From: "Roger W. Calton" <rcalton@caltonlaw.com>
Subject: ALJ Decision allows Pulstar as a method of chiropractic treatment
Date: October 19, 2011 1:35:02 PM EDT
To: "'Joseph Evans'" <jme@pulstar.us>

Dear Joe:

Enclosed you will find the Decision by Administrative Law Judge Gronau. In this case the Medicare contractor had disallowed chiropractic treatment using the PulStar FRAS, claiming that it did not meet the Medicare requirements for manual manipulation of the spine. The Judge decided that Pulstar does meet the requirements of the Medicare regulations and allowed treatment through use of the PulStar.

A copy of my memorandum on this issue is also enclosed.

Your testimony was invaluable on this issue.

Thanks for the help.

Regards,

Roger W. Calton
Calton Law Group, P.C.
31371 Rancho Viejo Road, Suite 104
San Juan Capistrano, CA 92675
949.495.3350

Memorandum re: PulStarFRAS and compensability under the Medicare Benefit Policy Manual

Manipulation by a chiropractor is a covered service, payable by Medicare. Manipulation of the spine can be performed in a variety of ways, either by a chiropractor directly using his hands, or by the chiropractor using a hand-held adjusting instrument which then creates the force necessary to create movement of the vertebrae, and is in compliance with the requirements set forth in the Medicare Benefit Policy Manual.

The PulStarFRAS, is a hand-held adjusting instrument which provides a controlled force thrust or impulse. The particular amount of force is manually controlled by the chiropractor through pushing a button on the side of the hand-held device.[1] Exhibit A is a photograph of the adjusting instrument. The blue button on the side of the hand-held device adjusts the amount of force. Exhibit B is a photograph of the device showing the computer screen as well. The amount of force is visualized on the screen in the upper right hand corner of the screen. The adjusting device can be used with either a single probe to contact the vertebrae (shown in Exhibit A), or a double probe (as shown in Exhibit B) The direction of the force is also controlled by the chiropractor, to accomplish the specific movement sought at each vertebrae level treated.

The term "FRAS" is an acronym for "Force Recording and Analysis System". The PulStar device is connected to a computer, which provides functionality in addition to the treatment or adjustment mode. The device can be used as a measuring device to help the chiropractor determine which vertebrae are functioning normally, and which are not, therefore, assisting with the decision of which are to be adjusted. In addition, however, the device then also provides a printed report which shows the levels of the spine and the areas which are normal and those which are abnormal. With respect to the adjustments performed, it also then creates a record of the vertebral levels adjusted and the amount of force utilized.

Chapter 15, Section 30.5 of the Medicare Benefit Policy Manual provides:

30.5 - Chiropractor's Services
(Rev. 23, Issued: 10-08-04, Effective: 10-01-04, Implementation: 10-04-04)
B3-2020.26

A chiropractor must be licensed or legally authorized to furnish chiropractic services by the State or jurisdiction in which the services are furnished. In addition, a licensed
chiropractor must meet the following uniform minimum standards to be considered a physician for Medicare coverage. Coverage extends only to treatment by means of manual manipulation of the spine to correct a

[1] In addition, the amount of force can be adjusted through manually adjusting the force setting through the keyboard or mouse, connected to the computer and the device.

subluxation provided such treatment is legal in the State where performed. All other services furnished or ordered by chiropractors are not covered.

If a chiropractor orders, takes, or interprets an x-ray or other diagnostic procedure to demonstrate a subluxation of the spine, the x-ray can be used for documentation. However, there is no coverage or payment for these services or for any other diagnostic or therapeutic service ordered or furnished by the chiropractor. For detailed information on using x-rays to determine subluxation, see §240.1.2.

In addition, in performing manual manipulation of the spine, some chiropractors use manual devices that are hand-held with the thrust of the force of the device being controlled manually. While such manual manipulation may be covered, there is no separate payment permitted for use of this device.

Additionally, then, Section 240.1.1 (Coverage of Chiropractic Services - Manual Manipulation) also allows for the use of a hand held device:

240.1 - Coverage of Chiropractic Services
(Rev. 1, 10-01-03)
B3-2251
240.1.1 - Manual Manipulation
(Rev. 1, 10-01-03)
B3-2251.1

Coverage of chiropractic service is specifically limited to treatment by means of manual manipulation, i.e., by use of the hands. Additionally, manual devices (i.e., those that are hand-held with the thrust of the force of the device being controlled manually) may be used by chiropractors in performing manual manipulation of the spine. However, no additional payment is available for use of the device, nor does Medicare recognize an extra charge for the device itself.

