

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**MEDICARE HOSPICE PROVIDER
COMPLIANCE AUDIT:
VITAS HEALTHCARE
CORPORATION OF FLORIDA**

*Inquiries about this report may be addressed to the Office of Public Affairs at
Public.Affairs@oig.hhs.gov.*



Amy J. Frontz
Deputy Inspector General
for Audit Services

July 2022
A-02-19-01018

Office of Inspector General

<https://oig.hhs.gov>

The mission of the Office of Inspector General (OIG), as mandated by Public Law 95-452, as amended, is to protect the integrity of the Department of Health and Human Services (HHS) programs, as well as the health and welfare of beneficiaries served by those programs. This statutory mission is carried out through a nationwide network of audits, investigations, and inspections conducted by the following operating components:

Office of Audit Services

The Office of Audit Services (OAS) provides auditing services for HHS, either by conducting audits with its own audit resources or by overseeing audit work done by others. Audits examine the performance of HHS programs and/or its grantees and contractors in carrying out their respective responsibilities and are intended to provide independent assessments of HHS programs and operations. These audits help reduce waste, abuse, and mismanagement and promote economy and efficiency throughout HHS.

Office of Evaluation and Inspections

The Office of Evaluation and Inspections (OEI) conducts national evaluations to provide HHS, Congress, and the public with timely, useful, and reliable information on significant issues. These evaluations focus on preventing fraud, waste, or abuse and promoting economy, efficiency, and effectiveness of departmental programs. To promote impact, OEI reports also present practical recommendations for improving program operations.

Office of Investigations

The Office of Investigations (OI) conducts criminal, civil, and administrative investigations of fraud and misconduct related to HHS programs, operations, and beneficiaries. With investigators working in all 50 States and the District of Columbia, OI utilizes its resources by actively coordinating with the Department of Justice and other Federal, State, and local law enforcement authorities. The investigative efforts of OI often lead to criminal convictions, administrative sanctions, and/or civil monetary penalties.

Office of Counsel to the Inspector General

The Office of Counsel to the Inspector General (OCIG) provides general legal services to OIG, rendering advice and opinions on HHS programs and operations and providing all legal support for OIG's internal operations. OCIG represents OIG in all civil and administrative fraud and abuse cases involving HHS programs, including False Claims Act, program exclusion, and civil monetary penalty cases. In connection with these cases, OCIG also negotiates and monitors corporate integrity agreements. OCIG renders advisory opinions, issues compliance program guidance, publishes fraud alerts, and provides other guidance to the health care industry concerning the anti-kickback statute and other OIG enforcement authorities.

Notices

THIS REPORT IS AVAILABLE TO THE PUBLIC
at <https://oig.hhs.gov>

Section 8M of the Inspector General Act, 5 U.S.C. App., requires that OIG post its publicly available reports on the OIG website.

OFFICE OF AUDIT SERVICES FINDINGS AND OPINIONS

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

Report in Brief

Date: July 2022

Report No. A-02-19-01018

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



Why OIG Did This Audit

The Medicare hospice benefit allows providers to claim Medicare reimbursement for hospice services provided to individuals with a life expectancy of 6 months or less and who have elected hospice care. Previous OIG reviews found that Medicare inappropriately paid for hospice services that did not meet certain Medicare requirements.

Our objective was to determine whether certain hospice services provided by Vitas Healthcare Corporation of Florida (Vitas) complied with Medicare requirements.

How OIG Did This Audit

Our audit covered 50,850 claims for which Vitas received Medicare reimbursement totaling \$210 million for certain hospice services provided during the period April 2017 through March 2019. We reviewed and evaluated a stratified sample of 100 claims for compliance with selected Medicare requirements. In addition, we submitted medical records associated with the sample to an independent medical review contractor who determined whether the documents supported the hospice services billed.

Medicare Hospice Provider Compliance Audit: Vitas Healthcare Corporation of Florida

What OIG Found

Vitas did not comply with Medicare requirements for 89 of the 100 claims in our sample. Specifically, the clinical record did not support the continuous home care (CHC) level of hospice care claimed for Medicare reimbursement (68 claims), the clinical record did not support the general inpatient level of hospice care claimed for Medicare reimbursement (28 claims), and CHC services were not documented or supported in the beneficiary's clinical record (23 claims). The total exceeds 89 because 27 claims contained more than 1 error.

These improper payments occurred because Vitas' policies and procedures were not effective to ensure that it maintained documentation to support the level of care and hospice services claimed for Medicare reimbursement. On the basis of our sample results, we estimated that Vitas received at least \$140 million in improper Medicare reimbursement for hospice services that did not comply with Medicare requirements.

What OIG Recommends and Vitas Comments

We made a series of recommendations to Vitas, including that it refund to the Federal Government the portion of the estimated \$140 million in Medicare overpayments that are within the 4-year claims reopening period; identify, report and return any overpayments in accordance with the 60-day rule; and strengthen its policies and procedures to ensure that hospice services comply with Medicare requirements.

In written comments on our draft report, Vitas disagreed with some of our recommendations and partially agreed with our findings. Vitas indicated that it voluntarily refunded payments to Medicare for nine sample claims and adjusted five other claims. Although Vitas acknowledged its obligations under the 60-day rule, it reviewed our audit findings and did not agree that a refund pursuant to the rule was warranted. Vitas also did not agree with our recommendation to strengthen its policies and procedures. Lastly, Vitas stated that OIG's sampling and extrapolation were not statistically valid.

After reviewing Vitas' comments, we adjusted our determinations for seven claims for CHC services for which the clinical record supported the number of units submitted to Medicare for payment. However, all of the claims had other errors; therefore, we maintain that our findings and recommendations, as revised, are valid. We also maintain that our sampling methodology and extrapolation were statistically valid.

TABLE OF CONTENTS

INTRODUCTION.....	1
Why We Did This Audit.....	1
Objective.....	1
Background.....	1
The Medicare Program.....	1
The Medicare Hospice Benefit.....	1
Medicare Requirements To Identify and Return Overpayments.....	3
Vitas Healthcare Corporation of Florida.....	4
How We Conducted This Audit.....	4
FINDINGS.....	5
Continuous Home Care Level of Care Not Supported.....	5
General Inpatient Level of Care Not Supported.....	6
Continuous Home Care Services Not Documented or Supported.....	7
RECOMMENDATIONS.....	9
VITAS COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE.....	9
Medical Review Contractor Determinations.....	10
Vitas Comments.....	10
Office of Inspector General Response.....	11
Medicare Requirements Related to Clinical Documentation.....	12
Vitas Comments.....	12
Office of Inspector General Response.....	13
Office of Inspector General Sampling Methodology.....	13
Vitas Comments.....	13
Office of Inspector General Response.....	14

APPENDICES

A: Audit Scope and Methodology17

B: Related Office of Inspector General Reports.....19

C: Statistical Sampling Methodology21

D: Sample Results and Estimates23

E: Vitas Comments24

INTRODUCTION

WHY WE DID THIS AUDIT

The Medicare hospice benefit allows providers to claim Medicare reimbursement for hospice services provided to individuals with a life expectancy of 6 months or less who have elected hospice care. Previous Office of Inspector General (OIG) reviews found that Medicare inappropriately paid for hospice services that did not meet certain Medicare requirements.¹

OBJECTIVE

Our objective was to determine whether certain hospice services provided by Vitas Healthcare Corporation of Florida (Vitas) complied with Medicare requirements.

BACKGROUND

The Medicare Program

Title XVIII of the Social Security Act (the Act) established the Medicare program, which provides health insurance coverage to people aged 65 and over, people with disabilities, and people with end-stage renal disease. The Centers for Medicare & Medicaid Services (CMS) administers the Medicare program.

Medicare Part A, also known as hospital insurance, provides for the coverage of various types of services, including hospice services.² CMS contracts with Medicare Administrative Contractors (MACs) to process and pay Medicare hospice claims in four home health and hospice jurisdictions.

The Medicare Hospice Benefit

To be eligible to elect Medicare hospice care, a beneficiary must be entitled to Medicare Part A and certified by a physician as being terminally ill (i.e., as having a medical prognosis with a life expectancy of 6 months or less if the illness runs its normal course).³ Hospice care is palliative (supportive), rather than curative, and includes, among other things, nursing care, medical social services, hospice aide services, medical supplies, and physician services.

¹ See Appendix B for a list of related OIG reports on Medicare hospice services.

² The Act §§ 1812(a)(4) and (5).

³ The Act §§ 1814(a)(7)(A) and 1861(dd)(3)(A) and 42 CFR §§ 418.20 and 418.3.

Beneficiaries eligible for the Medicare hospice benefit may elect hospice care by filing a signed election statement with a hospice.⁴ Upon election, the hospice assumes the responsibility for medical care of the beneficiary's terminal illness, and the beneficiary waives all rights to Medicare payment for services that are related to the treatment of the terminal condition or related conditions for the duration of the election.⁵ The hospice must establish an individualized plan of care⁶ for each beneficiary it serves and specifies the hospice care and services necessary to meet the patient and family specific needs.⁷

Hospice providers must establish and maintain a clinical record for each hospice patient.⁸ The record must include all services, whether furnished directly or under arrangements made by the hospice. Beneficiaries may revoke their election of hospice care and return to standard Medicare coverage at any time.⁹

Levels of Hospice Care

Medicare pays hospices a daily rate for each day a beneficiary is enrolled to receive the hospice benefit. Medicare makes this daily payment regardless of the number of services provided on a given day, including days when the hospice provides no services.¹⁰ The daily payments are based on one of four levels of hospice care:

- **Routine home care (RHC)**: A majority of hospice services are provided via RHC,¹¹ which includes scheduled, routine visits in the beneficiary's home (e.g., apartment, skilled nursing facility, or assisted living facility). RHC is the level of hospice care provided when the beneficiary is at home and is not receiving continuous care.¹²

⁴ 42 CFR § 418.24(a)(1).

⁵ The Act § 1812(d)(2)(A) and 42 CFR § 418.24(d). After our audit period, the text of 42 CFR § 418.24(d) was moved to 42 CFR § 418.24(e), effective October 1, 2019. 84 Fed. Reg. 38484, 38544 (Aug. 6, 2019).

⁶ The plan of care must be written by an interdisciplinary group that includes a physician, nurse, social worker, and a pastoral or other counselor.

⁷ 42 CFR §§ 418.200 and 418.56.

⁸ 42 CFR §§ 418.104 and 418.310.

⁹ Social Security Act, § 1812(d)(2)(B), 42 U.S.C. § 1395d(d)(2)(B); 42 CFR § 418.28.

¹⁰ 42 CFR § 418.302(e)(1).

¹¹ For dates of service on or after January 1, 2016, there are two daily payment rates for routine home care: a higher rate for the first 60 days and a lower rate for days 61 and beyond. 80 Fed. Reg. 47142, 47172 (Aug. 6, 2015).

¹² 42 CFR §§ 418.112 and 418.302(b)(1).

- **Continuous home care (CHC):** CHC is the level of hospice care provided to a beneficiary during a brief period of crisis and only as necessary to maintain the patient at home.¹³ A period of crisis is a period in which the beneficiary requires continuous care to achieve palliation¹⁴ and management of acute medical symptoms.¹⁵ A minimum of 8 hours of CHC—provided in 15-minute increments—is necessary to qualify for Medicare reimbursement. The 8 hours do not need to be continuous within the 24-hour period; however, an aggregate of 8 hours of primarily nursing care is required. Nursing care must be provided by a registered nurse or a licensed practical nurse. If nursing intervention is required for less than 8 aggregate hours (i.e., less than 32 15-minute increments) within a 24-hour period, then the care provided would be covered as a RHC day.¹⁶
- **Inpatient respite care (IRC):** To give the beneficiary’s caregiver a rest, IRC is provided when the beneficiary elects to get hospice care in an approved inpatient facility for up to 5 consecutive days.¹⁷
- **General inpatient (GIP) care:** The GIP level of hospice care is provided during a day the beneficiary receives hospice care in a hospital or an inpatient facility for pain control or acute or chronic symptom management that cannot be managed in other settings.¹⁸

Medicare Requirements To Identify and Return Overpayments

OIG believes that this audit report constitutes credible information of potential overpayments. Upon receiving credible information of potential overpayments, providers must exercise reasonable diligence to identify overpayments (i.e., determine receipt of and quantify any overpayments) during a 6-year lookback period. Providers must report and return any identified overpayments by the later of (1) 60 days after identifying those overpayments or (2) the date that any corresponding cost report is due (if applicable). This is known as the 60-day rule.¹⁹

¹³ The reimbursement rate for CHC is the highest daily rate that Medicare pays, and hospices are paid hundreds of dollars more on a daily basis for each beneficiary they certify as having received CHC rather than RHC.

¹⁴ Palliation focuses on the relief from physical suffering.

¹⁵ 42 CFR §§ 418.204(a) and 418.302(b)(2).

¹⁶ 42 CFR §§ 418.302(e)(3) and (4).

¹⁷ 42 CFR § 418.302(b)(3).

¹⁸ 42 CFR §§ 418.302(b)(4) and 418.202(e).

¹⁹ The Act § 1128J(d); 42 CFR §§ 401.301 to 401.305; and 81 Fed. Reg. 7654, (Feb. 12, 2016).

The 6-year lookback period is not limited by OIG's audit period or restrictions on the Government's ability to reopen claims or cost reports. To report and return overpayments under the 60-day rule, providers can request the reopening of initial claim determinations, submit amended cost reports, or use any other appropriate reporting process.²⁰

Vitas Healthcare Corporation of Florida

Vitas, located in Miramar, Florida, provides hospice services to beneficiaries throughout Florida. Vitas is a wholly owned subsidiary of the Chemed Corporation, which is headquartered in Cincinnati, Ohio. During the period April 1, 2017, through March 31, 2019 (audit period),²¹ Vitas provided CHC and/or GIP care to approximately 34,200 beneficiaries and received Medicare reimbursement of almost \$210 million.²² Palmetto GBA, LLC (Palmetto), serves as the MAC for Vitas.

