DEPARTMENT OF HEALTH AND HUMAN SERVICES
DEPARTMENTAL APPEALS BOARD

REVISED FINAL DECISION OF MEDICARE APPEALS COUNCIL
Docket Number: M-2009-620

In the case of	**Claim for**
American Health Network of Indiana, LLC, and Adam D. Perler, D.P.M. (Appellant)	Supplementary Medical Insurance Benefits (Part B)
**** (Beneficiary)	**** (HIC Number)
AdminaStar Federal (Contractor)	**** (ALJ Appeal Number)

INTRODUCTION

The Administrative Law Judge (ALJ) issued a Decision on Remand, dated March 5, 2009. The ALJ found that pressure-specified sensory device (PSSD) services were not covered by Medicare, that overpayment provisions of section 1870 of the Social Security Act (Act) did not apply to the appellants-providers (collectively, appellant), and that the beneficiaries were "without fault" and not liable for overpayments under section 1870(c) of the Act. The appellant has asked the Medicare Appeals Council to review this action. The Council grants the request for review because there is an error of law. *See* 20 C.F.R. §§ 404.967 and 404.970(a)(2), *incorporated by reference in* 42 C.F.R. § 405.856.[1]

[1] This case arises from appeals of decisions issued by Medicare carrier hearing officers. Accordingly, regulations in effect before enactment of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) govern appeals procedure. 20 C.F.R. part 404, Subparts J and R, *incorporated by reference at* 42 C.F.R. § 405.801(c); *see* "Medicare Program: Changes to the Medicare Claims Appeal Procedures," Final rule, 74 Fed. Reg. 65296, 65297 (December 9, 2009) and "Medicare Program: Changes to the Medicare Claims Appeal Procedures," Interim final rule with comment period, 70 Fed. Reg. 11420, 11425 (March 8, 2005).

The Medicare Appeals Council admits the following documents as exhibits (Exhs.) into the administrative record:

Exh. MAC2-1: Appellant's request for review, dated May 1, 2009, with enclosures

Exh. MAC2-2: Cover letter and Brief of American Health Network of Indiana, LLC, and Adam Perler, DPM, dated May 29, 2009[2]

Exh. MAC2-3: Interim Correspondence from the Medicare Appeals Council, dated June 25, 2009

Exh. MAC2-4: Proposed Decision of Medicare Appeals Council, dated January 25, 2010

Exh. MAC2-5: Request for Reconsideration and/or Modification of Decision of the Medicare Appeals Council Dated January 25, 2010, dated February 5, 2010

For the reasons below, the Council finds that the appellant's due process rights were not violated during the ALJ hearing process and that the ALJ was not required to disqualify himself from conducting the hearing. The Council affirms its prior findings that the PSSD device services were not medically reasonable and necessary, and therefore not covered by Medicare, and that the appellant was liable for non-covered costs. The Council finds that the appellant was not without fault under section 1870(b) of the Act and not entitled to waiver of overpayment recoupment by the Medicare carrier.

BACKGROUND

ALJ Decision I

The ALJ issued his first decision in this case on August 1, 2006. Remand Case Pleading Folder #1, Exh. P2 (ALJ Dec. I).[3] In

[2] Appellant's brief was submitted in one of two three-ring binders that also contain documents tabbed as Exhibits A – UU. For ease of reference, the Council has placed a copy of the brief only with the appellant's accompanying cover letter in the MAC Master File.

[3] The ALJ's first decision, the Council's Order of Remand, and the ALJ's Decision on Remand are contained as exhibits in brown files labeled as Remand Case Pleading Folders #1 and #2. The Council's citations to those documents shall be to ALJ Dec. I, Order of Remand, and ALJ Dec. II, respectively, after

that decision, the ALJ noted that the evidence failed to establish whether the Food and Drug Administration (FDA) had assigned the PSSD device to Category A, as an experimental and/or investigational device that cannot be covered by Medicare, or to Category B, as a non-experimental and/or investigational device that can be covered by Medicare. *Id.* at 5-6. The ALJ assumed for purposes of his decision that the device fell within Category B and was eligible for Medicare coverage. *Id.* at 6. The ALJ noted, however, that the Centers for Medicare & Medicaid (CMS) and CMS contractors had a longstanding policy denying coverage of PSSD on grounds that it was experimental/investigational. *Id.* In support, the ALJ cited five examples of nonbinding local coverage policies as reflecting that PSSD methodology "is essentially unproven and/or investigational." *Id.* at 7-8. The ALJ also considered scientific articles offered into evidence by the appellant, but found that the appellant had not established that the PSSD devices were reasonable and necessary under section 1862(a)(1) of the Act. *Id.* at 8-9. The ALJ also found that the provider was liable for the non-covered costs of PSSD under section 1879 of the Act. *Id.* at 9. The appellant initially sought Council review in a request for review dated September 21, 2006. *Id.,* Exh. P3.

Council Remand

After considering the request for review, the Council issued an Order of Remand to the Administrative Law Judge, dated November 12, 2008. Remand Case Pleading Folder #1, Exh. P6 (Order of Remand). In relevant part, the Council found "that the ALJ did not err in his conclusions concerning coverage of PSSD. We remand this case, however, because the ALJ did not make necessary findings regarding waiver of recovery of the overpayment pursuant to section 1870(b) of the Act." *Id.* at 3.

