

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
DEPARTMENTAL APPEALS BOARD

**DECISION OF MEDICARE APPEALS COUNCIL**  
**Docket Number: M-11-545**

**In the case of**

**Claim for**

Amigo Home Health Agency  
\_\_\_\_\_  
(Appellant)

Supplementary Medical  
Insurance Benefits  
\_\_\_\_\_  
(Part B)

\*\*\*\*  
\_\_\_\_\_  
(Beneficiaries)

\*\*\*\*  
\_\_\_\_\_  
(HIC Numbers)

TrailBlazer Health  
Enterprises  
\_\_\_\_\_  
(Contractor)

\*\*\*\*  
\_\_\_\_\_  
(ALJ Appeal Number)

The Administrative Law Judge (ALJ) issued an October 15, 2010, decision partially favorable to the appellant, a home health provider. The ALJ's decision addressed an extrapolated overpayment (initially \$973,426.83) assessed against the appellant for its claims for coverage of blood glucose testing services provided to beneficiaries between September 1, 2004 and June 30, 2008, and billed to Medicare under CPT<sup>1</sup> code 82962 (Glucose, blood by glucose monitoring devices(s) cleared by the FDA specifically for home use). The appellant sought Medicare Part B coverage for these tests, characterizing them as diagnostic laboratory tests, in addition to its Medicare Part A reimbursement for home health services. Before the ALJ, the appellant withdrew its objections to the statistical sample and extrapolation upon which the overpayment was based, leaving coverage for the services provided to the sixty-two sampled beneficiaries as the central issue before the ALJ. The ALJ

<sup>1</sup> CPT (Current Procedure Terminology) codes were designed by the American Medical Association to describe medical and surgical services performed by providers. Based upon the CPT system, the Center for Medicare and Medicaid Services (CMS) developed the Healthcare Common Procedure Coding System (HCPCS) for processing, screening, identifying, and paying Medicare claims. See 42 C.F.R. §§ 414.2 and 414.40. For purposes of this decision, the codes are essentially identical.

determined that, with the exception of one claim per beneficiary, the appellant had not satisfied the applicable Medicare Part B coverage criteria. Based on the non-coverage of certain claims, the ALJ also found the appellant liable for the resulting non-covered costs, under section 1879 of the Social Security Act (Act) and that the appellant was not entitled to waiver of recoupment of the overpayment, under section 1870 of the Act. The appellant has asked the Medicare Appeals Council to review this action. The appellant's request for review is entered into the record as Exhibit (Exh.) MAC-1.

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 reverses the ALJ's decision. We find that no blood glucose tests at issue before the ALJ are covered.

#### **LEGAL AUTHORITIES**

##### *Home Health Prospective Payment System (PPS)*

Generally, home health services provided to beneficiaries are paid under a prospective payment system (PPS) in a 60-day episode rate. See Medicare Benefit Policy Manual (MBPM) (IOM Pub. 100-02), ch. 7, § 10.1.A. Home health services in this bundled rate include six disciplines: skilled nursing, home health aide, physical therapy, speech-language pathology, occupational therapy, and medical social services. *Id.* The 60-day PPS rate also includes, in relevant part, "nonroutine medical supplies and therapies that could have been unbundled to part B prior to PPS." *Id.* "The law requires all medical supplies (routine and nonroutine) bundled to the agency while the patient is under a home health plan of care." *Id.* at § 10.11.B. Durable medical equipment (DME) and supplies covered as DME "are paid separately from the PPS rates and are excluded from the consolidated billing requirements governing PPS. The determining factor is the medical classification of the supply, not the diagnosis of the patient." *Id.*

##### *Blood Glucose Testing in a Home Health Episode*

In 2000, CMS issued PM AB-00-99, entitled "Glucose Monitoring Note," which was effective November 1, 2000. The policy provides, in part:

This Program Memorandum (PM) briefly notes Medicare policy for glucose monitoring for a patient whose stay is not covered by Medicare Part A but who is eligible for services under Medicare Part B. Another PM will be issued, Change Request 1362, Glucose Monitoring, to describe further coverage, payment and billing instructions for this service. . . . Section 1862(a)(1)(A) of the Social Security Act requires the service to be reasonable and necessary for diagnosis and treatment in order to be covered by Medicare. Sections 42 Code of Federal Regulations (CFR) 410.32 and 411.15 specify that for a laboratory service to be reasonable and necessary, it must not only be ordered by the physician but the ordering physician must also use the result in the management of the beneficiary's specific medical problem. Implicitly, the laboratory result must be reported to the physician promptly so that the physician can use the result and instruct continuation or modification of patient care; *this includes the physician's order for another laboratory service*. Compliance program guidance for laboratory services permits, but with strict limits, the conditions under which the physician's order for a repeat laboratory service can qualify as an order for another covered laboratory service.

(Emphasis supplied.)

