

Department of Health and Human Services

**OFFICE OF  
INSPECTOR GENERAL**

**MEDICARE HOSPICE PROVIDER  
COMPLIANCE AUDIT:  
PARTNERS IN CARE, INC.**

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July 2021  
A-09-18-03024

# ***Office of Inspector General***

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## Report in Brief

Date: July 2021

Report No. A-09-18-03024

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 Partners In Care, Inc. (Partners), complied with Medicare requirements.

### How OIG Did This Audit

Our audit covered 5,779 claims for which Partners (located in Bend, Oregon) received Medicare reimbursement of \$27.3 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: Partners In Care, Inc.

### What OIG Found

Partners received Medicare reimbursement for hospice services that did not comply with Medicare requirements. Of the 100 hospice claims in our sample, 53 claims complied with Medicare requirements. However, the remaining 47 claims did not comply with the requirements. Specifically, for 43 claims the clinical record did not support the beneficiary's terminal prognosis, and for the remaining 4 claims, the clinical record did not support the level of care claimed for Medicare reimbursement.

Improper payment of these claims occurred because Partners' policies and procedures were not effective in ensuring that the clinical documentation it maintained supported the terminal illness prognosis and that the appropriate level of care was provided. On the basis of our sample results, we estimated that Partners received at least \$11.2 million in unallowable Medicare reimbursement for hospice services.

### What OIG Recommends and Partners Comments

We recommend that Partners: (1) refund to the Federal Government the portion of the estimated \$11.2 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, Partners, through its attorney, generally did not concur with our recommendations. Partners disagreed with our findings for all but 2 of the 47 sampled claims we questioned. Partners stated that the clinical documentation it submitted for the sampled claims met Medicare requirements and that our independent medical review contractor's findings were inconsistent with hospice regulations and guidance. In addition, Partners' statistical expert challenged the validity of our statistical sampling methodology and the resulting extrapolation.

After reviewing Partners' comments, we maintain that our findings and recommendations are valid. We maintain that the clinical records that Partners submitted for the sampled claims questioned in our draft report did not meet Medicare requirements. In making that determination, our independent medical review contractor properly used the appropriate statutory and regulatory hospice criteria as the framework for its determinations. We also maintain that our sampling methodology and extrapolation were statistically valid and resulted in a legally valid and reasonably conservative estimate of the amount Medicare overpaid to Partners.

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## INTRODUCTION

### WHY WE DID THIS AUDIT

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

### OBJECTIVE

Our objective was to determine whether hospice services provided by Partners In Care, Inc. (Partners), 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 (GIP) care,

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<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 (CHC). 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

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<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

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<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>

### **Partners In Care, Inc.**

Partners is a not-for-profit provider located in Bend, Oregon, that furnishes hospice care and home health services to beneficiaries who live in Oregon. From January 1, 2016, through December 31, 2017 (audit period), Partners provided hospice services to 1,670 beneficiaries and received Medicare reimbursement of about \$27.6 million.<sup>19</sup> National Government Services, Inc. (NGS), serves as the MAC for Partners.

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

Partners received Medicare Part A reimbursement of \$27,582,887 for hospice services provided during our audit period, representing 6,379 paid claims. After we excluded 600 claims, totaling \$262,932, our audit covered 5,779 claims totaling \$27,319,955.<sup>20</sup> We reviewed a random sample of 100 of these claims, totaling \$478,696, 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.

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<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 (594 claims) or were identified in the Recovery Audit Contractor data warehouse as having been reviewed by another party (6 claims).

## FINDINGS

Partners received Medicare reimbursement for hospice services that did not comply with Medicare requirements. Of the 100 hospice claims in our sample, 53 claims complied with Medicare requirements. However, the remaining 47 claims did not comply with the requirements. Specifically, for 43 claims, the clinical record did not support the beneficiary's terminal prognosis, and for the remaining 4 claims, the clinical record did not support the level of care claimed for Medicare reimbursement. Improper payment of these claims occurred because Partners' policies and procedures were not effective in ensuring that the clinical documentation it maintained supported the terminal illness prognosis and that the appropriate level of care was provided.

On the basis of our sample results, we estimated that Partners received at least \$11.2 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, Partners 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 43 of the 100 sampled claims, the clinical record provided by Partners did not support the associated beneficiary's terminal prognosis. Specifically, the independent medical review

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<sup>21</sup> The statistical lower limit is \$11,278,891. 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).

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

#### **LEVEL OF CARE NOT SUPPORTED**

Medicare reimbursement for hospice services is made at predetermined payment rates—based on the level of care provided—for each day that a beneficiary is under the hospice's care. The four levels are: (1) routine home care, (2) GIP care, (3) inpatient respite care, and (4) CHC.<sup>25</sup> GIP care is provided in an inpatient facility for pain control or acute or chronic symptom management that cannot be managed in other settings, such as the beneficiary's home, and is intended to be short-term.<sup>26</sup> Routine home care is the least expensive level of hospice care, followed by inpatient respite care, GIP care, and CHC, which is the most expensive level of hospice care.

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

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<sup>25</sup> Definitions and payment procedures for specific level-of-care categories are codified at 42 CFR § 418.302. For dates of service on or after January 1, 2016, there are two daily payment rates for routine home care: a higher rate for the first 60 days and a lower rate for days 61 and beyond. 80 Fed. Reg. 47142, 47172 (Aug. 6, 2015).

<sup>26</sup> 42 CFR §§ 418.302(b)(4) and 418.202(e).

<sup>27</sup> For all four claims, we used the applicable payment rates and questioned the difference in payment amounts between the GIP and routine levels of care.

## RECOMMENDATIONS

We recommend that Partners In Care, Inc.:

- refund to the Federal Government the portion of the estimated \$11,278,891 for hospice services that did not comply with Medicare requirements and that are within the 4-year reopening period;<sup>28</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>29</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.

## PARTNERS COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, Partners, through its attorney, generally did not concur with our recommendations. Partners stated that our audit was fundamentally flawed in numerous respects and, as a result, our overpayment determination was invalid. Specifically, Partners disagreed with our findings for all but 2 of the 47 sampled claims questioned in our draft report and provided specific responses for each of the 47 claims.<sup>30</sup> Accordingly, Partners does not believe it was overpaid for hospice services except for the two sampled claims it agreed were in error. In addition, although Partners acknowledged its obligations under the 60-day rule, it did not agree that a refund pursuant to that rule was warranted. Lastly, Partners did not concur with our recommendation to strengthen its policies and procedures and stated that OIG confirmed during its exit interview that it had not identified any particular flaw or problem with Partners' policies and procedures.

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<sup>28</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>29</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.

<sup>30</sup> Partners agreed that the two claims were not fully supported by the available documentation. Partners stated that it has voluntarily refunded these payments.

Regarding our findings, Partners stated that the clinical documentation it submitted for the sampled claims met Medicare requirements and that OIG's independent medical review contractor's findings were inconsistent with hospice regulations and guidance. Partners contended that the contractor ignored beneficiaries' overall medical condition, focused on irrelevant points, and cherry-picked discrete bits of information, which resulted in misleading, incomplete, and unsupported conclusions. To further support its position, Partners engaged two hospice physicians who assessed the independent medical review contractor's determinations and the medical records that Partners submitted to OIG for each sampled claim questioned in our draft report. Based on their assessments, the two hospice physicians confirmed that the beneficiaries' medical records supported the certifications of terminal illness and the levels of care for all but two of the sampled claims.

Partners further stated that the statistical extrapolation process employed by OIG was unfounded and that statistical extrapolation was an inappropriate tool to utilize for the evaluation of hospice services because of the individualized nature of prognostication. Partners engaged a statistical expert, who analyzed OIG's statistical sampling methodology and extrapolation and stated that, even if extrapolation were appropriate, OIG's sampling and extrapolation were not statistically valid.

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

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

Partners' written comments, which summarized its position on our findings, conclusions, and recommendations, are included as Appendix E.<sup>31</sup>

After reviewing Partners' comments, we maintain that our findings and recommendations are valid. We did not inform Partners that there were not any flaws or problems with its policies and procedures, but rather emphasized that its policies and procedures were not effective in ensuring that the clinical documentation it maintained supported the terminal illness prognosis and that the appropriate level of care was provided. We also reviewed the statistical expert's report and maintain that our statistical sampling methodology and extrapolation were

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<sup>31</sup> Partners included multiple exhibits as part of its comments. These exhibits included a joint statement by the two physicians engaged by the hospice, reports related to our sampling methodology from a statistical expert, a claim-by-claim rebuttal of the findings in our draft report, and the curricula vitae of the two physicians and the statistical expert. Although the exhibits are not included as appendices in our final report, we considered the entirety of these documents in preparing our final report and will provide Partners' comments in their entirety to CMS.

statistically valid and resulted in a legally valid and reasonably conservative estimate of the amount that Medicare overpaid to Partners. 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 an overpayment exists and will recoup any overpayments consistent with CMS's policies and procedures, as well as determine whether the waiver provisions cited by Partners apply. Lastly, we did not reduce the overpayments we identified by amounts for services that Partners stated would otherwise be payable by Medicare because we have no assurance that Medicare would cover these services.

The following sections summarize Partners' comments and our responses.

## **MEDICARE REQUIREMENTS RELATED TO CLINICAL DOCUMENTATION**

### **Partners Comments**

Partners stated that the clinical documentation it provided supported the associated beneficiary's terminal prognosis and the need for a higher level of care for each of the sampled claims questioned in our draft report. Specifically, Partners stated that our independent medical review contractor's analysis was inconsistent with the fundamental tenets of hospice medicine and that its decisions failed to apply fundamental principles or to cite relevant medical literature. Furthermore, Partners stated that the contractor used similar boilerplate language in its determination letters, which Partners affirmed was an indication of the contractor's failure to apply the appropriate eligibility and level-of-care standards and to thoroughly review the medical records provided by Partners. Partners also contended that the independent medical review contractor cherry-picked discrete bits of information to support its decisions while disregarding other facts in the record that supported the beneficiary's terminal prognosis.

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

Based on our review of Partners' comments, including its hospice experts' analyses, we maintain that the clinical records that Partners submitted for the sampled claims questioned in our draft report did not meet Medicare requirements. In making that determination, our independent medical review contractor properly used the appropriate statutory and regulatory hospice criteria, as well as applicable Local Coverage Determination (LCD) guidelines, as the framework for its determinations. Specifically, our 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. Our independent medical review contractor did not cite medical literature because it used applicable Medicare requirements during its review and medical literature is not considered a Medicare requirement.

## **MEDICAL REVIEW PROCESS**

### **Partners Comments**

Partners maintained that OIG's medical review process was flawed because it included a review of only 1 month of records, which does not provide a "complete medical picture" of a beneficiary's condition. Partners stated that after it had produced the initial set of requested records, OIG requested that Partners provide records for the 12 months preceding the sampled claim but only for 21 of the 86 beneficiaries at issue. Partners also stated that all 21 beneficiaries for whom additional records were requested had a dementia or related diagnosis.

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

Contrary to Partners' assertion, our independent medical review contractor did not review only 1 month's worth of records. Rather, as mentioned above, 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>32</sup> Our contractor acknowledged the physician's terminal diagnosis and evaluated the necessary medical records for each hospice claim (including necessary historical medical 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.

## **INDEPENDENT MEDICAL REVIEW CONTRACTOR'S DETERMINATIONS**

### **Partners Comments**

Partners stated that our independent medical review contractor failed to apply the appropriate standards governing hospice eligibility and that its determinations related to terminal status were inconsistent with such laws. Specifically, Partners stated that it was improper for our independent medical review contractor to deny a claim merely on the basis that there was no decline in the beneficiary's medical condition or because the beneficiary showed improvement. Partners further contended that our contractor's determinations were made using the benefit of hindsight and not the information known at the time of certification. Partners also stated that our independent medical review contractor inappropriately relied on the Advanced Dementia Prognosis Tool (ADEPT) score tool as a basis to deny the beneficiaries' access to the hospice benefit. Lastly, Partners stated that our independent medical review contractor relied

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

on LCDs to determine whether a beneficiary met hospice eligibility requirements and that it improperly denied a claim when the beneficiary's condition did not meet an LCD.

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

We disagree with Partners' statements that our independent medical review contractor failed to apply appropriate Medicare hospice requirements (i.e., laws and regulations) when conducting its review and that its determinations of terminal status were inconsistent with hospice coverage requirements. As previously mentioned, our independent medical review contractor appropriately applied the standards set out in 42 CFR § 418.22(b)(2) to determine whether the terminal prognosis was supported. In making those determinations, our contractor considered the certifying physician's terminal diagnosis, as well as the medical records provided by the hospice for each sampled claim, guided by questions rooted in the Medicare requirements and the clinical knowledge of a licensed physician who specializes in hospice and palliative medicine and is familiar with Medicare hospice guidelines and protocols.

Our independent medical review contractor did not determine a claim to be unallowable because there was no decline in the associated beneficiary's medical condition or because the beneficiary showed improvement. Rather, our contractor evaluated *all* clinical conditions presented in the medical records collectively to obtain an overall clinical picture of the beneficiary, and based on information that was *available* and *known* at the time of certification or recertification, the contractor determined whether hospice eligibility requirements were met.

In addition, our independent medical review contractor did not determine a claim to be unallowable solely based on whether the beneficiary's condition did not meet ADEPT scores or LCD guidelines. We acknowledge that some beneficiaries who did not meet ADEPT scores or the guidelines in the hospice LCDs may still be appropriate for hospice care based on an individual assessment of the beneficiary's health status. Although our independent medical review contractor referenced the ADEPT score in conducting the medical review, the contractor properly used the appropriate statutory and regulatory hospice criteria, as well as applicable LCD guidelines, as tools 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.

