Department of Health and Human Services

**OFFICE OF INSPECTOR GENERAL**

# MEDICARE HOSPICE PROVIDER COMPLIANCE AUDIT: HOSPICE OF PALM BEACH COUNTY, INC.

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**Report in Brief**
Date: September 2022
Report No. A-02-20-01001

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

# Medicare Hospice Provider Compliance Audit: Hospice of Palm Beach County, Inc.

## 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 Hospice of Palm Beach County, Inc. (HPBC), complied with Medicare requirements.

## How OIG Did This Audit

Our audit covered 37,121 claims for which HPBC (located in Palm Beach, Florida) received Medicare reimbursement of $149 million for hospice services provided from April 2017 through March 2019. We reviewed a random sample of 100 claims. We evaluated compliance with selected Medicare billing requirements and submitted these sampled claims and the associated medical records to an independent medical review contractor to determine whether the services met coverage, medical necessity, and coding requirements.

## What OIG Found

HPBC received Medicare reimbursement for hospice services that did not comply with Medicare requirements. Of the 100 hospice claims in our sample, 60 claims complied with Medicare requirement. However, the remaining 40 did not comply with the requirements. Specifically, the clinical record did not support the beneficiary's terminal illness prognosis (30 claims), the clinical record did not support the level of care claimed (9 claims), and services were not supported in the medical record (3 claims). The total exceeds 40 because 2 claims contained more than 1 deficiency.

Improper payment of these claims occurred because HPBC's policies and procedures were not effective in ensuring the clinical documentation it maintained supported the terminal illness prognosis, the appropriate level of care was provided, and that services were supported. On the basis of our sample results, we estimated that HPBC received at least $42.3 million in improper Medicare reimbursement for hospice services.

## What OIG Recommends and HPBC Comments

We recommend that HPBC: (1) refund to the Federal Government the portion of the estimated $42.3 million in Medicare overpayments that are within the 4-year reopening period; (2) based upon the results of this audit, 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, HPBC disagreed with our findings and recommendations. Specifically, HPBC disagreed with all but 3 of the 40 sample claims questioned in our report. HBPC asserted that our conclusions were inaccurate or divergent from the clinical facts present in the medical records. HPBC also engaged a statistical expert who challenged the validity of our statistical sampling methodology and the resulting extrapolation.

After reviewing HPBC's comments, we maintain that our findings and recommendations are valid. We also reviewed HPBC's statistical expert's comments and maintain that our statistical methodology and extrapolation are statistically valid and resulted in a legally valid and reasonably conservative estimate of the amount overpaid by Medicare to HPBC.

The full report can be found at https://oig.hhs.gov/oas/reports/region2/22001001.asp.

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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) audits and evaluations 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 Hospice of Palm Beach County, Inc. (HPBC), 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 group[9] 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]

**Hospice of Palm Beach County, Inc.**

HPBC is a not-for-profit hospice provider located in West Palm Beach, Florida.[19] From April 1, 2017, through March 31, 2019 (audit period), HPBC provided hospice services to 12,762 beneficiaries and received Medicare reimbursement of almost $150 million.[20] Palmetto GBA, LLC (Palmetto) serves as the MAC for HPBC.

## HOW WE CONDUCTED THIS AUDIT

Our audit covered 37,121 claims totaling $149,850,136.[21] We reviewed a random sample of 100 of these claims, totaling $402,424, to determine whether hospice services complied with Medicare requirements. Specifically, we evaluated compliance with selected billing requirements and submitted these sampled claims and the associated medical records to an independent medical review contractor to determine whether the services met coverage, medical necessity, and coding requirements.

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

Appendix A contains the describes our audit scope and methodology, Appendix C describes 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' Provider Reimbursement Manual, Pub. 15-1-Part 1, § 2931.2; and 81 Fed. Reg. at 7670.

[19] HPBC is one of three hospices operated by Trustbridge, a nonprofit organization that offers hospice and palliative services throughout Florida's Broward and Palm Beach counties.

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

[21] In developing this sampling frame, we included hospice claims for which a payment was made from the Medicare Trust Fund and claims that were not identified in the Recovery Audit Contractor data warehouse as having been reviewed by another party.

## FINDINGS

HPBC received Medicare reimbursement for hospice services that did not comply with Medicare requirements. Of the 100 hospice claims in our sample, 60 claims complied with requirements, but 40 did not. Specifically:

- For 30 claims, the clinical record did not support the beneficiary's terminal prognosis.
- For nine claims, the clinical record did not support the level of care claimed for Medicare reimbursement.
- For three claims, the medical record did not support services claimed for SIA payments.[22]

Improper payment of these claims occurred because HPBC's policies and procedures were not effective in ensuring the clinical documentation it maintained supported the terminal illness prognosis, the appropriate level of care was provided, and that services were supported.

On the basis of our sample results, we estimated that HPBC received at least $42.3 million in improper Medicare reimbursement for hospice services.[23] As of the publication of this report, this unallowable amount includes claims outside the 4-year reopening period.[24] Notwithstanding, HPBC 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 reopening period.[25]

### 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 benefit periods, followed by an unlimited number of 60-day benefit periods. 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 group and the individual's attending physician, if any. For subsequent benefit periods, a written certification from the hospice medical director or the physician member of

[22] The total exceeds 40 because 2 claims contained more than 1 deficiency.

[23] Specifically, we estimated that HPBC received at least $42,336,162 in overpayments. To be conservative, we recommend recovery of overpayments at the lower limit of a two-sided 90-percent confidence interval. Lower limits calculated in this manner are designed to be less than the actual overpayment total 95 percent of the time.

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

[25] 42 CFR § 405.980(c)(4).

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.[26]

For 30 of the 100 sample claims, the clinical record provided by HPBC 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, (2) GIP care, (3) inpatient respite care, and (4) CHC. [27] 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.[28] Routine home care is the least expensive level of hospice care, followed by inpatient respite care, GIP care, and CHC which is the most expensive level of hospice care.

For nine claims in our sample, the associated beneficiary's clinical record did not support the need for the claimed level of care. Specifically, the associated beneficiaries' hospice care needs could have been met if HPBC had provided services at the less expensive routine level of care.[29]

**SERVICES NOT SUPPORTED**

Effective for hospice services with dates of beginning January 1, 2016, hospices can claim an 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.[30] The SIA payment is in

[26] 42 CFR §§ 418.22(b)(2) and 418.104(a).

[27] 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).

[28] 42 CFR §§ 418.302(b)(4) and 418.202(e).

[29] For seven of the nine claims, we used the applicable payment rates and questioned the difference in payment amounts between the claimed level of care and routine levels of care. For two other claims, we questioned the entire amount because the claims had more than one deficiency. For these claims, the terminal prognosis was not supported.

[30] 42 CFR § 418.302(b)(1).

addition to the daily routine home care rate. A minimum of 15 minutes (1 unit) of nursing and/or social worker services must be provided to receive the SIA payment. [31]

For three sample claims, HPBC received SIA payments for which it was not eligible. Specifically, HPBC was not eligible for SIA payments associated with 47 units that were not documented in the associated beneficiary's medical file.

## RECOMMENDATIONS

We recommend that Hospice of Palm Beach County, Inc.:

- refund to the Federal Government the portion of the estimated $42,336,162 for hospice services that did not comply with Medicare requirements and that are within the 4-year claims reopening period;[32]

- based upon the results of this audit, exercise reasonable diligence to identify, report and return any overpayments in accordance with the 60-day rule[33] 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.

## HPBC COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, HPBC, through its attorney, disagreed with our recommendations and disagreed with most of our findings. Specifically, HPBC disagreed with

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

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

all but 3 of the 40 sample claims questioned in our draft report.[34] Although HPBC acknowledged its obligations under the 60-day rule, it reviewed our audit findings and did not agree that additional refunds pursuant to the rule were warranted at this time. HPBC also did not agree with our recommendation to strengthen its policies and procedures because it believes it has robust policies and procedures to ensure that hospice services comply with Medicare requirements. However, HPBC did state that it will continue to routinely review and update its policies to ensure ongoing compliance with applicable laws.

HPBC asserted that OIG's audit is fundamentally flawed in numerous respects and, as a result, OIG's overpayment determinations are invalid. Specifically, HPBC 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. HPBC contended that the medical review contractor ignored patients' overall medical condition, focused on irrelevant points, and "cherry-picked" information that resulted in misleading, incomplete, and inaccurate conclusions.

HPBC further argued that statistical extrapolation was an inappropriate tool to utilize for the evaluation of hospice services because of the individualized nature of each patient's clinical profile and the subjective and inexact nature of a physician's level of care determinations (prognostication). HPBC engaged a statistical expert, who evaluated OIG's sampling and extrapolation methodologies, and claimed in a report that, even if extrapolation was appropriate, OIG's sampling and extrapolation were not statistically valid. Lastly, HPBC stated that the SIA related overpayments found in our sample cannot be used to estimate an extrapolated overpayment amount.

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

HPBC also stated that OIG's overpayment must be reduced to offset amounts for items and services (e.g., durable medical equipment, pharmaceuticals, and supplies) that would otherwise be payable by Medicare had the beneficiary not elected hospice.

We maintain that our findings and recommendations are valid. We also reviewed the report prepared by HPBC's statistical expert and maintain that our sampling methodology and extrapolation were statistically valid and resulted in a legally valid and reasonably conservative estimate of the amount overpaid by Medicare to HPBC. However, we note that OIG audit

[34] Accordingly, HPBC does not believe it was overpaid for hospice services except for three claims for which it agreed that it received excess SIA payments in error. HPBC stated that it can quantify and will refund all SIA-related overpayments in the sampling frame; therefore, they state these claims cannot be included in the projected disallowance.

recommendations do not 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 claims that we have recommended disallowing and determine whether an overpayment exists and if the waiver provisions cited by HPBC apply. Lastly, we did not reduce the overpayments we identified by amounts for services that HPBC stated would otherwise be payable by Medicare because we have no assurance that Medicare would cover these services.

A summary of HPBC's comments and our responses follows. HPBC's comments are included as Appendix E.[35]

## MEDICARE REQUIREMENTS RELATED TO CLINICAL DOCUMENTATION

### HPBC Comments

HPBC engaged an independent physician to analyze OIG's medical review contractor's findings and conclusions. According to HPBC, the physician confirmed that the certifications of terminal illness and levels of care for beneficiaries associated with our sample claims were supported by medical records. Specifically, HPBC stated that the medical review contractor's analyses were not supported by the medical records, contained factual errors, and failed to apply fundamental principles or cite relevant medical literature. Further, HPBC stated that the medical review contractor used similar boilerplate language in its determination letters, which HPBC asserted was an indication of the contractor's failure to apply the appropriate eligibility and level of care standards and to thoroughly review the associated medical records. HPBC 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, HPBC argued that the medical review process was flawed because it only included a review of 1 month of records (or less) for each hospice patient, which does not provide a complete medical picture of a beneficiary's condition.

