

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**MEDICARE HOSPICE PROVIDER
COMPLIANCE AUDIT:
SUNCOAST HOSPICE**

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Office of Inspector General

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Report in Brief

Date: May 2021

Report No. A-02-18-01001

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 hospice services provided by Suncoast Hospice (Suncoast) complied with Medicare requirements.

How OIG Did This Audit

Our audit covered 38,986 claims for which Suncoast received Medicare reimbursement totaling \$148.5 million for hospice services provided during the period July 2015 through June 2017. We reviewed a random sample of 100 claims. We evaluated the services for compliance with selected Medicare requirements and submitted records associated with them to an independent medical review contractor who determined whether the services met coverage, medical necessity, and coding requirements.

Medicare Hospice Provider Compliance Audit: Suncoast Hospice

What OIG Found

Suncoast did not comply with Medicare requirements for 49 of the 100 claims in our sample. For these claims, Suncoast claimed Medicare reimbursement for hospice services for which the clinical record did not support the beneficiary's terminal prognosis or the level of care claimed and for services that were not provided.

These improper payments occurred because Suncoast's policies and procedures for ensuring that claims for hospice services met Medicare requirements were not always effective. On the basis of our sample results, we estimated that Suncoast received at least \$47.4 million in Medicare reimbursement for hospice services that did not comply with Medicare requirements.

What OIG Recommends and Suncoast Comments

We recommend that Suncoast: (1) refund to the Federal Government the portion of the estimated \$47.4 million in Medicare overpayments that are within the 4-year claims reopening period; (2) exercise reasonable diligence to identify, report, and return 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 written comments on our draft report, Suncoast, through its attorney, disagreed with our recommendations and generally disagreed with our findings. Suncoast believed that the clinical documentation it submitted met Medicare requirements and that OIG's medical review contractor's denials were inconsistent with hospice regulations. Suncoast also engaged two statistical experts who challenged the validity of our statistical sampling and extrapolation methodologies. Lastly, Suncoast contended that the overpayments identified in the draft report should be waived and should also be offset by services that would otherwise be payable by Medicare.

After reviewing Suncoast's comments in their entirety, we maintain that our findings and recommendations are valid. We also maintain that our sampling and extrapolation were statistically valid and resulted in a legally valid and reasonably conservative estimate of the amount overpaid by Medicare. We note that CMS may reexamine disallowed claims and determine whether an overpayment exists and if the waiver provisions cited by Suncoast would apply. Lastly, we did not offset any overpayments because we have no assurance that Medicare would cover these services.

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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 hospice services provided by Suncoast Hospice (Suncoast) 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. The Medicare hospice benefit has four levels of care: (1) routine home care, (2) general inpatient (GIP) care,

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.

(3) inpatient respite care, and (4) continuous home care (CHC). Medicare provides an all-inclusive daily payment based upon the level of care.⁴

Beneficiaries eligible for the Medicare hospice benefit may elect hospice care by filing a signed election statement with a hospice.⁵ 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, except for services provided by the designated hospice directly or under arrangements or services of the beneficiary's attending physician if the physician is not employed by or receiving compensation from the designated hospice.⁶ The hospice must submit a notice of election (NOE) to its MAC within 5 calendar days after the effective date of election. If the hospice does not submit the NOE to its MAC within the required timeframe, Medicare will not cover and pay for days of hospice care from the effective date of election to the date that the NOE was submitted to the MAC.⁷

Beneficiaries are entitled to receive hospice care for two 90-day benefit periods, followed by an unlimited number of 60-day benefit periods.⁸ At the start of the initial 90-day benefit period of care, the hospice must obtain written certification of the beneficiary's terminal illness from the hospice medical director or the physician member of the hospice interdisciplinary group⁹ and the beneficiary's attending physician, if any. For subsequent benefit periods, a written certification by only the hospice medical director or the physician member of the hospice interdisciplinary group is required.¹⁰ The initial certification and all subsequent recertifications must include a brief narrative explanation of the clinical findings that supports a life expectancy

⁴ 42 CFR § 418.302. 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).

⁵ 42 CFR § 418.24(a)(1).

⁶ 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).

⁷ 42 CFR §§ 418.24(a)(2) and (a)(3).

⁸ 42 CFR § 418.21(a).

⁹ A hospice interdisciplinary group consists of individuals who together formulate the hospice plan of care for terminally ill beneficiaries. The interdisciplinary group must include a doctor of medicine or osteopathy, a registered nurse, a social worker, and a pastoral or other counselor, and may include others, such as hospice aides, therapists, and trained volunteers (42 CFR § 418.56).

¹⁰ 42 CFR § 418.22(c).

of 6 months or less.¹¹ The written certification may be completed no more than 15 calendar days prior to the effective date of election or the start of the subsequent benefit period.¹²

A hospice physician or hospice nurse practitioner must have a face-to-face encounter with each hospice beneficiary whose total stay across all hospices is anticipated to reach a third benefit period. The physician or nurse practitioner conducting the face-to-face encounter must gather and document clinical findings to support a life expectancy of 6 months or less.¹³

Effective for dates of service beginning January 1, 2016, hospices can claim a service intensity add-on (SIA) payment for direct patient care provided by a registered nurse and/or a social worker to a beneficiary receiving routine home care during the last 7 days of life.¹⁴

Hospice providers must establish and maintain a clinical record for each hospice patient.¹⁵ The record must include all services, whether furnished directly or under arrangements made by the hospice. Clinical information and other documentation that support the medical prognosis of a life expectancy of 6 months or less if the terminal illness runs its normal course must be filed in the medical record with the written certification of terminal illness.¹⁶

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.¹⁷

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

¹¹ 42 CFR § 418.22(b)(3).

¹² 42 CFR § 418.22(a)(3).

¹³ 42 CFR §§ 418.22(a)(4), (b)(3)(v), and (b)(4).

¹⁴ To be eligible for an SIA payment, the beneficiary must be discharged from the hospice due to death (42 CFR §§ 418.302(b)(1)(i) and (ii)).

¹⁵ 42 CFR §§ 418.104 and 418.310.

¹⁶ 42 CFR §§ 418.22(b)(2) and (d)(2).

¹⁷ The Act § 1128J(d); 42 CFR §§ 401.301 to 401.305; and 81 Fed. Reg. 7654, (Feb. 12, 2016).

under the 60-day rule, providers can request the reopening of initial claims determinations, submit amended cost reports, or use any other appropriate reporting process.¹⁸

Suncoast Hospice

Suncoast, located in Clearwater, Florida, is a member of Empath Health, a nonprofit healthcare network.¹⁹ Suncoast operates three hospice care centers that provide services to terminally ill beneficiaries, as well as support for their families. During the period July 1, 2015, through June 30, 2017 (audit period), Suncoast provided hospice services to approximately 12,400 beneficiaries and received Medicare reimbursement of almost \$149 million.²⁰ Palmetto GBA, LLC (Palmetto), serves as the MAC for Suncoast.

HOW WE CONDUCTED THIS AUDIT

Our audit covered \$148,516,965 in Medicare reimbursement for 38,986 claims for hospice services provided by Suncoast during the audit period.²¹ We reviewed a random sample of 100 of these claims to determine whether hospice services complied with Medicare requirements. Specifically, we evaluated compliance with selected billing requirements and submitted the 100 sampled claims and associated medical records to an independent medical review contractor who determined whether the services met coverage, medical necessity, and coding requirements.

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

Appendix A contains the details of our audit scope and methodology, Appendix C contains our statistical sampling methodology, and Appendix D contains our sample results and estimates.

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

¹⁹ The hospice is incorporated under the name The Hospice of the Florida Suncoast, Inc., and does business as Suncoast Hospice.

²⁰ Claims data for the period July 1, 2015, through June 30, 2017, was the most current data available when we started our audit.

²¹ In developing this sampling frame, we excluded from our audit, hospice claims that were identified in the Recovery Audit Contractor data warehouse as having been reviewed by another party.

FINDINGS

Suncoast received Medicare reimbursement for hospice services that did not comply with Medicare requirements. Of the 100 hospice claims in our sample, 51 claims complied with requirements, but 49 did not. Specifically:

- For 30 claims, the clinical record did not support the beneficiary's terminal prognosis.
- For 20 claims, the clinical record did not support the level of care claimed for Medicare reimbursement.
- For two claims, Suncoast claimed an SIA payment for services that were not provided.

The total exceeds 49 because 3 claims contained more than 1 of the above errors.

These improper payments occurred because Suncoast's policies and procedures were not effective to ensure that the clinical documentation it maintained supported the terminal illness prognosis and that the appropriate level of care was provided. In addition, Suncoast claimed SIA payments for services that were not provided because Suncoast staff incorrectly recorded time on their timesheets.

On the basis of our sample results, we estimated that Suncoast received at least \$47,363,971 in improper Medicare reimbursement for hospice services that did not comply with Medicare requirements.²² 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).²³ Notwithstanding, Suncoast 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.²⁴

TERMINAL PROGNOSIS NOT SUPPORTED

To be eligible for the Medicare hospice benefit, a beneficiary must be certified as being terminally ill. Beneficiaries are entitled to receive hospice care for two 90-day periods, followed by an unlimited number of 60-day periods. At the start of the initial 90-day period of care, the hospice must obtain written certification of the beneficiary's terminal illness from the hospice medical director or the physician member of the hospice interdisciplinary group and the

²² 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.

²³ 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).

²⁴ 42 CFR § 405.980(c)(4).

individual's attending physician, if any. For subsequent periods, a written certification from the hospice medical director or the physician member of the hospice interdisciplinary group is required. Clinical information and other documentation that supports the beneficiary's terminal prognosis must accompany the physician's certification and be filed in the medical record with the written certification of terminal illness.²⁵

For 30 of the 100 sample claims, the clinical record provided by Suncoast did not support the associated beneficiary's terminal prognosis. Specifically, the independent medical review contractor determined that the records for these claims did not contain sufficient clinical information and other documentation to support the medical prognosis of a life expectancy of 6 months or less if the terminal illness ran its normal course.

LEVEL OF CARE NOT SUPPORTED

Medicare reimbursement for hospice services is made at predetermined payment rates—based on the level of care provided—for each day that a beneficiary is under the hospice's care. The four levels are: (1) routine home care, (2) GIP care, (3) inpatient respite care, and (4) CHC.²⁶ GIP care is provided in an inpatient facility for pain control or acute or chronic symptom management that cannot be managed in other settings, such as the beneficiary's home, and is intended to be short-term.²⁷ CHC is provided during a period of crisis in which a patient requires continuous care, predominantly nursing care, to achieve palliation and management of acute medical symptoms necessary to maintain the individual at home.²⁸ CHC is the most expensive level of hospice care, followed by GIP care. Routine home care is the least expensive level of hospice care, followed by respite inpatient care, which is short-term care provided to relieve the beneficiary's caregiver (e.g., family member).

Our sample contained 25 claims for which Suncoast claimed Medicare reimbursement for a level of care with a higher payment rate (i.e., GIP or CHC). Specifically, Suncoast claimed reimbursement at the GIP payment rate for 23 claims and the CHC payment rate for 3 claims.²⁹ For 20 of these 25 claims, Suncoast received Medicare reimbursement at the GIP and/or CHC payment rate; however, the associated beneficiary's clinical record did not support the need for the claimed level of care. Specifically, 17 of these claims were billed at the GIP payment rate; however, the independent medical review contractor determined that the associated beneficiaries did not have uncontrolled pain or unmanaged symptoms that could not have been

²⁵ 42 CFR §§ 418.22(b)(2) and 418.104(a).

²⁶ Definitions and payment procedures for specific level-of-care categories are codified at 42 CFR § 418.302. 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).

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

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

²⁹ The total exceeds 25 because 1 claim contained services claimed at both the GIP and CHC level of care.

managed in another setting and that these beneficiaries received care that could have been provided at home. The remaining three claims were billed at the CHC payment rate; however, the independent medical review contractor determined that the associated beneficiaries' clinical records did not support the beneficiaries being in a period of crisis that required continuous care and that the pain management provided was consistent with routine home care. For all 20 claims, the associated beneficiaries' hospice care needs could have been met if Suncoast provided services at the less expensive routine level of care.³⁰

SERVICES NOT PROVIDED

Effective for hospice services provided on or after January 1, 2016, an SIA payment will be made for social worker and registered nurse visits, when provided during a routine home care visit in the last 7 days of life. A minimum of 15 minutes (1 unit) of social worker or nursing services must be provided to receive the SIA payment.³¹ The SIA payment is in addition to payment for services provided at the routine home care payment rate.³²

For 2 of the 100 sample claims, Suncoast claimed an SIA payment for services not provided.³³ Specifically, for one claim, Suncoast claimed 12½ hours (50 units) of service intensity nursing services; however, only ½ hour (2 units) of services were provided. For another claim, 1½ hours (6 units) of service intensity nursing services were claimed for a period after the beneficiary had passed away. According to Suncoast, these errors were the result of nurses incorrectly reporting service intensity time on their timesheets.

³⁰ For 18 of the 20 claims, we questioned the difference in payment rates between GIP or CHC level of care and routine level of care. The other two claims were also questioned because the terminal prognosis was not supported; therefore, we questioned the entirety of both claims.

³¹ 80 Fed. Reg. 47142, 47175 (Aug. 6, 2015). See also, CMS's *Medicare Claims Processing Manual*, Pub. 100-04, chapter 11, § 30.2.2.

³² 42 CFR § 418.302(b)(1).

³³ For these two claims, we questioned the difference between what was claimed and what was provided.

