

DEPARTMENT OF HEALTH AND HUMAN SERVICES
DEPARTMENTAL APPEALS BOARD

DECISION OF MEDICARE APPEALS COUNCIL
Docket Number: M-10-2001

In the case of

Claim for

American Home Podiatry
(Appellant)

Supplementary Medical
Insurance Benefits (Part B)

(Beneficiaries)

(HIC Number)

CIGNA Government Services
(Contractor)

(ALJ Appeal Number)

The Administrative Law Judge (ALJ) issued a decision dated November 17, 2008, which concerned an overpayment stemming from claims billed for podiatry services provided to 42 beneficiaries in 2004 and 2005.¹ The ALJ issued a partially favorable decision, finding that, for some claims, the contractor's overpayment demand was appropriate. See, e.g., decision attachment (Dec. Att.) at 1-2.² In other cases, the ALJ found that the records supported Medicare coverage for the podiatric services provided. See, e.g., Dec. Att. at 16. The ALJ further found the appellant liable for the "amount in controversy leftover [sic] from this judgment". Decision (Dec.) at 14. Through counsel, the appellant asked the Medicare Appeals Council to review this action.

¹ See Appendix A for a list of beneficiaries, health insurance claim numbers and Dates of Service.

² The ALJ issued a fourteen page decision which the Council will identify as "the decision" (Dec.). The ALJ also issued a 71-page "Decision Attachment" which the Council will identify as "Dec. Att.".

The Medicare Appeals Council (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). The Council enters the following exhibits (Exhs.) into the record:

MAC-1: Appellant's request for review, dated January 16, 2009.

MAC-2: "Order of [the Council] Remanding Case to [the ALJ]" (Order), dated August 14, 2009.

The Council has considered the full record and the exceptions in the appellant's request for review, and as explained more fully below, the Council hereby modifies in part and reverses in part the ALJ's decision. The Council concludes that, for all beneficiaries except A.G., M.H. and L.M., the appellant's exceptions present no basis for changing the ALJ's conclusion that the podiatry services at issue are not covered by Medicare. However, the Council modifies the ALJ's decision to present additional support, including medical testimony of Drs. Goldsmith, Luvison and Ramoska, as to why the claims for these beneficiaries are not covered by Medicare. For beneficiaries A.G., M.H., and L.M., the Council reverses the ALJ's favorable decisions finding that the medical documentation in each record lacks support to find Medicare coverage. The Council further issues a favorable decision for one service for beneficiary L.I.

DISCUSSION

I. The ALJ rightfully denied the appellant's requests for subpoenas.

In its request for review, the appellant contends that the ALJ did not address the issues of subpoenas. Specifically, the appellant states that the decision lacks mention of the ALJ's order to deny the appellant's request that CMS, through its contractors, obtain medical documentation from the nursing facilities at which the beneficiaries resided at the time the appellant provided the services at issue. Exh. MAC-1 at 17, referencing the ALJ's Pre-Hearing Order, dated July 24, 2008, Exh. 17.

Discovery is permissible only when the CMS elects to participate in the hearing as a party. 42 C.F.R. § 405.1037. The

regulations provide that subpoenas may be issued after a party has sought, but has not received, discovery and only then:

[w]hen it is reasonably necessary for the full presentation of a case, the [Council] may, on its own initiative or at the request of a party, issue subpoenas requiring a party to make books, records, correspondence, papers, or other documents that are material to an issue at the hearing available for inspection and copying.

42 C.F.R. §§ 405.1036(f)(1), 405.1036(f)(4), *see also* 42 C.F.R. §§ 405.1037, 405.1122(d)(1) and 405.1122(d)(4)(i).

At no level of adjudication has discovery previously been initiated; and in this matter, neither CMS nor its contractors have elected to participate as parties. 42 C.F.R. §§ 405.906, 405.1012. For these reasons, the Council finds that the appellant's requests for subpoenas to direct that AdvanceMed, CIGNA and the QIC obtain nursing home records were rightfully denied. Further, as the Council finds below, the appellant, not the contractor, has the burden of proof. The appellant may not seek a subpoena in order to shift that burden.

II. The Burden to Provide Sufficient Documentation for Medicare Coverage for Podiatry Services.

The majority of the appellant's argument to the Council is that

- CMS was best positioned to secure the applicable medical records,
- that it was precluded by the Health Insurance Portability and Accountability Act of 1996 (HIPAA) from accessing the relevant records, and
- that CMS was negligent in failing to get the necessary documentation in pursuit of its audit of the appellant.

Exh. MAC-1 at 7, 9-13.

The appellant concedes that it made no attempt to procure necessary medical documentation from nursing homes in support of Medicare coverage. Exh. MAC-1 at 14-17, *reference also pre-hearing CD, May 5, 2008, at 1:15:52 - 1:16:33, hearing CD at 10:47:44 - 10:48:13.* Standing alone, the failure to even attempt to obtain the records undercuts the argument that it

would have been impossible to obtain the records. In any case, as a matter of law, the appellant has the burden of proving entitlement to payments received, and may not shift the burden of proof to CMS or its contractors.

Section 1833(e) of the Act prohibits payment to any provider of services unless there has been furnished such information as may be necessary in order to determine the amounts due.³ It is the responsibility of the provider or supplier 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). The Administrative Procedure Act also clearly places the burden of proof on the appellant. 5 U.S.C. § 556(d).

The CIGNA Part B January 7, 2003, newsletter states

Documentation on File

Podiatrist may submit claims using the Q7, Q8 or Q9 modifiers to indicate to the carriers the findings they have made on the patient's condition. This does not relieve them of the responsibility of maintaining documentation on file. This documentation must be maintained and made available to the carriers at their request. Failure to produce appropriate documentation may result in denial of the claim. Podiatrists should consult their carriers to verify that they are meeting the documentation requirements for Medicare claims.

