

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**MEDICARE HOSPICE PROVIDER
COMPLIANCE AUDIT:
MISSION HOSPICE &
HOME CARE, INC.**

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Office of Inspector General

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Report in Brief

Date: July 2021

Report No. A-09-18-03009

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 Mission Hospice & Home Care, Inc. (Mission), complied with Medicare requirements.

How OIG Did This Audit

Our audit covered 6,142 claims for which Mission (located in San Mateo, California) received Medicare reimbursement of about \$37 million for hospice services provided from October 1, 2015, through September 30, 2017. We reviewed a random sample of 100 claims. We evaluated compliance with selected Medicare billing requirements and submitted these sampled claims and the associated medical records to an independent medical review contractor to determine whether the services met coverage, medical necessity, and coding requirements.

Medicare Hospice Provider Compliance Audit: Mission Hospice & Home Care, Inc.

What OIG Found

Mission received Medicare reimbursement for hospice services that did not comply with Medicare requirements. Of the 100 hospice claims in our sample, 66 claims complied with Medicare requirements. However, the remaining 34 claims did not comply with the requirements. Specifically, for 33 claims, the clinical record did not support the beneficiary's terminal prognosis, and for 1 claim, the clinical record did not support the level of care billed to Medicare. In addition, for a few claims, there was no evidence that beneficiaries elected hospice care before the periods covered by the sampled claims, or there was no support for physician services billed to Medicare.

Improper payment of these claims occurred because Mission's policies and procedures were not effective in ensuring that the clinical documentation it maintained supported the terminal illness prognosis, election statements were signed before the periods covered by the sampled claims, the appropriate level of care was billed, and physician services were supported. On the basis of our sample results, we estimated that Mission received at least \$10.5 million in unallowable Medicare reimbursement for hospice services.

What OIG Recommends and Mission Comments

We recommend that Mission: (1) refund to the Federal Government the portion of the estimated \$10.5 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.

Mission, through its attorney, disagreed with our determinations for all but 7 of the 34 sampled claims we questioned. Mission concurred in part with our first and second recommendations and disagreed with our third recommendation. Mission stated that it had made inquiries with its Medicare contractor to refund Medicare for the seven claims it agreed were in error. In addition, Mission challenged the validity of our statistical sampling methodology and the resulting extrapolation.

After reviewing Mission's comments, we maintain that our findings and recommendations are valid. 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 Mission.

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INTRODUCTION

WHY WE DID THIS AUDIT

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

OBJECTIVE

Our objective was to determine whether hospice services provided by Mission Hospice & Home Care, Inc. (Mission), complied with Medicare requirements.

BACKGROUND

The Medicare Program

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

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

The Medicare Hospice Benefit

To be eligible to elect Medicare hospice care, a beneficiary must be entitled to Medicare Part A and certified by a physician as being terminally ill (i.e., as having a medical prognosis with a life expectancy of 6 months or less if the illness runs its normal course).³ Hospice care is palliative (supportive), rather than curative, and includes, among other things, nursing care, medical social services, hospice aide services, medical supplies, and physician services. The Medicare hospice benefit has four levels of care: (1) routine home care, (2) general inpatient (GIP) care,

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

² The Act §§ 1812(a)(4) and (5).

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

(3) inpatient respite care, and (4) continuous home care (CHC). Medicare provides an all-inclusive daily payment based on the level of care.⁴

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

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

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

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

⁵ 42 CFR § 418.24(a)(1).

⁶ The Act § 1812(d)(2)(A) and 42 CFR § 418.24(d). After our audit period (October 1, 2015, through September 30, 2017), the text of 42 CFR § 418.24(d) was moved to 42 CFR § 418.24(e), effective October 1, 2019. 84 Fed. Reg. 38484, 38544 (Aug. 6, 2019).

⁷ 42 CFR §§ 418.24(a)(2) and (a)(3).

⁸ 42 CFR § 418.21(a).

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

¹⁰ 42 CFR § 418.22(c).

of 6 months or less.¹¹ The written certification may be completed no more than 15 calendar days before the effective date of election or the start of the subsequent benefit period.¹²

A hospice physician or hospice nurse practitioner must have a face-to-face encounter with each hospice beneficiary whose total stay across all hospices is anticipated to reach a third benefit period.¹³ The physician or nurse practitioner conducting the face-to-face encounter must gather and document clinical findings to support a life expectancy of 6 months or less.¹⁴

Hospice providers must establish and maintain a clinical record for each hospice patient.¹⁵ The record must include all services, whether furnished directly or under arrangements made by the hospice. Clinical information and other documentation that support the medical prognosis of a life expectancy of 6 months or less if the terminal illness runs its normal course must be filed in the medical record with the written certification of terminal illness.¹⁶

Medicare Requirements To Identify and Return Overpayments

OIG believes that this audit report constitutes credible information of potential overpayments. Upon receiving credible information of potential overpayments, providers must exercise reasonable diligence to identify overpayments (i.e., determine receipt of and quantify any overpayments) during a 6-year lookback period. Providers must report and return any identified overpayments by the later of: (1) 60 days after identifying those overpayments or (2) the date that any corresponding cost report is due (if applicable). This is known as the 60-day rule.¹⁷

The 6-year lookback period is not limited by OIG's audit period or restrictions on the Government's ability to reopen claims or cost reports. To report and return overpayments

¹¹ 42 CFR § 418.22(b)(3).

¹² 42 CFR § 418.22(a)(3).

¹³ Hospices that admit a patient who previously received hospice services (from the admitting hospice or from another hospice) must consider the patient's entire Medicare hospice stay to determine in which benefit period the patient is being served and whether a face-to-face visit will be required for recertification. 75 Fed. Reg. 70372, 70435 (Nov. 17, 2010).

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

¹⁵ 42 CFR §§ 418.104 and 418.310.

¹⁶ 42 CFR §§ 418.22(b)(2) and (d)(2).

¹⁷ The Act § 1128J(d); 42 CFR §§ 401.301–401.305; 81 Fed. Reg. 7654 (Feb. 12, 2016).

under the 60-day rule, providers can request the reopening of initial claims determinations, submit amended cost reports, or use any other appropriate reporting process.¹⁸

Mission Hospice & Home Care, Inc.

Mission is a nonprofit provider located in San Mateo, California, that furnishes hospice care to beneficiaries who live in California. From October 1, 2015, through September 30, 2017 (audit period), Mission provided hospice services to approximately 1,500 beneficiaries and received Medicare reimbursement of about \$37.3 million.¹⁹ National Government Services, Inc. (NGS), serves as the MAC for Mission.

HOW WE CONDUCTED THIS AUDIT

Mission received Medicare Part A reimbursement of \$37,329,352 for hospice services provided during our audit period, representing 6,466 paid claims. After we excluded 324 claims, totaling \$217,646, our audit covered 6,142 claims totaling \$37,111,706.²⁰ We reviewed a random sample of 100 of these claims, totaling \$605,507, to determine whether hospice services complied with Medicare requirements. Specifically, we evaluated compliance with selected billing requirements and submitted these sampled claims and the associated medical records to an independent medical review contractor to determine whether the services met coverage, medical necessity, and coding requirements.

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

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

¹⁸ 42 CFR §§ 401.305(d), 405.980(c)(4), and 413.24(f); CMS, *Provider Reimbursement Manual*—Part 1, Pub. No. 15-1, § 2931.2; 81 Fed. Reg. at 7670.

