Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

TWIN PALMS RECEIVED UNALLOWABLE MEDICARE PAYMENTS FOR CHIROPRACTIC SERVICES

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

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Office of Inspector General

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Report in Brief
Date: August 2019
Report No. A-04-16-07065

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

Twin Palms Received Unallowable Medicare Payments for Chiropractic Services

Why OIG Did This Review

In calendar years (CYs) 2014 and 2015, Medicare allowed payments of approximately $1.3 billion 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 Medicare claims data, we selected for review Twin Palms Chiropractic Health Center, Inc. (Twin Palms), in Venice, Florida. Our analysis indicated that Twin Palms was among the top five chiropractors in Florida based on three Current Procedural Terminology codes billed to Medicare for chiropractic services.

Our objective was to determine whether chiropractic services that Twin Palms billed were allowable in accordance with Medicare requirements.

How OIG Did This Review

For CYs 2014 and 2015, Twin Palms received Medicare Part B payments of $711,742 for 22,967 chiropractic services provided to Medicare beneficiaries. We excluded 619 chiropractic services as follows: services reviewed by the recovery audit contractors and other review entities (such as the Medicare Administrative contractors), services with payments less than $20, and services identified as cancelled. From the remaining 22,348 services, totaling $704,246 in Medicare payments, we selected 100 services using a simple random sample.

What OIG Found

Some chiropractic services that Twin Palms billed were not allowable in accordance with Medicare requirements. Of the 100 sampled chiropractic services in our sample, 46 were allowable in accordance with Medicare requirements. However, the remaining 54 services were not allowable: 42 services were medically unnecessary, 11 services were insufficiently documented, and 1 service was incorrectly coded. As a result, Twin Palms received $1,680 in unallowable payments.

On the basis of our sample results, we estimated that Twin Palms received unallowable Medicare payments of at least $317,038 for CYs 2014 and 2015. As of the publication of this report, this unallowable amount includes claims outside of the 4-year claims reopening period. These unallowable payments occurred because Twin Palms did not have policies and procedures to ensure that the chiropractic services billed to Medicare were medically necessary, adequately documented, and coded correctly.

What OIG Recommends and Twin Palms Comments

Among other things, we recommend that Twin Palms: (1) refund to the Federal Government the portion of the estimated $317,038 overpayment for claims for chiropractic services that did not comply with Medicare requirements and are within the 4-year claims reopening period and (2) establish policies and procedures to ensure that chiropractic services billed to Medicare are medically necessary, adequately documented in the medical records, and coded correctly.

In written comments on our draft report, Twin Palms partially concurred with our findings and recommendations. Through its attorney, Twin Palms agreed with our assessment of 27 of the 55 chiropractic services that we identified as not allowable in our draft report but disagreed with our findings on the remaining 28. Furthermore, Twin Palms provided additional documentation that it had not previously provided for eight claims. Based on the additional documentation, the independent medical review contractor reversed its decision on one claim and changed the determination from unallowable to allowable. With respect to the remaining claims, we maintain that our findings and recommendations are valid.

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INTRODUCTION

WHY WE DID THIS REVIEW

In calendar years (CYs) 2014 and 2015, Medicare allowed payments of approximately $1.3 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 Medicare claims data for CYs 2014 and 2015, we selected for review Twin Palms Chiropractic Health Center, Inc. (Twin Palms), in Venice, Florida. Our analysis indicated that Twin Palms was among the top five chiropractors in Florida based on three Current Procedural Terminology (CPT)[2] codes billed to Medicare for chiropractic services.

OBJECTIVE

Our objective was to determine whether chiropractic services that Twin Palms billed 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 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. First Coast Service Options, Inc. (First Coast), was the MAC that processed and paid the Medicare claims submitted by Twin Palms.

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.

[1] See Appendix B for a list of related OIG Medicare reports for chiropractic services.

[2] 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 most common therapeutic procedure performed by chiropractors is spinal manipulation, also called chiropractic adjustment. The purpose of this procedure is to restore joint mobility by manually applying a controlled force into joints that have become restricted in their movement because 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.[3]

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.[4] 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.[5] Depending on the number of spinal regions treated, chiropractors may bill Medicare for chiropractic manipulative treatment using one of three CPT[6] 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).

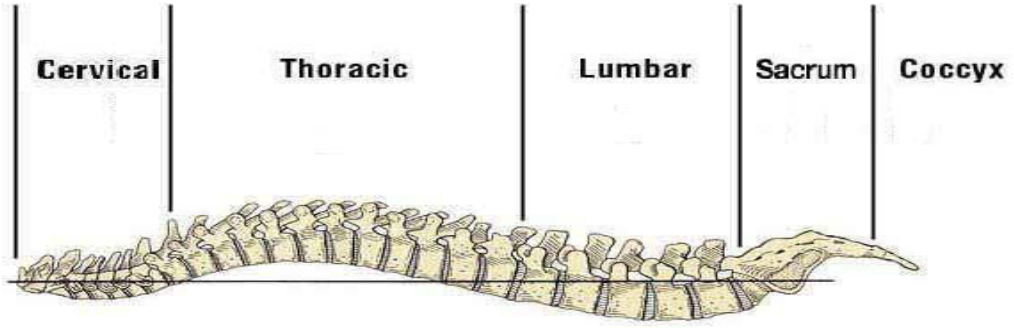
[3] CMS's *Medicare Benefit Policy Manual,* Pub. 100-02 (the Manual), chapter 15, § 30.5.

[4] Subluxation is a condition in which spinal bones are not in their normal position. 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).

[5] The Manual, chapter 15, § 240.1.4, and First Coast's Local Coverage Determination (LCD) for chiropractic services, L33840 (retired), which was in effect during our audit period. First Coast's current LCD for chiropractic services is L36617.

[6] **The five character codes and descriptions included in this report are obtained from Current Procedural Terminology (CPT®), copyright 2014–2015 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 or 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 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 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. Upon receiving credible information of a potential overpayment, providers 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]

[7] 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), and First Coast's LCD L33840).

[9] The Social Security Act (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).

Twin Palms Chiropractic Health Center, Inc.

Established in April 2001, Twin Palms is located in Venice, Florida. During CYs 2014 and 2015, Twin Palms employed four chiropractors who provided chiropractic services. Twin Palms billed Medicare for those services under one tax identification number.

