

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**MEDICARE HOSPICE PROVIDER
COMPLIANCE AUDIT:
HOSPICE COMPASSUS, INC.,
OF TULLAHOMA, TENNESSEE**

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Office of Inspector General

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

Report in Brief

Date: December 2020

Report No. A-02-16-01024

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



Why OIG Did This Audit

The Medicare hospice benefit allows providers to claim Medicare reimbursement for hospice services provided to individuals with a life expectancy of 6 months or less and who have elected hospice care. Previous OIG reviews found that Medicare inappropriately paid for hospice services that did not meet Medicare requirements.

Our objective was to determine whether hospice services provided by Hospice Compassus, Inc., of Tullahoma, Tennessee (Tullahoma), complied with Medicare requirements.

How OIG Did This Audit

Our audit covered 6,402 claims for which Tullahoma received Medicare reimbursement totaling \$19.6 million for hospice services provided during the period January 2014 through March 2016. We reviewed a random sample of 100 claims. We evaluated the services for compliance with Medicare requirements and submitted records associated with them to an independent medical review contractor.

Medicare Hospice Provider Compliance Audit: Hospice Compassus, Inc., of Tullahoma, Tennessee

What OIG Found

Tullahoma did not comply with Medicare requirements for 35 of the 100 claims in our sample. For these claims, Tullahoma claimed Medicare reimbursement for hospice services (1) for which the clinical record did not support the beneficiary's terminal prognosis, (2) that were not documented, and (3) for which the notice of election was not filed timely with the Medicare Administrative Contractor.

These improper payments occurred because Tullahoma's policies and procedures for ensuring that claims for hospice services met Medicare requirements were not always effective. On the basis of our sample results, we estimated that Tullahoma received at least \$3.4 million in Medicare reimbursement for hospice services that did not comply with Medicare requirements.

What OIG Recommends and Tullahoma Comments

We recommend that Tullahoma exercise reasonable diligence to identify, report, and return overpayments in accordance with the 60-day rule, and based on the results of our audit, identify, report, and return any additional overpayments as having been made in accordance with our recommendations. We also recommended that Tullahoma strengthen its procedures to ensure that hospice services comply with Medicare requirements.

In written comments on our draft report, Tullahoma, through its attorneys, generally disagreed with our findings and recommendations. Specifically, Tullahoma disagreed with all but 4 of the 68 claims questioned in our draft report. Tullahoma asserted that the medical review contractor misunderstood or misapplied coverage criteria related to the Medicare hospice benefit and glossed over the critical role of the hospice physician's certification of terminal illness. Additionally, Tullahoma believes that the records it provided supported the certifying physician's prognosis of terminal illness.

Based on the independent medical review contractor's reassessment of the cases disputed by Tullahoma, as well as an evaluation of Tullahoma's comments, we revised our determination for 35 claims. This resulted in 33 claims being allowable because 2 of the 35 claims remain unallowable for another reason. We revised our report and related recommendations accordingly. We maintain that our findings and recommendations, as revised, are valid.

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INTRODUCTION

WHY WE DID THIS AUDIT

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

OBJECTIVE

Our objective was to determine whether hospice services provided by Hospice Compassus, Inc., of Tullahoma, Tennessee (Tullahoma), complied with Medicare requirements.

BACKGROUND

The Medicare Program

Title XVIII of the Social Security Act (the Act) established the Medicare program, which provides health insurance coverage to people aged 65 and over, people with disabilities, and people with end-stage renal disease. The Centers for Medicare & Medicaid Services (CMS) administers the Medicare program.

Medicare Part A, also known as hospital insurance, provides for the coverage of various types of services, including hospice services.² CMS contracts with four Home Health and Hospice Medicare Administrative Contractors (MACs) to process and pay Medicare hospice claims.

The Medicare Hospice Benefit

To be eligible to elect hospice care, a beneficiary must be entitled to Medicare Part A and certified by a physician as being terminally ill (i.e., as having a medical prognosis with a life expectancy of 6 months or less if the illness runs its normal course).³ Hospice care is palliative (supportive), rather than curative, and includes, among other things, nursing care, medical social services, hospice aide services, medical supplies, and physician services. The Medicare hospice benefit has four levels of care: routine home care, continuous home care,

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

² The Act §§ 1812(a)(4) and (5).

³ The Act §§ 1814(a)(7)(A) and 1861(dd)(3)(A) and 42 CFR §§ 418.20 and 418.3.

inpatient respite care, and general inpatient (GIP) care. Each level has an all-inclusive daily rate.⁴

Beneficiaries eligible for the Medicare hospice benefit may elect hospice care by filing a signed notice of election (NOE) with a hospice.⁵ Upon election, the hospice assumes the responsibility for medical care of the beneficiary's terminal illness, and the beneficiary waives all rights to Medicare payment for services that are related to the treatment of the terminal condition or related conditions.⁶ The hospice must submit the NOE to its MAC within 5 calendar days after the effective date of election. If the hospice does not submit the NOE to its MAC within the required timeframe, Medicare will not cover and pay for days of hospice care from the effective date of election to the date that the NOE was submitted to the MAC.⁷

Beneficiaries are entitled to receive hospice care for two 90-day periods, followed by an unlimited number of 60-day periods.⁸ At the start of the initial 90-day period of care, the hospice must obtain written certification of the beneficiary's terminal illness from the hospice medical director or the physician member of the hospice interdisciplinary group⁹ and the beneficiary's attending physician, if any. For subsequent periods, a written certification by only the hospice medical director or the physician member of the hospice interdisciplinary group is required.¹⁰ The initial certification and all subsequent recertifications must include a brief narrative explanation of the clinical findings that supports a life expectancy of 6 months or less.¹¹ The written certification may be completed no more than 15 calendar days prior to the effective date of election or the start of the subsequent benefit period.¹²

A hospice physician or hospice nurse practitioner must have a face-to-face encounter with each hospice beneficiary whose total stay across all hospices is anticipated to reach a third benefit

⁴ 42 CFR § 418.302.

⁵ 42 CFR § 418.24(a)(1).

⁶ The Act § 1812(d)(2)(A) and 42 CFR § 418.24(d).

⁷ 42 CFR §§ 418.24(a)(2) and (a)(3).

⁸ 42 CFR § 418.21(a).

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

¹⁰ 42 CFR § 418.22(c).

¹¹ 42 CFR § 418.22(b)(3).

¹² 42 CFR § 418.22(a)(3).

period. The physician or nurse practitioner conducting the face-to-face encounter must gather and document clinical findings to support a life expectancy of 6 months or less.¹³

Hospice providers must establish and maintain a clinical record for each hospice patient.¹⁴ The record must include all services, whether furnished directly or under arrangements made by the hospice. Records should contain enough clinical factors and descriptive notes to show the illness is terminal and progressing in a manner that a physician would reasonably have concluded that the beneficiary's life expectancy was 6 months or less.¹⁵

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.¹⁶

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. The report and return overpayments 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.¹⁷

Hospice Compassus, Inc., of Tullahoma, Tennessee

Tullahoma, located in Tullahoma, Tennessee, is 1 of more than 140 healthcare programs operated by Hospice Compassus in 30 states across the United States.¹⁸ Tullahoma operates a freestanding hospice care center that provides services to terminally ill beneficiaries residing in Bedford, Cannon, Coffee, Franklin, Grundy and Moore Counties, as well as support for their families. Services offered by Tullahoma under its hospice benefit include physician, nursing, home health aide, counseling, medical social services, medical supplies, physical and

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

¹⁴ 42 CFR §§ 418.104 and 418.310.

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

¹⁶ The Act § 1128J(d); 42 CFR §§ 401.301 to 401.305; and 81 Fed. Reg. 7654, (Feb. 12, 2016).

¹⁷ 42 CFR §§ 401.305(d), 405.980(c)(4), and 413.24(f); CMS, Provider Reimbursement Manual – Part 1, Pub. 15-1, § 2931.2; and 81 Fed. Reg. 7654, 7670 (Feb. 12, 2016).

¹⁸ Hospice Compassus is a nationwide network of community-based hospice, palliative, and home health care services.

occupational therapy, short-term inpatient care, and speech pathology. During the period January 1, 2014, through March 31, 2016 (audit period),¹⁹ Tullahoma provided hospice services to approximately 1,900 beneficiaries and received Medicare reimbursement of \$19.6 million. Palmetto Government Benefits Administrator, LLC (Palmetto), serves as the MAC for Tullahoma.