CIGNA Part B January 7, 2003, newsletter, "Requirement for Payment of Medicare Claims for Foot and Nail Care Services", Exh. 8 at attachment 14. (Emphasis added).

Further, the Medicare Part B Reference Manual, provides

Services for which medical necessity may be questioned should be documented with additional clinical evidence. This evidence may include office records, physician notes or diagnoses characterizing the patient's physical status as being of such an acute or severe nature that more frequent services are appropriate.... All records must be available to the

³ The Secretary of Health and Human Services has full authority under section 205(a) to collect information as incorporated by section 1871 of the Act.

carrier upon request. Please maintain your patient's records on file in the event of a review.

Exh. 8 at attachment 17. (Emphasis added).

Thus, the burden to provide documentation lies with the provider or supplier of service; not with Medicare or its contractors. The appellant could have conditioned treatment on the beneficiary's express consent to release medical records, as is frequently the case.

The appellant further cites numerous sections of the Tennessee annotated code and "the federal law," specifically HIPAA, in its argument that the nursing home records were subject to numerous laws which essentially prevented the "removal of those records from the [skilled nursing facilities]". Exh. MAC-1 at 7. The appellant states that while CMS could have obtained the patients' complete medical records, it could not do so. *Id.* at 8.

The record indicates that AdvanceMed provided the appellant with information that "[HIPAA] permits disclosure of [PHI] without beneficiary authorization to carry out treatment, payment or health care authorizations". Exh. 1 at 1. AdvanceMed's statement is supported by the applicable legal authorities and guidance made available by the Office of Civil Rights (OCR), the sole entity within the Department of Health and Human Services (HHS) with jurisdiction over HIPAA enforcement.⁴ The OCR issued the *Standards for Privacy of Individually Identifiable Health Information* (e.g. the Privacy Rule) to implement HIPAA, which provides guidelines for the use and disclosure of an individual's protected health information (PHI) by covered entities subject to the Privacy Rule.⁵ According to the "Summary of the HIPAA Privacy Rule," a covered entity may not use or disclose PHI, except either: (1) as the Privacy Rule permits or requires; or (2) as the individual who is the subject of the information authorizes in writing. See also 45 C.F.R.

⁴ The Council notes that it is responding to the appellant's numerous claims about the legal actions it could take under the Privacy Rule. The Council makes no claims of jurisdiction over HIPAA matters. Within HHS, the Office for Civil Rights (OCR) has responsibility for implementing and enforcing the Privacy Rule.

⁵ See, e.g., Summary of the HIPAA Privacy Rule, Introduction, available at <http://www.hhs.gov/ocr/privacy/hipaa/understanding/summary/index.html>, last visited May 12, 2011.

§ 164.502(a). Generally, payment is one of the exceptions for which a covered entity is explicitly permitted to use and disclose PHI without an individual's authorization. 45 C.F.R. §§ 164.502(a)(1), 154.508. A covered entity may disclose PHI for the treatment activities, including payment, of another covered entity (e.g., the appellant) if both covered entities have a relationship with the individual at the time the services were provided and that the PHI pertains to that relationship.⁶ 45 C.F.R. § 164.506. The Tennessee annotated code explicitly states that its restrictions on the use of PHI does not imply that there are limitations that preclude treatment and health care transactions. See generally Tenn. Code Ann. § 68-11-312. Further, state laws that may be contrary to the Privacy Rule are preempted by the federal requirements, which means that the federal requirements will apply. 45 C.F.R. § 160.203.

Thus, the Council finds that the appellant had the burden to provide sufficient documentation to support its claims for Medicare coverage, but chose not to request the records. Accordingly, the Council finds that, since the appellant has the burden of proof, CMS was not negligent in not obtaining the pertinent medical records for the appellant.

III. Medicare Coverage for Podiatry Services provided to Nursing Facility Patients

BACKGROUND

AdvanceMed, a CMS PSC, selected a random sample of 42 beneficiaries, involving 42 medical records and 106 line items. Exh. 3 at 4. The PSC determined that some of the sample claims were not medically reasonable and necessary, resulting in an actual overpayment of \$3,112.07. *Id.* The PSC then extrapolated the sample results to the universe of claims, resulting in a total assessed overpayment of \$318,687 for the period at issue. *Id.* On December 15, 2006, CIGNA Government Services (CIGNA), issued a demand for repayment of for the claims the PSC determined had been billed in error. Exh. 4 at 1.

The contractor upheld the extrapolated overpayment. Exh. 6. The appellant then appealed to the Qualified Independent

⁶ See also "Uses and Disclosures for Treatment, Payment and Health Care Operations", OCR HIPAA Privacy Summary, April 2003, available at <http://www.hhs.gov/ocr/privacy/hipaa/understanding/coveredentities/usesanddisclosuresfortpo.html>.

Contractor (QIC), and the QIC subsequently issued an unfavorable reconsideration decision concurring with CIGNA and AdvanceMed that specific claims were not covered by Medicare. Exh. 10 at 3.

The QIC identified the separate reason for denials in nine unique categories:

- A. The medical records lack specific order for services requested from another provider;⁷
- B. There were no progress notes from the ordering physician which reflected the medical necessity for ordering the services;
- C. The order for a consult provided for these services lacks a provider signature;
- D. The orders for the services provided in the case file were non-specific;
- E. The available progress notes indicate "no acute infection;" therefore, the services are not covered by Medicare;
- F. The order for podiatry was not written by a physician;
- G. The documentation in the record does not indicate significant, separately identifiable service from the podiatry procedure performed;
- H. The order for podiatry consult was inappropriately altered and cannot be accepted as original medical documentation following the program integrity guidelines set forth in the Program Integrity Manual; and
- I. No orders for services in a nursing home were included in the beneficiary case file.

