Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

A NORTHERN CALIFORNIA PHYSICAL THERAPY PRACTICE CLAIMED UNALLOWABLE MEDICARE PART B REIMBURSEMENT FOR SOME OUTPATIENT THERAPY SERVICES

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



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> November 2016 A-09-14-02040

Office of Inspector General

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EXECUTIVE SUMMARY

Sierra Injury & Sports Rehab, Inc., improperly claimed at least \$583,000 in Medicare reimbursement for outpatient physical therapy services over a 2-year period.

WHY WE DID THIS REVIEW

In recent years, Medicare Part B payments for outpatient physical therapy have increased annually, with private-practice physical therapists generating payments of about \$1.9 billion in calendar year (CY) 2014. Previous Office of Inspector General reviews have identified claims for outpatient physical therapy services that were not reasonable, medically necessary, or properly documented and that were vulnerable to fraud, waste, and abuse. As part of a nationwide effort, we selected multiple physical therapists for review, including physical therapists associated with Sierra Injury & Sports Rehab, Inc. (Sierra), a private practice located in California. Our analysis indicated that one of Sierra's physical therapists was among the highest Medicare therapy billers in California.

Our objective was to determine whether claims for outpatient physical therapy services provided by Sierra complied with Medicare requirements.

BACKGROUND

Federal law and regulations provide for coverage of Medicare Part B outpatient physical therapy services. For these services to be covered, they must be medically reasonable and necessary, they must be provided in accordance with a plan of care established by a physician or qualified therapist and periodically reviewed by a physician, and the need for such services must be certified by a physician. Medicare Part B also covers outpatient physical therapy services performed by or under the personal supervision of a therapist in private practice. Federal law precludes payment to any provider of services or other person without information necessary to determine the amount due the provider.

HOW WE CONDUCTED THIS REVIEW

Our review covered 10,378 Medicare beneficiary days for outpatient physical therapy services, totaling \$1.1 million, provided by Sierra during CYs 2012 and 2013. A beneficiary day consisted of all outpatient therapy services provided on a specific date of service for a specific beneficiary for which Sierra received a payment from Medicare. We reviewed a random sample of 100 of those beneficiary days.

WHAT WE FOUND

Claims for outpatient physical therapy services provided by Sierra did not comply with Medicare requirements. Specifically, of the 100 beneficiary days in our random sample, Sierra properly claimed Medicare reimbursement for 36 beneficiary days. However, Sierra improperly claimed Medicare reimbursement for the remaining 64 beneficiary days, consisting of 62 beneficiary

days that had therapy services that were not medically necessary and 2 beneficiary days that did not meet Medicare documentation requirements.

These deficiencies occurred because Sierra did not have adequate policies and procedures to ensure that claims for outpatient physical therapy services complied with Medicare requirements. On the basis of our sample results, we estimated that Sierra improperly received at least \$583,335 in Medicare reimbursement for outpatient physical therapy services that did not comply with Medicare requirements. As of the publication of this report, this unallowable amount may include claims outside of the 4-year claim-reopening period.

WHAT WE RECOMMEND

We recommend that Sierra:

- refund to the Federal Government the portion of the estimated \$583,335 for claims for outpatient physical therapy services that did not comply with Medicare requirements and are within the 4-year claim-reopening period;
- for the remaining portion of the estimated \$583,335, which is outside of the Medicare reopening and recovery periods, exercise reasonable diligence to investigate the potential overpayments and work with the Medicare administrative contractor to return any identified overpayments in accordance with the 60-day repayment rule; and
- strengthen its policies and procedures to ensure that claims for outpatient physical therapy services comply with Medicare requirements.

AUDITEE COMMENTS AND OUR RESPONSE

In written comments on our draft report, Sierra, through its attorney, contested and objected to our finding that it submitted claims to Medicare that were medically unnecessary. Specifically, for the 64 beneficiary days that we found did not comply with Medicare requirements, Sierra disagreed with our finding for 62 beneficiary days and concurred that the remaining 2 beneficiary days were not properly payable because the records could not be produced. In addition, Sierra stated that it reserved its rights to appeal, on all grounds, for the 64 beneficiary days that we found were improperly claimed. Sierra requested that we amend our report to include the rejection of all findings and recommendations that any therapy services were not medically necessary.

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

TABLE OF CONTENTS

INTRODUCTION1
Why We Did This Review
Objective1
Background
How We Conducted This Review
FINDINGS
Services Were Not Medically Necessary
Documentation Did Not Meet Medicare Requirements
CONCLUSION4
RECOMMENDATIONS5
AUDITEE COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE5
Auditee Comments5
Office of Inspector General Response6
APPENDIXES
A: Related Office of Inspector General Reports
B: Audit Scope and Methodology9
C: Statistical Sampling Methodology
D: Sample Results and Estimates
E: Auditee Comments14

INTRODUCTION

WHY WE DID THIS REVIEW

In recent years, Medicare Part B payments for outpatient physical therapy have increased annually, with private-practice physical therapists generating payments of about \$1.9 billion in calendar year (CY) 2014. Previous Office of Inspector General (OIG) reviews have identified claims for outpatient physical therapy services that were not reasonable, medically necessary, or properly documented and that were vulnerable to fraud, waste, and abuse. As part of a nationwide effort, we selected multiple physical therapists for review, including physical therapists associated with Sierra Injury & Sports Rehab, Inc. (Sierra), a private practice located in California. Our analysis indicated that one of Sierra's physical therapists was among the highest Medicare therapy billers in California. (Appendix A lists related OIG reports on outpatient physical therapy services.)

OBJECTIVE

Our objective was to determine whether claims for outpatient physical therapy services provided by Sierra 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 program.

Medicare Part B covers services considered medically necessary to treat a disease or condition, including outpatient therapy services. CMS contracts with Medicare contractors to process and pay Part B claims.

Medicare Outpatient Physical Therapy Services

Medicare Part B provides coverage for outpatient physical therapy services.¹ Physical therapists evaluate and treat disorders of the musculoskeletal system. The goal of physical therapy is to restore maximal functional independence to each individual patient by providing services that aim to restore function, improve mobility, and relieve pain. Treatments such as exercise, heat, cold, electricity, and massage are used. These services are provided in many different settings; however, the majority of Medicare payments for outpatient therapy services are made to physical therapists practicing in an office setting.

For Medicare Part B to cover outpatient physical therapy services, the services must be medically reasonable and necessary, provided in accordance with a plan of care established by a

A Northern California Physical Therapy Practice's Outpatient Therapy Services (A-09-14-02040)

¹ The Act § 1832(a)(2)(C).

physician or qualified therapist, and periodically reviewed by a physician, and the need for such services must be certified by a physician.² Further, Medicare Part B pays for outpatient physical therapy services billed using standardized codes.³ Services furnished by physical therapists in private practice must be performed by or under the direct supervision of a qualified physical therapist.⁴ Finally, the Act precludes payment to any provider of services or other person without information necessary to determine the amount due the provider.⁵ These requirements are further described in CMS's *Medicare Benefit Policy Manual* (Benefit Manual), Pub. No. 100-02, chapter 15.

Sierra Injury & Sports Rehab, Inc.