HOW WE CONDUCTED THIS AUDIT

Our audit covered \$19,626,216 in Medicare reimbursement for 6,402 claims for hospice services provided by Tullahoma during the audit period. We reviewed a random sample of 100 of these claims to determine whether hospice services complied with Medicare requirements. We provided the associated medical records to an independent medical review contractor who determined whether there was sufficient documentation to support that (1) the associated beneficiaries were terminally ill, (2) hospice services provided were reasonable and necessary, and (3) Medicare requirements were met.

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

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

FINDINGS

Tullahoma received Medicare reimbursement for claims for hospice services that did not comply with Medicare requirements. Of the 100 hospice claims in our sample, 65 claims complied with Medicare requirements, but 35 did not. Specifically:

- For 22 claims, the clinical record did not support the beneficiary's terminal prognosis.
- For 13 claims, Tullahoma submitted claims for Medicare reimbursement for services that were not documented in the beneficiary's clinical record.
- For one claim, Tullahoma did not file the NOE for the associated beneficiary with Palmetto timely.

The total exceeds 35 because 1 claim contained more than 1 of the above errors.

¹⁹ Claims data for the period January 1, 2014, through March 31, 2016, was the most current data available when we started our audit.

These improper payments occurred because Tullahoma's policies and procedures were not effective to ensure that the clinical documentation it maintained supported the terminal illness prognosis. In addition, Tullahoma submitted claims to Medicare for services for which it did not provide supporting documentation. Lastly, while Tullahoma had procedures to ensure NOE requirements were met, it did not have specific procedures to address the timely filing of the NOE with the MAC.

On the basis of our sample results, we estimated that Tullahoma received at least \$3,464,856 in unallowable Medicare reimbursement for hospice services that did not comply with Medicare requirements.²⁰ As of the publication of this report, all unallowable claims in the sample are outside the 4-year claims reopening period.²¹ Notwithstanding, Tullahoma can request that a Medicare contractor reopen the initial determinations for those claims for the purpose of reporting and returning overpayments under the 60-day rule without being limited by the 4-year claims reopening period.²²

TERMINAL PROGNOSIS NOT SUPPORTED

To be eligible for the Medicare hospice benefit, a beneficiary must be certified as being terminally ill. Beneficiaries are entitled to receive hospice care for two 90-day periods, followed by an unlimited number of 60-day periods. At the start of the initial 90-day period of care, the hospice must obtain written certification of the beneficiary's terminal illness from the hospice medical director or the physician member of the hospice interdisciplinary group and the individual's attending physician, if any. For subsequent periods, a written certification from the hospice's physician is required. Clinical information and other documentation that support the beneficiary's terminal prognosis must accompany the physician's certification and be filed in the medical record with the written certification.²³

For 22 of the 100 sample claims, the clinical record provided by Tullahoma did not support the associated beneficiary's terminal prognosis. Specifically, the records for these claims did not contain sufficient clinical factors and descriptive notes to indicate that the associated beneficiary's illness was terminal and progressing in a manner that a physician would have reasonably concluded that the beneficiary's life expectancy was 6 months or less.

²⁰ To be conservative, we estimate overpayments at the lower limit of a two-sided 90-percent confidence interval. Lower limits calculated in this manner are designed to be less than the actual overpayment total 95 percent of the time.

²¹ 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).

²² 42 CFR § 405.980(c)(4).

²³ 42 CFR § 418.22(b)(2).

SERVICES NOT DOCUMENTED

No Medicare payment shall be made to any provider unless it has furnished the information necessary to determine the amount due.²⁴

For 13 of the 100 sample claims, there was no documentation to support some of the hospice services billed to Medicare. Specifically:

- For 12 sample claims, Tullahoma submitted claims for Medicare reimbursement that included aide and nursing services ordered by a physician and included in the associated beneficiary's care plan that were not documented in the beneficiary's clinical record.²⁵
- For two sample claims, Tullahoma claimed and received Medicare reimbursement for physician services that were not documented in the associated beneficiary's clinical record.^{26, 27}

NOTICE OF ELECTION NOT FILED TIMELY

Beneficiaries eligible for the Medicare hospice benefit may elect hospice care by filing a signed NOE with a hospice.²⁸ 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.²⁹ The hospice must submit the 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.³⁰

For 1 of the 100 sample claims, Tullahoma did not file the NOE with Palmetto within 5 days after the effective date of the election, as required. For this sample claim, the beneficiary

²⁴ The Act § 1815(a).

²⁵ These undocumented services did not impact the Medicare reimbursement Tullahoma received because they were not paid separately. Rather, they were included in an all-inclusive daily rate paid to the hospice. However, 1 of the 12 claims had another error that impacted the Medicare reimbursement Tullahoma received.

²⁶ Payment for these physician services was based on the physician fee schedule and not included in the all-inclusive daily rate paid to a hospice (42 CFR § 418.304(b)).

²⁷ The total exceeds 13 because 1 claim contained nursing and physician services that were not documented.

²⁸ 42 CFR § 418.24(a)(1).

²⁹ The Act § 1812(d)(2)(A) and 42 CFR § 418.24(d).

³⁰ 42 CFR §§ 418.24(a)(2) and (a)(3).

elected hospice care on December 4, 2014, however, Tullahoma did not file the NOE with Palmetto until March 19, 2015, 106 days after hospice care began. As a result, Tullahoma received unallowable Medicare reimbursement for the days before the NOE was filed.³¹

RECOMMENDATIONS

We recommend that Hospice Compassus, Inc., of Tullahoma, Tennessee:

- exercise reasonable diligence to identify, report, and return the estimated \$3,464,856 for hospice services that did not comply with Medicare requirements in accordance with the 60-day rule, and identify any of those returned overpayments as having been made in accordance with this recommendation;
- based on the results of this audit, exercise reasonable diligence to identify, report, and return any additional overpayments in accordance with the 60-day rule and identify any of those returned overpayments as having been made in accordance with this recommendation;³² and
- strengthen its procedures to ensure that hospice services comply with Medicare requirements.

HOSPICE COMPASSUS, INC., OF TULLAHOMA, TENNESSEE, COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments to our draft report, Tullahoma, through its attorneys, generally disagreed with our findings and recommendations.^{33, 34} Specifically, Tullahoma disagreed with all but 4 of the 68 sample claims questioned in our draft report and provided specific responses for each. Tullahoma agreed to return overpayments for the four claims it agreed were in error and to repay any improper claims identified outside of our audit period. However, Tullahoma did not agree with our recommendation to strengthen its procedures, as it believes its procedures are sufficiently strong to ensure that hospice services comply with Medicare requirements.

³¹ This claim had additional errors that resulted in the claim being questioned in its entirety.

³² 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.

³³ In a cover letter accompanying Tullahoma's attorneys' comments, Tullahoma disagreed with our draft report findings.

³⁴ The draft report had four recommendations, which we have revised to three. In the draft report, we recommended that Tullahoma refund to the Medicare program the portion of the estimated overpayment for claims incorrectly billed that are within the reopening period. We removed this recommendation because all of the incorrectly billed claims will be outside of the reopening period when this report is issued.

Tullahoma asserted that the medical review contractor misunderstood or misapplied the relevant coverage criteria related to the Medicare hospice benefit and glossed over the critical role of the physician's certification of terminal illness. Tullahoma stated that, because relevant regulations only require that clinical information and other documentation support the terminal prognosis, it is wrong to conclude that such supporting documentation must prove the validity of a physician's clinical judgement. Tullahoma further stated that it and its own hospice experts believe that the hospice records provided during the audit supported the certifying physician's prognosis of terminal illness. Therefore, according to Tullahoma, no hospice claim should be denied because the hospice records indeed support the certifying physician's prognosis of terminal illness such that they made an informed judgment on clinical eligibility. Lastly, Tullahoma indicated that OIG should not extrapolate the results of the audit since OIG's findings do not reflect a high or sustained level of payment error and Tullahoma was not subject to Medicare audits prior to this audit, thus making the use of extrapolation inappropriate. Tullahoma's comments are included as Appendix E.³⁵

Based on the results of the independent medical review contractor's reassessment of cases disputed by Tullahoma, as well as an evaluation of Tullahoma's written comments, we revised our determinations for 35 claims. This resulted in 33 claims being allowable since 2 of the 35 claims for which we revised our determinations (sample claims 13 and 97) remain unallowable for another reason.³⁶ Specifically, we are no longer questioning 34 claims for which we originally determined that the terminal prognosis was not supported and 1 claim for which we originally determined that the level of care was not supported. We revised our report and related recommendations accordingly. We maintain that our findings and recommendations, as revised, are valid.