Upon further appeal, the ALJ determined that the PSC's statistical sampling and subsequent extrapolation methodologies were valid. Dec. at 12-13. The appellant does not dispute the validity of the PSC's statistical sampling and subsequent extrapolation methodologies in its request for Council review. Thus, the Council adopts the ALJ's determination that the statistical sample was valid. Dec. at 12-13, *see also* 42 C.F.R. § 405.1112(c).

The ALJ issued a decision on claims that were previously covered and that the QIC "did not consider". *See, e.g.,* Dec. Att. at 2;

⁷ The QIC references LCD 9616, *PRN Orders in Nursing Home for Services and Consultations #9616*, which was retired on January 1, 2003. Exh. 24.

see also Program Safeguard Contractor (PSC) data compact disk (CD), "Attachment 5-MR Results Spreadsheet," Exh. 15. The applicable regulations state that when an appeal involves an overpayment, in which a statistical sample was used to extrapolate an overpayment amount, an ALJ must base his or her decision on a review of the entire statistical sample. See 42 C.F.R. 405.1064. Generally, the issues before the ALJ include all the issues brought out in decisions below. 42 C.F.R. § 405.1032(a). The ALJ may consider a new issue at the hearing if he or she notifies all the parties about the new issue any time before the start of the hearing. 42 C.F.R. § 405.1032(b). The appellant was made aware that the entire universe of claims would be at issue before the ALJ. Notice of Hearing, Exh. 18 at 2; reference also pre-hearing CD, May 5, 2008, at 1:07:35-1:07:45. Thus, the Council gives *de novo* review to the entire universe of claims that was before the ALJ.

The ALJ found that some of the services at issue met Medicare coverage and documentation requirements, and thus, had not been overpaid. See, e.g., beneficiary M.H., Dec. Att. at 44-45. Alternatively, the ALJ determined that other claims were not covered by Medicare, for the same denial reasons given by the QIC, and that they were correctly identified by the PSC as an overpayment. See, e.g., beneficiary N.B., Dec. Att. at 4-5.

On, August 14, 2009, the Council vacated the ALJ's November 17, 2008, decision because the Council, despite several attempts, was unable to retrieve the complete record from CMS. See Exh. MAC-2 at 1. Specifically, the case file lacked the "Master Exhibits" folder referenced in the ALJ's decision. *Id.* The Council therefore remanded the case to an ALJ to retrieve the missing files or for further proceedings. *Id.* The ALJ held a subsequent hearing to offer the appellant an opportunity to supplement the record and to recreate the case file. Reference pre-hearing CD, September 8, 2010, at 1:01:28 - 1:06:29. On September 27, 2010, the Council received a recreated case file; thus, the Council now vacates its previous Order of Remand dated August 14, 2009.

DE NOVO REVIEW

As a preliminary matter, the appellant asserts that the appellant was not subject to the same documentation requirements in previous audits, including an audit undertaken in 2000. Exh. MAC-1 at 3, 18. The appellant also argues that the ALJ failed

to discuss the substantive expert testimony given by the appellant's witness, Dr. Harry Goldsmith, M.D.. *Id.* at 16, reference also hearing CD at 1:13:47 - 02:40:12.

The Council conducts a *de novo* review of ALJ decisions, which includes a review of the contractors' determinations. Both substantive and procedural matters espoused in prior contractor and/or ALJ decisions are not precedential. Thus, findings from previous audits are neither material nor binding in the present case.

In reviewing the ALJ's decision, the Council finds that the ALJ relied extensively upon the medical documentation submitted for each beneficiary at issue. See Dec. at 4; see also Dec. att. at 1-71. Having reviewed the testimony of the medical experts, the Council finds that the experts' testimony was based on the medical documentation in the record. *Reference generally* Hearing CD. However, as stated above, the Council undertakes a *de novo* review which includes the medical documentation in each beneficiary's case file and the expert testimony given at the hearing by Drs. Goldsmith, Luvison and Ramoska.

APPLICABLE LEGAL AUTHORITIES

Medicare does not cover physician's services related to routine foot care, treatment of flat foot conditions, or the treatment of subluxations of the foot. Section 1862(1)(13) of the Social Security Act (the Act). Routine foot care is defined as the cutting or removal of corns or calluses, the trimming of the nails, routine hygienic care and any service performed in the absence of localized illness, injury or symptoms involving the feet. 42 C.F.R. 411.15(1). Exceptions include treatment of warts, mycotic toenails and the presence of systematic conditions:

C. Exceptions to Routine Foot Care Exclusion

1. Necessary and Integral Part of Otherwise Covered Services

In certain circumstances, services ordinarily considered to be routine may be covered if they are performed as a necessary and integral part of otherwise covered services, such as diagnosis and treatment of ulcers, wounds, or infections.

2. Treatment of Warts on Foot

The treatment of warts (including plantar warts) on the foot is covered to the same extent as services provided for the treatment of warts located elsewhere on the body.

3. Presence of Systemic Condition

The presence of a systemic condition such as metabolic, neurologic, or peripheral vascular disease may require scrupulous foot care by a professional that in the absence of such condition(s) would be considered routine (and, therefore, excluded from coverage). Accordingly, foot care that would otherwise be considered routine may be covered when systemic condition(s) result in severe circulatory embarrassment or areas of diminished sensation in the individual's legs or feet. (See subsection A.) In these instances, certain foot care procedures that otherwise are considered routine (e.g., cutting or removing corns and calluses, or trimming, cutting, clipping, or debriding nails) may pose a hazard when performed by a nonprofessional person on patients with such systemic conditions.

