

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**MEDICARE HOSPICE PROVIDER
COMPLIANCE AUDIT:
TIDEWELL HOSPICE, INC.**

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Office of Inspector General

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Report in Brief

Date: February 2021

Report No. A-02-18-01024

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



Why OIG Did This Audit

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

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

How OIG Did This Audit

Our audit covered 33,024 claims for which Tidewell received Medicare reimbursement totaling \$116.7 million for hospice services provided during the period April 2016 through March 2018. We reviewed a random sample of 100 claims. We evaluated the services for compliance with selected Medicare requirements and submitted records associated with them to an independent medical review contractor who determined whether the services met coverage, medical necessity, and coding requirements.

Medicare Hospice Provider Compliance Audit: Tidewell Hospice, Inc.

What OIG Found

Tidewell did not comply with Medicare requirements for 18 of the 100 claims in our sample. For these claims, Tidewell claimed Medicare reimbursement for hospice services for which the clinical record did not support the beneficiary's terminal illness prognosis or the level of care claimed and for services that were not eligible for Medicare reimbursement.

These improper payments occurred because Tidewell's policies and procedures for ensuring that claims for hospice services met Medicare requirements were not always effective. On the basis of our sample results, we estimated that Tidewell received at least \$8.3 million in Medicare reimbursement for hospice services that did not comply with Medicare requirements.

What OIG Recommends and Tidewell Comments

We recommend that Tidewell: (1) refund to the Federal Government the portion of the estimated \$8.3 million in Medicare overpayments that are within the 4-year claims reopening period; (2) 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.

In written comments on our draft report, Tidewell, through its attorney, generally disagreed with our findings. Tidewell agreed in part with our first two recommendations and did not agree with our third recommendation. Tidewell disagreed with all but five claims questioned in our draft report. Tidewell asserted that the independent medical review contractor's conclusions were inaccurate or divergent from the clinical facts present in the medical records and appears to have glossed over the critical role of the physician's certification of terminal illness. Tidewell also engaged a statistical expert who challenged the validity of our statistical sampling methodology and the resulting extrapolation.

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

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INTRODUCTION

WHY WE DID THIS AUDIT

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

OBJECTIVE

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

BACKGROUND

The Medicare Program

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

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

The Medicare Hospice Benefit

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

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

² The Act §§ 1812(a)(4) and (5).

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

(3) inpatient respite care, and (4) continuous home care (CHC). Medicare provides an all-inclusive daily payment based upon 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, 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 prior to the effective date of election or the start of the subsequent benefit period.¹²

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

Effective for dates of service beginning January 1, 2016, hospices can claim a service intensity add-on (SIA) payment for direct patient care provided by a registered nurse and/or a social worker to a beneficiary receiving routine home care during the last 7 days of life.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 42 CFR §§ 418.22(a)(4), (b)(3)(v), and (b)(4).

¹⁴ To be eligible for an SIA payment, the beneficiary must be discharged from the hospice due to death (42 CFR §§ 418.302(b)(1)(i) and (ii)).

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 to 401.305; and 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

Tidewell Hospice, Inc.

Tidewell, located in Sarasota, Florida, is a not-for-profit hospice that provides services to patients with advanced illness, as well as support for their families throughout Sarasota, Manatee, Charlotte, and DeSoto counties. During the period April 1, 2016, through March 31, 2018 (audit period), Tidewell provided hospice services to approximately 14,500 beneficiaries and received Medicare reimbursement of almost \$125.5 million.¹⁹ Palmetto GBA, LLC (Palmetto), serves as the MAC for Tidewell.

HOW WE CONDUCTED THIS AUDIT

Our audit covered \$116,731,731 in Medicare reimbursement for 33,024 claims for hospice services provided by Tidewell during the audit period.²⁰ We reviewed a random sample of 100 of these claims to determine whether hospice services complied with Medicare requirements. Specifically, we evaluated compliance with selected billing requirements and submitted the 100 sampled claims and associated medical records to an independent medical review contractor who determined 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 contains the details of our audit scope and methodology, Appendix C contains our statistical sampling methodology, and Appendix D contains our sample results and estimates.

¹⁸ 42 CFR §§ 401.305(d), 405.980(c)(4), and 413.24(f); CMS' Provider Reimbursement Manual, Pub. 15-1-Part 1, § 2931.2; and 81 Fed. Reg. at 7670.

¹⁹ Claims data for the period April 1, 2016, through March 31, 2018, was the most current data available when we started our audit.

²⁰ In developing this sampling frame, we excluded from our audit, hospice claims that were identified in the Recovery Audit Contractor (RAC) data warehouse as having been reviewed by another party and claims that were previously reviewed by the Zone Program Integrity Contractor (ZPIC).

FINDINGS

Tidewell received Medicare reimbursement for hospice services that did not comply with Medicare requirements. Of the 100 hospice claims in our sample, 82 claims complied with requirements, but 18 did not. Specifically:

- For nine claims, the clinical record did not support the beneficiary's terminal prognosis.
- For six claims, the clinical record did not support the level of care claimed for Medicare reimbursement.
- For four claims, Tidewell claimed an SIA payment for services that were not eligible for Medicare reimbursement.

The total exceeds 18 because 1 claim contained more than 1 of the above errors.

These improper payments occurred because Tidewell's policies and procedures were not effective to ensure that the clinical documentation it maintained supported the terminal illness prognosis and that the appropriate level of care was provided. In addition, Tidewell claimed SIA payments for phone calls made by social workers—not for direct (i.e., in-person) patient care.

On the basis of our sample results, we estimated that Tidewell received at least \$8,305,371 in improper Medicare reimbursement for hospice services that did not comply with Medicare requirements.²¹ As of the publication of this report, this unallowable amount includes claims outside the 4-year period for reopening for good cause (the 4-year claims reopening period).²² Notwithstanding, Tidewell can request that a Medicare contractor reopen the initial determinations for those claims for the purpose of reporting and returning overpayments under the 60-day rule without being limited by the 4-year claims reopening period.²³

TERMINAL PROGNOSIS NOT SUPPORTED

To be eligible for the Medicare hospice benefit, a beneficiary must be certified as being terminally ill. Beneficiaries are entitled to receive hospice care for two 90-day periods, followed by an unlimited number of 60-day periods. At the start of the initial 90-day period of care, the hospice must obtain written certification of the beneficiary's terminal illness from the hospice medical director or the physician member of the hospice interdisciplinary group and the

²¹ To be conservative, we estimate overpayments at the lower limit of a two-sided 90-percent confidence interval. Lower limits calculated in this manner are designed to be less than the actual overpayment total 95 percent of the time.

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).

individual's attending physician, if any. For subsequent 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 supports the beneficiary's terminal prognosis must accompany the physician's certification and be filed in the medical record with the written certification of terminal illness.²⁴

For 9 of the 100 sampled claims, the clinical record provided by Tidewell 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.

LEVEL OF CARE NOT SUPPORTED

Medicare reimbursement for hospice services is made at predetermined payment rates—based on the level of care provided—for each day that a beneficiary is under the hospice's care. The four levels are (1) routine home care, (2) GIP care, (3) inpatient respite care, and (4) CHC.²⁵ GIP care is provided in an inpatient facility for pain control or acute or chronic symptom management that cannot be managed in other settings, such as the beneficiary's home, and is intended to be short-term.²⁶ CHC is provided during a period of crisis in which a patient requires continuous care, predominantly nursing care, to achieve palliation and management of acute medical symptoms necessary to maintain the individual at home.²⁷ CHC is the most expensive level of hospice care, followed by GIP care. Routine home care is the least expensive level of hospice care, followed by respite inpatient care, which is short-term care provided to relieve the beneficiary's caregiver (e.g., family member).

Our sample contained 28 claims for which Tidewell claimed Medicare reimbursement for a level of care with a higher payment rate (i.e., GIP or CHC). Specifically, Tidewell claimed reimbursement at the GIP payment rate for 25 claims and the CHC payment rate for 3 claims. For 6 of these 28 claims, Tidewell received Medicare reimbursement at the GIP or CHC payment rate; however, the associated beneficiary's clinical record did not support the need for the claimed level of care. Specifically, five of these claims were billed at the GIP payment rate; however, the independent medical review contractor determined that the associated beneficiaries did not have uncontrolled pain or unmanaged symptoms that could not have been managed in another setting and that these beneficiaries received care that could have been

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

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

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

²⁷ 42 CFR §§ 418.204(a) and 418.302(b)(2).

provided at home. For these five claims, the associated beneficiaries' hospice care needs could have been met if Tidewell provided services at the less expensive routine level of care.²⁸ The remaining claim was billed at the CHC payment rate; however, the independent medical review contractor determined that the associated beneficiary's clinical record did not support the beneficiary being in a period of crisis that required continuous care. Rather, CHC was ordered to provide relief to the beneficiary's usual caregiver. As such, the independent medical review contractor determined that the less expensive inpatient respite level of care was appropriate.²⁹

SERVICES NOT ELIGIBLE FOR MEDICARE REIMBURSEMENT

Effective for dates of service on or after January 1, 2016, hospices can claim an SIA payment for direct patient care provided by a registered nurse and/or a social worker to a beneficiary receiving routine home care during the last 7 days of life.³⁰ The SIA payment is in addition to the payment for services provided at the routine home care payment rate. In order to receive an SIA payment, a minimum of 15 minutes (1 unit) of nursing or social worker services must be provided in person.³¹ Social workers' phone conversations are not eligible for SIA payments.³²

For 4 of the 100 sampled claims, Tidewell claimed an SIA payment for services that did not meet Medicare requirements for payment. Specifically, for each of these claims, the associated medical records indicated that the SIA payment was related to a social worker's phone call to the beneficiary's family. As a result, Tidewell received SIA payments for social worker services that were not eligible for Medicare reimbursement.

²⁸ For four of the five claims, we questioned the difference in payment rates between GIP and routine home care. The other claim was also questioned because the terminal prognosis was not supported; therefore, we questioned the entirety of this claim.

²⁹ For this one claim, we questioned the difference in payment rates between CHC and inpatient respite care.

³⁰ 42 CFR § 418.302(b)(1).

³¹ 80 Fed. Reg. 47142, 47175 (Aug. 6, 2015). See also, CMS's *Medicare Claims Processing Manual*, Pub. 100-04, chapter 11, § 30.2.2.

³² 80 Fed. Reg. 47142, 47173 (Aug. 6, 2015).

RECOMMENDATIONS

We recommend that Tidewell Hospice, Inc.:

- refund to the Federal Government the portion of the estimated \$8,305,371 for hospice services that did not comply with Medicare requirements and that are within the 4-year claims reopening period;³³
- based upon the results of this audit, exercise reasonable diligence to identify, report and return any overpayments in accordance with the 60-day rule³⁴ and identify any of those returned overpayments as having been made in accordance with this recommendation; and
- strengthen its policies and procedures to ensure that hospice services comply with Medicare requirements.

TIDEWELL HOSPICE, INC., COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, Tidewell, through its attorney, generally disagreed with our findings. Tidewell agreed in part with our first two recommendations and did not agree with our third recommendation. Specifically, Tidewell disagreed with all but 5 of the 18 sample claims questioned in our draft report.³⁵ Tidewell agreed to return overpayments for the five claims that it agreed were in error.³⁶ However, Tidewell does not believe it was overpaid for hospice services that are within the 4-year reopening period except for the limited instances for which it already initiated a refund. Tidewell stated it has effectuated repayments for unallowable SIA payments that were not part of our sample and outside of our audit period. Tidewell did not agree with our recommendation to strengthen its procedures, as it believes its

³³ 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.

³⁴ 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.

³⁵ The five claims included four claims for which Tidewell received SIA payments for social worker services not eligible for Medicare reimbursement and one claim for which the associated beneficiary's clinical record did not support the need for the CHC level of care.

³⁶ We could not verify that Tidewell made repayments for the five questioned claims.

procedures are sufficiently strong to ensure that hospice services comply with Medicare requirements.

Tidewell asserted that the independent medical review contractors' conclusions were inaccurate or divergent from the clinical facts present in the medical records associated with our sample claims. Further, Tidewell stated that the independent medical review contractor appears to have glossed over the critical role of the physician's certification of terminal illness. Tidewell noted that, because relevant regulations only require that clinical information and other documentation support a terminal prognosis, it is wrong to conclude that such supporting documentation must prove the validity of a physician's clinical judgement. Therefore, according to Tidewell, no hospice claim should be denied when records support the certifying physicians' prognosis of terminal illness such that they made informed judgments on clinical eligibility. Tidewell further stated that a hospice expert it hired to review our sample claims believes that the hospice records provided during the audit supported the certifying physician's prognosis of terminal illness or the level of care provided. In its comments, Tidewell included the hospice expert's analysis—a claim-by-claim rebuttal to certain findings in our draft report. As an appendix to its comments, Tidewell also provided attestations from the physicians that oversaw the care of the beneficiaries associated with our sample claims. In them, the physicians reaffirmed their terminal prognosis and, where appropriate, the beneficiary's need for a higher level of care. Finally, Tidewell stated that since the OIG had not disclosed the identity or qualifications of the Independent medical review contractor, it does not know whether the contractor had hospice care qualifications.