RECOMMENDATIONS

We recommend that Suncoast Hospice:

- refund to the Federal Government the portion of the estimated \$47,363,971 for hospice services that did not comply with Medicare requirements and that are within the 4-year claims reopening period;³⁴
- based upon the results of this audit, exercise reasonable diligence to identify, report, and return any overpayments in accordance with the 60-day rule³⁵ 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.

SUNCOAST HOSPICE COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, Suncoast, through its attorney, disagreed with our recommendations and generally disagreed with our findings. Specifically, Suncoast disagreed with all but 2 of the 49 sample claims questioned in our draft report.³⁶ Accordingly, Suncoast does not believe it was overpaid for hospice services except for the two claims it agreed were in error. Suncoast acknowledged its obligations under the 60-day rule; however, it did not agree that a refund pursuant to that rule was warranted. Lastly, Suncoast did not agree with our recommendation to strengthen its policies and procedures because it believes it has robust policies and procedures, and an effective corporate compliance program to ensure that hospice services comply with Medicare requirements.

³⁴ 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.

³⁵ 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.

³⁶ Suncoast agreed with two claims that contained SIA payments and for which timesheet coding errors occurred. One claim was solely questioned for the SIA payment. The other sample claim was questioned for other reasons and Suncoast only agreed with the SIA finding. Suncoast indicated that it refunded these SIA payments; however, CMS' common working file did not indicate any adjustments were made for these two claims.

Suncoast asserted that OIG's audit is fundamentally flawed in numerous respects and, as a result, OIG's overpayment determinations are invalid. Specifically, Suncoast 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. Suncoast contended that the medical review contractor ignored patients' overall medical condition, focused on irrelevant points, and cherry-picked discrete bits of information which resulted in misleading, incomplete, and inaccurate conclusions. To further support its position, Suncoast engaged three hospice physicians who assessed the independent medical review contractor's determinations and the medical records that Suncoast submitted to OIG for each sample claim questioned in our draft report. Based on their assessments, the three physicians reported that they believed that certifications of terminal illness and the levels of care for each sample claim were supported.

Suncoast further argued that the statistical extrapolation process employed by OIG was unfounded and that statistical extrapolation was an inappropriate tool to utilize for the evaluation of hospice services because of the individualized nature of prognostication. Suncoast engaged two statistical experts, each of whom evaluated OIG's sampling and extrapolation methodologies, and claimed that, even if extrapolation was appropriate, OIG's sampling and extrapolation were not statistically valid.

Suncoast also contended that sections 1870 and 1879 of the Act provide for the waiver of alleged overpayments, even if the beneficiaries at issue were not terminally ill, as long as the provider has a reasonable basis for assuming the claims it submitted were correct. Accordingly, Suncoast believed the overpayments identified by OIG should be waived because Suncoast relied on the clinical judgments of the beneficiaries' certifying physicians; therefore, Suncoast had a reasonable basis to believe the Medicare payments were correct.

Lastly, Suncoast stated that OIG's overpayments must be reduced to offset amounts for items and services, such as durable medical equipment, pharmaceuticals, and supplies, that would otherwise be payable by Medicare had the beneficiary not elected hospice.

Suncoast's written comments, which summarized its position on our findings, conclusions, and recommendations are included as Appendix E.³⁷

After reviewing Suncoast's comments, we maintain that our findings and recommendations are valid. We also 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 Suncoast. However, we note that OIG audit recommendations do not

³⁷ Suncoast included multiple exhibits as part of its comments. These exhibits included a joint statement by the three physicians engaged by the hospice, reports related to our sampling methodology from two statistical experts, a claim-by-claim rebuttal of the findings in our draft report, and the curricula vitae of its president and chief executive officer and the three hospice physicians. Although the exhibits are not included as appendices in our final report, we considered the entirety of these documents in preparing our final report and will provide Suncoast's comments in their entirety to CMS.

represent final determinations by the Medicare program but are recommendations to Department of Health and Human Services action officials. The action official—in this case, CMS—may reexamine cases that we have recommended disallowing and determine whether an overpayment exists and if the waiver provisions cited by Suncoast apply. Lastly, we did not reduce the overpayments we identified by amounts for services that Suncoast stated would otherwise be payable by Medicare because we have no assurance that Medicare would cover these services.

MEDICARE REQUIREMENTS RELATED TO CLINICAL DOCUMENTATION

Suncoast Comments

Suncoast asserted that the clinical documentation it provided supported the associated beneficiary's terminal prognosis and the need for a higher level of care for each of the sample claims questioned in our draft report. Specifically, Suncoast stated that the independent medical review contractor's analyses were inconsistent with the fundamental tenets of hospice medicine and that its decisions failed to apply fundamental principles or to cite relevant medical literature. Further, Suncoast stated that the medical review contractor used similar boilerplate language in its determination letters, which Suncoast asserted was an indication of the contractor's failure to apply the appropriate eligibility and level of care standards and to thoroughly review the medical records provided by Suncoast. Suncoast also claimed that the medical review contractor cherry-picked discrete bits of information to support its decisions while disregarding other facts in the record that supported the beneficiaries' terminal prognosis. Lastly, Suncoast argued that the medical review process was flawed because it only included a review of 1 month of records, which does not provide a "complete medical picture" of a beneficiary's condition.

Office of Inspector General Response

Based on our review of Suncoast's comments, including its hospice experts' analyses, we maintain that the clinical records submitted by Suncoast for the sample claims questioned in our draft report did not meet Medicare requirements. In making that determination, the independent medical review contractor properly used the appropriate statutory and regulatory hospice criteria, as well as applicable Local Coverage Determination (LCD) guidelines, as the framework for its determinations. Specifically, the medical review contractor applied standards set out in 42 CFR § 418.22(b)(2), which require clinical information and other documentation that support the medical prognosis to accompany the certification and be filed in the medical record. The contractor did not cite medical literature because it audited to Medicare requirements and medical literature is not considered a Medicare requirement. Further, contrary to Suncoast's claim, the medical review contractor did not review only 1 month's worth of records. Rather, the contractor evaluated the entire medical record provided by the hospice for each sample claim to determine whether Medicare requirements were met. This included, but was not limited to, hospice election records; the initial certification of terminal illness; recertifications that covered the sample claim under review; plans of care; medication

records; physician, nurse, hospice aide, and social worker notes; hospital medical records (if applicable), and billing documents. When the medical records and other available clinical factors supported the physician's medical prognosis or the need for a higher level of hospice care, the medical review contractor made a determination that Medicare requirements were met.

MEDICAL REVIEW CONTRACTOR'S DETERMINATIONS

Suncoast Comments

Suncoast asserted that the independent medical review contractor failed to apply the appropriate standards governing hospice eligibility and that its determinations related to terminal status were inconsistent with such laws. Specifically, Suncoast stated that it was improper for the medical review contractor to deny a claim merely on the basis that there was no decline in the beneficiary's medical condition or because the beneficiary showed improvement. Suncoast further alleged that the contractor's determinations were made using the benefit of hindsight and not on the information known at the time of certification. Lastly, Suncoast claimed that the medical review contractor relied on LCDs to determine whether the beneficiary met hospice eligibility requirements and that it improperly denied a claim when the beneficiary's condition did not meet an LCD.

Office of Inspector General Response

We disagree with Suncoast's assertions that the independent medical review contractor failed to apply appropriate Medicare hospice requirements (i.e., laws and regulations) when conducting its review and that its determinations of terminal status were inconsistent with hospice coverage requirements. As previously mentioned, the medical review contractor appropriately applied the standards set out in 42 CFR § 418.22(b)(2) to determine whether terminal prognosis was supported. In those determinations, the contractor considered the certifying physician's terminal diagnosis, as well as the medical records provided by the hospice for each sample claim, guided by questions rooted in the Medicare requirements and the clinical knowledge of a licensed physician who specializes in hospice and palliative medicine and is familiar with Medicare hospice guidelines and protocols. The medical review contractor did not deny a claim because there was no decline in the associated beneficiary's medical condition or because the beneficiary showed improvement. Rather, it evaluated all clinical conditions presented in the medical records collectively to obtain an overall clinical picture of the beneficiary and based on information that was available and known at the time of certification or recertification determined whether hospice eligibility requirements were met. We acknowledge that some beneficiaries who did not meet the guidelines in the hospice LCDs may still be appropriate for hospice care based upon an individual assessment of the beneficiary's health status. Accordingly, the independent medical review contractor merely used LCD guidelines as a tool to evaluate terminal prognosis. In conclusion, it was the opinion of our medical reviewers that the documentation in the medical records did not support the terminal prognosis. Therefore, we maintain that the medical review contractor consistently and

appropriately applied Medicare hospice eligibility requirements when it determined whether the certified terminal prognosis was supported.

OFFICE OF INSPECTOR GENERAL SAMPLING METHODOLOGY

Suncoast Comments

Suncoast challenged the validity of our statistical sampling and extrapolation methodologies, engaged two statistical experts to review those methodologies and provided copies of the statistical experts' reports. The statistical experts claim that OIG's sample was not statistically valid, and that extrapolation was not appropriate for calculating hospice overpayments given the individualized nature of prognostication. Specifically, the statistical experts stated the: (1) sampling frame contained two claims that had previously been reviewed by a Medicare contractor; (2) the precision was too wide to result in a valid estimate; (3) the audit findings did not meet the high error rate criteria in CMS's *Medicare Program Integrity Manual* (MPIM) to justify the use of extrapolation; (4) the order of the sampling frame was not sufficiently documented, and as such, OIG could have manipulated its sample selection; and (5) OIG improperly excluded potential underpayments from its universe. Lastly, Suncoast's attorney cited several court cases which it believed further supported its position that extrapolation is not appropriate when determining whether services provided to hospice patients were medically necessary.

Office of Inspector General Response

After reviewing the statistical experts' reports, 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.³⁸ 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.³⁹ 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., OIG/OAS' statistical software 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

³⁸ See *Yorktown Med. Lab., Inc. v. Perales*, 948 F.2d 84 (2d Cir. 1991); *Illinois Physicians Union v. Miller*, 675 F.2d 151 (7th Cir. 1982); *Momentum EMS, Inc. v. Sebelius*, 2013 U.S. Dist. LEXIS 183591 at *26-28 (S.D. Tex. 2013), adopted by 2014 U.S. Dist. LEXIS 4474 (S.D. Tex. 2014); *Anghel v. Sebelius*, 912 F. Supp. 2d 4 (E.D.N.Y. 2012); *Miniet v. Sebelius*, 2012 U.S. Dist. LEXIS 99517 (S.D. Fla. 2012); *Bend v. Sebelius*, 2010 U.S. Dist. LEXIS 127673 (C.D. Cal. 2010).

³⁹ See *John Balko & Assoc. v. Sebelius*, 2012 WL 6738246 at *12 (W.D. Pa. 2012), *aff'd* 555 F. App'x 188 (3d Cir. 2014); *Maxmed Healthcare, Inc. v. Burwell*, 152 F. Supp. 3d 619, 634-37 (W.D. Tex. 2016), *aff'd*, 860 F.3d 335 (5th Cir. 2017); *Anghel v. Sebelius*, 912 F. Supp. 2d 4, 18 (E.D.N.Y. 2012); *Transyd Enters., LLC v. Sebelius*, 2012 U.S. Dist. LEXIS 42491 at *13 (S.D. Tex. 2012).

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 Suncoast’s attorney referenced in support of the proposition that extrapolation is inappropriate for issues of medical necessity or terminal prognosis are limited to False Claims Act cases and therefore are inapplicable to OIG audit recommendations and CMS recoveries arising from OIG audits.

As previously mentioned, we used the Recovery Audit Contractor (RAC) data warehouse prior to selecting our sample to identify claims that were under review or had previously been reviewed by a Medicare contractor and excluded any such claims from our audit (see footnote 21). Further, we marked the claims in our sampling frame within the RAC data warehouse so they would not be selected by another entity. Despite these precautions, it is always possible that we will identify additional claims that have been reviewed by another entity after selecting our sample. However, contrary to Suncoast’s assertion, there is no law or regulation that restricts OIG’s ability to review such claims for any errors not identified by earlier reviews.⁴⁰

We disagree with Suncoast’s statistical experts’ assertions that our audit precision was too wide to result in a valid estimate. Specifically, to account for the precision of our estimate, we recommend recovery at the statistical lower limit of a two-sided 90-percent confidence interval. Lower limits calculated in this manner are designed to be less than the actual overpayment in the sampling frame 95 percent of the time. The use of the lower limit accounts for the precision of our estimate in a manner that generally favors the auditee.⁴¹ In 95 percent of the cases where the lower limit is less than the actual overpayment, the provider will pay substantially less, on average, given a less precise design. Suncoast focuses on the 5 percent of cases where the provider may have to pay more to the Federal Government; however, these cases are inherently rare, and when they arise, the amount the provider may have to over-reimburse to the government tends to be small.⁴²

As Suncoast and its statistical experts noted, the MPIM requirement that a determination of a sustained or high level of payment error must be made before extrapolation applies only to

⁴⁰ Although the OIG has the authority to review such claims, our standard approach for handling such claims is to treat them as having no overpayments if they are selected in the sample. This approach ensures an unbiased point estimate and a valid lower limit.

⁴¹ E.g., see *Puerto Rico Dep’t of Health*, DAB No. 2385, at 10 (2011); *Oklahoma Dep’t of Human Servs.*, DAB No. 1436, at 8 (1993) (stating that the calculation of the disallowance using the lower limit of the confidence interval gave the State the “benefit of any doubt” raised by use of a smaller sample size).

⁴² Suncoast’s statistical expert claims that in 5 percent of samples from our design, Suncoast would have to over-reimburse the Federal Government more than double than a design with the standard 10-percent precision. We disagree with this assertion as a factual matter. The positive skew of the data makes the lower limit more conservative than would be expected given the theoretical calculations. In our own tests of the current data, we found evidence that the less precise design is more conservative, on average, even for the 5 percent of cases highlighted by the statistical expert.