No other diagnostic or therapeutic service furnished by a chiropractor or under the chiropractor's order is covered. This means that if a chiropractor orders, takes, or interprets an x-ray, or any other diagnostic test, the x-ray or other diagnostic test, can be used for claims processing purposes, but Medicare coverage and payment are not available for those services. This prohibition does not affect the coverage of x-rays or other diagnostic tests furnished by other practitioners under the program. For example, an x-ray or any diagnostic test taken for the purpose of determining or demonstrating the existence of a subluxation of the spine is a diagnostic x-

ray test covered under §1861(s)(3) of the Act if ordered, taken, and interpreted by a physician who is a doctor of medicine or osteopathy.

Manual devices (i.e., those that are hand-held with the thrust of the force of the device being controlled manually) may be used by chiropractors in performing manual manipulation of the spine. However, no additional payment is available for use of the device, nor does Medicare recognize an extra charge for the device itself.

The applicable Medicare Benefits Policy Manual sections are Exhibit D.

Hand held adjusting devices originated decades ago with the Activator, which operated with a spring loaded thrusting mechanism to create the thrust used to move or reposition the vertebrae. (See Exhibit I). The Department of Health and Human Services issued a directive to Medicare Part B Carriers dated April 10, 1984, which states "This gives notice that spinal adjustment by means of a chiropractic "Activator" meets the requirements of manual manipulation outlined in the Medicare Carriers Manual, section 2251.1." (Exhibit E)

In a subsequent letter from the Director of the Office of Coverage and Eligibility Policy for the DHHS, they write: "We consider the chiropractic manipulation of the spine with the use of the Activator to meet the statutory requirement for manual manipulation.". (Exhibit F)

The Pulstar FRAS device was originally known as the "Precision Adjuster", developed by Kinetic Technology, Inc., in Pittsburg, Pa. Exhibit J is a photograph of the Precision Adjustor.

In a letter dated July 26, 1993, the Manager of Medicare Staff Services for Pennsylvania Blue Shield - Medicare, wrote to Mr. Robert Johnson at Kinetic Technology (predecessor to Sense Technology, Inc, the manufacturer of the device) the following:

> "Previously, the Health Care Financing Administration had determined that the use of an "Activator" met the requirements of a manual manipulation and therefore could be used by the chiropractor during his course of treatment.
>
> In reviewing your product, the 'Precision Adjustor', it appears that this device also allows the chiropractor to perform more comprehensive spinal manipulation and therefore meets the coverage requirements outlined above." (Exhibit G).

Exhibit H is a Policy Review and News document published by Highmark Blue Shield, one of the other Medicare intermediaries. In their section on chiropractic

manipulation (Page 22), they specifically recognize the Pulstar FRAS as being covered by Medicare, stating:

> "Adjustments can be provided manually or with the assistance of various mechanical or computer operated devices. Blue Shield does not allow additional payment for the use of the device or for the device itself. This includes, but is not limited to, computer-controlled systems such as the Forced Recording and Analysis (FRAS) System".

Exhibit K is the FDA's 510K Approval of the device, identifying indications for use to include musculoskeletal pain due to joint subluxation, restricted joint mobility, myofascial spasm, and ligamentous strain.

The final exhibit, L, is the resume of Dr. Joseph Evans, developer of the device and President of Sense Technology, Inc from 1989 to 2003. He holds a doctorate degree in engineering, and was formerly the head of the Biosciences and Medical Systems Department of the Westinghouse Research Labs.

Conclusion

The PulStarFRAS adjusting instrument fits squarely within the requirements of the Medicare Carriers Manual. It is a hand-held device with the thrust of the force of the device being controlled manually. This is accomplished by manually pushing the button on the side of the instrument to adjust the amount of force. Similarly, the Activator device is hand held, with the force adjusted by turning a knob which adjusts the amount of force. In both cases, the amount of force is determined and controlled by the chiropractor who is performing the service.

The capabilities of the PulStarFRAS far exceed those of the Activator, but yet the basic functionality allows it to fall within the Medicare Carriers Manual guidelines. Although there is no additional payment for use of the device, the chiropractor should be compensated for manipulation while using this device.

Roger W. Calton
Calton Law Group, P.C.
31371 Rancho Viejo Road, Suite 104
San Juan Capistrano, CA 92675

Department of Health and Human Services
Office of the Secretary

OFFICE OF MEDICARE HEARINGS AND APPEALS

Southern Field Office
100 S.E. 2nd Street Ste 1700
Miami, FL 33131
(305) 415-7400

August 12, 2011

Calton Law Group, P.C.
Roger W. Calton
31371 Rancho Viejo Road, #104
San Juan Capistrano, CA 92675

Subject: Notice of Decision / Dynamic Rehab Services, 1-690694743

Dear Appellant:

Enclosed is the decision of the Administrative Law Judge (ALJ) on your Medicare appeal. Please carefully review this notice and the attached decision.

