

Department of Health and Human Services

**OFFICE OF  
INSPECTOR GENERAL**

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

*Inquiries about this report may be addressed to the Office of Public Affairs at  
[Public.Affairs@oig.hhs.gov](mailto:Public.Affairs@oig.hhs.gov).*



**Amy J. Frontz  
Deputy Inspector General  
for Audit Services**

**May 2021  
A-09-18-03017**

# *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-09-18-03017

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 Ambercare Hospice, Inc. (Ambercare), complied with Medicare requirements.

### How OIG Did This Audit

Our audit covered 13,382 claims for which Ambercare (located in Albuquerque, New Mexico) received Medicare reimbursement of \$53.8 million for hospice services provided from January 1, 2016, through December 31, 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: Ambercare Hospice, Inc.

### What OIG Found

Ambercare received Medicare reimbursement for hospice services that did not comply with Medicare requirements. Of the 100 hospice claims in our sample, 48 claims complied with Medicare requirements. However, for the remaining 52 claims, the clinical record did not support the beneficiary's terminal prognosis.

Improper payment of these claims occurred because Ambercare's policies and procedures were not effective in ensuring that the clinical documentation it maintained supported the terminal illness prognosis. On the basis of our sample results, we estimated that Ambercare received at least \$24.6 million in unallowable Medicare reimbursement for hospice services.

### What OIG Recommends and Ambercare Comments

We recommend that Ambercare: (1) refund to the Federal Government the portion of the estimated \$24.6 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, Ambercare, through its attorney, stated that it disputed nearly all of our findings and did not concur with our recommendations. However, Ambercare agreed to refund any overpayments for the four claims it agreed were in error. Ambercare stated that our independent medical review contractor did not apply the correct standard to determine whether the beneficiary's clinical record supported a terminal prognosis and the beneficiary's eligibility to receive hospice services. In addition, Ambercare's statistical expert challenged the validity of our statistical sampling methodology and the resulting extrapolation.

After reviewing Ambercare's comments, we maintain that our findings and recommendations are valid. We also reviewed Ambercare'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 Ambercare.

## 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
Ambercare Hospice, Inc.....	4
How We Conducted This Audit.....	4
FINDING.....	5
Terminal Prognosis Not Supported.....	5
RECOMMENDATIONS.....	6
AMBERCARE COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE.....	6
Nonconcurrency With Recommendations.....	7
Ambercare Comments.....	7
Office of Inspector General Response.....	8
Concerns Related to Audit Process.....	8
Ambercare Comments.....	8
Office of Inspector General Response.....	8
Clinical Judgment and Support for Terminal Prognosis.....	9
Ambercare Comments.....	9
Office of Inspector General Response.....	9
Office of Inspector General Sampling Methodology.....	10
Ambercare Comments.....	10
Office of Inspector General Response.....	10
APPENDICES	
A: Audit Scope and Methodology.....	13

B: Related Office of Inspector General Reports.....	15
C: Statistical Sampling Methodology .....	16
D: Sample Results and Estimates.....	17
E: Ambercare Comments .....	18

## 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.<sup>1</sup>

### OBJECTIVE

Our objective was to determine whether hospice services provided by Ambercare Hospice, Inc. (Ambercare), 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.<sup>2</sup> 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).<sup>3</sup> 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 care,

---

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

<sup>2</sup> The Act §§ 1812(a)(4) and (5).

<sup>3</sup> 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. Medicare provides an all-inclusive daily payment based on the level of care.<sup>4</sup>

Beneficiaries eligible for the Medicare hospice benefit may elect hospice care by filing a signed election statement with a hospice.<sup>5</sup> 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.<sup>6</sup>

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.<sup>7</sup>

Beneficiaries are entitled to receive hospice care for two 90-day benefit periods, followed by an unlimited number of 60-day benefit periods.<sup>8</sup> 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<sup>9</sup> 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.<sup>10</sup> The initial certification and all subsequent recertifications must include a brief narrative explanation of the clinical findings that supports a life expectancy

---

<sup>4</sup> 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).

<sup>5</sup> 42 CFR § 418.24(a)(1).

<sup>6</sup> The Act § 1812(d)(2)(A) and 42 CFR § 418.24(d). After our audit period (January 1, 2016, through December 31, 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).

<sup>7</sup> 42 CFR §§ 418.24(a)(2) and (a)(3).

<sup>8</sup> 42 CFR § 418.21(a).

<sup>9</sup> 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).

<sup>10</sup> 42 CFR § 418.22(c).

of 6 months or less.<sup>11</sup> 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.<sup>12</sup>

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.<sup>13</sup> 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.<sup>14</sup>

Hospice providers must establish and maintain a clinical record for each hospice patient.<sup>15</sup> 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.<sup>16</sup>

### **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.<sup>17</sup>

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

---

<sup>11</sup> 42 CFR § 418.22(b)(3).

<sup>12</sup> 42 CFR § 418.22(a)(3).

<sup>13</sup> 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).

<sup>14</sup> 42 CFR §§ 418.22(a)(4), (b)(3)(v), and (b)(4).

<sup>15</sup> 42 CFR §§ 418.104 and 418.310.

<sup>16</sup> 42 CFR §§ 418.22(b)(2) and (d)(2).

<sup>17</sup> 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.<sup>18</sup>

### **Ambercare Hospice, Inc.**

Ambercare, located in Albuquerque, New Mexico, is a for-profit provider that furnishes hospice care, home health services, and personal care services to beneficiaries who live in New Mexico. From January 1, 2016, through December 31, 2017 (audit period), Ambercare provided hospice services to approximately 3,000 beneficiaries and received Medicare reimbursement of about \$55 million.<sup>19</sup> Palmetto GBA, LLC (Palmetto), serves as the MAC for Ambercare.

### **HOW WE CONDUCTED THIS AUDIT**

Ambercare received Medicare Part A reimbursement of \$55,482,172 for hospice services provided during our audit period, representing 14,873 paid claims. After we excluded 1,491 claims, totaling \$1,636,568, our audit covered 13,382 claims totaling \$53,845,604.<sup>20</sup> We reviewed a random sample of 100 of these claims, totaling \$397,050, 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.