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

²⁰ We excluded hospice claims that had a payment amount of less than \$1,000 (316 claims), had compromised beneficiary numbers (4 claims), or were identified in the Recovery Audit Contractor data warehouse as having been reviewed by another party (4 claims).

FINDINGS

Mission received Medicare reimbursement for hospice services that did not comply with Medicare requirements. Of the 100 hospice claims in our sample, 66 claims complied with Medicare requirements. However, the remaining 34 claims did not comply with the requirements:

- For 33 claims, the clinical record did not support the beneficiary's terminal prognosis. In addition, for 2 of these 33 claims, there was no evidence that either beneficiary elected hospice care by signing an election statement before the period covered by the sampled claim, and for 1 of these 33 claims, Mission provided documentation that did not support the physician service billed to Medicare.
- For one claim, the clinical record did not support the level of care and some physician services billed to Medicare.

Improper payment of these claims occurred because Mission's policies and procedures were not effective in ensuring that the clinical documentation it maintained supported the terminal illness prognosis, election statements were signed before the periods covered by the sampled claims, the appropriate level of care was billed, and physician services were supported.

On the basis of our sample results, we estimated that Mission received at least \$10.5 million in unallowable Medicare reimbursement for hospice services.²¹ As of the publication of this report, these overpayments include claims outside of the 4-year reopening period.²² Notwithstanding, Mission can request that a Medicare contractor reopen the initial determinations for those claims for the purpose of reporting and returning overpayments under the 60-day rule without being limited by the 4-year reopening period.²³

MEDICARE REQUIREMENTS

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

²¹ The statistical lower limit is \$10,564,396. To be conservative, we recommend recovery of overpayments at the lower limit of a two-sided 90-percent confidence interval. Lower limits calculated in this manner are designed to be less than the actual overpayment total at least 95 percent of the time.

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

²³ 42 CFR § 405.980(c)(4).

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

Payment may be made for hospice care provided to an individual if the individual makes an election to receive hospice care.²⁵ Beneficiaries eligible for the Medicare hospice benefit may elect hospice care by filing a signed election statement with a hospice. The election statement must include: (1) the individual's acknowledgment that he or she has been given a full understanding of the palliative rather than curative nature of hospice care and (2) the effective date of hospice care, which may be no earlier than the date of the election statement.²⁶ Hospices must maintain clinical records for each beneficiary, such as a signed copy of the election statement.²⁷

No Medicare payment shall be made to any provider unless it has furnished the information necessary to determine the amount due (the Act § 1815(a)).

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.²⁸ 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.²⁹ 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.

TERMINAL PROGNOSIS NOT SUPPORTED

For 33 of the 100 sampled claims, the clinical record provided by Mission did not support the associated beneficiary's terminal prognosis. Specifically, the independent medical review contractor determined that the records for these claims did not contain sufficient clinical

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

²⁵ The Act § 1812(d)(1) and 42 CFR § 418.200.

²⁶ 42 CFR §§ 418.24(a)(1), (b)(2), and (b)(4).

²⁷ 42 CFR § 418.104(a)(2).

²⁸ 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).

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

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.

In addition, for 2 of these 33 claims, there was no evidence that either beneficiary elected hospice care by signing an election statement before the period covered by the sampled claim. For the first claim, Mission stated that it could not locate the election statement. For the second claim, Mission provided an election statement that was signed and dated approximately 16 months after the period covered by the sampled claim. Furthermore, for 1 of these 33 claims, Mission billed Medicare for a physician service that was not supported by the beneficiary's clinical record.³⁰

LEVEL OF CARE NOT SUPPORTED

Our sample contained one claim for which Mission billed Medicare at the GIP level of care, which has a higher payment rate. However, the beneficiary's clinical record did not support the need for the level of care billed. The independent medical review contractor determined that the beneficiary did not have pain or symptoms that required the GIP level of care. The beneficiary's hospice care needs could have been met if Mission had provided services at the less expensive routine level of care.³¹ For the same sampled claim, Mission billed Medicare for some physician services that were not supported by the beneficiary's clinical record.

RECOMMENDATIONS

We recommend that Mission Hospice & Home Care, Inc.:

- refund to the Federal Government the portion of the estimated \$10,564,396 for hospice services that did not comply with Medicare requirements and that are within the 4-year reopening period;³²

³⁰ Payment for the physician service was based on the physician fee schedule for those physician services furnished by hospice employees or under arrangements with the hospice and was not included in the all-inclusive daily payment made to the hospice (42 CFR § 418.304(b)).

³¹ For the one claim, we used the applicable payment rates and questioned the difference in payment amounts between the GIP and routine levels of care.

³² OIG audit recommendations do not represent final determinations by Medicare. CMS, acting through a MAC or other contractor, will determine whether overpayments exist and will recoup any overpayments consistent with its policies and procedures. Providers have the right to appeal those determinations and should familiarize themselves with the rules pertaining to when overpayments must be returned or are subject to offset while an appeal is pending. The Medicare Part A and Part B appeals process has five levels (42 CFR § 405.904(a)(2)), and if a provider exercises its right to an appeal, the provider does not need to return overpayments until after the second level of appeal. Potential overpayments identified in OIG reports that are based on extrapolation may be re-estimated depending on CMS determinations and the outcome of appeals.

- based upon the results of this audit, exercise reasonable diligence to identify, report, and return any overpayments in accordance with the 60-day rule³³ 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.

MISSION COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, Mission, through its attorney, disagreed with our determinations for all but 7 of the 34 sampled claims questioned in our draft report and provided specific responses for each of the 34 claims. Mission did not comment on our finding that Mission billed Medicare for some physician services that were not supported by the beneficiary's clinical record. Mission concurred in part with our first and second recommendations and disagreed with our third recommendation. Mission stated that it had made inquiries with NGS to effectuate a refund to Medicare for the seven claims it agreed were in error. Mission also stated that NGS has instructed it not to make those refunds at this time but to wait for an overpayment demand.

Mission stated that our independent medical review contractor "used a rigid, post-hoc approach" to determine hospice eligibility under the Medicare benefit and largely ignored the critical role of the hospice physicians' reasonable clinical belief that the beneficiaries were terminally ill at the time the physicians completed the certifications of terminal illness. Mission cited a Federal court decision that noted: "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." Mission also stated that it engaged two highly experienced independent hospice and palliative care physicians (hospice experts) to review our sampled claims and that they disagreed with a significant majority of our findings. In addition, Mission reviewed our statistical sampling methodology and stated that our methodology and resulting extrapolation were not statistically valid. Mission's written comments are included as Appendix E.³⁴

After reviewing Mission's comments, we maintain that our findings and recommendations are valid. Our independent medical review contractor acknowledged the physician's terminal diagnosis and evaluated the clinical records provided by the hospice for each sampled claim

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

³⁴ Mission attached four exhibits to its comments, which contained the attorney's authorization to release information, the hospice experts' authorization to release information, the hospice experts' rebuttal statements for our findings, and the curricula vitae of the hospice experts. 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 Mission's comments in their entirety to CMS.

(including necessary historical clinical records), guided by questions rooted in the Medicare requirements, for its determinations.

