretary of HHS determines that “there is a sustained or high level of payment error” or in instances in which “documented educational intervention has failed to correct the payment error.” Great Lakes also stated that the sampling methodology, design, and extrapolations applied deviate significantly from acceptable, proper statistical sampling protocol. Great Lakes said that OIG employed an improper sample design, improper sample size, failure to test whether the sample mean follows a normal distribution, failure to draw an initial probe sample (i.e., a smaller test sample), and other issues.

Office of Inspector General Response

Great Lakes asserts that section 1893(f)(3) of the Social Security Act limits when the OIG can use statistical sampling and extrapolation. We agree with Great Lakes insofar as the Act does limit when a Medicare contractor is permitted to extrapolate, but this provision of the Act does not apply to OIG because OIG is not a Medicare contractor. OIG has the authority to extrapolate overpayments in our audits. Federal courts have consistently upheld statistical sampling and extrapolation as a valid means to determine overpayment amounts in Medicare and Medicaid.¹⁷

The legal standard for use of sampling and extrapolation is that it must be based on a statistically valid methodology, not the most precise methodology.¹⁸ We carefully reviewed Great Lakes’ and its external statistical expert’s response, and we disagree that our sample design and overpayment estimate deviate from acceptable, proper statistical sampling protocol. We properly executed our statistical sampling methodology in that we defined our sampling frame and sampling unit, randomly selected our sample, applied relevant criteria in evaluating the sample, and used the OIG/OAS statistical software to apply the correct formulas

¹⁷ See *Yorktown Med. Lab., Inc. v. Perales*, 948 F.2d 84 (2d Cir. 1991); *Illinois Physicians Union v. Miller*, 675 F.2d 151 (7th Cir. 1982); *Momentum EMS, Inc. v. Sebelius*, 2013 U.S. Dist. LEXIS 183591 at *26-28 (S.D. Tex. 2013), adopted by 2014 U.S. Dist. LEXIS 4474 (S.D. Tex. 2014); *Anghel v. Sebelius*, 912 F. Supp. 2d 4 (E.D.N.Y. 2012); *Miniet v. Sebelius*, 2012 U.S. Dist. LEXIS 99517 (S.D. Fla. 2012); *Bend v. Sebelius*, 2010 U.S. Dist. LEXIS 127673 (C.D. Cal. 2010).

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

for the extrapolation. Our methodology accounts for the difference between the sample and the sampling frame and for the potential non-normal distribution of the sample mean.

To account for the potential differences between the sample and the sampling frame¹⁹, we recommend recovery 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 in the sampling frame 95 percent of the time. The use of the lower limit accounts for both the sample design and sample size in a manner that favors the auditee. See Puerto Rico Dep't of Health, DAB No. 2385, at 10 (2011); Oklahoma Dep't of Human Servs., DAB No. 1436, at 8 (1993) (stating that the calculation of the disallowance using the lower limit of the confidence interval gave the State the "benefit of any doubt" raised by use of a smaller sample size).

Great Lakes contends that the validity of the lower limit is undermined by potential non-normality of the sample mean. To address this point, we compared our original approach against an alternative, known as the empirical likelihood method, that does not assume normality. The lower limit calculated using the empirical likelihood method was higher than our original calculation.²⁰ This result is not surprising given that the normal approximation is overly conservative in situations like the current one where the overpayment amounts are positively skewed

¹⁹ Great Lakes performed a statistical test purporting to show that the sample was "not representative of the universe." We do not agree that such tests are necessary. However, given such tests are performed, they must account for the weighting used in selecting the sample. We replicated the analysis performed by Great Lakes and found that it failed to account for the weighting. When the weighting was accounted for, the anomalies identified by Great Lakes disappeared.

²⁰ The empirical likelihood approach resulted in a lower limit of \$10,813,941, which is higher than the \$10,486,922 that we calculated using RAT-STATS.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

Our audit covered \$69,745,515 in Medicare payments to Great Lakes for 22,511 home health claims with episodes of care through dates in CYs 2014 and 2015. From this sample frame, we selected for review a stratified random sample of 100 home health claims with payments totaling \$341,150.

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

We limited our review of Great Lakes' 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 at Great Lakes from January through September 2017.

METHODOLOGY

To accomplish our objective, we:

- reviewed applicable Federal laws, regulations, and guidance;
- extracted Great Lakes' paid claims data from CMS's NCH file for the audit period;
- removed payments for low utilization payment adjustments,²¹ partial episode payments,²² and requests for anticipated payments²³ from the population to develop our sampling frame;
- selected a stratified random sample of 100 claims, totaling \$341,150, for detailed review (Appendix C);

²¹ If fewer than five visits are delivered during a 60-day episode, the home health agency is paid per visit, by visit type, with a low utilization payment adjustment, rather than by the episode payment method.

²² A partial episode payment is made when a beneficiary elects to transfer to another home health agency or is discharged and readmitted to the same home health agency during the 60-day episode.

²³ Episode payments are split between a request for anticipated payment (RAP), submitted by the home health agency as soon as an episode begins, and a home health claim, submitted after the end of the episode. For all episode payments, the home health claim payment amount will show the total payment for the episode, and the RAP will be canceled.

- reviewed available data from CMS's Common Working File for the sampled claims to determine whether the claims had been canceled or adjusted;
- obtained and reviewed billing and medical record documentation provided by Great Lakes to support the sampled claims;
- reviewed sampled claims for compliance with known risk areas;
- used an independent medical review contractor to determine whether the 100 claims contained in the sample were reasonable and necessary and met Medicare coverage and coding requirements;
- reviewed Great Lakes' procedures for billing and submitting Medicare claims;
- verified State licensure information for selected medical personnel providing services to the patients in our sample;
- calculated the correct payments for those claims requiring adjustments;
- used the results of the sample to estimate the total Medicare overpayments to Great Lakes for our audit period (Appendix D);
- discussed the results of our review with Great Lakes officials; and
- requested our medical reviewer review the additional documentation provided by Great Lakes in its comments to our draft report.

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

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

GENERAL MEDICARE REQUIREMENTS

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

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

OUTCOME AND ASSESSMENT INFORMATION SET DATA

The OASIS is a standard set of data elements that HHA clinicians use to assess the clinical needs, functional status, and service utilization of a beneficiary receiving home health services. CMS uses OASIS data to assign beneficiaries to the appropriate categories, called case-mix groups; to monitor the effects of treatment on patient care and 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 prospective payment systems. Case-mix groups represent specific sets of patient characteristics and are designed to classify patients who are similar clinically in terms of resources used.

CMS requires the submission of OASIS data as a condition of payment as of January 1, 2010 (42 CFR § 484.210(e); 74 Fed. Reg. 58077, 58110 (Nov. 10, 2009); and *CMS’s Medicare Program Integrity Manual*, Pub. No. 100-08, chapter 3, § 3.2.3.1).

COVERAGE AND PAYMENT REQUIREMENTS

To qualify for home health services, Medicare beneficiaries must (1) be homebound; (2) need intermittent skilled nursing care (other than solely for venipuncture for the purpose of obtaining a blood sample) or physical therapy or speech-language pathology, or occupational therapy;²⁴ (3) be under the care of a physician; and (4) be under a plan of care that has been established and periodically reviewed by a physician (the Act §§ 1814(a)(2)(C) and 1835(a)(2)(A), 42 CFR § 409.42, and the Manual, chapter 7, § 30).

²⁴ Effective January 1, 2012, CMS clarified the status of occupational therapy to reflect when it becomes a qualifying service rather than a dependent service. Specifically, 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 Act²⁵ added a requirement to §§ 1814(a)(2)(C) and 1835(a)(2)(A) of the Act stating that the physician must have a face-to-face encounter with the beneficiary. In addition, the physician responsible for performing the initial certification must document that the face-to-face patient encounter, which is related to the primary reason the patient requires home health services, occurred no more than 90 days prior to the home health start-of-care date or within 30 days of the start of the home health care by including the date of the encounter.²⁶

Confined to the Home

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

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

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

²⁵ 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.

²⁶ 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.

Revision 172 of § 30.1.1 (effective November 19, 2013) and Revision 208 of § 30.1.1 (effective January 1, 2015) covered different parts of our audit period.²⁷

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

Criteria One

The patient must either:

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

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

Criteria Two

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

Need for Skilled Services

Intermittent Skilled Nursing Care

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

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

²⁷ Coverage guidance is identical in both versions of § 30.1.1 in effect during our audit period. The only difference are minor revisions to a few examples.