On December 1, 2000, CMS issued PM AB-00-108 entitled "Glucose Testing." ALJ Master File, Exh. 2. This PM reviewed Medicare coverage and payment policy for glucose monitoring for inpatients whose care is not covered by Medicare Part A but who are eligible for services under Medicare Part B, as well as for home health patients under both Parts A and B. *Id.* at 3. The memorandum recognized that glucose monitoring for managing insulin therapy "often involves the use of an inexpensive hand-held device to evaluate a small sample of the patient's blood acquired through a finger stick. . . . Administration of the service several times a day is common in order to maintain tight control of glucose to prevent heart disease, blindness, and other complications of diabetes. This device is on the list of instruments that can be administered by providers registered under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), including providers registered with only a certificate of waiver." ALJ Master File, Exh. 2 at 1, *citing* section

1861(h) of the Act (glucose monitoring device and supplies as DME); 42 C.F.R. § 493, PM AB-00-61 (CLIA-waived instruments).<sup>2</sup>

PM AB-00-108 continues, providing:

[F]or a laboratory service to be reasonable and necessary, it must not only be ordered by the physician, but the *ordering physician must use the result in the management of the beneficiary's specific medical problem. Implicitly, the laboratory result must be reported to the physician promptly in order for the physician to use the result and instruct continuation or modification of patient care; this includes the physician's order for another laboratory service.*

\* \* \*

Denial of payment for a Part B covered laboratory service cannot be made on the basis that the service is routine care. Under Medicare, routine care determinations are applicable only for Part A nursing home services.

A covered home health service requires a home health employee to supervise, assist, record, and report on the patient's daily/weekly functional and medical activities. For some patients, their daily/weekly activities include glucose monitoring, often self-administered or administered with the help of a care giver who is not an employee of or affiliated with the home health provider. *If the patient maintains a home-use glucose monitoring device, a home health employee's supervision and assistance of a glucose monitoring service is encompassed in the payment for*

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<sup>2</sup> CMS allows that home health agencies (HHAs) - "may provide laboratory services only if issued a CLIA number and/or having a CLIA certificate of waiver. HHAs do not report laboratory services, even when on the HH plan of care, to a Medicare contractor using an institutional claim format. These services are always billed to Medicare contractors using a professional claim format . . . The survey process is used to validate that laboratory services in an HHA facility are being provided in accordance with the CLIA certificate." Medicare Claims Processing Manual (MCPM)(IOM Pub. 100-04), ch. 10, § 90.D (emphasis in original). The mere fact that the appellant is a CLIA-waived entity is insufficient to establish Medicare Part B coverage for the blood glucose monitoring services provided.

*the home health service. However, if the physician separately orders the employee to administer a glucose monitoring service for a Part B only patient who does not administer daily/weekly glucose monitoring and does not maintain a glucose monitoring device, the glucose monitoring is not encompassed in the home health benefit. If a home health agency receives a supplier number, a Form HCFA-1500 may be submitted to the carrier in accordance with physician and supplier billing instructions for filing Part B claims at [Medicare Carrier Manual Section 3001]. Corresponding laboratory costs and charges must be reported on the cost report when the home health agency is registered for CLIA testing with only a certificate of waiver. Sections 42 CFR 410.32 and 411.15 apply equally to a laboratory service in the home health setting. Therefore, if a home health employee carries and assists with the use of a home-use glucose monitoring device during a home health visit, a glucose monitoring service must be performed in accordance with laboratory coverage criteria to qualify for separate payment under the Medicare laboratory benefit. The blood glucose monitoring services must not only be ordered by the physician but the ordering physician must also receive and use the order's result in the management of a specific medical problem. The laboratory result must be reported to the physician promptly in order for the physician to use the result and instruct continuation or modification of patient care.*

ALJ Master File, Exh. 2 at 2-3, (*citing* section 1861(m) of the Act and Home Health Manual § 465) (emphasis supplied).

On November 23, 2001, CMS published a final rule concerning coverage of clinical diagnostic laboratory services under Medicare Part B. See Medicare Program; Negotiated Rulemaking: Coverage and Administrative Policies for Clinical Diagnostic Laboratory Services, 66 Fed. Reg. 58788 (Nov. 23, 2001). As an addendum to the rule, CMS issued 23 NCDs that became effective on November 25, 2002, including an NCD on blood glucose testing. See Medicare National Coverage Determination Manual (NCDM) (IOM Pub. 100-03) § 190.20. With an effective date of January 1, 2003, NCD section 190.20 applies generally to "blood samples used to determine glucose levels." The NCD recognizes that the convenience of a home blood glucose monitor "allows a patient to

have access to blood glucose values in less than a minute or so and has become the standard of care for control of blood glucose, even in the inpatient setting." Under the heading "**Limitations**," the NCD provides:

Frequent home blood glucose testing by diabetic patients should be encouraged. In stable, non-hospitalized patients who are unable or unwilling to do home monitoring, it may be reasonable and necessary to measure quantitative blood glucose up to four times annually.

Depending on the age of the patient, type of diabetes, degree of control, complications of diabetes, and other co-morbid conditions, more frequent testing than four times annually may be reasonable and necessary.

