

DEPARTMENT OF HEALTH AND HUMAN SERVICES
DEPARTMENTAL APPEALS BOARD

DECISION OF MEDICARE APPEALS COUNCIL
Docket Number: M-11-568

In the case of

Meridian Laboratory
Corporation

(Appellant)

(Beneficiary)

AdvanceMed Corporation (PSC)

(Contractor)

Claim for

Supplementary Medical
Insurance Benefits (Part B)

(HIC Number)

(ALJ Appeal Number)

INTRODUCTION

The Medicare Appeals Council has decided, on its own motion, to review the Administrative Law Judge's (ALJ's) decision, dated October 29, 2010, because there is an error of law material to the outcome of the claims. See 42 C.F.R. § 405.1110. The ALJ decision concerned an extrapolated overpayment derived from statistical sampling of diagnostic laboratory tests provided to the beneficiaries on dates of service listed on Attachment 1. The ALJ issued a fully favorable decision, finding that all services met Medicare coverage requirements and that there was no overpayment in this case.

The Council has carefully considered the record that was before the ALJ, as well as the memorandum, with any attachments, from the Centers for Medicare & Medicaid Services (CMS), dated November 23, 2010. The CMS memorandum is hereby entered into the record in this case as Exhibit (Exh.) MAC-1. For reasons set forth below, the Council finds that the services provided do not meet Medicare coverage requirements and are not covered by Medicare. The Council further upholds the statistical sampling and extrapolation methodology as valid in this case. The Council therefore reverses the ALJ's decision.

PRELIMINARY ADMINISTRATIVE RECORD ISSUES

On January 5, 2011, the appellant, through counsel, requested a copy of the hearing record from the Council in order to file exceptions to the agency referral. On January 19, 2011, the appellant submitted a reply brief to the agency referral and renewed its request for a copy of the hearing record. On March 18, 2011, the Council forwarded to the appellant a copy of the hearing record. On April 5, 2011, the appellant submitted a supplementary brief commenting on the record evidence.¹ The Council admits this interim correspondence into the record as Exhs. MAC-2 through MAC-5. These documents are in MAC Master File I.

The administrative record was forwarded to the Council by CMS in three boxes. The first box included a yellow file marked as the ALJ Master File and multiple other files and loose documents consisting of case records that had not been marked as exhibits or organized by the ALJ.² The second box contained individual beneficiary files with copies of procedural, medical, and claims records, as well as a copy of the ALJ decision and Notice of ALJ Hearing. The third box contained individual beneficiary files, as well as miscellaneous loose documents, with the individual beneficiary files containing some, but not all, of the documents in individual beneficiary files contained in the second box. The Council forwarded or made available all documents to the appellant on March 18, 2011. Exh. MAC-4.

To organize the administrative record for review, the Council admits certain documents into the administrative record as Exhs. MAC-6 through MAC-39, as set forth on Attachment 2. These

¹ A party's request for record evidence and the opportunity to comment on that evidence tolls the Council's 90-day adjudication time period until the end of the time allowed for response. Exh. MAC-4, at 2, quoting 42 C.F.R. § 405.1118 and citing 42 C.F.R. § 405.1110(d).

² CMS based its referral, in part, on documents in the record that had not been marked as exhibits by the ALJ. CMS described the state of the record it reviewed as follows: "Exhibits 1-16 are located in the yellow folder marked 'Master File.' Exh. 17 is in a spiral binder. Exhibits and other documents accompanying the QIC's April 16, 2010 Amended Reconsideration Letter are in the brown accordion folder. The request for reconsideration and other materials submitted to the QIC are in a blue folder marked '1 of 2' and a manila folder marked '2 of 2.' The Appellant's reconsideration request for reconsideration and related documents, including procedural documents from the beginning of the audit through the redetermination are in a manila folder marked '1 of 26.' We have grouped these folders together but otherwise attempted to leave the record as we found it." Exh. MAC-1, at 4 n.2.

documents are located in MAC Master Files II and III and supplement the record in ALJ Master File I.

BACKGROUND

At issue are diagnostic laboratory tests billed by the appellant clinical diagnostic laboratory to Medicare for beneficiaries with end-stage renal disease (ESRD) who receive regular kidney dialysis treatment, primarily at facilities of the Wake Forest Outpatient Dialysis Clinic. Exh. MAC-1, at 1.

Overpayment Determination, Redetermination, and Reconsideration

On December 15, 2006, Program Safeguard Contractor (PSC) AdvanceMed requested additional records from the appellant in post-payment review of Medicare claims. Exh. MAC-6, at 1. Between October 17, 2007, and October 23, 2007, the PSC also submitted a request for medical records to thirty-four physicians. Exh. MAC-8.

On September 29, 2008, the PSC issued a letter summarizing its review, stating that it had selected the appellant for investigation as a provider that "consistently billed aberrantly in comparison with their peers across their entire book of business." Exh. MAC-10, at 1. The PSC determined that the appellant had ranked first in number of aberrancies in the period reviewed and had the highest rank in number of services per beneficiary in a peer comparison study. *Id.* The PSC conducted a statistical sample of 120 claims involving 113 medical records, resulting in an 80% denial rate, with 18% of the claims auto-denied by the contractor. *Id.*³ The PSC determined that a high level of payment error existed, extrapolated the overpayment, found the appellant had been overpaid \$4,117,016.00, and found the appellant liable for the overpayment under section 1870 of the Social Security Act (Act). *Id.* at 1, 3. On October 7, 2008, Medicare contractor CIGNA Government Services issued an overpayment demand letter. Exh. MAC-11, at 1. On October 21, 2008, the appellant requested redetermination. Exh. MAC-12.

On December 11, 2008, the contractor issued a partially favorable redetermination decision, finding an extrapolated overpayment in the amount of \$3,994,242.00. Exh. MAC-22, at 2.

³ The sampling memorandum indicates a 96.67% error rate. Exh. MAC-9, at 5.