4. Mycotic Nails

In the absence of a systemic condition, treatment of mycotic nails may be covered.... The treatment of mycotic nails for a nonambulatory patient is covered only when the physician attending the patient's mycotic condition documents that (1) there is clinical evidence of mycosis of the toenail, and (2) the patient suffers from pain or secondary infection resulting from the thickening and dystrophy of the infected toenail plate. For the purpose of these requirements, documentation means any written information that is required by the carrier in order for services to be covered. Thus, the information submitted with claims must be substantiated by information found in the patient's medical record. Any information, including that contained in a form letter, used for documentation purposes is subject to

carrier verification in order to ensure that the information adequately justifies coverage of the treatment of mycotic nails.

Medicare Benefit Policy Manual (MBPM), (CMS Pub. 100-02), Ch. 15, § 290-C; see also 42 C.F.R. 411.15(1).

In the absence of a National Coverage Determination (NCD), the Medicare contractor is responsible for determining whether an item or service is reasonable and necessary. See preface to Coverage Issues Manual, *reprinted at* 54 Fed. Reg. 34555 (August 21, 1989). The Medicare contractor develops program guidance and may issue a local coverage determination (LCD) applicable to its service area.

NCDs are binding on fiscal intermediaries, carriers, QICs, ALJs and the Council. 42 C.F.R. § 405.1060(a)(4). Neither ALJs nor the Council are bound by CMS program guidance, such as program memoranda, manual instructions, and LCDs, but they will give substantial deference to those policies if they are applicable to 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 rationale for not following that policy must be explained. 42 C.F.R. § 405.1062(b).

CIGNA issued a LCD in effect for the dates of service at issue, *Medicare Part B Coverage of Services and Procedures in Nursing Facilities #9708*, LCD 9708. Exh. 23. This LCD contains an "Indications of Limitations of Coverage and/or Medical Necessity" section which states "this carrier will not cover any service or procedure that is performed on a resident of a [skilled nursing facility] unless:"

- The resident's attending physician evaluates the resident and authorizes the order for the service or procedure, or for the referral of the resident to another provider specialty.
- A named physician, whose attendance is requested only by the resident or the resident's interested family member or legal guardian, evaluates the resident and authorizes the order for the service or procedure. The attending physician must be notified of any change in resident's physical, mental or psychosocial status, or of the need to alter the resident's treatment significantly.

The LCD states the "reasons for denial" and "documentation requirements" are

Reasons for Denials

- When a service or procedure is not clearly documented in a *resident's medical record* with respect both to its medical necessity and nature.
- When a resident's attending physician does not evaluate the resident and authorize the order for a service or procedure or for a referral of a resident to another provider specialty.
- When another physician, whose attendance is required by a resident or a resident's interested family member or legal guardian, does not evaluate the resident and authorize the order for the service or procedure.
- When a "PRN" or "standing order" is written for any provider specialty or for any routine screening service, either on the physician's order sheet integral to a *resident's comprehensive care plan*, or elsewhere in the *resident's medical record*.

Documentation Requirements

The medical necessity for the nature of each service or procedure must be clearly documented by a physician, and this physician's authorization of the order for the service or procedure or for referral of the resident to another provider specialty, must be clearly recorded in the resident's medical record.

See LCD 9708, Exh. 23 (emphasis supplied).

Further, the CIGNA "Podiatry Specialty Manual" provides that the attending/primary physician will be actively involved in all aspects of the care of the patient:

- The resident's attending physician must evaluate the resident and authorize the order for the service or procedure, or for the referral of the resident to another provider specialty; ...

- The physician progress note or order (documentation) needs to clearly state the specific problem, symptom(s), reason (medical necessity) for the order for the specialist's service....
- Medicare reimbursement will be denied when a "PRN" or "standing order" is written for any provider specialty or for any routine screening service on the physician's order sheet and there is no documentation of the evaluation of the problem by the attending physician.

CIGNA Medicare has determined that the resident must be evaluated by the attending physician or other physician requested by the resident in order to determine the services and procedures that meet the Medicare program requirements. Reimbursement for services and procedures performed as a result of an order initiated by the nursing staff or any other non-physician staff of the facility rather than subsequent to an evaluation by a physician will be denied.

CIGNA "Podiatry Specialty Manual", Nursing Facility Patients, March 2003, *referencing* the MBPM, Exh. 8 at attachment 10. See also MBPM, Ch. 15, § 290; LCD 9708, Exh. 23.

REVIEW OF CLAIMS

The claims for podiatry services were submitted under the following HCPCS/CPT codes:⁸

- 10060: incision and draining of abscess (e.g. carbuncle, suppurative hidradenitis, cutaneous or subcutaneous abscess, cyst, furuncle or paronychia); simple or single.
- 10140: incision and drainage of hematoma, seroma or fluid collection.

⁸ The Centers for Medicare & Medicaid Services (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).

- 11721: debridement of nail(s) by any method; 6 or more.
- 11730: avulsion of nail plate, partial or complete, simple; single.