In some patients presenting with nonspecific signs, symptoms, or diseases not normally associated with disturbances in glucose metabolism, a single blood glucose test may be medically necessary. Repeat testing may not be indicated unless abnormal results are found or unless there is a change in clinical condition. If repeat testing is performed, a specific diagnosis code (e.g., diabetes) should be reported to support medical necessity. However, repeat testing may be indicated where results are normal in patients with conditions where there is a confirmed continuing risk of glucose metabolism abnormality (e.g., monitoring glucocorticoid therapy).

NCD § 190.20 at 3.

CMS issued Program Memorandum, PM AB-02-110 (July 31, 2002), to guide local contractors in their implementation of the NCDs that were published in the final rule. While this PM reminded contractors that NCDs are binding on all contractors and ALJs, it also acknowledged that the published NCDs may not provide complete guidance on some issues. "For example, some of the NCDs are silent regarding frequency. You may develop [a local medical review policy] that provides guidance regarding appropriate frequency."

The 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) (emphasis supplied).

Regulations at 42 C.F.R. part 424 establish general conditions for payment under Medicare Part B. The requirements for "medical and other health services furnished by providers under Medicare Part B" are found at 42 C.F.R. § 424.24.

During the period September 1, 2004, through December 31, 2006, the regulation at 42 C.F.R. § 424.24(f) provided -

*All other covered medical and other health services furnished by providers - (1) Content of certification.* The services were medically necessary.

(2) *Signature.* The certificate must be signed by a physician, nurse practitioner, clinical nurse specialist, or physician assistant who has knowledge of the case.

(3) *Timing.* The physician, nurse practitioner, clinical nurse specialist, or physician assistant may provide certification at the time the services are furnished or, if services are provided on a continuing basis, either at the beginning or at the end of a series of visits.

(4) *Recertification.* Recertification of continued need for services is not required.

**Effective January 1, 2007,** subsection 424.24(f) was redesignated as subsection 424.24(g) and a new subsection 424.24(f), which specifically addressed blood glucose testing, **added to the regulation.** The new subsection (f) provided -

*Blood glucose testing.* For each blood glucose test, the physician must certify that the test is medically necessary. A physician's standing order is not sufficient to order a series of blood glucose tests payable under the clinical laboratory fee schedule.

See 71 Fed. Reg. 69788 (Dec. 1, 2006)<sup>3</sup>.

Chapter 7, section 90.1, of the MCPM implements the regulations concerning payment of laboratory tests under Part B. Specifically, section 90.1, provides:

Medicare Part B may pay for a glucose monitoring device and related supplies under its durable medical equipment benefit if the equipment is used in the home or in an institution that is used as a home. . . .

Routine glucose monitoring of diabetics is never covered in a SNF, whether the beneficiary is in a covered Part A stay or not. Glucose monitoring may only be covered when it meets all the conditions of a covered laboratory service, *including use by the physician in modifying the patient's treatment.*

*Id.* (emphasis supplied).

The Medicare Benefit Policy Manual (MBPM) (IOM Pub. 100-02), provision on clinical laboratory services mirrors the Medicare Claims Processing Manual, providing: "Section 1862(a)(1)(A) of the Act provides that Medicare payment may not be made for services that are not reasonable and necessary. *Clinical laboratory services must be ordered and used promptly by the physician who is treating the beneficiary as described in 42 C.F.R. 410.32(a), or by a qualified nonphysician practitioner, as described in 410.32(a)(3).*" MBPM, ch. 15, § 80.1. (emphasis supplied).

#### **BACKGROUND<sup>4</sup>**

On August 21, 2008, TriCenturion, a Medicare Program Safeguard Contractor (PSC) notified the appellant of the preliminary results of its audit of the appellant's claims for Part B

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<sup>3</sup> In promulgating this new rule, the agency referred to its longstanding policy on coverage of blood glucose testing and cited Program Memorandum AB-00-108 as the most recent explanation of that policy. See *Medicare: Physician Fee Schedule (CY 2007); payment policies and relative value units*, 71 Fed. Reg. 69624, 69704 (Dec. 1, 2006).

<sup>4</sup> The Council notes that, before the ALJ, the appellant withdrew its contentions relative to the validity of the sample and extrapolation underlying this overpayment. See Dec. at 3. Accordingly, the Council will not recount the development of those aspects of the case.



coverage of blood glucose monitoring tests provided between September 1, 2004, and June 30, 2008. The PSC found that -

Amigo submitted claims to the Carrier for services that were previously paid by the Regional Home Health Intermediary (RHHI) which resulted in duplicate billing to Medicare. Specifically, Amigo submitted claims for glucose monitoring [HCPCS/CPT code 82962] as a laboratory service to the Carrier (Medicare Part B) when the service was previously paid under the RHHI (Medicare Part A) benefit. The submitted claims were for glucose monitoring services for beneficiaries who maintain a home use glucometer and received durable medical equipment (DME) such as diabetic test strips and lancets as a DME Medicare benefit previously paid for by a DMERC [Durable Medical Equipment Regional Carrier, now a Medicare contractor].