Your Appeal Rights

If you do not agree with the ALJ's decision, you may appeal the decision by filing a Request for Review with the Medicare Appeals Council (MAC). Other parties to your appeal and, in some cases, the Centers for Medicare and Medicaid Services (CMS) or its contractors may also ask the MAC to review the ALJ's decision. If no party appeals and the MAC does not review the ALJ's decision at the request of CMS or its contractors, the ALJ's decision is binding on all parties. You will have no right to ask a federal court to review the ALJ's decision.

If you are not already represented, you may appoint an attorney or other person to represent you in any filings or proceedings before the MAC. Legal aid groups may provide legal services at no charge. If you or your representative have not completed or submitted an Appointment of Representative form, please contact the MAC for further instructions or to obtain a form.

What to Include in Your Request for Review

Your appeal must identify the parts of the ALJ's decision with which you disagree, and explain why you disagree. For example, if you believe that the ALJ's decision is inconsistent with a statute, regulation, CMS ruling, or other authority, you should explain why the decision is inconsistent with that authority.

You may submit a Request for Review with the MAC in either of the following two ways:

1. Complete and submit the enclosed Request for Review Form (DAB-101).

2. Submit to the MAC a written request that contains all of the following information:

   - The beneficiary's name;
   - The beneficiary's Medicare Health Insurance Claim Number (HICN);
   - The item or service in dispute;
   - The specific date(s) the item(s) or service(s) were provided;
   - The date of the ALJ decision;
   - The ALJ appeal number;
   - The parts of the ALJ's decision with which you disagree and an explanation of why you disagree; and
   - Your name and signature and/or the name and signature of your representative.

Please send a copy of the ALJ's decision with your Request for Review.

When and Where to File the Request for Review

You must submit your request to the MAC **within sixty (60) days** of receipt of this notice. The MAC will assume you received this notice five (5) days after the date indicated at the top of this notice unless you show that you received this notice at a later date. If you file your Request for Review late, you must establish that you had good cause for submitting the request late.

Your Request for Review should be mailed to:

Department of Health and Human Services
Departmental Appeals Board
Medicare Appeals Council, MS 6127
Cohen Building Room G-644
330 Independence Ave., S.W.
Washington, D.C. 20201

Alternatively, you may fax your request to (202) 565-0227. If you send a fax, please **do not** also mail a copy. ***You must always send a copy of your Request for Review to the other parties to your appeal.*** If you do not have the addresses of the other parties, please contact our office.

What Procedures Apply to the MAC's Review of Your Appeal

The Medicare regulations at 42 C.F.R. Part 405, Subpart I, apply to this case.

How the MAC May Respond to Your Request for Review

The MAC will limit its review to the issues raised in the appeal, unless the appeal is filed by an unrepresented beneficiary. The MAC may change the parts of the ALJ's decision that you agree

with. The MAC may adopt, change, or reverse the ALJ's decision, in whole or in part, or it may send the case back to an ALJ for further action. The MAC may also dismiss your appeal.

Where to Obtain Additional Information About the MAC

Additional information about the MAC is available on the Departmental Appeals Board's website at http://www.hhs.gov/dab/reconsiderationqic.html. You can also obtain additional information by contacting the MAC at (202) 565-0100.

Questions About the Decision

If you would like additional information concerning the attached decision, please call or write this office at: (305) 415-7400.

Sincerely,

Kurt Gronau
U.S. Administrative Law Judge

Enclosures:
Form OMHA-152, Decision
Form OMHA-156, Exhibit List

CC.

Q2 Administrators
PO Box 183092
Columbus, OH 43218-3092

CIGNA Government Services
P.O. Box 20010
Nashville, TN 37202

AdvanceMed
520 Royal Parkway, Suite 100
Nashville, TN 37214

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OMHA - Miami

U.S. Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS
Southern Region
Miami, Florida

Appeal of:	[redacted] on [redacted];	ALJ Appeal No.:	**1-690694743**
Beneficiary:	**Multiple**	**Medicare Part B**	
HICN:	**Multiple**	Before:	**Kurt A. Gronau** U.S. Administrative Law Judge

DECISION

After carefully considering the evidence and arguments presented in the record, a **PARTIALLY FAVORABLE** decision is entered for Appellant [redacted].

Procedural History

Appellant filed assigned Medicare claims for chiropractic services provided to various beneficiaries during the period of January 1, 2006, through August 31, 2008 ("the dates of service"). The claims were subsequently paid by Medicare. On January 14, 2009, AdvancedMed Corporation ("AdvanceMed) contacted Appellant and requested additional medical documentation. Appellant was given a 30 day deadline to fulfill the records request. (Master File, Ex.A, pg. 6.) On February 9, 2009, Appellant timely responded by forwarding selected portions of medical records.