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

### **Partners Comments**

Partners challenged the validity of our statistical sampling methodology and extrapolation, 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 was not statistically valid and that extrapolation was not appropriate for calculating hospice overpayments given the individualized nature of prognostication. Specifically, the statistical expert stated that:

(1) the precision was too wide to result in a valid estimate; (2) the order of the sampling frame and the random number seed that was used to initialize the random number generator were not sufficiently documented, and as such, OIG could have manipulated its sample selection; (3) OIG unfairly targeted beneficiaries with Alzheimer’s or dementia and failed to consistently sample by claim; (4) OIG improperly excluded potential underpayments (i.e., zero-paid claims) from its universe; and (5) 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. Lastly, Partners’ attorney cited several court cases that it believed further supported its position that extrapolation is not appropriate when determining whether services provided to hospice patients were medically necessary.

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

After reviewing the statistical expert’s report, we maintain that our sampling methodology and extrapolation are statistically valid. Federal courts have consistently upheld statistical sampling and extrapolation as a valid means to determine overpayment amounts in Medicare and Medicaid.<sup>33</sup> 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>34</sup> We properly executed our statistical sampling methodology in that we defined our sampling frame and sampling unit, randomly selected our sample, applied relevant criteria in evaluating the sample, and used statistical sampling software (i.e., the OIG, Office of Audit Services (OAS), statistical software RAT-STATS) to apply the correct formulas for the extrapolation. The statistical lower limit that we use for our recommended recovery represents a conservative estimate of the overpayment that we would have identified if we had reviewed each and every claim in the sampling frame. The conservative nature of our estimate is not changed by the nature of the errors identified in this audit. Moreover, the court cases that Partners’ attorney referenced in support of the proposition that extrapolation is inappropriate for issues of medical necessity or terminal prognosis are limited to False Claims Act cases and therefore are inapplicable to OIG audit recommendations and CMS recoveries arising from OIG audits.

We disagree with the Partners statistical expert’s statement that our audit precision was too wide to result in a valid estimate. Specifically, to account for the precision of our estimate, we recommend recovery at the statistical lower limit of a two-sided 90-percent confidence interval. Lower limits calculated in this manner are designed to be less than the actual overpayment total in the sampling frame 95 percent of the time. The use of the lower limit

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<sup>33</sup> See *Yorktown Med. Lab., Inc. v. Perales*, 948 F.2d 84 (2d Cir. 1991); *Illinois Physicians Union v. Miller*, 675 F.2d 151 (7th Cir. 1982); *Momentum EMS, Inc. v. Sebelius*, 2013 U.S. Dist. LEXIS 183591 at \*26-28 (S.D. Tex. 2013), adopted by 2014 U.S. Dist. LEXIS 4474 (S.D. Tex. 2014); *Anghel v. Sebelius*, 912 F. Supp. 2d 4 (E.D.N.Y. 2012); *Miniet v. Sebelius*, 2012 U.S. Dist. LEXIS 99517 (S.D. Fla. 2012); *Bend v. Sebelius*, 2010 U.S. Dist. LEXIS 127673 (C.D. Cal. 2010).

<sup>34</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).

accounts for the precision of our estimate in a manner that generally favors the auditee.<sup>35</sup> Partners focuses on the 5 percent of cases when a provider may have to pay more to the Government; however, these cases are inherently rare, and the disadvantage to the provider in such cases tends to be small given the precision in this audit. If we had selected a larger sample size, the average effect and the most likely effect would have been that we would have recommended that Partners refund a larger amount to the Government.

The Partners statistical expert's statement that OIG did not sufficiently document the order of OIG's sampling frame and the random number seed is not correct. Our audit workpapers specifically contained detailed information on how the frame was sorted. That information was used by an auditor who was not part of the audit team to validate the sample selection. There was no manipulation of the sampling frame after the random numbers were generated. Rather, the sampling frame was finalized before generating the random numbers. We also note that the sampling frame was sorted using a field (in OIG's copy of CMS's National Claims History (NCH) file) that uniquely identifies claims. We also provided Partners with the random number seed that was used to generate the random numbers.

We disagree with Partners' statement that we targeted claims for beneficiaries with Alzheimer's or dementia and failed to consistently select our sample by claim. As stated in Appendix C, the sample unit was a Medicare Part A hospice claim and, after consecutively numbering the hospice claims in our sampling frame and generating 100 random numbers using the OIG, OAS, statistical software, we selected the corresponding claims. For each sampled claim, our independent medical review contractor reviewed the necessary medical records to determine whether they supported the terminal prognosis.

Partners relied 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 it did apply to OIG, it expressly allows for the removal of "claims/claim lines [that] are attributable to sample units for which there was no payment."<sup>36</sup> More generally, OIG may perform a statistical or nonstatistical review of a provider without covering all claims from that provider. Furthermore, OIG's statistical estimates are applied to only the frame from which the sample was drawn.

Lastly, as Partners and its statistical expert noted, the MPIM requirement that a determination of a sustained or high level of payment errors must be made before extrapolation applies only to Medicare contractors—not OIG.<sup>37</sup> We further note that the statutory provisions on which the MPIM guidelines are based do not prohibit CMS from accepting and acting on our monetary recommendation.

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<sup>35</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).

<sup>36</sup> MPIM, Pub. No. 100-08, chapter 8, § 8.4.3.2.

<sup>37</sup> See the Act § 1893(f)(3); MPIM, Pub. No. 100-08, chapter 8, § 8.4.

## **RECOMMENDATIONS**

### **Partners Comments**

Partners had the following comments on our three recommendations:

- Regarding our first recommendation, Partners stated that it has voluntarily refunded amounts received for two sampled claims that were not fully supported by the available documentation. However, Partners stated that it does not concur with this recommendation with respect to all other sampled claims found to be unallowable by our independent medical review contractor. Partners also stated that Partners and its expert physicians have thoroughly reviewed our independent medical review contractor's audit findings and have determined that Partners did not receive an overpayment with respect to these other sampled claims and that the findings for those sampled claims and our statistical extrapolation are improper and contrary to law. Partners stated that if any attempt is made by its MAC to recoup funds related to the sampled claims at issue in this audit, Partners intends to exercise all appeal rights available to it.
- Regarding our second recommendation, Partners acknowledged its obligations under the 60-day repayment rule. As noted above, Partners stated that it has voluntarily refunded amounts received for two sampled claims. However, Partners stated that it has determined that no other repayments under this rule are warranted.
- Regarding our third recommendation, Partners did not concur and stated that it has "robust policies and procedures and corporate compliance program." Partners also stated that its policies and procedures comply with and incorporate each and every Medicare requirement applicable to hospices. Partners stated that, although it routinely and proactively reviews its policies and procedures to ensure compliance with the ever-changing Medicare requirements, it disagrees that any particular flaws exist in its current policies and procedures that allowed ineligible patients to be certified for hospice or allowed provision of unnecessary GIP care. In addition, Partners stated that our draft report did not identify any particular flaws.

### **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 an 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 results of the appeal.

We maintain that improper payment of the 47 sampled claims occurred because Partners' policies and procedures were not effective in ensuring that the clinical documentation it maintained supported the terminal illness prognosis and that the appropriate level of care was provided.

## APPENDIX A: AUDIT SCOPE AND METHODOLOGY

### SCOPE

Our audit covered 5,779 hospice claims for which Partners received Medicare reimbursement totaling \$27,319,955 for services provided from January 1, 2016, through December 31, 2017 (audit period). These claims were extracted from CMS's NCH file.

We did not assess Partners' 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 Partners' office in Bend, Oregon.

### 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 NGS officials to gain an understanding of the Medicare requirements related to hospice services;
- met with Partners officials to gain an understanding of Partners' policies and procedures related to providing and billing Medicare for hospice services and reviewed those policies and procedures;
- obtained from CMS's NCH file 6,379 hospice claims, totaling \$27,582,887,<sup>38</sup> for the audit period;
- excluded 594 claims, totaling \$246,157, that had a payment amount of less than \$1,000 and additionally excluded 6 claims, totaling \$16,775, that were identified in the Recovery Audit Contractor data warehouse as having been reviewed by another party;
- created a sampling frame consisting of 5,779 hospice claims, totaling \$27,319,955;
- selected a simple random sample of 100 hospice claims from the sampling frame;

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<sup>38</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 Partners for hospice services; and
- discussed the results of our audit with Partners officials.

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

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

## APPENDIX B: RELATED OFFICE OF INSPECTOR GENERAL REPORTS

| Report Title  | Report Number                          | Date Issued |
|---|--|-------------|
| <i>Medicare Hospice Provider Compliance Audit: Mission Hospice &amp; Home Care, Inc.</i>                            | <a href="#"><u>A-09-18-03009</u></a>   | 7/8/2021    |
| <i>Medicare Hospice Provider Compliance Audit: Northwest Hospice, LLC</i>   | <a href="#"><u>A-09-20-03035</u></a>   | 6/23/2021   |
| <i>Medicare Hospice Provider Compliance Audit: Professional Healthcare at Home, LLC</i>                             | <a href="#"><u>A-09-18-03028</u></a>   | 6/10/2021   |
| <i>Medicare Hospice Provider Compliance Audit: Franciscan Hospice</i>   | <a href="#"><u>A-09-20-03034</u></a>   | 5/18/2021   |
| <i>Medicare Hospice Provider Compliance Audit: Ambergare Hospice, Inc.</i>  | <a href="#"><u>A-09-18-03017</u></a>   | 5/14/2021   |
| <i>Medicare Hospice Provider Compliance Audit: Alive Hospice, Inc.</i>  | <a href="#"><u>A-09-18-03016</u></a>   | 5/14/2021   |
| <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 Partners provided during our audit period, representing 6,379 paid claims totaling \$27,582,887. We excluded 594 claims, totaling \$246,157, that had a payment amount of less than \$1,000 and additionally excluded 6 claims, totaling \$16,775, 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 5,779 claims totaling \$27,319,955. 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 using a field in OIG's copy of CMS's NCH file that uniquely identifies claims. We consecutively numbered the hospice claims in our sampling frame from 1 to 5,779. 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 Partners for unallowable hospice services at the lower limit of the two-sided 90-percent confidence interval. Lower limits calculated in this manner are designed to be less than the actual overpayment total 95 percent of the time.

## APPENDIX D: SAMPLE RESULTS AND ESTIMATES

**Table 1: Sample Details and Results**

| Number of Claims in Sampling Frame | Value of Sampling Frame | Sample Size | Value of Sample | Number of Unallowable Claims | Value of Overpayments in Sample |
|------------------------------------|-------------------------|-------------|-----------------|------------------------------|---------------------------------|
| 5,779                              | \$27,319,955            | 100         | \$478,696       | 47                           | \$239,208                       |

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

|                |              |
|----------------|--------------|
| Point estimate | \$13,823,839 |
| Lower limit    | 11,278,891   |
| Upper limit    | 16,368,787   |

## APPENDIX E: PARTNERS COMMENTS

### **HUSCH BLACKWELL**

Bryan K. Nowicki  
Partner

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January 22, 2021

#### **VIA ELECTRONIC FILING**

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

Re: Partners in Care, Inc.  
A-09-18-03024

Dear Ms. Ahlstrand:

Partners in Care, Inc. (“PIC”) appreciates the opportunity to provide comments in response to the United States Department of Health and Human Services, Office of Inspector General’s (“OIG’s”) draft report entitled *Medicare Hospice Provider Compliance Audit: Partners In Care, Inc.* (“Draft Report”). PIC’s comments to the Draft Report, including the report’s conclusions and recommendations, are set forth below.<sup>1</sup>

#### **INTRODUCTION**

PIC is a not-for-profit hospice that serves rural communities in Central Oregon. It is the only independent, non-hospital-based hospice in the area. PIC was first formed in 1979 by a small group of volunteers. In 1986, PIC began providing home health services in addition to hospice to support patient continuity of care. In 1990, PIC became Medicare certified, and in 2003, PIC built its Hospice House to provide inpatient hospice care. To this day, PIC continues to provide both hospice and home health services, as well as many other programs to support its rural communities, including bereavement counseling, educational seminars, and a grief camp for children.

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<sup>1</sup> This letter and Exhibits 1-3 and 49-50 do not include any protected health information (“PHI”), and therefore we ask that they be attached as an appendix to the OIG’s final audit report once it is made public. Exhibits 4-48 contain PHI and we ask that these exhibits not be included within the publicly available version of the OIG’s final audit report.

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The Draft Report is disappointing and at odds with PIC's history, leadership, reputation in the community for quality care, policies and procedures, and culture of compliance, all of which are confirmed by the data compiled by the federal Centers for Medicare & Medicaid Services ("CMS"). From a scant review of only 1.57%<sup>2</sup> of the claims for payment that PIC submitted to Medicare over a two-year period (100 claims and 86 patients), the OIG has concluded that PIC received an alleged overpayment of \$11,278,891.00, which is nearly *half* of the care provided by PIC. This conclusion resulted from a review of limited patient medical records by a Medical Review Contractor retained by the OIG to assess whether PIC admitted patients who qualified for hospice, *i.e.*, had a medical prognosis that his or her life expectancy is six months or less if the illness runs its normal course, and whether those patients were afforded the appropriate level of care. But, the Medical Review Contractor failed to adhere to the law and standards of practice when reviewing PIC's claims.