The attached spreadsheet indicates that a majority of claims were denied because "[t]he physician who is treating the beneficiary and uses the results in the management of the beneficiary's specific medical problem must be the one to order diagnostic laboratory tests" (Reason B) and "[t]he additional information requested from treating physician did not contain a signed and dated physician's order" (Reason E). See, e.g., Exh. MAC-23, at 4. On February 10, 2009, the appellant requested QIC reconsideration. Exh. MAC-34.⁴

On April 10, 2009, the QIC issued an unfavorable reconsideration decision that encompassed thirty-eight HCPCS codes.⁵ Exh. ALJ-3A, at 1-3. The rationale for the majority of denials was that the record contained insufficient documentation to justify medical necessity for additional laboratory work "above and beyond monthly ESRD composite panel." See, e.g., Exh. ALJ-2, at 1 (Beneficiary J.A.). On June 12, 2009, the appellant requested an ALJ hearing. Exh. ALJ-3.

ALJ Remand and Decision

On August 12, 2009, the ALJ issued an order, remanding the case to the QIC. Exh. ALJ-5. In part, the ALJ stated that "the burden is on the QIC to obtain those parts of a beneficiary's medical record that are relevant to the specific claim(s) being reviewed." *Id.* at 4, quoting 42 C.F.R. §§ 410.32(d)(3)(i),(ii). The ALJ also found that the appellant had not received notice that medical necessity would be an issue in the reconsideration decision. *Id.* at 4-5. The ALJ found, in part, that the QIC had deprived the appellant of its due process rights and remanded the case for the QIC to obtain "information [that] can be only provided by CMS or its contractors" *Id.* at 5. The ALJ instructed the QIC to allow the appellant additional time to obtain documentation of medical necessity from the ordering physician. *Id.*

⁴ On January 22, 2009, the contractor issued a second partially favorable redetermination, reflecting overpayment of \$3,952,814.00. Exh. MAC-31, at 1-2. The appellant requested reconsideration of both redetermination decisions. Exh. MAC-34, at 1 n.1. The second redetermination decision reflects adjustments in the overpayment based on appellant submissions after contractor reopening. Exh. MAC-24, at 9-10.

⁵ CMS has developed the Healthcare Common Procedure Coding System (HCPCS) to establish "uniform national definitions of services, codes to represent services, and payment modifiers to the codes." 42 C.F.R. § 414.40(a).

On January 26, 2010, and again on March 25, 2010, the ALJ's office notified the QIC of the binding nature of the ALJ remand order. Exhs. MAC-39 and MAC-40. On April 9, 2010, the appellant requested that the case be escalated from the QIC to the ALJ. Exh. ALJ-10. On April 16, 2010, the QIC issued an amended unfavorable decision, in part finding that CMS had complied with its obligations under 42 C.F.R. § 410.32(d). Exh. ALJ-11, at 3. On April 28, 2010, the appellant filed its second request for ALJ hearing and motion for a decision in appellant's favor. Exh. ALJ-12.

On September 28, 2010, the ALJ conducted a telephone hearing, at which counsel for the appellant appeared and the ALJ heard testimony from appellant President Kyle Stephens, Nursing Supervisor Teresa Hoosier, and expert witness Dr. Anthony Bleyer. Dec. at 1. The Council has audited the recording of that hearing. On October 29, 2010, the ALJ issued a fully favorable decision.

In pertinent part, the ALJ stated that Mr. Stephens testified that the appellant "receives a standing order indicating the tests needed" and ICD-9-CM diagnosis codes, and that lab test results "are provided to the physician electronically or on paper." Dec. at 6. The ALJ next stated that "[t]he physician then uses the results to treat his patient." *Id.* Regarding medical necessity, the ALJ noted counsel's contention that "the physician's order and the supplied physician attestations are sufficient." *Id.* The ALJ then found that Medicare's requirements for medical necessity had been met. *Id.*

The ALJ also found that the appellant was "not subject to the treating physician rule," which, according to the ALJ, requires that laboratory tests be ordered by the physician who is treating the beneficiary and using the results of these tests in treatment. Dec. at 6. The ALJ determined that "[i]t would be unreasonable, burdensome, and contrary to the doctor/patient relationship for a laboratory with no connection to the physician or patient outside of providing an ordered test to determine medical necessity." *Id.* The ALJ also stated that it was "unreasonable and overly burdensome for Meridian to be required to follow-up with the ordering physician for the purposes of identifying how the results of the test were used, as the lab is never in a position to know how the physician proceeds with treatments after the test results are provided." *Id.* The ALJ concluded that, "[i]n the instant matter, medical necessity is found when the physician supplies an order with the

appropriate ICD9 code." *Id.* at 7. The ALJ cited the testimony of Dr. Bleyer and Ms. Hoosier that such a process constituted "the standard of the medical community" and that medical necessity was further supported by physician attestations. *Id.*

The ALJ next found that the QIC erred in denying coverage by relying on a Federal Register discussion about glucose testing in a skilled nursing facility (SNF). Dec. at 7, *citing* 71 Fed. Reg. 69705. The ALJ further found that the Federal Register authority "is inapposite with regards to the requirements of 42 C.F.R. 410.32(a)." *Id.* After quoting the regulation, the ALJ found that "[t]here is no requirement in 42 C.F.R. 410.32(a) which calls for the Appellant to acquire the longitudinal medical history of the beneficiary and decide whether the testing is necessary, and then obtain the information as to how the test results are used by the physician in his treatment of the patient." *Id.* The ALJ found that the appellant had complied with 42 C.F.R. § 410.32(a) requirements. *Id.*

The ALJ concluded that the claims for diagnostic laboratory services provided on the dates of service "are payable," except denials for "double billing and composite rate." Dec. at 8, *citing* section 1862(a)(1)(A) of the Act; 42 C.F.R. § 411.15. The ALJ found the appellant responsible for overpayments received for double billing and composite rate claims. *Id.*, *citing* section 1870 of the Act.

