

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**MEDICARE HOSPICE PROVIDER
COMPLIANCE AUDIT:
ALIVE HOSPICE, INC.**

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



Amy J. Frontz
Deputy Inspector General
for Audit Services

May 2021
A-09-18-03016

Office of Inspector General

<https://oig.hhs.gov>

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

Office of Audit Services

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

Office of Evaluation and Inspections

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

Office of Investigations

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

Office of Counsel to the Inspector General

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

Notices

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

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

OFFICE OF AUDIT SERVICES FINDINGS AND OPINIONS

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

Report in Brief

Date: May 2021

Report No. A-09-18-03016

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



Why OIG Did This Audit

The Medicare hospice benefit allows providers to claim Medicare reimbursement for hospice services provided to individuals with a life expectancy of 6 months or less who have elected hospice care. Previous OIG audits and evaluations 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 Alive Hospice, Inc. (Alive), complied with Medicare requirements.

How OIG Did This Audit

Our audit covered 11,969 claims for which Alive (located in Nashville, Tennessee) received Medicare reimbursement of \$45.8 million for hospice services provided from October 1, 2015, through September 30, 2017. 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.

Medicare Hospice Provider Compliance Audit: Alive Hospice, Inc.

What OIG Found

Alive received Medicare reimbursement for hospice services that did not comply with Medicare requirements. Of the 100 hospice claims in our sample, 76 claims complied with Medicare requirements. However, the remaining 24 claims did not comply with the requirements. Specifically, for 16 claims, the clinical record did not support the beneficiary's terminal prognosis, and for the remaining 8 claims, the clinical record did not support the level of care claimed for Medicare reimbursement.

Improper payment of these claims occurred because Alive's policies and procedures were not effective in ensuring that the clinical documentation it maintained supported the terminal illness prognosis and that the appropriate level of care was provided. On the basis of our sample results, we estimated that Alive received at least \$7.3 million in unallowable Medicare reimbursement for hospice services.

What OIG Recommends and Alive Comments

We recommend that Alive: (1) refund to the Federal Government the portion of the estimated \$7.3 million for hospice services that did not comply with Medicare requirements and that are within the 4-year reopening period; (2) based upon the results of this audit, 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 written comments on our draft report, Alive, through its attorney, strongly disagreed with our methodology and findings and did not concur with our recommendations. However, Alive agreed to refund any overpayments for the two sampled claims it agreed were in error. Alive stated that our independent medical review contractor repeatedly failed to view the medical record as a whole and elevated the medical reviewer's judgment above that of the certifying physician's judgment. In addition, Alive's statistical expert challenged the validity of our statistical sampling methodology and the resulting extrapolation.

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

TABLE OF CONTENTS

INTRODUCTION.....	1
Why We Did This Audit.....	1
Objective.....	1
Background.....	1
The Medicare Program.....	1
The Medicare Hospice Benefit.....	1
Medicare Requirements To Identify and Return Overpayments.....	3
Alive Hospice, Inc.....	4
How We Conducted This Audit.....	4
FINDINGS.....	5
Terminal Prognosis Not Supported.....	5
Level of Care Not Supported.....	6
RECOMMENDATIONS.....	7
ALIVE COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE.....	7
Nonconcurrency With Recommendations.....	8
Alive Comments.....	8
Office of Inspector General Response.....	9
Concerns Related to Audit Process.....	9
Alive Comments.....	9
Office of Inspector General Response.....	10
Clinical Judgment and Support for Terminal Prognosis.....	10
Alive Comments.....	10
Office of Inspector General Response.....	11
Support for Level of Care.....	11
Alive Comments.....	11
Office of Inspector General Response.....	12

Office of Inspector General Sampling Methodology 12
 Alive Comments 12
 Office of Inspector General Response 12

APPENDICES

A: Audit Scope and Methodology 15
B: Related Office of Inspector General Reports..... 17
C: Statistical Sampling Methodology 18
D: Sample Results and Estimates..... 19
E: Alive Comments 20

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 Alive Hospice, Inc. (Alive), 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 on the level of care.⁴

Beneficiaries eligible for the Medicare hospice benefit may elect hospice care by filing a signed election statement with a hospice.⁵ Upon election, the hospice assumes the responsibility for medical care of the beneficiary's terminal illness, and the beneficiary waives all rights to Medicare payment for services that are related to the treatment of the terminal condition or related conditions for the duration of the election, except for services provided by the designated hospice directly or under arrangements or services of the beneficiary's attending physician if the physician is not employed by or receiving compensation from the designated hospice.⁶

The hospice must submit a notice of election (NOE) to its MAC within 5 calendar days after the effective date of election. If the hospice does not submit the NOE to its MAC within the required timeframe, Medicare will not cover and pay for days of hospice care from the effective date of election to the date that the NOE was submitted to the MAC.⁷

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

⁴ 42 CFR § 418.302. For dates of service on or after January 1, 2016, there are two daily payment rates for routine home care: a higher rate for the first 60 days and a lower rate for days 61 and beyond. 80 Fed. Reg. 47142, 47172 (Aug. 6, 2015).

⁵ 42 CFR § 418.24(a)(1).

⁶ The Act § 1812(d)(2)(A) and 42 CFR § 418.24(d). After our audit period (October 1, 2015, through September 30, 2017), 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 before 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.¹³ 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.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 Hospices that admit a patient who previously received hospice services (from the admitting hospice or from another hospice) must consider the patient's entire Medicare hospice stay to determine in which benefit period the patient is being served and whether a face-to-face visit will be required for recertification. 75 Fed. Reg. 70372, 70435 (Nov. 17, 2010).

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

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 §§ 401.301–401.305; 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

Alive Hospice, Inc.

Alive, located in Nashville, Tennessee, is a nonprofit provider that furnishes hospice care to beneficiaries who live in the Middle Tennessee region. The hospice care includes compassionate end-of-life care, palliative care, bereavement support, and community education. From October 1, 2015, through September 30, 2017 (audit period), Alive provided hospice services to approximately 5,500 beneficiaries and received Medicare reimbursement of about \$47 million.¹⁹ Palmetto GBA, LLC (Palmetto), serves as the MAC for Alive.

HOW WE CONDUCTED THIS AUDIT

Alive received Medicare Part A reimbursement of \$46,788,699 for hospice services provided during our audit period, representing 13,774 paid claims. After we excluded 1,805 claims, totaling \$991,674, our audit covered 11,969 claims totaling \$45,797,025.²⁰ We reviewed a random sample of 100 of these claims, totaling \$397,560, 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 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—Part 1*, Pub. No. 15-1, § 2931.2; 81 Fed. Reg. at 7670.

¹⁹ Claims data for the period October 1, 2015, through September 30, 2017, were the most current data available when we started our audit.

²⁰ We excluded hospice claims that had a payment amount of less than \$1,000 (1,796 claims), were identified in the Recovery Audit Contractor data warehouse as having been reviewed by another party (5 claims), or had compromised beneficiary numbers (4 claims).

FINDINGS

Alive received Medicare reimbursement for hospice services that did not comply with Medicare requirements. Of the 100 hospice claims in our sample, 76 claims complied with Medicare requirements. However, the remaining 24 claims did not comply with the requirements. Specifically, for 16 claims, the clinical record did not support the beneficiary's terminal prognosis, and for the remaining 8 claims, the clinical record did not support the level of care claimed for Medicare reimbursement. Improper payment of these claims occurred because Alive's policies and procedures were not effective in ensuring that the clinical documentation it maintained supported the terminal illness prognosis and that the appropriate level of care was provided.

On the basis of our sample results, we estimated that Alive received at least \$7.3 million in unallowable Medicare reimbursement for hospice services.²¹ As of the publication of this report, these overpayments include claims outside of the 4-year reopening period.²² Notwithstanding, Alive 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.²³

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 the hospice interdisciplinary group is required. Clinical information and other documentation that support the beneficiary's medical prognosis must accompany the physician's certification and be filed in the medical record with the written certification of terminal illness.²⁴

For 16 of the 100 sampled claims, the clinical record provided by Alive did not support the associated beneficiary's terminal prognosis. Specifically, the independent medical review

²¹ The statistical lower limit is \$7,389,854. 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 at least 95 percent of the time.

²² 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).

²³ 42 CFR § 405.980(c)(4).

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

contractor determined that the records for these claims did not contain sufficient clinical information and other documentation to support the medical prognosis of a life expectancy of 6 months or less if the terminal illness ran its normal course.

LEVEL OF CARE NOT SUPPORTED

Medicare reimbursement for hospice services is made at predetermined payment rates—based on the level of care provided—for each day that a beneficiary is under the hospice’s care. The four levels are: (1) routine home care, (2) GIP care, (3) inpatient respite care, and (4) CHC.²⁵ 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.²⁶ 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.

Our sample contained 19 claims for which Alive claimed Medicare reimbursement for a level of care with a higher payment rate (i.e., GIP care). For 8 of these 19 claims, Alive received reimbursement at the GIP payment rate; however, the associated beneficiary’s clinical record did not support the need for the claimed level of care. The independent medical review contractor determined that the associated beneficiaries received pain control or acute or chronic symptom management that could have been managed in another setting. For all eight sampled claims, the associated beneficiaries’ hospice care needs could have been met if Alive had provided services at the less expensive routine level of care.²⁷

²⁵ 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).

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

²⁷ For all eight claims, we used the applicable payment rates and questioned the difference in payment amounts between the GIP and routine levels of care.

RECOMMENDATIONS

We recommend that Alive Hospice, Inc.:

- refund to the Federal Government the portion of the estimated \$7,389,854 for hospice services that did not comply with Medicare requirements and that are within the 4-year reopening period;²⁸
- based upon the results of this audit, exercise reasonable diligence to identify, report, and return any overpayments in accordance with the 60-day rule²⁹ 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.