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

The OIG's Medical Review Contractor also failed to apply the appropriate standards for assessing patient eligibility established by the applicable statutes and regulations.<sup>3</sup> Specifically, the statutes and regulations have been interpreted to provide that a certifying hospice physician's eligibility determination is clinically deficient *only* if no reasonable physician, applying his or her clinical judgment, could have concluded that the patient was eligible for the Medicare hospice benefit.<sup>4</sup> Nothing within the Medical Review Contractor's decisions make this necessary showing. Rather, the Medical Review Contractor cherry-picked discrete bits of information to

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<sup>2</sup> The OIG reviewed 100 claims for 86 patients out of the 6,379 claims for 1,556 patients cared for by PIC from January 1, 2016 to December 31, 2017. Of the 86 patients reviewed, the OIG has alleged an overpayment with respect to 38 of those patients.

<sup>3</sup> See, e.g., *United States v. AseraCare, Inc.*, 938 F.3d 1278 (11<sup>th</sup> Cir. 2019)

<sup>4</sup> *Id.* Although *AseraCare* arose under the False Claims Act, the court acknowledged in its decision that its "primary task on appeal [was] to clarify the scope of the hospice eligibility requirements, which are set out in the federal Medicare statute" and its implementing regulations. *Id.* at 1291. Accordingly, this standard governs all applications of the Medicare hospice eligibility laws and regulations, including applications in OIG's audit, and is not limited to False Claims Act cases.

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rationalize its decisions while ignoring the patients' overall medical condition, contrary to federal law and the standards of care and practice recognized by the medical community.

Additionally, the OIG's Medical Review Contractor failed to give *any* deference to the certifying hospice physicians, as required, resulting in the unsupported conclusion that the clinical determinations made by these physicians, who have years of experience in hospice and are Board-certified in Hospice and Palliative Care Medicine, were wrong. One of these physicians is a Fellow of the American Academy of Hospice and Palliative Medicine. This illogical result is possibly explained by the flawed review process. As explained in these comments, the process used by the OIG to evaluate medical necessity may work well for most Medicare items or services, but it is incompatible with hospice services.

Likewise, the statistical extrapolation process employed by the OIG to convert its review of 1.57% of PIC's claims to an overpayment totaling \$11.2 million dollars, nearly half of all Medicare payments received by PIC, is unfounded. Statistical extrapolation is an inappropriate tool to utilize for the evaluation of the practice of hospice medicine because of the individualized nature of prognostication. Even if extrapolation were appropriate, the sampling and extrapolation in this matter have been determined by an expert statistician to be invalid for a number of reasons, any one of which warrants the OIG's reconsideration of its use of the sampling and extrapolation to determine the estimated overpayment.

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

Overall, the Draft Report will significantly decrease beneficiary access to the hospice benefit if it is not reconsidered and revised. If hospices and physicians were to use the criteria and standards used by the OIG's Medical Review Contractor, it will mean some of the most vulnerable Medicare beneficiaries will not be able to access hospice care until they are showing signs and symptoms of actively dying, which is directly contrary to the intent of Congress and CMS.<sup>5</sup> The active dying process occurs over hours or days, whereas the Medicare hospice benefit was meant to provide patients believed by a physician to be in their *last six months of life* comprehensive treatment to manage their symptoms in an effort to maintain their (and their families') quality of life, dignity, and peace. Beneficiaries should not suffer and be denied access

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<sup>5</sup> CMS revised the hospice regulations in 1990 to encourage physicians to certify *more* patients for hospice. See 55 Fed. Reg. 50832 (Dec. 11, 1990); see also GAO, *Program Provisions and Payments Discourage Hospice Participation* (Sept. 29, 1989), available at <http://gao.gov/products/HRD-89-111>.

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to such care as a result of an ill-fitted audit process carried out by an unidentified reviewer whose qualifications and experience are in serious doubt.

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

### BACKGROUND INFORMATION ON PIC

PIC's history and culture provide necessary context when reviewing and considering the OIG's conclusions and recommendations. This context, including PIC's culture and commitment to serving its community and providing quality patient care, reveals the OIG's conclusions and recommendations to be anomalous and suspect.

PIC is a non-profit hospice that was first formed by a group of volunteers under the name Friends of Hospice in 1979, before the Medicare hospice benefit even existed. At that time, it was one of the only hospices in Oregon seeing patients. In 1986, Friends of Hospice began providing home health services for individuals in the community. In 1988, it became accredited by the Oregon Hospice Association, and then became Medicare-certified in 1990 as Hospice of Bend. Hospice of Bend changed its name to HospiceCenter, Inc., and, in 2009, merged with Central Oregon Home Health & Hospice to create Partners in Care, Inc. PIC currently serves five counties in rural Central Oregon, providing both hospice and home health services. It also operates Hospice House, the only inpatient hospice facility in Central Oregon and one of only a handful of inpatient hospices in the state. In addition, it offers the communities it serves bereavement counseling services, educational seminars, and a grief camp for children. For the time period under review, PIC's average daily hospice census was approximately 210 patients, and it had 140-150 employees.

As a non-profit, PIC is governed by a Board of Directors composed of seven volunteers from the community, including Dr. Stephen Kornfeld, who is a renowned oncologist who served as medical director for PIC from 1991 to 2005. Each member of the Board of Directors is actively engaged in PIC's efforts to provide quality care in compliance with all state and federal laws. In addition to its Board of Directors, PIC's current leadership team is very experienced in hospice care and active in the industry. Mr. Eric Alexander became PIC's executive director in 2006. Dr. Lisa Lewis, who is board-certified in Hospice and Palliative Care Medicine and also certified by the Hospice Medical Director Certification Board, is PIC's current medical director. She was promoted to medical director in 2010, after having worked with PIC as a hospice physician since 2005. Dr. Jenny Blechman, who is board-certified in Hospice and Palliative Care Medicine, certified by the Hospice Medical Director Certification Board, and a Fellow of the

HB: 4813-4854-2676.4

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American Academy of Hospice and Palliative Medicine, joined PIC in 2012. Drs. Lewis and Blechman cared for the patients reviewed by the OIG's Medical Review Contractor.

PIC provides exemplary and compliant care to its patients. Bend, Oregon has long been a beacon of end-of-life care, having been featured in a 2001 documentary about end-of-life care by The Joint Commission on Accreditation of Healthcare Organizations.<sup>6</sup> Data analysis in 2003 also reflected that Deschutes County, Oregon spent the least Medicare dollars for end-of-life care out of 306 cities analyzed. This was largely believed to be attributed to the focus on education and planning for end-of-life, an effort undertaken by PIC and Bend's close-knit medical community. More recent data from PIC's Family Experience of Care Survey reflects that PIC provides very high quality of care, with 94% of families responding that they would recommend PIC (as compared to the national average of 84%). PIC scored higher than the national average in all of the survey categories. The CMS Quality of Care data also showed PIC was above average with respect to every single quality of care indicator used by CMS, with PIC scoring 100% on three of those indicators. PIC is also regularly surveyed by the Oregon Health Authority, the agency in Oregon that licenses hospices, which is also the state survey agency for CMS. PIC has not had any complaint surveys and has never had any condition-level deficiencies cited during any of its routine surveys in at least the last 10 years.

In addition to providing high quality care, PIC has robust policies and procedures and corporate compliance program. The OIG confirmed during its exit interview that it had not identified any particular flaw or problem with PIC's policies and procedures. The Draft Report similarly does not identify any specific policy or procedure that is improper or requires modification. Rather, the Draft Report generally indicates PIC's policies and procedures were ineffective, despite the OIG's own statements to the contrary and data *confirming* the policies are effective.<sup>7</sup> PIC's policies and procedures are based on the Medicare Conditions of Participation, as well as industry standards. They thoroughly address admission criteria and certification process and are regularly reviewed and revised. Nothing within these policies and procedures incentivize staff or physicians based on the number of certifications or recertifications. Further, the policies and procedures clearly identify steps to be taken should a patient not meet the admission criteria.

<sup>6</sup> See Rebecca Merritt, Medicare hospice spending lowest here, The Bulletin (Mar. 2, 2003), available at [https://www.bendbulletin.com/localstate/medicare-hospice-spending-lowest-here/article\\_bbfa6707-0287-5819-86a6-4971f6574007.html](https://www.bendbulletin.com/localstate/medicare-hospice-spending-lowest-here/article_bbfa6707-0287-5819-86a6-4971f6574007.html).

<sup>7</sup> The OIG's position in the Draft Report appears to result from the conclusions of the Medical Review Contractor. In other words, the OIG has concluded that there must be something wrong with PIC's policies and procedures because the Medical Review Contractor found reason to deny or down-code certain claims. The OIG ignores the more likely explanation: the Medical Review Contractor denied or down-coded claims because the Medical Review Contractor failed to properly apply basic tenets of hospice medicine in a manner consistent with the Medicare hospice benefit. See Exhibit 1, Joint Statement of Dr. Edward W. Martin and Dr. John Mulder Regarding the OIG's Audit of Hospice of Partners in Care, Inc.

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PIC's compliance program is a safety net ensuring the effectiveness of its policies, procedures, and practices. PIC's employees are required to attend annual training on compliance through Relias LLC. Employees are also routinely educated regarding PIC's hotline number for reporting compliance concerns. PIC has not received any indication from any audit or other billing review that any systemic problems exist with respect to its physicians' eligibility determinations. To the contrary, given the current enforcement environment for hospices, PIC's physicians have become more conservative in evaluating hospice eligibility, and there have been multiple occasions when PIC's physicians' determinations to discharge patients have been overturned by CMS's Quality Improvement Organization, KEPERO. PIC's physicians also regularly attend training and educational sessions provided by Dr. Janet Bull, who is at the forefront of research in hospice and palliative medicine and is a frequent speaker and author on hospice matters. Many of PIC's patients have attending physicians in the area who continue to be actively involved in their care even after admission to PIC. None of these physicians have ever expressed concern over the quality of care or the admission practices of PIC.

The effectiveness of the hospice's policies and procedures and compliance program are demonstrated by CMS's PEPPER reports. PEPPER<sup>8</sup> reports provide statistics for key markers used to identify questionable billing practices so that hospices may target and improve problematic areas. The reports include data on live discharges, long lengths of stay,<sup>9</sup> and top five diagnoses. For all of the target areas covered in the reports, PIC has been below the percentile that CMS deems a high risk for improper payments (the 80<sup>th</sup> percentile). With respect to long lengths of stay, PIC's PEPPER report for the time period under review<sup>10</sup> shows that only 13.2% of its patients had a long length of stay, putting PIC in the 37.1 percentile nationwide. This means 62.9% of hospices nationwide have a higher percentage of patients with long lengths of stay as compared to PIC. In other words, the PEPPER reports reflect PIC surpasses most other hospices with respect to accurate prognostication.

PIC recognizes that, like all providers, it is not infallible.<sup>11</sup> However, PIC's history, leadership, policies and procedures, corporate compliance program, and culture make it apparent that any issues that occur are aberrant and far from widespread. There is nothing systemic within PIC's history or culture that would have caused nearly *half* of all PIC's eligibility determinations to be erroneous. Rather, the OIG's Draft Report is indicative of an overzealous medical review

<sup>8</sup> Program for Evaluating Payment Patterns Electronic Report ("PEPPER").

<sup>9</sup> Long Length of Stay patients are those whose combined days of service is greater than 180 days.

<sup>10</sup> For federal fiscal year ("FY") 2017 (October 1, 2016 to September 30, 2017).

<sup>11</sup> In the process of reviewing the OIG's Draft Report, PIC has determined that two claims were not fully supported by the available documentation. For Sample #7, PIC, along with Dr. Martin and Dr. Mulder, determined that the documentation reflected the patient likely should have been discharged on or before August 10, 2016, rather than August 21, 2016. For Sample #64, PIC, along with Dr. Martin and Dr. Mulder, determined that the documentation regarding eligibility for April 2017 was not as strong as the documentation for all other patients at issue. Out of an abundance of caution, PIC is submitting voluntarily repayments with respect to these patients and dates of service. Based on its experts' review of the other patient documentation and claims at issue, PIC is confident that the issues with respect to these two claims were isolated and not the result of any systematic breakdown of PIC's policies.

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contractor with limited or no experience with hospice care. If OIG's conclusion were correct, it would mean that the clinical judgment of numerous certifying physicians, who personally treated the patients and had absolutely no incentive to improperly admit them for hospice care, was incorrect. Such conclusion lacks credibility when considering the foregoing information.

### RESPONSE TO THE OIG'S DRAFT REPORT

#### I. Summary of the Draft Report

In this audit, the OIG reviewed a very narrow snapshot of PIC's overall operations. As a part of its audit, the OIG selected a sample of 100 claims out of the 6,379 claims submitted by PIC for the time period of January 1, 2016 to December 31, 2017. The claims selected for review represent only 1.57% of the claims submitted by PIC for that time period. The 100 claims selected by the OIG were associated with hospice services provided to 86 different hospice patients. During that two-year time period, PIC provided hospice care to 1,558 Medicare beneficiaries and received \$27,582,887.00 in Medicare reimbursement.

After requesting and receiving limited records from PIC for these 100 claims, the OIG then had its Medical Review Contractor review the records. The OIG's Medical Review Contractor determined that 53 of the claims reviewed met all Medicare requirements, while 47 did not. Of those 47 claims, 43 were denied because the Medical Review Contractor concluded that records accompanying the properly signed physician certification or recertification did not support the medical prognosis of a terminal illness. The remaining 4 claims were down-coded from the General Inpatient ("GIP") level of care to the routine home care level of care because, although the patient was clinically eligible for hospice services, the Medical Review Contractor concluded that the documentation did not support the GIP level of care.