Requiring Skills of a Licensed Nurse

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

General Principles Governing Reasonable and Necessary Skilled Nursing Care

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

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

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

Reasonable and Necessary Therapy Services

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

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

Documentation Requirements

Face-to-Face Encounter

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

Plan of Care

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

APPENDIX C: SAMPLE DESIGN AND METHODOLOGY

TARGET POPULATION

The population consisted of Great Lakes' claims for home health services that it provided to Medicare beneficiaries with episodes of care that ended in CYs 2014 and 2015.

SAMPLING FRAME

The sampling frame consisted of an Excel spreadsheet containing 22,511 home health claims, valued at \$69,745,515, from CMS's NCH file.²⁸

SAMPLE UNIT

The sample unit was a Medicare home health paid claim.

SAMPLE DESIGN AND SAMPLE SIZE

We used the following stratified random sample:

Stratum	Frame Information			Sample Size
	Payment Range	Count Total	Dollar Total	
1	<=\$3,350	14,867	\$34,744,181	50
2	>\$3,350	7,644	35,001,334	50
Total		22,511	\$69,745,515	100

SOURCE OF RANDOM NUMBERS

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

METHOD FOR SELECTING SAMPLE ITEMS

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

ESTIMATION METHODOLOGY

We used the OIG/OAS statistical software to estimate the total amount of overpayments paid to Great Lakes 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

²⁸ Our sampling frame excluded home health claim payments for low utilization payment adjustments, partial episode payments, and requests for anticipated payments.

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	14,867	\$34,744,181	50	\$117,884	18	\$30,608
2	7,644	35,001,334	50	223,266	20	33,506
Total	22,511	\$69,745,515	100	\$341,150	38	\$64,114

ESTIMATES

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

Point estimate	\$14,223,426
Lower limit	10,486,922
Upper limit	17,959,929

APPENDIX E: TYPES OF ERRORS BY SAMPLE ITEM

STRATUM 1 (Samples 1–25)

Sample	Not Homebound	Did Not Require Skilled Services	Overpayment
1	X		\$1,324
2			
3			
4			
5			
6			
7			
8	X		693
9			
10			
11	X		1,687
12	X		1,333
13			
14	X		1,422
15			
16			
17			
18			
19			
20			
21			
22	X		1,236
23	X		785
24			
25			

STRATUM 1 (Samples 26–50)

Sample	Not Homebound	Did Not Require Skilled Services	Overpayment
26			
27			
28		X	3,224
29	X		3,058
30	X	X	2,874
31			
32			
33		X	1,403
34			
35			
36	X	X	1,844
37			
38			
39	X		2,314
40			
41			
42			
43	X		352
44		X	1,637
45			
46	X	X	1,991
47			
48		X	1,649
49		X	1,784
50			

STRATUM 2 (Samples 51–75)

Sample	Not Homebound	Did Not Require Skilled Services	Overpayment
51			
52			
53	X		321
54			
55			
56			
57			
58	X		1,340
59			
60			
61	X		834
62	X	X	1,630
63			
64	X		1,315
65	X		3,002
66	X		1,545
67	X		1,190
68			
69			
70			
71			
72			
73	X		3,956
74			
75			

STRATUM 2 (Samples 76–100)

Sample	Not Homebound	Did Not Require Skilled Services	Overpayment
76		X	\$703
77			
78			
79			
80			
81	X		1,178
82			
83			
84			
85	X		2,585
86			
87			
88	X		626
89	X		1,406
90			
91			
92			
93	X		2,000
94			
95		X	2,479
96			
97		X	1,119
98	X	X	3,475
99	X		796
100	X	X	2,005
Total	30	14	\$64,114²⁹

²⁹ The sum of the column does not equal the total due to rounding.

APPENDIX F: GREAT LAKES HOME HEALTH SERVICES, INC., COMMENTS

Great Lakes Home Health Services, Inc.

February 27, 2018

Sheri Fulcher
Regional Inspector General for Audit Services
Office of Audit Services, Region V
233 North Michigan, Suite 1360
Chicago, IL 60601

Dear Ms. Fulcher:

We appreciate the opportunity to respond to the OIG's Draft Report dated December 12, 2017, relating to the review of 2014 and 2015 claims data, prior to its final publication.

Attached, you will find our formal, detailed response to the Draft Report which has been carefully prepared by third party experts and our external legal counsel at Greenberg Traurig. As a part of the public record, our attached response is the primary means by which we will outline significant concerns and disagreements we have with the Draft Report's findings and with the audit process as a whole. To that end, we thank you in advance for your careful and thoughtful review of our response.

As with any audit, we take the review process seriously, and we have dedicated considerable time and resources to this audit since we were first notified in August 2016. We have engaged outside legal, clinical and statistical experts in order to provide the OIG the critical information and perspective to ensure an accurate assessment. We have provided comprehensive information that supports our compliance and clearly refutes the Draft Report findings. However, the Draft Report disregards this information and continues to include incorrect conclusions, many of which are due to a flawed process, a lack of understanding, and a failure to review the complete patient records. It is most unfortunate that all the resources, time and funds required to pursue this administrative process could have been better used to further advance quality care to the patients we are trusted to serve. This all could have been avoided, had an accurate assessment of our record been undertaken.

As a respected provider of home health services for nearly a quarter century, GLHHS has always recognized that it is our special obligation and privilege to care for some of our nation's sickest and most at-risk patient populations. Our patients are individuals living with disabilities, and older Americans who want to age in place safely and comfortably. The populations we serve are among the most vulnerable beneficiaries in the Medicare program – underscoring the importance of seamless, quality home health. We do not take this responsibility lightly.

GLHHS operates in a highly regulated industry, and we take seriously the importance of meeting the myriad regulatory requirements necessary to ensure compliance. We are responsible stewards of the Medicare program under which we operate, and we have *always* fostered a culture of compliance – it is a central pillar to our company. Our Board of Directors, management team and employees dedicate extensive time and resources in order to ensure that we operate squarely within the guidelines set by our government partners.

GLHHS 001

996 Cooper Street | Jackson, MI 49202

We contend that had the OIG performed the audit using its own staff rather than an outside contractor, the results of the audit would be much more accurate. From the outset, we found the Draft Report and the review process to be inconsistent, lacking a thorough review of important and necessary details to make accurate and informed assessments. As such, we engaged independent subject matter advisors – who are regarded as some of the most qualified industry experts – to review the same information analyzed by the OIG auditors. Their intensive line-by-line review of the same information produced very different findings from those of the OIG, further underscoring our concerns about the audit process. We trust you will review their findings, and their expert qualifications, in their entirety.

Our third party consultants performed a detailed review of claims identified by the OIG as having technical errors. In *all but nine* of those records, our experts found that GLHHS was in full compliance with regulations. They concluded that **GLHHS has a billing accuracy rate of 94.3%, representing an actual billing error rate of only 5.7% – a rate significantly lower than the industry average.** This demonstrates extraordinary compliance and diligence by our staff. Importantly, where errors were identified, we took the necessary steps to refund Medicare.

It should be further noted that this desk audit is simply no match for the accuracy and judgement of physicians and skilled professionals who assessed and treated the patients in their home. The OIG contractor demonstrated a fundamental lack of understanding of the application of Medicare's homebound requirements and a misunderstanding of the necessity of skilled visits prescribed by a physician. In many instances, the contractor misconstrued an ability to ambulate and disregarded a patient's cognitive and psychological limitations in determining homebound status as defined by regulation. Even more disappointing is the contractor's use of a patient's condition outside of the home health episode to determine homebound status during the episode – a clear disregard for the Medicare requirements for the benefit. Further, the contractor's process for identifying alleged coding errors disregarded the patients' complete medical record. In fact, the process used for reaching their coding conclusions was unable to be replicated by our third-party auditors.

In closing, we strongly believe our attached response effectively challenges and discredits the erroneous findings within the OIG's Draft Report. We fully expect that any Final Report from the OIG will more accurately reflect GLHHS' compliance with the Medicare home health billing requirements. We believe that by releasing accurate data in the Final Report, the OIG can more effectively enforce Medicare billing requirements and address high industry error rates that may cause confusion and disruption in the delivery of home health services. We contend that the release of an inherently flawed Final Report would undermine the effectiveness of compliant providers, like GLHHS, who provide a high quality, cost effective care solution to the Medicare program.

Again, we greatly appreciate the opportunity to review and comment on the OIG's Draft Report. Thank you in advance for your careful review and consideration of the attached detailed analysis prepared by our legal, clinical and statistical advisors.

