Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

MEDICARE HOSPICE PROVIDER COMPLIANCE AUDIT: FRANCISCAN HOSPICE

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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: May 2021
Report No. A-09-20-03034

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 Franciscan Hospice (Franciscan) complied with Medicare requirements.

How OIG Did This Audit

Our audit covered 21,537 claims for which Franciscan (located in University Place, Washington) received Medicare reimbursement of $101.5 million for hospice services provided from January 1, 2016, through December 31, 2017. We reviewed a random sample of 100 claims. We evaluated compliance with selected Medicare billing requirements and submitted these sampled claims and the associated medical records to an independent medical review contractor to determine whether the services met coverage, medical necessity, and coding requirements.

Medicare Hospice Provider Compliance Audit: Franciscan Hospice

What OIG Found

Franciscan received Medicare reimbursement for hospice services that did not comply with Medicare requirements. Of the 100 hospice claims in our sample, 79 claims complied with Medicare requirements. However, the remaining 21 claims did not comply with the requirements. Specifically, for 19 claims, the clinical record did not support the beneficiary's terminal prognosis, and for the remaining 2 claims, there was no documentation to support the hospice services that Franciscan billed to Medicare.

Improper payment of these claims occurred because Franciscan's policies and procedures were not effective in ensuring that the clinical documentation it maintained supported the terminal illness prognosis and the hospice services billed to Medicare. On the basis of our sample results, we estimated that Franciscan received at least $13 million in unallowable Medicare reimbursement for hospice services.

What OIG Recommends and Franciscan Comments

We recommend that Franciscan: (1) refund to the Federal Government the portion of the estimated $13 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 identify any of those returned overpayments as having been made in accordance with this recommendation; and (3) strengthen its policies and procedures to ensure that hospice services comply with Medicare requirements.

In written comments on our draft report, Franciscan disagreed with our findings for 12 of the 19 sampled claims for which the clinical record did not support the beneficiary's terminal prognosis and said that a physician's clinical judgment is fundamental in determining that prognosis. Franciscan also disagreed with our use of extrapolation across the audit period. Franciscan agreed with our second recommendation and disagreed with our first and third recommendations.

After reviewing Franciscan's comments, we maintain that our findings and recommendations are valid. Federal regulations require that clinical information and other documentation support the beneficiary's terminal prognosis and be filed in the medical records. The report contains the details of our response.

The full report can be found at https://oig.hhs.gov/oas/reports/region9/92003034.asp.

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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 Franciscan Hospice (Franciscan) 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 care,

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[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. 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 group[9] 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 (January 1, 2016, through December 31, 2017), the text of 42 CFR § 418.24(d) was moved to 42 CFR § 418.24(e), effective October 1, 2019. 84 Fed. Reg. 38484, 38544 (Aug. 6, 2019).

[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]

Franciscan Hospice

Franciscan, located in University Place, Washington, is a nonprofit provider that furnishes hospice and palliative care, including nursing and medical care, physical therapy, in-home medical equipment, bereavement counseling, massage, aromatherapy, and music therapy. From January 1, 2016, through December 31, 2017 (audit period), Franciscan provided hospice services to approximately 6,100 beneficiaries and received Medicare reimbursement of about $103 million.[19] National Government Services, Inc. (NGS), serves as the MAC for Franciscan.

HOW WE CONDUCTED THIS AUDIT

Franciscan received Medicare Part A reimbursement of $102,634,214 for hospice services provided during our audit period, representing 23,459 paid claims. After we excluded 1,922 claims, totaling $1,147,394, our audit covered 21,537 claims totaling $101,486,820.[20] We reviewed a random sample of 100 of these claims, totaling $468,212, to determine whether hospice services complied with Medicare requirements. Specifically, we evaluated compliance with selected billing requirements and submitted these sampled claims and the associated medical records to an independent medical review contractor to determine whether the services met coverage, medical necessity, and coding requirements.

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

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

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[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 January 1, 2016, through December 31, 2017, were the most current data available when we started our audit.

[20] We excluded hospice claims that had a payment amount of less than $1,000 (1,888 claims), were identified in the Recovery Audit Contractor data warehouse as having been reviewed by another party (17 claims), or had compromised beneficiary numbers (17 claims).

FINDINGS

Franciscan received Medicare reimbursement for hospice services that did not comply with Medicare requirements. Of the 100 hospice claims in our sample, 79 claims complied with Medicare requirements. However, the remaining 21 claims did not comply with the requirements. Specifically, for 19 claims, the clinical record did not support the beneficiary's terminal prognosis, and for the remaining 2 claims, there was no documentation to support the hospice services that Franciscan billed to Medicare. Improper payment of these claims occurred because Franciscan's policies and procedures were not effective in ensuring that the clinical documentation it maintained supported the terminal illness prognosis and the hospice services billed to Medicare.