Medicare contractors—not the OIG.⁴³ We further note that the statutory provisions upon which the MPIM guidelines are based do not prohibit CMS from accepting and acting upon our monetary recommendation.

Suncoast’s statistical expert’s claim that the OIG did not document the order of OIG’s sampling frame is also not correct. Our audit workpapers specifically contained detailed information on how the frame was sorted. That information was used by an auditor not part of the audit team to validate the sample selection. There was no manipulation of the sampling frame after the random sample was selected. Rather, the sampling frame was finalized prior to generating the random numbers. We also note that the sampling frame was sorted using a field in OIG’s copy of CMS’s National Claims History (NCH) file, that uniquely identifies claims.

Lastly, Suncoast’s statistical experts relied heavily on the MPIM in its arguments that the removal of zero-paid claims ignored statistical principles. As previously stated, the MPIM does not apply to OIG. However, if it did, it expressly allows for the removal of claims/claim lines that are attributable to sample units for which there was no payment.⁴⁴ More generally, OIG may perform a statistical or non-statistical review of a provider without covering all claims from that provider. Further, when an extrapolation is used, the OIG only projects to the frame from which the sample was drawn.

⁴³ See the Act § 1893(f)(3); CMS MPIM, Pub. No. 100-08, ch. 8, § 8.4 (effective January 2, 2019).

⁴⁴ CMS MPIM, Pub. No. 100-08, ch. 8, § 8.4.3.2 (effective January 2, 2019).

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

Our audit covered 38,986 hospice claims for which Suncoast received Medicare reimbursement totaling \$148,516,965 for services provided from July 1, 2015, through June 30, 2017 (audit period). These claims were extracted from CMS's NCH file.

We did not assess Suncoast's 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 fieldwork at Suncoast's office in Clearwater, Florida.

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 Suncoast officials to gain an understanding of its policies and procedures related to providing and billing Medicare for hospice services and reviewed those policies and procedures;
- obtained 39,040 hospice claims totaling \$148,700,614,⁴⁵ from the CMS NCH file, for the audit period;
- excluded 54 claims, totaling \$183,649, that were identified in the RAC data warehouse as having been reviewed by another party;
- created a sampling frame consisting of 38,986 hospice claims, totaling \$148,516,965;
- selected a random sample of 100 hospice claims from the sampling frame;
- reviewed data from CMS's Common Working File and other available data for the sampled claims to determine whether the claims had been canceled or adjusted;

⁴⁵ We excluded claims that were zero-paid; however, an individual line can have a zero payment.

- worked with Palmetto to identify the date the NOEs were submitted for each sampled claim and determined the timeliness of the submission;
- obtained medical records for the 100 sampled claims and provided them to an independent medical review contractor, who determined whether the hospice services complied with Medicare requirements;
- reviewed the independent medical review contractor's results and summarized the reason(s) a claim was determined to be improperly reimbursed;
- estimated the amount of the improper Medicare payments made to Suncoast for hospice services; and
- discussed the results of our audit with Suncoast 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 generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

APPENDIX B: RELATED OFFICE OF INSPECTOR GENERAL REPORTS

Report Title	Report Number	Date Issued
<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 38,986 Medicare Part A reimbursed claims, totaling \$148,516,965, for hospice services provided by Suncoast from July 1, 2015, through June 30, 2017.⁴⁶ 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 simple random sample.

SAMPLE SIZE

We selected a sample of 100 Medicare Part A hospice claims.

SOURCE OF THE RANDOM NUMBERS

We generated the random numbers with the OIG/OAS statistical software.

METHOD FOR SELECTING SAMPLE ITEMS

We consecutively numbered the hospice claims in 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 Suncoast for unallowable hospice services 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.

⁴⁶ The sampling frame excludes zero-paid claims and claims that were identifiable in the RAC data warehouse as having been reviewed by another party.

APPENDIX D: SAMPLE RESULTS AND ESTIMATES

Sample Details and Results

Number of Claims in Frame	Value of Frame	Sample Size	Value of Sample	Number of Unallowable Claims	Value of Overpayments in the Sample
38,986	\$148,516,965	100	\$379,758	49	\$155,260

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

Point Estimate	\$60,529,542
Lower Limit	\$47,363,971
Upper Limit	\$73,695,112

APPENDIX E: SUNCOAST HOSPICE COMMENTS

HUSCH BLACKWELL

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November 18, 2020

VIA ELECTRONIC FILING

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

Re: The Hospice of the Florida Suncoast, Inc. d/b/a Suncoast Hospice
A-02-18-01001

Dear Ms. Tierney:

The Hospice of the Florida Suncoast, Inc. d/b/a Suncoast Hospice (“Suncoast”) appreciates 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: Suncoast* (“Draft Report”). Suncoast’s comments to the Draft Report, including the report’s conclusions and recommendations, are set forth below.¹

INTRODUCTION

Suncoast is a historic and exemplar non-profit hospice that serves a large aging community in Florida. Its leadership team is highly experienced in hospice care and active in the industry, having assisted with shaping the Medicare hospice benefit. The Draft Report is both disappointing and at odds with Suncoast’s history and leadership, as well as its comprehensive policies and procedures and corporate compliance program, all of which are shown to be effective by data compiled by the federal Centers for Medicare & Medicaid Services (“CMS”). From a scant review of only 0.26% of the claims for payment that Suncoast submitted to Medicare over a two-year period, each representing only one month or less of services for certain

¹ This letter and Exhibits 1-5 and 51-54 do not include any protected health information (“PHI”), and therefore we ask that they be attached as an appendix to the OIG’s final audit report once it is made public. Exhibits 6-50 and 55 do contain PHI, and we ask that these exhibits not be included within the publicly available version of the OIG’s final audit report.

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Medicare beneficiaries, the OIG has concluded that Suncoast received an alleged overpayment of \$47,363,971. This conclusion resulted from a review of patient medical records by a Medical Review Contractor retained by the OIG to assess whether Suncoast admitted patients who qualified for hospice, *i.e.*, had a medical prognosis that his or her life expectancy is 6 months or less if the illness runs its normal course, and whether those patients were afforded the appropriate level of care. This conclusion was made using a review process that failed to adhere to the law and standards of practice.

Suncoast engaged three renowned hospice physicians to evaluate its patient records and the OIG's Medical Review Contractor's assessments of the claims at issue. These expert hospice physicians have confirmed that Suncoast's patient records supported the reasonable clinical judgments of the Suncoast physicians who certified the patients at issue were eligible for hospice and who determined each patient's appropriate level of hospice care. Significantly, these expert hospice physicians expressed deep concern over the clear lack of understanding of hospice eligibility reflected in the OIG's Medical Review Contractor's decisions. The Contractor's summaries are misleading, incomplete, focus on irrelevant data points, and, most importantly, fail to provide any explanation regarding how those data points relate to each patient's prognosis. As detailed in these comments, the Medical Review Contractor clearly disregarded numerous hospice principles set out in CMS guidance documents.

The OIG's Medical Review Contractor also failed to apply the appropriate standards for assessing patient eligibility established by the U.S. Court of Appeals for the Eleventh Circuit in *United States v. AseraCare, Inc.*² Specifically, the *AseraCare* court explained that a certifying hospice physician's eligibility determination is clinically deficient *only* if no reasonable physician, applying his or her clinical judgment, could have concluded that the patient was eligible for the Medicare hospice benefit.³ Nothing within the Medical Review Contractor's decisions make this necessary showing. Rather, the Medical Review Contractor merely cherry-picked discrete bits of information to rationalize its decisions while ignoring the patients' overall medical condition, contrary to federal law and the standards of care and practice recognized by the medical community. Contrary to *AseraCare*, the OIG's Medical Review Contractor failed to give *any* deference to the certifying hospice physicians, resulting in the unsupported conclusion that the clinical determinations made by more than 50 different physicians, many of whom have over a decade of hospice experience and are Board-certified in Hospice and Palliative Care Medicine, were wrong. This illogical result is possibly explained by the flawed review process.

² 938 F.3d 1278 (11th Cir. 2019)

³ Although *AseraCare* arose under the False Claims Act, the Eleventh Circuit acknowledged in its decision that its "primary task on appeal [was] to clarify the scope of the hospice eligibility requirements, which are set out in the federal Medicare statute" and its implementing regulations. *Id.* at 1291. Accordingly, this standard governs all applications of the Medicare hospice eligibility laws and regulations, including applications in OIG's audit, and is not limited to False Claims Act cases.

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As explained in these comments, the process used by the OIG to evaluate medical necessity may work well for most Medicare items or services, but it is incompatible with hospice services.

Likewise, the statistical extrapolation process employed by the OIG to convert its review of less than one-half of one percent of Suncoast's claims to an overpayment totaling tens of millions of dollars is unfounded. Statistical extrapolation is an inappropriate tool to utilize for the evaluation of the practice of hospice medicine because of the individualized nature of prognostication. Even if extrapolation were appropriate, the sampling and extrapolation in this matter have been determined by two expert statisticians to be invalid for a number of reasons, any one of which warrants the OIG's reconsideration of its use of the sampling and extrapolation to determine the estimated overpayment.

The Social Security Act ("Act") also supports waiver of the overpayments in this case pursuant to federal law because Suncoast submitted the claims at issue in reliance on the clinical judgments of the certifying physicians, which are not shown by the OIG's Medical Review Contractor's summaries to be unreasonable. Lastly, the Draft Report does not include a required offset based on items and services for which there is no dispute regarding medical necessity, such as durable medical equipment, pharmacy, radiology, labs, and Medicare is required to cover regardless of whether the patient was terminally ill.

Overall, the Draft Report will significantly decrease beneficiary access to the hospice benefit if it is not reconsidered and revised. If hospices and physicians were to use the criteria and standards used by the OIG's Medical Review Contractor, it will mean some of the most vulnerable Medicare beneficiaries will not be able to access hospice care until they are showing signs and symptoms of actively dying, which is directly contrary to the intent of Congress and CMS.⁴ Hospice was intended to provide patients believed to be in their last six months of life comprehensive treatment to manage their symptoms in an effort to maintain their (and their families') quality of life, dignity, and peace. Beneficiaries should not suffer and be denied access to such care as a result of an ill-fitted audit process carried out by an unidentified reviewer whose qualifications and experience are in serious doubt.

In light of the foregoing, and as discussed in detail below, the OIG's audit is fundamentally flawed in numerous respects and, as a result, its overpayment determination is invalid. For these reasons, we respectfully request that the OIG reconsider the claim decisions and the conclusions made in the Draft Report.

⁴ CMS revised the hospice regulations in 1990 to *encourage* physicians to certify *more* patients for hospice. See 55 Fed. Reg. 50832 (Dec. 11, 1990); see also GAO, *Program Provisions and Payments Discourage Hospice Participation* (Sept. 29, 1989), available at <http://gao.gov/products/HRD-89-111>.

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BACKGROUND INFORMATION ON SUNCOAST

Information concerning Suncoast, the steps Suncoast takes to ensure compliance with Medicare hospice requirements, and the quality of care provided by Suncoast comprises appropriate context for the OIG's conclusions and recommendations. This context, including Suncoast's commitment to patient care and its robust and demonstrably effective compliance program, reveals the OIG's conclusions and recommendations to be anomalous and suspect.

I. Suncoast's History and Leadership Demonstrate its Devotion to Providing Top Quality and Compliant Hospice Care

Suncoast is a non-profit hospice that was first formed by a group of volunteers in 1977 under the name Elisabeth Kubler-Ross Hospice, Incorporated. As one of the first non-profit hospices formed in the United States, Suncoast is a leader in the industry. Having been established before the Medicare hospice benefit even existed, Suncoast and its leaders were active in the development and refinement of the Medicare hospice benefit. Today, Suncoast is a member of Empath Health, Inc. ("Empath Health"), a non-profit corporation formed in 2008. Suncoast continues to be an essential and active member of its community that offers end-of-life care to both adults and children. It has two satellite offices along with three inpatient units in Pinellas County, Florida, which has a population of nearly one million and is a part of the Tampa Bay-St. Petersburg-Clearwater metropolitan statistical area. Suncoast's average daily census is 1,211, and it employs over 1,000 employees. In addition to offering hospice care through Suncoast, Empath Health offers extensive HIV/AIDS services, a Program for All-Inclusive Care for the Elderly (PACE), home health care, palliative care, community counseling, and advance care planning. Suncoast provides these services regardless of a patient's ability to pay.

As a non-profit corporation, Suncoast is governed by a Board of Directors, led by Mr. Benjamin Hayes. The current Vice Chairperson, Ms. Martha Lenderman, M.S.W., is the former president of the Area Agency on Aging of Pasco-Pinellas, Inc., and a renowned expert on the Florida Mental Health Act. The Board Treasurer is Mr. Charles (Clay) Whetstone, a C.P.A. There are 12 other local community leaders and professionals on the Board, all of whom take seriously their obligations as board members to actively monitor and engage in Suncoast's extensive efforts to provide quality care in compliance with all state and federal laws.

The President and Chief Executive Officer of Empath Health and Suncoast is Mr. Rafael J. Sciuillo.⁵ Mr. Sciuillo has 34 years of experience in end-of-life care, having worked with state, regional, and national legislators to shape public policy to improve care for the dying. Mr. Sciuillo is past chairperson and current board member of the National Hospice and Palliative Care Organization (NHPCO). He was awarded the NHPCO's Founder's Award, which recognizes "an individual of national or international stature with longevity and inspiration in the hospice movement who has evidenced a pioneer spirit in opening the frontier of healthcare and hospice."