---

<sup>18</sup> 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.

<sup>19</sup> Claims data for the period January 1, 2016, through December 31, 2017, were the most current data available when we started our audit.

<sup>20</sup> We excluded hospice claims that had a payment amount of less than \$1,000 (1,183 claims), had compromised beneficiary numbers (303 claims), or were identified in the Recovery Audit Contractor data warehouse as having been reviewed by another party (5 claims).

## FINDING

Ambercare received Medicare reimbursement for hospice services that did not comply with Medicare requirements. Of the 100 hospice claims in our sample, 48 claims complied with Medicare requirements. However, for the remaining 52 claims, the clinical record did not support the beneficiary's terminal prognosis. Improper payment of these claims occurred because Ambercare's policies and procedures were not effective in ensuring that the clinical documentation it maintained supported the terminal illness prognosis.

On the basis of our sample results, we estimated that Ambercare received at least \$24.6 million in unallowable Medicare reimbursement for hospice services.<sup>21</sup> As of the publication of this report, these overpayments include claims outside of the 4-year reopening period.<sup>22</sup> Notwithstanding, Ambercare 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.<sup>23</sup>

### 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.<sup>24</sup>

For 52 of the 100 sampled claims, the clinical record provided by Ambercare did not support the associated beneficiary's terminal prognosis. Specifically, the independent medical review contractor determined that the records for these claims did not contain sufficient clinical information and other documentation to support the medical prognosis of a life expectancy of 6 months or less if the terminal illness ran its normal course.

---

<sup>21</sup> The statistical lower limit is \$24,665,520. 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.

<sup>22</sup> 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).

<sup>23</sup> 42 CFR § 405.980(c)(4).

<sup>24</sup> 42 CFR §§ 418.22(b)(2) and 418.104(a).

## RECOMMENDATIONS

We recommend that Ambercare Hospice, Inc.:

- refund to the Federal Government the portion of the estimated \$24,665,520 for hospice services that did not comply with Medicare requirements and that are within the 4-year reopening period;<sup>25</sup>
- based upon the results of this audit, exercise reasonable diligence to identify, report, and return any overpayments in accordance with the 60-day rule<sup>26</sup> 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.

### AMBERCARE COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, Ambercare, through its attorney, stated that it disputed nearly all of our findings and did not concur with our recommendations. Ambercare disagreed with our determinations for all but 4 of the 52 sampled claims questioned in our draft report and provided specific responses for each of the 52 claims. Ambercare agreed to refund or repay any overpayments for the four claims it agreed were in error.

Ambercare stated that OIG's independent medical review contractor did not apply the correct standard to determine whether the beneficiary's clinical record supported a terminal prognosis and the beneficiary's eligibility to receive hospice services. Furthermore, Ambercare stated that our independent medical review contractor repeatedly found that documentation was insufficient because it did not satisfy Local Coverage Determination (LCD) criteria. Ambercare stated that LCD guidelines are not mandatory and that failure to meet those guidelines cannot support a claim denial. In addition, Ambercare stated that our independent medical review contractor repeatedly failed to consider the totality of each patient's circumstances and each patient's individualized clinical condition and needs.

---

<sup>25</sup> 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.

<sup>26</sup> 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.

Ambercare 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. Ambercare's comments are included as Appendix E.<sup>27</sup>

After reviewing Ambercare's comments, we maintain that our findings and recommendations are valid. We also reviewed the report prepared by Ambercare'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 Ambercare. The following sections summarize Ambercare's comments and our responses.

## **NONCONCURRENCE WITH RECOMMENDATIONS**

### **Ambercare Comments**

Ambercare did not concur with our three recommendations as follows:

- Regarding our first recommendation, Ambercare stated that based on a review by a third-party expert, 48 of the 52 sampled claims were supported by the patient's clinical record and billed appropriately. Ambercare agreed to refund or repay any overpayments associated with the remaining four sampled claims. In addition, Ambercare stated that our sampling methodology was not statistically valid and should not be used as a basis to calculate an extrapolated overpayment. Ambercare stated that it intends to vigorously challenge our findings for the 48 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, Ambercare 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, Ambercare 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, Ambercare disagreed that its procedures allowed any systemic issues to occur. Ambercare stated that OIG has not identified any

---

<sup>27</sup> Ambercare attached four exhibits to its comments, which contained resumes and curricula vitae of the external consultants it hired to review the beneficiary clinical records that our independent medical review contractor determined were not supported, those external consultants' rebuttal statements for our findings, supplemental beneficiary clinical records, and the Ambercare 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 Ambercare's comments separately in their entirety to CMS.

particular policies or procedures that it believes to be lacking or insufficient and that the findings reflect a largely 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 52 sampled claims occurred because Ambercare's policies and procedures were not effective in ensuring that the clinical documentation it maintained supported the terminal illness prognosis.

### **CONCERNS RELATED TO AUDIT PROCESS**

#### **Ambercare Comments**

Ambercare stated that it has numerous concerns with OIG's audit process. Ambercare stated that the draft report does not provide a single reason why Ambercare specifically was selected for audit.

Ambercare stated that it has serious concerns about the qualifications of our independent medical review contractor, and OIG has not provided any substantive information by which Ambercare can assess the contractor. Ambercare also stated that without receiving information about our contractor, Ambercare can assess the reviewer only through his or her individual medical determinations of the audited claims.

Ambercare stated that our independent medical review contractor repeatedly found that documentation was insufficient because it did not satisfy LCD criteria. Ambercare also stated that LCD guidelines are not mandatory and that failure to meet those guidelines cannot support a claim denial.

### **Office of Inspector General Response**

We selected Ambercare 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.

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 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.<sup>28</sup>

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**

### **Ambercare Comments**

Ambercare 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. Ambercare cited several court cases and stated that a difference in clinical judgment cannot render the physician’s certification false or invalid for billing purposes.

