DEPARTMENT OF HEALTH AND HUMAN SERVICES
DEPARTMENTAL APPEALS BOARD

DECISION OF MEDICARE APPEALS COUNCIL

In the case of	**Claim for**
KGV Easy Leasing Corporation (Appellant)	Supplementary Medical Insurance Benefits (Part B)
**** (Beneficiaries)	**** (HIC Numbers)
National Heritage Insurance Corporation (Contractor)	**** (ALJ Appeal Number)

The Administrative Law Judge (ALJ) issued a decision dated July 16, 2009, which concerned an overpayment determination assessed against the appellant for diagnostic testing services provided to multiple beneficiaries on various dates in 2005 and 2006. The overpayment was based on an extrapolation, following a post-payment audit review, by the California Benefit Integrity Support Center (CBISC), of sixty-six claims for Medicare coverage of diagnostic testing services provided to sixty-five beneficiaries.[1] The ALJ determined that the appellant's documentation did not support Medicare coverage for any of the audited claims and that the appellant was liable for the resulting overpayment. The appellant has asked the Medicare Appeals Council to review this action. The appellant's request for review has been entered into the record as Exhibit (Exh.) MAC-1.

[1] The beneficiaries and their respective dates of service are identified in the Beneficiary List attached to this decision.

The Council reviews the ALJ's decision *de novo*. 42 C.F.R. § 405.1108(a). The Council will limit its review of the ALJ's action to the exceptions raised by the party in the request for review, unless the appellant is an unrepresented beneficiary. 42 C.F.R. § 405.1112(c). As set forth below, the Council modifies the ALJ's decision.

BACKGROUND

The appellant operates an Independent Diagnostic Testing Facility (IDTF). The CBISC conducted a post-payment audit review of sixty-six claims for Medicare coverage of diagnostic testing services, provided by the appellant, to sixty-five beneficiaries, between February 10, 2005, and February 21, 2006. The record does not contain the CBISC letter notifying the appellant of the audit results. The record does, however, contain what appears to be the auditor worksheet which provides a claim-by-claim breakdown of the reason for non-coverage. The worksheet demonstrates that the CBISC denied each claim because of inadequate documentation. ALJ Master File Exh. 3. The appellant has not, at any subsequent level of review, challenged the underlying mechanics of the audit or the extrapolation of the audit results to the universe of claims. Rather, the appellant has focused its argument on the adequacy of the documentation provided in support of those claims.

Following the audit, on June 10, 2008 the Medicare contractor, National Heritage Insurance Company, issued a demand letter notifying the appellant that it had received a Medicare overpayment totaling $953,535.94. The appellant requested a redetermination. In an August 21, 2008, redetermination the Medicare contractor found that "the documentation is insufficient to support the services . . . all previously paid services are considered overpayments." ALJ Master File Exh. 4 at 1-2.[2]

The appellant requested reconsideration by a Qualified Independent Contractor (QIC). The QIC identified the record "contained in the case file" as consisting of the "Redetermination letter" and Reconsideration request." ALJ Master File Exh. 7 at 2. The QIC then denied coverage finding:

[2] Other than the first page, the pages in this exhibit were, apparently, not in chronological order when paginated as an exhibit. For example, Redetermination page 2 is exhibit page 6, while Redetermination page 3 is exhibit page 2. The Council cites to the actual Redetermination pagination.

> Documentation was not submitted to support performance of the services. Medical records . . . such as office notes, progress notes, physician orders, operative notes, diagnostic test results, etc., must indicate the medical necessity for performing the service. There was no indication of symptoms or physical findings that would justify the performance of the services in accordance with Medicare guidelines.

ALJ Master File Exh. 7 at 3.

The appellant's request for hearing before an ALJ, included a thirty-two page Brief, its Exhibits 1-25 and Attachments A-F. *See* ALJ Master File Exh. 10. On March 30, 2009, the ALJ conducted a pre-hearing conference, with the appellant's representative and a consultant employed by the appellant. At this conference, the ALJ addressed the content of the record. The ALJ emphasized the appellant's duty to adequately document its claims as well as the fact that good cause must be shown for any new documentation submitted by a party after the QIC reconsideration. The appellant asserted its position that it had, to the degree possible, documented its claims and questioned whether the Medicare contractor had forwarded the appellant's entire documentary submission to the QIC. *See* Pre-Hearing CD (March 30, 2009).