⁵ See **Exhibit 1**, Curriculum Vitae of Mr. Rafael J. Sciuillo.

He was one of the founders of the Institute to Enhance Palliative Care, which was formed in collaboration with the University of Pittsburgh to improve access to and quality of palliative care in Pennsylvania. Similarly, Empath Health's full-time Ethics and Compliance Officer, Ms. Laura Mosby, LCSW, has been actively involved with hospice and end-of-life care for the past 28 years, is a certified Hospice Administrator, and is a member of NHPCO's Regulatory Committee.

II. Suncoast's Quality of Care, Policies and Procedures, and Compliance Program

Suncoast provides exemplary and compliant care to its patients, evidenced by its survey history, its accreditation by The Joint Commission, and its ratings from the family caregivers' survey and Hospice Item Set (HIS). Suncoast is regularly surveyed by the Florida Agency for Health Care Administration (AHCA), the agency in Florida that licenses hospices, which is also the state survey agency for the Centers for Medicare and Medicaid Services ("CMS"). Suncoast had *no* deficiencies cited during any of the 10 surveys conducted by AHCA between December 2013 to January 2020, which includes the time period under review. Suncoast has also been continuously accredited by The Joint Commission since 2014. With respect to the family caregivers' survey, Suncoast's overall rating and the caregivers' willingness to recommend Suncoast are above the national average. Suncoast is also above the national average on the quality of care measures identified on the CMS Hospice Compare web site.

In addition to providing high quality care, Empath Health has robust and effective policies and procedures and corporate compliance program. Copies of Suncoast's policies and procedures were provided to the OIG, and the OIG confirmed during its exit interview that it had not identified any particular flaw or problem with them. The Draft Report similarly does not identify any specific policy or procedure that is improper or requires modification. Rather, the Draft Report generally indicates Suncoast's policies and procedures were ineffective, despite the OIG's own statements to the contrary and data *confirming* the policies are effective.⁶ Empath Health's policies and procedures thoroughly address admission criteria and the certification process. These policies and procedures do not include any incentives to the staff or physicians, most of whom are Board-certified in Hospice and Palliative Care Medicine, for the number of certifications or recertifications. Further, the policies and procedures clearly identify steps to be taken should a patient not meet the admission criteria.

⁶ The OIG's position in the Draft Report appears to result from the conclusions of the Medical Review Contractor. In other words, the OIG has concluded that there must be something wrong with Suncoast's policies and procedures because the Medical Review Contractor found reason to deny or downcode certain claims. The OIG ignores the more likely explanation: the Medical Review Contractor denied or downcoded claims because the Medical Review Contractor failed to properly apply basic tenets of hospice medicine in a manner consistent with the Medicare hospice benefit. See Exhibit 2, Joint Statement of Dr. Joan Harrold, Dr. Edward W. Martin, and Dr. John Mulder Regarding the OIG's Audit of Hospice of the Florida Suncoast, Inc.

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The effectiveness of the hospice's policies and procedures and compliance program are demonstrated by CMS's PEPPER reports. PEPPER⁷ reports provide statistics for key markers used to identify questionable billing practices so that hospices may target and improve problematic areas. The reports include data on live discharges, long lengths of stay,⁸ and top five diagnoses. For all of the target areas covered in the reports, Suncoast has been far below the percentile that CMS deems a high risk for improper payments (the 80th percentile). In fact, with respect to long lengths of stay, Suncoast's most recent PEPPER report⁹ shows that only 10.8% of its patients had a long length of stay, putting Suncoast in the 22.7 percentile nationwide. This means 77.3% of hospices nationwide have a higher percentage of patients with long lengths of stay as compared to Suncoast. For the time period covered by the OIG's review, there were very similar percentages of patients with long lengths of stay (only 11.8% in FY 2016 and 10.8% in FY 2017). In other words, the PEPPER reports reflect Suncoast surpasses most other hospices with respect to accurate prognostication.

Beyond its policies and procedures, Suncoast has taken steps to ensure compliance with the various Medicare requirements including the accuracy of eligibility and level of care determinations. Employees are regularly educated regarding eligibility and documentation requirements, and clinical employees receive annual competency reviews. Education plans are developed as needed to assure clinical competency. To ensure appropriateness of higher levels of care, such as General Inpatient ("GIP"), the patient is assessed daily by a physician or nurse practitioner. Any patient remaining at a GIP level of care for longer than five days is evaluated by the inpatient unit's leadership team. Suncoast, as a non-profit, has implemented these measures to be effective stewards of the federal funds it receives for its patients.

Empath Health's compliance program is a safety net ensuring the effectiveness of these policies, procedures, and practices. In addition to its full-time compliance officer, Empath Health has an Ethics and Compliance Committee and Program Integrity Committee, made up of multiple disciplines, which meet quarterly to provide oversight and direction on regulatory requirements. Empath Health's Ethics and Compliance Plan is consistent with the OIG's guidance¹⁰ and memorializes the commitment of Suncoast's Board of Directors, Ethics and Compliance Officer, Ethics and Compliance Committee, and all hospice staff to actively participate and uphold the hospice's commitment to compliance.¹¹ Employees are routinely educated regarding the Ethics and Compliance Plan, and they are provided with a hotline number

⁷ Program for Evaluating Payment Patterns Electronic Report ("PEPPER").

⁸ Long Length of Stay patients are those whose combined days of service is greater than 180 days.

⁹ For federal fiscal year ("FY") 2019 (October 1, 2018 to September 30, 2019).

¹⁰ See OIG, Compliance Guidance, <http://oig.hhs.gov/compliance/compliance-guidance/index.asp>.

¹¹ For example, in responding to the OIG's audit, Suncoast learned of a systems error that created minor Service Intensity Add-on ("SIA") overpayments for some patients. After investigating the issue, an error in the timesheet coding was discovered and voluntary refunds were made to Suncoast's Medicare Administrative Contractor ("MAC"). These voluntary refunds included repayment of the SIA payments received for Patients #30 (\$138.15) and #56 (\$55.26). Additionally, Suncoast's corporate compliance officer provided focused reeducation to ensure the timesheet coding error did not reoccur.

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to report concerns. Suncoast’s Hospice Medical Director and the compliance department routinely perform internal audits focusing on a broad array of clinical situations, such as reviews of patients with long lengths of stay, patients with certain diagnoses, or patients requiring higher levels of care.

Suncoast recognizes that, like most providers, it is not infallible. However, Suncoast’s background, leadership, policies and procedures, corporate compliance program, and culture of compliance make it apparent that any issues that occur are aberrant and far from widespread. The OIG’s conclusion to the contrary ignores Suncoast’s background, policies, and practices and is indicative of an overzealous medical review contractor with limited or no experience with hospice care. If OIG’s conclusion were correct, it would mean that the clinical judgment of over 50 different certifying physicians, who personally treated the patients, was incorrect. Such conclusion lacks credibility when considering the foregoing information.

RESPONSE TO THE OIG’S DRAFT REPORT

I. Summary of the Draft Report

In this audit, the OIG reviewed a very narrow snapshot of Suncoast’s overall operations. As a part of its audit, the OIG selected a random sample of 100 claims out of the 38,986 claims submitted by Suncoast for the time period of July 2015 to June 2017, which represents 0.26% of the claims submitted by Suncoast for that time period. The 100 claims selected by the OIG were associated with only one month (or less) of hospice services provided to 100 different hospice patients. During that time period, Suncoast provided hospice care to over 11,743 Medicare beneficiaries and received \$148,516,965 in Medicare reimbursement.

After requesting and receiving records from Suncoast for these 100 patients for this one month or less of service, the OIG then had its Medical Review Contractor review the records. The OIG’s Medical Review Contractor determined that 51 of the claims reviewed met all Medicare requirements, while 49 of the claims did not. Of those 49 claims, 30 were denied because the Medical Review Contractor concluded that records accompanying the properly signed physician certification or recertification did not support the medical prognosis of a terminal illness; 17 were downcoded from GIP to the routine home care level of care because, although the patient was clinically eligible for hospice services, the Medical Review Contractor concluded that the documentation did not support the GIP level of care; one was partially denied because the Medical Review Contractor concluded that the service intensity add-on payment was not supported; and one was partially denied and downcoded because the Medical Review Contractor concluded that the GIP level of care and service intensity add-on were not supported.

The OIG extrapolated the error rate for the sample of claims determined by its Medical Review Contractor to the entire universe of claims submitted by Suncoast 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 Suncoast received approximately \$47,363,971 in improper payments. Nothing in the

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Draft Report suggests that Suncoast 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 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 that hospice services comply with Medicare requirements. In the next sections of this letter, Suncoast provides its analysis of the Draft Report and then responds to these recommendations.

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

A. The Clinical Documentation for the Claims Reviewed by the Medical Review Contractor Met All Requirements.

Suncoast provided properly signed and clinically supported physician certifications and recertifications for each patient whose claim was denied by the Medical Review Contractor. Suncoast also provided documentation demonstrating that the patients who received a higher level of hospice care in fact required that level of care. Highly trained and experienced physicians signed these certifications and made level of care determinations using their clinical judgment, basing their judgment on the patients' conditions. This case involves rejection of the clinical judgment of over *50 different certifying physicians* who personally treated the patients at issue. Many of these physicians have worked in hospice for years and are Board-certified in Hospice and Palliative Care Medicine, and rejecting these certifications impugns their expertise and reputation.

Suncoast engaged three independent, highly experienced, and renowned hospice physicians, Drs. Joan Harrold, Edward Martin, and John Mulder, who are Board-certified in Hospice and Palliative Care Medicine, to further analyze the Medical Review Contractor's findings and conclusions.¹² These physicians re-assessed the medical records and confirmed, as set forth in the individual patient responses included with this letter ("Patient Response Summaries"),¹³ that the certifications of terminal illness and the levels of care for those patients were supported by the medical records. These conclusions by these three expert physicians are supported by their extensive experience with hospice, as well as peer-reviewed medical literature, to which they cite in the Patient Response Summaries.¹⁴

¹² See Exhibits 3, 4, and 5, Curricula Vitae of Drs. Harrold, Martin, and Mulder, respectively.

¹³ See Exhibits 6-50. These exhibits are comprised of Suncoast's responses to the bases for the OIG's claim denials. Following each Patient Response Summary is a copy of the medical records previously produced to the OIG, which are now paginated for purposes of citation. Some of the exhibits also include additional medical records that were not previously produced to the OIG. Exhibit 55 details which records are newly produced with this letter.

¹⁴ Approximately 47 different medical articles were cited by these three expert physicians throughout their Patient Response Summaries including the following: Bradbury K. Understanding the Relation between BMI and

The Medical Review Contractor's decisions for these patients, on the other hand, are not supported by the medical records, fail to apply fundamental principles of hospice medicine as recognized by the medical community, and fail to include citation to any relevant medical literature. The Medical Review Summaries use the same or similar boilerplate language for each claim at issue, which is indicative of the Contractor's failure to apply the appropriate eligibility and level of care standards and thoroughly review the medical records provided by Suncoast. This approach evidences a results-oriented outcome approach in which the Contractor cherry-picked discrete bits of information to support its denials while disregarding other facts in the record supporting the patients' terminal prognoses. Drs. Harrold, Martin, and Mulder have provided a Joint Physician Statement expressing their deep disappointment and concern over the clear lack of understanding of hospice eligibility reflected in the Medical Review Summaries.¹⁵ In their Joint Physician Statement, these hospice physicians detail how the analyses provided by the Medical Review Contractor are inconsistent with the standard of practice, undermine the purpose of hospice care, and are antithetical to the hospice benefit. The physicians describe how the Medical Review Contractor repeatedly contradicted themselves and ignored key clinical data in favor of irrelevant factors. The Medical Review Contractor's lack of understanding is best shown through the following examples:

- Patient #54 – The Medical Review Contractor determined Patient #54 was not eligible for hospice services for the month of service under review, which was during Patient #54's first benefit period. Dr. Mulder strongly disagreed after a thorough review of Patient #54's medical record, which demonstrated that this 82-year-old with metastatic pancreatic cancer had a terminal prognosis during this period. Medical literature, cited

Mortality. *BMJ* 2019;364:11219; Brown MA, Sampson EL, Jones L. and Barron EM, Prognostic indicators of 6-month mortality in elderly people with advanced dementia: A systematic review. *Palliat Med.* 2012;27(5):389-400; Jayes R, Arnold R, Fromme E. Does This Dementia Patient Meet the Prognosis Eligibility Requirements for Hospice Enrollment? *J Pain Symptom Manage.* 2012;44(5):750-756; Heyman A, Wilkinson WE, Hurwitz BJ, Helms MJ, Haynes CS, Utley CM, Gwyther LP. Early-onset Alzheimer's disease: clinical predictors of institutionalization and death. *Neurology* 1987;37(6):980-984; Harris P, Stalam T, et al. Can Hospices Predict which Patients Will Die within Six Months? *J Palliat Med.* 2014;17(8):894-898; Mitchell SL, Miller SC, Teno JM, et al. Prediction of 6-Month Survival of Nursing Home Residents With Advanced Dementia Using ADEPT vs Hospice Eligibility Guidelines. *JAMA* 2010;304(17):1929-1935; Mitchell SL, Miller SC, Teno JM, et al. The Advanced Dementia Prognostic Tool: A Risk Score to Estimate Survival in Nursing Home Residents with Advanced Dementia. *J Pain Symptom Manage.* 2010;40(5):639-651; Mitchell SL, Teno JM, Kiely DK et al. The clinical course of advanced dementia. *N Engl J Med.* 2009;361(16):1529-38; Morrison RS, Siu AL. Survival in end-stage dementia following acute illness. *JAMA* 2000;284(1):47-52; Myers J, Kim A, Flanagan J, Selby D. Palliative performance scale and survival among outpatients with advanced cancer. *Support Care Cancer.* 2015;23(4):913-918; Deeb A, Haque S, Olowokure O. Pulmonary metastases in pancreatic cancer, is there a survival influence? *J Gastrointest Oncol.* 2015;6(3):E48-E51; Sud M, Tangri N, Pintilie M, et al. Progression to Stage 4 chronic kidney disease and death, acute kidney injury and hospitalization risk: a retrospective cohort study. *Nephrol Dial Transplant.* 2016;31(7):1122-1130; Kim AS, Youn CH, Ko HJ, Kim HM. The survival time of terminal cancer patients: Prediction based on clinical parameters and simple prognostic scores. *J Palliat Care* 2014;30(1):24-31; Smith K, Greenwood C. Weight Loss and Nutritional Considerations in Alzheimer Disease. *J Nutr Elder.* 2008;27(3-4):381-403.