### Office of Inspector General Response

We maintain that the clinical records submitted by HPBC for the sample claims questioned in our draft report did not meet Medicare requirements. Despite using boilerplate language, the independent medical review contractor properly used the appropriate statutory and regulatory hospice criteria, including 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

[35] HPBC included multiple exhibits as part of its comments. These exhibits included a statement by the physician engaged by the hospice, the engaged physician's curricula vitae, a claim-by-claim rebuttal of the findings in our draft report, its statistical expert's report on our sampling methodology, and the statistical expert's curricula vitae. 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 HPBC's comments in their entirety to CMS.

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 HPBC's assertion, the medical review contractor did not review only 1 month's worth of records (or less) for each hospice patient or "cherry-pick" information. 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; 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 level of hospice care provided, the medical review contractor determined that Medicare requirements were met.

**MEDICAL REVIEW CONTRACTOR'S DETERMINATIONS**

**HPBC Comments**

HPBC asserted that the independent medical review contractor failed to apply many well-established hospice principles and the appropriate standards governing hospice eligibility. Specifically, HPBC stated that it was improper for the medical review contractor to deny a claim solely on the basis that there was no decline in the beneficiary's medical condition or because the beneficiary showed improvement. HPBC further alleged that the contractor's determinations were made using the benefit of hindsight and not on the information known at the time the care was provided. In addition, HPBC stated that the medical review contractor denied hospice benefits because the contractor relied on a predetermined list of clinical benchmarks that are not required to support a terminal prognosis. Further, HPBC claimed that the medical review contactor relied on LCDs to determine whether a beneficiary met hospice eligibility requirements and that it improperly denied a claim when the beneficiary's condition did not meet an LCD. As examples, HPBC described four sample claims (numbers 8, 9, 72, and 78) for which it believed the associated beneficiaries' certifications of terminal illness and levels of care were supported by medical records but were considered unallowable by the independent medical review contractor.[36]

Lastly, HPBC stated that the medical review contractor failed to apply the law consistent with the 2019 *United States v. AseraCare, Inc.* decision.[37] According to HPBC, *AseraCare* states that "a certifying hospice physician's eligibility determination is clinically deficient only if no reasonable physician . . . could have concluded the patient was eligible for the Medicare hospice benefit" and that "medical record supporting a physician's clinical judgment is not required to *prove* the validity of that clinical judgment."

[36] In exhibits attached to its comments, HPBC included what it described as "Patient Response Summaries" rebutting the claims denied or partially denied by the independent medical review contractor.

[37] 938 F.3d 1278 (11th Cir. 2019).

**Office of Inspector General Response**

We disagree with HPBC'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 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 the information that was available and known at the time of certification or recertification, determined whether hospice eligibility requirements were met. We acknowledge that hospice care may still be appropriate for some beneficiaries who did not meet guidelines detailed in LCDs, based upon an individual assessment of the beneficiaries' health status. Accordingly, the independent medical review contactor merely used LCD guidelines as a tool to evaluate terminal prognosis. Finally, it was the opinion of OIG's medical reviewer contractor that the documentation in the medical records did not always support the terminal prognosis.

Regarding the four sample claims that HPBC described in its comments as incorrectly determined to be unallowable, we note that the independent medical review contractor determined that the associated medical records did not support the terminal prognosis or the need for the level of hospice care provided. Therefore, we maintain that the medical review contractor consistently and appropriately applied Medicare hospice eligibility requirements. Specifically:

- Sample claim number 8: HPBC stated that the associated beneficiary had numerous prognoses that impacted comorbid and secondary conditions, as well as unintentional weight loss. However, the independent medical review contractor determined that there was no documentation of secondary conditions[38] and that the beneficiary had gained weight since admission. Therefore, the terminal prognosis of less than 6 months was not supported.

- Sample claim number 9: HPBC stated that the associated beneficiary had several comorbid and secondary conditions that contributed to her terminal prognosis and that she lost 10.4 percent of her body weight in under 2 months. However, the independent

[38] Such as stage III/IV pressure ulcer, aspiration pneumonia, frequent infections, or sepsis.

medical review contractor determined that the beneficiary's medical file did not document secondary conditions or ongoing weight loss. Therefore, the terminal prognosis of less than 6 months was not supported.

- Sample claim number 72: HPBC stated that the associated beneficiary required a higher level of care due to labored breathing and elevated heart rate in addition to frequent medication interventions and adjustments to control her pain. However, the medical review contractor determined that although the medical file documented that the beneficiary was imminently dying and unresponsive, the symptoms were being well controlled on scheduled subcutaneous (i.e., not intravenous) doses of morphine. The beneficiary was not in crisis; therefore, the predominance of services provided did not require nursing support. As a result, the continuous home care services provided was not required.

- Sample claim number 78: HPBC stated that the associated beneficiary's unstable medical condition and risk of recurrent stroke and seizure required around-the-clock monitoring by a nurse and frequent administration of several intravenous medications. However, the medical review contractor determined the beneficiary's medical condition did not warrant a short-term inpatient stay for pain control or acute or chronic symptom management that could not feasibly be provided in other settings. Specifically, the medical file did not document that any frequent or continuous intravenous medication or drips were ordered or administered. Rather, medication was administered subcutaneously, which does not require an inpatient setting. Therefore, the general inpatient care services provided were not required.

In addition to its exhibits, which included a claim-by-claim rebuttal, HPBC's comments included several examples that, according to HPBC, demonstrate that the medical review contractor improperly denied claims because beneficiaries' conditions had not declined or their conditions had improved or stabilized. HPBC stated that the contractor did not base their determinations from the perspective of the hospice at the time the care was provided. For these examples, we maintain that the medical review contractor determined that the associated medical file did not support a terminal prognosis of 6 months or less or that the level of care provided was required.

For example, for sample claim number 58, HPBC stated that the medical review contractor denied hospice eligibility for a 90-year-old beneficiary who weighed 100 pounds but began to eat all of her meals because she was given an appetite stimulate despite having a primary diagnosis of cerebral atherosclerosis (i.e., a neurological condition) for which the LCD does not require any weight loss or poor appetite. Further, the medical review contractor noted that there was no evidence of significant decline. However, we note that the medical review contractor also determined that the there was no documentation of secondary conditions (e.g., stage III/IV pressure ulcer, aspiration pneumonia, frequent infections, or sepsis). In addition, the beneficiary was alert and the documentation supported improved and healing of a stage 2

pressure ulcer. Therefore, the medical review contractor determined that the medical file did not support a prognosis of 6 months or less.

We also disagree with HPBC's *AseraCare*-based assertion that the eligibility determination can be questioned only if no reasonable physician . . . could have concluded that the patient was eligible for the hospice benefit. To the contrary, in *AseraCare*, the Eleventh Circuit rejected the Government's concern that, under the court's reading of the eligibility framework, if a physician certified a patient as terminally ill, CMS would be required to reimburse the hospice provider unless CMS could determine that no other reviewer could possibly conclude the patient was terminally ill.[39] Although the *AseraCare* case was about the circumstances under which certifications of terminal illness could be deemed false for purposes of Federal False Claims Act liability, the Eleventh Circuit clearly acknowledged that CMS is statutorily prohibited from paying for services that are not reasonable and necessary for the palliation or management of terminal illness and that CMS retains a well-established right to review and deny payments for claims that do not meet that standard. Accordingly, we maintain the validity of our findings.

## OFFICE OF INSPECTOR GENERAL SAMPLING METHODOLOGY

### HPBC Comments

HPBC challenged the validity of our statistical sampling and extrapolation methodologies, engaged a statistical expert to review OIG's sampling methodology, and provided a copy of the statistical expert's report. HPBC stated that extrapolation is not appropriate for calculating overpayments in the hospice context due to the individualized nature of prognostication. HPBC also stated that OIG's statistical methodology was fundamentally flawed and the extrapolated overpayment amount is statistically invalid. According to HPBC's statistical expert: (1) OIG did not provide documentation sufficient to recreate the sampling frame or the sample, (2) OIG's sample size was too small to yield an accurate estimate of a two-sided 90-percent confidence interval and standard precision of 10 percent, (3) the sample units were not statistically independent because OIG sampled by claim—not by beneficiary or episode of care, (4) OIG improperly excluded zero-paid claims from its universe, and (5) the payment error rate is not high enough to permit the use of extrapolation. Lastly, HPBC stated that the SIA payments identified as unsupported in our draft report were due to a Palmetto system error as well as an electronic medical record (EMR) system error. HPBC stated that it can quantify total SIA overpayments in the sampling frame through a case-by-case review; therefore, OIG is not permitted to use sampling to estimate this amount.

### Office of Inspector General Response

After reviewing the statistical expert's report, we maintain that our sampling and extrapolation methodologies are statistically valid. Federal courts have consistently upheld statistical

[39] *AseraCare,* 938 F.3d at 1295.

sampling and extrapolation as a valid means to determine overpayment amounts in Medicare and Medicaid.[40] 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.[41] We properly executed our statistical sampling methodology in that we defined our sampling frame and sample unit, randomly selected our sample, applied relevant criteria in evaluating the sample, and used statistical sampling software (i.e., RAT-STATS) to apply the correct formulas for the extrapolation.

The statistical lower limit that we use for our recommended recovery represents a conservative estimate of the overpayment that we would have identified if we had reviewed each and every claim in the sampling frame. The conservative nature of our estimate is not changed by the nature of the errors identified in this audit. Moreover, the court cases that HPBC's attorney referenced in support of the proposition that extrapolation is inappropriate for individualized prognostication in hospices[42] are limited to False Claims Act cases and therefore are inapplicable to OIG audit recommendations and CMS recoveries arising from OIG audits.