Following the pre-hearing conference, on May 8, 2009, the appellant submitted to the ALJ a thirty-six page Brief, two Declarations and its Exhibits 1-29.[3] *See* ALJ Master File Exh. 11.

On May 20, 2009, the ALJ conducted an in-person hearing at which both the appellant's representative and its consultant testified. At the outset of the hearing the ALJ identified clinical records in the appellant's May 8th submission (appellant Exhibit 29) as not having been in the record before the QIC. The ALJ's asked the appellant to explain why this documentation had not been submitted to the QIC. The appellant noted that "Nobody requested [them] from us." ALJ Hearing CD (May 20, 2009) at (approx.) minutes 7:30-8:00. With regard to the documentation for forty-one beneficiaries, the appellant

[3] There was a certain degree of duplication in the documentation which the appellant submitted to the ALJ as part of its request for hearing and in its post-conference submission.

indicated that with the passage of time, approximately two years, these physician's offices were out of business and could not be located. The appellant contended that, it "made every single attempt" to obtain the records, noting that it had photographed the last known addresses for the physicians' offices. Hearing CD at (approx.) minutes 8:30-9:30.

The ALJ framed the appellant's position as being "that the diagnostics tests report constituted 'substantial compliance' and the provider [appellant] was excused from compliance [presumably with Medicare documentation requirements] based on . . . 'justifiable reliance' on the doctor's orders." Dec. at 2.

The ALJ summarized the pertinent aspects of the appellant's testimony as being that "clinical notes for 41 of 65 Beneficiaries could not be located and were not available." Dec. at 3. The appellant's supporting documentation associated with these beneficiaries is found in the record at ALJ Master File Exhibit 12.[4] Generally, the beneficiary-specific documentation in this exhibit consists of health insurance claim forms, test order forms, a general report of the tests results referencing graphic read outs, patient/beneficiary identification information and assignments of benefits.

Regarding the remaining twenty-four beneficiaries, the appellant testified that the "only clinical records available" were patient assessment forms. Dec. at 3. The documentation in question for these twenty-four beneficiaries is found in the record at ALJ Master File Exhibit 13.[5] The ALJ noted that the appellant's testimony did not address the content of these forms on an individual beneficiary basis and, in response to the ALJ's inquiry, noted that they had not been "provided to the QIC because they were not requested." Based on this testimony the ALJ directed the appellant to provide, by post-hearing hearing submission a "summary and narrative discussion" showing good cause for the "untimely filing" of the documentation relative to these twenty-four beneficiaries. Dec. at 3.

[4] Appellant Exhibit 28. The Council cites to the ALJ's identification of this exhibit.

[5] Appellant Exhibit 29. The Council cites to the ALJ's identification of this exhibit.

The appellant responded to the ALJ's direction in a brief, dated May 22, 2009. *See* ALJ Master File Exh. 14. There, the appellant explained that it had not submitted the patient assessment forms to the QIC in reliance upon "instructions" in the Medicare contractor's redetermination, which provided - "You need not resubmit documentation that was submitted as part of the redetermination. This documentation will be forwarded to the QIC as part of the case file utilized in the reconsideration process." *See* Dec. at 3; ALJ Master File Exh. 14 at 1 and Exh. 4 at 5.