The OIG extrapolated the error rate for the sample of claims determined by its Medical Review Contractor to the entire universe of claims submitted by PIC to Medicare during the two-year time frame for this audit. As a result of the extrapolation, the OIG alleges in its Draft Report that PIC received approximately \$11,278,891.00 in improper payments. Nothing in the Draft Report suggests that PIC acted fraudulently or that it knowingly submitted incorrect information to the government.

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

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

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

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

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

<sup>12</sup> See **Exhibits 2 and 3**, Curricula Vitae of Dr. Martin and Dr. Mulder, respectively.

<sup>13</sup> See **Exhibits 4-48**. These exhibits are comprised of PIC's responses to the bases for the OIG's claim denials. Following each Patient Response Summary is a copy of the medical records previously produced to the OIG, which are now paginated for purposes of citation. No additional medical records that were not previously produced are included.

<sup>14</sup> Approximately 25 different medical articles were cited by these two expert physicians throughout their Patient Response Summaries including the following: Baker J, Libretto T, Henley W, Zeman A. A Longitudinal Study of Epileptic Seizures in Alzheimer's Disease. *Front Neurol.* 2019 Dec 4;10:1266; Beerli, MS, Goldbourt, U. Late-Life Dementia Predicts Mortality Beyond Established Midlife Risk Factors. *Am J Geriatr Psychiatry.* 2010; 19(1): 79-87; Benítez Brito N, Suárez Llanos JP, Fuentes Ferrer M, Oliva García JG, Delgado Brito I, et al. Relationship between Mid-Upper Arm Circumference and Body Mass Index in Inpatients. *PLoS One.* 2016 Aug 5;11(8):e0160480; Brown MA, Sampson EL, Jones L, Barron AM. Prognostic indicators of 6-month mortality in elderly people with advanced dementia: a systematic review. *Palliat Med.* 2013;27(5):389-400; Bukowy EA, Thiel E. Decision Making for Patients with Advanced Dementia and a Hip Fracture #388. *J Palliat Med.* 2020;23(3):422-423; Chandra SM, Da Silva-Gane M, Marshall C, Warwicker P, Greenwood RN, Farrington K. Survival of elderly patients with stage 5 CKD: comparison of conservative management and renal replacement therapy. *Nephrol Dial Transplant.* 2011;26(5):1608-1614; de Lau LM, Schipper CM, Hofman A, Koudstaal PJ, Breteler MM. Prognosis of Parkinson

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The Medical Review Contractor's decisions for these patients, on the other hand, are not supported by the medical records, fail to apply fundamental principles of hospice medicine as recognized by the medical community, and fail to include citation to any relevant medical literature.<sup>15</sup> The Medical Review Summaries use the same or similar boilerplate language for each claim at issue, which is indicative of the Contractor's failure to apply the appropriate eligibility and level of care standards and thoroughly review the medical records provided by PIC. This approach evidences a results-oriented outcome approach in which the Contractor cherry-picked discrete bits of information to support its denials while disregarding other facts in the record supporting the patients' terminal prognoses.

Dr. Martin and Dr. Mulder have provided a Joint Physician Statement expressing their deep disappointment and concern over the clear lack of understanding of hospice eligibility reflected in the Medical Review Summaries.<sup>16</sup> In their Joint Physician Statement, Dr. Martin and Dr. Mulder detail how the analyses provided by the Medical Review Contractor are inconsistent with the standard of practice, undermine the purpose of hospice care, and are antithetical to the hospice benefit. The physicians describe how the Medical Review Contractor repeatedly contradicted themselves and ignored key clinical data in favor of irrelevant factors.

The Medical Review Contractor's lack of understanding is best shown through the following examples:

- Patient #88 – The Medical Review Contractor determined Patient #88 was not eligible for hospice services for dates of service September 1-30, 2016. Not only did these dates of service occur during Patient #88's first benefit period, the first date of the review period, September 1, 2016, was also the day Patient #88 was admitted to hospice. Dr. Mulder strongly disagreed with the Medical Review Contractor's denial of this patient's eligibility after he thoroughly reviewed Patient #88's medical record, which demonstrated that this 86-year-old with nephrolithiasis and multiple comorbid conditions had a terminal prognosis during this period. Patient #88 did in fact die a little more than five months after these dates of service (so, the certifying physician's prognosis was accurate). The Medical Review Contractor relied on factually false and immaterial factors in finding Patient #88 not eligible. For example, the Medical Review Contractor asserted

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disease: risk of dementia and mortality: the Rotterdam Study. *Arch Neurol.* 2005;62(8):1265-1269; Farlow MR, Shamliyan TA. Benefits and harms of atypical antipsychotics for agitation in adults with dementia. *Eur Neuropsychopharmacol.* 2017;27(3):217-231; Faxén-Irving G, Basun H, Cederholm T. Nutritional and cognitive relationships and long-term mortality in patients with various dementia disorders. *Age Ageing.* 2005;34(2):136-141; García-Ptacek S, Kåreholt I, Farahmand B, Cuadrado ML, Religa D, et al. Body-mass index and mortality in incident dementia: a cohort study on 11,398 patients from SveDem, the Swedish Dementia Registry. *J Am Med Dir Assoc.* 2014;15(6):447.e1-447.e4477; Harrold, J, et al. Is the Palliative Performance Scale a Useful Predictor of Mortality in a Heterogeneous Hospice Population? *J Palliat Med.* 2005; 8(3): 492-502.

<sup>15</sup> While there is a citation to an article on The Advanced Dementia Prognostic Tool (ADEPT), this is a general citation that does not relate to the patients under review.

<sup>16</sup> See Exhibit 1.

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the patient had “[n]o progressive inanition or signs and symptoms noted,” which is directly contradicted in the medical record. Likewise, the Medical Review Contractor’s claim that Patient #88 did not demonstrate certain symptoms, such as recurrent, intractable infections or multiple stage III/IV pressure ulcers, ignores the various other relevant symptoms this patient experienced and that contributed to his terminal prognosis. Dr. Mulder concluded that the Medical Review Contractor’s unfavorable decision “is medically insupportable.”

- Patient #30 – The Medical Review Contractor determined Patient #30 was not eligible for hospice services for dates of service August 8-31, 2016, which, like Patient #88 above, included the patient’s admission to hospice. Dr. Martin concluded from his review of the medical record that Patient #30 had a terminal prognosis during these dates of service and was appropriately certified by the Hospice’s physician. Patient #30 was a 94-year-old with severe aortic stenosis who was admitted on August 8, 2016 and who suffered from multiple comorbidities, including chronic kidney disease (stage 3), coronary artery disease, and polymyalgia rheumatica. At the time of admission, Patient #30 weighed only 115 lbs. and had a body mass index of only 18.6 despite significant bilateral edema in the lower extremities. The Medical Review Contractor provided several irrelevant clinical points for the unfavorable decision, including that Patient #30 did not lead a bed-to-chair existence, which is not required for hospice eligibility. In addition to concluding that Patient #30 was eligible, Dr. Martin opined that had PIC not appropriately admitted her when it did, Patient #30 would have likely “landed in the hospital” and potentially died without the benefit of hospice care.
- Patient #38 – The Medical Review Contractor determined Patient #38, a 98-year-old with a recent displaced right hip fracture and history of stroke, was not eligible for the general inpatient (“GIP”) level of care on dates of service February 16-20, 2016. Patient #38 was admitted to hospice at the GIP level of care directly from the hospital after a multi-day stay, as contemplated by CMS guidance. She was admitted to GIP after the hospital determined her to be too high a risk for surgery but still in need of higher intensity care and pain management. While on GIP, Patient #38 required close monitoring and multiple doses of medication, including parenteral morphine for pain, subcutaneous Lorazepam for anxiety, and a 25-mcg fentanyl patch. Patient #38 ultimately died at 2:25 am on February 20, 2016. Based on his review of Patient #38’s medical record, Dr. Martin agreed with the decision to initiate GIP services following Patient #38’s hospitalization, finding that Patient #38’s “case is exactly the type of case where GIP care is appropriate.” Dr. Martin further opined that routine home care would have likely resulted in “great suffering” for Patient #38, given her discomfort and symptoms while in the hospital and GIP.

These examples, along with the Patient Response Summaries attached as Exhibits 4-48, demonstrate that the Medical Review Contractor’s determinations lack credibility. Taking into

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consideration the clinical judgment of the original certifying physicians (and giving those clinical judgments the appropriate weight), the attached Patient Response Summaries and the Joint Physician Statement prepared by Dr. Martin and Dr. Mulder demonstrate the flaws in the process used by the Medical Review Contractor, which warrants reconsideration of the OIG's audit process, claim denials, and conclusions in the Draft Report.

### B. Flawed Medical Review Process.

The impropriety of the above-referenced claim denials is perhaps explained by the flawed review process. Not only were the number of claims reviewed *de minimis* (representing only 1.57% of PIC's claims for the time period), the records originally requested by the OIG to evaluate the medical necessity of the claims were insufficient to provide a reasonable basis for the OIG's findings and conclusions, as required by the GAO's Government Auditing Standards.<sup>17</sup> For 76 of the patients, the OIG originally requested records for only one month (or less) of services. For 10 of the patients, the OIG originally requested records for two or three non-consecutive months of service. The OIG implicitly recognized the inadequacy of its original audit plan when it requested additional records for certain patients after receiving the initially requested patient records from PIC.

The fact that the audit plan initially required collection of only one-month of records (or 2-3 non-consecutive months of records) for the patients at issue is indicative of a failure to truly understand the hospice benefit. PIC's expert physicians have expressed concern with the OIG's process of requesting and reviewing only one month of records for each hospice patient. Reviewing documents supporting a single claim may be appropriate for auditing the medical necessity of a single item or service, but it is not well suited for hospice, which involves prognostication of life expectancy based on the patient's "complete medical picture"<sup>18</sup> and ongoing, multidisciplinary treatment. Determining whether any patient is eligible for hospice services necessarily requires evaluation of the trajectory of the beneficiary's condition over a period of time. As explained by Dr. Martin and Dr. Mulder, conducting a limited review of only one month (or records for 2-3 non-consecutive months) of a hospice patient's records does not provide the "complete medical picture" of the patient to allow for prognostication within the standard of practice.

As noted above, the OIG appears to have recognized the inadequacy of its original audit plan and initial records request, but only for select patients. More specifically, after PIC produced the initial set of requested records, the OIG subsequently requested that PIC provide records for the 12 months preceding the sampled claim, but only for 21 out of the 86 patients at issue. All 21 patients for whom additional records were requested had a dementia or related diagnosis. A similar request was *not* made for the other 65 patients, despite this implicit

<sup>17</sup> See, generally, United States Government Accountability Office ("GAO"), Government Auditing Standards, Ch. 8 (2018 Revision), available at <https://www.gao.gov/assets/700/693136.pdf>.

<sup>18</sup> See *AseraCare*, 938 F.3d at 1293; 42 C.F.R. sec. 418.102(b).

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recognition by the OIG that the originally requested records was likely inadequate to make a reasonable determination regarding the patient's prognosis. Compounding this issue is the fact that the review of these limited records was performed by someone whose name and credentials are unknown to the OIG. Because the OIG lacked sufficient, appropriate evidence to support its conclusions, the Draft Report must be reconsidered in light of the information in this letter and the Patient Response Summaries prepared by two highly qualified hospice physicians.

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

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

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

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

##### a. Terminality does not require a decline in condition.

The absence of decline during a benefit period, in itself, is not a proper reason to conclude that a beneficiary does not have a terminal illness.<sup>19</sup> CMS has "also acknowledge[d] that at recertification, not all patients may show measurable decline."<sup>20</sup> Based on CMS guidance, a federal district court has excluded proposed expert testimony that would have claimed that a patient must show decline to remain eligible for hospice.<sup>21</sup> Despite this well-established

<sup>19</sup> See *Vista Hospice Care*, No. 3:07-CV-00604-M, 2016 WL 3449833, at \*16 (N.D. Tex. June 20, 2016); *Bethany Hospice Servs. of W. Pa. v. Dep't of Pub. Welfare*, 88 A.3d 250, 255 (Pa. Commw. Ct. 2013) (describing "decline" as "an additional requirement over and above the factual question of whether a patient is terminally ill."). See also Palmetto GBA, Hospice Coalition Questions and Answers (Sept. 23, 2008) (affirming comments in November 14, 2006 Hospice Coalition and stating that "[t]here is no requirement that 'significant documented decline' must be included" to substantiate that a patient has a terminal prognosis of six months or less).

<sup>20</sup> Medicare Program; Hospice Wage Index for Fiscal Year 2010, 74 Fed. Reg. 39384, 39399 (Aug. 6, 2009).

<sup>21</sup> *Vista Hospice Care*, 2016 WL 3449833, at \*15 (citing Medicare Program; FY 2015 Hospice Wage Index and Payment Rate Update; Hospice Quality Reporting Requirements and Process and Appeals for Part D Payment for Drugs for Beneficiaries Enrolled in Hospice, 79 Fed. Reg. 50452, 50471 (Aug. 22, 2014)) ("The Court also would not allow Dr. Steinberg to make statements regarding the standards for hospice eligibility that are belied by the

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principle, a large majority of the claim denials by the OIG's Medical Review Contractor were based on a purported lack of decline.<sup>22</sup> This basis for denial is contrary to the position of CMS and what the court in *Vista Hospice Care* identified as the appropriate interpretation of the hospice benefit. In fact, the Local Coverage Determination ("LCD") on which the reviewers relied expressly states: "[P]atients in the terminal stage of their illness who originally qualify for the Medicare hospice benefit but stabilize or improve while receiving hospice care, yet have a *reasonable expectation of continued decline* for a life expectancy of less than six months, remain eligible for hospice care."<sup>23</sup>

Moreover, some of these patients *actually declined*, but the reviewer still denied their eligibility because the decline was slow or not "major."<sup>24</sup> The reviewer denied a patient in her late 80's with Parkinson's disease, congestive heart failure, a stroke, and dementia, whose PPS declined from 40% to 30% and who had generalized edema and increased somnolence, because she had "very slow decline."<sup>25</sup> Another patient in her 90's who weighed only 94 pounds, having lost 24 pounds preceding hospice election, had a decline in PPS from 60% to 40% in one month as a result of a significant fall.<sup>26</sup> The reviewer inexplicably dismissed this decline because it resulted from the patient's fall, despite that the fall was an expected consequence of the patient's terminal condition. So, even if decline were required, these patients did experience decline during the denied dates of service, as detailed in the Patient Response Summaries. Therefore, as a matter of law, the claim denials based merely on the absence of decline are improper. Moreover, as a matter of fact, the claim denials based on the absence of decline, *when there actually was decline*, are improper as well.