Tidewell also engaged a statistical expert who analyzed OIG's sampling methodology and, based on that analysis, claimed there were inconsistencies in OIG's universe and sample, and that the sample and resulting extrapolation were not statistically valid. Tidewell also stated that OIG should not extrapolate the results of the audit since our findings do not contain a sustained or high level of payment error and since Tidewell was not subject to Medicare audits prior to this audit, thus making the use of extrapolation inappropriate. Tidewell's comments are included as Appendix E. Tidewell's statistical expert's report is included as Appendix F.³⁷

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

³⁷ Tidewell included several other attachments to its comments (e.g., attestations from the physicians that oversaw the care of the beneficiaries associated with our sample claims). We did not include these documents because were they voluminous, and some contained proprietary and personally identifiable information; however, they will be provided in their entirety to CMS.

TERMINAL PROGNOSIS NOT SUPPORTED

Tidewell Comments

Tidewell disagreed with our determinations for all nine claims in our draft report for which the independent medical review contractor found that the associated beneficiary's clinical records did not support the terminal illness prognosis. Tidewell asserted that there were inconsistencies in the independent medical review contractor's analysis and approach. Specifically, Tidewell stated that the contractor applied inconsistent and erroneous standards when determining whether documentation supported a terminal prognosis. Tidewell went on to state that the independent medical review contractor appeared to have used a rigid, post-hoc perspective on hospice eligibility and glossed over the critical role of the hospice physician's clinical belief that the beneficiaries were terminally ill. Lastly, Tidewell contended that while the independent medical review contractor appropriately summarized the facts and medical conditions reflected in the clinical record of each sample claim, it did not arrive at the appropriate clinical conclusions based on those facts.

Office of Inspector General Response

Based on our review of Tidewell's comments, including its hospice expert's analysis, we maintain that the clinical records for the nine claims did not support the associated beneficiary's terminal prognosis. We disagree with Tidewell's assertions that there were inconsistencies in the independent medical review contractor's analysis and approach, that the contractor's conclusions were inaccurate or divergent from the clinical facts, and unsupported by a reasonable clinical review. We also disagree that the contractor glossed over the critical role of the physician's certification of terminal illness. We used an independent medical review contractor that was a licensed physician who specializes in hospice and palliative medicine and is familiar with Medicare hospice guidelines and protocols. In conducting the medical review, the contractor properly used the appropriate statutory and regulatory hospice criteria, as well as applicable Local Coverage Determination (LCD) guidelines, as the framework for its determination of terminal status. Specifically, the medical review contractor applied standards set out in 42 CFR § 418.22(b)(2), which requires clinical information and other documentation that support the medical prognosis to accompany the certification and be filed in the medical record.³⁸ In addition, the independent medical review contractor did not gloss over the critical role of the hospice physician's certification of terminal illness. Rather, the contractor acknowledged the physician's terminal diagnosis and evaluated the medical records for each hospice claim, guided by questions rooted in the Medicare requirements, to determine whether the certified terminal prognosis was supported. When the medical records and other available clinical factors supported the physician's medical prognosis, a determination that hospice eligibility criteria were met was made.

³⁸ Applicable LCD guidelines also state that the documentation must contain enough information to support terminal illness upon review.

LEVEL OF CARE NOT SUPPORTED

Tidewell Comments

Tidewell disagreed with five of the six claims identified in our draft report for which the associated beneficiary's clinical record did not support the need for GIP level of care (four claims) or CHC level of care (one claim).³⁹ For each of these claims, Tidewell stated that the payment rate claimed was reasonable and necessary given the patient's clinical condition. Specifically, for the four claims for which the independent medical review contractor found the need for the GIP level of care was not supported, Tidewell contended that the associated beneficiaries were suffering from acute exacerbations of symptoms that could not have been effectively managed outside of a facility setting and, as such, the GIP level of care was appropriate. To further support its contention that the GIP level of care was appropriate, Tidewell referred to guidance from Palmetto (issued August 2019) related to the GIP level of care. According to the guidance, the GIP level of care is appropriate when a patient needs medication adjustment, observation, or other stabilizing treatment. Lastly, for the one other claim for which the independent medical review contractor found that the need for the CHC level of care was not supported, Tidewell asserted that that level of care was appropriate because the beneficiary was in crisis and needed such care to manage their acute symptoms and maintain the beneficiary at home.

Office of Inspector General Response

After reviewing Tidewell's comments, including its hospice expert's analysis, we maintain that the clinical records for these five claims did not support the need for the claimed payment rate. Specifically, for the four claims for which the independent medical review contractor found the need for the GIP level of care was not supported, the contractor determined that the associated beneficiaries did not have uncontrolled pain or unmanaged symptoms that could not have been managed in another setting. Additionally, the Palmetto guidance referenced by Tidewell was not met. Specifically, the independent medical review contractor found that the clinical records for the four beneficiaries did not support that they required or were receiving frequent medication adjustments or the need for frequent observation by a physician or nurse. For the one claim billed at the CHC payment rate, the independent medical review contractor determined that the care provided was predominantly non-skilled and provided for the convenience of the family.

³⁹ For the remaining claim, Tidewell acknowledged that the beneficiary had been admitted for inpatient respite care but due to a coding error, the GIP level of care was incorrectly claimed and reimbursed.

OFFICE OF INSPECTOR GENERAL SAMPLING METHODOLOGY

Tidewell Comments

Tidewell challenged the validity of our statistical sampling methodology, engaged a statistical expert to review OIG's sampling methodology and provided a copy of the statistical expert's report. The statistical expert claims that OIG's sample and extrapolation are not statistically valid and therefore are not an adequate foundation for seeking recoupment of \$8,305,371 because: (1) OIG made multiple mistakes in documenting and selecting its sample; (2) the audit findings did not meet the high error rate criteria in CMS's *Medicare Program Integrity Manual* (MPIM) to justify the use of extrapolation; (3) the precision was too wide to result in a valid estimate; (4) the order of the sampling frame was not sufficiently documented, and as such, OIG could have manipulated its sample selection; and (5) OIG ignored statistical principles by excluding zero paid claims from its sampling frame.

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.⁴⁰ We properly executed our statistical sampling methodology in that we defined our sampling frame and sampling unit, randomly selected our sample, applied relevant criteria in evaluating the sample, and used statistical sampling software (i.e., OIG/OAS' statistical software RAT-STATS) to apply the correct formulas for the extrapolation. After selecting our sample, we identified three claims in the sampling frame that were under review by a CMS contractor. Our general approach for handling such claims is to treat them as having no overpayments if they are selected in the sample. This approach ensures an unbiased point estimate and a valid lower limit. Contrary to the statistical expert's assertions, there was only one sample selected and it was selected from the original sampling frame (33,027). The reduced sampling frame count (33,024) was only used to calculate the estimated overpayment amount. Lastly, Tidewell's expert notes that the paid amounts for two sampled claims differ between the results file and the sampling frame file. As our methodology describes below, we reviewed data from CMS's Common Working File for all 100 sampled claims to determine whether the claims had been canceled or adjusted and determined that Tidewell had adjusted these two claims. Accordingly, we used the adjusted payment amounts for these two claims to ensure our overpayment calculation reflected the correct payment amounts. Contrary to the statistical expert's claim, those adjustments do not reflect a different sample.

We note the MPIM requirement cited by the statistical expert (that a determination of a sustained or high level of payment error must be made before extrapolation) applies only to

⁴⁰ 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).

Medicare contractors—not OIG.⁴¹ We further note that the statutory provisions upon which the MPIM guidelines are based do not prohibit CMS from accepting and acting upon our monetary recommendation.

We disagree with Tidewell’s statistical expert’s assertion that our audit precision was too wide to result in a valid estimate. Specifically, to account for the precision of our estimate, we recommend recovery at the statistical lower limit of a two-sided 90-percent confidence interval. Lower limits calculated in this manner are designed to be less than the actual overpayment 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.⁴² In 95 percent of the cases where the lower limit is less than the actual overpayment, the provider will pay substantially less, on average, given a less precise design. The provider focuses on the 5 percent of cases where the provider may have to pay more to the Federal Government; however, these cases are inherently rare, and when they arise, the amount the provider may have to over-reimburse to the government tends to be small.⁴³

The statistical expert’s claim that OIG did not sufficiently document the order of OIG’s sampling frame is also not correct. Our audit workpapers specifically contained detailed information on how the frame was sorted. That information was used by an auditor not part of the audit team to validate the sample selection. There was no manipulation of the sampling frame after the random sample was selected. Rather, the sampling frame was finalized prior to generating the random numbers. We also note that the sampling frame was sorted using the DSY_VW_REC_LNK_NUM field, which uniquely identifies claims in OIG’s copy of CMS’s National Claims History (NCH) file.

Lastly, Tidewell’s statistical expert relied heavily on the MPIM in its arguments that the removal of zero-paid claims ignored statistical principles. As previously stated, the MPIM does not apply to OIG. However, if it did, it expressly allows for the removal of claims/claim lines that are attributable to sample units for which there was no payment.⁴⁴ More generally, OIG may perform a statistical or non-statistical review of a provider without covering all claims from that provider.

⁴¹ See Social Security Act § 1893(f)(3); CMS MPIM, Pub. No. 100-08, ch. 8, § 8.4.1.4 (effective January 2, 2019).

⁴² 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).

⁴³ Tidewell’s statistical expert claims that in 5 percent of samples from our design, Tidewell would have to over-reimburse the Federal Government over 4-and-a-half times more than a design with 10-percent precision. We disagree with this assertion as a factual matter. The positive skew of the data makes the lower limit more conservative than would be expected given the theoretical calculations. In our own tests of the current data, we found evidence that the less precise design is more conservative, on average, even for the 5 percent of cases highlighted by the statistical expert.

⁴⁴ CMS MPIM, Pub. No. 100-08, ch. 8, § 8.4.3.2 (effective January 2, 2019).

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

Our audit covered 33,024 hospice claims for which Tidewell received Medicare reimbursement totaling \$116,731,731 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 Tidewell'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 Tidewell's office in Sarasota, Florida.

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 Palmetto officials to gain an understanding of the Medicare requirements related to hospice services;
- met with Tidewell officials to gain an understanding of its policies and procedures related to providing and billing Medicare for hospice services and reviewed those policies and procedures;
- obtained 35,441 hospice claims, totaling \$125,461,450,⁴⁵ from the CMS NCH file, for the audit period;
- excluded 2,414 claims, totaling \$8,721,460, that were identified in the RAC data warehouse as having been reviewed by another party;
- created a sampling frame consisting of 33,027 hospice claims, totaling \$116,739,990;
- selected a random sample of 100 hospice claims from the sampling frame;

⁴⁵ We excluded claims that were zero-paid; however, an individual line can have a zero payment.

- identified and excluded 3 claims, totaling \$8,259, that were previously reviewed by the ZPIC;⁴⁶
- created an adjusted sampling frame consisting of 33,024 hospice claims, totaling \$116,731,731, to calculate the statistical estimate;
- 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;
- worked with Palmetto to identify the date the NOEs were submitted for each sampled claim and determined the timeliness of the submission;
- obtained medical records for the 100 sampled claims and provided them to an independent medical review contractor, who determined whether the hospice services complied with Medicare requirements;
- reviewed the independent medical review contractor's results and summarized the reason(s) a claim was determined to be improperly reimbursed;
- estimated the amount of the improper Medicare payments made to Tidewell for hospice services; and
- discussed the results of our audit with Tidewell 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.

⁴⁶ These 3 claims were not part of our random sample of 100 claims.

APPENDIX B: RELATED OFFICE OF INSPECTOR GENERAL REPORTS

Report Title	Report Number	Date Issued
<i>Medicare Hospice Provider Compliance Audit: Hospice Compassus, Inc., of Tullahoma, Tennessee</i>	<u>OAS-02-16-01024</u>	12/16/2020
<i>Medicare Hospice Provider Compliance Audit: Hospice Compassus, Inc., of Payson, Arizona</i>	<u>OAS-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>OAS-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>OAS-02-11-01016</u>	9/23/2014
<i>Servicios Suplementarios de Salud, Inc., Improperly Claimed Medicare Reimbursement for Some Hospice Services</i>	<u>OAS-02-11-01017</u>	8/7/2014

APPENDIX C: STATISTICAL SAMPLING METHODOLOGY

SAMPLING FRAME

The sampling frame was an Access database containing 33,027 Medicare Part A reimbursed claims, totaling \$116,739,990, for hospice services provided by Tidewell from April 1, 2016, through March 31, 2018.⁴⁷ The data was extracted from the CMS NCH file. After selecting the sample, we identified three claims in the sampling frame that were previously reviewed by a ZPIC. None of these claims appeared in the sample. To account for these three claims, we used an adjusted frame size of 33,024, totaling \$116,731,731, when calculating our statistical estimate.

SAMPLE UNIT

The sample unit was a Medicare Part A hospice claim.