ALIVE COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, Alive, through its attorney, strongly disagreed with our methodology and findings and did not concur with our recommendations. Alive disagreed with our determinations for all but 2 of the 24 sampled claims questioned in our draft report and provided specific responses for each of the 24 claims. Alive agreed to refund or repay any overpayments for the two claims it agreed were in error.

Alive stated that OIG's independent medical review contractor repeatedly failed to view the medical record as a whole and elevated the medical reviewer's judgment above that of the certifying physician's judgment. Furthermore, Alive stated that our independent medical review contractor repeatedly found that documentation was insufficient because it did not satisfy Local Coverage Determination (LCD) criteria. Alive stated that LCD guidelines are not mandatory and that failure to meet those guidelines cannot support a claim denial. In addition, Alive stated that our independent medical review contractor applied criteria and rules that are both not applicable and not appropriate for reviewing hospice eligibility and level of care.

²⁸ 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.

²⁹ 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.

Alive engaged a statistical expert, who analyzed our statistical sampling methodology and, based on that analysis, stated that our methodology is not statistically valid and should not be used as a basis to calculate an extrapolated overpayment. Alive's comments are included as Appendix E.³⁰

After reviewing Alive's comments, we maintain that our findings and recommendations are valid. We also reviewed the report prepared by Alive's statistical expert and maintain that our statistical sampling methodology and extrapolation were statistically valid and resulted in a legally valid and reasonably conservative estimate of the amount that Medicare overpaid to Alive. The following sections summarize Alive's comments and our responses.

NONCONCURRENCE WITH RECOMMENDATIONS

Alive Comments

Alive did not concur with our three recommendations as follows:

- Regarding our first recommendation, Alive stated that based on a review by a third-party expert and its own clinical review of the beneficiaries' clinical records, 22 of the 24 sampled claims were supported by the patient's clinical record and billed appropriately. Alive agreed to refund or repay any overpayments associated with the remaining two sampled claims. In addition, Alive stated that our sampling methodology was not statistically valid and should not be used as a basis to calculate an extrapolated overpayment. Alive stated that it intends to vigorously challenge our findings for the 22 sampled claims and any sampling methodology used to calculate and extrapolate overpayments by exercising its rights to appeal any adverse findings through the Medicare administrative appeals process.
- Regarding our second recommendation, Alive acknowledged its legal obligation to exercise reasonable diligence to identify potential overpayments within the preceding 6 years based on receipt of credible information that an overpayment may exist. However, Alive stated that it disagreed with our findings and believes that the vast majority of the sampled claims are supported by the patients' clinical records and were billed appropriately.
- Regarding our third recommendation, Alive disagreed that its policies and procedures allowed any systemic issues to occur. Alive stated that OIG has not identified any

³⁰ Alive attached four exhibits to its comments, which contained curricula vitae of the external consultants and internal medical reviewers it hired to review the beneficiary clinical records that our independent medical review contractor determined were not supported, those external consultants' and internal medical reviewers' rebuttal statements for our findings, and the Alive statistical expert's review of our statistical sampling methodology. Because these documents contain proprietary and personally identifiable information, we have excluded them from this report, but we are providing Alive's comments in their entirety to CMS.

particular policies or procedures that it believes to be lacking or insufficient and that the findings reflect an effective compliance program.

Office of Inspector General Response

We clarified in the footnote to our first recommendation that OIG audit recommendations do not represent final determinations by Medicare. Action officials at CMS, acting through a MAC or other contractor, will determine whether a potential overpayment exists and will recoup any overpayments consistent with CMS's policies and procedures. If a disallowance is taken, a provider has the right to appeal the determination that a payment for a claim was improper (42 CFR § 405.904(a)(2)). An overpayment based on extrapolation is re-estimated depending on the result of the appeal.

We maintain that improper payment of the 24 sampled claims occurred because Alive's policies and procedures were not effective in ensuring that the clinical documentation it maintained supported the terminal illness prognosis and that the appropriate level of care was provided.

CONCERNS RELATED TO AUDIT PROCESS

Alive Comments

Alive stated that our audit process was flawed. Alive also stated that although our objective was to determine whether hospice services provided by Alive complied with Medicare requirements, the draft report failed to provide any explanation for why Alive was selected for the audit in the first place. Alive further stated that although Alive and OIG have had several written communications, OIG has provided no explanation for why Alive was selected for the audit.

Alive stated that it has significant concerns about the qualifications of our independent medical review contractor and that OIG has not provided any substantive information by which Alive can assess the contractor. Alive further stated that although OIG confirmed its independent medical review contractor was certified by a recognized American specialty board in hospice, Alive has no ability to evaluate the certification or to further assess the experience of the contractor.

Alive stated that throughout the review, our independent medical review contractor exhibited a misunderstanding of Medicare guidelines, protocols, and acceptable standards of review. Alive also stated that our contractor repeatedly found that documentation was insufficient because it did not satisfy LCD criteria or because of the patient's score according to the Advanced Dementia Prognostic Tool (ADEPT). Alive stated that LCD guidelines are not mandatory and that failure to meet those guidelines cannot support a claim denial. Finally, Alive stated that the ADEPT score is not even part of the LCD guidelines for patients with Alzheimer's disease or dementia, and it is not an accurate means of predicting a dementia patient's prognosis.

Office of Inspector General Response

We selected Alive for a compliance audit through the use of computer matching, data mining, and data analysis techniques that identified hospice claims that were at risk for noncompliance with Medicare billing requirements. In addition, we selected Alive, in part, based on consultation with another OIG component. More specifically, after Alive entered into a settlement agreement with the U.S. Department of Justice, OIG determined that Alive needed additional oversight.³¹ However, Alive refused to enter into a corporate integrity agreement (CIA) sufficient to protect Federal health care programs. Therefore, OIG identified Alive as being in a high-risk category.

We used an independent medical review contractor that is a licensed physician who specializes in hospice and palliative medicine and is familiar with Medicare hospice guidelines and protocols. Although our independent medical review contractor referenced the ADEPT score in conducting the medical review, the contractor properly used the appropriate statutory and regulatory hospice criteria, as well as applicable LCD guidelines, as the framework for determining terminal status. Specifically, our independent medical review contractor applied standards set out in 42 CFR § 418.22(b)(2), which requires that clinical information and other documentation that support the medical prognosis accompany the physician's written certification of terminal illness and be filed in the medical record.³²

We acknowledge that some beneficiaries who did not meet the guidelines in the hospice LCDs may still be appropriate for hospice care based upon an individual assessment of the beneficiary's health status. Accordingly, our independent medical review contractor merely used LCD guidelines as a tool to evaluate the terminal prognosis. We maintain that our independent medical review contractor consistently and appropriately applied Medicare hospice eligibility requirements when it determined whether the certified terminal prognosis was supported.

CLINICAL JUDGMENT AND SUPPORT FOR TERMINAL PROGNOSIS

Alive Comments

Alive stated that the findings in our draft report are based entirely on a subjective difference in clinical opinion and that our independent medical review contractor determined in his or her own medical opinion that the portion of the patient's clinical records assessed did not support the terminal prognosis or the GIP level of care. Alive cited several court cases and stated that a

³¹ For more information, see the U.S. Department of Justice press release, available at <https://www.justice.gov/usao-mdtn/pr/alive-hospice-pays-us-and-tennessee-over-15-million-resolve-false-claims-act-lawsuit>. Accessed on April 13, 2021.

³² Applicable LCD guidelines also state that the documentation must contain enough information to support terminal illness upon review.

difference in clinical judgment cannot render the physician’s certification false or invalid for billing purposes.

Alive disagreed with our determinations for 14 of the 16 sampled claims in our draft report for which our independent medical review contractor found that the associated beneficiaries’ clinical records did not support the terminal illness prognosis. Alive stated that our contractor consistently failed to apply the appropriate standard for assessing whether the clinical record supported the terminal prognosis. Alive also stated that our independent medical review contractor considered only a limited “snapshot” of the patient’s records in making a determination and, therefore, consistently failed to consider all of the relevant factors and information related to the patient’s life expectancy.

Office of Inspector General Response

As previously mentioned, we used an independent medical review contractor that is a licensed physician who specializes in hospice and palliative medicine and is familiar with Medicare hospice guidelines and protocols. In conducting the medical review, our contractor properly used the appropriate statutory and regulatory hospice criteria, as well as applicable LCD guidelines, as the framework for its determinations. Our contractor acknowledged the physician’s terminal diagnosis and evaluated the medical records for each hospice claim (including necessary historical clinical records), guided by questions rooted in the Medicare requirements, to determine whether the certified terminal prognosis was supported. When the medical records and other available clinical information supported the physician’s medical prognosis of a life expectancy of 6 months or less if the terminal illness runs its normal course, a determination that hospice eligibility criteria were met was made. In addition, the decisions in the court cases that Alive referenced addressed whether a difference in clinical judgment can render a physician certification false for purposes of False Claims Act liability and therefore are inapplicable to OIG audit recommendations and CMS recoveries arising from OIG audits.

Based on our review of Alive’s comments, including its external consultants’ and internal medical reviewers’ analyses, we maintain that the clinical records for each of the 16 sampled claims did not support the associated beneficiary’s terminal prognosis. For the reasons stated above, we disagree with Alive’s statement that our independent medical review contractor failed to apply the appropriate standard for assessing whether the clinical record supported the terminal prognosis. We also disagree that our contractor considered only a limited “snapshot” of patient records in making determinations on the claims.

SUPPORT FOR LEVEL OF CARE

Alive Comments

Alive disagreed with our determinations for the eight sampled claims in our draft report for which our independent medical review contractor found that the associated beneficiaries’ clinical records did not support the need for the GIP level of care. Alive stated that our

contractor retrospectively analyzed patients' clinical records, applied standards that are inapplicable to GIP care, and second-guessed the medical necessity of GIP care based on conditions that patients lacked or treatments that patients did not receive.