Sincerely,

/Adam Nielsen/

Adam Nielsen
Chief Executive Officer

GLHHS 002

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February 27, 2018

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

Re: RESPONSE TO DHHS, OIG DRAFT AUDIT REPORT A-05-16-00057

Dear Ms. Fulcher:

GLHHS,¹ through its counsel, submits this letter in response to the U.S. Department of Health and Human Services (“HHS”), Office of Inspector General’s (“OIG”) draft audit report A-05-16-00057 dated December 12, 2017 (the “Draft Report”).²

The Draft Report contains numerous and significant legal and factual errors which we believe should be corrected prior to issuance of a Final Report. From our work and from discussions with you, we believe these errors are primarily the result of outside reviewers and contractors (“outside contractor”) in developing the audit tool and conducting the review of the medical and technical issues of home health eligibility and billing. Accordingly, most of the comments in this reply are directed toward the work of the outside contractor. We would like to meet with your team to discuss our concerns, and we appreciate your careful consideration of these issues which are important to GLHHS as well as the home health community.

Specifically, the Draft Report contains the following legal and factual errors:

- The outside contractor did not apply Medicare’s homebound requirements correctly. In addition, it appears they did an incomplete review of medical records as the outside contractor failed to take into account appropriate legal requirements or disregarded the complete patient information that demonstrated homebound status;
- The outside contractor misinterpreted the “skilled services” requirement and failed to appreciate the professional and licensure distinction applying to the various services. For example, the outside contractor incorrectly concluded that certain physical or occupational therapy services could be provided by “home caregivers”

¹ Great Lakes Home Health Services, Inc.

² In accordance with our prior communication with David Markulin, Assistant Regional Inspector General for Audit Services, this response is timely submitted by the February 28, 2018 extended submission deadline.

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when, in fact, such services can only be provided by professionals who are licensed by the State of Michigan to do so;

- The outside contractor's findings related to the Health Insurance Prospective Payment System ("HIPPS") payment codes ("HIPPS Codes") are incorrect because it did not base its analysis on the GLHHS OASIS Concise Report which accurately reflected each patient's condition per the documentation in the GLHHS clinical record; and
- The extrapolation method used to calculate the alleged overpayments in the Draft Report is unreliable and statistically invalid because it is based on a flawed sample design, rendering invalid any effort to apply findings to a broader universe.

The OIG instituted this work plan audit to determine why there is a high error rate in the Medicare Home Health Program. The Draft Report states that in 2016, the improper payment error rate for home health claims was 42%, or about \$7.7 billion. It further provides that improper payments to home health agencies accounted for more than 18% of the total fee-for-service improper payments, or about \$41 billion, in 2016.³

GLHHS' billing compliance is far better than the industry average.⁴ In fact, upon expert review, GLHHS' actual billing accuracy rate is 94.3% and compliance error rate is only 5.7% when utilizing the proper standards.

Compliance with Medicare technical billing requirements is, and remains, a central priority to GLHHS. GLHHS worked cooperatively with the Office of Audit Services ("OAS") throughout the audit process in an effort to correct errors it identified prior to the release of the Draft Report. The outside contractor did not make any effort to understand or correct these errors. This response is intended to demonstrate that GLHHS has an excellent record of compliance and makes far fewer errors than most home health agencies. When GLHHS identifies an error, it works diligently to correct the error.⁵

We submit this response in the spirit of cooperation and belief that OIG will allow us to work with it to address the deficiencies in the Draft Report with the goal of ensuring that any final findings accurately reflect GLHHS' compliance with the home health billing requirements and are instructive for the Centers for Medicare & Medicaid Services ("CMS"), physicians, home health agencies, and Medicare contractors. Alternatively, should the OIG adopt the Draft

³ See Draft Report, page 1.

⁴ According to the Draft Report, GLHHS' alleged improper payment rate would be 31%, and as such is well below the home health industry average as a percentage. The Draft Report concludes that \$105,783 of the \$341,150 billed and collected by GLHHS was incorrectly billed. A billing error rate is calculated by dividing the amount of fees alleged to be improperly billed by the total amount of reimbursement received, or in this case \$105,783 divided by \$341,150. This results in an alleged billing error rate of 31%. While GLHHS contends that the billing error rate is actually 5.7%, even utilizing the erroneously inflated 31% rate in the Draft Report, GLHHS' billing error rate is substantially below the industry average.

⁵ Indeed, in instances where GLHHS agreed with the outside contractor's analysis that claims were incorrectly billed, it immediately repaid those funds to the appropriate Medicare contractor.

Report without working with us to address these deficiencies, we present this response to rebut the Draft Report's inaccurate findings and conclusions.

Throughout the audit, GLHHS has been transparent with OIG and attempted to work through the problems with the audit identified in this response. At the exit conference on September 28, 2017, when the findings contained in the Draft Report were initially shared, GLHHS attempted to discuss these errors. In the months that followed, GLHHS continued to try to have an open dialog to resolve these errors.⁶ Regrettably, these efforts did not prove fruitful as the very fundamental errors of the outside contractor remain in the Draft Report.

With the expectation that the OIG will work to resolve the audit, GLHHS appreciates and is taking this opportunity to provide its response to the Draft Report. Given that that the OIG has advised GLHHS that the findings can change since the Draft Report is "subject to further review and revision," GLHHS expects that the OIG will carefully consider the very real concerns voiced by GLHHS and not issue a final report identical to the Draft Report. In essence, GLHHS sees this response as a vital part of a fair process; akin to an informal appeal process where all information can again be assessed in more detail by both parties and, perhaps, with additional reviewers to ensure that findings that are accurate and reasonable and do not result in errors that result in extreme unfairness to GLHHS and potentially damaging to the reputation of the OIG/OAS.

While there are material concerns with the Draft Report, we appreciate that the OIG has indicated in its Draft Report that its "recommendations do not represent final determinations by the Medicare program, but are recommendations to HHS action officials." Nevertheless, it is in the best interests of the OIG, GLHHS, CMS and Medicare beneficiaries for the parties to resolve the errors contained in the Draft Report now.

We request that the Draft Report not be finalized until the OIG addresses the issues we have presented. We appreciate the OIG's careful review of these concerns, and we believe that, if afforded an opportunity to meet with your team, both parties' questions and concerns can be meaningfully discussed and resolved. We would like to meet in person, review this information, and have some assurances of corrections. If, as we hope, OIG elects to review the work of the outside contractor and redraft the Draft Report, GLHHS respectfully requests the opportunity to supplement this response.

⁶ GLHHS' efforts are detailed in Appendix A to the draft response, which Appendix has not been made publically available.

Official Response to OIG Draft Report A-05-16-00057

I. INTRODUCTION: OVERVIEW OF GLHHS AND HOME HEALTH.

GLHHS,⁷ through its counsel, submits this letter in response to the U.S. Department of Health and Human Services (“HHS”), Office of Inspector General’s (“OIG”) draft audit report A-05-16-00057 dated December 12, 2017 (the “Draft Report”)⁸.

GLHHS is a home health care agency deeply committed to providing compassionate, high quality care to its patients and has done so for nearly a quarter century. It is dedicated to ensuring full compliance with the varied and complex laws and regulations that govern its operations.

Physicians play the most vital and crucial role in the ordering and provision of home health services. To qualify for services, a physician must first (1) certify the need for skilled services; (2) certify that the patient is homebound; and (3) conduct a face-to-face evaluation of the patient. In essence, home health services cannot be initiated until the physician makes a medical determination that the patient is eligible and the services are necessary. The home health agency, however, is ultimately responsible for the care, and must comply with the physician’s order for services by providing care. The home health agency must review the physician’s order and conduct an assessment to ensure that the patient is in fact eligible for the Medicare benefit, and the plan of care is consistent with what the physician has ordered. Both the physician and the home health agency should ensure that the patient is eligible and a plan of care is appropriate. If the home health agency determines that their assessment is different, or that alternative services must be ordered, the physician must agree that changes are to be made to the plan of care or eligibility of the patient to receive the care.

Home health agencies, and especially GLHHS, take their obligation to verify patient eligibility and ordering requirements very seriously. If it is later determined that the patient did not meet the requirements for home health at the beginning of care, the agency must bear the financial consequences of incorrect certification.

Home health services have been subject to many changes in eligibility requirements, specifically through guidance updates relating to technical billing surrounding the eligibility requirements.

The Draft Report was part of a routine work plan audit by OIG to better understand home health billing. We were told that no home health agency was targeted because of any concern by OIG regarding compliance. As GLHHS was informed by OIG, it was selected solely as a result of its size. The purpose of a work plan audit is to allow the OAS to produce an accurate

⁷ Great Lakes Home Health Services, Inc.

⁸ In accordance with our prior communication with David Markulin, Assistant Regional Inspector General for Audit Services, this response is timely submitted by the February 28, 2018 extended submission deadline.

and independent assessment of the administration of the Medicare program. To meet that goal, it is vital that any final report be accurate and that the outside contractor apply the correct criteria when conducting their assessment.

GLHHS welcomes the opportunity to review potential errors so that it can proactively remedy them and prevent reoccurrence. Indeed, CMS and all participants in the home health continuum, i.e., home health agencies, physicians, and Medicare contractors, benefit by having clear guidance and a sound understanding of Medicare's home health requirements.