HOW WE CONDUCTED THIS AUDIT

Our audit covered \$209,782,129 in Medicare reimbursement for 50,850 claims for CHC and/or GIP care provided by Vitas during the audit period. We reviewed a stratified random sample of 100 of these claims to determine whether hospice services complied with certain Medicare requirements. Specifically, we evaluated compliance with certain billing requirements and submitted the 100 sampled claims and associated clinical records to an independent medical review contractor who determined whether the documents supported the hospice services billed.

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, and Appendix D contains our sample results and estimates.

²⁰ 42 CFR §§ 401.305(d), 405.980(c)(4), and 413.24(f); CMS's Provider Reimbursement Manual, Pub. 15-1-Part 1, § 2931.2; and 81 Fed. Reg. at 7670.

²¹ During the audit period, Vitas was operating under a 5-year corporate integrity agreement with OIG to review and monitor hospice eligibility and levels of care billed.

²² Claims data for the period April 1, 2017, through March 31, 2019, was the most current data available when we started our audit.

FINDINGS

Vitas claimed Medicare reimbursement for CHC and/or GIP care that did not comply with certain Medicare requirements. Of the 100 hospice claims in our sample, 11 claims complied with requirements, but 89 did not. Specifically:

- For 68 claims, the clinical record did not support the CHC level of hospice care claimed for Medicare reimbursement.
- For 28 claims, the clinical record did not support the GIP level of hospice care claimed for Medicare reimbursement.
- For 23 claims, Vitas submitted claims for Medicare reimbursement for CHC services that were not documented or supported in the beneficiary's clinical record.

The total exceeds 89 because 27 claims contained more than 1 of the above errors.

These improper payments occurred because Vitas' policies and procedures were not effective to ensure that it maintained documentation to support the level of care and hospice services claimed for Medicare reimbursement.

On the basis of our sample results, we estimated that Vitas received at least \$140,370,745 in improper Medicare reimbursement for hospice services that did not comply with Medicare requirements.²³ As of the publication of this report, this unallowable amount includes claims outside the 4-year period for reopening for good cause (the 4-year claims reopening period).²⁴ Notwithstanding, Vitas can request that a Medicare contractor reopen the initial determinations for those claims for the purpose of reporting and returning overpayments under the 60-day rule without being limited by the 4-year claims reopening period.²⁵

CONTINUOUS HOME CARE LEVEL OF CARE NOT SUPPORTED

CHC is the level of hospice care provided during a brief period of crisis and only as necessary to maintain the patient at home (42 CFR §§ 418.302(b)(2) and 418.204(a)).

Vitas claimed reimbursement at the CHC payment rate for 72 of the 100 sample claims. For 4 of the 72 claims, the medical review contractor determined that the beneficiary's clinical record

²³ To be conservative, we estimate overpayments at the lower limit of a two-sided 90-percent confidence interval. Lower limits calculated in this manner are designed to be less than the actual overpayment total 95 percent of the time.

²⁴ 42 CFR § 405.980(b)(2) (permitting a contractor to reopen within 4 years for good cause) and 42 CFR § 405.980(c)(2) (permitting a party to request that a contractor reopen within 4 years for good cause).

²⁵ 42 CFR § 405.980(c)(4).

supported the need for CHC level of care; however, the remaining 68 claims were not supported.²⁶ In general, the beneficiaries' medical records indicated that the beneficiary's symptoms did not support that the beneficiary was in a period of crisis.

The unsupported claims occurred because Vitas' policies and procedures did not ensure that hospice services complied with Medicare requirements. Specifically, the policies and procedures did not ensure that beneficiaries' clinical record supported the need for CHC level of care.

Example: Beneficiary Not in Period of Crisis

The level of hospice care for the beneficiary associated with one sampled claim was changed from RHC to CHC for 7 days due to a change in the beneficiary's level of consciousness, an upper respiratory infection (pneumonia), and a urinary tract infection. The beneficiary's plan of care and physician's orders included antibiotics for the infections. For the 7 days of CHC, there was no documentation in the medical record that the beneficiary was experiencing uncontrolled pain, uncontrolled agitation, or respiratory distress. Additionally, medical records indicated that infrequent doses of medication were given for agitation with positive effects. Although the beneficiary had worsening dementia, she was able to respond appropriately to questions at times. Also, she was able to control her bladder most of the time and there was no documentation of foul-smelling urine or of a follow-up urinalysis after the antibiotic treatment. Additionally, no frequent medication changes were ordered, and the beneficiary's son was able to administer the medication. As such, there was no indication in the clinical documentation to support that the beneficiary was in a period of crisis during which CHC was necessary.

GENERAL INPATIENT LEVEL OF CARE NOT SUPPORTED

GIP care is provided in a hospital or an inpatient facility for pain control or acute or chronic symptom management that cannot be managed in other settings (e.g., the beneficiary's home) and is intended to be short-term. These services are provided to ensure that any new or worsening symptoms are intensively addressed so that the beneficiary can return to a lower level of hospice care. As with all covered hospice services, hospices are required to provide GIP care if it is needed by the beneficiary.²⁷

For 35 of our 100 sample claims, Vitas claimed reimbursement for GIP care. For 7 of the 35 claims, the clinical record supported the GIP care services claimed for Medicare

²⁶ Our audit did not determine eligibility for hospice services. Rather, for claims that did not meet the billing of the CHC level of care, we questioned the difference in payment amounts between the level of care claimed for Medicare reimbursement and the RHC rate.

²⁷ The Act, § 1861(dd)(2)(A)(i), 42 U.S.C. § 1395x(dd)(2)(A)(i).

reimbursement; however, the remaining 28 claims were not supported.²⁸ Although Vitas maintained numerous nursing assessments and notes in beneficiaries' clinical records, the clinical records did not contain evidence to support that the beneficiaries needed GIP care for pain control or acute or chronic symptom management that could not be managed in other settings.

The unsupported claims occurred because Vitas' policies and procedures did not ensure that hospice services complied with Medicare requirements. Specifically, the policies and procedures did not ensure that beneficiaries' clinical record contained evidence to support that the beneficiaries needed GIP care.

Example: General Inpatient Level of Care Not Supported

A beneficiary associated with one claim was ordered to receive GIP care for shortness of breath and, for 8 days, was moved to a hospital. During this inpatient stay, she had intermittent confusion but was able to make her needs known. Other symptoms included shortness of breath, which was treated with nebulizer treatments. Pain was controlled with oral medications. There was no documentation of any continuous intravenous drips or medications ordered or administered during the inpatient stay. Infrequent doses of medications were given for agitation and pain. The beneficiary's medical condition did not require symptom management that could only be provided in an inpatient setting. Documentation indicated that the services could have been provided in her home.

CONTINUOUS HOME CARE SERVICES NOT DOCUMENTED OR SUPPORTED

For a hospice to claim the CHC payment rate, it must provide a minimum of 8 hours of nursing, hospice aide, and/or homemaker care during a 24-hour day, which begins and ends at midnight. (We refer to this as the 8-hour requirement.) This care does not need to be continuous, but it must reflect the needs of a beneficiary in crisis. In addition to meeting the 8-hour requirement, services provided must be predominantly nursing care. CHC services are billed and paid based on each visit from a nurse, hospice aide and/or homemaker for a date of service. No Medicare payment shall be made to any provider unless it has furnished the information necessary to determine the amount due (the Act § 1815(a)).

²⁸ Our audit did not determine eligibility for hospice services. Rather, for claims that did not meet the billing of the GIP level of care, we questioned the difference in payment amounts between the level of care claimed for Medicare reimbursement and the RHC rate.

For 23 of the 72 claims for which Vitas claimed reimbursement at the CHC payment rate, the clinical record was either missing documentation or the documentation provided did not support the CHC services billed to Medicare for a specific date of service.²⁹ Specifically:

- For 7 claims, Vitas did not provide documentation to support that it met the 8-hour requirement for a single date of service. Specifically, for four claims, Vitas did not provide support for at least 8-hours of hospice services billed. In addition, for four claims, Vitas provided timesheets, payroll records, or chaplain records instead of nursing, hospice aide and/or homemaker care notes that would have supported the services claimed.³⁰ Finally, for one claim, Vitas billed for nursing services prior to the period of crisis.³¹
- For 4 claims, Vitas did not meet the predominant nursing care requirement. For one of the four claims, a timesheet was provided in substitution of nursing, hospice aide, and/or homemaker care notes. The other three claims were missing documentation to support the requirement.
- For 14 claims, Vitas met the 8-hour requirement and/or the predominance of nursing care requirement but did not provide support for all hospice services (i.e., each 15-minute increment of nursing, hospice aide, and/or homemaker) claimed.

The total exceeds 23 because 2 claims did not meet both the 8-hours and predominance of nursing care requirements. The unsupported claims occurred because Vitas' policies and procedures were not always effective to ensure all supporting documents were maintained in the beneficiary's clinical medical records.

²⁹ For each of the 23 claims, the medical review contractor also found that the clinical documentation did not support the beneficiary being in a period of crisis. Although we identified multiple findings for each of the claims, we questioned the cost only once.

³⁰ Timesheet or payroll records are not evidence of direct time spent with the beneficiary.

³¹ The total exceeds 7 because 2 claims contain more than 1 error.

RECOMMENDATIONS

We recommend that Vitas Healthcare Corporation of Florida:

- refund to the Federal Government the portion of the estimated \$140,370,745 for hospice services that did not comply with Medicare requirements and that are within the 4-year claims reopening period;³²
- based upon the results of this audit, exercise reasonable diligence to identify, report and return any overpayments in accordance with the 60-day rule³³ and identify any of those returned overpayments as having been made in accordance with this recommendation; and
- strengthen its policies and procedures to ensure that hospice services comply with Medicare requirements.

VITAS COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, Vitas, through its attorney, disagreed with some of our recommendations and partially agreed with our findings. Vitas indicated that it voluntarily refunded payments to Medicare for nine sample claims and adjusted five other claims. Although Vitas acknowledged its obligations under the 60-day rule, it reviewed our audit findings and did not agree that a refund pursuant to the rule was warranted. Vitas also did not agree with our recommendation to strengthen its policies and procedures because it believes it has robust policies and procedures to ensure that hospice services comply with Medicare requirements. However, Vitas did state that it will continue to routinely review and update its policies to ensure ongoing compliance with applicable laws.

Vitas asserted that OIG's audit is fundamentally flawed in numerous respects and, as a result, OIG's overpayment determinations are invalid. Specifically, Vitas believed that the clinical documentation it submitted for the sample claims met Medicare requirements and that OIG's medical review contractor's denials were inconsistent with hospice regulations and guidance. Vitas contended that the medical review contractor ignored patients' overall medical condition,

³² OIG audit recommendations do not represent final determinations by Medicare. CMS, acting through a MAC or other contractor, will determine whether overpayments exist and will recoup any overpayments consistent with its policies and procedures. Providers have the right to appeal those determinations and should familiarize themselves with the rules pertaining to when overpayments must be returned or are subject to offset while an appeal is pending. The Medicare Part A and Part B appeals process has five levels (42 CFR § 405.904(a)(2)), and if a provider exercises its right to an appeal, the provider does not need to return overpayments until after the second level of appeal. Potential overpayments identified in OIG reports that are based on extrapolation may be re-estimated depending on CMS determinations and the outcome of appeals.

³³ This recommendation does not apply to any overpayments that are both within our sampling frame (i.e., the population from which we selected our statistical sample) and refunded based upon the extrapolated overpayment amount. Those overpayments are already covered in the previous recommendation.

focused on irrelevant points, and “cherry-picked” information that resulted in misleading, incomplete, and inaccurate conclusions.

Vitas further argued that statistical extrapolation was an inappropriate tool to utilize for the evaluation of hospice services because of the individualized nature of each patient’s clinical profile and the subjective and inexact nature of a physician’s level of care determinations (prognostication). Vitas engaged a statistical expert, who evaluated OIG’s sampling and extrapolation methodologies, and claimed in a report that, even if extrapolation was appropriate, OIG’s sampling and extrapolation were not statistically valid.

Prior to providing written comments on our draft report, Vitas provided additional documentation for some sample claims. After reviewing Vitas’ comments and the additional documentation, we adjusted our determinations for seven claims to indicate that the clinical records for the claims support the number of units submitted to Medicare for payment. All seven adjusted claims had multiple errors and remain as findings in this final report. Therefore, the overall number of claims in error and our recommended financial disallowance did not change. We maintain that our findings and recommendations, as revised, are valid. We also reviewed the report prepared by Vitas’ statistical expert and maintain that our sampling methodology and extrapolation were statistically valid and resulted in a legally valid and reasonably conservative estimate of the amount overpaid by Medicare to Vitas.

A summary of Vitas’ comments and our responses follows. Vitas’ comments are included as Appendix E.³⁴

MEDICAL REVIEW CONTRACTOR DETERMINATIONS

Vitas Comments

Vitas disagreed with the medical review contractor’s determination for 63 of the 68 sample claims for which CHC level of care was not supported as well as the medical review contractor’s determination for all 28 claims for which the GIP level of care was not supported by clinical documentation. For five sample claims for which the clinical record did not support the CHC level of hospice, Vitas stated that it made voluntary repayments to Medicare.³⁵

Vitas stated that information presented on the medical review contractor’s determinations was hand-selected or “cherry-picked” and did not fully consider each patient’s condition. Additionally, Vitas stated that the determinations applied incorrect information and misstated or ignored key clinical data. Vitas also disputed information presented in OIG’s examples on

³⁴ Vitas included its statistical expert’s report on our sampling methodology as an exhibit to its comments. Although we did not include the exhibit in our final report, it was considered in its entirety in preparing our final report and will be provided to CMS.