TriCenturion conducted cross-claims data analysis and identified Medicare beneficiaries maintaining a home-use glucose monitoring device for self monitoring, for whom Amigo is also billing claims for glucose monitoring laboratory services and home health services concurrently (when the actual glucose monitoring service is encompassed in the payment for the home health service). In addition, TriCenturion conducted cross-claims analysis reviewing Part B, DME, and RHHI claims and identified a pattern indicating Amigo systematically submitted claims for Part B glucose monitoring services prior to or subsequent to DME claims for Medicare beneficiaries. These beneficiaries were also receiving home health services paid for by RHHI while Amigo submitted claims for glucose monitoring services under Medicare Part B, thus resulting in a 100% error rate for Part B claims meeting the criteria. According to Medicare guidelines, DME supplies were not necessary when Amigo performed glucose monitoring services in the home and used their own equipment. Medicare guidelines address [that] there are some specific relevant Medicare requirements with respect to glucose monitoring and Medicare Part B payment for a glucose monitoring device and related disposable supplies under its DME [benefit] if the equipment is used in the home. . . . Further, Medicare guidelines specifically address that

glucose monitoring services are encompassed in the RHHI benefit for beneficiaries who maintain a home-use glucometer. . . .

ALJ Master File, Exh. 1 at 105-107 (footnotes omitted).

On October 20, 2008, the appellant's Medicare contractor (TrailBlazer Health Enterprises) formally notified the appellant of the \$973,426.83 overpayment. Exh. 1 at 100. The appellant requested a redetermination. The contractor issued an unfavorable redetermination on March 9, 2009 (*Id.* at 95) and an amended redetermination on April 3, 2009. *Id.* at 84-86. There, the contractor indicated that coverage was denied because the claims in question constituted duplicate billings. *Id.* at 85.

The appellant requested reconsideration by a Qualified Independent Contractor (QIC). The QIC issued a partially favorable reconsideration, reducing the overpayment to \$804,147.70. Exh. 1 at 5-19.

Under medical necessity, the QIC extensively reviewed Medicare coverage requirements for clinical laboratory services. Exh. 1 at 8-14, *citing* Sections 1862(a)(1)(A) and 1861(s)(3) of the Act); 42 C.F.R. §§ 410.32(a), 424.24(f); PM AB-00-108; National Coverage Determination Manual (NCDM) (IOM Pub. 100-03), ch. 1, pt. 3, § 190.20 (NCD 190.20); MBPM, ch. 15, § 80.1; Local Medical Review Policy (LMRP) for Blood Glucose Monitoring (L15721), Local Coverage Determination (LCD) L14227 "Frequency for Laboratory Tests," and successor LCD L26817.<sup>5</sup>

With respect to medical necessity, the QIC framed the issue as "whether the beneficiaries' blood glucose tests constitute covered diagnostic laboratory tests." Exh. 1 at 14. The QIC

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<sup>5</sup> A Local Coverage Determination, as established by Section 522 of the Benefits Improvement and Protection Act, is a decision by a fiscal intermediary or carrier whether to cover a particular service on an intermediary-wide or carrier-wide basis in accordance with Section 1862(a)(1)(A) of the Act (*i.e.*, a determination as to whether the service is reasonable and necessary). The difference between LMRPs and LCDs is that LCDs consist only of "reasonable and necessary" information, while LMRPs may also contain category or statutory provisions.

The final rule establishing LCDs was published November 11, 2003. Effective December 7, 2003, CMS' contractors began issuing LCDs instead of LMRPs. Over the next 2 years (until December 31, 2005) contractors converted all existing LMRPs into LCDs and articles.

noted that documentation submitted by the appellant indicated that "the beneficiaries generally had diabetes and many were on insulin." *Id.* at 14. The QIC reasoned that the -

Home Health Certification(s) and Plan(s) of Care each had a standing order for blood sugar testing and what action the home health personnel were to take based on the blood sugar measurements. The evidence shows that the blood sugar services in this appeal were provided secondary to pre-existing standing orders, some of which had been in place for several months. The tests were not ordered individually in response to a change in the beneficiaries' clinical condition. We find that the standing orders are not sufficient orders for the blood sugar tests at issue under . . . [42] CFR 410.32, PM AB-00-108, and (for services after May 6, 2006) under the carrier's LCDs, L14227 and L26817.

Additionally, the medical records do not show that the physician was promptly notified of most of the test results or that the Home Health Agency received additional physician orders or instructions affecting/modifying the beneficiaries' diabetes care.

We note that the physician had certified the beneficiaries' plans of care that contained the standing orders for the blood glucose measurements; this fact is insufficient to meet the requirements of a covered diagnostic laboratory service. Although the blood glucose tests at issue may have been provided according to the appropriate standard of care, the issue is whether the services meet the requirements of covered diagnostic laboratory test. The evidence . . . indicates that the blood glucose determinations were routine blood glucose monitoring services.

Exh. 1 at 14-15.

The QIC also denied coverage for certain claims lines based upon the duplication of certain claims (Unfavorable II-C) and the absence (Unfavorable II-B) or inadequacy (Unfavorable II-D) of supporting documentation. Exh. 1 at 15-16.