The Council finds that the guidance available to the appellant at the time of service, specifically CIGNA LCD 9708, gave clear instruction concerning when Medicare will cover podiatric care provided to beneficiaries residing in a skilled nursing facility. Thus the Council finds no reason to deviate from the coverage guidance in the LCD, Medicare manual and various CIGNA policy articles then effective.⁹

Similar to the findings of the adjudicators at levels below, the Council finds that the medical documentation in each beneficiary's medical record lacks the prerequisite specificity to support Medicare coverage. The Council notes that while one deficiency is sufficient to deny Medicare coverage, many of the claims at issue have multiple deficiencies.¹⁰

A. Beneficiary Case Files that Lack Orders, or Contain Undated Orders, for Podiatric Services

Dr. Goldsmith, the appellant's medical expert, testified that Medicare coverage is indicated for established podiatric patients without an order and/or referral from an attending physician. Reference hearing CD at 01:38:07 - 01:40:22. The Council, however, relies on the applicable legal authority which directly contradicts Dr. Goldsmith's opinion. The applicable Medicare regulation requires that the attending physician must evaluate the resident and authorize the order for the podiatric service or procedure for each date of service. LCD 9708, Exh. 23; see also CIGNA "Podiatry Specialty Manual", Nursing Facility Patients, March 2003, referencing the MBPM, Exh. 8 § 10.

⁹ LCD 9708 was effective in its revised format for dates of service January 1, 2004, through the date of the carrier's transition to a Medicare Administrative Contractor (MAC) on January 7, 2009. For more information about the MAC transitions, visit Medicare Contracting Reform at www.cms.gov/medicarecontractingreform.

¹⁰ The Council notes that because the claims have multiple deficiencies, beneficiaries are listed in multiple categories. See Appendix B for a detailed listing of each beneficiary and the categories for which the associated podiatric claims are denied, except beneficiary L.I. and L.M. who receive individual review.

The record for beneficiary C.Mi. does not contain an order for podiatric treatment. The records for beneficiaries N.B., J.Br. and R.M. contain undated orders; thus, the Council cannot ascertain from these records whether a physician initiated an order for podiatric service prior to the service being provided to the beneficiaries at issue.

The record for beneficiary H.A. indicates that the appellant provided podiatry and E/M services to the beneficiary on July 29, 2004. Beneficiary H.A. case file, Exh. 10 at 1. The record also contains a podiatry order which states "podiatrist to eval/treat for mycotic nails" for "charting dates 08/01/04 through 08/31/04". *Id.*, Exh. 9 at 1. Thus, beneficiary H.A.'s file lacks a valid order for the date of service at issue.

Accordingly, the Council concurs with the ALJ's conclusion that the medical documentation for beneficiaries H.A., N.B., J.Br., C.Mi. and R.M. is insufficient to support Medicare coverage.

B. Beneficiary Case Files that Lack Orders for Podiatric Services Signed by a Physician

The records for beneficiaries B.B., C.Bre., E.B., W.B., A.G., C.G., Q.G., J.L., C.Mu., R.M., D.R., V.S., R.T., C.T. and J.W. lack orders for podiatry services that are signed by an attending physician. Dr. Ramoska, one of the two treating podiatrists whose claims are at issue, testified that orders for podiatrist services were valid for Medicare payment only when signed by the attending physician ordering the services. *Reference* hearing CD 10:02:16 - 10:02:59. During the hearing, the appellant's counsel later contradicts this testimony when stating that the applicable regulations do not require that the attending physician sign the order. *Id.* at 10:51:48 - 10:52:22. Dr. Goldsmith testified that QIC should not have denied claims for the lack of a physician's signature because the order signed by a non-physician staff member, such as a nurse, is in effect once initiated by the physician (e.g. a telephone order). *Reference* hearing CD at 01:55:17 - 01:59:33.

The regulations in the applicable LCD and Podiatry Specialty Manual explicitly state that

- The medical necessity for the nature of each service or procedure must be clearly documented by a physician, and this physician's authorization of the

- order for the service or procedure or for referral of the resident to another provider specialty, must be clearly recorded in the resident's medical record; (LCD 9708, Exh. 23) and
- reimbursement for services and procedures performed as a result of an order initiated by the nursing staff or any other non-physician staff of the facility rather than subsequent to an evaluation by a physician will be denied. (CIGNA "Podiatry Specialty Manual", Nursing Facility Patients, March 2003, Exh. 8 at attachment 10).

In these cases, the orders for podiatry services were signed by either a licensed practical nurse or registered nurse and not a physician. See, e.g., beneficiary B.B. case file, Exh. 10 at 1. Without evidence of an attending physician's signature, the records lack proof that a physician, and not a nurse, initiated the order for podiatry services.¹¹ The Council notes that Medicare does not exclude telephone orders taken by a nurse, but will deny claims for podiatric services based on orders that lack an appropriate signature that indicates a qualified physician initiated the service. The Council considered the physicians' testimony regarding orders signed by nursing facility staff other than the attending physician. Specifically, Dr. Ramoska testified that after the physician gives the order to the nurse, he or she later signs the order and that the original, more legible, files remain at the nursing facility where the beneficiaries resided. Reference hearing CD at 10:02:16 - 10:02:59, 10:18:27 - 10:19:40. The Council finds that while the appellant attests to the presence of physician signatures in the documentation maintained at the nursing facilities, the records that the appellant provided lack this evidence.

Therefore the Council concurs with the ALJ's conclusion that the medical documentation for beneficiaries B.B., C.Bre., E.B., W.B., C.G., Q.G., J.L., C.Mu., R.M., D.R., V.S., R.T., C.T. and J.W. is insufficient to support Medicare coverage. The Council reverses the ALJ's conclusion for beneficiary A.G. finding, as stated above, the order lacks the prerequisite attending physician's signature for Medicare coverage.