The statistical expert's claim that OIG did not provide documentation sufficient to recreate the sampling frame or the sample is not correct. Following the exit conference, we provided HPBC with several workpapers, including, but not limited to, the sampling plan, sampling frame, random number seed, and selected sample items.[43] Therefore, we maintain that HPBC has the information it needs to recreate the sampling frame and identify the individual sample items.[44]

The statistical expert's statement that OIG's sample was too small to yield an accurate estimate is not correct. Small sample sizes (e.g., smaller than 100) have routinely been upheld by the

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

[41] *See John Balko & Assoc. v. Sebelius*, 2012 U.S. Dist. LEXIS 183052 at *34-35 (W.D. Pa. 2012), *aff'd* 555 F. App'x 188 (3d Cir. 2014); *Maxmed Healthcare, Inc. v. Burwell*, 152 F. Supp. 3d 619, 634–37 (W.D. Tex. 2016), *aff'd*, 860 F.3d 335 (5th Cir. 2017); *Anghel v. Sebelius*, 912 F. Supp. 2d 4, 18 (E.D.N.Y. 2012); *Miniet v. Sebelius*, 2012 U.S. Dist. LEXIS 99517 at *17 (S.D. Fla. 2012); *Transyd Enters., LLC v. Sebelius*, 2012 U.S. Dist. LEXIS 42491 at *13 (S.D. Tex. 2012).

[42] HPBC's attorney referenced *U.S. ex rel. Michaels v. Agape Senior Cmty., Inc.,* 2015 WL 3903675, at *8 (D.S.C. June 25, 2015) and *United States ex rel. Wall v. Vista Hospice Care, Inc.*, 2016 WL 3449833, at *11 (N.D. Tex. June 20, 2016).

[43] We note that these files are identified in the statistical expert's report as being provided to HPBC.

[44] We note that the statistical expert stated on page 9 of HPBC's exhibit that he was " . . . able to re-create OIG's sample using this seed . . . ."

Departmental Appeals Board and Federal courts.[45] The legal standard for a sample size is that it must be sufficient to be statistically valid, not that it be the most precise methodology.[46] Sample size is incorporated into the computation of the confidence interval, with a smaller sample size generally resulting in a smaller lower limit. Because absolute precision is not required, any imprecision in the sample may be remedied by recommending recovery at the lower limit, which was done in this audit.[47] This approach results in an estimate that is lower than the actual overpayment amount 95 percent of the time, and thus it generally favors the provider.[48]

Additionally, we disagree with HPBC statistical expert's statement that the sample unit used for this audit is not statistically independent because OIG sampled by claim and not beneficiary. The proofs for the unbiased nature of our estimate and the conservative nature of the lower limit require random selection of the sample units (in this case, claims). We performed this selection using a valid random number generator. The proofs underlying our methods do not make any assumptions about the distribution of beneficiaries in the sampling frame or in the sample.[49]

We also disagree that OIG violated statistical principles by excluding zero-paid claims from the universe.[50] Generally, OIG may perform a statistical or non-statistical review of a provider without covering all claims from that provider. Further, when extrapolation is used, OIG only projects to the sampling frame from which the sample was drawn. Therefore, contrary to HPBC's assertion, a valid sampling frame does not need to include all zero-paid claims within the audit period.

HPBC asserts that any recoupment amount extrapolated from a sample must ultimately comply with the requirements of the MPIM to be enforceable. However, as HPBC acknowledges in its

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

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

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

[48] *See Puerto Rico Dep't of Health*, DAB No. 2385, at 10-11 (2011); *Oklahoma Dep't of Human Servs.*, DAB No. 1436, at 8 (1993) (stating that the calculation of the disallowance using the lower limit of the confidence interval gave the State the "benefit of any doubt" raised by use of a smaller sample size).

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

[50] In the exhibit report, HPBC's statistical expert relied heavily on CMS's *Medicare Program Integrity Manual* (MPIM), which does not apply to OIG (as acknowledged by the statistical expert on page 4 of the HPBC's exhibit). However, we note that MPIM, ch. 8, § 8.4.3.2 expressly allows for the removal of claims/claim lines attributable to sample units for which there was no payment.

comments, the MPIM requirement that a determination of a sustained or high level of payment error must be made before extrapolation applies only to Medicare contractors—not the OIG.[51] 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.

Lastly, we disagree with HPBC's assertion that OIG is not permitted to include SIA overpayment amounts in the estimate of total improper payments because HPBC states it is able to identify all impacted claims and quantify the overpayment through a case-by-case review. The estimate presented in this report represents the total amount of all improper Medicare payments made to HPBC for hospice services in our sampling frame, it does not represent a specific SIA overpayment amount. However, CMS, acting through a Medicare administrative contractor or other contractor, will determine whether overpayments exist and will recoup any overpayments consistent with its policies and procedures. We will calculate any alternate estimates as necessary to assist CMS in this process.

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

## APPENDIX A: AUDIT SCOPE AND METHODOLOGY

### SCOPE

Our audit covered 37,121 hospice claims for which HPBC received Medicare reimbursement totaling $149,850,136 for services provided from April 1, 2017, through March 31, 2019 (audit period). These claims were extracted from CMS's National Claims History (NCH) file.

We did not assess HPBC'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 from October 2019 to December 2021.

### METHODOLOGY

To accomplish our objective, we:

- reviewed applicable Medicare laws, regulations, and guidance;
- met with CMS officials to gain an understanding of the Medicare hospice benefit;
- had discussions with Palmetto officials to gain an understanding of the Medicare requirements related to hospice services;
- met with HPBC's 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 37,153 hospice claims, totaling $149,994,364[52] from the CMS NCH file, for the audit period;
- excluded 32 claims, totaling $144,228, that were identified in the Recovery Audit Contractor (RAC) data warehouse as having been reviewed by another party;
- created a sampling frame consisting of 37,121 hospice claims, totaling $149,850,136;
- selected a random sample of 100 hospice claims from the sampling frame;

[52] The hospice claims extracted from the CMS NCH file had a payment from the Medicare Trust Fund; however, an individual line can have a zero payment.

- 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;

- 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, evaluated compliance with selected Medicare billing requirements and provided them to an independent medical review contractor, which determined whether the hospice services complied with Medicare requirements;

- reviewed the independent medical review contractor's results and summarized the reason or reasons a claim was determined to be improperly reimbursed;

- used the results of the sample to estimate the amount of the improper Medicare payments made to HPBC for hospice services in our sampling frame; and

- discussed the results of our audit with HPBC 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 |
|---|---|---|
| *Medicare Hospice provider Compliance Audit Vitas Healthcare Corporation of Florida* | A-02-19-01018 | 7/14/2022 |
| *Medicare Hospice Provider Compliance Audit: Partners In Care, Inc.* | A-09-18-03024 | 7/12/2021 |
| *Medicare Hospice Provider Compliance Audit: Mission Hospice & Home Care, Inc.* | A-09-18-03009 | 7/8/2021 |
| *Medicare Hospice Provider Compliance Audit: Northwest Hospice, LLC* | A-09-20-03035 | 6/23/2021 |
| *Medicare Hospice Provider Compliance Audit: Professional Healthcare at Home, LLC* | A-09-18-03028 | 6/10/2021 |
| *Medicare Hospice Provider Compliance Audit: Franciscan Hospice* | A-09-20-03034 | 5/18/2021 |
| *Medicare Hospice Provider Compliance Audit: Ambercare Hospice, Inc.* | A-09-18-03017 | 5/14/2021 |
| *Medicare Hospice Provider Compliance Audit: Alive Hospice, Inc.* | A-09-18-03016 | 5/14/2021 |
| *Medicare Hospice Provider Compliance Audit: Suncoast Hospice* | A-02-18-01001 | 5/7/2021 |
| *Medicare Hospice Provider Compliance Audit: Tidewell Hospice, Inc.* | A-02-18-01024 | 2/22/2021 |
| *Medicare Hospice Provider Compliance Audit: Hospice Compassus, Inc., of Tullahoma, Tennessee* | A-02-16-01024 | 12/16/2020 |
| *Medicare Hospice Provider Compliance Audit: Hospice Compassus, Inc., of Payson, Arizona* | A-02-16-01023 | 11/19/2020 |
| *Safeguards Must Be Strengthened to Protect Medicare Hospice Beneficiaries From Harm* | OEI-02-17-00021 | 7/3/2019 |
| *Hospice Deficiencies Pose Risks to Medicare Beneficiaries* | OEI-02-17-00020 | 7/3/2019 |
| *Vulnerabilities in the Medicare Hospice Program Affect Quality Care and Program Integrity: An OIG Portfolio* | OEI-02-16-00570 | 7/30/2018 |
| *Hospices Should Improve Their Election Statements and Certifications of Terminal Illness* | OEI-02-10-00492 | 9/15/2016 |
| *Hospices Inappropriately Billed Medicare Over $250 Million for General Inpatient Care* | OEI-02-10-00491 | 3/30/2016 |
| *Hospice of New York, LLC, Improperly Claimed Medicare Reimbursement for Some Hospice Services* | OAS-02-13-01001 | 6/26/2015 |

| | | |
|---|---|---|
| *Medicare Hospices Have Financial Incentives To Provide Care in Assisted Living Facilities* | OEI-02-14-00070 | 1/13/2015 |
| *The Community Hospice, Inc., Improperly Claimed Medicare Reimbursement for Some Hospice Services* | OAS-02-11-01016 | 9/23/2014 |
| *Servicios Suplementarios de Salud, Inc., Improperly Claimed Medicare Reimbursement for Some Hospice Services* | OAS-02-11-01017 | 8/7/2014 |

## APPENDIX C: STATISTICAL SAMPLING METHODOLOGY

### SAMPLING FRAME

The sampling frame was an Access database containing 37,121 Medicare Part A reimbursed claims, totaling $149,850,136, for hospice services provided by HPBC from April 1, 2017, through March 31, 2019.[53] 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, Office of Audit Services (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 HPBC for hospice services in our sampling frame. 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.

[53] The sampling frame included claims for which a payment was made from the Medicare Trust Fund and claims that were not identified 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 |
|---|---|---|---|---|---|
| 37,121 | $149,850,136 | 100 | $402,424 | 40 | $148,856 |

### Estimated Value of Overpayments
***(Limits Calculated for a 90-Percent Confidence Interval)***

| | |
|---|---|
| Point Estimate | $55,256,869 |
| Lower Limit | $42,336,162 |
| Upper Limit | $68,177,577 |

## APPENDIX E: HPBC COMMENTS

HUSCH BLACKWELL

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July 12, 2022

**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: Hospice of Palm Beach County, Inc.
A-02-20-01001

Dear Ms. Tierney:

Hospice of Palm Beach County, Inc. ("HPBC") 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: Hospice of Palm Beach County, Inc.* ("Draft Report"). HPBC's comments to the Draft Report, including the report's conclusions and recommendations, are set forth below.[1]

### INTRODUCTION

HPBC is one of the oldest non-profit hospices in Florida, having been established in 1978 by community leaders to provide end-of-life care for the area's aging population. Its long-tenured leadership team has over 100 years in combined hospice experience. HPBC is one of the oldest non-profit hospices in Florida, and it was also one of the first 100 hospices to become Medicare-certified. It has also earned The Joint Commission accreditation for meeting the highest performance standards of care, and it created a nationally-recognized Hospice and Palliative Medicine Fellowship Program for physicians wishing to specialize in hospice care.