Office of Inspector General Response

After reviewing Alive's comments, including its external consultants' and internal medical reviewers' analyses, we maintain that the clinical records for the eight sampled claims did not support the need for the claimed GIP level of care. Specifically, for these eight claims, our independent medical review contractor determined that the associated beneficiaries received pain control or acute or chronic symptom management that could have been managed in another setting.

OFFICE OF INSPECTOR GENERAL SAMPLING METHODOLOGY

Alive Comments

Alive challenged the validity of our statistical sampling methodology, engaged a statistical expert to review our sampling methodology, and provided a copy of the statistical expert's report. The statistical expert stated that our sample and extrapolation are not statistically valid and should not be used as a basis to calculate an extrapolated overpayment because: (1) the audit findings did not meet the high-error-rate criteria in the Social Security Act and CMS's *Medicare Program Integrity Manual* (MPIM) to justify the use of extrapolation, (2) the audit findings did not meet the error rate criteria in OIG's CIA to justify the use of extrapolation, (3) OIG ignored statistical principles by excluding underpayments or unpaid (i.e., zero-paid) claims from the universe of claims, (4) OIG's sample is not sufficient to achieve the standard precision and confidence level for this type of statistical estimate, (5) OIG did not provide information sufficient to re-create the sampling frame and sample or OIG's overpayment estimate, (6) OIG did not state the sort order of the sampling frame, and (7) OIG failed to provide information connecting claims to overpaid amounts.

Office of Inspector General Response

After reviewing the statistical expert's report, we maintain that our sampling methodology and extrapolation are statistically valid. 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.³³ 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

³³ See *John Balko & Assoc. v. Sebelius*, 2012 WL 6738246 at *12 (W.D. Pa. 2012), *aff'd* 555 F. App'x 188 (3d Cir. 2014); *Maxmed Healthcare, Inc. v. Burwell*, 152 F. Supp. 3d 619, 634–37 (W.D. Tex. 2016), *aff'd*, 860 F.3d 335 (5th Cir. 2017); *Anghel v. Sebelius*, 912 F. Supp. 2d 4, 18 (E.D.N.Y. 2012); *Transyd Enters., LLC v. Sebelius*, 2012 U.S. Dist. LEXIS 42491 at *13 (S.D. Tex. 2012).

the sample, and used statistical sampling software (i.e., the OIG, Office of Audit Services (OAS), statistical software RAT-STATS) to apply the correct formulas for the extrapolation.

The statutory and manual requirement that a determination of a sustained or high level of payment errors must be made before extrapolation can be used applies only to Medicare contractors.³⁴ In addition, OIG no longer uses the 5-percent error-rate threshold in its CIAs. Moreover, even in prior CIAs that used the 5-percent error-rate threshold, the threshold was used to determine when an additional claims sample (referred to as a “full sample”) needed to be selected and reviewed based on the results of a probe sample (referred to as a “discovery sample”). The entity under the CIA was required to extrapolate the results of the full sample, regardless of the error rate.³⁵

Alive relies heavily on the MPIM in its arguments that the removal of zero-paid claims ignored statistical principles. The MPIM does not apply to OIG. Even if this manual applied to OIG, it expressly allows for the removal of “claims/claim lines [that] are attributed to sample units for which there was no payment.”³⁶ More generally, OIG may perform a statistical or nonstatistical review of a provider without covering all claims from that provider.

To account for the precision of our estimate, we recommend recovery at the statistical lower limit of a two-sided 90-percent confidence interval. Lower limits calculated in this manner are designed to be less than the actual overpayment total in the sampling frame 95 percent of the time. The use of the lower limit accounts for the precision of our estimate in a manner that generally favors the auditee.³⁷ Alive focuses on the 5 percent of cases when a provider may have to pay more to the Government; however, these cases are inherently rare, and the disadvantage to the provider in such cases tends to be small given the precision in this audit. If we had selected a larger sample size, the average effect and the most likely effect would have been that we would have recommended that Alive refund a larger amount to the Government.

We provided Alive with sufficient information to re-create the statistical sample and to calculate our estimate given the overpayments amounts in our sample. The sampling frame was sorted by the HICN (a beneficiary identification number) and the DSY_VW_REC_LNK_NUM (a unique field that can be tied back to OIG’s copy of the Medicare National Claims History (NCH) file). After being sorted by these fields, the frame was numbered before we generated the random numbers for the sample. There is no legal or technical requirement that the sort

³⁴ See the Act § 1893(f)(3); MPIM, Pub. No. 100-08, chapter 8, § 8.4.

³⁵ Furthermore, the 5-percent error-rate threshold is a contractual term of the CIA and therefore applies only to the party to the CIA.

³⁶ MPIM, Pub. No. 100-08, chapter 8, § 8.4.3.2.

³⁷ E.g., see *Puerto Rico Dep’t of Health*, DAB No. 2385, at 10 (2011); *Oklahoma Dep’t of Human Servs.*, DAB No. 1436, at 8 (1993) (stating that the calculation of the disallowance using the lower limit of the confidence interval gave the State the “benefit of any doubt” raised by use of a smaller sample size).

order of the sampling frame be declared in writing in advance of generating the random numbers.

We also provided Alive with the medical review determinations underlying the errors identified in our audit. Because Alive stated that it does not have sufficient information to connect the sample overpayment amounts to the medical review determinations, we will work with Alive to ensure that it has the necessary information to make this connection.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

Our audit covered 11,969 hospice claims for which Alive received Medicare reimbursement totaling \$45,797,025 for services provided from October 1, 2015, through September 30, 2017 (audit period). These claims were extracted from CMS's NCH file.

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

We performed fieldwork at Alive's office in Nashville, Tennessee.

METHODOLOGY

To accomplish our objective, we:

- reviewed applicable Medicare laws, regulations, and guidance;
- met with CMS officials to gain an understanding of the Medicare hospice benefit;
- met with Palmetto officials to gain an understanding of the Medicare requirements related to hospice services;
- met with Alive officials to gain an understanding of Alive's policies and procedures related to providing and billing Medicare for hospice services and reviewed those policies and procedures;
- obtained from CMS's NCH file 13,774 hospice claims, totaling \$46,788,699,³⁸ for the audit period;
- excluded 1,796 claims, totaling \$961,936, that had a payment amount of less than \$1,000; 5 claims, totaling \$17,486, that were identified in the Recovery Audit Contractor data warehouse as having been reviewed by another party; and 4 claims, totaling \$12,252, that had compromised beneficiary numbers;
- created a sampling frame consisting of 11,969 hospice claims, totaling \$45,797,025;
- selected a simple random sample of 100 hospice claims from the sampling frame;

³⁸ We excluded claims that were zero-paid; however, an individual claim 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;
- obtained medical records for the 100 sampled claims 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 Alive for hospice services; and
- discussed the results of our audit with Alive officials.

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

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

APPENDIX B: RELATED OFFICE OF INSPECTOR GENERAL REPORTS

Report Title	Report Number	Date Issued
<i>Medicare Hospice Provider Compliance Audit: Suncoast Hospice</i>	<u>A-02-18-01001</u>	5/7/2021
<i>Medicare Hospice Provider Compliance Audit: Tidewell Hospice, Inc.</i>	<u>A-02-18-01024</u>	2/22/2021
<i>Medicare Hospice Provider Compliance Audit: Hospice Compassus, Inc., of Tullahoma, Tennessee</i>	<u>A-02-16-01024</u>	12/16/2020
<i>Medicare Hospice Provider Compliance Audit: Hospice Compassus, Inc., of Payson, Arizona</i>	<u>A-02-16-01023</u>	11/19/2020
<i>Safeguards Must Be Strengthened To Protect Medicare Hospice Beneficiaries From Harm</i>	<u>OEI-02-17-00021</u>	7/3/2019
<i>Hospice Deficiencies Pose Risks to Medicare Beneficiaries</i>	<u>OEI-02-17-00020</u>	7/3/2019
<i>Vulnerabilities in the Medicare Hospice Program Affect Quality Care and Program Integrity: An OIG Portfolio</i>	<u>OEI-02-16-00570</u>	7/30/2018
<i>Hospices Should Improve Their Election Statements and Certifications of Terminal Illness</i>	<u>OEI-02-10-00492</u>	9/15/2016
<i>Hospices Inappropriately Billed Medicare Over \$250 Million for General Inpatient Care</i>	<u>OEI-02-10-00491</u>	3/30/2016
<i>Hospice of New York, LLC, Improperly Claimed Medicare Reimbursement for Some Hospice Services</i>	<u>A-02-13-01001</u>	6/26/2015
<i>Medicare Hospices Have Financial Incentives To Provide Care in Assisted Living Facilities</i>	<u>OEI-02-14-00070</u>	1/13/2015
<i>The Community Hospice, Inc., Improperly Claimed Medicare Reimbursement for Some Hospice Services</i>	<u>A-02-11-01016</u>	9/23/2014
<i>Servicios Suplementarios de Salud, Inc., Improperly Claimed Medicare Reimbursement for Some Hospice Services</i>	<u>A-02-11-01017</u>	8/7/2014

APPENDIX C: STATISTICAL SAMPLING METHODOLOGY

SAMPLING FRAME

We obtained Medicare Part A claims data for hospice services that Alive provided during our audit period, representing 13,774 paid claims totaling \$46,788,699. We excluded 1,796 claims, totaling \$961,936, that had a payment amount of less than \$1,000; 5 claims, totaling \$17,486, that were identified in the Recovery Audit Contractor data warehouse as having been reviewed by another party; and 4 claims, totaling \$12,252, that had compromised beneficiary numbers. As a result, the sampling frame consisted of 11,969 claims totaling \$45,797,025. The data were extracted from the CMS NCH file.