The Medicare claims data that we reviewed indicated that Twin Palms billed all of its chiropractic services using the AT modifier. Further, it billed the majority (97 percent) of its services using CPT code 98941, which had the second highest physician fee schedule amount among the three CPT codes covered by Medicare for chiropractic services.

Table 1 shows the allowed amount for Sarasota County, Florida, on the Medicare fee schedule for each CPT code during CYs 2014 and 2015.

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

Period	CPT 98940	CPT 98941	CPT 98942
January 1–December 31, 2014	$28.04	$41.48	$53.54
January 1–June 30, 2015	27.90	40.74	53.24
July 1–December 31, 2015	28.04	40.95	53.51

HOW WE CONDUCTED THIS REVIEW

For CYs 2014 and 2015, Twin Palms received Medicare Part B payments of $711,742 for 22,967 chiropractic services provided to Medicare beneficiaries. We excluded 619 chiropractic services as follows: services that were reviewed by the recovery audit contractors (RACs) and other review entities (such as the MACs), services with payments less than $20, and services that we identified as cancelled using the CMS Common Working File (CWF). From the remaining 22,348 services, totaling $704,246 in Medicare payments, we selected 100 services using a simple random sample. Twin Palms provided us with copies of medical records as support for these services. In turn, we provided those copies to an independent 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 C contains the details of our statistical sampling methodology, and Appendix D contains our sample results and estimates.

FINDINGS

Some chiropractic services that Twin Palms billed were not allowable in accordance with Medicare requirements. Of the 100 chiropractic services in our sample, 46 were allowable in accordance with Medicare requirements. However, the remaining 54 services were not allowable:

- 42 services were medically unnecessary,
- 11 services were insufficiently documented, and
- 1 service was incorrectly coded.

As a result, Twin Palms received $1,680 in unallowable Medicare payments. On the basis of our sample results, we estimated that Twin Palms received unallowable Medicare payments of at least $317,038 for CYs 2014 and 2015. These unallowable payments occurred because Twin Palms did not have policies and procedures to ensure that chiropractic services billed to Medicare were medically necessary, adequately documented, and correctly coded. As of the publication of this report, this unallowable amount includes claims outside of the 4-year period for reopening for good cause (the 4-year claims reopening period).[10] Notwithstanding, Twin Palms can request that a Medicare contractor reopen the initial determinations for those claims for the purpose of reporting and returning overpayments under the 60-day rule.[11]

CHIROPRACTIC SERVICES WERE NOT ALLOWABLE IN ACCORDANCE WITH MEDICARE REQUIREMENTS

Services Were Medically Unnecessary

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, for chiropractic services to be reimbursable, (1) they must have a direct therapeutic relationship to the patient's condition, (2) 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

[10] 42 CFR § 405.980(b)(2) (permitting a contractor to reopen within 4 years for good cause) and 42 CFR § 405.980(c)(2) (permitting a party to request that a contractor reopen within 4 years for good cause).

[11] 42 CFR § 405.980(c)(4).

and generally predictable period of time (chapter 15, § 240.1.5). See Appendix E for these requirements.

Of the 100 sampled chiropractic services, 42 services were medically unnecessary. The results of the medical review indicated that these services did not meet one or more of the following Medicare requirements:

- Subluxation of the spine was not present or was not treated with manual manipulation or both (7 services).

- Manual manipulation of the spinal subluxation was maintenance therapy or was not appropriate for treatment of the patient's condition or both (26 services).

- Manual manipulation of the spinal subluxation would not be expected to result in improvement within a reasonable and generally predictable period (9 services).

For example, Twin Palms received payment for a chiropractic service provided to a 76-year-old Medicare beneficiary. The independent medical review contractor found that the medical records did not support the medical necessity of the service because none of the Medicare requirements listed above had been met. Further, the independent medical review contractor stated: "Absent detection of a subluxation on this date, no further improvement would be possible . . . . A reexamination was completed absent any report of subluxations . . . or manipulation . . . on this date . . . . The care was not medically necessary."

Services Were Insufficiently Documented

The Manual and First Coast's LCD require that the initial visit and all subsequent visits to the chiropractor meet specific documentation requirements (the Manual, chapter 15, § 240.1.2, and FCSO's LCD L33840).

The following must be documented for initial visits: (1) patient history; (2) description of present illness; (3) evaluation of musculoskeletal/nervous system through physical examination; (4) primary diagnosis of subluxation, including the level of subluxation; (5) treatment plan; and (6) date of the initial treatment or, according to the LCD, date of exacerbation or reinjury of existing condition (the Manual, chapter 15, § 240.1.2(A), and FCSO's LCD L33840).

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;[12] (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

[12] 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.

effectiveness; and (3) the treatment given on the day of the visit (the Manual, chapter 15, § 240.1.2(B), and FCSO's LCD L33840).

Of the 100 sampled chiropractic services, 4 were insufficiently documented for the initial chiropractic visit and 7 were insufficiently documented for both the initial and subsequent chiropractic visits. The independent medical review contractor determined that the medical records for these visits did not meet the documentation requirements specified in the Manual and First Coast's LCD L33840.

For example, Twin Palms received payment for a chiropractic service provided on May 28, 2015, to a Medicare beneficiary. After reviewing the medical records provided, the independent medical review contractor stated: "[C]hiropractic care on 5/28/2015 did not meet Medicare coverage criteria as billed . . . . There was no report as to the levels of care/manipulation provided . . . . There is no documentation of the levels of care treated and therefore no support for the billed code (98941)."

Service Was Incorrectly Coded

Depending on the number of spinal regions treated, chiropractors may bill Medicare for chiropractic manipulative treatment using CPT codes 98940, 98941, or 98942.

Of the 100 sampled chiropractic services, 1 service was incorrectly coded. The claim for this service was billed with a CPT code related to treatment of more spinal regions than what the medical records supported. Twin Palms billed this service using CPT code 98941, instead of billing for this service using CPT code 98940.[13]

Twin Palms received payment for a chiropractic service provided on February 27, 2015, to a Medicare beneficiary. After reviewing the medical records provided, the medical review contractor stated: "[T]he record does not support the code billed. The record reflects that two regions (cervical and thoracic) of the spine were treated with manual manipulation. Therefore, code 98940 would be appropriate, and code 98941 was inaccurately reported on the claim."