[1] This letter and Exhibits 1-2 and 40-41 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 3-39 do contain PHI, and we ask that these exhibits not be included within the publicly available version of the OIG's final audit report.

HB: 4860-5834-5255.2

From a review of only 0.269%[2] of the claims for payment that this non-profit hospice submitted to Medicare over a two-year period, the OIG has concluded that it received an alleged overpayment of $42,336,162. This conclusion is based on a review of limited patient medical records by a Medical Review Contractor retained by the OIG to assess whether HPBC admitted patients who qualified for hospice, *i.e.*, had a medical prognosis that his or her life expectancy is six months or less if the illness runs its normal course, and whether those patients were afforded the appropriate level of care. But, the Medical Review Contractor failed to adhere to the law and standards of practice when reviewing HPBC's claims, and many of its summaries contain factual errors.

In response to this Draft Report, HPBC engaged an independent physician who is well-qualified in hospice medicine to evaluate its patient records and the OIG's Medical Review Contractor's assessments of the claims at issue. This independent expert physician has confirmed that HPBC's patient records supported the reasonable clinical judgments of the HPBC physicians who certified that the patients at issue were eligible for hospice and who determined each patient's appropriate level of hospice care. Significantly, as with other hospice physicians reviewing similar OIG audits, this physician has expressed concern over the apparent lack of understanding of hospice medicine reflected in the Medical Review Contractor's assessments. The Contractor's assessments 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. It is our understanding the OIG has not independently requested from, nor verified, proof of the qualifications of the physicians or clinicians used by its Medical Review Contractor to review hospice claims.

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.*[3] 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.[4] 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

[2] The OIG reviewed 100 claims out of the 37,121 claims for 1,556 patients cared for by HPBC from April 1, 2017 to March 31, 2019. Of the 100 claims reviewed, the OIG has alleged an overpayment with respect to 40 of those claims, which totaled $148,856.

[3] 938 F.3d 1278 (11th Cir. 2019)

[4] 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.

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 judgments made by more than 28 different hospice physicians, many of whom have over a decade (or two) of hospice experience, are Board-certified in Hospice and Palliative Care Medicine, and are Fellows in the American Academy of Hospice and Palliative Medicine,[5] were wrong when certifying these patients, the majority of whom were over 90-years-old.[6] This illogical result is possibly explained by the flawed review process. 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 HPBC'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 an expert statistician 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 HPBC 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, and labs that 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.[7] The active dying process occurs over hours or days, whereas the Medicare hospice

[5] For example, six claims denied by the OIG's Medical Review Contractor are associated with four physicians who have over 10 years' experience and are Fellows in the American Academy of Hospice and Palliative Medicine. Two of these physicians also teach hospice medicine. A total of 22 claims that were denied involve patients certified by physicians with over 10 years of experience in hospice medicine.

[6] Of the 30 patients denied based on eligibility, two were over 100 years old, 14 were ages 90-99, and nine were between 86-89 years old.

[7] 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.

benefit was meant to provide patients believed *by a physician* to be in their last *six months* of life comfort care in order to maintain their (and their families') quality of life, dignity, and peace. Beneficiaries should not suffer and be denied access to comfort 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.

**BACKGROUND INFORMATION ON HPBC**

The Draft Audit Report is wholly inconsistent with HPBC's history, leadership, accreditation, reputation, and culture of compliance. As a historical and locally-based non-profit, with its sole mission to provide families in the community with access to compassionate and quality hospice services, HPBC has taken all necessary steps to ensure compliance with the Medicare program.

HPBC is a non-profit hospice that was originally formed by a group of community leaders in 1978 to provide end-of-life care for everyone who needed it, regardless of their ability to pay or financial status. This was before the Medicare hospice benefit existed. At that time, it was one of the first hospices in the area. When Medicare created the hospice benefit in 1983, recognizing the benefits and cost-savings associated with end-of-life care, HPBC became one of the first 100 hospices to be certified. In 2014, HPBC joined together with its sister-location Hospice by the Sea to form Trustbridge, Inc. (formerly known as Spectrum Health, Inc.). Trustbridge is currently the largest provider of hospice care in the area. In 2009, HPBC became one of the only hospices to earn The Joint Commission's Gold Seal of Approval for Home Care Accreditation, meaning it has met the most rigorous quality and safety standards of care for patients.

As a non-profit corporation, HPBC is governed by a Board of Directors, comprised of 10 volunteers from the local community. The members of the Board of Directors are highly credentialed and are actively engaged in HPBC's efforts to provide quality care in compliance with all state and federal laws. The Board is currently chaired by Ms. Barbara Bolton Litten, Esq. Ms. Litten has been a business litigation attorney for over 26 years. Prior to becoming an attorney, she was the Chief Executive Officer of a large not-for-profit corporation based in Southwest Florida. She has been a member of the Board of Directors since 2010. Prior to her becoming chair, Mr. Randy Levitt served in that capacity. Mr. Levitt is a Senior Vice President at Morgan Stanley and is both a CPA and attorney. He served as chairman from 2017 to 2021 and remains on the Board. Two other members of the board are healthcare regulatory attorneys, Marian Pealman Nease and Heather Miller.

In addition to its Board of Directors, HPBC's current leadership team is very experienced in hospice care and active in the industry. Mr. David Fielding has been the President and Chief Executive Officer since 1998. Prior to taking this role 24 years ago, Mr. Fielding held leadership positions with two other large hospice companies for 9 years. Dr. Faustino Gonzalez, Chief Medical Officer and Medical Director for HPBC, is board-certified in Internal Medicine with an added qualification in Hospice & Palliative Medicine. He has also been a Fellow of the American Academy of Hospice and Palliative Medicine since 2010. He has over 21 years' experience in hospice care, and he has published over 13 peer-review articles and has given more than a dozen presentations at various conferences and symposiums on end-of-life and palliative care, including presentations for the American Academy of Hospice and Palliative Medicine and the Veterans Administration.

HPBC provides exemplary and compliant care to its patients, evidenced by its Gold Seal of Approval for Home Care Accreditation from The Joint Commission, and its survey history. HPBC has been continuously accredited by The Joint Commission since 2009. HPBC had no condition-level findings on the last two surveys conducted by The Joint Commission in 2018 and 2022. HPBC is also 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"). HPBC had no deficiencies representing serious or immediate risk or harm to patients during the time period at issue or after. Because of its reputation for providing high quality care, HPBC was able to join in a consortium with the University of Miami Miller School of Medicine, JFK Medical Center, and West Palm Beach Veterans Administration Center to create a Hospice and Palliative Medicine Fellowship program. This fellowship program prepares physicians for board-certification in hospice and palliative medicine and was nationally accredited by the Accreditation Council for Graduate Medical Education in 2010.

As part of a large organization, HPBC has very robust policies and procedures and corporate compliance plan. The OIG confirmed during its exit interview that it had not identified any particular flaw or problem with these policies and procedures. The Draft Report similarly does not identify any specific policy or procedure that is improper or requires modification. Rather, the Draft Report generally indicates HPBC's policies and procedures were ineffective, despite the OIG's own statements there were no particular flaw or problem with the policies.[8] HPBC's policies and procedures regarding certification of hospice eligibility are based on the federal statutes and regulations, requiring that the physician determine the patient's eligibility

[8] 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 HPBC's policies and procedures because the Medical Review Contractor found reason to deny or down-code certain claims. The OIG ignores the more likely explanation: the Medical Review Contractor denied or down-coded 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 1**, Physician Statement of Dr. Leedy Regarding the OIG's Audit of Hospice of Palm Beach County, Inc.

based on the physician's clinical judgment regarding the normal course of the patient's terminal illness. As required by law, HPBC's policies require the physician to prepare a brief written narrative reflecting the patient's clinical circumstances justifying the terminal prognosis, and expressly require that the clinical information supporting the terminal prognosis be documented in the medical record. All of these patients had signed certifications in which their treating physicians attested that they had a terminal prognosis based on those physicians' clinical judgment. Nothing in the policies and procedures encourages or incentivizes physicians or hospice staff to certify ineligible patients for hospice. To the contrary, the policies make clear that if a patient is ineligible, a more appropriate referral will be made.

HPBC has taken steps to implement and ensure compliance with its policies and procedures through regular education of its Board members, leadership, physicians, and staff. HPBC has a director of excellence and knowledge who coordinates for all physicians and staff necessary training to provide quality care in compliance with the Medicare requirements. During the time period at issue, the HPBC physicians were required to attend education on interdisciplinary group meetings and documentation standards, an annual two-part Rapid Regulatory Compliance program through HealthStream, which included corporate compliance; and Relias LLC educational sessions on physician narratives and relatedness determinations. HPBC's other clinical staff also attended the two-part Rapid Regulatory Compliance program through HealthStream, sessions on prognostication tools and hospice eligibility, and several Relias LLC educational sessions touching on the Medicare hospice benefit and its requirements. Physicians and staff alike attend training sessions any time HPBC's policies and procedures are updated.

In addition to this training, HPBC's Compliance Plan ensures the effectiveness of its policies, procedures, and practices. HPBC's Compliance Plan is consistent with the OIG's guidance[9] and memorializes the commitment of HPBC's Board of Directors and all hospice staff to actively participate and uphold the hospice's commitment to compliance. Board members and HPBC's leadership attend annual training on the Compliance Plan. There is also a dedicated, full-time Corporate Compliance Officer, who is supported by a Compliance Department made up of a full-time Director of Compliance and two full-time compliance nurses. In addition to its full-time Compliance Officer and Compliance Department, HPBC has a Compliance Steering Committee, which provides oversight and direction on regulatory requirements.

The Compliance Department conducts an annual risk assessment, identifying potential areas of risk using internal audit findings as well as governmental guidance and opinions, to develop an audit plan. It then conducts internal audits based on this plan and frequently engages outside consultants to conduct reviews. The results of these reviews are documented, trended, and reported to the Compliance Steering Committee, CEO, the Governance Committee, and the

[9] *See* OIG, Compliance Guidance, http://oig.hhs.gov/compliance/compliance-guidance/index.asp. HPBC confirmed with legal counsel in 2018 that its Compliance Plan met both the United States Sentencing Commission Guidelines and the OIG's guidelines.

