

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**A QUEENS CHIROPRACTOR
RECEIVED IMPROPER
MEDICARE PAYMENTS FOR
CHIROPRACTIC SERVICES**

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Office of Inspector General

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Report in Brief

Date: December 2018

Report No. A-02-15-01003

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



Why OIG Did This Review

In 2012 and 2013, Medicare Part B allowed approximately \$1.4 billion of payments for chiropractic services provided to Medicare beneficiaries nationwide. Previous OIG reviews found that Medicare inappropriately paid for chiropractic services that were medically unnecessary, incorrectly coded, or undocumented. After analyzing 2012 and 2013 Medicare claims data, we selected for review a chiropractic practice located in Queens, New York (Queens Chiropractor), which was the third highest-paid provider of Medicare chiropractic services in New York State during that time.

Our objective was to determine whether chiropractic services provided by the Queens Chiropractor complied with Medicare requirements.

How OIG Did This Review

Our review covered 6,768 claims for which the Queens Chiropractor received Medicare Part B reimbursement totaling \$650,470 for 28,200 chiropractic services during the period January 1, 2012, through August 31, 2014 (audit period). We reviewed a random sample of 100 claims. We obtained medical records for the sample claims and provided those medical records to a medical review contractor who determined whether the services were allowable in accordance with Medicare requirements.

A Queens Chiropractor Received Improper Medicare Payments for Chiropractic Services

What OIG Found

Nearly all Medicare Part B payments to the Queens Chiropractor did not comply with Medicare requirements. Of the 100 sample claims for which the Queens Chiropractor received Medicare Part B reimbursement, 95 did not comply with Medicare requirements; the remaining 5 did. These improper payments occurred because the Queens Chiropractor did not have any policies and procedures to ensure that chiropractic services provided to Medicare beneficiaries were medically necessary and sufficiently documented.

On the basis of our sample results, we estimated that the Queens Chiropractor improperly received at least \$518,821 in Medicare reimbursement for chiropractic services provided during the audit period. As of the publication of this report, this unallowable amount includes claims outside the 4-year claim-reopening period.

What OIG Recommends

We recommend that the Queens Chiropractor (1) refund to the Federal Government the portion of the estimated \$518,821 in identified improper payments for claims incorrectly billed that are within the reopening period, (2) for the remaining portion of the estimated \$518,821 in improper payments for claims that are outside of the Medicare reopening period, exercise reasonable diligence to identify and return improper payments in accordance with the 60-day rule, and identify any returned improper payments as having been made in accordance with this recommendation, (3) exercise reasonable diligence to identify and return any additional similar improper payments outside of our audit period, in accordance with the 60-day rule, and identify any returned overpayments as having been made in accordance with this recommendation, and (4) develop policies and procedures to ensure that any future chiropractic services billed to Medicare comply with Medicare requirements.

In written comments on our draft report, the Queens Chiropractor, through its attorney, did not indicate concurrence or nonconcurrence with our recommendations. Rather, the attorney questioned the validity of our medical review contractor's determinations as well as our statistical sampling, and provided a statistical expert's report on our sampling methodology and overpayment estimation. After reviewing the attorney's comments and the statistical expert's report, we maintain that our findings and recommendations are valid. We used a qualified medical review contractor to determine whether our sample claims were reasonable and necessary and met Medicare requirements. We also properly executed our statistical sampling methodology.

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INTRODUCTION

WHY WE DID THIS REVIEW

In calendar years (CYs) 2012 and 2013, Medicare Part B allowed approximately \$1.4 billion for chiropractic services provided to Medicare beneficiaries nationwide. Previous Office of Inspector General (OIG) reviews found that Medicare inappropriately paid for chiropractic services that were medically unnecessary, incorrectly coded, or undocumented.¹ After analyzing CYs 2012 and 2013 Medicare claims data, we selected for review a chiropractic practice located in Queens, New York (Queens Chiropractor), which was the third highest-paid provider of Medicare chiropractic services in New York State during that time.

OBJECTIVE

Our objective was to determine whether chiropractic services provided by the Queens Chiropractor complied with Medicare requirements.

BACKGROUND

Administration of the Medicare Program

The Medicare program 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 a multitude of medical and other health services, including chiropractic services. Medicare Administrative Contractors (MACs) contract with CMS to process and pay Part B claims. National Government Services (NGS) was the MAC that processed and paid the Medicare claims submitted by the Queens Chiropractor.

Chiropractic Services

Chiropractic services focus on the body's main structures—the skeleton, the muscles, and the nerves. Chiropractors make adjustments to these structures, particularly the spinal column. They do not prescribe drugs or perform surgical procedures, although they refer patients for these services if they are medically indicated. Most patients seek chiropractic care for back pain, neck pain, and joint problems.

The most common therapeutic procedure performed by chiropractors is known as spinal manipulation, also called chiropractic adjustment. The purpose of spinal manipulation is to restore joint mobility by manually applying a controlled force into joints that have become

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

restricted in their movement as a result of a tissue injury. When other medical conditions exist, chiropractic care may complement or support medical treatment.

Medicare Coverage of Chiropractic Services

Medicare Part B covers chiropractic services provided by a qualified chiropractor. To provide such services, a chiropractor must be licensed or legally authorized by the State or jurisdiction in which the services are provided.²

Medicare requires that chiropractic services be reasonable and necessary for the treatment of a beneficiary's illness or injury, and Medicare limits coverage of chiropractic services to manual manipulation (i.e., by using the hands) of the spine to correct a subluxation (when spinal bones are misaligned).³ Chiropractors may also use manual devices to manipulate the spine.

To substantiate a claim for manipulation of the spine, the chiropractor must specify the precise level of subluxation.⁴ Depending on the number of spinal regions treated, chiropractors may bill Medicare for chiropractic manipulative treatment using one of three Current Procedural Terminology (CPT)⁵ codes: 98940 (for treatment of one to two regions), 98941 (for treatment of three to four regions), and 98942 (for treatment of five regions).⁶ The CPT code for extraspinal chiropractic manipulative treatment (98943) is not covered by Medicare. Figure 1 on the following page illustrates the five regions of the spine, from the cervical area (neck) to the coccyx (tailbone).

² CMS's *Medicare Benefit Policy Manual*, Pub. 100-02 (the Manual), chapter 15, § 30.5.

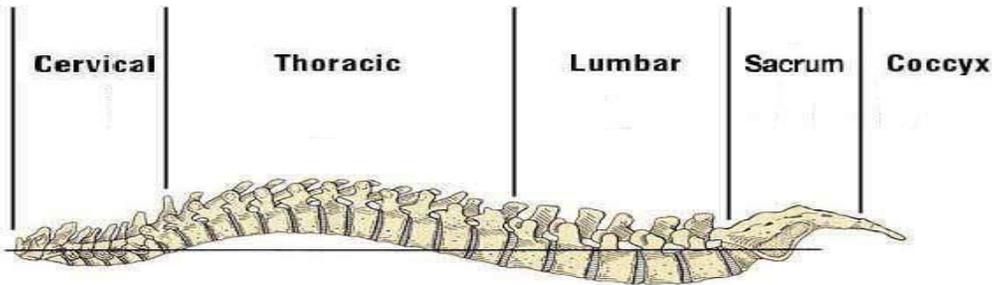
³ The Manual defines subluxation "as a motion segment in which alignment, movement integrity, and/or physiological function of the spine are altered, although contact between joint surfaces remains intact" (chapter 15, § 240.1.2).

⁴ The Manual, chapter 15, § 240.1.4, and NGS's Local Coverage Determination (LCD) for chiropractic services (L27350).

⁵ **The five character codes and descriptions included in this report are obtained from Current Procedural Terminology (CPT®), copyright 2002–2013 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures. Any use of CPT outside of this report should refer to the most current version of the Current Procedural Terminology available from AMA. Applicable FARS/DFARS apply.**

⁶ "Revised Requirements for Chiropractic Billing of Active/Corrective Treatment and Maintenance Therapy." Full Replacement of Change Request (CR) 3063, CMS Transmittal 23, CR 3449, October 8, 2004.