The Federal court decision that Mission referenced addressed whether a difference in clinical judgment can render a physician certification false for purposes of False Claims Act liability and therefore is inapplicable to OIG audit recommendations and CMS recoveries arising from OIG audits. Our independent medical review contractor did not require that documentation *prove* the medical prognosis. Instead, our contractor considered each beneficiary's clinical picture and found 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.

We also maintain that our statistical sampling methodology and extrapolation were statistically valid and resulted in a legally valid and reasonably conservative estimate of the amount that Medicare overpaid to Mission.

The following sections summarize Mission's comments and our responses.

INDEPENDENT MEDICAL REVIEW CONTRACTOR

Mission Comments

Mission stated that it was not provided with our independent medical review contractor physicians' curricula vitae or other biographical information. Mission stated that it cannot, therefore, ascertain the physicians' qualifications, board certifications (if any), or perspective and experience with hospice and palliative medicine. Mission also stated that its hospice experts found that our independent medical review contractor applied an inconsistent approach to determine clinical eligibility for hospice services and the need for higher levels of care consistent with the legal requirements of the Medicare hospice benefit. In addition, Mission stated that our contractor appeared in most instances to appropriately summarize the salient facts and medical conditions reflected in each sampled claim, but did not synthesize these facts or the patients' comorbidities and other clinical conditions into appropriate clinical conclusions.

Office of Inspector General Response

We used an independent medical review contractor that is a licensed physician who specializes in hospice and palliative medicine and is familiar with Medicare hospice guidelines and protocols. The 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 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.³⁵ As previously mentioned, our contractor acknowledged the physician's terminal diagnosis and evaluated the clinical records provided by the hospice for each sampled claim (including necessary historical clinical records), guided by questions rooted in the Medicare requirements, to determine whether the certified terminal prognosis was supported. The 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. When the clinical 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.

MISSION HOSPICE EXPERTS' REVIEW FINDINGS

Mission Comments

Mission stated that its hospice experts found record support for hospice eligibility and the higher level of care (as applicable) in 27 of the 34 sampled claims that our independent medical review contractor determined did not comply with Medicare requirements. Mission stated that for those beneficiaries who only partially met the applicable LCD guidelines, they each nevertheless exhibited a terminal prognosis that qualified them for the Medicare hospice benefit. Mission stated that LCDs in the hospice context are merely guidelines; patients can be (and often are) terminally ill without fully meeting corresponding hospice LCD elements. In addition, Mission stated that the NGS hospice LCD specifically notes: "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." Mission also stated that our independent medical review contractor misapplied the Advanced Dementia Prognostic Tool (ADEPT). Finally, Mission stated that, for one beneficiary for which our contractor asserted a level-of-care concern, the level of care that Mission provided was reasonable and necessary given the beneficiary's clinical condition and need at that time.

Office of Inspector General Response

After reviewing Mission's comments, including its hospice experts' analyses, we maintain that the clinical records for each of the 27 sampled claims did not support the associated beneficiary's terminal prognosis or the need for the claimed GIP level of care. Although our independent medical review contractor referenced the ADEPT in conducting the medical review, the contractor properly used the appropriate statutory and regulatory hospice criteria, as well as applicable LCD guidelines, as the framework for its determinations. We acknowledge that some beneficiaries who did not meet the guidelines in the hospice LCDs may still be

³⁵ Applicable LCD guidelines also state that the documentation must contain enough information to support terminal illness upon review.

appropriate for hospice care based upon an individual assessment of the beneficiary's health status. Accordingly, our independent medical review contractor merely used LCD guidelines as a tool to evaluate the terminal prognosis. In conclusion, it was the opinion of our contractor that the documentation in the clinical records did not support the terminal prognosis. Therefore, 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.

For the one sampled claim for which Mission billed Medicare at the GIP level of care, our independent medical review contractor determined that the associated beneficiary did not have pain or symptoms that required that level of care. The beneficiary's hospice care needs could have been met if Mission had provided services at the less expensive routine level of care.

OFFICE OF INSPECTOR GENERAL SAMPLING METHODOLOGY

Mission Comments

Mission challenged the validity of our statistical sampling methodology and extrapolation. Mission stated that although OIG engages in a standardized sampling plan for its provider compliance audits, Mission observes that the representativeness of OIG's sample and reliability of the overall estimate is questionable because: (1) OIG's exclusion of claims that had a payment amount of less than \$1,000 inappropriately skews the representativeness of the sample and (2) the use of a 100-claim sample was simply too small. Furthermore, Mission stated that OIG should forgo extrapolation because the clinical review findings do not reflect a high or sustained level of payment error for which extrapolation is justified according to CMS extrapolation procedures. Finally, Mission stated that the extrapolation is defective because it "failed to account for Medicare repayments related to the OIG audit time period that were already made by Mission as a result of its 'hospice aggregate cap.'"

Office of Inspector General Response

After reviewing Mission's comments, we maintain that our sampling methodology and extrapolation are statistically valid. The legal standard for use of sampling and extrapolation is that it must be based on a statistically valid methodology, not the most precise methodology.³⁶ We properly executed our statistical sampling methodology in that we defined our sampling frame and sample unit, randomly selected our sample, applied relevant criteria in evaluating the sample, and used statistical sampling software (i.e., the OIG, Office of Audit Services (OAS), statistical software RAT-STATS) to apply the correct formulas for the extrapolation.

³⁶ 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).

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 only to the sampling frame from which the sample was drawn.

Although Mission takes issue with our sample size of 100 claims, sample sizes smaller than 100 have routinely been upheld by the Departmental Appeals Board and Federal courts.³⁷ To account for the precision of our estimate, we recommend recovery at the statistical lower limit of a two-sided 90-percent confidence interval. Lower limits calculated in this manner are designed to be less than the actual overpayment total in the sampling frame 95 percent of the time. The use of the lower limit accounts for the precision of our estimate in a manner that generally favors the auditee.³⁸ 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 Mission refund a larger amount to the Government.

The Social Security Act and *Medicare Program Integrity Manual* (MPIM) requirement that a determination of a sustained or high level of payment error must be made before extrapolation can be used applies only to Medicare contractors—not OIG.³⁹

The aggregate cap limits the total aggregate payments that any individual hospice may receive in a cap year to an allowable amount based on an annual per-beneficiary cap amount and the number of beneficiaries served. The aggregate cap ensures that hospice care does not exceed the cost of conventional medical care at the end of life. Any amount paid to a hospice for its claims in excess of the aggregate cap is considered an overpayment and must be repaid to Medicare. If a provider's covered days of hospice care or Medicare payments are adjusted through an audit or other review, the MAC may recalculate the aggregate cap if the amount is material.⁴⁰ A hospice that believes its payments have not been properly determined may request a review from the MAC or the Provider Reimbursement Review Board.⁴¹

³⁷ See *Anghel v. Sebelius*, 912 F. Supp. 2d 4, 10 (E.D.N.Y. 2012) (upholding a sample size of 95 claims); *Transyd Enters., LLC v. Sebelius*, 2012 U.S. Dist. LEXIS 42491 at *30-31 (S.D. Tex. 2012) (upholding a sample size of 30 claims).

³⁸ 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).

³⁹ See the Act § 1893(f)(3); MPIM, Pub. No. 100-08, chapter 8, § 8.4.

⁴⁰ See CMS's *Medicare Benefit Policy Manual* (MBPM), Pub. No. 100-02, chapter 9, § 90.2.5.