On the basis of our sample results, we estimated that Franciscan received at least $13 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, Franciscan can request that a Medicare contractor reopen the initial determinations for those claims for the purpose of reporting and returning overpayments under the 60-day rule without being limited by the 4-year reopening period.[23]

TERMINAL PROGNOSIS NOT SUPPORTED

To be eligible for the Medicare hospice benefit, a beneficiary must be certified as being terminally ill. Beneficiaries are entitled to receive hospice care for two 90-day benefit periods, followed by an unlimited number of 60-day benefit periods. At the start of the initial 90-day benefit period of care, the hospice must obtain written certification of the beneficiary's terminal illness from the hospice medical director or the physician member of the hospice interdisciplinary group and the individual's attending physician, if any. For subsequent benefit periods, a written certification from the hospice medical director or the physician member of the hospice interdisciplinary group is required. Clinical information and other documentation that support the beneficiary's medical prognosis must accompany the physician's certification and be filed in the medical record with the written certification of terminal illness.[24]

For 19 of the 100 sampled claims, the clinical record provided by Franciscan did not support the associated beneficiary's terminal prognosis. Specifically, the independent medical review

[21] The statistical lower limit is $13,027,841. To be conservative, we recommend recovery of overpayments at the lower limit of a two-sided 90-percent confidence interval. Lower limits calculated in this manner are designed to be less than the actual overpayment total at least 95 percent of the time.

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

[23] 42 CFR § 405.980(c)(4).

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

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

SERVICES NOT DOCUMENTED

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)).

For 2 of the 100 sampled claims, there was no documentation to support the hospice services billed to Medicare:

- For one sampled claim, Franciscan claimed and received Medicare reimbursement for a physician service that was not documented in the associated beneficiary's clinical record.[25]

- For one sampled claim, Franciscan claimed and received Medicare reimbursement for an emergency department service that was not documented in the associated beneficiary's clinical record.

RECOMMENDATIONS

We recommend that Franciscan Hospice:

- refund to the Federal Government the portion of the estimated $13,027,841 for hospice services that did not comply with Medicare requirements and that are within the 4-year reopening period;[26]

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[25] 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)).

[26] 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 rule[27] 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.

FRANCISCAN COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, Franciscan stated that it respectfully disagreed with more than half of our findings and also disagreed with our use of extrapolation across the audit period. Specifically, Franciscan disagreed with our findings for 12 of the 19 sampled claims for which the clinical record did not support the beneficiary's terminal prognosis and provided specific responses for 5 of the 12 claims. (Franciscan did not comment on the two sampled claims for which no documentation was provided to support the hospice services billed to Medicare.) In addition, Franciscan agreed with our second recommendation and disagreed with our first and third recommendations. However, Franciscan stated that it would "refund the sample claims it does not challenge."

In its specific comments on our findings, Franciscan stated that a physician's clinical judgment is fundamental in determining (or certifying) the terminal prognosis and involves assessing the beneficiary's full clinical picture. Franciscan also stated that our independent medical review contractor incorrectly utilized the Local Coverage Determinations (LCDs) as a checklist for hospice eligibility. Finally, Franciscan stated that extrapolation is inappropriate absent a "sustained or high level of payment error (meaning 50 percent or more)." Franciscan's comments are included in their entirety as Appendix E.

After reviewing Franciscan's comments, we maintain that our findings and recommendations are valid. Federal regulations require that clinical information and other documentation support the beneficiary's terminal prognosis and be filed in the medical records. Below is a summary of Franciscan's comments and our responses.

TERMINAL PROGNOSIS NOT SUPPORTED

Franciscan Comments

Franciscan disagreed with our findings for 12 of the 19 sampled claims that had a lack of support for a terminal prognosis. For each of these 12 claims, Franciscan's third-party auditor

[27] 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.

found that the patient's medical record supported the certifying physician's clinical judgment that the patient met hospice criteria with a life expectancy of 6 months or less.

Franciscan emphasized the importance of a physician's clinical judgment in determining a patient to be terminally ill, thereby qualifying the patient for the Medicare hospice benefit. Franciscan stated that a beneficiary is eligible for this benefit if the appropriate physician makes a clinical judgment that the patient is terminally ill in light of the patient's complete medical picture, as evidenced by the patient's medical records. Furthermore, Franciscan cited a Federal court decision that noted: "[N]one of the relevant [statutory or regulatory] language states that the documentary record underpinning a physician's clinical judgement must prove the prognosis as a matter of medical fact." Lastly, Franciscan stated that the court decision 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."

Franciscan stated that our independent medical review contractor incorrectly utilized the LCDs as a checklist for hospice eligibility instead of considering patients' unique combination of illnesses. Franciscan also stated that given that LCDs are guidelines and not binding, they should not be considered the exact criteria used for determining terminal illness.

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. Our contractor properly used the appropriate statutory and regulatory hospice criteria, as well as applicable 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.[28] Our contractor acknowledged the physician's terminal diagnosis and evaluated the medical records for each hospice claim (including necessary historical clinical records), guided by questions rooted in the Medicare requirements, to determine whether the certified terminal prognosis was supported. The Federal court decision that Franciscan 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. However, our 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 the sampled 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.

