

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**A MICHIGAN CHIROPRACTOR
RECEIVED UNALLOWABLE
MEDICARE PAYMENTS FOR
CHIROPRACTIC SERVICES**

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Office of Inspector General

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EXECUTIVE SUMMARY

A Michigan Chiropractor received at least \$339,000 over 2 years for chiropractic services that were not allowable in accordance with Medicare requirements.

WHY WE DID THIS REVIEW

In calendar years (CYs) 2012 and 2013, Medicare allowed approximately \$1.4 billion of payments for chiropractic services provided to Medicare beneficiaries nationwide. A previous Office of Inspector General review found that in CY 2006, Medicare inappropriately paid an estimated \$178 million (of the \$466 million reviewed) for chiropractic services that were medically unnecessary, incorrectly coded, or undocumented. After analyzing Medicare claim data for CYs 2012 through 2013, we selected multiple providers for review, including a chiropractic clinic based in Michigan (Michigan Chiropractor).

Our objective was to determine whether chiropractic services billed by the Michigan Chiropractor were allowable in accordance with Medicare requirements.

BACKGROUND

Medicare Part B covers, among other services, chiropractic services provided by a qualified chiropractor. Medicare requires that these services be reasonable and necessary for the treatment of a beneficiary's illness or injury. Medicare limits coverage of chiropractic services to manual manipulation of the spine to correct a subluxation (when spinal bones lose their normal position). To receive payment from Medicare, a chiropractor must document the services as required by the Centers for Medicare & Medicaid Services' *Medicare Benefit Policy Manual* and the applicable Local Coverage Determination for chiropractic services. In addition, depending on the number of spinal regions treated, chiropractors may bill Medicare for chiropractic manipulative treatment using one of three procedure codes.

HOW WE CONDUCTED THIS REVIEW

We reviewed a random sample of 100 chiropractic services from 10,688 services that the Michigan Chiropractor provided to Medicare beneficiaries for which it received Medicare Part B payments of \$392,032 for CYs 2012 and 2013. We provided copies of medical records for these services to a medical review contractor to determine whether the services were allowable in accordance with Medicare requirements.

WHAT WE FOUND

Of the 100 sampled chiropractic services, 8 were allowable in accordance with Medicare requirements. The remaining 92 services were not allowable. Specifically, the medical records did not support the medical necessity for the 92 sampled chiropractic services. As a result, the Michigan Chiropractor received \$3,347 in unallowable Medicare payments.

On the basis of our sample results, we estimated that the Michigan Chiropractor received overpayments of at least \$339,625 for CYs 2012 and 2013. These overpayments occurred because the Michigan Chiropractor did not have adequate policies and procedures to ensure that the medical necessity of chiropractic services billed to Medicare was adequately documented in the medical records.

WHAT WE RECOMMEND

We recommend that the Michigan Chiropractor:

- refund \$339,625 to the Federal Government and
- establish adequate policies and procedures to ensure that chiropractic services billed to Medicare are adequately documented in the medical records.

AUDITEE COMMENTS AND OUR RESPONSE

In written comments on our draft report, the Michigan Chiropractor did not agree with our recommendation to refund overpayments to the Federal Government and described the associated findings as “allegations of error [that] are unjustified.” The Michigan Chiropractor agreed in part with our second recommendation and described corrective actions that it said it would take “so that compliance with Medicare coverage requirements is more clearly demonstrated in the [medical record] documentation.” The Michigan Chiropractor also requested a complete copy of the files related to this review, including internal memorandums, minutes of internal meetings, internal notes, workpapers, and information on our statistical sampling methodology.

After reviewing the Michigan Chiropractor’s comments, we maintain that our findings and recommendations are valid. Further, we provided detailed medical review results for each of the 100 sampled services—the basis for our findings—to the Michigan Chiropractor on November 19, 2015, and we provided electronic copies of the sampling frame to the Michigan Chiropractor on July 27, 2016.

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INTRODUCTION

WHY WE DID THIS REVIEW

In calendar years (CYs) 2012 and 2013, Medicare allowed approximately \$1.4 billion of payments for chiropractic services provided to Medicare beneficiaries nationwide. A previous Office of Inspector General (OIG) review found that in CY 2006, Medicare inappropriately paid an estimated \$178 million (of the \$466 million reviewed) for chiropractic services that were medically unnecessary, incorrectly coded, or undocumented.¹ After analyzing Medicare claim data for CYs 2012 through 2013, we selected multiple providers for review, including a chiropractic clinic based in Michigan (Michigan Chiropractor).

OBJECTIVE

Our objective was to determine whether chiropractic services billed by the Michigan Chiropractor were allowable in accordance 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 permanent kidney 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. Wisconsin Physicians Service Insurance Corporation (WPS) was the MAC that processed and paid the Medicare claims submitted by the Michigan 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 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 restricted in their movement as a result of a tissue injury. When other medical conditions exist, chiropractic care may complement or support medical treatment.

¹ *Inappropriate Medicare Payments for Chiropractic Services* (OEI-07-07-00390), issued May 2009.

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.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). The figure on the following page illustrates the five regions of the spine, from the cervical area (neck) to the coccyx (tailbone).

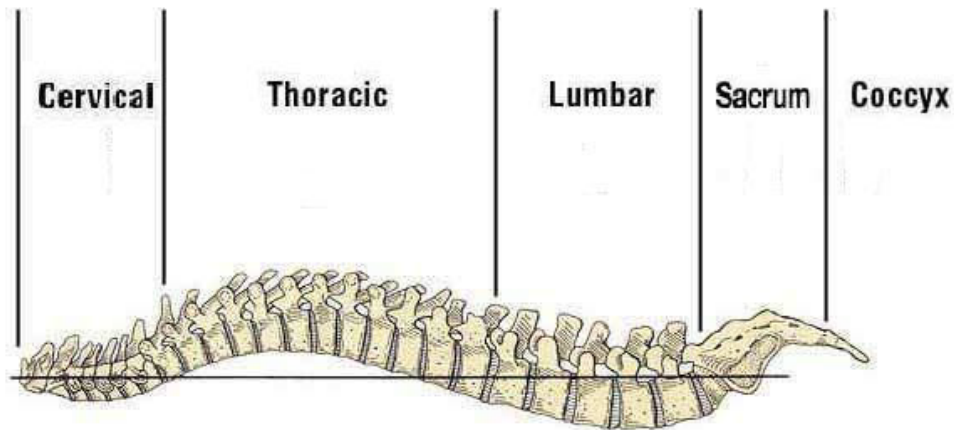
² CMS's *Medicare Benefit Policy Manual*, Pub. No. 100-02 (the Manual), chapter 15, section 30.5.