TWIN PALMS RECEIVED UNALLOWABLE MEDICARE PAYMENTS

Twin Palms received $1,680 in unallowable Medicare payments for the 54 chiropractic services that did not meet Medicare requirements. On the basis of our sample results, we estimated that Twin Palms received unallowable payments of at least $317,038 for CYs 2014 and 2015. As of the publication of this report, this unallowable amount includes claims outside of the 4-year claims reopening period.

[13] To calculate the unallowable amount for the service, we used the difference between the amount paid to the provider under CPT code 98941 and the amount that should have been paid to the provider under CPT code 98940. The paid amount is equal to the allowed amount, less the beneficiary share (i.e., deductibles and coinsurance).

TWIN PALMS DID NOT HAVE POLICIES AND PROCEDURES

The unallowable Medicare payments occurred because Twin Palms did not have policies and procedures to ensure that chiropractic services billed to Medicare were medically necessary, adequately documented, and coded correctly.

RECOMMENDATIONS

We recommend that Twin Palms:

- refund to the Federal Government the portion of the estimated $317,038 overpayment for claims for chiropractic services that did not comply with Medicare requirements and are within the 4-year claims reopening period;[14]

- exercise reasonable diligence for the remaining portion of the estimated $317,038 overpayment for claims that are outside of the 4-year claims reopening period to identify and return the overpayments in accordance with the 60-day rule and identify any returned overpayments as having been made in accordance with this recommendation;

- exercise reasonable diligence to identify and return any additional similar overpayments 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

- establish policies and procedures to ensure that chiropractic services billed to Medicare are medically necessary, adequately documented in the medical records, and correctly coded.

[14] 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 or other contractor, will determine whether a potential overpayment exists and will recoup any overpayments 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 decision by the Office of Medicare Hearings and Appeals. 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 overpayment based on extrapolation is re-estimated depending on the result of the appeal.

TWIN PALMS COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, Twin Palms partially concurred with our findings and recommendations. Twin Palms also provided information on actions that it had taken, or planned to take, to address our findings on our second and third recommendations. Twin Palms' comments are included in their entirety as Appendix F.

MEDICAL REVIEW FINDINGS WERE INCORRECT

Auditee Comments

Through its attorney, Twin Palms disagreed that 28 claims were unallowable. Twin Palms stated that its attorney's independent medical reviewer determined that these claims were allowable as billed and three were allowable at a lower reimbursement level. For 8 of these 28 claims, Twin Palms provided additional medical documentation that it had not previously provided to us. In addition, the Twin Palms attorney questioned the credibility of the independent medical review contractor's clinical conclusions because we did not provide the contractor's name to him during the review. The Twin Palms attorney also questioned whether the independent medical review contractor was "licensed in the practice of chiropractic or ha[d] any clinical training or experience . . . to render a clinical determination that services were medically unnecessary."

Regarding the services that we deemed insufficiently documented, Twin Palms referred to a subsequent visit to the chiropractor that we selected for review. Twin Palms stated that our analysis focused on the initial visit, which was not part of the sample nor at issue with the sample. Twin Palms also stated that it would try to more clearly indicate elements that were either unreported or irrelevant to the patient's complaints or condition to prevent erroneous denials in the future.

Twin Palms stated that it would provide training to its staff regarding the need to more clearly document the specific factors supporting the necessity of care and the standards of medical necessity. In addition, Twin Palms will exercise reasonable diligence in identifying any similar error in claims beyond the reopening period but within the 6-year lookback period established in the 60-day rule (42 CFR § 401.305) and refund any identified overpayments within 60 days as required by the rule.

Twin Palms staff will also "undergo additional education regarding the need to properly code from the record and will be advised to evaluate this issue in future internal audits."

Office of Inspector General Response

In response to Twin Palms' disagreement that it improperly billed 28 claims, an independent medical review contractor reviewed the medical records and determined whether each claim was allowable in accordance with Medicare requirements. Our report reflects the results of

that review. Regarding the credibility of the clinical conclusions, the medical review contractor was a chiropractor licensed in chiropractic medicine.

Twin Palms provided additional documentation that it had not previously provided for eight claims, which we submitted to the independent medical review contractor for review. After reviewing the additional documentation that Twin Palms provided, the medical review contractor reversed one previously unallowable claim and sustained the remaining seven unallowable claims.[15] Accordingly, we recalculated the estimated Medicare overpayments, and our report reflects the revised results of the recalculation.

In response to the attorney's concerns that our analysis focused on the initial visit and that the initial visit was not part of the sample nor at issue with the sample, the Manual and First Coast's LCD both require that the initial visit and all subsequent visits to the chiropractor meet specific documentation requirements (the Manual, chapter 15, § 240.1.2, and FCSO's LCD L33840). Therefore, the reviewer applied the applicable criteria to the sample item and made determinations for our findings and recommendations in accordance with Medicare requirements for chiropractic services.

We maintain that our findings and recommendations as revised are valid.

AUDIT METHODOLOGY DID NOT CONFORM TO OAS GUIDELINES

Auditee Comments

The attorney also questioned our audit methodology and stated that the audit did not conform to guidelines set forth in OAS's *The Audit Process* guidance (second edition, January 2005). According to Twin Palms' attorney, audit testimonial evidence was limited to Twin Palms' understanding of CMS's coverage requirements. Furthermore, Twin Palms' attorney stated that the auditors did not consult any of the treating providers or patients regarding the care provided, and either did not consider or misconstrued relevant criteria.

Office of Inspector General Response

Twin Palms' attorney referred to OAS's *The Audit Process* (second edition, January 2005) and questioned the development of evidence during our audit process. However, OAS's *The Audit Process* (fifth edition, May 2018) states that, "The measure of the validity of evidence for audit purposes lies in the nature of the evidence and the judgment of the audit team." Our audit evidence included the medical records for each of the 100 sample items. In addition, we did not limit our audit testimonial evidence to Twin Palms' understanding of CMS's coverage

[15] Based on the additional documentation, the medical review contractor reversed one unallowable claim that it had determined to be insufficiently documented. In addition, the medical review contractor sustained three unallowable claims because they lacked sufficient documentation. Furthermore, the medical reviewer sustained three claims originally deemed medically unnecessary. Lastly, one claim that had originally been disallowed because it was deemed medically unnecessary was sustained because it lacked sufficient documentation.

requirements. We met with the owner, the chiropractic provider registered under the National Provider Identifier (NPI) selected for our review, and the attorney to get an understanding of Twin Palms' policies and procedures. We did not consult any of the patients because the medical records were provided to the independent medical review contractor who determined whether each service was allowable in accordance with Medicare requirements. The OIG independent medical review contractor considered relevant, applicable criteria to determine whether Twin Palms billed services in compliance with Medicare requirements.