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

USE OF EXTRAPOLATION

Franciscan Comments

Franciscan stated that our findings reflect a financial error rate of 20 percent, which drops by more than half after correcting for inaccuracies identified by Franciscan's third-party auditor. Franciscan stated that, under CMS's standards, medical reviewers are directed to extrapolate only in the event of a "sustained or high-level payment error, meaning 50 percent or more" (*Medicare Program Integrity Manual* (MPIM), chapter 8, § 8.4.1.4). Franciscan stated that while these standards apply directly to Medicare review contractors (e.g., MACs and Recovery Audit Contractors), the standards should not be ignored in the context of an OIG audit recommending extrapolation. Franciscan also stated that because Medicare overpayments are at issue in this audit, the MAC that processes and demands any applicable overpayments at OIG's recommendation is subject to Federal law limiting the use of extrapolation to recover overpayments.

Franciscan requested that, at a minimum, we remove any recommendations related to extrapolation until the MAC has made a determination regarding repayment and Franciscan has had the opportunity to challenge that determination through the appeal process.

Office of Inspector General Response

The MPIM requirement cited by Franciscan (that a determination of a sustained or high level of payment error must be made before extrapolation) applies only to Medicare contractors, not OIG.[29] In addition, the statutory provisions upon which the MPIM guidelines are based do not prohibit CMS from accepting and acting upon our monetary recommendation.

Removing our recommendation related to extrapolation until the MAC has made a determination, as Franciscan requested, is not necessary. As stated in the footnote of our first recommendation, a 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.

RECOMMENDATIONS

Franciscan Comments

Franciscan had the following comments on our recommendations:

- Franciscan stated that given the foregoing, it disagreed with our first recommendation as written. However, Franciscan stated that it will refund the sampled claims it does not challenge.

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

- Franciscan stated that it agreed with our second recommendation in that exercising reasonable diligence to identify, report, and return overpayments in the audited sample is required by Federal law and regulations. Franciscan also stated that it will refund certain sampled claims and will evaluate and address any additional overpayments in accordance with the 60-day rule.

- Franciscan stated that in general, it disagreed with our third recommendation to the extent it suggests that Franciscan's policies and procedures did not ensure hospice services complied with Medicare requirements. Franciscan also stated that it reviews and, as appropriate, revises its policies and procedures as part of its compliance program; educates its employees on Medicare requirements and company policies; and re-educates appropriate personnel to ensure understanding of Medicare coverage standards.

Office of Inspector General Response

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

We maintain that the improper payments occurred because Franciscan's policies and procedures were not effective in ensuring that the clinical documentation it maintained supported the terminal illness prognosis and the hospice services billed to Medicare.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

Our audit covered 21,537 hospice claims for which Franciscan received Medicare reimbursement totaling $101,486,820 for services provided from January 1, 2016, through December 31, 2017 (audit period). These claims were extracted from CMS's National Claims History (NCH) file.

We did not assess Franciscan'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 Franciscan's office in University Place, Washington.

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 Franciscan officials to gain an understanding of Franciscan'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 23,459 hospice claims, totaling $102,634,214,[30] for the audit period;
- excluded 1,888 claims, totaling $953,338, that had a payment amount of less than $1,000; 17 claims, totaling $126,596, that were identified in the Recovery Audit Contractor data warehouse as having been reviewed by another party; and 17 claims, totaling $67,460, that had compromised beneficiary numbers;
- created a sampling frame consisting of 21,537 hospice claims, totaling $101,486,820;
- selected a simple random sample of 100 hospice claims from the sampling frame;

[30] 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 Franciscan for hospice services; and

- discussed the results of our audit with Franciscan 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
Medicare Hospice Provider Compliance Audit: Alive Hospice, Inc.	A-09-18-03016	5/14/2021
Medicare Hospice Provider Compliance Audit: Ambercare Hospice, Inc.	A-09-18-03017	5/14/2021
Medicare Hospice Provider Compliance Audit: Suncoast Hospice	A-02-18-01001	5/7/2021
Medicare Hospice Provider Compliance Audit: Tidewell Hospice, Inc.	A-02-18-01024	2/22/2021
Medicare Hospice Provider Compliance Audit: Hospice Compassus, Inc., of Tullahoma, Tennessee	A-02-16-01024	12/16/2020
Medicare Hospice Provider Compliance Audit: Hospice Compassus, Inc., of Payson, Arizona	A-02-16-01023	11/19/2020
Safeguards Must Be Strengthened To Protect Medicare Hospice Beneficiaries From Harm	OEI-02-17-00021	7/3/2019
Hospice Deficiencies Pose Risks to Medicare Beneficiaries	OEI-02-17-00020	7/3/2019
Vulnerabilities in the Medicare Hospice Program Affect Quality Care and Program Integrity: An OIG Portfolio	OEI-02-16-00570	7/30/2018
Hospices Should Improve Their Election Statements and Certifications of Terminal Illness	OEI-02-10-00492	9/15/2016
Hospices Inappropriately Billed Medicare Over $250 Million for General Inpatient Care	OEI-02-10-00491	3/30/2016
Hospice of New York, LLC, Improperly Claimed Medicare Reimbursement for Some Hospice Services	A-02-13-01001	6/26/2015
Medicare Hospices Have Financial Incentives To Provide Care in Assisted Living Facilities	OEI-02-14-00070	1/13/2015
The Community Hospice, Inc., Improperly Claimed Medicare Reimbursement for Some Hospice Services	A-02-11-01016	9/23/2014
Servicios Suplementarios de Salud, Inc., Improperly Claimed Medicare Reimbursement for Some Hospice Services	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 Franciscan provided during our audit period, representing 23,459 paid claims totaling $102,634,214. We excluded 1,888 claims, totaling $953,338, that had a payment amount of less than $1,000; 17 claims, totaling $126,596, that were identified in the Recovery Audit Contractor data warehouse as having been reviewed by another party; and 17 claims, totaling $67,460, that had compromised beneficiary numbers. As a result, the sampling frame consisted of 21,537 claims totaling $101,486,820. 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, Office of Audit Services (OAS), statistical software.