Agency Referral

On referral, CMS argues that the "42 CFR 410.32 expressly place[s] the burden and the liability on the diagnostic laboratory to support that the services are reasonable and necessary and otherwise meet coverage requirements," consistent with the obligations of all entities that bill Medicare. Exh. MAC-1, at 2, *citing* 42 C.F.R. § 410.32; section 1833(e) of the Act. CMS states that the PSC first contacted the treating physicians to obtain medical records and maintains that "[t]he ALJ erred in finding that the Appellant is not responsible for furnishing documentation that supports that services it billed were reasonable and necessary and otherwise met coverage requirements." *Id.* at 3.

CMS also argues that "the ALJ erred in finding that standing orders for high volume, repeat testing furnished to dialysis patients by a clinical laboratory" satisfy the requirements of 42 § C.F.R. 410.32(a). Exh. MAC-1, at 3. CMS explains that

"[m]ost routinely furnished ESRD-related testing is payable to the dialysis facility under the facility's composite rate." *Id.* CMS argues that, excepting serum aluminum and serum ferritin tests furnished every three months, non-composite rate laboratory tests must meet the requirements of 42 C.F.R. § 410.32(a), "which require that clinical laboratory services be ordered and used promptly by the physician who is treating the beneficiary." *Id.*, citing Medicare Benefit Policy Manual (MBPM)(Pub. 100-02) Ch. 15, § 80.1.⁶ CMS also maintains that "standing orders are not usually acceptable documentation for covered laboratory services." *Id.*

CMS concludes that "the treating physician sends standing orders to the dialysis clinic, the clinic forwards the orders to the laboratory, and the laboratory then reports the results to the dialysis clinic." Exh. MAC-1, at 3. CMS states that "[t]ests not reported promptly to the physician and tests not ordered by the treating physician to treat a specific medical problem do not meet the requirements of covered diagnostic tests." *Id.*

Appellant Exceptions I

On January 19, 2011, the appellant submitted exceptions to the referral, without having reviewed the administrative record, and requested oral argument. Exh. MAC-3, at 1 n.1, 2 n.2. The Council denies the appellant's request for oral argument, as the case does not "raise[] an important question of law, policy or fact that cannot be readily decided based on written submissions alone." 42 C.F.R. § 405.1124(a). There is no right to a hearing before the Council. 42 C.F.R. § 405.1108(a).

The appellant begins by stating that the QIC and CMS have "confused the issues in this case, imposed incorrect legal standards, ignored the mandates of the Administrative Law Judge (ALJ), and repeatedly shifted its arguments and its concerns." Exh. MAC-3, at 1-2. The appellant argues, instead, that "the ALJ applied the correct legal standard in this case [and] Meridian urges the [Council] not to accept this referral." *Id.* at 2. The appellant does not contest overpayments for composite rate tests, but states that "[m]any of the tests at issue here . . . are not composite rate tests." Exh. MAC-1, at 2 n.3.

Generally, the appellant asserts that the CMS referral analysis "would require the laboratory to obtain documentation from the

⁶ Manuals issued by CMS can be found at <http://www.cms.hhs.gov/manuals>.

physician that shows how he or she used the test results in his or her management of the patient." Exh. MAC-3, at 6. The appellant also argues that CMS wrongly contends that the ALJ erred in placing the burden of obtaining documentation of medical necessity on the QIC, which, the appellant maintains, is now an irrelevant issue in any event, given the ALJ's evidentiary hearing. *Id.* The appellant again argues that the QIC erred in raising the issue of medical necessity for the first time upon reconsideration (*id.* at 8) and that CMS erroneously analyzes the case under the "treating physician regulation in 42 C.F.R. § 410.32." *Id.* at 8-9. The appellant asserts that laboratories would have difficulty obtaining medical records from treating physicians. *Id.* at 10.

The appellant also argues that medical necessity is not determined based upon a physician's use of laboratory test results, but "at the time that the physician orders them, based on the patient's diagnosis, prognosis, and other clinical information." Exh. MAC-3, at 10. In support, the appellant quotes Compliance Program Guidance for Clinical Laboratories issued by the Office of Inspector General (OIG) for the Department of Health and Human Services (HHS). *Id.* at 11. The appellant also maintains that language in negotiated rulemaking commentary also supports that medical necessity determinations are made by the physician at the time the test is ordered, "not based on how the physician later uses the results of the test." *Id.* at 11, *citing* "Negotiated Rulemaking: Coverage and Administrative Policies for Clinical Diagnostic Laboratory Services," 66 Fed. Reg. 58788, 58791 (Nov. 23, 2001). The appellant also points to statutory support for its assertion that "when physicians are required to furnish laboratories or other entities with evidence of medical necessity, such as diagnosis codes, that information must be furnished at the time the test is ordered." *Id.* at 12, *quoting* Section 1842(p)(4) of the Act. The appellant summarizes that "the law does not require proof of how the physician used the test results. It requires the physician to provide evidence of medical necessity *when he or she orders the test.*" *Id.* (emphasis in original).