SAMPLE UNIT

The sample unit was a Medicare Part A hospice claim.

SAMPLE DESIGN

We used a simple random sample.

SAMPLE SIZE

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

SOURCE OF THE RANDOM NUMBERS

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

METHOD OF SELECTING SAMPLE ITEMS

We sorted the sampling frame by the HICN (a beneficiary identification number) and the DSY_VW_REC_LNK_NUM (a unique field that can be tied back to OIG's copy of the NCH file). We consecutively numbered the hospice claims in our sampling frame from 1 to 11,969. After generating 100 random numbers, we selected the corresponding frame items.

ESTIMATION METHODOLOGY

We used the OAS statistical software to calculate our estimates. We estimated the total amount of improper Medicare payments made to Alive for unallowable hospice services at the lower limit of the two-sided 90-percent confidence interval. Lower limits calculated in this manner are designed to be less than the actual overpayment total 95 percent of the time.

APPENDIX D: SAMPLE RESULTS AND ESTIMATES

Table 1: Sample Details and Results

Number of Claims in Sampling Frame	Value of Sampling Frame	Sample Size	Value of Sample	Number of Unallowable Claims	Value of Overpayments in Sample
11,969	\$45,797,025	100	\$397,560	24	\$90,138

**Table 2: Estimated Value of Overpayments in the Sampling Frame
(Limits Calculated for a 90-Percent Confidence Interval)**

Point estimate	\$10,788,567
Lower limit	7,389,854
Upper limit	14,187,280

APPENDIX E: ALIVE COMMENTS³⁹

BASS BERRY + SIMS

January 22, 2021

VIA KITEWORKS & FEDERAL EXPRESS

Ms. Lori Ahlstrand
Regional Inspector General for Audit Services
Department of Health and Human Services Office of Inspector General
Office of Audit Services, Region IX
90 7th Street, Suite 3-650
San Francisco, CA 94103

Re: Office of Audit Services Draft Report Number A-09-18-03016

Dear Ms. Ahlstrand:

I am writing on behalf of my client, Alive Hospice, Inc. ("Alive"), in response to the U.S. Department of Health and Human Services ("HHS"), Office of Inspector General's ("OIG") draft audit report A-09-18-03016, dated November 17, 2020 (the "Draft Report").¹ Alive appreciates the opportunity to submit this response.

The Draft Report contains significant factual and legal errors and mischaracterizes the facts to support findings where there are none. Many of these errors result from the OIG's reliance on an outside contractor to review the medical and technical requirements of hospice eligibility. Overall, an analysis of the OIG's medical reviewer's opinions reveals a consistent and problematic theme: the OIG's reviewer repeatedly failed to view the medical record as a whole and elevated the OIG reviewer's judgment above that of the certifying physician's judgment. The OIG's medical reviewer also repeatedly found documentation was insufficient because it did not satisfy Local Coverage Determination ("LCD") criteria. LCD guidelines, however, are not mandatory, and failure to meet those guidelines cannot support a claim denial. Finally, the OIG's medical reviewer applied criteria and rules that are both not applicable and not appropriate for the review of hospice eligibility and level of care.

Despite reviewing the sampled claims for a multitude of errors (*e.g.*, billing, coverage, medical necessity, coding, *etc.*), the OIG found only a portion of the claims to be noncompliant, and only in two limited respects: (1) the documentation reviewed did not support the beneficiary's prognosis, or (2) the general inpatient ("GIP") level of care was not medically necessary. Alive disputes these findings because the review was flawed legally and factually. Further, except for a

¹ Although the Draft Report requested that Alive provide written comments in response to the Draft Report within 30 days from the date of the Draft Report, the OIG granted an extension of time until January 22, 2021 to respond.

³⁹ OIG Note: We redacted text in selected places in this appendix because it is personally identifiable information.

January 22, 2021

Page 2

delayed signature date on one physician certification (which did not result in any financial impact), the Draft Report found no other errors with the sampled claims.

Alive strongly disagrees with both the methodology and the findings of the Draft Report and does not concur with the OIG's three recommendations. The OIG's outside medical reviewer's findings essentially reflect no more than a difference in medical opinion about an individual patient's condition, and, thus, do not constitute systemic "error" supporting extrapolation.

I. ALIVE DOES NOT CONCUR WITH OIG RECOMMENDATIONS

For the reasons set forth below, Alive does not concur with any of the three recommendations in the Draft Report.

A. OIG RECOMMENDATION NUMBER ONE

Refund to the Federal Government the portion of the estimated \$7.3 million for hospice services that did not comply with Medicare requirements and that is within the 4-year reopening period.

ALIVE RESPONSE: ALIVE DOES NOT CONCUR WITH THIS RECOMMENDATION.

The OIG's findings regarding the audited claims are flawed. Based upon a review of a third party expert, and its own clinical review of the beneficiaries' medical records, which are detailed in the rebuttal statements submitted with this response, 22 of the 24 audited claims the OIG found to be improper were supported by the patient's medical records and were billed appropriately. A difference in clinical judgment between the OIG's medical reviewer and the certifying physician cannot render the certifying physician's terminal prognosis invalid. Moreover, the OIG's sampling methodology is not statistically valid and should not be used as a basis to calculate an extrapolated overpayment. Alive acknowledges 2 of the 100 audited claims arguably could be viewed as lacking sufficient documentation to support the beneficiary's terminal prognosis. That lack of documentation notwithstanding, Alive believes the claims are appropriate as its physicians consistently made a good faith determination that each beneficiary who received hospice services was eligible for those services and signed a certification supporting this determination. Nonetheless, Alive will refund or repay any overpayments associated with those two individual claims. Because those instances were isolated and not sustained or systemic, however, any extrapolated overpayment based upon those two claims to a broader universe of claims is inappropriate.

As for the remaining 22 claims, Alive intends to vigorously challenge negative claims findings and any sampling methodology used to calculate and extrapolate overpayments following the issuance of a final report by exercising its rights to appeal any adverse findings through the Medicare administrative appeals process. Alive anticipates the vast majority of the alleged overpayments related to a beneficiary's terminal prognosis or the appropriate level of care will be eliminated entirely through the appeals process. Therefore, any refund to the Medicare program on those grounds now would be inappropriate.

B. OIG RECOMMENDATION NUMBER TWO

Based upon the results of this audit, exercise reasonable diligence to identify, report, and return any overpayments in accordance with the 60-day rule and identify any of those returned overpayments as having been made in accordance with this recommendation.

ALIVE RESPONSE: ALIVE DOES NOT CONCUR WITH THIS RECOMMENDATION.

Alive acknowledges its legal obligation to exercise reasonable diligence to identify potential overpayments within the preceding six years based upon receipt of credible information that an overpayment may exist.² The Centers for Medicare & Medicaid Services (“CMS”) has acknowledged, however, a provider that receives notice of a potential overpayment through an audit may reasonably determine additional investigation of potential additional overpayments is premature during the audit appeals process.³ As noted above, Alive disagrees with the OIG’s findings and believes the vast majority of the audited claims are supported by the patient’s medical record and were billed appropriately, subject to a reasonable and acceptable variance rate.

C. OIG RECOMMENDATION NUMBER THREE

Strengthen its policies and procedures to ensure that hospice services comply with Medicare requirements.

ALIVE RESPONSE: ALIVE DOES NOT CONCUR WITH THIS RECOMMENDATION.

Alive disagrees that its policies and procedures allowed any systemic issues to occur. The OIG’s findings illustrate Alive already employs effective procedures to ensure compliance with applicable Medicare requirements. This finding is consistent with Alive’s performance in other key metrics such as the PEPPER assessment, and as noted above, Alive disagrees with the OIG’s findings. The OIG has not identified any particular policies and procedures it believes to be lacking or insufficient, and the OIG’s findings reflect an effective compliance program. Alive continuously evaluates whether opportunities exist to improve its procedures and processes and will continue to do so.

II. BACKGROUND

Alive is a 501(c)(3) charitable nonprofit organization that provides compassionate and end-of-life care, palliative care, bereavement support and community education. Alive was one of the nation’s first hospice providers, founded in 1975 by a pair of pioneering physicians committed to helping patients live in comfort until death occurred and families to grieve with support. Alive is dedicated to three core goals: (1) providing comprehensive care for terminally ill patients and their families; (2) offering support for grieving adults and children; and (3) serving the community as a center for research and education. Alive treats pediatric and adult patients, regardless of illness or age. As a non-profit, Alive is dedicated to caring for *all* patients in need of hospice – regardless of their ability to pay.

² See 42 C.F.R. § 401.305.

³ See Medicare Program; Reporting and Returning Overpayments, 81 Fed. Reg. 7,654, 7,667 (Feb. 12, 2016).

Alive is accredited by the Joint Commission and has held its Gold Seal of Approval for many years. In 2018-2020, Alive made the Hospice Honors elite list from HEALTHCAREfirst. Hospice Honors acknowledges high performing agencies by analyzing performance of Hospice CAHPS quality measures. On the CMS Hospice Compare website, Alive ranks above the 90th percentile in all measures and above the national average in almost every category, including the percentage of patients who got an assessment of all HIS quality measures at the beginning of hospice care to meet the HIS Comprehensive Assessment Measure requirements.