Board of Directors at least quarterly. Monthly audit findings are reported to the department stakeholders on a regular basis. During the time period at issue, audits were conducted on the use of general inpatient ("GIP") care for five or more days, crisis care provided for longer than three days, and patients with a length of stay longer than 180 days. These audits were conducted by pulling a sample on a weekly or bi-monthly basis. Staff counseling and education is conducted if the results reveal a pattern or trend.

In addition to conducting audits based on its annual risk assessment, the Compliance Department also conducts investigations based on reports it receives through various sources. All physicians, staff, and volunteers are provided with a Compliance Hotline number to report concerns related to compliance. This toll-free Compliance Hotline number is maintained by a third-party contractor to ensure anonymity, and it is posted throughout the HPBC offices. The Compliance Department also hosts a "Compliance and Ethics Week" every November, during which staff participate in games designed to educate them on the Compliance Plan and where or how to report compliance concerns, including the Compliance Hotline. All staff members are also asked to review HPBC's Conflict of Interest/Code of Conduct Policy every year and complete an attestation form that asks staff members to disclose compliance-related issues. Because of HPBC's culture emphasizing compliance, most compliance reports are received directly by the Corporate Compliance Officer or Director of Compliance. A review of the HPBC's reports and internal audits and investigations does not reveal any pattern or systemic problems with respect to eligibility or level of care determinations.[10]

The effectiveness of the hospice's policies and procedures and Compliance Plan are demonstrated by CMS's PEPPER reports. PEPPER[11] 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,[12] and top five diagnoses. For the target areas related to certification of potentially ineligible patients, HPBC has been far below the percentile that CMS deems a high risk for improper payments (the 80th percentile). With respect to long lengths of stay, HPBC's PEPPER report for the three federal fiscal years through fiscal year 2019[13] showed that only 10.1% of its patients had a long length of stay, putting HPBC in the 19.8 percentile nationwide. This means 80.2% of hospices nationwide had a higher percentage of patients with long lengths of stay as compared to HPBC

[10] HPBC's culture of compliance is further demonstrated by voluntary repayments made in the past in response to its internal investigations. On December 22, 2017, HPBC made a voluntary repayment to Palmetto in the amount of $91,623.83 for evaluation and management services performed by physician, Dr. Randy Fox, which were determined to be potential overpayments using a statistically valid random sample. On March 4, 2020, HPBC made a voluntary repayment to Palmetto and the Florida Agency for Health Care Administration after determining physician narratives for two patients were potentially defective. On March 18, 2022, HPBC made a voluntary repayment to Palmetto for GIP claims submitted for three patients that were determined to be potential overpayments following an internal investigation that involved detailed chart reviews.
[11] Program for Evaluating Payment Patterns Electronic Report ("PEPPER").
[12] Long Length of Stay patients are those whose combined days of service is greater than 180 days.
[13] For federal fiscal year ("FY") 2019 (October 1, 2018 to September 30, 2019).

during this time period. In other words, the PEPPER reports reflect HPBC surpassed most other hospices with respect to accurate prognostication.

HPBC recognizes that, like all providers, it is not infallible. However, its history, leadership, policies and procedures, Compliance Plan, ongoing staff and physician education, and overall culture make it apparent that any issues that occur are aberrant and far from widespread. The OIG's conclusion to the contrary ignores HPBC's background, policies, and culture and is indicative of an overzealous medical review contractor that appears to lack a clear understanding of the hospice standard of practice, as well as the statutes and regulations governing hospice. If OIG's conclusion were correct, it would mean that the clinical judgment of over **28 different certifying physicians**, who personally treated the patients and had absolutely no incentive to improperly admit them for hospice care, 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 HPBC's overall operations. As a part of its audit, the OIG selected a random sample of 100 claims out of the 37,121 claims submitted by HPBC for the time period of April 2017 to March 2019, which represents 0.269% of the claims submitted by HPBC 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, HPBC provided hospice care to 12,762 Medicare beneficiaries and received $149,850,136 in Medicare reimbursement.

After requesting and receiving records from HPBC 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 60 of the claims met all Medicare requirements, while 40 of the claims did not. Of those 40 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; 7 were downcoded from a higher level of care 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 higher level of care; and three were partially denied because the Medical Review Contractor concluded that the service intensity add-on ("SIA") payment was not supported.[14]

[14] As a result of the OIG's audit, HPBC learned of an error in its EMR system that created minor Service Intensity Add-on ("SIA") overpayments for some patients. Due to the nature of the technological issue, HPBC is able to identify all impacted claims in the sampling frame and quantify, based on a case-by-case review, the total SIA

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 HPBC 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 HPBC received approximately $42,336,162 in improper payments. Nothing in the Draft Report suggests that HPBC 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, HPBC 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.

HPBC provided properly signed and clinically supported physician certifications and recertifications for each patient whose claim was denied by the Medical Review Contractor. HPBC 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 audit involves rejection of the clinical judgment of over **28 different certifying physicians** who personally treated the patients at issue, the majority of whom were over 90-years-old. Many of these physicians have worked in hospice for years and are Board-certified in Hospice and Palliative Care Medicine. Some of them are Fellows in the American Academy of Hospice and Palliative Medicine, the highest honor that can be bestowed on a Board-certified hospice physician. Some of them even teach hospice and palliative medicine. Rejecting the clinical judgments of these physicians impugns their expertise and reputation.

HPBC engaged an independent physician with impeccable credentials, Dr. Stephen A. Leedy, MD, MA, HMDC, FAAHPM, to further analyze the Medical Review Contractor's findings and conclusions.[15] Dr. Leedy assessed the medical records that were provided to the OIG and confirmed, as set forth in the individual patient responses included with this letter ("Patient Response Summaries"),[16] that the certifications of terminal illness and the levels of care

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overpayment amount. Once it has completed this quantification, the HPBC will voluntarily refund to Palmetto the total SIA overpayment amount.

[15] *See* **Exhibit 2**, Curriculum Vitae of Dr. Leedy.

[16] *See* **Exhibits 3-39**. These exhibits are comprised of HPBC's responses to the bases for the OIG's claim denials.

for those patients were supported by the medical records. These conclusions by Dr. Leedy are supported by his extensive experience with hospice, as well as peer-reviewed medical literature, to which he cites in the Patient Response Summaries.[17]

The Medical Review Contractor's decisions for these patients, on the other hand, are not supported by the medical records, are rife with factual errors, 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 HPBC. 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. Dr. Leedy has provided a Physician Statement expressing his deep disappointment and concern over the lack of understanding of hospice eligibility reflected in the "Rationale" of the Medical Review Summaries.[18] In his Physician Statement, Dr. Leedy details how the Contractor's analyses are inconsistent with the standard of practice, undermine the purpose of hospice care, and are antithetical to the hospice benefit. He further describes how the Rationales across patients are contradictory and downplay or ignore key clinical data in favor of select details cherry-picked from the medical records. The Medical Review Contractor's lack of understanding is best shown through the following examples:

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[17] Dr. Leedy cited to the following in the Patient Response Summaries: De Stefani, Pietraroia, Fernandes-Silva, et al., *Observational Evidence for Unintentional Weight Loss in All-Cause Mortality and Major Cardiovascular Events: A Systematic Review and Meta-Analysis*, 8 SCI. REP. 15447 (2018) (accessible at https://www.nature.com/articles/s41598-018-33563-z); Francis Lau et al., *Use of the Palliative Performance Scale (PPS) for End-of-Life Prognostication in a Palliative Medicine Consultation Service*, Vol. 37 No. 6 J. OF PAIN AND SYMPTOM MANAGEMENT (February 23, 2009) (accessible at https://www.jpsmjournal.com/article/S0885-3924(08)00660-X/fulltext); Hicks, Rabins, and Black, *Predictors of Mortality in Nursing Home Residents With Advanced Dementia*, AM. J. OF ALZHEIMER'S DISEASE & OTHER DEMENTIAS 439-445 (August 2010, doi:10.1177/1533317510370955); McMinn, Steel, and Bowman, *Investigation and Management of Unintentional Weight Loss in Older Adults*, THE BMJ 342:d1732 (2011) (accessible at https://www.bmj.com/content/342/bmj.d1732); Mitchell, Kiely, Hamel, et al., *Estimating Prognosis for Nursing Home Residents With Advanced Dementia*, 291(22) JAMA 2734 (2004) (accessible at https://jamanetwork.com/journals/jama/fullarticle/198894); Mulinda et al., *Pituitary Macroadenomas Treatment & Management*, MEDSCAPE (Aug. 2021) (accessible at https://emedicine.medscape.com/article/123223- treatment); Russell et al., *Advanced Heart Failure: A Call to Action*, 14(6) CONGESTIVE HEART FAILURE (2008); *see also* Zhang et al., *Brain Natriuretic Peptide as the long-term cause of mortality in patients with cardiovascular disease: a retrospective cohort study*, 8(9) INTERNATIONAL J. CLINICAL & EXPERIMENTAL MED. (2015); Taylor, Bell, Breiding, and Xu, *Traumatic Brain Injury-Related Emergency Department Visits, Hospitalizations, and Deaths – United States, 2007 and 2013*, 66(9) CENTERS FOR DISEASE CONTROL AND PREVENTION MORBIDITY AND MORTALITY WEEKLY REPORT SURVEILLANCE SUMMARIES, 1-16 (March 17, 2017) (accessible at https://www.cdc.gov/mmwr/volumes/66/ss/ss6609a1.htm); Wolfram Doehner, Dementia and the heart failure patient, *European Heart Journal Supplements*, Volume 21, Issue Supplement L, December 2019, Pages L28-L31.

[18] *See* **Exhibit 1**.

- Sample #8 – The Contractor determined Sample #8, who met the LCD guidelines, was not eligible for hospice services for dates of service May 1-31, 2017. This 92-year-old patient had a primary diagnosis of senile degeneration of the brain with a Functional Assessment Staging Tool ("FAST") score of 7C and a Palliative Performance Scale ("PPS") score of only 30%, as well as numerous prognosis-impacting comorbid and secondary conditions, including osseous defects in her right shoulder and right leg, muscle weakness, and a coccygeal wound. She also required a potent transdermal opioid analgesic for hip and low back pain, and she suffered from anorexia, eating less than 25% of meals. During the denied month of service, she exhibited severe nutritional compromise, and multiple factors documented throughout the medical record support that she was significantly malnourished. Accordingly, Dr. Leedy concluded from his review of the medical record that this patient had a terminal prognosis during these dates of service and was appropriately certified. The Contractor provided several irrelevant clinical points to support the unfavorable decision, many of which indicated a misplaced focus on body mass index ("BMI"), which is not required to demonstrate hospice eligibility, to the exclusion of other information bearing on terminality. Specifically, the Contractor glossed over this patient's unintentional weight loss of 4.6% of her body weight in only 6 weeks, her increased contractures and kyphosis that made it difficult to measure her height, her dysphagia, and her anorexia that impaired her nutritional intake. In addition to concluding that this patient was eligible, Dr. Leedy opined that the Contractor "selectively ignored information in the medical record to reach a misguided conclusion."