Lastly, we considered Tullahoma's comments on the use of estimation in this audit and maintain that our statistical approach resulted in a legally valid and reasonably conservative estimate of the amount overpaid by Medicare to Tullahoma. Federal courts have consistently upheld statistical sampling and extrapolation as a valid means to determine overpayment amounts in Medicare and Medicaid.³⁷ We also note that the requirement that a determination

³⁵ Tullahoma included attachments to its comments that contained physician attestations of terminal illness for beneficiaries associated with some of the error claims, a claim-by-claim rebuttal to the medical review findings in our draft report, Hospice Compassus' current clinical eligibility policy, and résumés and curriculum vitae of the external reviewers it hired to review the records of the patients that OIG's medical review contractor determined were ineligible. These documents contain proprietary and personally identifiable information and have been excluded from this report but will be provided separately in their entirety to CMS.

³⁶ The number of claims in error was revised from 68 in the draft report to 35 in the final report.

³⁷ 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).

of a sustained or high level of payment error must be made before extrapolation applies only to Medicare contractors.³⁸

TERMINAL PROGNOSIS NOT SUPPORTED

Tullahoma Comments

Tullahoma disagreed with our determinations for 52 of the 56 claims identified in our draft report as not meeting hospice eligibility requirements (i.e., the clinical record did not support the terminal prognosis).³⁹ Tullahoma argued that there were inconsistencies in the independent medical review contractor's analysis. In addition, Tullahoma stated that the contractor applied erroneous standards when determining whether documentation supported a terminal prognosis and glossed over the critical role of the hospice physician's certification of terminal illness. Lastly, Tullahoma contended that the medical review contractor did not use a reasonable approach when deciding clinical eligibility for hospice services.

Office of Inspector General Response

The independent medical review contractor reassessed all 52 claims for which Tullahoma disagreed with the determination that the clinical record did not support the associated beneficiary's terminal prognosis. For this review, the medical review contractor considered Tullahoma's comments on our draft report and its attachments, the previously reviewed medical records, as well as its original determinations. Upon consideration of the independent medical review contractor's review results, we revised the determinations for 34 claims. We maintain that clinical records for the beneficiaries associated with the remaining 22 claims did not support the terminal illness prognosis.

Tullahoma's contentions that there were inconsistencies in the independent medical review contractor's analysis, that the contractor misunderstood or misapplied hospice coverage criteria when determining whether documentation supported a terminal prognosis, and that the contractor did not use a reasonable approach when deciding clinical eligibility for hospice services are not accurate. We also disagree that the contractor glossed over the critical role of the hospice physicians' certifications of terminal illness. The independent medical review contractor used the appropriate statutory and regulatory hospice criteria, as well as applicable Local Coverage Determination (LCD) guidelines, as the framework for its determination of terminal status. Specifically, the medical review contractor applied standards set out in 42 CFR § 418.22(b)(2), which requires clinical information and other documentation that support the

³⁸ See Social Security Act § 1893(f)(3); CMS Medicare Program Integrity Manual, Pub. No. 100-08, ch. 8, § 8.4 (effective January 2, 2019).

³⁹ Tullahoma has initiated repayments for the four claims it agreed with, as well as repayment for claims outside the audit period for the associated beneficiaries.

medical prognosis to accompany the certification and be filed in the medical record.⁴⁰ In addition, the independent medical review contractor did not gloss over the critical role of the hospice physician's certification of terminal illness. Rather, the contractor acknowledged the physician's terminal diagnosis and evaluated the medical records for each hospice claim, 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 factors supported the physician's medical prognosis, a determination that hospice eligibility criteria were met was made.

SERVICES NOT DOCUMENTED

Tullahoma Comments

Tullahoma disagreed with our determination that, for 13 claims, there was no documentation to support some of the hospice services billed to Medicare. Specifically, for the 12 claims identified in our draft report as missing supporting documentation of skilled nursing and aide services, Tullahoma stated that the independent medical review contractor may have misunderstood that Medicare pays for hospice services on a per diem rate, irrespective of whether services are provided on a particular day, and missing records for a single service do not render any portion of these claims as unallowable. In addition, Tullahoma disagreed that there was no documentation to support some of the physician services on the two claims identified in our draft report as missing documentation to support physician services.⁴¹

Office of Inspector General Response

After reviewing Tullahoma's comments, we maintain that our findings related to these 13 claims are valid. We agree that the undocumented skilled nursing and aide services did not impact the Medicare reimbursement Tullahoma received. As noted in our report, these services were not paid separately but included in the all-inclusive daily rate paid to Tullahoma. Accordingly, we did not calculate an overpayment for those services but still reported them as services that did not comply with Medicare requirements. We maintain that two claims were missing documentation to support some physician services and appropriately questioned those services.⁴²

⁴⁰ Applicable LCD guidelines also state that the documentation must contain enough information to support terminal illness upon review.

⁴¹ The total exceeds 13 because 1 claim contained both nursing and physician services that were not documented.

⁴² The remainder of these two claims were allowed.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

Our audit covered 6,402 hospice claims for which Tullahoma received Medicare reimbursement totaling \$19,626,216 for services provided from January 1, 2014, through March 31, 2016. These claims were extracted from CMS's National Claims History (NCH) file.

We did not assess Tullahoma's overall internal control structure. Rather, we limited our review of internal controls to those applicable to our objective. Our review 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 Tullahoma's office in Tullahoma, Tennessee.

METHODOLOGY

To accomplish our objective, we:

- reviewed applicable Medicare laws, regulations, and guidelines;
- met with CMS officials to gain an understanding of the Medicare hospice benefit;
- met with Palmetto officials to gain an understanding of the Medicare requirements related to hospice services;
- met with Tullahoma officials to gain an understanding of Tullahoma's policies and procedures related to providing and billing Medicare for hospice services and reviewed those policies and procedures;
- obtained from the CMS NCH file a sampling frame of 6,402 hospice claims, totaling \$19,626,216, for the audit period;
- selected a random sample of 100 hospice claims from the sampling frame;
- reviewed data from CMS's Common Working File and other available data for the sample claims to determine whether the claims had been canceled or adjusted;
- worked with Palmetto to identify the date the NOEs were submitted for each sample claim and determined the timeliness of the submission;
- obtained medical records for the 100 sample claims and provided them to an independent medical review contractor, who determined whether the hospice services complied with Medicare requirements;

- reviewed the medical review contractor’s results and summarized the reason(s) 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 Tullahoma for hospice services;
- discussed the results of our audit with Tullahoma officials; and
- requested the independent medical review contractor perform a reassessment of the 53 claims questioned in our draft report that involved a medical review determination.

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

APPENDIX C: STATISTICAL SAMPLING METHODOLOGY

TARGET POPULATION

The target population consisted of all Medicare Part A reimbursed claims for hospice services provided by Tullahoma from January 1, 2014, through March 31, 2016.

SAMPLING FRAME

The sampling frame was an Access database containing 6,402 claims totaling \$19,626,216.⁴³ The data was extracted from the CMS NCH file.

SAMPLE UNIT

The sample unit was a Medicare Part A hospice claim.

SAMPLE DESIGN

We used a simple random sample.

SAMPLE SIZE

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

SOURCE OF THE RANDOM NUMBERS

We generated the random numbers with the OIG, Office of Audit Services (OAS), statistical software.

METHOD FOR SELECTING SAMPLE ITEMS

We consecutively numbered the hospice claims in our sampling frame from 1 to 6,402. 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 Tullahoma 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 improper payment total 95 percent of the

⁴³ The sampling frame excludes hospice services that were identifiable in the Recovery Audit Contractor data warehouse as having been reviewed by another party and zero paid claims.

time. We also used the software to calculate the corresponding point estimate and upper limit of the 90-percent confidence interval.