To make the final report instructive, we want to take this opportunity to explain our concerns and objections to the audit process and findings in general. It is important that the public, and particularly the health provider industry, understand that the process underlying the Draft Report is inherently flawed, harms the Medicare program, and may very well harm other providers, like GLHHS, who provide high quality care to the Medicare population. GLHHS has invested its resources and efforts in responding to the initial requests as well as the Draft Report with the goal that the audit findings are corrected to align with the Medicare regulations, Medicare coding rules, and sound sampling and statistical models. While reasonable, accurate findings will surely benefit GLHHS, they will also strengthen the OIG's important work in assessing and enforcing Medicare billing requirements and addressing high industry error rates that may cause confusion and disruption in the offering of a valued and cost-effective benefit to Medicare beneficiaries.

In instances where a work plan audit identifies deficiencies with opaque eligibility requirements and flawed application by an outside contractor, due process and fairness mandate that it work with providers to produce an audit that accurately reflects a comprehensive view of the home health benefit by examining the entire medical record and fully understand the administrative requirements. We believe that the Draft Report, given its reliance upon a flawed review conducted by an outside contractor, does not assist the government in its responsibilities to properly administer Medicare program eligibility.

The following provides evidence of the errors that were made in interpreting technical billing issues and incomplete review of records that occurred during the conduct of the audit.

II. OVERVIEW OF DRAFT REPORT FINDINGS.

As part of a routine work plan audit, OIG conducted an audit of GLHHS claims for the years 2014 and 2015. It selected a sample of 100 claims which it stratified into two categories (claims less than \$3,350 and claims above \$3,350) with half of the claims selected from each category. OIG then sent the claims to an outside contractor for review. Accordingly, the findings in the Draft Report are based almost exclusively upon the opinions of the outside contractor, as OIG did not independently review the claims. The outside contractor identified 59 claims that it concluded, in whole or in part, did not comply with the Medicare payment requirements.

The alleged overpayment amount paid on those claims was \$105,783 out of the \$341,150 in total claims paid to GLHHS for the entire sample.⁹ The Draft Report then seeks to inappropriately extrapolate these findings to the entire universe of GLHHS Claims paid by Medicare over the audit years of 2014 and 2015 (\$69,745,515) and concludes that based upon the lower limit of a 90% confidence level, the total amount of the alleged overpayment is \$17,882,732. We disagree with the alleged overpayment amount of \$105,783 out of the \$341,150 and with the authority to extrapolate – the sample taken was flawed and the law limits the types of overpayments that may be extrapolated.

Specifically, the outside contractor concluded that GLHHS incorrectly billed Medicare because (1) beneficiaries were not homebound (39 claims; 15 full-episode, 24 part-episode); (2) beneficiaries did not require skilled services (28 claims; 6 full-episode, 22 part-episode); or (3) claims were assigned with incorrect HIPPS Codes (6 claims). GLHHS strenuously disagrees with the findings and conclusions of the outside contractor, as set forth in detail below.

In order to ensure its compliance with all Medicare regulations, GLHHS, through its counsel, retained an outside expert Simone Healthcare Consultants (“Simione”) a leading expert in home health auditing and compliance, to conduct a full audit of the claims.¹⁰ Simione issued a report to GLHHS opining that only 9 out of the 59 claims reviewed had any errors (“Simione Expert Report”). In terms of dollars billed to Medicare, **GLHHS has a billing accuracy rate of 94.3%** which demonstrates extraordinary compliance and diligence by GLHHS.¹¹

In addition, GLHHS, through counsel, retained an outside statistical expert, the Berkeley Research Group (“BRG”), to review the statistical sampling methodology and provide a written report (the “BRG Expert Report”).¹² BRG concluded that OIG’s sampling methodology was invalid for purpose of extrapolation as a result of, among other things, a flawed sample design and the limitations under law as to whether extrapolation may be utilized in this circumstance.

III. ANALYSIS OF DRAFT REPORT.

A. The Outside Contractor’s Analysis of Technical Billing Requirements Is Wrong.

GLHHS has serious concerns, based upon extensive review of the claims and Medicare billing requirements, that the findings of the outside contractor, which form the basis of the Draft Report, reflect a significant lack of understanding of the guidance and program billing requirements for home health services during the period of the claims that were reviewed. We

⁹ See Appendix C to the Draft Report.

¹⁰ Simione’s Expert Report is attached as Appendix B to the draft response, which Appendix has not been made publically available.

¹¹ Simione found that for 9 of claims it reviewed resulted in total overpayments to GLHHS of \$19,657.18. Based upon the total amount paid for the sample claims, this results in a billing error rate of only 5.7% (\$19,657.18/\$341,150).

¹² BRG’s Expert Report is attached as Appendix C to the draft response, which Appendix has not been made publically available.

believe that the audit tool did not apply the appropriate guidance and that the medical review of the files did not examine the complete file.

Prior to the Draft Report's release, GLHHS identified and discussed many errors with OAS, but there were no corrections. The failure to correct these errors is a serious disservice to OIG and the home health community which results in the expenditure of significant time and resources. Having an outside contractor conduct a flawed review provides no useful guidance to OIG and detracts from laudable efforts to identify areas of concern and ways to correct them.

1. The Outside Contractor's Conclusions of Homebound Status Are Erroneous.

The outside contractor alleges that GLHHS billed in error claims either for beneficiaries who were not "homebound" or for services that were not medically necessary. However, it is important to note that these are decisions that are driven by the clinical conditions and presentation of the beneficiary as determined by a qualified clinician. The outside contractor did not seem to understand the homebound requirement, did not follow CMS's guidance, and apparently created its own standard for homebound by assessing how far a patient can ambulate in his or her home as a measure of whether the patient is homebound. This standard finds no basis in the law, regulations or CMS guidance, nor is it medically sound.

A physician must certify both the homebound status and need for skilled services. These determinations are required by CMS and are made by a physician who has made a clinical evaluation based on the totality of the patient's condition. CMS also recognizes that the entire medical record needs to be evaluated and considered by the physician when certifying homebound status or medical necessity of skilled services.¹³

The definition of "homebound" is essential to ensuring patients, providers, Medicare contractors, and CMS have clear criteria for determining patient eligibility. However, the term homebound has generated substantial confusion among practitioners and even CMS. The standard has been so confusing that courts have even ordered CMS to review and change language in its regulations, manuals, and guidance.¹⁴

The plain language of the statute and guidance reveal that the definition of "homebound" permits a beneficiary to qualify even if he or she is not bedridden, or can walk with assistance, or has a condition or conditions that make leaving the home without assistance unadvisable.

¹³ See 76 Fed. Reg. 68526, 68596 (November 4, 2011).

¹⁴ See *Jimmo v. Burwell*, No. 5:11-CV-17 (D. Vt. Aug. 17, 2016); *Jimmo v. Sebellus*, No. 5:11-CV-17 (D. Vt. Oct. 25, 2011).

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." In order to determine whether a provider has complied with the Medicare homebound requirements, it is essential to review the medical record as a whole and apply the precise Medicare criteria and guidance.

The Statute states that a beneficiary is homebound if the individual is confined to his or her home because of:

a condition, due to an illness or injury, that restricts the ability of the individual to leave his or her home except with the assistance of another individual or the aid of a supportive device (such as crutches, a cane, a wheelchair, or a walker), or if the individual has a condition such that leaving his or her home is medically contraindicated. While an individual does not have to be bedridden to be considered "confined to his home", the condition of the individual should be such that there exists a normal inability to leave home and that leaving home requires a considerable and taxing effort by the individual. Any absence of an individual from the home attributable to the need to receive 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.¹⁵

Guidance on how physicians, home health agencies, and Medicare contractors assess "homebound" eligibility has evolved. Prior to 2011, CMS's policy provided that a person was considered homebound if their ability to leave home was *restricted*. For example, if a beneficiary requires the aid of supportive devices, the assistance of another person, or if leaving home was medically contraindicated, these facts established the requisite restriction on the ability to leave home without a taxing effort.

In the 2011 Medicare Home Health Prospective Payment System Rate Update for Calendar Year 2012 final rule, CMS provided a "Clarification to Benefit Policy Manual Language on 'Confined to the Home' Definition."¹⁶ The policy change was included with unrelated materials and went unnoticed by providers until October 2013 when CMS had to send out a Transmittal about the update to the Medicare Benefit Manual. Under this new rule, as of November 19, 2013, CMS began **requiring** Medicare beneficiaries to meet two sets of criteria

¹⁵ 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).