Sierra operates one physical therapy office, located in Yuba City, California. Sierra was established in January 1990. During CYs 2012 and 2013, Sierra's professional staff consisted of three physical therapists, two physical therapy assistants, and one rehabilitation technician.

Sierra's claims are processed and paid by Noridian Healthcare Solutions, LLC, the Part B Medicare administrative contractor (MAC) for providers in Jurisdiction E, which includes California. Previously, the MAC was Palmetto GBA, LLC.

HOW WE CONDUCTED THIS REVIEW

Our review covered Sierra's claims for Medicare Part B outpatient physical therapy services provided during CYs 2012 and 2013. Our sampling frame consisted of 10,378 beneficiary days,⁶ totaling \$1,086,144, of which we reviewed a random sample of 100 beneficiary days. An independent medical review contractor determined whether the services for the 100 sampled beneficiary days were provided in accordance with Medicare 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 B 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.

² The Act §§ 1862(a)(1)(A), 1861(p), and 1835(a)(2)(C); 42 CFR §§ 410.60 and 410.61.

³ Standardized codes used by providers are called Healthcare Common Procedure Coding System codes to report units of service.

⁴ 42 CFR § 410.60(c).

⁵ The Act § 1833(e).

⁶ A beneficiary day consisted of all outpatient physical therapy services provided on a specific date of service for a specific beneficiary for which Sierra received a payment from Medicare.

FINDINGS

Claims for outpatient physical therapy services provided by Sierra did not comply with Medicare requirements. Specifically, of the 100 beneficiary days in our random sample, Sierra properly claimed Medicare reimbursement for 36 beneficiary days. However, Sierra improperly claimed Medicare reimbursement for the remaining 64 beneficiary days, consisting of:

- 62 beneficiary days that had therapy services that were not medically necessary and
- 2 beneficiary days that did not meet Medicare documentation requirements.

These deficiencies occurred because Sierra did not have adequate policies and procedures to ensure that claims for outpatient physical therapy services complied with Medicare requirements. On the basis of our sample results, we estimated that Sierra improperly received at least \$583,335 in Medicare reimbursement for outpatient physical therapy services that did not comply with Medicare requirements. As of the publication of this report, this unallowable amount may include claims outside of the 4-year claim-reopening period.⁷

SERVICES WERE NOT MEDICALLY NECESSARY

For services to be payable, a beneficiary must have the need for physical therapy services (Benefit Manual, chapter 15, § 220). For services to be covered, they must be reasonable and necessary (the Act § 1862(a)(1)(A) and Benefit Manual, chapter 15, § 220).

Services are reasonable and necessary if it is determined that services were safe and effective, were of appropriate duration and frequency within accepted standards of medical practice for the particular diagnosis or treatment, and met the patient's medical needs (*Medicare Program Integrity Manual*, chapter 3, § 3.6.2.2). Medicare requires that outpatient physical therapy services be provided in accordance with a written plan established before treatment begins (42 CFR § 410.60).

For 62 beneficiary days, Sierra received Medicare reimbursement for therapy services for which the beneficiaries' medical records did not support the medical necessity of the services. The results of the medical review indicated that these services did not meet one or more Medicare requirements:⁸

- The amount, frequency, and duration of services were not reasonable (61 beneficiary days).
- Given the beneficiary's diagnoses, complexities, severities, and interaction of current active conditions, the care was not appropriate (61 beneficiary days).

⁷ 42 CFR § 405.980(b).

⁸ The total number of deficiencies exceeds 62 because some beneficiary days contained more than 1 deficiency.

- Services did not require the skills of a physical therapist (20 beneficiary days).
- There was no expectation of significant improvement within a reasonable and predictable period of time (19 beneficiary days).
- Services were not specific, were not an effective treatment for the beneficiary's condition, or both (17 beneficiary days).
- Services were not provided under and in accordance with a physician's signed plan of care (3 beneficiary days).

For example, Sierra received payment for physical therapy provided on June 5, 2013, to a 74-year-old Medicare beneficiary. The medical review contractor determined that the therapy service did not meet Medicare coverage requirements because the medical records showed that the beneficiary had reached a plateau with the treatment that had already been provided (indicating that the amount, frequency, and duration of services were not reasonable). The medical review contractor concluded that an independent home exercise program would have met the beneficiary's needs.

DOCUMENTATION DID NOT MEET MEDICARE REQUIREMENTS

Medicare requires that therapists maintain a treatment note for each treatment day and each therapy service (Benefit Manual, chapter 15, § 220.3B). The treatment note must document the (1) date of treatment, (2) identification of each specific service provided and billed, (3) total timed-code treatment minutes and total treatment time in minutes, and (4) signature and professional identification of the therapist who furnished or supervised the services (Benefit Manual, chapter 15, § 220.3E).

For two beneficiary days, Sierra received Medicare reimbursement for therapy services that were not documented in accordance with Medicare requirements. Specifically, Sierra did not provide us with treatment notes to support the services billed. For example, Sierra received payment for physical therapy services provided on August 6, 2012, to an 83-year-old Medicare beneficiary. However, Sierra did not provide treatment notes to indicate that the beneficiary was seen, evaluated, or treated by a physical therapist on that date.

CONCLUSION

Sierra did not have adequate policies and procedures to ensure that claims for outpatient physical therapy services complied with Medicare requirements. On the basis of our sample results, we estimated that Sierra improperly received at least \$583,335 in Medicare reimbursement for outpatient physical therapy services that did not comply with Medicare requirements. As of the publication of this report, this unallowable amount may include claims outside of the 4-year claim-reopening period.

RECOMMENDATIONS

We recommend that Sierra:

- refund to the Federal Government the portion of the estimated \$583,335 for claims for outpatient physical therapy services that did not comply with Medicare requirements and are within the 4-year claim-reopening period;
- for the remaining portion of the estimated \$583,335, which is outside of the Medicare reopening and recovery periods, exercise reasonable diligence to investigate the potential overpayments and work with the MAC to return any identified overpayments in accordance with the 60-day repayment rule; and
- strengthen its policies and procedures to ensure that claims for outpatient physical therapy services comply with Medicare requirements.

AUDITEE COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, Sierra, through its attorney, contested and objected to our finding that it submitted claims to Medicare that were medically unnecessary. Specifically, for the 64 beneficiary days that we found did not comply with Medicare requirements, Sierra disagreed with our finding for 62 beneficiary days and concurred that the remaining 2 beneficiary days were not properly payable because the records could not be produced. In addition, Sierra stated that it reserved its rights to appeal, on all grounds, for the 64 beneficiary days that we found were improperly claimed. Sierra requested that we amend our report to include the rejection of all findings and recommendations that any therapy services were not medically necessary.

Sierra's comments are included as Appendix E. Sierra also provided appendixes with comments on each of the 100 beneficiary days in our sample, but we did not include the appendixes because they were too voluminous. We are separately providing Sierra's comments and appendixes in their entirety to CMS.