APPENDIX D: SAMPLE RESULTS AND ESTIMATES

Sample Details and Results

Number of Claims in Frame	Value of Frame	Sample Size	Value of Sample	No. of Unallowable Claims in Sample	Value of Unallowable Claims in Sample
6,402	\$19,626,216	100	\$312,110	35 ⁴⁴	\$80,307

**Estimated Value of Unallowable Claims
(Limits Calculated for a 90-Percent Confidence Interval)**

Point estimate	\$5,141,241
Lower limit	3,464,856
Upper limit	6,817,626

⁴⁴ Twenty-four of these 35 claims had errors that affected Medicare reimbursement.

APPENDIX E: HOSPICE COMPASSUS, INC., OF TULLHAOMA, TENNESSEE, COMMENTS



November 15, 2019

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

Re: Report Number: A-02-16-01024

Dear Ms. Tierney,

On behalf of Compassus, thank you for the opportunity to provide comments to the HHS Office of Inspector General's ("OIG") draft report on the Compassus hospice program in Tullahoma, Tennessee that focused on Medicare hospice services provided from January 2014 through March 2016.

Compassus is a provider of hospice and palliative care services, furnishing care and support to individuals in their last phase of life. Last year, Compassus cared for over 37,570 patients and their families in 140 locations across the United States. Our Tullahoma, TN hospice program has been serving that community since 2006. Our core tenets include delivering high-quality patient-centric care, expanding access to qualified individuals, and putting compliance at the forefront every day. We operate in a highly regulated environment and are acutely aware of our responsibility to ensure that patients who meet Medicare's clinical eligibility standards, as determined by physicians, receive our hospice services. To that end, we have in place a highly-developed process for conducting clinical eligibility assessments. Our admissions practices include a certification of terminal illness from two physicians (if the beneficiary designates an attending physician), and the comprehensive clinical assessment of a registered nurse who is trained in hospice and palliative care.

As part of our planning around OIG's audit of our Tullahoma program, we engaged independent hospice experts and external legal counsel to evaluate those Medicare claims that OIG identified as unsupported. Our legal counsel's response, which incorporates the findings of the independent hospice experts, is included with this letter and sets forth specific reasons for Compassus' nonconcurrency with OIG's findings and any alternative corrective action planned or taken. As that response describes, Compassus' independent hospice experts disagree with OIG's initial clinical review findings.



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We take the OIG’s audit of our Tullahoma program very seriously. Since OIG first notified us of the preliminary audit findings in September 2018, we have worked with reasonable diligence to identify the issues that could lead to a potential overpayment. With regard to one of the OIG draft reports observations, we disagree that Compassus’ policies and procedures are ineffective or require substantive modification. Our clinical operations team works diligently to ensure that our policies are best in class and fully reflect the values of Compassus and our legal obligations. Our team also ensures that our policies evolve over time to reflect the current regulatory requirements and procedural best practices that help us care for our patients in the best way we can. Providing end of life care for patients consistent with the Medicare hospice benefit requirements is a responsibility we embrace with the utmost care and diligence.

Throughout this process, Compassus has provided sufficient information to demonstrate its compliance with Medicare’s requirements for hospice care. As OIG knows, just because a hospice patient does not pass away within six months of being certified as terminally ill does not mean that the patient did not qualify for hospice care or that the certifying physicians were wrong. CMS has long recognized that issues of life and death do not always follow an exact trajectory or timeline. Based on the independent review conducted, we believe that OIG’s draft report contains numerous incorrect and inaccurate conclusions and that the certifying physicians were correct to certify and recertify eligibility for all but one of the patients in OIG’s sample. In particular, the conclusions of OIG’s contracted reviewers do not reflect clinically appropriate practices or a clear understanding of hospice.

We do not have information on the physician reviewers the OIG used in connection with its audit of the clinical records, as that information was not made available to us. The independent experts Compassus engaged, including a nationally known hospice clinical consultant team and two board certified hospice and palliative care physicians who oversee substantial hospice programs, reviewed these records and determined that there was adequate support for the terminal condition of nearly every the claim in the sample. Consistent with its obligations under the Sixty Day Rule, Compassus has effectuated a refund for any amounts at issue. The expert review determined that just four of the one hundred sampled claims did not demonstrate sufficient clinical eligibility – that level of accuracy, 96%, is substantially higher than that of the industry, and the Tullahoma program’s PEPPER data reflects an exemplary hospice. This not only affirms that our processes, policies, and procedures are effective at the Tullahoma hospice program, but also that our clinicians are making clinically appropriate decisions around prognosis and that the clinical records sufficiently support those determinations. Above all, we are caring for our end-of-life patients and their families and caregivers with compassion and appropriate goals of care.

Simply put, while we embrace OIG’s audits of health care entities participating in the Medicare program, here we disagree with OIG’s draft audit findings. The detailed rationale for this is included



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in the attached report and we hope that OIG will duly consider this information as it finalizes its findings.

Sincerely,

A handwritten signature in blue ink that reads "James A. Deal".

James A. Deal
Chief Executive Officer
Compassus

Morgan Lewis

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November 15, 2019

BY FEDERAL EXPRESS AND ELECTRONIC MAIL

Brenda M. Tierney
Regional Inspector General for Audit Services
U.S. Dep't. of Health & Human Services, Office of Audit Services Region II
Jacob K. Javitz Federal Building
26 Federal Plaza, Room 3900
New York, NY 10278

Re: Compassus Tullahoma; OIG Report A-02-16-01024

Dear Ms. Tierney:

Community Hospices of America – Tennessee, LLC (d/b/a Hospice Compassus – Tennessee) (“Compassus”), through its counsel, submits this letter in response to the U.S. Department of Health and Human Services (“HHS”), Office of Inspector General’s (“OIG”) draft audit report (A-02-16-01024) dated August 2, 2019 (the “Draft Report”). Compassus appreciates OIG allowing an extension through November 15, 2019, to provide comments to the Draft Report. Compassus disagrees with 52 of 56 of OIG’s claim audit findings as to hospice eligibility and disagrees with all of the remaining Draft Audit findings. Certain of the more jarring and unsupported review findings of OIG’s independent medical review contractor (“IMRC”) are discussed in this letter response.

In general, Compassus fundamentally disagrees with the OIG’s IMRC findings inasmuch as the medical reviewers appear to have misunderstood or misapplied the relevant coverage criteria related to the Medicare hospice benefit and glossed over of the critical role under the Medicare hospice benefit of the hospice physicians’ certifications of terminal illness related to their reasonable clinical belief that the beneficiaries were terminally ill. As described in greater detail below, one of the lynchpins to qualifying for the Medicare hospice benefit is the subjective clinical determinations by one or more certifying physicians as to whether an individual is terminally ill, meaning that individual has a life expectancy of six months or less if the illness runs its normal course. The Centers for Medicare & Medicaid Services (“CMS”) has specifically noted that terminal prognostication is not an exact science and made clear that hospice claims should not be denied when a certifying physician has a

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good faith clinical belief that a patient will pass away in six (6) months or less. Importantly, physicians are not required to prognosticate with 100% certainty. As a Federal Court of Appeals recently found in the *AseraCare* decision, under the Medicare hospice benefit the certifying physician's certification of terminal illness ("CTI") must be given great weight and that:

[T]he relevant regulations require only that "clinical information and other documentation that support the prognosis . . . accompany the certification" and "be filed in the medical record." This "medical prognosis" is, itself, "based on the physician's . . . clinical judgment." 42 C.F.R. § 418.22(b). To conclude that the supporting documentation must, standing alone, prove the validity of the physician's initial clinical judgment would read more into the legal framework [of the Medicare statute] that its language allows. . . [t]hat is, the [certifying] physician's clinical judgment dictates eligibility as long as it represents a reasonable interpretation of the relevant medical records."¹

Further, the Court correctly found that the hospice clinical record in "support" of the physicians' certifications of terminal illness not have to be a detailed chronicle of every detail of the hospice patient's clinical condition that "proves" the patient was terminally ill.² That appears to have been the OIG's IMRC reviewers' erroneous approach to their clinical record review, and below we detail our support for our conclusion. In sum, in its audit of Compassus, the OIG applied the wrong legal documentation standard as to what the Medicare hospice benefit requires to support a terminal prognosis and support a claim for hospice services that were indeed furnished. OIG's Draft Report does not conclude services were not furnished; nor does the Draft Report contend, because it cannot, that the hospice physicians failed to certify in good faith that each patient had a terminal prognosis for each hospice benefit period under review. Instead, the Audit Report findings are premised on a review of a cold hospice record whereby the OIG reviewers found insufficient record support for the contemporaneous clinical decision making of the hospice physicians who certified the patients as terminally ill during the audit period. Our experts also disagree with the OIG IMRC review findings as to whether the hospice records support the determinations by the Compassus hospice physicians that these patients would, more likely than not, die within six months if the illnesses ran their normal course.