¹⁶ 76 Fed. Reg. 68526, 68599 (Nov. 4, 2011).

before the home health agency considers whether the patient has the ordinary inability to leave home. The explanation for the policy change was stated as:

To address the recommended changes of the Office of Inspector General (OIG) to the home health benefit policy manual, CMS proposed to clarify its “confined to the home” definition to more accurately reflect the definition as articulated in the Act...These changes present the requirements first and more closely align our policy manual with the Act to prevent confusion and promote a clearer enforcement of the statute and more definitive guidance to [home health agencies] for compliance...¹⁷

Put another way, the Medicare law deems an individual to be “confined to the home,” or “homebound,” when the following two criteria are met:

Criterion One (satisfy at least one criterion):

1. Because of illness or injury, the individual needs the aid of supportive devices such as crutches, canes, wheelchairs, and walkers; the use of special transportation; or the assistance of another person to leave their place of residence; or
2. The individual has a condition such that leaving his or her home is medically contraindicated.

Criterion Two (satisfy both criteria):

1. There must exist a normal inability to leave home; and
2. Leaving home must require a considerable and taxing effort.¹⁸

The accompanying 2013 CMS policy manual provides even more clarity stating:

Medicare considers beneficiaries homebound, if, because of illness or injury, they have conditions that **restrict** their ability to leave their places of residence. Homebound 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 treatment.¹⁹

¹⁷ CMS Pub. 100-02, transmittal 172, October 18, 2013 Home Health Clarification to Benefit Policy Manual Language on Confined to Home Definition.

¹⁸ See 42 U.S.C. §§ 1395f(a)(2)(C) (Part A), 1395n(a)(2)(A)(i) (Part B), and 1395n(a)(F) (further discussion of homebound criteria), as amended by the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA), Pub. L. No. 106-554 (Dec. 21, 2000).

¹⁹ U.S. Dep’t of Health and Human Services, Office of Inspector General (OIG), *Documentation of Coverage Requirements for Medicare Home Health Claims*, OEI-01-08-00390 (March 2012).

a. The Ability to Ambulate Does Not Disqualify a Patient from Being Homebound.

The plain language of the Statute and guidance makes clear that the definition of “homebound” is not as narrow as has been wrongly assumed by the outside contractor. A beneficiary may qualify as homebound even if he or she is not bedridden. CMS has stated that “Medicare considers beneficiaries homebound, if, because of illness or injury, they have conditions that restrict their ability to leave their places of residence. Homebound beneficiaries may leave their residences only infrequently with ‘considerable and taxing effort’ for short durations or for health care treatment.” In line with the Statute, the Medicare Benefit Manual provides that even when a patient is able to leave his or her residence on occasion without assistance, that patient may still qualify as “homebound” so long as doing so requires a “considerable and taxing effort.”

CMS itself, acknowledges that a patient who can ambulate certainly can be considered homebound. Specifically, CMS has explained that “occasional absences from the home for nonmedical purposes.” In contrast the outside contractor adopts an extremely narrow reading of the term “homebound,” and appears to fail to appreciate these complexities and the extent to which providers, CMS and the courts have diligently worked to better address the complexity of complying with the Statute, including its intent.²⁰

In line with the Statute, the Medicare Benefit Manual provides further clarification that even when a patient is able to leave his or her residence on occasion without assistance, that patient may still qualify as “homebound” so long as doing so requires a “considerable and taxing effort.”²¹ CMS itself explains 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, attendance at a family reunion, funeral, graduation, or other infrequent or unique event would not necessitate a finding that the patient is not homebound.”²² Based on these standards, physicians order home health services when patients, in those physicians’ medical judgment, are “homebound.”²³

²⁰ During conversations between GLHHS and OIG before the Draft Report was issued, the OIG indicated that it relied on the outside contractors for all clinically based determinations and understanding of the technical billing requirements. OIG staff also stated that they did not independently review the clinically dependent findings nor could the following issues be submitted to those outside contractors for re-evaluation based on the information provided by GLHHS. Therefore, the Draft Report is devoid of determinations made based on a full evaluation of the clinical record upon which those determinations were supposed to be made. It is clear that the outside contractor did not correctly apply Medicare’s homebound requirements.

²¹ Medicare Benefit Policy Manual, Pub. 100-02, Ch. 7, § 30.1.1 (Rev. 298).

²² *Id.* (emphasis added).

²³ The outside contractor did not apply the correct standard in its determinations that 39 claims did not meet Medicare coverage criteria for homebound status either completely or partially. The Office of Inspector General Internal Controls Questionnaire CIN: A-05-16-00057, which the outside contractor presumably relies on, cites the homebound definition contained within the Medicare Benefit Policy Manual (chapter 7, §30.1.1, revised October 1, 2003). As discussed above, on October 18, 2013 CMS issued changes to the Medicare Benefit Policy Manual (chapter 7, §30.1.1). These policy changes were implemented on November 19, 2013. The GLHHS claims at issue

The outside contractor applied a standard for homebound inconsistent with the Medicare law's requirements and, as Simone observed, "**referenced criteria for evaluating homebound status that were never contained in the Medicare regulations.**"²⁴ It appears that based on the denial patterns of the contractor, simple ambulation is the only criteria by which to identify homebound status. This compromised the outside contractor's conclusions, rendering them unreliable and incorrect. By way of example, the outside contractor cited a patient's ability to ambulate a defined distance within the home,²⁵ a patient's access to assistive devices such as rolling walkers and transport chairs,²⁶ and an analysis of the architectural features of a patient's home as reasons patients did not qualify as homebound.²⁷ Application of these criteria is unfounded and inappropriate for determining homebound status.

b. Examples of Outside Contractor Errors Regarding Homebound Status.

The above fundamental errors are exemplified by an analysis of the claims reviewed by the outside contractor. The examples demonstrate the outside contractor's significant errors:

Sample 37.

The outside contractor determined this patient was not homebound due to his ability, on the physical therapy visit dated 9/8/15, to ambulate 130 feet, and that the patient was residing in a ranch style home with ramp access and a spouse who was available for assistance.

The outside contractor failed to consider:

- The 9/8/15 note referenced in the review refers to care provided by the inpatient rehabilitation physical therapist at the skilled nursing facility **prior to home health services beginning.**
- Home health services began on 9/15/15. This patient was admitted to home health services after a 3 week inpatient skilled nursing facility stay after he had fallen down his basement stairs at home.
- On 9/15/15 when home health services began, the nurse documents homebound qualifications of: decreased muscle coordination and strength, required the use of

in the Draft Report spanned service dates from November 2013 through November 2015, thus the definition for "homebound" from the 2013 Medicare Benefit Policy would be applicable to all of the claims.

²⁴ See Simone Expert Report at 3.

²⁵ See Sample 5 (relying exclusively on the patient's ability to "ambulate 100 feet" in determining homebound status); see also Samples 27, 29, 61, 62, 66, 85, 88, 89, 97 and 100 (focusing on the patients' abilities to ambulate certain distances as being dispositive of a homebound determination).

²⁶ See Sample 75 (focusing on the patient's ability to "ambulate within the household with a wheelchair"); see also samples 22, 23, 63, and 100 (focusing on, *inter alia*, the patients' access to assistive devices such as rolling walkers and transport chairs).

²⁷ See Sample 37 (noting that the patient "lived in a ranch home with a ramp"); see also Samples 8, 37, 58, 62, 65 and 82 (focusing on, *inter alia*, the wheelchair accessibility of the beneficiaries' homes).

- walker, required assistance with all ADLs, patient is "very weak", and high fall risk.
- The 9/17/15 Physical Therapy evaluation documents the patient can only ambulate 15 feet, with a rolling walker and caregiver assistance.
 - The 9/21/15 occupational therapy evaluation documents that the patient has experienced significant decline in functional mobility, and even documents the patient "was impaired and backing up with walker proved dangerous as he lost balance backward each time and OTR kept patient from falling".
 - By 9/23/15 (only 8 days from the home health start of care visit) the PTA documented that the patient has declined further, wife is having to provide more assistance, and they have decided to transition to hospice services.

The outside contractor incorrectly utilized documentation from outside of the home health benefit period to disqualify the patient for service as the patient clearly had physical limitations. Homebound status can only be evaluated in the patient's home, and the environment in a skilled nursing facility (i.e., even floors, no carpet to trip or get stuck on, and staff availability) is very different than that of an 84 year olds' home environment where he had fallen down his stairs resulting in him being admitted to the hospital and having pneumonia. Further, the patient ended up transferring to hospice services within 9 days of the admission to home health due to his rapid decline in status, and passed away 10 days later. The record clearly demonstrates that the patient was at high risk for falls and could only ambulate with significant assistance; and thus, had a condition such that leaving his or her home was medically contraindicated.

Sample 58.

