

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**MEDICARE HOSPICE PROVIDER
COMPLIANCE AUDIT:
PROFESSIONAL HEALTHCARE
AT HOME, LLC**

*Inquiries about this report may be addressed to the Office of Public Affairs at
Public.Affairs@oig.hhs.gov.*



Amy J. Frontz
Deputy Inspector General
for Audit Services

June 2021
A-09-18-03028

Office of Inspector General

<https://oig.hhs.gov>

The mission of the Office of Inspector General (OIG), as mandated by Public Law 95-452, as amended, is to protect the integrity of the Department of Health and Human Services (HHS) programs, as well as the health and welfare of beneficiaries served by those programs. This statutory mission is carried out through a nationwide network of audits, investigations, and inspections conducted by the following operating components:

Office of Audit Services

The Office of Audit Services (OAS) provides auditing services for HHS, either by conducting audits with its own audit resources or by overseeing audit work done by others. Audits examine the performance of HHS programs and/or its grantees and contractors in carrying out their respective responsibilities and are intended to provide independent assessments of HHS programs and operations. These audits help reduce waste, abuse, and mismanagement and promote economy and efficiency throughout HHS.

Office of Evaluation and Inspections

The Office of Evaluation and Inspections (OEI) conducts national evaluations to provide HHS, Congress, and the public with timely, useful, and reliable information on significant issues. These evaluations focus on preventing fraud, waste, or abuse and promoting economy, efficiency, and effectiveness of departmental programs. To promote impact, OEI reports also present practical recommendations for improving program operations.

Office of Investigations

The Office of Investigations (OI) conducts criminal, civil, and administrative investigations of fraud and misconduct related to HHS programs, operations, and beneficiaries. With investigators working in all 50 States and the District of Columbia, OI utilizes its resources by actively coordinating with the Department of Justice and other Federal, State, and local law enforcement authorities. The investigative efforts of OI often lead to criminal convictions, administrative sanctions, and/or civil monetary penalties.

Office of Counsel to the Inspector General

The Office of Counsel to the Inspector General (OCIG) provides general legal services to OIG, rendering advice and opinions on HHS programs and operations and providing all legal support for OIG's internal operations. OCIG represents OIG in all civil and administrative fraud and abuse cases involving HHS programs, including False Claims Act, program exclusion, and civil monetary penalty cases. In connection with these cases, OCIG also negotiates and monitors corporate integrity agreements. OCIG renders advisory opinions, issues compliance program guidance, publishes fraud alerts, and provides other guidance to the health care industry concerning the anti-kickback statute and other OIG enforcement authorities.

Notices

THIS REPORT IS AVAILABLE TO THE PUBLIC
at <https://oig.hhs.gov>

Section 8M of the Inspector General Act, 5 U.S.C. App., requires that OIG post its publicly available reports on the OIG website.

OFFICE OF AUDIT SERVICES FINDINGS AND OPINIONS

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

Report in Brief

Date: June 2021

Report No. A-09-18-03028

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 Professional Healthcare at Home, LLC (Professional Healthcare), complied with Medicare requirements.

How OIG Did This Audit

Our audit covered 3,458 claims for which Professional Healthcare (located in Fairfield, California) received Medicare reimbursement of \$20.3 million for hospice services provided from April 1, 2016, through March 31, 2018. 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: Professional Healthcare at Home, LLC

What OIG Found

Professional Healthcare 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, for the remaining 21 claims, the clinical record did not support the beneficiary's terminal prognosis. In addition, for 1 of these 21 claims, there was no documentation that a hospice physician or hospice nurse practitioner had a required face-to-face encounter with the beneficiary. Improper payment of these claims occurred because Professional Healthcare's policies and procedures were not effective in ensuring that the clinical documentation it maintained supported the terminal illness prognosis. On the basis of our sample results, we estimated that Professional Healthcare received at least \$3.3 million in unallowable Medicare reimbursement for hospice services.

What OIG Recommends and Professional Healthcare Comments

We recommend that Professional Healthcare: (1) refund to the Federal Government the portion of the estimated \$3.3 million in Medicare overpayments that are within the 4-year claims reopening period; (2) based upon the results of this audit, exercise reasonable diligence to identify, report, and return overpayments in accordance with the 60-day rule; and (3) strengthen its policies and procedures to ensure that hospice services comply with Medicare requirements.

Professional Healthcare, through its attorney, stated that it disputed nearly all of our findings and did not concur with our recommendations. Professional Healthcare disagreed with our determinations for all 21 questioned sampled claims but agreed to return any overpayment for 1 claim for which the beneficiary's clinical record lacked documentation of a required face-to-face encounter. Professional Healthcare stated that our independent medical review contractor erred by consistently relying on only a limited portion of the clinical record to assess the certifying physician's terminal prognosis. In addition, Professional Healthcare's statistical expert challenged the validity of our statistical sampling methodology and the resulting extrapolation.

After reviewing Professional Healthcare's comments, we maintain that our finding and recommendations are valid. We also reviewed Professional Healthcare's statistical expert's comments and maintain that our sampling methodology and extrapolation were statistically valid and resulted in a legally valid and reasonably conservative estimate of the amount that Medicare overpaid to Professional Healthcare.

TABLE OF CONTENTS

INTRODUCTION.....	1
Why We Did This Audit.....	1
Objective.....	1
Background.....	1
The Medicare Program.....	1
The Medicare Hospice Benefit.....	1
Medicare Requirements To Identify and Return Overpayments.....	3
Professional Healthcare at Home, LLC.....	4
How We Conducted This Audit.....	4
FINDING.....	5
Medicare Requirements.....	5
Terminal Prognosis Not Supported.....	6
RECOMMENDATIONS.....	6
PROFESSIONAL HEALTHCARE COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE.....	7
Nonconcurrency With Recommendations.....	8
Professional Healthcare Comments.....	8
Office of Inspector General Response.....	8
Concerns Related to Audit Process.....	9
Professional Healthcare Comments.....	9
Office of Inspector General Response.....	9
Clinical Judgment and Support for Terminal Prognosis.....	10
Professional Healthcare Comments.....	10
Office of Inspector General Response.....	10
Office of Inspector General Sampling Methodology.....	11
Professional Healthcare Comments.....	11
Office of Inspector General Response.....	11

APPENDICES

A: Audit Scope and Methodology	14
B: Related Office of Inspector General Reports.....	16
C: Statistical Sampling Methodology	17
D: Sample Results and Estimates.....	18
E: Professional Healthcare Comments.....	19

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 Professional Healthcare at Home, LLC (Professional Healthcare), 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,

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 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 (April 1, 2016, through March 31, 2018), 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

Professional Healthcare at Home, LLC

Professional Healthcare, doing business as Kindred Hospice, is a for-profit provider located in Fairfield, California, that furnishes hospice care to beneficiaries who live in California. From April 1, 2016, through March 31, 2018 (audit period), Professional Healthcare provided hospice services to approximately 1,000 beneficiaries and received Medicare reimbursement of about \$20.5 million.¹⁹ National Government Services, Inc. (NGS), serves as the MAC for Professional Healthcare.

HOW WE CONDUCTED THIS AUDIT

Professional Healthcare received Medicare Part A reimbursement of \$20,583,610 for hospice services provided during our audit period, representing 3,680 paid claims. After we excluded 222 claims, totaling \$195,935, our audit covered 3,458 claims totaling \$20,387,675.²⁰ We reviewed a random sample of 100 of these claims, totaling \$602,411, 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 April 1, 2016, through March 31, 2018, 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 (206 claims), had compromised beneficiary numbers (11 claims), or were identified in the Recovery Audit Contractor data warehouse as having been reviewed by another party (5 claims).

FINDING

Professional Healthcare 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, for the remaining 21 claims, the clinical record did not support the beneficiary's terminal prognosis. In addition, for 1 of these 21 claims, there was no documentation that a hospice physician or hospice nurse practitioner had a required face-to-face encounter with the beneficiary. Improper payment of these claims occurred because Professional Healthcare's policies and procedures were not effective in ensuring that the clinical documentation it maintained supported the terminal illness prognosis.