SAMPLE DESIGN

We used a simple random sample.

SAMPLE SIZE

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

SOURCE OF THE RANDOM NUMBERS

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

METHOD FOR SELECTING SAMPLE ITEMS

We consecutively numbered the hospice claims in our sampling frame. After generating 100 random numbers, we selected the corresponding frame items.

ESTIMATION METHODOLOGY

We used the OIG/OAS statistical software to estimate the total amount of improper Medicare payments made to Tidewell for unallowable hospice services during the audit period. 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 improper payment total 95 percent of the time.

⁴⁷ The sampling frame excluded zero-paid claims and 2,414 claims that were identifiable in the Recovery Audit Contractor data warehouse as having been reviewed by another party.

APPENDIX D: SAMPLE RESULTS AND ESTIMATES

Sample Details and Results

Number of Claims in Adjusted Frame	Value of Adjusted Frame	Sample Size	Value of Sample	Number of Unallowable Claims	Value of Overpayments in the Sample
33,024	\$116,731,731	100	\$363,497	18	\$46,569

Estimated Value of Overpayments
(Limits Calculated for a 90-Percent Confidence Interval)

Point Estimate	\$15,378,781
Lower Limit	\$8,305,371
Upper Limit	\$22,452,192

APPENDIX E: TIDEWELL HOSPICE, INC., COMMENTS



Dear Ms. Tierney:

Tidewell Hospice serves more than 1,000 patients every day and more than 9,000 patients and their families every year. Our patients and their families come from Florida counties with a large population of senior citizens – Sarasota, Manatee, Charlotte and DeSoto.

We provide our end-of-life patients and their families with compassion and world-class hospice care. Tidewell has operated its hospice program for more than 40 years, having opened at a time before Medicare began covering hospice services for its beneficiaries. Our not-for-profit mission of providing world-class care to patients is the north star guiding our organization.

We strongly advocate for the very best care for our patients and our commitment to our patients is unwavering. We respectfully disagree with the OIG contractors' findings with respect to the real-time, patient-focused clinical judgments of our medical professionals.

Also, Tidewell Hospice is committed to ensuring that our hospice patients meet Medicare's clinical eligibility standards to receive our end-of-life care services, as determined by physicians under Medicare's rules. For instance,

- We have in place a highly-developed process for conducting Medicare clinical eligibility reviews;
- Our admissions practices include a certification of terminal illness from two physicians;
- A comprehensive clinical assessment is made by a registered nurse trained in hospice and palliative care; and
- Changes in a patient's level of care must be approved by a physician based on the patient's active symptoms.

Providing end-of-life care for patients consistent with Medicare hospice benefit requirements is a responsibility that we fully embrace. As stewards of both the Medicare program's funds and our patients' care, our team members must balance Medicare's stringent benefit requirements with providing our patients with ethical and responsible medical care based on the changing needs of each individual patient under our care.

It is within this environment that we have diligently and carefully reviewed the HHS Office of Inspector General's (OIG) Draft Audit Report of our hospice program that

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focuses on Medicare hospice services provided from April 1, 2016 to March 31, 2018. We take the OIG's audit of our hospice program very seriously. Since the OIG first notified us of the preliminary audit findings, we have worked diligently to identify the issues that could lead to a potential Medicare overpayment. We fundamentally disagree with the OIG Draft Report's observations that Tidewell's policies and procedures are, in part, ineffective or require substantive modification. From Tidewell's critical lens, our policies, procedures, and people, have been at the core of our not-for-profit mission for which we stand. Our commitment to patient advocacy and compliance are steadfast every day.

In response to the OIG's audit of our program, we engaged independent and acclaimed experts to review the OIG's claims sample. The experts include a hospice physician expert, an experienced PhD statistician, as well as external legal counsel.

Dr. Janet Bull, the independent expert engaged by Tidewell, is a board-certified hospice and palliative care physician and is the past President (2017) of the American Academy of Hospice and Palliative Medicine. Dr. Bull reviewed each of the records where OIG concluded Medicare coverage was not authorized and determined that there was adequate record support for the terminal condition of each of the claims for the patients in the sample.

This level of clinical accuracy and thorough documentation is significantly above the industry average. This not only affirms that our processes, policies, and procedures are effective, but also that our clinicians are making appropriate and informed decisions around prognosis and that the clinical records sufficiently support those determinations around prognosis.

CMS has long recognized that issues of life and death do not always follow a precise or predictable trajectory or timeline. Our experts find many of the OIG's outside medical review contractor findings to be unsupported. The findings of our experts are presented in a case-by-case detailed response in the package submitted by our legal counsel. Tidewell's independent hospice expert fundamentally disagrees with the OIG contractor's clinical review findings in nearly every sampled claim for which they believed clinical support was lacking and provided substantiation for her views. We believe the Tidewell certifying physicians were correct to certify and recertify eligibility for the hospice patients selected in OIG's sample.

In certain cases, gauging each patient's end of life journey is not as precise as the physician, payor, patient or family would like it to be. Just because a hospice patient, who elected hospice care, does not pass away within six months from when a physician determined the patient was terminally ill, does not mean that the patient did

not qualify for hospice care. Nor does it mean that the certifying physicians were wrong in their medical prognostication. Plainly stated, death and dying is individualized from person to person and Tidewell walks with our patients every step of the way.

Our detailed response follows this letter. We hope that you and the agency will carefully consider it as part of a review of your findings. Thank you.

~~Yours~~ in the mission,

/Jonathan Fleece/

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Tidewell Hospice

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November 3, 2020 (revised 11/17/20)

BY FEDERAL EXPRESS AND ELECTRONIC MAIL

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

Re: Tidewell Hospice, Inc.; Report No. A-02-18-01024

Dear Ms. Tierney:

Tidewell Hospice, Inc. ("Tidewell"), through its counsel,¹ submits this letter in response to the U.S. Department of Health and Human Services ("HHS"), Office of Inspector General's ("OIG") draft audit report (A-02-18-01024) dated September 4, 2020 (the "Draft Report"). Tidewell appreciates OIG allowing an extension through November 4, 2020, to provide comments to the Draft Report.² Tidewell respectfully disagrees with all of the Draft Report's unfavorable determination findings related to hospice eligibility (9 claims) and clinical need for a higher level of care (5 claims). The payments for those fourteen (14) claim denials totaled \$46,456.44.³ Tidewell agrees with the four (4) denials for the Service Intensity Add-on ("SIA") payment that totaled \$112.06, as well as one (1) denial for higher level of care. In sum, Tidewell believes the review findings of OIG's

¹ The individuals listed in Attachment A hereby authorize the release of their personally identifiable information included in this letter and consequently OIG need not redact such information in its final audit report. **Attachment A – Authorizations for PII.**

² These comments were updated on November 17, 2020 in response to request by OIG for clarification.

³ For one claim, OIG made an unfavorable finding both as to hospice clinical eligibility and whether a higher level of care for a single day was reasonable and necessary. Tidewell furnished respite care on that day and the charge reflects a respite care day. However, on account of an error in the revenue code field on that claim, Tidewell agrees with OIG's finding that it mistakenly billed for the general inpatient level of care (\$530.91 (the difference between general inpatient and respite care payments)), but disagrees with OIG's finding as to hospice eligibility (\$4,150.89).

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supported inasmuch as their medical reviewers appeared to have used a rigid, post-hoc perspective on hospice eligibility under the Medicare benefit and glossed over the critical role under the law of the hospice physicians' reasonable clinical belief that the beneficiaries were terminally ill. As described in greater detail below, one of the lynchpins to qualifying for the Medicare hospice benefit is the reasonable clinical determinations by one or more certifying physicians as to whether an individual is terminally ill, meaning that individual has a life expectancy of six months or less if the illness runs its normal course. The Centers for Medicare & Medicaid Services ("CMS") has specifically noted that terminal prognostication is not an exact science and made clear that hospice claims should not be denied when a certifying physician has a good faith clinical belief that the patient's medical condition will likely result in death in six (6) months or less. Importantly, physicians are not required to prognosticate with 100% certainty. As the United States Court of Appeals for the Eleventh Circuit (which includes Florida) found in its *AseraCare* decision, under the Medicare hospice benefit the certifying physician's certification of terminal illness ("CTI") must be given great weight and that:

[T]he relevant regulations require only that "clinical information and other documentation that support the prognosis . . . accompany the certification" and "be filed in the medical record." This "medical prognosis" is, itself, "based on the physician's . . . clinical judgment." 42 C.F.R. § 418.22(b). To conclude that the supporting documentation must, standing alone, prove the validity of the physician's initial clinical judgment would read more into the legal framework [of the Medicare statute] that its language allows. . . [t]hat is, the [certifying] physician's clinical judgment dictates eligibility as long as it represents a reasonable interpretation of the relevant medical records.³

Further, the Eleventh Circuit court correctly found that the hospice clinical record in "support" of the physicians' CTI does not have to be a chronicle of every detail of the hospice patient's clinical condition that "proves" the patient was terminally ill.⁴

The OIG IMRC reviewers appeared to have applied an overly narrow and legally impermissible approach to their hospice clinical record review as to what the Medicare hospice benefit requires to support a terminal prognosis. OIG's Draft Report does not conclude medically appropriate services were not furnished; nor does the Draft Report contend that the hospice physicians failed to certify in good faith that each patient had a terminal prognosis for each hospice benefit period under review. Instead, the Audit Report findings are premised on conclusions of the IMRC reviewers who for 9 patients found insufficient record support for the contemporaneous clinical decision making of the hospice physicians who certified the patients as terminally ill during the audit period. Tidewell engaged a renowned independent hospice and palliative care physician to review the same records (Janet Bull, M.D., FAAHPM), and Dr. Bull disagrees with each of the 9 OIG IMRC

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

⁴ *Id.* at 1293-94.

terminal prognosis for each hospice benefit period under review. Instead, the Audit Report findings are premised on conclusions of the IMRC reviewers who for 9 patients found insufficient record support for the contemporaneous clinical decision making of the hospice physicians who certified the patients as terminally ill during the audit period. Tidewell engaged a renowned independent hospice and palliative care physician to review the same records (Janet Bull, M.D., FAAHPM), and Dr. Bull disagrees with each of the 9 OIG IMRC review findings as to whether the hospice records support the determinations by the hospice physicians that these patients would, more likely than not, die within six months if the illnesses ran their normal course.

The *AseraCare* opinion is instructive here because it is the most complete explication by a federal court of the Medicare hospice benefit's legal requirements on the documentation that "supports" a terminal prognosis and the role of that documentation in support of a physician's CTI, especially when one physician reviewer believes the records do not support the patient was terminally ill and when another physician reviewer disagrees. That *AseraCare* opinion spends several pages discussing the Medicare hospice benefit legal requirements⁶ as to how the Medicare statute must be interpreted. Importantly for purposes of the OIG's reconsideration of its Draft Report findings and why its IMRC reviewers' findings are legally flawed, the Court noted that:

[H]ad Congress or CMS intended the patient's medical records to objectively demonstrate terminal illness, it could have said so. Yet Congress said nothing to indicate that the medical documentation presented with a claim must prove the veracity of the clinical judgment on an after-the-fact review. And CMS's own choice of the word "support" – instead of, for example, "demonstrate" or "prove" – does not imply the level of certitude the Government wishes to attribute to it.⁷

The Court went on to observe "[m]ore broadly, CMS's rulemaking commentary signals that well-founded clinical judgments should be granted deference."⁸

The Court in *AseraCare* had it right. Tidewell respectfully requests that OIG reconsider its IMRC medical review findings in a manner consistent with the *AseraCare* decision's binding interpretation (for Florida and other states within the Eleventh Circuit) of the Medicare hospice statute and corresponding regulatory framework. For OIG to embrace its IMRC's findings when they run counter to the intended purpose of Medicare statute, Medicare's hospice coverage, and the holding of the Eleventh Circuit will not protect the Medicare hospice benefit, but rather will do it (and our client Tidewell's patients) an injustice by further perpetuating a legally faulty medical documentation standard. To be clear, this is not to suggest that hospice physician judgments warrant unfettered deference under the Medicare program. Tidewell believes, to the contrary, those certifying physicians' clinical

⁶ *Id.* at 1291-94.

⁷ *Id.* at 1294.

⁸ *Id.* at 1295.

judgments must be reasonable. To that very point, and critical to OIG's consideration of Tidewell's comments to the Draft Report:

[W]hile there is no question that clinical judgments must be tethered to a patient's valid medical records, it is equally clear that the law is designed to give physicians meaningful latitude to make informed judgments without fear that those judgments will be second-guessed after the fact by laymen in a liability proceeding.⁹

For the reasons offered in the balance of this response letter (which contains no PHI or other identifiable patient information), and in the detailed, claim-by-claim response in the confidential attachment (which contains protected health information and which Tidewell presumes will not be publicly posted by OIG), Tidewell strongly believes, as does the hospice physician expert it engaged to review OIG's claim denial determinations (Janet Bull, M.D., FAAHPM), that the hospice records do support the Tidewell certifying physicians' prognosis of terminal illness such that they made informed judgments on clinical eligibility. In further support of the informed clinical judgments of the certifying physicians as to terminal prognosis, Tidewell also provides attestations from those hospice physicians who oversaw the care of these Tidewell patients. In particular, these physicians continue to affirm their reasonable clinical view that their respective patients at issue in this OIG audit were eligible for Medicare hospice care (or a higher level of care, as applicable) during the period under review. **Attachment B – Physician Attestations** (which also contain protected health information and which Tidewell presumes will not be publicly posted by OIG).