³⁵ For one of the claims, Vitas indicated that it voluntarily repaid the entire amount. Vitas indicated that it repaid portions of the four other claims.

pages 6 and 7 of the report. For instance, Vitas stated the CHC example in the draft report misstated or ignored clinical data. Vitas stated that the “upper respiratory infection” could be interpreted as a head cold when, in fact, it was pneumonia verified by chest x-ray. Moreover, Vitas asserted that the patient case summary ignored the order for “a mobile x-ray team to come to the patient’s home” and that “the patient was experiencing a state of delirium.”

Vitas also stated that the audit was not performed in accordance with generally accepted government auditing standards (GAGAS) because OIG did not establish the criteria that it applied to the findings. Similarly, Vitas stated that OIG appears to have applied standards that do not exist in Federal regulations or guidance.³⁶ In particular, Vitas stated that “in *all* (emphasis in original) of the GIP claims deemed ineligible by the medical reviewers, their decision appeared to be premised on the presence or absence of [intravenous] medications. There is no requirement that medications be provided [intravenously] in order to be eligible for GIP care, and in many cases it is not appropriate or warranted.”

Vitas also contended that OIG failed to recognize Vitas hospice physicians’ determinations regarding hospice level of care. According to Vitas, these determinations were made in real time and are more credible than the review process performed by OIG.

Office of Inspector General Response

We disagree that the examples presented in the report misstate or ignore key clinical information. The examples represent a summary of the patient’s case and the conclusion made by the medical reviewers. The examples were not intended to provide a point-by-point description of entire patient case files. The determination letters contain a chronology of services provided, criteria used by the medical reviewer, the conclusion, and rationale for the conclusion. Vitas did not provide new medical records for the examples. Nevertheless, we clarified that the upper respiratory infection was pneumonia for the CHC example. No other changes to the examples were warranted or needed.

In accordance with the Inspector General Act of 1978, 5 U.S.C. App. 3, our audits are intended to provide an independent assessment of Department of Health and Human Services programs and operations. We conduct our audits in accordance with GAGAS, which require that audits be planned and performed so as to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions. Therefore, we also disagree with Vitas’ assertions regarding the information presented on the medical review contractor’s determinations and the criteria and standards used by the contractor. OIG used an independent medical review contractor that used a licensed physician who specializes in

³⁶ In its comments, Vitas also cited *U.S. v. AseraCare Inc.*, 938 F.3d 1278 (11th Cir. 2019), a case in which the Eleventh Circuit held that a clinical judgment of terminal illness could not be deemed false, for purposes of the federal False Claims Act, when there was only a reasonable disagreement between medical experts as to the accuracy of that conclusion, with no other evidence to prove falsity. Vitas relies on the *AseraCare* decision for Vitas’ assertion that “a later reversal of a hospice physician’s level of care determination is appropriate only if no reasonable physician . . . could have concluded that the patient required that elevated level of care.”

hospice and palliative medicine and is familiar with Medicare hospice guidelines and protocols. In conducting the medical review, the contractor considered all clinical records supplied to OIG, properly stated, and used the statutory and regulatory hospice criteria as the framework for its determinations.³⁷ The contractor applied standards set out in 42 CFR § 418.204(a) to determine if the clinical records supported a period of crisis in which a patient requires clinical continuous care to achieve palliation and management of acute medical symptoms. The contractor also applied 42 CFR § 418.302(b)(4) to determine whether a patient's medical condition warranted a general inpatient stay for pain control or acute chronic symptom management that could not be managed in other settings. Each of the contractor's determinations—including those described in our examples—included details on the contractor's conclusion and the rationale for its decision.

We also disagree that OIG failed to recognize Vitas hospice physicians' determinations regarding the hospice level of care provided. As stated previously, our medical review contractor considered all clinical records supplied to OIG, including plans of care and physician orders for the level of care, and used the statutory and regulatory hospice criteria as the framework for its determinations. Moreover, we disagree with Vitas' *AseraCare*-based assertion that the level of care can be questioned only if no reasonable physician . . . could have concluded that the patient required that elevated level of care. To the contrary, in *AseraCare*, the Eleventh Circuit rejected the Government's concern that, under the court's reading of the eligibility framework, if a physician certified a patient as terminally ill, CMS would be required to reimburse the hospice provider unless CMS could determine that no other reviewer could possibly conclude the patient was terminally ill.³⁸ Although the *AseraCare* case was about the circumstances under which certifications of terminal illness could be deemed false for purposes of Federal False Claims Act liability, the Eleventh Circuit clearly acknowledged that CMS is statutorily prohibited from paying for services that are not reasonable and necessary for the palliation or management of terminal illness and that CMS retains a well-established right to review and deny payments for claims that do not meet that standard. Accordingly, we maintain the validity of our findings related to sample claims for which the level of care billed was not supported.

MEDICARE REQUIREMENTS RELATED TO CLINICAL DOCUMENTATION

Vitas Comments

Vitas agreed with our determinations for 4 of the 28 sample claims that we identified in our draft report as CHC services that were not documented or supported in the beneficiary's clinical record. For another five of these claims, Vitas stated that it adjusted the level of service prior to the issuance of the draft report so that it claimed RHC services—not CHC services—for the claims. For the remaining 19 claims, Vitas believes it had support for services provided and

³⁷ Specifically, the medical review contractor reviewed and summarized nurse and aide notes, phone logs, nursing and aide assessments, and physician notes.

³⁸ *AseraCare*, 938 F.3d at 1295.

billed. Further, Vitas stated that OIG discounted evidence to support that claims met CHC billing requirements and, instead, required other information that is not required by any regulation or guideline.³⁹ According to Vitas, OIG misread documents provided by Vitas and should reconsider the conclusions related to the 8-hour requirement, predominantly nursing care requirement, and billing CHC in 15-minute increments. Finally, VITAS stated that OIG issued the draft report without considering or incorporating any of the additional information Vitas raised during the exit conference and in a follow-up written communication prior to the release of the draft report.

Office of Inspector General Response

We acknowledge that Vitas took action to adjust the level of care on some claims identified in the draft report as having deficiencies. Specifically, Vitas adjusted five claims after we communicated the audit sample to the hospice. For audit purposes, any claim adjusted after the start of the audit can still be deemed unallowable for estimation and reporting purposes. In addition, as noted on page 7 of the report, we maintain that timesheets are not valid support for direct patient care.⁴⁰

Vitas provided OIG with additional documentation, including technical concerns related to our draft findings. After reviewing the additional documentation, we revised our determinations for seven claims, which are reflected in this final report. We note that we still determined the claims to be in error because the medical review contractor determined CHC level of care was not supported. Therefore, the overall number of claims in error and our recommended financial disallowance did not change.

OFFICE OF INSPECTOR GENERAL SAMPLING METHODOLOGY

Vitas Comments

Vitas challenged the validity of our statistical sampling and extrapolation methodologies, engaged a statistical expert to review OIG's sampling methodology, and provided a copy of the statistical expert's report. Vitas stated that extrapolation is not appropriate for calculating overpayments in the hospice context due to the individualized nature of prognostication. Vitas also stated that OIG's statistical methodology was fundamentally flawed and the extrapolated overpayment amount is statistically invalid. According to Vitas' statistical expert: (1) OIG did not provide documentation sufficient to recreate the sampling frame or the sample, (2) OIG improperly excluded zero-paid claims from its universe, (3) OIG's sample failed *samptest*, which shows the two-sided confidence level of OIG overpayment estimate "falls as low as 73.8%,"

³⁹ For example, Vitas stated that it is not required to maintain documentation that includes 'start and end times' for the provision of services. Vitas also stated that there is no basis for OIG to ignore timesheets or payroll records that support meeting the 8-hour requirement.

⁴⁰ Vitas provided screenshots of timesheets which indicated the names of its employees, a date and time, discipline of the employee and type of visit. The timesheets did not include notes documenting direct patient care.

(4) OIG's sample size was too small to yield an accurate estimate of two-sided 90-percent confidence interval and OIG used a sample unit that is not statistically independent, and (5) OIG made an error in the formula it used to calculate the precision of the overpayment estimate.

Office of Inspector General Response

After reviewing the statistical expert's report, we maintain that our sampling and extrapolation methodologies are statistically valid. Federal courts have consistently upheld statistical sampling and extrapolation as a valid means to determine overpayment amounts in Medicare and Medicaid.⁴¹ 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.⁴² We properly executed our statistical sampling methodology in that we defined our sampling frame and sampling unit, randomly selected our sample, applied relevant criteria in evaluating the sample, and used statistical sampling software (i.e., RAT-STATS) to apply the correct formulas for the extrapolation.

The statistical lower limit that we use for our recommended recovery represents a conservative estimate of the overpayment that we would have identified if we had reviewed each and every claim in the sampling frame. The conservative nature of our estimate is not changed by the nature of the errors identified in this audit. Moreover, the court cases that Vitas' attorney referenced in support of the proposition that extrapolation is inappropriate for individualized prognostication in hospices are limited to False Claims Act cases and therefore are inapplicable to OIG audit recommendations and CMS recoveries arising from OIG audits.

The statistical expert's claim that OIG did not provide documentation sufficient to recreate the sampling frame or the sample is not correct. Following the exit conference, we provided Vitas with several workpapers, including, but not limited to, the sampling plan, sampling frame, random number seed for each stratum and selected sample items.⁴³ We also indicate the sort order of the sampling frame within the sample methodology found in Appendix C of the report. The sampling frame was sorted using the DSY_VW_REC_LNK_NUM field, which uniquely identifies claims in OIG's copy of CMS's National Claims History file. Therefore, we maintain

⁴¹ 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 at *17 (S.D. Fla. 2012); *Bend v. Sebelius*, 2010 U.S. Dist. LEXIS 127673 (C.D. Cal. 2010).

⁴² See *John Balko & Assoc. v. Sebelius*, 2012 U.S. Dist. LEXIS 183052 at *34-35 (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); *Miniet v. Sebelius*, 2012 U.S. Dist. LEXIS 99517 at *17 (S.D. Fla. 2012); *Transyd Enters., LLC v. Sebelius*, 2012 U.S. Dist. LEXIS 42491 at *13 (S.D. Tex. 2012).

⁴³ These files are detailed in the statistical expert's report (Exhibit 1) as being provided to Vitas.

that Vitas has the information it needs to recreate the sampling frame and identify the individual sample items.⁴⁴

OIG disagrees that it violated statistical principles by excluding zero-paid claims from the universe.⁴⁵ Generally, OIG may perform a statistical or non-statistical review of a provider without covering all claims from that provider. Further, when extrapolation is used, OIG only projects to the sampling frame from which the sample was drawn. Therefore, contrary to Vitas' assertion, a valid sampling frame does not need to include all zero-paid claims within the audit period.

Vitas' statistical expert stated that our sample failed *samptest*, a computer simulation test used to evaluate sampling plans. We do not believe that such testing is required; however, even if it were required, the statistical expert performed the test incorrectly by including both the upper and lower limits in the analysis. The lower limit is the relevant quantity, because it is the estimate we used for the recommended recovery amount. When the test is performed on the lower limit, it affirms the validity of our estimate.

The statistical expert's statement that "OIG's sample was too small to yield an accurate estimate of the two-sided 90% confidence interval" is not correct. Small sample sizes, e.g., smaller than 100, have routinely been upheld by the Departmental Appeals Board and Federal courts.⁴⁶ The legal standard for a sample size is that it must be sufficient to be statistically valid, not that it be the most precise methodology.⁴⁷ Note that sample size is incorporated into the computation of the confidence interval, with a smaller sample size generally resulting in a smaller lower limit. Because absolute precision is not required, any imprecision in the sample may be remedied by recommending recovery at the lower limit, which was done in this audit.⁴⁸ This approach results in an estimate that is lower than the actual overpayment amount 95 percent of the time, and thus it generally favors the provider.⁴⁹

⁴⁴ The statistical expert stated on page 10 of Exhibit 1, ". . . I was able to re-create OIG's sample using these seeds . . ."

⁴⁵ In Vitas Exhibit 1, the statistical expert relied heavily on CMS's *Medicare Program Integrity Manual* (MPIM). The MPIM does not apply to OIG (as acknowledged by the statistical expert on page 5 of Exhibit 1). However, we note that MPIM, ch. 8, § 8.4.3.2 expressly allows for the removal of claims/claim lines that are attributable to sample units for which there was no payment.

⁴⁶ See *Anghel v. Sebelius*, 912 F. Supp. 2d 4 (E.D.N.Y. 2012) (upholding a sample size of 95 claims); *Transyd Enters., LLC v. Sebelius*, 2012 U.S. Dist. LEXIS 42491 (S.D. Tex. 2012) (upholding a sample size of 30 claims).

⁴⁷ See *John Balko & Assoc. v. Sebelius*, 2012 U.S. Dist. LEXIS 183052 at *34-35 (W.D. Pa. 2012), *aff'd* 555 F. App'x 188 (3d Cir. 2014); *Miniet v. Sebelius*, 2012 U.S. Dist. LEXIS 99517 at *17 (S.D. Fla. 2012).

⁴⁸ See *Pruchniewski v. Leavitt*, 2006 U.S. Dist. LEXIS 101218 at *51-52 (M.D. Fla. 2006).

⁴⁹ See *Puerto Rico Dep't of Health*, DAB No. 2385, at 10-11 (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).