METHOD OF SELECTING SAMPLE ITEMS

We sorted the sampling frame by the FI_DOC_CLM_CNTL_NUM (a claim identification number) field, and we consecutively numbered the hospice claims in our sampling frame from 1 to 21,537. 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 Franciscan 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
21,537	$101,486,820	100	$468,212	21	$93,785

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

Point estimate	$20,198,445
Lower limit	13,027,841
Upper limit	27,369,050

APPENDIX E: FRANCISCAN COMMENTS[31]

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P 253.426.4101
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February 1, 2021

Via FedEx & Electronic Mail

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

Re: OAS Audit No. A-09-20-03034

Dear Ms. Ahlstrand:

Franciscan Hospice ("Franciscan") submits this letter in response to the Office of Inspector General, Office of Audit Services ("OIG") draft report dated November 18, 2020 ("Draft Report") and appreciates OIG providing an extension of the due date through February 1, 2021. Franciscan acknowledges its obligation to bill Medicare appropriately for hospice services and to provide medically necessary care to program beneficiaries. After reviewing the OIG's Draft Report, Franciscan respectfully disagrees with more than half of the findings, particularly those challenging the existence of a terminal prognosis. Franciscan also disagrees with the OIG's use of extrapolation across the audit period. Franciscan requests the OIG reconsider certain of its findings and that its published report reflect the concerns outlined below.

I. Introduction

Franciscan Hospice ("Franciscan") is operated under St. Joseph Medical Center, a subsidiary of CHI Franciscan, a non-profit, faith-based health system in the Pacific Northwest, which operates 11 hospitals and over 200 sites of care, providing a range of services across the care continuum. Franciscan provides comprehensive end-of-life hospice care to terminally ill patients in their homes throughout King, Kitsap and Pierce counties in the State of Washington, covering a service area of 4,400 square miles. If a patient's needs cannot be met at home,

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

Franciscan offers inpatient 24-hour hospice care in a home-like setting provided by clinicians who specialize in end-of-life care. In general, Franciscan's care includes medical pain management, emotional and spiritual support, practical support for caregivers, and bereavement support.

Focusing on compassion and quality of care, and given the specialized training Franciscan's team maintains, the hospice program has received several awards for providing superior palliative care over the years:

- Distinguished Service Award (Business Examiner)
- New grant awarded from Employees Community Fund of Boeing
- The Circle of Life Award and NOVA Award (American Hospital Association)
- The Partnership Award (Astra Zeneca)
- Models of Excellence in High-Risk Patient Management (AMA/Pfizer)
- The Acclaim Award (American Medical Group Association)
- The Employee Community Fund Award of Boeing Puget Sound
- The Cambia Health Foundation Sojourns Award for Palliative Care

For almost 30 years, Franciscan has played a critical role in the community providing high quality, necessary care to individuals at the end of life. It is, thus, important that Franciscan address OIG's findings suggesting anything to the contrary.

II. Franciscan Disagrees with the Majority of OIG's Findings Related to Certifications of Terminal Illness

Through OIG's review of 100 hospice claims from January 1, 2016 through December 31, 2017, OIG contends that Franciscan did not comply with Medicare requirements for 21 claims amounting to $93,785, leading to an extrapolated amount of $13 million. Of the 21 claims, OIG contends 19 claims lacked clinical records to support the beneficiary's terminal prognosis and two claims lacked documentation to support the hospice services billed. Franciscan disagrees with OIG's findings for 12 of the 19 claims OIG found unsupported by a terminal prognosis.

In instances where Franciscan disagrees with OIG's findings of lack of support of a terminal prognosis, Franciscan's third party auditor found the patient's medical record supported the certifying physician's clinical judgment that the patient met hospice criteria with a life expectancy of six months or less. As explained in further detail below, a physician's clinical judgment is fundamental in determining, and certifying to, terminal prognosis and involves assessing the beneficiary's full clinical picture. The OIG reviewers incorrectly utilized the Local Coverage Determinations ("LCD") regarding terminal illness issued by National Government Services, Inc. ("NGS") as a checklist for hospice eligibility, instead of considering patients' unique combination of illnesses.