In its favorable coverage findings, the QIC determined, without record citation, that the "documentation shows that theses (*sic*)

services were done, the physician was promptly notified and that orders were received. Therefore, Medicare can allow the services identified on the attached spreadsheet as favorable . . . ." Exh. 1 at 10; see also Exh. 8 at 3-23.

The appellant requested a hearing before an ALJ. The ALJ conducted a hearing on September 30, 2010, at which the appellant was represented by counsel. The appellant presented testimony from its billing consultant, Administrator and Chief Operating Officer (Chief O.O.) for Finances. Dec. at 2. The appellant's billing consultant explained the CLIA billing process and opined that since the various physician orders were beneficiary-specific, they were not "standing orders." The Administrator also testified that since the orders were beneficiary-specific, they were not "standing orders." Rather, in the Administrator's view, a "standing order" was more of an institutional-based order, for example a hospital emergency department's protocol for the steps involved in the immediate treatment of a heart attack patient. The Administrator next discussed the content of the file for Beneficiary A.Ga., one of the five exemplar beneficiary files<sup>6</sup> offered by the appellant. The Administrator testified that the physician was notified promptly of aberrant blood glucose readings, i.e., those above and/or below designated limits for hyperglycemia or hypoglycemia. The Administrator indicated that the physician responded to those notifications by issuing supplemental orders reflecting changes mandated by the test result. The Administrator also testified that, absent aberrant results, the physician was notified of all test results on a weekly basis. The Administrator averred that this reporting and response protocol occurred in every case. The appellant's Chief O.O. testified as to his understanding of the appellant's general billing practices with the caveat that some of the practices at issue in this case predated the start of his tenure. The Chief O.O. testified that appellant's billing consultant had developed the appellant's now questioned Part B billing practice, initially billing the claims and ultimately training certain of the appellant's staff to bill. The Chief O.O. contended that the appellant had no reason to believe the Part B claims would not be paid as billed, but noted that, once they were called into question, the appellant ceased billing blood glucose testing as a Part B service. See, generally, ALJ Hearing CD (Sept. 30, 2010).

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<sup>6</sup> The five "exemplar" files were those for Beneficiaries A.B., N.D., A.Ga., E.P. and A.Ra.

In the ensuing decision the ALJ generally indicated that while standing orders "may be understood to describe both recurring orders specific to the care of an individual patient and as routine orders for services delivered to a population of patients. . . . Standing orders may be used for laboratory tests ONLY if several conditions are met." Dec. at 15.

Pertinent to blood glucose testing, the ALJ recounted that -

CMS has specifically instructed as follows in CR5443, Transmittal 258 dated 12/22/06, under technical refinements to the Clinical Laboratory Fee Schedule:

Medicare separately pays for a blood glucose test only when the service meets all of the conditions of payment for a test payable under the clinical laboratory fee schedule including that the test must be ordered by the physician who is treating the beneficiary and the physician must use the results in the management of the beneficiary's specific medical condition. For payment to be made for a blood glucose test under Medicare Part B, a physician **must certify** . . . each test is medically necessary. In summary, reimbursement of each lab test provided under a standing order for a recurring or serial evaluation is subject to medical necessity review. All such orders must be written for a specific patient, and each instance of the test must be necessary. Each result must be reviewed with appropriate action taken by the treating physician including any appropriate change in the frequency or duration of testing. CMS *One-Time Special Notification*, Pub. 100-20, Transmittals, 2006, Transmittal #258, Date: December 22, 2006 Payment Amounts and Policies in the 2007 Medicare Physician Fee Schedule and the Telehealth Originating Site Facility Fee Payment Amount.

Review of each Beneficiary file reflects the (*sic*) each blood glucose test was ordered by the treating physician, timely reported the (*sic*) treating

physician, and the results used in the treatment of each Beneficiary. The tests at issue were not performed under a standing order, which would prevent the Appellant from receiving Medicare coverage and payment. However, the inquiry does not end there. Pursuant to 42 C.F.R. § 424.24(f), the physician must certify each blood glucose test was medically necessary.

Here, this certification is accomplished when the treating physician signed each of the Home Health Plans of Care. This occurred every 60 days and billing cycle of the Appellant follows this pattern (each claim set forth in Exhibit "A" contains units billed of CPT 82962 during a 60 day Home Health benefit period). Consequently, for each 60 day Home Health OASIS certification period, the record reflects the treating physician certified, ordered, and used the results of only one (1) blood glucose test provided by the Appellant. For all other tests, the record reflects the Appellant provided a blood glucose test ordered and used by the treating physician. None of these other tests were certified, as required by 42 C.F.R. § 424.24(f), by the treating/ordering physician. Therefore, while each test appears to be medically necessary, none of these other tests can be covered by Medicare. Where the Appellant received payment for each of these tests, the Appellant received an overpayment.

Dec. at 16-17 (emphasis in original).

Turning to liability for non-covered costs, the ALJ found that the appellant had not provided Advance Beneficiary Notices to any of the beneficiaries. Given this finding and appellant's imputed knowledge of Medicare coverage requirements, the ALJ found the appellant liable for the non-covered costs under section 1879 of the Act. Dec. at 17.