-SAMPLING PROCESS WAS INVALID

Auditee Comments

The attorney questioned the validity of our sampling process. The attorney contended that the exclusion of services with payment amounts of less than $20 biased the overpayments in the sampling frame to a higher value, resulting in a higher projected overpayment amount. The attorney also referred to the exclusion of 619 services reviewed by other entities. In this respect, the attorney stated that Twin Palms had been the subject of only one audit in the audit period. According to the attorney, a medical review contractor had reviewed only 40 claims, and Twin Palms was unaware of any analysis of the remaining 581 services.[16]

The attorney questioned the statistical effect of the claims in the sample that are outside the 4-year claims reopening period. Specifically, the attorney stated that, because the final report has not yet been published, it is impossible to determine exactly how many services must be excluded from the sample. The attorney also stated that the report does not indicate the impact that the removal of these claims from the sampling frame would have on the statistical validity of the sample as drawn.

Finally, the attorney stated that the report provides no detail regarding the process we followed to determine that Twin Palms received unallowable Medicare payments of $324,360 for CYs 2014 and 2015.

Office of Inspector General Response

In response to the attorney's concerns regarding the exclusion of 619 chiropractic service lines from the sampling frame, we excluded these service lines as follows: 37 claims containing 98 service lines that were reviewed by another entity, 3 claims with single service lines that we identified as cancelled using the CMS CWF, and 518 service lines for services with payments less than $20. Given that the lower dollar payments were excluded from the sampling frame prior to pulling the sample and are not covered by our statistical estimate, the attorney's concerns about bias from these claims are not warranted.

[16] Twin Palms' attorney made an error regarding the total chiropractic service lines count in his original response. The attorney subtracted the 40 claims from the excluded 619 services and concluded that 581 claims remained. However, the correct number of remaining claims should have been 579 (619-40=579).

Further, the presence of claims in our sampling frame that are outside the 4-year claims re-opening period does not impact our ability to produce a valid statistical estimate. Our report includes the total overpayment for the full sampling frame. The date for the tolling of the 4-year claims reopening period will not be set until after the report is published. Once that date is known, we will estimate the overpayments within the 4-year claims reopening period using standard, well accepted methods for calculating unbiased sub-population estimates.[17]

In response to the attorney's concerns regarding the statistical validity, Federal courts have consistently upheld statistical sampling and extrapolation as a valid means to determine overpayment amounts in Medicare.[18]

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.[19] We properly executed our statistical sampling methodology in that we defined our sampling frame and sampling unit, randomly selected our sample, applied relevant criteria in evaluating the sample, and used statistical sampling software (i.e., RAT-STATS) to apply the correct formulas for the extrapolation. The use of statistical sampling and extrapolation to determine overpayment amounts in Medicare does not violate due process because the auditee is given the opportunity to appeal the audit results through the Medicare appeals process.[20]

Regarding the portion of the estimated overpayments for claims that are outside of the 4-year claims reopening period, we recommended that the auditee identify and return the overpayments in accordance with the 60-day rule.

CLAIMS WERE DENIED BASED ON MEDICAL RECORD DOCUMENTATION

Auditee Comments

The attorney questioned the standard of review used by the OIG independent medical review contractor. The attorney stated that a significant number of the services were denied based on

[17] *See* Section 2.13 of Cochran, William G. 1977. *Sampling Techniques*, 3rd edition.

[18] *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).

[19] *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).

[20] *See Transyd Enters., LLC v. Sebelius*, 2012 U.S. Dist. LEXIS 42491 at *34 (S.D. Tex. 2012).

the medical record documentation. According to the attorney, the statutory provision only requires submission of information sufficient to determine the amount of payment due, such as the CMS-1500 form.

More specifically, the attorney stated that the Medicare Benefit Policy Manual does not impose documentation requirements or strict compliance with documentation content guidance for services performed by a licensed chiropractor to correct a subluxation that has resulted in a neuromusculoskeletal condition. If the chiropractor identified the subluxation and performed manual manipulation of the spine, the statutory basis for determining that the service was not covered would be the question of whether the service was medically necessary.

Furthermore, the attorney said that "conclusions regarding the necessity of care based on conformance with documentation content guidance (missing elements of the history), the nature of the presenting condition (acute or chronic), or the duration of a care plan would be improper and lead to an erroneous result."

Office of Inspector General Response

In response to the Twin Palms attorney's comments regarding the standard of review and the conclusions reached by the OIG independent medical review contractor, we contracted with an independent medical review to determine whether Twin Palms billed services in compliance with Medicare requirements. We maintain that our findings and recommendations as revised are valid.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

For CYs 2014 and 2015, Twin Palms received Medicare Part B payments of $711,742 for 22,967 chiropractic services provided to Medicare beneficiaries. We excluded 619 chiropractic services as follows: services that the RACs and other review entities (such as the MACs) reviewed, services with payments less than $20, and services that we identified as cancelled using the CMS CWF. From the remaining 22,348 services, totaling $704,246 in Medicare payments, we selected 100 services using a simple random sample. Twin Palms provided us with copies of medical records as support for these services. In turn, we provided those copies to an independent medical review contractor to determine whether the 100 chiropractic services were allowable in accordance with Medicare requirements.

We did not review Twin Palms' overall internal control structure. 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 onsite fieldwork at Twin Palms' office in Venice, Florida, from September 2016 to July 2017.

METHODOLOGY

To accomplish our objective, we:

- reviewed applicable Federal laws, regulations, and guidance;
- interviewed Twin Palms officials to obtain an understanding of their 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 Twin Palms, with service dates ending in CYs 2014 and 2015;
- created a sampling frame of 22,348 chiropractic services from the NCH data and randomly selected a sample of 100 services;
- obtained medical records from Twin Palms for the 100 sampled services and provided them to the independent medical review contractor, who determined whether each service was allowable in accordance with Medicare requirements;
- reviewed and summarized the independent medical review contractor's results;

- estimated the amount of the unallowable payments for chiropractic services; and

- shared the results of our review to Twin Palms officials.