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, section 240.1.4, and WPS's Local Coverage Determination (LCD) for chiropractic services (L30328).

⁵ CPT is a uniform coding system consisting of descriptive terms and identifying codes that are used primarily to identify medical services and procedures provided by physicians and other health care professionals. **The five character codes and descriptions included in this report are obtained from Current Procedural Terminology (CPT®), copyright 2012 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.**

Figure: 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.⁶ Because Medicare considers claims without the AT modifier to be claims for services that are maintenance therapy, it will deny these claims.⁷ 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 document the services provided during the initial and subsequent visits as required by 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).

The Michigan Chiropractor

The Michigan Chiropractor was established in 1975 in Michigan. During CYs 2012 and 2013, the Michigan Chiropractor employed six chiropractors. These six chiropractors provided chiropractic services to their patients, and the Michigan Chiropractor billed Medicare for those services under one tax identification number.

The Medicare claim data that we reviewed showed that all of the chiropractic services provided by the Michigan Chiropractor were billed with the AT modifier. Further, 93 percent of the services were billed with CPT code 98942, which had the highest physician fee schedule amount among the three CPT codes covered by Medicare for chiropractic services.

Table 1 on the following page shows the allowed amount on the Medicare fee schedule for each CPT code during CYs 2012 and 2013 for Michigan.

⁶ 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.

⁷ 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 (WPS's LCD L30328).

Table 1: Medicare-Allowed Amount for Each CPT Code for Chiropractic Services

Period	CPT 98940	CPT 98941	CPT 98942
January 1 – December 31, 2012	\$26.19	\$36.95	\$46.83
January 1 – December 31, 2013	26.51	37.22	49.47

HOW WE CONDUCTED THIS REVIEW

For CYs 2012 and 2013, the Michigan Chiropractor received Medicare Part B payments of \$393,857 for 12,675 chiropractic services provided to Medicare beneficiaries. We excluded 1,987 chiropractic services for which the payment was either less than \$25.01 (1,986 services) or included in a separate OIG review (1 service). From the remaining 10,688 services, totaling \$392,032 in Medicare payments, we selected 100 services using a simple random sample. The Michigan Chiropractor provided us with copies of medical records as support for these services. In turn, we provided those copies to a medical review contractor to determine whether the 100 chiropractic 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 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 B contains the details of our statistical sampling methodology, Appendix C contains our sample results and estimates, and Appendix D contains details on the Medicare payment requirements for chiropractic services.

FINDINGS

Of the 100 sampled chiropractic services, 8 were allowable in accordance with Medicare requirements. The remaining 92 services were not allowable. Specifically, the medical records did not support the medical necessity for the 92 sampled chiropractic services. As a result, the Michigan Chiropractor received \$3,347 in unallowable Medicare payments.

On the basis of our sample results, we estimated that the Michigan Chiropractor received overpayments of at least \$339,625 for CYs 2012 and 2013. These overpayments occurred because the Michigan Chiropractor did not have adequate policies and procedures to ensure that the medical necessity of chiropractic services billed to Medicare was adequately documented in the medical records.

CHIROPRACTIC SERVICES WERE NOT ALLOWABLE IN ACCORDANCE WITH MEDICARE REQUIREMENTS

Medicare Requirements

The Social Security Act (the Act) states that 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 (§ 1862(a)). Federal regulations state that Medicare Part B pays for a 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 (42 CFR § 410.21(b)).

The Manual states that (1) chiropractic maintenance therapy is not considered to be medically reasonable or necessary and is therefore not payable (chapter 15, § 30.5(B)); (2) the manipulative services provided must have a direct therapeutic relationship to the patient's condition, and the patient must have a subluxation of the spine (chapter 15, § 240.1.3); and (3) 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 (chapter 15, § 240.1.5). The Manual and WPS's LCD require that the initial visit and all subsequent visits to the chiropractor meet specific documentation requirements. See Appendix D for these requirements.

The following must be documented for subsequent visits: (1) patient history, including a review of the chief complaint, changes since the last visit, and a system review if relevant;⁸ (2) physical examination of the area of the spine involved in the diagnosis, an assessment of change in the patient's condition since the last visit, and an evaluation of treatment effectiveness; and (3) the treatment given on the day of the visit (the Manual, chapter 15, § 240.1.2(B), and WPS's LCD L30328).

Medical Records Did Not Support Medical Necessity

The medical records did not support the medical necessity for 92 of the 100 sampled chiropractic services. Specifically, results of the medical review indicated that these services, as documented in the medical records, did not meet Medicare requirements for the following reasons:

- For 32 services, there was no evidence of spinal subluxation.
- Spinal subluxation was evident for the remaining 60 services. However, the services did not meet one or more Medicare requirements:⁹
 - Manual manipulation of the spinal subluxation was not supported in the medical record (9 services).

⁸ A system 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.

⁹ The total errors listed in the bullets below exceed 60 because some of the services had more than one error.

- Manual manipulation of the spinal subluxation was maintenance therapy or was not appropriate for treatment of the patient's condition or both (57 services).
- Manual manipulation of the spinal subluxation would not be expected to result in improvement within a reasonable and generally predicable period of time (60 services).

For example, the Michigan Chiropractor received a payment for a chiropractic service provided on November 20, 2013, to a 72-year-old beneficiary. This was the 167th service that this beneficiary had received since September 28, 2011. The medical review contractor found that the medical records did not support that the patient was treated with manual manipulation. Further, the contractor stated that, at this point in the patient's care, chiropractic manual manipulation was not likely to result in improvement in the patient's condition in a reasonable period. Specifically, the contractor stated that there was no quantifiable clinical change in the patient's condition when compared to the results of prior treatments. Therefore, the contractor concluded that it was medically reasonable to expect that future treatment would yield the same clinical outcome.

THE MICHIGAN CHIROPRACTOR RECEIVED UNALLOWABLE MEDICARE PAYMENTS

The Michigan Chiropractor received \$3,347 in unallowable Medicare payments for the 92 sampled chiropractic services that did not meet Medicare requirements. On the basis of our sample results, we estimated that the Michigan Chiropractor received overpayments of at least \$339,625 for CYs 2012 and 2013.

THE MICHIGAN CHIROPRACTOR DID NOT HAVE ADEQUATE POLICIES AND PROCEDURES

The overpayments occurred because the Michigan Chiropractor did not have adequate policies and procedures to ensure that the medical necessity of chiropractic services billed to Medicare was adequately documented in the medical records. Specifically, the Michigan Chiropractor did not have procedures to adequately document, in the medical records, clinical findings showing that the treatment actually improved the condition of the patient. The Michigan Chiropractor also did not have procedures to document qualitative or quantitative measures by which it could be proven that future progression of care would demonstrate treatment effectiveness.