DETAILED RESPONSE TO OIG DRAFT REPORT A-02-18-01024

Tidewell fully disagrees with the Draft Report's determination on thirteen (13) of the eighteen (18) claims (for which Medicare payment was \$41,774.64) where OIG determined Medicare requirements were not met. Tidewell partially disagrees with one (1) claim where OIG asserts that the patient was not eligible for Medicare hospice services and that Tidewell billed for a higher level of care. Tidewell received Medicare payment of \$4,681.80 for this month of service and disagrees with OIG's eligibility determination but agrees that it received an excess payment \$530.91 (the payment differential between GIP and respite care). The financial value of the four (4) SIA claims with which Tidewell agrees with the Draft Report findings is \$112.06. Tidewell's fundamental disagreement relates to the conclusions of the IMRC reviewers, which are inaccurate or divergent from the clinical facts present, unsupported by a reasonable clinical review of the record, and stem from a lack of credit for the certifying hospice physician's prospective decision-making on terminal status.

The specific responses for each clinical denial reason are contained in **Attachment C – Tidewell Expert Response**. In addition, several HIPAA de-identified examples of where the IMRC reviewers arrived at incorrect clinical conclusions are set forth below.

⁹ *Id.*

I. INTRODUCTION: OVERVIEW OF TIDEWELL AND HOSPICE CARE

Tidewell Hospice is a not-for-profit hospice located on the Gulf Coast of Florida that has supported its community with high quality hospice services for over 40 years, before the Medicare hospice benefit was established. Tidewell serves more than 1,000 patients each day in Sarasota, Manatee, Charlotte, and DeSoto counties. As an established and leading provider of hospice care, Tidewell is acutely aware that its program operates in a highly regulated environment and acts as a steward of Medicare and other valuable healthcare program funds. Tidewell has, since its inception, believed that hospice care can provide beneficiaries who elect the benefit with the best care for patients and their families living with terminal illness in a home or home-like setting, consistent with the patient's desires for end-of-life care and at a considerable savings over expensive, acute care in settings like hospitals. While high quality end-of-life care is its highest priority, Tidewell also has demonstrated a keen focus on appropriately documenting those services.

Tidewell offers hospice and palliative care services, including general inpatient care, respite care, spiritual care, physical and occupational therapy, dietary counseling, grief counseling, and hospice aides among other services. Tidewell employs or contracts with a team of leading hospice physicians (including its primary Medical Director and Chief Medical Officer Neville Sarkari, M.D., FACP) and nurse practitioners, in addition to a full contingent of nursing staff, aides, social workers, chaplains, and volunteers. Tidewell operates eight (8) bright and cheerful Hospice Houses specifically designed for inpatient hospice care (general inpatient care and respite care) that are staffed 24 hours a day with daily physician care and staff that specializes in end-of-life care. Tidewell also offers programs to enhance end of life care, such as Tidewell Honors Veterans, a comprehensive program focused on respectfully celebrating veterans and providing care that recognizes the unique challenges that may exist in military families.

Hospice care is a comprehensive suite of services identified and coordinated by a patient's attending physician (if the patient has one), a hospice physician, and interdisciplinary group ("IDG") to provide for the physical, psychosocial, spiritual, and emotional needs of a terminally ill patient and their family members. As required by law, Tidewell is certified to provide hospice care by CMS, accredited by Community Health Accreditation Partners (CHAP), and meets the required hospice Conditions of Participation. According to CMS regulations, "terminally ill individuals" are patients with a medical prognosis including a life expectancy of six (6) months or less, if the illness runs its normal course. In order to be eligible for the hospice benefit under Medicare, a patient must be eligible for Part A benefits and be certified as terminally ill by a physician. Each patient is assessed by a hospice medical director for hospice eligibility, in consultation with the patient's attending physician (if the patient has one). When considering admission, medical directors assess the patient's terminal condition, other health conditions, and the clinically relevant information supporting each diagnosis. A medical director may obtain clinically relevant information directly or indirectly from the patient's attending physician and/or through hospice nurses' assessment of the patient and the patient's medical history, as well

as other pertinent sources. For the initial ninety-day certification period, the medical director (or a physician member of the IDG) and attending physician must both sign the written CTI (again, if the patient has so designated an attending). For each subsequent certification period the medical director (or a physician member of the IDG) may certify a patient's terminal status. Each certification of terminal illness must be supported by the patient's condition as reflected in the hospice's medical records.

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

II. SUMMARY OF DRAFT REPORT FINDINGS

As part of its audit, OIG selected 100 claims submitted by Tidewell between April 1, 2016 and March 31, 2018. During this time, Tidewell submitted 33,024 Medicare claims for reimbursement for hospice care provided to approximately 9,000 patients and their families annually for which Tidewell received an approximate total of \$116.7 million in Medicare payments. From these 100 random claims, the IMRC determined eighteen (18) did not comply with one or more Medicare requirements. OIG then extrapolated the financial results of this sample to the complete universe of Medicare paid claims during the audit period and estimated that Tidewell received \$8.3 million in Medicare overpayments.

OIG identified three (3) distinct bases for denial among Tidewell's claims:

- 1) The medical record did not support terminal illness (nine (9) claims);
- 2) The medical record did not support the need for a higher level of care (six (6) claims);
- 3) Service intensity add-on payments were made for social worker telephonic visits instead of in-person visits in the last seven days of life (four (4) claims).

There are nineteen (19) total errors but only eighteen (18) total claims because one (1) of the claims was determined by OIG to have both a clinical eligibility and higher level of care error. The Draft Report asserts that while Tidewell had policies and procedures related to determining eligibility, they were not effective to ensure that the Medicare requirements were met and that the appropriate level of care was provided.

To remedy these issues, the Draft Report makes several recommendations, namely that Tidewell should: (1) return overpayments received within the four (4)-year claims reopening period; (2) use reasonable diligence to identify and return improper payments falling outside of the four-year reopening period in accordance with the "60-Day Rule"; and (3) strengthen its procedures to ensure that Tidewell's hospice services comply with Medicare requirements. Tidewell addresses each of these recommendations below.

III. ANALYSIS OF DRAFT REPORT

Tidewell and its external advisors have reviewed the Draft Report and in those efforts, engaged Janet Bull, MD, FAAHPM, an experienced and skilled hospice physician and recent former president of the American Academy of Hospice and Palliative Medicine, to conduct a comprehensive review of the records OIG's IMRC determined did not meet Medicare eligibility and level of care requirements.¹⁰ Tidewell also engaged Dr. R. Mitchell Cox, a PhD statistician with decades of experience in Medicare overpayment sampling matters, to evaluate OIG's statistical sampling methodology.¹¹ Finally, Tidewell evaluated its own policies and procedures related to the issues identified by OIG.

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

- Inconsistencies in Analysis and Approach of the IMRC Reviewers;
- Tidewell's Hospice Expert Review Methodology;
- Tidewell's Hospice Expert Review Findings;
- OIG's Review and Credible Information;
- Tidewell's Ongoing Compliance Program and Training; and
- Improper Use of Extrapolation and Dr. Cox's Position Related to the OIG's Statistical Sampling Methodology.

1. INCONSISTENCIES AMONG THE OIG'S IMRC REVIEWERS

OIG furnished Tidewell with its clinical summaries setting forth the determinations made by one or more IMRC physicians, as well as coders in certain instances, of the one hundred (100) claims reviewed where the IMRC determined 19 of those 100 resulted in Tidewell being overpaid. Based on its own review, Tidewell believes that the OIG's IMRC reviewers applied inconsistent and erroneous clinical standards when deciding whether documentation supported a terminal prognosis or higher level of care.

Tidewell was not provided with the OIG's IMRC physicians' curricula vitae or other biographical information. Tidewell cannot, therefore, ascertain the IMRC physicians' qualifications, board certifications (if any) or perspective and experience with hospice and palliative medicine. The review conducted by Dr. Bull found that the IMRC reviewers applied an inconsistent approach to determine clinical eligibility for hospice services and need for higher levels of care consistent with the legal requirements of the Medicare hospice benefit.¹² As discussed in more detail below, the reviewers appeared in most instances to appropriately summarize the salient facts and medical conditions reflected in each sampled record, but did not synthesize these facts or the patients' comorbidities and other clinical

¹⁰ Dr. Bull's CV is included as **Attachment D – Dr. Bull CV**.

¹¹ Dr. Cox's CV is included as **Attachment E – Dr. Cox CV**.

¹² See discussion *supra* at pp. 2-3.

conditions into appropriate clinical conclusions. Accordingly, Tidewell appreciates the opportunity to have the OIG and its IMRC consider the findings of Tidewell's hospice clinical review expert attached hereto. Dr. Bull's opinions evidence a well-founded, "whole patient" approach to determining clinical eligibility, and Tidewell asks that OIG apply these findings to its final report.

2. TIDEWELL HOSPICE EXPERT'S REVIEW METHODOLOGY

As noted, Dr. Bull has substantial clinical experience in hospice and palliative care medicine and an expert level understanding of the clinical indicators of eligibility for the Medicare hospice benefit. Dr. Bull frequently assists hospice organizations in understanding terminal disease progression, hospice eligibility issues, and related hospice documentation. She leads and conducts research on terminal prognostication topics. Dr. Bull has significant hospice-specific experience in community hospice, including those with inpatient units for general inpatient and respite care. Dr. Bull regularly reviews hospice medical records and compares the contents of those records to applicable local coverage determinations ("LCDs") and other established hospice documentation guidelines.

Tidewell provided Dr. Bull with access to the identical set of records it had submitted to the OIG. Dr. Bull conducted an independent clinical review of each patient's medical record for whom the IMRC reviewers asserted that the beneficiary was ineligible for hospice care or, as applicable, ineligible for a higher level of care. Dr. Bull determined whether the certification or recertification related to each claim at issue was reasonably supported by the documented clinical indicators. Importantly, Dr. Bull's review does not only reflect her singular view as a hospice clinician. It relies on substantive medical literature that many hospice physicians routinely reference for assessing hospice clinical eligibility and answering the question, "Is this patient terminally ill?" This literature includes:

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

3. TIDEWELL HOSPICE EXPERT'S REVIEW FINDINGS

Dr. Bull found record support for hospice eligibility and the higher level of care (as applicable) in every one of the 14 instances the IMRC had found a lack of hospice eligibility or support for a higher level of care.¹³ (Dr. Bull did not review those errors specifically related to the SIA payment. Tidewell separately assessed those issues as discussed below.)

¹³ As discussed in more detail herein, Patient #30 had a coding error in the revenue code field that led to a respite care day being paid at the GIP level.

Dr. Bull's review indicated that for those patients who only partially met the applicable LCD guidelines, they each nevertheless exhibited a terminal prognosis that qualified them for the Medicare hospice benefit. LCDs in the hospice context are merely guidelines; patients can be (and often are) terminally ill without fully meeting corresponding hospice LCD elements. The Palmetto hospice LCDs specifically note that a patient that "does not meet the criteria outlined" in the LCD may still be "deemed appropriate for hospice care." See Palmetto LCD L34547. Dr. Bull also found that, for each patient where OIG's IMRC asserted a level of care concern, the level of care provided by Tidewell was reasonable and necessary given the patient's clinical condition and need.

Dr. Bull reviewed the nine (9) claims at issue with respect to eligibility and determined that for each of them, the certifying physician's prognostication that the individual was terminally ill was appropriate. Dr. Bull also reviewed the five (5) claims for which OIG's IMRC asserted that the higher level of care provided was not necessary. Each of the clinical details and Dr. Bull's assessment related to these patients appear in **Attachment C**, but several illustrations of where the IMRC's review was deficient are summarized below.