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

AUDITEE COMMENTS

Comments on Ethical Principles

Sierra stated that we failed to adhere to the ethical principles that guide the work of auditors who conduct audits in accordance with generally accepted government auditing standards. Specifically, Sierra commented that (1) we used an outside reviewer who was not free of conflicts of interests, lacked independence, failed to maintain an attitude of impartiality, and averted intellectual honesty; (2) our relationship with the outside reviewer incentivized the reviewer to deem claims unallowable; and (3) the outside reviewer lacked professional behavior

and qualifications. Sierra noted examples of what it stated were evidence of the medical reviewer's lack of professional behavior and qualifications, such as the disregard for CMS's daily-note documentation requirements. In addition, Sierra commented that our relationship with the outside reviewer exposed our inappropriate use of government information, resources, and positions for personal gain.

Comments on Findings and Recommendations

Sierra stated that it disagreed with the medical reviewer on 62 beneficiary days in which the conclusion was that the claim was not payable. Sierra commented that the noted deficiencies were based on the reviewer's subjective assessment of medical necessity and that the reviewer did not have primary knowledge of each beneficiary's medical condition. Sierra stated that the reviewer did not properly apply Medicare documentation requirements.

Sierra stated that our sampling process was self-interested, fundamentally flawed, and statistically invalid. Specifically, Sierra commented that our calculation of the sample size, which represented less than 1 percent of the beneficiary days, was deficient and that there was no evidence that a 100-sample set was statistically valid. Sierra also commented that CMS itself acknowledges that sample size has a direct bearing on the precision of the estimated overpayment. Finally, Sierra commented that our use of extrapolation was improper because it was based on a flawed sample set that did not satisfy the prerequisites for the use of extrapolation.

Sierra stated that it reserved the right to appeal all of the claims that were part of our audit through the CMS appeals system and also reserved the right to provide additional information for each claim at that time.

OFFICE OF INSPECTOR GENERAL RESPONSE

We conducted this audit in accordance with generally accepted government auditing standards. We obtained an independent medical review of the sampled beneficiary days for medical necessity, documentation, and coding requirements, and our report reflects the results of that review. The independent contractor had no affiliation with the U.S. Department of Health and Human Services, OIG, the beneficiaries, or the provider involved in this audit. The independent contractor's reviewers were board certified in Physical Medicine and Rehabilitation. The independent contractor examined all of the medical records and documentation that Sierra submitted, including the daily notes, and carefully considered this information to determine whether claims for outpatient physical therapy services provided by Sierra complied with Medicare requirements. On the basis of the independent contractor's conclusions, we determined that Sierra improperly claimed Medicare reimbursement for 64 beneficiary days, consisting of 62 beneficiary days that had therapy services that were not medically necessary and 2 beneficiary days that did not meet Medicare documentation requirements. We continue to stand by those determinations.

Federal courts have consistently upheld statistical sampling and extrapolation as a valid means to determine overpayment amounts in Medicare. 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. Small sample sizes, e.g., smaller than 100 claims, have routinely been upheld by the Departmental Appeals Board and Federal courts. The legal standard for a sample size is that it must be sufficient to be statistically valid, not that it be the most precise methodology.

By recommending recovery for our audit at the lower limit of a 90-percent confidence interval, we account for the sample size, the universe size, and the overall precision in a manner that is favorable to Sierra. In fact, if we had used a larger, more precise sample, the expected result would be a higher lower limit and thus a higher recommended recovery.

We properly executed our statistical sampling methodology in that we defined our sampling frame and sampling unit, randomly selected our sample, applied relevant Medicare requirements in evaluating the sample, and used statistical sampling software (i.e., RAT-STATS) to apply the correct formulas for the extrapolation. Our extrapolation was restricted to the sampling frame from which our statistical sample was drawn. We did not use our sample results to estimate any overpayments associated with items that were outside of our frame (e.g., claims less than 25 dollars).

We acknowledge that Sierra has the right to appeal any of our individual determinations through the normal appeals process.

⁹ See Momentum EMS, Inc. v. Sebelius, 2014 WL 199061 at *9 (S.D. Tex. 2014); Anghel v. Sebelius, 912 F. Supp. 2d 4 (E.D.N.Y. 2012); Miniet v. Sebelius, 2012 U.S. Dist. LEXIS 99517 (S.D. Fla. 2012); Bend v. Sebelius, 2010 U.S. Dist. LEXIS 127673 (C.D. Cal. 2010).

¹⁰ 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); Anghel v. Sebelius, 912 F. Supp. 2d 4, 18 (E.D.N.Y. 2012); Transyd Enter., LLC v. Sebelius, 2012 U.S. Dist. LEXIS 42491 at *13 (S.D. Tex. 2012).

¹¹ See Anghel v. Sebelius, 912 F. Supp. 2d 4, 10 (E.D.N.Y. 2012) (upholding a sample size of 95 claims); *Transyd Enter., LLC v. Sebelius*, 2012 U.S. Dist. LEXIS 42491 at *30–31 (S.D. Tex. 2012) (upholding a sample size of 30 claims).

¹² 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); Miniet v. Sebelius, 2012 U.S. Dist. LEXIS 99517 at *17 (S.D. Fla. 2012).

APPENDIX A: RELATED OFFICE OF INSPECTOR GENERAL REPORTS

Report Title	Report Number	Date Issued
A Kansas Physical Therapy Practice Claimed Unallowable Medicare Part B Reimbursement for Some Outpatient Therapy Services	<u>A-07-14-01146</u>	8/22/2016
A Florida Physical Therapy Practice Claimed Unallowable Medicare Part B Reimbursement for Some Outpatient Therapy Services	<u>A-04-15-07054</u>	6/30/2016
A South Texas Physical Therapist Claimed Unallowable Medicare Part B Reimbursement for Outpatient Physical Therapy Services	<u>A-06-14-00064</u>	6/14/2016
A Florida Physical Therapy Practice Claimed Unallowable Medicare Part B Reimbursement for Some Outpatient Therapy Services	<u>A-04-15-07055</u>	4/22/2016
A Texas Physical Therapist Claimed Unallowable Medicare Part B Reimbursement for Outpatient Therapy Services	<u>A-06-14-00065</u>	3/17/2016
Boulevard Health Care Program, Inc., Improperly Claimed Medicare Reimbursement for Outpatient Physical Therapy Services	<u>A-02-14-01004</u>	10/29/2015
AgeWell Physical Therapy & Wellness, P.C., Claimed Unallowable Medicare Part B Reimbursement for Outpatient Therapy Services	A-02-13-01031	6/15/2015
An Illinois Physical Therapist Claimed Unallowable Medicare Part B Reimbursement for Outpatient Therapy Services	<u>A-05-13-00010</u>	8/20/2014
Spectrum Rehabilitation, LLC, Claimed Unallowable Medicare Part B Reimbursement for Outpatient Therapy Services	A-02-11-01044	6/10/2013
Questionable Billing for Medicare Outpatient Therapy Services	OEI-04-09-00540	12/21/2010

APPENDIX B: AUDIT SCOPE AND METHODOLOGY

SCOPE

Our review covered Sierra's claims for Medicare Part B outpatient physical therapy services provided during CYs 2012 and 2013. Our sampling frame consisted of 10,378 beneficiary days, ¹³ totaling \$1,086,144, of which we reviewed a random sample of 100 beneficiary days.

We limited our review of internal controls to those applicable to our objective. Specifically, we obtained an understanding of Sierra's policies and procedures for documenting and billing Medicare for outpatient therapy services. Our review enabled us to establish reasonable assurance of the authenticity and accuracy of the data obtained from CMS's National Claims History (NCH) file, but we did not assess the completeness of the file.