On the basis of our sample results, we estimated that Professional Healthcare received at least \$3.3 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, Professional Healthcare 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 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

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. The face-to-face encounter must occur before, but no more than 30 calendar days

²¹ The statistical lower limit is \$3,358,906. 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).

before, the third benefit period recertification, and every benefit period recertification thereafter, to gather clinical findings to determine continued eligibility for hospice care. The narrative associated with the third benefit period recertification and every subsequent recertification must include an explanation of why the clinical findings of the face-to-face encounter support a life expectancy of 6 months or less. The physician or nurse practitioner who performs the face-to-face encounter must attest in writing that such an encounter occurred.²⁵

TERMINAL PROGNOSIS NOT SUPPORTED

For 21 of the 100 sampled claims, the clinical record provided by Professional Healthcare did not support the associated beneficiary's terminal prognosis. Specifically, the independent medical review contractor determined that the records for these claims did not contain sufficient clinical information and other documentation to support the medical prognosis of a life expectancy of 6 months or less if the terminal illness ran its normal course. In addition, for 1 of these 21 claims, there was no documentation that a hospice physician or hospice nurse practitioner had a required face-to-face encounter with the beneficiary.

RECOMMENDATIONS

We recommend that Professional Healthcare at Home, LLC:

- refund to the Federal Government the portion of the estimated \$3,358,906 for hospice services that did not comply with Medicare requirements and that are within the 4-year reopening period;²⁶
- based upon the results of this audit, exercise reasonable diligence to identify, report, and return any overpayments in accordance with the 60-day rule²⁷ and identify any of those returned overpayments as having been made in accordance with this recommendation; and

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

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.

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.

- strengthen its policies and procedures to ensure that hospice services comply with Medicare requirements.

PROFESSIONAL HEALTHCARE COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, Professional Healthcare, through its attorney, stated that it disputed all of our findings and did not concur with our recommendations. Professional Healthcare disagreed with our determinations for all 21 sampled claims questioned in our draft report and provided specific responses for each of the 21 claims. However, Professional Healthcare agreed to refund or repay any overpayment for the one claim for which the beneficiary's clinical record lacked documentation of a required face-to-face encounter.

Professional Healthcare stated that courts have recognized that a difference in two physicians' clinical judgments cannot render the certifying physician's judgment invalid. In addition, Professional Healthcare stated that our independent medical review contractor erred by consistently relying on only a limited portion of a patient's clinical record to assess the certifying physician's terminal prognosis, which was based on a full assessment of the patient's complete medical condition. Furthermore, Professional Healthcare stated that our independent medical review contractor repeatedly found that documentation was insufficient because it did not satisfy Local Coverage Determination (LCD) criteria. Professional Healthcare stated that LCD guidelines are not mandatory, and failure to meet those guidelines cannot support a claim denial.

Professional Healthcare engaged a statistical expert, who analyzed our statistical sampling methodology and, based on that analysis, stated that our methodology is not statistically valid and should not be used as a basis to calculate an extrapolated overpayment. Professional Healthcare's comments are included as Appendix E.²⁸

After reviewing Professional Healthcare's comments, we maintain that our finding and recommendations are valid. We also reviewed the report prepared by Professional Healthcare's statistical expert and maintain that our statistical sampling methodology and extrapolation were statistically valid and resulted in a legally valid and reasonably conservative estimate of the amount that Medicare overpaid to Professional Healthcare. The following sections summarize Professional Healthcare's comments and our responses.

²⁸ Professional Healthcare attached three exhibits to its comments, which contained curricula vitae of its internal auditor and statistical expert, the internal auditor's rebuttal statements for our findings, and the statistical expert's review of our statistical sampling methodology. 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 Professional Healthcare's comments in their entirety to CMS.

NONCONCURRENCE WITH RECOMMENDATIONS

Professional Healthcare Comments

Professional Healthcare did not concur with our three recommendations as follows:

- Regarding our first recommendation, Professional Healthcare stated that it had been unable to locate documentation for one sampled claim for which the beneficiary's clinical record lacked documentation of a required face-to-face encounter. Professional Healthcare stated that it will refund or repay any overpayment associated with this claim. Nonetheless, Professional Healthcare stated that based on its own clinical review of the beneficiaries' medical records, all 21 sampled claims that OIG found to be improper were supported by the patient's clinical record and billed appropriately. In addition, Professional Healthcare stated that our sampling methodology was not statistically valid and should not be used as a basis to calculate an extrapolated overpayment. Professional Healthcare stated that it intends to vigorously challenge our findings for the 21 sampled claims and any sampling methodology used to calculate and extrapolate overpayments by exercising its rights to appeal any adverse findings through the Medicare administrative appeals process.
- Regarding our second recommendation, Professional Healthcare acknowledged "its legal obligation to exercise reasonable diligence to identify potential overpayments within the preceding six years based on receipt of credible information that an overpayment may exist." However, Professional Healthcare stated that it disagreed with our findings and believes that the sampled claims are supported by the patients' clinical records and were billed appropriately.
- Regarding our third recommendation, Professional Healthcare disagreed that its policies and procedures allowed any systemic issues to occur. Professional Healthcare stated that OIG has not identified any particular policies or procedures that it believes to be lacking or insufficient and that the findings reflect a largely effective compliance program.

Office of Inspector General Response

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

We maintain that our findings and recommendations are valid and that improper payment of the 21 sampled claims occurred because Professional Healthcare's policies and procedures were not effective in ensuring that the clinical documentation it maintained supported the terminal illness prognosis.

CONCERNS RELATED TO AUDIT PROCESS

Professional Healthcare Comments

Professional Healthcare stated that it has numerous concerns with our audit process. Professional Healthcare also stated that the draft report did not provide a single reason why Professional Healthcare was selected for audit.

Professional Healthcare stated that it has serious concerns about the qualifications of our independent medical review contractor and that OIG has not provided any substantive information by which Professional Healthcare can assess the contractor. In addition, Professional Healthcare stated that the medical review determinations contain the same vague statement that the reviewer is a physician and holds a board certification. Professional Healthcare stated that without receiving any information about the reviewer, it can assess the reviewer only through his or her individual medical determinations of the sampled claims.

Professional Healthcare stated that our independent medical review contractor repeatedly found that documentation was insufficient either because it did not satisfy LCD criteria or because of the patient's score according to the Advanced Dementia Prognostic Tool (ADEPT). Professional Healthcare stated that LCD guidelines are not mandatory and that failure to meet those guidelines cannot support a claim denial. Finally, Professional Healthcare stated that the ADEPT score is not even part of the LCD guidelines for patients with Alzheimer's disease or dementia, and it is not an accurate means of predicting a dementia patient's prognosis.

Office of Inspector General Response

We selected Professional Healthcare for a compliance audit through the use of computer matching, data mining, and data analysis techniques that identified hospice claims that were at risk for noncompliance with Medicare billing requirements.

We used an independent medical review contractor that is a licensed physician who specializes in hospice and palliative medicine and is familiar with Medicare hospice guidelines and protocols. Although our independent medical review contractor referenced the ADEPT score in conducting the medical review, the contractor properly used the appropriate statutory and regulatory hospice criteria, as well as applicable LCD guidelines, as the framework for determining terminal status. Specifically, our independent medical review contractor applied standards set out in 42 CFR § 418.22(b)(2), which requires that clinical information and other

documentation that support the medical prognosis accompany the physician's written certification of terminal illness and be filed in the medical record.²⁹

We acknowledge that some beneficiaries who did not meet the guidelines in the hospice LCDs may still be appropriate for hospice care based upon an individual assessment of the beneficiary's health status. Accordingly, our independent medical review contractor merely used LCD guidelines as a tool to evaluate the terminal prognosis. 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.