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

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

APPENDIX B: RELATED OFFICE OF INSPECTOR GENERAL REPORTS

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

APPENDIX C: STATISTICAL SAMPLING METHODOLOGY

TARGET POPULATION

The population consisted of chiropractic services provided during CYs 2014 and 2015, for which Twin Palms received Medicare payment.

SAMPLING FRAME

For CYs 2014 and 2015, Twin Palms received Medicare Part B payments of $711,742 for 22,967 chiropractic services provided to Medicare beneficiaries. We excluded 619 chiropractic services as follows: services that were reviewed by the RACs and other review entities (such as the MACs), services with payments less than $20, and services that we identified as cancelled using the CMS Common Working File (CWF). The resulting sampling frame contained 22,348 services totaling $704,246 in Medicare payments to Twin Palms.

SAMPLE UNIT

The sample unit was a chiropractic service for which Twin Palms received a payment from Medicare.

SAMPLE DESIGN

We used a simple random sample.

SAMPLE SIZE

The sample size was 100 chiropractic services.

SOURCE OF RANDOM NUMBERS

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

METHOD FOR SELECTING SAMPLE UNITS

We consecutively numbered the sample units in the sampling frame from 1 to 22,348. After generating 100 random numbers, we selected the corresponding frame items.

ESTIMATION METHODOLOGY

We used the OIG/OAS statistical software to estimate the amount of the unallowable payments for chiropractic services. To be conservative, we recommended recovery of unallowable Medicare payments at the lower limit of a two-sided 90-percent confidence interval. Lower

limits calculated in this manner will be less than the actual unallowable payment total at least 95 percent of the time.

APPENDIX D: SAMPLE RESULTS AND ESTIMATES

Table 2: Sample Results

Frame Size	Value of Frame	Sample Size	Value of Sample	Number of Unallowable Services	Value of Unallowable Services
22,348	$704,246	100	$3,166	54	$1,680

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

Point estimate	$375,397
Lower limit	317,038
Upper limit	433,756

APPENDIX E: MEDICARE PAYMENT REQUIREMENTS FOR CHIROPRACTIC SERVICES

MEDICAL NECESSITY

The Act states: "[N]o 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: "[T]he 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 and First Coast's LCD 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 and LCD L33840).

CODING

First Coast's LCD identifies three CPT codes that may be used to bill Medicare for chiropractic services (LCD L33840). Depending on the number of spinal regions treated, chiropractors may bill Medicare for chiropractic manipulative treatment using CPT codes 98940, 98941, or 98942.

DOCUMENTATION

The Manual and First Coast's LCD require that the initial visit and all subsequent visits meet specific documentation requirements (chapter 15, § 240.1.2 and LCD L33840).

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 or, according to the LCD, date of exacerbation or reinjury of existing condition.

The following must be documented for subsequent visits:

1. History

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

2. Physical exam

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

3. Documentation of treatment given on day of visit.

[redacted] [redacted]

June 25, 2018

Department of Health and Human Services
Office of Inspector General
Office of Audit Services, Region VII
61 Forsyth Street SW, Suite 3T41
Atlanta, GA 30303

via US Mail Certified Return Receipt

ATTN: Denise Novak
Assistant Regional Inspector General for Audit Services

via e-mail (Denise.Novak@oig.hhs.gov)

Re: **RESPONSE TO REPORT CONCLUSIONS / REQUEST FOR INFORMATION**
Report Number A-04-16-07065
Twin Palms Chiropractic Health Center, Inc. [redacted]

Ms. Nowak:

Please be advised this law firm represents [redacted] ("Twin Palms") in the above captioned matter. We are in receipt of your draft audit report dated May 31, 2018.

APPOINTED LEGAL REPRESENTATIVE

Twin Palms has appointed this law firm as its legal representative. This response shall act as my entry of appearance on Twin Palms' behalf. Twin Palms 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. Twin Palms has executed an Appointment of Representative form, appointing the undersigned and this firm as its representative. This form is attached.

DEFECTS WITH THE SAMPLING AND AUDIT PROCESS

As a general matter, the audit methodology leading to the conclusions expressed in the report (A-04-16-07065) dated May 2018 ("Draft Report") did not conform 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 Twin Palms' understanding of CMS coverage requirements. No specific testimonial evidence was requested or developed regarding the rationale for the performance of the services included in the sample and it is not apparent that the auditor consulted any of the treating providers or patients regarding the care at issue. Additionally, the auditor failed to consider or misconstrued the relevant criteria as is detailed below. These failures are contrary to HHS, OIG, OAS own audit guidance and is in part, the basis for the error in the conclusions expressed in the Draft Report.

* Admitted to the practice of law before the Supreme Court of California, (CalBar ID 260146), the United States Supreme Court, the United States Third Circuit Court of Appeals and the US District Courts for the Southern District of California and the Western District of Pennsylvania.

Office of Inspector General - The deleted text has been redacted because it is personally identifiable information.

While OAS indicates submission of the requested records to a "independent medical review contractor" this individual or entity is not identified and therefore it cannot be determined whether the individual is licensed in the practice of chiropractic or has any clinical training or experience relative to the practice of chiropractic that would permit that person to render a clinical determination that services were medically unnecessary. Since the necessity of care was challenged for 43 of the 55 services denied, the credibility of what is a clinical conclusion for a majority of the audit result is not demonstrated.

With respect to the validity of the sampling process, the Draft Report indicates that 619 services were excluded because they were reviewed by other audit contractors. Twin Palms has been the subject of only one other audit of services in the audit period. A discovery or probe sample of forty (40) claims with service dates from November 7, 2014 to January 21, 2015 were reviewed by [redacted] a supplemental medical review contractor who reported adverse findings with only eleven (11) services. [redacted] adverse findings were that the documentation did not conform to CMS initial or subsequent visit documentation requirements (4), that the documentation did not evidence performance of chiropractic manipulation (4), or that the documentation supported a lower level of code than was reported (3). We are unaware of any analysis of the remaining 581 services and cannot confirm that the services evaluated by [redacted] were among the 619 services that were removed from the sampling frame.