¹¹ Reference Dr. Goldsmith's testimony that it is standard practice for a physician to sign his or her initials next to items of service to authorize them as opposed to "standing orders" that may be "suggestions" for patient care. Hearing C.D. at 01:24:54 - 01:27:46

C. Beneficiary Case Files that Contain Standing Orders for Podiatric Services

In reviewing the recording of the ALJ hearing, Dr. Ramoska testified that he was aware that periodic, non-standing orders were required for Medicare coverage of podiatric claims. Reference hearing CD 9:56:15-9:56:23. Dr. Goldsmith testified that usage of the term "PRN," which he defined as "as needed," does not bar coverage and states that "standing orders" are those that are created prior to the attending physician's evaluation of a beneficiary residing in a nursing facility. *Id.* at 01:24:54 - 01:28:49, 01:41:41 - 01:42:33.

Case files for beneficiaries S.B., E.D., C.F., J.F., M.F., J.H., L.Harb., L.Harr., J.P. and P.R. contain orders that state, for example, "[the beneficiary] may have podiatry care" (see, e.g., beneficiary E.D. case file, Exh. 13 at 8) or "podiatry to see [the beneficiary] every 2-3 months for painful mycotic nail and for nail trimming" (see, e.g., beneficiary S.B. case file, Exh. 9 at 1).

Despite Dr. Goldsmith's testimony, the Council finds that standing orders, e.g., orders for podiatric services "as needed," "PRN" or with a recurrent time frame, are insufficient for Medicare coverage pursuant to the applicable legal authorities. The governing LCD states that claims will be denied for Medicare coverage when a "PRN" or "standing order" is written for any podiatric service, either on the physician's order sheet integral to a resident's comprehensive care plan, or elsewhere in the resident's medical record. LCD 9708, Exh. 23. CIGNA's Podiatry Specialty Manual instructs that podiatric claims will be denied when a "PRN" or "standing order" is written for specialty or screening service on the physician's order sheet without supporting documentation of the evaluation of the problem by the attending physician. CIGNA "Podiatry Specialty Manual", Exh. 8 § 10.

Therefore the Council concurs with the ALJ's conclusion that the medical documentation indicates the orders for beneficiaries S.B., E.D., C.F., J.F., M.F., J.H., L.Harb., L.Harr., J.P. and P.R. were standing orders and thus insufficient to support Medicare coverage.

D. Beneficiary Case Files that lack Supporting Documentation for Medicare Coverage of Podiatric Services

In its request for review, the appellant claims that the ALJ erred in concluding that "the progress notes generated by a podiatrist to document the medical necessity and provision of services are *per se* insufficient documentation according to Medicare rules and regulations." Exh. MAC-1 at 2-3. Additionally, the appellant attests that the ALJ ignored the beneficiaries' underlying disease states detailed in the extensive medical reports that were prepared by either Dr. Luvison or Dr. Ramoska on the dates of service at issue, (*Id.* at 5), that every record has sufficient documentation as indicated by the attending podiatrist, (*Id.* at 12), and that "Medicare rules and regulations do not require documentation other than by the treating specialist" (*Id.* at 14). Reference also hearing CD at 10:48:14 - 10:49:26.

The medical necessity for, and nature of, each service or procedure must be clearly documented by a physician, and this physician's authorization of the order for the service or procedure, must be clearly recorded in the [SNF resident's] medical record. LCD 9708, Exh. 23. Further, CIGNA guidance provides that the attending physician's order be supported by his or her progress notes or other documentation which clearly state the specific problem, symptom(s) and the reason for the order. Exh. 8 at attachment 10.

Additionally, CIGNA's Medicare Part B Reference Manual, provides

[s]ervices for which medical necessity may be questioned should be documented with additional clinical evidence. This evidence may include office records, physician notes or diagnoses characterizing the patient's physical status as being of such an acute or severe nature that more frequent services are appropriate.

Id. at attachment 17.

The medical documentation for beneficiaries N.A., B.B., C.Bro., E.B., J.Bo., N.B., S.B., W.B., D.C., Z.C., J.D., J.F., M.F., A.G., C.G., F.G., Q.G., L.Harr., J.L., M.H., C.Mu., M.M., R.Me., R.Mo., J.P., R.P., D.R., P.R., V.S., R.T. and J.W. are comprised

of 1) an order for podiatry services,¹² and 2) the appellant's own report, from the dates of service at issue, detailing the beneficiaries' medical history, the physical condition, the treatment given and the plan for future care. See, e.g., beneficiary C.Bro. case file, Exh. 10 at 1.

The Council finds that the ALJ's individual decision included comprehensive background on each beneficiary. See, e.g., beneficiary C.Bro., Dec. Att. at 16. The Council concurs with the ALJ that while the appellant made this information available in the record through its own podiatry reports; the applicable legal authorities direct that the beneficiaries' records must contain supporting documentation from an attending physician charged with the primary care of the nursing facility resident. See LCD 9708, Exh. 23. (Emphasis added).

Therefore the Council concludes that the medical documentation present in the case files for beneficiaries N.A., B.B., C.Bro., E.B., J.Bo., N.B., S.B., W.B., D.C., Z.C., J.D., J.F., M.F., A.G., C.G., F.G., Q.G., L.Harr., J.L., M.H., C.Mu., M.M., R.Me., R.Mo., J.P., R.P., D.R., P.R., V.S., R.T. and J.W. lacks medical documentation from the beneficiaries' attending physicians and therefore is insufficient to support Medicare coverage according to the applicable legal authorities. The Council reverses the ALJ's conclusion for beneficiaries C.Bro. and M.H. finding, as stated above, that the records for these beneficiaries lack supporting documentation necessary for Medicare coverage.