CLINICAL JUDGMENT AND SUPPORT FOR TERMINAL PROGNOSIS

Professional Healthcare Comments

Professional Healthcare stated that the findings in our draft report are based entirely on a subjective difference in clinical opinion and that our independent medical review contractor determined in his or her own medical opinion that the portion of the patient's clinical record assessed did not support the terminal prognosis. Professional Healthcare cited several court cases and stated that a difference in clinical judgment cannot render the physician's certification false or invalid for billing purposes.

Professional Healthcare disagreed with our determinations for the 21 sampled claims in our draft report for which our independent medical review contractor found that the associated beneficiaries' clinical records did not support the terminal illness prognosis. Professional Healthcare stated that our contractor consistently failed to apply the appropriate standard for assessing whether the clinical record supported the terminal prognosis. Professional Healthcare also stated that our independent medical review contractor failed to consider all of the relevant factors and information related to the patient's life expectancy and based the findings on a limited "snapshot" portion of the patient's clinical record.

Office of Inspector General Response

As previously mentioned, we used an independent medical review contractor that is a licensed physician who specializes in hospice and palliative medicine and is familiar with Medicare hospice guidelines and protocols. In conducting the medical review, our contractor properly used the appropriate statutory and regulatory hospice criteria, as well as applicable LCD guidelines, as the framework for its determinations. 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

²⁹ Applicable LCD guidelines also state that the documentation must contain enough information to support terminal illness upon review.

in the Medicare requirements, to determine whether the certified terminal prognosis was supported. 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. In addition, the decisions in the court cases that Professional Healthcare referenced addressed whether a difference in clinical judgment can render a physician certification false for purposes of False Claims Act liability and therefore are inapplicable to OIG audit recommendations and CMS recoveries arising from OIG audits.

Based on our review of Professional Healthcare's comments, we maintain that the clinical records for each of the 21 sampled claims did not support the associated beneficiary's terminal prognosis. For the reasons stated above, we disagree with Professional Healthcare's statement that our independent medical review contractor failed to apply the appropriate standard for assessing whether the clinical record supported the terminal prognosis. We also disagree that our contractor considered only a limited "snapshot" portion of patient records in making determinations on the claims.

OFFICE OF INSPECTOR GENERAL SAMPLING METHODOLOGY

Professional Healthcare Comments

Professional Healthcare challenged the validity of our statistical sampling methodology, engaged a statistical expert to review our sampling methodology, and provided a copy of the statistical expert's report. The statistical expert stated that our sample and extrapolation are not statistically valid and should not be used as a basis to calculate an extrapolated overpayment because: (1) the audit findings did not meet the high-error-rate criteria in the Social Security Act and CMS's *Medicare Program Integrity Manual* (MPIM) to justify the use of extrapolation, (2) the audit findings did not meet the 5-percent error rate criteria in OIG's Corporate Integrity Agreement (CIA) to justify the use of extrapolation, (3) OIG ignored statistical principles by excluding underpayments or unpaid (i.e., zero-paid) claims from the universe of claims, (4) OIG's sample is not sufficient to achieve the standard precision and confidence level for this type of statistical estimate, (5) OIG did not provide information sufficient to re-create the sampling frame and sample or OIG's overpayment estimate, (6) OIG did not state the sort order of the sampling frame, and (7) OIG failed to provide the random-number seed that was used to initialize the random number generator.

Office of Inspector General Response

After reviewing the statistical expert's report, we maintain that our sampling methodology and extrapolation are statistically valid. The legal standard for use of sampling and extrapolation is

that it must be based on a statistically valid methodology, not the most precise methodology.³⁰ We properly executed our statistical sampling methodology in that we defined our sampling frame and sample unit, randomly selected our sample, applied relevant criteria in evaluating the sample, and used statistical sampling software (i.e., the OIG, Office of Audit Services (OAS), statistical software RAT-STATS) to apply the correct formulas for the extrapolation.

The statutory and manual requirement that a determination of a sustained or high level of payment errors must be made before extrapolation can be used applies only to Medicare contractors—not OIG.³¹ In addition, OIG no longer uses the 5-percent error-rate threshold in its CIAs. Moreover, even in prior CIAs that used the 5-percent error-rate threshold, the threshold was used to determine when an additional claims sample (referred to as a “full sample”) needed to be selected and reviewed based on the results of a probe sample (referred to as a “discovery sample”). The entity under the CIA was required to extrapolate the results of the full sample, regardless of the error rate.³²

Professional Healthcare relies heavily on the MPIM in its arguments that the removal of zero-paid claims ignored statistical principles. The MPIM does not apply to OIG. Even if this manual applied to OIG, it expressly allows for the removal of “claims/claim lines [that] are attributed to sample units for which there was no payment.”³³ More generally, OIG may perform a statistical or nonstatistical review of a provider without covering all claims from that provider. Furthermore, OIG’s statistical estimates are applied only to the sampling frame from which the sample was drawn.

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.³⁴ Professional Healthcare focuses on the 5 percent of cases where the provider may have to pay more to the Government; however, these cases are inherently rare, and when they arise, the amount the provider may have to over-reimburse to the

³⁰ 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).

³¹ See the Act § 1893(f)(3); MPIM, Pub. No. 100-08, chapter 8, § 8.4.

³² Furthermore, the 5-percent error-rate threshold is a contractual term of the CIA and therefore applies only to the party to the CIA.

³³ MPIM, Pub. No. 100-08, chapter 8, § 8.4.3.2.

³⁴ 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).

Government tends to be small. 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 Professional Healthcare refund a larger amount to the Government.

We provided Professional Healthcare with sufficient information to re-create the statistical sample and to calculate our estimate given the overpayment amounts in our sample. We also provided Professional Healthcare with the medical review determinations underlying the errors identified in our audit. Because Professional Healthcare stated that it does not have sufficient information to connect the sample overpayment amounts to the medical review determinations, we will work with Professional Healthcare to ensure that it has the necessary information to make this connection. The sampling frame was sorted using a field in OIG's copy of CMS's National Claims History (NCH) file that uniquely identifies claims. After being sorted by this field, the frame was numbered before we generated the random numbers for the sample. We also provided Professional Healthcare with the random-number seed that was used to generate the random numbers.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

Our audit covered 3,458 hospice claims for which Professional Healthcare received Medicare reimbursement totaling \$20,387,675 for services provided from April 1, 2016, through March 31, 2018 (audit period). These claims were extracted from CMS's NCH file.

We did not assess Professional Healthcare'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 Professional Healthcare's office in Fairfield, 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 Professional Healthcare officials to gain an understanding of Professional Healthcare'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 3,680 hospice claims, totaling \$20,583,610,³⁵ for the audit period;
- excluded 206 claims, totaling \$118,047, that had a payment amount of less than \$1,000; 11 claims, totaling \$59,170, that had compromised beneficiary numbers; and 5 claims, totaling \$18,718, that were identified in the Recovery Audit Contractor data warehouse as having been reviewed by another party;
- created a sampling frame consisting of 3,458 hospice claims, totaling \$20,387,675;
- selected a simple random sample of 100 hospice claims from the sampling frame;