Both during and after the period at issue in the OIG's audit, Alive has an effective, established, and robust compliance program to ensure ongoing compliance with applicable (and evolving) Medicare coverage, documentation, and billing requirements. That program specifically includes each of the seven fundamental elements of an effective compliance program set forth in the OIG's compliance program guidance for hospice providers, including:

- Implementing written policies, procedures, and standards of conduct;
- Designating a compliance officer and compliance committee;
- Conducting effective training and education;
- Developing effective lines of communication;
- Enforcing standards through well-publicized disciplinary guidelines;
- Conducting internal monitoring and auditing; and
- Responding promptly to detected offenses and developing corrective action.⁴

Specifically, Alive employs an all-inclusive, top-down approach to compliance. Alive employs an executive-level, full-time compliance officer and has a multidisciplinary compliance committee that routinely meets to discuss compliance matters, including Alive's ongoing audit work. Each Alive employee who sees patients or is involved in billing or coding receives comprehensive and targeted compliance training at new-hire orientation, as well as ongoing training, including mandatory annual follow-up training.

Alive's robust audit process is in place to ensure its claims are billed appropriately. Alive conducts both regular and targeted audits based on the Medicare conditions of participation. If the auditors cannot locate required documentation, or if documentation is otherwise lacking with respect to any claim, the claim is not billed. Alive also conducts numerous quality assurance and performance improvement audits. Alive's strong commitment to compliance, including the fruits of its robust audit program, is reflected in its results.

According to its most recent PEPPER report, Alive is not considered an "outlier" for any of the data points tracked within the report and routinely scores significantly lower than the national, jurisdictional, and state average. For PEPPER reports, the lower the score as compared

⁴ Compliance Program Guidance for Hospice Providers, 64 Fed. Reg. 54,031 (Oct. 5, 1999).

to the established benchmarks, the better the score. Alive's previous PEPPER reports reflect similarly favorable results compared to other hospice providers and demonstrate Alive is not an outlier for any of the listed data points during the time period relevant to the claims audited by the OIG. Most recently in the summer of 2020, Alive received formal notification from its Medicare Administrative Contractor that a Targeted Probe and Education review conducted in December of 2019 resulted in a 0% charge denial rate and a 0.0% claim/claim line denial rate. Alive was removed from medical review after the initial round. This audit further proves Alive has an effective compliance program.

III. CONCERNS RELATED TO THE OIG'S AUDIT PROCESS

The OIG's audit process is flawed. The OIG's stated objective of the audit was to "determine whether hospice services provided by Alive Hospice, Inc. (Alive), complied with Medicare requirements." However, the Draft Report fails to provide *any* explanation for why Alive was selected for the audit in the first place. Instead, the Draft Report simply states that "[p]revious OIG audits and evaluations found that Medicare inappropriately paid for hospice services that did not meet certain Medicare requirements." Rather than focusing on hospice providers with questionable quality and/or billing track records, the OIG chose – inexplicably – to focus on a well-established, not-for-profit hospice that is Gold Seal Approved under The Joint Commission, with a strong and consistent history of high quality scores, exceptional PEPPER reports, and a recent Medicare contractor audit resulting in a 0% claim denial.

At the Exit Conference on November 16, 2020, Alive asked the OIG again about "how" and "why" Alive was selected for this Audit. The OIG refused to answer the question, and Alive was told to put the question in writing so the OIG could address the question properly. On November 24, 2020, Alive followed up with a letter that specifically asked the OIG for the "criteria for the selection of Alive for this Audit." Although Alive and the OIG have had several subsequent written communications, the OIG has – to date – provided no explanation for why Alive was selected for the audit. Thus, it appears the only data that the OIG used to identify Alive for audit is the amount it bills Medicare for hospice services.

Alive also has significant concerns about the qualifications of the OIG's unidentified medical reviewer. The OIG has not provided any substantive information by which Alive can assess the medical reviewer. Instead, each of the reviewer's medical determinations contains the same vague statement that the reviewer is a physician who is "licensed to practice medicine, is knowledgeable in the treatment of the enrollee's medical condition, and is familiar with the guidelines and protocols in the area of treatment under review." The statement also says that 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." Although the OIG further confirmed that the physician reviewer is certified by a recognized American specialty board in hospice, Alive has no ability to evaluate the certification or to further assess the experience of the medical reviewer. Thus, without receiving any information about the reviewer, Alive can only assess the reviewer through his or her individual medical determinations of the audited claims. The OIG also explained that it selected the medical review contractor because the contractor was "determined to be a responsive and responsible bidder, and represented the best value to the Government."

As detailed below, virtually all of the reviewer's findings that the patients' medical records do not support a terminal prognosis or the GIP level of care are flawed. Specifically, the reviewer focused only on a limited "snapshot" of the patient's record, which is not the standard for determining whether documentation supports a terminal prognosis or GIP-level care for purposes of Medicare requirements. Throughout the review, the OIG's reviewer exhibited a consistent misunderstanding of the Medicare guidelines, protocols, and acceptable standards of review.

For example, the reviewer also found, in several instances, that GIP-level care was not appropriate because the "patient did not require eight hours or more of direct nursing care." There is no eight-hour requirement for GIP care, as that is a requirement for continuous home care, not GIP.⁵ This lack of knowledge of the basic regulatory requirements alone should exclude the reviewer's opinions as a reliable basis upon which to make recommendations.

Additionally, the OIG's reviewer repeatedly found that documentation was insufficient either because it did not satisfy LCD criteria or due to the patient's score according to the Advanced Dementia Prognostic Tool ("ADEPT"). LCD guidelines are not mandatory, however, and failure to meet those guidelines cannot support a claim denial. Moreover, the ADEPT score is not even part of the LCD guidelines for patients with Alzheimer's disease or dementia, and it is not an accurate means of predicting a dementia patient's prognosis. Even the physicians who developed the ADEPT score concluded – in the article the OIG's medical reviewer cites repeatedly in his medical determinations – that the score "has only moderate accuracy in predicting survival in advanced dementia patients."⁶ That the reviewer consistently concluded that patients' medical records did not support a terminal prognosis or GIP level of care on any of these grounds establishes the reviewer is *not* qualified to accurately assess the hospice services that Alive provided to Medicare beneficiaries.

In addition to the clinical errors underlying the Draft Report, the OIG's statistical sampling and extrapolation methodology also was flawed. As discussed in more detail below, the OIG's sample is flawed because it is not representative of the broader universe of Alive's claims nor is it large enough to produce a standard precision and confidence level. In addition, the OIG failed to provide sufficient information to recreate either the sampling frame and the sample or the OIG's overpayment estimate. For all of these reasons, extrapolation of purported overpayments across the universe of Alive's claims is inappropriate and the OIG's extrapolated overpayment estimate should be withdrawn.

IV. RESPONSE TO OIG'S FINDINGS

The Draft Report alleges Alive did not comply with Medicare billing requirements for 24 of the 100 hospice claims audited, resulting in an alleged overpayment of \$7,389,854. The OIG found for 16 claims, the clinical record did not support the beneficiary's terminal prognosis, and, for the remaining 8 claims, the clinical record supported hospice eligibility but did not support the

⁵ See Medicare Benefit Policy Manual, Ch. 9 – Coverage of Hospice Services Under Hospital Insurance, Section 40.2.1 (Continuous Home Care) and 40.1.5 (Short-Term Inpatient Care).

⁶ Susan L. Mitchell, Susan C. Miller, Joan M. Teno, Roger B. Davis, & Michele L. Shaffer, *The Advanced Dementia Prognostic Tool: A Risk Score to Estimate Survival in Nursing Home Residents with Advanced Dementia*, 40 J. Pain Symptom Mgmt. 639 (2010).

January 22, 2021

Page 7

level of care claimed for Medicare reimbursement. The Draft Report does not identify any other issues or errors related to the audited claims.

Alive takes these allegation seriously and disputes the OIG's findings. To evaluate the OIG's findings objectively, Alive engaged [REDACTED] a reputable third-party auditor with substantial experience in hospice, to review the allegedly improper claims. The [REDACTED] auditors have over 30 years of experience in hospice operations and associated Medicare reimbursement criteria. Attached as Exhibit A are the curricula vitae of the [REDACTED] auditors.

Alive also is uniquely resourced for reviewing the OIG's findings in that its Chief Medical Officer, [REDACTED] is a nationally recognized physician with hospice experience. [REDACTED] has served as a professor in the family medicine departments of several medical institutions across the United States and has presented and written numerous articles on end of life care. He currently serves as Alive's Chief Medical Officer. Likewise, [REDACTED] is board certified in both family medicine and hospice and palliative medicine, practicing for more than eleven years in advanced symptom management and primary medicine. She has served for two years as Interim Chief Medical Officer at Alive, and has served as an inpatient unit Medical Director at Alive for the past seven years. [REDACTED] also actively participates in numerous hospice and palliative medicine professional organizations. Attached as Exhibit B are the curricula vitae of [REDACTED] also completed an in-depth clinical review of each claim at issue in this audit.

As explained in more detail in the individual rebuttal statements prepared by [REDACTED] and the individual rebuttal statements prepared by [REDACTED] which are attached as collective Exhibit C (organized by patient), the experts independently concluded the OIG's preliminary findings in 22 of the claims are in error and are not supported by the patients' medical records.⁷ We highlight the disparity between the OIG's external reviewer and the Alive experts by presenting their analysis of certain specific audited claims and the examples set forth in the Draft Report below.

Because of the significant number of inaccurate findings and the questionable qualifications of the OIG's medical reviewer, Alive submits the OIG's medical findings must be reconsidered. Alive therefore requests the audited claims be resubmitted for medical review with the appropriate standards and criteria applied to that re-review. As discussed herein and in the accompanying rebuttal statements, the OIG's medical reviewer applied incorrect criteria during the audit and issued inaccurate findings.