A. Medicare Hospice Requirements for Terminal Prognosis

Medicare beneficiaries are eligible for hospice services only if a physician certifies that the individual is terminally ill "***based on the physician's or medical director's clinical judgment regarding the normal course of the individual's illness***."[1] Terminal illness is defined as a medical prognosis that the individual's life expectancy is six months or less if illness runs its normal course.[2] CMS acknowledges that predicting life expectancy is not always exact, and a beneficiary who lives longer than expected is not a reason to terminate benefits.[3] There is no limit to the number of hospice benefit periods, and patients may receive hospice care beyond six months.[4] The key is that a physician, in his/her own clinical judgment, determined the patient to be terminally ill thereby qualifying for the Medicare hospice benefit.[5]

A hospice may discharge a patient from its care if it determines the patient is no longer terminally ill.[6] CMS expects the hospice's interdisciplinary group to monitor patients and, if there are indications of improvement such that hospice may no longer be appropriate, discharge planning begins.[7] Discharge is <u>not</u> "the result of a single moment."[8] Further, because a hospice medical director assesses and evaluates the "full clinical picture" of a beneficiary to determine whether the patient still has a medical prognosis of six months or less, regardless of whether the beneficiary stabilizes or improves, determining appropriateness of discharge is not an exact science.[9]

CMS reiterates the importance of clinical judgment and assessment of the patient's unique circumstances throughout its guidance regarding certification. Specifically, at the start of a beneficiary's initial 90-day hospice benefit period, a hospice must obtain written certification of terminal illness from the individual's attending physician and the hospice's medical director or physician member of the interdisciplinary group.[10] This written certification must: (i) specify the patient's prognosis is for a life expectancy of six months or less if the terminal illness runs its normal course; (ii) be accompanied by clinical documentation to support the medical prognosis; and (ii) must include a brief narrative explanation of clinical findings to support the life expectancy of six months or less, which reflects the patient's individual clinical circumstances, among other requirements.[11]

In subsequent 90- or 60-day hospice benefit periods, the medical director or physician member of the interdisciplinary group recertifies at the beginning of the period that the patient is terminally ill "based on [the physician's] ***clinical judgment***."[12] If a patient's coverage is anticipated to reach a third benefit period, and for every period thereafter, then a hospice physician or hospice nurse practitioner must have a

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[1] 42 U.S.C. § 1395f(a)(7) (emphasis added); 42 C.F.R. § 418.22(b).
[2] 42 U.S.C. § 1395x(dd)(3)(A); 42 C.F.R. § 418.3.
[3] Medicare Benefit Policy Manual, Ch. 9 § 10.
[4] *See* 42 U.S.C. § 1395d(d)(1).
[5] *See* 78 Fed. Reg. 48234, 48247 (Aug. 7, 2013) ("We believe that the certifying physicians have the best clinical experience, competence and judgment to make the determination that an individual is terminally ill").
[6] 42 C.F.R. § 418.26(a).
[7] Medicare Benefit Policy Manual, Ch. 9 § 20.2.3.
[8] *Id.*
[9] *See* 79 Fed. Reg. 50452, 50471 (Aug. 22, 2014).
[10] 42 U.S.C. § 1395f(a)(7)(A).
[11] 42 C.F.R. § 418.22(b).
[12] *Id.* § 1395f(a)(7) (emphasis added).

face-to-face encounter with the patient to "***gather clinical findings to determine continued eligibility*** for hospice care."[13] Such requirements support that certifications are based on clinical judgment.

Federal courts similarly emphasize the importance of physician judgment in certifying patients as terminally ill for the Medicare hospice benefit. In a detailed analysis of Medicare's requirements for hospice eligibility, the Eleventh Circuit concludes in *United States v. AseraCare* that:

> The language of the statute [governing Medicare hospice certifications of terminal illness] and implementing regulations makes plain that the clinical judgment of the patient's attending physician (or the provider's medical director, as the case may be) lies at the center of the eligibility inquiry. Under this language, a patient is eligible for the Medicare hospice benefit if the appropriate physician makes a clinical judgment that the patient is terminally ill in light of the patient's complete medical picture, as evidenced by the patient's medical records.[14]

The *AseraCare* Court further notes that "none of the relevant [statutory or regulatory] language states that the documentary record underpinning a physician's clinical judgment must prove the prognosis as a matter of medical fact."[15] Of great importance here, "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."[16] Instead, the "physician's clinical judgment dictates eligibility as long as it represents a reasonable interpretation of the relevant medical records."[17] While Federal Courts of Appeals are divided as to *AseraCare*'s interpretation of falsity under the FCA,[18] those courts that disagree with *AseraCare* do not challenge *AseraCare*'s robust interpretation of the Medicare hospice benefit statute and regulations instructive to the OIG's audit of Franciscan.