The outside contractor determined that this patient was not homebound due to (1) her ability on 5/23/14 to ambulate without an assistive device in her room and her ability to use a cane in the facility; (2) the fact that she was residing in an accessible residence and had caregiver assistance available; and (3) the fact that her cardiac condition was stable and the left ventricular assist device ("LVAD") was working to enhance her cardiac function.

The outside contractor failed to consider:

- The patient's LVAD was one of the reasons that the patient was homebound, as the need for the LVAD constitutes a condition that rendered leaving the home medically contraindicated. Indeed, the physician's face-to-face form includes that as the reason in itself for homebound status.
- On the 5/23/14 physical therapy visit, the physical therapist also documents range of motion and lower extremity strength deficits, pain, and inability to ambulate on uneven surfaces. Moreover, the notes state that despite her increase in strength, she has "limited coordination and balance that can cause instability, pain and falls".
- By 6/22/14 the patient had further decline, including an inability to get out of bed without assistance, and required the re-initiation of physical therapy services.

Sample 75.

The outside contractor determined this patient was not homebound as of 07/31/2014 due to her ability to transfer at a contact guard assist level of function and her ability to ambulate 45 feet. Also, the outside contractor noted that although she had limited ambulatory mobility at a household level, she was using her power wheelchair with safe operation.

The outside contractor failed to consider the patient's physical and mental limitations. For instance, the outside contractor failed to take into account that:

- The patient had Alzheimer's disease with dementia, was oxygen dependent, and had an indwelling urinary catheter. She was **frequently confused**, forgetful, and could not recall events of the past 24 hours.
- On the 7/22/14 physical therapy reassessment visit, the physical therapist documents the patient's attempt to ambulate with a wheeled walker which resulted in **loss of balance backward**, and that attempts to transfer from the power wheelchair to the couch have a **higher risk of falling**.
- On the 7/29/14 PTA visit, the patient has difficulty with standing exercises and her oxygen levels drop.
- On the 7/31/14 PTA visit, the patient required rest breaks due to shortness of breath, plus verbal cues to perform tasks safely. The patient **was only able to perform 2 exercises this date before having to sit down**.
- On 8/19/14, it is documented the caregiver is going to be having surgery and he will need to find someone to care for the patient.

Throughout the documentation, GLHHS staff noted **concerns with the patient's ability to safely navigate** the power wheelchair.

Sample 11.

The outside contractor determined that as of 9/1/2015, the patient was no longer homebound. She was able to self-correct as needed when walking and was able to ambulate 200 feet. The patient was residing in an accessible assisted living facility and attendance at exercise classes within the facility was recommended.

The outside contractor failed to consider the patient's mental and physical limitations:

- The patient **has Alzheimer's disease and resides in a memory care unit**.
- The documentation on 9/1/15 also states that patient cannot recall the events of the past 24 hours, is unable to recall prior HEP instruction, and **has memory loss to the extent that supervision is required**.
- On 9/8/15, it is documented that **the patient cannot stand without assistance** and is progressively weaker.
- Documentation in the record (8/11/15 and 10/9/15) also shows that patient is **required to wear a safety alarm when seated due to frequent falls when attempting to stand on her own**.

A review of the outside contractor's work demonstrates its systematic misunderstanding that a patient does not qualify as homebound unless he or she is bedridden or cannot ambulate within the home. The law provides a wholly different standard that we believe rejects the outside contractor's interpretation. GLHHS reviewed all of the 39 claims that the Draft Report concluded were disallowed because the outside contractor stated that the beneficiary did not meet homebound status. Only 4 of those identified errors²⁸ constituted errors in homebound status and GLHHS requests that the OIG conduct a thorough review of the remaining 35 claims.

In accordance with the Statute, the determination of a beneficiary's homebound status was made by a **licensed physician** who must assess the beneficiary's condition through a face-to-face medical evaluation after having **undertaken a review of the beneficiary's medical history**.²⁹ It is only after that evaluation and that a GLHHS employee will quantify the patient's condition through the use of OASIS. The home health agency's initial intake and evaluation are initiated once the threshold determination by the **physician's medically-reasoned determination** that the beneficiary is confined to the home or is homebound.

Of great concern is that these sorts of fundamental errors typified the outside contractor's work. We request that OIG review these claims again in light of the information we are presenting in this response in order ensure that the final report accurately utilized the appropriate standards and reflects the care GLHHS has provided.

2. The Outside Contractor Incorrectly Concluded that "Skilled Services" Were Not Medically Necessary.

The Draft Report identified 28 "errors"³⁰ based upon its conclusion that the patients in question received "skilled services" that were not "medically-necessary." The ordering physician and the home health agency assessing the need through the course of care rely upon determinations of the need for "skilled or intermittent" care offered through skilled nursing or therapy services. Such services may be offered by a nurse, or a physical therapist, occupational therapist or speech-language pathologist based on State laws and professional standards to offer the services that are determined necessary.

²⁸ GLHHS proactively accepted responsibility for each of these 4 claims and remitted payments accordingly, prior to the issuance of the Draft Report. One of such claims also contained errors for Medical Necessity status, resulting in nine total errors related to Homebound and Medical Necessity.

²⁹ 42 U.S.C. § 1395n(a)(2)(A).

³⁰ The Draft Report deemed fourteen samples errors on the grounds that those patients were both not homebound and did not require medically-necessary skilled services.

Upon Simone's review, only 6 of these samples constituted errors based on the regulations.³¹ The Draft Report confused the significant distinctions between the services provided by physical and occupational therapists and those provided by "home caregivers." It is important to note that home health agencies receive physician orders that document that the patient is in need of skilled home health services and is eligible for the home health benefit. Home health agencies then must use the tools required to assess whether the patient meets the eligibility criteria and the skilled services, including therapy services that have been ordered.

Ignoring the law's requirements in qualifying for skilled services, the outside contractor determined that some patients did not qualify for skilled services from a physical therapist or occupational therapist on the grounds that the patient's caregiver could perform the same role. In addition, the outside contractor confused the legally distinct roles and requirements that different therapy service professionals provide.³² Such conclusions are inconsistent with Medicare program requirements. Rehabilitation professions, like other medical specialties, provide therapy services; however, each is a specific discipline with a specific scope of practice as defined by state licensure laws and professional standards. As Simone observed, "an understanding of these distinctions is critical to assessing whether the skilled services provided were medically necessary."³³ The outside contractor failed to distinguish these differences.

Specific examples of these errors are included in the following claims reviewed by the outside reviewer.

Sample 87.

The outside contractor concluded that a quadriplegic patient was not entitled to physical therapy services as prescribed by a physician because the patient's rehabilitation needs were "being addressed through the occupational therapy being provided." In this patient's case, the physician ordered a regimen for multiple sessions of physical therapy to help the patient

³¹ GLHHS proactively accepted responsibility for each of these 6 claims and remitted payments accordingly, prior to the issuance of the Draft Report. One of such claims also contained errors for Homebound status, resulting in nine total errors related to Homebound and Medical Necessity.

³² See Medicare Benefit Policy Manual at § 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).").

³³ See Simone Expert Report at 4.

manage pain and improve shoulder strength, followed by a regimen of occupational therapy treatments designed to improve her fine motor coordination to promote her feeding skills and other self-care. The services were provided in succession; the fine motor skill development encouraged by the occupational therapist could not begin until the patient's pain and shoulder strength needs were met by her physical therapist.

- 10/27/14: Physical therapy assessment performed
- 10/30/14: Skilled nursing assessment performed
- 11/20/14: Occupational therapy evaluation performed
- 11/22/14: Physical therapy plan of care completed
- 12/9/14: Patient died

In finding that the physical therapy services were duplicative of the occupational therapy services and thus not medically necessary, the outside contractor and Draft Report makes clear that there was no attempt to distinguish these two types of services, and the outside contractor apparently failed to recognize that the services were provided *in succession*. The outside contractor should have distinguished among these various specialized services and its improper normative judgments concerning the services ordered. Again, this kind of error typified the outside contractor's work.

Sample 48.

The outside contractor determined that skilled nursing services were no longer needed after the second visit as the patient was stable and had available caregivers willing and able to provide wound care.

The outside contractor failed to consider:

- **The assisted living staff are not licensed nurses.** Therefore they are not skilled to assess wound or vital sign changes that would warrant a change to the wound care being provided.
- **The availability of a caregiver does not disqualify a patient** for the Medicare home health benefit.
- The caregivers in this instance did indeed perform wound care when the licensed nurse was not there, but the nurse was medically necessary to assess and evaluate the wound status, vital signs, and patient status. The nurses initiated wound order changes twice in this episode of care, which would be **outside the scope of the assisted living staff**.

Sample 52.

The outside contractor determined that the occupational therapy services provided were duplicative and not medically necessary.