Figure 1: The Five Regions of the Spine



Medicare requires chiropractors to place the AT (Acute Treatment) modifier on a claim when providing active/corrective treatment for subluxation.⁷ Because Medicare considers claims without the AT modifier to be claims for services that are maintenance therapy, it will deny these claims.⁸ However, inclusion of the AT modifier does not always indicate that the service provided was reasonable and necessary.

To receive payment from Medicare, a chiropractor must have documentation to support the services provided during the initial and subsequent visits as required by the Social Security Act (the Act), the Manual and the applicable MAC's LCD for chiropractic services. Medicare pays the beneficiary or the chiropractor the amount allowed for payment according to the physician fee schedule, less the beneficiary share (i.e., deductibles and coinsurance).

Medicare Requirements to Identify and Return Overpayments

OIG believes that this audit report constitutes credible information of potential overpayments. Providers that receive notification of these potential overpayments must (1) exercise reasonable diligence to investigate the potential overpayment, (2) quantify any overpayment amount over a 6-year lookback period, and (3) report and return any overpayments within 60 days of identifying those overpayments (60-day rule).⁹

The Queens Chiropractor

The Queens Chiropractor was established in October 2010 with an office in Queens, New York. The Queens Chiropractor's owner has been a licensed chiropractor in New York State since March 2009. During the period January 1, 2012, through August 31, 2014 (audit period), the

⁷ The Manual, chapter 15, § 240.1.3. A modifier is a two-character code reported with a CPT code and is designed to give Medicare and commercial payers additional information needed to process a claim.

⁸ Maintenance therapy includes services that seek to prevent disease, promote health, and prolong and enhance the quality of life or to maintain or prevent deterioration of a chronic condition (the Manual, chapter 15, §§ 30.5(B) and 240.1.3(A)).

⁹ The Act § 1128J(d); 42 CFR part 401 subpart D; 42 CFR §§ 401.305(a)(2) and (f); and 81 Fed. Reg. 7654, 7663 (Feb. 12, 2016).

Queens Chiropractor employed one other chiropractor. The two chiropractors provided chiropractic services to patients, and billed Medicare for those services under one tax identification number. The Medicare claims data showed that the owner was the performing provider on 71 percent of the claims that the Queens Chiropractor received Medicare reimbursement for services provided during our audit period.

The Medicare claims data also showed that all of the chiropractic services provided by the Queens Chiropractor were billed with the AT modifier. The Queens Chiropractor did not submit any claims for chiropractic services with CPT code 98942, the code with the highest Medicare fee schedule amount.¹⁰ Rather, the Queens Chiropractor billed the majority (98 percent) of services with CPT code 98940, the code with the lowest fee schedule amount. The remaining services were submitted with CPT code 98941, the code with the second-highest fee schedule amount.

In December 2014, the Queens Chiropractor moved its office to a new location in Queens, New York. Since that time, the Queens Chiropractor has not submitted any Medicare claims for chiropractic services because the Queens Chiropractor believed an enrollment application for the new location had to first be submitted to CMS. As of January 2018, the Queens Chiropractor has not submitted an application to Medicare for the new location; however, Medicare enrollment records indicate the Medicare provider number associated with the chiropractic practice is still active.¹¹

HOW WE CONDUCTED THIS REVIEW

Our review covered 6,768 claims for which the Queens Chiropractor received Medicare reimbursement totaling \$650,470 for 28,200 chiropractic services provided during our audit period. We reviewed a random sample of 100 claims. The Queens Chiropractor provided us with medical records for 97 claims¹² and we provided those medical records to a medical review contractor to determine whether the services were allowable 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

¹⁰ On October 17, 2008, NGS implemented a system edit that identified claims with CPT code 98942 for manual review. As a result of this edit, chiropractic usage of CPT code 98942 decreased.

¹¹ Information obtained from CMS's Provider Enrollment, Chain, and Ownership System on April 9, 2018.

¹² According to the Queens Chiropractor's owner, the medical record for the beneficiary associated with one sample claim had been lost. Two other sample claims were included in an audit conducted by the zone program integrity contractor and were cancelled as a result of that audit after we selected the sample; therefore, we did not obtain the medical records for these claims.

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.

FINDINGS

Nearly all Medicare Part B payments to the Queens Chiropractor did not comply with Medicare requirements. Of the 100 sample claims for which the Queens Chiropractor received Medicare Part B reimbursement, 95 did not comply with Medicare requirements; the remaining 5 did.¹³ Specifically, 92 claims contained chiropractic services that were not medically necessary, 91 claims contained chiropractic services that were not sufficiently documented, and for 2 claims, there was no documentation to support the chiropractic services billed to Medicare.¹⁴

These improper payments occurred because the Queens Chiropractor did not have any policies and procedures to ensure that chiropractic services provided to Medicare beneficiaries were medically necessary and sufficiently documented.

As a result, the Queens Chiropractor received \$8,468 in unallowable payments. On the basis of our sample results, we estimated that the Queens Chiropractor received unallowable Medicare payments of at least \$518,821 provided during the audit period.¹⁵ As of the publication of this report, this unallowable amount includes claims outside of the 4-year claims reopening period.¹⁶

CHIROPRACTIC SERVICES DID NOT COMPLY WITH MEDICARE REQUIREMENTS

Services Not Medically Necessary

No payment may be made for any expenses incurred for items or services that are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.¹⁷ Additionally, Medicare Part B pays for a

¹³ The two claims that were cancelled after we selected our sample were counted as non-errors and are included in the number of claims that complied with Medicare requirements.

¹⁴ The total exceeds 95 because 90 claims contained more than 1 deficiency.

¹⁵ 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 will be less than the actual overpayment total 95 percent of the time.

¹⁶ 42 CFR § 405.980(b)(2) (reopening for good cause).

¹⁷ Section 1862(a) of the Act.

chiropractor's manual manipulation of the spine to correct a subluxation only if the subluxation has resulted in a neuromusculoskeletal condition for which manual manipulation is appropriate treatment.¹⁸

Chiropractic maintenance therapy is not considered to be medically reasonable or necessary; therefore, it is not payable under the Medicare program.¹⁹ In addition, manipulative services provided must have a direct therapeutic relationship to the patient's condition, and the patient must have a subluxation of the spine.²⁰ Finally, the chiropractor should be afforded the opportunity to effect improvement or arrest or retard deterioration of the condition within a reasonable and generally predictable period of time.²¹

Of the 100 sample claims, 92 contained chiropractic services that were not medically necessary. Specifically, the results of the medical review indicated that services on these claims did not meet one or more of the Medicare requirements related to medical necessity:

- Manual manipulation of the spinal subluxation would not be expected to result in improvement within a reasonable and generally predictable period of time (90 claims).
- Manual manipulation of the spinal subluxation was maintenance therapy or was not appropriate for treatment of the beneficiary's condition (90 claims).
- Subluxation of the spine was not present or was not treated with manual manipulation (two claims).²²

For example, the Queens Chiropractor received payment for chiropractic services provided to a 69-year-old Medicare beneficiary. The medical review contractor determined that the medical records did not support the medical necessity of the chiropractic services because the beneficiary was receiving maintenance therapy rather than active treatment. During our audit period, the Queens Chiropractor received Medicare reimbursement totaling \$2,141 for 94 chiropractic services provided to this beneficiary.

¹⁸ 42 CFR § 410.21(b).

¹⁹ The Manual, chapter 15, § 30.5(B).

²⁰ The Manual, chapter 15, § 240.1.3.

²¹ The Manual, chapter 15, § 240.1.5.

²² The total exceeds 92 because 90 claims contained more than 1 deficiency.