³⁵ 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 Professional Healthcare for hospice services; and
- discussed the results of our audit with Professional Healthcare 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: Franciscan Hospice</i>	<u>A-09-20-03034</u>	5/18/2021
<i>Medicare Hospice Provider Compliance Audit: Alive Hospice, Inc.</i>	<u>A-09-18-03016</u>	5/14/2021
<i>Medicare Hospice Provider Compliance Audit: Ambercare Hospice, Inc.</i>	<u>A-09-18-03017</u>	5/14/2021
<i>Medicare Hospice Provider Compliance Audit: Suncoast Hospice</i>	<u>A-02-18-01001</u>	5/7/2021
<i>Medicare Hospice Provider Compliance Audit: Tidewell Hospice, Inc.</i>	<u>A-02-18-01024</u>	2/22/2021
<i>Medicare Hospice Provider Compliance Audit: Hospice Compassus, Inc., of Tullahoma, Tennessee</i>	<u>A-02-16-01024</u>	12/16/2020
<i>Medicare Hospice Provider Compliance Audit: Hospice Compassus, Inc., of Payson, Arizona</i>	<u>A-02-16-01023</u>	11/19/2020
<i>Safeguards Must Be Strengthened To Protect Medicare Hospice Beneficiaries From Harm</i>	<u>OEI-02-17-00021</u>	7/3/2019
<i>Hospice Deficiencies Pose Risks to Medicare Beneficiaries</i>	<u>OEI-02-17-00020</u>	7/3/2019
<i>Vulnerabilities in the Medicare Hospice Program Affect Quality Care and Program Integrity: An OIG Portfolio</i>	<u>OEI-02-16-00570</u>	7/30/2018
<i>Hospices Should Improve Their Election Statements and Certifications of Terminal Illness</i>	<u>OEI-02-10-00492</u>	9/15/2016
<i>Hospices Inappropriately Billed Medicare Over \$250 Million for General Inpatient Care</i>	<u>OEI-02-10-00491</u>	3/30/2016
<i>Hospice of New York, LLC, Improperly Claimed Medicare Reimbursement for Some Hospice Services</i>	<u>A-02-13-01001</u>	6/26/2015
<i>Medicare Hospices Have Financial Incentives To Provide Care in Assisted Living Facilities</i>	<u>OEI-02-14-00070</u>	1/13/2015
<i>The Community Hospice, Inc., Improperly Claimed Medicare Reimbursement for Some Hospice Services</i>	<u>A-02-11-01016</u>	9/23/2014
<i>Servicios Suplementarios de Salud, Inc., Improperly Claimed Medicare Reimbursement for Some Hospice Services</i>	<u>A-02-11-01017</u>	8/7/2014

APPENDIX C: STATISTICAL SAMPLING METHODOLOGY

SAMPLING FRAME

We obtained Medicare Part A claims data for hospice services that Professional Healthcare provided during our audit period, representing 3,680 paid claims totaling \$20,583,610. We excluded 206 claims, totaling \$118,047, that had a payment amount of less than \$1,000; 11 claims, totaling \$59,170, that had compromised beneficiary numbers; and 5 claims, totaling \$18,718, 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 3,458 claims totaling \$20,387,675. 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 3,458. 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 Professional Healthcare 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
3,458	\$20,387,675	100	\$602,411	21	\$142,945

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

Point estimate	\$4,943,028
Lower limit	3,358,906
Upper limit	6,527,150

APPENDIX E: PROFESSIONAL HEALTHCARE COMMENTS³⁶

BASS BERRY + SIMS

January 19, 2021

VIA KITEWORKS & FEDERAL EXPRESS

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

Re: Office of Audit Services Draft Report Number A-09-18-03028

Dear Ms. Ahlstrand:

Professional Healthcare at Home, LLC (“PHH”) submits this response to the draft Report Number A-09-18-03028 that the Office of Inspector General, Office of Audit Services (the “OIG”) issued to PHH on November 19, 2020 (the “Report”).¹

In its initial review of a sample of PHH’s claims, the OIG found a portion of those claims to be noncompliant with Medicare regulations in a single respect: that the documentation reviewed did not support the beneficiary’s terminal prognosis. Although it audited a number of other aspects of the sampled claims, including Medicare billing, coverage, medical necessity, and coding requirements, the OIG’s Report sets forth virtually no other errors. Except for a single face-to-face encounter for 1 of the 100 sampled claims, the Report did not find *any* other errors with *any* of the sampled claims. As such, the vast majority of the audited claims were 100% compliant, and even those for which the OIG found a single error were compliant with the vast majority of requirements that the OIG audited.

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

¹ Although the Report requested that PHH provide written comments in response to the Report within 30 days from the date of the Report, PHH requested an extension of time to submit its written response on November 23, 2020. On November 23, 2020, the OIG confirmed an extension of time until January 18, 2021. Because January 18, 2021 is a federal holiday, the OIG confirmed an extension of time until January 19, 2021.

³⁶ OIG Note: We redacted text in selected places in this appendix because it is personally identifiable information.

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

I. PHH Does Not Concur with OIG Recommendations

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

OIG Recommendation #1: Refund to the Federal Government the portion of the estimated \$3,358,906 for hospice services that did not comply with Medicare requirements and that is within the 4-year reopening period.

PHH Response: PHH does not concur with this recommendation. With the exception of a single face to face technical documentation issue for which PHH concurs with the findings,² all of the OIG’s findings with respect to the audited claims are flawed. Based upon its own clinical review of the beneficiaries’ medical records, which is detailed in the rebuttal statements submitted with this response, all of the 21 audited claims that the OIG found to be improper were supported by the patient’s medical records and were billed appropriately. Moreover, a difference in clinical judgment between the OIG’s medical reviewer and the certifying physician cannot render the certifying physician’s terminal prognosis invalid. And, the OIG’s sampling methodology is not statistically valid and should not be used as a basis to calculate an extrapolated overpayment. As such, PHH intends to vigorously challenge negative claims findings and any sampling methodology used to calculate and extrapolate overpayments following the issuance of a final report by exercising its rights to appeal any adverse findings through the Medicare administrative appeals process. PHH anticipates the vast majority of the alleged overpayments related to a beneficiary’s terminal prognosis will be eliminated entirely through the appeals process. Therefore, any refund to the Medicare program on those grounds at this juncture would be premature.

Not only did the patients’ medical records support the physicians’ terminal prognosis for all 100 of the audited claims, but the OIG does not dispute that those physicians made good faith and thoughtful determinations that each beneficiary who received hospice services was eligible for those services. PHH will refund or repay any overpayment associated with the one claim for which the beneficiary’s medical record lacked documentation of a required face-to-face encounter. Because that sole instance was isolated and not in any way sustained or systemic, however, any extrapolated overpayment of that claim to a broader universe of claims is inappropriate.

OIG Recommendation #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

² PHH has been unable to locate documentation of a face-to-face encounter for the one patient (Sample No. 30) for which the OIG found the medical record lacked required face-to-face documentation. Nonetheless, PHH confirmed through its review of the medical records that the records for all 21 of the allegedly improper claims supported the certifying physician’s determination of a terminal prognosis. PHH’s position, as set forth in more detail throughout this response, is that all of the OIG’s clinical findings with respect to terminal prognosis are flawed. PHH will refund reimbursement it received for the single claim that lacked supporting face-to-face documentation.

identify any of those returned overpayments as having been made in accordance with this recommendation.

PHH Response: PHH does not concur with this recommendation. PHH acknowledges its legal obligation to exercise reasonable diligence to identify potential overpayments within the preceding six years based upon receipt of credible information that an overpayment may exist.³ The Centers for Medicare & Medicaid Services (“CMS”) has acknowledged, however, that a provider that receives notice of a potential overpayment through an audit may reasonably determine that additional investigation of potential additional overpayments is premature during the audit appeals process.⁴ As noted above, PHH disagrees with the OIG’s findings and believes that the audited claims are supported by the patients’ medical records and were billed appropriately.

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

PHH Response: PHH does not concur with this recommendation. PHH disagrees that its policies and procedures allowed any systemic issues to occur. The OIG’s draft audit findings included only a single alleged issue with respect to the audited claims: that the patient’s medical record did not sufficiently support the terminal prognosis.⁵ As noted above, PHH disagrees with the OIG’s findings. In addition, the OIG has not identified any particular policies or procedures that it believes to be lacking or insufficient, and the OIG’s findings reflect a largely effective compliance program. PHH constantly evaluates whether opportunities exist to improve its procedures and processes and will continue to do so.

II. Background

PHH is dedicated to providing terminally ill patients with the care and dignity they deserve. PHH’s compassionate hospice care program includes a team of physicians, licensed nurses, nursing assistants, social workers, and chaplains who provide the physical, emotional, and spiritual resources needed for beneficiaries to make the most of every moment based on that patient’s specific needs and goals. PHH’s hospice care is specially designed to comfort patients and their family members in end-of-life situations and to provide both the support and the pain and symptom management necessary to do so.