⁴¹ 42 CFR § 418.311; MBPM, Pub. 100-02, chapter 9, § 90.3.

RECOMMENDATIONS

Mission Comments

Mission concurred in part with our first and second recommendations and disagreed with our third recommendation, as follows:

- Regarding our first recommendation, Mission disagreed insofar as it does not believe it was overpaid the recommended refund amount for hospice services that are within the 4-year reopening period. Mission stated that it disagreed with our independent medical review contractor in most instances in which the contractor determined that patients were not eligible for hospice services. Mission stated that it concurred regarding certain claims referred to in its comments (i.e., the seven sampled claims it agreed were in error), but also stated that, per NGS's instruction, it is awaiting instruction on effectuating refunds of those claims.
- Regarding our second recommendation, Mission concurred only insofar as exercising reasonable diligence to identify and return improper payments upon having credible evidence of a potential Medicare overpayment is a statutory and regulatory obligation. Mission stated that it has already attempted to effectuate repayments for any Medicare payments that, in Mission's determination, were determined to be overpayments (i.e., for the seven sampled claims it agreed were in error). Mission stated that it did not identify any systemic hospice service billing issues that would compel Mission to conduct additional reviews at this time.
- Regarding our third recommendation, Mission stated that it believes its currently existing procedures are sufficiently strong to ensure that hospice services reasonably comply with Medicare requirements. Mission also stated that its compliance policies and procedures have evolved over time and are appropriate both with regard to the initial admission process and recertifications. Mission stated that it reviews and updates its policies and procedures from time to time to ensure compliance with regulatory requirements and appropriate clinical standards. In addition, Mission stated that it has a dedicated team of hospice and compliance professionals to develop, implement, and train staff on its compliance and clinical operations.

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 result of the appeal.

We maintain that improper payment of the 34 sampled claims occurred because Mission's policies and procedures were not effective in ensuring that the clinical documentation it maintained supported the terminal illness prognosis and that the appropriate level of care was provided.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

Our audit covered 6,142 hospice claims for which Mission received Medicare reimbursement totaling \$37,111,706 for services provided from October 1, 2015, through September 30, 2017 (audit period). These claims were extracted from CMS's National Claims History (NCH) file.

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

We performed fieldwork at Mission's office in San Mateo, California.

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 Mission officials to gain an understanding of Mission's policies and procedures related to providing and billing Medicare for hospice services and reviewed those policies and procedures;
- obtained from CMS's NCH file 6,466 hospice claims, totaling \$37,329,352,⁴² for the audit period;
- excluded 316 claims, totaling \$184,888, that had a payment amount of less than \$1,000; 4 claims, totaling \$17,026, that had compromised beneficiary numbers; and 4 claims, totaling \$15,732, that were identified in the Recovery Audit Contractor data warehouse as having been reviewed by another party;
- created a sampling frame consisting of 6,142 hospice claims, totaling \$37,111,706;
- selected a simple random sample of 100 hospice claims from the sampling frame;

⁴² 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 Mission for hospice services; and
- discussed the results of our audit with Mission 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: Northwest Hospice, LLC</i>	A-09-20-03035	6/23/2021
<i>Medicare Hospice Provider Compliance Audit: Professional Healthcare at Home, LLC</i>	A-09-18-03028	6/10/2021
<i>Medicare Hospice Provider Compliance Audit: Franciscan Hospice</i>	A-09-20-03034	5/18/2021
<i>Medicare Hospice Provider Compliance Audit: Alive Hospice, Inc.</i>	A-09-18-03016	5/14/2021
<i>Medicare Hospice Provider Compliance Audit: Ambergare Hospice, Inc.</i>	A-09-18-03017	5/14/2021
<i>Medicare Hospice Provider Compliance Audit: Suncoast Hospice</i>	A-02-18-01001	5/7/2021
<i>Medicare Hospice Provider Compliance Audit: Tidewell Hospice, Inc.</i>	A-02-18-01024	2/22/2021
<i>Medicare Hospice Provider Compliance Audit: Hospice Compassus, Inc., of Tullahoma, Tennessee</i>	A-02-16-01024	12/16/2020
<i>Medicare Hospice Provider Compliance Audit: Hospice Compassus, Inc., of Payson, Arizona</i>	A-02-16-01023	11/19/2020
<i>Safeguards Must Be Strengthened To Protect Medicare Hospice Beneficiaries From Harm</i>	OEI-02-17-00021	7/3/2019
<i>Hospice Deficiencies Pose Risks to Medicare Beneficiaries</i>	OEI-02-17-00020	7/3/2019
<i>Vulnerabilities in the Medicare Hospice Program Affect Quality Care and Program Integrity: An OIG Portfolio</i>	OEI-02-16-00570	7/30/2018
<i>Hospices Should Improve Their Election Statements and Certifications of Terminal Illness</i>	OEI-02-10-00492	9/15/2016
<i>Hospices Inappropriately Billed Medicare Over \$250 Million for General Inpatient Care</i>	OEI-02-10-00491	3/30/2016
<i>Hospice of New York, LLC, Improperly Claimed Medicare Reimbursement for Some Hospice Services</i>	A-02-13-01001	6/26/2015
<i>Medicare Hospices Have Financial Incentives To Provide Care in Assisted Living Facilities</i>	OEI-02-14-00070	1/13/2015
<i>The Community Hospice, Inc., Improperly Claimed Medicare Reimbursement for Some Hospice Services</i>	A-02-11-01016	9/23/2014
<i>Servicios Suplementarios de Salud, Inc., Improperly Claimed Medicare Reimbursement for Some Hospice Services</i>	A-02-11-01017	8/7/2014

APPENDIX C: STATISTICAL SAMPLING METHODOLOGY

SAMPLING FRAME

We obtained Medicare Part A claims data for hospice services that Mission provided during our audit period, representing 6,466 paid claims totaling \$37,329,352. We excluded 316 claims, totaling \$184,888, that had a payment amount of less than \$1,000; 4 claims, totaling \$17,026, that had compromised beneficiary numbers; and 4 claims, totaling \$15,732, 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 6,142 claims totaling \$37,111,706. 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 6,142. 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 Mission 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
6,142	\$37,111,706	100	\$605,507	34	\$225,166

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

Point estimate	\$13,829,680
Lower limit	10,564,396
Upper limit	17,094,964

APPENDIX E: MISSION COMMENTS

Morgan Lewis

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April 9, 2021

BY FEDERAL EXPRESS AND ELECTRONIC MAIL

Lori A. Ahlstrand
Regional Inspector General for Audit Services
U.S. Dep't. of Health & Human Services, Office of Audit Services Region IX
90 – 7th Street, Suite 3-650
San Francisco, CA 94103

Re: Mission Hospice & Home Care, Inc.; Report No. A-09-18-03009

Dear Ms. Ahlstrand:

Mission Hospice & Home Care, Inc. (“Mission”), through its counsel,¹ 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-09-18-03009) dated January 26, 2021 (the “Draft Report”). Mission appreciates OIG allowing an extension through April 12, 2021, to provide comments to the OIG’s Draft Report.