In the remand order, the Council reviewed applicable legal authorities, including the CMS policy that an item or device is not covered by Medicare as "reasonable and necessary" under section 1862(a)(1) of the Social Security Act (Act) when scientific research and studies fail to establish that it is either "safe" and "effective" and not "experimental" or when the record does not establish that the item or device is generally

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the initial citation to the record. The Council shall also cite to the appellant's brief in support of the request for review as "Brief" and to the Request for Reconsideration and/or Modification of the Council's Proposed Decision as "Request for Reconsideration and/or Modification."

accepted in the medical community as safe and effective for the condition treated. Order of Remand at 5 (string citation omitted). The Council found that the ALJ did not err in denying coverage for PSSD, in part, based upon the persuasive authority of "a number of LCDs [Local Coverage Determinations] issued by CMS contractors in jurisdictions other than Indiana [which conclude] that PSSD was not covered by Medicare *because it was regarded as experimental and investigational*." *Id.* at 7 (emphasis supplied).

The Council also considered and rejected appellant's arguments that scientific and medical articles in the record established that PSSD was not experimental and investigational. Order of Remand at 7-8. The Council noted that articles published in 2005 and 2006 indicated that PSSD was "beginning to gain acceptance" at that time, after the dates of service. *Id.* The Council also noted that AdminaStar Federal, then the Medicare carrier for Indiana, had issued a draft LCD in 2006, which considered peer-reviewed literature and found that "Quantitative sensory testing (QST) with the Pressure-Specified Sensory Device is considered investigational and will not be currently covered by Medicare." *Id.* The Council acknowledged that the draft LCD was not in effect during the dates of service, but found that "it is further evidence that the ALJ did not err in concluding that PSSD was still regarded as experimental and investigational in 2003 and 2004." *Id.* The Council also found that the ALJ did not err in finding the appellant liable for non-covered costs under section 1879 of the Act. *Id.*, n.6.

The Council then considered the appellant's arguments for waiver of overpayment under section 1870 of the Act. Order of Remand at 8-9. The Council rejected the appellant's argument that the draft LCD demonstrated that the appellant could not have known that AdminaStar would consider PSSD investigational and therefore that "they should be regarded as without fault within the meaning of section 1870 of the Act." *Id.* at 8. The Council found that "Section 1870(b) of the Act provides that an overpaid provider or supplier is obligated to refund the overpayment unless he or she is 'without fault.'" *Id.* at 8-9. The Council also found that a provider is deemed to be "without fault absent evidence to the contrary" when a contractor attempts to recoup payment more than three years after the initial determination. *Id.* at 9.

The Council further found that the ALJ failed to make a "without fault" determination under section 1870(b) and remanded the case

for further proceedings. Order of Remand at 9. The Council's remand instructions read as follows:

> On remand, the ALJ shall:
>
> 1. Afford the parties the opportunity for a new hearing on the issue of whether the appellants were without fault, within the meaning of section 1870(b) of the Act in receiving the overpayments at issue in this case.
>
> 2. Issue a new decision consistent with this order.
>
> The ALJ may take further action not inconsistent with this order.

Id.

ALJ Decision II

Upon remand, the ALJ conducted a hearing on January 27, 2009, and issued a twenty-eight page Decision on Remand, dated March 5, 2009. Remand Case Pleading Folder #2, Exh. P15 (ALJ Dec. II). The ALJ first stated that the Council had remanded the case for a finding on "whether the appellant should be held financially harmless as a provider who is 'without fault' under the statutory provisions of *Section 1870(c)*" of the Act. *Id.* at 1 (emphasis supplied). In his summary, the ALJ stated that he had considered and rejected the appellant's motion to disqualify the ALJ for reasons of bias and partiality during the hearing. *Id.* at 2. The ALJ then stated that he received testimony on the issue of whether the appellant was "without fault." *Id.* The ALJ ultimately denied the appellant's motion to remove the ALJ as well as "the request for waiver of overpayments . . . ." *Id.* The ALJ then decided "*sua sponte*" that the first ALJ decision incorrectly found the beneficiaries not liable under section 1879 of the Act "and reverses so much of that decision and instead holds the beneficiaries financially harmless under the provisions of § 1870 (of the Act)." *Id.*

Appellant's Request for Review

The appellant again sought Council review and submitted a thirty-two page brief in support, with two three-ring binders of exhibits. Exhs. MAC2-1 and MAC2-2 (Brief). The appellant framed the two issues for appeal as follows:

1. Whether the appellants were "without fault," within the meaning of Section 1870(b) of the Act, in receiving the overpayments at issue in this case.

2. Whether the ALJ engaged in misconduct and improperly refused to disqualify himself.

Brief at 4.

Appellant's Brief presents the background and history of PSSD testing (Brief at 7-15). Appellant also asserts that Medicare should cover PSSD (*id.* at 15-23); that the ALJ failed to follow the Council's instructions on remand and Dr. Perler was without fault under section 1870(b) of the Act (*id.* at 23-28); and that the ALJ "engaged in improper ex parte contacts and should have disqualified himself." *Id.* at 28-32.[4]

Proposed Decision of Medicare Appeals Council, dated January 25, 2010

The Council subsequently issued the Proposed Decision of Medicare Appeals Council, dated January 25, 2010. In its decision, the Council addressed appellant's contentions in three general areas of discussion:

- The ALJ was not disqualified from conducting the ALJ hearing upon remand from the Council. The administrative record did not support that the ALJ was prejudiced or partial with respect to a party or had an interest in the matter before him, pending for decision. Proposed Decision at 6-10.
- The ALJ erred in reopening coverage and liability findings and in determining that the without fault provisions of section 1870 of the Act did not apply to the appellant. *Id.* at 10.
- The appellant was not "without fault" under section 1870(b) of the Act in creating the overpayment for PSSD services in this case. *Id.* at 10-14.