In the decision, the ALJ discussed statutory and regulatory authority pertaining to Medicare coverage of diagnostic tests. *See* Dec. at 3-7; *see, also,* sections 1861(s)(3), 1833(e), 1835(a)(2)(B), 1861 (a)(1)(A) and (a)(7) of the Social Security Act (Act) and 42 C.F.R. §§ 410.32 and 410.33. The ALJ then denied coverage for the sixty-five claims finding that the record did not contain sufficient documentation to establish that the specific services were medically reasonable and necessary. The ALJ first cited the appellant's concession that clinical records for forty-one beneficiaries could not be located and were not available. The ALJ then addressed the appellant's untimely submission of documentation with regard to the remaining twenty-four beneficiaries. The ALJ concluded that the appellant's explanation, that it had not submitted this documentation to the QIC because the QIC had not requested it, did not establish good cause for the late submission. The ALJ excluded the documentation, but also found that, even if admitted, it did not demonstrate that the related services were medically reasonable and necessary. Dec. at 8-10. Additionally, the ALJ found that the limitation of liability provisions at section 1879 of the Act did not apply to the appellant and that the appellant remained liable for the cost of the non-covered services. Dec. at 10.

In its request for review, the appellant argues that the ALJ's conclusion that the appellant did not "provide sufficient medical documentation to support the medical necessity of the performed tests, is unreasonable, unjustified and is not supported by any evidence." The appellant contends, generally, that the documentation in the record supports Medicare coverage. The appellant asserts that it presented substantial evidence, demonstrating that the tests at issue complied with the "medical necessity requirements" of the Act. The appellant reasserts that ALJ Master File Exhibit 12 (documentation, pertinent to

forty-one beneficiaries) and ALJ Master File Exhibit 13 (the documentation pertinent to twenty-four beneficiaries) "contain all the material relevant to support the medical necessity of the tests performed . . . ." The appellant maintains that the treating physician's statements in ALJ Master File Exhibit 12 demonstrate the required medical necessity of the diagnostic services provided to all the beneficiaries in question. Exh. MAC-1 at 1-5.

Additionally, the appellant asserts that the ALJ erred in excluding evidence, because the ALJ knew that the appellant relied "on the fact that the patients' medical records will be forwarded to the QIC by the individuals who conducted the process of redetermination and [the appellant] had no idea . . . that the documents were never forwarded." Exh. MAC-1 at 5-6.

The appellant also contends that it is entitled to a waiver of liability, under section 1879 of the Act, because it had a "reasonable good faith belief" that the services in issue were medically reasonable and necessary. Exh. MAC-1 at 5.

DISCUSSION

Below, the Council first considers and reverses the ALJ's exclusion of evidence. The Council then examines the substantive merits of the appellant's claims and addresses the appellant's liability for the overpayment and waiver of recoupment of the overpayment.

Excluded Evidence

The regulation at 42 C.F.R. § 405.1018(c) provides that evidence not submitted prior to the issuance of a QIC reconsideration, must be accompanied by an explanation showing good cause why such evidence was not submitted to the QIC.

Having considered the evidence and the appellant's arguments, both written and those presented in the pre-hearing conference and the hearing, the Council finds that the appellant provided good cause for the "untimely" submission of the documentation found in ALJ Master Exhibits 12 and 13 (Appellant Exhibit 29).

As recounted above, throughout the pre-hearing conference and the hearing itself, the ALJ repeatedly emphasized that the appellant bore the burden of documenting its claims for Medicare

coverage. Additionally, the ALJ appeared to place entirely upon the appellant, the responsibility for ensuring that the record before the ALJ was complete. In response, the appellant contended that it had submitted documentation supporting its claims to the Medicare contractor and relied upon the instructions in the redetermination as a basis for presuming the record was physically complete. The appellant maintained that it was not until after receiving the QIC reconsideration that it was aware of a possibility that there was missing documentation. *See* Pre-Hearing CD (March 30, 2009) and ALJ Hearing CD (May 20, 2009).

In conducting a redetermination, a contractor reviews the evidence and findings upon which an initial determination was based, as well as any additional evidence a party submits or the contractor obtains on its own. 42 C.F.R. § 405.948. For purposes of the redetermination at issue, the initial determination was the June 10, 2008, demand letter issued by the Medicare contractor, which, in turn was based upon the audit findings generated by the CBISC. Among other items, a notice of redetermination, affirming an unfavorable initial determination, must provide a statement of any specific missing documentation that must be submitted with a request for reconsideration. 42 C.F.R. § 405.956(b)(6).