Additionally, we disagree with Vitas statistical expert's statement that the sample unit used for this audit is not statistically independent because OIG sampled by claim and not beneficiary. The proofs for the unbiased nature of our estimate and the conservative nature of the lower limit require random selection of the sample units (here claims) from each stratum. We performed this selection using a valid random number generator. The proofs underlying our methods do not make any assumptions about the distribution of beneficiaries in the sampling frame or in the sample.⁵⁰

OIG used the correct formula to compute the estimated overpayment as the lower limit by using the normal distribution to construct the 90-percent confidence interval.⁵¹ We believe that the normal distribution is appropriate when stratum sizes are sufficiently large.⁵² For this audit, the sample sizes were either 34 or 33 per stratum, which indicates the normal distribution was appropriate and that we did not overstate the lower limit of the confidence interval. Therefore, as previously stated, we properly executed our statistical sampling methodology in that we defined our sampling frame and sampling unit, randomly selected our sample, applied relevant criteria in evaluating the sample, and used statistical sampling software (i.e., RAT-STATS) to apply the correct formulas for the extrapolation.

⁵⁰ See e.g., Cochran, William G., *Sampling Techniques*: 3rd edition, Wiley, New York, 1977. The text provides the detailed proofs underlying design-based sampling methods for stratified and simple random sampling used by OIG. The type of independence cited by Vitas is not referenced in any of these proofs.

⁵¹ See *Sampling Techniques*, equation 5.15.

⁵² See discussion in section 5.4 of *Sampling Techniques*.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

Our audit covered 50,850 hospice claims for which Vitas received Medicare reimbursement totaling \$209,782,129 for CHC and/or GIP care from April 1, 2017, through March 31, 2019 (audit period).⁵³ These claims were extracted from CMS's National Claims History (NCH) file.

We did not assess Vitas' overall internal control structure. Rather, we limited our review of internal controls to those applicable to our objective. Our audit enabled us to establish reasonable assurance of the authenticity and accuracy of the data obtained from the NCH file, but we did not assess the completeness of the file.

We performed audit work from September 2019 through November 2021.

METHODOLOGY

To accomplish our objective, we:

- reviewed applicable Medicare laws, regulations, and guidance;
- met with CMS officials to gain an understanding of the Medicare hospice benefit;
- met with Palmetto officials to gain an understanding of the Medicare requirements related to hospice services;
- met with Vitas officials to gain an understanding of Vitas' policies and procedures related to providing and billing Medicare for CHC and GIP care;
- created a sampling frame of 50,850 claims for CHC and/or GIP care from the CMS NCH file, totaling \$209,782,129, for the audit period;
- selected a stratified random sample of 100 claims for CHC and/or GIP care from the sampling frame;
- reviewed data from CMS's Common Working File for the sampled claims to determine whether the claims had been canceled or adjusted;
- obtained medical records for the 100 sampled claims and provided them to an independent medical review contractor, who determined whether the level of care billed to Medicare complied with certain Medicare requirements;

⁵³ A sampled claim (month) can contain more than one level of hospice care.

- reviewed and summarized the results of the independent medical review contractor's determinations;
- reviewed the claims for CHC and GIP care to determine whether certain documentation and nursing requirements were met;
- summarized the reason(s) a claim was determined to be improperly reimbursed;
- estimated the amount of the improper Medicare payments made to Vitas for CHC and GIP care; and
- discussed the results of our audit with Vitas officials.

See Appendix C for our statistical sampling methodology and Appendix D for our sample results and estimates.

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

APPENDIX B: RELATED OFFICE OF INSPECTOR GENERAL REPORTS

Report Title	Report Number	Date Issued
<i>Medicare Hospice Provider Compliance Audit: Partners In Care, Inc.</i>	<u>OAS-09-18-03024</u>	7/12/2021
<i>Medicare Hospice Provider Compliance Audit: Mission Hospice & Home Care, Inc.</i>	<u>OAS-09-18-03009</u>	7/8/2021
<i>Medicare Hospice Provider Compliance Audit: Northwest Hospice, LLC</i>	<u>OAS-09-20-03035</u>	6/23/2021
<i>Medicare Hospice Provider Compliance Audit: Professional Healthcare at Home, LLC</i>	<u>OAS-09-18-03028</u>	6/10/2021
<i>Medicare Hospice Provider Compliance Audit: Franciscan Hospice</i>	<u>OAS-09-20-03034</u>	5/18/2021
<i>Medicare Hospice Provider Compliance Audit: Alive Hospice, Inc.</i>	<u>OAS-09-18-03016</u>	5/14/2021
<i>Medicare Hospice Provider Compliance Audit: Ambercare Hospice, Inc.</i>	<u>OAS-09-18-03017</u>	5/14/2021
<i>Medicare Hospice Provider Compliance Audit: Suncoast Hospice</i>	<u>OAS-02-18-01001</u>	5/7/2021
<i>Medicare Hospice Provider Compliance Audit: Tidewell Hospice, Inc.</i>	<u>OAS-02-18-01024</u>	2/22/2021
<i>Medicare Hospice Provider Compliance Audit: Hospice Compassus, Inc., of Tullahoma, Tennessee</i>	<u>OAS-02-16-01024</u>	12/16/2020
<i>Medicare Hospice Provider Compliance Audit: Hospice Compassus, Inc., of Payson, Arizona</i>	<u>OAS-02-16-01023</u>	11/19/2020
<i>Safeguards Must Be Strengthened to Protect Medicare Hospice Beneficiaries From Harm</i>	<u>OEI-02-17-00021</u>	7/3/2019
<i>Hospice Deficiencies Pose Risks to Medicare Beneficiaries</i>	<u>OEI-02-17-00020</u>	7/3/2019
<i>Vulnerabilities in the Medicare Hospice Program Affect Quality Care and Program Integrity: An OIG Portfolio</i>	<u>OEI-02-16-00570</u>	7/30/2018

<i>Hospices Should Improve Their Election Statements and Certifications of Terminal Illness</i>	<u>OEI-02-10-00492</u>	9/15/2016
<i>Hospices Inappropriately Billed Medicare Over \$250 Million for General Inpatient Care</i>	<u>OEI-02-10-00491</u>	3/30/2016
<i>Hospice of New York, LLC, Improperly Claimed Medicare Reimbursement for Some Hospice Services</i>	<u>OAS-02-13-01001</u>	6/26/2015
<i>Medicare Hospices Have Financial Incentives To Provide Care in Assisted Living Facilities</i>	<u>OEI-02-14-00070</u>	1/13/2015
<i>The Community Hospice, Inc., Improperly Claimed Medicare Reimbursement for Some Hospice Services</i>	<u>OAS-02-11-01016</u>	9/23/2014
<i>Servicios Suplementarios de Salud, Inc., Improperly Claimed Medicare Reimbursement for Some Hospice Services</i>	<u>OAS-02-11-01017</u>	8/7/2014

APPENDIX C: STATISTICAL SAMPLING METHODOLOGY

SAMPLING FRAME

The sampling frame was an Access database containing 50,850 claims for CHC and/or GIP care hospice services, totaling \$209,782,129. The sampling frame included claims submitted by Vitas for services provided from April 1, 2017, through March 31, 2019, with paid amounts greater than \$0 that had not been previously reviewed by a CMS contractor. The data was extracted from the CMS NCH file.

SAMPLE UNIT

The sample unit was a Medicare Part A hospice claim.

SAMPLE DESIGN

We used a stratified random sample as follows:

Stratum	Stratum Definition	Number of Frame Units	Sample Size	Dollar Value of Frame Units
1	Claims ≤ \$4,075.41	31,513	34	\$60,127,998
2	Claims > \$4,075.41 and ≤ \$8,329.39	13,275	33	76,677,302
3	Claims > \$8,329.39	6,062	33	72,976,829
Total		50,850	100	\$209,782,129

SAMPLE SIZE

We selected a sample of 100 Medicare Part A hospice claims using the per stratum sample sizes defined in the sample design.

SOURCE OF THE RANDOM NUMBERS

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

METHOD FOR SELECTING SAMPLE ITEMS

We sorted the items in each stratum by a unique NCH claim field (DSY_VW_REC_LNK_NUM), and then consecutively numbered the hospice claims in each stratum of our sampling frame. After generating 100 random numbers, we selected the corresponding frame items.

ESTIMATION METHODOLOGY

We used the OIG/OAS statistical software to estimate the total amount of improper Medicare payments made to Vitas for unallowable CHC and/or GIP care during the audit period. To be conservative, we recommend recovery of overpayments at the lower limit of a two-sided 90-percent confidence interval. Lower limits calculated in this manner are designed to be less than the actual improper payment total 95 percent of the time.

APPENDIX D: SAMPLE RESULTS AND ESTIMATES

Sample Details and Results

Stratum Number	Number of Claims	Dollar Value of Claims	Sample Size	Dollar Value of Sample	Number of Unallowable Claims in the Sample	Dollar Value of Overpayments in the Sample
1	31,513	\$60,127,998	34	\$67,960	25	\$43,117
2	13,275	76,677,302	33	191,286	33	139,181
3	6,062	72,976,829	33	429,006	31	307,783
Total	50,850	\$209,782,129	100	\$688,252	89	\$490,081

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

Point Estimate	\$152,490,501
Lower Limit	\$140,370,745
Upper Limit	\$164,610,258

APPENDIX E: VITAS COMMENTS

HUSCH BLACKWELL

Bryan K. Nowicki
Partner

33 E. Main Street, Suite 300
Madison, WI 53703
Direct: 608.234.6012
Fax: 608.258.7138
bryan.nowicki@huschblackwell.com

February 17, 2022

VIA FEDERAL EXPRESS (TRACKING NO. 7760 7158 2971)
AND ELECTRONIC FILING

Brenda M. Tierney
Regional Inspector General for Audit Services
Office of Audit Services, Region II
Office of Inspector General
Department of Health and Human Services
26 Federal Plaza, Room 3900
New York, NY 10278

Re: Vitas Healthcare Corporation of Florida
A-02-19-01018

Dear Ms. Tierney:

We represent Vitas Healthcare Corporation of Florida (“VITAS”) in relation to this matter. We appreciate the opportunity to provide comments in response to the United States Department of Health and Human Services, Office of Inspector General’s (“OIG’s”) draft report entitled *Medicare Hospice Provider Compliance Audit: Vitas Healthcare Corporation of Florida* (“Draft Report”). VITAS’s comments on the Draft Report, including the report’s conclusions and recommendations, are set forth below.

INTRODUCTION

VITAS Healthcare Corporation (“VITAS Healthcare”), VITAS’s parent company, has more than 40 years of experience in hospice care and is the nation’s largest single-source provider of end-of-life care. VITAS Healthcare professionals provide care to thousands of hospice patients every day in 14 states and the District of Columbia. VITAS Healthcare leads the hospice community in the practice and development of hospice care, its physicians have literally “written the book” on hospice medicine, and VITAS Healthcare’s charitable activities are unmatched:

- VITAS Healthcare is a Founding Benefactor of the Duke Institute on Care at the End of Life, the nation’s first comprehensive institute for the advancement of research, education and caregiving for those near death.

HB: 4876-2247-4758.8

HUSCH BLACKWELL

Ms. Brenda M. Tierney

February 17, 2022

Page 2

- The authoritative hospice text, originally published in 2002 and reprinted in 2011 as *End-of-Life Care: A Practical Guide*, was compiled by former VITAS Healthcare Chief Medical Officer Barry M. Kinzbrunner, MD, FACP, FAAHPM, with contributions by 19 VITAS Healthcare clinicians—from physicians to chaplains, and every hospice discipline in between.
- VITAS Healthcare has won the Trailblazer Health Award presented by the Rainbow/PUSH Coalition in recognition of VITAS Healthcare’s ongoing efforts to expand awareness of and access to hospice services for African Americans.
- VITAS Healthcare provided \$13 million in genuine charity care to hospice patients nationwide in 2020. This represents an average of one percent (1 %) of our gross revenues—a ratio that few, if any, hospice providers can match.
- 4,550 trained VITAS Healthcare volunteers provided 121,732 hours of care during 2020.

VITAS Healthcare offers the full range of Medicare-mandated hospice services to its patients. When Congress established the Medicare Hospice Benefit in 1982, it provided for four separate levels of care:

- Routine Home Care (“RHC”). RHC is for the hospice patient receiving hospice care at home in accordance with a plan of care that is established on admission and revised as needed. Hospices are reimbursed a flat per diem rate for intermittent services furnished in the home.
- Inpatient Respite Care (“Respite”). Respite care is utilized on a limited basis when the patient’s caregivers would benefit from some respite from the day-to- day care they are providing at home.
- General Inpatient Care (“GIP”). GIP is provided when the patient’s medical condition warrants a short-term inpatient stay for pain control or acute or chronic symptom management that cannot feasibly be provided in other settings.
- Continuous Home Care (“CHC”). CHC is provided to hospice patients only during a period of crisis as necessary to maintain the patient at home.

For 2020, hospices across the state of Florida provided 3.42% of their days of care at a higher acuity level of care (*i.e.*, GIP or CHC), whereas VITAS provides only 3.26% of its days of care at a higher acuity level of care. VITAS is committed to providing **both** higher acuity levels of care (*i.e.*, GIP **and** CHC) when appropriate. The following chart illustrates this circumstance:

HB: 4876-2247-4758.8

HUSCH BLACKWELL

Ms. Brenda M. Tierney
 February 17, 2022
 Page 3

Level of Care	% Days of Care Per Level of Care (Other Providers)	% Days of Care on Higher Level of Care (VITAS)
GIP	3.02%	1.43%
CHC	.40%	1.83%
Total	3.42%	3.26%

The Draft Report is disappointing and at odds with VITAS’s history, leadership, policies and procedures, and culture of compliance. The Draft Report focused on two levels of care that VITAS provided to its hospice patients: GIP and CHC. From a scant review of only 0.197%¹ of the claims for CHC and/or GIP that VITAS submitted to Medicare over a two-year period, the OIG concluded that VITAS received an alleged overpayment of \$140,370,745, which amounts to over one-half the total amount billed by VITAS for such care during that two-year period. The OIG’s performance audit² of these claims, however, failed to adhere to applicable laws and standards of professional practice.