¹⁵ See Exhibit 3.

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by Dr. Mulder in his summary of Patient #54, supports this position, indicating that metastatic cancer like Patient #54's has a quick and certain terminal trajectory between 3.5 and 6 months. This timeframe is likely shorter for someone with the multiple comorbid and secondary conditions Patient #54 suffered, such as hypertension, atrial fibrillation, a cardiac pacemaker, and dementia. The Contractor, however, relied on factually false and immaterial factors in finding Patient #54 not eligible. For example, the Contractor asserted the patient had "no evidence of metastasis," which is directly contradicted in the medical record. Likewise, Dr. Mulder determined the Contractor's focus on Patient #54's lack of decubitus ulcers, delirium, impaired appetite, or reduced hydration, ignored the terminal nature of this patient's advanced disease. Dr. Mulder concluded that the Contractor's unfavorable decision "is medically insupportable."

- Patient #10 – The Medical Review Contractor determined Patient #10 was not eligible for the 13-days of service under review, which included the patient's admission to hospice. However, Dr. Harrold determined that Patient #10 had a terminal prognosis during these dates of service and was appropriately certified. Patient #10 was a widower over 89 years old with a primary diagnosis of nutritional deficiency and who suffered from multiple comorbidities, including coronary artery disease, atrial fibrillation, dementia, and an ileocecal mass. Patient #10 had a significant fall earlier in the year that resulted in a hospitalization and had lost 21 pounds (13.6% total body weight), in the months leading up to the hospice admission, due in part to a declining appetite. The patient was also dependent on all activities of daily living and had a Palliative Performance Scale ("PPS") score of just 30%. The Contractor provided just five irrelevant and/or inaccurate rationale points for its unfavorable decision, including that Patient #10's Functional Assessment Staging ("FAST") score was only 6E, even though Patient #10 did not have a primary diagnosis of Alzheimer's disease (rendering the FAST tool inappropriate). Ultimately, Dr. Harrold concluded that it was "inconceivable" that Patient #10 would not be found eligible for hospice care, considering the patient's diagnosis, history, and condition on admission.
- Patient #17 – The Medical Review Contractor determined Patient #17, a 69-year-old with metastatic lung cancer and unilateral vocal cord paralysis, was not eligible for the GIP level of care received during the month under review. Patient #17 was admitted to hospice at the GIP level of care directly from the hospital after a multi-day stay, as contemplated by CMS guidance. While in the hospital, it was found that Patient #17's cancer had spread to the liver, that the patient had bilateral pleural effusions resulting in 1150 cc of fluid being drained from the lungs, and the patient had a poor appetite, episodes of vomiting, and lethargy. The patient was admitted to GIP at 10:00 pm and passed away just two hours later, at 12:00 am the next day. In the two hours spent on GIP, Patient #17 required close monitoring and multiple doses of medication, including morphine for dyspnea, sublingual Ativan for anxiety, and an injection of Haldol. Based on his review of Patient #17's medical record, Dr. Martin concluded that the initiation of

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GIP services following Patient #17's hospitalization and the hospice physician's life expectancy projection of hours to days were appropriate. Dr. Martin further opined that routine home care would have resulted in "unnecessary suffering" for Patient #17 given the patient's discomfort and symptoms while in the hospital and upon admission.

The irrationality of the above-referenced claim denials is perhaps explained by the flawed review process. Suncoast's three expert physicians have expressed concern with the OIG's process of reviewing only one month of records for each hospice patient. Reviewing documents supporting a single claim may be appropriate for auditing the medical necessity of a single item or service, but it is not well suited for hospice, which involves prognostication of life expectancy based on the patient's "complete medical picture"¹⁶ and ongoing, multidisciplinary treatment. Conducting a limited review of only one month of a hospice patient's records does not provide a "complete medical picture" of the patient's condition to allow for prognostication within the standard of practice. Drs. Harrold, Martin, and Mulder confirm this in their Joint Physician Statement. Although they believe the records reviewed by the Medical Review Contractor adequately supported the patients' eligibility and level of care, there were records outside the time period that bolstered those conclusions. Compounding this issue is the fact that this limited review was performed by someone whose name and credentials are unknown to the OIG.

Taking into consideration the clinical judgment of the original certifying physicians, the attached Patient Response Summaries prepared by Drs. Mulder, Martin, and Harrold, and the Joint Physician Statement from these three physicians, it is apparent there are flaws in the process used by the Medical Review Contractor, which warrants reconsideration of the OIG's audit process, claim denials, and conclusions made in the Draft Report.

B. The Medical Review Contractor's Denials Are Inconsistent with the Law and Guidance Concerning the Medicare Hospice Benefit.

The Medical Review Contractor's determinations regarding the terminal status of the patients at issue are inconsistent with the law governing hospice services and hospice eligibility determinations. As described below and in the attached Patient Response Summaries, which were prepared by Drs. Mulder, Martin, and Harrold, the Medical Review Contractor's determinations failed to follow the *appropriate* standards and principles governing hospice eligibility. When applying the correct standards for eligibility under the Medicare hospice benefit, it is clear that the beneficiaries were eligible, and the level of care was appropriate.

¹⁶ See *AseraCare*, 938 F.3d at 1293; 42 C.F.R. sec. 418.102(b).

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1. The Medical Review Contractor Failed to Apply Many of the Well-Established Hospice Principles.

The Draft Report is inconsistent with many well-established hospice principles, including the following:

a. Terminality does not require a decline in condition.

The absence of decline during a benefit period, in itself, is not a proper reason to conclude that a beneficiary does not have a terminal illness.¹⁷ CMS has “also acknowledge[d] that at recertification, not all patients may show measurable decline.”¹⁸ Based on CMS guidance, a federal district court has excluded proposed expert testimony that would have claimed that a patient must show decline to remain eligible for hospice.¹⁹ Despite this well-established principle, the OIG’s Medical Review Contractor repeatedly denied a patient’s eligibility based on the fact that the patient had not declined.²⁰ This basis for denial is contrary to the position of CMS and what the court in *Vista Hospice Care* identified as the appropriate interpretation of the hospice benefit. Moreover, some of these patients *actually declined*, but the reviewer still denied their eligibility because the decline was slow or not “significant.” For one patient, the reviewer stated: “Patient had a slow progressive decline without major complications.”²¹ For another patient, the reviewer stated the patient “had some functional decline but remained ambulatory.”²² A patient with cancer was denied because her “tumor [was] very slow growing.”²³ So, even if decline were required, these patients did experience decline during the denied dates of service, as detailed in the Patient Response Summaries. Therefore, as a matter of law, claim denials based merely on the absence of decline are improper. Moreover, as a matter of fact, claim denials based on the absence of decline, *when there actually was decline*, are improper as well.

¹⁷ See *Vista Hospice Care*, No. 3:07-CV-00604-M, 2016 WL 3449833, at *16 (N.D. Tex. June 20, 2016); *Bethany Hospice Servs. of W. Pa. v. Dep’t of Pub. Welfare*, 88 A.3d 250, 255 (Pa. Commw. Ct. 2013) (describing “decline” as “an additional requirement over and above the factual question of whether a patient is terminally ill.”). See also Palmetto GBA, Hospice Coalition Questions and Answers (Sept. 23, 2008) (affirming comments in November 14, 2006 Hospice Coalition and stating that “[t]here is no requirement that ‘significant documented decline’ must be included” to substantiate that a patient has a terminal prognosis of six months or less).

¹⁸ Medicare Program; Hospice Wage Index for Fiscal Year 2010, 74 Fed. Reg. 39384, 39399 (Aug. 6, 2009).

¹⁹ *Vista Hospice Care*, 2016 WL 3449833, at *15 (citing Medicare Program; FY 2015 Hospice Wage Index and Payment Rate Update; Hospice Quality Reporting Requirements and Process and Appeals for Part D Payment for Drugs for Beneficiaries Enrolled in Hospice, 79 Fed. Reg. 50452, 50471 (Aug. 22, 2014)) (“The Court also would not allow Dr. Steinberg to make statements regarding the standards for hospice eligibility that are belied by the record. Thus, the Court would not permit [the relator’s expert] to say that a patient must show measurable decline in order to remain eligible for the [Medicare Hospice benefit]”).

²⁰ See OIG Medical Review Summary for Samples #37, 39, 51, 54, 59, 72, 82, 87, 89, and 94.

²¹ See OIG Medical Review Summary for Sample #37.

²² See OIG Medical Review Summary for Sample #54.

²³ See OIG Medical Review Summary for Sample #34.

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b. Patient improvement or stabilization does not disqualify a person from the hospice benefit.

CMS has long recognized that apparent improvement in an individual's symptoms may not mean that the individual's *prognosis* has improved.²⁴ Hospices treat the whole person using a multidisciplinary approach, which often results in an improvement or stabilization of symptoms. CMS has thus acknowledged that it can be difficult to distinguish a sustainable stabilization in a patient's condition from the *impression* of stabilization that could not be maintained by the patient if discharged from hospice. This point was reaffirmed in *AseraCare*, discussed *infra*, where the court acknowledged that, because predicting life expectancy is not an exact science, the Medicare framework recognizes that "patients with an initial prognosis of terminality can improve over time" without losing their right to coverage.²⁵

Here, however, the Medical Review Contractor improperly denied claims based on patients' purported improvement or stabilization.²⁶ For example, the Contractor denied patients whose weight remained stable or had improved based on interventions implemented by Suncoast.²⁷ Such factors are not proper to deny patients access to the hospice benefit. Furthermore, relying on improvement or stabilization of a patient's symptoms effectively punishes the hospice for providing good care.

c. Denials relying on the benefit of hindsight must be overturned.

It is clear that the Medical Review Contractor improperly made clinical eligibility determinations using the benefit of hindsight, rather than evaluating the records from the perspective of the hospice at the time the care was provided. The applicable regulation and Medicare Benefit Policy Manual make clear that the certification of a patient's eligibility for hospice must be based on the patient's medical records or examination of the patient *at the time of the certification*.²⁸ Several court cases have overturned denials related to eligibility for certain Medicare benefits that "impermissibly relied on the benefit of hindsight, which of course is always 20-20."²⁹ For example, when Medicare contractors denied skilled nursing care because the records showed the patient was stable throughout the certification period, courts overturned the denials because "[t]he services must...be viewed from the perspective of the condition of the

²⁴ 70 Fed. Reg. at 70540; *see also* 79 Fed. Reg. at 50471.

²⁵ *AseraCare*, 938 F.3d at 1282.

²⁶ *See* OIG Medical Review Summary for Samples #7, 11, 29, 33, 37, 48, 51, 52, 55, 60, 65, 72, 77, and 91.

²⁷ *See* OIG Medical Review Summary for Samples #29 and 55.

²⁸ *See* 42 C.F.R. § 418.22(b)(3)(iii); *see also*, CMS, Medicare Benefit Policy Manual, CMS Pub. No. 100-02, Ch. 9, § 20.1.

²⁹ *See Folland On Behalf of Smith v. Sullivan*, No. 90-348, 1992 WL 295230, at *7 (D. Vt. Sept. 1, 1992); *see also*, e.g., *Jimmo v. Burwell*, No. 5:11-CV-17, 2016 WL 4401371, at *12 (D. Vt. Aug. 17, 2016); *Anderson v. Sebelius*, No. 5:09-CV-16, 2010 WL 4273238, at *7 (D. Vt. Oct. 25, 2010). The *Jimmo* case involved a class action lawsuit filed against the Secretary challenging denials of skilled care based on use of a covert "rule of thumb" standard that required beneficiaries have restorative potential in order to qualify for skilled nursing care.

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patient *when the services were ordered* and what was, at that time, reasonably expected to be appropriate treatment for the illness or injury throughout the certification period.”³⁰ Further, courts have noted that Medicare beneficiaries shouldn’t have to risk deterioration to their health in order to validate the care they’re receiving.³¹ These same principles equally apply to hospice and are consistent with the CMS guidance.³²

For many of the patients denied on the basis that they were not eligible, the Medical Review Contractor relied on the fact that the patients had not shown certain symptoms during the period under review. For one Alzheimer’s patient who had a FAST score of 7D, a PPS score of 20%, multiple stage 3 and 4 pressure ulcers, and an infection requiring antibiotics, the reviewer determined she was not eligible because she had not aspirated during the period under review and she was receiving adequate nutrition via feeding tube.³³ A patient with inoperable ovarian cancer that progressed despite chemotherapy was denied because she was able to maintain her independence and she had not had any documented vaginal bleeding during the month under review.³⁴ For another patient who was unable to hold her own head up, could only speak unintelligible words, and had difficulty swallowing, the Contractor stated its rationale for denying the patient was the fact that the patient had not had any decubitus ulcers or infections during the period under review.³⁵

It would have been impossible for the hospice physician to know at the time of certification, or even during portions of the month-long period under review, that the beneficiary would not experience ulcers or infections at some later point. Moreover, even the Medical Review Contractor could only know with the improper use of hindsight that, for example, a patient ultimately would not aspirate during the month at issue. Yet, the Medical Review Contractor denied the entire claim rather than define when exactly within that month the failure to aspirate should result in a change to the patient’s prognosis.³⁶

Based on the foregoing, it is clear that the reviewer improperly applied a retrospective analysis to the question of each beneficiary’s eligibility, in direct contravention of CMS guidance and case law. Therefore, the denials must be reconsidered and redetermined without the improper use of hindsight.