The outside contractor failed to consider:

- The record reflects occupational therapy skilled interventions focused on instruction, assistance and education related to functional activities of **ADL/IADL** skills (showing for instance), while physical therapy skilled interventions focused on transfers in preparation to perform gait skills, upright balance exercises and tasks.
- Occupational therapy was medically necessary to provide compensatory strategies in performing ADLs and **improve safety**.

Sample 38.

The outside contractor determined that at the third occupational therapy visit, there was no new therapeutic content being provided and skilled occupational therapy could have been discontinued after 10/7/2014.

The outside contractor failed to consider:

- The patient received only 2 weeks of home health services immediately following shoulder surgery.
- The occupational therapy plan of care, which consisted of only 7 visits, was absolutely reasonable, necessary and skilled for post shoulder surgery. The skill of the occupational therapist was required to assure patient safety with these exercises. For instance, a patient does not have the required skill level to determine if the pendulum, isometric, or range of motion exercises they are performing are being completed properly to **assure no damage or dislocation**.
- The exercises instructed and supervised by the OT were **upgraded at every visit to progress the patient** through the plan of care.

3. The Outside Contractor Misapplied Coding Standards and Billing Protocols.

Finally, the outside contractor concluded that GLHHS assigned incorrect HIPPS Codes to 6 claims. The Draft Report states that the OASIS and other supporting medical records did not support the billing code that GLHHS used. GLHHS, however, maintains that the HIPPS Codes assigned to those claims were absolutely accurate and that the outside contractor did not understand the intricacies involved in assigning HIPPS Codes to home health claims. **The outside contractor ignored information transmitted to the government and the complete patient record in arriving at its conclusion.** The outside contractor did not use the correct tools and processes in arriving at its conclusions.

GLHHS provided a great deal of information to the OIG about HIPPS coding during the audit. As a result, GLHHS can only conclude that the outside contractor ignored this information. The following summary explains how HIPPS Codes should be selected and why the HIPPS Codes selected by GLHHS are accurate.

GLHHS' electronic medical record includes a report titled, "OASIS Concise Report" which documents the OASIS item responses as **transmitted to CMS**. Simone used this OASIS Concise Report to validate the specific diagnosis codes and OASIS responses used in order to generate the HIPPS Code and subsequent episode payment. The OIG provided Grouper Screenshots ("OIG Grouper Screenshots") that documented the OIG diagnosis coding and select OASIS responses that resulted in their alleged HIPPS Codes. Simone compared the OIG Grouper Screenshots to the OASIS Concise Report and the GLHHS clinical record documentation.

For each of the 6 claims, Simone determined that the outside contractor's alleged HIPPS Code was wrong because it was not based on the GLHHS OASIS Concise Report which accurately reflected each patient's condition per the documentation in the GLHHS clinical record. The HIPPS Codes used by GLHHS were correct and were also validated by Simone's OASIS calculator that calculates the HIPPS based on all the material criteria: early/late episode; number of therapy visits; OASIS item answers; CBSA code; wage index; and rates.

GLHHS notified OIG of these errors on several occasions, provided documentation identifying these errors, and downloaded printouts of the errors to the OAS' secure portal on 2 separate occasions.³⁴ We can only assume that this information was communicated to the outside contractor and that the contractor chose to ignore this information. While the Draft Report identifies only 6 claims with alleged incorrect HIPPS Codes, the fundamental and glaring mistakes made by the outside contractor calls into question all of their work.

Sample 13.

According to the OIG Grouper Screenshots, **the data inputted from the auditor does NOT match GLHHS' documentation.**

- M1610 was incorrectly entered by the outside contractor as a 0. GLHHS answered that OASIS item as a 2.

³⁴ GLHHS' efforts are detailed in Appendix A to the draft response, which Appendix has not been made publically available.

Sample 51.

According to the OIG Grouper Screenshots, **the data inputted from the auditor does NOT match GLHHS' documentation.**

- M1242 was incorrectly entered by the outside contractor as a 2. GLHHS answered that OASIS item as a 3.
- The outside contractor incorrectly entered the number of therapy visits as the projected number of visits of 13. The outside contractor should have entered the actual number of therapy visits provided and billed by GLHHS which was 10.

Sample 71.

According to the OIG Grouper Screenshots, **the data inputted from the auditor does NOT match GLHHS' documentation.**

- M1320 ulcer was incorrectly entered by the outside contractor as a 2. GLHHS answered that OASIS item as a 3.
- M1860 was incorrectly entered by the outside contractor as a 2. GLHHS answered that OASIS item as a 3.
- The outside contractor incorrectly entered the number of therapy visits as the projected number of visits of 14. The outside contractor should have entered the actual number of therapy visits provided and billed by GLHHS which was 23.

B. Homecare Has Been Improperly Targeted Because of Alleged "Error Rates" That Were Due in Part to Ambiguous Requirements.

The genesis of this work plan audit is the focus by CMS on home health technical billing requirements and whether there are errors made in complying with such requirements. According to CMS, the home health industry's "error rate" demonstrates that the industry has struggled to comply with Medicare program requirements. It claims the industry has experienced "error rates" of 51% in 2014, 59% in 2015, and 42% in 2016.³⁵ Importantly, error rates of this magnitude point to a fundamental flaw in the entire regulatory system for payment to this industry. In other words, the conclusion that half of the bills are submitted incorrectly is telling that the current home health billing framework is broken and not usable.

The OIG's initial audit found that based on its review of 100 claims (totaling \$341,150) submitted by GLHHS, 59 of the claims did not meet multiple Medicare billing requirements. As detailed above, we contend that only 9 of the claims reviewed by OIG had any errors that actually resulted in overpayments. Based on the erroneous conclusion that 59 of the reviewed

³⁵ CMS, *Medicare Fee-For-Service Improper Payments Report 2016 2* (July 27, 2017) (Referencing the error rates for 2015 and 2016); CMS, *Medicare Fee-For-Service Improper Payments Report 2014 2* (July 7, 2015) (Referencing the error rate for 2014).

claims resulted in overpayments, the OIG concluded that GLHHS was overpaid by \$105,783 for these claims.

This fact is critical in that despite unclear billing requirements, GLHHS still fared much better than its peers. It is important to recognize that GLHHS' error rate is well below the CMS reported national average error rate of 51-59% for 2014-15, the years for which OIG reviewed GLHHS' claims. But more significantly, when the Medicare payment rules are properly applied to GLHHS' claims, their **actual billing error rate is only 5.7%. This means that GLHHS' billed correctly 94.3% of the time.**³⁶

Nevertheless, the error rates cited by CMS generally point to a lack of uniformity and consistency regarding home health documentation requirements that has created a subjective and overly complicated system for physicians, home health agencies, and Medicare contractors. This problem ultimately hurts patients' access to services and increases improper payments to providers. As the home health industry has protested to CMS, the improper payment rate has been shown through CERT testing to be primarily attributable to issues of insufficient documentation. A significant portion of the error rate during the period reviewed is due to the face-to-face requirement, which lacks consistency and does not account for a patient's complete medical record. Furthermore, Medicare contractors have applied subjective and inconsistent review standards, both among the Medicare contractors and within the same Medicare contractor, of records home health agencies submit for approval.

CMS has acknowledged that the ill-explained documentation requirements it implemented in recent years played a major role in the home health improper payment rate. CMS noted that recent marked improvements in the home health improper payment rate are attributable to revisions of the face-to-face encounter requirements, which took effect in January 2015, as well as probe and educate reviews. Thus, it comes as little surprise that when physicians, providers and Medicare contractors have clear and consistent rules, procedures and guidelines, the home health improper pay rates improved from about 42% to 32.3% between fiscal years 2016 and 2017. In addition, CMS has initiated an Appeal Settlement Initiative which settles disputed claims at 62% of claim amount for claims under review. CMS's willingness to settle these claims for significantly less than the full amount owed indicates that CMS is aware that the claims review process is flawed and unfair – more than 62% of the time.

The recent improvements in the industry error rate raises significant concerns about the standard of review applied to the GLHHS' claims at issue. By CMS' own acknowledgment, during the period at issue for GLHHS' audit, it applied a standard of review which it now acknowledges resulted in a catastrophic error rate, but the Draft Report makes no acknowledgement of this fact. In light of these facts, the Draft Report's "error rate" for GLHHS is misleading and inaccurate.

³⁶ Even assuming that the Draft Report's numbers are correct, which we adamantly contest, the OIG's purported billing error rate for GLHHS of 31% is far lower than the industry average for the years in question.