As an attachment to its "Good Cause" Brief to the ALJ, the appellant submitted a July 3, 2008, U.S. Postal Service Receipt for certified mail showing delivery to of a 4 pound, 12 ounce package to NHIC, the Medicare contractor. *See* ALJ Master File Exh. 14

Summarizing the facts of the case, the redetermination found, specifically:

> 5. On July 7, 2008, we received your request for a redetermination.
>
> 6. The overpayment demand letter, CAL-BISC final notice and spreadsheet, medical records and medical literature were submitted with your request.

ALJ Master File Exh. 4 at 2.

The substantive basis of the redetermination is that the appellant's claims were not covered by Medicare because "the documentation is insufficient to support the services." *Id.* at 3. The redetermination does not identify missing documentation. As the ALJ noted in the pre-Hearing conference, the Redetermination instructions pertaining to QIC review alert the appellant as to its responsibility to submit any additional evidence to the QIC prior to the Reconsideration decision. *See* Pre-Hearing CD (March 30, 2009) and ALJ Master File Exh. 4 at 12. However, as the appellant has noted before both the ALJ and the Council, those same instructions, specifically provide that the appellant does "not need to resubmit documentation that was submitted as part of the redetermination. This information will be forwarded to the QIC as part of the case file utilized in the reconsideration process." ALJ Master File Exh. 4 at 12.

Upon reconsideration, the QIC reviews the evidence and findings upon which the initial determination, including the redetermination, was based as well as any additional evidence a party submits or the QIC obtains on its own. 42 C.F.R. § 405.968(a)(1). Evidence submitted with a reconsideration request must include "any missing documentation identified in the notice of redetermination, consistent with § 405.956(b)(6)." 42 C.F.R. § 405.966(a)(1).

The transmittal sheet from NHIC to the QIC does not indicate that NHIC forwarded any documentation to the QIC. Exh. 2. The QIC Reconsideration identified the records in the case file as "Redetermination letter" and "Reconsideration request." ALJ Master File Exh. 7 at 2. Denying coverage, the QIC first found that "[d]ocumentation was not submitted to support the performance of services," then concluded that "no documentation was submitted." *Id.* at 3.

Thus, the evidence credibly establishes that the appellant submitted substantial documentation to the contractor, and that the contractor failed to forward that documentation to the QIC. In turn, the QIC did not forward the documentation to the ALJ. The evidence supports a conclusion that the appellant has shown good cause for the (re-)submission of the documents, in ALJ Master File Exhibits 12 and 13 (Appellant's Exhibits 28 and 29) after the QIC reconsideration. The Council reverses the ALJ's exclusion of that documentation. Below, the Council will consider that evidence in assessing the appellant's claims for the beneficiaries.

Appellant's Claims

In its request for review, the appellant argues that the ALJ's conclusion, that the appellant did not "provide sufficient medical documentation to support the medical necessity of the performed tests, is unreasonable, unjustified and is not supported by any evidence." The appellant contends, generally, that the documentation in the record supports Medicare coverage. The appellant asserts that it presented substantial evidence, demonstrating that the tests at issue complied with the "medical necessity requirements" of the Act. The appellant reasserts that the its beneficiary-specific documentation contains "all the material relevant to support the medical necessity of the tests performed . . . ." Exh. MAC-1 at 1-5.

Diagnostic testing may be covered by Medicare pursuant to section 1861(s)(3) of the Act. Section 1862(a)(1)(A) of the Social Security Act bars coverage of items and services that are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. Section 1833(e) of the Act 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." The regulations also make clear that it is the responsibility of the appellant to furnish sufficient information to enable the contractor to determine whether payment is due and the amount of the payment. 42 C.F.R. § 424.5(a)(6). Further, in the context of durable medical equipment, the courts have ruled that the Secretary may require medical documentation, in addition to a physician's order or certification of medical necessity, to support medical reasonableness and necessity for durable medical equipment (DME). *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). Thus, the appellant had the burden to provide sufficient documentation, evidence and testimony that indicates the services provided are covered by Medicare.