³⁰ *Anderson*, 2010 WL 4273238, at *7.

³¹ *See, e.g., Folland*, 1992 WL 295230, at *7; *Anderson*, 2010 WL 4273238, at *7.

³² CMS, Medicare Benefit Policy Manual, CMS Pub. No. 100-02, Ch. 9, § 20.2.3.

³³ *See* OIG Medical Review Summary for Sample #68.

³⁴ *See* OIG Medical Review Summary for Sample #81.

³⁵ *See* OIG Medical Review Summary for Sample #37.

³⁶ Additionally, this is yet another instance in which the hospice is being punished for providing good care that prevented patients from having ulcers or infections.

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d. Clinical benchmarks are not required to demonstrate terminality.

Law and guidance, including *AseraCare*, has made clear that in enacting the statutory and regulatory framework governing hospice, Congress and CMS “were careful to place the physician’s clinical judgment at the center of the inquiry,” and specifically chose not to impose “a more rigid set of criteria for eligibility determinations that would have minimized the role of clinical judgment.”³⁷ Indeed, the *AseraCare* court explained, “CMS has considered and expressly declined to impose defined criteria that would govern the physician’s exercise of judgment.”³⁸ Instead, the determination of hospice eligibility under Medicare is “centered on the subjective ‘clinical judgment’ of a physician as to a patient’s life expectancy.”³⁹ Further, in 2008, CMS proposed a rule that would identify “criteria” that must be considered in certifying patients as terminally ill,⁴⁰ but subsequently removed the word “criteria,” however, “in order to remove any implication that there are specific CMS clinical benchmarks in this rule that must be met in order to certify terminal illness.”⁴¹ Accordingly, it is improper to rely on specific clinical criteria to deny eligibility.

Here, contrary to *AseraCare* and CMS guidance, the Medical Review Contractor relied on the absence of a certain set of clinical criteria in order to deny the eligibility of beneficiaries despite the fact that these beneficiaries showed numerous other signs and symptoms that supported their eligibility. For nearly all of the patients, the reviewer indicated whether the patients had a lack of infections, lack of wounds, lack of weight loss, clear lung sounds, lack of recurrent aspiration or choking, or good appetite, as if all hospice patients undoubtedly show such symptoms and the lack of such symptoms is proof the person is not eligible.⁴² For instance, the fact that several patients could ambulate apparently meant to the reviewer that those patients could not have had a terminal prognosis, despite there being numerous other factors to consider.⁴³ Because a predetermined list of clinical benchmarks are not required to support a terminal prognosis, it was inappropriate for the reviewer to rely on the lack of those symptoms as a basis to deny the patients access to the hospice benefit. Further, using such clinical

³⁷ *AseraCare*, 938 F.3d at 1301.

³⁸ *Id.*

³⁹ *Id.* at 1291.

⁴⁰ See *Vista Hospice Care*, 2016 WL 3449833, at *3.

⁴¹ See *id.* (quoting 73 Fed. Reg. 32088, 32138 (June 5, 2008)).

⁴² See, e.g., OIG Medical Review Summary for Samples #7, 10, 11, 26, 29, 33, 35, 37, 38, 39, 43, 52, 54, 55, 68, 72, 78, 82, and 87.

⁴³ See OIG Medical Review Summary for Samples #26, 54, 65, 82, and 94. One such patient could only ambulate 40 feet before stopping due to dyspnea. See OIG Medical Review Summary for Sample #65. Another patient had a fall when self-ambulating. See OIG Medical Review Summary for Samples #26. The implication is that unless a patient is bed- or chair-bound, the Contractor does not consider them eligible for hospice.

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benchmarks without regard to the patient's whole condition is inconsistent with clear directives from CMS.⁴⁴

e. LCDs are not requirements—they are “safe harbors.”

It is well-established that Local Coverage Determinations (“LCDs”) are guidelines, “not clinical benchmarks or mandatory requirements for hospice eligibility.”⁴⁵ Indeed, they “are not binding and should not be considered ‘the exact criteria used for determining’ terminal illness.”⁴⁶ Thus, “[m]eeting the clinical criteria in the LCDs for the patient’s primary diagnosis is *one path* to eligibility under the [Medicare Hospice Benefit], but hospices may ‘otherwise demonstrate to the [MAC] that the patient has a terminal prognosis.’”⁴⁷ Each of the OIG’s Medical Review Summaries rely on LCDs to deny the claims at issue.⁴⁸ Under applicable law, however, meeting an LCD is a basis to approve a claim, but failure to meet an LCD is not a basis to deny a claim. The Medical Review Summaries fail to make a critical and necessary determination, *i.e.*, that the medical record for the patient at issue did not support a terminal prognosis even outside the constraints of the LCD. Accordingly, it is improper to deny these patients’ eligibility based on a purported failure to “meet” an LCD. The Medical Review Contractor’s determinations should be reconsidered in light of the appropriate use of LCDs.

2. The Medical Review Contractor Failed to Apply the Law Consistent with the Recent *AseraCare* Decision.

The medical review determinations referenced in the Draft Report are inconsistent with the central holdings of *AseraCare*,⁴⁹ a landmark decision of the U.S. Court of Appeals for the Eleventh Circuit, which identified the governing standards for evaluating hospice eligibility determinations. Suncoast is located within the jurisdiction of the Eleventh Circuit, and *AseraCare* is the governing law for Suncoast and for the federal government in that jurisdiction.

⁴⁴ Medicare Program; FY 2015 Hospice Wage Index and Payment Rate Update; Hospice Quality Reporting Requirements and Process and Appeals for Part D Payment for Drugs for Beneficiaries Enrolled in Hospice, 79 Fed. Reg. 50452, 50469 (Aug. 22, 2014) (“We... expect that the individual’s whole condition plays a role in that prognosis.”); Medicare Program; FY 2014 Hospice Wage Index and Payment Rate Update, 78 Fed. Reg. 48234 (Aug. 7, 2013) (“certification of terminal illness is based on the unique clinical picture of the individual...”).

⁴⁵ *AseraCare*, 938 F.3d at 1283. Other hospice contractor LCDs also acknowledge that “[s]ome patients may not meet these guidelines, yet still have a life expectancy of 6 months or less.” See CGS LCD for Hospice Determining Terminal Status (L34538) (and earlier versions applicable to the dates at issue); see also NGS LCD for Hospice – Determining Terminal Status (L33393) (and earlier versions applicable to the dates at issue).

⁴⁶ *AseraCare*, 938 F.3d at 1288. The Act expressly provides that LCDs are not binding upon qualified independent contractors. See § 1869(c)(3)(B)(ii) of the Act.

⁴⁷ *Vista Hospice Care*, 2016 WL 3449833, at *4 (third alteration in original) (citation omitted).

⁴⁸ See, generally, OIG Medical Review Summaries.

⁴⁹ 938 F.3d 1278 (11th Cir. 2019).

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As noted earlier, although *AseraCare* arose under the False Claims Act, the standards set out in the decision applies to all applications of the Medicare hospice eligibility laws and regulations.⁵⁰

Based on a comprehensive analysis of this legal framework, the *AseraCare* court expounded upon three standards that govern any audit of hospice services, including the present one: (1) a “clinical standard,” which holds that two physicians using their clinical judgment about a patient’s terminal prognosis could disagree and neither be wrong; (2) a “documentation standard,” which requires only that the medical record *support* the physician’s clinical determination as to hospice eligibility, rather than *prove* the determination as a “matter of medical fact”; and (3) a “competency standard,” which permits a later reversal of certifying physicians’ hospice eligibility determinations only if a competent reviewer (*i.e.*, a qualified *physician*) finds that no reasonable physician, applying his or her clinical judgment, could have concluded that the patient was hospice eligible. Here, the Medical Review Contractor’s analysis falls short of all three of these standards.

a. **The Clinical Standard: The Medical Review Contractor Improperly Based Its Determinations on a Reasonable Disagreement with the Hospice Physicians.**

In its decision, the *AseraCare* court made clear that “the clinical judgment of the patient’s attending physician (or the provider’s medical director, as the case may be) lies at the center of the eligibility inquiry.”⁵¹ The court further 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 without fear that those judgments will be second-guessed after the fact by laymen in a liability proceeding.⁵²

As the Court further explained, “[n]othing in the statutory or regulatory framework suggests that a clinical judgment regarding a patient’s prognosis is invalid or illegitimate merely because an unaffiliated physician reviewing the relevant records after the fact disagrees with that clinical judgment.”⁵³

The *AseraCare* court’s holding is consistent with Congress and CMS’s prior acknowledgment of the hospice physician’s central role and the complexities and uncertainties involved in prognostication. CMS has acknowledged that “[i]t is the physician’s responsibility to assess the patient’s medical condition and determine if the patient can be certified as

⁵⁰ See *supra* note 3.

⁵¹ *Id.* at 1293.

⁵² *Id.* at 1295.

⁵³ *Id.* at 1296.

terminally ill.”⁵⁴ 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.⁵⁵ CMS has also long recognized that a terminal prognosis is far from a “guarantee” of death within six months, and some patients have the “good fortune to live longer than predicted by a well-intentioned physician.”⁵⁶ “The fact that a beneficiary lives longer than expected in itself is not cause to terminate benefits.”⁵⁷ Because prognostication is not an exact science, hospice physicians do not need to prognosticate with 100% certainty to establish a patient’s eligibility for hospice. Rather, CMS has stated that eligibility for hospice exists for patients whose clinical status is “more likely than not to result in a life expectancy of six months or less.”⁵⁸ Congress confirmed this approach to hospice eligibility when it eliminated the 210-day limit on the Medicare hospice benefit.⁵⁹

The *AseraCare* court also recognized that “predicting life expectancy is not an exact science,” and no “certitude can be expected of physicians in the practice of treating end-of-life illness.”⁶⁰ As a result, the court concluded that there are vagaries in prognostication that can lead to divergent, yet equally valid and supported, predictions of life expectancy. The court did not consider it appropriate or a valid application of the Medicare hospice benefit to allow a mere difference of opinion between clinicians to result in an adverse consequence for the hospice. If anything, the hospice physician is entitled to “meaningful latitude” in his or her prognostications.⁶¹

In other words, under *AseraCare*, two reasonable physicians using their clinical judgment can come to two different conclusions about a patient’s prognosis (and therefore hospice eligibility), and neither would be wrong. Accordingly, a later reversal of a certifying physician’s hospice eligibility determination is appropriate only if no reasonable physician, applying his or her clinical judgment, could have concluded that the patient was eligible for the Medicare hospice benefit. This standard gives appropriate deference to the certifying physicians, as required by the hospice legal framework and in numerous other cases.

Nowhere in the Draft Report, nor in its enclosed documentation, did the OIG reference the appropriate standard described in *AseraCare* or even identify any standard its reviewer used

⁵⁴ 70 Fed. Reg. at 70539.

⁵⁵ Exec. Dir. of Office of Vt. Health Access *ex rel. Cave v. Sebelius*, 698 F. Supp. 2d 436, 441 (D. Vt. 2010).

⁵⁶ Correspondence from Nancy-Ann Min DeParle, HCFA Administrator, date-stamped Sept. 12, 2000. See also CMS, Medicare Benefit Policy Manual, CMS Pub. No. 100-02, Ch. 9, § 10 (“The fact that a beneficiary lives longer than expected in itself is not cause to terminate benefits.”).

⁵⁷ CMS, Medicare Benefit Policy Manual, CMS Pub. No. 100-02, Ch. 9, § 10.

⁵⁸ See Medicare Program; FY 2014 Hospice Wage Index and Payment Rate Update, 78 Fed. Reg. 48234, 48247 (Aug. 7, 2013) (emphasis added).

⁵⁹ 142 Cong. Rec. S9582 (daily ed. Aug. 2, 1996) (statement of Sen. Breaux).

⁶⁰ *AseraCare*, 938 F.3d at 1282, 1293, 1296.

⁶¹ *Id.* at 1295.

for the after-the-fact evaluation of the hospice physicians' clinical judgment. The Medical Review Contractor does not indicate at any point in its Medical Review Summaries that no reasonable physician could have certified the patients as hospice-eligible. Rather, the Medical Review Contractor has shown, at best, that based on its *post hoc* review of certain records, it merely disagreed with the clinical judgment of the skilled and experienced physicians who certified the patients as terminally ill based on the totality of the patients' circumstances and the physicians' best medical judgments regarding what they expected to happen in the normal course of the patients' terminal illnesses. Likewise, the Medical Review Summaries do not set forth a reasoned basis for declining to give weight or deference to the certifying physicians. Under *AseraCare*, that is not enough to refute the hospice physicians' equally reasonable conclusion (reached based on the physicians' clinical judgment at the time they were treating the patients) that the patients had a terminal prognosis.

The OIG cannot base its Draft Report only on a reasonable disagreement between the physicians who certified and recertified these patients (*i.e.*, the physicians who actually cared for the patients and appropriately applied their clinical judgment to make eligibility determinations) and its Medical Review Contractor who reviewed those certifications years later. The law requires more, yet the Medical Review Summaries fail to provide it.