Services Not Sufficiently Documented

The initial visit and all subsequent visits to a chiropractor must meet certain documentation requirements. For the initial visit, the following must be documented: (1) patient history; (2) description of present illness; (3) evaluation of musculoskeletal/nervous system; (4) diagnosis; (5) treatment plan, including recommended level of care, specific treatment goals, and objective measures to evaluate treatment effectiveness; and (6) date of the initial treatment. For subsequent visits, the following must be documented: (1) patient history, including a review of the chief complaint, changes since the last visit, and a system review;²³ (2) physical examination of the area of the spine involved in the diagnosis, an assessment of the change in the patient's condition since the last visit, and an evaluation of treatment effectiveness; and (3) the treatment provided.²⁴

Of the 100 sample claims, 91 contained chiropractic services that were not sufficiently documented.²⁵ Specifically, the medical records for these services did not meet documentation requirements specified in the Manual and NGS's LCD because they did not include: (1) an evaluation of treatment effectiveness (91 claims), (2) an assessment of the change in the patient's condition since the last visit (90 claims), and (3) evidence of a physical examination (66 claims). The Queens Chiropractor did not provide any other documentation to support these services.

For example, the Queens Chiropractor received payment for a chiropractic service provided to a 72-year-old Medicare beneficiary. The medical review contractor determined that the record did not support Medicare coverage because the medical record contained minimal information related to the beneficiary's condition to support the effectiveness of care and necessity of continued treatment. The documentation that was present did not support the medical necessity of continued care. During our audit period, the Queens Chiropractor received a total of \$460 for 20 chiropractic services provided to this beneficiary.

Services Not Documented

To receive payment from Medicare, a chiropractor must have documentation to support the services claimed. No payment may be made to any provider of services unless information has been furnished to determine the amounts due the provider.²⁶

²³ A systems review is an inventory of body systems that the chiropractor obtains by asking the patient a series of questions to identify signs or symptoms that the patient may be experiencing or has experienced.

²⁴ The Manual, chapter 15, § 240.1.2(B) and NGS's LCD L27350.

²⁵ All 91 claims included subsequent visits that were not sufficiently documented. One other claim included an initial visit that was insufficiently documented.

²⁶ Section 1833(e) of the Act.

For 2 of the 100 sample claims, the Queens Chiropractor did not provide any documentation to support the services claimed. For one of the claims, the Queens Chiropractor stated that it could not find the medical record for the associated beneficiary. For the other claim, a medical record was provided; however, it did not contain documentation to support the sampled service.

THE QUEENS CHIROPRACTOR RECEIVED UNALLOWABLE MEDICARE PAYMENTS

The Queens Chiropractor received \$8,468 in unallowable Medicare payments for the 95 chiropractic services that did not meet Medicare requirements. On the basis of our sample results, we estimated that the Queens Chiropractor received unallowable Medicare payments of at least \$518,821 provided during the audit period. As of the publication of this report, this unallowable amount includes claims outside of the 4-year claims reopening period.

THE QUEENS CHIROPRACTOR DID NOT HAVE ADEQUATE POLICIES AND PROCEDURES

The unallowable Medicare payments occurred because the Queens Chiropractor did not have any policies and procedures to ensure that the chiropractic services provided to Medicare beneficiaries were medically necessary and sufficiently documented.

RECOMMENDATIONS

We recommend that the Queens Chiropractor:

- refund to the Federal Government the portion of the estimated \$518,821 in identified improper payments for claims incorrectly billed that are within the reopening period;²⁷
- for the remaining portion of the estimated \$518,821 in improper payments for claims that are outside of the Medicare reopening period, exercise reasonable diligence to identify and return improper payments in accordance with the 60-day rule, and identify any returned improper payments as having been made in accordance with this recommendation;

²⁷ OIG audit recommendations do not represent final determinations by the Medicare program but are recommendations to Department of Health and Human Services action officials. Action officials at CMS, acting through a MAC, will determine whether a potential improper payment exists and will recoup any improper payments consistent with its policies and procedures. If a disallowance is taken, providers have the right to appeal the determination that a payment for a claim was improper (42 CFR § 405.904(a)(2)). The Medicare Part A/B appeals process has five levels, including a contractor redetermination, a reconsideration by a Qualified Independent Contractor, and a hearing before an Administrative Law Judge. If a provider exercises its right to an appeal, it does not need to return funds paid by Medicare until after the second level of appeal. An improper payment based on extrapolation is reestimated depending on the result of the appeal.

- exercise reasonable diligence to identify and return any additional similar improper payments outside of our audit period, in accordance with the 60-day rule, and identify any returned overpayments as having been made in accordance with this recommendation; and
- develop policies and procedures to ensure that any future chiropractic services billed to Medicare comply with Medicare requirements.

QUEENS CHIROPRACTOR COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

QUEENS CHIROPRACTOR COMMENTS

In written comments on our draft report, the Queens Chiropractor, through its attorney, did not indicate concurrence or nonconcurrence with our recommendations. Rather, the attorney “posit[ed] that the claims in question were eligible for Medicare Part B reimbursements.” In addition, the attorney questioned the validity of our medical review contractor’s determinations as well as our statistical sampling. The Queens Chiropractor’s comments are included as Appendix E.

The attorney stated that he randomly selected 15 of our sample claims and determined that the Queens Chiropractor’s documentation for the claims supported their eligibility for Medicare reimbursement. Specifically, the attorney stated that the chiropractic services associated with the claims were reasonable and necessary, and sufficiently documented. The attorney argued that our medical reviewer found the chiropractic services associated with our sample claims to be “maintenance care” and not “active treatment” because the progression of a beneficiary’s illness was not resolved within a few visits. The attorney went on to state that there were “glaring inaccuracies and misstatements of facts” contained in the medical reviewers’ reports and that the discussion of the 15 claims highlighted the flaws and unreliability of the medical review results. The attorney contended that the medical records showed that manual manipulations were used to correct specific spinal subluxations and that they supported the treatment of active conditions—not maintenance care. According to the attorney, these findings illustrate that all of the claims we determined to be in error were eligible for Medicare reimbursement.

The attorney also challenged the validity of our statistical sampling methodology and overpayment estimation (SSOE), engaged an individual that the attorney identified as a premier expert in statistical sampling to review OIG’s SSOE, and provided a copy of their statistical expert’s report.²⁸ The attorney based these challenges on section 8.4.2 of CMS’s *Medicare Program Integrity Manual* (MPIM), which sets forth the requirements that, according to the attorney, the OIG must comply with to ensure that statistically valid methods are used. According to the attorney, the statistical expert concluded that our statistical sampling and

²⁸ We did not include their statistical expert’s report as an appendix because it was voluminous.

overpayment estimation was flawed because: (1) we used incorrect methods for estimation and extrapolation, (2) we failed to use a statistically valid random sample, (3) our findings were not accurately measured, and (4) the sampling methodology was not reviewed by a statistician. For these reasons, the statistical expert believes that our statistical sampling and extrapolation methodology failed to comply with “the fundamental laws and assumptions of statistics and probability and the MPIM requirements,” and therefore, the estimated overpayment should be invalidated.

OFFICE OF INSPECTOR GENERAL RESPONSE

After reviewing the attorney’s comments, we maintain that our findings and recommendations are valid. Specifically, the attorney is incorrect in asserting that our findings relied on a medical review that contained inaccuracies and misstatements of fact and did not consider all the information in the medical records. We used a medical review contractor that was a licensed, actively practicing chiropractor, who was knowledgeable of chiropractic guidelines and protocols. The medical review contractor did not find services to be medically unnecessary or identify services as maintenance care solely because the progression of a beneficiary’s illness was not resolved within a few visits. Rather, for each sample claim, the contractor considered Medicare requirements, chiropractic treatment standards, and each beneficiary’s individual circumstances before assessing the medical necessity of the services provided. Additionally, we sought assistance from the MAC to determine whether the chiropractor’s services met Medicare requirements. Both the medical review contractor and the MAC found that the chiropractor’s medical records lacked evidence to support the effectiveness of the care provided and the need for continued treatment.