VITAS separately evaluated its patient records and the OIG’s assessments of the claims at issue. VITAS confirmed that its patient records supported the reasonable clinical judgments of the physicians who determined each patient’s appropriate level of hospice care. Moreover, VITAS has identified substantial and fundamental flaws in the OIG’s medical review and audit process. In particular, it has found that the OIG’s determinations fail to follow applicable law and guidance, focus on irrelevant data points, and fail to provide sufficient explanations regarding how those data points relate to each patient’s unique condition. For these reasons and as explained herein, the audit failed to “obtain reasonable assurance that evidence is sufficient and appropriate to support the auditors’ findings and conclusions in relation to the audit objectives” as required under GAGAS 6.03. Due to these failings the audit was not performed in accordance with GAGAS and should be reperfomed following the standards as discussed herein.

Moreover, the statistical extrapolation process employed by the OIG to convert its audit of 0.197% of VITAS’s CHC/GIP claims to an overpayment totaling over \$140 million, nearly half of all Medicare payments received by VITAS for such claims, is statistically inadequate. The sampling and extrapolation in this matter have been determined by an independent expert statistician to be invalid for a number of reasons, any one of which warrants the OIG’s

¹ The OIG reviewed 100 claims out of the 50,850 claims for CHC and/or GIP submitted by VITAS from April 1, 2017 to March 31, 2019.

² In the Draft Report, the OIG states that this audit was performed under Generally Accepted Government Auditing Standards (“GAGAS”), which includes Standard 6.02: “For performance audits conducted in accordance with GAGAS, the requirements and guidance in chapters 1 through 3, 6, and 7 apply.” GAGAS 2.10 “Performance audits are defined as audits that provide findings or conclusions based on an evaluation of sufficient, appropriate evidence against criteria.” Performance audits provide objective analysis to assist management and those charged with governance and oversight in using the information to improve program performance and operations, reduce costs, facilitate decision making by parties with responsibility to oversee or initiate corrective action, and contribute to public accountability.”

HB: 4876-2247-4758.8

HUSCH BLACKWELL

Ms. Brenda M. Tierney
February 17, 2022
Page 4

reconsideration of its use of the sampling and extrapolation to determine the estimated overpayment.

For these reasons, we respectfully request that the OIG reconsider the claim decisions and the preliminary conclusions made in the Draft Report and to consider the GAGAS requirements for audit assurance of fairness.

COMMENTS ON THE OIG'S DRAFT REPORT

I. Summary of the Draft Report

In this audit, the OIG reviewed a very narrow snapshot of VITAS's overall operations. As a part of its audit, the OIG selected a sample of 100 claims for CHC and/or GIP care out of the 50,850 such claims submitted by VITAS for the time period of April 1, 2017 to March 31, 2019. The claims selected for review represent only 0.197% of such claims submitted by VITAS for that time period.

The OIG requested and received limited records from VITAS for these 100 claims. The OIG then reviewed the records and determined that 11 of the claims complied with Medicare requirements but 89 did not. Specifically, the OIG determined that: (i) for 68 claims, the clinical record did not support the CHC level of hospice care, (ii) for 28 claims, the CHC services were not documented, and (iii) for 28 claims, the medical record did not support the GIP level of hospice care.³ These claims were all downcoded to the routine home care level of care. The OIG does not take issue with the fact that each of these patients had a terminal prognosis; rather, the OIG's focus is only on the appropriateness of the level of care provided to these terminally ill individuals.

The OIG extrapolated the error rate for the sample of claims determined by its medical reviewers to the entire universe of claims submitted by VITAS to Medicare during the two-year time frame for this audit. As a result of the extrapolation, the OIG alleges in its Draft Report that VITAS received approximately \$140,370,745 in improper payments. Nothing in the Draft Report suggests that VITAS acted fraudulently or that it knowingly submitted incorrect information to the government.

The OIG concludes its report by making three recommendations: (1) refund the portion of the alleged overpayment that is within the four-year claim reopening period; (2) exercise reasonable diligence to identify, report, and return any overpayments in accordance with the 60-day rule; and (3) strengthen its policies and procedures to ensure that hospice services comply with Medicare requirements. In the next sections of this letter, VITAS provides its analysis of the Draft Report and then responds to these recommendations.

³ The total exceeds 89 because 31 claims allegedly contained more than one of these errors.

HUSCH BLACKWELL

Ms. Brenda M. Tierney
February 17, 2022
Page 5

II. Analysis of the OIG's Audit Process and Determinations

A. The Clinical Documentation for Claims Reviewed by the OIG Applicable Met Requirements

VITAS's experienced hospice physicians are particularly attuned to the care of hospice patients, including when those patients require elevated levels of care to address periods of crisis in a home setting (CHC) and to manage pain and control symptoms in an inpatient setting (GIP). Based on the results of the OIG's review of medical records for certain VITAS patients, VITAS has concerns with the quality and accuracy of the OIG's medical review process related to both CHC and GIP. VITAS believes that the review process used by the OIG in assessing medical records was inherently flawed, that the OIG failed to apply well-recognized principles of hospice medicine in a manner consistent with applicable law, and that the OIG cannot ignore the flaws by its team members' improper assertions of findings and remain within the GAGAS mandatory requirements⁴. Accordingly, we request that the OIG reconsider its determinations regarding the provision of CHC and GIP care to VITAS's patients.⁵

1. The Clinical Documentation Supports the Provision of CHC Care to VITAS Hospice Patients

VITAS hospice physicians understand, apply, and appropriately document the circumstances that relate to a patient's need for CHC. These physicians exercise their clinical judgement to determine appropriateness for CHC in a manner that is consistent with applicable law and federal guidelines. Federal regulations allow hospice to provide CHC, *i.e.*, predominantly nursing care provided in a home setting on a 24-hour continuous basis, during periods of crisis. 42 C.F.R. § 418.204(a). A "period of crisis" is "a period in which the individual requires continuous care to achieve palliation and management of acute medical symptoms." *Id.*

The Medicare Benefit Policy Manual (the "Manual") provides additional guidance to hospices regarding CHC, including a non-exhaustive set of exemplar circumstances that support CHC. For example, the Manual states that "[i]f a patient's caregiver has been providing a skilled level of care for the patient and the caregiver is unwilling or unable to continue providing care, this may precipitate a period of crisis because the skills of a nurse may be needed to replace the services that had been provided by the caregiver."⁶ The Manual also states that CHC care "can also be given when a patient resides in a long term care facility" and that "[n]ursing care in the

⁴ See GAGAS Chapter 2 and 6 including but not limited to 6.37: "... Auditors should use criteria that are relevant to the audit objectives and permit **consistent** (emphasis added) assessment of the subject matter..."

⁵ The OIG's reconsideration should include a review of all claims disallowed based on the purported lack of eligibility for CHC and GIP care, except for certain aspects of the claims relating to Patient #s 30, 71, 73, 85, and 90. VITAS has decided to make a voluntary repayment to Medicare for the entire elevated level of care component of the claim relating to Patient #30 and for certain portions of the elevated care component of the claims relating to Patient #s 71, 73, 85, and 90.

⁶ CMS, Medicare Benefit Policy Manual, CMS Pub. No. 100-02, Ch. 9, § 40.2.1.

HUSCH BLACKWELL

Ms. Brenda M. Tierney
February 17, 2022
Page 6

hospice setting can include skilled observation and monitoring when necessary, and skilled care needed to control pain and other symptoms.” *Id.*

These laws and guidelines intersect with the exercise of clinical judgment by hospice physicians, and governing case law favors deference to hospice physicians in making critical clinical judgments concerning their patients’ healthcare in the hospice setting. *AseraCare*⁷ is a landmark decision of the U.S. Court of Appeals for the Eleventh Circuit which identified the governing standards for evaluating hospice eligibility determinations pursuant to the applicable statutes and regulations. *Aseracare* is the prevailing law in the Eleventh Circuit, which includes Florida and which, therefore, applies to this audit. As noted earlier, although *AseraCare* arose under the False Claims Act, the standards set out in the decision apply to all applications of the Medicare hospice laws and regulations. The *Aseracare* court recognized:

CMS’s rulemaking commentary signals that well-founded clinical judgments should be granted deference [and]...the law is designed to give physicians meaningful latitude to make informed judgments . . .⁸

The recognition of the hospice physician’s central role, both by CMS and the court in *AseraCare*, is consistent with other cases requiring “extra weight” or deference be given to a treating physician’s contemporaneous informed opinion unless there is a reasoned basis for declining to do so.⁹ As one court aptly stated:

It is a well-settled rule...that the expert medical opinion of a patient’s treating physician is to be accorded deference by the Secretary and is binding unless contradicted by substantial evidence....This rule may well apply with even greater force in the context of Medicare reimbursement. The legislative history of the Medicare statute makes clear the essential role of the attending physician in the statutory scheme: “The physician is to be the key figure in determining utilization of health services.”¹⁰

Under *AseraCare*’s interpretation of the applicable laws, two reasonable physicians using their clinical judgment can come to two different conclusions about a patient’s condition, and neither would be wrong. Accordingly, a later reversal of a hospice physician’s level of care determination is appropriate only if no reasonable physician, applying his or her clinical judgment, could have concluded that the patient required that elevated level of care. This standard gives appropriate deference to the hospice physicians, as required by the hospice legal framework.

In its Draft Report, however, the OIG appears to have applied standards for the provision of CHC that do not exist in the regulations or guidance, and that are contrary to the guiding

⁷ *United States v. Aseracare, Inc.*, 938 F.3d 1278 (11th Cir. 2019).

⁸ *Id.* at 1295.

⁹ *Exec. Dir. of Office of Vt. Health Access ex rel. Cave v. Sebelius*, 698 F. Supp. 2d 436, 441 (D. Vt. 2010).

¹⁰ See *Gartmann v. Sec’y of U.S. Dep’t of Health and Human Servs.*, 633 F. Supp. 671, 680-81 (E.D.N.Y. 1986) (citing *Hultsman v. Weinberger*, 495 F.2d 1276, 1279 (3d Cir. 1974); *Kuebler v. Sec’y of the U.S. Dep’t of Health and Human Servs.*, 579 F. Supp. 1436, 1440 (E.D.N.Y. 1984); *Breeden v. Weinberger*, 377 F. Supp. 734, 737 (M.D.La. 1974); *Reading v. Richardson*, 339 F. Supp. 295, 300-01 (E.D.Mo. 1972).

HUSCH BLACKWELL

Ms. Brenda M. Tierney
February 17, 2022
Page 7

principles of the appropriate exercise of clinical judgement described in *Aseracare*. On Page 4 of the Draft Report, for example, the OIG includes a sole clinical example of a CHC patient that its medical reviewers determined was not in a period of crisis:

The level of hospice care for the beneficiary associated with one sampled claim was changed from RHC to CHC for 7 days due to a change in the beneficiary's level of consciousness, an upper respiratory infection, and a urinary tract infection. The beneficiary's plan of care and physician's orders included antibiotics for the infections. For the 7 days of CHC, there was no documentation in the medical record that the beneficiary was experiencing uncontrolled pain, uncontrolled agitation, or respiratory distress. Additionally, medical records indicated that infrequent doses of medication were given for agitation with positive effects. Although the beneficiary had worsening dementia, she was able to respond appropriately to questions at times. Also, she was able to control her bladder most of the time and there was no documentation of foul-smelling urine or of a follow-up urinalysis after the antibiotic treatment. Additionally, no frequent medication changes were ordered, and the beneficiary's son was able to administer the medication. As such, there was no indication in the clinical documentation to support that the beneficiary was in a period of crisis during which CHC was necessary.

This summary begins with incorrect information, and misstates or ignores key clinical data throughout. What is characterized as simply an upper respiratory infection, which could be interpreted as a head cold, was in fact pneumonia that was verified by chest x-ray. Additionally, the fact that the hospice physician ordered a mobile x-ray team to come to the patient's home illustrates how symptomatic the patient was, and yet this was not included in the summary. This patient had significant changes in their level of consciousness with agitation and confusion in the presence of two serious infections. This combination of change in level of consciousness in the context of serious infections demonstrates that the patient was experiencing a state of delirium, which again was not identified. While most non-hospice patients would require hospitalization for these issues, CMS recognizes that hospice patients often wish to stay home rather than seek hospital care and this is the purpose of the CHC benefit – to provide skilled care during such a crisis “as necessary to maintain an individual at home.”¹¹ Indeed, the change in this patient's level of consciousness caused by the delirium along with the respiratory distress were the reasons the CHC was started.

Delirium is a serious neurologic condition that typically presents as a sudden change in a patient's level of consciousness and alertness. It usually is diagnosed by the observation that the patient alternates between periods of lethargy and agitation. It often waxes and wanes in intensity and may be accompanied by hallucinations. The development of delirium is considered a medical emergency because it is a life-threatening occurrence and has been shown to shorten life expectancy even after it has resolved. It can be caused by a large number of triggers including infections, bladder retention, lack of oxygen, failure of any organ, and many medications. A

¹¹ Manual, Ch. 9, § 40.2.1.

HUSCH BLACKWELL

Ms. Brenda M. Tierney
February 17, 2022
Page 8

change in the level of consciousness in a terminally ill hospice patient must be evaluated and monitored for the development of delirium and the cause and symptoms treated if possible.