In a letter dated February 26, 2010, AdvanceMed informed Appellant that following an audit via statistical sampling methodology and extrapolation, it was determined that an overpayment had occurred in the amount of [redacted] The statistical sampling was conducted by AdvancedMed which is a program safeguard contractor (PSC) for the Centers for Medicare and Medicaid Services (CMS). (Master File Ex. E)

Subsequently, CIGNA Government Services sent a letter dated March 4, 1010, notifying Appellant of a Medicare payment in error, resulting in the overpayment of [redacted].

On March 31, 2010, the Appellant requested a redetermination, which was denied by CIGNA on April 23, 2010. The Appellant subsequently requested a reconsideration on June 25, 2010.

On August 25, 2010, Q2 Administrators, the QIC, issued a Partially Favorable decision. Specifically, the determination was fully favorable to Appellant on 9 out of 50 beneficiaries, and was partially favorable to Appellant on 3 additional beneficiaries. Thus, the total amount of the overpayment was reduced to [REDACTED] By letter dated September 13, 2010, AdvanceMed then re-extrapolated the claimed overpayment from the actual overpayment of [REDACTED] an extrapolated claim of overpayment of [REDACTED].

Appellant filed a timely request for an Administrative Law Judge ("ALJ") hearing regarding the QIC's decision which was received by the Office of Medicare Hearings and Appeals on October 21, 2010. The amount in controversy satisfied the jurisdictional requirement for an ALJ hearing specified under Title XVIII of the Social Security Act ("the Act"), §1869(b)(1)(E).

On April 11, 2011, a telephonic pre-hearing conference was conducted where issues for adjudication were presented and approved. Roger Calton, Esq. participated as Appellant's counsel. A live in-person hearing was held on the matter on May 19, 2011, presided by the Honorable Kurt A. Gronau. Present at the hearing were Appellant's counsel, Roger Calton. Dr. Peter Cox was also present to provide sworn testimony on his own behalf. AdvanceMed was given notice of the hearing but declined to appear. Statistician Dr. Bruce Kardon, Ph.D. provided additional testimony as an expert witness with respect to the validity of AdvanceMed's statistical sampling methodology and subsequent extrapolation.

This decision is bifurcated into two parts. Part I will address the sampling methodology used by AdvanceMed in projecting the alleged overpayment. Part II will address the medical necessity for claims that comprise the sample.

Issues

PART I

1. Whether the sampling methodology used by AdvanceMed is sufficiently reliable so as to uphold the projected overpayment and whether the overpayment assessment was based upon a statistically valid sample and subsequent extrapolation.

PART II

1. Whether the services at issue are covered and payable by Medicare under Title XVIII of the Social Security Act.
2. If the undersigned finds that the services provided are excluded from Medicare coverage, a subsidiary issue is whether the liability of the Appellant may be waived pursuant to §1879 or §1870 of the Act.

Findings of Fact

Reg. 36386, 36387 (June 23, 2005). The ALJs within OMHA issue the final decisions of the Secretary, except for decisions reviewed by the Medicare Appeals Council. *Id.*

A hearing before an ALJ is only available if the remaining amount in controversy is $110 or more. See 71 Fed. Reg. 2247 (January 13, 2006) and 42 CFR §405.1006 as modified by SSA §1869(b)(1)(E)(i). The request for hearing is timely if filed within sixty days after receipt of a QIC Reconsideration. See 42 CFR §405.1002(a)(1).

B. Scope of Review

For all appeals stemming from a QIC, the ALJ appeals process is governed by 42 CFR §§405.1000 *et seq.* 42 CFR §405.1032 states, "[t]he issues before the administrative law judge include all the issues brought out in the initial, reconsidered or revised determination that were not decided entirely in your favor. However, if evidence presented before or during the hearing causes the administrative law judge to question a fully favorable determination, he or she will notify you and will consider it an issue at the hearing."

C. Standard of Review

"The [Office of Medicare Hearings and Appeals]...is staff[ed] with administrative law judges who conduct 'de novo' hearings...." 70 Fed. Reg. 36386 (June 23, 2005); *see also In re Atlantic Anesthesia Associates, P.C.*, MAC (June 2004) ("An ALJ qualified and appointed pursuant to the Administrative Procedure Act acts as an independent finder of fact in conducting a hearing pursuant to §1869 of the Act. This requires *de novo* consideration of the facts and law.")

II. Principles of Law

A. Statutes and Regulations

The Medicare program, Title XVIII of the Social Security Act (42 U.S.C. §§ 1395 – 1395ccc), is administered through the Centers for Medicare and Medicaid Services.

Section 1831 established of the Act establish the Supplemental Medical Insurance Program for the aged and disabled under Part B.

Section 1832 of the Act establishes the scope of benefits that are provided to beneficiaries under Medicare Part B insurance program. Under 1832(a)(2)(B) of the Act, and individual is entitled to have payment made on his behalf for medical and other health services furnished by a provider of services or by others under arrangement with them made by a provider of services.