A. DIFFERENCE IN CLINICAL JUDGMENT DOES NOT RENDER THE CERTIFYING PHYSICIAN'S TERMINAL PROGNOSIS INVALID.

To be eligible for Medicare coverage of hospice services, a beneficiary must be entitled to coverage under Medicare Part A and must be certified as terminally ill, meaning the beneficiary

⁷ In addition to the rebuttal statements, Alive is submitting with its response additional portions of the medical record for Sample Patient No. 88, which further support the patient's terminal prognosis. Those medical records are included with the rebuttal statement for Sample Patient No. 88 as part of Exhibit C.

has a life expectancy of six months or less if the illness runs its normal course.⁸ A physician's certification of terminal illness or underlying clinical judgment of eligibility is the sole criterion set by Congress for establishing a patient's eligibility for the Medicare hospice benefit.⁹ CMS has specifically noted terminal prognostication is not an exact science and has declined to create clinical benchmarks that must be satisfied to certify a patient as terminally ill.¹⁰ To the contrary, CMS specifically removed language from the regulations at issue that could be construed to imply that such benchmarks exist.¹¹ A beneficiary's prognosis considers the diagnoses and all other things that relate to the beneficiary's life expectancy.¹²

Importantly, determining whether a beneficiary is terminally ill is necessarily a subjective clinical judgment based on review of the beneficiary's terminal condition, other related or unrelated health conditions, and current clinically relevant information supporting all diagnoses.¹³ CMS has repeatedly emphasized that physicians are exclusively vested with determining whether a patient's condition is terminal.¹⁴ In some contexts, such as for cardiac procedures, a physician's certification of medical necessity can be proven "false" for False Claims Act or billing purposes.¹⁵ However, the hospice eligibility determination is unique in that, by design, it requires assessing the patient's prognosis based on the physician's own judgment.¹⁶ Courts have recognized a physician's "clinical judgment of terminal illness warranting hospice benefits under Medicare cannot be deemed false . . . when there is only a reasonable disagreement between medical experts as to the accuracy of that conclusion."¹⁷

Similarly, courts have rejected "that the supporting documentation must, standing alone, prove the validity of the physician's initial clinical judgment."¹⁸ The physician's judgment dictates eligibility, and the medical records must merely support, rather than prove, that judgment.¹⁹ Rather than tasking its medical reviewer to prove or disprove the hospice's eligibility determination, CMS determined the "goal of any review for eligibility is to ensure that hospices are *thoughtful* in their eligibility determinations."²⁰ CMS has long recognized making terminal prognoses is "not an exact science" and has acknowledged the deference owing to the physician's exercise of his or her "best

⁸ 42 C.F.R. §§ 418.3, 418.20.

⁹ See 42 U.S.C. § 1395f(a)(7)(A).

¹⁰ 73 Fed. Reg. 32088, 32138 (Jun. 5, 2008).

¹¹ See *id.*

¹² 78 Fed. Reg. 48234, 48245-46 (Aug. 7, 2013).

¹³ 42 C.F.R. § 418.22(b); 42 C.F.R. § 418.25(b).

¹⁴ 78 Fed. Reg. 48234, 48247; see also 70 Fed. Reg. 70532, 70539 (stating "[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"); 73 Fed. Reg. 32088, 32138 (explaining that there are no objective or "clinical benchmarks" that "must be met" for a physician "to certify terminal illness").

¹⁵ See, e.g., *U.S. ex rel. Polukoff v. St. Mark's Hosp.*, 895 F.3d 730, 743 (10th Cir. 2018).

¹⁶ *United States v. AseraCare, Inc.*, 938 F.3d 1278, 1281, 1300 n.15 (11th Cir. 2019) (distinguishing *Polukoff* and holding a physician's reasonable clinical judgment of terminal illness cannot be false under the FCA where there is only a reasonable disagreement between medical experts as to the accuracy of that conclusion).

¹⁷ *Id.* at 1281; see also *U.S. ex rel. Wall v. Vista Hospice Care, Inc.*, 2016 WL 3449833, at *17 (N.D. Tex. June 20, 2016) (a "physician's disagreement with a certifying physician's prediction of life expectancy is not enough to show falsity").

¹⁸ *Id.* at 1294.

¹⁹ *Id.*

²⁰ 79 Fed. Reg. 50452, 50470 (Aug. 22, 2014) (emphasis added).

clinical judgment” in making this determination.²¹ CMS guidance highlights that, without exception, “certifying physicians have the best clinical experience, competence and judgment to make the determination that an individual is terminally ill.”²² CMS has emphasized a physician who determines a patient is terminally ill “need not be concerned” about the risk of CMS penalties when certifying an individual for hospice care.²³

The alleged error findings in the Draft Report are based entirely on a subjective difference in clinical opinion. The Draft Report does not attack or challenge any certifying physician’s clinical determination of a terminal prognosis. The OIG’s medical reviewer did not find for *any* of the audited claims that the certifying physician failed to make that determination based on the physician’s good faith clinical judgment or that any physician was not thoughtful in determining the patient had a terminal prognosis and was eligible to receive hospice services. Instead, the OIG’s reviewer determined, in his or her own medical opinion, the portion of the patient’s medical record the reviewer assessed did not support the terminal prognosis or the GIP level of care. As the Eleventh Circuit recognized in *AseraCare*, a difference in clinical judgment cannot render the physician’s certification false or invalid for billing purposes. Thus, because the OIG’s findings of error were based solely on a difference of clinical judgment and because that subjective difference does not render the claims improper, the Draft Report’s findings provide no basis for the recovery of an overpayment from Alive.²⁴

B. THE PATIENTS’ MEDICAL RECORDS SUPPORT A TERMINAL PROGNOSIS FOR 14 OF THE 16 ALLEGEDLY IMPROPER CLAIMS IDENTIFIED IN THE DRAFT REPORT.

Even if a difference in clinical judgment could effectively invalidate the certifying physician’s determination of terminal prognosis – which it cannot – the OIG medical reviewer’s clinical findings were flawed for virtually all of the 16 claims that the reviewer deemed were billed improperly. As set forth above, the physician’s judgment dictates hospice eligibility, and the medical records must merely support, rather than prove, that judgment. CMS acknowledges a certifying physician is best positioned to make a terminal prognosis, and the goal of any eligibility review is to ensure that hospices are thoughtful in their eligibility determinations.

The OIG alleges the patient’s medical record does not support a terminal prognosis under Medicare standards for 16 of the 100 audited claims. Alive disagrees with 14 of those 16 determinations. The medical determinations provided by the OIG reveal that the OIG’s medical reviewer consistently failed to apply the appropriate standard for assessing whether the medical record supports the terminal prognosis.

CMS has specifically noted terminal prognostication is not an exact science and has made clear hospice claims should not be denied when a certifying physician has a good faith clinical belief that a patient will pass away in six months or less. Further, physicians are not required to

²¹ 79 Fed. Reg. 50452, 50470-71 (Aug. 22, 2014); 78 Fed. Reg. 48234, 48243.

²² 78 Fed. Reg. 48234, 48247.

²³ CMS Program Memorandum: Provider Education Article: *Hospice Care Enhances Dignity and Peace As Life Nears Its End*, at 2 (Mar. 28, 2003).

²⁴ As stated above, Alive acknowledges the clinical records for 2 of the 16 allegedly improper claims may be viewed as lacking sufficient documentation to support the terminal prognosis.

prognosticate with 100% certainty. Reflecting this understanding, CMS has specifically declined to create clinical benchmarks that must be satisfied to make a terminal prognosis and has advised that a certifying physician should consider the overall diagnoses and all other things that relate to the beneficiary's life expectancy in making a certification.

The OIG's review does not follow these guidelines. The medical reviewer failed to consider all of the relevant factors and information related to the patient's life expectancy. The Draft Report explains:

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.

Despite the well-established 60 and 90-day benefit periods, the OIG's medical reviewer remarkably requested only 21-30 days of hospice medical records to determine eligibility and considered only a limited "snapshot" of the patient's records in making determinations. Thus, the OIG's medical reviewer consistently failed to consider all of the relevant factors and information related to the patient's life expectancy. Such a review is necessarily and inappropriately limited.

The certifying physician, on the other hand, had access to all available factors and information relevant to the patient's life expectancy for the *entire* benefit period being certified, and the Draft Report does not find that any physician failed to consider such information. This limitation further underscores the inherent flaws in both the OIG's audit process and the OIG's reviewer's findings.

The OIG's medical reviewer's consistently flawed analysis is evident in a number of the OIG's medical determinations. For example:

- **Sample Patient No. 18.** This 66-year-old patient was admitted to hospice due to sclerosing mesenteritis and co-morbidities, including malignant neoplasm of the liver and intrahepatic bile duct, unspecified intestinal obstruction, failure to thrive, and diabetes. In the year prior to her hospice admission, Patient had multiple hospitalizations and operations as a result of her metastatic carcinoid tumor, including a colostomy followed by an ileostomy due to a small bowel obstruction. The month prior to her hospice admission, she had increasing weakness, fatigue, pain, nausea, vomiting, and anorexia with decreased urine and ostomy output. She also had lost twenty-two pounds over the six months prior to her hospice admission and showed signs of depression. During the period of interest, Patient's PPS score was consistently 40%, indicating that she remained primarily in sitting and lying positions, was unable to do most activity, was suffering from extensive disease, and mainly required assistance for self-care. Because of hospice staff's intervention, including initiating medication management through Fentanyl patches and MISR, Patient's pain control improved, but records show she continued to experience episodes of pain, particularly in her legs where she had bilateral lower extremity edema 3-4+.

Patient had a poor appetite, eating only 25% of her meals and, some days, eating nothing at all.

The OIG contends the patient's medical record does not support a terminal prognosis for the dates of service 1/1/2017 – 1/31/2017. In contrast to the patient's medical records, which clearly evidence the patient's declining condition, the OIG medical reviewer stated the patient demonstrated limited decline, had controlled symptoms, and a normal appetite. Patient's medical records are filled with evidence that refutes these assertions, demonstrating that the patient experienced a significant decline prior to and during her hospice admission, attained some pain control purely because of the hospice team's interventions, and suffered from a decreasing appetite. All of these are clinical indicators a certifying physician would correctly and validly assess and rely upon in concluding this patient had a terminal prognosis during the time period of interest and was in need of palliative care.