Not only did the OIG not include the fact that the patient was obviously experiencing delirium, they go on to state, “there was no documentation in the medical record that the beneficiary was experiencing uncontrolled pain, uncontrolled agitation, or respiratory distress.” The medical records, however, clearly show that the patient had episodes of tachypnea and was described by CHC staff as having labored breathing. These episodes clearly demonstrate exactly the opposite of what the reviewers claimed in their summary.

While the patient did at times respond to the psychotropic medications, there were other episodes evident in the record that required hours of continuous pharmacologic and non-pharmacologic interventions to palliate her agitation and achieve a point where she stopped screaming. Like pharmacologic treatments, non-pharmacologic treatments require skilled care to implement the interventions and to observe for efficacy, interactions, and potential adverse effects. The variable nature of delirium symptoms clearly fits the “skilled observation and monitoring when necessary, and skilled care needed to control pain and other symptoms” description discussed in the same section of the Manual as an appropriate rationale for the need for CHC.¹²

So, in this single example of CHC care hand-selected to exemplify how CHC was not supported, the reviewers either (i) missed clear and obvious conditions and symptoms such that they did not include them in the review, or (ii) for whatever reason mischaracterized or omitted symptoms and conditions to find the patient not in a period of crisis. While these failures are readily apparent in the single example that the OIG included in its Draft Report, from VITAS’s review of the scant summaries of other patients’ records, it is clear that these types of errors are pervasive throughout the review.

Another example of the OIG’s flawed review process and determination relates to patient #28. In the OIG’s summary of patient #28, they acknowledge the presence of delirium **14 times** yet deny there is a crisis stating, “The patient had intermittent symptoms of pain and agitation.” The so-called “intermittent” nature of the issues faced by this patient does not eliminate the support for CHC, but bolsters it because the hallmark of delirium is the fact that it waxes and wanes. The unpredictable course and nature of the condition is what makes management so difficult and necessitates “skilled observation and monitoring” by nursing staff at the bedside. The apparent lack of understanding of the nature of agitation and delirium in the dying patient is particularly concerning in view of the fact that 34 of the other denied CHC claims specifically dealt with so-called “intermittent” agitation. It is concerning that the medical review either omitted these clear signs of crisis or simply failed to recognize them for what they were. In either case, it raises serious questions about the quality, qualification, and hospice experience of the OIG’s medical review team.

Moreover, the OIG’s determinations appear to pervasively rely on conclusory statements about which no appropriate or meaningful explanation is provided. Many of the OIG’s

¹² *Id.*

HUSCH BLACKWELL

Ms. Brenda M. Tierney

February 17, 2022

Page 9

determinations end with the phrase “there was no indication in the clinical documentation to support that the beneficiary was in a period of crisis during which CHC was necessary.” This phrase occurs more than 200 times in their determination summaries *without any explanation of the criteria they used to define a crisis*. This is not performed in accordance with GAGAS’s requirements¹³. For example, the medical determination summary for patient #77 noted that the patient had tachypnea up to 30 respirations per minute with abnormal lung sounds, moderate respiratory distress and “deep labored breathing” despite use of 5lpm of oxygen. The patient’s tube feeding needed to be stopped at times (which demonstrated that the patient required close monitoring to determine when the artificial nutrition was safe or unsafe) and required dosing with morphine as often as every 2 hours and the initiation of antibiotics. Throughout the crisis, the patient required the use of accessory muscles to help her breathe,¹⁴ a sign of significant respiratory distress. Yet the patient was still determined by the reviewers to not be in crisis.

Further, the instances in which the OIG determined that the medical record supported a need for CHC further demonstrates the arbitrary and inconsistent nature of the OIG’s adverse determinations that are untethered to any regulatory requirement or guideline. These are further failures of the OIG to ensure their team conducts the Performance Audit in accordance with GAGAS requirements for appropriate criteria, consistency and replicability of findings. For example, for patient #45, the OIG validated the presence of a crisis stating, “The period of crisis began at approximately 0400 on 7/10/2018 at which time the patient began to require frequent doses of morphine about every 1-3 hours for respiratory symptom control.” The same patient, on the previous day, required 3 doses of morphine, a dose of Levsin, and 2 doses of Ativan all between midnight and 5am. Yet this previous day was determined by the OIG to not support CHC while the next day was determined by the OIG to support CHC. The lack of any other explanation for the decision leaves VITAS to conclude that the review team’s determinations were simply arbitrary.

Also, there appears to be an effort on the part of the reviewers to determine the exact moment the crisis starts and stops. That time then appears to be used to approve the span in-between these two moments. In the real world, however, a crisis does not always have an exact starting point, and rarely has an exact ending point. That is why the Manual does not go to great lengths to help clinicians establish an exact start and stop point for the time of crisis. In fact, it does not even describe the word “crisis” or give clinicians a roadmap to determine when the patient is experiencing a period of crisis. Instead, the Manual provides examples of activities that occur during the midnight-to-midnight timeframe, showing that in many cases the team cannot be exactly sure when the crisis started, but gradually comes to the realization that the patient is in crisis. Any reasonable review of this guidance would conclude that it is the purview of the hospice physician to determine that the patient is experiencing a period of crisis. That purview is supported by the

¹³ See GAGAS Standard 6.37 “Auditors should identify criteria. ... Criteria identify the required or desired state or expectation with respect to the program or operation. Criteria provide a context for evaluating evidence and understanding the findings, conclusions, and recommendations included in the report. Auditors should use criteria that are relevant to the audit objectives and permit consistent assessment of the subject matter.”

¹⁴ The use of accessory muscles refers to a patient using their abdominal and or shoulder muscles to try to force air in and out of their lungs.

HUSCH BLACKWELL

Ms. Brenda M. Tierney
February 17, 2022
Page 10

applicable regulations and the *Aseracare* decision, and the OIG has not come close to sufficiently demonstrating that the hospice physicians' determinations were unreasonable or unsupported under prevailing law, CMS guidance, industry standards, and professional audit standards that GAGAS requires and which the report was drafted under.

For these reasons, VITAS requests that the OIG reconsider its preliminary determinations regarding the CHC level of care, and reverse those adverse determinations using the appropriate criteria that ensures a consistent result.

2. The Clinical Documentation Supports the Provision of GIP Care to VITAS Hospice Patients

As with the provision of CHC care described above, VITAS hospice physicians understand, apply, and appropriately document the circumstances that relate to a patient's need for GIP. These physicians exercise their clinical judgement to determine appropriateness for GIP in a manner that is consistent with applicable law and federal guidelines. Federal regulations allow hospice to provide GIP, *i.e.*, care in an inpatient facility, for pain control and symptom management. 42 C.F.R. § 418.108(a).

The Manual provides additional guidance to hospices regarding GIP, including a non-exhaustive set of exemplar circumstances that support GIP. For example, the Manual states that GIP is appropriate "for pain control or acute or chronic symptom management that cannot feasibly be provided in other settings."¹⁵ The Manual also states that GIP "may be needed in some cases when a patient elects the hospice benefit at the end of a covered hospital stay" and that "appropriate general inpatient care include[s] a patient in need of medication adjustment, observation, or other stabilizing treatment, such as psycho-social monitoring."¹⁶

Also, as with CHC, the laws and guidelines relating to GIP intersect with the exercise of clinical judgment by hospice physicians, and the principles identified in the *Aseracare* case (described above) apply equally to the clinical judgment involved in determining whether a patient's condition warrants GIP. This includes the latitude granted to and the deference that should be afforded to the hospice physician's exercise of clinical judgment.

Once again, however, in its Draft Report the OIG appears to have applied standards for the provision of GIP that do not exist in the regulations or guidance, and that are contrary to the guiding principles of the appropriate exercise of clinical judgement described in *Aseracare*. GAGAS requires the OIG to take the appropriate guidance and law into consideration before coming to a finding. It should further cite what guidance and law was applicable to the audit and applied to the audit to give it appropriate context.¹⁷ In this case it did not. On Page 8 of the Draft Report, for

¹⁵ Manual, Ch. 9, § 40.1.5.

¹⁶ *Id.*

¹⁷ *See* GAGAS Standard 6.15 "Obtaining an understanding of the program under audit helps auditors to assess the relevant risks associated with the program and the impact of the risks on the audit objectives, scope, and methodology... a. Thus, understanding the laws and legislative history establishing a program and the provisions of any contracts or grant agreements is essential to understanding the program itself. Obtaining that understanding is

HUSCH BLACKWELL

Ms. Brenda M. Tierney
February 17, 2022
Page 11

example, the OIG includes a sole clinical example of a patient that its medical reviewers determined did not warrant GIP:

A beneficiary associated with one claim was ordered to receive GIP care for shortness of breath and, for 8 days, was moved to a hospital. During this inpatient stay, she had intermittent confusion but was able to make her needs known. Other symptoms included shortness of breath, which was treated with nebulizer treatments. Pain was controlled with oral medications. There was no documentation of any continuous intravenous drips or medications ordered or administered during the inpatient stay. Infrequent doses of medications were given for agitation and pain. The beneficiary's medical condition did not require symptom management that could only be provided in an inpatient setting. Documentation indicated that the services could have been provided in her home.

Like the OIG's sole example of a CHC patient, which begs the question of consistency as applicable to the audit universe, this summary also begins with incorrect information and misstates or ignores key clinical data throughout. It implies that the patient was at home prior to the hospice's decision to have the patient "moved to a hospital." Review of the provided records show, however, that the patient was actually admitted to hospice care directly from a hospital as a result of her hospitalization for respiratory failure and sepsis that included intubation, mechanical ventilation and a thoracentesis to drain bilateral pleural effusions (a fluid collection around the lungs). After the patient was extubated, she required high-flow oxygen. Most patients suffering through a similar hospital stay would not be sent directly home following this type of hospital course, even on home health. At a minimum, such a patient would spend time in a skilled nursing facility or rehab center first. Similarly, as shown above, CMS has recognized that patients admitted directly to hospice from a hospitalization may require inpatient care.¹⁸ That is exactly what this patient, and many of the other patients included in the OIG audit, required and received. Therefore, the OIG must, under GAGAS, reassess the facts underlying this finding since they are shown to be unsupported by the data the OIG currently possesses. Otherwise, the OIG would knowingly be issuing an inaccurate report without proper assurances of accuracy.

The rationale in the Draft Report above also stated, "Pain was controlled with oral medications. There was no documentation of any continuous intravenous drips or medications ordered or administered during the inpatient stay. Infrequent doses of medications were given for agitation and pain. The beneficiary's medical condition did not require symptom management that could only be provided in an inpatient setting." This is another example of the medical reviewer using non-regulatory expectations as a basis for their eligibility determinations. Indeed, in *all* of

also a necessary step in identifying the provisions of laws, regulations, contracts, or grant agreements that are significant within the context of the audit objectives" and GAGAS Standard 6.28 "Auditors should identify any provisions of laws, regulations, contracts or grant agreements that are significant within the context of the audit objectives and assess the risk that noncompliance with provisions of laws, regulations, contracts or grant agreements could occur.¹⁷ Based on that risk assessment, the auditors should design and perform procedures to obtain reasonable assurance of detecting instances of noncompliance with provisions of laws, regulations, contracts, or grant agreements that are significant within the context of the audit objectives."

¹⁸ Manual, Ch. 9, § 40.1.5.

HB: 4876-2247-4758.8

HUSCH BLACKWELL

Ms. Brenda M. Tierney
February 17, 2022
Page 12

the GIP claims deemed ineligible by the medical reviewers, their decision appeared to be premised on the presence or absence of IV medications. There is no requirement that medications be provided via IV in order to be eligible for GIP care, and in many cases it is not appropriate or warranted. The OIG, however, improperly relies on and applies an impermissible extra-regulatory standard within the draft report to determine that the level of care was unwarranted. This is not an appropriate reliance on a third party or team member reviewer under industry and audit standards.

There is no direction in the CMS regulations or manuals on the type of medications a hospice physician should order or the method of administration in order to warrant GIP care. If the OIG has a standard or criterion they applied, then it should be stated in the report for management's review. A patient admitted to hospice directly from an acute care hospitalization in a physical condition as complicated as the one this patient endured is exactly the type of scenario covered in the Manual quoted above. The Manual goes on to state "[o]ther examples of appropriate general inpatient care include a patient in need of medication adjustment, observation, or other stabilizing treatment, such as psycho-social monitoring."¹⁹ This, too, is the exact care that the patient received during her time under GIP care. The patient's medications were adjusted and oral medications were used so that the patient ultimately could be cared for on home hospice, where caregivers do not have the same capabilities as are present in a hospital. This is a textbook example of not only a patient who is eligible for GIP, but also why GIP was created by the government in the first place.

Even when a patient on GIP did receive IV medications, the OIG appears to have applied yet another extra-regulatory standard outside legal and GAGAS allowances to deny a GIP claim. In a number of the denied GIP claims, although the patient received IV medications the claims were denied because the patient did not receive "*frequent or continuous* IV medications." For example, patient #57 required parenteral Ativan, Haldol and Zofran in addition to intermittent IV fluids for dehydration. Additionally, the patient required increasing doses of sublingual morphine in order to control his terminal shortness of breath and agitation during his last few days of life. Despite acknowledging the need for parenteral medications as well as the IV fluids, the OIG's rationale for denial included "[t]here was no documentation of any frequent or continuous IV medications ordered or administered." There is no requirement for IV medication in the first place, let alone "frequent or continuous" IV medication.