RECOMMENDATIONS

We recommend that the Michigan Chiropractor:

- refund \$339,625 to the Federal Government and
- establish adequate policies and procedures to ensure that chiropractic services billed to Medicare are adequately documented in the medical records.

AUDITEE COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

AUDITEE COMMENTS

In written comments on our draft report, the Michigan Chiropractor did not agree with our recommendation to refund overpayments to the Federal Government and described the associated findings as “allegations of error [that] are unjustified.” The Michigan Chiropractor agreed in part with our second recommendation and described corrective actions that it said it would take “so that compliance with Medicare coverage requirements is more clearly demonstrated in the [medical record] documentation.” A summary of the Michigan Chiropractor’s specific comments follows.

In response to our recommendation to refund \$339,625 to the Federal Government, the Michigan Chiropractor stated that the 92 instances in which we found that the medical records did not support the medical necessity for the chiropractic services were inaccurate and should be removed from the report. Specifically, the Michigan Chiropractor said that we “failed to consider or misconstrued the relevant criteria” in reaching our conclusions. In this regard, the Michigan Chiropractor made the following statements:

- The Michigan Chiropractor said there were defects with our audit process because our audit methodology, which limited the testimonial evidence that we obtained to an “apparent inquiry” of the Michigan Chiropractor’s general understanding of CMS coverage requirements, did not comply with our internal protocol. We did not, according to the Michigan Chiropractor, obtain specific testimonial evidence regarding the rationale for the chiropractic services included in our sample. The Michigan Chiropractor added that it is “not apparent that the chiropractic consultant/auditor consulted any of the treating providers regarding the care at issue.”
- Regarding the 32 chiropractic services that we disallowed for lack of evidence of spinal subluxation, the Michigan Chiropractor said that this finding was erroneous. The Michigan Chiropractor stated that the medical review contractor “imposed a requirement for documentation of subluxation at each encounter, which is not supported by relevant provisions of [the Manual].” The Michigan Chiropractor acknowledged that “subluxation is a statutory condition of payment” but stated that “demonstration of subluxation is an initial visit requirement.” Thus, the medical review contractor “improperly required compliance with the subluxation requirement in the subsequent visit notation.”
- Regarding the other 60 chiropractic services that we disallowed, the Michigan Chiropractor said that we incorrectly did so because the medical review contractor imposed an “improvement standard” that is “improper as a matter of law” and not supported by Medicare requirements. Specifically:
 - According to the Michigan Chiropractor, Medicare requirements provide that a service is covered as reasonable and necessary if the service is performed either “for the diagnosis or treatment of illness or injury; or ... to improve the

functioning of a malformed body member.... [The] improvement [standard] is required only where functional impairment exists with respect to a ‘malformed body member.’” (Emphasis in original.) In this context, the Michigan Chiropractor said that the medical review contractor “incorrectly imposed the improvement standard to patients that required treatment as a result of an illness or injury.”

- The Michigan Chiropractor said that Medicare requirements provide for coverage through “manual manipulation of the spine to correct a subluxation that has resulted in a neuromusculoskeletal condition.” The Michigan Chiropractor also stated that Medicare requirements are “limited” to providing that the “manipulation must constitute ‘appropriate treatment’ for the neuromusculoskeletal condition.” In this regard, the Michigan Chiropractor interpreted Medicare requirements as to what should be included in the analysis of medical necessity with respect to manipulative treatment. To these points, the Michigan Chiropractor said that the Medicare requirements “neither expressly nor impliedly [impose] an improvement standard as a condition of coverage” and that “for treatment of an injury or illness, coverage is warranted where the manipulation is simply ‘appropriate’ for the condition.”
- The Michigan Chiropractor stated that a determination of whether manipulation is “appropriate” requires reference to the LCD, which defines diagnosis codes for which manipulation is considered medically necessary. However, according to the Michigan Chiropractor, the medical review contractor “ignored the LCD provisions that detail the conditions ([diagnosis] codes) for which manipulation is deemed medically necessary.” In this respect, the Michigan Chiropractor said, for each of the 60 chiropractic services that we had disallowed, “the [medical record] documentation justified the appropriateness of the manipulation given that the patient presented with a condition caused by illness or injury and that condition was one for which manipulation was considered medically necessary under the relevant LCD.”
- Regarding the 57 chiropractic services (of the 60) that we disallowed because manual manipulation of the spinal subluxation was maintenance therapy or not appropriate for treatment or both, the Michigan Chiropractor said, “[m]aintenance care is simply another way of saying that the care is not medically necessary.” The Michigan Chiropractor interpreted the maintenance therapy provisions to mean that “a conclusion that care was maintenance would be appropriate only where there was no expectation that care would result in a recovery of the acute symptoms associated with the underlying chronic condition” and that “only care that is ‘continuous and ongoing’ for the same condition could potentially be included within the definition of maintenance.” In this context, the Michigan Chiropractor stated that, “[r]ather than analyze and apply the definition of maintenance properly, the [medical review contractor] simply concluded that where there was no evidence of long-term improvement in the patient’s condition, the care was maintenance and not medically necessary.”

- The Michigan Chiropractor said that if an additional analysis were performed, then “it is likely” that some of the sampled chiropractic services, rather than being denied outright, could be “down coded” from the higher-paying CPT code 98942 to a lower-paying CPT code. The Michigan Chiropractor requested additional time to perform this analysis.
- The Michigan Chiropractor also requested a complete copy of the files related to this review, including internal memorandums, minutes of internal meetings, internal notes, workpapers, and information on our statistical sampling methodology.

The Michigan Chiropractor’s comments, from which we have redacted proprietary and personally identifiable information, are included as Appendix E.

OFFICE OF INSPECTOR GENERAL RESPONSE

After reviewing the Michigan Chiropractor’s comments, we maintain that our findings and recommendations are valid. Our responses to the Michigan Chiropractor’s specific comments follow.