The Council then found that the PSSD services billed were not reasonable and necessary under section 1862(a)(1) of the Act and

[4] It appears that a substantial portion of the appellant's Brief to the Council duplicates arguments made in its hearing brief to the ALJ.

were not covered by Medicare. The Council further found that the appellant was liable for the non-covered costs under section 1879 of the Act and also found that the appellant was not without fault under section 1870(b) of the Act and not entitled to waiver of recoupment of the overpayment. Proposed Decision at 15.

Appellant Request for Reconsideration and/or Modification of Decision of the Medicare Appeals Council Dated January 25, 2010, dated February 5, 2010

In response to the Proposed Decision, the appellant filed the Request for Reconsideration and/or Modification of Decision of the Medicare Appeals Council Dated January 25, 2010, dated February 5, 2010, and received by the Council on February 12, 2010 (Request for Reconsideration and/or Modification). Exh. MAC2-5, at 1-5. The appellant presents four arguments in support of Council reconsideration and/or modification of the Proposed Decision.

First, the appellant contends that the Proposed Decision conflicts with two prior Council decisions "implicitly recognizing that such [PSSD] testing was reasonable and necessary under Medicare coverage standards" when, in those cases, the "only issue was the coding choice." Exh. MAC2-5, at 2.

Second, the appellant argues that "[a]s shown in the extensive bibliography submitted by the Appellants, as well as excerpts of multiple articles and copies of articles, substantial medical literature existed prior to 2005 and 2006 supporting PSSD testing." Exh. MAC2-5, at 2-3 (emphasis in original). The appellant also contends that "numerous ALJ decisions . . . clearly evidence a prevailing view in Indiana and elsewhere that PSSD testing was medically necessary." *Id.* at 3. The appellant points out "the complete absence of any medical evidence stating that PSSD testing was *not* accepted prior to 2005 and 2006." *Id.* at 3 (emphasis supplied).

Third, the appellant argues that the Council cites to no evidence supporting its finding that the appellant "knew or should have known" that the PSSD services were not covered by Medicare under section 1862(a)(1) of the Act. *Id.* at 3. The appellant notes a "vague" statement by the Council, with "[n]o citation to the record or to any document," that local coverage

policies and technology assessments relied upon by the ALJ (as a basis for finding the PSSD services not covered) had been issued before the instant dates of service. *Id.* The appellant states that "even the ALJ acknowledged that there was no local coverage determination (LCD) or national coverage determination (NCD) addressing PSSD testing." *Id.* The appellant asserts that there is "no specific evidence in the record showing how Dr. Perler actually knew (or why he, as an Indiana podiatrist, should have known) that PSSD testing was non-covered." *Id.* at 3-4. The appellant cites to Dr. Perler's testimony that the "overwhelming weight of [scientific] articles" established that PSSD was medically necessary and would be covered. *Id.* The appellant states that the Council's "reference to PSSD being a 'subset of QST' provides no basis for its ruling." *Id.* at 4. The appellant summarizes that "the fact that there was no LCD, NCD or other evidence showing that Dr. Perler had actual knowledge that PSSD testing was covered should be determinative under Section 1870(b) *and coverage should be allowed here."* *Id.* (emphasis supplied).

Finally, the appellant argues that the Proposed Decision "complete fails to address the issue raised by Appellants as to the ALJ's improper ex parte contacts." Exh. MAC2-5, at 4. The appellant asserts that the Council "totally ignores" this "fundamental due process issue on appeal . . . ." *Id.* The appellant professes not to understand the Council's "reticence given the clear rules for the conduct of ALJ proceedings." *Id., citing, e.g.,* 42 C.F.R. § 405.1000(d). The appellant avers that "ALJs do not have a roving commission to gather evidence in secret and without the knowledge of the Appellant or its counsel." *Id.* The appellant concedes that Medicare appeals are non-adversarial and asserts that "ALJs may hire experts and gather evidence," but states that "this may not be done on a secret or ex parte basis." *Id.* The appellant summarizes that "[i]t is undisputed in this situation that the ALJ *based his decision, in part, on evidence outside the record and which was not admitted into evidence."* *Id.* at 4-5 (emphasis supplied). The appellant states that it is unfortunate that "the Council nowhere addresses this misconduct in its [proposed] decision." *Id.* at 5.

DISCUSSION

1. The ALJ Was Not Disqualified From Conducting The Hearing On Remand. The Record Does Not Support That the ALJ Was Prejudiced Or Partial With Respect To A Party Or Had An Interest In The Matter Pending For Decision.