We conducted our audit from December 2014 through May 2016 and performed fieldwork at Sierra's office in Yuba City, California.

METHODOLOGY

To accomplish our objective, we:

- reviewed applicable Medicare laws, regulations and guidance;
- interviewed Noridian Healthcare Solutions, LLC, officials to obtain an understanding of the Medicare requirements related to outpatient therapy services;
- interviewed Sierra officials to gain an understanding of Sierra's policies and procedures related to providing and billing Medicare for outpatient therapy services;
- obtained a database of claims from CMS's NCH file containing the claims for outpatient therapy services provided by Sierra during CYs 2012 and 2013;
- performed data analysis on the NCH file to identify our sampling frame of 10,378 beneficiary days, totaling \$1,086,144 (Appendix C);
- selected a random sample of 100 beneficiary days from the sampling frame (Appendix C);
- reviewed available data from CMS's Common Working File for the sampled claims to determine whether the claims had been canceled or adjusted;

¹³ A beneficiary day consisted of all outpatient therapy services provided on a specific date of service for a specific beneficiary for which Sierra received a payment from Medicare.

- obtained medical record documentation from Sierra for the 100 sampled beneficiary days and provided the medical records to an independent medical review contractor, who determined whether each outpatient therapy service was allowable in accordance with Medicare requirements;
- used the results of the sample review to calculate the estimated total unallowable Medicare reimbursement paid to Sierra for services provided during CYs 2012 and 2013 (Appendix D); and
- provided the results of our review to Sierra officials.

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 C: STATISTICAL SAMPLING METHODOLOGY

POPULATION

The population consisted of all Medicare Part B claims for outpatient physical therapy services that Sierra provided during CYs 2012 and 2013.

SAMPLING FRAME

The sampling frame was a Microsoft Access database containing 10,378 beneficiary days for Medicare Part B outpatient therapy services, totaling \$1,086,144, provided by Sierra during CYs 2012 and 2013.

To identify our sampling frame, we excluded claims that had been reviewed, were currently under review, or were excluded from review by the Recovery Audit Contractor. From the lines of service associated with the remaining claims, we excluded each line of service for which payment was \$0. From the remaining lines of service, we grouped the information by beneficiary Health Insurance Claim number and date of service to identify the beneficiary days and excluded each beneficiary day for which payment was less than \$25.

SAMPLE UNIT

The sample unit was a beneficiary day. A beneficiary day consisted of all outpatient therapy services provided on a specific date of service for a specific beneficiary for which Sierra received a payment from Medicare. The beneficiary days were limited to payment amounts greater than or equal to \$25.

SAMPLE DESIGN

We used a simple random sample.

SAMPLE SIZE

We selected a sample of 100 beneficiary days.

SOURCE OF THE RANDOM NUMBERS

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

METHOD FOR SELECTING SAMPLE UNITS

We consecutively numbered the sample units in the sampling frame. After generating 100 random numbers, we selected the corresponding frame items.

ESTIMATION METHODOLOGY

We used the OIG, OAS, statistical software to calculate our estimates. We estimated the total unallowable Federal reimbursement paid to Sierra for services provided during CYs 2012 and 2013. The lower limit was calculated using a two-sided 90-percent confidence interval. Lower limits calculated in this manner will be less than the actual overpayment total 95 percent of the time.

APPENDIX D: SAMPLE RESULTS AND ESTIMATES

Table 1: Sample Results

No. of Beneficiary Days in Sampling Frame		Sample Size	Value of Sample	No. of Unallowable Beneficiary Days	Value of Unallowable Beneficiary Days
10,378	\$1,086,144	100	\$10,394	64	\$6,468

Table 2: Estimated Value of Unallowable Beneficiary Days (Limits Calculated for a 90-Percent Confidence Interval)

Point estimate	\$671,264
Lower limit	583,335
Upper limit	759,192

APPENDIX E: AUDITEE COMMENTS



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August 8, 2016

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

Dear Ms. Ahlstrand:

Please accept this letter in response to the Draft Report regarding the audit conducted by the Office of Inspector General ("OIG") of the Department of Health & Human Services with respect to Sierra Injury & Sports Rehab, Inc. ("Sierra"), specifically Report Number A-09-14-02040. We would appreciate your sincere attention to the concerns we raise in this letter.

It is our understanding that the audit documented in the Draft Report was to be conducted pursuant to generally accepted government audit standards (the "Standards" or "GAGAS"). The Standards are documented in the Government Auditing Standards, also known as the "Yellow Book," which is published by the U.S. Government Accountability Office. These Standards establish how auditors are expected to conduct their audits. Among these are the Ethical Principles that guide both the Standards themselves and the auditors in their work. The conduct of the OIG in this audit causes us to question whether it is familiar with either the Standards or their guiding Ethical Principles. We hope the OIG will respond to these concerns with more than a boilerplate, perfunctory response that all its recommendations are valid, as it normally does - both Sierra and the public deserve better than that.

With respect to the so-called findings put forth in the Draft Report, Sierra contests and objects to any assertion by the auditors that it submitted claims to Medicare that were medically unnecessary. Moreover, Sierra reserves its rights to appeal, on all grounds, for the 64 beneficiary days the OIG has wrongfully asserted were improperly claimed.

I. Ethical Principles

According to Gene L. Dodaro, Comptroller General of the United States, "[t]hese [S]tandards provide the foundation for government auditors to lead by example in the areas of



independence, transparency, accountability, and quality through the audit process." Yellow Book, p.1 (Opening Letter). In this context, the transparent and ethical conduct of auditors is critical to the public being able to hold the government accountable for its actions. "Because auditing is essential to government accountability to the public, the public expects audit organizations and auditors who conduct their work in accordance with GAGAS to follow ethical principles." Yellow Book, § 1.11. To better appreciate the manner in which auditors must act ethically, the Government Accountability Office has provided guidance to its accepted principles of ethical conduct.

The ethical principles that guide the work of auditors who conduct audits in accordance with GAGAS are

- a. the public interest;
- b. integrity;
- c. objectivity;
- d. proper use of government information;, resources, and positions; and
- e. professional behavior.

Yellow Book, § 1.14. It is the failure to adhere to these Ethical Principles by the OIG in this audit that causes us concern, and we hope it both causes concern for the OIG and leads to better practices. To explain, the guidelines for each of the Ethical Principles will be addressed in the context of this audit.

A. Objectivity

It is important to begin with objectivity, the Ethical Principle listed third above, because in this context it is the keystone to the legitimacy of any audit and the one most blatantly offended here. Indeed, the absence of independence in this audit invalidates the results.

The credibility of auditing in the government sector is based on auditors' objectivity in discharging their professional responsibilities. Objectivity includes independence of mind and appearance when providing audits, maintaining an attitude of impartiality, having intellectual honesty, and being free of conflicts of interest. . . . The concepts of objectivity and independence are closely related. Independence impairments impact objectivity.

Yellow Book, § 1.19.

The OIG in this case utilized an outside reviewer to analyze the samples. Under the circumstances presented here, the use of such a reviewer – alone and in combination with the conduct of the OIG itself – undermines the objectivity of this audit on multiple grounds and requires the proposed findings and recommendation be rejected.