Ambercare disagreed with our determinations for 48 of the 52 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. Ambercare stated that our contractor consistently failed to apply the appropriate standard for assessing whether the clinical record supported the terminal prognosis. Ambercare also stated that our independent medical review contractor’s analysis was limited to a “snapshot” of the patient’s medical condition at a particular point in time, as illustrated by only a portion of the patient medical record.

### **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

---

<sup>28</sup> Applicable LCD guidelines also state that the documentation must contain enough information to support terminal illness upon review.

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 Ambercare 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 Ambercare's comments, including its external consultants' analyses, we maintain that the clinical records for each of the 52 sampled claims did not support the associated beneficiary's terminal prognosis. For the reasons stated above, we disagree with Ambercare'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's analysis was limited to a "snapshot" of the patient's medical condition at a particular point in time.

## **OFFICE OF INSPECTOR GENERAL SAMPLING METHODOLOGY**

### **Ambercare Comments**

Ambercare 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 corporate integrity agreement (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.<sup>29</sup> We properly executed our statistical sampling methodology in that we defined our sampling frame and sample unit, randomly selected our sample, applied relevant criteria in evaluating the sample, and used statistical sampling software (i.e., 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.<sup>30</sup> 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.<sup>31</sup>

Ambercare 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.”<sup>32</sup> 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.<sup>33</sup> Ambercare 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

---

<sup>29</sup> 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).

<sup>30</sup> See the Act § 1893(f)(3); MPIM, Pub. No. 100-08, chapter 8, § 8.4.

<sup>31</sup> Furthermore, the 5-percent error-rate threshold is a contractual term of the CIA and therefore applies only to the party to the CIA.

<sup>32</sup> MPIM, Pub. No. 100-08, chapter 8, § 8.4.3.2.

<sup>33</sup> 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).

been that we would have recommended that Ambercare refund a larger amount to the Government.

We provided Ambercare 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 FI\_DOC\_CLM\_CNTL\_NUM (a claim identification number) field and then numbered before we generated the random numbers for the sample. There is no legal or technical requirement that the sort order of the sampling frame be declared in writing in advance of generating the random numbers.

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

## APPENDIX A: AUDIT SCOPE AND METHODOLOGY

### SCOPE

Our audit covered 13,382 hospice claims for which Ambercare received Medicare reimbursement totaling \$53,845,604 for services provided from January 1, 2016, through December 31, 2017 (audit period). These claims were extracted from CMS's National Claims History (NCH) file.

We did not assess Ambercare'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 Ambercare's office in Albuquerque, New Mexico.

### 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 Ambercare officials to gain an understanding of Ambercare'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 14,873 hospice claims, totaling \$55,482,172,<sup>34</sup> for the audit period;
- excluded 1,183 claims, totaling \$615,592, that had a payment amount of less than \$1,000; 303 claims, totaling \$1,004,598, that had compromised beneficiary numbers; and 5 claims, totaling \$16,378, that were identified in the Recovery Audit Contractor data warehouse as having been reviewed by another party;
- created a sampling frame consisting of 13,382 hospice claims, totaling \$53,845,604;
- selected a simple random sample of 100 hospice claims from the sampling frame;

---

<sup>34</sup> 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 Ambercare for hospice services; and
- discussed the results of our audit with Ambercare 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**

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

## **APPENDIX C: STATISTICAL SAMPLING METHODOLOGY**

### **SAMPLING FRAME**

We obtained Medicare Part A claims data for hospice services that Ambercare provided during our audit period, representing 14,873 paid claims totaling \$55,482,172. We excluded 1,183 claims, totaling \$615,592, that had a payment amount of less than \$1,000; 303 claims, totaling \$1,004,598, that had compromised beneficiary numbers; and 5 claims, totaling \$16,378, that were identified in the Recovery Audit Contractor data warehouse as having been reviewed by another party. As a result, the sampling frame consisted of 13,382 claims totaling \$53,845,604. 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 FI\_DOC\_CLM\_CNTL\_NUM (a claim identification number) field, and we consecutively numbered the hospice claims in our sampling frame from 1 to 13,382. 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 Ambercare 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**

<b>Number of Claims in Sampling Frame</b>	<b>Value of Sampling Frame</b>	<b>Sample Size</b>	<b>Value of Sample</b>	<b>Number of Unallowable Claims</b>	<b>Value of Overpayments in Sample</b>
13,382	\$53,845,604	100	\$397,050	52	\$220,324

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

Point estimate	\$29,483,817
Lower limit	24,665,520
Upper limit	34,302,113

## APPENDIX E: AMBERCARE COMMENTS<sup>35</sup>

BASS BERRY + SIMS



November 23, 2020

### 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 7<sup>th</sup> Street, Suite 3-650  
San Francisco, CA 94103

**Re: Office of Audit Services Draft Report Number A-09-18-03017**

Dear Ms. Ahlstrand:

Ambercare Hospice, Inc. (“Ambercare”) submits this response to the draft Report Number A-09-18-03017 that the Office of Inspector General, Office of Audit Services (the “OIG”) issued to Ambercare on September 17, 2020 (the “Report”).<sup>1</sup>

In its initial review of a sample of Ambercare’s claims, the OIG found a portion of those claims to be noncompliant with Medicare regulations in a single respect: that the documentation reviewed did not support the beneficiary’s terminal prognosis. Although it audited a number of other aspects of the sampled claims, the OIG’s draft report did not find *any* other errors with *any* of the 100 sampled claims. As such, many of the audited claims were 100% compliant, and even those for which the OIG found a single error were compliant with the vast majority of requirements that the OIG audited.