Addressing the appellant's eligibility for waiver of recoupment of the overpayment, the ALJ acknowledged the appellant's argument that it had relied, to its detriment, on the advice of its "billing expert" in billing Medicare for coverage of these services. However, the ALJ found that the appellant's "unfortunate reliance upon the

services of . . . [its billing expert] does not provide sufficient evidentiary support to trigger any mechanism of waiver under section 1870(b) of the Act." Rather, the ALJ reasoned, the appellant "had access to Medicare guidelines regarding physician's services, and could have avoided the overpayment through a simple reading of the Federal regulations directly related to the services billed." Dec. at 17-18. Accordingly, the ALJ found that the appellant was not eligible for a waiver of recoupment of the overpayment. *Id.* at 18.

On December 12, 2010, the ALJ issued an Order *Nunc Pro Tunc*, clarifying his ultimate conclusion to provide -

The Appellant has established the medical necessity of one (1) blood glucose test (CPT 82962) per billed claim (only when occurring every 60 days) and met all conditions of Medicare coverage payment for the same (*billed claims are set forth in attached Exhibit "A"*). The Appellant did not receive an overpayment for one (1) blood glucose test (CPT 82962) per billed claim (only when occurring every 60 days)." (*sic*) for all instances wherein the additional language failed to be generated electronically (*sic*).

Order at 2.

In its request for review the appellant asserts that the version of the regulation at 42 C.F.R. § 424.24(f), "from April 7, 2000 - December 1, 2006, specifically permitted a physician to order [and to certify] a series of blood glucose tests which is exactly what the physicians . . . did in this case." See Exh. MAC-1 at 2-3. Further, the appellant maintains that it was fully compliant with the December 1, 2006, regulatory revision, (creating a new 42 C.F.R. § 424.24(f) and moving former subsection (f) to subsection § 424.24(g)), which "specifically provides that physician recertification of services provided on a 'continuing basis' is not required." <sup>7</sup> Exh. MAC-1 at 3-4.

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<sup>7</sup> Contrary to the appellant's recitation of the pertinent law at the earlier stages of its request for review, (*see, e.g.,* Exhibit MAC-1 at 3), the revision to 42 C.F.R. § 424.24(f) was published on December 1, 2006, *but did not become effective until January 1, 2007.* See 71 Fed. Reg. 69624. The appellant subsequently noted the January 1, 2007, effective date of the revised section 424.24(f). Exh. MAC-1 at 13, ¶23.

The appellant also contends that the ALJ failed to address adequately address errors in the QIC's reconsideration. The appellant specifically disputes what it characterizes as the QIC's finding that "diagnostic services are bundled into the rate for home health services." The appellant notes that diagnostic services are not included within bundled home health services (see MBPM, ch. 7, § 10.11) and suggests that if Medicare intended to bundle diagnostic services into the home health rate, the "specific instruction in this regard would exist, as it does for hospice and skilled nursing care." Exh. MAC-1 at 5. The appellant challenges additional QIC findings under the broader argument that -

every patient in the sample was diagnosed with Diabetes Mellitus . . . and required blood glucose testing. The medical necessity of each claim . . . was supported by such diagnosis combined with multiple other co-morbidity diagnoses. It can be inferred from the physicians ordering such services that they determined that blood glucose testing more frequently than four times per year was reasonable and necessary for the patient.

Exh. MAC-1 at 8, ¶17.

The appellant asserts that the QIC erred in applying LCD L26817 to what the appellant characterized as over "half the denied II-A claim lines" which predated LCD's L26817 and its predecessor's (L14227) effective date. Exh. MAC-1 at 10-12. To the extent the QIC denied the claims for lack of documentation (Unfavorable II-B claims), the appellant asserts that it sent all information to CMS in a timely fashion and should not be responsible for these non-covered costs because it did not receive timely notice of missing information. Exh. MAC-1 at 12. The appellant also asserts that, while it agrees that duplicate claims should not be reimbursed, contrary to the QIC's categorization (Unfavorable II-C claims), there are no duplicate claims. *Id.*

### **DISCUSSION**

As noted above, the Council reviews an ALJ's decision *de novo*. 42 C.F.R. § 405.1108(a). Having considered the record in the context of the applicable coverage authorities, the Council concludes that none of the blood glucose tests at issue before



the ALJ can be covered by Medicare. The ALJ erred in finding that "the tests at issue **were not** performed under a standing order, which would prevent the Appellant from receiving Medicare coverage and payment." See Dec. at 17 (emphasis supplied). The ALJ also erred in applying the blood glucose testing certification requirement found at 42 C.F.R. § 424.24(f), to services predating that regulation's January 1, 2007, effective date. See Dec. at 17

The Council, in accordance with the NCD and CMS policy, recognizes the medical necessity of frequent glucose testing of patients with diabetes. In this case, the record suggests that the appellant performed frequent blood glucose monitoring on home health patients pursuant to what the Council finds to be standing physician orders on the forms identified as **Home Health Certification and Plan of Care**.<sup>8</sup> Generally, test results were reported to the treating physician once per week. Only aberrant readings, as defined by prescribed "medically acceptable" upper and lower test result readings, were reported immediately.