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

CMS has long recognized that apparent improvement in an individual's symptoms may not mean that the individual's *prognosis* has improved.<sup>27</sup> Hospices treat the whole person using a multidisciplinary approach, which often results in an improvement or stabilization of symptoms. CMS has thus acknowledged that it can be difficult to distinguish a sustainable stabilization in a patient's condition from the *impression* of stabilization that could not be maintained by the patient if discharged from hospice. This point was reaffirmed in the *AseraCare* case, discussed *infra*, where the court acknowledged that, because predicting life expectancy is not an exact

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record. Thus, the Court would not permit [the relator's expert] to say that a patient must show measurable decline in order to remain eligible for the [Medicare Hospice benefit].

<sup>22</sup> See OIG Medical Review Summary for Samples #6, 8, 18, 21, 24, 25, 37, 41, 43, 50, 53, 61, 65, 67, 72, 73, 76, 78, 81, 83, 84, 85, 90, 92, and 95.

<sup>23</sup> See NGS LCD for Hospice – Determining Terminal Status (L33393) (and earlier versions applicable to the dates at issue).

<sup>24</sup> See OIG Medical Review Summary for Samples #41, 43, 65, 67, 84, 92, and 95.

<sup>25</sup> See OIG Medical Review Summary for Sample #41.

<sup>26</sup> See OIG Medical Review Summary for Sample #43.

<sup>27</sup> 70 Fed. Reg. at 70540; see also 79 Fed. Reg. at 50471.

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science, the Medicare framework recognizes that “patients with an initial prognosis of terminality can improve over time” without losing their right to coverage.<sup>28</sup> The very LCD on which the Medical Review Contractor relied includes similar language (cited above).

Here, however, the Medical Review Contractor improperly denied claims based on patients’ purported improvement or stabilization.<sup>29</sup> For example, the Contractor denied patients whose weight remained stable or had improved based on interventions implemented by PIC.<sup>30</sup> For one patient in her 90’s, her weight was so low at admission (81 pounds with a 14.8 BMI), she could not have lost any further weight, yet the reviewer cited the stabilization of her weight as a part of its rationale for denying the patient’s eligibility.<sup>31</sup> For another patient in her mid-90’s, the reviewer indicated that the patient’s FAST and PPS were stable, so she was not eligible, while at the same time recognizing (yet dismissing) that the patient had a 12 percent weight loss.<sup>32</sup>

Relying on improvement or stabilization of a patient’s symptoms to deny claims effectively punishes the hospice for providing good care and palliation of the patient’s symptoms, exactly what hospices are supposed to do. Accordingly, denials on these bases are without legal basis *and* establish poor policy. Therefore, these denials must be reconsidered.

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

It is clear that the Medical Review Contractor improperly made clinical eligibility determinations using the benefit of hindsight, rather than evaluating the records from the perspective of the hospice at the time the care was provided. The applicable regulation and Medicare Benefit Policy Manual make clear that the certification of a patient’s eligibility for hospice must be based on the patient’s medical records or examination of the patient *at the time of the certification*.<sup>33</sup> Several court cases have overturned denials related to eligibility for certain Medicare benefits that “impermissibly relied on the benefit of hindsight, which of course is always 20-20.”<sup>34</sup> For example, when Medicare contractors denied skilled nursing care because the records showed the patient was stable throughout the certification period, courts overturned the denials because “[t]he services must...be viewed from the perspective of the condition of the

<sup>28</sup> *AseraCare*, 938 F.3d at 1282.

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

<sup>30</sup> See OIG Medical Review Summary for Samples #29 and 55.

<sup>31</sup> See OIG Medical Review Summary for Samples #17.

<sup>32</sup> See OIG Medical Review Summary for Samples #6.

<sup>33</sup> See 42 C.F.R. § 418.22(b)(3)(iii); see also, CMS, Medicare Benefit Policy Manual, CMS Pub. No. 100-02, Ch. 9, § 20.1.

<sup>34</sup> See *Folland On Behalf of Smith v. Sullivan*, No. 90-348, 1992 WL 295230, at \*7 (D. Vt. Sept. 1, 1992); see also, e.g., *Jimmo v. Burwell*, No. 5:11-CV-17, 2016 WL 4401371, at \*12 (D. Vt. Aug. 17, 2016); *Anderson v. Sebelius*, No. 5:09-CV-16, 2010 WL 4273238, at \*7 (D. Vt. Oct. 25, 2010). The *Jimmo* case involved a class action lawsuit filed against the Secretary challenging denials of skilled care based on use of a covert “rule of thumb” standard that required beneficiaries have restorative potential in order to qualify for skilled nursing care.

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patient *when the services were ordered* and what was, at that time, reasonably expected to be appropriate treatment for the illness or injury throughout the certification period.”<sup>35</sup> Further, courts have noted that Medicare beneficiaries shouldn’t have to risk deterioration to their health in order to validate the care they’re receiving.<sup>36</sup> These same principles equally apply to hospice and are consistent with the CMS guidance.<sup>37</sup>

For many of the patients denied on the basis that they were not eligible, the Medical Review Contractor relied on the fact that the patients had not shown certain symptoms *during* the period under review.<sup>38</sup> The claim for a patient in her 90’s with protein calorie malnutrition, dementia, and chronic obstructive pulmonary disease was denied because although she was continuing to lose weight (down from 100 to 79 pounds despite nutritional supplements), had recurrent urinary tract infections, had new skin breakdown, had a fall, and needed adjustments in medications for increased agitation, she had no recurrent or intractable *serious* infections during the period under review.<sup>39</sup> Another patient in her late 80’s was denied because although she continued to experience a 10% weight loss from the date of her admission through the period under review, her weight stabilized during the period under review.<sup>40</sup> It would have been impossible for the hospice physician to know at the time of certification or recertification, or even during portions of the month-long period under review, that a beneficiary would not experience specific symptoms, such as continued weight loss, at some later point. Moreover, even the Medical Review Contractor could only know with the improper use of hindsight that, for example, a patient ultimately would not continue to have weight loss or other symptoms during the month at issue. Yet, the Medical Review Contractor denied the entire claim rather than define when exactly within that month the failure to have such symptoms should result in a change to the patient’s prognosis.<sup>41</sup>

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

d. Clinical benchmarks are not required to demonstrate terminality.

Law and guidance has made clear that in enacting the statutory and regulatory framework governing hospice, Congress and CMS “were careful to place the physician’s clinical judgment at the center of the inquiry,” and specifically chose not to impose “a more rigid set of criteria for

<sup>35</sup> *Anderson*, 2010 WL 4273238, at \*7.

<sup>36</sup> See, e.g., *Folland*, 1992 WL 295230, at \*7; *Anderson*, 2010 WL 4273238, at \*7.

<sup>37</sup> CMS, Medicare Benefit Policy Manual, CMS Pub. No. 100-02, Ch. 9, § 20.2.3.

<sup>38</sup> See OIG Medical Review Summary for Sample #7, 13, 17, 18, 29, 30, 41, 53, 65, 67, 73, 76, 78, 90, 92.

<sup>39</sup> See OIG Medical Review Summary for Sample #92.

<sup>40</sup> See OIG Medical Review Summary for Sample #90.

<sup>41</sup> Additionally, this is yet another instance in which the hospice is being punished for providing good care that prevented patients from having wounds or infections.

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eligibility determinations that would have minimized the role of clinical judgment.”<sup>42</sup> Indeed, “CMS has considered and expressly declined to impose defined criteria that would govern the physician’s exercise of judgment.”<sup>43</sup> Instead, the determination of hospice eligibility under Medicare is “centered on the subjective ‘clinical judgment’ of a physician as to a patient’s life expectancy.”<sup>44</sup> Further, in 2008, CMS proposed a rule that would identify “criteria” that must be considered in certifying patients as terminally ill,<sup>45</sup> but subsequently removed the word “criteria,” however, “in order to remove any implication that there are specific CMS clinical benchmarks in this rule that must be met in order to certify terminal illness.”<sup>46</sup> Accordingly, it is improper to rely on specific clinical criteria to deny eligibility.

Here, contrary to existing law and CMS guidance, the Medical Review Contractor relied on the absence of a certain set of clinical criteria in order to deny the eligibility of beneficiaries despite the fact that these beneficiaries showed numerous other signs and symptoms that supported their eligibility. For nearly all of the patients, the reviewer indicated whether the patients had not had aspiration pneumonia, lack of wounds, lack of weight loss, good appetite, or lack of recurrent fevers as if all hospice patients undoubtedly show such symptoms and the lack of such symptoms is proof the person is not eligible. For instance, the fact that several patients could ambulate short distances without assistance apparently meant to the reviewer that those patients could not have had a terminal prognosis, despite there being numerous other factors to consider.<sup>47</sup>

Most concerning is the fact that the Medical Review Contractor cited the Advanced Dementia Prognosis Tool (ADEPT) score for 32 of the 47 denied claims. While the OIG asserted that the ADEPT score was not a basis for any decision, this assertion appears at odds with the OIG’s Medical Review Summaries for these 32 claims, which included the ADEPT scoring matrix beneath the “Rationale” heading. The ADEPT score is not an appropriate tool for determining ineligibility for hospice. The creators of this tool specifically noted that the ADEPT score has “only moderate accuracy in predicting survival in advanced dementia.”<sup>48</sup> Furthermore, the Medical Review Contractor used this tool for patients who did not have a primary diagnosis

<sup>42</sup> *AseraCare*, 938 F.3d at 1301.

<sup>43</sup> *Id.*

<sup>44</sup> *Id.* at 1291.

<sup>45</sup> See *Vista Hospice Care*, 2016 WL 3449833, at \*3.

<sup>46</sup> See *id.* (quoting 73 Fed. Reg. 32088, 32138 (June 5, 2008)).

<sup>47</sup> See OIG Medical Review Summary for Samples #6, 13, 18, 43, 53, 64, and 81. The implication is that unless a patient is bed- or chair-bound, the Contractor does not consider them eligible for hospice. However, numerous patients were determined to be ineligible despite their inability to ambulate. Additionally, for one patient, the reviewer’s denial rationale included the fact that patient could still ambulate by using walls and furniture for support as reason he was not eligible, but the reviewer’s rationale failed to note the patient had two recent falls with injury, a strong indication the patient was actually not able to ambulate. See OIG Medical Review Summary for Sample #53.

<sup>48</sup> See Mitchell SL, Miller SC, Teno JM, Davis RB, Shaffer ML. The advanced dementia prognostic tool: a risk score to estimate survival in nursing home residents with advanced dementia. *J Pain Symptom Manage*. 2010;40(5):639-651, at 650.

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of dementia, and also miscalculated the score, demonstrating a significant misunderstanding of the tool and hospice eligibility in general.<sup>49</sup>

Because a predetermined list of clinical benchmarks or certain tools, like ADEPT, are not required to support a terminal prognosis, it was inappropriate for the reviewer to rely on them as a basis to deny the patients access to the hospice benefit. Further, using such clinical benchmarks or tools without regard to the patient's whole condition is inconsistent with clear directives from CMS.<sup>50</sup>

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

Each of the OIG's Medical Review Summaries rely on NGS's LCD L33393 to deny the claims at issue.<sup>51</sup> The summaries make clear that the Medical Review Contractor treated the guidelines in L33393 as absolute requirements that must be met, despite that the LCD itself states: “Some patients may not meet these guidelines, yet still have a life expectancy of six months or less. Coverage for these patients may be approved if documentation otherwise supporting a less than six-month life expectancy is provided.” This LCD also states:

The word “should” in the disease specific guidelines means that on medical review the guideline so identified will be given great weight in making a coverage determination. **It does not mean, however, that meeting the guideline is required.** The only requirement is that the documentation supports the beneficiary's prognosis of six months or less, if the illness runs its normal course.

Many of the disease-specific criteria cited in the Medical Review Summaries in support of the claim denials, particularly those summaries for Alzheimer's or dementia patients, treat the disease-specific criteria as requirements, rather than mere guidelines as directed in the LCD. For example, the disease specific guidelines for Dementia due to Alzheimer's Disease and Related Disorders sets out two separate criteria indicating that patients “*should*” meet them. However, the Medical Review Summaries denied patients, without further discussion, if the patients did not have documentation supporting those optional criteria, thereby treating those criteria as requirements despite the plain language of the LCD stating they are **not requirements**.

<sup>49</sup> See, e.g., OIG Medical Review Summary for Samples #24 and 72 (showing use of the ADEPT score for patients with primary diagnosis of Chronic Obstructive Pulmonary Disease and Parkinson's Disease, respectively, as well as the Medical Review Contractor's miscalculation of one patient's score as 9, when it was actually 20.4).