- Regarding the Michigan Chiropractor’s assertion that our audit methodology did not comply with our internal protocol, we conducted this audit in accordance with generally accepted government auditing standards and the OIG, Office of Audit Services (OAS), Audit Policies and Procedures Manual. Specifically, we planned and performed the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. The evidence that we obtained, including primarily documentary evidence as well as testimonial evidence, provided a reasonable basis for our findings and conclusions.
- Regarding the Michigan Chiropractor’s statement that “demonstration of subluxation [in the 32 chiropractic services that we disallowed] is an initial visit requirement,” LCD L30328 states: “The precise level of the subluxation must be specified by the chiropractor to substantiate a claim for manipulation of the spine.” This LCD provision applies to initial *and subsequent* claims submitted for Medicare payment. A single reference to subluxation on the initial visit does not provide an indication as to whether that subluxation has or has not been corrected at a later date. In this regard, the medical review contractor found that, for these 32 chiropractic services, the medical records did not reflect evidence of the presence of subluxation.
- Regarding the other 60 chiropractic services that we disallowed, the Michigan Chiropractor’s assertion that we applied the “improvement standard” for malformed body members (from the Medicare reasonable and necessary exclusion provision) is incorrect.
 - The Michigan Chiropractor incorrectly applied that provision, which excludes from Medicare coverage items and services that are not reasonable and necessary. However, the mere fact that a service is not within the exclusion provision does not make it a Medicare-covered service. On the contrary, Medicare coverage of chiropractic services is a limited benefit that “extends only to treatment by means

of manual manipulation of the spine to correct a subluxation” (the Manual, chapter 15, § 30.5).

- In contrast to the Michigan Chiropractor’s assertion that Medicare requirements do not impose an “improvement standard,” these requirements mandate that “the manipulative services rendered must have a direct therapeutic relationship to the patient’s condition and provide reasonable expectation of recovery or improvement of function” (the Manual, chapter 15, § 240.1.3).
- The diagnosis codes listed in the LCD are the only covered diagnosis codes that support medical necessity; however, these codes do not define medical necessity. Thus, the presence of a listed diagnosis code in the medical records or other documentation does not determine the medical necessity of the care. Further, the medical review contractor used the portions of the medical record that the Michigan chiropractor gave us to examine the appropriateness of the services that were claimed for Medicare payment.
- Regarding the 57 chiropractic services (of the 60) that we disallowed because manual manipulation of the spinal subluxation was maintenance therapy or not appropriate for treatment or both, Medicare requirements are clear. According to the Manual, “[w]hen further clinical improvement cannot reasonably be expected from continuous ongoing care, and the chiropractic treatment becomes supportive rather than corrective in nature, the treatment is then considered maintenance therapy” (the Manual, chapter 15, § 30.5(B)). The medical records for the 57 services, according to the medical review contractor, did not reflect active treatment and were correctly classified as maintenance therapy.
- The medical review contractor found that the medical records did not support the medical necessity for the 92 chiropractic services. Thus, the use of a lower-paying CPT code, which the Michigan Chiropractor suggested might be the course of action after additional analysis, would not be appropriate.
- We provided the Michigan Chiropractor with the results of the medical review contractor’s conclusions—the basis for the findings in this report—on November 19, 2015. In addition, we provided electronic copies of the sampling frame to the Michigan Chiropractor on July 27, 2016.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

For CYs 2012 and 2013, the Michigan Chiropractor received Medicare Part B payments of \$393,857 for 12,675 chiropractic services provided to Medicare beneficiaries. We excluded 1,987 chiropractic services for which the payment was either less than \$25.01 (1,986 services) or included in a separate OIG review (1 service). From the remaining 10,688 services, totaling \$392,032 in Medicare payments, we selected 100 services using a simple random sample. The Michigan Chiropractor provided us with copies of medical records as support for these services. In turn, we provided those copies to a medical review contractor to determine whether the 100 chiropractic services were allowable in accordance with Medicare requirements.

We did not review the overall internal control structure of the Michigan Chiropractor. Rather, we limited our review of internal controls to those that were applicable to the objective of our audit.

We performed our audit, which included on-site fieldwork at the Michigan Chiropractor's office in Michigan, from July 2014 to November 2015.

METHODOLOGY

To accomplish our objective, we:

- reviewed applicable Federal laws, regulations, and guidance;
- interviewed Michigan Chiropractor officials to obtain an understanding of the Michigan Chiropractor's procedures for (1) providing chiropractic services to beneficiaries, (2) maintaining documentation for services, and (3) billing Medicare for services;
- obtained from CMS's National Claims History (NCH) file the Medicare Part B claims for chiropractic services provided by the Michigan Chiropractor, with service dates ending in CYs 2012 and 2013;
- created a sampling frame of 10,688 chiropractic services from the NCH data and selected a random sample of 100 services;
- obtained medical records and other documentation from the Michigan Chiropractor for the 100 sampled services and provided them to the medical review contractor, who determined whether each service was allowable in accordance with Medicare requirements;¹⁰
- reviewed and summarized the medical review contractor's results;

¹⁰ For chiropractic services initially determined to be medically unnecessary by a claims review analyst, the medical record review was completed by a clinical reviewer to make the final determination.

- estimated the amount of the unallowable payments for chiropractic services; and
- provided the results of our review to the Michigan Chiropractor on November 19, 2015.

See Appendix B for the details of our statistical sampling methodology and Appendix C 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: STATISTICAL SAMPLING METHODOLOGY

POPULATION

The population consisted of chiropractic services provided during CYs 2012 and 2013, for which the Michigan Chiropractor received Medicare payment.

SAMPLING FRAME

For CYs 2012 and 2013, the Michigan Chiropractor received Medicare Part B payments of \$393,857 for 12,675 chiropractic services provided to Medicare beneficiaries. From the population of chiropractic services, we excluded 1,987 services for which the payment was either less than \$25.01 (1,986 services) or included in a separate OIG review (1 service). After we removed these 1,987 services, the resulting sampling frame contained 10,688 services totaling \$392,032 in Medicare payments to the Michigan Chiropractor. We obtained the claim data from CMS's NCH file.

SAMPLE UNIT

The sample unit was a chiropractic service for which the Michigan Chiropractor received a payment from Medicare.

SAMPLE DESIGN

We used a simple random sample.

SAMPLE SIZE

We selected a sample of 100 services.

SOURCE OF RANDOM NUMBERS

We generated the random numbers with the OIG, OAS, statistical software.

METHOD FOR SELECTING SAMPLE UNITS

We consecutively numbered the sample units in the frame from 1 to 10,688. After generating 100 random numbers, we selected the corresponding frame items.

ESTIMATION METHODOLOGY

We used the OAS statistical software to estimate the amount of the unallowable payments for chiropractic services. 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 at least 95 percent of the time.