The NCD encourages "[f]requent home blood glucose testing by diabetic patients." The NCD further notes that for stable non-hospitalized patients, unable or unwilling to do home monitoring, it may be reasonable and necessary to perform blood glucose tests up to four times per year.<sup>9</sup> Addressing repeat testing, the NCD states only that "repeat testing may not be indicated unless abnormal results are found or unless there is a change in clinical condition." These restrictions are consistent with CMS policy concerning Part B payment for clinical laboratory services, and specifically, blood glucose testing, as articulated in the manuals and Program Memoranda.

PM AB-00-108 notes that "nursing and physician duties [related to testing] . . . are paid predominately under other payment systems, such as the state nursing home payment system or the physician payment system." ALJ Master File, Exh. 2 at 2. The Council grants substantial deference to CMS policy that "a glucose monitoring service must be performed in accordance with laboratory coverage criteria to qualify for *separate payment*

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<sup>8</sup> While the plans of care differed for certain beneficiary specific features, e.g., type and dosage of insulin to be administered, the Council notes that for purposes of blood glucose testing the plans were virtually identical in content. See, e.g., claim files for Beneficiaries A.B., E.P. and S.S.

<sup>9</sup> The PSC found that Medicare records indicated that each beneficiary maintained a home-use glucose testing device for self monitoring. See, *infra* at 9.

under the Medicare laboratory benefit." *Id.* (emphasis supplied.) The program memorandum also provides:

Glucose monitoring measures blood sugar levels for the purposes of managing insulin therapy (shots, medication, and diet). The service often involves the use of an inexpensive hand-held device to evaluate a small sample of the patient's blood acquired through a finger stick. The device measures blood glucose values immediately on a digital display so as to permit self-administration in the home. If a physician separately orders the performance of a glucose monitoring service for a patient who can not (*sic*) self-administer, clinical staff generally will administer a glucose monitoring service along with their other duties.

ALJ Master File, Exh. 2 at 1.<sup>10</sup>

PM AB-00-108 specifically explains:

If the patient maintains a home-use glucose monitoring device, *a home health employee's supervision and assistance of a glucose monitoring service is encompassed in the payment for the home health service.* However, if the physician separately orders the employee to administer a glucose monitoring service for a *Part B only patient* who does not administer daily/weekly glucose monitoring and does not maintain a glucose monitoring device, the glucose monitoring is not encompassed in the home health benefit.

ALJ Master File, Exh. 2 at 3 (emphasis supplied). The Council finds it reasonable that "a glucose monitoring service must be performed in accordance with laboratory coverage criteria to qualify for *separate payment* under the Medicare laboratory benefit." *Id.* at 2 (emphasis supplied).

Pursuant to 42 C.F.R. § 405.1060(a)(4), an NCD is binding on ALJs and the Council. At the same time, while ALJs and the

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<sup>10</sup> The program memorandum explains that "Medicare Part B may pay for a glucose monitoring device and related disposable supplies under its durable medical equipment benefit if the equipment is used in the home or in an institution that is used at a home." ALJ Master File, Exh. 2 at 1, n.1.

Council are not bound by CMS program guidance, they must give those policies substantial deference if applicable in a particular case. 42 C.F.R. § 405.1062(a). If an ALJ or the Council declines to follow a policy in a particular case, the reasons why such policy was not followed must be explained. 42 C.F.R. § 405.1062(b).

The coverage requirements set forth in the CMS program memoranda and manuals referenced above are consistent with the coverage requirements established in the NCD. The NCD does not mandate separate Part B coverage of finger stick glucose testing for beneficiaries in a 60-day PPS episode under the Medicare Part A home health benefit, nor does it address the reasonableness and necessity of routine testing in that setting. In fact, in addressing frequency, the NCD states only that "repeat testing may not be indicated unless abnormal results are found or unless there is a change in clinical condition." These restrictions are consistent with CMS policy restricting Part B payment for clinical laboratory services, and specifically, blood glucose testing, as articulated in the manuals and Program Memoranda.

At the ALJ hearing, the appellant identified five exemplar beneficiary files to support its coverage argument and its Administrator offered testimony specific to one of those five, Beneficiary A.G. Pertinent to the "exemplar" files the appellant provided documents identified as "Supplemental Plans of Treatment" (Supplemental Plans). The appellant's Administrator testified that the Supplemental Plans were issued by treating physicians in response to their beneficiaries' reported aberrant blood glucose readings. Having reviewed the record, the Council does not find these Supplemental Plans in the preexisting records of the "exemplar" beneficiaries or for other beneficiary files examined. To the extent that some files do contain Supplemental Plans, their content does not reflect new instructions, responsive to aberrant test results. Rather, they contain the same general content found in that beneficiary's preexisting and subsequent plans of care. See, e.g., claim files for Beneficiaries M.A., A.Cal., A.Can. and (exemplar file) N.D.