As the *AseraCare* Court also points out, LCDs regarding terminal status are not mandatory requirements for hospice eligibility.[19] NGS, the Medicare Administrative Contractor ("MAC") servicing Franciscan, issued LCD L33393 on terminal status. LCD L33393 considers a patient to have a life expectancy of six months or less if the patient meets (i) non-disease specific "decline in clinical status" guidelines or (ii) baseline non-disease specific guidelines plus applicable disease specific guidelines.[20] Disease specific guidelines include, for example, cancer diagnoses, dementia, heart disease, and pulmonary disease. While NGS considers patients to be terminal if they meet the clinical variables specified in LCD L33393, even NGS acknowledges in the LCD that some terminal patients may not meet these guidelines

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[13] 42 C.F.R. § 418.22(a)(4)(i) (emphasis added).
[14] *United States v. AseraCare, Inc.*, 938 F.3d 1278, 1293 (11th Cir. 2019).
[15] *Id.* at 1293.
[16] *Id.* at 1294.
[17] *Id.*
[18] The Third Circuit in *United States ex rel. Druding v. Care Alternatives*, 952 F.3d 89 (3rd Cir. 2020) departed from the Eleventh Circuit's holding that a "mere difference of reasonable opinion between physicians, without more, as to the prognosis for a patient seeking hospice benefits does not constitute an objective falsehood" for FCA liability. *AseraCare, Inc.*, 938 F.3d at 1301. The Ninth Circuit in *United States ex rel. Winters v. Gardens Regional Hospital & Medical Center, Inc.*, 953 F.3d 1108, 1119 (9th Cir. 2020), held that a physician's false certifications of medical necessity can give rise to FCA liability if made with requisite intent, but concluded its holding did not conflict with *AseraCare*.
[19] *Id.* at 1283.
[20] NGS, LCD L33393: *Hospice – Determining Terminal Status*, at 5 (Jan. 27, 2021). *Available at* https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=33393&ContrId=272.

and coverage may still be approved.[21] Given that LCDs are guidelines and not binding, they "should not be considered the exact criteria used for determining terminal illness."[22]

B. Franciscan Engaged a Qualified Third-Party Auditor to Review the OIG's 21 Claim Findings

Franciscan takes the OIG's contentions of improper billing seriously and engaged a qualified third party auditor, [redacted] and its physician reviewer [redacted] (the "Auditor"), to review OIG's 21 claim findings. Franciscan's Auditor has significant experience reviewing health care provider billing and supporting medical record documentation, including with hospice providers. [redacted] has been a physician for over twenty-six years and has years of experience as a physician auditor, expert witness, and counselor regarding medical necessity and documentation requirements. He served as the lead medical reviewer of medical necessity audits as part of HHS-approved Independent Review Organizations for health care providers, including hospice providers, subject to Corporate Integrity Agreements.

Franciscan provided the Auditor access to the same record set supplied to the OIG for the 100 claim sample. The Auditor reviewed the records to determine if the records supported the certifying physician's conclusion that the patient's life expectancy was six months or less if the illness ran its normal course and whether the physician certification was reasonable. In doing so, the Auditor reviewed records against Medicare regulations and LCD L33393, where applicable, and also considered these records in the context of peer-reviewed, scientific findings related to the hospice certification process.

C. Franciscan Auditor Review Findings

Franciscan's Auditor disagreed with OIG's findings for 12 of the 19 claims deemed erroneous for lack of documentation to support a terminal prognosis. In these instances, medical records supported a terminal prognosis as well as the certifying physician's judgment that the patients met hospice coverage criteria during the time in question. Across the claims at issue, the OIG auditor primarily focused on whether the patient's clinical status met guidelines for terminal illness in NGS' LCD L33393. But, this is a fatal flaw, as LCD L33393 cannot be used as a final checklist for determining terminal prognosis. Rather, it is a guideline, and ultimately the patient's full clinical picture must be considered in determining projected life expectancy.

While all 12 claims incorrectly decided by OIG reviewers warrant further consideration, Franciscan summarizes five below.

- **Sample No. 75** – The review period was July 1, 2016 through July 31, 2016 for this 85-year-old male admitted to hospice in March 2015 with dementia complicated by multiple co-morbidities including CAD, atrial fibrillation, peripheral vascular disease, and heart failure. The OIG reviewer concluded that a prognosis of six months or less

[21] *Id.* at 4.

[22] *AseraCare, Inc.*, 938 F.3d at 1288.

was not supported and services provided were not reasonable or medically necessary for palliation. The OIG reviewer cited a lack of deterioration and describing the patient's obesity despite acknowledging factors such as total assistance needed for all activities of daily living, incontinence, a non-healing stump above a right knee amputation, and the patient's co-morbidities. The OIG reviewer's decision did not account for evidence of the patient's worsening cardiovascular function with abnormal vital signs, indications of gangrene in the patient's leg, or the patient's progressive, severe dementia. Notably, the patient's late April 2016 face-to-face visit showed the patient was barely conscious and responsive, not responding to voice or touch, with loss of head and trunk control. Just before the patient's July 2016 recertification, the June 2016 face-to-face documented "no sign of improvement" with abnormal vital signs such as low blood pressure, distant heart sounds, and necrotic leg tissue. The patient's mortality index ("MRI") was 11.2 and palliative performance score ("PPS") was 30%. Peer-reviewed, evidence-based studies show that (i) more than 50% of dementia hospice patients with similar PPS die within six months,[23] and (ii) MRI scores greater than 11 indicate a greater than 50% mortality rate within six months.[24] The patient was hospice-appropriate given documented clinical indications.