The *AseraCare* opinion is instructive insofar as it is the most complete explication by a federal court of the Medicare hospice benefit's legal requirements on the documentation that "supports" a terminal prognosis and the role of that documentation in support of a physician's CTI. That decision spends several pages discussing the Medicare hospice benefit legal requirements³ as to how the Medicare statute must be interpreted. Importantly for

¹ *United States v. AseraCare, Inc.*, 938 F.3d 1278, 1294 (2019).

² *Id.* at 1293-94.

³ *Id.* at 1291-94.

purposes of the OIG's reconsideration of its Draft Report findings and why its IMRC physician reviewers' findings are legally flawed, the Court notes that:

[H]ad Congress or CMS intended the patient's medical records to objectively demonstrate terminal illness, it could have said so. Yet Congress said nothing to indicate that the medical documentation presented with a claim must prove the veracity of the clinical judgment on an after-the-fact review. And CMS's own choice of the word "support" – instead of, for example, "demonstrate" or "prove" – does not imply the level of certitude the Government wishes to attribute to it.⁴

The Court goes on to observe "[m]ore broadly, CMS's rulemaking commentary signals that well-founded clinical judgments should be granted deference."⁵ The Court in *AseraCare* has it right. Compassus respectfully requests that OIG reconsider its IMRC medical review findings with the court's legal findings squarely in mind. To fail to do so will not protect the Medicare hospice benefit, but rather will do it (and our client Compassus) an injustice by further embracing a legally faulty medical documentation standard under the Medicare hospice benefit. That is not to say that hospice physician judgments warrant unfettered deference under the Medicare hospice benefit. Compassus believes, to the contrary, those clinical judgments should be reasonable. To that very point, and Compassus believes critical to OIG's consideration of these comments to the Draft Report,

[W]hile there is no question that clinical judgments must be tethered to a patient's valid medical records, it is equally clear that 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.⁶

For the reasons offered in the balance of this response letter, and in the detailed, claim-by-claim response in the confidential attachment (which contains protected health information and which Compassus presumes will not be publicly posted by OIG), Compassus strongly believes, as do the two hospice physician experts it engaged to review OIG's claim denial determinations, that the hospice records do support the certifying physicians' prognosis of terminal illness such that they made informed judgments on clinical eligibility. In further support of the informed clinical judgments of the certifying physicians as to terminal prognosis, Compassus has also secured attestations from those physicians who oversaw the care of these patients (who still remain with the organization) that affirm their reasonable clinical view that their respective patients at issue in this OIG audit were eligible for hospice during the period under review. **Attachment A.**

⁴ *Id.* at 1294.

⁵ *Id.* at 1295.

⁶ *Id.*

OFFICIAL RESPONSE TO OIG DRAFT REPORT A-02-16-01024

Compassus disagrees with the Draft Report's determination on fifty-two (52) of the fifty-six (56) claims where OIG determined hospice eligibility requirements were not met. Compassus's fundamental disagreement relates to the conclusions of the IMRC reviewers, which are inaccurate or divergent from the clinical facts present and unsupported by a reasonable clinical review of the record. In addition, Compassus further disagrees with the substance and import of the finding that thirteen (13) claims purportedly did not contain documentation in support of services. Compassus disagrees with the finding that the general inpatient level of care furnished with respect to one (1) claim was not supported. Compassus also disagrees that it failed to comply with the Notice of Election filing requirements identified in the Draft Report on four (4) claims.

The specific responses to each clinical denial are contained in the attached appendix. **Attachment B.** In addition, several examples of when the IMRC reviewers arrived at incorrect clinical conclusions are set forth below.

I. INTRODUCTION: OVERVIEW OF COMPASSUS AND HOSPICE CARE

Compassus is a nationwide network of community-based hospice, palliative and home health care services. Founded in 2006, Compassus has grown to become the third-largest hospice provider in the nation with more than one hundred and forty (140) locations in over thirty (30) states. As a large provider of hospice care, Compassus is acutely aware that its hospice programs operate in a highly regulated environment. While high quality end-of-life care is its highest priority, Compassus programs also have a keen focus on appropriately documenting those services.

Compassus operates a freestanding hospice care center in Tullahoma, Tennessee ("Tullahoma"). Tullahoma serves hospice beneficiaries in Bedford, Cannon, Coffee, Franklin, Grundy, and Moore counties. At its Tullahoma location, Compassus offers hospice and palliative care, including general inpatient care, respite care, spiritual care, physical and occupational therapy, dietary counseling, grief counseling, and hospice aides among other services.

Hospice care is a comprehensive suite of services identified and coordinated by a patient's attending physician (if the patient has elected one), hospice physician, and interdisciplinary group ("IDG") to provide for the physical, psychosocial, spiritual, and emotional needs of a terminally ill patient and their family members. As required by law, Tullahoma has a valid Medicare provider agreement with CMS and meets the required hospice Conditions of Participation. According to CMS regulations, "terminally ill individuals" are patients with a medical prognosis including a life expectancy of six (6) months or less, if the disease runs its normal course. In order to be eligible for the hospice benefit under Medicare, a patient must be eligible for Part A benefits and be certified as terminally ill by a physician. Each patient is assessed by a hospice medical director for hospice eligibility, in consultation with the patient's attending physician (if the patient has

one). When considering admission, medical directors assess the patient's terminal condition, other health conditions, and the clinically relevant information supporting each diagnosis. A medical director may obtain clinically relevant information directly or indirectly from the patient's attending physician and/or through hospice nurses' assessment of the patient and the patient's medical history, as well as other pertinent sources. For the initial ninety-day certification period, the medical director (or a physician member of the IDG) and attending physician must both sign the written CTI; for each subsequent certification period the medical director (or a physician member of the IDG) may certify a patient's terminal status without conferring with the attending physician. Each CTI must be supported by the patient's condition as reflected in their medical records.

To satisfy these requirements, Compassus has implemented a comprehensive set of policies and procedures for determining clinical eligibility for hospice and effectuating admissions. For example, Compassus has developed a thorough process for conducting eligibility assessments that includes 1) receiving and processing a referral from a healthcare provider, patient, or patient's family/friend; 2) obtaining relevant medical records related to the certification of its physicians, 3) the physical assessment by a registered nurse and 4) the concurrence by the patient that they are terminally ill. Compassus's current clinical eligibility policy is set forth in **Attachment C**.

II. SUMMARY OF DRAFT REPORT FINDINGS

OIG selected claims submitted by Tullahoma between January 1, 2014 and March 31, 2016 for its review. During this time, Tullahoma submitted six thousand four hundred and two (6,402) claims for reimbursement for hospice care provided to approximately nineteen hundred (1,900) Medicare beneficiaries, for which Tullahoma received a total of \$19.6 million. From these claims, OIG directed its physician contractors to review 100 random claims, sixty-eight of which the contractor asserted did not comply with one or more Medicare requirements. OIG then extrapolated the results of this sample, notwithstanding the individualized care and conditions of each patient, and estimated by extrapolation that Payson received \$10.9 million to which it was not entitled.

OIG identified four (4) primary issues among Tullahoma's claims:

- 1) Beneficiaries did not meet eligibility requirements (fifty six (56) claims);
- 2) Claims were not supported by proper documentation (thirteen (13) claims);
- 3) Reimbursement rates claimed were higher than beneficiaries required (one (1) claim); and
- 4) Notices of election were not timely filed with Tullahoma's Medicare Administrative Contractor ("MAC"), Palmetto GBA ("Palmetto") (four (4) claims).⁷

⁷ Although OIG identified only one instance of this issue in its Draft Report, it identified four instances in the physician and coding summary documents. We are therefore addressing all four instances.