- Patient 9 – Dates of Service occurring in 2016. Eighty six (86) year old male patient with chronic obstructive pulmonary disease, carotid artery disease and carotid stenosis, and heart arrhythmias. Prior to hospice election and admission in April 2016, the patient had been hospitalized with pneumonia and had experienced a 15 pound weight loss. At admission, he weighed 100 pounds with a BMI of 17 and lost 12 pounds over the next two weeks, indicating a significant and steady decline. On July 1st, the patient was transferred to a VA home because of his inability to appropriately care for himself at home. The IMRC recommends denial of hospice care after the patient is transferred to the VA home because, approximately two weeks later, the patient stabilizes and begins to show signs of improvement. The patient revoked care on July 16 after his condition unexpectedly improved. The IMRC's Monday morning quarterback review had the 20/20 hindsight knowledge that the patient showed sudden and unexpected improvement. But that improvement could not have reasonably been known to the certifying physicians or hospice at the time of certification or even in early July when he was transferred to a new residential setting. And it certainly does not justify denial of hospice care from July 1 to July 16. The patient clearly qualified for hospice care upon admission and, until the very end of his hospice care before he revoked, he had showed no signs of clinical improvement. When he stabilized, hospice care was no longer provided or billed to Medicare. Here the hospice benefit was utilized just as Congress and CMS anticipated it would for patients whose condition suddenly and unexpectedly improves.
- Patient 30 – Dates of Service occurring in 2016. Seventy seven (77) year old female with Parkinson's disease, anorexia, and osteoporosis. She had a recent history of falls

and a pelvic fracture and her PPS fluctuated between 40% and 30%. Over the course of the year prior to her admission to Tidewell Hospice, she had lost 16 pounds (from 113 pounds in November 2015 to 97 in October 2016), which is greater than 10% of her body weight. She had also recently been hospitalized for urosepsis. Despite the patient exhibiting all of the typical conditions of a progressively dying person (falls, infections, hospitalizations, and weight loss), the IMRC reviewer concluded the patient was ineligible for the Medicare hospice benefit.

Furthermore, the IMRC denied a GIP stay for this patient on November 1, 2016. The patient did not receive GIP on this day but instead received respite care services. Although Tidewell intended to bill for a respite care day, a coding error in the revenue code field resulted in a payment at the GIP level. Tidewell agrees that, to the extent OIG's IMRC finds this beneficiary eligible for hospice services, the November 1 2016 date of service should be paid at a respite, not GIP, rate.

- Patient 48 – Dates of Service occurring in 2017. Male patient older than eighty nine years old with a primary diagnosis of congestive heart failure, with significant comorbidities, including anorexia, chronic kidney disease, chronic obstructive pulmonary disease and atrial fibrillation. The patient was admitted to hospice on January 27, 2017 but the IMRC denied services starting on February 1, 2017, alleging that the patient did not qualify for hospice care.

By all accounts, the patient was showing signs of a progressively terminal illness. He had a recent emergency room visit for weakness and heart failure exacerbation. His labs at the emergency room revealed a highly elevated brain natriuretic peptide level of greater than 5,500 pg/ml (normal limits are less than 100 pg/ml). In addition, he had a creatinine level of 2.1 (normal limits for men are less than 1.4) and a glomerular filtration rate of 35cc/min (normal limit >90 cc/min), which is consistent with Stage 3B renal failure. Thus, not only was he suffering from heart failure, he was a single step from end-stage renal disease. The patient did not strictly meet every criterion of the applicable LCD, but had advanced age, recent infections, nutritional decline, weight loss, and worsening cardiac and kidney function. Dr. Bull applied the Porock Index, which uses a series of factors to predict the probability of death, and found that based upon this index the patient had a greater than 50% likelihood of death in six months based on his clinical condition at admission. Notably, the IMRC attempted to apply the ADEPT tool to this patient. While we applaud the use of a tool outside of the LCD (given both the LCD and other prognostication tools are intended to assist physicians to exercise their reasonable medical judgment as to whether it is more likely than not a patient will die within six months if the terminal illness runs its normal course), the ADEPT tool is only appropriate for patients with dementia. Patient 48 did not suffer from dementia and thus it was inappropriate for the IMRC reviewer to apply the ADEPT tool for this patient.

- Patient 54 – Dates of Service occurring in 2017. Seventy six (76) year old female patient with a primary diagnosis of acute renal failure, with significant comorbidities, including a gastrointestinal bleed, respiratory failure, congestive heart failure, diabetes, and hypercapnia. The patient received GIP level care from March 23 to March 27 as a result of pain, diarrhea, tachypnea, anxiety, agitation, and confusion. She required frequent nursing assessments and had mental and physical changes while receiving GIP care. She became less responsive and was still agitated and moaned with grimacing noted. She required the administration of frequent oxycodone for her pain and Ativan for anxiety and developed pruritus for which Benadryl was started.

The OIG IMRC reviewer concluded Patient 54 did not qualify for GIP level of care because she did not need intravenous (IV/Sq) medication administration. However, as Dr. Bull notes, guidance from Palmetto specifically states that patients can qualify for GIP if they are in need of medication adjustment, observation, or other stabilizing treatment – it does not require a specific type or method of administration for medications for GIP coverage. Palmetto, *Hospice General Inpatient Care* at pg. 10, August 13, 2019. In addition, this guidance explains “If a patient [coming from a hospital inpatient admission, as was the case here] continues to need pain control or symptom management, GIP can be an appropriate option.” *Id.* at pg. 12. In this particular case, Patient 54 continued to deteriorate, leading to her death on March 27, 2017 while on GIP. The GIP services rendered were necessary for the symptom management of this individual with frequent medication administrations during her dying process and the particular type of medication adjustments she received do not disqualify her from coverage.

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

4. OIG’S REVIEW AND CREDIBLE INFORMATION OF OVERPAYMENT

Tidewell is keenly aware of the requirements under the 60-Day Rule, which generally requires a provider to report and return any identified and calculated Medicare or Medicaid overpayment within 60 days of such identification. As further expanded by CMS in its 2016 rulemaking preamble to its regulation (42 CFR § 401.301), under the 60-Day Rule CMS expects that providers with credible information of a potential overpayment should engage in the exercise of reasonable diligence to determine if a Medicare Part A or B overpayment exists. Rulemaking preamble further suggests that determinations from the Federal government, such as MAC reviews or the OIG’s pending audit here, may constitute “credible

information” that gives rise to a provider’s obligation to engage in the exercise of reasonable diligence.

The OIG audit review and its preliminary results have prompted Tidewell to treat the information as credible information of a potential overpayment, and it has undertaken a careful and diligent review of its technical documentation, policies and procedures, as well as undertaken a detailed and independent clinical review by an outside hospice physician expert related to those findings. For the reasons noted above, Tidewell fundamentally disagrees with the findings of the OIG’s IMRC physicians, and finds its own expert’s findings (and the contemporaneous and reasonable clinical decisions of its certifying hospice physicians) compelling, especially in light of the *AseraCare* decision. Consequently, Tidewell has not, following its reasonable diligence, and with the exception of certain SIA claims as described further below, identified additional Overpayments arising from OIG’s audit. However, Tidewell continues to monitor for receipt of credible information of overpayments.

5. TIDEWELL’S ONGOING COMPLIANCE AND TRAINING

Tidewell’s review did not uncover any systemic compliance issues with either clinical or technical documentation requirements that would necessitate a material compliance program enhancement. That said, Tidewell regularly engages in compliance program assessments, with enhancements developed as appropriate. These include compliance training, internal audits, and corrective actions for detected compliance shortcomings.

Notably the Program for Evaluating Payment Patterns Electronic Report (“PEPPER”) data distributed by a CMS contractor for the period under review demonstrates a hospice program in Tidewell that was and is well-functioning, compares favorably to other hospice programs, and exceeds Medicare standards. In all PEPPER metrics, including live discharges, long length of stay, single diagnoses, long GIP stays, and top terminal diagnoses, Tidewell’s PEPPER data reveals no outlier concerns for which CMS recommends internal monitoring. Tidewell had a live discharge rate between 3.0% and 4.0% during the years under review, whereas the jurisdictional 80th percentile (the threshold for concern on PEPPER data) hovered at 13%. Similarly, Tidewell’s long length of stay population was at 8.2% and 7.0% during the two years of the OIG’s review period, compared to a jurisdictional 80th percentile of 25.3% and 24.8%, respectively. Tidewell’s percentage of cancer patients was 29.7%, and represented Tidewell’s most common principal diagnosis. This is in line with the jurisdictional cancer diagnosis of 29.5% of all decedents. Simply put, these PEPPER metrics, created and distributed by CMS’s contractor (TMF Health Quality Institute), combined with the intensive and independent expert review Tidewell conducted, do not provide any indicia that compliance or control enhancements at this program are warranted on account of the findings in the OIG Draft Audit.

Moreover, Tidewell is able to demonstrate the efficacy of its existing compliance program as a result of OIG’s review. As noted above, OIG’s audit revealed a documentation

issue related to SIA payments of which Tidewell had not previously been aware. In its audit, OIG denied four SIA claims on the basis that the services were performed by a social worker via phone, and not in person. Social worker encounters in hospice are often done by telephone, but Medicare SIA rules do not permit such telephonic visits to be billed. While Tidewell understands the billing requirements for SIA services and recognizes that phone-based social worker services do not qualify for the SIA payment, a coding transcribing issue in Tidewell's system led to these types of telephonic services being placed onto SIA claims by Tidewell's electronic medical record unwittingly. As background, Tidewell uses "service codes" for various purposes to distinguish between in-person social worker visits and telephonic social worker encounters. These service codes have been in place at Tidewell since before the SIA add-on payment was established by Medicare in 2016. Prior to this time, both in-person and telephonic visits were coded to the same HCPCS code (G0155) because the modality of the service had no impact on Medicare payment and both types of service fit the description of the HCPCS code ("services of clinical social worker in home health or hospice settings"). Subsequent to the 2016 effective date for Medicare SIA payments, Tidewell inadvertently failed to capture and code differently social worker in-person and telephonic visits. Medicare's SIA payments are automatically made based on the hospice-reported HCPCS codes. There is no separate payment request beyond reporting of the HCPCS code that triggers Medicare's SIA payments when those registered nurse or social worker visits are warranted by the patient's condition in the last seven days of life.

Following receiving the OIG's draft audit, Tidewell recognized the coding glitch in its system that was causing telephonic visits to be translated to G0155 CPT codes on its Medicare claim reporting. Tidewell's Compliance team promptly discontinued that coding glitch and had it corrected on a prospective basis in its EMR system. Furthermore, recognizing its obligations under the 60-Day Rule and now in receipt of credible information of a potential overpayment as a result of OIG's audit, Tidewell conducted a comprehensive lookback of its SIA payments dating back to January 1, 2016, the date SIA payments were first made by Medicare. Tidewell identified those instances where the G0155 code was made for a social worker telephonic visit, quantified the amount overpayment, and reported and refunded those amounts back to Palmetto. Furthermore, Tidewell continues to examine the findings of the OIG in order to ensure that payments made to it are appropriate.

6. OIG'S USE OF EXTRAPOLATION

OIG appeared to use its standard provider audit methodology to extrapolate the results of a 100 claim sample review to the universe of all of the Medicare claims submitted by Tidewell within the time period under review. Recognizing the significant impact OIG's extrapolation has on the financial estimates of the audit (for every \$1 denied in the sample, OIG is recommending an overpayment of \$187), Tidewell engaged Dr. Cox to undertake an analysis of OIG's sampling methodology. Although OIG engages in a standardized sampling plan for its provider compliance audits, Tidewell and Dr. Cox observed that here the representativeness of OIG's sample and reliability of the overall estimate were lacking.

As detailed in his report enclosed as **Attachment F – Dr. Cox Statistical Expert Report**, Dr. Cox had serious procedural and statistical concerns with the OIG sampling methodology. Dr. Cox found that the extrapolation was not sufficiently reliable to make a demand for overpayment even at the lower bounds of its estimate based on its results. Specifically, there was inconsistency in the universe and sample that was ultimately used in the extrapolation, as well as significant incidents of non-sampling (human) error introduced. Dr. Cox further determined that OIG’s review, given the significant number of claims in whatever universe OIG actually used and the heterogeneity in payments, HCPCS codes, and claim lines at issue, was so significantly imprecise as to make the extrapolation process improper. Given the heterogeneity of the Tidewell universe, the use of a 100 claim sample was too small. OIG’s sample and resulting extrapolation were not statistically valid.

Not only does Tidewell have serious concerns about the underlying validity and representativeness of OIG’s sample, OIG should also forgo extrapolation for two additional reasons. First, in accordance with CMS’s recent revisions to its extrapolation procedures in the case of Medicare audits, the clinical review findings do not reflect a high or sustained level of payment error for which extrapolation is justified. More specifically, the IMRC’s financial error rate was low – approximately 12.5% of the total audited dollars in the sample. Once OIG corrects the significant misunderstanding the IMRC’s reviewers had regarding hospice care, the remaining error rate will be approximately 0.2%, well below the 50% threshold CMS now looks to as a standard for whether contractors should engage in extrapolation of their Medicare audit results. While Tidewell recognizes OIG is not a CMS contractor, and accordingly OIG maintains it is not bound by CMS instructions related to statistical sampling, a consistent approach across Medicare audits is appropriate, especially when the use of extrapolation has, as is the case here, a punitive effect on a provider.

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

IV. RESPONSE TO RECOMMENDATIONS

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

- *Tidewell should refund to the Federal Government the portion of the estimated \$8,305,371 million for hospice services that did not comply with Medicare requirements and that are within the 4-year claims reopening period.*

Tidewell disagrees with this recommendation insofar as it does not believe it was overpaid for hospice services that are within the four-year claims reopening period (except for the limited instances where a refund has already been initiated for SIA payments or where there was a minor coding error). Tidewell disagrees with OIG’s IMRC in every instance

where that contractor determined that the services did not comply with Medicare hospice eligibility requirements. Tidewell concurs regarding refunds related to certain SIA payments and, because those refunds have already been effectuated, no additional refund is necessary.