Section 1833(e) of the Social Security Act, mandates that "[n]o payment shall be made to any provider of services unless there has been furnished such information as may be necessary in order to determine the amounts due such provider. . ." *See also* 42 C.F.R. § 424.5(a)(6), (establishing sufficient information to determine that payment is due).

Section 1861(s)(1) of the Act, defines "medical and other health services" to include among many other things, physicians' services." *See also*, 42 CFR §410.10(a).

Sections 1861(q) of the Act, defines "physicians' services" to mean professional services performed by physicians, including surgery, consultation, and home, office, and institutional calls. The term "physician", when used in connection with the performance of any function or action, means (1) a doctor of medicine or osteopathy legally authorized to practice medicine and surgery by the State in which he performs such function or action (including a physician within the meaning of section 1101(a)(7)). *See also* 42 C.F.R. 410.10(k).

Section 1862(a)(1)(A) of the Act provides that "[n]otwithstanding any other provision of the Act, no payment shall be made for any expenses incurred for items and 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." *See also* 42 CFR §411.15(k).

Section 1870 of the Act provides that if an overpayment is found to exist, the issue is whether waiver of recovery of the Medicare overpayment is permissible pursuant to §1870 of the Act. According to the law, Medicare looks first to whether the provider, the appellant in this case, was at fault with respect to the overpayment. If the provider is not liable, the beneficiary is liable to the extent he benefited from the overpayment. A provider is determined to be without fault if the overpayment was determined subsequent to 3 years from when the claim was originally paid. *See also (42 CFR 405.350) in evaluating fault...provider practiced reasonable care in accepting the payment.*

Section 1879 of the Act limits the liability of the beneficiary and providers of services if the services are found to be not medically reasonable and necessary under Section 1862(a)(1)(A) or care was custodial in nature under Section 1862(a)(9) of the Act. Payment will only be made pursuant to this section if neither the beneficiary nor the provider knew or could reasonably have been expected to know that the services were not covered. *See also* 42 CFR §411.404; 42 CFR §411.406.

Section 1893 of the Act established the Medicare Integrity Program. Pursuant to this provision, the Secretary of Health and Human Services is authorized to enter into contracts designed to strengthen the integrity of the Medicare program. Relevant to the instant case is Section 1893(h) of the Act, which created Recovery Audit Contractors (RACs). RACs receive payment under the contract only on amounts recovered from providers or correct amounts paid to providers. Payment is contingent on amounts recovered or correct amounts paid. See §1893(h)(1). Subsection (h)(4) provides that "audit and recovery activities may be conducted during a fiscal year with respect to payments made under part A or B during such fiscal year; and retrospectively (for a period of not more than 4 fiscal years prior to such fiscal year)."

B. Policy and Guidance

Section 1871(a)(2) of the Act states that unless promulgated as a regulation by CMS, no rule, requirement, or statement of policy, other than a National Coverage Determination (NCD), can establish or change a substantive legal standard governing the scope of benefits or payment for services under the Medicare program. However, in lieu of binding regulations with the full force and effect of law, CMS and its contractors have issued policy guidance that describe criteria for

coverage of selected types of medical items and services in the form of manuals and local medical review policies (LMRPs) or local coverage determinations (LCDs).

Section 1869(f)(1) of the Act provides that National Coverage Determinations are binding upon Administrative Law Judges. *See also* 42 CFR §405.1060. There is no National Coverage Determination for the services at issue.

Section §1869(f)(2) of the Act provides that Administrative Law Judges will give substantial deference to local coverage determinations (LCDs), local medical review policies (LMRPs), or CMS program guidance when applicable, and if they do not follow the policy they must explain why in their decision. *See also* 42 CFR §405.1062. For the dates of service at issue, Cigna Government Services promulgated Local Coverage Determination (LCD) L5751 regarding chiropractic services.

Also considered are the manuals and rulings issued by the Centers for Medicare and Medicaid Services (CMS) in implementing the Medicare program. Specific to the instant case, the Medicare Benefits Policy Manual, Publication 100-2, Ch. 15 §30.5 sets forth the basic coverage rules for chiropractor's services and Ch. 15, §240 sets forth additional coverage rules for chiropractic services. The Medicare Claims Processing Manual, Publication 100-4, Ch. 12, § 220 sets forth the general payment rules for chiropractic services.

III. Principals of Law - Statistical Review

As an alternative to individualized claims adjudication, sampling has been used by government agencies as a means to determine overpayments in instances involving large numbers of beneficiaries and claims.[1] The Act provides requirements that Medicare contractors must follow when extrapolating overpayment amounts via sampling.