Three (3) of the claims were alleged to have more than one error. OIG asserted that while Tullahoma had policies and procedures related to determining eligibility, they were not effective to ensure that the requirements were met and the appropriate level of care was provided. Moreover, although Tullahoma had policies pertaining to Notices of Election, those policies did not specifically address the timely filing of these notices with the MAC. Finally, OIG asserts that Tullahoma submitted claims without supporting documentation.

To remedy these issues, OIG made several recommendations. OIG recommended that Tullahoma return overpayments received within the four (4)-year claims reopening period, use reasonable diligence to identify and return improper payments falling outside of the four-year reopening period and the audit period in accordance with the "60-Day rule," and strengthen its procedures to ensure that Tullahoma's hospice services comply with Medicare requirements.

III. ANALYSIS OF DRAFT REPORT

Compassus and its external advisors have reviewed the Draft Report. In addition, Compassus engaged two (2) separate independent reviews – one performed by a nationally recognized hospice consulting firm and the other by the Chief Medical Officer of a renowned hospice system as well as a professor and Medical Director of Palliative Care Leadership Centers. Compassus also evaluated its own policies and procedures related to the issues identified by OIG.

Compassus respectfully asks the OIG to consider the following related to its Draft Report findings:

- Inconsistencies in analysis and approach of the IMRC Reviewers;
- Compassus's Expert Review Methodology;
- Compassus's Expert Review Findings;
- OIG's Review and Credible Information;
- Compliance Enhancements and Training;
- Technical Documentation Issues; and
- Use of Extrapolation.

1. INCONSISTENCIES IN THE IMRC REVIEWERS USED BY OIG

OIG furnished Compassus with confidential clinical summaries setting forth the determinations made by one or more Independent Medical Review Contractor (“IMRC”) physicians, as well as coders in certain instances, of the one hundred (100) claims reviewed. Based on its own review, Compassus believes that the OIG’s IMRC physicians applied inconsistent and erroneous clinical standards when deciding whether documentation supported a terminal prognosis.

Compassus was not provided with the OIG’s IMRC physicians’ curricula vitae or other biographical information. Compassus cannot, therefore, ascertain which of the available board certifications the IMRC physicians held in hospice and palliative medicine. Compassus’ experts’ review suggests, however, that the IMRC reviewers did not apply a reasonable approach to determine clinical eligibility for hospice services consistent with the legal requirements of the Medicare hospice benefit.⁸ The IMRC clinical review findings also demonstrated a lack of consistency from summary to summary. As discussed in more detail below, the reviewers appeared to appropriately summarize the salient facts and medical conditions reflected in each sampled record, but did not synthesize these facts into appropriate – or even reasonable – clinical conclusions. Accordingly, Compassus believes that OIG should consider the findings of Compassus’s hospice clinical review experts included within the attachment hereto. Compassus believes its experts’ opinions evidence a well-founded, “whole patient” approach to determining clinical eligibility from a desk-audit record review, and Compassus asks that OIG apply these findings to its final report.

2. COMPASSUS EXPERTS’ REVIEW METHODOLOGY

- * Compassus received initial information related to the OIG’s audit findings in September 2018. [REDACTED], a nationally-recognized hospice auditing and consulting organization, was engaged at that time to review the pertinent hospice records. [REDACTED] utilizes a team of clinicians with substantial hospice-specific experience to review medical records and compare the contents of those records to applicable local coverage determinations (“LCDs”) and other established hospice documentation guidelines.

Compassus provided the reviewers access to the identical set of records submitted to the OIG. Thereafter, the [REDACTED] reviewers evaluated these records from two perspectives: 1) whether the records contained appropriate documentation to meet the technical regulatory conditions of payment for Medicare hospice services and 2) whether the records contained appropriate documentation evidencing a patient’s clinical eligibility for Medicare hospice services.

Compassus thereafter engaged Dr. [REDACTED], the Chief Medical Officer at a major hospice organization, and Dr. [REDACTED], HMDC, FAAFP, FAAHPM, a physician and professor who specializes in hospice and palliative medicine at the University of Kentucky. Both physicians have substantial clinical experience in hospice and palliative

⁸ See discussion *supra* at pp. 2-3.

*** OIG Note:** The name of the organization hired by Tullahoma to review hospice records and the names of the physicians that reviewed the records have been redacted because they are personally identifiable information.

care medicine and an expert level understanding of the clinical indicators of eligibility for the Medicare hospice benefit. Dr. [REDACTED] is involved in the daily assessment of hospice patients' clinical condition and Medicare requirements. Since 2000, Dr. [REDACTED] has been both a practitioner and a professor of clinical and palliative medicine at various institutions, including University of Southern California, Yale School of Medicine, and University of Connecticut. In those roles, Dr. [REDACTED] was not only engaged in the day-to-day assessment of patients for determining terminal prognosis, but also undertook substantive clinical research projects as well as assessment of the Medicare program's coverage criteria and terminal prognosis predictors for hospice care. The physician experts' CVs are included as **Attachment D**.

Dr. [REDACTED] and Dr. [REDACTED] conducted an independent clinical review of each patient's medical records for each of the claims that the IMRC reviewers determined was ineligible. Dr. [REDACTED] and Dr. [REDACTED] did not simply adopt [REDACTED] determinations, but rather conducted a separate independent review of the clinical eligibility of each patient based on the documentation available. Dr. [REDACTED] and Dr. [REDACTED] determined whether the certification or recertification related to each claim at issue was reasonably supported by the documented clinical indicators. Importantly, Dr. [REDACTED] and Dr. [REDACTED] reviews do not only reflect their singular view as hospice clinicians. It relies on substantive medical literature that many hospice physicians routinely reference for assessing hospice clinical eligibility and answering the question, "Is this patient terminally ill?". This literature includes:

- Lynn J, Adamson DM, "Refining and reforming health care for the last years of life". The RAND Corporation, 2006.
- Mortality Risk Index (MRI): Mitchell SL, Kiely DK, Hamel MB, et.al. Estimating prognosis for nursing home resident with advanced dementia. JAMA 2004; 291:2734-2740.
- Salpeter, Luo, Malter, Stuart, "Systematic Review of Noncancer Presentations with Median Survival of 6 months or less" Amer. J. of Med., 125, 2012.

3. COMPASSUS EXPERT REVIEW FINDINGS

Dr. [REDACTED], Dr. [REDACTED], and the [REDACTED] reviewers reviewed each of the claims that the IMRC reviewers determined did not qualify for Medicare payment. They found sufficient record support for eligibility in all but four instances. Importantly, for the four claims (Patient 8, Patient 40, Patient 55 and Patient 90) for which the records did not clearly support Medicare hospice eligibility, Compassus has effectuated a refund, and not only for the claims under OIG review, but additional periods outside of the review period. Compassus understands its obligations under the 60-Day Rule and after exercising reasonable diligence, it has appropriately refunded identified Medicare overpayments.

Compassus hospice experts' findings illustrate that the substantial majority of the patients determined by the OIG's IMRC physicians to be not terminally ill were indeed eligible for the Medicare hospice benefit. The review indicated that many of the patients at

issue partially met the LCD guidelines for hospice, but that every patient determined eligible nevertheless exhibited a terminal prognosis that qualified them for the Medicare hospice benefit. LCDs in the hospice context are merely guidelines; patients can be (and often are) terminally ill without fully meeting corresponding hospice LCD elements. The Palmetto LCDs specifically note that a patient that “does not meet the criteria outlined” in the LCD may still be “deemed appropriate for hospice care.” See Palmetto LCD L34547.

Dr. [REDACTED] and Dr. [REDACTED] reviewed the 56 claims at issue and determined that for 52 out of the 56, the certifying physician's prognostication that the individual was terminally ill was appropriate. This stands in stark contrast to the IMRC reviewers' determinations and several of their disagreements warrant further discussion, as summarized below.