Both during and after the period at issue in the OIG’s audit, PHH implemented a robust compliance program to ensure compliance with applicable Medicare coverage, documentation, and billing requirements. That program specifically includes each of the seven fundamental elements of an effective compliance program set forth in the OIG’s compliance program guidance for hospice providers, including:

- Implementing written policies, procedures and standards of conduct;

³ See 42 C.F.R. § 401.305.

⁴ See Medicare Program; Reporting and Returning Overpayments, 81 Fed. Reg. 7,654, 7,667 (Feb. 12, 2016).

⁵ Although the OIG’s Report found that 1 of the 100 audited claims lacked documentation of a required face-to-face encounter, a 99 percent compliance rate for documenting face-to-face encounters indicates a robust and effective compliance function and does not suggest that PHH’s policies and procedures require strengthening in that area.

- Designating a compliance officer and compliance committee;
- Conducting effective training and education;
- Developing effective lines of communication;
- Enforcing standards through well-publicized disciplinary guidelines;
- Conducting internal monitoring and auditing; and
- Responding promptly to detected offenses and developing corrective action.⁶

In particular, a large team of individuals participates in each aspect of PHH's compliance efforts. The compliance function traces directly through a full-time Chief Compliance Officer, Vice President of Compliance, Regional President, Area Vice President, Regional Director of Operations, and down to the agency director. Each PHH employee who sees patients or plays any role in billing or coding receives comprehensive compliance training at new-hire orientation as well as annual follow-up training. Any employee who does not complete the required compliance training is suspended and prohibited from working.

PHH also has robust audit processes in place to ensure specifically that its claims are billed appropriately. Each PHH hospice agency is subject to random audits based on the Medicare conditions of participation and thoroughly examine compliance with those conditions. If the auditors cannot locate required documentation with respect to any claim, the claim is not billed. PHH also conducts regional quality assurance and performance improvement audits. PHH conducts a monthly pre-bill audit of patient admissions to confirm before billing that all patients admitted for service are eligible to receive hospice services and eligibility is documented thoroughly. Before billing, each claim must satisfy every element of PHH's pre-billing checklist, which is based on Medicare coverage, documentation, and billing requirements. The admission billing audit is conducted initially at the hospice program level with additional review and confirmation conducted at the applicable billing location.

With respect to the one alleged issue identified in the OIG's audit – documentation of terminal prognosis – PHH provides its employees with comprehensive training about both determining and documenting hospice eligibility. That training includes extensive instruction and guidance for differentiating between terminal and chronic illness. PHH trains its employees that many patients suffer from chronic and debilitating illnesses but are not terminally ill with a prognosis of six months or less to live and that a total care patient is not necessarily terminally ill. Although the beneficiary's medical record need only support the terminal prognosis, PHH trains its employees that the documentation should "paint the picture" of hospice eligibility, including by documenting evidence of decline in the patient's clinical status.

PHH's commitment to compliance is demonstrated by its results. According to its most recent PEPPER report, PHH is not an outlier nationally, within its jurisdiction, or within its state for its percentage of live discharge patients, percentage of long length of stay patients, or the amount of routine home care that it provides in assisted living facilities, nursing facilities, or skilled nursing facilities. PHH's previous PEPPER reports reflect similarly favorable results

⁶ Compliance Program Guidance for Hospice Providers, 64 Fed. Reg. 54,031 (Oct. 5, 1999).

compared to other hospice providers and demonstrate PHH was not an outlier for any of those data points during the time period relevant to the claims audited by the OIG. PHH's quality measures similarly reflect a compliant and highly effective hospice program. Its Consumer Assessment of Healthcare Providers and Systems (CAHPS) data and Hospice Item Set (HIS) data illustrate a highly rated degree of care, with PHH consistently receiving high scores on the relevant quality measures. In its HIS data in particular, PHH achieved a CMS quality aggregate score of at least 98.9 for the reporting time periods including and since the audit period. In addition, PHH is not aware of being the subject of any other investigation or enforcement action related to potential billing or reimbursement issues conducted by the OIG, United States Department of Justice, or other government enforcement authority.

III. Concerns Related to the OIG's Audit Process

PHH has numerous concerns with the OIG's audit process. At the outset, it appears the OIG selected PHH for audit simply because PHH bills Medicare for hospice services. Attempting to explain "why we did this audit," the Report does not provide a single reason why PHH specifically was selected for audit. Instead, the Report states generally that previous OIG "audits and evaluations found that Medicare inappropriately paid for hospice services that did not meet certain Medicare requirements." The Report references and attaches as an appendix a "list of related OIG reports on Medicare hospice services." The Report does not explain, however, how any of those reports are related to PHH or to this audit. In fact, many of the reports appear to have no relation in any way to PHH or its audit; three of them pertain to hospice providers that have no relation to PHH, and one of them pertains to overbilling for General Inpatient ("GIP") care even though the OIG's Report includes no findings related to GIP care.

After PHH specifically asked for additional information about the criteria used to select the agency for audit, the OIG vaguely responded that it selected PHH "through a risk-based approach that includes the use of computer matching, data mining, and data analysis techniques" but that more detailed information "is not publicly available." The OIG refused to answer whether the agency was selected due to an indication of non-compliance or whether total Medicare reimbursement to the agency was a consideration. Thus, it appears the only data that the OIG used to identify PHH for audit is the number of dollars it bills Medicare for hospice services. Indeed, PHH's PEPPER reports confirm PHH was not an outlier for any of the data points tracked in those reports either during the time period relevant to the audited claims or at any subsequent time.

Although the Report's first paragraph asserts the OIG found that PHH was not compliant for 21 of the 100 claims reviewed, that 21 percent "error rate" is extremely misleading. The OIG's medical determinations reflect that the medical reviewer audited up to thirteen separate items related to six different clinical factors, including eligibility, certification of terminal illness, face-to-face encounter, hospice covered services, payment for hospice care, and coding. Other than documenting a single face-to-face encounter for 1 of the 100 sampled claims, the only adverse finding set forth in the Report is that the medical reviewer determined that the patient's medical record did not support a terminal prognosis for 21 of the audited claims, representing just one of the audited items. Thus, based on the OIG's own conclusions, nearly 80 percent of the audited claims were 100% compliant for *all* of the audited items, and the remaining claims

were compliant for the vast majority of the audited items, with the documentation issue representing the sole exception.

PHH also has serious concerns about the qualifications of the OIG's unidentified medical reviewer. The OIG has not provided any substantive information by which PHH can assess the medical reviewer. Instead, each of the reviewer's medical determinations contains the same vague statement that the reviewer is a physician who is "licensed to practice medicine," "knowledgeable in the treatment of the enrollee's medical condition," and "familiar with the guidelines and protocols in the area of treatment under review." While noting the reviewer holds a board certification, the reviewer's qualifications do not even reference hospice and could be used – and presumably have been used – for any licensed physician of any training or qualification whatsoever. Without receiving any information about the reviewer, PHH can only assess the reviewer through his or her individual medical determinations of the audited claims.

As discussed below, *all* of the reviewer's findings that the patients' medical records do not support a terminal prognosis are flawed. Specifically, the reviewer consistently relied on only a limited portion of the patient's medical record to assess the certifying physician's terminal prognosis, which was based on a full assessment of the patient's complete medical condition. Reviewing a limited "snapshot" of a patient's medical record simply is not the standard for determining whether documentation supports a terminal prognosis for purposes of Medicare requirements.