It should also be noted that some of the inaccuracies and misstatements of facts the attorney referred to dealt with the medical review contractor stating that there were “gaps” in the medical records when there were none. We followed the protocol used by CMS in conducting its Comprehensive Error Rate Testing reviews, which was to provide records for 6 months prior to the date of service under review. We also provided the initial evaluation and any subsequent re-evaluations associated with the service date, as well as 3 months after the date of service, so that the medical review contractor would have sufficient information related to the onset of the medical condition being treated and a history of that treatment that would assist in determining whether the treatment had been effective. The “gaps” identified by the medical review contractor were notes that were after the date of an initial or subsequent evaluation but more than 6 months prior to the date of service. While the medical review contractor noted these “gaps” in their determination letters, they acknowledged that these records would not have impacted their determinations.

We also carefully reviewed the report prepared by the attorney’s statistical expert and maintain that our sampling methodology and overpayment estimation was statistically valid. Federal courts have consistently upheld statistical sampling and extrapolation as a valid means

to determine overpayment amounts in Medicare and Medicaid.²⁹ The legal standard for use of sampling and extrapolation is that it must be based on a statistically valid methodology, not the most precise methodology.³⁰ We properly executed our statistical sampling methodology in that we defined our sampling frame and sampling unit, randomly selected our sample,³¹ applied relevant criteria in evaluating the sample, and used statistical sampling software (i.e., RAT-STATS) to apply the correct formulas for the extrapolation. In addition, we performed simulation testing and verified that the concerns raised by the statistical expert about the distribution of the sample mean did not impact the validity of our estimates. Lastly, although the MPIM requirements cited apply to Medicare contractors—not the OIG—our sampling methodology, as detailed in Appendix C, was approved by a statistician. That approval is maintained in our working papers and can be provided upon request.

²⁹ See *Yorktown Med. Lab., Inc., v. Perales*, 948 F.2d 84 (2d Cir. 1991); *Illinois Physicians Union v. Miller*, 675 F.2d 151 (7th Cir. 1982); *Momentum EMS, Inc., v. Sebelius*, 2013 U.S. Dist. LEXIS 183591 at *26-28 (S.D. Tex. 2013), adopted by 2014 U.S. Dist. LEXIS 4474 (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).

³⁰ See *John Balko & Assoc. v. Sebelius*, 2012 WL 6738246 at *12 (W.D. Pa. 2012), *aff'd* 555 F. App'x 188 (3d Cir. 2014); *Maxmed Healthcare, Inc. v. Burwell*, 152 F. Supp. 3d 619, 634–37 (W.D. Tex. 2016), *aff'd*, 860 F.3d 335 (5th Cir. 2017); *Anghel v. Sebelius*, 912 F. Supp. 2d 4, 18 (E.D.N.Y. 2012); *Transyd Enters., LLC, v. Sebelius*, 2012 U.S. Dist. LEXIS 42491 at *13 (S.D. Tex. 2012).

³¹ The randomness of our sample is directly supported by the validated, replicable method used to select the sample items. In reviewing their statistical expert's report, we identified errors in the expert's analysis which led the expert to incorrectly conclude that the differences between the sample and frame were larger than would be expected given a random sample.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

Our review covered 6,768 chiropractic claims for which the Queens Chiropractor received Medicare reimbursement totaling \$650,470 for 28,200 chiropractic services provided to Medicare beneficiaries during our audit period. These claims were extracted from CMS's National Claims History (NCH) file.

We did not review the overall internal control structure of the Queens Chiropractor. Rather, we limited our review of internal controls to those that were significant to the objective of our audit. Specifically, we obtained an understanding of the Queens Chiropractor's policies and procedures related to chiropractic services. Our review 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 the Queens Chiropractor's office in Queens, New York.

METHODOLOGY

To accomplish our objective, we:

- reviewed applicable Federal laws, regulations, and guidance;
- interviewed NGS officials to obtain an understanding of Medicare reimbursement requirements and NGS's claims-processing procedures related to chiropractic services;
- interviewed the sole owner of the Queens Chiropractor to obtain an understanding of the Queens Chiropractor's policies and procedures for providing chiropractic services to beneficiaries, maintaining documentation for services, and billing Medicare for such services;
- obtained from CMS's NCH file a sampling frame of 6,768 chiropractic claims, totaling \$650,470 for our audit period;
- selected a random sample of 100 chiropractic claims from the sampling frame;
- reviewed data from CMS's Common Working File and other available data for the sampled claims to determine whether the claims had been cancelled or adjusted;
- obtained medical records and other documentation from the Queens Chiropractor for 97 of the 100 sample claims;

- reviewed the medical records and other documentation provided by the Queens chiropractor to support the sampled claims;
- provided the medical records and other documentation to the medical review contractor, who determined whether each service was allowable in accordance with Medicare requirements;
- reviewed the medical review contractor's results and summarized the reason a claim was determined to be improperly reimbursed;
- used the results of the sample to estimate the amount of the improper Medicare payments made to the Queens Chiropractor for chiropractic services; and
- discussed the results of our review with the Queens Chiropractor.

See Appendix C for the details of our statistical sampling methodology and Appendix D for our sample results and estimates.

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

APPENDIX B: RELATED OFFICE OF INSPECTOR GENERAL REPORTS

Report Title	Report Number	Date Issued
<i>Medicare Needs Better Controls To Prevent Fraud, Waste, and Abuse Related to Chiropractic Services</i>	<u>A-09-16-02042</u>	2/12/2018
<i>A Brooklyn Chiropractor Received Unallowable Medicare Payments for Chiropractic Services</i>	<u>A-02-13-01047</u>	8/9/2017
<i>Hundreds of Millions in Medicare Payments for Chiropractic Services Did Not Comply With Medicare Requirements</i>	<u>A-09-14-02033</u>	10/18/2016
<i>A Michigan Chiropractor Received Unallowable Medicare Payments for Chiropractic Services</i>	<u>A-07-14-01148</u>	8/8/2016
<i>CMS Should Use Targeted Tactics To Curb Questionable And Inappropriate Payments For</i>	<u>OEI-01-14-00200</u>	9/29/2015
<i>Alleviate Wellness Center Received Unallowable Medicare Payments for Chiropractic Services</i>	<u>A-09-14-02027</u>	7/22/2015
<i>Advanced Chiropractic Services Received Unallowable Medicare Payments for Chiropractic Services</i>	<u>A-07-13-01128</u>	5/27/2015
<i>Diep Chiropractic Wellness, Inc., Received Unallowable Medicare Payments for Chiropractic Services</i>	<u>A-09-12-02072</u>	11/20/2013
<i>Inappropriate Medicare Payments for Chiropractic Services</i>	<u>OEI-07-07-00390</u>	5/5/2009
<i>Chiropractic Services in the Medicare Program: Payment Vulnerability Analysis</i>	<u>OEI-09-02-00530</u>	6/5/2005

APPENDIX C: STATISTICAL SAMPLING METHODOLOGY

POPULATION

The population consisted of all Medicare Part B claims for chiropractic services provided by the Queens Chiropractor during the period January 1, 2012, through August 31, 2014 (audit period). A claim could contain more than one line of service.

SAMPLING FRAME

The sampling frame is an Access database containing 6,768 chiropractic claims, totaling \$650,470, paid to the Queens Chiropractor for 28,200 services provided during our audit period. The claims data was extracted from the CMS's NCH file.

SAMPLE UNIT

The sample unit was a chiropractic claim.

SAMPLE DESIGN

We used a simple random sample.

SAMPLE SIZE

The sample size was 100 chiropractic claims.

SOURCE OF RANDOM NUMBERS

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

METHOD FOR SELECTING SAMPLE UNITS

We consecutively numbered the sample units in the sampling frame from 1 to 6,768. After generating 100 random numbers, we selected the corresponding frame items.