Mission is a local, independent nonprofit organization serving patients and families in the San Mateo and Santa Clara County area with quality, compassionate end-of-life care and education. Since its founding in 1979, Mission has provided thousands of patients and their families with physical, emotional, and spiritual support throughout the journey from a life-limiting diagnosis through death and bereavement. Mission appreciates the critical role that the Medicare program plays in connection with hospice care in the United States. The Medicare hospice benefit has grown from just 23 percent of Medicare decedents utilizing the hospice benefit in 2000, to 44 percent in 2010, and up to 51 percent in 2020, according to MedPAC data. The Medicare hospice benefit is central to providing quality, end-of-life palliative care options for Medicare beneficiaries.

Mission understands that OIG is conducting audits of various hospice programs across the United States, although it remains unclear what clinical review standards the OIG’s independent medical reviewer is using in connection with this and other hospice

¹ Counsel hereby authorizes the release of personally identifiable information included in this letter and requests that OIG not redact such information. **Attachment A.**

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Mission Response to OIG Draft Report

April 9, 2021

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program audits. Mission respectfully disagrees with OIG's determination in its Draft Report for twenty-six (26) of the thirty-three (33) claims for which OIG believed did not meet Medicare requirements related to hospice eligibility. Mission also disagrees with OIG's Draft Report finding related to one (1) claim in which OIG asserted that the clinical record did not support the higher level of care billed. In sum, Mission believes the review findings of OIG's independent medical review contractor ("IMRC") are largely in error as discussed in more detail in this letter response. For those seven (7) claims for which Mission agreed with OIG's findings, Mission made inquiries with its Medicare Administrative Contractor (NGS) to effectuate a refund of these claims consistent with its 60 Day Rule report and refund obligations. NGS instructed Mission not to make those refunds at that time but rather to wait for an overpayment demand. Mission has followed NGS's direction on this.

OIG has not disclosed to Mission as part of its audit process the identity or qualifications of its IMRC or its reviewers, and consequently Mission cannot ascertain or confirm whether the IMRC has adequate or appropriate hospice care review qualifications. Nevertheless, it appears that the IMRC medical reviewers used a rigid, post-hoc approach to determine hospice eligibility under the Medicare benefit and largely ignored the critical role of the hospice physicians' reasonable clinical belief that the beneficiaries were terminally ill at the time they completed the certifications of terminal illness. One of the lynchpins to qualifying for the Medicare hospice benefit is the reasonable 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 good faith clinical belief that the patient's medical condition will likely result in death in six (6) months or less. Importantly, physicians are not required to prognosticate with 100% certainty. As a Federal Court of Appeals found in a 2019 decision that addressed at length the background of the Medicare hospice benefit, the certifying physician's certification of terminal illness ("CTI") must be given great weight. The court also observed 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] than 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.²

² *United States v. AseraCare, Inc.*, 938 F.3d 1278, 1294 (2019).

Further, the court correctly found that the hospice clinical record in “support” of the physicians’ CTI does not have to be a chronicle of every detail of the hospice patient’s clinical condition that “proves” the patient was terminally ill.³

The OIG IMRC reviewers appeared to have applied an overly prescriptive approach as to what the Medicare hospice benefit requires to support a terminal prognosis. OIG’s Draft Report does not conclude medically inappropriate services were furnished; nor does the Draft Report conclude that the Mission hospice physicians failed to certify in good faith that each patient had a terminal prognosis for each hospice benefit period under review. Instead, the Draft Report findings are premised on IMRC reviewers’ conclusions that, for the patients at issue, there was insufficient record support for the contemporaneous clinical decision-making of the hospice physicians who certified the patients as terminally ill during the audit period. To test those conclusions, Mission engaged two highly experienced independent hospice and palliative care physicians (Clevis Parker, M.D. and Lauren Templeton, D.O.) to review the hospice records at issue.⁴ Drs. Parker and Templeton disagree with the significant majority of the OIG IMRC review findings as to whether the hospice records support the determinations by the 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 on this narrow point because 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, especially when one physician reviewer believes the records do not support the patient was terminally ill and when another physician reviewer disagrees. That *AseraCare* opinion spends several pages discussing the Medicare hospice benefit and the legal requirements⁵ as to how the statute must be interpreted. Importantly for purposes of the OIG’s reconsideration of its Draft Report findings and why its IMRC reviewers’ findings were produced based upon a legally flawed review methodology, the Court noted 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.⁶

³ *Id.* at 1293-94.

⁴ Dr. Parker and Dr. Templeton hereby authorize the release of personally identifiable information included in this letter. **Attachment B**.

⁵ *Id.* at 1291-94.

⁶ *Id.* at 1294.

The court went on to observe “[m]ore broadly, CMS’s rulemaking commentary signals that well-founded clinical judgments should be granted deference.”⁷

The court in *AseraCare* had it right. Mission respectfully requests that OIG and its IMRC reconsider the Draft Report medical review findings with this explanation of the Medicare hospice benefit squarely in mind. Embracing the IMRC’s findings when they run counter to the intended purpose of Medicare hospice coverage will not serve to protect the Medicare hospice benefit, but rather will perpetuate a legally faulty hospice documentation review standard. To be clear, this is not to suggest that hospice physician judgments warrant unfettered deference under the Medicare program. Mission believes, to the contrary, those certifying physicians’ clinical judgments must be reasonable. To that very point, and critical to OIG’s consideration of Mission’s 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.⁸

For the reasons offered in the balance of this response letter (which contains no PHI or other identifiable patient information), and in the detailed, claim-by-claim response in the confidential attachment (that contains Mission’s hospice experts’ review findings with protected health information and that Mission presumes will not be publicly posted by OIG), Mission strongly believes, as do its hospice physician experts that the vast majority of the hospice records in the audit sample sufficiently support the Mission certifying physicians’ prognosis of terminal illness.

DETAILED RESPONSE TO OIG DRAFT REPORT A-09-18-03009

Mission disagrees with the Draft Report’s determination on twenty-seven (27) of the thirty-four (34) claims where OIG determined Medicare requirements were not met. Mission’s fundamental disagreement relates to the conclusions of the OIG’s IMRC reviewers that are inaccurate or divergent from the clinical facts present in the hospice record, unsupported by a reasonable clinical review of the record, and stem from an improper lack of credit for the certifying hospice physician’s decision-making on terminal status at the time the certifications were made.

The specific responses to each clinical denial are contained in the attached appendix, labeled as **Attachment C – Mission Expert Response**. In addition, several examples of where the IMRC reviewers arrived at incorrect clinical conclusions are set forth below.

⁷ *Id.* at 1295.

⁸ *Id.*

I. INTRODUCTION: OVERVIEW OF MISSION AND HOSPICE CARE

Mission Hospice is a not-for-profit hospice located in San Mateo, California that has supported its community with high quality hospice services for over 40 years, before the Medicare hospice benefit was established. Mission serves approximately than 160 patients each day in San Mateo and Santa Clara counties. As an established and leading provider of hospice care, Mission is acutely aware that its program operates in a highly regulated environment and acts as a steward of Medicare and other valuable healthcare program funds. Mission has, since its inception, believed that hospice care can provide beneficiaries who elect the benefit with the best care for patients living with terminal illness in a home or home-like setting, consistent with the patient's desires for end-of-life care and at a considerable savings over expensive, acute care settings like hospitals. While high quality end-of-life care is its highest priority, Mission also has demonstrated a keen focus on appropriately documenting those services.