The Draft Report also indicates exclusion of services with a payment amount of less than $20 without explanation. Exclusion of approved services that resulted in a lower payment amount would tend to bias the overpayment in the sample to a higher value resulting in a higher projected overpayment amount since it is unclear whether these claims were eliminated from the only the sample or both the sample and the universe/sampling frame.

The Draft Report indicates that certain claims in the sample were outside the permissible 4-year re-opening period for a "good cause." 42 C.F.R. § 405.980(b)(2). Because the Final Report has not yet been published, it is impossible to determine exactly how many services must be excluded from the sample; however, as of this date, it appears that at least one of the denied services (patient [redacted] for [redacted] and an undetermined number of approved services would be excluded. Regardless, the Draft Report does not indicate the impact that the removal of these claims from the sample, universe or both would have on the statistical validity of the sample as drawn. The apparent presumption in the Draft Report is that such elimination would have no effect although no data is submitted to demonstrate that any statistical tests were performed to demonstrate that the remaining portion of the sample remained sufficiently sized to be statistically valid or was representative of the remaining portion of the sampling frame.

Finally, the Draft Report provides no detail regarding the process it followed to determine that Twin Palms received unallowable Medicare payments of at least $324,360 for CYs 2014 and 2015. Only a vague description of its sampling and projection process is provided in violation of the Medicare Program Integrity requirements for documentation of a statistical sampling and overpayment estimation analysis.

STANDARD OF REVIEW

The audit report concluded that 55 of the 100 services included in the sample were non-compensable for a variety of reasons including allegations of technical content deficiencies in the

documentation and/or that care was medically unnecessary. It is notable at the outset that the documentation approach and content was consistent throughout; however, a significant number of the services in the sample that were denied were denied on the basis of documentation content concerns. The report also indicates that all services were reported with modifier AT. This should not be of concern since the reporting of the AT modifier simply indicates the provider's belief at the time the claim was submitted that the care was medically necessary. Additionally, any service reported without the AT modifier would have been denied and excluded from the sample.

The above issues aside, given the allegations, it is appropriate to review the various statutory and regulatory provisions pertaining to both the information requirements and the standards of medical necessity relevant to coverage of spinal manipulation performed by a licensed doctor of chiropractic.

Relative to the information necessary, the Social Security Act at Section 1833(e) contains the following requirement:

> *(e) Information for determination of amounts due*
>
> *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.* (Emphasis added).

This statutory provision only requires submission of "information" sufficient to determine the amount of payment due. As such, submission of a CPT code on a CMS-1500 form would be sufficient for this purpose and any related documentation to support that such services were rendered.

Turning to the necessity requirements, the Medicare regulations at 42 C.F.R. §410.21 contain the following 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.*** (Emphasis added).

As a result, coverage of services performed by a licensed doctor of chiropractic is limited to manual manipulation of the spine (or manipulation performed using an instrument controlled by the hands) to correct a subluxation that has resulted in a neuromusculoskeletal condition. This requirement neither expressly nor impliedly imposes a documentation requirement or permits the conclusion that strict compliance with the documentation content guidance found in the Medicare Benefit Policy Manual ("MBPM") is a condition of payment.

Even where a documentation requirement is implied, it is clear that the documentation must substantiate that the coverage requirements are met and as such, the regulations do not address

what might be considered appropriate documentation for this purpose. Regardless, it is clear that the regulations do not permit a conclusion that coverage is predicated on the content of the record. Additionally, considering that once a subluxation and associated neuromusculoskeletal condition has been identified and manual manipulation of the spine has been performed, the only apparent statutory basis for determining that the service was not covered would be where it could be demonstrated that the service was not medically necessary.

The reasonableness and necessity of chiropractic care is related to the concept of coverage and is addressed in the regulations in a section entitled *"GENERAL EXCLUSIONS AND EXCLUSION OF PARTICULAR SERVICES."* A review of the federal regulations at Section 411.15(k) (1) reveals the following citation relevant to the reasonableness and necessity for services performed by a licensed doctor of chiropractic under exclusions to coverage.

> *(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.* (Emphasis added).

This regulatory provision defines 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.

Where the service performed and reported meets *EITHER* of these criteria, the service is considered reasonable and necessary. Again, no documentation content requirement or standard is expressed or implied by this requirement other than the information needed to demonstrate conformance with the regulatory standard of necessity.

The CMS interpretive guidance found in the CMS Internet-Only Manuals pertaining to the necessity of chiropractic manipulation expands on these requirements further but does not impose a specific "documentation" requirement as alleged in the Draft Report based on its conclusions. The relevant CMS guidance is found in the MBPM, Internet Only Manual (IOM) Pub 100-02, Chapter 15, Section 240.1.3 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.* (Emphasis added).

Beyond the express provision above, the concept of necessity is addressed further at Section 240.1.5 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.* (Emphasis added).

The above provision makes clear that spinal manipulation for a chronic condition can be covered provided there is either a "reasonable expectation of recovery or improvement of function" **OR** there is an expectation that the care will "arrest or retard deterioration" in that condition.

By distilling the necessity guidance found in MBPM Sections 240.1.3 and 240.1.5, and as pointed out by [redacted] in his report, it is apparent that the documentation must establish the following three components of information to support a conclusion that spinal manipulation is medically necessary and covered.

1) Existence of subluxation as demonstrated by physical examination or x-ray;

2) Existence of a significant health problem in the form of a neuromusculoskeletal (NMS) condition for which manipulation will provide direct care; and

3) A reasonable expectation that manipulation will result in recovery or improvement of function **OR** will arrest (stop) or retard (slow) deterioration in that condition within a reasonable and predictable period of time.

Any determination of necessity not based on these three criteria exclusively would be invalid and contrary to the statutory, regulatory and interpretive guidance pertaining to the coverage of spinal manipulation. For that reason, conclusions regarding the necessity of care based on conformance with documentation content guidance (missing elements of the history), the nature of the presenting condition (acute or chronic) or the duration of a care plan would be improper and lead to an erroneous result.

Applying the above standard of analysis, each allegation of error was addressed by an independent expert who is a licensed doctor of chiropractic, a certified professional coder (CPC), certified professional chiropractic coder (CCPC) and a certified professional medical auditor (CPMA). [redacted] report is attached. As indicated in his report, [redacted] concluded that twenty-five (25) of the fifty-five (55) services were compensable as billed, three (3) services were

compensable at a lower level and there was concurrence with the denial in twenty-seven (27) of the cases reviewed.