The OIG's reviewer also repeatedly found that documentation was insufficient either because it did not satisfy LCD criteria or due to the patient's score according to the Advanced Dementia Prognostic Tool (ADEPT). LCD guidelines are not mandatory, however, and failure to meet those guidelines cannot support a claim denial. In *Azar v. Allina Health Services*, the Supreme Court held that any Medicare rule, requirement, or statement of policy that establishes or changes a "substantive legal standard" governing the scope of benefits, payment for services, or eligibility of individuals to receive benefits must go through notice-and-comment rulemaking.⁷ LCD guidelines are not promulgated through notice-and-comment rulemaking. The Department of Health and Human Services Office of the General Counsel expressly acknowledged the Supreme Court's holding in *Allina* and its effect on Medicare rules, regulations, and sub-regulatory guidance in an advisory opinion last month.⁸ Moreover, the ADEPT score is not even part of the LCD guidelines for patients with Alzheimer's disease or dementia, and it is not an accurate means of predicting a dementia patient's prognosis. Even the physicians who developed the ADEPT score concluded – in the article that the OIG's medical reviewer cites repeatedly in his medical determinations – that the score "has only moderate accuracy in predicting survival in advanced dementia patients."⁹ That the reviewer consistently concluded patients' medical records did not support a terminal prognosis on any of these grounds establishes that the reviewer is *not* qualified to accurately assess the hospice services that PHH provided to Medicare beneficiaries.

⁷ 139 S. Ct. 1804 (2019).

⁸ Dep't of Health & Human Services, Office of the General Counsel Op. No. 20-05 (Dec. 3, 2020).

⁹ Susan L. Mitchell, Susan C. Miller, Joan M. Teno, Roger B. Davis, & Michele L. Shaffer, *The Advanced Dementia Prognostic Tool: A Risk Score to Estimate Survival in Nursing Home Residents with Advanced Dementia*, 40 J. Pain Symptom Mgmt. 639 (2010).

In addition to the clinical errors underlying the Report, the OIG's statistical sampling and extrapolation methodology also were flawed. As discussed in more detail below, the OIG's sample is flawed because it is not representative of the broader universe of PHH's claims nor is it large enough to produce a standard precision and confidence level. In addition, the OIG failed to provide sufficient information to recreate either the sampling frame and the sample or the OIG's overpayment estimate. For all of these reasons, extrapolation of purported overpayments across the universe of PHH's claims is inappropriate.

IV. Response to OIG's Findings

The OIG's Report alleges that PHH did not comply with Medicare billing requirements for 21 out of the 100 hospice claims that the OIG audited, resulting in an alleged overpayment of \$3,358,906. Specifically, the OIG found that each of the allegedly improper 21 claims was billed improperly for the same reason: the beneficiary's medical record failed to support a terminal prognosis. The OIG's Report does not identify any other issue or error related to the audited claims other than a single instance of missing face-to-face documentation.

PHH takes allegations of improper billing seriously. To evaluate the OIG's findings, PHH conducted a clinical review of all the allegedly improper claims. PHH's auditor has over thirteen years of experience in hospice clinical operations and Medicare participation and reimbursement criteria. The PHH reviewer also has significant experience in hospice performing compliance audits, developing policies and procedures, and conducting survey readiness. Attached as Exhibit A to this response is the PHH auditor's curriculum vitae.

The PHH auditor reviewed the 21 allegedly improper claims and concluded the OIG's findings for all 21 of those claims are flawed because the patients' medical records actually do support the terminal prognosis for those claims. The auditor prepared rebuttal statements for those 21 claims, which are attached as Exhibit B to this response.¹⁰ In addition, certain of the specific audited claims that underscore the OIG medical reviewer's flawed approach and analysis are discussed in more detail below.

Because of the significant number of inaccurate findings and the questionable qualifications of the OIG's medical reviewer, PHH submits the OIG's medical findings must be reconsidered. Accordingly, PHH requests the audited claims be resubmitted for medical review with the appropriate standards and criteria applied to that re-review. As discussed herein and in the accompanying rebuttal statements, the OIG's medical reviewer applied incorrect criteria during the audit and issued inaccurate findings.

A. Difference in Clinical Judgment Does Not Render the Certifying Physician's Terminal Prognosis Invalid.

To be eligible for Medicare coverage of hospice services, a beneficiary must be entitled to coverage under Medicare Part A and must be certified as terminally ill.¹¹ A physician's certification of terminal illness or underlying clinical judgment of eligibility is the sole criterion

¹⁰ In addition to the rebuttal statements, PHH is submitting with its response additional portions of the medical record for Sample Patient No. 40, which further support the patient's terminal prognosis. Those medical records are included with the rebuttal statement for Sample Patient No. 40 as part of Exhibit B.

¹¹ 42 C.F.R. § 418.20.

set by Congress for establishing a patient's eligibility for the Medicare hospice benefit.¹² A beneficiary is terminally ill when he or she has a medical prognosis indicating that his or her life expectancy is six months or less if the illness runs its normal course.¹³ CMS has declined to create clinical benchmarks that must be satisfied to certify a patient as terminally ill.¹⁴ To the contrary, CMS specifically removed language from the regulations at issue that could be construed to imply that such benchmarks exist.¹⁵ A beneficiary's prognosis considers the diagnoses and all other things that relate to the beneficiary's life expectancy.¹⁶

Importantly, the determination of whether a beneficiary is terminally ill is necessarily a subjective clinical judgment based on review of the beneficiary's diagnosis of the terminal condition, other related or unrelated health conditions, and current clinically relevant information supporting all diagnoses.¹⁷ CMS has repeatedly emphasized that physicians are exclusively vested with determining whether a patient's condition is terminal.¹⁸ In some contexts, such as for cardiac procedures, a physician's certification of medical necessity can be proven "false" for False Claims Act or billing purposes.¹⁹ However, the hospice eligibility determination is unique in that, by design, it requires assessing the patient's prognosis based on the physician's own judgment.²⁰ As such, courts have recognized that a physician's "clinical judgment of terminal illness warranting hospice benefits under Medicare cannot be deemed false . . . when there is only a reasonable disagreement between medical experts as to the accuracy of that conclusion."²¹

Similarly, courts have rejected "that the supporting documentation must, standing alone, prove the validity of the physician's initial clinical judgment."²² The physician's judgment dictates eligibility, and the medical records must merely support, rather than prove, that judgment.²³ To be sure, rather than tasking its medical reviewers to prove or disprove the hospice's eligibility determination, CMS determined the "goal of any review for eligibility is to ensure that hospices are *thoughtful* in their eligibility determinations."²⁴ CMS has long recognized that making terminal prognoses is "not an exact science" and has acknowledged the deference owing to the physician's exercise of his or her "best clinical judgment" in making this determination.²⁵ CMS guidance highlights that, without exception, "certifying physicians have

¹² See 42 U.S.C. § 1395f(a)(7)(A).

¹³ 42 C.F.R. § 418.3.

¹⁴ 73 Fed. Reg. 32088, 32138 (Jun. 5, 2008).

¹⁵ See *id.*

¹⁶ 78 Fed. Reg. 48234, 48245-46 (Aug. 7, 2013).

¹⁷ 42 C.F.R. § 418.22(b); 42 C.F.R. § 418.25(b).

¹⁸ 78 Fed. Reg. 48234, 48247; see also 70 Fed. Reg. 70532, 70539 (stating that "[i]t is the physician's responsibility to assess the patient's medical condition and determine if the patient can be certified as terminally ill"); 73 Fed. Reg. 32088, 32138 (explaining here are no objective or "clinical benchmarks" that "must be met" for a physician "to certify terminal illness").

¹⁹ See, e.g., *U.S. ex rel. Polukoff v. St. Mark's Hosp.*, 895 F.3d 730, 743 (10th Cir. 2018).

²⁰ *United States v. AseraCare, Inc.*, 938 F.3d 1278, 1281, 1300 n.15 (11th Cir. 2019) (distinguishing *Polukoff* and holding a physician's reasonable clinical judgment of terminal illness cannot be false under the FCA where there is only a reasonable disagreement between medical experts as to the accuracy of that conclusion).

²¹ *Id.* at 1281; see also *U.S. ex rel. Wall v. Vista Hospice Care, Inc.*, 2016 WL 3449833, at *17 (N.D. Tex. June 20, 2016) (a "physician's disagreement with a certifying physician's prediction of life expectancy is not enough to show falsity").

²² *Id.* at 1294.

²³ *Id.*

²⁴ 79 Fed. Reg. 50452, 50470 (Aug. 22, 2014) (emphasis added).