APPENDIX C: SAMPLE RESULTS AND ESTIMATES

Table 2: Sample Results

Services in Frame	Value of Frame	Sample Size	Value of Sample	Number of Unallowable Services	Value of Unallowable Services
10,688	\$392,032	100	\$3,646	92	\$3,347

Table 3: Estimated Value of Unallowable Services
(Limits Calculated for a 90-Percent Confidence Interval)

Point estimate	\$357,735
Lower limit	339,625
Upper limit	375,845

APPENDIX D: MEDICARE PAYMENT REQUIREMENTS FOR CHIROPRACTIC SERVICES

MEDICAL NECESSITY

The Act states: "... no payment may be made ... for any expenses incurred for items or services— (1) (A) which ... are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member" (§ 1862(a)).

Federal regulations state: "Medicare Part B pays only for a chiropractor's manual manipulation of the spine to correct a subluxation if the subluxation has resulted in a neuromusculoskeletal condition for which manual manipulation is appropriate treatment" (42 CFR § 410.21(b)).

The Manual states:

Under the Medicare program, Chiropractic maintenance therapy is not considered to be medically reasonable or necessary, and is therefore not payable.... When further clinical improvement cannot reasonably be expected from continuous ongoing care, and the chiropractic treatment becomes supportive rather than corrective in nature, the treatment is then considered maintenance therapy [chapter 15, § 30.5(B)].

The Manual also states: "... the manipulative services rendered must have a direct therapeutic relationship to the patient's condition and provide reasonable expectation of recovery or improvement of function. The patient must have a subluxation of the spine as demonstrated by x-ray or physical exam...." (chapter 15, § 240.1.3).

The Manual further states: "The chiropractor should be afforded the opportunity to effect improvement or arrest or retard deterioration in such condition within a reasonable and generally predictable period of time" (chapter 15, § 240.1.5).

DOCUMENTATION

The Act states: "No payment shall be made to any provider of services or other person under this part unless there has been furnished such information as may be necessary in order to determine the amounts due such provider or other person under this part for the period with respect to which the amounts are being paid or for any prior period" (§ 1833(e)).

The Manual and WPS's LCD require that the initial visit and all subsequent visits meet specific documentation requirements (the Manual, chapter 15, § 240.1.2, and LCD L30328).

The following must be documented for initial visits:

1. History

2. Description of the present illness including:

Mechanism of trauma;
Quality and character of symptoms/problem;
Onset, duration, intensity, frequency, location, and radiation of symptoms;
Aggravating or relieving factors;
Prior interventions, treatments, medications, secondary complaints; and
Symptoms causing patient to seek treatment.

3. Evaluation of musculoskeletal/nervous system through physical examination.

4. Diagnosis: The primary diagnosis must be subluxation, including the level of subluxation, either so stated or identified by a term descriptive of subluxation. Such terms may refer either to the condition of the spinal joint involved or to the direction of position assumed by the particular bone named.

5. Treatment Plan: The treatment plan should include the following:

Recommended level of care (duration and frequency of visits);
Specific treatment goals; and
Objective measures to evaluate treatment effectiveness.

6. Date of the initial treatment.

The following must be documented for subsequent visits:

1. History

Review of chief complaint;
Changes since last visit;
System reviews if relevant.

2. Physical exam

Exam of area of spine involved in diagnosis;
Assessment of change in patient condition since last visit;
Evaluation of treatment effectiveness.

3. Documentation of treatment given on day of visit.



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January 11, 2015

Department of Health and Human Services
Office of Inspector General
Office of Audit Services, Region VII
601 East 12th Street, Room 0429
Kansas City, MO 64103

ATTN: Chris Bresette
Audit Manager

via e-mail (Chris.Bresette@oig.hhs.gov) and US Mail

Re: **RESPONSE TO REPORT CONCLUSIONS /
REQUEST FOR INFORMATION**
Report Number A-07-14-01148

REDACTED

To whom it may concern:

Please be advised this law firm represents

REDACTED

 (**RDCT**) in the above captioned matter. We are in receipt of your audit report dated December 15, 2015. This report was received on December 17, 2015.

APPOINTED LEGAL REPRESENTATIVE

RDCT has appointed this law firm as its legal representative. This response shall act as my entry of appearance on **RDCT**'s behalf. **RDCT** hereby authorizes your office to release any and all identifiable health information to me regarding the patients involved in this case. My contact information is found above.

While an Appointment of Representative form is to be filled out by Medicare beneficiaries and not providers and is therefore not required as a matter of law, to the extent that you may require one, **RDCT** has executed an Appointment of Representative form, which is attached.

DEFECTS WITH THE CHIROPRACTIC AUDITOR'S AUDIT PROCESS

As a general matter, the audit methodology did not comply with HHS, OIG, OAS audit guidance published by OAS in *The Audit Process*, (2d ed. January 2005). While the Draft report indicates that general testimonial evidence was obtained, such evidence was limited to an apparent inquiry regarding **RDCT**'s understanding of CMS coverage requirements. No specific testimonial evidence was requested or developed regarding the rationale for the services included in the sample and it is not apparent that the chiropractic consultant/auditor consulted any of the treating providers regarding the care at issue. Additionally, the chiropractic auditor failed to consider or misconstrued the relevant criteria as is detailed below. These failures are contrary to HHS, OIG, OAS

¹¹ Office of Inspector General Note: The date just beneath the letterhead has a typographical error. The year should read 2016.

* Admitted to the practice of law before the Supreme Court of California, (CalBar ID **RDCT**), the United States Supreme Court and the US District Courts for the Southern District of California and the Western District of Pennsylvania.

own audit guidance and is in part, the basis for the error in the conclusions expressed in the Draft report.

BASES FOR DISAGREEMENT WITH SUBSTANTIVE DETERMINATION

1. Denials on the Basis that Subluxation was not Documented are Erroneous.

While the Draft report notes overall that 92 of the 100 services reviewed were determined to be not medically necessary, review of the chiropractic consultant’s analysis reveals that the denial of 32 of those services was based on the allegation that there was no evidence of subluxation. Review of the chiropractic auditor’s report reveals that the auditor imposed a requirement for documentation of subluxation at each encounter, which is not supported by relevant provisions of the MBPM.

While clear that the existence of a subluxation is a statutory condition of payment for chiropractic treatment and that CMS guidance allows for demonstration of subluxation by X-ray or P.A.R.T. analysis, the P.A.R.T. standards at section 240.1.2 do not require such analysis at each encounter. Such a conclusion is supported by the subsequent visit documentation guidance pertaining to physical examination, which is contained in this same section of the MBPM (at section 240.1.2.2.B) as follows.

The following documentation requirements apply whether the subluxation is demonstrated by x-ray or by physical examination.