- **Sample Patient No. 25.** This 82-year-old patient was admitted to hospice due to Alzheimer's disease and co-morbidities, including heart failure, CAD, and a history of multiple strokes. He had mumbling speech, a non-ambulatory status, an inability to stay awake, and an inability to self-feed. He required 24/7 live-in caregivers, was dependent for all of his activities of daily living, and needed total lift assistance. Patient had a PPS that ranged between 30-40% and a FAST score of 7D.

The OIG contends the patient's medical record does not support a terminal prognosis for the dates of service 3/11/2016 – 3/31/2016. After acknowledging Patient's FAST score of 7D, the medical reviewer proceeded to focus on clinical indicators that he or she believed the patient lacked, ignoring not only the patient's FAST score, which strongly supports hospice eligibility, but all other evidence in the record supporting Patient's terminal prognosis. Further, the OIG reviewer cited to the patient's ADEPT score of 13.9, urging that this score predicted only a 34% chance of mortality in six months. As detailed above, the ADEPT score is not part of LCD guidelines for patients with Alzheimer's disease or dementia, is not an accurate method for predicting a patient's prognosis, and, thus, should not be a factor used to overturn this patient's appropriateness for hospice care. Despite what the reviewer asserted was not included in the record, the documentation exhibited many of the clinical indicators that a certifying physician would correctly and validly assess in determining a terminal prognosis with Alzheimer's disease and other co-morbidities based on good faith clinical judgment.

- **Sample Patient No. 55.** This 76-year-old patient was admitted to hospice due to end stage chronic obstructive pulmonary disease (COPD) and co-morbidities, including acute respiratory failure, cancer of the prostate and bladder, and coronary artery disease. Prior to admission to hospice, Patient had a hospital stay due to an exacerbation of COPD with acute respiratory failure. He never

recovered to his baseline and had increasing oxygen needs. He needed maximum help with activities of daily living, had labored respirations, experienced dyspnea at rest, and was receiving inhalation therapy of Ipratropium for his labored respirations. He had a PPS score of 50%, evidencing ambulation that was mainly sitting or lying, the need for considerable assistance with self-care, normal or reduced intake, potential periods of confusion, an inability to do any work, and extensive disease. The patient continued to experience a downward trajectory of decline, passing away within five months of the dates under review.

The OIG contends the patient's medical record does not support a terminal prognosis for the dates of service 7/1/2016 – 7/31/2016. The OIG medical reviewer selectively pulled out of context portions of the medical record that show the patient having some quality days. Not only would this have been impossible without the interventions of hospice staff, it mischaracterizes and ignores the extensive evidence supporting this patient's terminal prognosis. According to the reviewer, the factors that made hospice appropriate at Patient's admission subsided when his acute illness resolved. But, this is not the case. Patient consistently faced the debilitating impact of exacerbation of COPD with acute respiratory failure, resulting in, among other sequelae, physical limitations, an increasing need for oxygen, and dyspnea at rest. The continuous decline in Patient's condition resulted in his death December 6, 2016, within five months of the episode of care at issue. The certifying physician's good faith medical determination of a terminal prognosis was not only supported by the patient's condition and reflected in the medical record, but it was also quite accurate in hindsight.

As these examples demonstrate, the OIG medical reviewer's findings with respect to documentation supporting terminal prognosis are demonstrably flawed. Throughout the review of audited claims, the OIG's reviewer applied specific clinical benchmarks to determine whether the terminal prognosis was appropriate. The patient's medical record, however, need only support the certifying physician's determination, not prove it. That is particularly true where the OIG's reviewer based his or her findings on a limited "snapshot" of the patient's medical record. For 14 of the 16 claims identified in the Draft Report as not terminally ill, the medical records clearly support the certifying physician's terminal prognosis.

Accordingly, Alive requests the OIG's medical reviewer reconsider the claims for which the reviewer initially found that the patient's medical record does not support the terminal prognosis, particularly in light of the rebuttal statements that Alive is submitting with this response. Alternatively, Alive requests the OIG engage a different, qualified medical reviewer to audit the claims at issue, as the initial reviewer's medical determinations reflect a fundamental lack of understanding of hospice services generally and relevant Medicare regulations and guidance specifically.

C. THE PATIENTS' MEDICAL RECORDS SUPPORT GENERAL INPATIENT CARE FOR ALL 8 OF THE ALLEGEDLY IMPROPER CLAIMS IDENTIFIED IN THE DRAFT REPORT.

Much like the clinical findings related to the certifying physician's determination of terminal prognosis, the OIG medical reviewer's clinical findings with respect to the 8 claims involving GIP care were also flawed. GIP care is permitted when a patient's condition warrants a short-term inpatient stay for pain control or acute or chronic symptom management that cannot be adequately achieved in other settings. Importantly, CMS does not limit the propriety of GIP care to patients suffering from certain conditions or to patients needing certain types of treatment. Rather, the patient must merely require "an intensity of care directed towards pain control and symptom management that cannot be managed in any other setting."²⁵

For the 8 GIP claims in question, patients' medical records consistently evidence patients in significant need of pain control, acute symptom management, medication adjustment, or other stabilizing treatment in an inpatient setting. And, not surprisingly, for many of these patients, the dates of service in question ended with the patient's death on the inpatient unit. But, again, instead of relying upon the clinical judgments of the clinicians directly treating the patients at issue, OIG's medical reviewer retrospectively analyzes patients' medical records, applying standards that are inapplicable to GIP care, such as noting a failure to provide eight hours of continuous nursing care that is a requirement for continuous home care, and second guessing the medical necessity of GIP care based on the conditions patients *lacked* or treatments patients *did not* receive. On this basis, the OIG alleges that patients' medical records fail to support the medical necessity of patients' GIP care for 8 of the 100 audited claims. Alive disagrees with all 8 of those determinations.

The OIG's medical reviewer's consistently flawed analysis is evident in a number of the OIG's medical determinations. For example:

- **Sample Patient No. 9.** This 88-year-old patient was admitted to hospice due to sepsis secondary to E. Coli, respiratory failure, and renal failure and comorbidities, including diabetes and mild dementia. Prior to hospice admission, Patient was hospitalized with general weakness and for kidney stone follow-up. He was diagnosed with renal failure and underwent dialysis for a Creatine level of 10. He required intubation status post cystoscopy, with left stent removal, extraction of kidney stones, and right stent placement. During this time, he also had seizure activity and significant hyponatremia. He was treated for Candida pyelonephritis and E. Coli UTI/sepsis. Despite aggressive therapy, broad spectrum antibiotics, and IV fluids, Patient continued to decline with poor oral intake and severe pain, including pain so severe he could not be touched. Patient was transferred to GIP care for pain control, including intravenous analgesics. He was also experiencing anxiety, requiring intravenous medications for control. Patient passed away on the inpatient unit October 26, 2015.

The OIG contends the patient's medical record does not support the medical necessity of the GIP level of care for the dates of service 10/16/2015 –

²⁵ Medicare Benefit Policy Manual, Ch. 9 – Coverage of Hospice Services Under Hospital Insurance, Section 40.1.5 (Short-Term Inpatient Care).

10/26/2015. Rather than focusing on the clear evidence in Patient's medical record supporting his need for pain control and continuous medication adjustment in the GIP setting, OIG's medical reviewer hypothesizes about what *could* have been done for this patient, including attempting to administer medications sublingually and topically. These assertions not only incorrectly question the decisions of the clinicians who had the benefit of physically seeing and treating this patient, they also ignore the patient's medical condition, including his severe agitation and obtunded state, which would have prevented administration of medications by mouth or sublingually. Further, the reviewer fails to acknowledge this patient's perpetual and extreme pain and the hospice staff's continual adjustment of his medications during the time period of interest. In addition to Patient's medical record, which clearly demonstrates the patient's need for care in the GIP setting, Patient's death on October 26, 2015, strongly supports that, during the time period in question, Patient's pain and acute condition could not have been managed in any other setting.

- **Sample Patient No. 14.** This 78-year-old patient was admitted to hospice due to untreatable metastatic lung cancer and co-morbidities, including, but not limited to: chronic obstructive pulmonary disease, hyperlipidemia, hypertension, aortic thrombus, and rectal bleeding. In the month prior to her hospice admission, Patient had pronounced disease progression and became bedbound. She had poor responsiveness, slept over 18 hours per day, had minimal oral intake, and had experienced significant weight loss. She had recently been in the emergency department due to a UTI and altered mental status. Patient was transferred to GIP care October 29, 2015, for extensive wound care to a stage four wound on her coccyx with serosanguineous drainage and for pain control. On November 9, 2015, Patient passed away on the inpatient unit.

The OIG contends the patient's medical record does not support the medical necessity of the GIP level of care for the dates of service 11/1/2015 – 11/9/2015. Despite countless indications in the patient's medical record that this patient was in dire need of pain control and wound care that could only be provided in a GIP setting, the reviewer reached conclusions about what the patient did *not* need and misapplied numerous standards that are irrelevant to GIP eligibility. Each day during the episode of care in question, Patient's medical records document that Patient's pain medications were adjusted to alleviate her severe pain and anxiety and that Patient received critical treatment for her stage four wound, which, notably, is the most serious type of wound a patient can have and is, in combination with Patient's other conditions, not "routinely addressed at home or in [a] skilled facility," as reviewer asserted. The reviewer also stated Patient did not require GIP because her "[c]are needs did not require eight hours or more of direct nursing." This requirement is inapplicable to GIP care; rather, it is a requirement for continuous home care, which is not at issue here. The patient's death on November 9, 2015, within the dates of service in question, only further emphasizes that care in the GIP setting was medically necessary for this patient.