<sup>50</sup> Medicare Program; FY 2015 Hospice Wage Index and Payment Rate Update; Hospice Quality Reporting Requirements and Process and Appeals for Part D Payment for Drugs for Beneficiaries Enrolled in Hospice, 79 Fed. Reg. 50452, 50469 (Aug. 22, 2014) (“We... expect that the individual's whole condition plays a role in that prognosis.”); Medicare Program; FY 2014 Hospice Wage Index and Payment Rate Update, 78 Fed. Reg. 48234 (Aug. 7, 2013) (“certification of terminal illness is based on the unique clinical picture of the individual....”).

<sup>51</sup> See, generally, OIG Medical Review Summaries.

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Even despite the plain language of the LCD, it is well-established by case law that LCDs are guidelines, “not clinical benchmarks or mandatory requirements for hospice eligibility.”<sup>52</sup> Indeed, they “are not binding and should not be considered ‘the exact criteria used for determining’ terminal illness.”<sup>53</sup> Thus, “[m]eeting the clinical criteria in the LCDs for the patient’s primary diagnosis is *one path* to eligibility under the [Medicare Hospice Benefit], but hospices may ‘otherwise demonstrate to the [MAC] that the patient has a terminal prognosis.’”<sup>54</sup> In other words, meeting an LCD is a basis to approve a claim, but failure to meet an LCD is not a basis to deny a claim. The Medical Review Summaries fail to make this critical and necessary distinction, *i.e.*, that the medical record for the patient at issue did not support a terminal prognosis even outside the constraints of the LCD. Accordingly, it is improper to deny these patients’ eligibility based on a purported failure to “meet” an LCD. The Medical Review Contractor’s determinations should be reconsidered in light of the appropriate use of LCDs.

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

The medical review determinations referenced in the Draft Report are inconsistent with the central holdings of *AseraCare*,<sup>55</sup> a landmark decision of the U.S. Court of Appeals for the Eleventh Circuit, which identified the governing standards for evaluating hospice eligibility determinations pursuant to the applicable statutes and regulations. As noted earlier, although *AseraCare* arose under the False Claims Act, the standards set out in the decision apply to all applications of the Medicare hospice eligibility laws and regulations.<sup>56</sup>

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

<sup>52</sup> *AseraCare*, 938 F.3d at 1283. See NGS LCD for Hospice – Determining Terminal Status (L33393) (and earlier versions applicable to the dates at issue). Other hospice contractor LCDs also acknowledge that “[s]ome patients may not meet these guidelines, yet still have a life expectancy of 6 months or less.” See CGS LCD for Hospice Determining Terminal Status (L34538) (and earlier versions applicable to the dates at issue).

<sup>53</sup> *AseraCare*, 938 F.3d at 1288. The Act expressly provides that LCDs are not binding upon qualified independent contractors. See § 1869(c)(3)(B)(ii) of the Act.

<sup>54</sup> *Vista Hospice Care*, 2016 WL 3449833, at \*4 (third alteration in original) (citation omitted).

<sup>55</sup> 938 F.3d 1278 (11<sup>th</sup> Cir. 2019).

<sup>56</sup> See *supra* note 4.

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concluded that the patient was hospice eligible. Here, the Medical Review Contractor's analysis falls short of all three of these standards.

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

In its decision, the *AseraCare* court made clear that "the clinical judgment of the patient's attending physician (or the provider's medical director, as the case may be) lies at the center of the eligibility inquiry."<sup>57</sup> The court further recognized:

CMS's rulemaking commentary signals that well-founded clinical judgments should be granted deference [and]....the law is designed to give physicians meaningful latitude to make informed judgments without fear that those judgments will be second-guessed after the fact by laymen in a liability proceeding.<sup>58</sup>

As the Court further explained, "[n]othing in the statutory or regulatory framework suggests that a clinical judgment regarding a patient's prognosis is invalid or illegitimate merely because an unaffiliated physician reviewing the relevant records after the fact disagrees with that clinical judgment."<sup>59</sup> The *AseraCare* court's holding is consistent with Congress and CMS's prior acknowledgment of the hospice physician's central role and the complexities and uncertainties involved in prognostication. CMS has acknowledged that "[i]t is the physician's responsibility to assess the patient's medical condition and determine if the patient can be certified as terminally ill."<sup>60</sup>

The recognition of the hospice physician's central role, both by CMS and the court in *AseraCare*, is consistent with other cases requiring "extra weight" or deference be given to a treating physician's contemporaneous informed opinion unless there is a reasoned basis for declining to do so.<sup>61</sup> As one court aptly stated:

It is a well-settled rule...that the expert medical opinion of a patient's treating physician is to be accorded deference by the Secretary and is binding unless contradicted by substantial evidence....This rule may well apply with even greater force in the context of Medicare reimbursement. The legislative history of the Medicare statute makes clear the essential role of the attending

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<sup>57</sup> *Id.* at 1293.

<sup>58</sup> *Id.* at 1295.

<sup>59</sup> *Id.* at 1296.

<sup>60</sup> 70 Fed. Reg. at 70539.

<sup>61</sup> *Exec. Dir. of Office of Vt. Health Access ex rel. Cave v. Sebelius*, 698 F. Supp. 2d 436, 441 (D. Vt. 2010).

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physician in the statutory scheme: “The physician is to be the key figure in determining utilization of health services.”<sup>62</sup>

This rule holds true regardless of whether or not the patient dies within six months. CMS has also long recognized that a terminal prognosis is far from a “guarantee” of death within six months, and some patients have the “good fortune to live longer than predicted by a well-intentioned physician.”<sup>63</sup> “The fact that a beneficiary lives longer than expected in itself is not cause to terminate benefits.”<sup>64</sup> Because prognostication is not an exact science, hospice physicians do not need to prognosticate with 100% certainty to establish a patient’s eligibility for hospice. Rather, CMS has stated that eligibility for hospice exists for patients whose clinical status is “*more likely than not* to result in a life expectancy of six months or less.”<sup>65</sup> Congress confirmed this approach to hospice eligibility when it eliminated the 210-day limit on the Medicare hospice benefit.<sup>66</sup>

The *AseraCare* court also recognized that “predicting life expectancy is not an exact science,” and no “certitude can be expected of physicians in the practice of treating end-of-life illness.”<sup>67</sup> As a result, the court concluded that there are vagaries in prognostication that can lead to divergent, yet equally valid and supported, predictions of life expectancy. The court did not consider it appropriate or a valid application of the Medicare hospice benefit to allow a mere difference of opinion between clinicians to result in an adverse consequence for the hospice. If anything, the hospice physician is entitled to “meaningful latitude” in his or her prognostications.<sup>68</sup>

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

<sup>62</sup> See *Gartmann v. Sec'y of U.S. Dep't of Health and Human Servs.*, 633 F. Supp. 671, 680-81 (E.D.N.Y. 1986) (citing *Hultzman v. Weinberger*, 495 F.2d 1276, 1279 (3d Cir. 1974); *Kuebler v. Sec'y of the U.S. Dep't of Health and Human Servs.*, 579 F. Supp. 1436, 1440 (E.D.N.Y. 1984); *Breeden v. Weinberger*, 377 F. Supp. 734, 737 (M.D.La. 1974); *Reading v. Richardson*, 339 F. Supp. 295, 300-01 (E.D.Mo. 1972)).

<sup>63</sup> Correspondence from Nancy-Ann Min DeParle, HCFA Administrator, date-stamped Sept. 12, 2000. See also CMS, Medicare Benefit Policy Manual, CMS Pub. No. 100-02, Ch. 9, § 10 (“The fact that a beneficiary lives longer than expected in itself is not cause to terminate benefits.”).

<sup>64</sup> CMS, Medicare Benefit Policy Manual, CMS Pub. No. 100-02, Ch. 9, § 10.

<sup>65</sup> See Medicare Program; FY 2014 Hospice Wage Index and Payment Rate Update, 78 Fed. Reg. 48234, 48247 (Aug. 7, 2013) (emphasis added).

<sup>66</sup> 142 Cong. Rec. S9582 (daily ed. Aug. 2, 1996) (statement of Sen. Breaux).

<sup>67</sup> *AseraCare*, 938 F.3d at 1282, 1293, 1296.

<sup>68</sup> *Id.* at 1295.

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to the certifying physicians, as required by the hospice legal framework and in numerous other cases.

Nowhere in the Draft Report, nor in its enclosed documentation, did the OIG reference the appropriate standard described in *AseraCare* or even identify any standard its reviewer used for the after-the-fact evaluation of the hospice physicians' clinical judgment. The Medical Review Contractor does not indicate at any point in its Medical Review Summaries that no reasonable physician could have certified the patients as hospice eligible. Rather, the Medical Review Contractor has shown, at best, that based on its *post hoc* review of limited records, it merely disagreed with the clinical judgment of the skilled and experienced physicians who certified the patients as terminally ill based on the totality of the patients' circumstances and the physicians' best medical judgments regarding what they expected to happen in the normal course of the patients' terminal illnesses. Likewise, the Medical Review Summaries do not set forth a reasoned basis for declining to give weight or deference to the certifying physicians. Under *AseraCare*, that is not enough to refute the hospice physicians' equally reasonable conclusion (reached based on the physicians' clinical judgment at the time they were treating the patients) that the patients had a terminal prognosis.

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

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

The *AseraCare* court recognized that, under the plain language of the Medicare Statute and implementing regulations, "a patient is eligible for the Medicare hospice benefit if the appropriate physician makes a clinical judgment that the patient is terminally ill in light of the patient's complete medical picture, as *evidenced* by the patient's medical records."<sup>69</sup> However, the court held that the medical record supporting the physician's clinical judgment is not required to *prove* the validity of that clinical judgment. Rather, as explained by the court, the physician's clinical judgment is the "controlling condition of reimbursement" and supporting documentation need not, "standing alone, prove the validity of the physician's initial clinical judgment."<sup>70</sup> If such were the case, the physician certification requirement would be superfluous.

The Medical Review Contractor's analysis and resulting determinations do not reflect the current standard for evaluating the hospice medical record, as set forth in *AseraCare*. The

<sup>69</sup> *Id.* at 1293 (emphasis added).

<sup>70</sup> *Id.* at 1291, 1294.

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reviewer's findings that the documentation did not support patient eligibility or level of care is flawed because the reviewer recited only cherry-picked factors tending to support his or her conclusion while completely disregarding other highly probative facts that support the patients' certifications and recertifications and level of care. Identification of a few discrete facts that could only *arguably* support the claim denials does not satisfy the standard for evaluating documentation under *AseraCare*. At best, the reviewer's determinations accomplish nothing more than stating that the medical record supports two divergent opinions regarding terminality, which fails to demonstrate that the patient was certified in error. By ignoring other facts in the record supporting the certifications and recertifications, the OIG reviewer applied a much more exacting standard in the course of its review. Accordingly, the Medical Review Summaries should be rejected.

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

Following *AseraCare*, it is clear that the *post hoc* scrutiny of treating physicians' contemporaneous "properly formed and sincerely held clinical judgment[s]" is not enough to undermine the physicians' eligibility determinations.<sup>71</sup> Rather, a reversal of certifying physicians' hospice eligibility determinations is appropriate *only* if, based on a reasonable interpretation of the relevant medical records, one can conclude that *no reasonable physician*, applying his or her clinical judgment, could have concluded that the patient was eligible for the Medicare hospice benefit. A necessary corollary of this holding (and the first two standards described above) is a requirement that the individuals conducting this *post hoc* review be qualified to provide "a reasonable interpretation" of the medical record to determine what a "reasonable physician" would or would not conclude. In other words, under the central principles outlined in *AseraCare*, only a trained hospice physician is competent to evaluate the exercise of clinical judgment by the experienced hospice physicians.

Here, PIC's skilled and experienced physicians certified the patients reviewed by the Medical Review Contractor as terminally ill based on the totality of the patients' circumstances and the physicians' best medical judgments regarding what they expected to happen in the normal course of the patients' terminal illnesses. PIC's physicians' clinical judgment was further reviewed and affirmed by Dr. Martin and Dr. Mulder, who are Board-certified in Hospice and Palliative Care Medicine.<sup>72</sup> The OIG, on the other hand, has not identified either the Medical Review Contractor or the physician who reviewed, and ultimately disagreed with, the treating

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<sup>71</sup> *AseraCare*, 938 F.3d at 1297.

<sup>72</sup> See Exhibits 2 and 3.

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hospice physicians' contemporaneous eligibility and level of care determinations, much less identified his or her credentials and qualifications.<sup>73</sup>

It is concerning that the OIG refuses to provide more detail concerning the physician reviewer's qualifications so that its audit process is as transparent and credible as possible. From our past correspondence with the OIG, we understand that the OIG does not itself know the physician reviewer qualifications but relies, instead, on the generic representations made by the contractor during the competitive bidding process.<sup>74</sup> We have included with this letter copies of PIC's expert physicians' curricula vitae.<sup>75</sup> It is difficult to fathom how the OIG can find a completely anonymous reviewer more credible than these physicians who are in the top echelon of hospice physicians in the United States.

The Joint Physician Statement prepared by Dr. Martin and Dr. Mulder makes clear that the qualifications of the Contractor's anonymous reviewer are in serious doubt. Other providers have also recently raised concern about the qualifications of the Contractor's medical reviewer.<sup>76</sup> The OIG's failure to verify the qualifications of the Contractor's reviewer after having received credible concerns about his or her qualifications is arbitrary, capricious, and unreasonable. It also renders the Draft Report not credible. And, under recent guidance issued to all administrative agencies, withholding information concerning the reviewer's qualifications is a derogation of the provider's due process rights.<sup>77</sup>

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

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<sup>73</sup> The end of each Medical Review Summary includes the following generic statement:

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

<sup>74</sup> We requested the names, credentials, certifications, and hospice experience of the physicians, nurses, and all other individuals who performed or participated in the review of PIC's records for the OIG. In response, the OIG indicated: "Regarding the qualifications of the Physicians, under the terms of the contract with the medical review contractor, Maximus Federal Services, Inc., the OIG does not receive copies of the physician reviewer resumes."