ESTIMATION METHODOLOGY

We used the OAS statistical software to calculate our estimates. We estimated the total improper Medicare reimbursement paid to the Queens Chiropractor during our audit period at the lower limit of a two-sided 90-percent confidence interval. We also used the software to calculate the corresponding point estimate and upper limit of the 90-percent confidence interval.

APPENDIX D: SAMPLE RESULTS AND ESTIMATES

Sample Results

Frame Size	Value of Frame	Sample Size	Value of Sample	Number of Claims with Improper Payments	Value of Claims with Improper Payments
6,768	\$650,470	100	\$8,748	95	\$8,468

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

Point Estimate	\$573,141
Lower limit	\$518,821
Upper limit	\$627,461

APPENDIX E: QUEENS CHIROPRACTOR COMMENTS

Via FedEx 8133 8294 1704

August 10, 2018

Ms. Brenda M. Tierney
Regional Inspector General for Audit Services
U.S. Department of Health and Human Services
Office of Inspector General
Office of Audit Services, Region II
Jacob K. Javits Federal Building
26 Federal Plaza, Room 3900
New York, NY 10278

Re: A Queens Chiropractor Received Improper Medicare Payments for Chiropractic Services, Report No. A-02-15-01003

Dear Ms. Tierney:

Please be advised of this firm's continued representation of Jaeho Shin, D.C. ("Dr. Shin" or "Chiropractor") in matters before the U.S. Department of Health and Human Services, Office of Inspector General ("OIG"). Please see attached a fully executed Appointment of Representative Form (CMS-1696). We are in receipt of OIG's draft audit report dated June 7, 2018 ("Draft Report"). Please allow this letter to serve as Dr. Shin's formal response to the allegation contained in the Draft Report.

Pursuant to Centers for Medicare and Medicaid Services ("CMS")'s Medicare Benefit Policy Manual (the "Manual") and the National Government Services' Local Coverage Determination ("LCD"), to be eligible for Medicare coverage the following elements must present: 1) subluxation of spine was present; 2) subluxation of the spine was treated with manual manipulation; 3) manual manipulation of the spinal subluxation was appropriate for the treatment of the patient's condition and was not maintenance therapy; 4) manual manipulation of the spinal subluxation would be expected to result in improvement within a reasonable and predictable length of time; 5) initial visit notice contain sufficient documentation to support the finding of subluxation and its treatment plan; 6) subsequent visit note contain sufficient documentation to support the finding for on-going manual manipulation of a spinal subluxation.

Dr. Shin posits that the claims in question were eligible for Medicare Part B reimbursements. The chiropractic services rendered were reasonable and necessary for the treatment of the beneficiary's illness and/or injury. The manual manipulations were utilized to correct specific spinal subluxations. The treatments were provided to address acute conditions, rather than for maintenance care. The documentation was sufficient to support the corresponding claims.

I. Records Review

Illustratively, our office randomly selected fifteen (15) claims from the OIG's sample which are attached for your convenience and are separately discussed below:

Sample #4

Enrollee abbreviation: H.W.

Dates of Service: 06/26/2012 – 07/24/2012

In the Medical Professional Reviewer Report, the OIG reviewer concluded that “[t]he reevaluation visit lack details surrounding the causal incident; therefore it is not clear if the subluxation being treated is an acute condition.” Nowhere in the Manual or the LCD do they require a description of the “causal incident” for a subluxation. Rather, “the symptoms must be related to the level of subluxation that has been cited ... [t]he location of pain must be described and whether the particular vertebra listed is capable of producing pain in the area determined.” In the re-evaluation examination on 05/08/2012, it was documented that the patient suffered bilateral lower back pain with stiffness, spasm, soreness, aching, and sharp and non-radiating pain. Pain score was at 7-8/10. On examination, misalignments of the L3, L4, and L5 vertebrae were noted. There were marked decreases in range of motion with pain on movements. This patient has been an established patient since 2010 and was treated exclusively for illness at the thoracic and cervical areas. The sudden and severe onset of lumbar pain on 05/08/2012 indicates an acute condition. According to the 05/08/2012 progress note, the treatment plan was CMT and myofascial release. The patient was to return in 1-2 weeks or PRN. In the subsequent visits, there was marked improvement represented by a consistent decrease in VAS scores. At the dates of service, the pain score was at 5 and sharp pain and tingling sensation have dissipated. While the treatment progress was noted to be slower than expected, there is no evidence that there will be no improvement to the lumbar subluxation. The OIG reviewer also referenced the fluctuation in ROM as evidence of a lack of progress. It should be noted ROM was noted to have increased on a single visit on 06/12/2012. For the remaining visits, decrease of ROM was documented, but it was no longer painful on movement.

The OIG reviewer's findings appear to predicate on the assumption that because the progression of the illness was not resolved within a few visits, the chiropractic services must be maintenance care, and not treatment for an active condition. As shown above, since there are objective functional improvements in the illness, it was reasonable to expect that continued manual manipulation with result in improvement within a reasonable and predictable period of time.

Sample #10

Enrollee abbreviation: M.L.

Dates of Service: 11/12/2012 – 12/15/2012

In the Medical Professional Reviewer Report, the OIG reviewer concluded that “there has been no quantifiable objective clinical change with treatment in the past and therefore it is medically reasonable to expect the same clinical outcome with future treatment.” Since the cervical subluxation was a new condition presented on 11/12/2012, it is impossible to have any “quantifiable objective clinical change with treatment in the past”. This, therefore, is not a valid

basis for denying reimbursement for the chiropractic services. Moreover, there are sufficient records indicating a finding of subluxation. The 11/12/2012 re-evaluation documented misalignments of the C1, C2, C3, and C4 vertebra and asymmetry at the cervical region. The patient reported pain at 7-8/10 and decreased in ROM with pain on movement. The OIG reviewer further concluded that the treatment plan lacks specificity, thus medical necessity was not established. This is false. There are objective measures demonstrating improvements. The shooting pain has subsided as of 12/15/2012. In subsequent visits on 01/05/2013 and 01/12/2013, there were documented decrease of pain 5-6/10 and increased ROM without pain. These support that the cervical condition was an acute illness that was responsive to manual manipulation.

The OIG reviewer's findings appear to predicate on the assumption that because the progression of the illness was not resolved within a few visits, the chiropractic services must be maintenance care, and not treatment for an active condition. As shown above, since there are objective functional improvements in the illness, it was reasonable to expect that continued manual manipulation with result in improvement within a reasonable and predictable period of time.

Sample #11

Enrollee abbreviation: K.J.

Dates of Service: 09/20/2013 – 09/24/2013

In the Medical Professional Reviewer Report, the OIG reviewer is critical of the lack of "Specific treatment goals" and "Specific objective evaluation" documented in the 07/01/2013 re-evaluation exam. It should be noted that this patient had been treated for lumbar pain since 11/04/2011. At the 11/04/2011 initial evaluation, the treatment plan was noted as "[C]hiropractic manipulative therapy full spine as needed for restriction finding upon motion palpation; patient will be seen 1-2 times/week[:]; [f]ollow up plans: Re-exam after 6 weeks if given treatment protocol is not responsive." The short-term goal was decreasing pain, muscle tightness, and increase ROM. The long-term goal was to improve patient's activity of daily living and prevent complications and attain highest functional level of physical conditions." On 07/01/2013, the patient presented with complaint of lower back pain that started a week ago without any incident. Patient reported the pain was worsening since its onset and described a sharp and shooting pain that radiated to the left thigh, tingling sensation, aching, and stiffness. It was noted that the patient had spine surgery in 2003. The records showed misalignments at L4 and L5. The patient also exhibited decreased ROM with pain on flexion and extension. In the 07/01/2013 progress note, the "Plan/Recommendation" was noted to be "continue with current corrective treatment." As such, it is clear that following the 07/01/2013 re-evaluation, it was decided that the best course of action was to follow the treatment plan established in the initial evaluation.