§1893(f)(3) of the Social Security Act, provides the following limitation on the use of extrapolation by a Medicare Contractor:

> A Medicare contractor may not use extrapolation to determine overpayment amounts to be recovered by recoupment, offset, or otherwise unless the Secretary determines that—
> (A) there is a sustained or high level of payment error; or
> (B) documented educational intervention has failed to correct the payment error.
>
> There shall be no administrative or judicial review under section 1869, section 1878, or otherwise, of determinations by the Secretary of sustained or high levels of payment errors under this paragraph. (*See also* CMS Pub. 100-08, §3.10.1.4)

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[1] *Chaves County Home Health Service v. Sullivan,* 931 F.2d 914, 289 U.S. App. D.C. 276 (DC, 1991). *See also Sullivan v. Everhart,* 494 U.S. 83, 110 S.Ct. 960, 964-66, 108 L.Ed.2d 72 (1990) (upholding as permissible the Secretary's construction of provisions of the Social Security Act as allowing a net calculation of over and under-payments of benefits).

The CMS policy regarding statistical sampling and extrapolation can be found in the Medicare Program Integrity Manual (CMS Pub. 100-08). Among its other requirements, this publication requires that the following documents be maintained by Medicare Contractors conducting a statistical sampling and extrapolation:

1. Documentation of Sampling Methodology – The PSC or Medicare contractor BI or MR unit shall maintain complete documentation of the sampling methodology that was followed. (CMS Pub. 100-08, §3.10.4.4).

2. Documentation of Universe and Frame - An explicit statement of how the universe is defined and elements included made and maintained in writing. Further, the form of the frame and specific details as to the period covered, definition of the sampling units, identifiers for the sampling unit(s) (e.g. claim numbers, carrier control number, etc.), and dates of services and source must be specified and recorded in your record of how the sampling was done. A record must be kept of the random numbers actually used in the sample and how they were selected. Sufficient documentation must be kept so that the sampling frame can be re-created, should the methodology be challenged. You must keep a copy of the frame. (CMS Pub. 100-08, §3.10.4.4.1).

Additional guidance can be found in CMS Program Memorandum Transmittal B-01-01, *effective* January 8, 2001, which was reissued without modification as Transmittal B-02-007, dated February 7, 2002 and as Transmittal B-03-022 dated March 21, 2003, which contains numerous provisions regarding required documentation and oversight, including:

1. <u>Documentation of Universe and Frame</u> - An explicit statement of how the universe is defined and elements included must be in writing. Further, the form of the frame and specific details as to the period covered, definition of the sampling units, identifiers for the sampling units (e.g. claim numbers, carrier control number, etc.), and dates of services and source must be specified and recorded in your record of how the sampling was done. A record must be kept of the random numbers actually used in the sample and how they were selected. Sufficient documentation must be kept so that the sampling frame can be re-created, should the methodology be challenged. You must keep a copy of the frame. *Id.* at IV, D, 1.

2. <u>Sampling methodology</u> – Copies of the statistician-approved sampling methodology must be submitted to the Regional Office. *Id.* at IV, D, 3.

3. <u>Notification of review</u> – When the physician is not notified of the review, advance approval must be obtained from the Regional Office. *Id.* at VI, A, 1.

4. <u>Information to be included in the Demand Letter</u>
    a. A description of the universe, the frame, and the sample design;
    b. A definition of the sampling unit, the sampling selection procedure ...;
    c. The time period under review;
    d. The sample results, including the overpayment estimation methodology and the calculated sampling error as estimated from the sample results; and
    e. The amount of the actual overpayment/underpayment from each of the claims reviewed.

f. Also include a list of any problems/issues identified during the review, and any recommended corrective actions. *Id.* at VII, A.

The policy also provides guidance regarding how a Carrier should proceed with Changes Resulting from Appeals. It states in relevant part that, "If the decision on appeal upholds the sampling methodology but revises one or more of the revised initial claim determinations, the estimate must be recomputed." *Id.* at IX, B.

CMS Program Memorandum Transmittal B-03-022, dated March 21, 2003 discusses the use of statistical sampling for overpayment estimation in great detail. In its discussion of when statistical sampling is appropriate it adopts the following rule from Part D of CMS Program Memorandum Transmittal AB-00-72, dated August 7, 2000:

> Your use of statistical sampling to determine overpayments may be used in conjunction with other corrective actions. Review that involves the use of statistical sampling may be utilized when there is a "major level of concern" regarding the physician or supplier's billing, reimbursement, and/or utilization.

According to Transmittal AB-00-72 the proper tool for determining the proper level of concern in post-payment review is the provider's service specific error rate ("Error Rate") which is determined by dividing the "(net) dollar amount of services paid in error as determined by Medical Review" by the "dollar amount of services medically reviewed."