In addition, the OIG’s findings with respect to the lone issue addressed – documentation of terminal prognosis – are both legally and factually flawed. Courts have recognized a difference in two physicians’ clinical judgments cannot render the certifying physician’s judgment invalid. In addition, the OIG’s medical reviewer erred by consistently relying on only a limited portion of the patient’s medical record to assess the certifying physician’s terminal prognosis, which was based on a full assessment of the patient’s complete medical condition. That error renders elevating the OIG’s medical reviewer’s judgment above the clinical judgment of the certifying physician all the more inappropriate. The OIG’s medical reviewer also repeatedly found that documentation was insufficient because it did not satisfy Local Coverage

---

<sup>1</sup> Although the Report requested that Ambercare provide written comments in response to the Report within 30 days from the date of the Report, Ambercare requested an extension of time to submit its written response on September 21, 2020. On September 25, 2020, the OIG confirmed an extension of time for an additional 30 calendar days until November 16, 2020. On November 12, 2020, the OIG confirmed an additional seven-day extension of time for Ambercare’s response to November 23, 2020.



---

<sup>35</sup> OIG Note: We redacted text in selected places in this appendix because it is personally identifiable information.

November 23, 2020

Page 2

Determination (“LCD”) criteria. LCD guidelines, however, are not mandatory, and failure to meet those guidelines cannot support a claim denial. For the reasons discussed below, Ambercare disputes nearly all of the findings contained in the Report and does not concur with any of the OIG’s three recommendations.

#### **I. Ambercare Does Not Concur with OIG Recommendations**

For the reasons set forth below and as discussed in more detail herein, Ambercare does not concur with any of the three recommendations set forth in the Report.

**OIG Recommendation #1:** Refund to the Federal Government the portion of the estimated \$24,665,520 for hospice services that did not comply with Medicare requirements and that is within the 4-year reopening period.

**Ambercare Response:** Ambercare does not concur with this recommendation. The vast majority of the OIG’s findings with respect to the audited claims are flawed. Based upon a review by a third-party expert engaged by Ambercare, which is detailed in the rebuttal statements submitted with this response, 48 of the 52 audited claims that the OIG found to be improper were supported by the patient’s medical records and were billed appropriately. Moreover, a difference in clinical judgment between the OIG’s medical reviewer and the certifying physician cannot render the certifying physician’s terminal prognosis invalid. And, the OIG’s sampling methodology is not statistically valid and should not be used as a basis to calculate an extrapolated overpayment. As such, Ambercare 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. Ambercare anticipates the vast majority of the alleged overpayments related to a beneficiary’s terminal prognosis will be eliminated entirely through the appeals process. Therefore, any refund to the Medicare program on those grounds at this juncture would be premature.

Ambercare acknowledges that 4 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, Ambercare believes its physicians consistently made a good faith and thoughtful determination that each beneficiary who received hospice services was eligible for those services. Nonetheless, Ambercare will refund or repay any overpayments associated with those four individual claims. Because those instances were isolated and not sustained or systemic, however, any extrapolated overpayment based upon those four claims to a broader universe of claims is inappropriate.

**OIG Recommendation #2:** Based upon the results of the 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.

**Ambercare Response:** Ambercare does not concur with this recommendation. Ambercare 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.<sup>2</sup> The Centers for Medicare & Medicaid Services (“CMS”) has acknowledged, however, that a provider that receives notice of a potential overpayment through an audit may reasonably determine that additional investigation of potential additional overpayments is premature during the audit appeals process.<sup>3</sup> As noted above, Ambercare disagrees with the OIG’s findings and believes that 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.

**OIG Recommendation #3:** Strengthen its procedures to ensure that hospice services comply with Medicare requirements.

**Ambercare Response:** Ambercare does not concur with this recommendation. Ambercare disagrees that its procedures allowed any systemic issues to occur. The OIG’s draft audit findings included only a single alleged issue with respect to the audited claims: that the patient’s medical record did not sufficiently support the terminal prognosis. As noted above, Ambercare disagrees with the OIG’s findings. In addition, the OIG has not identified any particular policies or procedures that it believes to be lacking or insufficient, and the OIG’s findings reflect a largely effective compliance program. Ambercare constantly evaluates whether opportunities exist to improve its procedures and processes and will continue to do so.

## II. Background

Ambercare is a leading provider of home health, hospice, and personal care services in New Mexico. Ambercare is one of the longest-standing providers of hospice care in New Mexico and is dedicated to providing terminally ill patients with the quality of life and dignity they deserve. Ambercare’s hospice care program includes a compassionate team of physicians, licensed nurses, nursing assistants, social workers, and chaplains focused on addressing the specific clinical, psychological, spiritual, and emotional needs of each individual patient. Ambercare provides competent care coupled with personalized treatments so that patients and their families receive comfort in a challenging end-of-life situation.

Ambercare was acquired by Addus Homecare Corporation in May 2018, after the time period at issue in the OIG’s audit. Prior to the acquisition, Ambercare had developed and implemented a compliance program to ensure compliance with applicable Medicare coverage, documentation, and billing requirements. That program has continued after the acquisition, and it 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:

- o Implementing written policies, procedures and standards of conduct;
- o Designating a compliance officer and compliance committee;
- o Conducting effective training and education;
- o Developing effective lines of communication;

---

<sup>2</sup> See 42 C.F.R. § 401.305.

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

- Enforcing standards through well-publicized disciplinary guidelines;
- Conducting internal monitoring and auditing; and
- Responding promptly to detected offenses and developing corrective action.<sup>4</sup>

In particular, a large team of individuals participates in each aspect of Ambercare's compliance efforts, including a full-time Compliance Officer, Director of Clinical Compliance and Education, and two Quality Assurance Managers. Each Ambercare location undergoes an annual site operations audit led by those individuals that entails a comprehensive assessment of more than seventy-five specific operational items to ensure that each location complies with applicable regulations and requirements.