* * *

2. Physical Exam

*Exam of area of spine involved in diagnosis
Assessment of change in patient condition since last visit;
Evaluation of treatment effectiveness.*

In the cases where this allegation of error was made, the course of treatment was initiated prior to the visit under review. As the documentation for subsequent visits apply whether subluxation is demonstrated by x-ray or physical examination, the “exam of area of spine involved in diagnosis” cannot be read to require a formal “P.A.R.T.” examination for the purpose of establishing a diagnosis of subluxation at each encounter. Instead, demonstration of subluxation is an initial visit requirement. To conclude that subluxation must be demonstrated at each encounter would be foolish not to mention harmful to the patient where subluxation was demonstrated by x-ray. Additionally, the conclusion that subluxation must be demonstrated by physical examination at each encounter would render CMS’ instruction that subluxation can be demonstrated by either x-ray or physical examination meaningless.

Because subluxation was established for each patient at the initial encounter, and because the chiropractic reviewer’s analysis improperly required compliance with the subluxation requirement in the subsequent visit notation, which is contrary to published CMS guidance, these denials should be reversed and this finding removed from the report.

2. **Denials on the Basis of Medical Necessity are Not Defensible When the Appropriate Standards are Applied.**

Review of the chiropractic consultant’s analysis reveals that while 92 services were deemed not medically necessary, 60 of these services were not compensable on the basis that performance of manipulation was not supported in the medical record (9 services), the care constituted non-covered maintenance care (57 services) and that for all 60 services, manipulation would not be expected to result in improvement within a reasonable and generally predictable period of time.

Lack of Improvement

The denial of all 60 services was improper because the chiropractic auditor incorrectly imposed an “improvement standard” that is not supported by the SSA, the regulations or the interpretive provisions found in the Medicare Benefit Policy Manual. The actual validity of reimbursement under Medicare is derived from the following federal statutory and regulatory references related to coverage of services performed by a licensed Doctor of Chiropractic.

The reasonableness and necessity of care is generally addressed in the regulations within the section entitled “*GENERAL EXCLUSIONS AND EXCLUSION OF PARTICULAR SERVICES.*” A review of these provisions reveals the following regarding medical necessity as it pertains to coverage under Medicare.

*(k) Any services that are not reasonable and necessary for one of the following purposes:
(1) For the diagnosis or treatment of illness or injury **or** to improve the functioning of a malformed body member.*

42 C.F.R. § 411.15(k)(1) (emphasis added).

The regulations clearly express that a service is covered as “reasonable and necessary” if it meets **EITHER** one of the two following criteria:

- 1) The service is performed for the diagnosis **or** treatment of illness or injury; **or**
- 2) The service is performed to **improve the functioning of a malformed** body member.

Fundamentally, where the service meets **EITHER** of these criteria, the service is considered reasonable and necessary. With respect to the second component of the regulatory provision, improvement is required only where functional impairment exists with respect to a “malformed body member.” Malformation refers to idiopathic or congenital deformities and therefore the improvement standard is inapplicable to treatment for conditions caused by illness or injury. In the cases reviewed, the chiropractic auditor incorrectly imposed the improvement standard to patients that required treatment as a result of an illness or injury.

With respect to services by a licensed chiropractor, the Medicare regulations contain the following additional requirement:

(b) Limitations on services.

*(1) Medicare Part B pays only for a chiropractor's manual manipulation of the spine to correct a subluxation if the subluxation has resulted in a neuromusculoskeletal condition for which manual manipulation is **appropriate treatment.***

42 C.F.R. §410.21(emphasis added).

As a result, coverage of services performed by a licensed Doctor of Chiropractic is limited to manual manipulation of the spine to correct a subluxation that has resulted in a neuromusculoskeletal condition. Additionally, the regulatory provision requires that manipulation must constitute “appropriate treatment” for the neuromusculoskeletal condition. This requirement neither expressly nor impliedly imposes an improvement standard as a condition of coverage and is therefore consistent with the delineation found at Section 411.15(k)(1).

Looking beyond the binding regulatory standards, the necessity of chiropractic manipulation is addressed in the Medicare Benefit Policy Manual (“MBPM”) as follows:

*The patient must have a significant health problem in the form of a **neuromusculoskeletal condition necessitating treatment**, and the manipulative services rendered must have a **direct therapeutic relationship to the patient’s condition** and provide **reasonable expectation of recovery or improvement of function**. The patient must have a **subluxation of the spine as demonstrated by x-ray or physical exam**, as described above.*

Internet Only Manual (“IOM”) Pub 100-2, Chapter 15, § 240.1.3(emphasis added).

While the chiropractic auditor generally references this standard, he or she not only ignores the regulatory standards, but also ignores the additional guidance in the MBPM pertaining to the type of condition, outcome and the anticipated duration for which services may be necessary as follows.

*The chiropractor **should be afforded the opportunity to effect improvement or arrest or retard deterioration** in such condition within a reasonable and generally predictable period of time. **Acute** subluxation (e.g., strains or sprains) problems **may require as many as three months** of treatment but some require very little treatment. In the first several days, treatment may be quite frequent but decreasing in frequency with time or as improvement is obtained.*

***Chronic** spinal joint condition implies, of course, the condition has existed for a longer period of time and that, in all probability, the involved joints have already “set” and fibrotic tissue has developed. This condition **may require a longer treatment time**, but not with higher frequency.*

Some chiropractors have been identified as using an “intensive care” concept of treatment. Under this approach multiple daily visits (as many as four or five in a single day) are given in the office or clinic and so-called room or ward fees are charged since the patient is confined to bed usually for the day. The room or ward fees are not covered and reimbursement under Medicare will be limited to not more than one treatment per day.

Id. at §240.1.5 (emphasis added).

By distilling the provisions of each section in the context of the binding regulatory standards from which they are derived, it is apparent that there are three components to the analysis of medical

necessity with respect to manipulative treatment as follows:

- 1) Existence of subluxation as demonstrated by physical examination or x-ray (at the initial encounter);
- 2) Existence of a significant health problem in the form of a neuromusculoskeletal (NMS) condition for which manipulation is appropriate treatment (will provide direct care); and
- 3) There exists a reasonable expectation that manipulative treatment of a malformed body member will result in recovery or improvement of function **OR** that treatment for an injury or illness will arrest or retard deterioration in that condition or will cause recovery of that condition within a reasonable and predictable period of time (at the initial encounter).

Therefore, a determination of necessity is not possible without analysis of these three criteria exclusively. Note that similar to and consistent with the regulatory standard of necessity reviewed above, there is a bifurcated approach to the analysis of whether treatment is medically necessary under the provisions of the MBPM cited above. Specifically, there is an improvement of function element, which is consistent with the regulatory provision pertaining to treatment of “malformed body members.” There is also a second element that permits a determination of necessity where the treatment is expected to arrest or retard deterioration in the patient’s condition or is expected to cause recovery (resolution) of that condition. This conclusion regarding this element of the guidance is consistent with the regulatory coverage, which, for treatment of an injury or illness, coverage is warranted where the manipulation is simply “appropriate” for the condition.