Analysis

PART I

Introduction

The Administrative Law Judge conducted a *de novo* review of all matters relevant to these proceedings, to include the aforementioned issues, *supra,* related to the statistical sample, extrapolation and overpayment determination conducted by AdvanceMed. Throughout the appeals process additional documentation was accepted and admitted into the record. The undersigned has given careful consideration to the sworn testimony provided at the hearing and has reviewed all of the submitted documentation in its entirety. Accordingly, the following Decision is based upon a preponderance of the evidence now in the record.

Statistical Sampling, Extrapolation and Overpayment Determination

The overpayment determination was calculated using statistical sampling methodology, derived from a universe of previously paid claims. The record contained complete documentation of the sampling methodology used which included statements of how the universe was defined, specific claim information, medical records, and a copy of the frame. The QIC held that AdvanceMed performed a valid statistical overpayment calculation, but reversed recoupment for several beneficiaries in the sample. Appellant now challenges the validity of the sampling methodology and estimated overpayment on multiple grounds (discussed below). In considering the merits of

the contractor presented. Next, he noted that the 2 strata were defined respectively based on paid amounts as 1) <$65, and 2) $65 to $99,999 and that there was no clear analysis as to why the strata were defined this way or why 2 strata were utilized.

Additionally, he argued that using the contractor's method, the sample size used by the contractor was not determined by proper statistical methods. There was insufficient detail and data to determine the correctness of the sample size utilized. He further indicated that normally with the high coefficient of variation, a large sample of claims is needed; namely at least 375 in this audit for Stratum 1 and 371 for Stratum 2. Consequently the sample sizes (30 in each stratum) used in the audit was inadequate. Dr. Kardon further noted that the overpayment should be based on the number of percent of denied claims rather than denied dollars as it reduces the distortion and avoids making unnecessary assumptions about the data. The 0 paid dollar claims were excluded which rendered the overpayment estimate higher. Finally, he testified that the methodology employed and extrapolated findings by the contractor are in violation of the Program Integrity Manual. Dr. Kardon's testimony is credited in this regard.

Sample is not Representative and Therefore Invalid

Presumably, any type of sampling unit is permissible under Medicare rules "as long as the total aggregate of such units covers the population of mis-paid [sic] amounts." However, AdvanceMed's chosen sample in this case is clearly not an accurate representation of the frame from which it was selected, thus adversely impacting the projected overpayment calculation. Therefore, the present statistical sample is invariably flawed. Additionally, the MPIM requires ZPIC and PSC contractors to look for underpayments in addition to overpayment in order to off-set any estimated amount due. This was not done as such claims were in fact excluded by AdvanceMed from the frame. Thus, it is the conclusion of the undersigned that due to the above-mentioned misrepresentations, the statistical sample and subsequent extrapolated estimated overpayment is invalid *in toto*.

PART II

Whether Documentation Sufficiently Supports Medical Necessity

Having overturned the statistical basis upon which the overpayment projection was based, the undersigned now turns to a discussion of the appropriateness of the services provided to each individual beneficiary in the sample.

The appellant contends that they provided sufficient medical documentation at the QIC level, to establish the medical necessity for the services at issue. Specifically, at the hearing the appellant argued that they submitted sufficient medical documentation for all claims at issue that demonstrate that the treatments were properly prescribed, treatment plan was established, and the overall chiropractic and physical therapy treatments were medically necessary. After review of the submitted medical documentation, the ALJ has determined that medical necessity was not established for all the claims at issue. The medical necessity analyses are listed below.

I. Favorable Decisions

According to Medicare Benefit Policy - Basic Coverage Rules (PUB. 100-02), Chapter 15 - Covered Medical and Other Health Services, §240, Chiropractic Services: coverage is specifically limited to treatment by means of manual manipulation, i.e., by use of the hands. Additionally, manual devices (i.e., those that are hand-held with the thrust of the force of the device being controlled manually) may be used by chiropractors in performing manual manipulation of the spine. The manual also indicates the documentation requirements for the initial and subsequent visits. For initial visits, documentation should include a history of the beneficiary indicating symptoms causing patient to seek treatment; family history if relevant; past health history (general health, prior illness, injuries, or hospitalizations; medications; surgical history); mechanism of trauma; quality and character of symptoms/problem; onset, duration, intensity, frequency, location and radiation of symptoms; aggravating or relieving factors; and prior interventions, treatments, medications, secondary complaints. The record should also include evaluation of musculoskeletal/nervous system through physical examination, diagnosis, a detailed treatment plan, indicating the recommended level of care (duration and frequency of visits); specific treatment goals; and objective measures to evaluate treatment effectiveness, and date of initial treatment. Documentation for subsequent visits should include: a history of the beneficiary indicating a review of chief complaint; changes since last visit; system review if relevant, a physical exam and documentation of treatment given on day of visit.