The appellant initially asserts that the Council may not need to consider its arguments concerning ALJ disqualification if the Council finds that the appellant's liability for overpayment should be waived as a matter of law. Brief at 28. The appellant nonetheless asks that the Council "pronounce upon the propriety of the conduct of the ALJ," given that such a ruling would have "salutary effect in curbing the abuses that occurred here." *Id.*

The appellant states that ALJ committed misconduct through "*ex parte* gathering of evidence without notice to Appellant's counsel." Brief at 29. The appellant points to an email that the ALJ "secretly sent to Sensory Management Services [who is] the manufacturer and marketer of the PSSD." *Id. citing* Exh. U.[5] The appellant also refers to attempted contacts by the ALJ with the FDA and CMS. *Id.* According to the appellant, the ALJ's conduct fails to meet standards in Title 42, C.F.R. part 405, including requirements that the ALJ issue a decision "based on the hearing record." *Id.* at 30*, citing* 42 C.F.R. §§ 405.1000(d), 405.1042(a)(1)-(2), 405.1046(a).[6] The appellant also argues that counsel responded in a timely manner to ALJ orders concerning the additional information and/or evidence for the administrative record. *Id.* at 31. In summary, the appellant maintains that the ALJ had no justification "in conducting investigations and obtaining evidence outside the record in this case" and that "[t]he ALJ's misconduct created the appearance of bias and impartiality." *Id.* at 32. The

[5] The email from the ALJ to the PSSD manufacturer is dated June 20, 2006. Remand Case Pleading Folder #2, Exh. P15, at 38. The ALJ had previously conducted the hearing on May 23, 2006, and subsequently issued his first decision on August 1, 2006. The Council notes counsel's statement, in an affidavit dated January 12, 2009, that he became aware of the ALJ's purportedly improper contacts "subsequent to the [May 23, 2006] hearing." *Id.* at 36. As discussed herein, the Council finds no reason to overturn the ALJ decision, or to remand the case to another ALJ for another hearing and decision, based upon the allegations of bias, prejudice, and partiality set forth in the affidavit or in the Brief. *Id.* at 37.

[6] As noted above, this case arose from carrier hearing officer decisions and pre-BIPA/MMA regulations apply. The appellant's citations to post-BIPA/MMA regulations are therefore erroneous.

appellant concludes that the ALJ had a duty to disqualify himself and refused to do so. *Id.* The Council disagrees.

The Social Security Act provides that an individual dissatisfied with an initial determination of a Medicare claim is entitled to reconsideration and "a hearing thereon . . . to the same extent as is provided [for Social Security claims] in section 205(b)" of the Act. Section 1869(b)(1) of the Act. The United States Supreme Court has recognized that hearings conducted under section 205(b) are non-adversarial and that the ALJ has a "duty to investigate the facts and develop the arguments both for and against granting benefits . . . ." *Sims v. Apfel,* 530 U.S. 103, Westlaw (WL) p.7, (2000)(plurality), *citing Richardson v. Perales,* 402 U.S. 389, 400-401 (1971). In so doing, the Court noted procedural regulations which state that these hearings are conducted in "an informal, nonadversary manner." *Id., citing* 20 C.F.R. § 404.900(b). The Court has rejected the argument that due process is violated when the adjudicator in a non-adversarial hearing serves more than one function, combining "advocate-judge-multiple-hat" roles. *Richardson v. Perales,* 402 U.S. 389, WL pp.12-13 (1971).

Instead, federal courts have recognized that, "in light of the unique non-adversarial nature of administrative hearings," the ALJ's duty "to develop the record fully and fairly" is both "well-settled" and "independent of the claimant's burden to press his case." *Scott v. Astrue*, 529 F.3d 818, 824 (8th Cir. 2008)(citations omitted). In short, in non-adversarial administrative hearings, the issue is one of "procedur[al] integrity and fundamental fairness." *Richardson v. Perales,* WL p.12. The ALJ's duty to develop the record fully and fairly also extends to cases in which the appellant is represented by counsel. *Bishop v. Sullivan*, 900 F.2d 1259, 1262 (8th Cir. 1990).

Courts have also recognized a rebuttable presumption *against* ALJ bias. "ALJs and other similar quasi-judicial administrative officers are presumed to be unbiased. This presumption can be rebutted by a showing of conflict of interest of some other specific reason for disqualification." *Rollins v. Massanari*, 261 F.3d 853, 857-58 (9th Cir. 2001), *citing Verduzco v. Apfel*, 188 F.3d 1087, 1089 (9th Cir. 1999). "[E]xpressions of impatience, dissatisfaction, annoyance, and even anger, that are within the bounds of what imperfect men and women . . . sometimes display" are insufficient to establish bias. *Id.* at 858*, citing Liteky v. United States*, 510 U.S. 540, 555-56

(1994). Instead, a party is "required to show that the ALJ's behavior, in the context of the whole case, was 'so extreme as to display clear inability to render fair judgment.'" *Id., citing Liteky,* 510 U.S. at 551. Mere allegations that an ALJ has prejudged a case or the fact that an ALJ asked "pointed questions or [displayed] expressions of disbelief . . . plainly [do] not show bias." *Valentine v. Commissioner, Social Security Administration*, 574 F.3d 685, 690 (9th Cir. 2009).

Consistent with the above caselaw, the regulatory standard for ALJ disqualification is as follows:

> An administrative law judge shall not conduct a hearing if he or she is prejudiced or partial with respect to any party or has any interest in the matter pending for decision. If you object to the administrative law judge who will conduct the hearing, you must notify the administrative law judge at your earliest opportunity. The administrative law judge shall consider your objections and shall decide whether to proceed with the hearing or withdraw. If he or she withdraws, the Associate Commissioner for Hearings and Appeals, or his or her delegate, will appoint another administrative law judge to conduct the hearing. If the administrative law judge does not withdraw, you may, after the hearing, present your objections to the Appeals Council as reasons why the hearing decision should be revised or a new hearing held before another administrative law judge.