- **Sample No. 39** – The review period was November 1, 2016 through November 30, 2016 for this 75-year-old female admitted to hospice in September 2016 with dementia and a recent hospitalization for sepsis, acute respiratory failure, aspiration with dysphagia, uncontrolled diabetes, and an abnormally low albumin level. For this initial certification period, the OIG reviewer concluded that a prognosis of six months or less was not supported and services provided were not reasonable or medically necessary for palliation, citing that no progressive decline was documented and concluding the patient was expected to decline but not within a six month window. Specifically, the OIG reviewer concluded a 29% probability of death within six months. But, the patient's medical record documents a different outcome. By November 2016, the patient's PPS dropped to 30%, down from 60%, and she had worsening confusion and hallucinations. Her dementia with evidence of malnutrition, recent severe infection, and recent functional decline supported terminal prognosis. Peer-reviewed, evidence-based studies show that more than 50% of dementia hospice patients with similar PPS

[23] Harris, Pamela S. et al., *Can Hospices Predict which Patients Will Die within Six Months?*. J. PALLIATIVE MED., Vol. 17, No. 8 (2014), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4118712/ [hereinafter "*Can Hospices Predict?*"]; Harrold, Joan et al., *Is the Palliative Performance Scale a Useful Predictor of Mortality in a Heterogeneous Hospice Population?* J. PALLIATIVE MED., Vol. 8, No. 3 (2005), *available at* https://www.liebertpub.com/doi/10.1089/jpm.2005.8.503?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%20%200pubmed [hereinafter "*Is the Palliative Performance Scale a Useful Predictor?*"]

[24] Mitchell, Susan L. et al., *Estimating Prognosis for Nursing Home Residents with Advanced Dementia*, JAMA (2004), *available at* https://jamanetwork.com/journals/jama/fullarticle/198894 [hereinafter "*Estimating Prognosis*"].

scores die within six months.[25] The patient was hospice-appropriate given documented clinical indications.

- **Sample No. 94** – The review period was July 1, 2016 through July 30, 2016 for this 99-year-old female admitted to hospice in February 2016 with dementia complicated by a recent gastrointestinal ("GI") bleeding in the context of prior pulmonary embolism. The OIG reviewer concluded that a prognosis of six months or less was not supported and services provided were not reasonable or medically necessary for palliation, citing no documentation of recurrent serious infections or progressive inanition and all systems noted as well managed. Yet again, the patient's medical record reveals facts supporting a different conclusion. Leading up to the first recertification period, the patient was bedbound and exhibited neurological deterioration in that she could not communicate but "parroted" back questions when asked. The patient's PPS was low and declined to 30% from 40%, and she had an MRI score of 9 or greater, indicating a 57% change of mortality in six months. June nursing notes indicated worsening dementia, and no improvement in July. Further, the OIG reviewer concludes there were no reports of further GI bleeding yet ignores the medical risks associated with the patient's untreated GI bleeding source plus un-anticoagulated pulmonary embolus tendency given the need to cease previously prescribed warfarin. The patient had an increased risk of a sudden deadly event. Peer-reviewed, evidence-based studies show that (i) more than 50% of dementia hospice patients with similar PPS die within six months,[26] and (ii) MRI scores greater than 9 indicate a greater than 50% mortality rate within six months.[27] The patient was hospice-appropriate given documented clinical indications.

- **Sample No. 81** - The review period was November 1, 2016 through November 30, 2016 for the same patient referenced above in sample number 94. The OIG reviewer concluded that a prognosis of six months or less was not supported and services provided were not reasonable or medically necessary for palliation, citing no recurrent infections, no progressive inanition, and stable PPS and FAST scores, among other items. Yet, just before the October 2016 recertification, the September 2016 face-to-face visit documented a "gradual clinical deterioration" and weight loss. Her MRI score was 9 or greater and PPS was 30%. The patient was bedbound and sleeping 20 hours per day. Recertification of the patient's terminal prognosis was based on these facts establishing clinical decline. Peer-reviewed, evidence-based studies show that (i) more than 50% of dementia hospice patients with similar PPS scores die within six months,[28] and (ii) MRI scores greater than 9 indicate a greater than 50% mortality rate

[25] *Can Hospices Predict?*, *supra* note 3; *Is the Palliative Performance Scale a Useful Predictor?*, *supra* note 3.
[26] *Can Hospices Predict?*, *supra* note 3; *Is the Palliative Performance Scale a Useful Predictor?*, *supra* note 3.
[27] *Estimating Prognosis, supra* note 4.

[28] *Can Hospices Predict?*, *supra* note 3; *Is the Palliative Performance Scale a Useful Predictor?*, *supra* note 3.

within six months.[29] The patient was hospice-appropriate given documented clinical indications.