²⁵ 79 Fed. Reg. 50452, 50470-71 (Aug. 22, 2014); 78 Fed. Reg. 48234, 48243.

the best clinical experience, competence and judgment to make the determination that an individual is terminally ill.”²⁶ CMS has emphasized that a physician who determines a patient is terminally ill “need not be concerned” about the risk of CMS penalties when certifying an individual for hospice care.²⁷

The alleged findings of error in the OIG’s Report are based entirely on a subjective difference in clinical opinion. The Report does not attack or challenge any certifying physician’s clinical determination of a terminal prognosis. The OIG’s medical reviewer did not find for *any* of the audited claims that the certifying physician failed to make that determination based on the physician’s good faith clinical judgment or that any physician was not thoughtful in determining that the patient had a terminal prognosis and was eligible to receive hospice services. Instead, the OIG’s reviewer determined in his or her own medical opinion, the portion of the patient’s medical record that the reviewer assessed did not support the terminal prognosis. As the Eleventh Circuit recognized in *AseraCare*, that difference in clinical judgment cannot render the physician’s certification false or invalid for billing purposes. Thus, because the OIG’s findings of error were based solely on a difference of clinical judgment, and because that subjective difference does not render the claims improper, the Report’s findings provide no basis for the recovery of an overpayment from PHH.

B. The Patients’ Medical Records Support a Terminal Prognosis for All 21 of the Allegedly Improper Claims Identified in the OIG’s Report.

Even if a difference in clinical judgment could effectively invalidate the certifying physician’s determination of terminal prognosis – which it cannot – the OIG’s medical reviewer’s clinical findings were flawed for all 21 of the claims that the reviewer deemed were billed improperly. As set forth above, the physician’s judgment dictates hospice eligibility, and the medical records must merely support, rather than prove, that judgment. CMS acknowledges a certifying physician is best positioned to make a terminal prognosis, and the goal of any eligibility review is to ensure that hospices are thoughtful in their eligibility determinations.

The OIG alleges the patient’s medical record does not support a terminal prognosis under Medicare standards for 21 of the 100 audited claims. PHH disagrees with all 21 of those determinations. The medical determinations provided by the OIG reveal that the OIG’s medical reviewer consistently failed to apply the appropriate standard for assessing whether the medical record supports the terminal prognosis.

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

²⁶ 78 Fed. Reg. 48234, 48247.

²⁷ CMS Program Memorandum: Provider Education Article: *Hospice Care Enhances Dignity and Peace As Life Nears Its End*, at 2 (Mar. 28, 2003).

In addition, CMS has specifically declined to create clinical benchmarks that must be satisfied to make a terminal prognosis and has advised that a certifying physician should consider the overall diagnoses and all other things that relate to the beneficiary's life expectancy in making a certification. The OIG's medical reviewer consistently failed to consider all of the relevant factors and information related to the patient's life expectancy. The OIG's reviewer's analysis was limited to a "snapshot" of the patient's medical condition at a particular point in time as illustrated by only a portion of the patient's medical record. In fact, the audit time period under review for each claim was only 30 days, which is not a complete hospice benefit period. Such a review is necessarily and inappropriately limited. The certifying physician, on the other hand, had access to all available factors and information relevant to the patient's life expectancy for the *entire* benefit period being certified, and the Report does not find that any physician failed to consider such information. This limitation further underscores the inherent flaws in both the OIG's audit process and the OIG's reviewer's findings.

The OIG's medical reviewer's consistently flawed analysis is evident in a number of the OIG's medical determinations. For example:

- **Sample Patient No. 8.** This 69-year-old patient was admitted to hospice due to Parkinson's disease with co-morbidity of Alzheimer's disease with behavioral disturbance. He was bedbound, experienced pain with turning, and was dependent for all activities of daily living. He continued to have poor skin integrity as evidenced by the deteriorating wound to the sacrum from stage I to stage II and was unable to continue with a condom catheter due to wound development. He experienced loss of muscle mass with MAC decreasing from 28.5 cm to 28 cm. The record also indicates a decrease in appetite from consuming 75% to 50% at times and continued difficulty swallowing. Continued agitation and hallucinations were reported, consistent with his Parkinson's diagnosis. The patient continued to experience a downward trajectory of decline and passed away within 7 months of the dates under review.

The OIG contends the patient's medical record does not support a terminal prognosis for the dates of service 6/1/2017 – 6/30/2017. The OIG's medical reviewer provides almost no support for that finding other than repeated, unsupported statements that "there was no documented evidence of decline" and there were no "other measures of significant decline between admission and current episode." To the contrary, the record contains numerous different indications of clear decline. And, the patient ultimately passed away within seven months of the episode of care at issue. The certifying physician's good faith medical determination of a terminal prognosis was not only supported by the patient's condition and reflected in the medical record at the time of recertification, but it was also quite accurate in hindsight.

- **Sample Patient No. 31.** This 81-year-old patient was admitted to hospice for Alzheimer's disease with co-morbidities of Parkinson's disease and stage 3 chronic kidney disease. She was bedbound, totally debilitated, and dependent for turning and all activities of daily living. She continued to have poor skin integrity with a documented stage 4 and multiple stage 3 wounds in the

preceding months. The patient's MAC decreased from 27 to 23. Her FAST score declined from 7C to 7D. Her cognitive skills remained diminished with disorientation and nonsensical speech.

The OIG contends that the patient's medical record does not support a terminal prognosis for the dates of service 7/1/2016 – 7/31/2016. The OIG's medical reviewer consistently referred to what was *not* reflected in the patient's medical record while ignoring the support for the terminal prognosis that the record contained. The OIG reviewer stated that there was no documentation of significant weight loss or difficulty of oral intake, ignoring both that the patient was bedbound and that her MAC decreased from 27 to 23. Despite what the reviewer asserted was not included in the record, the documentation exhibited many of the clinical indicators that a certifying physician would correctly and validly assess in determining a terminal prognosis with Alzheimer's disease and progression of Parkinson's disease based on good faith clinical judgment.

- **Sample Patient No. 42.** This 75-year-old patient was admitted to hospice for Parkinson's disease with co-morbidities of diabetes, atherosclerotic heart disease, and congestive heart failure. During the period in question, he declined from ambulatory with a walker to chair-bound and non-ambulatory. The patient also fell five times during this episode of care, one of which required a visit to the emergency room. His FAST score declined from 6B to 6D, and his PPS score declined to 30%. He became increasingly weak, and his cognitive skills remained diminished, with increased confusion and hallucinations.

The OIG contends that the patient's medical record does not support a terminal prognosis for the dates of service 3/4/2018 – 3/31/2018, the episode of care immediately following the patient's admission to hospice. The OIG's medical reviewer acknowledged that "there was a temporary decline during the episode" but reasoned that the claim was not proper because "the patient rebounded back to prior status." Not only did the patient not return to his "prior status" upon admission, but, even if he did, the patient's medical record clearly supports a terminal prognosis as the patient's "prior status." The patient experienced five falls in less than a month. Both his physical condition and his cognitive ability continued to decline during this initial episode of care. The patient's medical record contains clear clinical indicators of a terminal prognosis due to Parkinson's disease and the progression of dementia and heart disease.

- **Sample Patient No. 61.** This 93-year-old patient was admitted to hospice due to chronic obstructive pulmonary disease with co-morbidities of dementia and aortic valve stenosis. He had bladder obstruction and recurrent urinary tract infections. His FAST score was 6D, and his PPS score was 40%. He a high fall risk and experienced shortness of breath with minimal exertion. He had lost almost 13 pounds in the last month. He was dependent for five of six activities of daily living.