- Patient 5 – Review Period in January 2015 - female patient aged 100 or older with Alzheimer's disease, osteoarthritis, hypertension and congestive heart failure (CHF). The patient was actively dying during the review period, but the IMRC asserted that the hospice care should be denied because the care provided was allegedly not consistent with hospice care. Rather inexplicably, the IMRC reviewer concluded:

[The patient's] goals of care and treatment were not consistent with hospice standards. She was treated with antibiotics for infections when the antibiotic use was not necessary for comfort care. She received antibiotics for a urinary tract infection in early December 2014 as documented in the face-to-face on 12/5/2014 and again in late December, during the last period, as documented in the nursing visit on 12/20/2014. The patient was not hospice appropriate and her symptoms were documented as well managed. As stated, she continued to receive routine medical care for infections that were a common complication of her condition. The treatments were not necessary for her comfort, were not consistent with hospice standards and unnecessarily prolonged her hospice stay. The care she received was consistent with routine home care for advanced illness, not hospice standard care.

These are startling conclusions – essentially that under the Medicare hospice benefit, hospices should help hasten the death of their patients lest it not be “consistent with hospice standards.” All care, including antibiotics, were within the standards of hospice practice and were reasonable and necessary. The medical record indicates medication adjustments and the treatment of infections, such as urinary tract infections. While there has been some clinical research related to the effectiveness of antibiotics in end-of-life care, the general consensus in the medical community is that antibiotics remain an important part of palliative care, particularly if a patient is weeks – as opposed to days – from death. This patient passed away on January 31, 2015, which was over a month from the last use of antibiotics to treat the patient's recurrent infections. The patient was clearly hospice appropriate and the IMRC's

reference to antibiotics as the sole reason for finding the patient was not terminally ill highlights the inadequacy of that IMRC reviewer's position.

- Patient 13 – Review Period in September 2015 – a seventy eight (78) year old female with cachexia, chronic liver disease, lupus, Dementia, esophageal stenosis, gastritis, hepatitis C, hypertension, and chronic pain with narcotic dependence and osteoarthritis. Notably, the patient passed away after only four (4) days on Tullahoma service. The patient was admitted directly onto the GIP level of care from an acute care hospital with a rapid decline in status.

Without support, the IMRC reviewer asserts that the patient did not require a drip or frequent changes in medication regimen or frequent physician review. The IMRC reviewer therefore posits that “two physician visits would have been sufficient” and that the patient could have been cared for at a “skilled nursing level of care.” While it is not clear what the “skilled nursing level of care” is (given that GIP also provides a skilled nursing level of care), the IMRC reviewer's findings are incorrect nonetheless.

To begin with, medication drips are not a requirement for GIP level of care. Although medication changes are also not a requirement for GIP clinical eligibility, they often support the need for that level of care. Here, the IMRC reviewer, substituting his/her own clinical judgment for that of the physicians caring for Patient 13 at the time, appears to gloss over the fact the patient's medical record indicates several instances of medication adjustments during the very short inpatient hospice stay. A patient admitted from an intensive care unit onto hospice sometimes, as was the case here, has significant care needs that cannot be reasonably managed at home or another non-facility setting, which is exacerbated by a patient such as this who has chronic pain with narcotic dependency, suggesting a need for more specialized and tailored pain management in this instance.

- Patient 23 – Review Period in January 2016 – an eighty two (82) year old female patient with a primary diagnosis of metastatic colon cancer. She had significant comorbidities, including chronic kidney disease, Alzheimer's, diabetes with wounds, and anemia. By all accounts, the patient was on a rapidly declining terminal trajectory. Nevertheless, the IMRC reviewer asserted that:

The Certification of Terminal Illness provided limited information related to the colon cancer, disease progression or the patient's condition to determine prognosis or progression of disease. Although the patient did need palliative intervention she was not hospice appropriate without a prognosis of six months or less.

This is factually untrue and does not support that the patient was ineligible for hospice care. The CTI at issue indicates the presence of metastatic cancer as well as increased

agitation, continued pain at 7-8/10, increased tiredness and increased sleep, and a decrease in appetite with 50-75% of meals daily. This is more than sufficient and demonstrable CTI record evidence of decline supporting the certifying physician's clinical judgment that Patient 23 was terminally ill. Importantly, the patient's PPS was 40% and she could only ambulate using a walker or wheelchair. This level of functional status in metastatic cancers is associated with a prognosis of six months or less. Notably, while Palmetto does not have a specific LCD covering cancers, other Medicare hospice LCDs suggest eligibility for terminal cancers when a patient has a PPS of 70% or less, the cancer has progressed to a metastatic phase, and the patient declines further intervention. This particular patient's records show that Patient 23 was well into her terminal decline. The certifying physician believed the patient was terminally ill and the hospice IDG team who cared for the patient believed that the patient was terminally ill, but the IMRC physician, based solely on the contents of a CTI, somehow concluded hospice care was not reasonable or necessary. The OIG should not credit such a clearly erroneous conclusion.

- Patient 31 – Review Period in August 2015 – an 84 year old male with NYHA Class IV heart disease, a PPS of 40%, and significant co-morbidities including chronic kidney disease, hyperlipidemia, gout, and anemia. Notably, the patient passed away 35 days after the period under OIG review. The IMRC reviewer concluded the patient was not terminally ill on the basis that the care given was inconsistent with hospice care, noting specifically that the existence of an implantable cardiac defibrillator/pacemaker “conflicts with the hospice philosophy.” The IMRC reviewer's position is not only flatly wrong, but irrelevant as to whether the patient was eligible for the Medicare hospice benefit. Of importance here, as the IMRC reviewer specifically noted, the patient “did not want to pursue further treatment” for cardiac disease and elected, as was his right, to receive hospice care.

During the period under review, the patient showed increased somnolence and behavioral changes. The physical exam showed increasing crackles in the lungs, pale appearance and cool to touch. Function declined with dyspnea at 50 feet of walking versus 75 feet in the past. The patient continued to have pursed-lip breathing after any activity. His PPS declined from 50% to 40% with more bed rest. Pain continued and the patient had a weight loss of 7 pounds since admission. By all accounts, the patient was in a terminal trajectory.

Ignoring these clear indicators of terminality, the IMRC reviewer instead focused solely on the fact that the patient had a *previously* implanted pacemaker, which the IMRC reviewer intoned is purportedly not part of the “hospice philosophy.” To be clear, the pacemaker was not implanted while the patient was receiving hospice services. Instead, it appears that the IMRC reviewer would prefer that the patient undergo surgical removal of the implanted pacemaker to qualify for hospice services. This is a clinically absurd position and one that, Compassus suggests, reflects the lack of that IMRC reviewer's experience with hospice care. The concept of “hospice

philosophy” is not one that precludes a patient from receiving services they are otherwise eligible for because they continue to receive medical treatment or have intact implanted medical devices. It is the preference of the patient or family – not a third-party reviewer – on whether to continue using a defibrillator or pacemaker and, quite often, and we might add – fully consistent with the goals of care under the “hospice philosophy” many patients continue to make use of cardiac devices while on hospice service. In any event, and in fact, this patient passed away soon after the OIG review period.

This is another instance where the IMRC reviewer appears to correctly identify the relevant clinical factors that would make a patient terminally ill, but then “reaches” for a basis to conclude nonetheless that the patient was not terminally ill. This is precisely the kind of erroneous clinical second-guessing the *AseraCare* court found the Medicare statute does not allow.

The IMRC’s approach to these and other patients in the OIG audit sample is generally concerning. The OIG has asserted significant liability against the Tullahoma hospice program as a result of its review based in many instances on the IMRC reviewers’ personal musings and clinically unsupported views about “hospice philosophy,” and not on whether the certifying physician had a reasonable basis, as supported by and tethered to the clinical records, to conclude that the patient had a prognosis of six months or less to live if the illness runs its normal course. The findings of the IMRC appear substantially misplaced and do not demonstrate a reliable clinical eligibility review.

Moreover, these IMRC reviewers’ errors are exaggerated by OIG’s potential use of extrapolation. The OIG should closely scrutinize the work of the IMRCs because it appears that there are significant misunderstandings of hospice eligibility and misapplications of the hospice clinical guidelines. In either case, the OIG should substantially revise its Draft Report to reflect that, in all but four instance, the claims at issue met Medicare requirements for patients who were clinically eligible for the Medicare hospice benefit.

Additionally, Compassus experts’ reviews disagreed with the single instance where the IMRC reviewers asserted that Compassus provided a higher level of care than was warranted by the patient’s condition. In this instance, the patient was suffering from acute exacerbations of symptoms that could not have been effectively managed outside of a facility setting. This patient’s symptoms never resolved to the point where it was safe and medically appropriate to change the patient’s level of care. Accordingly, OIG should revise its findings in the Draft Report that there was an instance where the services provided exceeded the level of care necessary.