Furthermore, contrary to the OIG reviewer's contention, the records for the dates of service and beyond indicate a decreased in pain as reflected in the reduced VAS scores. Increased ROM was noted on subsequent visits and noted with no pain, which is a demonstrable improvement from the 07/01/2013 re-evaluation.

The OIG reviewer's findings appear to predicate on the assumption that because the progression of the illness was not resolved within a few visits, the chiropractic services must be maintenance care, and not treatment for an active condition. As shown above, since there are

objective functional improvements in the illness, it was reasonable to expect that continued manual manipulation with result in improvement within a reasonable and predictable period of time.

Sample #17

Enrollee abbreviation: Y.L.

Dates of Service: 07/03/2013-07/31/2013

In the Medical Professional Reviewer Report, the OIG reviewer claimed that the VAS scores remained relatively unchanged between the 03/20/2013 re-evaluation and the dates of service. This is false. On 03/20/2013, it was documented that “patient notes that the pain grade is 7-8/10.” As of 07/03/2013, the VAS score was noted at 4-5/10. This is a significant and quantifiable improvement resulting from the chiropractic treatment. In fact, the improvement continued as evidenced that, on 07/24/2013 and 07/31/2013, the VAS scores were at 3-4/10. On the progress notes for each dates of services, the pain was noted to be improving. Furthermore, as of 07/24/2013, the lumbar spasm and sharp pain have been alleviated. The patient’s condition continued to improve until an incident on 09/18/2013 which exacerbated her lumbar condition and a re-evaluation was then aptly conducted.

The OIG reviewer’s findings appear to predicate on the assumption that because the progression of the illness was not resolved within a few visits, the chiropractic services must be maintenance care, and not treatment for an active condition. As shown above, since there are objective functional improvements in the illness, it was reasonable to expect that continued manual manipulation with result in improvement within a reasonable and predictable period of time.

Sample # 18

Enrollee abbreviation: K.L.

Dates of Service: 03/03/2014 – 03/24/2014

The OIG reviewer’s finding is riddled with factual inaccuracies. First, the reviewer found that “there is a gap between visits notes from 11/21/2011 and 8/26/2013.” This is false. More than sixty (60) pages of Chiropractic Daily Progressive Notes for those treatment dates were submitted to the OIG. In addition, this so-called gap in care, even if true, is not relevant to medical necessity for treatments rendered on the dates of service which originated from a re-evaluation on 08/12/2013. Also, the OIG’s reviewer falsely claimed that a re-evaluation was performed on 08/23/2013. There is nothing in the records indicating that the patient was seen on 08/23/2013, much less being re-evaluated. In truth, as the reviewer noted elsewhere in his/her report, a re-evaluation was actually performed on 08/12/2013 and it revealed a new lumbar subluxation after the patient fell down in her living room. From the 08/23/2013 re-evaluation to the dates of service, it was documented that the patient’s lumbar ROM has increased without pain. While the pain fluctuated throughout the treatment course, back spasm and soreness were resolved. Clearly, these objective findings show significant and quantifiable improvement and that the chiropractic treatment was medically necessary and was for treatment of an active condition.

Sample # 20

Enrollee abbreviation: H.J.C.

Dates of Service: 03/26/2013 – 04/23/2013

In the Medical Professional Reviewer Report, the OIG reviewer's finding is riddled with factual inaccuracies. First, the reviewer found that "[n]o additional care was reported [from 12/10/2011] until 9/25/2012." This is false. As evidenced by the progress notes, the patient was treated more than eighteen (18) times between 12/10/2011 to 09/25/2012. In addition, this so-called gap in care, even if true, is not relevant to medical necessity for treatments rendered on the dates of service with originated from a re-evaluation on 01/08/2013. Also, the reviewer also claimed that "VAS score [sic] remain relatively unchanged over the course of more than five month of treatment." This is likewise inaccurate. The treatment course for the lumbar subluxation between the re-evaluation and the dates of service spans merely three months. It is unclear which five-month treatment the reviewer is referencing. Furthermore, subsequent visits following the dates of service show that the patient continued to improve. As of 07/09/2013, the VAS score was at 2-3/10, which represents a significant and quantifiable improvement of the patient's condition. In fact, the lumbar subluxation was seemingly resolved since the subsequent visits concentrated exclusively on treatment at the cervical region and there is no noted complaint of the lumbar area.

The OIG reviewer's findings appear to predicate on the assumption that because the progression of the illness was not resolved within a few visits, the chiropractic services must be maintenance care, and not treatment for an active condition. As shown above, since there are objective functional improvements in the illness, it was reasonable to expect that continued manual manipulation with result in improvement within a reasonable and predictable period of time.

Sample # 25

Enrollee abbreviation: J.A.S.

Dates of Service: 12/11/2012 – 12/18/2012

In the Medical Professional Reviewer Report, the OIG reviewer's finding is riddled with factual inaccuracies. Specifically, the reviewer found that "[t]here is a gap in the treatment record between daily progress notes dated 2/7/2012 and 5/15/2012 [.]". This is false. As evidenced by the progress notes submitted to the OIG, the patient was treated more than six (6) times between 02/07/2012 to 05/15/2012. Also, contrary to the reviewer's claim, there was a significant and quantifiable improvement in the cervical pain. On 09/18/2012, the patient's VAS score was at 7-8/10. The pain consistently improved in the subsequent visits. Despite what appear to be a setback at the beginning of December 2012, the overall trend of the pain scores was in a downward trajectory. As of 12/18/2012, the VAS score was at 3. Furthermore, increased ROM without pain was noted. These signifies significant and objective improvement to the cervical subluxation.

The OIG reviewer's findings appear to predicate on the assumption that because the progression of the illness was not resolved within a few visits, the chiropractic services must be maintenance care, and not treatment for an active condition. As shown above, since there are objective functional improvements in the illness, it was reasonable to expect that continued manual manipulation with result in improvement within a reasonable and predictable period of time.

Sample # 46

Enrollee abbreviation: K.L.

Dates of Service: 02/21/2012 - 03/17/2012

The OIG reviewer stated that “there is scant quantifiable clinical evidence provided in regard to the patient’s condition to support the effectiveness of care and necessity of treatment.” This is false. At the re-evaluation on 10/10/2011, the patient complained of bilateral lower back pain after multiple incidents. The VAS score was at 8-9/10. Decreased ROM with pain was documented. In subsequent treatments, there was graduate, albeit slow, improvement in pain. As of 03/17/2012, the VAS score was at 5-6/10. The shooting, throbbing, and stabbing pain had been resolved. There was a consistent record of improvement in lumbar ROM. These improvements support the effectiveness and necessity of the chiropractic treatment. In fact, following the 03/17/2012 visit, chiropractic treatment was not needed for approximately ten (10) months until the patient was re-evaluated on 01/31/2014 for a new condition.

The OIG reviewer’s findings appear to predicate on the assumption that because the progression of the illness was not resolved within a few visits, the chiropractic services must be maintenance care, and not treatment for an active condition. As shown above, since there are objective functional improvements in the illness, it was reasonable to expect that continued manual manipulation with result in improvement within a reasonable and predictable period of time.

Sample # 58

Enrollee abbreviation: J.S.

Dates of Service: 01/27/2014 - 02/24/2014

The OIG reviewer’s finding is riddled with factual inaccuracies. Specifically, the reviewer found that “[t]here is no daily progress note found in the record for the date of the re-evaluation visit on 1/24/2013.” This is false. The 1/24/2013 progress note was included in the records produced to the OIG. According to this progress note, the patient presented with complaint for bilateral lower back pain with stiffness, soreness and aching. The VAS pain scale was at 5/10. Muscle tenderness and trigger point pain was noted on piriformis, gluteus m, quadriceps, and hamstring. Additionally, the reviewer erred in stating that “[t]he first daily progress note found for this apparent re-entry into care on 1/24/2013 is 7/22/2013.” This is objectively untrue. Between 01/24/2013 to 07/22/2013, the patient was seen by the Chiropractor twelve (12) times. Each of these visits was recorded in the daily progress notes submitted to the OIG.