Certain determinations made by the OIG defy any reasonable medical justification and directly contradict applicable guidelines. For example, patient #26 was a 67-year-old woman with pancreatic cancer and pneumonia. She was initially treated in her home on routine hospice care where she experienced worsening respiratory distress despite use of BiPAP respiratory support. She was changed to a GIP level of care after developing "excruciating and uncontrolled" pain in her left arm despite the use of both long-acting transdermal fentanyl and an oral opiate. Over the course of the 4 days on GIP level of care, the patient had multiple changes in her pain medication regimen and was evaluated for possible deep vein thrombosis as well as consideration of a complex regional pain syndrome. Adjuvant pain therapy in the form of Neurontin was also added in an attempt to control these symptoms. Although the medical reviewer noted the patient was

¹⁹ *Id.*

HUSCH BLACKWELL

Ms. Brenda M. Tierney
February 17, 2022
Page 13

experiencing "severe intractable left arm pain" the reviewer appeared to discount its significance by stating that "patient had similar pain one year earlier, radiologic workup reportedly did not establish cause of pain" in the justification for denying eligibility.

To deny reasonable and necessary management of pain based on the irrelevant justification that the patient had previously had similar pain a year prior to this episode flies in the face of any reasonable interpretation of CMS guidelines and policies regarding hospice care planning and shows a callous disregard for the patient's suffering. The OIG's reviewers acknowledge all the oral and sublingual medications the patient received but again make an unsubstantiated and contradictory comment that the patient did not receive IV medication and thus "services could have been provided in the home setting." As previously noted, the Manual contradicts the OIG's reviewers' proposition for denial when it states "[o]ther examples of *appropriate general inpatient care* (emphasis added) include a patient in need of medication adjustment, observation, or other stabilizing treatment, such as psycho-social monitoring."²⁰

For these reasons, VITAS requests that the OIG reconsider its determinations regarding the GIP level of care, and reverse those adverse determinations for failing to meet established criteria²¹, as they are inconsistent with published CMS and industry guidance resulting in an unsubstantiated finding under GAGAS, CMS rules and law. The draft report does not provide the audit organization with reasonable assurance that the performance audit was performed and the report was issued in accordance with professional standards and legal and regulatory requirements.²²

B. The CHC Services Provided by VITAS Were Appropriately Documented

VITAS also has concerns with the review process related to whether CHC services were appropriately documented.²³ In concluding that VITAS did not appropriately document CHC services, it appears that the OIG or OIG staff or team members misread documents provided by VITAS. Moreover, the OIG's conclusion is inconsistent with decisions of CMS contractors and Administrative Law Judges ("ALJs") at the Office of Medicare Hearings and Appeals ("OMHA").²⁴ These flaws in the OIG's review process should be corrected in a new report after

²⁰ *Id.*

²¹ See GAGAS Standard 3.72 "The staff assigned to conduct an audit in accordance with GAGAS should collectively possess the technical knowledge, skills, and experience necessary to be competent for the type of work being performed before beginning work on that audit.

a. knowledge of GAGAS applicable to the type of work they are assigned...
d. skills appropriate for the work being performed; for example, skills in
(5) specialized knowledge in subject matters, such as scientific, medical,..."

²² See GAGAS Standards 3.91 and 6.12.

²³ See GAGAS Standard 3.84

²⁴ See GAGAS Standard 3.91 "Audit organizations should establish policies and procedures for audit performance, documentation, and reporting that are designed to provide the audit organization with reasonable assurance that audits are performed and reports are issued in accordance **with professional standards and legal and regulatory requirements**" (emphasis added).

HUSCH BLACKWELL

Ms. Brenda M. Tierney
February 17, 2022
Page 14

careful review and the claims at issue should be allowed as meeting professional, legal and CMS standards.

On pages 5 and 6 of the Draft Report, the OIG identifies three areas of concern related to supposedly “missing” or inadequate documentation. In each case, as described in greater detail below, the OIG’s conclusions are unsupported by the record that was produced for their staff assigned to conduct the audit or a third-party vendor participating in the audit but under OIG guidance to review.

1. VITAS Met the 8-Hour Requirement

To qualify for CHC payments, a “hospice must provide a minimum of 8 hours of non-continuous nursing, hospice aide, and/or homemaking care during a 24-hour day, which begins and ends at midnight.”²⁵ The documents provided to the OIG by VITAS support VITAS’s compliance with this 8-hour requirement. These documents consisted of clinical notes, timesheets, and payroll records, all of which have been accepted by CMS contractors and ALJs as evidence of compliance with the 8-hour requirement.

The OIG, however, appears to have discounted this evidence and required other information that is not required by any regulation or guideline to be created or maintained. For example, the OIG identified 9 claims where it contends the documents did not support the 8-hour requirement. The OIG faulted VITAS for documentation that did not include ‘start and end times’ for the provision of services, and also stated that timesheets and payroll records are not evidence of direct time spent with the beneficiary. The OIG’s conclusions are not supported by the applicable laws or guidance. There is no basis for the OIG to ignore timesheets or payroll records that support meeting the 8-hour requirement. In fact, on multiple occasions VITAS has relied on such documentation to obtain favorable decisions from CMS contractors and ALJs regarding the 8-hour requirement. VITAS has had similar success in relying on documents that do not have ‘start and end times.’

The OIG should reconsider its review team’s conclusions relating to the 8-hour requirement. It should consider all of the evidence that VITAS has presented (which CMS contractors and ALJs have relied on) and it should not require information (such as ‘start and end times’) that have no regulatory basis. OIG cannot avoid this reanalysis by delegating the responsibility for accuracy to a team member or third-party vendor participating in the audit. The auditor is responsible for the final report to the audit entity and this Draft Report is insufficient as shown herein.²⁶

²⁵ Manual, Ch. 9, §40.2.1.

²⁶ See GAGAS Standards including but not limited to: 1.24, 2.14, 3.13, 3.64, 3.72, 3.84, 3.91, 6.12, 6.15, 6.28 and 6.37.

HUSCH BLACKWELL

Ms. Brenda M. Tierney
February 17, 2022
Page 15

2. VITAS Met the “Predominantly Nursing Care” Requirement

CHC care “must be predominantly nursing care” to qualify for payment.²⁷ The documents provided to the OIG by VITAS, consisting of clinical notes, timesheets, and payroll records, support VITAS’s compliance with this nursing care requirement and have been accepted by CMS contractors and ALJs as evidence of compliance with this requirement.

The OIG assigned team, however, again discounted appropriate evidence supporting this requirement and misread other relevant documentation. For example, the OIG identified 5 claims where it contends that documents did not support this “predominantly nursing care” requirement. Timesheet and payroll information for certain of those claims, however, appears to have been ignored by the OIG. Moreover, for at least one claim (#42), the OIG appears to have misread a document that shows a care shift beginning on 11/22/18 and continuing up to midnight that same day and into 11/23/18. By misreading this documentation, the OIG ignored information establishing an additional two hours of skilled care from 10:00 p.m. to midnight on 11/22/18, and that supports the appropriateness of the CHC claim for that day. In short, there is no missing documentation in this claim, and full credit for the services provided is warranted.

Given this evidence, the OIG should reconsider its conclusions regarding the “predominantly nursing care” requirement and adjust its findings consistent with the above information.

3. VITAS Documentation Supported Its CHC Billing

CHC care is billed in 15-minute increments.²⁸ These increments, however, do not change the two threshold billing requirements: (i) that the patient is in a crisis situation and (ii) that the hospice provides more than the minimum of 8 hours of nursing, hospice aide, and/or homemaker care—predominantly nursing—during a 24-hour day which begins and ends at midnight. The documents provided to the OIG by VITAS, consisting of clinical notes, timesheets, and payroll records, support VITAS’s compliance with these threshold requirements and have been accepted by CMS contractors and ALJs as evidence of compliance with this requirement.

For 16 claims (some of which relate to multiple days of CHC care), the OIG concedes that VITAS has met these threshold requirements but nonetheless denies them because VITAS “did not provide support for all hospice services (i.e., each 15-minute increment of nursing, hospice aide, and/or homemaker) claimed.” The OIG reaches this result, yet again, by inappropriately discounting appropriate evidence supporting the services provided and by misreading other relevant documentation. For example:

²⁷ See 42 U.S.C. § 418.204(a).

²⁸ CMS, Medicare Claims Processing Manual, Pub. No. 100-04, § 30.1.

HUSCH BLACKWELL

Ms. Brenda M. Tierney

February 17, 2022

Page 16

- For 10 CHC days within the 16 denied claims, all 15-minute increments are properly supported by timesheet and payroll information that the OIG inappropriately ignored.
- Several CHC days with the 16 denied claims appear to involve documents that the OIG simply misread, but that include sufficient information to support the billing.
 - Documentation for Patient #40 showed evidence of bedside presence and care at all times during the denied 15-minute increments with noted vital signs (Temperature, Pulse, Respirations) being recorded despite the reviewers claims to the contrary.
 - For patient #76, the OIG claimed that the documentation failed to support 96 CHC 15 minute increments on February 27, 2019. However, VITAS only submitted a claim for 52 15 minute increments of CHC for that day.
 - For patients #78 and #81, the OIG reviewers misread documentation.
 - For patient #78, VITAS provided documentation relating to 5/12/17 supporting 8 15-minute increments of skilled nursing services provided from 3:00 p.m. to 5:00 p.m., but the OIG failed to credit this time period in its review.
 - For patient #81, the OIG stated that for 7/12/18 6 units of CHC were “unsupported.” However, documentation provided by VITAS showed that a nurse provided care from 11:50 p.m. on 7/11/17 to 1:30 a.m. on 7/12/17. It appears that the OIG ignored the 6 15-minute increments of care provided on 7/12/17 because the note originated on 7/11/17.
 - Documentation for patient #61 evidenced the clinician inadvertently misdated the care document a month earlier (4/2/18 vs 5/2/18). The patient was not receiving CHC during April 2018, but the documentation provided by VITAS demonstrated the CHC care provided in May 2018.

VITAS raised these issues during the exit conference that was held on October 1, 2021 and in a follow-up written communication on November 16, 2021, prior to the release of the Draft Report. VITAS showed the OIG that the reviewers misread dates in their technical review. Despite the provision of this evidence, the OIG went ahead (apparently without further analysis) and issued the Draft Report without considering or incorporating any of the additional information. This does not reflect a “good faith...gathering of information and the objective evaluation of the sufficiency

HB: 4876-2247-4758.8

HUSCH BLACKWELL

Ms. Brenda M. Tierney
February 17, 2022
Page 17

and appropriateness of evidence” as required by GAGAS.²⁹ The OIG should correct its Draft Report now.

The OIG should reconsider its draft conclusions regarding documentation of CHC in light of the criteria information provided above, and reverse its position on claim denials.

In summary, of the 28 claims (representing 35 days) at issue where VITAS billed CHC and the reviewers identified technical issues, VITAS believes that 25 of these days were inappropriately denied for the reasons stated above. Moreover, VITAS adjusted the claims relating to 6 additional days to down-code the level of care to routine home care prior to the OIG issuing the Draft Report.³⁰ Therefore, out of the 100 claims reviewed by OIG/OAS, as of the issuance of the Draft Report VITAS concurs with the OIG’s non-clinical documentation findings relating only to 41 15-minute increments of CHC provided during 4 days of patient care.³¹ Accordingly, the OIG does not contend and VITAS is not stating that 4 24-hour days failed to meet the non-clinical documentation requirements. Rather, the 41 15-minute increments or which VITAS is conceding error comprise just 10.25 hours of CHC out of a universe of 12,753.25 hours (51,013 15-minute increments) of CHC that the OIG reviewed. This represents an error rate of just 0.08%. Even accepting the OIG’s overgeneralization that 35 days (rather than 4 days) of patient care involved CHC overpayments, the resulting error rate would remain extremely small given that a limited number of 15-minute increments of CHC care are at issue in each of those 35 days.

C. The Failure to Apply the Correct Legal Principles for Hospice Eligibility is Arbitrary and Capricious

The OIG failed to recognize the regulatory provisions and hospice principles referenced above in its evaluation of the hospice physicians’ contemporaneous determinations regarding hospice level of care. The determinations of the trained hospice physicians, which were made in real time, are more credible and, importantly, more significant under applicable hospice law and regulations as previously cited herein, than the review process performed by the OIG.

To avoid an “arbitrary and capricious” determination, the decision must evidence that the OIG “examined the relevant data and provided an explanation of its decision that includes a rational connection between the facts found and the choice made.”³² Here, the OIG repetitively

²⁹ See GAGAS Standard 3.64.

³⁰ These relate to Patient #s 36, 39, 41, 69, and 99 (two days).

³¹ VITAS concurs with the following patients, and the attendant number of units:

- Patient #4 – 13 units
- Patient #40 – 7 units
- Patient #56 – 12 units
- Patient #81 – 9 units

³² *Cumberland County Hospital System, Inc. v. Price*, 2017 WL 1048102 (E.D. N.C. 2017) (quoting *Ohio Vall. Envt’l Coal.*, 556 F.3d at 192) (internal quotations omitted); *U.S. Telecom Ass’n v. FCC*, 227 F.3d 450, 460 (D.C. Cir. 2000) (noting that under the arbitrary and capricious standard “an agency must cogently explain why it has

HUSCH BLACKWELL

Ms. Brenda M. Tierney
February 17, 2022
Page 18

cited clinical criteria that are not legally mandatory and cherry-picked evidence from the medical record without a full consideration of each patient's condition and without taking into account the hospice physicians' credible clinical judgments. The OIG also failed to connect the facts and information about each patient to the determination that the documentation was insufficient. Moreover, the reviewer simply listed criteria without providing any explanation as to how those criteria relate to that particular patient's unique clinical situation. This failure to apply the correct legal principles and connect them to the patients results in arbitrary and capricious determinations by the OIG.³³

D. The Extrapolation of the Alleged Overpayment is Invalid and Inappropriate

We ask that the OIG reconsider its use of sampling and extrapolation to arrive at the estimated overpayment here for at least two reasons. First, extrapolation is not appropriate for calculating overpayments in the hospice context due to the individualized nature of prognostication. Second, the OIG's statistical methodology was fundamentally flawed, and the extrapolated overpayment amount is statistically invalid.