The appellant next argues that CMS errs in arguing that standing orders cannot provide the basis for "repeated and frequent testing" of ESRD patients, in that "it never even considered this issue when evidence regarding standing orders was presented in the QIC proceedings." Exh. MAC-3, at 13. The appellant asserts that it is, essentially, unfair for CMS to raise the issue of standing orders for the first time upon referral,

"given the QIC's failure to consider the issue when it had the opportunity or to raise it before the ALJ." *Id.* The appellant then cites to "appellate guidelines" issued by the Departmental Appeals Board concerning issues not previously raised before the ALJ. *Id.* at 13-14. The appellant states that "standing orders are routinely used for dialysis patients precisely because they require a large amount of repeat testing, due to their chronic condition." *Id.* at 14. The appellant also points out that "CMS and the OIG have recognized the validity and appropriateness of standing orders for laboratory tests," in that "the OIG did not outlaw the use of standing orders" in Compliance Guidance for Clinical Laboratories, while CMS has recognized that an Advance Beneficiary Notice (ABN) can be used to shift liability for non-covered charges over the course of prolonged treatment and services. *Id.* at 14-15, quoting CMS Program Memorandum, CMS Pub. 60AB, Transmittal No. AB-02-114 (July 31, 2002), at 12. The appellant also argues that blood glucose monitoring cases for beneficiaries in SNFs do not apply, as "nursing homes were billing for patients who did *self-testing* to monitor their glucose" *Id.* at 15, citing HCFA Program Memorandum, HCFA Pub. 60AB Transmittal No. AB-00-108 (Dec. 1, 2000)(emphasis in original). The appellant maintains that "Meridian supplied the test results" to the physician and no question can be legitimately raised "about whether the results were actually sent to the physicians" *Id.* at 16.

The appellant finally asserts that CMS errs in arguing that the ALJ could not rely on physician attestations of test orders, because, the appellant reasons, CMS cannot ask the Council to weigh evidence as a basis for referral when CMS did not participate in the ALJ hearing. Exh. MAC-3, at 17. The appellant further asserts that CMS cannot object to the absence of statements in physician attestations about the use of the test results, as such an objection involves a question of fact, not an issue of law. *Id.* The appellant cites to decisions by ALJs and the Departmental Appeals Board that permit "after the fact" submission of statements to cure gaps in the evidentiary record. *Id.* n.54 (citations omitted). The appellant maintains that "when the physician states he or she intended to order the tests, it seems implied that he or she believed they were medically necessary for the patient." *Id.* at 18 n.55.

Appellant Exceptions II

The Council forwarded the administrative record to the appellant on March 18, 2011, and granted twenty days for submission of

additional argument. Exh. MAC-4. On April 5, the appellant submitted supplementary argument, stating that "Meridian is taking this opportunity to comment on several aspects of the evidence that were not available when we filed our initial exceptions." Exh. MAC-5, at 1. The appellant again asserts that CMS cannot argue that the ALJ improperly remanded the case to the QIC for additional development, as the ALJ subsequently held an evidentiary hearing. *Id.* at 1-2. The appellant also argues, again, that Medicare cannot require clinical laboratories "to go back to physicians, after the laboratory had performed the requested testing and issued the results, and determine what use the physician had made of the particular test results." *Id.* at 2. The appellant declares that "there really is no question about the fact that the physicians used the test results in their treatment of these [ESRD] patients" *Id.* The appellant repeats its prior argument that the issue of standing orders for laboratory tests cannot be raised at this point and that, even if it could, the ALJ received expert testimony from Dr. Bleyer that standing orders serve multiple functions and "are commonly used in dialysis facilities throughout the country." *Id.* at 3.

APPLICABLE LEGAL STANDARDS

Medical Necessity of Diagnostic Laboratory Tests

Part B of the Medicare program includes benefits 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 1832(a)(2)(B) of the Act. "Medical and other health services" include "diagnostic laboratory tests" Section 1861(s)(3) of the Act.

The Secretary implemented these statutory provisions through regulations in 42 C.F.R. part 410. In pertinent part, the regulations provide:

(a) *Ordering diagnostic tests.* All diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests must be ordered by the physician who is treating the beneficiary, that is, the physician who furnishes a consultation or treats a beneficiary for a specific medical problem and who uses the results in the management of the beneficiary's specific medical problem. Tests not ordered by the physician who is treating the beneficiary are not

reasonable and necessary (see § 411.15(k)(1) of this chapter).

* * * * *

(d) *Diagnostic laboratory tests* -

(1) *Who may furnish services.* Medicare Part B pays for covered diagnostic laboratory tests that are furnished by any of the following: . . . (v) A laboratory, if it meets the applicable requirements for laboratories of part 493 of this chapter

(2) *Documentation and recordkeeping requirements* -

(i) *Ordering the service.* The physician (or qualified nonphysician practitioner, as defined in paragraph (a)(3) of this section), who orders the service must maintain documentation of medical necessity in the beneficiary's medical record.

(ii) *Submitting the claim.* The entity submitting the claim must maintain the following documentation:

(A) The documentation that it receives from the ordering physician or nonphysician practitioner.

(B) The documentation that the information that it submitted with the claim accurately reflects the information it received from the ordering physician or nonphysician practitioner.

(iii) *Requesting additional information.* The entity submitting the claim may request additional diagnostic and other medical information to document that the services it bills are reasonable and necessary. If the entity requests additional documentation, it must request material relevant to the medical necessity of the specific test(s), taking into consideration current rules and regulations on patient confidentiality.

(3) *Claims review.*

(i) *Documentation requirements.* Upon request by CMS, the entity submitting the claim must provide the following information:

(A) Documentation of the order for the service billed (including information sufficient to enable CMS to identify and contact the ordering physician or nonphysician practitioner).

(B) Documentation showing accurate processing of the order and submission of the claim.

(C) Diagnostic or other medical information supplied to the laboratory by the ordering physician or nonphysician practitioner, including any ICD-9-CM code or narrative description supplied.

(ii) *Services that are not reasonable and necessary.* If the documentation provided under paragraph (d)(3)(i) of this section does not demonstrate that the service is reasonable and necessary, CMS takes the following actions:

(A) Provides the ordering physician or nonphysician practitioner information sufficient to identify the claim being reviewed.

(B) Requests from the ordering physician or nonphysician practitioner those parts of a beneficiary's medical record that are relevant to the specific claim(s) being reviewed.

(C) If the ordering physician or non-physician practitioner does not supply the documentation requested, informs the entity submitting the claim(s) that the documentation has not been supplied and denies the claim.

(iii) *Medical necessity.* The entity submitting the claim may request additional diagnostic and other medical information from the ordering physician or nonphysician practitioner to document that the services it bills are reasonable and necessary. If the entity requests additional documentation, it must request material relevant to the medical necessity of the specific test(s), taking into consideration current rules and regulations on patient confidentiality.