20 C.F.R. 404.940.

The Council has audited the hearing recordings for the pre-hearing conference on April 18, 2006; the first ALJ hearing on May 23, 2006; the post-hearing conference on July 25, 2006; and the ALJ hearing on January 27, 2009. The Council has also considered the email in the record from the ALJ to the manufacturer of the PSSD device concerning FDA classification of the PSSD device. The Council finds that the ALJ's conduct of all hearings and attempts to develop the factual record, in the context of the case as a whole, do not constitute a denial of due process or warrant ALJ disqualification or removal from presiding over this case.

First, under the federal caselaw and regulatory standard cited above, there is no evidence that the ALJ has a conflict of

interest or is prejudiced or partial against the appellant. Second, there is no indication that the ALJ's conduct or comments to appellant or its counsel, during any of the multiple proceedings in this matter, bear any resemblance to conduct "so extreme as to display clear inability to render fair judgment . . . ." *Rollins v. Massanari*, 261 F.3d at 858. Third, the ALJ sustained counsel's objection on the issue of administrative notice that the PSSD device was a Category B device, and the ALJ then assumed, for purposes of his decision, that the services were eligible for Medicare coverage. ALJ Dec. I, at 2.[7] The ALJ's coverage denial is based on the reasonable and necessary provisions in section 1862(a)(1) of the Act, not FDA categorization of the PSSD device.[8] *Id.* at 9.

The Council finds that the appellant's contentions concerning due process violations, as set forth in its Request for Reconsideration and/or Modification, also provide no basis for overturning the ALJ decision. It is simply incorrect to state that, in its Proposed Decision, the Council "nowhere" addressed the appellant's arguments concerning the ALJ's email request to the manufacturer of the PSSD device for FDA categorization of that device. As fully discussed above, the appellant initially argued that the ALJ's conduct was a due process violation that constituted bias and demonstrated partiality against the appellant. In the Proposed Decision, the Council found, under

[7] The ALJ erred in citing 42 C.F.R. § 411.15(o) as a basis for coverage denial. There is no indication that the PSSD devices are Category B devices furnished in clinical trials governed by FDA-approved protocols. ALJ II at 9-10. In any event, ALJ references to FDA categorization are harmless error, as CMS uses FDA categorization only "as *a factor* in making Medicare coverage decisions." 42 C.F.R. §§ 405.203(c), 405.205(a)(2)(emphasis supplied). As the Council has affirmed, the coverage denial in this case is based upon the "reasonable and necessary" provisions of section 1862(a)(1) of the Act, for items and services deemed experimental and/or investigational, following a review of scientific literature in the record and/or local coverage policies of Medicare contractors.

[8] The Council notes that National Government Services, Inc. (NGS) is the successor Durable Medical Equipment Medicare Administrative Contractor (DME MAC) to AdminaStar, with jurisdiction for Indiana. NGS issued the "LCD for Neuromuscular Junction Testing (L25563)," effective December 1, 2007, which states that neuromuscular junction testing by repetitive motor nerve testing billed under CPT code 95937 (also billed by the appellant in this case) "is not considered reasonable and necessary for indications other than those listed above." LCD L25563, "Limitations." The LCD also provides that Quantitative Sensory Testing (QST), including PSSD, is not "reasonable and necessary for the diagnosis or treatment of diabetic neuropathy." *Id.* While LCD L25563 was not in effect during the dates of service, it is consistent with the AdminaStar Federal draft LCD, as well as the technology assessments and local coverage policies cited by the ALJ for coverage denial.

the relevant legal standards, that no due process violation occurred, that the ALJ's conduct did not demonstrate bias or partiality against the appellant, and that the ALJ was justified in conducting the hearing. While the appellant's arguments appear to have shifted from bias and partiality to focus on due process, the Council finds no basis for overturning the ALJ decision and awarding the relief requested by the appellant, which includes another remand for a new hearing and decision by a different ALJ.

First, the appellant cites to the incorrect regulatory standards governing ALJ conduct. Exh. MAC2-5, at 4; *see supra* fn.1, 20 C.F.R. § 404.953(a). Even if the appellant's citation were correct, the appellant notes that the ALJ decision must be based upon evidence offered at the hearing "or otherwise admitted into the record." Exh. MAC2-5, at 4. The ALJ entered the evidence about which the appellant complains into the administrative record, sustained the appellant's objection on that issue, and found the PSSD services were not covered by Medicare on different grounds. As the ALJ summarized, "[t]his judge's efforts were unsuccessful at filling the factual gap in this case, so he took administrative notice of an absent fact which had no prejudicial effect on the appellant." ALJ Dec. II, at 8. The ALJ's inquiry concerning FDA categorization of the PSSD device from the manufacturer and marketer of that device, after inquiries to counsel as well as the relevant government agencies, does not constitute a due process violation in the context of this non-adversarial Medicare appeal. This outcome is particularly indicated when the record supports that the appellant learned of the ALJ inquiry after the first ALJ hearing, on May 23, 2006, yet failed to raise the issue for over two years and a half years, by first filing Appellants' Motion to Disqualify Administrative Law Judge, dated January 12, 2009. Finally, as noted above, the appellant concedes the ALJ's duty to develop the factual record, as occurred in this case, a concession that is consistent with the federal caselaw, regulations, and administrative authority cited above.