At both the hearing and in its written argument, the appellant asserts that because the Plans of Care contained beneficiary-specific instructions, they cannot be standing orders. Rather, the appellant proposes that a standing order is more in the form of a cross-cutting institutional treatment order. The Council finds that a "standing order" under Medicare administrative

authority does not fall within the definition proposed by the appellant and, apparently, employed by the ALJ. In this case, the treating physicians generally ordered blood glucose testing for home health beneficiaries on the Home Health Certification and Plan of Care, pertaining to a 60-day episode of care and in relation to a sliding scale of insulin dosage. Those orders remained in place throughout the particular home health episode for each beneficiary.

The Council has reviewed the records for the exemplar and other beneficiaries. This review supports a conclusion finding that the ALJ erred in finding any home blood glucose testing covered under Medicare Part B. The Council finds, instead, that the physician orders for home health blood glucose testing for the beneficiaries in this case fall within the ambit of the term "standing order," as discussed in PM-AB-00-108 and other Medicare authority herein.

Contrary to the ALJ's findings, the beneficiaries generally had a standing order, renewed every 60 days, for regular blood glucose testing and a sliding scale of insulin administration depending upon the glucose reading. But the record contains no indication that the treating physicians received "prompt notification" the results of **each and every** of the beneficiaries home blood glucose tests ordered by the physician on each of the POCs, or that the physician promptly considered the results of each and every test in determining treatment strategy, including **whether to perform any** of the subsequent blood sugar checks. Instead, the appellant's hearing testimony indicates test results were generally reported on a weekly basis, with sporadic telephone calls to physicians' office based upon extreme blood sugar readings, i.e., results which fell outside the upper and lower test result ranges established by the physician's standing orders. Repeated testing multiple times each day thereafter continued under the terms of the standing order to the Plan of Care.

As noted above, the appellant also contends that blood glucose testing services provided prior to the January 1, 2007, effective date of 42 C.F.R. § 424.24(f) should be covered under Medicare Part B because under the prior version 42 C.F.R. § 424.24(f) it was not required to recertify a "continued need for services." See 42 C.F.R. § 424.24(f)(4). The new version of 42 C.F.R. § 424.24(f) is specifically directed to blood glucose testing, while the older version (now at subsection 424.24(g)) concerned "all other covered medical and health

services furnished by providers." However, Program Memorandum AB-00-108 directly addresses blood glucose testing providing -

If the patient maintains a home-use glucose monitoring device, a home health employee's supervision and assistance of a glucose monitoring service is encompassed in the payment for the home health service. However, if the physician separately orders the employee to administer a glucose monitoring service for a Part B only patient who does not administer daily/weekly glucose monitoring and does not maintain a glucose monitoring device, the glucose monitoring is not encompassed in the home health benefit.

ALJ Master File, Exh. 2 at 3.

Based upon the specific guidance in PM AB-00-108, the Council finds it reasonable that "a glucose monitoring service must be performed in accordance with laboratory coverage criteria to qualify for *separate payment* under the Medicare laboratory benefit." ALJ Master File, Exh. 2 at 3 (emphasis supplied). As part of "laboratory coverage criteria" the glucose test results must be reported to the physician promptly for use in the treatment of a patient/beneficiary. ALJ Master File, Exh. 2 at 3. As noted above, only aberrant test results were reported to the treating physicians. This long-standing policy predates, and is not inconsistent with, the more specific certification requirements in the amended 42 C.F.R. § 424.24(f). The regulation was intended only to clarify and strengthen program criteria. See, e.g., 71 Fed. Reg. 69624, 69704-69705 (Dec. 1, 2006).

Moreover, the appellant asserts that in "each sampled claim, the home health employee was not supervising or assisting the patient in self-testing, but was administering the blood glucose test 'in accordance with laboratory cover criteria' per orders from the patients' physicians." Exh. MAC-1 at 7, ¶15. However, it is not clear from the record that the beneficiaries did "not maintain glucose monitoring device," as the PSC found. Program Memorandum AB-00-108 explicitly establishes a two-prong prerequisite for approval of a blood glucose testing as a Part B laboratory service; a patient must "not administer" daily or weekly blood glucose monitoring and must not "maintain" *i.e.*, own and use, a glucose monitoring device.

The appellant did not challenge the ALJ's conclusions regarding liability, under section 1879 of the Act or eligibility for waiver of recoupment, under section 1870(b) of the Act. Accordingly, the appellant remains liable for the resulting noncovered costs and is not entitled to a waiver of recoupment of the overpayment.

Based upon the foregoing analysis, the Council concludes that **none** of the blood glucose tests at issue before the ALJ are covered under Medicare Part B. The Council leaves undisturbed the QIC's limited coverage findings. The Medicare contractor will recalculate the overpayment in a manner consistent with this decision. The ALJ's decision is reversed.

MEDICARE APPEALS COUNCIL

/s/ Clausen J. Krzywicki  
Administrative Appeals Judge

/s/ Gilde Morrisson  
Administrative Appeals Judge

April 24, 2012