<sup>75</sup> See **Exhibits 2 and 3**.

<sup>76</sup> See, e.g., OIG, Medicare Home Health Agency Provider Compliance Audit: Mission Home Health of San Diego (Aug. 2020), at page 12.

<sup>77</sup> See Memorandum for the Deputy Secretaries of Executive Departments and Agencies from Paul J. Ray, Administrator, Office of Information and Regulatory Affairs, Implementation of Section 6 of Executive Order 13924 (August 31, 2020).

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

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

To avoid an “arbitrary and capricious” determination, the decision must evidence that the OIG “examined the relevant data and provided an explanation of its decision that includes a rational connection between the facts found and the choice made.”<sup>78</sup> Here, the Medical Review Contractor repetitively and rotely cited clinical criteria that are not legally mandatory and cherry-picked evidence from the medical record without a holistic consideration of each patient’s condition, without taking into account the hospice physicians’ credible clinical judgments. The Contractor’s reviewer also failed to connect the facts and information about each patient to the determination that the documentation was insufficient. Moreover, the reviewer simply listed criteria without providing any explanation as to how that criteria relates to that particular patient’s unique clinical situation. This failure to apply the correct legal principles and connect them to the patients results in arbitrary and capricious determinations by the OIG.<sup>79</sup>

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

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

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<sup>78</sup> *Cumberland County Hospital System, Inc. v. Price*, 2017 WL 1048102 (E.D. N.C. 2017) (quoting *Ohio Vall. Envt'l Coal.*, 556 F.3d at 192) (internal quotations omitted); *U.S. Telecom Ass'n v. FCC*, 227 F.3d 450, 460 (D.C. Cir. 2000) (noting that under the arbitrary and capricious standard “‘an agency must cogently explain why it has exercised its discretion in a given manner’ and that explanation must be ‘sufficient to enable [the court] to conclude that the [agency’s] action] was the product of reasoned Draft Report-making’” (quoting *A.L. Pharma, Inc. v. Shalala*, 62 F.3d 1484, 1491 (D.C. Cir. 1995)).

<sup>79</sup> *Caring Hearts Personal Home Services, Inc. v. Burwell*, 824 F.3d 968, 970-71 (10<sup>th</sup> Cir. 2016) (“For surely one thing no agency can do is apply the wrong law to citizens who come before it, especially when the right law would appear to support the citizen and not the agency.” (citing *Lax v. Astrue*, 489 F.3d 1080 (10<sup>th</sup> Cir. 2007) (“We review the [agency] Draft Report to determine whether the factual findings are supported by substantial evidence in the record and whether the correct legal standards were applied.”); also citing *Sandoval v. Aetna Life & Cas. Ins. Co.*, 967 F.2d 377, 380 n. 4 (10<sup>th</sup> Cir. 1992) (“In our view, both lack of substantial evidence and a mistake of law would be indicia of arbitrary and capricious actions and thus may be subsumed under the arbitrary and capricious label.”)).

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### 1. Extrapolation is Not Appropriate for Calculating Hospice Overpayments Given The Individualized Nature of Prognostication.

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

This unique nature of hospice prognostication is supported by several cases, which have noted that extrapolation is inappropriate in the hospice context. In *U.S. ex rel. Michaels v. Agape Senior Cnty., Inc.*, the court held that statistical sampling and extrapolation could not be used to establish liability since "each and every claim at issue" was "fact-dependent and wholly unrelated to each and every other claim."<sup>80</sup> The *Agape* court stated that extrapolation is unsuitable for circumstances where determination of medical necessity or terminal prognosis requires a highly fact-intensive inquiry and review of each individual patient's medical record.<sup>81</sup> Where the nature of the claim requires an individualized determination, that determination cannot be replaced by "Trial by Formula."<sup>82</sup> Furthermore, the *Vista Hospice Care* court acknowledged that the permissibility of statistical sampling and extrapolation turns on "the degree to which the evidence is reliable in proving or disproving the elements of the relevant cause of action."<sup>83</sup> As both the *Agape* and *Vista Hospice Care* courts recognized, answering whether certain services furnished to hospice patients were medically necessary is not a question for which extrapolation can be an effective tool due to the absolute individuality of each claim for hospice services.<sup>84</sup> The *AseraCare* decision further supports the conclusions of *Agape* and *Vista Hospice Care* since it recognized that vagaries of prognostication can lead to divergent, yet equally valid and supported predictions of life expectancy.

While extrapolation from sampling may be appropriate where the evidence establishes that a provider's objective approach was similar in all cases, making the sample a reasonable basis for extrapolation to the whole, this is not the case when it comes to determinations of terminality.<sup>85</sup> The permissibility of statistical sampling turns on the degree to which the evidence

<sup>80</sup> See *U.S. ex rel. Michaels v. Agape Senior Cnty., Inc.*, No. CA 0:12-3466-JFA, 2015 WL 3903675, at \*2 (D.S.C. June 25, 2015), order corrected, No. CA 0:12-3466-JFA, 2015 WL 4128919 (D.S.C. July 6, 2015), and aff'd in part, appeal dismissed in part sub nom. *U.S. ex rel. Michaels v. Agape Senior Cnty., Inc.*, 848 F.3d 330 (4th Cir. 2017).

<sup>81</sup> *Id.* at \*8. See also *United States v. Medco Phys. Unlimited*, No. 98-C-1622, 2000 U.S. Dist. LEXIS 5843, at \*23 (N.D. Ill. Mar. 15, 2000) (on motion for summary judgment, rejecting extrapolation of expert's findings from a sixteen-claim sample to support a conclusion that every claim defendant submitted to Medicare was fraudulent and noting lack of "case law or other authority to support such a request").

<sup>82</sup> *Vista Hospice Care* at \*11.

<sup>83</sup> *Vista Hospice Care* at \*13 (quoting *Tyson Foods, Inc. v. Bouaphakeo*, 136 S. Ct. 1036, 1046 (2016)).

<sup>84</sup> *Agape*, 2015 WL 3903675, at \*8; *Vista Hospice Care* at \*11.

<sup>85</sup> *Vista Hospice Care*, 2016 WL 3449833, at \*12.

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is reliable in proving or disproving the elements of the relevant cause of action.<sup>86</sup> Statistical sampling, therefore, cannot be used to establish an overpayment related to alleged ineligible patients, as the underlying determination of eligibility for hospice is inherently subjective, patient-specific, and dependent on the judgment of involved physicians, as discussed above.

The OIG's findings that certification or a certain level of care was inappropriate in one patient's case should not be imputable to other claims involving—in addition to different conditions and different physicians—different caregivers, different facilities, and different time periods.<sup>87</sup> Every hospice patient is entirely unique, and the hospice benefit allows patients to receive an array of services provided by a complex interdisciplinary team, the nature of such services depending on the individual patient's medical needs.<sup>88</sup> Furthermore, every hospice physician has a unique set of skills and experiences, and, again, courts have recognized that two physicians can disagree concerning a patient's prognosis, and neither physician be wrong.<sup>89</sup> This recognized variability in clinical judgment, which variability is entirely appropriate between reasonable physicians, eliminates the predictability of the outcome of a medical record review that is essential to a valid extrapolation. In purporting to extrapolate from one claim, the OIG has taken one physician's clinical judgment regarding one patient's terminal prognosis or level of care and applied it to other physicians' prognostications for other patients, whose backgrounds and medical needs are each distinct from the sampled patient claim. It is impractical, if not impossible, to extrapolate properly by accounting for all the relevant variables associated with hospice care. It is inappropriate, therefore, to extrapolate from one physician's prognostication regarding one patient to another physician's conclusions about a completely different patient.<sup>90</sup>

Further, although the Act grants permission to use extrapolation in certain circumstances, it does not mandate such use in every type of audit.<sup>91</sup> In other words, the statute contemplates circumstances when extrapolation is neither necessary nor reasonable. In this matter, the Act should not be interpreted to permit use of extrapolation in circumstances where Congress clearly did not intend it.<sup>92</sup> Such interpretation would also produce absurd results. If a particular application of a statute produces an absurd result, the courts should and will interpret the statute to reflect what Congress would have intended had it confronted the absurdity.<sup>93</sup>

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<sup>86</sup> See *id.* at \*11.

<sup>87</sup> See *id.* at \*13.

<sup>88</sup> See 42 C.F.R. § 418.202; *see also* Medicare Program; Hospice Wage Index for Fiscal Year 2012, 76 Fed. Reg. 47301, 47302 (Aug. 4, 2011) (“A hospice uses an interdisciplinary approach to deliver medical, nursing, social, psychological, emotional, and spiritual services through use of a broad spectrum of professional and other caregivers with the goal of making the individual as physically and emotionally comfortable as possible.”).

<sup>89</sup> See *Vista Hospice Care*, 2016 WL 3449833, at \*17.

<sup>90</sup> See *id.* at \*13.

<sup>91</sup> See § 1893(f)(3) of the Act (42 U.S.C. § 1395ddd(f)(3)).

<sup>92</sup> Compare § 1879 of the Act to § 1893(f)(3) of the Act.

<sup>93</sup> The Supreme Court has consistently adjusted statutory commands in order to avoid absurd results. *See, e.g.* *Clinton v. City of New York*, 524 U.S. 417, 429 (1998) (“[a]cceptance of the Government's new-found

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The payment model Congress designed for hospices includes many features to ensure that hospices take responsibility for virtually all end of life care for their patients, while providing overall cost-savings to the Medicare trust.<sup>94</sup> This responsibility and burden that Congress has imposed on hospices, and that hospices freely accept, is incompatible with the additional, draconian consequences that would result if extrapolation were permitted. In particular, permitting extrapolation in this context would result in groundless overpayment determinations that fail to acknowledge either the benefits of individualized care that hospice agencies provide beneficiaries or, more importantly, the concept that two physicians using their clinical judgment about a patient's terminal prognosis could disagree and neither be wrong.<sup>95</sup> Furthermore, the Supreme Court, as well as the Fifth Circuit have made clear that sampling and extrapolation cannot always be used to prove liability, and courts are required to engage in a particularized analysis of whether extrapolation from a particular data set can reliably prove the elements of the specific claim.<sup>96</sup> Therefore, even though there is authority to utilize statistical sampling and extrapolation, it is an arbitrary and capricious exercise of agency discretion to utilize it in the area of hospice benefit eligibility and level of care determinations.<sup>97</sup>

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

PIC engaged Dr. Mitchell Cox to evaluate the OIG's statistical sampling and extrapolation methodology. Dr. Cox has decades of experience providing independent analysis of statistical sampling and extrapolation in the healthcare context.<sup>98</sup> He has served as a statistical expert in numerous appeals of overpayment determinations before Administrative Law Judges and in federal court. Attached as Exhibit 50 is Dr. Cox's Expert Report, which identifies and explains multiple process and statistical concerns with respect to the OIG's statistical sampling methodology and extrapolation.<sup>99</sup> Dr. Cox's reports demonstrates that, for each of the flaws identified below, the extrapolation is statistically invalid.

First, the precision and the confidence level are the two most important parameters for a statistical estimate.<sup>100</sup> To have a standard precision of 10% and a two-sided 90% confidence

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reading...would produce an absurd and unjust result which Congress could not have intended.") (quotations omitted); *see also, e.g., Pub. Citizen v. U.S. Dep't of Justice*, 491 U.S. 440, 470 (1989).

<sup>94</sup> These features include an all-inclusive per diem rate that covers all hospice services, including skilled nursing, physician administrative services, medical social services, therapies, home health aides, counseling, on-call services, medical equipment, and prescription drugs. *See* 42 C.F.R. § 418.302. Two payment caps limit the government's obligations. *See* 42 C.F.R. § 418.302(f), 418.308, 418.309. One cap limits the number of days of inpatient care and the other sets an aggregate dollar limit on the average annual payment per beneficiary. *Id.*

<sup>95</sup> *AseraCare*, 983 F.3d at 1285.

<sup>96</sup> *Vista Hospice Care* at \*13 (citing *Wal-Mart Stores, Inc. v. Dukes*, 564 U.S. 338, 367; *In re Chevron U.S.A., Inc.*, 109 F.3d 1016, 1017 (5th Cir. 1997)).

<sup>97</sup> *See, generally, supra* notes 78-79.