4. OIG’S REVIEW AND CREDIBLE INFORMATION

As noted above, Compassus is keenly aware of the requirements under the 60-Day Rule, which generally require a provider to report and return any identified overpayment

within 60 days of identification and calculation. As further expanded by CMS in its 2016 rulemaking preamble to its regulation at 42 CFR § 401.301, under the 60-Day Rule CMS expects that providers with credible information of a potential overpayment should engage in the exercise of reasonable diligence to determine if a Medicare Part A or B overpayment exists. Rulemaking preamble further suggests that determinations from the Federal government, such as MAC reviews or the OIG's pending audit here, may constitute "credible information" that gives rise to a provider's obligation to engage in the exercise of reasonable diligence. The Tullahoma OIG review and its preliminary results have prompted Compassus to do just that, undertaking a careful review of the Tullahoma program's technical documentation, policies and procedures, as well as a detailed clinical review conducted by several independent hospice experts. For the reasons noted above, Compassus fundamentally disagrees with the findings of the OIG's IMRC physicians, and finds its own expert reviewers' findings compelling, especially now in light of the *AseraCare* decision.

5. COMPLIANCE ENHANCEMENTS AND TRAINING

Although Compassus did not uncover any systemic compliance issues at its Tullahoma program from either a clinical or technical documentation standpoint, Compassus engages in regular compliance program assessment, with enhancements developed as appropriate. These include regular compliance training, internal audits, and corrective actions for detected compliance shortcomings.

Notably, however, the Program for Evaluating Payment Patterns Electronic Report ("PEPPER") data for the period under review demonstrates a hospice program in Tullahoma that was and is well-functioning and exceeds Medicare standards. In all PEPPER metrics, including live discharges, long length of stay, single diagnoses, long GIP stays, and top terminal diagnoses, Tullahoma's PEPPER data reveals no outlier concerns. It had a live discharge rate between 6.3% and 8.3% during the years under review, whereas the jurisdictional 80th percentile (the threshold for concern on PEPPER data) hovered at 17%. Similarly, Tullahoma's long length of stay was at 9.5% and 11.9% during the two years of the OIG's review period, compared to a jurisdictional 80th percentile of 24.5% and 25.5%, respectively. Tullahoma's percentage of cancer patients was 31.3%, representing the Tullahoma hospice program's top diagnosis. This is in line with the jurisdictional cancer diagnosis of 30.4% of all decedents. Simply put, these PEPPER metrics, created and distributed by CMS's contractor (TMF Health Quality Institute), combined with the intensive and independent expert review Compassus conducted, do not provide any indicia that compliance enhancements at this program are warranted on account of the OIG draft Audit Report findings.

6. TECHNICAL ISSUES

OIG identified limited technical documentation deficiencies during the course of its review. Specifically, OIG asserted four instances where a patient's Notice of Election ("NOE") form was not timely submitted in accordance with regulations. In each of these

instances, however, the patient's admission occurred long before the effective date of the NOE Medicare filing requirement OIG relies upon.

The regulation requiring the submission of the NOE within five (5) days of the patient's admission went into effect on October 1, 2014, which is in the middle of the OIG's audit review period. This requirement was originally scheduled to be effective April 1, 2014, but CMS permitted hospices until October 1, 2014 to implement this requirement. It appears that the IMRC reviewers misunderstood this, as they denied a number of claims on the basis that an NOE was not timely filed between the period of January 1, 2014 and October 1, 2014 for the following patients:

- 1) Patient 14 (4/1/14 to 4/12/14);
- 2) Patient 27 (1/16/14 to 1/22/14);
- 3) Patient 58 (5/16/14 to 5/31/14); and
- 4) Patient 85 (8/6/14 to 8/11/14).

In these instances, the admission and review periods are before the NOE filing requirement was enforced. Therefore, there is no valid basis to conclude that the Tullahoma program was under a Medicare requirement to have filed the additional form. Subsequent to the NOE filing effective date, Compassus had no instances of admissions with late NOE filing. Compassus inquiry into this issue did not reveal a systemic concern about the timely filing of the NOE.

7. EXTRAPOLATION

OIG appeared to use its standard provider audit methodology to extrapolate the results of the clinical audit to the universe of all of the Medicare claims submitted by Tullahoma within the time period under review. Though Compassus has not reviewed and are not commenting on the legitimacy and accuracy of OIG's extrapolation methodology, OIG should forgo extrapolation for two reasons.

First, in accordance with CMS's recent revisions to its extrapolation procedures in the case of Medicare audits, the clinical review findings do not reflect a high or sustained level of payment error for which extrapolation is justified. More specifically, once OIG corrects the significant errors identified in the IMRC review, the remaining error rate will be well below 50%, one of the thresholds CMS now looks to prior to its contractors engaging in extrapolated audits. While OIG is not a CMS contractor, a consistent approach across Medicare audits is appropriate.

Second, Tullahoma was not subject to Medicare audits prior to the OIG audit and thus extrapolation is not appropriate. The statute only indicates that extrapolation is

appropriate in instances of a “high or sustained” level of payment error, neither of which are the case in this review.

IV. RESPONSE TO RECOMMENDATIONS

In the Draft Report, OIG gave four recommendations. Compassus concurs in part with two of the recommendations and disagrees with two recommendations. Compassus’s specific concurrence or non-concurrence is set out below.

- *Compassus should refund to the Federal Government the portion of the estimated \$10.9 million for hospice services that did not comply with Medicare requirements and that are within the 4-year claims reopening period.*

Compassus disagrees insofar as it does not believe it was overpaid for hospice services that are within the four-year claims reopening period (except for the limited instances where a refund has already been initiated). Compassus disagrees with OIG’s IMRC in virtually every instance where that contractor determined that the services did not comply with Medicare requirements.

- *Compassus should exercise reasonable diligence to identify and return improper payments in accordance with the 60-day-rule for the remaining portion of the estimated \$10.9 million, which is outside of the 4-year claims reopening period, and identify any returned improper payments as having been made in accordance with this recommendation.*

Compassus concurs with this recommendation insofar as exercising reasonable diligence to identify and return improper payments identified for the claims reviewed by OIG’s external consultant is a statutory and regulatory requirement. Compassus has already effectuated repayments for any Medicare claims that, as a result of its external review, were determined to be overpayments, irrespective of whether they were within or outside of the four-year claims reopening period. Although Compassus did determine that certain limited claims were not eligible for Medicare payment, Compassus did not identify any systemic issues that would compel Compassus to conduct additional reviews at its Tullahoma hospice program.

- *Compassus should exercise reasonable diligence to identify and return any additional similar overpayments outside of our audit period, in accordance with the 60-day rule, and identify any returned overpayments as having been made in accordance with this recommendation.*

Compassus concurs with this recommendation insofar as it has ongoing responsibilities to repay identified Medicare overpayments in accordance with statutory and regulatory requirements. As noted above, Compassus has exercised reasonable diligence

with respect to the issues raised by OIG and has not identified any additional Medicare overpayments or systemic issues arising from the OIG audit. Compassus continues to conduct frequent auditing at its Tullahoma program in accordance with its compliance policies and procedures.

- *Compassus should strengthen its procedures to ensure that hospice services comply with Medicare requirements.*

Compassus disagrees with this recommendation to “strengthen” its procedures because it believes its procedures are sufficiently strong to ensure that hospice services comply with Medicare requirements. As the independent experts’ review demonstrated, the vast majority of the claims reviewed by OIG complied with Medicare requirements. Compassus Tullahoma’s procedures are consistent, timely and appropriate both with regard to the initial admission process and recertifications. However, Compassus reviews and updates its policies and procedures from time to time to ensure compliance with regulatory requirements and appropriate clinical standards. Compassus has a dedicated team of hospice and compliance professionals to develop, implement, and train staff on its compliance and clinical operations.

V. CONCLUSION

Compassus, through its counsel, appreciates the opportunity to provide the comments to the OIG for its consideration and inclusion in its final audit report. Compassus respectfully requests that OIG consider the information contained in the comments herein and the corresponding appendices and modify its Final Report findings accordingly.

Sincerely,

/Howard Young/

Howard J. Young

Enclosures