- Sample #9 – The Contractor determined Sample #9, who met the LCD guidelines, was not eligible for hospice services for dates of service September 29-30, 2017. This 78-year-old patient had a primary diagnosis of frontotemporal dementia with a FAST score of 7A and several comorbid and secondary conditions contributing to her terminal prognosis. Notably, she had lost 10.4% of her body weight in under 2 months and was anorexic and cachectic. The Contractor relied on factually false and immaterial factors in finding her ineligible. For example, the Contractor noted "that there was no documentation of ongoing weight loss," which is directly contradicted in the medical record and would have been apparent had the Contractor not artificially and inappropriately constrained the review to just two days of care. Similarly, despite acknowledging her FAST score of 7A, which meets the applicable Palmetto LCD guidelines, the Contractor determined this patient to be ineligible, ignoring clinical factors indicating a progression towards 7C and downplaying the significance of her staggeringly low BMI of just 16. Dr. Leedy concluded that this patient was eligible for hospice services and added that the Contractor's "woefully inadequate understanding of the details of hospice eligibility, including what appears to be a complete lack of reference to LCD guidelines, and evidence of inadequate medical record review, calls into questions the validity of the review."

- Sample #72 – The Contractor determined Sample #72 was not eligible for continuous home care ("CHC") for dates of service August 1-3, 2017. This 91-year-old patient had a primary hospice diagnosis of cerebrovascular disease and a PPS score of only 10%, meaning she was comatose and not consuming anything by mouth. Dr. Leedy concluded that she was eligible for CHC services during this three-day period because she required a higher level of care for the unstable vital signs of tachypnea (labored breathing) and tachycardia (elevated heart rate), in addition to frequent medication interventions and adjustments to control her pain. Notably, she died on the final day of the denied dates of service. Yet, the Contractor commented that the "documentation does not support that she was in crisis." To the contrary, Dr. Leedy's review of the records revealed "clear signs of distress, including pain and dyspnea," which are "exactly the situation that warrants CHC." In fact, the care provided in this case is "an exemplar of the successful use of CHC," as the patient was able to die peacefully in her own home.

- Sample #78 – The Contractor determined Sample #78 was not eligible for GIP care for dates of service September 1-8, 2017. This 81-year-old patient had a primary diagnosis of acute catastrophic hemorrhagic cerebrovascular accident and a PPS of 20% that further declined to 10% on September 3, 2017. He was admitted to hospice at the GIP level of care following an emergency room visit for a severe stroke and significant neurologic symptoms. Dr. Leedy agreed with the decision to initiate GIP services because this patient's unstable medical condition (including worsening tachypnea, tachycardia, hypotension, pain, lung congestion, and agitation) and risk of recurrent stroke and seizure due to the severity of his brain damage required around-the-clock nursing monitoring and frequent administration of several intravenous medications. He died on the final day of the denied dates of service. The Contractor's claim that "[t]here is no documentation that any frequent or continuous intravenous medication or drips were ordered or administered" is blatantly inaccurate. Moreover, the Contractor's comment that "[a]s needed medication was required rarely" misrepresents this patient's fragile condition and the need for frequent intervention. According to Dr. Leedy, it is incorrect to suggest that this patient was not eligible for GIP services because the many medications needed to control his worsening symptoms were promptly scheduled rather than administered on an as-needed basis.

The irrationality of the above-referenced claim denials is perhaps explained by the flawed review process. HPBC's independent expert physician has expressed concern with the OIG's process of reviewing only one month of records (or less) 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"[19] and ongoing, multidisciplinary treatment. Conducting a limited review of only one month (or less) 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. Dr. Leedy confirms this in his Physician Statement. Although he believes the records reviewed by the Medical Review Contractor adequately supported the patients' eligibility and level of care, the OIG should have sought and reviewed the patients' other records if there was any doubt concerning their eligibility or level of care. 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 Dr. Leedy, and Dr. Leedy's Physician Statement, 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 prepared by Dr. Leedy, 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.

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, described further below, but it is important to note at the outset that the Medical Review Contractor's summaries of the records were often factually incorrect. As just one example, the Contractor denied the eligibility of a 103-year-old with a primary hospice diagnosis of atherosclerotic heart disease, purportedly because she did not have any documented chest pain or documented pain. However, the records clearly documented that this non-verbal patient had generalized pain and analgesics were administered to control it throughout the time period under review.[20] While these errors have been addressed in the individual Patient Response Summaries, we point them out here because they call into question the validity of the entire review.

[19] *See AseraCare,* 938 F.3d at 1293; 42 C.F.R. § 418.102(b).
[20] *See* OIG Medical Review Summary for Sample #71; *see also* Exhibit 28.

a. Terminality does not require a decline in condition.

The absence of decline during a single month under review is not a proper reason to conclude that a beneficiary does not have a terminal illness.[21] CMS has "also acknowledge[d] that at recertification, not all patients may show measurable decline."[22] 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.[23] Despite this well-established principle, the OIG's Medical Review Contractor repeatedly denied eligibility based on the fact that the patient had not "significantly declined."[24] 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, these patients ***actually declined***, but the Contractor still denied their eligibility because the decline was slow or not "significant." For one patient, the Contractor acknowledged the patient had declined but indicated the decline was "slow in progressing[.]"[25] For a 90-year-old patient with a primary diagnosis of pituitary macroadenoma with extrasellar extension (meaning a tumor growing in the pituitary gland in the brain that has extended beyond the gland and into the surrounding tissue), the Contractor focused on a CT scan that showed the tumor had not grown, disregarding the patient's nine hospitalizations, weight loss, falls, and a decline in functional abilities evidenced by a decreasing PPS score.[26]

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.

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[21] *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).

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

[23] *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]").

[24] *See* OIG Medical Review Summary for all 30 samples that were denied based on eligibility for hospice.

[25] *See* OIG Medical Review Summary for Sample #98.

[26] *See* OIG Medical Review Summary for Sample #86; *see also* Exhibit 35.

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.[27] 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.[28]

Here, however, the Medical Review Contractor improperly denied claims based on patients' purported improvement or stabilization.[29] For example, the Contractor denied patients whose weight remained stable or had improved, failing to recognize that some of the weight gain experienced by these patients had negative prognostic implications.[30] As another example, the Contractor denied the eligibility of a 97-year-old patient with untreated stomach cancer because her pain was "well managed" by the hospice.[31] However, the fact that the hospice was providing the patient with large doses of opioid analgesics to keep her escalating pain caused by a progressive stomach neoplasm in check does not mean her prognosis had improved. The Contractor also denied the eligibility of a 90-year-old patient who weighed only 100 pounds because she was given Marinol, an appetite stimulate, and she began to eat 100% of her meals, despite the fact that this patient's primary diagnosis was cerebral atherosclerosis, the LCD for which does not require any weight loss or poor appetite.[32] Even if these factors were appropriately interpreted by the Contractor to be signs of improvement of the patients' prognoses (which the hospice denies), it remains improper to discharge a patient until the hospice has sufficient evidence that the stabilization or improvement can be maintained. If the hospice has sufficient evidence to make that determination, it appropriately discharges patients with an extended prognosis, as evidenced by the records reviewed by the Contractor.[33]

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[27] 70 Fed. Reg. at 70540; *see also* 79 Fed. Reg. at 50471.
[28] *AseraCare,* 938 F.3d at 1282.
[29] *See, e.g.,* OIG Medical Review Summary for Samples #25, 26, 33, 34, 44, 53, 56, 58, 60, 62, 65, 67, 68, 73, 79, 86, 92, and 98.
[30] *See, e.g.,* OIG Medical Review Summary for Samples #26, 33, 68, 92, and 98. The Contractor cited weight gain as a sign the patients' prognoses had improved, but the weight gain experienced by these patients was the result of fluid retention, which has negative prognostic implications.
[31] *See* OIG Medical Review Summary for Sample #73.
[32] *See* OIG Medical Review Summary for Sample #58.
[33] That is exactly what the hospice did when one of the patients under review showed improvement in prognosis after being transferred to a skilled nursing facility, where she began to thrive from the increased custodial care and socialization. *See* OIG Medical Review Summary for Sample #74.

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.*[34] 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."[35] 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 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."[36] 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.[37] These same principles equally apply to hospice and are consistent with the CMS guidance.[38]

For many of the patients denied on the basis that they were not eligible, the Medical Review Contractor appears to have relied on the fact that certain symptoms were not documented for these patients *during* the month under review. For every patient denied based on eligibility, regardless of diagnosis, the Contractor cited that the patients did not have documentation of any stage III or IV pressure ulcers, aspiration pneumonia, frequent infections, or sepsis, none of which are required by any applicable LCD. Some patients actually experienced these signs or symptoms, but the Contractor did not count them because the patient responded to treatment. For example, one patient was hospitalized twice between January 2018 and April 2018 for pneumonia, but the Contractor denied his eligibility for the month of June 2018 because he did not have any documented aspiration pneumonia.[39] For other patients, recurrent urinary tract infections did not count as "frequent infections" to support the patients' eligibility because, according to the Contractor, the infections responded to antibiotics.[40]

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[34] *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.

[35] *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.

[36] *Anderson*, 2010 WL 4273238, at *7.

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

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

[39] *See* OIG Medical Review Summary for Sample #33.

[40] *See* OIG Medical Review Summary for Sample #53, and 58, 61, 67.

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 these issues or, if they were experiencing these issues, would respond well to treatment. Moreover, even the Medical Review Contractor could only know with the improper use of hindsight that, for example, a patient ultimately would not experience these signs and symptoms during the month at issue or the patients' symptoms would resolve. Yet, the Medical Review Contractor denied the entire claim rather than define when exactly within that month the failure to experience a specific sign or symptom should result in a change to the patient's prognosis.[41] Furthermore, by focusing on these specific symptoms, the Contractor is not only conducting a hindsight evaluation of the records but is also ignoring other important signs and symptoms relevant to determining a patient's terminal prognosis, which are described further below and in the Patient Response Summaries.