The method of determining whether manipulation is “appropriate,” is not addressed in either the regulations or the MBPM guidance. Instead, this determination requires reference to the local coverage determination (“LCD”), which defines the conditions (by ICD code) for which manipulation is considered medically necessary. Because all of the care at issue was provided for treatment of an injury or illness, the analysis of necessity is therefore appropriately confined to the following.

1. Was there a subluxation associated with a complaint caused by injury or illness?
2. Was there a NMS condition that was directly related to the subluxation?
3. Is the diagnosis code for the patient’s NMS condition included in the LCD list of diagnosis codes for which manipulation is considered medically necessary?

Contrary to the analytical approach commanded by the regulations, MBPM and LCD, the chiropractic auditor instead imposed absolute enforcement of an “improvement standard” for all conditions. This is not only contrary to the binding regulatory standard of necessity, but is inconsistent with the MBPM requirements pertaining to necessity. Such a deviation from the express regulatory standard as well as published guidance violates the Medicare Program Integrity Manual (“MPIM”) provisions found at Pub 100-8, Ch. 13, §13.5.3 not to mention OAS audit guidance pertaining to identification and imposition of appropriate criteria. Because of these significant errors in the auditor’s analysis, the auditor’s conclusions have no credibility, are inaccurate, and must be reversed.

Beyond merely identifying error in the auditor’s conclusions, it is notable that as a matter of clinical fact, the patient’s subluxations and NMS conditions were associated with injury or illness in every case. Each patient presented with aggravating or other mitigating factors, which were in many cases recognized by the auditor, but ignored in his or her analysis of necessity. Ultimately,

these clinical facts justified a conclusion that the care was for treatment of an injury. As a result, in each of these cases, the documentation justified the appropriateness of the manipulation given that the patient presented with a condition caused by illness or injury and that condition was one for which manipulation was considered medically necessary under the relevant LCD.

Contrary to the above analytical approach and the relevant guidance, the auditor imposed a requirement that “evidence of improvement” must be documented for patients who presented with conditions associated with an illness or injury. Imposing such a precondition to a determination of coverage and payment is improper as a matter of law. The auditor also ignored the LCD provisions that detail the conditions (ICD codes) for which manipulation is deemed medically necessary. These errors demonstrate conclusively that the auditor’s conclusions are inaccurate and must therefore be discarded.

Non-Covered Maintenance Care

As noted above, while all 60 services were denied on the basis that the documentation did not contain evidence of “improvement”, 57 of those services were additionally denied on the basis that the care constituted non-covered maintenance care.

Maintenance care is simply another way of saying that the care is not medically necessary. As such, it is not a surprise to find that Maintenance Therapy is addressed within the section of the MBPM (§240.1.3) that is entitled “Necessity for Treatment.” The MBPM addresses maintenance therapy as follows.

Maintenance therapy includes services that seek to prevent disease, promote health and prolong and enhance the quality of life, or maintain or prevent deterioration of a chronic condition. When further clinical improvement cannot reasonably be expected from continuous ongoing care, and the chiropractic treatment becomes supportive rather than corrective in nature, the treatment is then considered maintenance therapy.

Id. at §240.1.3.A

Comparison of this definition, to the provisions of Section 240.1.5, which require coverage for care designed to arrest or retard deterioration in a patient’s condition suggest a conflict within the guidance. However, where we read each provision of the MBPM in the context of the binding regulatory standards for necessity cited above, such conflict is easily resolved. Recall that under the regulations there are two general categories of conditions for which care might be necessary. The first is treatment of an injury/illness, the other is treatment of a malformed body member. In this context, treatment designed to prevent the onset of an illness, promote good health, prevent deterioration of a chronic condition or merely enhance the quality of life is appropriately non-covered since such patients would neither have an injury or illness, nor would they have a malformed body member. In the context of patients with chronic conditions, prevention of deterioration is included as maintenance care; however, in the regulatory context, a conclusion that care was maintenance would be appropriate only where there was no expectation that care would result in a recovery of the acute symptoms associated with the underlying chronic condition.

Additionally, with apparent respect to treatment of either injury/illness or a malformed body member, only care that is “continuous and ongoing” for the same condition could potentially

be included within the definition of maintenance. As a result, episodic care associated with documented flare-ups of a patient's underlying chronic condition or periodic care to address regression in a patient's condition are types of care that fall outside the scope of what could be considered maintenance care.

With respect to the element addressing "improvement," the concept of improvement is applicable only to "continuous and ongoing care." Additionally, "improvement" is limited in scope to clinical improvement as opposed to functional improvement. In the case of a flare-up, which often occurs between presentations in cases where the schedule of treatment is either periodic or episodic, there is often a worsening that occurs between presentations for care, either due to natural regression in the patient's condition, or due to an external exacerbating event. In such cases, the treatment results in clinical improvement, even where such improvement may be short lived.

Rather than analyze and apply the definition of maintenance properly, the chiropractic auditor simply concluded that where there was no evidence of long-term improvement in the patient's condition, the care was maintenance and not medically necessary. As a result, the conclusions regarding maintenance care are inaccurate, unsustainable as a matter of law and must be reversed.

3. Use of CPT 98942

While not explicitly addressed in the OAS draft report as a basis for error, there is mention that a significant number of services were reported using CPT 98942. While there is insufficient time to perform service-specific analysis of each claim, it is suspected that while subluxations were demonstrated and manipulation was provided to five (5) regions of the spine in each case where CPT 98942 was reported, the clinical facts may possibly suggest that the necessity for the manipulation would not be supported in all five (5) regions under the analytical standard outlined above. It is likely that with appropriate analysis, some of the services in the sample, rather than being denied outright, would be down coded instead. We request additional time to perform such analysis so that we may amend our response accordingly.

CORRECTIVE ACTION MEASURES

While clear that the allegations of error are unjustified for the reasons provided, it is recognized that improvements could be made relative to more clearly documenting the type of condition, the intended purpose of the care rendered, the patient's response to treatment, and changes in the patient's condition consistent with the regulatory and MBPM definitions of necessity. Providers will undergo additional education regarding the relevant provisions of the MBPM as well as the current WPS LCD (L34585) and monitoring of documentation changes will occur so that compliance with Medicare coverage requirements is more clearly demonstrated in the documentation.