First, the reviewer was selected solely by the OIG, without input from Sierra.



Second, the OIG has not disclosed how the reviewer was selected.

Third, the OIG has not disclosed the qualifications of the reviewer.

Fourth, following the selection, the OIG refused, despite multiple requests on multiple occasions, to disclose the identity of the reviewer.

Fifth, the OIG refused to disclose whether there was a single reviewer or multiple reviewers.

Sixth, the OIG has not disclosed how much money it has paid the reviewer for work done on this matter.

Seventh, the OIG has not disclosed how many previous matters this reviewer has worked for the OIG, or how much money it has paid the reviewer for work on those matters.

Eighth, the OIG has not disclosed how many other matters it has contracted the reviewer to work for the OIG, or how much money it has agreed to pay the reviewer for work anticipated on those matters.

Ninth, the OIG has not disclosed whether the reviewer has any other financial interest in the matter against Sierra.

Tenth, the OIG has not disclosed – in fact, refused to disclose – the specific review criteria upon which the reviewer's decisions were made and which the OIG accepted without question.

Eleventh, the OIG refused an in-person exit interview.

Twelfth, the OIG refused to disclose the reasons for denial. It was only following our repeated requests for those reasons and the multiple requests for the OIG to supplement the spreadsheet findings that the OIG finally provided its so-called "reasons," which only indicated the claims were "not medically necessary" without any explanation or detail.

The lack of transparency exhibited by the OIG, combined with the multiple factors that demonstrate the outside reviewer's bias in favor of the OIG, invalidates the objectivity of the audit. Indeed, the circumstances of this audit run counter to the hallmarks of objectivity. Recall that "[o]bjectivity includes independence of mind and appearance when providing audits, maintaining an attitude of impartiality, having intellectual honesty, and being free of conflicts of interest." Yellow Book, § 1.19. The facts here demonstrate the outside reviewer clearly was not free of conflicts of interest, lacked independence of mind, failed to maintain an attitude of impartiality, and averted intellectual honesty, as will be discussed further below with respect to qualifications. Accordingly, the OIG has failed to live up to the Standards and the Ethical Principle of objectivity and its findings and recommendations for this audit should be rejected.



B. Integrity

Not only did the OIG fail to act objectively in this audit, it also failed to conduct itself with integrity.

Public confidence in government is maintained and strengthened by auditors performing their professional responsibilities with integrity. Integrity includes auditors conducting their work with an attitude that is objective, fact-based, nonpartisan, and nonideological with regard to audited entities and users of the auditors' reports.

Yellow Book, § 1.17.

The goals of such an Ethical Principle should be self-evident; indeed, such a principle is intuitive and should not need to be articulated. The circumstances of this audit, however, make one question whether the OIG is so obtuse as to be incapable of appreciating such a fundamental principle or has brazenly shunned it.

As detailed above with respect to the lack of objectivity in this audit, the relationship between the OIG and the outside reviewer incentivized the reviewer to deem claims unallowable. Such findings would ensure the OIG was better positioned to garner an improper windfall and ensure the outside reviewer would again be hired by the OIG for future audits. Whether there were other, additional financial incentives is unknown because the OIG has withheld all information regarding its financial relationship with the outside reviewer. How can the OIG not understand the impropriety of this arrangement? Or does the OIG appreciate the impropriety but consider itself beyond reprimand for such conduct? In either regard it is deplorable and an affront to the integrity with which we expect our government to conduct itself.

The OIG's failure to conduct itself in an objective, nonpartisan manner offends the Standards and the Ethical Principle of integrity. As a result, the OIG's findings and recommendations should be rejected.

C. Professional Behavior

The Ethical Principle calling for professional behavior was offended in this audit on multiple grounds.

High expectations for the auditing profession include compliance with all relevant legal, regulatory, and professional obligations and avoidance of any conduct that might bring discredit to auditors' work, including actions that would cause an objective third party with knowledge of the relevant information to conclude that the auditors' work was professionally deficient. Professional behavior includes auditors putting forth an honest effort in performance of their duties and professional services in accordance with the relevant technical and professional standards.

Yellow Book, § 1.24.



The bias with which this audit was conducted brings discredit to the work done by the OIG. Indeed, any objective third party with knowledge of the OIG's lack of transparency and its reliance on the findings of an outside reviewer who has been incentivized to skew the results to the benefit of himself and the OIG would easily conclude that the auditors' work was professionally deficient. This alone warrants the rejection of the OIG's findings and recommendations; however, there are additional factors that call into question the qualifications of the outside reviewer and also necessitate rejection of the OIG's findings and recommendations.

We note the following evidence of the reviewer's lack of professional behavior and qualifications:

Lack of Professional Behavior, Example #1: Disregard for CMS daily note documentation requirements. In conducting the review, the reviewer ignored the CMS guidelines that describe the required and optional elements for information in a daily note. In fact, the reviewer essentially re-labeled the optional elements as required elements and wrongfully determined various daily notes to be insufficient because they lacked optional information. Additionally, the reviewer appears to have invented requirements and rejected claims based upon his fabricated requirements. For example in Claim #92, the reviewer noted that a claim was unallowable because on the date under review (7/10/2012) a physical exam was not performed to measure functional status, but a physical exam is neither a required nor an optional element that Medicare requires in the daily note. It is difficult to imagine a more blatant example of the reviewer's self-interested efforts to declare claims unallowable.

Furthermore, the reviewer often noted that certain elements were missing from the documentation related to the claim under review when such information was not required. For example in Claim #1, the reviewer deemed the claim unallowable because the patient's response to treatment was not noted, even though CMS does not require that such information be included in a daily note.

According to CMS, the required elements and optional elements for documentation in the therapy daily treatment note are as follows:

Documentation of each treatment shall include the following required elements:

- · Date of treatment; and
- Identification of each specific intervention/modality provided and billed, for both timed and untimed codes . . .; and
- Total timed code treatment minutes and total treatment time in minutes. . . . ;
 and

¹ The masculine term "himself" or any similar term such as "him" or "his" in this letter are used in a generic sense simply because the OIG has refused to disclose the quantity or identity of the reviewer(s). For ease of reference, the reviewer is assumed to be singular and male.



 Signature and professional identification of the qualified professional who furnished or supervised the services and a list of each person who contributed to that treatment. . . .

Documentation of each treatment may also include the following optional elements to be mentioned only if the qualified professional recording the note determines they are appropriate and relevant. If these are not recorded daily, any relevant information should be included in the progress report.

- · Patient self-report;
- Adverse reaction to intervention;
- Communication/consultation with other providers (e.g., supervising clinician, attending physician, nurse, another therapist, etc.);
- · Significant, unusual or unexpected changes in clinical status;
- · Equipment provided; and/or
- Any additional relevant information the qualified professional finds appropriate.

Medicare Benefits Policy Manual, Chapter 15, §220.3, subsection E.

The reviewer's unilateral elevation of optional elements to required elements along with the creation and imposition of elements not sanctioned by CMS demonstrate the reviewer was unqualified to participate in this audit. Even more worrisome is that, as mentioned, such blatant improper conduct reeks of self-interested efforts to wrongfully deem claims as unallowable in order to garner improper refunds for CMS and assure future work for himself. This reviewer has demonstrated his lack of professional behavior, which alone warrants rejection of the OIG's findings and recommendations in this audit.