42 C.F.R. § 410.32. CMS has stated that "[c]linical laboratory services must be ordered and used *promptly* by the physician who is treating the beneficiary" MBPM Ch. 15, § 80.1 (emphasis supplied).

Section 1862(a)(1)(A) of the Act provides that Medicare does not pay for items or services that "are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member" *Id.* CMS issues national coverage determinations (NCDs) as determinations by the Secretary on whether an item or service is covered by Medicare on a national basis. 42 C.F.R.

§ 405.1060(a)(1). "NCDs are made under section 1862(a)(1) of the Act as well as under other applicable provisions of the Act" and are "binding on [Medicare contractors], QICs, ALJs, and the [Council]." 42 C.F.R. §§ 405.1060(a)(3),(4). CMS has issued an NCD concerning laboratory tests for beneficiaries on dialysis treatment, which states as follows:

Laboratory tests are essential to monitor the progress of CRD [chronic renal disease] patients. The following list and frequencies of tests constitute the level and types of routine laboratory tests that are covered. Bills for other types of tests are considered nonroutine. Routine tests at greater frequencies must include medical justification. Nonroutine tests generally are justified by the diagnosis. The routinely covered regimen includes the following tests:

Per Dialysis

- All hematocrit or hemoglobin and clotting time tests furnished incident to dialysis treatments.

Per Week

- Prothrombin time for patients on anticoagulant therapy, and
- Serum Creatinine

Per Week or Thirteen Per Quarter

- BUN

Monthly

- CBC,
- Serum Calcium,
- Serum Chloride,
- Serum Potassium,
- Serum Bicarbonate,
- Serum Phosphorous,
- Total Protein,
- Serum Albumin,
- Alkaline Phosphatase,
- AST,
- SGOT, and
- LDH.

Guidelines for tests other than those routinely performed include:

- Serum Aluminum - one every 3 months, and

- Serum Ferritin - one every 3 months

[Discussion of Hepatitis B vaccination]

Laboratory tests are subject to the normal coverage requirements. If the laboratory services are performed by a free-standing facility, the facility must meet the conditions of coverage for independent laboratories.

National Coverage Determination Manual (NCDM) Ch. 1, § 190.10 (emphasis supplied). The above listed tests are routinely covered by Medicare and payable under the composite rate for outpatient maintenance dialysis (prospective payment system or PPS), while two tests are separately payable based upon the diagnosis of end stage renal disease, without additional documentation. MBPM Ch. 11, § 30.2.

All items or services billed to the Medicare program must meet the coverage requirements of section 1862(a)(1) of the Act in order for payment to be made. Section 1833(e) of the Act also prohibits payment "to any provider of services or other person under this part unless there has been furnished such information as may be necessary in order to determine the amounts due." *Id.* Regulations make clear that the beneficiary, provider, or supplier must furnish sufficient information to enable the contractor to determine whether payment is due and the amount of payment. 42 C.F.R. § 424.5(a)(6).

The Council notes that, in the context of durable medical equipment (DME), federal courts have recognized that the Secretary may require medical documentation, in addition to certificates of medical necessity (CMNs), to support medical reasonableness and necessity. See *Maximum Comfort v. Secretary of Health & Human Services*, 512 F.3d 1081 (9th Cir. 2007), *petition for cert. denied*, 129 S.Ct. 115 (U.S. Oct. 6, 2008) (No. 07-1507); accord *MacKenzie Medical Supply, Inc. v. Leavitt*, 506 F.3d 341 (4th Cir. 2007); *Gulfcoast Medical Supply, Inc. v. Secretary, HHS*, 468 F.3d 1347 (11th Cir. 2006). Moreover, the Medicare Program Integrity Manual (MPIM) provides that "neither a physician's order . . . nor a supplier prepared statement nor a physician attestation by itself provides sufficient documentation of medical necessity, even though it is signed by the treating physician or supplier. There must be information in the patient's medical record that supports the medical necessity

for the item and substantiates the answers on the . . . supplier prepared statement or physician attestation (if applicable)." MPIM (Pub. 100-08) Ch. 5, § 5.2.

In negotiated rulemaking of the final rule for clinical laboratory services, CMS explicitly declined to exempt clinical laboratories from documentation of medical necessity requirements, in relevant part, as follows:

Documentation and Recordkeeping Requirements

Comment: Three commenters expressed concern about the process by which diagnostic information supporting medical necessity is to be collected from the ordering physician. Another commenter further suggested that our guidelines state the baseline effort required for obtaining documentation by the entity submitting the claim. The commenter suggested that claims should be denied only if the required effort for obtaining the documentation has been met.

Response: We acknowledge the burden that accompanies the task of collecting diagnostic information to support medical necessity. However, the Act requires that Medicare only pay for services that are reasonable and necessary. Medicare cannot pay for services that do not meet this standard simply because the laboratory has expended a specified amount of effort to obtain documentation. We have, however, identified a process for requesting documentation that we believe reduces the burden on the laboratories for collecting and submitting information to us.

[Discussion of final rule].

Comment: Twenty-six commenters expressed concern that the [proposed rule] makes it possible for laboratories to be held liable for claims denial due to the lack of information supporting medical necessity. That is, the commenters were concerned that the laboratories would be the entity experiencing the loss if the physician does not submit the information supporting medical necessity. The commenters believe that the [proposed rule] will result in unfairness and financial hardships for the laboratory industry. Several commenters suggested

that in the final rule, laboratories should not be financially responsible in this situation. . . .