Based on the foregoing, it is clear that the Contractor 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.

d. Clinical benchmarks are not required to demonstrate terminality.

Law and guidance 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."[42] Indeed, the *AseraCare* court explained, "CMS has considered and expressly declined to impose defined criteria that would govern the physician's exercise of judgment."[43] 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."[44] Further, in 2008, CMS proposed a rule that would identify "criteria" that must be considered in certifying patients as terminally ill,[45] 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."[46] Accordingly, it is improper to rely on specific clinical criteria to deny eligibility.

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[41] 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.
[42] *AseraCare,* 938 F.3d at 1301.
[43] *Id.*
[44] *Id.* at 1291.
[45] *See Vista Hospice Care,* 2016 WL 3449833, at *3.
[46] *See id.* (quoting 73 Fed. Reg. 32088, 32138 (June 5, 2008)).

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 all of the patients denied on the basis of eligibility, the Contractor cited the purported lack of stage III or IV pressure ulcers, aspiration pneumonia, frequent infections, or sepsis, regardless of the patient's primary diagnosis, as if all hospice patients undoubtedly show such symptoms and the lack of such symptoms is proof the person is not eligible. Because a predetermined list of clinical benchmarks is not required to support a terminal prognosis, it was inappropriate for the Contractor to rely on the lack of those symptoms as a basis to deny the patients access to the hospice benefit. Further, using such clinical benchmarks without regard to the patient's whole condition is inconsistent with clear directives from CMS.[47] It also bears repeating that many of these patients *had* experienced these signs and symptoms, but the Contractor improperly ignored or downplayed them.

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."[48] Indeed, they "are not binding and should not be considered 'the exact criteria used for determining' terminal illness."[49] 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.'"[50] Each of the OIG's Medical Review Summaries cite to an LCD to deny the claims at issue.[51] 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.

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[47] 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….").

[48] *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); s*ee also* NGS LCD for Hospice – Determining Terminal Status (L33393) (and earlier versions applicable to the dates at issue).

[49] *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.

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

[51] *See, generally*, OIG Medical Review Summaries.

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*,[52] a landmark decision of the U.S. Court of Appeals for the Eleventh Circuit, which identified the governing standards for evaluating hospice eligibility determinations. HPBC is located within the jurisdiction of the Eleventh Circuit, and *AseraCare* is the governing law for HPBC and for the federal government in that jurisdiction. 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.[53]

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."[54] 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.[55]

[52] 938 F.3d 1278 (11th Cir. 2019).
[53] *See supra* note 3.
[54] *Id.* at 1293.
[55] *Id.* at 1295.

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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."[56]

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 terminally ill."[57] 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.[58] 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."[59] "The fact that a beneficiary lives longer than expected in itself is not cause to terminate benefits."[60] 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."[61] Congress confirmed this approach to hospice eligibility when it eliminated the 210-day limit on the Medicare hospice benefit.[62]

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."[63] 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.[64]

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[56] *Id.* at 1296.
[57] 70 Fed. Reg. at 70539.
[58] *Exec. Dir. of Office of Vt. Health Access ex rel. Cave v. Sebelius*, 698 F. Supp. 2d 436, 441 (D. Vt. 2010).
[59] 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.").
[60] CMS, Medicare Benefit Policy Manual, CMS Pub. No. 100-02, Ch. 9, § 10.
[61] *See* Medicare Program; FY 2014 Hospice Wage Index and Payment Rate Update, 78 Fed. Reg. 48234, 48247 (Aug. 7, 2013) (emphasis added).
[62] 142 Cong. Rec. S9582 (daily ed. Aug. 2, 1996) (statement of Sen. Breaux).
[63] *AseraCare*, 938 F.3d at 1282, 1293, 1296.
[64] *Id.* at 1295.

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 Contractor used 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."[65] 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:

[65] *Id.* at 1293 (emphasis added).

> 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.[66]

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."[67] If such were the case, the physician certification requirement would be superfluous.

The Medical Review Contractor's analyses and resulting determinations do not reflect the current standard for evaluating the hospice medical record, as set forth in *AseraCare*. The Contractor's findings that the documentation did not support patient eligibility or level of care is flawed because the Contractor cited only cherry-picked factors tending to support its denials while completely disregarding other highly probative facts that supported the patients' certifications and recertifications and level of care determinations. 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 HPBC emphatically rejects—does not satisfy the standard for evaluating documentation under *AseraCare*. At best, the Contractor's determinations accomplish nothing more than stating that the medical record supports two divergent opinions regarding terminality, which fails to demonstrate that the patients were certified in error. By ignoring other facts in the record supporting the certifications and recertifications, the OIG Medical Review Contractor 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.[68] 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

[66] *Id.* at 1293-94.
[67] *Id.* at 1291, 1294.
[68] *AseraCare*, 938 F.3d at 1297.

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

Here, HPBC'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. HPBC's physicians' clinical judgment was further reviewed and affirmed by Dr. Leedy, who is Board-certified in Hospice and Palliative Care Medicine and a Fellow of the American Academy of Hospice and Palliative Medicine.[69] The OIG, on the other hand, has not identified either the Medical Review Contractor or the physicians who reviewed, and ultimately disagreed with, the certifying physicians' contemporaneous eligibility and level of care determinations, much less identified their credentials and qualifications.[70]

It is concerning that the OIG has refused to provide more detail concerning the physician reviewers' qualifications so that its audit process is as transparent and credible as possible. Even when HPBC requested this information, the OIG responded that it does not obtain the physician reviewer resumes but relies, instead, on the generic representations made by the Medical Review Contractor during the competitive bidding process regarding the qualifications of the reviewers. We have included with this letter copies of our independent expert physician's curriculum vitae.[71] It is difficult to fathom how the OIG can find a completely anonymous reviewer more credible than the certifying physicians and Dr. Leedy, who are highly experienced in hospice and well-credentialed.

Dr. Leedy's Physician Statement makes clear that the qualifications of the Medical Review Contractor's anonymous reviewers are in serious doubt. Numerous other providers have recently raised concern about the qualifications of the Medical Review Contractor's medical reviewer.[72] The OIG's failure to verify the qualifications of the Contractor's reviewers after

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[69] *See* **Exhibit 2**.

[70] 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.

[71] *See* **Exhibit 2**.

[72] *See, e.g.,* OIG, Medicare Home Health Agency Provider Compliance Audit: Mission Home Health of San Diego (Aug. 2020), at page 12; OIG, Medicare Home Health Agency Provider Compliance Audit: Suncoast Hospice (May 2021), at page 22; OIG, Medicare Home Health Agency Provider Compliance Audit: Ambercare Hospice, Inc. (May

having received credible concerns about their 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 reviewers' qualifications is a derogation of the provider's due process rights.[73]

In conclusion, the OIG has not demonstrated—and cannot demonstrate based on this review—that no reasonable physician would conclude that HPBC'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."[74] 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 also failed to connect the facts and information about each patient to the determination that the documentation was insufficient. Moreover, the Contractor simply listed criteria without providing any explanation as to how that criteria relates to that particular

2021), at pages 8, 22; OIG, Medicare Home Health Agency Provider Compliance Audit: Partners In Care, Inc. (July 2021), at pages 23-24.

[73] *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). This memorandum has not been rescinded by the new administration.

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

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.[75]

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. 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.[76]

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."[77] The *Agape* court stated that extrapolation is unsuitable for circumstances where determination of medical necessity or terminal prognosis

[75] *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.")).
[76] *Id.*
[77] *See U.S. ex rel. Michaels v. Agape Senior Cmty., Inc.*, No. CA 0:12-3466-JFA, 2015 WL 3903675, at *2 (D.S.C. June 25, 2015), order corrected, No. CA 0:12-3466-JFA, 2015 WL 4128919 (D.S.C. July 6, 2015), and aff'd in part, appeal dismissed in part sub nom. *United States ex rel. Michaels v. Agape Senior Cmty., Inc.*, 848 F.3d 330 (4th Cir. 2017).

requires a highly fact-intensive inquiry and review of each individual patient's medical record.[78] Where the nature of the claim requires an individualized determination, that determination cannot be replaced by "Trial by Formula."[79] 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."[80] 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.[81] 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.[82] 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.[83] 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.[84] 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.[85] Furthermore, every hospice physician has a unique set of skills and experiences, and, again, courts have recognized that two physicians can disagree concerning a patient's prognosis, and neither physician be wrong.[86] This

[78] *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").
[79] *Vista Hospice Care* at *11.
[80] *Vista Hospice Care* at *13 (quoting *Tyson Foods, Inc. v. Bouaphakeo*, 136 S. Ct. 1036, 1046 (2016)).
[81] *Agape*, 2015 WL 3903675, at *8; *Vista Hospice Care* at *11.
[82] *Vista Hospice Care*, 2016 WL 3449833, at *12.
[83] *See id.* at *11.
[84] *See id.* at *13.
[85] *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.").
[86] *See Vista Hospice Care*, 2016 WL 3449833, at *17.

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.[87]

Further, although the Act grants permission to use extrapolation in certain circumstances, it does not mandate such use in every type of audit.[88] 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.[89] 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.[90]

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.[91] 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.[92] Furthermore, the 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

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[87] *See id.* at *13.
[88] *See* § 1893(f)(3) of the Act (42 U.S.C. § 1395ddd(f)(3)).
[89] *Compare* § 1879 of the Act *to* § 1893(f)(3) of the Act.
[90] 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).
[91] 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.*
[92] *AseraCare*, 983 F.3d at 1285.

specific claim.[93] 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.[94]

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

HPBC engaged Dr. R. Mitchell Cox to evaluate the OIG's statistical sampling and extrapolation methodology. Dr. Cox has decades of experience providing independent analysis of statistical sampling and extrapolation in the healthcare context.[95] He has served as a statistical expert in numerous appeals of overpayment determinations before Administrative Law Judges and in federal courts. Attached as Exhibit 40 is Dr. Cox's Expert Report, which identifies and explains multiple procedural and statistical concerns with respect to the OIG's statistical sampling methodology and extrapolation.[96] Each of the flaws detailed in Dr. Cox's report demonstrates that the extrapolation is statistically invalid.