This lack of clarity is a grave problem for the entire industry. Indeed GLHHS was audited because CMS believes that, in general, home health agencies are unable to bill correctly. The fault, however, lies in the technical billing requirements. GLHHS may have more resources to expend to decipher the cryptic requirements than smaller agencies. Moreover, GLHHS was forced to undergo this audit and expend great resources to respond to the Draft Report. This includes, but is not limited to, providing information to the OIG regarding the multiple errors in the analysis conducted by the outside contractor. Quite simply, it is unfair to assume that an entire provider group billed incorrectly when the source of such errors is the unclear and ambiguous regulations proffered by CMS. Neither GLHHS, nor any other home health agency, should be forced to defend its practices because of inadequate billing guidelines.

C. There Is No Legal or Factual basis to Justify Extrapolation.

Finally, the Draft Report seeks to extrapolate erroneous findings to the entire universe of claims billed by GLHHS during this time period. Extrapolation in this instance is invalid and unfair. First, as a fundamental consideration, the error rate upon which the extrapolation is based is simply wrong. As a percentage of billings, GLHHS' billing error rate was only 5.7%, far below the industry average.

1. There Is No Legal Basis to Justify Extrapolation.

Current law permits extrapolation by a Medicare contractor if the Secretary of HHS determines that "there is a sustained or high level of payment error" or in instances where "documented educational intervention has failed to correct the payment error."³⁷ GLHHS neither currently has, nor has it ever had, a high level of payment error or documented intervention from OIG. Further, GLHHS has been told that the audit is considered a work plan audit, and GLHHS itself was not targeted by OIG. Thus, extrapolation in this instance was not proper in that: (1) the Secretary of HHS did not document a sustained or high level of payment error prior to the audit; and (2) there was no documented payment error and thus, the Secretary did not attempt any educational intervention to correct such a non-existent payment error.

2. There Is No Factual Basis for Extrapolation and The Sampling Methodology Renders Any Extrapolation Invalid.

Under the law, GLHHS' 5.7% billing error rate is not a high rate to justify extrapolation. This rate is well below industry averages and demonstrates superior compliance.

Further, even if a correct error rate were used, the sample from which claims were drawn is not proper or valid for extrapolation purposes. This issue is addressed at length in the BRG Expert Report, which opines that the sampling methodology, design, and extrapolations applied by the outside contractor deviate significantly from acceptable, proper statistical sampling protocol. These errors were caused by an improper sample design, improper sample

³⁷ 42 U.S.C. 1395ddd(f)(3).

size, failure to test whether the sample was within a normal distribution, failure to draw a probe sample, and other issues identified in the BRG Expert Report. Consequently, any conclusions regarding extrapolations of alleged overpayments to a larger universe of claims are completely unreliable and invalid.

BRG identifies twelve separate flaws in the statistical analysis utilized by the Draft Report. Even taken in isolation, any one of these flaws would be enough to render the entire audit statistically unreliable; taken together the twelve flaws rendered the audit completely invalid. BRG summarizes the inherent flaws that render the extrapolation invalid as follows:

Opinion #1. OIG's flawed sample design and incorrect application of statistical methodology introduced numerous sources of non-sampling error, making a meaningful evaluation of the sample impossible.

Opinion #2. OIG's findings indicate that 59 claims in the sample allegedly had errors which impacted the pricing of the relevant claim. This is inconsistent with errors found by a secondary third-party audit of the same sample.

Opinion #3. The documentation provided by OIG is incomplete and lacks required data points, which prevented BRG from analyzing if the sample is representative of the relevant universe of claims.

Opinion #4. OIG's calculated overpayment amount is based on an arbitrarily chosen sample size that is insufficient to yield a representative sample.

Opinion #5. The distribution of alleged overpayments and their means in repeated sampling in OIG's sample is not normal ("bell shaped") at the given sample size, therefore the lower confidence limit does not provide a 90% probability that the population mean exceeds the value computed which is a necessary condition for the extrapolation methodology (based on a point estimate) to be valid.

Opinion #6. OIG's failure to stratify by year and HIPPS codes leads to erroneous results that cannot be used for extrapolation purposes.

Opinion #7. OIG's audit represents only an insufficiently small fraction of the range of possible rate code and year combinations in the universe, apparently without analyzing whether there is any relationship between year, rate code, and alleged erroneous payments. Without knowing whether and to what degree any such relationships hold, the resulting extrapolations are not reliable.

Opinion #8. OIG failed to conduct a statistically valid probe sample drawn from the existing large and complex universe, which contained a large degree of variation and uncertainty about factors impacting potential overpayments.

Opinion #9. OIG's sample did not adequately represent the complexity of the health conditions of patients in the universe of claims.

Opinion #10. OIG's documentation does not show any evidence that its sample size considered: (a) confidence level; (b) precision or margin of error; or (c) variation of alleged overpayments, as required for reliability.

Opinion #11. Statistical hypothesis tests show that OIG's sample is not representative of the universe and, therefore, should not be used to extrapolate overpayments.

Opinion #12. OIG's audit lacks the necessary due care and quality control as required for all audit organizations, both government and nongovernmental, that conduct government audits.

Not only does GLHHS not have a history of a high level of payment error or educational intervention by OIG, the repayment recommendation is based on a work plan audit and not a targeted audit. Additionally, the foundation for the repayment recommendation is not based in sound statistical methods. Thus, we urge the OIG to eliminate the recommendation to CMS that GLHHS repay an amount that includes an extrapolation to CMS as there is no legal or factual basis for such a recommendation.

IV. RESPONSE TO RECOMMENDATIONS

The Draft Report makes recommendations regarding ongoing compliance. As stated above, GLHHS takes its compliance obligations extremely seriously, and addresses each recommendation in turn.

- A. Refund a Portion of the Estimated \$17,882,732 Overpayment for Claims Within the Reopening Period and for the Remaining Portion of the Estimated \$17,882,732 Overpayment for Claims 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.**

All claims have been paid. Further, prior to issuance of the Draft Report, GLHHS identified 9 claims where, in whole or in part, it incorrectly billed for services. As a result, it repaid \$19,657.18 to National Government Services. Critically, this was a proactive response by GLHHS prior to receiving the Draft Report. It is particularly telling of GLHHS' commitment to compliance that it repaid some of the claims presented as examples in the Draft Report. Specifically, GLHHS repaid Samples 30 and 46, which we believe represent Examples 2 and 3 in the Draft Report. GLHHS proactively repaid these claims prior to the receipt of the draft report identifying the OIG's concern on these claims. GLHHS does not believe it has any repayment obligation with regards to the remaining 50 claims as these claims complied with the conditions

for payment and the conditions for home health services. Accordingly, GLHHS does not believe that those claims are subject to the 60-day repayment rule.

B. Exercise Reasonable Diligence to Identify and Return Any Additional Similar Overpayment Outside of Audit Period, in Accordance with the 60-Day Rule, and Identify Any Returned Overpayments as Having Been Made in Accordance with This Recommendation.

In a further effort to comply, GLHHS audited claims for years 2016 and 2017. In this regard, the results of the audit reveal a similar low error rate. The difference between the original audit billing error rate and the current billing audit rate is likely due to increases in acuity for the years 2016 and 2017. GLHHS will refund any amounts erroneously billed in accordance with its requirements under the 60-day rule.

C. Strengthen its Procedures to Ensure that: (1) the Homebound Statuses of Medicare Beneficiaries Are Verified and Continually Monitored and the Specific Factors Qualifying Beneficiaries as Homebound are Documented; (2) Beneficiaries Are Receiving Only Reasonable and Necessary Skilled Services; and (3) Ensure that Appropriate Billing Codes Are Assigned When Submitting Claims for Medicare Reimbursement.

GLHHS takes its compliance obligations seriously and continually evaluates its procedures to strength them to assure compliance. GLHHS has complied with its obligations and has achieved a very low billing error rate as a result of its compliance efforts.

V. CONCLUSION

GLHHS demonstrated a high level of compliance when compared to the industry. According to CMS studies, the average home care billing error rate was 42% in 2016. GLHHS billing error rate based on an expert audit was 5.7%. This low error rate demonstrates exceptional care and diligence in billing. As demonstrated in this response, GLHHS correctly applies the appropriate requirements in assessing homebound status, the need for skilled services, and correctly applies appropriate codes 94.3% of the time. The outside contractor utilized in the audit failed to apply the correct standards and, as addressed, applied a definition of homebound that is not supported by the regulations or by any CMS guidance.

GLHHS places its highest level of priority on providing excellent care and in complying with all CMS requirements. At no time has OIG raised any issues regarding the quality of GLHHS services. With regard to compliance with CMS guidelines, GLHHS has demonstrated its compliance with all requirements.

On behalf of GLHHS, we welcome the opportunity to respond to any remaining questions or concerns that you may have.

Sincerely,

/Nancy E. Taylor/

Nancy E. Taylor
Shareholder
Greenberg Traurig

Enclosures