- **Sample Patient No. 45.** This 70-year-old patient was admitted to hospice due to cancer of the bronchus and co-morbidities, including: history of cerebral infarction with hemiplegia and hemiparesis and chronic kidney disease stage four. Patient was diagnosed with lung cancer in November 2016. He started but did not tolerate chemotherapy, resulting in hospital and rehab admissions and, ultimately, the patient being deemed ineligible for further treatment. He then had a month-long decline with progressive weakness, fatigue, and pain. In the month leading up to Patient's hospice admission, he lost six pounds and became bedbound due to weakness and left hemiparesis. On February 21, 2017, the patient was transferred to GIP for pain and agitation. At the time of his transfer, he was declining and would no longer take pills, and his family had been sitting up with him trying to keep him calm. Patient was not very coherent, was confused, and was unable to answer questions or report his pain, though he appeared uncomfortable. From 2/21/2017 to 2/28/2017, Patient remained agitated and in need of pain management and grew progressively less responsive, with his PPS score dropping from 30% on 2/21/2017 to 20% on 2/26/2017. By 2/28/2017, Patient's PPS declined to 10%, evidencing his transition to the active dying process.

The OIG contends the patient's medical record does not support the medical necessity of the GIP level of care for the dates of service 2/21/2017 – 2/28/2017. But, the patient's medical record makes clear that the GIP setting was the only setting in which Patient could receive the appropriate pain control and symptom management for his severe agitation and pain. Contrary to the reviewer's assertions, the medical record explicitly supports that Patient's pain could not have been managed at the routine home care level of care and that his illness did in fact require GIP care. Focusing on the medications the patient *did not* receive or the medications that were *not* tried, the reviewer ignores the patient's persistent pain and agitation, the patient's continuous need for subcutaneous infusions with titration for pain control and agitation management, and hospice staff's frequent adjustments to Patient's medication regimen to ensure adequate symptom control. Despite what the reviewer insisted was not included in the record, the documentation exhibited many of the clinical indicators a certifying physician would correctly and validly assess in determining a patient qualified for GIP care.

As these examples demonstrate, the OIG medical reviewer's findings with respect to the documentation supporting the medical necessity of GIP care are demonstrably flawed. In each record, rather than acknowledging the clear documentation supporting GIP care, the reviewer substitutes his or her clinical judgment to reach a conclusion that the GIP level of care was inappropriate. For all 8 of the claims identified in the Draft Report as not qualifying for GIP, the medical records strongly evidence patients' need for care in the GIP setting.

Accordingly, like the terminal prognosis claims, Alive requests the OIG medical reviewer reconsider the claims for which the reviewer initially found that the patient's medical record does not support care at the GIP level. Alternatively, Alive requests the OIG engage a different, more

qualified medical reviewer to audit the claims at issue as the initial reviewer's medical determinations reflect a fundamental lack of understanding of hospice services generally and Medicare regulations and guidance related to GIP care specifically.

D. EXTRAPOLATION OF OVERPAYMENT OBLIGATIONS IS INAPPROPRIATE.

Alive objects to the OIG's use of extrapolation to arrive at an estimated overpayment amount. Extrapolation of Medicare overpayments is inappropriate unless there exists a "sustained or high level of payment error."²⁶ For purposes of extrapolation, a sustained or high level of payment error constitutes an error rate greater than or equal to a 50 percent error rate.²⁷ That is not the case here. Even accepting the OIG's initial audit results and alleged "error rate", the OIG found 76 of the 100 claims were 100% compliant with Medicare requirements and the remaining 24 claims were 100% compliant in every aspect that the OIG audited except for (1) whether the documentation supports the terminal prognosis, or (2) whether GIP level of care was appropriate.²⁸

In addition, even those remarkable compliance rates are conservative, as the OIG's medical reviewer erred in almost all of his findings that were adverse to Alive, which reduces the error rate to only 2%. A comprehensive review of the beneficiaries' complete medical records supports the certifying physician's determinations and establishes that Alive provided hospice services only to beneficiaries who were eligible for such services, including the corresponding level of care. Because no "sustained or high level of payment error" exists – even under the OIG's initial, un rebutted findings – extrapolation is inappropriate. In addition, Alive's auditors determined that the patient's medical record did not support a terminal prognosis for only 2 of the 100 sampled claims, constituting an error rate of 2%. The OIG's own guidelines for claims reviews conducted pursuant to a Corporate Integrity Agreement require an error rate of 5% or greater to extrapolate the results of the sample across the full population of claims. Thus, extrapolation based on such a low error rate is inappropriate even under the OIG's own guidelines.

Extrapolation of the audit results across a broader set of claims also is inappropriate because the OIG's sampling and extrapolation methodology was flawed. Alive engaged [REDACTED] to evaluate the OIG's statistical sampling and extrapolation methodology. [REDACTED] is an expert in audit sampling and has extensive experience reviewing the sampling and extrapolation methods in reviews similar to the OIG's audit. He has a Ph.D. in Mathematical Statistics from Columbia University. [REDACTED] expertise focuses on experimental design/statistical inference, queuing theory/discrete event simulation, and optimal control and numerical methods, among other areas. He has over thirty years of experience conducting statistical and economic analyses similar to his analysis relative to the OIG's audit and Draft Report. Attached as **Exhibit D** to this response is the Expert Report of [REDACTED] which addresses whether the statistical

²⁶ 42 U.S.C. § 1395ddd(f)(3).

²⁷ See Medicare Program Integrity Manual, § 8.4.1.4. Although Alive recognizes the Medicare Program Integrity Manual is not binding on the OIG, the purported overpayments identified in the Draft Report would be overpayments from Medicare, and extrapolation of Medicare overpayments absent a sustained or high level of payment error is inappropriate.

²⁸ As noted previously, except for a delayed signature date on one physician certification (which did not result in any financial impact), the Draft Report found no other errors with the sampled claims.

sampling methodology underlying the OIG's audit warrants the extrapolation of the sample findings to a broader universe of Alive's claims.

As discussed more fully in the [REDACTED] Report, the OIG's sampling methodology is flawed in numerous respects. Each flaw stands either on its own or in combination to invalidate the OIG's overpayment estimate. Moreover, as the [REDACTED] Report explains, the OIG's recoupment demand should be withdrawn as it is not supported under OIG regulations, Medicare guidelines and generally accepted statistical principles.

First, the OIG ignored statistical principles by excluding potential underpayments or unpaid claims from its universe of claims. Removing such claims is, by itself, fatal to extrapolation. Removing those claims from the overall universe inappropriately alters the calculation of the amount that Alive should have been paid. And, that defect cannot be cured by sampling more claims or by drawing a new sample because the overall universe of claims is flawed. Extrapolation of audit results to conclude an overpayment existed across a broader universe of claims is only appropriate where the extrapolation was made from a *representative* sample and was statistically significant.²⁹ The OIG has not established that its sample is representative of the total universe of Alive's claims.

The [REDACTED] Report also explains the OIG's sample is not sufficient to achieve the standard precision and confidence level for this type of statistical estimate. The OIG did not follow its own guidelines for controlling the precision of its estimate. Had the OIG followed its own guidelines, it would have determined that a sample of 908 claims rather than 100 claims was required to achieve a standard precision of 10% at the two-sided 90% confidence level used by the OIG. Such a precision and confidence level are required to ensure that the recoupment amount does not exceed the actual overpayment amount.

In addition to the sampling flaws noted above, the OIG's extrapolation methodology also is demonstrably flawed. The OIG did not provide information sufficient to recreate either the sampling frame and the sample or the OIG's overpayment estimate. The OIG did not state the sort order of the sampling frame, which permitted the OIG to use any one of a large number of samples for extrapolation. Notably, without stating the sort order, the OIG was free to use any sort order it chose, including a sort order that would intentionally maximize the recoupment amount. The OIG also failed to provide information connecting claims to overpaid amounts. Without that information, Alive cannot confirm the overpayment estimate was extrapolated from the claims listed in the sample file. Alive therefore cannot confirm that the estimate is valid, regardless of whether the underlying sample is valid, thereby rendering the OIG's extrapolation methodology invalid. On those grounds, even if the sample is determined to be valid – which it is not – the OIG's extrapolation methodology is invalid and cannot be used. Therefore, the OIG's overpayment estimate should be withdrawn.

V. CONCLUSION

For the reasons discussed herein, the OIG's findings as set forth in the Draft Report are flawed. With respect to the patients' terminal prognosis, the OIG's medical reviewer did not apply

²⁹ See *Chaves County Home Health Serv., Inc. v. Sullivan*, 931 F.2d 914, 921-22 (D.C. Cir. 1991).

January 22, 2021

Page 18

the correct standard to determine whether the patient's medical record supports a terminal prognosis and the patient's eligibility to receive hospice services. The OIG's reviewer also consistently failed to consider the totality of each patient's circumstances and each patient's individualized clinical condition and needs. The beneficiaries' medical records fully support the terminal prognosis, the medical necessity and the level of care of the hospice services for 22 of the 24 audited claims that the OIG found to be billed in error.

Alive understands it will have the opportunity to challenge the Draft Report's findings on appeal and is confident those findings will be overturned. Nonetheless, Alive submits it should not be forced to incur the time and expense of an appeal in light of the flawed findings and requests that the OIG review and withdraw those findings without the need for an appeal. Alive is committed to providing only the highest quality hospice services to its patients while maintaining strict compliance with all applicable laws, rules, and regulations, and it appreciates the opportunity to comment on the OIG's findings before the Draft Report is finalized.

Sincerely,

[REDACTED]

[REDACTED]

Enclosures