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

Tidewell concurs with this recommendation only insofar as exercising reasonable diligence to identify and return improper payments upon having credible evidence of a potential Medicare overpayment is a statutory and regulatory obligation. Tidewell has already effectuated repayments for any Medicare SIA payments that, in Tidewell's determination, were found to be overpayments. Tidewell did not identify any systemic hospice service billing issues (related to terminal eligibility or level of care medical necessity) that would compel Tidewell to conduct additional reviews at this time. Tidewell continues to examine its claims and payments for credible information of overpayments.

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

Tidewell disagrees with this recommendation to "strengthen" its procedures because it believes its existing procedures are sufficiently strong to ensure that hospice services comply with Medicare requirements. As Dr. Bull's review demonstrated, the hospice service claims reviewed by OIG complied with Medicare requirements. Tidewell's procedures are consistent, timely and appropriate both with regard to the initial admission process and recertifications. Tidewell reviews and updates its policies and procedures from time to time to ensure compliance with regulatory requirements and appropriate clinical standards. Tidewell has a dedicated team of hospice and compliance professionals to develop, implement, and train staff on its compliance and clinical operations.

V. CONCLUSION

Tidewell, through its counsel, appreciates the opportunity to provide the comments to the OIG for its consideration by its Office of Audit Services team, its IMRC, and the inclusion of these comments in OIG's final audit report. Tidewell respectfully requests that OIG consider the information contained in both this response and its corresponding appendices and modify its Final Report findings accordingly.

Sincerely,

/Howard Young/

Howard J. Young
Counsel for Tidewell Hospice

Enclosures

APPENDIX F: STATISTICAL EXPERT REPORT

**Tidewell Hospice Comments to Draft OIG Audit Report
A-02-18-01024
Attachment F**

Dr. Cox Statistical Expert Report

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October 28, 2020

Jacob J. Harper, Esq.
Morgan, Lewis & Bockius LLP
1111 Pennsylvania Avenue, NW | Washington, DC 20004-2541

RE: HHS OIG Audit - Medicare Claims Statistical Sampling for Extrapolated
Overpayment Estimation
Tidewell Hospice, Inc.
Audit Period: Dates of Service from 04/01/2016 to 03/31/2018

Dear Mr. Harper:

At your request, I have reviewed the sampling and extrapolation methods used by the Office of Audit Services of the Department of Health and Human Services Office of Inspector General (henceforth "OIG") in its review of payments to Tidewell Hospice, Inc. (henceforth "Tidewell" or "the provider") made for claims with dates of service between April 1, 2016, through March 31, 2018. This letter contains my expert report. I reserve the right to add additional comments.

Qualifications

I am an expert in audit sampling and have experience in reviewing the sampling and extrapolation methods in Medicare overpayment reviews. I have served as an expert on statistical sampling in over seventy-five different cases with Medicare and other health insurance claims. I have testified by phone or in person in more than thirty different health care claims hearings or depositions. I have a Ph.D. in Mathematical Statistics from Co-

lumbia University. A further summary of my background is attached to the end of this report.

Independence

I am independent and have no conflicts of interest in this case. I had no contact with anyone at Tidewell prior to this case. I am paid for my time. My compensation does not depend upon the outcome of this case.

Documents/Files Reviewed

I received from you the files below along with a request to review these files and assess their adequacy in support of an overpayment extrapolation of Medicare claims previously paid by Medicare to Tidewell Hospice. The content of these files is as follows:

- [1] ***Sampling Plan (A-02-18-01024).pdf***: The Sampling Plan containing some, but not all, of the parameters and procedural steps needed to replicate the sample and the overpayment estimate. Not furnished are the sort order of the sampling frame and the random number seed used to generate the random numbers needed for sample selection. The plan is signed by Marlyn Griffis, Michael Guarnieri, and Jared Smith – Audit Manager, Regional Statistical Specialist, and Statistician, respectively – at the HHS Office of Inspector General Office of Audit Services. The plan is dated 08/20/18 and was revised on 10/19/18. The revised portions appear in red type and are annotated with the initials “nyg.”
- [2] ***Copy of Random Numbers (A-02-18-01024).xlsx***: The output of the RAT-S-TATS¹ Single Stage Random Number generation program consisting of the random numbers along with the seed number used to initialize the program.
- [3] ***Copy of Variable appraisal input file (A-02-18-01024).xlsx***: A spreadsheet containing two worksheets as follows:
 - [3.a] ***universe***: Despite its name, this worksheet contains the count and total payment for the claims in the revised sampling frame, not the universe.
 - [3.b] ***error table***: A worksheet containing for the claims in the sample the paid amounts and the overpaid amounts resulting from the medical review. The worksheet is formatted in such a way as to allow it to be used as input into the RAT-STATS Unrestricted Variable Appraisal program.

¹ RAT-STATS is a collection of computer programs written by OIG’s Office of Audit Services and is the primary software used by this office for conducting statistical audits, see [OIG] in the list of references on page 17.

- [4] **Variable Appraisal (A-02-18-01024).pdf**: The output obtained by running the RAT-STATS Unrestricted Variable Appraisal program on the input contained in the worksheet [3.b].
- [5] **CIN A-02-18-01024 Tidewell Sample Frame.accdb**: A Microsoft Access database containing information relating to the statistical sampling conducted by OIG against Tidewell. The database contains five tables and six queries as follows:
- [5.a] **1 Tidewell - Original Universe From AATS**: A table containing one record for every service line in the universe containing the details (claim number, beneficiary, dates of service, claim paid amount, etc.) for this service line.
- [5.b] **2 Summary of Claims**: A query grouping all the service lines in the universe table, [5.a], by claim number.
- [5.c] **3 RAC Exclusions**: A table containing one record for each of the 2,416² excluded RAC claims that are mentioned in section 3 of the Sampling Plan, [1].
- [5.d] **4a Sample Frame - Post RAC Exclusion (FI_DOC_CLM_CNTL_NUM)**: A query which outputs the records for the claims in [5.b] minus those claims that have the number of a RAC excluded claim (item [5.c]) as the value of the FI_DOC_CLM_CNTL_NUM field.
- [5.e] **4b Sample Frame - Post RAC Exclusion (FI_ORIG_CLM_CNTL_NUM)**: A query which outputs the records for the claims in [5.d] minus those claims that have the number of a RAC excluded claim as the value of the FI_ORIG_CLM_CNTL_NUM field. The resulting output consists of the claims in [5.b] minus the claims in [5.c].
- [5.f] **5 Random Number**: A table containing the random numbers used for sample selection. This is the table version of the spreadsheet [2].
- [5.g] **6 Sample Frame Final (Query 4b) w Auto number**: A table containing the output of the query [5.e] and augmented with an additional field named "Record Number" containing the sequence number of the claim. This is the original sampling frame before being revised by having the ZPIC excluded claims removed.
- [5.h] **7 Random Sample 100 Claims**: A table containing the records for those claims in the original sampling frame table (item [5.g]) that are contained in the sample. The table is augmented with an additional field named "Sample Number" containing the sample number of the claim.
- [5.i] **8 ZPIC Exclusions**: A table containing the claim numbers of the 35 ZPIC excluded claims. All but three of these appear in the RAC excluded claims (item [5.c]) which were removed from the original sampling frame (item [5.g]). These three claims are mentioned in footnote 3 of the Sampling Plan as having been removed from the revised sampling frame.

² The Sampling Plan erroneously states that there are 2,414.

[5.j] **9 Sample Frame FINAL – Post ZPIC Exclusions:** A query which takes as input the original sampling frame (item [5.g]) and removes the ZPIC excluded claims to produce the revised sampling frame.

[6] **A021801024DRAFTREPORTSdpdf [preview].pdf:** OIG’s draft report on the audit against Tidewell. For the purposes of the current report, the most important section is Appendix D entitled “Sample Results and Estimates” which gives the extrapolated results from the most recent (as of September 2020) medical review results. The values for the overpayment estimate and the precision that appear in the current report are taken from this appendix. The report is fronted by a cover letter dated September 4, 2020 from Brenda Tierney, Regional Inspector General for Audit Services at OIG, to Alan Weldy, Chief Legal and Compliance Officer at Tidewell.

Conclusion 1. OIG made multiple mistakes in documenting and selecting its sample. These mistakes resulted in multiple inconsistencies between the sample and the Sampling Plan, between the sample and the other sampling materials, and among the sampling materials themselves. The net effect of these mistakes is that OIG’s sample is not statistically valid and therefore cannot be used to extrapolate an overpayment estimate.

OIG made multiple mistakes in documenting and drawing its sample. This resulted in multiple inconsistencies among the items it provided for review. These inconsistencies mean that there is no one sample that is consistent with all of the sampling materials but instead that any sample that is consistent with a subset of the sampling materials is inconsistent with the remaining materials. In fact, depending upon which subset of these materials we start from, we can obtain two different sampling frames and three different samples. One of these samples was drawn from one of these frames, another sample was drawn from the other frame, and the third sample was drawn from neither frame. It is the third sample that OIG used to extrapolate its overpayment estimate of \$8,305,371. We will now describe these samples and, for each, the subset of the sampling materials from which they arise.

- The first sampling frame was documented in OIG’s revised Sampling Plan, [1], and has 33,024 claims.³ This frame is produced by the query entitled “9 Sample Frame FINAL – Post ZPIC Exclusions” in the Access database, [5.j]. The sample selected from this frame in accordance with OIG’s revised Sampling Plan is the one that OIG should have used to extrapolate its overpayment estimate. The size (= 33,024) of this

³ According to footnote 3 of the Sampling Plan and the handwritten annotation accompanying this footnote, the Sampling Plan was revised on 10/19/18 by an individual with initials “nyg.” Footnote 3 and the changes resulting from this revision appear in red font in the Sampling Plan.

sampling frame appears in the output, [4], of the RAT-STATS Variable Unrestricted Appraisal program – the program that OIG ran to extrapolate its overpayment estimate – indicating that OIG used this size as input into this program. This size, along with the total value of the claims in this sampling frame, also appears in the first worksheet, [3.a], of the spreadsheet, [3], whose second worksheet, [3.b], contains the values⁴ that OIG actually extrapolated. I will call this first frame and sample “frame A” and “sample A.”

- The second sampling frame has 33,027 claims and was documented in OIG’s original Sampling Plan, prior to revision. This frame is produced by the query entitled “4b Sample Frame - Post RAC Exclusion (FI_ORIG_CLM_CNTL_NUM)” and resides in the table entitled “6 Sample Frame (Query 4b) w Auto Number.” The second sample is produced from this frame by the query entitled “7 Random Sample 100 Claims.” This sample is consistent with this query, the original Sampling Plan, and the random numbers in Table 5 in the Access database, but it is not consistent with any of the other sampling materials. For example, the frame size that was used to generate the random numbers in Table 5 is 33,027 and differs from the frame size (= 33,024) that was used to extrapolate the overpayment estimate, as mentioned in the preceding paragraph. I will call the second frame and sample “frame B” and “sample B.” Although frames A and B differ by only 3 claims⁵ and although the same random number seed was used to select both samples A and B, these samples are completely different and have only 17 out of their 100 claims in common.⁶
- The third sample appears in the input worksheet [3.b] to the RAT-STATS Variable Appraisal program that OIG used to extrapolate its overpayment amount. Actually, this sample does not appear in this spreadsheet nor does it appear in any of the other materials provided by OIG – only the record numbers, paid amounts, and audited overpaid amounts for the claims in this sample appear in this spreadsheet. So we are unable to identify the particular claims in this sample; however, because the claim paid amounts in this sample differ from the claim paid amounts in samples A and B, we can say that this is an altogether new sample which we will call sample C. In fact, a comparison of the claim paid amounts in samples A and C shows that these samples can have in common at most 28 out of their 100 claims. We can go further and say that not only does sample C differ from samples A and B but it differs from every other sample that could be drawn from this universe. This is because two of the paid amounts in sample C do not appear in the claim payment amount column (the column with heading CLM_PMT_AMT) of the universe table (Table 1 in the Access database). These are the claim payment amounts of \$6,785.82 and \$7,220.88 that appear

⁴ These values belong to sample C – see my discussion in the third bulleted paragraph.

⁵ These three claims are the ZPIC exclusions (Table 8 in the Access database) which do not appear in frame A but do appear in frame B because they are not RAC exclusions (Table 3).

⁶ The reason for this is twofold – (1) The two sets of random numbers that were used to select these two samples are different because the sizes of their respective frames are different and these sizes were inputs to the computer program that generated these numbers, and (2) the off-sets, and hence the record numbers, of the claims in the frames are different and the random numbers are matched with these record numbers to select the claims in the sample.

in cells B100 and B101 of the worksheet [3.b]. So Sample C was not produced by any of the queries in the Access database nor does it reside in any table in this database. In spite of this, sample C was used by OIG to extrapolate its reimbursement demand of \$8,305,371.