Response: The commenters do not seem to recognize that the [proposed rule] does not change the current provisions for liability on claims due to lack of information supporting medical necessity. Section 1862(a)(1)(A) of the Act provides that, notwithstanding any other provision of the Act, payment may not be made for services that are not reasonable and necessary for the diagnosis or treatment of illness or injury. Presently, all entities that bill the Medicare program are held liable when they bill for services and are not able to produce documentation of the medical necessity of the service. Although the Committee discussed at length the special circumstances related to laboratories, which frequently do not have direct contact with the patient, the Committee recognized that *the law does not provide the authority to exempt laboratories from the provision related to medical necessity.*

In addition, we do not agree that the provision related to denial of claims for laboratory services when documentation is not provided is unfair. Rather, we believe it would be unfair to exempt laboratories from this provision while continuing to require it for other providers and suppliers. For example, durable medical equipment (DME) suppliers frequently do not have direct contact with beneficiaries but are dependent upon physician documentation of medical need in order to receive payment.

Final Rule, "Medicare Program; Negotiated Rulemaking: Coverage and Administrative Policies for Clinical Diagnostic Laboratory Services," 66 Fed. Reg. 58788, 58800-01 (Nov. 23, 2001)(emphasis supplied).

A beneficiary or provider/supplier may be held liable for Medicare claims denied coverage as not "reasonable and necessary," under section 1862(a)(1)(A) of the Act, based upon prior knowledge of non-coverage that includes constructive knowledge derived from Medicare issuances. Section 1879 of the Act; 42 C.F.R. §§ 411.404, 411.406. A beneficiary or provider/supplier may also be found to be not "without fault" in creating an overpayment and therefore not entitled to waiver of the overpayment amount. Section 1870 of the Act; Medicare Financial Management Manual (MFMM)(Pub. 100-06) Ch. 3, § 90. A

provider may be found to be "without fault, if it exercised reasonable care in billing for, and accepting, the payment; i.e., it made full disclosure of all material facts; **and** on the basis of the 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" MFMM Ch. 3, § 90.

Medicare Appeals

Medicare appeals regulations provide five stages of claim adjudication before federal court rights: initial determination, redetermination, reconsideration, ALJ hearing, and Council review. 42 C.F.R. § 405.904(a)(2). In relevant part, "[a] reconsideration consists of an independent, on-the-record review of an initial determination, including the redetermination *and all issues related to payment of the claim.*" 42 C.F.R. § 405.968(a)(emphasis supplied). Similarly, "[t]he issues before the ALJ include *all* the issues brought out in the initial determination, redetermination, or reconsideration that were not decided entirely in a party's favor." 42 C.F.R. §§ 405.1032(a); see also Notices, "Organization, functions, and authority delegations: Medicare Hearings and Appeals Office," 70 Fed. Reg. 36386, 36387 (June 23, 2005)("Administrative Law Judges (ALJs) . . . conduct impartial 'de novo' hearings") The Council, as well, "undertakes a de novo review" of the ALJ decision. 42 C.F.R. § 405.1100(c). Federal courts have also recognized that "lower-level decisions rendered by contractors and ALJs are non-precedential," that decisions within the Medicare appeals process may conflict with the decisions of lower adjudicators, and that "indeed, the Medicare appeals process was specifically designed to allow for this result." *Almy v. Sebelius*, Civil Action No. RDB-08-1245, at 13 (D.Md. September 3, 2010).

DISCUSSION

Medical Necessity Challenges

The Council finds that the ALJ erred in concluding that the medical necessity of the diagnostic laboratory test claims was established based upon physician orders, appellant order forms, and physician attestations. Medical necessity of items and services billed to Medicare must be supported by independent clinical documentation in the record, which the laboratory must provide on request by the Medicare contractor. 42 C.F.R.

§ 410.32(d). The ALJ erred in finding coverage solely because the "physician who is treating the beneficiary" ordered the test and used the results in management of the beneficiaries' treatment. Dec. at 7, *citing* 42 C.F.R. § 410.32(a).

As a threshold issue, CMS has issued a national coverage determination which specifies the "[l]aboratory tests [that] are essential to monitor the progress of CRD [chronic renal disease] patients" and at what frequency. NCD 190.10. These "routine" tests are included in the ESRD composite billing rate and "[u]nder the composite rate, a dialysis facility must furnish all of the necessary dialysis services, equipment, and supplies." MBPM, Ch. 11, § 30. Consistent with this statement, CMS explains that "[m]ost items and services related to the treatment of the patient's end-stage renal disease are covered under the composite rate payment." *Id.* "The composite rate is payment for the complete dialysis treatment except for physicians' professional services, separately billable laboratory services, and separately billable drugs." *Id.*

In short, payment to an ESRD facility under the composite rate assumes that the ESRD facility will provide all items and services typically associated with treatment of an ESRD patient. The NCD establishes those laboratory tests that CMS has determined are routinely provided to ESRD patients. These represent the tests which CMS considers to be usual, repetitive, or routine for ESRD patient, given that the composite billing rate is intended to include all usual services required for dialysis treatment. Other laboratory tests not listed within the NCD would not be considered routinely associated with the needs of a dialysis patient. Such "non-routine" tests would therefore have to meet requirements for individual physician's orders. 42 C.F.R. § 410.32(a); MBPM Ch. 11, § 30.2.1.

The physician treating the beneficiary for a specific medical problem must both order the laboratory tests and use the test results to manage the beneficiary's medical problem. 42 C.F.R. § 410.32(a); MBPM Ch. 15, § 80.1. This is a regulatory requirement, not a mere guideline or recommendation. Contrary to the ALJ's discussion suggesting otherwise, the regulation and administrative authority would not require that the appellant provide "the longitudinal medical history of the beneficiary and . . . information as to how the test results are used by the physician in his treatment of the patient" in order to support the medical necessity of the tests ordered. Dec. at 7. There are, however, indices of more general reliability with individ-

ually ordered tests that do not apply to standing orders similar to those found in the record.⁷ When a specific laboratory test is individually ordered by a physician, the fact of such order highly suggests that the physician seeks the information for the future care or management of the patient's condition. Moreover, such individualized order suggests that the physician is anticipating the timely receipt of the results for use in immediate reliance or decisionmaking. However, standing orders do not show such immediate physician involvement in the testing request or, by extension, in reliance upon those results.