More specifically, Medicare regulations at 42 C.F.R. § 410.32 set out the conditions for coverage of diagnostic tests under Part B. The regulations provide, in relevant part: "All . . .

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." 42 C.F.R. § 410.32(a)

The regulation at section 410.32(d)(2) addresses, specifically, the documentation and recordkeeping requirements for diagnostic laboratory tests.

> (i) *Ordering the serv*ice. The physician or (qualified nonphysican 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.

Addressing the claims review process, section 410.32(d)(2) provides:

> (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 nonphysician 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.

Generally, the regulation at 42 C.F.R. § 410.33 sets out the criteria for Medicare coverage of testing by an IDTF such as that operated by the appellant. In pertinent part, the regulation at section 410.33 cross references the requirements in section 42 C.F.R. § 410.32.

A. The Forty-One Beneficiaries

Before the ALJ, the appellant conceded that the documentation for forty-one of the sixty-five beneficiaries at issue, found in ALJ Master File Exhibit 12 (Appellant's Exhibit 28), did not contain clinical records. Specifically, those records "could not be located and were not available." Dec. at 3; *see, also*, Pre-Hearing CD (March 30, 2009) and ALJ Hearing CD (May 20, 2009). The appellant noted that the fourteen physicians associated with these claims had gone out of business. Before the ALJ, the appellant noted that it made every effort to locate these doctors through traditional means of contact, through their local medical associations and even to go so far as to appear at, and photograph, their last known business address. *See* ALJ Master File Exh. 11 at *Declaration of Gregory Davidov (May 8, 2009);* Pre-Hearing CD (March 30, 2009) and ALJ Hearing CD (May 20, 2009).

The Council has examined the documentation in ALJ Master File Exhibit 12. Generally, the documentation for each beneficiary consists of patient identification and Medicare claims forms, assignments of claims, confirmation of the tests having been performed and diagnostic tests results in the form of graphs, charts or readouts sometimes accompanied by a physician's interpretation of the results. This information does not document that the referring physician was the treating physician, that the treating physician used the results in managing the patient, or present a complete clinical picture of the medical conditions that presumptively warranted the testing. Considered either alone or in the context of the appellant's concession as to the inadequacy of this documentation, the Council concludes that this documentation does not demonstrate medical necessity of the claims for Medicare coverage of the diagnostic testing for the forty-one beneficiaries identified in that exhibit.

B. The Twenty-Four Beneficiaries

The ALJ's consideration of the evidence for these beneficiaries, which he excluded (ALJ Decision at 10) was contrary to 42 C.F.R. § 405.1028(c) which provides that if an ALJ determines that good cause does not exist for submission of evidence for the first time at the ALJ level, "the ALJ must exclude the evidence from the proceeding and *not consider it* in reaching a decision." (Emphasis added.)

Having found that the appellant has demonstrated good cause for submission of the documentation in ALJ Master File Exhibit 13, after the QIC reconsideration, the Council now examines this documentation and its impact upon the claims for the twenty-four associated beneficiaries.

With two exceptions, the beneficiary-specific documentation in ALJ Master File Exhibit 13 consists of patient assessments, patient identification and Medicare claims forms, assignments of claims, confirmation of the tests having been performed and diagnostic tests results in the form of graphs, charts or readouts accompanied by a physician's interpretation of the results. The patient assessments are, in most cases, generic forms dated June 20, 2008, well after the dates of service at issue. With the exception of one of the two beneficiaries discussed below, the records are devoid of any contemporaneous pre- or post-test documentation demonstrating the need for the testing services or explaining how the test results impacted the subsequent treatment of the beneficiary.

There were two distinct claims associated with Beneficiary D.H. For date of services, September 23, 2005, the documentation submitted fails as described in the preceding paragraph. There was no documentation for the claim associated with the July 27, 2005, date of service.

The claim file for beneficiary H.S. contains documentation pertaining to post-testing care. The test results for this beneficiary's nerve conduction study performed on September 22, 2005, were classified as "normal." The follow-up/plan of care, dated September 29, 2005, calls for more testing. While this documentation is more than most in the files, it is an otherwise inadequate demonstration of medical necessity for the testing at issue.