Ambercare also has robust audit processes in place to ensure specifically that its claims are billed appropriately. Ambercare conducts a monthly pre-bill audit of a minimum of 50% of all patient admissions to confirm before billing that all patients admitted for service are eligible to receive hospice services and eligibility is documented thoroughly. Ambercare also audits the records of active patients receiving services to confirm compliance with Medicare regulations on an ongoing basis. Ambercare conducts active patient audits at least quarterly and audits at least 10% of its patients' records based on total patient census at the time of the audit. Ambercare also conducts quarterly audits of the medical records of at least 10% of all live discharges or revocations, patient transfers, and patient deaths during each quarter. Finally, Ambercare reviews the medical records of all patients who are recertified for hospice services after being on service for six months or longer. Those reviews are conducted before the end of the benefit period and before billing to ensure the documentation supports claim submission for the services provided. Any claim deemed not to be compliant and that cannot be corrected is not billed.

Ambercare's commitment to compliance is demonstrated by its results. According to its most recent PEPPER report, Ambercare is not an outlier for any of the data points tracked within the report. In addition, Ambercare ranks in the 2<sup>nd</sup> percentile nationally for percentage of live discharges for patients who are not terminally ill and the 34<sup>th</sup> percentile nationally both for live discharges based on revocations and for live discharges of patients with a length of stay of 61 – 179 days. Ambercare's previous PEPPER reports reflect similarly favorable results compared to other hospice providers and demonstrate Ambercare was not an outlier for any of the listed data points during the time period relevant to the claims audited by the OIG. It is not aware of being the subject of any other investigation or enforcement action related to potential billing or reimbursement issues conducted by the OIG, United States Department of Justice, or other government enforcement authority.

### **III. Concerns Related to the OIG's Audit Process**

Ambercare has numerous concerns with the OIG's audit process. At the outset, it appears the OIG selected Ambercare for audit simply because Ambercare bills Medicare for hospice services. Attempting to explain "why we did this audit," the Report does not provide a single reason why Ambercare specifically was selected for audit. Instead, the Report states generally that previous OIG "audits and evaluations found that Medicare inappropriately paid for hospice

---

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

services that did not meet certain Medicare requirements.” The Report references and attaches as an appendix a “list of related OIG reports on Medicare hospice services.” The Report does not explain, however, how any of those reports are related to Ambercare or to this audit. In fact, many of the reports appear to have no relation in any way to Ambercare or its audit; three of them pertain to hospice providers that have no relation to Ambercare, and one of them pertains to overbilling for General Inpatient (“GIP”) care even though the OIG’s Report includes no findings related to GIP care. Thus, it appears that the only data that the OIG used to identify Ambercare for audit is the number of dollars it bills Medicare for hospice services. Indeed, Ambercare’s PEPPER reports confirm Ambercare was not an outlier for any of the data points tracked in those reports either during the time period relevant to the audited claims or at any subsequent time.

Although the Report’s first paragraph asserts the OIG found that Ambercare was not compliant for 52 of the 100 claims reviewed, that 52 percent “error rate” is extremely misleading. The OIG’s medical determinations reflect that the medical reviewer audited up to thirteen separate items related to six different clinical factors, including eligibility, certification of terminal illness, face-to-face encounter, hospice covered services, payment for hospice care, and coding. The only adverse finding set forth in the Report is that the medical reviewer determined that the patient’s medical record did not support a terminal prognosis for 52 of the audited claims, representing just one of the audited items. Thus, approximately half of the audited claims were 100% compliant for all of the audited items, and the remaining claims were compliant for the vast majority of the audited items, with the documentation issue representing the sole exception.

Ambercare also has serious concerns about the qualifications of the OIG’s unidentified medical reviewer. Although the OIG stated it contracted with the medical reviewer through an entity named [REDACTED] the OIG has not provided any substantive information by which Ambercare 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,” “knowledgeable in the treatment of the enrollee’s medical condition,” and “familiar with the guidelines and protocols in the area of treatment under review.” The reviewer’s qualifications do not even reference hospice and could be used – and presumably has been used – for any licensed physician of any training or qualification whatsoever. In addition, in response to Ambercare’s request for information about the medical reviewer, the OIG confirmed it does not even receive resumes for the physician reviewers with whom it contracts and the reviewer for this audit “represented the best value to the Government.” Without receiving any information about the reviewer, Ambercare can only assess the reviewer through his or her individual medical determinations of the audited claims.

As discussed below, virtually all of the reviewer’s findings that the patients’ medical records do not support a terminal prognosis are flawed. Specifically, the reviewer consistently relied on only a limited portion of the patient’s medical record to assess the certifying physician’s terminal prognosis, which was based on a full assessment of the patient’s complete medical condition. Reviewing a limited “snapshot” of a patient’s medical record simply is not the standard for determining whether documentation supports a terminal prognosis for purposes of Medicare requirements. The OIG’s reviewer also repeatedly found that documentation was insufficient because it did not satisfy LCD criteria. LCD guidelines, however, are not mandatory, and failure to meet those guidelines cannot support a claim denial. That the reviewer

November 23, 2020

Page 6

consistently concluded that patients' medical records did not support a terminal prognosis on any of these grounds establishes that the reviewer is *not* qualified to accurately assess the hospice services that Ambercare provided to Medicare beneficiaries.

In addition to the clinical errors underlying the 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 Ambercare'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 Ambercare's claims is inappropriate.

#### IV. Response to OIG's Findings

The OIG's Report alleges that Ambercare did not comply with Medicare billing requirements for 52 out of the 100 hospice claims that the OIG audited, resulting in an alleged overpayment of \$24,665,520. Specifically, the OIG found that each of the allegedly improper 52 claims was billed improperly for the same reason: the beneficiary's medical record failed to support a terminal prognosis. The OIG's Report does not identify any other issue or error related to the audited claims.

Ambercare takes allegations of improper billing seriously. To evaluate the OIG's findings objectively, Ambercare engaged [REDACTED] a well-respected third-party auditor with substantial experience in hospice care, to review the allegedly improper claims. Each of the [REDACTED] auditors has over fifteen years of experience in hospice clinical operations and Medicare reimbursement criteria. Each [REDACTED] reviewer also has significant experience in hospice performing compliance audits, developing policies and procedures, and conducting survey readiness. Attached as Exhibit A to this response are the [REDACTED] auditors' curriculum vitae.