The OIG reviewer’s findings appear to predicate on the assumption that because the progression of the illness was not resolved within a few visits, the chiropractic services must be maintenance care, and not treatment for an active condition. As shown above, since there are objective functional improvements in the illness, it was reasonable to expect that continued manual manipulation with result in improvement within a reasonable and predictable period of time.

Sample # 64

Enrollee abbreviation: L.L.

Dates of Service: 11/15/2012 – 11/26/2012

The OIG reviewer concluded that “there is no clear indication of any quantitative functional objective improvements” and, therefore, “medical necessity cannot be established.” This is false. On the 08/29/2012 re-evaluation, the patient complained of lower back pain without incident. The

VAS score was at 7-8/10. Decreased in ROM with pain was noted. Throughout the treatment course, the records documented improvements in pain and increases in ROM. As of 11/26/2012, the VAS score was at 4-5/10. Muscle tenderness was resolved, and the sharp pain was not longer felt. Clearly, these objective findings show significant and quantifiable improvement and that the chiropractic treatment was medically necessary and was for treatment of an active condition.

The OIG reviewer's findings appear to predicate on the assumption that because the progression of the illness was not resolved within a few visits, the chiropractic services must be maintenance care, and not treatment for an active condition. As shown above, since there are objective functional improvements in the illness, it was reasonable to expect that continued manual manipulation with result in improvement within a reasonable and predictable period of time.

Sample # 66

Enrollee abbreviation: M.K.

Date of Service: 03/30/2013

The OIG reviewer concluded that “[t]he re-evaluation note 2/2/2013 does not specify specific treatment goals.” This is incorrect. In the 02/02/2013 re-evaluation note, the Chiropractor noted the “Specific Treatment Goals” as “↓ Pain ↑ ROM”. Thus, contrary to the reviewer's claim, the Chiropractor was capable of referencing these goals during the treatment course. The reviewer also referenced a gap in care between 02/02/2013 to 03/23/2013 and concluded, without explanation, that it was not prudent “to treat an acute subluxation with corrective treatment and expected demonstrable gains.” First, it should be noted that this “gap” in treatment coincided with the lunar new year. Flushing, New York, where the Chiropractor's practice is located, consists predominantly of an Asian population. This so-called gap in care is likely due to scheduling conflicts during a holiday season. Furthermore, according to the 03/23/2013 progress note, the patient's condition was largely unchanged from the re-evaluation. It was not unreasonable for the Chiropractor to continue manual manipulation treatment and to expect a reasonable improvement in the patient's lumbar condition. Moreover, on the date of service, the VAS score showed a marked improvement. While the ROM had decreased, it was without pain on manipulation. Clearly, these objective findings show significant and quantifiable improvement and that the chiropractic treatment was medically necessary and was for treatment of an active condition.

The OIG reviewer's findings appear to predicate on the assumption that because the progression of the illness was not resolved within two visits, the chiropractic services must be maintenance care, and not treatment for an active condition. As shown above, since there are objective functional improvements in the illness, it was reasonable to expect that continued manual manipulation with result in improvement within a reasonable and predictable period of time.

Sample # 70

Enrollee abbreviation: K.K.

Dates of Service: 10/20/2012 – 10/22/2012

The OIG reviewer's finding is riddled with factual inaccuracies. Specifically, the reviewer found that the dates of service was a follow-up visit from 09/28/2011 and “[t]here are no re-examinations found in the record to support the new areas of treatment.” This is plainly untrue. On

04/30/2012, the patient was re-evaluated following a complaint for neck, mid and lower back pain which resulted from a slip and fall incident. At this visit, the VAS scores ranged between 7-9/10. There were noted decreases in ROM in the cervical and lumbar areas with pain. Asymmetries were found at the C0, C1, C6, C7, T1, T2, L3, L4, and L5, which support subluxation. The specific treatment goals were to decrease pain and improve on all activities of daily living. By all measures, this is an acute condition resulting from a traumatic event. The reviewer further claimed that there was no significant quantitative documented improvement. This is likewise inaccurate. According to the progress notes on the dates of service, the VAS scores had decreased to 4-5/10. There were noted increase in ROM without pain. Dull and sharp pain, spasm, and soreness had been resolved. Further, muscle tenderness and trigger point pain had dissipated in the trapezius, levator scapular, TFL, gluteus m areas. Clearly, these objective findings show significant and quantifiable improvement and that the chiropractic treatment was medically necessary and was for treatment of an active condition.

Sample # 83

Enrollee abbreviation: E.C.

Dates of Service: 10/07/2013 – 10/28/2013

The OIG reviewer's finding is riddled with factual inaccuracies. Specifically, the reviewer found there was no interim re-evaluation between the 06/24/2013 visit and the dates of service "to support continued treatment of these continued flares/exacerbations that were unresponsive to the relatively similar treatment given for over three months of care." This is false. As shown in the records, the patient was re-evaluated on 09/20/2013. At that time, the patient presented with complaint of lower back pain that started three days ago. The patient stated that she lifted a heavy laundry bag than heard a "click" sound and began to experience localized pain. In the progress note, decrease ROM in the lumbar without pain was noted. Muscle tenderness and trigger point pain was noted on the erector spinae, piriformis, gluteus m, and the hamstrings. This new condition was treated for less than one month by the Chiropractor. While the pain scores remained relatively static throughout this period, as of 10/28/2013, conditions to the piriformis and gluteus m areas have been resolved. Clearly, these objective findings show significant and quantifiable improvement and that the chiropractic treatment was medically necessary and was for treatment of an active condition.

The OIG reviewer's findings appear to predicate on the assumption that because the progression of the illness was not completely resolved within four visits, the chiropractic services must be maintenance care, and not treatment for an active condition. As shown above, since there are objective functional improvements in the illness, it was reasonable to expect that continued manual manipulation with result in improvement within a reasonable and predictable period of time.

Sample # 85

Enrollee abbreviation: G.G.

Dates of Service: 08/23/2012 – 09/27/2012

The OIG reviewer was critical of the sufficiency of documentation between 12/31/2010 and 08/02/2012. Specifically, the reviewer found that "[o]ver one year passes between the first initial

evaluation on 12/31/2010 and the next initial evaluation report on 1/6/2012. There is no further document found to evaluate the care during the 12/31/2010 episode of care. Almost seven months had passed between the initial evaluation on 1/6/12 and the next re-evaluation note dated 8/2/2012.” These facts, while true, are entirely irrelevant to determine the medical necessity of care for the dates of service in question. The patient was re-evaluated on 08/02/2012 and reported lower back pain which resulted from a fall. The records indicated subluxations at L-4 and L-5. VAS score was at 6-9/10. This lumbar condition was a new and active condition since all previous visits were related to the cervical region. Following four (4) weeks of treatment, there were marked improvements documented in the records. As of 09/27/2012, the pain score has been decreased to 4-5/10. Increased ROM with pain was noted. Subjective improvement included resolution of cramps, spasm, and sharp pain. Furthermore, hypertonicity on erector spinae, piriformis, hamstring, and psoas have been resolved. Clearly, these objective findings show significant and quantifiable improvement and that the chiropractic treatment was medically necessary and was for treatment of an active condition.

Sample # 99

Enrollee abbreviation: L.G.

Dates of Service: 01/5/2012 – 03/12/2012

The OIG reviewer concluded that “there are no quantifiable objective findings found on the daily progress notes that show an increase in functioning or progress towards stated objective treatment goals.” This is false. According to the 11/19/2011 initial evaluation, the treatment goals were to decrease pain and allow the patient to return to normal activity as soon as possible. The progress notes for the dates of service record a downward trend of the VAS score. At the initial evaluation, the VAS score was at 7-9/10. As of 03/12/2011, the VAS score was at 4-6/10. Furthermore, the subjective complaint of spasm, cramps, and sharp pain were seemingly resolved. There was objective finding of resolution of muscle tenderness, spasm, and trigger point pain on piriformis, gluteus m, and hamstring. Since the patient apparently reacted well with treatment, a re-evaluation was not indicated. Clearly, these objective findings show significant and quantifiable improvement and that the chiropractic treatment was medically necessary and was for treatment of an active condition.