Lack of Professional Behavior, Example #2: Identifying treatment as excessive during the first or second week of therapy. The reviewer often noted that therapy was excessive, and in fact made this determination without regard to the actual visit number that was under review. For example in Claim #32, the visit under review was the sixth visit, yet the reviewer noted that "the number of treatments were excessive." Such a conclusion is simply implausible under these circumstances. Moreover, not only does the reviewer's conduct in this example demonstrate the reviewer failed to review whether the specific claim was properly payable, but also that he went beyond the scope of the authorized review. The lack of professional behavior pervasively exhibited by this reviewer requires the OIG's findings and recommendations be rejected.

Lack of Professional Behavior, Example #3: Application of an "improvement standard" that does not exist. The reviewer improperly utilized a non-existent Medicare "improvement standard" to deem multiple claims unallowable. For example in Claim #54 the



reviewer noted treatment should be based on "expectation of significant improvement within a reasonable and predictable period of time." This was done without apparent consideration for the beneficiary's significant complexities and co-morbidities and whether the beneficiary was undergoing maintenance therapy. Additionally, it offends the standards established through the *Jimmo v Sebelius* settlement.

CMS reached a Settlement Agreement in the *Jimmo v. Sebelius* class action suit. The Settlement Agreement set forth a series of specific steps to be undertaken by CMS including new provider education and clarification to existing program guidance with the goal to ensure that claims are correctly adjudicated in accordance with existing Medicare policy. This was meant to ensure that Medicare beneficiaries receive the full coverage to which they are entitled. CMS was compelled, in their educational campaign to all those that make Medicare determinations, to ensure that the reviewers not deny coverage for therapy services because the underlying conditions of a beneficiary may not or will not improve.

In the CMS national provider call on December 19, 2013, CMS provided the following information:

- The settlement agreement is intended to clarify that when skilled nursing or skilled therapy services are required in order to provide care that is reasonable and necessary to prevent or slow further deterioration, coverage cannot be denied based on the absence of potential for improvement or restoration.
- The *Jimmo v. Sebelius* Settlement Agreement includes language specifying that "Nothing in this Settlement Agreement modifies, contracts, or expands the existing eligibility requirements for receiving Medicare coverage."
- Accordingly, any actions undertaken in connection with this settlement do not represent an expansion or contraction of coverage, but rather, serve to clarify existing policy so that Medicare claims will be adjudicated consistently and appropriately.

For the time period of the audit here, an improvement standard was not in place. As a result, therapy provided with the intent of maintaining the patient's progress or preventing a loss of function was appropriate. The recommendation for continued care in every case was recommended by the physical therapist and was properly certified by the treating physician who referred the patient for skilled physical therapy services. As CMS noted in the above referenced call:

- No "Improvement Standard" is to be applied in determining Medicare coverage for maintenance claims that require skilled care.
- Skilled nursing or therapy services are covered where such services are necessary
 to maintain the patient's current condition or prevent or slow further deterioration safely and
 effectively.

Therefore, specific documentation was not required to signal improvement expectations, and we refute the reviewer's application of a non-existent improvement standard. The physical



therapy services were appropriately rendered based upon the CMS clarification that an "improvement standard" was not to be applied. This demonstrates the reviewer is either not familiar with the CMS requirements or is purposefully utilizing inapplicable standards that cannot be met in order to declare there was no compliance. Again, such unprofessional behavior is unacceptable and must result in the rejection of the OIG's findings and recommendations.

Lack of Professional Behavior, Example #4: Disregarding the documentation of improvement documented through the CMS claims-based Functional Limitation Reporting ("FLR") required in 2013. The reviewer often noted on the date under review that the beneficiary was not improving or progressing. For example in Claim #56 the reviewer commented that the patient had reached a plateau. We disagree that the patient had reached a plateau as progress was consistently reported. In fact, a comparison of the initial FLR (evaluation) to the subsequent FLR clearly reveals there was patient improvement, i.e., on 4/17/13 the impairment rating assessed by the therapist improved to 60-80% impaired, and by 5/20/13 the impairment rating improved again to 40-60%. This documented decrease in impairment level – and corresponding improvement – is the intended basis of documentation that CMS is looking for in the mandatory reporting of functional limitations to support the medical necessity of skilled therapy. The reviewer's conduct in this regard is unacceptable because it again demonstrates either ignorance of the CMS requirements or lack of attention to the content of the reports. As a result, the OIG's findings and recommendations must be rejected.

Lack of Professional Behavior, Example #5: Using frequency and duration standards that are intended for management of injured workers but inapplicable to Medicare beneficiaries. The reviewer regularly suggested a frequency and duration for therapy that was not based upon CMS guidance, and in fact was based upon standards not generally applicable to physical therapy treatments for Medicare beneficiaries. In denying claims for medical necessity the reviewer regularly offered an opinion such as: "A typical course of treatment for this condition would include up to 9 treatment sessions over 8 weeks." Such opinions by the reviewer were made without reference to the specific patient condition and without apparent acknowledgement or consideration of the patient's complexities and comorbidities. For example, in Claim #47 the 87-year-old female patient presented for therapy with diagnoses of low back pain, hip pain and knee pain with complexities and co-morbidities of arthritis, heart disease and emphysema. The reviewer noted that treatment was excessive, when in fact this patient had only completed 11 of the 12 prescribed and certified visits under her plan of care. Given the fact that this 87-year-old woman lived alone and presented with the above noted complexities and co-morbidities the evaluating therapist and referring physician concurred that 12 therapy visits were necessary. Accordingly, Sierra asserts the plan of care was appropriate, and strongly objects to any conclusion that 11 therapy sessions were "excessive."

Another particularly egregious example of the reviewer's misconduct can be found in his rejection of Claim #59. That claim also was denied for excessive treatments. The beneficiary was a 74-year-old male who had recently suffered a stroke and was in his first course of skilled therapy post-stroke. The claim date in question was visit #10, and we find it incomprehensible that a patient who needed the help of caregivers at home to assist with basic tasks and other functional activities would be denied this basic level of skilled physical therapy intervention on the ground that it was excessive. Therapy for this patient also was directed to educating the



caregivers as part of the patient's transition to home. Putting aside the heartlessness of such a denial, it offends Medicare guidelines, the Standards, and the Ethical Principles.

As noted above, the reviewer's conclusions were made without reference to the specific patient condition and without apparent acknowledgement or consideration of the patient's complexities and co-morbidities. Instead, the reviewer utilized guidelines that were intended to predict and/or curb utilization for worker's compensation care or actuarial statistics that managed care plans utilize in approving therapy services and/or limiting therapy access per the payor policy. We object to the lack of transparency in utilizing guidelines for this audit that do not reflect the policy guidance provided by CMS in the Medicare Benefits Policy Manual, Ch. 15, §§ 220–230, nor in the pertinent local coverage determinations issued by either PalmettoGBA or Noridian (during the applicable periods). The reviewer's application – and the OIG's acceptance – of guidelines that are wholly inapplicable is shameful. Their use of guidelines that do not govern the utilization of therapy is tantamount to creating policy that CMS has not written, implemented, or communicated to the therapy constituency groups such as the American Physical Therapy Association.