Mission offers a continuum of hospice and palliative care services, including general inpatient care, respite care, spiritual care, physical and occupational therapy, dietary counseling, grief counseling, and hospice aides among other services. Mission employs or contracts with a team of experienced hospice physicians and nurse practitioners, in addition to a full contingent of nursing staff, aides, social workers, chaplains, and volunteers. In addition to its home- and facility-based services, Mission operates the Mission House, a six-bed hospice house specifically designed for inpatient hospice care that is staffed 24 hours a day with daily physician care and staff that specialize in end-of-life care. Mission also offers programs to enhance end of life care and provide education and support to caregivers, such as the Family Caregiver Alliance, a program developed to support caregivers with important information on caring for a terminally ill loved one.

Hospice care is a comprehensive suite of services identified and coordinated by a patient's attending physician (if the patient has one), a 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, Mission is certified to provide hospice care by CMS, accredited by the Joint Commission, and meets the required Medicare 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 illness 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 (again, if the patient has so designated an attending). For each subsequent certification period the medical director (or a physician member of the IDG) may certify a patient's terminal status. Each certification of terminal illness must be supported by the patient's condition as reflected in the hospice's medical records.

To satisfy these requirements, Mission has implemented a comprehensive set of procedures for determining clinical eligibility for hospice and effectuating admissions. For example, Mission 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) physical assessment by a registered nurse, and 4) the consent by the patient that they are terminally ill and elect hospice/palliative care rather than curative care for the terminal condition.

II. SUMMARY OF DRAFT REPORT FINDINGS

As part of its audit, OIG selected 100 Medicare claims submitted by Mission between October 1, 2015 and September 30, 2017. During this time, Mission submitted 6,466 Medicare claims for reimbursement for hospice care provided to approximately 1,500 Medicare beneficiaries, for which Mission received an approximate total of \$37 million in Medicare payments. From these 100 random claims, the IMRC determined thirty four (34) did not comply with one or more Medicare requirements. OIG then attached Medicare payment implications to those IMRC findings and extrapolated the financial results of this sample to the complete universe of Medicare paid claims during the audit period and estimated that Mission received \$10.5 million in Medicare overpayments. Given that Mission, like most hospices, serves mostly Medicare beneficiaries, the effect of extrapolation of a 100 claim sample in these OIG audits has a disproportionate and punitive effect on the hospice, particularly when, as discussed below, the hospice has already made repayments for cap liability covering the same period as the extrapolation.

OIG identified two (2) primary bases for denial among Mission's claims:

- 1) The medical record associated with the claim did not support terminal illness (thirty three (33) claims); and
- 2) The medical record associated with the claim did not support the need for a higher level of care (one (1) claim).

Additionally, OIG asserts that for two (2) claims, there was no evidence that the beneficiary elected hospice care, and for two (2) claims, there was insufficient support of physician services billed to Medicare. The Draft Report asserts that while Mission had policies and procedures related to determining eligibility, they were not effective to ensure that the Medicare requirements were met and that the appropriate level of care was provided.

To remedy these issues, the Draft Report makes several recommendations, namely that Mission should: (1) return overpayments received within the four (4)-year claims reopening period; (2) 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 (3) strengthen its procedures to ensure that Mission’s hospice services comply with Medicare requirements. Mission addresses each of these findings and recommendations below.

III. ANALYSIS OF DRAFT REPORT

Mission and its external advisors have reviewed the Draft Report and in those efforts, engaged Dr. Parker and Dr. Templeton, two highly experienced and skilled hospice physicians, to conduct a comprehensive review of the records OIG’s IMRC determined did not meet Medicare eligibility and level of care requirements. Mission also evaluated its own policies and procedures related to the issues identified by OIG.

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

- Inconsistencies in Analysis and Approach of the IMRC Reviewers;
- Mission’s Hospice Expert Review Methodology;
- Mission’s Hospice Expert Review Findings;
- OIG’s Review as a Basis for Credible Information of an Overpayment;
- Mission’s Ongoing Compliance Program and Training; and
- Use of Extrapolation and OIG’s Statistical Sampling Methodology.

1. INCONSISTENCIES AMONG THE OIG’S IMRC REVIEWERS

Upon request, OIG furnished Mission with its IMRC’s clinical summaries setting forth the determinations made by one or more IMRC physicians, as well as coders in certain instances, of the one hundred (100) claims reviewed where OIG determined 34 of those 100 resulted in Mission being overpaid. Mission was not provided with the OIG’s IMRC physicians’ curricula vitae or other biographical information. Mission cannot, therefore, ascertain the IMRC physicians’ qualifications, board certifications (if any) or perspective and experience with hospice and palliative medicine. The review conducted by Dr. Parker and Dr. Templeton found that the IMRC reviewers applied an inconsistent approach to determine clinical eligibility for hospice services and need for higher levels of care consistent

with the legal requirements of the Medicare hospice benefit.⁹ As discussed in more detail below, the reviewers appeared in most instances to appropriately summarize the salient facts and medical conditions reflected in each sampled record, but did not synthesize these facts or the patients' co-morbidities and other clinical conditions into appropriate clinical conclusions. Accordingly, Mission appreciates the opportunity to have the OIG and its IMRC consider the findings of Mission's hospice clinical review expert attached hereto. Dr. Parker's and Dr. Templeton's opinions evidence a well-founded, "whole patient" approach to determining clinical eligibility, and Mission asks that OIG apply these findings when crafting its final report.

2. MISSION HOSPICE EXPERT'S REVIEW METHODOLOGY

As noted, Dr. Parker and Dr. Templeton have substantial clinical experience in hospice and palliative care medicine and an expert level understanding of the clinical indicators of eligibility for the Medicare hospice benefit. In addition to their work practicing as hospice medical directors at large hospice organizations, Mission's physician experts frequently assist other hospice organizations in understanding terminal disease progression, hospice eligibility issues, and related hospice documentation through their work as consultants with a nationally recognized hospice consulting firm. Dr. Parker and Dr. Templeton have significant hospice-specific experience in community hospice, including those with inpatient units for general inpatient and respite care. These physicians regularly review hospice medical records and compare the contents of those records to applicable local coverage determinations ("LCDs") and other established hospice documentation guidelines. Dr. Parker's and Dr. Templeton's CVs are attached as **Attachment D**.

Mission provided its hospice physician experts with access to the identical set of records submitted to OIG as part of this OIG audit. These physicians then conducted an independent clinical review of each patient's medical record for whom the IMRC reviewers asserted that the beneficiary was ineligible for hospice care or, as applicable, ineligible for a higher level of care. Dr. Parker and Dr. Templeton determined whether the certification or recertification related to each claim at issue was reasonably supported by the documented clinical indicators.

3. MISSION HOSPICE EXPERT REVIEW FINDINGS

Dr. Parker and Dr. Templeton found record support for hospice eligibility and the higher level of care (as applicable) in twenty-seven (27) of the thirty-four (34) instances the IMRC asserted a lack of hospice eligibility or support for a higher level of care.

Dr. Parker and Dr. Templeton's review indicated that for those patients who only partially met the applicable LCD guidelines, they each nevertheless exhibited a terminal prognosis that qualified them for the Medicare hospice benefit. LCDs in the hospice context

⁹ See discussion *supra* at pp. 2-3.