The [REDACTED] auditors reviewed the 52 allegedly improper claims and concluded the OIG's findings for 48 of those 52 claims are flawed because the patients' medical records actually do support the terminal prognosis for those claims. The [REDACTED] auditors prepared rebuttal statements for those 48 claims, which are attached as Exhibit B to this response. Moreover, for 17 of the 52 allegedly improper claims, the [REDACTED] auditors reviewed additional portions of the patient's medical record to conduct a comprehensive assessment of the record's support for the patient's terminal prognosis. In each instance those records support the patient's terminal prognosis, and those records are attached collectively as Exhibit C to this response.<sup>5</sup> In addition, certain of the specific audited claims that underscore the OIG medical reviewer's flawed approach and analysis are discussed in more detail below.

Because of the significant number of inaccurate findings and the questionable qualifications of the OIG's medical reviewer, Ambercare submits the OIG's medical findings must be reconsidered. Accordingly, Ambercare requests the audited claims be resubmitted for medical review with the appropriate standards and criteria applied to that re-review. As discussed

---

<sup>5</sup> Ambercare is submitting labeled supplemental medical records for Sample Patient Nos. 8, 10, 13, 18, 20, 22, 26, 32, 39, 45, 48, 57, 61, 66, 67, 73 and 90.

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.<sup>6</sup> 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.<sup>7</sup> A beneficiary is terminally ill when he or she has a medical prognosis indicating that his or her life expectancy is six months or less if the illness runs its normal course.<sup>8</sup> CMS has declined to create clinical benchmarks that must be satisfied to certify a patient as terminally ill.<sup>9</sup> To the contrary, CMS specifically removed language from the regulations at issue that could be construed to imply that such benchmarks exist.<sup>10</sup> A beneficiary's prognosis considers the diagnoses and all other things that relate to the beneficiary's life expectancy.<sup>11</sup>

Importantly, the determination of whether a beneficiary is terminally ill is necessarily a subjective clinical judgment based on review of the beneficiary's diagnosis of the terminal condition, other related or unrelated health conditions, and current clinically relevant information supporting all diagnoses.<sup>12</sup> CMS has repeatedly emphasized that physicians are exclusively vested with determining whether a patient's condition is terminal.<sup>13</sup> 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.<sup>14</sup> 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.<sup>15</sup> As such, courts have recognized that 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."<sup>16</sup>

Similarly, courts have rejected "that the supporting documentation must, standing alone, prove the validity of the physician's initial clinical judgment."<sup>17</sup> The physician's judgment

<sup>6</sup> 42 C.F.R. § 418.20.

<sup>7</sup> See 42 U.S.C. § 1395f(a)(7)(A).

<sup>8</sup> 42 C.F.R. § 418.3.

<sup>9</sup> 73 Fed. Reg. 32088, 32138 (Jun. 5, 2008).

<sup>10</sup> See *id.*

<sup>11</sup> 78 Fed. Reg. 48234, 48245-46 (Aug. 7, 2013).

<sup>12</sup> 42 C.F.R. § 418.22(b); 42 C.F.R. § 418.25(b).

<sup>13</sup> 78 Fed. Reg. 48234, 48247; see also 70 Fed. Reg. 70532, 70539 (stating that "[i]t is the physician's responsibility to assess the patient's medical condition and determine if the patient can be certified as terminally ill"); 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").

<sup>14</sup> See, e.g., *U.S. ex rel. Polukoff v. St. Mark's Hosp.*, 895 F.3d 730, 743 (10th Cir. 2018).

<sup>15</sup> *United States v. AseraCare, Inc.*, 938 F.3d 1278, 1281, 1300 n.15 (11th Cir. 2019) (distinguishing *Polukoff* and holding that 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).

<sup>16</sup> *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").

<sup>17</sup> *Id.* at 1294.

dictates eligibility, and the medical records must merely support, rather than prove, that judgment.<sup>18</sup> To be sure, rather than tasking its medical reviewers 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."<sup>19</sup> CMS has long recognized that making terminal prognoses is "not an exact science" and has acknowledged the deference owing to the physician's exercise of his or her "best clinical judgment" in making this determination.<sup>20</sup> 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."<sup>21</sup> CMS has emphasized that 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.<sup>22</sup>

The alleged findings of error in the OIG's Report are based entirely on a subjective difference in clinical opinion. The 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 that 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 that the reviewer assessed did not support the terminal prognosis. As the Eleventh Circuit recognized in *AseraCare*, that 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 Report's findings provide no basis for the recovery of an overpayment from Ambercare.<sup>23</sup>

#### **B. The Patients' Medical Records Support a Terminal Prognosis for 48 of the 52 Allegedly Improper Claims Identified in the OIG's Report.**

Even if a difference in clinical judgment could effectively invalidate the certifying physician's determination of terminal prognosis – which it cannot – the OIG's medical reviewer's clinical findings were flawed for virtually all of the 52 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 52 of the 100 audited claims. Ambercare disagrees with 48 of those 52

---

<sup>18</sup> *Id.*

<sup>19</sup> 79 Fed. Reg. 50452, 50470 (Aug. 22, 2014) (emphasis added).

<sup>20</sup> 79 Fed. Reg. 50452, 50470-71 (Aug. 22, 2014); 78 Fed. Reg. 48234, 48243.

<sup>21</sup> 78 Fed. Reg. 48234, 48247.

<sup>22</sup> CMS Program Memorandum: Provider Education Article: *Hospice Care Enhances Dignity and Peace As Life Nears Its End*, at 2 (Mar. 28, 2003).

<sup>23</sup> As stated above, Ambercare acknowledges that the clinical records for 4 of the 52 allegedly improper claims may be viewed as lacking sufficient documentation to support the terminal prognosis.

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.