Section § 240.1.3 of the above-mentioned manual further states that Medicare will consider chiropractic manipulative services to be medically necessary for a beneficiary experiencing a significant neuro musculoskeletal condition due to subluxation of the spine. At the start of chiropractic therapy it is expected that the chiropractor will effect improvements or arrest deterioration in such condition within a reasonable timeframe. The medical records must show the usefulness of continued chiropractic treatment. When further clinical improvement cannot reasonably be expected from continuance ongoing care, and chiropractic treatment becomes supportive rather than corrective in nature, the treatment is then considered maintenance therapy.

For the claims listed as FAVORABLE in the attachment, the undersigned has found that the appellant submitted sufficient medical documentation that satisfies all the requirements listed in the above-mentioned manual. Therefore, the services at issue are medically necessary.

II. Unfavorable Decisions

As mentioned above, Medicare Benefit Policy - Basic Coverage Rules (PUB. 100-02), Chapter 15 - Covered Medical and Other Health Services, §240 Chiropractic Services, requires specific medical documentation be included in each patient's medical record. Specifically, the appellant failed to include the following medical records in all of the unfavorable decisions: the medical history of the beneficiaries which would have been obtained at the initial visits and indicated symptoms causing the patients to seek treatment; family history if relevant; past health history (general health, prior illness, injuries, or hospitalizations; medications; surgical history); mechanism of trauma; quality and character of symptoms/problem; onset, duration, intensity, frequency, location and radiation of symptoms; aggravating or relieving factors; and prior interventions, treatments, medications, secondary complaints. Additionally, the appellant failed to provide clear evidence of the date of the initial treatments and all subsequent visits thereafter for each of the beneficiaries listed as UNFAVORABLE in the attachment. Therefore, without said documentation, the undersigned was unable to ascertain whether the beneficiaries had new

or acute injuries. The notes instead suggested the beneficiaries' conditions were chronic and the treatments were supportive rather than corrective in nature demonstrating that the chiropractic manipulations at issue were maintenance treatments, which are not covered by Medicare. Accordingly, the appellant has not provided sufficient medical documentation that clearly illustrates the medical necessity for the chiropractic manipulative treatments at issue.

Waivers of Liability

A) §1879 of the Act

If the undersigned finds that the services in question were not medically necessary, §1879 of the Act allows Medicare to make payments for the services provided that the beneficiary and/or the provider did not know or could not have reasonably known that the services would be excluded. The undersigned finds that the beneficiaries did not know and could not have been expected to know that the services provided would not be reimbursed. The record is devoid of any evidence which suggests that the beneficiaries knew or could have been expected to know that the services would not be reimbursed by Medicare.

As a participant in the Medicare program, the Appellant is obligated to familiarize itself with the applicable law and policy regarding coverage requirements and cost reimbursement for Medicare Part B services. Moreover, constructive knowledge is established by receipt of the various publications and issuances pertaining to Medicare guidelines. After considering all the applicable coverage and payment issues, including limitation on liability under §1879 of the Act, the Appellant is held financially liable for the non-covered services and any overpayment resulting from this decision and order.

B. §1870 of the Act

Section 1870 of the title XVIII of the Act governs situations in which Medicare has discovered that it overpaid providers of services, individuals, or beneficiaries. Medicare may recoup overpayment amounts from providers of services, or individuals; however, Medicare may not recoup an overpayment amount when the provider of services or individual is "without fault." *See also*, 42 U.S.C. § 1395gg(b); 42 C.F.R. § 405.350 *et seq*. In this case, recovery of any incorrect payment would be barred after January 1, 2006. Therefore, Medicare recoupment is prohibited for payments made to the Appellant with respect to the medical services provided to beneficiaries during the dates of service prior to January 1, 2006.

Conclusions of Law

Appellant and the carrier are instructed to refer to Attachment A for the decisions regarding each beneficiary at issue.

Medicare may not recoup overpayments from Appellant for the treatments which were found to be medically reasonable and necessary. See Attachment A.

Appellant must reimburse Medicare for overpayments for services which were not medically reasonable and necessary. Appellant is liable for amounts resulting from unfavorable decisions. See Attachment A.

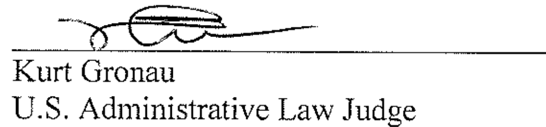
The sample size and the methodology employed to arrive at the sample size is not statistically valid and is not supportable. The methodology employed in analyzing the claims comprising the sample and the resulting extrapolation to determine the overpayment, were statistically invalid.

Order

The Medicare Contractor is **DIRECTED** to process the claim in accordance with this decision.

SO ORDERED.

Dated: AUG 12 2011



Kurt Gronau
U.S. Administrative Law Judge