With respect to physician use of the test results in this case, the Council notes, moreover, that the results of the tests performed by the appellant laboratory were not, in fact, furnished directly to the ordering physicians, but rather were sent to the dialysis facility. Audit; see Exh. MAC-19, at 2-3 (Routine tests results are "loaded into the [dialysis facility's] computer system and are reviewed by the physician and signed off on each month as part of the patient care plan.") Test results are thus posted on-line and the ordering physician can view them (or not) as desired. *Id.* This process does not assume the same level or degree of involvement by a physician that occurs when a specific test is ordered and performed and the test result is delivered directly to the ordering physician.

The contractor's findings which formed the basis for this overpayment action also suggest that the standing orders in the record do not represent the standard of care for ESRD testing or that the ordered tests are reasonable and necessary. On December 15, 2006, and again on January 16, 2007, the PSC requested additional documentation from the appellant to support coverage of the tests billed. Exhs. MAC-6 and MAC-7. In October 2007, the PSC wrote thirty-four ordering physicians to obtain supporting documentation. Exh. MAC-8. On September 29, 2008, the PSC notified the appellant of the results of its review, consisting of an extrapolated overpayment for non-covered services. Exh. MAC-10. The PSC stated that it began

⁷ The Council need not and does not decide whether standing orders, alone, are sufficient to establish medical necessity of laboratory tests as a general rule. The Council's analysis in this referral focuses primarily upon the documentation supplied by the appellant to support the medical necessity of those tests, consistent with the requirements of 42 C.F.R. § 410.32. The Council notes, however, that the appellant's own standing order forms, signed by ordering physicians, state variations of the principle that "[t]he medical necessity for tests ordered *must be noted in the patient's permanent medical record.*" Beneficiary V.A Exh. 2, at 1 (emphasis supplied).

its investigation into the appellant's billings, since it "ranked first in number of aberrancies" (overutilization) in comparison with its peers. *Id.* at 1. The fact that the appellant was an "outlier" in relation to its peers in billing frequency of the tests at issue indicates that other clinical laboratories and physicians were not ordering or billing these types of non-routine tests at the rate and frequency in which the appellant's standing orders resulted here. In extrapolating the overpayment, the PSC review also noted a payment error rate of 95.14%, confirming a "high level of payment error." Exh. MAC-9, at 1; section 1893(f)(3) of the Act.⁸

Regulations make clear that the laboratory itself must provide any additional and relevant documentation requested by the Medicare program to support the medical necessity of the claims that it submitted. 42 C.F.R. § 410.32(d)(3)(i)(C). When documentation submitted does not meet that requirement, CMS contacts the "ordering physician . . . [for] those parts of a beneficiary's medical records that are relevant to the specific claim(s) being reviewed." 42 C.F.R. § 410.32(d)(3)(ii)(B). If the ordering physician does not supply the requested information, CMS "informs the entity submitting the claim(s) that the documentation has not been supplied and denies the claim." 42 C.F.R. § 410.32(d)(3)(ii)(C). Regarding medical necessity, "[t]he entity submitting the claim may request additional diagnostic and other medical information from the ordering physician or nonphysician practitioner to document that the services it bills are reasonable and necessary." 42 C.F.R. § 410.32(d)(3)(iii).⁹

Thus, both statutes and regulations require suppliers to provide, when requested, documentation supporting that services billed meet the requirement of being "reasonable and necessary" for patient diagnosis or treatment. Sections 1833(e) and 1862(a)(1)(A) of the Act; 42 C.F.R. § 410.32(d); *Maximum Comfort v. Secretary of Health & Human Services*, *supra*. In commentary

⁸ "Determinations by the Secretary of sustained or high levels of payment errors in accordance with section 1893(f)(3)(A) of the Act" are not appealable under Medicare regulations and are therefore not reviewable by Medicare contractors, QICs, ALJs or the Council. 42 C.F.R. § 405.926(p). The PSC made a determination of a high level of payment error in its review. Exh. MAC-9, at 1. Appellant's arguments that the PSC extrapolation may be invalid, based on a potentially lower payment error rate, are unavailing.

⁹ The Compliance Program Guidance for Clinical Laboratories issued by the HHS Office of Inspector General (OIG) cited by the appellant arises under different aspects of the Medicare program and establishes no legal standards for coverage evaluation. *See, e.g.*, Exh. MAC-3, at 15 n.46.

to the final rule, CMS considered and rejected the ALJ's conclusion that it would be "unreasonable, burdensome, and contrary to the doctor/patient relationship for a laboratory with no connection to the physician or patient outside of providing an ordered test to determine medical necessity." Dec. at 6. Contrary to the ALJ's finding, the Medicare program provides that a clinical laboratory that bills Medicare for outpatient laboratory services for ESRD patients, including tests that are not included in the composite rate, "may request additional diagnostic and other medical information from the ordering physician or nonphysician practitioner to document that the services it bills are reasonable and necessary." 42 C.F.R. § 410.32(d)(3)(iii). More directly, CMS stated: "Although the Committee discussed at length the special circumstances related to laboratories, which frequently do not have direct contact with the patient, the Committee recognized that the law does not provide the authority to exempt laboratories from the provision related to medical necessity." 66 Fed. Reg. at 58801. The ALJ therefore erred in finding that a physician order with a diagnostic code, physician attestation, and test results suffice as documentation that tests are "reasonable and necessary" under section 1862(a)(1)(A) of the Act. Dec. at 7.

The Council has also reviewed the physician and employee declarations upon which the ALJ relied. Exh. ALJ-17. The general format of the declarations is that a treating nephrologist declares that he or she has reviewed medical records of the patients, "intended" to order the laboratory tests, and believed those tests to be necessary on a monthly basis. See, e.g., *Id.* Tab 1, at 1-2 (Bleyer Declaration); *id.* Tab 2, at 1-2 (Burkart Declaration). While the Council accepts the physician's declarations as stated, a physician's belief that diagnostic laboratory tests are necessary on a monthly basis is insufficient, standing alone, to establish medical necessity under section 1862(a)(1)(A) of the Act.