Although the audit tool included in the OIG's medical determinations asks whether the patient's medical record supports the medical prognosis of the terminal illness, the patient-specific determinations illustrate that the OIG's reviewer applied a different, impermissible standard. Rather than analyze whether the medical record *supports* the terminal prognosis, the OIG's reviewer consistently analyzed whether the medical record conclusively *establishes* the terminal prognosis. Medicare regulations do not require, however, that the medical record establish a terminal prognosis, and courts have expressly rejected such a standard.

In addition, 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 medical reviewer consistently failed to consider all of the relevant factors and information related to the patient's life expectancy. The OIG's reviewer's analysis was limited to a "snapshot" of the patient's medical condition at a particular point in time as illustrated by only a portion of the patient's medical record. In fact, the audit time period under review for each claim was only 30 days, which is not a complete hospice benefit period. 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 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. 15.** This 89-year-old patient was admitted to hospice with End Stage Cerebral Vascular Disease. She also had dementia, coronary artery disease, status post myocardial infarction, hypertension, and arthropathies. She had a non-healing venous stasis ulcer to her left ankle that caused her pain and was at risk for infection. She had been in significant pain, and her doctor had recently increased her MS Contin for comfort. Her appetite had significantly decreased, and she lost 23 pounds within six months. Her FAST score was documented as a 7A and her PPS was 40%.

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. The OIG's medical reviewer reasoned that "documentation was vague in support of a prognosis of 6 months or less." The patient's medical record was not vague. It illustrates a patient whose body was rapidly wasting away. The patient lost 23 pounds within six months, and her BMI of 16.63 was well below the normal range and placed her in the adult failure to thrive category. Her body's inability to heal itself illustrates her continual decline. Her lung sounds were diminished throughout her stay, and her capillary refill was greater than seconds (indicating poor circulation). The OIG medical reviewer's statement that the

patient reported no pain ignores that pain management was in effect through three routine pain medications and morphine for breakthrough pain. Throughout her stay, the patient was sleeping increasingly more during the day and eventually only waking for meals (compared to sleeping 5 to 8 hours per day in the earlier part of January 2017). The patient's medical record clearly illustrates a declining condition and supports a terminal prognosis.

- **Sample Patient No. 23.** This 94-year-old patient was admitted to hospice due to colon cancer with co-morbidities including dementia, congestive heart failure, cardiomyopathy, two myocardial infarctions, status post coronary artery bypass grafting, hypertension, and type II diabetes. He had a history of ventricular clot and ischemic heart disease. The patient was on three liters of oxygen and had hypoxemia at rest on room air. The patient pursued both radiation and chemotherapy but was unable to tolerate the chemotherapy. After stopping chemotherapy, he immediately returned to the hospital with intractable diarrhea, increasing progressive weakness and malaise, and multiple falls causing residual pain. He was found to have a serious GI tract infection that required IV antibiotics to treat. Upon leaving the hospital, the patient's condition and prognosis were very poor, and he required total assistance with activities of daily living. Without chemotherapy, the patient was expected to decline rapidly, and he opted for a DNR.

The OIG contends the patient's medical record does not support a terminal prognosis for the dates of service 6/1/2016 – 6/30/2016. The OIG's medical reviewer offered some seemingly random observations about the patient's condition while ignoring most of the substantial support in the patient's medical record for the terminal prognosis. The reviewer observed there was "no appetite problem reported," the patient's urine output was consistently documented as "adequate," and the patient's "skin remained intact." The reviewer's rationale did not even acknowledge the patient's numerous co-morbidities, hospital stay, or cessation of chemotherapy, instead observing that the patient's history of rectal cancer was documented as "stable" in January 2016 – six months before the episode of care at issue. In addition, the OIG's medical reviewer acknowledged that the patient's PPS decreased from 50% to 40% and his KPS decreased from 50 to 40 during this time period. The patient's medical record illustrates a declining condition and fully supports a terminal prognosis.

- **Sample Patient No. 81.** This 96-year-old patient was admitted to hospice with end stage congestive heart failure, A-Fib, hypertension, gastric ulcer, kidney disorder, history of deep vein thrombosis, bradycardia, edema, and hypothyroidism. She was classified with the most debilitating form of heart failure – NYHA Class IV – and experienced hypoxia on room air. Oxygen was ordered for the patient due to shortness of breath and hypoxia on room air. She was recently hospitalized with a chief complaint of weakness. She presented with circumoral cyanosis and cyanotic nail beds upon face-to-face examination. Her weight was recorded as low as 106 pounds with a BMI of 19.4, which was considered "failure to thrive." The record noted loose fitting

clothes and decreased skin turgor. She had a PPS score of 40% and had two stage II wounds on admission (one to left buttock and one to her foot).

The OIG contends the patient's medical record does not support a terminal prognosis for the dates of service 5/1/2017 – 5/31/2017. The OIG's medical reviewer improperly focused on what conditions were not present in the medical record rather than on what conditions *were* reflected. During the applicable dates of service under review, the patient's status progressively worsened. Her oxygen saturation levels dropped into the 80's despite wearing continuous supplemental oxygen. Her circulation was poor as evidenced by cyanotic lower extremities as well as circumoral cyanosis. Her blood pressure was erratic, and she was hypertensive at rest. Her skin was cool to the touch. She became very weak and experienced unresponsiveness, including during an examination by a skilled nurse. She had a low weight and BMI, and was frequently noted to be thin. Notably, the patient's disease process continued to progress as the certifying physician believed that it would, and the patient passed away on 10/15/2017, approximately five months after the dates of service for this claim. The patient's severe symptoms, which deteriorated throughout this time frame, illustrate and support her poor prognosis.

- **Sample Patient No. 88.** This 89-year-old patient was admitted to hospice with dementia. She also had congestive heart failure, hypertension, malnutrition, thrombocytopenia and syncopal episodes. She was recently hospitalized with a syncopal episode. While in the hospital, she was diagnosed with a urinary tract infection and was treated with IV antibiotics. It was suspected that a hypoxic event caused her syncope. She weighed 114 pounds, and her BMI was 23.0. Her weight history was 150 pounds. She presented with poor circulation to her legs, and her feet appeared greyish/purple in color. The patient had a FAST score of 7a and a PPS of 40%. She required special care and assistance and used oxygen for shortness of breath. The patient was unable to make her needs known and spoke in "word salad." She was dependent for her activities of daily living.