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are merely guidelines; patients can be (and often are) terminally ill without fully meeting corresponding hospice LCD elements. The NGS hospice LCD specifically notes that “[s]ome 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.” See NGS LCD L33393. Dr. Parker also found that, for one patient where OIG’s IMRC asserted a level of care concern, the level of care provided by Mission was reasonable and necessary given the patient’s clinical condition and need at that time.

Dr. Parker and Dr. Templeton reviewed the thirty-three (33) claims at issue with respect to eligibility and determined that for twenty-six (26) of them, they could identify sufficient documentation that would support a reasonable certifying physician’s prognostication that the individual was terminally ill. Each of the clinical details related to these patients appear in **Attachment C**, but several illustrative examples of where the IMRC’s review was deficient are summarized below.

- Patient 16 – Dates of Service: March 2017. Seventy nine (79) year old female patient admitted to hospice in February 2017 with advanced nonverbal dementia as well as a recent hospitalization for urosepsis. She was essentially unresponsive, sleeping most of the time, and eating only bites of meals. She had a FAST 7A and required assistance with all activities of daily living (ADLs). Although the IMRC reviewer asserted that the patient did not have documented septicemia within the past 12 months, she was admitted to a hospital for urosepsis (caused by a bacterial infection) immediately prior to her hospice admission. Additionally, as is thematic in the IMRC’s review, the IMRC reviewer applied the ADEPT tool to assert that the patient did not have a 6-month mortality. However, the ADEPT tool is only applicable to dementia patients who reside in a long-term care facility, such as a nursing home. It is not intended for use with patients who live at home with full-time caregivers. Nevertheless, the IMRC reviewer used it as the primary justification to assert that the patient was not hospice eligible. The IMRC further asserted that the patient had improved functional status and that her functional decline was only caused by an acute illness. Notably, the IMRC acknowledges that the patient “appeared to have a prognosis of six months or less” upon admission but asserts that, less than a month into the patient’s first benefit period, Mission should have discharged the patient from care because she was no longer hospice eligible. Still, the IMRC reviewer concedes that the patient continued only “to eat a few bites” of food and that the patient’s appetite was decreased/poor. The IMRC’s conclusion is flawed and does not realistically reflect the status of this patient or her eligibility for hospice care under the Medicare benefit.
- Patient 46 - Dates of Service: January 2016. Eighty eight (88) year old female patient admitted to hospice in February 2015 with Alzheimer’s dementia, decreased function, and multiple falls. In a narrative statement from December 2015, the certifying physician indicated that the patient was much slower to process direction

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during the last face-to-face visit than during the one occurring in September 2015. At that time, she could no longer bear weight or pivot, where previously she had been able to ambulate several steps with a caregiver's assistance. She also exhibited a 0.5 cm decrease in her mid-arm circumference and exhibited facial wasting. During the period at issue, the IMRC acknowledges that the patient had a FAST score of 7C, indicating advanced illness. Despite this, the IMRC reviewer asserted that because the patient did not have congestive heart failure or shortness of breath and was not bedfast, she was not terminally ill. Once again, the IMRC misapplied the ADEPT tool to a patient who did not reside in a long-term care facility, where the patient population and the type of care received is very different from that of home-based patients. The IMRC cited irrelevant medical characteristics about the patient to call her eligibility into question, but does not meaningfully acknowledge the advanced and progressive dementia that this patient suffered from. Consequently, the IMRC's review cannot be used in this case to deny the hospice care provided to this patient.

- Patient 72 – Dates of Service: January 2017. Eighty eight (88) year old male admitted to hospice care in October 2016 with Parkinson's disease, dysphagia, and a decubitus ulcer. The patient began to exhibit decreased mobility and rigidity and requires total care for ADLs. In addition, the patient had an admission to the hospital due to choking on food and was now on a pureed diet. The patient's significant dysphagia is the precursor to aspiration pneumonia.

During the period under review, the hospice physician recertified the patient for hospice services, finding that he remained bed/chair bound and continued to have some dysphagia and decreased oral intake. Notably, the patient had a decline of 3 cm in his mid-arm circumference from the prior certification period, indicating continuing decline. This is particularly important because the patient was advanced to regular foods during this period, which indicates that the weight loss was not due to his inability to swallow. The patient slept 12-14 hours per day and continued to require around-the-clock care. During this time, the patient experienced tremors in all extremities.

The IMRC asserted that this patient was not eligible for hospice care because his "speech was clear" and he was "able to make needs known," the loss of weight did not equate to an inability to maintain sufficient fluid and calorie intake, there were no increasing visits to the ER, inpatient admissions, or physician visits, and the patient had no infections or cough. These criteria are, similar to other reviews, largely irrelevant to whether this Parkinson's patient was terminally ill. The IMRC acknowledges that "[t]here are no specific criteria for Parkinsonism" but nevertheless ascribes particular importance to certain clinical indications and less importance to others. Clinical findings like no cough or having the ability to make needs known do not portend a patient who is only chronically ill when that patient is losing weight despite caloric intake, is bed/chair bound, requires assistance with all ADLs, and sleeps the majority of the day. Moreover, the very point of hospice care is to avoid

additional hospitalizations and is undertaken *in lieu of* physician visits. Therefore, the assertions of the IMRC with respect to this patient do not pass muster, particularly where the review period is in the first six months of the patient's hospice election.

The IMRC's faulty clinical review approach in the OIG audit sample has significant consequences for a community-based, not-for-profit hospice. Because of the use of its extrapolation methodology, each error by the IMRC reviewer creates a disproportionate effect on the overpayment estimate. The OIG has estimated significant liability for Mission that in many instances resulted from the IMRC reviewers' overly restrictive view of the Medicare hospice benefit and misapplication of relevant guidelines. The OIG should ensure its IMRC appropriately reconsiders its review findings, ensuring it applies the legally required view of the Medicare hospice benefit.

4. OIG'S REVIEW AND CREDIBLE INFORMATION OF AN OVERPAYMENT

Mission 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 its identification and calculation of a Medicare overpayment. As further expanded by CMS in its 2016 rulemaking preamble to its regulation at 42 C.F.R. § 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 OIG review and its preliminary results have prompted Mission to do just that, and it has undertaken a careful review of its technical documentation and its policies and procedures, as well as a detailed and independent clinical review by an outside hospice consulting firm. For the reasons noted above, Mission fundamentally disagrees with the majority of the OIG's IMRC physicians, and finds its own experts' findings (and the contemporaneous and reasonable clinical decisions of its certifying hospice physicians) compelling. Furthermore, Mission notes that its financial error rate associated with the audited claims, as determined by its outside expert hospice physicians who collectively have decades of hospice experience, is only approximately 7%. This percentage is well below the 15% threshold used by various Medicare contractors, including the hospice Medicare Administrative Contractors, to assess whether additional auditing is necessary in the context of targeted probe and educate reviews.

5. MISSION'S ONGOING COMPLIANCE AND TRAINING

Mission's internal review did not uncover a systemic compliance concern with either clinical or technical documentation requirements that would necessitate a material compliance program enhancement. In addition, Mission has significantly enhanced its compliance program since the period under review in OIG's audit (2015 to 2017). This has

included the addition of new compliance resources, including a full time, dedicated compliance officer, enhanced clinical and technical documentation auditing, and significant education and training on hospice documentation.