First, the OIG failed to prove that it used a statistically valid random sample because it did not provide documentation sufficient to re-create the sampling frame or the sample. Specifically, 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 to show that the sample was not improperly drawn or manipulated. The failure to fix and document the order of the claims in the sampling frame prior to sample selection means the sample does not conform to basic statistical requirements and is not statistically valid. Here, the OIG's statistician did not provide documentation to support the proper ordering of the sampling frame. Specifically, the OIG failed to provide the sort order of the sampling frame and the random number seed that was used to initialize the random number generator. The former is needed to re-create the sampling frame, and the latter is needed to re-create the sample. Accordingly, it cannot be determined that the OIG drew a statistically valid random sample in this audit and extrapolation.

Second, the precision and the confidence level are the two most important parameters for a statistical estimate. To have a standard precision of 10% and a two-sided 90% confidence interval, which the OIG claims it used, a sample size of 530 claims (instead of the 100 claims that the OIG reviewed) would have been required. According to the OIG's own guidelines, the sample here is only 19% of the size that it should have been, and the precision is 23.38% (more than double the standard precision of 10%). Even if an overpayment exists, which HPBC denies, this inadequate sample size may mean that HPBC is being asked to significantly over-reimburse

[93] *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)).
[94] *See, generally, supra* notes 72-73.
[95] **Exhibit 41**, Curriculum Vitae of Dr. Cox.
[96] **Exhibit 40**, Statistical Expert Report of Dr. Cox.

the government 133.8% more than it would have had to reimburse if the precision had been 10%, which, again, would have required a sample size of 530 claims.

Third, the reason the OIG's sample is too small to yield an acceptable value for the precision is that the OIG sampled by claim and not by beneficiary or episode of care, and claims belonging to the same beneficiary and episode of care are not statistically independent. The OIG's sample size determination procedure fails because its sampling units – claims – are not statistically independent where there are multiple claims belonging to the same beneficiary or episode of care. In this case, a sizable fraction of the beneficiaries and episodes of care in the OIG's sampling frame had multiple claims, so a sizable fraction of the claims in the OIG's sampling frame cannot be assumed to be statistically independent. The OIG's sampling procedure ignored this fact, resulting in a sample too small to achieve an acceptable value of the precision and possibly resulting in the OIG asking Trustbridge to reimburse much more than it otherwise would.

Fourth, the OIG violated statistical principles when it improperly removed potential underpayments from its sampling frame and thereby introduced a bias towards overpayments into its sampling frame and into its sample. In the OIG's sampling plan, the OIG states that zero-paid claims (potential underpayments) were excluded from the universe. Since the zero-paid claims were excluded from the universe, they were not available to be selected for the sample here and thus did not factor into the extrapolated overpayment. Statistical principles require the inclusion of zero-paid claims in the universe. This exclusion of unpaid and potentially underpaid claims puts HPBC at an extreme disadvantage because it likely resulted in an improperly inflated extrapolated amount that the OIG has deemed an overpayment. There is absolutely no legal, administrative, or statistical justification for the OIG to have removed the zero-paid claims from the universe.

Finally, 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 its draft report that "CMS, acting through a MAC [Medicare Administrative Contractor] 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 MPIM. While HPBC 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. Of course, any recoupment amount extrapolated from a sample, including the current one, must ultimately comply with the requirements of the MPIM to be enforceable.

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 MPIM, § 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%. From the audit of HPBC by the OIG, the financial error rate (the total dollar amount allegedly paid in error divided by the total dollar amount paid for all claims in the sample) is 0.37 or 37%. Therefore, HPBC's overpayment did not meet the minimum high error rate standard of 50% set out in the MPIM, and the MAC tasked with determining whether an overpayment exists will not be permitted to extrapolate.

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

3. The SIA-Related Overpayments Identified by the OIG Cannot Form Basis of Extrapolation

Because the total service intensity add-on ("SIA") overpayment amount in the sampling frame can be quantified through a case-by-case review, the SIA overpayments identified by the OIG with respect to three sampled claims cannot be used to estimate an extrapolated SIA overpayment amount.

The OIG determined that the HPBC received $335.57 in improper SIA payments for sampled claims 63, 70, and 100. Upon investigation, the HPBC found that the root cause of the SIA overpayments was both a Palmetto system error, as well as a technological issue within its electronic medical record ("EMR") system that inadvertently over-reported certain SIA-eligible units on the claims. HPBC is able to identify all impacted claims in the sampling frame and quantify, based on a case-by-case review, the total SIA overpayment amount for each claim. Once it has completed this quantification, the HPBC will voluntarily refund to Medicare the total SIA overpayment amount for all claims impacted by these issues.

Because the total SIA overpayment amount in the sampling frame can be quantified manually and repaid accurately without the use of statistical sampling, the OIG is not permitted to use sampling to extrapolate a total estimated SIA overpayment amount. Statistical sampling may be used to estimate overpayments "when claims are voluminous…*and when a case-by-case review is not administratively feasible.*"[97] The justification for and constitutional soundness of statistical sampling rests on it being "the only feasible method available" for the government to determine overpayments in some cases.[98] Courts have refused, however, to allow statistical sampling when

[97] HCFA Ruling No. 86-1 (emphasis added); *see also Chaves Cnty. Home Health Serv., Inc. v. Sullivan*, 931 F.2d 914, 919 (D.C. Cir. 1991) (stating that courts permit "the use of statistical sampling to determine whether there has been a pattern of overpayments . . . *where case-by-case review would be too costly*") (emphasis added); *Rio Home Care, LLC v. Azar*, 2019 WL 1411805, at *16 (S.D. Tex. Mar. 11, 2019) (describing HCFA Ruling 86-1 as the "seminal ruling on the use of statistical sampling to project overpayments to Medicare providers").

[98] *See Dominion Ambulance, L.L.C. v. Azar*, 968 F.3d 429, 441–42 (5th Cir. 2020); *see also Chaves Cnty. Home Health Serv.*, 931 F.2d at 923.

it is *not* the only method available to establish overpayment—for example, when discrete claims can be analyzed and reviewed to determine whether they were billed in error.[99] Here, since case-by-case review *is* administratively feasible and statistical sampling *is not* the only method available to determine overpayment, statistical sampling and extrapolation is inappropriate and not permissible. Accordingly, the OIG should remove from its $42,336,162 estimated overpayment the amount that was based on a legally impermissible extrapolation of the $335.57 in SIA overpayments identified in the three sampled claims.

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.[100]

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.[101]

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…."[102] To be

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[99] *See, e.g. U.S. ex rel. Michaels v. Agape Senior Cmty., Inc.*, 2015 WL 3903675, at *7 (D.S.C. June 25, 2015), order corrected, 2015 WL 4128919 (D.S.C. July 6, 2015), and aff'd in part, appeal dismissed in part sub nom. *United States ex rel. Michaels v. Agape Senior Cmty.*, Inc., 848 F.3d 330 (4th Cir. 2017) (citing *United States v. Friedman*, 1993 U.S. Dist. LEXIS 21496 (D. Mass. July 23, 1993)).
[100] *Caring Hearts Pers. Home Servs., Inc. v. Burwell*, 824 F.3d 968, 970 (10th Cir. 2016) (emphasis added).
[101] *See* 42 C.F.R. § 418.22. *See also* 142 Cong. Rec. S9582 (Aug. 2, 1996) (statement of Sen. Breaux).
[102] *See* Act § 1870, 42 U.S.C. § 1395gg; *see also* CMS, Medicare Financial Management Manual ("MFMM"), CMS Pub. 100-06, Ch. 3 § 90.

"without fault," the provider is only required to have been reasonable, *i.e.*, that it had a *reasonable* basis for its *assumption* regarding payment.

Here, HPBC understandably relied on the reasonable clinical judgment of the patients' skilled physicians and had a "reasonable basis for assuming the payment[s] [were] correct."[103] The Patient Response Summaries demonstrate this reasonable basis. The Medical Review Contractor has failed to show that HPBC 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, HPBC 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."[104] For these reasons, HPBC 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. Such an adjustment is required by long-standing secondary payer and CMS policies[105] 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.[106] 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 equipment, pharmacy, radiology, labs, and therapies.[107] Any alleged overpayment must be adjusted to reflect those amounts paid for services that would otherwise

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[103] *Id.*

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

[105] *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).

[106] *See* CMS, Medicare Benefit Policy Manual ("MBPM"), Pub No., 100-02, 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.

[107] 142 Cong. Rec. S9582 (daily ed. Aug. 2, 1996) (statement of Sen. Breaux).

have been paid for by Medicare, including, but not limited to, pharmaceuticals, durable medical equipment, and physician services, including physician visits.

## 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. HPBC'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.

HPBC has already voluntarily refunded amounts received for two claims with an SIA overpayment (Sample #63 and 100) and is in the process of identifying and voluntarily refunding other SIA overpayments that were the result of a Palmetto system error and EMR system error, including the SIA payment for Sample #70.[108] HPBC does not concur with this recommendation with respect to all other claims denied by the Medical Review Contractor.[109] HPBC and its expert physician have thoroughly reviewed the audit findings by the OIG and have determined that HPBC 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 with respect to these other claims. The rationale for HPBC's determinations is set forth in this letter and the Patient Response Summaries prepared by its independent expert physician, Dr. Leedy. If any attempt is made by HPBC's MAC to recoup funds related to the OIG's audit, HPBC 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.

HPBC acknowledges its obligations under the 60-Day Repayment Rule. As noted above, HPBC has voluntarily refunded amounts received for two claims and will be making further voluntary repayments associated with SIA overpayments currently being investigated. However, besides claims involving SIA payments, HPBC has determined that no other repayments under this rule are warranted at this time. The Draft Report indicates that the OIG believes its report constitutes credible information of potential overpayments, and, therefore, HPBC 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

[108] On April 8, 2022, HPBC made a voluntary repayment to Palmetto for service intensity add-on payments received from April 1, 2017 to March 31, 2019. This refund included a repayment of SIA payments for two individuals included in the OIG sample (Samples 63 and 100).
[109] This includes all 37 claims denied on the basis of eligibility or level of care.

noted above, HPBC and its expert physician have thoroughly reviewed the audit findings by the OIG and have determined that it did not receive any other overpayments and that the OIG's claim denials and statistical extrapolation are improper and contrary to law. Accordingly, HPBC 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.

HPBC does not concur with this recommendation. As already discussed, HPBC has robust policies and procedures and corporate compliance program, which are shown by a number of CMS data sets to be effective. HPBC's policies and procedures comply with ***and incorporate*** the Medicare requirements. While HPBC 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 or CHC care. Moreover, the Draft Report does not identify any particular flaws. To be sure, HPBC has confirmed through an independent expert physician 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/EMS
Enclosures

HB: 4860-5834-5255.2