The OIG contends that the patient's medical record does not support a terminal prognosis for the dates of service 6/1/2016 – 6/30/2016. The OIG's medical reviewer consistently cherry-picked selective portions of the patient's medical record while either ignoring or discounting other portions that clearly support a terminal prognosis. The OIG's reviewer asserted that the patient was "able to express self and hold a conversation" based on one social worker note, but acknowledged that the patient's FAST score was 7a – ability to speak limited to approximately a half-dozen intelligible words or fewer in an average day. The OIG's reviewer acknowledged that the patient's BMI dropped from 23 to 15.63 but noted strangely that "no weight is documented." The reviewer acknowledged the patient's co-morbid conditions of heart failure and severe protein-calorie malnutrition but asserted without basis that the comorbid and secondary conditions "did not contribute to a prognosis of six months or less." The patient's medical record reflects continued declination and no indication of stabilization. The patient could not make her needs known and was

dependent for all activities of daily living. Her BMI dropped from 23 on admission to 15.63 just three months later. The documentation supports her terminal prognosis.

- **Sample Patient No. 100.** This 98-year-old patient was admitted to hospice for Senile Degeneration of the brain, with comorbid conditions including Diabetes, Osteoporosis, Arthritis, and Dementia. The patient was non-ambulatory and dependent for all activities of daily living. Her score on the PPS scale ranged from 40-30%. During the relevant time period, the patient's weight decreased from 101 pounds to 70 pounds, representing a loss of 30% of her body weight. The patient's BMI of 17.5 was also indicative of Protein Calorie Malnutrition. The patient was spoon-fed; she frequently ate only one full meal per day (breakfast). The patient slept all day and was non-verbal.

The OIG contends the patient's medical record does not support a terminal prognosis for the dates of service 3/1/2016 – 3/31/2016. The OIG's medical reviewer consistently either misconstrued or ignored key indicators in the patient's medical record. The OIG reviewer stated the patient "was noted as not having an appetite problem" and "was documented as having a fair appetite." The OIG reviewer acknowledged, however, that the patient's BMI of 17.5 was below normal weight range. In fact, the patient was cachectic; she lost 30% of her body weight within six months and showed signs of malnutrition. The OIG reviewer asserted without basis that "the patient did not have contributing comorbid or secondary conditions," but the patient's malnutrition and weight loss were likely a direct manifestation of her advancing dementia, contributing to her terminal prognosis. The patient passed away on 11/20/2016, and her medical record supports her terminal prognosis.

As these examples demonstrate, the OIG's 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" portion of the patient's medical record. For 48 of the 52 claims identified in the Report as not terminally ill, the medical records clearly support the certifying physician's terminal prognosis.

Accordingly, Ambercare 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 Ambercare is submitting with this response. Alternatively, Ambercare 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. Extrapolation of Overpayment Obligations is Inappropriate.

Ambercare 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."<sup>24</sup> 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.<sup>25</sup> That is not the case here. Even accepting the OIG's initial audit results, the OIG found 48 of the 100 claims were 100% compliant with Medicare requirements and that the remaining 52 claims were 100% compliant in every aspect that the OIG audited except for one, whether the documentation supports the terminal prognosis. 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 Ambercare, which reduces the error rate to only 4%. A comprehensive review of the beneficiaries' complete medical records supports the certifying physician's determinations and establishes that Ambercare provided hospice services only to beneficiaries who were eligible for such services. Because no "sustained or high level of payment error" exists – even under the OIG's initial, un rebutted findings – extrapolation is inappropriate. In addition, Ambercare's independent auditor determined that the patient's medical record did not support a terminal prognosis for only 4 of the 100 sampled claims, constituting an error rate of 4%. 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. Ambercare engaged ██████████ to evaluate the OIG's statistical sampling and extrapolation methodology. ██████████ 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. ██████████ 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 Report. Attached as Exhibit D to this response is the Expert Report of ██████████ which addresses whether the statistical sampling methodology underlying the OIG's audit warrants the extrapolation of the sample findings to a broader universe of Ambercare's claims.

As discussed more fully in the ██████████ Report, the OIG's sampling methodology is flawed in numerous respects. 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 Ambercare 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 that an overpayment existed across a

<sup>24</sup> 42 U.S.C. § 1395ddd(f)(3).

<sup>25</sup> See Medicare Program Integrity Manual, § 8.4.1.4. Although Ambercare recognizes the Medicare Program Integrity Manual is not binding on the OIG, the purported overpayments identified in the Report would be overpayments from Medicare, and extrapolation of Medicare overpayments absent a sustained or high level of payment error is inappropriate.

broader universe of claims is only appropriate where the extrapolation was made from a *representative* sample and was statistically significant.<sup>26</sup> The OIG has not established that its sample is representative of the total universe of Ambercare's claims.

The [REDACTED] Report also explains that 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 158 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 that 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, Ambercare cannot confirm that the overpayment estimate was extrapolated from the claims listed in the sample file. Ambercare 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.

#### D. Conclusion

For the reasons discussed herein, the OIG's findings as set forth in the Report are flawed. With respect to the patients' terminal prognosis, the OIG's medical reviewer did not apply 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 both the terminal prognosis and the medical necessity of hospice services for 48 of the 52 audited claims that the OIG found to be billed in error.

Ambercare understands it will have the opportunity to challenge the Report's findings on appeal and is confident that those findings will be overturned. Nonetheless, Ambercare 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. Ambercare 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 Report is finalized.

---

<sup>26</sup> See *Chaves County Home Health Serv., Inc. v. Sullivan*, 931 F.2d 914, 921-22 (D.C. Cir. 1991).

November 23, 2020  
Page 15

Sincerely,

[REDACTED]

[REDACTED]

Enclosures