Overall, the reviewer's application of standards dictated by worker's compensation care or actuarial standards instead of CMS standards establish the reviewer's lack of qualifications to conduct this review and lack of professional behavior. Recall that with respect to the Ethical principle of professional behavior, the guidance requires "avoidance of any conduct that might bring discredit to auditors' work, including actions that would cause an objective third party with knowledge of the relevant information to conclude that the auditors' work was professionally deficient." Yellow Book, § 1.24. All of the examples described above demonstrate the reviewer engaged in conduct - repeatedly and pervasively - that discredits his conclusions and the OIG's acceptance of those conclusions in its findings and recommendations. Indeed, any objective third party would certainly conclude the reviewer's conduct in this audit, e.g., conversion of daily treatment note optional elements to required elements, fabrication of other elements, failure to review the claims specified, going beyond the scope of the authorized review, utilizing a nonexistent improvement standard, wrongly asserting there was no documentation of improvement, and applying worker's compensation guidelines to reject Medicare beneficiary claims, demonstrate the reviewer was incredibly unqualified to conduct this audit. That the OIG spent taxpayer money for such an unqualified person to conduct this audit is another example of the lack of professional behavior that pervasively undermined the validity of this audit. The persistent unprofessional behavior exhibited in this audit require one result: rejection of the OIG's findings and recommendations.

D. Proper Use of Government Information, Resources, and Positions

The circumstances of the audit undermine multiple aspects of the Ethical Principle regarding proper use of governmental authority. First, we consider the personal interests of those involved in the audit. "Government information, resources, and positions are to be used for official purposes and not inappropriately for the auditor's personal gain or in a manner contrary to law or detrimental to the legitimate interests of the audited entity or the audit organization." Yellow Book, § 1.20. As noted above, the OIG nurtured a relationship with an outside reviewer that better positioned the OIG to appear as though it were legitimately recouping government



monies, thereby garnering financial and professional rewards for the OIG and the outside reviewer. "Misusing the position of an auditor for financial gain or other benefits violates an auditor's fundamental responsibilities." Yellow Book, § 1.23. Furthermore, the lack of transparency by the OIG prevents Sierra or the public from assessing the full extent of the inappropriate relationship. The impropriety of the relationship and the cover up — both individually and in combination — expose the OIG's inappropriate use of government information, resources, and positions for personal gain.

Second, the Standards instruct that the public has the right to government information. "In the government environment, the public's right to the transparency of government information has to be balanced with the proper use of that information." Yellow Book, § 1.21. It is precisely OIG's failure to be transparent in identifying the outside reviewer, the number of reviewers, the method of selecting the reviewer, the past, present, and future remuneration paid or guaranteed to the reviewer, etc., that prevents Sierra and the public from determining the extent of the impropriety. Indeed, "[a]countability to the public for the proper use and prudent management of government resources is an essential part of auditors' responsibilities." Yellow Book, § 1.22. Based upon evidence of the improper use of government resources and without the transparency needed to evaluate the scope of the misuse, the findings and recommendations of the OIG must be rejected.

E. Public Interest

The first of the Ethical Principles is addressed last because of its overarching application, both generally and specifically in this context.

The public interest is defined as the collective well-being of the community of people and entities the auditors serve. Observing integrity, objectivity, and independence in discharging their professional responsibilities assists auditors in meeting the principle of serving the public interest and honoring the public trust. The principle of the public interest is fundamental to the responsibilities of auditors and critical in the government environment.

A distinguishing mark of an auditor is acceptance of responsibility to serve the public interest. This responsibility is critical when auditing in the government environment. GAGAS embodies the concept of accountability for public resources, which is fundamental to serving the public interest.

Yellow Book, §§ 1.15-1.16. The OIG's failure to observe integrity, objectivity, and independence in this audit has been evidenced above. At a minimum, the OIG has forgotten that accountability for the exercise of its vast authority begins with transparency, at worst, it has purposefully eschewed that fundamental obligation.

The OIG's actions in this audit do not serve the public interest; rather, the actions undercut and destabilize the system whose integrity the OIG is meant to uphold. Simply put, the system cannot endure if the OIG continues to conduct audits in the manner it did in this case. Subjecting honest providers to misguided, blatantly biased, opaque scrutiny does not encourage providers to continue aiding those of our population covered by Medicare who look to the



providers to sustain or improve their quality of life. Instead, the OIG's actions of the sort exhibited in this audit encourage providers to affirmatively opt out of Medicare, which would deprive the Greatest Generation and the Baby Boomers from receiving the quality care they may need and most certainly deserve. Such a result is not in the public interest.

This Ethical Principle, like the four others, has been violated by the OIG. The failure to observe integrity, objectivity, and independence in this audit and abjuring its obligation to the public trust preclude the OIG from receiving the ill-gotten benefit of its actions. As a result, the OIG's findings and recommendations must be rejected.

II. Sierra Objects to OIG's Findings and Recommendations

A. All Services Provided by Sierra Were Medically Necessary

We disagree with the reviewer on 62 claims in which the conclusion was that the claim was not payable. As explained in detail above, the findings and recommendations of the OIG are ill-founded. The offenses to the Ethical Principles demonstrated in this audit are pervasive and result in unreliable and unacceptable conclusions. Accordingly, the findings and recommendations must be rejected.

In addition, in the appendices that accompany this letter, we address each of the 100 claims substantively to demonstrate why, in addition to the vast grounds highlighted in this letter, the conclusions of the reviewer and the findings and recommendations of the OIG are unacceptable for each claim the OIG asserts is unallowable. Of the grounds discussed in the appendices, for example, the reviewer used a template with six possible areas of deficiency all being categorized as issues of medical necessity. Noted deficiencies and resultant determination of claims as non-payable were based upon the reviewer's subjective assessment of medical necessity. The reviewer was not the primary care physician, specialty physician, or physical therapist and so did not have primary knowledge of each beneficiary's medical condition including complexities and co-morbidities.

Of note, in most outpatient private practice physical therapy clinics a large portion of the referrals for medically necessary therapy are for a post-surgical course of rehabilitation. Absent any major complexities or co-morbidities these post-surgical patients generally follow a predictive course of rehabilitation that is based upon the clinic's specific rehabilitation protocol or the protocol of the referring surgeon and in all instances is based upon the judgment and knowledge of the physical therapist. The case load at Sierra is not reflective of this type of patient, and the OIG sampling of claims reflects that Sierra has a case load of generally complex patients with remarkable past medical histories and past episodes of physical therapy. The beneficiaries in the samples often presented for evaluation with more than one diagnosis, and in many cases additional diagnoses were added during the course of treatment.

The reviewer often improperly referenced that the required daily treatment note did not include items such as patient examination, reporting of patient response to treatment, objective tests and measurements, and other non-required elements. It is obvious at this point that the reviewer did not properly apply Medicare documentation requirements. As a result, for all the

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24



reasons identified in this letter and the appendices, we object to any findings and recommendations that allege a claim is unallowable and urge that such conclusions be rejected.

B. Reserve the Right to Appeal and Provide Documents at a Later Time

Sierra reserves the right to appeal all of the claims that were deemed not medically necessary through the CMS appeals system and reserve the right to provide additional information for each denied sample claim at that time.