The OIG reviewer’s findings appear to predicate on the assumption that because the progression of the illness was not resolved within two visits, the chiropractic services must be maintenance care, and not treatment for an active condition. As shown above, since there are objective functional improvements in the illness, it was reasonable to expect that continued manual manipulation with result in improvement within a reasonable and predictable period of time.

Based on the foregoing, there are glaring inaccuracies and misstatements of facts contained in the OIG’s Medical Professional Reviewer Reports. The above exercise highlights the flaws and unreliability of the OIG’s medical records reviews. The Chiropractor maintains that the patient records support payment of the claims submitted and requests that the OIG reverses its decisions for these claims.

II. Statistical Sampling and Overpayment Extrapolation

With respect to the OIG's statistical sampling and overpayment estimation ("SSOE") in this case, we have engaged a premier expert in statistical sampling, Harold S. Haller, PhD ("Dr. Haller") to review the sampling and extrapolation methodology employed by the OIG. A copy of Dr. Haller's declaration is attached for your reference. The Medicare Program Integrity Manual ("MPIM") sets forth instructions to ensure that a "statistically valid sample is drawn and that statistically valid methods are used." MPIM, § 8.4.1.1 – General Purpose. In light of the universal applicability of the MPIM in Medicare audits, the OIG must comply with all of the MPIM requirements in conducting its SSOE.

Section 8.4.2 of the MPIM lists six (6) conjunctive requirements for a statistically valid SSOE:

- 1) Define the universe correctly;
- 2) Define the frame correctly;
- 3) Define the sampling unit correctly;
- 4) Obtain a random sample;
- 5) Accurately measure the variable of interest; and
- 6) Use correct formula for estimation and extrapolation.

MPIM § 8.4.2 (Rev. 377, 05-27-2011); *see also* Sampling Techniques, William G. Cochran, Chapter 1, the Principle Steps in a Sample Survey, Section 1.3, page 4. These six conjunctive requirements represent the minimum standards that must be met for a probability sample to be valid. Based upon Dr. Haller's analysis of the statistical data maintained by the OIG, the OIG's methodology fails to meet the laws and assumptions of probability and statistics and the requirements as set forth in the Medicare Program Integrity Manual ("MPIM"). Specifically, the SSOE is flawed for the following reasons:

- a) The OIG used incorrect methods for estimation and extrapolation.

In this case, the OIG utilized a lower limit of a two-sided 90% confidence interval to compute the alleged overpayment amount. Section 8.4.5.1 of the MPIM states that, in most situations, a lower limit of a one-sided 90% confidence interval may be used when the probability sample meets the six conjunctive requirements of § 8.4.2. In theory, under this confidence interval limit, there is a 90% probability that the estimated overpayment will be lower than actual amount owed. In order to employ this, or any, confidence limit, the laws and assumptions of probability and statistics requires that the sample average overpayment be normally distributed. *See* Cochran, Sampling Techniques, page 95. As illustrated by Dr. Haller, the distribution of the average overpayment of the sample was not "bell shaped" or normally distributed. In utilizing the *Shapiro-Wilk* Goodness of Fit test, a widely accepted test to detect departure from normality, Dr. Haller proves that the distribution of average overpayments in OIG's 100 sample unit is abnormal. To further support his conclusion, Dr. Haller ran 200 and 1,000 simulations using the inverse of the culminative distribution function of the average overpayments from the sample and the probability theorem. Both simulations conclusively prove that the average overpayments distribution of OIG's sample was not normal. In light of this abnormality, the OIG deviated from the generally accepted standards of statistics and probability for applying the lower limit of a one-sided 90% confidence interval in its overpayment estimation.

Clearly, the OIG ignored the laws and assumptions of probability and statistics. It follows that the OIG used incorrect methods for estimation and extrapolation and did not meet the sixth requirement of the § 8.4.2 of the MPIM. Therefore, the estimated overpayment amount must be invalidated.

b) The OIG failed to use a statistically valid random sample (“SVRS”) in its extrapolation.

According to *Cochran*, in order to formulate a valid SSOE, one must obtain a SVRS. *See Sampling Techniques*, William G. Cochran, Chapter 1, the Principle Steps in a Sample Survey, Section 1.3, page 4. If the basic underlying selection of a sample does not meet the SVRS criteria, then no matter how sound the statistical methods applied are, the result would be useless and invalid upon extrapolation. *See Protestant Memorial Medical Center, Inc. v. The Dep’t of Public Aid*, 295 Ill. App. 3d 249, 255-56 (1998). On extensive testing, Dr. Haller concludes to a reasonable degree of statistics and probability certainty that there is a less than 0.035% probability that the sample drawn by the OIG was a SVRS. Due to this statistical improbability, the SSOE fails the fourth requirement of § 8.4.2 of the MPIM.

Furthermore, courts have accepted the definition of a SVRS as one that is “representative, efficient, and random.” Upon utilizing the Kolmogorov-Smirnov one-sample Goodness of Fit test, Dr. Haller concludes to a 99% confidence that the OIG’s sample was biased when compared to the frame. Under the generally accepted notion that “if possibilities of bias exists, no fully objective conclusions can be drawn from a sample”, the OIG’s extrapolation must be invalidated. *See Yates, Frank, Sampling Methods for Census and Surveys*, Charles Griffin & Co., 1960, pages 9-10.

c) The OIG’s audit findings were not accurately measured.

The fifth conjunctive requirement of the MPIM § 8.4.2 is to accurately measure the variable of interest and overpayments. In this audit, it is impossible for accurately measuring the overpayments by the OIG because 95% of the denials were for medical necessity. Based on the progress notes alone, the OIG reviewers must subjectively determine if the chiropractic services provided were medically necessary. There are no operational and objectively applicable definitions provided for the determination of medical necessity. As discussed in Section I above, the OIG’s reviewers’ reports are riddled with misstatements of facts, inaccuracies in the treatment course and patients’ condition, and there were glaring inconsistencies in interpreting the Chiropractor’s clinical findings. In his declaration, Dr. Haller highlights the inherent inaccuracies of medical necessity determinations and their inadequacy for a valid SSOE.

Consequently, the overpayments associated with audited medical necessity services cannot be measured with sufficient accuracy and, hence, reliability of the extrapolation of an auditor’s findings across a frame. The OIG, therefore, fails the fifth requirement of § 8.4.2 of the MPIM.

d) The sampling methodology was not reviewed by a statistician.

Section 8.4.1.5 of the MPIM states that “[t]he sampling methodology used to projected overpayments must be reviewed by a statistician, or by a person with equivalent expertise in

probability sampling and estimation methods.” In this case, none of the sampling data documents produced by the OIG identifies the statistician who oversaw this audit. There is no indication that the audit was reviewed and approved by a qualified individual. As such, it evidenced that the OIG has failed to satisfy the MPIM § 8.4.1.5 requirement.

Because of the reasons listed above, the estimated overpayment amount must be invalidated.

III. Conclusion

Based on the foregoing, it is evidenced that the claims submitted fully complied with the Medicare Part B billing requirements. Furthermore, the statistical sampling and extrapolation methodology employed by the OIG fails to comply with the fundamental laws and assumptions of statistics and probability and the MPIM requirements. As such, we respectfully request that the OIG reconsider its decisions and retract its recommendation for recoupment.

Thank you for your assistance. Should you like to further discuss this matter, please do not hesitate to contact the undersigned.

Yours Truly,

/s/ John J. Rivas
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JR/el

Encl. as indicated.

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