BASES FOR DISAGREEMENT WITH SUBSTANTIVE DETERMINATION

A. Services Were Medically Unnecessary

While the Draft Report correctly states that no payment may be made for medically unnecessary services, and correctly identifies most of the statutory, regulatory and interpretive guidance provisions applicable to making such a determination, it is apparent that those standards were incorrectly applied in some cases as follows.

1. Subluxation of the spine was not present or was not treated with manual manipulation or both (7 services).

While clear that the existence of a subluxation is a statutory condition of payment for chiropractic treatment, CMS guidance allows for demonstration of subluxation by x-ray or P.A.R.T. analysis. It is also clear that the x-ray and P.A.R.T. standards at section 240.1.2 of the Medicare Benefit Policy Manual ("MBPM") do not require a demonstration of subluxation 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.*

There is a notable absence of the requirement to repeatedly demonstrate the existence of subluxation and there is no requirement for a statement that subluxation exists in the documentation for a subsequent visit.

In the cases where this allegation of error was made, the service-specific audit findings indicate that the auditor did find evidence of subluxation. As an example, in the case of patient [redacted] for date of service [redacted] the service specific findings include the following statement: "Subluxations were identified on examination with evidence of spasms and ROM decrease" evidencing not only the subluxation, but the associated neuromusculoskeletal conditions associated with the subluxation. Notwithstanding recognition that appropriate evidence of subluxation was found, the visit was denied, in part, on the basis that "[n]o subluxation diagnosis was provided." Apparently, the auditor is anticipating an ICD-10 code in the record even though such a code was reported on the CMS-1500 claim and is easily ascertainable from the content of the record. Regardless, this is not an appropriate basis for declaring a service as medically unnecessary.

With respect to the allegation that the patient was not treated with manual manipulation, it is notable that the documentation guidance published by CMS in the MBPM relative to documentation of chiropractic treatment states only as follows. "Treatment given on the day of visit." IOM Pub 100-02, Chapter 15, §240.1.2.2.B. Contrary to this standard, services were denied, in part, based on the allegation that the documentation did not sufficiently detail the treatment provided. The following are examples of the allegations made.

> *Coding review found that documentation of specific areas treated was not found. The record says there was treatment of "3-4 regions." As there is no documentation of levels treated, the billed code cannot be substantiated.*

Patient [redacted] DOS [redacted]

> *Review of the coding found that the provider billed code 98941, but the levels of manipulation/care were not found in the record and therefore the code cannot be substantiated.*

Patient [redacted] DOS [redacted]

> *Review of the coding found that there is no documentation of the levels of care treated to substantiate the billed code (98941).*

Patient [redacted] DOS [redacted]

As noted in the expert report of [redacted]

> *In the overwhelming majority of cases for which this allegation of error was made, the documentation* ***clearly reflects performance of manipulation*** *and* ***the specific levels where manipulation was performed are either expressly stated or can be easily ascertained from the subluxation levels listed in the exam portion of the notation.*** *In many of the cases, the objective findings of subluxation had the accompanying statement that* ***adjustment was provided to the segments found to be subluxated.*** (Emphasis added).

Notwithstanding the substantive error expressed in the Draft Report with respect to its conclusions regarding, not only the performance of manual manipulation, but the declaration of the vertebral levels treated, there is no requirement in the MBPM to document either the specific vertebral levels or the specific regions manipulated. Even if the documentation guidance in the MBPM could be construed as implicitly requiring documentation of either the specific vertebral levels or regions where manipulative treatment was performed, this information was either expressly provided or was easily determined from the location of subluxation documented in the record. Certainly, the OAS auditor is not suggesting that areas not exhibiting subluxation were manipulated or that the areas that did exhibit subluxation were not. Such a conclusion could only be based on a presumption that the chiropractor was incompetent, which has neither been alleged nor demonstrated. As a result, denials on this basis are not justified and should be reversed.

CORRECTIVE ACTION: None is required.

2. **Manual manipulation of the spinal subluxation was maintenance therapy or was not appropriate for treatment of the patient's condition or both (27 services)** and/oree **Manual manipulation of the spinal subluxation would not be expected to result in improvement within a reasonable and generally predictable period of time (9 services).**

Before addressing the specific allegations in comparison to [redacted] conclusions, it isee important to note that 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 analysis in the Draft Report appears to simply conclude that in all cases where there was no evidence of long-term improvement in the patient's condition, the care was maintenance and not medically necessary.

As noted in [redacted] expert report there is concurrence that medical necessity was not established in twenty-seven (27) cases as indicated in the service-specific results at Appendix B of his report. It is notable that the rationale detailed in the spreadsheet included with the Draft Report focuses solely on the improvement element of the CMS definition of necessity found in the MBPM as a basis for error. A complete review of the MBPM provisions pertaining to coverage of chiropractic manipulation reveal that care of a chronic condition can be medically necessary and care of such a condition can be necessary where the expectation is that the care will result in either arresting or retarding deterioration in the patient's condition (See IOM Pub 100-02, Chapter 15, §240.1.5). While [redacted] concurred in the denial for 27 of the 36 services denied on the basis of necessity, his concurrence was based not only on the conclusion that the documentation failed to demonstrate either an expectation of or actual improvement, but also because the documentation also failed to provide evidence that there was an expectation of deterioration and that the care provided was anticipated to arrest or retard such deterioration.

Denials inconsistent with [redacted] more credible and complete application of the binding CMS standards of necessity should be reversed.

CORRECTIVE ACTION: Given concurrence with a number of medical necessity denials, the practice will undergo additional education regarding the standards of necessity as outlined above and will additionally be trained regarding the need to more clearly document the specific factors supporting the necessity of care as outlined above. Patients presenting for treatment whose condition does not qualify for coverage, will be presented with an Advanced Beneficiary Notice and advised of the non-covered nature of their treatment and obligation to pay for such services personally. The practice will also exercise reasonable diligence in identifying any similar error in claims beyond the re-opening period but within the 6-year look-back period established in the 60-day rule (42 C.F.R. §401.305) and refund any identified overpayment within 60 days as required by the rule.