Accordingly, the Council has considered the appellant's contentions and the entire administrative record. The Council finds that the ALJ did not violate the appellant's due process rights. The Council also finds that the record does not support that the ALJ had any conflict of interest or demonstrated prejudice or partiality against the appellant. The Council further finds that the ALJ provided the appellant a full and fair opportunity to present its case. The Council therefore

finds that the appellant's allegations of ALJ bias and misconduct and due process violations provide no basis for overturning the ALJ decision or remanding this case to a different ALJ for another hearing and decision.

2. The ALJ Erred In Sua Sponte Reopening Issues Of Coverage And Liability And In Finding That The Without Fault Provisions Of Section 1870 Do Not Apply To The Appellant.

Regulations provide that the ALJ "*shall* take any action that is ordered by the [Council] and *may* take any additional action *that is not inconsistent with the [Council's] remand order.*" 20 C.F.R. 404.977(b). This regulation gives the Council's remand order the force and effect of law. As noted above, in its Order of Remand, the Council affirmed the ALJ's finding that PSSD services were not covered by Medicare because they were not reasonable and necessary under section 1862(a)(1) of the Act and that the appellant was liable for the non-covered costs under section 1879 of the Act. The Council's findings on those questions are conclusive and establish the "law of the case" on coverage and liability issues. The ALJ's decision to revisit those questions on remand is "inconsistent with the [Council's] remand order," and undercuts important legal principles of finality and the hierarchy of review. The ALJ's analysis and findings on the issues of coverage and limitation on liability on remand are therefore vacated. The Council's findings that the services are not covered by Medicare because they are not reasonable and necessary and that the appellant is liable for non-covered costs remain in effect.

In its Request for Reconsideration and/or Modification, the appellant asserts that the Proposed Decision conflicts with prior Council decisions on the issue of coverage of PSSD services. This argument is unavailing. First, the Council has held, in this case, that the ALJ erred in reopening the issue of coverage and affirmed the ALJ's initial findings that the PSSD services were not covered by Medicare. Even if coverage were an open issue (and it is not), in response to the appellant's contentions, the Council does not have the administrative records in the cases cited by the appellant and is therefore unable to determine whether those cases may be persuasive or instructive here. As appellant acknowledges, Council decisions are not precedential. The Council also notes, however, that the issue in both of the decisions provided by the appellant is confined to whether PSSD services were correctly coded by the

appellant under CPT code 95937 (as occurred in this case) or whether they should have been coded as an unlisted procedure under CPT code 95999. While the Council concluded in those cases that the services were covered when billed under CPT code 95999, the decisions contain no analysis concerning whether the services were experimental and/or investigational and therefore not reasonable and necessary under section 1862(a)(1) of the Act. As the Council has found that, based upon the record before it, the PSSD services are not covered by Medicare because they are experimental and investigational and thus not reasonable and necessary under section 1862(a)(1) of the Act, the Council now finds the decisions cited by the appellant are inapposite and not persuasive in this case.[9]

3. The Appellant Is Not Without Fault Under Section 1870(b) of the Act

The Council finds that the ALJ erred in summarizing the issue on remand as being whether the appellant was entitled to waiver of overpayment based upon subsection (c) of section 1870 of the Act. ALJ Dec. II at 1. The issue on remand, as ordered by the Council, was to determine whether the appellant is "without fault" under the provisions of section 1870, subsection (b).

Section 1870(b) states, in part, that where more than the correct amount has been paid "*to a provider of services*" for items or services provided to "an individual" and the Secretary determines that the overpaid amount "cannot be recouped *from such provider of services . . . or (B)* that *such provider of services* . . . was without fault with respect" to the overpayment, at that point, "proper adjustments" may be made in payments to individuals. Section 1870(b) of the Act (emphasis supplied). The statute further clearly discusses "without fault" provisions solely in relation to providers: "For purposes of clause (B) of paragraph (1), *such provider of services . . .* shall, in the absence of evidence to the contrary, be deemed to be *without fault* if the Secretary's determination that [the overpayment] was made subsequent to the

[9] For similar reasons, the Council also rejects appellant's arguments that other ALJ decisions "clearly evidence a prevailing view in Indiana and elsewhere that PSSD testing was medically necessary." Exh. MAC2-5, at 4. Like Council decisions, ALJ decisions are not precedential, the Council does not have the record in those cases before it, the appellant submitted no evidence that there were no unfavorable ALJ decisions rendered during the same time frame, and the record in this case contains ample evidence in local coverage policies and technological assessments, as cited by the ALJ, that PSSD testing was not reasonable and necessary prior to 2005 and 2006.

third year following the year in which notice was sent to such individual that such amount had been paid." *Id.* (emphasis supplied).

The provisions of the Medicare Financial Management Manual (MFMM) cited by the Council in its remand reflect the long-standing and considered interpretation of section 1870 by the Secretary. Order of Remand at 6, *citing* MFMM, Ch. 3, § 90. That interpretation establishes contingent liability for the beneficiary *only if the provider is without fault. Id.; see also* MFMM, Ch. 3, § 70.