Needless to say, there should not be this proliferation of possible samples, which is due entirely to the lack of consistency in OIG's sampling materials. The sampling materials should be consistent with one and only one sample from which the overpayment estimate is extrapolated. This is not merely a preference – it is required for the statistical validity of the sample. And statistical validity is required to form a valid overpayment estimate. Addressing this point, for example, the Medicare Program Integrity Manual (henceforth "MPIM" and [MPIM] in the list of references on page 17) states –

*8.4.1.1 – General Purpose
(Rev. 377, Issued: 05-27-11, Effective: 06-28-11, Implementation: 06-28-11)*

... An appeal challenging the validity of the sampling methodology must be predicated on the actual statistical validity of the sample as drawn and conducted. ...

and

*8.4.2 - Probability Sampling
(Rev. 377, Issued: 05-27-11, Effective: 06-28-11, Implementation: 06-28-11)*

Regardless of the method of sample selection used, the PSC or ZPIC BI unit or the contractor MR unit shall follow a procedure that results in a probability sample. ...

This last excerpt states the requirement for a statistically valid sample in terms of the equivalent concept of a probability sample. The equivalence of these two concepts is stated in the continuation of this excerpt –

... If a particular probability sample design is properly executed, i.e., defining the universe, the frame, the sampling units, using proper randomization, accurately measuring the variables of interest, and using the correct formulas for estimation, then assertions that the sample and its resulting estimates are "not statistically valid" cannot legitimately be made. In other words, a probability sample and its results are always "valid."

OIG failed to satisfy all of the requirements for statistical validity. Its sample design, as presented in its Sampling Plan, was not properly executed because it formed neither the universe nor frame correctly nor did it use proper randomization. Its universe failed to contain at least two claims that appeared in the sample and the sampling frame contained three claims that were excluded by a result of a prior ZPIC review and therefore should have been excluded from the frame according to the revised Sampling Plan. This is a basic, fundamental flaw in the execution of this sampling exercise. OIG simply used the wrong data set when extrapolating Tidewell's data. These errors caused the sample used for extrapolation (sample C) to have no more than 28 out of its 100 claims in common with the sample that can be generated from the Sampling Plan (sample A).

Proper randomization was not used because the random numbers in Table 5 were generated assuming a frame size of 33,027 claims instead of 33,024 claims, the frame size given in the Sampling Plan. This caused 84 of these 100 random numbers to be incorrect. Two of the payment amounts that were extrapolated do not appear in the universe (Table 1) indicating that either the claims underlying these payment amounts were not drawn from the universe or these payment amounts are "variables of interest" that were not "accurately measured." We don't know which it is because the extrapolated claims are not identified in any of the sampling materials. Finally, the "correct formulas for estimation" were not used because these formulas assume a frame size of 33,024 claims (see [4]) but OIG instead used a frame of size 33,027.

In view of this multiplicity of errors, OIG's sample is not statistically valid and cannot be used as the basis for estimating an extrapolated overpayment of \$8,305,371 from Tidewell Hospice's audit.

Conclusion 2. The OIG's audit findings did not meet the high error rate criterion of the Medicare Program Integrity Manual justifying the use of extrapolation.

Section 8.4.1.4, entitled "Determining When Statistical Sampling May Be Used," of the MPIM states –

The contractor shall use statistical sampling when it has been determined that a sustained or high level of payment error exists. ... For purposes of extrapolation, a sustained or high level of payment error shall be determined to exist through a variety of means, including, but not limited to:

- *high error rate determinations by the contractor or by other medical reviews (i.e. greater than or equal to 50 percent from a previous pre – or post – payment review).*

Two error rates are commonly used in Medicare extrapolations. There is the claim error rate, which is the number of claims in the sample paid in error divided by the number of claims in the sample, and there is the financial error rate, which is the total dollar amount paid in error for claims in the sample divided by the total dollar amount paid for claims in the sample. For OIG's audit against Tidewell, both of these error rates can be calculated from the values in the RAT-STATS Unrestricted Variable Appraisal program output ([4] in the list of items reviewed on pages 2-3). The claim error rate is then $18/100 = 18\%$ and the financial error rate is $\$46,568.50/\$363,497.22 = 13\%$. While the MPIM does not say which of these error rates is referenced in the passage above, neither of them comes close to meeting the minimum error rate of 50% required by the MPIM. For this reason alone, to be consistent with Medicare extrapolation standards, OIG should not utilize extrapolation. Furthermore, there has been no prior pre- or post-payment review of Tidewell that has yielded an error rate of greater than 50%. Should OIG insist on use of extrapolation, the Medicare contractor (Palmetto GBA) for Tidewell remains bound by CMS instructions and manuals on the use of extrapolation and should not extrapolate any error rate for the reasons noted above.

Conclusion 3. OIG's precision of 46% is one of the worst precisions I have seen in the more than seventy-five Medicare cases I have reviewed. A precision this bad means that in the event that Tidewell is asked to over-reimburse, or reimburse more than it has been overpaid, it will have to over-reimburse four-and-a-half times what it would have had to over-reimburse if the precision had been a more standard 10%. We have no way of knowing whether Tidewell is one of the 5% of providers who are being asked to over-reimburse.

The precision and the confidence level are the two most important parameters characterizing a statistical estimate. Because of this, statisticians usually design their experiments to achieve pre-selected values of these two parameters. Medicare contractors commonly use the generally accepted values of 10% for the precision and 90% for the confidence level are used. The auditor is then 90% confident that the overpayment estimate will lie within 10% of the true overpayment value or – because of the symmetry of the distribution of the overpayment estimate with respect to the overpayment value – 95% confident that the overpayment estimate will not exceed the true overpayment by more than 10%. A statistician would express this by saying that the two-sided confidence level is 90% and

the one-sided confidence level is 95%.⁷ By then setting the reimbursement amount equal to 10% less than the estimated overpayment, the auditor is assured that 95% of the time the reimbursement amount will not exceed the actual overpayment.

Statisticians control the precision and confidence level by proper selection of the sample size. The way they usually do this is with statistical software. The precision is a measure of the variability or spread of the overpayment estimate. Therefore, a precision of 46% means that, in the event that the provider is asked to over-reimburse, or reimburse more than it has been overpaid, it will be asked to over-reimburse more than four-and-a-half times what it would have had to over-reimburse if the precision had been a more standard 10%. This is because a precision of 46% is more than four-and-a-half times the standard precision of 10%.⁸ We have no way of knowing whether Tidewell is one of the 5% of providers who will be asked to over-reimburse.⁹ If it is, then it is likely that it will have to reimburse much more than it was overpaid because OIG has made no attempt to control the precision. This is one of the very few cases I have seen in which Central Limit Theorem (CLT) projection has been used without any attempt to control the precision and it results in one of the worst precisions I have seen in any Medicare extrapolation. The maximum precision value selectable with the RAT-STATS Variable Sample Size Determination program is 15%, which is three times more precise than the value OIG achieved.

An unavoidable consequence of using statistical extrapolation to determine the reimbursement amount is that the provider will sometimes be asked to reimburse more than it has been overpaid. The usual way of controlling the size and frequency of this adverse occurrence is through the use of statistical software to determine the appropriate sample size. In just about every other CLT extrapolation I have seen, the auditor has used a sample size determination program, such as RAT-STATS, to simultaneously control the confidence level and the precision. OIG didn't do this but instead decided, arbitrarily and without any justification, to use a sample of size 100. As a result, the amount Tidewell is

⁷ Without the qualifiers "one-sided" or "two-sided", the terms "confidence interval" and "confidence level" always mean the two-sided versions of these quantities. This is in agreement with the prevailing use of these terms in the statistical literature.

⁸ The reimbursement amount is $e - p$, where e is the point estimate of the overpayment and p is the precision amount. Hence, the difference between the reimbursement amount and the actual overpayment a is $e - p - a$. This is the amount I have called the over-reimbursement amount and it can be written as $(e - a) - p$. This amount scales with the precision p since both of its terms, $(e - a)$ and p , do. In particular, in the event that the provider is asked to over-reimburse, the over-reimbursement will scale with the precision and the provider will have to over-reimburse 4.6 times more with a precision of 46% than with a precision of 10% (since 46 is 4.6 times more than 10). This proves my statement in Conclusion 3.

⁹ A confidence level of 10% means that 5% of the time the reimbursement amount, which is the lower bound of the confidence interval, will exceed the actual overpayment amount. Actually, the probability that Tidewell is being asked to over-reimburse is higher than 5% because OIG has possibly biased its overpayment estimate upward by removing underpayments from the universe – see my discussion under Conclusion 5. This is why it is doubly important in this case that the precision be controlled.

being asked to reimburse could be much more than it owes and much more than it would have had to pay if correct procedure had been followed.

OIG's attempt to extrapolate from the sample to the population with a 46% precision is a violation of Medicare standards and generally accepted statistical methods and is grossly unfair to Tidewell. Therefore, it is my professional opinion that OIG's overpayment determinations should be withdrawn.

The foregoing conclusion and supporting facts are identical in all relevant respects to those contained in the report I wrote and the testimony I gave at the administrative law hearing in the case for which final judgment was rendered in *Central Louisiana Home Health Care, LLC v. Price*, 2018 WL 7888523 (E.D. La. 2018).¹⁰ The statistical extrapolation in that case was upheld by the CMS contractors who conducted the redetermination and reconsideration but it was ruled invalid by the administrative law judge who cited a woefully inadequate precision rate in support of his decision. Although the administrative law judge's decision was reversed upon appeal by the Medicare Appeals Council, it was ultimately upheld by the U.S. District Court for the Western District of Louisiana in the decision referenced above.

Conclusion 4. OIG's sampling frame is ordered by the *DSY_VW_REC_LNK_NUM* field in its Sampling Frame table. This field is a 12 digit number that has no apparent relationship to any independently assigned number or identifier. Without some assurance that this field was assigned by Medicare or some other independent entity and not by OIG, we have no assurance that the sample is a statistically valid random sample.

The random numbers used for sample selection are assigned to the claims in the order in which they appear in the frame. Therefore, by changing the order of the claims in the frame, the auditor can arrange for a given set of random numbers to be assigned to any claims he desires. Because an auditor can so arrange for the random numbers to be used in this manner, the auditor can completely determine the composition of the sample by changing the order of the claims in the frame. Because of this, the order of claims in the frame should be fixed and documented prior to sample selection. The MPIM says,

¹⁰ The precision percent in the current case is actually much worse (46% versus 32.46%) than in *Central Louisiana*. Therefore, the arguments presented in this Conclusion have even greater force here than in *Central Louisiana*.

*8.4.4.4.1 - Documentation of Universe and Frame
(Rev. 377, Issued: 05-27-11, Effective: 06-28-11, Implementation: 06-28-11)*

...
Further, the form of the frame and specific details as to the period covered, definition of the sampling unit(s), identifiers for the sampling units (e.g., claim numbers, carrier control numbers), and dates of service and source shall be specified and recorded in your record of how the sampling was done. ... Sufficient documentation shall be kept so that the sampling frame can be re-created, should the methodology be challenged. ...

OIG has not kept “sufficient documentation ... so that the sampling frame can be re-created” because it did not document the order of this frame in its Sampling Plan or elsewhere, and the frame cannot serve as documentation for its own creation. Although OIG did not document the order of its sampling frame, it can be seen from the frame itself (Table 6 in the Access database) that it is ordered by increasing value of the *DSY_VW_REC_LNK_NUM* field. However, even if OIG had documented this fact in its Sampling Plan, this would not have satisfied MPIM 8.4.4.4.1 because the *DSY_VW_REC_LNK_NUM* field has no relation to any independently assigned field in the sampling frame or universe tables,¹¹ and there is therefore no assurance that its value was determined prior to sample selection. OIG does not say how it derived this value. Unless the field or fields used to order the sampling frame are derived from identifiers or control numbers that are assigned by Medicare or some other independent entity, we cannot be sure that they were assigned prior to and independently of sample selection and we cannot be sure that the sample is statistically valid. Examples of identifiers which are frequently used by auditors to order their frames are the CCN (Claim Control Number), the HICN (Health Insurance Claim Number), and the dates of service. None of those identifiers were used to order the sampling frame.

Since OIG did not document the sort order of its sampling frame prior to sample selection using independently assigned identifiers, there is nothing to prevent manipulation of this sort order to yield any sample whatsoever. While I am not asserting any ill intent on the part of OIG, the sample does not hold up to basic statistical requirements and cannot, therefore, be statistically valid. It should not be used as the basis for OIG’s extrapolation.

¹¹ The fact that the *DSY_VW_REC_LNK_NUM* field has no relation to any other field in the sampling frame or universe tables can be seen from the fact that it is neither monotonically increasing or decreasing with respect to any of these fields. A further consequence of this fact is that the order imposed on the sampling frame by the *DSY_VW_REC_LNK_NUM* field is different than the order imposed on it by any other field or combination of fields.