- b. ***The Documentation Standard: The Medical Review Contractor Improperly Demanded that the Medical Record Prove, Rather than Support, a Patient's Terminal Prognosis.***

The *AseraCare* court recognized that, under the plain language of the Medicare Statute and implementing regulations, "a patient is eligible for the Medicare hospice benefit if the appropriate physician makes a clinical judgment that the patient is terminally ill in light of the patient's complete medical picture, as *evidenced* by the patient's medical records."⁶² However, the court held that the medical record supporting the physician's clinical judgment is not required to *prove* the validity of that clinical judgment, explaining:

Importantly, none of the relevant language states that the documentary record underpinning a physician's clinical judgment must prove the prognosis as a matter of medical fact. . . . Nor does this framework state or imply that the patient's medical records must unequivocally demonstrate to an unaffiliated physician, reviewing the records after the fact, that the patient was likely to die within six months of the time the certifying physician's clinical judgment was made.⁶³

⁶² *Id.* at 1293 (emphasis added).

⁶³ *Id.* at 1293-94.

In other words, *AseraCare* held that the physician’s clinical judgment is the “controlling condition of reimbursement” and supporting documentation need not, “standing alone, prove the validity of the physician’s initial clinical judgment.”⁶⁴ If such were the case, the physician certification requirement would be superfluous.

The Medical Review Contractor’s analysis and resulting determinations do not reflect the current standard for evaluating the hospice medical record, as set forth in *AseraCare*. The Medical Review Contractor merely paid lip service to this *AseraCare* standard, as evidenced by its clinical review findings in the Medical Review Summaries. The reviewer’s findings that the documentation did not support patient eligibility or level of care is flawed because the reviewer recited only cherry-picked factors tending to support his or her conclusion while completely disregarding other highly probative facts that support the patients’ certifications and recertifications and level of care. Identification of a few discrete facts that could only *arguably* support their conclusions that the patients were not terminally ill or did not require the level of care received—a point that Suncoast emphatically rejects—does not satisfy the standard for evaluating documentation under *AseraCare*. To satisfy that standard, the reviewer needed to be able to conclude that the medical record does not support the hospice physician’s certification or level of care determination, but the reviewer’s determinations lack this necessary conclusion. As a result, at best, the reviewer’s determinations accomplish nothing more than stating that the medical record supports two divergent opinions regarding terminality, which fails to demonstrate that the patient was certified in error. By ignoring other facts in the record supporting the certifications and recertifications, the OIG reviewer applied a much more exacting standard in the course of its review. Accordingly, the Medical Review Summaries should be rejected.

c. *The Competency Standard: The Medical Review Contractor Is Not Qualified to Evaluate the Exercise of Clinical Judgment by the Experienced Hospice Physicians.*

Following *AseraCare*, it is clear that the *post hoc* scrutiny of treating physicians’ contemporaneous “properly formed and sincerely held clinical judgment[s]” is not enough to undermine the physicians’ eligibility determinations.⁶⁵ Rather, a reversal of certifying physicians’ hospice eligibility determinations is appropriate *only* if, based on a reasonable interpretation of the relevant medical records, one can conclude that *no reasonable physician*, applying his or her clinical judgment, could have concluded that the patient was eligible for the Medicare hospice benefit. A necessary corollary of this holding (and the first two standards described above) is a requirement that the individuals conducting this *post hoc* review be qualified to provide “a reasonable interpretation” of the medical record to determine what a “reasonable physician” would or would not conclude. In other words, under the central

⁶⁴ *Id.* at 1291, 1294.

⁶⁵ *AseraCare*, 938 F.3d at 1297.

principles outlined in *AseraCare*, only a trained hospice physician is competent to evaluate the exercise of clinical judgment by the experienced hospice physicians.

Here, Suncoast's skilled and experienced physicians certified the patients reviewed by the Medical Review Contractor as terminally ill based on the totality of the patients' circumstances and the physicians' best medical judgments regarding what they expected to happen in the normal course of the patients' terminal illnesses. Suncoast's physicians' clinical judgment was further reviewed and affirmed by Drs. John Mulder, Edward Martin, and Joan Harrold, who are Board-certified in Hospice and Palliative Care Medicine.⁶⁶ The OIG, on the other hand, has not identified either the Medical Review Contractor or the physician who reviewed, and ultimately disagreed with, the physicians' contemporaneous eligibility and level of care determinations, much less identified his or her credentials and qualifications.⁶⁷

It is concerning that the OIG has refused to provide more detail concerning the physician reviewer's qualifications so that its audit process is as transparent and credible as possible. Even when Suncoast requested this information, the OIG responded that it does not obtain the physician reviewer resumes but relies, instead, on the representations made by the contractor during the competitive bidding process regarding the qualifications of the its reviewers.⁶⁸ We have included with this letter copies of our three expert physicians' curricula vitae.⁶⁹ It is difficult to fathom how the OIG can find a completely anonymous reviewer more credible than these physicians who are perhaps the most qualified hospice physicians in the United States.

⁶⁶ See Exhibits 3, 4 and 5.

⁶⁷ The end of each Medical Review Summary includes the following generic statement:

The physician who reviewed this case is licensed to practice medicine, is knowledgeable in the treatment of the enrollee's medical condition, and is familiar with guidelines and protocols in the area of treatment under review. Additionally, the physician holds a current certification from a recognized American medical specialty board in an area appropriate to the treatment of services under review, and has no history of disciplinary action or sanctions against their license.

⁶⁸ The OIG also has not provided to Suncoast copies of materials related to its audit that Suncoast specifically requested. For example, the OIG has not disclosed the following:

- Drafts of reports or notes related to the audit or Suncoast;
- Documents regarding the material terms, including financial terms, of contracts with third parties retained by OIG to review information or perform tasks in connection with the audit or Suncoast;
- Deliberative communications between the OIG and third parties regarding the patients whose health information was reviewed in connection with the audit or Suncoast;
- Notes related to interviews of Suncoast's current or former employees, patients, or patients' family members;
- Documentation, including written determination letters, relating to the claims that the physician reviewers determined were "allowed;" and

Accordingly, Suncoast's comments regarding the Draft Report are necessarily limited by the information it the OIG chose to provide to Suncoast.

⁶⁹ See Exhibits 3, 4, and 5.

The Joint Physician Statement prepared by Drs. Mulder, Martin, and Harrold, makes clear that the qualifications of Contractor’s anonymous reviewer are in serious doubt. Another provider has also very recently raised concern about the qualifications of the Contractor’s medical reviewer.⁷⁰ The OIG’s failure to verify the qualifications of the Contractor’s reviewer after having received credible concerns about his or her qualifications is arbitrary, capricious, and unreasonable. It also renders the Draft Report not credible. And, under recent guidance issued to all administrative agencies, withholding information concerning the reviewer’s qualifications is a derogation of the provider’s due process rights.⁷¹

In conclusion, the OIG has not demonstrated—and cannot demonstrate based on this review—that no reasonable physician would conclude that Suncoast’s patients were eligible for the Medicare hospice benefit. The OIG’s conclusions, therefore, fall short of the standards required under *AseraCare*.

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

The Medical Review Contractor failed to recognize the above well-established principles, in addition to those further detailed in *AseraCare*, in its retrospective evaluation of the hospice physicians’ contemporaneous determinations regarding eligibility for hospice and level of care. The determinations of the trained hospice physicians, which were made in real time—some after seeing the patient in person while conducting the face-to-face visit—are more credible and, importantly, more significant under applicable hospice law and regulations, than the review process performed by the Medical Review Contractor.

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.”⁷² Here, the Medical Review Contractor repetitively and rotely cited clinical criteria that are not legally mandatory and cherry-picked evidence from the medical record without a holistic consideration of each patient’s condition, without taking into account the hospice physicians’ credible clinical judgments. The Contractor’s reviewer also failed to connect the facts and information about each patient to the

⁷⁰ See OIG, Medicare Home Health Agency Provider Compliance Audit: Mission Home Health of San Diego (Aug. 2020), at page 12.

⁷¹ See Memorandum for the Deputy Secretaries of Executive Departments and Agencies from Paul J. Ray, Administrator, Office of Information and Regulatory Affairs, Implementation of Section 6 of Executive Order 13924 (August 31, 2020).

⁷² *Cumberland County Hospital System, Inc. v. Price*, 2017 WL 1048102 (E.D. N.C. 2017) (quoting *Ohio Vall. Emt’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 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))).

determination that the documentation was insufficient. Moreover, the reviewer simply listed criteria without providing any explanation as to how that criteria relates 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.⁷³

C. The Extrapolation of the Alleged Overpayment Here 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 Prognostication.

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 prognostication. Such an attempted calculation premised on clinical eligibility for hospice cannot provide a reasonably reliable estimated overpayment.

The definitions of eligibility for hospice care are not operationally defined because of the need for subjective clinical judgments by individual physicians in the hospice context.⁷⁴ Consequently, overpayments associated with audited services relative to hospice patients' life expectancy cannot be measured with sufficient accuracy to allow for extrapolation of an auditor's findings across a population with sufficient confidence.⁷⁵

This unique nature of hospice prognostication 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."⁷⁶ The *Agape* court stated that extrapolation is

⁷³ *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.")).

⁷⁴ **Exhibit 53.**

⁷⁵ *Id.*

⁷⁶ 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,

unsuitable for circumstances where determination of medical necessity or terminal prognosis requires a highly fact-intensive inquiry and review of each individual patient's medical record.⁷⁷ Where the nature of the claim requires an individualized determination, that determination cannot be replaced by "Trial by Formula."⁷⁸ 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."⁷⁹ 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.⁸⁰ The *AseraCare* decision further supports the conclusions of *Agape* and *Vista Hospice Care* since it recognized that vagaries of prognostication can lead to divergent, yet equally valid and supported predictions of life expectancy.

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 terminality.⁸¹ The permissibility of statistical sampling turns on the degree to which the evidence is reliable in proving or disproving the elements of the relevant cause of action.⁸² Statistical sampling, therefore, cannot be used to establish an overpayment related to alleged ineligible patients, as the underlying determination of eligibility for hospice is inherently subjective, patient-specific, and dependent on the judgment of involved physicians, as discussed above.

The OIG's findings that certification or 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.⁸³ 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.⁸⁴ Furthermore, every hospice

appeal dismissed in part sub nom. *United States ex rel. Michaels v. Agape Senior Cmty., Inc.*, 848 F.3d 330 (4th Cir. 2017).

⁷⁷ *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").

⁷⁸ *Vista Hospice Care* at *11.

⁷⁹ *Vista Hospice Care* at *13 (quoting *Tyson Foods, Inc. v. Bouphakeo*, 136 S. Ct. 1036, 1046 (2016)).

⁸⁰ *Agape*, 2015 WL 3903675, at *8; *Vista Hospice Care* at *11.

⁸¹ *Vista Hospice Care*, 2016 WL 3449833, at *12.

⁸² See *id.* at *11.

⁸³ See *id.* at *13.

⁸⁴ 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.").

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.⁸⁵ This recognized variability in clinical judgment, which variability 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 terminal prognosis or level of care and applied it to other physicians' prognostications for other patients, whose backgrounds and medical needs are each 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 prognostication regarding one patient to another physician's conclusions about a completely different patient.⁸⁶

Further, although the Act grants permission to use extrapolation in certain circumstances, it does not mandate such use in every type of audit.⁸⁷ In other words, the statute contemplates circumstances when extrapolation is neither necessary nor reasonable. In this matter, the Act should not be interpreted to permit use of extrapolation in circumstances where Congress clearly did not intend it.⁸⁸ Such interpretation would also produce absurd results. If a particular application of a statute produces an absurd result, the courts should and will interpret the statute to reflect what Congress would have intended had it confronted the absurdity.⁸⁹

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.⁹⁰ 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 beneficiaries or, more importantly, the concept that two physicians using their clinical judgment about a patient's terminal prognosis could disagree and neither be wrong.⁹¹ Furthermore, the

⁸⁵ See *Vista Hospice Care*, 2016 WL 3449833, at *17.

⁸⁶ See *id.* at *13.

⁸⁷ See § 1893(f)(3) of the Act (42 U.S.C. § 1395ddd(f)(3)).

⁸⁸ Compare § 1879 of the Act to § 1893(f)(3) of the Act.

⁸⁹ The Supreme Court has consistently adjusted statutory commands in order to avoid absurd results. See, e.g., *Clinton v. City of New York*, 524 U.S. 417, 429 (1998) (“[a]cceptance of the Government’s new-found reading... would produce an absurd and unjust result which Congress could not have intended.”) (quotations omitted); see also, e.g., *Pub. Citizen v. U.S. Dep’t of Justice*, 491 U.S. 440, 470 (1989).

⁹⁰ 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.*

⁹¹ *AseraCare*, 983 F.3d at 1285.

Supreme Court, as well as the Fifth Circuit have made clear that sampling and extrapolation cannot always be used to prove liability, and courts are required to engage in a particularized analysis of whether extrapolation from a particular data set can reliably prove the elements of the specific claim.⁹² Therefore, even though there is authority to utilize statistical sampling and extrapolation, it is an arbitrary and capricious exercise of agency discretion to utilize it in the area of hospice benefit eligibility and level of care determinations.⁹³

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

Suncoast engaged Dr. Mitchell Cox and Dr. Harold Haller to evaluate the OIG's statistical sampling and extrapolation methodology. Both Dr. Cox and Dr. Haller have decades of experience providing independent analysis of statistical sampling and extrapolation in the healthcare context.⁹⁴ Both have served as statistical experts in numerous appeals of overpayment determinations before Administrative Law Judges and in federal court. Attached as Exhibits 53 and 54 to this response are the Expert Reports of Dr. Cox and Dr. Haller, which address their multiple process and statistical concerns regarding the OIG's statistical sampling methodology and extrapolation.⁹⁵ Their reports demonstrate that, for each of the flaws identified below, the extrapolation is statistically invalid.