<sup>98</sup> **Exhibit 49, Curriculum Vitae of Dr. Cox**

<sup>99</sup> **Exhibit 50, Expert Report of Dr. Cox**

<sup>100</sup> **Exhibit 50.**

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interval, which the OIG claims that it used, a sample size of 320 claims (instead of the 100 claims that the OIG reviewed) would have been required.<sup>101</sup> According to the OIG's own guidelines, the sample here is only 31% of the size that it should have been and the precision is 18.41% (nearly double the more standard precision of 10%).<sup>102</sup> Even if an overpayment exists, which PIC denies, this inadequate sample size may mean that PIC is being asked to significantly over-reimburse the government 84.1% more than it would have to reimburse if the precision had been 10%, which, again, would have required a sample size of 320 claims.<sup>103</sup>

Second, the OIG failed to prove that it used a Statistically Valid Random Sample because: (1) it did not provide documentation showing that the order of claims in the frame was fixed and documented prior to sample selection; and (2) a review of the claims in the sample shows the claims are not representative of PIC's patient population. The order of claims in a sampling frame should be fixed and documented before the sample is selected—doing so shows that the sample was not improperly drawn or manipulated.<sup>104</sup> Here, the OIG's statisticians did not provide documentation to support the proper ordering of the sampling frame.<sup>105</sup> Specifically, the OIG failed to provide the sort order of the sampling frame and the random number seed that was used to initialize the random number generator.<sup>106</sup> The former is needed to recreate the sampling frame, and the latter is needed to recreate the sample. Thus, it cannot be determined that the OIG drew a statistically valid random sample in this audit and extrapolation.<sup>107</sup> This apparent failure to fix and document the order of the claims in the sampling frame prior to sample selection means that the sample does not hold up to basic statistical requirements and thus cannot be statistically valid.<sup>108</sup>

Additionally, 26 of the 86 beneficiaries in the OIG's sample, or 30%, were patients with Alzheimer's disease or dementia, but no more than 15% of the beneficiaries in OIG's sampling frame were such patients.<sup>109</sup> This suggests unfair targeting of a select type of patient. CMS has indicated in the Federal Register that it is necessary to review the claims selected for the sample in part to determine "whether the sample claims were appropriately selected for a representative sample of the universe."<sup>110</sup> The fact that the sample is not representative of PIC's patient population further undermines PIC's faith that the statistical sampling was properly performed.

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<sup>101</sup> [Exhibit 50](#).

<sup>102</sup> [Exhibit 50](#).

<sup>103</sup> [Exhibit 50](#).

<sup>104</sup> [Exhibit 50](#).

<sup>105</sup> [Exhibit 50](#).

<sup>106</sup> [Exhibit 50](#).

<sup>107</sup> [Exhibit 50](#).

<sup>108</sup> [Exhibit 50](#).

<sup>109</sup> [Exhibit 50](#).

<sup>110</sup> 82 Fed. Reg. 4974, 5064-65 (Jan. 17, 2017).

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Third, the OIG's sample does not satisfy one of the fundamental requirements for statistical sampling because it is not a true probability sample.<sup>111</sup> This is because the OIG failed to consistently sample by claims.<sup>112</sup> For any claim in its sample belonging to an Alzheimer's or dementia patient, OIG reviewed not only the claim at issue, but also medical records associated with claims submitted for the patient during a twelve month 'lookback' period. Thus, for this type of beneficiary, which as discussed above is already over-represented in the sample, the sampling was done effectively by beneficiary, and not by claim, despite the OIG's assertion in its sampling plan that the sampling unit was a claim.<sup>113</sup> Additionally, to request the additional records reviewed for these patients, the OIG needed to know the patients' identities, meaning the auditor was not blinded from knowing the patients' identities.<sup>114</sup> Thus, its decision to allow or deny a claim was not just a function of the claims, but a function of the patient as well.<sup>115</sup> This destroyed the independence of the sampling units, as much as a clinical trial would be destroyed if the patient and the physician knew whether the patient was receiving a placebo or the treatment.<sup>116</sup>

Fourth, the OIG improperly excluded potential underpayments from its universe. In the OIG's sampling plan, the OIG states that zero-paid claims (underpayments) were excluded from the universe.<sup>117</sup> Since the zero-paid claims were excluded from the universe, they were not available to be selected for the sample here and thus did not factor into the extrapolated overpayment.<sup>118</sup> Statistical principles require the inclusion of zero-paid claims in the universe.<sup>119</sup> This exclusion of unpaid or underpaid claims puts PIC at an extreme disadvantage because it likely resulted in an improperly inflated extrapolated amount that the OIG has deemed an overpayment.<sup>120</sup>

Finally, the extrapolation is unfounded because the payment error rate derived from the OIG's review is not high enough to permit the use of extrapolation.<sup>121</sup> The OIG stated in the draft report that "CMS, acting through a MAC or other contractor, will determine whether overpayments exist and will recoup any overpayments consistent with its policies and

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<sup>111</sup> **Exhibit 50.**

<sup>112</sup> **Exhibit 50.**

<sup>113</sup> Per Dr. Cox, the OIG could have avoided this issue by reviewing the medical records falling within the audit period for *all* of the beneficiaries, and chosen beneficiaries, rather than claims, as the sampling unit. PIC would have supported this approach because reviewing a more comprehensive set of medical records provides a more complete picture of a patient's eligibility for hospice services.

<sup>114</sup> **Exhibit 50.**

<sup>115</sup> **Exhibit 50.**

<sup>116</sup> **Exhibit 50.**

<sup>117</sup> **Exhibit 50.**

<sup>118</sup> **Exhibit 50.**

<sup>119</sup> **Exhibit 50.**

<sup>120</sup> **Exhibit 50.** Per Dr. Cox "there is no way to estimate the harm inflicted on the Hospice by the removal of the zero-paid claims because the OIG also removed these claims from all of the audit materials provided to the Hospice."

<sup>121</sup> **Exhibit 50.**

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procedures.”<sup>122</sup> The policies and procedures followed by CMS include the Medicare Program Integrity Manual (“MPIM”). While PIC realizes that the OIG is not a Medicare contractor and, accordingly, maintains that it is not bound by the MPIM, the MPIM is a reliable recitation of established statistical principles.<sup>123</sup> Under section 1893(f)(3) of the Act, extrapolation is only permitted if the Secretary of the Department of Health and Human Services determines there is a “sustained or high level of payment error.” Under the current Medicare Program Integrity Manual, Chapter 8, § 8.4.1.4, a finding of “sustained or high level of payment error” cannot be based upon a post-payment review error rate unless the error rate is greater than 50%.<sup>124</sup> From the audit of PIC by the OIG, the claim error rate (total number of claims allegedly paid in error divided by the number of the claims in the sample) is 0.47 or 47%.<sup>125</sup> Therefore, PIC’s overpayment did not meet the minimum high error rate standard of 50% set out in the MPIM.<sup>126</sup>

### E. Liability for the OIG’s Overpayment Determination Must Be Waived Under Sections 1879 and 1870 of the Act.

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

In seeming recognition of the complexity of the Medicare maze, Congress [in Section 1879] indicated that providers *who didn’t know and couldn’t have reasonably been expected to know* that their services weren’t permissible when rendered generally don’t have to repay the amounts they received from CMS. A sort of good faith affirmative defense, if you will.<sup>127</sup>

Under *Caring Hearts*, CMS must forgive “mistakes” of the provider if the provider’s purported mistakes were reasonable and supported the propriety of the services provided. Moreover, section 1879(g)(2) expressly includes mistakes related to determination that a hospice patient is not terminally ill. Congress specifically added Section 1879(g)(2) to expand this waiver to determinations that a patient is not terminally ill as a means of providing some financial protection for hospices, since hospices must assume a significant financial burden for their

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<sup>122</sup> [Exhibit 50](#).

<sup>123</sup> [Exhibit 50](#).

<sup>124</sup> While this parameter was not added to the MPIM until January 2, 2019, courts may apply this type of administrative guidance retroactively when doing so does not create “manifest injustice.” See e.g., *SEC v. Chenery Corp.*, 332 U.S. 194 (1947); *Laborers’ International Union of North America, AFL-CIO v. Foster Wheeler Corp.*, 26 F.3d 375 (3d Cir. 1994); *Retail, Wholesale and Department Store Union v. NLRB*, 466 F.2d 380 (1972); *Francisco-Lopez v. Attorney Gen. United States*, 970 F.3d 431 (3d Cir. 2020).

<sup>125</sup> [Exhibit 50](#).

<sup>126</sup> [Exhibit 50](#).

<sup>127</sup> *Caring Hearts Pers. Home Servs., Inc. v. Burwell*, 824 F.3d 968, 970 (10th Cir. 2016) (emphasis added).

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patients based on an inherently imprecise clinical judgment regarding whether a patient's terminal illness will follow the normal course.<sup>128</sup>

Similarly, waiver of liability is required under Section 1870 if a provider is "without fault" because it "had a reasonable basis for assuming that the payment was correct...."<sup>129</sup> To be "without fault," the provider is only required to have been reasonable, *i.e.*, that it had a reasonable basis for its *assumption* regarding payment.

Here, PIC understandably relied on the reasonable clinical judgment of the patients' skilled physicians and had a "reasonable basis for assuming the payment[s] [were] correct."<sup>130</sup> The Patient Response Summaries demonstrate this reasonable basis. The Medical Review Contractor has failed to show that PIC should have known that its physicians' certification would be deemed in error years later or that the physicians' certifications or level of care determinations were unreasonable. When viewed in light of the *correct* standard for evaluating hospice eligibility, PIC did not and could not reasonably have known or been expected to know that any of the patients under review would be determined years later to not be terminally ill. After all, "physicians applying their clinical judgment about a patient's projected life expectancy could disagree, and neither physician [] be wrong."<sup>131</sup> For these reasons, PIC requests that the OIG address and evaluate waiver under Sections 1879 or 1870 before issuing its final report.

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

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

Such an adjustment is required by long-standing secondary payer and CMS policies<sup>132</sup> and dictated by administrative law decisions and subsequent CMS guidance confirming

<sup>128</sup> See 42 C.F.R. § 418.22. See also 142 Cong. Rec. S9582 (Aug. 2, 1996) (statement of Sen. Breaux).

<sup>129</sup> See Act § 1870, 42 U.S.C. § 1395gg; see also CMS, Medicare Financial Management Manual ("MFMM"), CMS Pub. 100-06, Ch. 3 § 90.

<sup>130</sup> *Id.*

<sup>131</sup> *AseraCare*, 938 F.3d at 1296; see also *Vista Hospice Care, Inc.*, 2016 WL 3449833, at \*17.

<sup>132</sup> See Medicare Prescription Drug Benefit Manual ("MPDBM"), CMS Pub. 100-18, Ch. 14 § 50.14.4. CMS has applied this reconciliation policy to hospices, indicating hospices "are entitled to seek compensation from the Part D sponsor...." See Memorandum from Tracey McCutcheon, Acting Director, Medicare Drug Benefit and C & D Data Grp., to All Part D Plan Sponsors & Medicare Hospice Providers (Mar. 10, 2014). Further, under Medicare secondary payer rules, the primary payer "shall reimburse the [secondary payer] for any payment... with respect to an item or service if it is demonstrated that such primary plan has or had a responsibility to make payment with respect to such item or service." Act § 1862(b)(2)(B)(ii).

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Medicare liability for paying an unbundled rate for services when the basis for denying a bundled payment rate is the location where the services were provided.<sup>133</sup> Congress has confirmed that, absent hospice care, the government is otherwise required to pay for “whatever palliative services are needed to manage [the patient’s] terminal illness” such as durable medical equipment, pharmacy, radiology, labs, and therapies.<sup>134</sup> As both a payer and bundled rate service provider, hospices must be treated accordingly, and an alleged overpayment must be adjusted to reflect those amounts paid for services that would otherwise have been paid for by Medicare, including, but not limited to, pharmaceuticals, durable medical equipment, and supplies.

In this case, the alleged overpayment should be reduced by at least \$623,062.00, to offset amounts for items and services otherwise payable by Medicare.<sup>135</sup> The offset adjustment per claim was extrapolated by Dr. Cox based on the sampling plan. We request that the OIG revise its Draft Report to include this required adjustment.

### **III. Response to Recommendations in the OIG’s Draft Report**

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

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

PIC has voluntarily refunded amounts received for two claims.<sup>136</sup> PIC does not concur with this recommendation with respect to all other claims denied by the Medical Review Contractor. PIC and its expert physicians have thoroughly reviewed the audit findings by the Medical Review Contractor and have determined that PIC did not receive an overpayment with respect to these other claims and that those claim denials and the OIG’s statistical extrapolation are improper and contrary to law. The rationale for PIC’s determinations are set forth in this letter and the Patient Response Summaries prepared by the expert physicians contracted by PIC to review the claim denials by the OIG. If any attempt is made by PIC’s MAC to recoup funds related to the claims at issue in this audit, PIC intends to exercise all appeal rights available to it.

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<sup>133</sup> See CMS, Medicare Benefit Policy Manual, Ch. 6 § 10-10.1 (“[p]ayment may be made under Part B for physician services and for [certain] nonphysician medical and other health services... when furnished by a participating hospital (either directly or under arrangements) to an inpatient of the hospital, but only if payment for these services cannot be made under Part A” when the “inpatient admission was not reasonable and necessary,... and if waiver of liability payment [was] not made”). See also MFMM, Ch. 3 § 170.1.

<sup>134</sup> 142 Cong. Rec. S9582 (daily ed. Aug. 2, 1996) (statement of Sen. Breaux).

<sup>135</sup> See **Exhibit 50**.

<sup>136</sup> See *supra* note 11.

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

PIC acknowledges its obligations under the 60-Day Repayment Rule. As noted above, PIC has voluntarily refunded amounts received for two claims. However, PIC has determined that no other repayments under this rule is warranted. The Draft Report indicates that the OIG believes its report constitutes credible information of potential overpayments, and, therefore, PIC must “exercise reasonable diligence to identify overpayments” for a 6-year lookback period pursuant to the requirements of the 60-day rule in § 1128J(d) of the Act and 42 C.F.R. § 401.305 applies. As noted above, PIC and its expert physicians have thoroughly reviewed the audit findings by the OIG and have determined that it did not receive any other overpayments and that the OIG’s claim denials and statistical extrapolation are improper and contrary to law. Accordingly, PIC has met the obligations of § 1128J(d) of the Act and 42 C.F.R. § 401.305 as set out by CMS in 81 Fed. Reg. 7654 (Feb. 12, 2016).

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

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

### CONCLUSION

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

Sincerely,



Bryan K. Nowicki

BKN/EMP  
Enclosures

HB: 4813-4854-2676.4