1. Extrapolation is Not Appropriate for Calculating Hospice Overpayments Given The Individualized Nature of Hospice Level of Care Determinations

The OIG's attempted calculation of an overpayment amount through statistical sampling and extrapolation fails to take into consideration the unique nature of hospice, including each hospice patient's relevant clinical profile, and the subjective and inexact nature of each hospice physician's level of care determination. Such an attempted calculation cannot provide a reasonably reliable estimated overpayment.

This unique nature of hospice care is supported by several cases, which have noted that extrapolation is inappropriate in the hospice context. In *U.S. ex rel. Michaels v. Agape Senior Cmty., Inc.*, the court held that statistical sampling and extrapolation could not be used to establish liability since "each and every claim at issue" was "fact-dependent and wholly unrelated to each and every other claim."³⁴ The *Agape* court stated that extrapolation is unsuitable for circumstances where determination of medical necessity requires a highly fact-intensive inquiry and review of

exercised its discretion in a given manner' and that explanation must be 'sufficient to enable [the court] to conclude that the [agency's action] was the product of reasoned Draft Report-making'" (quoting *A.L. Pharma, Inc. v. Shalala*, 62 F.3d 1484, 1491 (D.C. Cir. 1995)).

³³ *Caring Hearts Personal Home Services, Inc. v. Burwell*, 824 F.3d 968, 970-71 (10th Cir. 2016) ("For surely one thing no agency can do is apply the wrong law to citizens who come before it, especially when the right law would appear to support the citizen and not the agency." (citing *Lax v. Astrue*, 489 F.3d 1080 (10th Cir. 2007) ("We review the [agency] Draft Report to determine whether the factual findings are supported by substantial evidence in the record and whether the correct legal standards were applied."); also citing *Sandoval v. Aetna Life & Cas. Ins. Co.*, 967 F.2d 377, 380 n. 4 (10th Cir. 1992) ("In our view, both lack of substantial evidence and a mistake of law would be indicia of arbitrary and capricious actions and thus may be subsumed under the arbitrary and capricious label.")).

³⁴ See *U.S. ex rel. Michaels v. Agape Senior Cmty., Inc.*, No. CA 0:12-3466-JFA, 2015 WL 3903675, at *2 (D.S.C. June 25, 2015), order corrected, No. CA 0:12-3466-JFA, 2015 WL 4128919 (D.S.C. July 6, 2015), and aff'd in part, appeal dismissed in part sub nom. *U.S. ex rel. Michaels v. Agape Senior Cmty., Inc.*, 848 F.3d 330 (4th Cir. 2017).

HB: 4876-2247-4758.8

HUSCH BLACKWELL

Ms. Brenda M. Tierney
February 17, 2022
Page 19

each individual patient's medical record.³⁵ Where the nature of the claim requires an individualized determination, that determination cannot be replaced by "Trial by Formula."³⁶ Furthermore, the *Vista Hospice Care* court acknowledged that the permissibility of statistical sampling and extrapolation turns on "the degree to which the evidence is reliable in proving or disproving the elements of the relevant cause of action."³⁷ As both the *Agape* and *Vista Hospice Care* courts recognized, answering whether certain services furnished to hospice patients were medically necessary is not a question for which extrapolation can be an effective tool due to the absolute individuality of each claim for hospice services.³⁸

While extrapolation from sampling may be appropriate where the evidence establishes that a provider's objective approach was similar in all cases, making the sample a reasonable basis for extrapolation to the whole, this is not the case when it comes to determinations of hospice levels of care.³⁹ Statistical sampling, therefore, cannot be used to establish an overpayment related to hospice levels of care because the underlying determination of eligibility for hospice is inherently subjective, patient-specific, and dependent on the judgment of involved physicians.

The OIG's findings that a certain level of care was inappropriate in one patient's case should not be imputable to other claims involving—in addition to different conditions and different physicians—different caregivers, different facilities, and different time periods.⁴⁰ Every hospice patient is entirely unique, and the hospice benefit allows patients to receive an array of services provided by a complex interdisciplinary team, the nature of such services depending on the individual patient's medical needs.⁴¹ Furthermore, every hospice physician has a unique set of skills and experiences, and again, courts have recognized that two physicians can disagree concerning a patient's prognosis, and neither physician be wrong.⁴² This recognized variability in clinical judgment, which is entirely appropriate between reasonable physicians, eliminates the predictability of the outcome of a medical record review that is essential to a valid extrapolation. In purporting to extrapolate from one claim, the OIG has taken one physician's clinical judgment regarding one patient's level of care and applied it to other physicians' prognostications for other patients, whose backgrounds and medical needs are distinct from the sampled patient claim. It is impractical, if not impossible, to extrapolate properly by accounting for all the relevant variables associated with hospice care. It is inappropriate, therefore, to extrapolate from one physician's

³⁵ *Id.* at *8. See also *United States v. Medco Phys. Unlimited*, No. 98-C-1622, 2000 U.S. Dist. LEXIS 5843, at *23 (N.D. Ill. Mar. 15, 2000) (on motion for summary judgment, rejecting extrapolation of expert's findings from a sixteen-claim sample to support a conclusion that every claim defendant submitted to Medicare was fraudulent and noting lack of "case law or other authority to support such a request").

³⁶ *Vista Hospice Care* at *11.

³⁷ *Vista Hospice Care* at *13 (quoting *Tyson Foods, Inc. v. Bouaphakeo*, 136 S. Ct. 1036, 1046 (2016)).

³⁸ *Agape*, 2015 WL 3903675, at *8; *Vista Hospice Care* at *11.

³⁹ *Vista Hospice Care*, 2016 WL 3449833, at *12.

⁴⁰ See *id.* at *13.

⁴¹ See 42 C.F.R. § 418.202; see also Medicare Program; Hospice Wage Index for Fiscal Year 2012, 76 Fed. Reg. 47301, 47302 (Aug. 4, 2011) ("A hospice uses an interdisciplinary approach to deliver medical, nursing, social, psychological, emotional, and spiritual services through use of a broad spectrum of professional and other caregivers, with the goal of making the individual as physically and emotionally comfortable as possible.").

⁴² See *Vista Hospice Care*, 2016 WL 3449833, at *17.

HB: 4876-2247-4758.8

HUSCH BLACKWELL

Ms. Brenda M. Tierney
February 17, 2022
Page 20

clinical judgment regarding one patient to another physician's conclusions about a completely different patient.⁴³

The payment model Congress designed for hospices includes many features to ensure that hospices take responsibility for virtually all end-of-life care for their patients, while providing overall cost-savings to the Medicare trust.⁴⁴ This responsibility and burden that Congress has imposed on hospices, and that hospices freely accept, is incompatible with the additional, draconian consequences that would result if extrapolation were permitted. In particular, permitting extrapolation in this context would result in groundless overpayment determinations that fail to acknowledge either the benefits of individualized care that hospice agencies provide to beneficiaries or, more importantly, the concept that two physicians using their clinical judgment about a patient's condition could disagree and neither be wrong.⁴⁵ Therefore, it is an arbitrary and capricious exercise of agency discretion to utilize extrapolation in the area of hospice benefit level of care determinations.

2. The OIG's Sampling and Extrapolation of VITAS's Claims are Statistically Invalid

VITAS engaged Dr. R. Mitchell Cox to evaluate the OIG's statistical sampling and extrapolation methodology. Dr. Cox has decades of experience providing independent analysis of statistical sampling and extrapolation in the healthcare context.⁴⁶ He has served as a statistical expert in numerous appeals of overpayment determinations before Administrative Law Judges and federal courts. Attached as Exhibit 2 is Dr. Cox's Expert Report, which identifies and explains multiple processes and statistical concerns with respect to the OIG's statistical sampling methodology and extrapolation.⁴⁷ The points identified below from Dr. Cox's report demonstrate that the extrapolation is statistically invalid.

First, the OIG did not provide documentation sufficient to re-create the sampling frame or the sample. This allowed the OIG's statistician to use any sample whatsoever for extrapolation. Obviously, the statistician should not have this freedom but instead should be limited to using a uniquely determined sample that is fully documented in the sampling materials.

Second, the OIG violated statistical principles by improperly excluding potential underpayments from its sampling universe. In the OIG's sampling plan, the OIG states that zero-paid claims (potential underpaid claims) were excluded. Since the zero-paid claims were excluded from the sampling universe, they were not available to be selected for the sample here and thus

⁴³ See *id.* at *13.

⁴⁴ These features include an all-inclusive per diem rate that covers all hospice services, including skilled nursing, physician administrative services, medical social services, therapies, home health aides, counseling, on-call services, medical equipment, and prescription drugs. See 42 C.F.R. § 418.302. Two payment caps limit the government's obligations. See 42 C.F.R. § 418.302(f), 418.308, 418.309. One cap limits the number of days of inpatient care and the other sets an aggregate dollar limit on the average annual payment per beneficiary. *Id.*

⁴⁵ *AseraCare*, 983 F.3d at 1285.

⁴⁶ **Exhibit 1**, Curriculum Vitae of Dr. Cox.

⁴⁷ **Exhibit 2**, Expert Report of Dr. Cox.

HUSCH BLACKWELL

Ms. Brenda M. Tierney
February 17, 2022
Page 21

did not factor into the extrapolated overpayment. Statistical principles require the inclusion of zero-paid claims in the sampling universe. This exclusion of unpaid or underpaid claims puts VITAS at an extreme disadvantage because it likely resulted in an improperly inflated extrapolated amount that the OIG has deemed an overpayment. There is absolutely no legal, administrative, or statistical justification for OIG to have removed the zero-paid claims from the sampling frame.

Third, the OIG's sample fails *samptest*, a computer simulation used to evaluate sampling plans. Use of *samptest* shows that the two-sided confidence level of OIG's overpayment estimate falls as low as 73.8%, which is well outside the confidence interval required by paragraphs 12 and 14 of the OIG's Sampling Plan. OIG's failure to satisfy this requirement is a direct result of its failure to follow its own sampling guidelines.

Fourth, the OIG's sample was too small to yield an accurate estimate of two-sided 90% confidence interval, which the OIG required itself to achieve in its own sampling plan, because the OIG sampled by claim and not by beneficiary, and claims belonging to the same beneficiary and episode of care are not statistically independent. This is the underlying reason why the two-sided confidence level of OIG's overpayment estimate falls as low as 73.8% using *samptest*, as discussed above.

Lastly, the OIG's calculation of the reimbursement demand is incorrect due to an error in the formula it used to calculate the precision of the overpayment estimate. The correct formula gives a reimbursement demand of \$140,217,092 instead of \$140,370,745.

Any one of Conclusions 1 through 5 stands either on its own or in combination with the other conclusions to invalidate OIG's overpayment estimate. In Dr. Cox's professional opinion, the OIG's Sampling Plan is not an adequate foundation for statistical sampling for overpayment estimation. Therefore, the OIG's estimate for the population is not supportable under OIG regulations, Medicare guidelines, and generally accepted statistical principles.

E. Response to Recommendations in the OIG's Draft Report

There are three recommendations in the Draft Report: (1) refund the portion of the alleged overpayment that is within the 4-year claim reopening period; (2) exercise reasonable diligence to identify, report, and return any overpayments in accordance with the 60-day rule; and (3) strengthen its policies and procedures to ensure hospice services comply with Medicare requirements. VITAS's position with respect to these recommendations is set forth below.

1. Response to OIG Recommendation to Refund of The Alleged Improper Payments Within the 4-year Claim Reopening Period

VITAS has voluntarily refunded amounts received for the claims identified above.⁴⁸ VITAS does not agree with this recommendation with respect to all other claims denied by the OIG. VITAS has thoroughly reviewed the OIG's audit findings and has determined that VITAS

⁴⁸ See *supra*, n.5 and n.31.

HUSCH BLACKWELL

Ms. Brenda M. Tierney
February 17, 2022
Page 22

did not receive an overpayment with respect to these other claims and that those claim denials and the OIG's statistical extrapolation are improper and contrary to law. The rationale for VITAS's determinations are set forth in this letter. If any attempt is made by VITAS's Medicare Administrative Contractor ("MAC") to recoup funds related to the claims at issue in this audit, then VITAS intends to exercise all appeal rights available to it.

2. Response to OIG Recommendation to Refund of Other Overpayments in Accordance with 60-Day Repayment Rule

VITAS acknowledges its obligations under the 60-Day Repayment Rule. The Draft Report indicates that the OIG believes its report constitutes credible information of potential overpayments, and, therefore, VITAS must "exercise reasonable diligence to identify overpayments" for a 6-year lookback period pursuant to the requirements of the 60-day rule in § 1128J(d) of the Act and 42 C.F.R. § 401.305. VITAS has thoroughly reviewed the audit findings by the OIG and has determined that it did not receive any other overpayments. Accordingly, VITAS has met these requirements as set out by CMS in 81 Fed. Reg. 7654 (Feb. 12, 2016).

3. Response to OIG Recommendation to Strengthen its Policies and Procedures

VITAS does not concur with this recommendation. VITAS has robust policies and procedures that comply with *and incorporate* each and every Medicare requirement applicable to hospices. VITAS disagrees that any particular flaws exist in its current policies and procedures that allowed the provision of unnecessary CHC or GIP care, or led to inadequate documentation of such care. Moreover, the Draft Report does not identify any particular flaws. Nonetheless, VITAS shall continue to routinely review and update its policies to ensure ongoing compliance with applicable law.

CONCLUSION

Thank you for the opportunity to present these comments to the Draft Report. We appreciate the work that the OIG has put into this effort, and we respectfully request that the OIG consider these comments in reviewing and revising the Draft Report.

Sincerely,

/ Bryan K. Nowicki/

Bryan K. Nowicki
Partner

Enclosures

HB: 4876-2247-4758.8