E. Remaining Beneficiaries L.I. and L.M.

For the beneficiaries listed above in sections A., B., C. and D., the Council has established that the podiatric claims at issue cannot be covered by Medicare because the individual medical records lack the physician orders and documentation that meet the prerequisites for Medicare coverage as set forth in the applicable legal authorities. Thus, the Council now reviews the podiatric claims for the two remaining beneficiaries who, unlike the beneficiaries listed above, have additional medical documentation that warrants individual review: beneficiaries L.I. and L.M..

¹² As established in the prior discussions labeled A., B., and C., some orders for podiatry services are insufficient to meet the threshold documentation requirements for Medicare coverage.

Beneficiary L.I.

The appellant submitted a claim for podiatric services provided to the beneficiary on October 7, 2004. Upon post-payment review, the PSC determined that only the claim for the debridement of 6 or more nails, HCPCS/CPT code 11721, was correctly paid. See PSC CD, "Attachment 5 - MR Results Spreadsheet," Exh. 15. The evaluation and management (E/M) claim, HCPCS/CPT code 99312-25, was denied.

The carrier upheld the PSC's determination and, upon further review, the QIC also denied the claim for an E/M visit on the date of service at issue. Exh. 10. The QIC did not evaluate Medicare coverage for HCPCS/CPT code 11721. *Id.* The QIC determined that the medical documentation lacked evidence to show that the beneficiary's physician ordered the E/M services at issue and that progress notes supporting Medicare coverage were absent. *Id.* at 25. The ALJ determined that there was no supporting documentation from the beneficiary's attending physician that indicated the beneficiary had a condition that required podiatry services. Dec. att. at 45-46.

The appellant did not offer testimony regarding the E/M services or debridement procedure provided to the specific beneficiary at issue; however the appellant generally asserts that the medical documentation it provided is sufficient for Medicare coverage. Exh. MAC-1.

Debridement: 11721

Debridement by a podiatrist can be covered as an exception to routine foot care if

[t]he presence of a systemic condition such as metabolic, neurologic, or peripheral vascular disease may require scrupulous foot care by a professional that in the absence of such condition(s) would be considered routine (and, therefore, excluded from coverage). Accordingly, foot care that would otherwise be considered routine may be covered when systemic condition(s) result in severe circulatory embarrassment or areas of diminished sensation in the individual's legs or feet. (See subsection A.) In these instances, certain foot care procedures that otherwise are considered routine (e.g., cutting or

removing corns and calluses, or trimming, cutting, clipping, or debriding nails) may pose a hazard when performed by a nonprofessional person on patients with such systemic conditions.

MBPM, Ch. 15, § 290-C; see also 42 C.F.R. 411.15(1).

The MBPM lists arteriosclerosis as one of the examples of systemic conditions that could indicate that debridement by a podiatrist is covered by Medicare. MBPM, Ch. 15, § 290-D.

The beneficiary's treating physician, Dr. Vegors, evaluated her the day before the podiatric services at issue. Beneficiary L.I. case file, Exh. 10 at 1. Dr. Vegors noted that "the extremities show a trace of ankle edema on the left and none on the right and poor peripheral pulses." *Id.* The beneficiary had diagnoses of pneumonia, hypertension, cerebral vascular disease, muscle weakness, osteoporosis, hypertensive cardiovascular disease, senile dementia and arteriosclerotic heart disease. *Id.*, Exh. 11 at 1. The record indicates that beneficiary L.I. was referred for a podiatry consult "for hypertrophic nails". *Id.*, Exh. 12 at 1.

The Council finds that the record contains sufficient documentation of diminished circulation due to diffuse vascular disease to support Medicare coverage for debridement on the date of service at issue.

E/M service: 99312-25

Dr. Goldsmith testified that E/M claims are only appropriate on the same date of service as the podiatry service if there was an identifiably separate service provided and the additional service was billed with a "-25" modifier. *Reference* hearing CD 01:59:34 - 02:06:24, 02:13:28 - 02:15:44.

The appellant claimed E/M services at the 99312 level:

- Subsequent nursing facility care, per day, for the evaluation and management of a new or established patient, which requires at least two of these three key components:
 - 1) An expanded problem focused interval history;
 - 2) an expanded problem focused examination; and

3) medical decision making of moderate complexity.

Counseling and/or coordination of care with other providers or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the patient is responding inadequately to therapy or has developed a minor complication. Physicians usually spend 25 minutes at the bedside and on the patient's facility floor or unit.

CMS has issued documentation guidelines for evaluation and management services.¹³ The 1997 Documentation Guidelines describe several different types of physician examinations and also provide content and documentation requirements for examinations directed at certain medical systems or body areas.

By definition, the beneficiary would need to have developed a complication, or responded inadequately to therapy, and required two of the three elements: an expanded problem focused interval history, an expanded problem focused examination and/or medical decision making of moderate complexity. The record indicates that the beneficiary was referred to the podiatrist for hypertrophic nails and had been experiencing bilateral foot pain. See beneficiary L.I. case file, Exhs. 11, 12. Dr. Ramoska noted that the beneficiary had "no reoccurrence of the ingrown nail from last visit per my excellent treatment". *Id.*, Exh. 11 at 1. Further, the record indicates that the beneficiary experienced "no digital abnormalities" other than "very elongated," "thickened" and "hypertrophic nails" that "could lead to medical complications if left untreated." *Id.* Further, Dr. Ramoska noted there were "no other digital abnormalities or systemic illness could be found to cause pain in the nail area." *Id.*

Having reviewed the available medical documentation, the Council concurs with the ALJ that the record lacks supporting documentation for Medicare coverage of the E/M service. Dr. Ramoska's medical documentation of the services he provided do not support subsequent nursing facility care at the level billed. The records do not indicate that the beneficiary had a complication or an ongoing problem to support coverage at the

¹³ The E/M documentation guidelines are available from the CMS website at http://www.cms.gov/MLNEdWebGuide/25_EMDOC.asp

E/M level claimed. Thus, the Council finds that the E/M service, claimed under HCPCS/CPT 99213-25, is not covered by Medicare.