Sierra also acknowledges and concurs with the OIG that 2 claims were not properly payable in that the records could not be reproduced (Samples #51 and #52). Sierra reserves the right to appeal and provide the relevant documentation.

C. OIG's Sampling Process is Flawed

The OIG has created a sampling process that artificially skews the value of the claims in its favor so it can recover more than it is entitled. Besides providing the OIG with a windfall, it creates the contrived appearance that the OIG is providing a public service and should be commended when in reality it should be scrutinized and condemned for its disservice.

Rather than taking an accurate, random sampling so that claims of all types and values might be included, the OIG purposefully only selects samples that have high monetary values. This permits the OIG to generate a much higher average value for each claim in a small sample set and then apply that high value across the spectrum of claims thereby inflating the amount it will claim is owed to CMS. This is an outrageous abuse of authority and it must be discontinued across the board. With respect to this case, there are multiple reasons why it should not be utilized.

First, in its Draft Report, the OIG indicated there were 10,378 beneficiary days from which it generated its set of 100 sample claims. This sample set represents less than 1% of the beneficiary days it purports to be analyzing. From among all those beneficiary days, "we [the OIG] excluded each line of service for which payment was \$0." Draft Report, App. C., p.9. Additionally, the OIG "excluded each beneficiary day for which payment was less than \$25." *Id.* The exclusion of the low value claims – the number of which the OIG, yet again, has not disclosed – drastically distorts the average value of the claims in favor of the OIG.

Second, the calculation of the sample size itself, less than 1% of the beneficiary days, is deficient. There is no evidence that a 100-sample set is statistically valid in this context. Moreover, the OIG has not disclosed its basis for determining that such a small sample size was statistically valid. Unsurprisingly, CMS guidance provides that "[a] challenge to the validity of the sample . . . that the particular sample size is too small to yield meaningful results . . . is without merit as it fails to take into account all of the other factors that are involved in the sample design." Medicare Program Integrity Manual, ch.8, § 8.4.4.3. What CMS fails to recognize both generally and with respect to this audit is that the failings of the sample size is not the only factor that demonstrates the sampling was deficient. Notably, CMS acknowledges in the same guidance that sample size is a critical factor in determining whether an estimate is accurate.



The size of the sample (i.e., the number of sampling units) will have a direct bearing on the precision of the estimated overpayment, but it is not the only factor that influences precision. The standard error of the estimator also depends on (1) the underlying variation in the target population, (2) the particular sampling method that is employed (such as simple random, stratified, or cluster sampling), and (3) the particular form of the estimator that is used (e.g., simple expansion of the sample total by dividing by the selection rate, or more complicated methods such as ratio estimation).

Medicare Program Integrity Manual, ch.8, § 8.4.4.3 (emphasis added). Thus, while sample size is one of multiple factors, CMS itself acknowledges that sample size has "a direct bearing on the precision of the estimated overpayment" and so is of critical importance. Indeed, it is an especially important factor when the OIG fails to offer any evidence that satisfies the other factors necessary to support sampling. Transparency is crucial in this regard to ensure the OIG has adhered to the Standards, but just as in nearly all other aspects of this audit the OIG has chosen to obfuscate the process.

The sampling process utilized by the OIG is self-interested, fundamentally flawed, and statistically invalid, which nullify the results. Accordingly, the use of sampling should not be condoned in this audit and the findings and recommendations based on the sampling should be rejected. Any alleged overpayment should be based on the actual value of the only claims that are currently insufficient — two claims that lack certain documentation — and not on any sampling.

D. OIG's Use of Extrapolation is Improper

The OIG improperly utilized extrapolation to give the appearance that it is entitled to a windfall from Sierra. Based upon its extrapolation methods the OIG claims Sierra should refund \$583,335 to the government. These methods cannot be sustained because it is based on a flawed sample set, as explained above, and they do not satisfy the prerequisites for the use of extrapolation.

Extrapolation may not be used to determine alleged overpayment amounts unless "(A) there is a sustained or high level of payment error; or (B) documented educational intervention has failed to correct the payment error." 42 U.S.C. § 1395ddd(f)(3). In this instance, the OIG does not explain why it used extrapolation, it simply declares that it did and expects acceptance of its self-interested, arbitrary decision. This lack of explanation, while not surprising given the general lack of transparency by the OIG, actually is revealing because it unveils the OIG's inability to satisfy either prerequisite.

First, the OIG cannot legitimately demonstrate there is a sustained or high level of payment error. In light of the revelations in this letter and its supporting exhibits, we know that there are two claims that are currently deficient, and those due to missing documentation. This represents, at most, 2% of the claims sampled – far from any objective understanding of sustained or high level of payment error. As a result, use of extrapolation on this basis is improper and any alleged overpayment should be based on the actual value of the two claims



involved and not on any extrapolation derived therefrom. The values of these two claims are \$59.88 and \$86.35, for a combined total of \$146.23.

Second, the OIG cannot demonstrate that educational intervention has failed to correct the payment error. The OIG has not attempted to provide educational intervention. Sierra, however, independently and proactively provided educational training to its staff covering fraud and abuse and Medicare documentation, coding, and billing, and should receive credit for such from the OIG. Given that there are only two currently unallowable claims based upon missing documentation, i.e., a filing error, educational intervention is both the better option for addressing the error and ensuring the error does not occur again. As a result, use of extrapolation amounts to overkill and any alleged overpayment should be based on the actual value of the two claims involved and not on any extrapolation derived therefrom.

Overall, the use of extrapolation was improper and the findings and recommendations based on any extrapolation should be rejected. Any alleged overpayment should be based on the actual value of the only claims that are currently insufficient – two claims that lack certain documentation – and not on any extrapolation.

III. Concur that 36 Claims Were Allowable

The Draft Report indicated that Sierra "properly claimed Medicare reimbursement for 36 beneficiary days." Sierra concurs with this finding and reiterates that this should have been the finding for at least 62 of the remaining beneficiary days as well.

IV. Conclusion

Sierra is a rural physical therapy facility that prides itself on its honest operations and the quality of life its services bring to so many in its community. Unfortunately, this benevolent facility, its employees, and its patients have become the victim of a misguided OIG. The almost innumerable acts of unprofessional, biased, and intellectually dishonest conduct by the OIG and its reviewer have been shocking to discover. The evidence demonstrating the persistent violations of the Standards and the Ethical Principles should serve as a clarion call to revamp the manner in which the OIG conducts its audits.

In light of the discussion above and in the supporting exhibits in the accompanying appendices, which address the individual claims, Sierra requests that the OIG amend its Draft Report. Such amendments should include the rejection of all findings and recommendations that any therapy services were not medically necessary. All such findings are illegitimate in light of the biased, unqualified reviewer who made those findings. To the extent any overpayment refund is still recommended, such a refund should be limited to the two claims currently deemed to not meet the Medicare documentation requirements, the values of which are \$59.88 and \$86.35, for a combined total of \$146.23. Moreover, any overpayment refund should be that total amount – \$146.23 – and not based upon an inapplicable extrapolation calculation or statistical sampling.



Sierra reserves its rights to appeal all of the claims that were part of the audit through the CMS appeals system and reserves the right to provide additional information for each claim at that time.

Sincerely yours,

Robert G. Marasco

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15