B. Services Were Insufficiently Documented (11)

While the Draft Report correctly identifies the elements of information outlined in the MBPM for initial and subsequent visits, there is an apparent presumption that merely filling in the blanks so to speak is a condition of payment or necessary to establish the necessity of the care. In the example given, however, the allegation was based on the allegation that "[t]here was no report as to the levels of care/manipulation provided. . . . .There is no documentation of the levels of care treated

and therefore no support for the billed code (98941)." The error with this allegation is addressed above and will not be repeated but in other cases, there were concerns expressed regarding the content of the treatment plan (see patient [redacted] for [redacted] While the visit under review was a subsequent visit, the analysis focused not on the visit in the sample but on the initial visit of [redacted], which was not part of the sample. With respect to the initial encounter, which was not at issue in the sample, the complaint was that the documentation at the initial visit "lacked specific treatment goals and objective measures to assess effectiveness."

At the outset, it is necessary to point out that the CMS guidance merely indicates what "should" be included in a treatment plan not what must be included. IOM Pub 100-02, Ch. 15 §240.1.2.2.A, Additionally, objective measures used in the evaluation of treatment effectiveness are the examination findings, which were clearly evident. Finally, as noted above, the documentation content guidance does not supplant the analysis of necessity but merely outlines the information that **MIGHT** be relevant in making such a determination. A conclusion to the contrary would be justified only if compliance with the content requirements of the guidance was either a statutory condition of payment or a statutory pre-condition to a determination of medical necessity. Neither is true and therefore arbitrary conclusions that care was medically unnecessary due to alleged documentation content deficiencies are unjustified and should be reversed.

CORRECTIVE ACTION: While the basis for error is invalid, the practice will endeavor to more clearly indicate each element of information where reported and indicate elements of information that were either un-reported or not relevant to the patient's complaints or condition as a means of preventing such erroneous denials in the future.

C. Service Was Incorrectly Coded (1)

The basis for this allegation was that in the one case where this allegation was made, "[t]he claim for this service was billed with a CPT code related to treatment of more spinal regions than what the medical records supported." As noted in [redacted] service-specific analysis, there was concurrence with this finding in the single case where this allegation was made. However, in two other cases, while the documentation supported manipulation to sufficient regions based on the code level reported, [redacted] concluded that the necessity of care was not demonstrated for all of the regions receiving treatment (see patient [redacted] for [redacted] and patient [redacted] for DOS [redacted] The Draft Report should be revised consistent with [redacted] analysis and conclusions.

CORRECTIVE ACTION: Given concurrence with the single error of mis-coding based on the number of regions supported by the documentation as well as the additional error pertaining to the reporting of treatment in regions where necessity was not supported, the practice will undergo additional education regarding the need to properly code from the record and will be advised to elevate this issue in future internal audits. Education on the standards of necessity as addressed above will include the need to validate the necessity of treatment in each region where performed. As the overall error in the sample is *de minimis*, it is not clear that an audit of additional claims for this issue is necessary; however, in the context of the analysis of claims beyond the sampling frame for necessity addressed above, this audit criteria will be included in that analysis and any identified errors will be disclosed and refunded as required under the 60-day rule (42 C.F.R. §401.305).

WRITTEN EVIDENTIARY DEMAND/REQUEST FOR INFORMATION

To the extent that the findings of the Draft Report are unchanged, Twin Palms will undoubtedly receive a refund demand by the local Medicare Administrative Contractor thereby triggering the administrative appeal process. So that Twin Palms will be afforded the opportunity of providing a more detailed response to the substantive allegations of error as well as the validity of the purported SSOE, additional information is necessary. Twin Palms 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 Twin Palms, 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 Twin Palms being selected for audit;
- Any internal memoranda or other internal documents relating to any review of Twin Palms' claims;
- Minutes of any meetings conducted by OAS internally or with any other party concerning this or any prior review;
- A copy of Twin Palms' 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 auditor(s) that performed the review;
- A copy of any internal notes whether on paper or electronic pertaining to communication between members of the OAS or between OAS and the chiropractic auditor relative to the audit of Twin Palms;
- A copy of any worksheets or work papers prepared by the chiropractic auditor or OAS personnel relevant to Twin Palms' 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 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 Twin Palms, the following information:

- **Sample Size:** Appendix A of your report indicates a sample size of 100 paid services from Calendar Year 2014 and 2015. No methodology or calculations were provided to demonstrate the basis for the determination that a 100-service sample was statistically sufficient for this period. The type of sample drawn and the reason for its selection was not disclosed. Please provide this information so that we may validate the statistical validity of the sample size and sample type.

- **Sample Testing:** There is no evidence that the sample, as drawn, was tested for representativeness with the claims included in the sampling frame. There are no tests to even determine if the dates of service in the sample were distributed consistent with the dates of service in the sampling frame. Please provide any calculations and the results associated with any tests of the statistical validity of the sample.

- **Universe and Sampling Frame:** The Draft Report at Appendix A indicates, after exclusion of a number of claims allegedly reviewed by other integrity contractors and services with payments of less than $20, a sampling frame of 22,348 services claims for CY 2014 and 2015. The rationale for exclusion of certain 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. Additionally, please provide an electronic spreadsheet for both the universe and sampling frame in the format detailed below or simply include an indicator relative to whether a service was excluded from the universe when creating the sampling frame.

- **Sample Selection:** The Draft Report at Appendix C indicates selection of a sample of 100 services from the sampling frame of 22, 348 services and also indicates that random numbers were generated using an unidentified OIG/OAS "statistical software" program. While the selection process appears appropriate, 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 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 these formulas chosen and any assumptions made were not disclosed. As a result, we require that you provide details regarding the projection calculation or formula as well as the input values for each variable to include the source of those values.

Consistent with 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.

- For services included in the sampling frame, the 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 (presumably 1/1/2014 through 12/31/2015).

- Assuming performance of an unrestricted variable size determination methodology, indicate whether a probe sample or an estimated error rate was used in the calculation of the sample size.

  - 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, 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.

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.

The information requested above may be provided on electronic media or may be e-mailed to me [redacted] 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. The requested materials and all future correspondence in this matter should be sent to me at the following address.

[redacted]

Thank you for your consideration.

Sincerely,

[redacted]

Enclosure
Expert Report of [redacted]
Appointment of Representative Form

cc: Twin Palms Chiropractic Health Center, Inc.