First, per the OIG's own statisticians, the target population should have excluded certain claims that were previously adjudicated, but Dr. Haller found that two claims that were previously adjudicated and approved following prior audits were in the sampling frame. This is a fundamental flaw because the inclusion of inappropriate claims irrevocably changes the probability of which claims are selected for the sample, thus corrupting the sampling frame and rendering it impossible to draw a statistically valid random sample.

Second, the precision and the confidence level are the two most important parameters for a statistical estimate. Here, the precision level is 21.79%, over double the industry standard of 10%. To have a precision of 10%, a sample size of 462 claims (instead of the 100 claims that the OIG reviewed) would have been required. Even if an overpayment exists, which Suncoast denies, this poor precision level may mean that Suncoast is being asked to over-reimburse more than double what it would be required to reimburse if the precision had been 10%, or, in other words, the OIG is only 77.5% confident that the true overpayment is less than the demand.⁹⁶

⁹² *Vista Hospice Care* at *13 (citing *Wal-Mart Stores, Inc. v. Dukes*, 564 U.S. 338, 367; *In re Chevron U.S.A., Inc.*, 109 F.3d 1016, 1017 (5th Cir. 1997)).

⁹³ See, generally, *supra* notes 72-73.

⁹⁴ Exhibits 51 and 52, Curricula Vitae of Dr. Haller and Dr. Cox, respectively.

⁹⁵ Exhibits 53 and 54, Expert Reports of Dr. Haller and Dr. Cox, respectively.

⁹⁶ Exhibits 53 and 54.

Third, the extrapolation is unfounded because the payment error rate derived from the OIG’s review is not high enough to permit the use of extrapolation. The OIG stated in the draft report that “CMS, acting through a MAC or other contractor, will determine whether overpayments exist and will recoup any overpayments consistent with its policies and procedures.” The policies and procedures followed by CMS include the Medicare Program Integrity Manual (“MPIM”). While Suncoast realizes that the OIG is not a Medicare contractor and, accordingly, maintains that it is not bound by the MPIM, the MPIM is a reliable recitation of established statistical principles.⁹⁷ Under section 1893(f)(3) of the Act, extrapolation is only permitted if the Secretary of the Department of Health and Human Services determines there is a “sustained or high level of payment error.” Under the current Medicare Program Integrity Manual, Chapter 8, § 8.4.1.4, a finding of “sustained or high level of payment error” cannot be based upon a post-payment review error rate unless the error rate is greater than 50%.⁹⁸ From the audit of Suncoast by the OIG, the error rate (total overpayment dollars divided by the total dollars paid for the 100 claims in the sample) is 0.41 or 41%.⁹⁹ Therefore, Suncoast’s overpayment did not meet the minimum high error rate standard of 50% set out in the MPIM.¹⁰⁰

Fourth, the OIG failed to prove that it used a Statistically Valid Random Sample because it did not provide documentation showing that the order of claims in the frame was fixed and documented prior to sample selection. The order of claims in a sampling frame should be fixed and documented before the sample is selected—doing so shows that the sample was not improperly drawn or manipulated.¹⁰¹ Here, the OIG’s statisticians did not provide documentation to support the proper ordering of the sampling frame.¹⁰² Thus, it cannot be determined that the OIG drew a statistically valid random sample in this audit and extrapolation.¹⁰³ This apparent failure to fix and document the order of the claims in the sampling frame prior to sample selection means that the sample does not hold up to basic statistical requirements and thus cannot be statistically valid.¹⁰⁴

Fifth, the OIG improperly excluded potential underpayments from its universe. In the OIG’s sampling plan, the OIG states that zero-paid claims (underpayments) were excluded from the universe.¹⁰⁵ Since the zero-paid claims were excluded from the universe, they were not

⁹⁷ Exhibit 54.

⁹⁸ While this parameter was not added to the MPIM until January 2, 2019, courts may apply this type of administrative guidance retroactively when doing so does not create “manifest injustice.” See e.g., *SEC v. Chenery Corp.*, 332 U.S. 194 (1947); *Laborers’ International Union of North America, AFL-CIO v. Foster Wheeler Corp.*, 26 F.3d 375 (3d Cir. 1994); *Retail, Wholesale and Department Store Union v. NLRB*, 466 F.2d 380 (1972); *Francisco-Lopez v. Attorney Gen. United States*, 970 F.3d 431 (3d Cir. 2020).

⁹⁹ Exhibit 53.

¹⁰⁰ Exhibit 53.

¹⁰¹ Exhibit 54.

¹⁰² Exhibit 54.

¹⁰³ Exhibit 54.

¹⁰⁴ Exhibit 54.

¹⁰⁵ Exhibit 54.

available to be selected for the sample here and thus did not factor into the extrapolated overpayment.¹⁰⁶ Statistical principles require the inclusion of zero-paid claims in the universe.¹⁰⁷ This exclusion of unpaid or underpaid claims put Suncoast at an extreme disadvantage because it likely resulted in an improperly inflated extrapolated amount that the OIG has deemed an overpayment.¹⁰⁸

D. Liability for the OIG's Overpayment Determination Must Be Waived Under Sections 1879 and 1870 of the Act.

Sections 1879 and 1870 of the Act provide for the waiver of alleged overpayment amounts *even if* the patients at issue were not terminally ill. The Hospice met the requirements for those waivers. Under the *Caring Hearts* case, the federal Court of Appeals for the Tenth Circuit described Section 1879 as follows:

In seeming recognition of the complexity of the Medicare maze, Congress [in Section 1879] indicated that providers *who didn't know and couldn't have reasonably been expected to know* that their services weren't permissible when rendered generally don't have to repay the amounts they received from CMS. A sort of good faith affirmative defense, if you will.¹⁰⁹

Under *Caring Hearts*, CMS must forgive "mistakes" of the provider if the provider's purported mistakes were reasonable and supported the propriety of the services provided. Moreover, section 1879(g)(2) expressly includes mistakes related to determination that a hospice patient is not terminally ill. Congress specifically added Section 1879(g)(2) to expand this waiver to determinations that a patient is not terminally ill as a means of providing some financial protection for hospices, since hospices must assume a significant financial burden for their patients based on an inherently imprecise clinical judgment regarding whether a patient's terminal illness will follow the normal course.¹¹⁰

Similarly, waiver of liability is required under Section 1870 if a provider is "without fault" because it "had a reasonable basis for assuming that the payment was correct...."¹¹¹ To be "without fault," the provider is only required to have been reasonable, *i.e.*, that it had a *reasonable* basis for its *assumption* regarding payment.

¹⁰⁶ Exhibit 54.

¹⁰⁷ Exhibit 54.

¹⁰⁸ Exhibit 54. Per Dr. Cox "there is no way to estimate the harm inflicted on the Hospice by the removal of the zero-paid claims because the OIG also removed these claims from all of the audit materials provided to the Hospice."

¹⁰⁹ *Caring Hearts Pers. Home Servs., Inc. v. Burwell*, 824 F.3d 968, 970 (10th Cir. 2016) (emphasis added).

¹¹⁰ See 42 C.F.R. § 418.22. See also 142 Cong. Rec. S9582 (Aug. 2, 1996) (statement of Sen. Breaux).

¹¹¹ See Act § 1870, 42 U.S.C. § 1395gg; see also CMS, Medicare Financial Management Manual ("MFMM"), CMS Pub. 100-06, Ch. 3 § 90.

Here, Suncoast understandably relied on the reasonable clinical judgment of the patients' skilled physicians and had a "reasonable basis for assuming the payment[s] [were] correct."¹¹² The Patient Response Summaries demonstrate this reasonable basis. The Medical Review Contractor has failed to show that Suncoast should have known that its physicians' certification would be deemed in error years later or that the physicians' certifications or level of care determinations were unreasonable. When viewed in light of the *correct* standard for evaluating hospice eligibility, Suncoast did not and could not reasonably have known or been expected to know that any of the patients under review would be determined years later to not be terminally ill. After all, "physicians applying their clinical judgment about a patient's projected life expectancy could disagree, and neither physician [] be wrong."¹¹³ For these reasons, Suncoast requests that the OIG address and evaluate waiver under Sections 1879 or 1870 before issuing its final report.

E. The OIG Must Include an Offset Based Upon Amounts Otherwise Payable by Medicare.

The alleged overpayment identified by the OIG fails to incorporate an adjustment based upon the amounts Medicare would have otherwise paid for these beneficiaries had they not been terminally ill and elected hospice. In effect, without including such adjustment, the government effectively receives a windfall because it has received the benefit of those items and services (and the costs incurred by Suncoast to provide those items and services) without paying for them.

Such an adjustment is required by long-standing secondary payer and CMS policies¹¹⁴ and dictated by administrative law decisions and subsequent CMS guidance confirming Medicare liability for paying an unbundled rate for services when the basis for denying a bundled payment rate is the location where the services were provided.¹¹⁵ Congress has confirmed that, absent hospice care, the government is otherwise required to pay for "whatever palliative services are needed to manage [the patient's] terminal illness" such as durable medical

¹¹² *Id.*

¹¹³ *AseraCare*, 938 F.3d at 1296.; *see also Vista Hospice Care, Inc.*, 2016 WL 3449833, at *17.

¹¹⁴ *See* Medicare Prescription Drug Benefit Manual ("MPDBM"), CMS Pub. 100-18, Ch. 14 § 50.14.4. CMS has applied this reconciliation policy to hospices, indicating hospices "are entitled to seek compensation from the Part D sponsor...." *See* Memorandum from Tracey McCutcheon, Acting Director, Medicare Drug Benefit and C & D Data Grp., to All Part D Plan Sponsors & Medicare Hospice Providers (Mar. 10, 2014). Further, under Medicare secondary payer rules, the primary payer "shall reimburse the [secondary payer] for any payment...with respect to an item or service if it is demonstrated that such primary plan has or had a responsibility to make payment with respect to such item or service." Act § 1862(b)(2)(B)(ii).

¹¹⁵ *See* CMS, Medicare Benefit Policy Manual, Ch. 6 § 10-10.1 ("[p]ayment may be made under Part B for physician services and for [certain] nonphysician medical and other health services...when furnished by a participating hospital (either directly or under arrangements) to an inpatient of the hospital, but only if payment for these services cannot be made under Part A" when the "inpatient admission was not reasonable and necessary,... and if waiver of liability payment [was] not made"). *See also* MFMM, Ch. 3 § 170.1.

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equipment, pharmacy, radiology, labs, and therapies.¹¹⁶ As both a payer and bundled rate service provider, hospices must be treated accordingly, and an alleged overpayment must be adjusted to reflect those amounts paid for services that would otherwise have been paid for by Medicare, including, but not limited to, pharmaceuticals, durable medical equipment, and supplies.

In this case, the alleged overpayment should be reduced by at least \$3,562,378, to offset amounts for items and services otherwise payable by Medicare.¹¹⁷ The offset adjustment per claim was extrapolated by Dr. Haller based on the sampling plan. We request that the OIG revise its Draft Report to include this required adjustment.

III. 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. Suncoast's position with respect to these recommendations is set forth below.

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

Suncoast does not concur with this recommendation. Suncoast and its expert physicians have thoroughly reviewed the audit findings by the OIG and have determined that Suncoast did not receive an overpayment and that the Medical Review Contractor's claim denials and the OIG's statistical extrapolation are improper and contrary to law. The rationale for Suncoast's determinations are set forth in this letter and the Patient Response Summaries prepared by the three expert physicians contracted by Suncoast to review the claim denials by the OIG. If any attempt is made by Suncoast's MAC to recoup funds related to the OIG's audit, Suncoast intends to exercise all appeal rights available to it.

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

Suncoast acknowledges its obligations under the 60-Day Repayment Rule but does not concur with the OIG's recommendation that a refund pursuant to that rule is warranted. The Draft Report indicates that the OIG believes its report constitutes credible information of potential overpayments, and, therefore, Suncoast 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 applies. As noted above, Suncoast and its expert

¹¹⁶ 142 Cong. Rec. S9582 (daily ed. Aug. 2, 1996) (statement of Sen. Breaux).

¹¹⁷ See **Exhibit 53**.

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physicians have thoroughly reviewed the audit findings by the OIG and have determined that it did not receive an overpayment and that the OIG's claim denials and statistical extrapolation are improper and contrary to law. Accordingly, Suncoast has met the obligations of § 1128J(d) of the Act and 42 C.F.R. § 401.305 as set out by CMS in 81 Fed. Reg. 7654 (Feb. 12, 2016).

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

Suncoast does not concur with this recommendation. As already discussed, Suncoast has robust policies and procedures and corporate compliance program, which are shown by a number of CMS data sets to be effective. Suncoast's policies and procedures comply with *and incorporate* the Medicare requirements. While Suncoast routinely and proactively takes steps to strengthen its practices to ensure compliance with the everchanging Medicare requirements, it disagrees that any particular flaws exist in its current policies and procedures that allowed ineligible patients to be certified for hospice or allowed provision of unnecessary GIP care. Moreover, the Draft Report does not identify any particular flaws. To be sure, Suncoast has confirmed through expert physicians that its claims were appropriate. As noted throughout, the Draft Report is significantly flawed and is indicative of an overzealous, inexperienced Medical Review Contractor.

CONCLUSION

Thank you once again 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

BKN/EMP
Enclosures

HB: 4816-7575-5197.9