The ALJ's reliance upon *Visiting Nurses Association of Southwest Indiana, Inc. v. Shalala,* 213 F.3d 252 (7th Cir. 2000) and *MacKenzie Medical Supply, Inc. v. Leavitt*, 506 F.3d 341 (4th Cir. 2007) is misplaced. *VNA of Southwest Indiana* involves Medicare Part A payments under cost-reports, while *MacKenzie Medical Supply* fails to note that distinction and adopts the *VNA of Southwest Indiana* holding without critical analysis. Moreover, the *VNA of Southwest Indiana* Court stated the issue as being whether providers were entitled to waiver of overpayment liability under section 1870(c). *Id.*, 213 F.3d at 355-56. After its analysis, the Court concluded that "no waiver under [section 1870(c)] is possible for the providers." *Id.* at 357; *see also id.* at 359. The Council agrees. The Council also agrees that the Secretary may recoup provider overpayments. *Id.* at 358, *citing* 42 C.F.R. §§ 405.370-78.

The Council finds no inconsistency between the Court's holding in *Visiting Nurses Association of Southwest Indiana* that the providers were not entitled to the relief requested under section 1870(c) of the Act, and the Council's remand for the ALJ to determine whether the provider was "without fault" under section 1870(b). The Council also finds no conflict between this case and the longstanding CMS policy that a Medicare contractor finds a provider "without fault" when the provider exercised "reasonable care" in billing and accepting Medicare payment for items and services provided to beneficiaries, claims resulting in overpayments. Order of Remand at 6, *citing* MFMM, Ch. 3, § 90.[10] The ALJ erred in disregarding the Council's

[10] The manual provides examples of a provider exercising "reasonable care" and being "without fault" in billing and accepting payment for services. A provider is deemed to be without fault when it made "full disclosure of all material facts" and "on the basis of information available to it, including, but not limited to, the Medicare instructions and regulations, it had a reasonable basis for assuming that the payment was correct, or, if it had

remand, and in concluding that an analysis of the "without fault" provision of section 1870(b) does not apply to providers.

In this case, it is undisputed that the Secretary, through the contractor, determined that more than the correct amount had been paid to a provider of services. There is no indication that the Secretary determined that the overpayment could not be recouped from the provider. Before any adjustments may be made to payments to individuals, the Secretary must thus determine whether the provider to whom the overpayment was made is "without fault." It is that determination that was the sole issue before the ALJ on remand and which the Council now decides.

A provider is deemed to be without fault, in the absence of evidence to the contrary, when the Secretary's determination of an overpayment occurs more than three years after the year in which payment was made. Section 1870 of the Act (text). In this case, the appellant referenced redetermination decisions and notices of overpayment in its brief. Brief at 1-2. Attachments to the carrier redetermination decisions and notices of overpayment reflect dates of initial payment. The relevant dates are as follows:

Redetermination	Dates Claims Paid	Overpayment Notice
Perler I	12/15/03 – 12/14/04	08/12/05
Perler II	09/07/04 – 10/11/04	04/21/05
Perler III	05/07/04 – 09/02/04	04/21/05
Perler IV	11/13/03 – 11/04/04	08/12/05
Perler V	07/08/04 – 10/18/04	04/21/05

The record indicates that none of the notices of overpayment to the provider were more than three years after the dates of initial payment. The Council thus finds that the appellant is not presumed to be without fault under section 1870(b) of the Act.

The Council next turns to whether the appellant is without fault under CMS administrative authority interpreting section 1870(b). The Council has reviewed and considered the testimony of Dr. Perler during all ALJ hearings and the arguments of counsel, both during the hearings and in submissions to the ALJ and the Council. Dr. Perler testified that he completed a portion of

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reason to question the payment; *it promptly brought the question to the [contractor's] attention." Id.* (emphasis supplied).

his podiatric training with Dr. Dellon, the inventor and patentholder of the PSSD device. Dr. Perler stated that he then bought the PSSD machine in 2003 and that the Medicare carrier initially paid claims submitted. He testified that he sought the advice of medical practice staff and consultants in determining that he should bill Medicare claims for PSSD devices using CPT code 95937. The record reflects that he did so in this case. He also testified that he spoke with colleagues in both Indiana and Florida, who advised him that Medicare regularly paid for their PSSD claims. Upon questioning by the ALJ, he stated that no one from Medicare, including the Medicare contractor, had advised him that PSSD claims would *not* be covered.

Counsel for the appellant argued that it would be virtually impossible for a physician to get a verbal decision on coverage from a contractor representative and that, even if such a decision were given, it would not be binding, as Medicare coverage policy is set forth in National Coverage Determinations issued by CMS and local coverage policies issued by the contractors. Counsel also argued that Dr. Perler had no basis for believing that Medicare would not pay for the PSSD services billed to Medicare during dates of service in 2003 and 2004.

The Council notes that Dr. Perler indicated that Medicare initially paid for PSSD services billed under CPT Code 95937. Within two years of those claims, the contractor notified the appellant that an overpayment existed. The Council also notes that the local coverage policies and technology reports cited by the ALJ as a basis for finding PSSD experimental and investigational were either originally issued before the dates of service or cite to bibliography authority that predate the dates of service. Those articles refer to PSSD as a subset of QST, which has not been covered in cases of diabetic neuropathy. Dr. Perler testified that he used PSSD on diabetic patients with peripheral neuropathy to determine whether they were good candidates for surgery on nerve decompression. The Council also notes Dr. Perler’s testimony that he trained with Dr. Dellon, the inventor and patentholder of PSSD; that he or his assistant received PSSD training and annual certification by Sensory Management Company, the PSSD manufacturer; and that he bought the PSSD device in 2003. The Council again notes that scientific literature cited in the Order of Remand indicates that PSSD was only beginning to gain acceptance in 2005 and 2006.