WRITTEN EVIDENTIARY DEMAND/REQUEST FOR INFORMATION

To the extent that the findings of the Draft Report are unchanged, **RDCT** will undoubtedly receive a refund demand by the local Medicare Administrative Contractor thereby triggering the administrative appeal process. So that **RDCT** will be afforded the opportunity of providing a more detailed response to the substantive allegations of error as well as the validity of the SSOE, additional information is necessary. **RDCT** asserts its right to inspect and receive copies of all

information and evidence pertaining to this audit that are contained in the OAS files pursuant to Medicare Carriers Manual §12019.4 (mandating the Carrier to make available all file evidence for inspection by an appellant upon request).

On behalf of **[RDCT]** we request a complete copy of the file relating to this review including, but not limited to:

- All correspondence relating to this post-payment review including but not limited to memoranda, data analysis reports and or other documents detailing the decision making process that resulted in **[RDCT]** being placed on pre-payment review;
- Any internal memoranda or other internal documents relating to any review of **[RDCT]** documentation;
- Minutes of any meetings conducted by OAS internally or with any other party concerning this or any prior review;
- A copy of **[RDCT]** Medicare utilization profile, Comparative Billing Report (“CBR”) and any other information that established the reason for this review;
- A copy of any instructions provided to the chiropractic auditor that performed the analysis in this case;
- A copy of all memoranda and correspondence exchanged between OAS and the chiropractic auditor;
- A copy of any internal notes pertaining to communication with the chiropractic auditor;
- A copy of any worksheets or work papers prepared by the chiropractic auditor or OAS personnel relevant to **[RDCT]** overpayment determination; and
- The names and titles/credentials of all individuals involved in the selection of the sample and statistical projection by OAS, as well as the name, title and credentials of the chiropractic auditor that made the determinations regarding the services included in the sample.

Additionally, so that we may evaluate the validity of the statistical sampling and overpayment estimate (“SSOE”), we additionally request, on behalf of **[RDCT]** the following information:

- **Sample Size:** Appendix B of your report indicates a sample size of 100 paid claims. No methodology or calculations were provided to demonstrate the basis for the determination that a 100 claim sample was statistically sufficient. Please provide this information so that we may validate the statistical validity of the sample size.

- **Sample Testing:** There is no evidence that the sample, as drawn, was tested for representativeness with the claims included in the sampling frame. Please provide any calculations and the results associated with any tests of the validity of the sample.
- **Universe and Sampling Frame:** The Draft report at Appendix B indicates a universe of 12,675 claims for CY 2012 and 2013. The Draft report also indicates exclusion of 1,987 services on the basis that the payment amount was less than \$25.01. The rationale for exclusion of these claims was not provided and no analysis of the impact of such an exclusion to the overpayment estimate was performed. This information is important since exclusion of lower value claims would tend to bias any alleged financial error in a sample pulled from the resulting sampling frame upward. Please provide the basis for excluding these 1,987 claims from the sampling frame. Additionally, please provide an electronic spreadsheet for the universe and sampling frame in the format detailed below.
- **Sample Selection:** While the Draft report indicates generation of random numbers using some unnamed “statistical software” and details what appears to be an appropriate selection process, because details of the process used to generate the random numbers, the random numbers themselves, and an electronic spreadsheet containing the claims and their respective control numbers that were included in the sampling frame was not provided, the validity of this process could not be verified. We request that spreadsheets detailing the universe and sampling frame be provided as well as complete details demonstrating correlation between the random numbers generated and the samples selected from the sampling frame be provided so that we may further evaluate the statistical validity of the sample size and random selection process. The format of the data necessary for the universe and sampling frame is provided below.
- **Projection:** Again, unnamed OAS statistical software was used to estimate the projected portion of the overpayment. The lower limit of a two-sided 90 percent confidence interval was recommended; however, the specific formulas used and the rationale for use of that approach were not disclosed. As a result, we require that you provide details regarding the projection calculation as well as the values for each variable to include the source of those values.

Based on the above, we demand the following information relative to each claim line included in the universe. Those claims that were included in the sampling frame as well as those claims/claim lines selected for the 100 claim sample should also be identified. This information should be provided in an electronic (Excel [.xls] or .csv) format.

- Control Number used for Random Selection
- Beneficiary ID (name and HICN)
- Claim number (with no blanks imbedded in the number)
- Claim line number
- Type of service
- Procedure code
- Principle diagnosis code
- Date of service

- Date paid
- Amount billed for each claim line
- Amount allowed for each claim line
- Amount paid for each claim line
- Amount overpaid for each claim line
- Stratum or cluster code (if applicable)
- A code indicating if the claim line is a duplicate
- A code indicating if the claim line was in the sampling frame
- A code indicating if the claim line was in the sample
- A code indicating if the claim line is a \$0.00 paid claim
- A code or descriptive information indicating the reason for denial.

Beyond the universe information above, please also provide the following regarding your sample size determination methodology:

- The time-period encompassed by the sample if different that the dates services included in the sampling frame (1/1/2012 through 12/31/2013).
- Assuming performance of an unrestricted variable size determination methodology, indicate whether a probe sample or an estimated error rate was used.
 - If a probe sample was used, please provide the probe sample data in excel format.
 - If an estimated error rate was used, please provide the estimated error rate used, the total amount, standard deviation, confidence level and precision values used as well as the source of these values.
- Relative to random selection, please provide details regarding the specific software used, the input variables, seed number, and output data detailing the random numbers generated so that we may validate that the appropriate samples were, in fact, randomly selected.
- Finally, please provide details regarding the methodology used to calculate the projected portion of the overpayment to include all formulas, inputs and the confidence/precision assumptions utilized.

The information requested above may be provided on electronic media or may be e-mailed to me (mmiscoe@miscoehealthlaw.com) using secure FTP delivery methodologies. If the information is supplied on a password protected compact disc or other electronic media such as a USB flash drive, please provide the password by separate correspondence to preserve the integrity of the information.

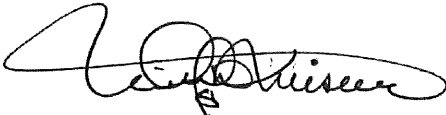
Please tender the information requested above as soon as possible. To the extent permissible, we wish to amend this response with a more detailed response to the factual allegations as well as a detailed response to the statistical projection.

Please submit the requested materials and all future correspondence in this matter to me at the following address.

Miscoe Health Law, LLC.
Michael D. Miscoe, Esq.
1032 Peninsula Drive
Central City, PA 15926

Thank you for your consideration.

Sincerely,

A handwritten signature in black ink, appearing to read "Michael D. Miscoe", written over a horizontal line.

Michael D. Miscoe, Esq.

Enclosure

cc:

REDACTED