Conclusion 5. OIG ignored statistical principles by excluding potential underpayments from its universe.

In footnote 2 of its Sampling Plan, OIG states the following:

We excluded claims that were zero-paid ...

This says that OIG removed all the zero-paid, or unpaid, claims from its universe. The fact that OIG removed the unpaid claims can also be seen by noting that there are no nonzero entries in the third column in the Universe table of the Sampling Data database.

This removal of the unpaid claims is a direct violation of the MPIM which states

*8.4.3.2 - Defining the Universe, the Sampling Unit, and the Sampling Frame
(Rev. 377, Issued: 05-27-11, Effective: 06-28-11, Implementation: 06-28-11)*

The universe and sampling frame will usually cover all relevant claims or line items for the period under review.

*8.4.3.2.2 - The Sampling Unit
(Rev. 377, Issued: 05-27-11, Effective: 06-28-11, Implementation: 06-28-11)*

*...
In principle, any type of sampling unit is permissible as long as the total aggregate of such units covers the population of potential mis-paid amounts.*

*8.4.5.2 - Calculation of the Estimated Overpayment Amount
(Rev. 377, Issued: 05-27-11, Effective: 06-28-11, Implementation: 06-28-11)*

*...
Sampling units that are found to be underpayments, in whole or in part, are recorded as negative overpayments and shall also be used in calculating the estimated overpayment.*

None of these conditions are satisfied by OIG's universe. Its universe covers neither all claims relevant to calculating the net overpayment nor the population of potential mis-paid amounts because OIG has removed from the universe the unpaid claims. Also, the "underpayments in whole" mentioned in the last passage above are those underpaid claims which were entirely unpaid. Since OIG removed these claims from its universe,

they are not available to be selected for the sample or to be used in calculating the correct amount Tidewell should have been paid. The MPIM disallows this with the unambiguous language, "shall also be used in calculating the estimated overpayment." The fact that OIG removed these unpaid claims from its universe is, by itself, fatal to its extrapolation. There is no way to repair this defect by adding additional claims to the existing sample or by drawing an altogether new sample because the unpaid claims have been removed from the universe from which the sampling units are drawn. There is also no way to estimate the harm inflicted on Tidewell by the removal of the unpaid claims because neither the number of these claims nor the underpayment they represent are known since OIG also removed these claims from all the other audit materials it provided..

The unpaid claims are claims for which Tidewell may be owed payment but is prevented from getting it because these claims were removed from the universe. This means that the underpayments they represent were not estimated as part of the total *net* overpayment or underpayment.

The MPIM requires auditors to net the underpayments against the overpayments when using statistical extrapolation to determine a *net* overpayment or underpayment amount. The following excerpts from the MPIM mention underpayments, mispayments, under-billing, under-coding, and denials:

8.4.3.2.2 - The Sampling Unit

(Rev. 377, Issued: 05-27-11, Effective: 06-28-11, Implementation: 06-28-11)

...

In principle, any type of sampling unit is permissible as long as the total aggregate of such units covers the population of potential mis-paid amounts.

8.4.4.3-Worksheets

(Rev. 377, Issued: 05-27-11, Effective: 06-28-11, Implementation: 06-28-11)

...

The amount that should have been paid (either over or underpaid amount);

8.4.4.4 - Overpayment/Underpayment Worksheets

(Rev. 377, Issued: 05-27-11, Effective: 06-28-11, Implementation: 06-28-11)

...

Underpayments identified during reviews shall be similarly documented.

8.4.5.1 - The Point Estimate

(Rev. 377, Issued: 05-27-11, Effective: 06-28-11, Implementation: 06-28-11)

...

In simple random or systematic sampling the total overpayment in the frame may be estimated by calculating the mean overpayment, net of underpayment, in the sample and multiplying it by the number of units in the frame.

8.4.5.2 - Calculation of the Estimated Overpayment Amount

(Rev. 377, Issued: 05-27-11, Effective: 06-28-11, Implementation: 06-28-11)

...

Sampling units that are found to be underpayments, in whole or in part, are recorded as negative overpayments and shall also be used in calculating the estimated overpayment.

8.4.6.3 - Conducting the Review

(Rev. 377, Issued: 05-27-11, Effective: 06-28-11, Implementation: 06-28-11)

...

Document the amount of all overpayments and underpayments and how they were determined.

8.4.7.1 - Recovery From Provider or Supplier

(Rev. 377, Issued: 05-27-11, Effective: 06-28-11, Implementation: 06-28-11)

...

the amount of the actual overpayment/underpayment from each of the claims reviewed.

3.5.2 - Case Selection

(Rev. 377, Issued: 05-27-11, Effective: 06-28-11, Implementation: 06-28-11)

...

The MACs, CERT, Recovery Auditors, and ZPICs shall document all incorrectly paid, denied, or under-coded (e.g., billed using a HCPCS or other code that is lower than what is supported by medical documentation) items or services.

...

Services that were denied, but are reinstated as a result of re-adjudication shall be reported as negative values.

*3.6.1 - Determining Overpayments and Underpayments
(Rev. 377, Issued: 05-27-11, Effective: 06-28-11, Implementation: 06-28-11)*

...
MACs and ZPICs shall net out the dollar amount of services underpaid during the cost accounting period, meaning that amounts owed to providers are balanced against amounts owed from providers.

*3.7.1.1- Provider Error Rate
(Rev. 377, Issued: 05-27-11, Effective: 06-28-11, Implementation: 06-28-11)*

...
****Net out (subtract) the dollar amount of charges underbilled*

The ten quotes above from ten different sections of the MPIM all state the requirement that sampling units identified as underpayments shall be used in estimating the total net overpayment. In particular, the first quote above from MPIM §8.4.3.2.2 is a condition on the sampling frame (“total aggregate of such units”) and states the requirement that this frame “covers the population of potential mis-paid amounts.” The fundamental reason for this provision is to arrive at the correct payment amount, which could potentially be greater than what Medicare previously paid.

Against the ten passages above, Medicare contractors sometimes cite the following passage from MPIM §8.4.3.2.1 to support an interpretation that the MPIM allows the removal of the unpaid claims from the universe:

Part A Claims: For providers reimbursed through cost report, the universe of claims from which the sample is selected shall consist of fully and partially adjudicated claims obtained from the shared systems ...

For providers reimbursed under PPS, the universe of claims from which the sample is selected will consist of all fully and partially paid claims submitted by the provider for the period under review.

Medicare contractors who exclude the unpaid claims from the universe often interpret the term “partially paid” in the passage above to exclude the unpaid claims. It appears that OIG charted a similar course. The problem with this is threefold:

- 1) It conflicts with the passages we have quoted above from the MPIM which state the requirement that the unpaid claims shall be included in the universe and sampling frame.

- 2) It conflicts with the standard dictionary definition of the word “partially” as “not totally” rather than “not empty” or “not zero.”
- 3) It has implications that are demonstrably inconsistent with the MPIM.

We have already shown 1), and 2) can be verified by looking up the definitions of “partially” in various dictionaries (see, for example, www.onelook.com for definitions from many of the most popular dictionaries). We will now show that this interpretation of MPIM §8.4.3.2.1 is inconsistent with the rest of the MPIM. This is true because –

- a) Consider a type of Medicare claim that involves an item, so we can represent a claim as being associated with a definable thing (as opposed to a service). For instance, DME typically involves payments which are all-or-nothing and which are either correct payments or 100% overpayments or underpayments. For example, a claim for a wheelchair would be a correct payment if the claim is paid and the wheelchair is medically necessary and a 100% overpayment or underpayment otherwise. Specifically, if a claim wasn’t paid by Medicare, but was medically necessary and otherwise complied with Medicare guidelines, it would be a 100% underpayment. For cases involving these types of claims, every underpayment would be a zero payment and OIG’s interpretation of §8.4.3.2.1 would allow a Medicare contractor to remove *all* of them from the universe. This would mean that the resulting overpayment estimate would be an estimate of the *gross* overpayment, not the *net* overpayment, because there is no possibility of including potential underpayments in this calculation. This example, in which OIG’s interpretation of §8.4.3.2.1 is in direct conflict with all ten of the above quoted passages from the MPIM, shows that this interpretation cannot be correct.
- b) The extrapolation is intended to estimate the correct payment due to Tidewell based on a medical review of the claims in the universe. Necessarily, this medical review cannot be performed on claims which are removed from the universe. Instead, the original payment determinations for these claims will stand. Hence, the medical review will not be an independent review of the unpaid claims if the latter are removed from the universe. OIG’s interpretation of §8.4.3.2.1 would permit total removal of these claims from a sample.
- c) Allowing the unpaid claims to be removed from the universe opens the door for abuse because it allows Medicare or a Medicare contractor to permanently remove any claim from any future audit by simply denying initial payment on this claim. OIG’s interpretation of §8.4.3.2.1 requires us to believe that the MPIM supports this.

In summary, OIG’s failure to include the unpaid claims in its extrapolation, besides being in direct conflict with the letter and intent of the MPIM, is grossly unfair to Tidewell and requires that the extrapolation be invalidated. There is no way to repair this defect by

sampling more claims or by drawing an altogether new sample because the unpaid claims have been removed from the universe from which the sample is drawn. There is also no way to estimate the harm inflicted on Tidewell by the removal of the unpaid claims because OIG also removed these claims from all the other audit materials furnished to Tidewell. Its overpayment estimate should be withdrawn .

Summary

Any one of Conclusions 1 through 5 stands either on its own or in combination with the other conclusions to invalidate OIG's overpayment estimate. Conclusions 3 alone formed the basis for the U. S. District Court's decision in *Central Louisiana Home Health Care, LLC v. Price* to reverse a final CMS agency decision and invalidate an extrapolation that was less egregious than the current one.

In my professional opinion, OIG's sample and extrapolation are not an adequate foundation for seeking a recoupment of \$8,305,371 from this provider. In my opinion, OIG's overpayment estimate is not supportable under OIG regulations, Medicare guidelines, and generally accepted statistical principles.

In my professional opinion OIG's statistical methodology is fatally flawed. In my opinion, OIG's statistical methodology cannot be accepted as valid statistical evidence.

Sincerely,



Ross Mitchell Cox, Ph.D.
Managing Member
R. M. Cox LLC

References:

[MPIM] Center for Medicare and Medicaid Services, *Medicare Program Integrity Manual*, CMS Pub. 100-08.

[OIG] Office of Inspector General, *RAT-STATS | Compliance | Office of Inspector General | U.S. Department of Health and Human Services*, <https://oig.hhs.gov/compliance/rat-stats/index.asp>.

[FAQ] Office of Inspector General, U.S. Department of Health and Human Services, *Corporate Integrity Agreement, FAQ*, <https://oig.hhs.gov/faqs/corporate-integrity-agreements-faq.asp#q13>.

Background of Ross Mitchell Cox, PhD:

Education

Ph.D. Mathematical Statistics

- Columbia University, New York, NY
- Thesis: Stationary and Discounted Control of Diffusion Processes

B.A. Mathematics

- Duke University, Durham, NC

Professional Expertise

- Experimental design / statistical inference
- Queueing theory / discrete event simulation
- Stochastic processes / Monte Carlo simulation
- Kalman and adaptive filtering
- Optimal control and numerical methods

Work Experience

11/08 – present Statistical Consultant/Expert Witness

- Review of the sampling and extrapolation methodologies in over seventy-five different Medicare and medical claims overpayment reviews
- Documentation of findings in evidentiary briefs submitted to the court
- Presentation of live testimony in over thirty administrative law hearings

9/15 – 9/16 *Qualcomm Atheros, Inc.*, Senior Staff Engineer

- Design and development of inSIGHT, a VDSL2 customer premises diagnostic tool

9/12 – 9/15, *Ikanos Communications*, Principal Digital Signal Processing Engineer

- Design and development of a VDSL2 customer premises noise monitor

3/08 – 9/12, *Scientific Research Corporation*, Senior Systems Engineer

- Modeling and simulation of wireless networks
- Statistical analysis of simulation results

5/03 – 3/08, *Conexant Systems*, Principal Engineer

- xDSL modem design and development
- Online statistical estimation and compensation of data channel characteristics

8/02 – 5/03, *Bloomberg L.P.*, R&D Systems Programmer

- Designed and programmed a real-time fault monitor for a financial data network

12/96 – 12/01, *Lucent Technologies Bell Laboratories*, Member Technical Staff

- Voiceband modem design and development
- Online statistical estimation and compensation of data channel characteristics

8/93 – 12/95, *AT&T Bell Laboratories*, Member Technical Staff

- Performance analysis of telecommunication systems
- Designed and programmed a billing system fault monitor utilizing a ~200 state numerically stable Kalman filter

8/87 – 8/93, *AT&T Bell Laboratories, Federal Systems Advanced Technology Division*

- Mathematical analysis and computer simulation

2/84 – 8/87, *Grumman Aerospace Corporate Research Center*

- Research Scientist

Patents

- Monitoring of Periodic Patterns, US Patent No. 5768284
- Configuring Transmission Systems, US Patent No. 11686420