The record, as a whole, supports that Dr. Perler, a member of a group medical practice in Indiana, submitted claims to Medicare through his administrative and support staff. Those claims were submitted under a CPT code that did not accurately describe the services provided. The carrier later sought to recoup monies paid for the incorrectly billed services. The appellant then sought to bill the PSSD services under a different code. Scientific and medical literature did not establish that PSSD testing was reasonable and necessary, under Medicare coverage standards, during the dates of service. Multiple technological assessments and contractor policies issued and in effect during the dates of services, as cited by the ALJ, stated that QST and PSSD were experimental and investigational.

In its Request for Reconsideration and/or Modification, the appellant asserts that the Council failed to cite supporting authority for this finding. This ignores the Council's above reference, also contained in the Proposed Decision, to the five local coverage policies and technology assessment cited by the ALJ. *See* ALJ Decision I, at 7-8, *citing* Main Folder #3, Exhs. A7, at 2; A13, at 2; A14, at 2; A17, at 2; A22, at 7; A26, at 1.[11] Further, contrary to appellant's assertion that Medicare paid Dr. Perler for PSSD services "for years," Medicare paid Dr. Perler for the claims at issue when billed under an incorrect CPT code. It sought repayment after discovering the incorrect payment.

The appellant strenuously argues that there is no "specific evidence in the record showing how Dr. Perler actually knew (or why he, as an Indiana podiatrist, should have known) that PSSD testing was non-covered." Exh. MAC2-5, at 4. The standard for knowledge under section 1870 does not require that Dr. Perler concede actual knowledge on the record. Instead, the inquiry is whether Dr. Perler, or his administrative support staff, exercised reasonable care in billing for those services. As the

[11] The appellant fails to cite to any specific scientific article to support its argument that PSSD services were not experimental or investigational. Nonetheless, the Council notes that many of the articles listed in the appellant's bibliography of scientific or medical articles were either authored or co-authored by Dr. Dellon, the inventor of the PSSD device at issue who sold the device to the appellant and participated in the appellant's podiatric training. Medicare recognizes that testimonials or case studies by sponsors with a financial interest in the outcome are insufficient evidence of a general acceptance by the medical community and do not support that a device or service is reasonable and necessary. Medicare Program Integrity Manual (MPIM), Pub. 100-08, Ch. 13, § 13.7.1; *see also* MPIM Ch. 13, § 13.5.1 (experimental and investigational services are not reasonable and necessary).

administrative standards state, reasonable care includes promptly contacting Medicare if there is a reason to question a payment received. The record contains no evidence of any such inquiry by Dr. Perler or his administrative support staff or billing/coding consultants.

Further, as evidenced by his testimony, Dr. Perler and his staff were in regular contact with the inventor and patentholder of the PSSD device, as well as its manufacturer and marketer, before and during the dates of service. During this time, the Indiana carrier had issued no local coverage determination, although it issued a proposed LCD in 2006. However, as the ALJ found, Medicare carriers in other states had found PSSD services were experimental and investigational and, thus, not reasonable and necessary and not covered by Medicare. The Council finds that, based upon contacts with Dr. Dellon and Sensory Management Services, Dr. Perler and his staff and consultants had reason to question whether Medicare would pay for PSSD services billed under an incorrect CPT code during the period at issue, a period when multiple carriers had already found PSSD services were experimental and investigational and not covered by Medicare.[12] As noted, the record is devoid of any inquiry to Medicare by the appellant, his staff, or his consultants.

The Council thus finds that the appellant was not "without fault" and did not exercise "reasonable care" in billing for PSSD services under section 1870(b) of the Act. The Council finds that the contractor may recoup the overpayments.

FINDINGS

The Medicare Appeals Council has carefully considered the entire record and makes the following findings:

1. The appellant submitted claims to Medicare for PSSD services with dates of service in 2003 and 2004.

2. The PSSD services were experimental and/or investigational during the dates of service and were thus not reasonable and necessary under section 1862(a)(1) of the Act. The PSSD services are therefore not covered by Medicare.

[12] The appellant's argument that PSSD is distinguishable from QST lacks force. For example, as discussed above, the Indiana LCD includes PSSD as a subset of QST that is not covered by Medicare as experimental and investigational.

3. The appellant is liable for the non-covered costs under section 1879 of the Act.

4. The ALJ erred in making coverage and liability findings upon remand. The coverage and liability findings of the ALJ's decision on remand are vacated.

5. The appellant is not without fault in creating the overpayments under section 1870(b) of the Act and CMS administrative authority.

6. The Medicare contractor may recoup the overpayments.

DECISION

It is the decision of the Medicare Appeals Council that the PSSD services are not reasonable and necessary under section 1862(a)(1) of the Act, and thus not covered by Medicare, and that the appellant is liable for non-covered costs under section 1879 of the Act. The appellant is also not without fault in creating the overpayments, and is not entitled to waiver of recoupment of the overpayments under section 1870(b) of the Act.

MEDICARE APPEALS COUNCIL

/s/ Clausen J. Krzywicki
Administrative Appeals Judge

/s/ Susan S. Yim
Administrative Appeals Judge

Date: February 25, 2010