- **Sample No. 12** – The review period was May 1, 2017 through May 31, 2017 for this 72-year-old female admitted to hospice in January 2017 with severe dementia plus complicating seizures, low BMI, and abnormally low albumin level. The OIG reviewer concluded that a prognosis of six months or less was not supported and services provided were not reasonable or medically necessary for palliation, citing no evidence of decline or signs of a likely new or worsening serious comorbidity. However, leading up to the patient's first recertification on April 23, 2017, the patient showed clinical decline with weight loss, increased agitation, and PPS remaining low at 40%. At the time of re-certification, the medical record supported the certifying physician's judgment of terminal prognosis. While the OIG reviewer concluded the patient had a 6% probability of death in the next six months, peer-reviewed, evidence-based studies show that more than 50% of dementia hospice patients with similar PPS die within six months.[30]

  With this patient, Franciscan clinicians thereafter recognized a trend of sustained improvement and properly discharged the patient from hospice. The OIG reviewer ignored the patient's discharge at the conclusion of the certification period, instead applying the patient's clinical status retroactively against Franciscan despite Franciscan's appropriate discharge. This case demonstrates that Franciscan monitored its hospice patients, discharging them if they no longer were terminally ill.

For the following seven sample numbers, Franciscan's Auditor similarly found sufficient support for Medicare coverage including terminal prognosis: 19, 33, 34, 35, 40, 49, and 91. This amounts to 12 claims that OIG reviewers incorrectly concluded were billed in error.

Given the errors in the medical review, Franciscan requests OIG reconsider the records and revise its findings in the Draft Report, to account for the 12 audited claims that were appropriately billed. At your request, Franciscan will work with the Auditor to prepare a claim-by-claim analysis of the disputed cases for your review.

III. Extrapolation is Inappropriate Absent a "Sustained or High Level of Payment Error"

OIG's initial audit findings reflect a financial error rate of 20 percent, but this drops by more than half after correcting for inaccuracies identified by Franciscan's Auditor. Such a nominal error rate is not suggestive of a systemic error requiring extrapolation. Indeed, under CMS' standards, medical reviewers are directed to extrapolate only in the event of a "sustained or high level payment error" rate, meaning 50 percent or more.[31] While these standards apply directly to

[29] *Estimating Prognosis*, *supra* note 4.
[30] *Can Hospices Predict?*, *supra* note 3; *Is the Palliative Performance Scale a Useful Predictor?*, *supra* note 3.
[31] Medicare Program Integrity Manual, Ch. 8, § 8.4.1.4; *see also* 42 U.S.C. § 1395ddd(f)(3).

Medicare review contractors (*e.g.,* UPICs, RACs, the SMRC, and MACs), they should not be ignored in the context of an OIG audit recommending extrapolation. The OIG acknowledges its recommendation does not represent a final determination by Medicare and defers to CMS, acting through a MAC, to determine any overpayment amount. Because Medicare overpayments are at issue here, the MAC that processes and demands any applicable overpayments at OIG's recommendation is subject to federal law limiting the use of extrapolation to recover overpayments.[32]

At a minimum, Franciscan respectfully requests that OIG remove any recommendations related to extrapolation until the MAC has made a determination regarding repayment and Franciscan has had the opportunity to challenge that determination through the appeal process.

IV. Franciscan's Response to OIG's Recommendations

- **Recommendation No. 1**: ***Refund the Federal Government the portion of the estimated $13,027,841 for hospice services that did not comply with Medicare requirements and that are within the 4-year reopening period.***

  Given the foregoing, Franciscan disagrees with this recommendation as written; however, Franciscan will refund the sample claims it does not challenge.

- **Recommendation No. 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 identify any of those returned overpayments as having been made in accordance with this recommendation.***

  Franciscan agrees with this recommendation in that exercising reasonable diligence to identify, report, and return overpayments in the audited sample is required by federal law and regulation. Franciscan will refund certain sample claims and, consistent with its compliance program and monitoring and auditing processes, will evaluate and address any additional overpayments in accordance with the 60-day rule.

- **Recommendation No. 3**: ***Strengthen its policies and procedures to ensure that hospice services comply with Medicare requirements.***

  In general, Franciscan disagrees with this recommendation to the extent it suggests that Franciscan's policies and procedures did not ensure hospice services complied with Medicare requirements. Franciscan reviews and, as appropriate, revises its policies and procedures as part of its compliance program. Franciscan also educates its employees on Medicare requirements and company policies regarding the same. Franciscan has

[32] 42 U.S.C. § 1395ddd(f)(3).

re-educated appropriate personnel and will continue to do so to ensure understanding of Medicare coverage standards.

V. Conclusion

Franciscan understands the authority the OIG has to audit Franciscan's Medicare services and ensure program integrity. However, certain inaccuracies in the OIG's audit findings produced an inflated error rate and resulted in incorrect conclusions. Franciscan respectfully requests the OIG remedy those inaccuracies and revise its findings.

Franciscan thanks the OIG for the opportunity to provide its response and consider the above information. If you have any questions regarding this letter, please contact [redacted] System Vice President and Associate General Counsel directly at [redacted] or by email at [redacted]

Sincerely,

[redacted]

[redacted]
Corporate Responsibility Officer
CHI Franciscan

cc: [redacted]