The OIG contends the patient's medical record does not support a terminal prognosis for the dates of service 9/1/2017 – 9/30/2017. The OIG's medical reviewer consistently cherry-picked selective portions of the patient's medical record while either ignoring or mischaracterizing other portions that clearly support a terminal prognosis. The reviewer acknowledged that the patient's PPS declined from 50% to 40% and that the patient was dependent for five of six ADLs, but noted that the patient was "able to ambulate with walker or cane, and able to self-propel wheelchair." Rather than acknowledge that the patient had lost almost 13 pounds over the last month, the reviewer stated misleadingly that the patient's "weight appeared to fluctuate throughout the 11 months" the patient was on service. Significantly, the OIG's reviewer found that the patient's ADEPT score was 17.8, suggesting a 57% probability of a prognosis of six months or less. Nonetheless, the reviewer ignored that score in the rationale for findings. Thus, the OIG's medical reviewer selectively relies on the patient's ADEPT score – which is not binding on or mandatory for hospice eligibility – and only considered it to be significant when the score did not reflect a prognosis of six months or less. Such arbitrary application and findings cannot refute the certifying physician's valid clinical judgment of a terminal prognosis.

As these examples demonstrate, the OIG's medical reviewer's findings with respect to documentation supporting terminal prognosis are demonstrably flawed. Throughout the review of audited claims, the OIG's reviewer applied specific clinical benchmarks to determine whether the terminal prognosis was appropriate. The patient's medical record, however, need only support the certifying physician's determination, not prove it. That is particularly true where the OIG's reviewer based his or her findings on a limited "snapshot" portion of the patient's medical record. For all 21 of the claims identified in the Report as not terminally ill, the medical records clearly support the certifying physician's terminal prognosis.

Accordingly, PHH requests the OIG's medical reviewer reconsider the claims for which the reviewer initially found that the patient's medical record does not support the terminal prognosis, particularly in light of the rebuttal statements that PHH is submitting with this response. Alternatively, PHH requests the OIG engage a different, qualified medical reviewer to audit the claims at issue, as the initial reviewer's medical determinations reflect a fundamental lack of understanding of hospice services generally and relevant Medicare regulations and guidance specifically.

C. Extrapolation of Overpayment Obligations is Inappropriate.

PHH objects to the OIG's use of extrapolation to arrive at an estimated overpayment amount. Extrapolation of Medicare overpayments is inappropriate unless there exists a "sustained or high level of payment error."²⁸ For purposes of extrapolation, a sustained or high level of payment error constitutes an error rate greater than or equal to a 50 percent error rate.²⁹

²⁸ 42 U.S.C. § 1395ddd(f)(3).

²⁹ See Medicare Program Integrity Manual, § 8.4.1.4. Although PHH recognizes the Medicare Program Integrity Manual is not binding on the OIG, the purported overpayments identified in the Report would be overpayments from Medicare, and extrapolation of Medicare overpayments absent a sustained or high level of payment error is inappropriate.

That is not the case here. Even accepting the OIG's initial audit results, the OIG found 79 of the 100 claims were 100% compliant with Medicare requirements and that 20 of the remaining 21 claims were 100% compliant in every aspect that the OIG audited except for one, whether the documentation supports the terminal prognosis.

In addition, even those remarkable compliance rates are conservative, as the OIG's medical reviewer erred in almost all of his findings that were adverse to PHH, which reduces the error rate to only 1% based on missing documentation of a single face-to-face encounter for one patient. A comprehensive review of the beneficiaries' complete medical records supports the certifying physician's determinations and establishes that PHH provided hospice services only to beneficiaries who were eligible for such services. Because no "sustained or high level of payment error" exists – even under the OIG's initial, un rebutted findings – extrapolation is inappropriate. In addition, PHH's auditor determined that the patient's medical record supported a terminal prognosis for all 100 of the sampled claims, constituting a perfect error rate of 0%. The OIG's own guidelines for claims reviews conducted pursuant to a Corporate Integrity Agreement require an error rate of 5% or greater to extrapolate the results of the sample across the full population of claims. Thus, extrapolation based on such a low error rate is inappropriate even under the OIG's own guidelines.

Extrapolation of the audit results across a broader set of claims also is inappropriate because the OIG's sampling and extrapolation methodology was flawed. PHH engaged [REDACTED] to evaluate the OIG's statistical sampling and extrapolation methodology. [REDACTED] is an expert in audit sampling and has extensive experience reviewing the sampling and extrapolation methods in reviews similar to the OIG's audit. He has a Ph.D. in Mathematical Statistics from Columbia University. [REDACTED] expertise focuses on experimental design/statistical inference, queuing theory/discrete event simulation, and optimal control and numerical methods, among other areas. He has over thirty years of experience conducting statistical and economic analyses similar to his analysis relative to the OIG's audit and Report. Attached as Exhibit C to this response is the Expert Report of [REDACTED], which addresses whether the statistical sampling methodology underlying the OIG's audit warrants the extrapolation of the sample findings to a broader universe of PHH's claims.

As discussed more fully in the [REDACTED] Report, the OIG's sampling methodology is flawed in numerous respects. First, the OIG ignored statistical principles by excluding potential underpayments or unpaid claims from its universe of claims. Removing such claims is, by itself, fatal to extrapolation. Removing those claims from the overall universe inappropriately alters the calculation of the amount that PHH should have been paid. And, that defect cannot be cured by sampling more claims or by drawing a new sample because the overall universe of claims is flawed. Extrapolation of audit results to conclude that an overpayment existed across a broader universe of claims is only appropriate where the extrapolation was made from a *representative* sample and was statistically significant.³⁰ The OIG has not established that its sample is representative of the total universe of PHH's claims.

The [REDACTED] Report also explains that the OIG's sample is not sufficient to achieve the standard precision and confidence level for this type of statistical estimate. The OIG did not even attempt to control the precision, resulting in a precision of 32% -- one of the worst

³⁰ See *Chaves County Home Health Serv., Inc. v. Sullivan*, 931 F.2d 914, 921-22 (D.C. Cir. 1991).

January 19, 2021

Page 14

precisions that [REDACTED] has seen in the more than 80 Medicare extrapolations he has reviewed. This precision fails to ensure that the recoupment amount does not exceed the actual overpayment amount. The OIG's attempt to extrapolate from the sample to the population with a 32% precision is a violation of OIG requirements and generally accepted statistical methods and is improper.

In addition, the OIG failed to provide information sufficient to recreate either the sampling frame or the sample. The OIG did not state the sort order of the sampling frame, which permitted the OIG to use any one of a large number of samples for extrapolation. Notably, without stating the sort order, the OIG was free to use any sort order that it chose, including a sort order that would intentionally maximize the recoupment amount. Similarly, the OIG also failed to provide the random number seed that was used to initialize the random number generator. Without that information, PHH cannot recreate the sample that the OIG used. The OIG's failure to document that seed allowed it to use any seed it desired, each of which would provide a different sample and hence a different overpayment amount. Thus, the OIG was free to experiment with different seeds and use the one that, based on characteristics of the claims in the sample generated from the seed, was likely to produce the highest overpayment estimate. For all of these reasons, even if the sample is determined to be valid – which it is not – the OIG's extrapolation methodology is invalid and cannot be used.

D. Conclusion

For the reasons discussed herein, the OIG's findings as set forth in the Report are flawed. With respect to the patients' terminal prognosis, the OIG's medical reviewer did not apply the correct standard to determine whether the patient's medical record supports a terminal prognosis and the patient's eligibility to receive hospice services. The OIG's reviewer also consistently failed to consider the totality of each patient's circumstances and each patient's individualized clinical condition and needs. The beneficiaries' medical records fully support both the terminal prognosis and the medical necessity of hospice services for all 21 of the audited claims that the OIG found to be billed in error.

PHH understands it will have the opportunity to challenge the Report's findings on appeal and is confident that those findings will be overturned. Nonetheless, PHH submits it should not be forced to incur the time and expense of an appeal in light of the flawed findings and requests that the OIG review and withdraw those findings without the need for an appeal. PHH is committed to providing only the highest quality hospice services to its patients while maintaining strict compliance with all applicable laws, rules, and regulations, and it appreciates the opportunity to comment on the OIG's findings before the Report is finalized.

Sincerely,

[REDACTED]
[REDACTED]

Enclosures