Again, this information does not document that the referring physician was the treating physician, that the treating physician used the results in managing the patient, or present a complete clinical picture of the medical conditions that presumptively warranted the testing. The documentation submitted by the appellant for the twenty-four beneficiaries, found at ALJ Master File Exhibit 13, does not demonstrate that the claims in issue were medically reasonable and necessary for purposes of Medicare coverage.

As discussed above, the claim-specific evidence of record does not demonstrate that the diagnostic tests provided were medically reasonable and necessary. A large part of the appellant's remaining evidence consists of general excerpts from medical journals and manuals, billing statements (which while showing that a service was billed to Medicare, do not go to the question of the medical necessity for that service) and general statements by physicians that they ordered a service to treat a particular beneficiary. None of this information contains sufficient information or documentation to demonstrate the need for the services provided. This evidence does not support a determination that the services provided to these beneficiaries were medically reasonable and necessary

LIABILITY

In its request for review the appellant requested a waiver of liability under section 1879 of the Act based upon its "good faith belief" that the services were medically reasonable and necessary. The appellant has confused, no doubt inadvertently, the waiver of recoupment provisions found in section 1870 of the Act with the limitation of liability provisions in section 1879.

Limitation on liability - Section 1879

Section 1879 of the Act limits a provider's liability where it did not know, and could not reasonably be expected to know, that Medicare did not cover the services at issue. However, as a provider participating in the Medicare program, the appellant is considered to have constructive knowledge of CMS manual instructions, bulletins, contractors' written guides, and directives. CMS Manual System, Medicare Claims Processing (MCPM), CMS Pub. 100-04, Ch. 30, §§ 40.1, 40.1.1. As noted by the ALJ, the appellant "is required to be familiar with Medicare rules and regulations . . . holding providers liable when the documentation is inadequate to support a finding of medical necessity." Dec. at 9. Thus, the Council finds that the ALJ did not err in finding that the limitation of liability provision of section 1879 did not apply to the appellant. Accordingly, the appellant remains liable for the non-covered services pursuant to section 1879 of the Act.

Waiver of Recoupment of Overpayment - Section 1870

Section 1870 of the Act allows for a waiver of recoupment of an overpayment to a provider if it is without fault in incurring the overpayment. A provider is without fault if it exercised reasonable care in billing and accepting Medicare payment. Medicare Financial Management (MFMM), (CMS Pub. 100-06), Ch. 3, § 90. The MFMM further explains that the provider should have known about a policy or rule if the policy or rule is in the provider manual or in the regulations. *Id.* at 90.1. As noted by the ALJ, the appellant did not submit sufficient documentation substantiating that the services were medically reasonable and necessary. *See, generally,* Dec. at 9-10. Thus, the appellant was not without fault in creating the overpayment. As the appellant was not "without fault" in creating the overpayments, no waiver of recoupment of the overpayments is warranted.

FINDINGS

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

- The appellant has demonstrated good cause for submission of the documentation in ALJ Master File Exhibit 13 (appellant Exhibit 29) after the QIC reconsideration.

- The appellant has not adequately documented the medical necessity of the diagnostic testing services provided to the sixty-five beneficiaries at issue in this case.

- The limitation of liability provisions at section 1879 of the Act do not apply to the appellant.

- The appellant was not "without fault" in creating the overpayments. Consequently, no waiver of recoupment of the overpayments is warranted under section 1870 of the Act.

DECISION

It is the decision of the Medicare Appeals Council that all the services at issue are not medically reasonable and necessary under section 1862(a)(1) of the Act. It is the further decision of the Council that the appellant is liable under section 1879 of the Act and not entitled to waiver of recoupment of the overpayment under section 1870. The ALJ's decision is modified.

MEDICARE APPEALS COUNCIL

/s/ Clausen J. Krzywicki
Administrative Appeals Judge

/s/ Gilde Morrisson
Administrative Appeals Judge

Date: February 24, 2010