Notably the Program for Evaluating Payment Patterns Electronic Report (“PEPPER”) data distributed by a CMS contractor for the period under review demonstrates a hospice program that compares favorably to other hospice programs and meets and exceeds Medicare expectations for hospice care. In all PEPPER metrics, including live discharges, long length of stay, single diagnoses, long GIP stays, and top terminal diagnoses, Mission’s PEPPER data reveals no outlier concerns for which CMS recommends internal monitoring. Mission had a live discharge rate between 11.2% and 12.1% during the years under review, approximately half of the state 80th percentile (the threshold for concern on PEPPER data), which hovered between 22.4% and 23.5%. Similarly, Mission’s long length of stay population was at 17.1% and 16.6% during the two years of the OIG’s review period, compared to a jurisdictional 80th percentile of 23.4% and 25.4% and a state 80th percentile of 28.2% and 31.8%. Mission’s percentage of cancer patients was 35%, and represented Mission’s most common principal diagnosis. This percentage is greater than the jurisdictional cancer percentage of 31.4% for 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 Mission conducted, do not provide indicia that Mission’s compliance controls were ineffective.

6. EXTRAPOLATION

OIG used its standard provider audit methodology to extrapolate the results of a 100 claim sample review to the universe of all of the Medicare claims submitted by Mission within the time period under review. This extrapolation has a significant impact on the financial estimates of the audit (for every \$1 audited and denied in the sample, OIG is estimating an overpayment of \$47). Accordingly, Mission closely reviewed OIG’s sampling methodology and execution of this extrapolation. Although OIG engages in a standardized sampling plan for its provider compliance audits, Mission observes that here the representativeness of OIG’s sample and reliability of the overall estimate is questionable.

Mission remains concerned that there was inconsistency in the universe and sample that was ultimately used in the extrapolation, as well as significant incidents of non-sampling (human) error introduced. For instance, the decision to exclude claims that had a payment amount of less than \$1,000 inappropriately skews the representativeness of the sample. In many cases, patients may be admitted to hospice and pass away within the first several days of their care. These patients are not represented in OIG’s sample and, therefore, the audit findings are inherently misleading. Moreover, given the heterogeneity of the Mission universe, the use of a 100 claim sample was simply too small. Mission asserts that OIG’s sample and resulting extrapolation were not statistically valid.

Not only does Mission have serious concerns about the underlying validity and representativeness of OIG's sample, OIG should also forgo extrapolation for two additional 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, the IMRC's financial error rate was below 50% – approximately 37% of the total audited dollars in the sample. Once OIG corrects the significant misunderstanding the IMRC's reviewers had regarding hospice care, the remaining error rate will be approximately 7%, well below the 50% threshold CMS now looks to as a standard for whether contractors should engage in extrapolation of their Medicare audit results. While Mission recognizes OIG is not a CMS contractor, and accordingly OIG maintains it is not bound by CMS instructions related to statistical sampling, a consistent approach across Medicare audits is appropriate, especially when the use of extrapolation has, as is the case here, a punitive effect on a provider.

Second, Mission was not subject to Medicare audits prior to the OIG audit that had identified meaningful payment errors. The underlying Medicare statute only permits extrapolation in instances of a "high or sustained" level of payment error, neither of which are the case in this review. Thus, extrapolation is not appropriate.

Separately, OIG's extrapolation is *ab initio* defective because it failed to account for Medicare repayments related to the OIG audit time period that were already made by Mission as a result of its "hospice aggregate cap." In addition to basic billing and coding requirements, hospices participating in the Medicare program are subject to additional Medicare payment limitations. Specifically, total Medicare payment to a hospice during a "cap year" is limited by the "hospice cap," which is calculated by multiplying the total number of patients cared for by the hospice during the "cap year" by the cap amount. During the time period at issue, the annual aggregate cap amount increased from \$27,382.63 to \$28,404.99. Note that, unlike Medicare's hospice per diem payments, the aggregate cap amount is not wage-adjusted, so hospices in higher wage areas like Mission (in California's Bay Area) are disproportionately impacted by the hospice aggregate cap.

Mission made hospice aggregate cap repayments throughout the period under OIG audit. For services provided in 2015/2016 (cap years cross multiple calendar years), Mission repaid Medicare \$2,406,049 as a result of the hospice cap calculation. For services in 2016/2017, Mission repaid \$1,314,536 for its Medicare hospice cap liability. Thus, for the two years subject to OIG's audit, Mission already repaid nearly \$4 million to Medicare. Fundamentally, as Congress intended, the Medicare hospice aggregate cap has already regulated and addressed Mission's longer length of stay Medicare beneficiary payments.

From a statistical extrapolation standpoint, OIG's extrapolated estimate appears to fail to take into account the financial impact of Mission's hospice cap repayment for the years under audit. Mission requests that OIG consider the impact of the Medicare hospice aggregate cap on Mission's total Medicare payments during the audit period at issue. If OIG is not willing to withdraw its extrapolation for the reasons discussed above, OIG must

employ an extrapolation calculation that accounts for Mission's aggregate cap repayment amounts.

IV. RESPONSE TO RECOMMENDATIONS

In its Draft Report, OIG set forth three recommendations. Mission concurs in part with two of the recommendations and disagrees with one recommendation. Mission's specific concurrence or nonconcurrence is set out below.

- *Mission should refund to the Federal Government the portion of the estimated \$10,564,396 for hospice services that did not comply with Medicare requirements and that are within the 4-year claims reopening period.*

Mission disagrees with this recommendation insofar as it does not believe it was overpaid this amount for hospice services that are within the four-year claims reopening period. Mission disagrees with OIG's IMRC in most instances where that contractor determined that patients were not eligible for hospice services. Mission concurs regarding certain claims as outlined herein, but, per the instruction of NGS, is awaiting instruction on effectuating refunds of those claims.

- *Mission should exercise reasonable diligence to identify, report and return any overpayments in accordance with the 60-day, and identify any of those returned overpayments as having been made in accordance with this recommendation.*

Mission concurs with this recommendation only insofar as exercising reasonable diligence to identify and return improper payments upon having credible evidence of a potential Medicare overpayment is a statutory and regulatory obligation. Mission has already attempted to effectuate repayments for any Medicare payments that, in Mission's determination, were determined to be overpayments (although was instructed by NGS to delay such repayment). Mission did not identify any systemic hospice service billing issues that would compel Mission to conduct additional reviews at this time.

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

Mission recognizes that compliance and process improvement often move strong organizations to "strengthen" its procedures, but it believes its currently existing procedures are sufficiently strong to ensure that hospice services reasonably comply with Medicare requirements. As Mission's physician expert review demonstrated, the hospice service claims reviewed by OIG largely complied with Medicare requirements. Mission's compliance policies and procedures have evolved over time and appropriate both with regard to the initial admission process and recertifications. Mission reviews and updates its policies and procedures from time to time to ensure compliance with regulatory requirements and

appropriate clinical standards. Mission has a dedicated team of hospice and compliance professionals to develop, implement, and train staff on its compliance and clinical operations.

V. CONCLUSION

Mission appreciates the opportunity to provide comments to the OIG for its consideration and inclusion in OIG's final audit report. Mission respectfully requests that OIG consider the information contained in both this response and its corresponding appendices and modify its Final Report findings accordingly.

Sincerely,

/Howard Young/

Howard J. Young
Counsel for Mission Hospice & Home Care, Inc.

Enclosures