The appellant also repeatedly refers to 42 C.F.R. § 410.32(a) as the "treating physician" rule which establishes medical necessity based on a treating physician's order and use of results, and the ALJ considered that principle in finding the services covered by Medicare. Dec. at 6 ("Meridian is not subject to the treating physician rule . . ."). First, as discussed above, the laboratory's obligations to provide supporting documentation to establish medical necessity are founded in 42 C.F.R. § 410.32(d), not 42 C.F.R. § 410.32(a). Second, the appellant's repeated references to the "treating

physician rule" appear to suggest that adjudicators apply the "treating physician rule" historically associated with disability determinations by the Social Security Administration.

However, CMS has expressly rejected application of that principle in CMS Ruling 93-1, which is binding on the Council, ALJs, and all administrative adjudicators. 42 C.F.R. § 405.1063. CMS issued Ruling 93-1 in response to litigation concerning coverage of Medicare Part A services, and the Ruling provides that no presumptive weight should be assigned to a treating physician's medical opinion in determining the medical necessity of inpatient hospital or skilled nursing facility services. Moreover, the Ruling adds parenthetically that the Ruling does not "by omission or implication" endorse the application of the treating physician rule to services not addressed in the Ruling. In addition, the regulations at 20 C.F.R. part 404, subpart P and part 416, subpart I, which govern disability determinations made by the Social Security Administration under titles II and XVIII of the Act, do not apply to determinations of medical necessity under title XVIII of the Act. Finally, and more recently, at least one federal court has expressly declined to extend this Social Security disability principle to Medicare Part B cases. In *Arruejo v. Thompson*, 2001 WL 1563699 (E.D.N.Y. 2001), the court observed:

The treating physician rule has never been extended to apply in Medicare cases. Prior to the codification of the rule, the Second Circuit had several opportunities to consider its applicability to Medicare cases, but has never read the rule so expansively

Arruejo at 13. The Council therefore rejects the ALJ's findings that a treating physician's order and use of test results, with supporting physician declaration, establish medical necessity of the diagnostic laboratory tests billed by, and payable to, the appellant clinical laboratory. The Council finds that the documentation in the record does not establish that the services are reasonable and necessary and the services are, therefore, not covered by Medicare.

Procedural Challenges

The appellant also argues that the QIC erred in raising the issue of medical necessity for the first time upon reconsideration. See, e.g., Exh. MAC-3, at 3. Medicare appeals regulations authorize adjudicators to conduct a full review of

all evidentiary and legal issues raised in an appeal, as a function of *de novo* review or a function of the review of any issue related to payment. 42 C.F.R. §§ 405.968(a), 405.1032(a), 405.1000(d), 405.1100(c); 70 Fed. Reg. at 36387; *Almy v. Sebelius*, *supra* at 13. The Notice of Hearing issued by the ALJ states the issues for resolution as whether "all" Medicare coverage requirements are met and the issues raised in the redetermination and reconsideration. Exh. ALJ-15, at 2. An adjudicator may always determine whether an item or service is "reasonable and necessary" in a coverage analysis.

Departmental Appeals Board guidelines cited by the appellant concern provider exclusions and civil money penalties for skilled nursing facility non-compliance with program requirements, which arise under different provisions of the Medicare program, are adjudicated by a different division of the Departmental Appeals Board, do not apply to Council review of Medicare Part B claims, and are not relevant to this appeal. See, e.g., Exh. MAC-3, at 13-14. Given the Council's findings that the laboratory services are not covered by Medicare, the Council need not and does not address arguments concerning the propriety of the ALJ remand to the QIC. See, e.g., Exh. MAC-5, at 1-2. The Council concludes that appellant's procedural challenges provide no basis for upholding the ALJ's decision.

CONCLUSION

The appellant has argued throughout this appeal, and the ALJ found, that the standing orders for laboratory tests in this case are sufficient to establish Medicare coverage of those services. The Council finds that, based on the record under review, they are not. The PSC's initial audit determinations found approximately 5% of the sample claims payable. Exh. MAC-9, at 1; Exh. MAC-10, at 1. On redetermination, the contractor determined that still more claims could be paid and issued a partially favorable decision. Exhs. MAC-22; MAC-23, at 4, 5, 11. The QIC issued an unfavorable reconsideration, affirming the redetermination denials. Exh. ALJ-11, at 3. It is clear that the contractor found during review that some beneficiary claims files contained sufficient documentation of Medicare coverage of sampled claims.

As the appellant has not raised any arguments pertaining to individual claims, either before the ALJ or in its exceptions to the Council, the Council does not perform individual claims adjudication in this decision. The Council notes that the

contractor reviewed all documents submitted by the appellant and found coverage for claims for which there were individualized orders and which otherwise met coverage requirements. Similarly, the appellant has raised no arguments concerning the validity of the statistical sample, which the Council therefore affirms. The PSC made a determination of a high payment error rate for purposes of extrapolation, and that determination is not subject to appeal. 42 C.F.R. § 405.926(p), *citing* Section 1893(f)(3)(A) of the Act.

DECISION

It is the decision of the Medicare Appeals Council that the diagnostic laboratory services provided to the beneficiaries are not reasonable and necessary under section 1862(a)(1)(A) of the Act and are not covered by Medicare. The statistical sampling methodology and extrapolation of overpayment are valid. The appellant is liable for the non-covered charges and extrapolated overpayment under sections 1879 and 1870 of the Act. The ALJ decision is reversed.

MEDICARE APPEALS COUNCIL

/s/ Gilde Morrisson
Administrative Appeals Judge

/s/ Constance B. Tobias, Chair
Departmental Appeals Board

Date: June 24, 2011