Beneficiary L.M.

The appellant submitted a claim for podiatric services provided to the beneficiary on June 3, 2004. Upon post-payment review, the PSC determined that only the claim for the debridement of 6 or more nails, HCPCS/CPT code 11721, was correctly paid. See PSC CD, "Attachment 5 - MR Results Spreadsheet," Exh. 15. The two claims for single, partial or complete, avulsion of nail plate, HCPCS/CPT codes 11730-51-CC and 11730-CC, were denied.

The carrier upheld the PSC's determination and, upon further review, the QIC also denied the claim for the nail avulsion finding that the medical records lack evidence of nail infection or injected anesthesia. Exh. 10 at 25. The QIC did not evaluate Medicare coverage for HCPCS/CPT code 11721. *Id.* The ALJ determined that there was supporting documentation from the beneficiary's attending physician that indicated the beneficiary required avulsions and thus reversed the QIC and determined the appellant was not overpaid for the podiatry services at issue. Dec. att. at 48-49.

The appellant did not offer testimony regarding the podiatric services provided to the specific beneficiary at issue; however the appellant generally asserts that the medical documentation it provided is sufficient for Medicare coverage. Exh. MAC-1.

Debridement: 11721

As stated above, debridement by a podiatrist can be covered as an exception to routine foot care if there is the presence of a systemic condition which may be covered when systemic condition(s) result in severe circulatory embarrassment or areas of diminished sensation in the individual's legs or feet. MBPM, Ch. 15, § 290-C; see also 42 C.F.R. 411.15(1).

The record indicates that Dr. Luvison, one of the two treating podiatrists whose claims are at issue, received an order from the attending physician to "evaluate and treat thickened painful toenails." Beneficiary L.M. case file, Exh. 14 at 2. The record lacks indication from a beneficiary's treating physician concerning the need for debridement services or a description of

the beneficiary's condition. Thus, the Council finds that the record lacks support for the debridement service at issue.

Avulsion: 11730

Dr. Goldsmith testified that infection is "one of the least frequent reasons for avulsion" and that avulsion, without the presence of infection, is the standard of podiatric care. *Reference* hearing CD 01:16:19 - 01:17:49, 01:22:49 - 01:24:14.

As stated above, the MBPM further gives guidance on Medicare coverage for exceptions to routine foot care:

The treatment of mycotic nails for a nonambulatory patient is covered only when the physician attending the patient's mycotic condition documents that (1) there is clinical evidence of mycosis of the toenail, and (2) the patient suffers from pain or secondary infection resulting from the thickening and dystrophy of the infected toenail plate. For the purpose of these requirements, documentation means any written information that is required by the carrier in order for services to be covered.

MBPM, Ch. 15, § 290.

As stated above, Dr. Luvison received an order from the attending physician to "evaluate and treat thickened painful toenails." Beneficiary L.M. case file, Exh. 14 at 2. Dr. Luvison noted that the beneficiary experienced pain at the "ingrown right and left hallux nail" but that there was "no infection noted or reason for antibiotics (sic) warranted at this time." Exh. 16 at 1. While the Council takes into consideration Dr. Goldsmith's testimony that avulsion treatment is the podiatric standard of care, the Medicare guidelines for coverage categorize avulsion treatment, absent infection, as routine foot care which is not a Medicare benefit. MBPM, Ch. 15, § 290; *see also* 42 C.F.R. § 411.15(l). Accordingly, the Council reverses the ALJ's conclusions and finds that the avulsion services at issue are not covered by Medicare.

**LIMITATION ON LIABILITY and WAIVER OF RECOUPMENT OF OVERPAYMENT
- SECTIONS 1870 and 1879 of the Act**

In her decision, the ALJ found that the beneficiaries' records lacked evidence that the beneficiaries knew or could be expected to know that the services would not be covered by Medicare. Thus, the ALJ found the appellant liable for the "amount in controversy leftover [sic] from this judgment". Dec. at 14.

Regarding liability, the appellant asserts in the introduction but not in specific exceptions that

- it should have been determined that liability was waived because [the appellant] could not know and could not have been expected to know that the items and services were not reasonable and necessary and would not be paid. If the previous ALJ determined that medical necessity and the services performed could be satisfied by the documentation in the podiatric record, [the appellant] could not have been expected to conclude that additional records were needed from the [facilities at which it provided services]". Exh. MAC-1 at 4.
- and, to the "best of [its] knowledge, [the ALJ's decision] may be the only decision in the country holding that as a matter of law, medical records generated by a treating provider are insufficient documentation for purposes of Medicare Part B payment." *Id.* at 17.

Section 1879 of the Act provides that a beneficiary or supplier may be liable for the cost of an item or service that is not "reasonable and necessary" based upon prior knowledge of noncoverage. Act at § 1879(a); 42 C.F.R. §§ 411.400, 411.404, 411.406; Medicare Claims Processing Manual (MCPM), Pub. 100-04, Ch. 30 at § 40. A beneficiary is deemed to have knowledge of noncoverage if the supplier provides written notice to the beneficiary explaining why it believes that Medicare will not cover the item or service. 42 C.F.R. § 411.404(b). A supplier has actual or constructive knowledge of noncoverage based upon "[i]ts receipt of CMS notices, including manual issuances, bulletins, or other written guides or directives from [Medicare contractors]" and "[i]ts knowledge of what are considered

acceptable standards of practice by the local medical community." 42 C.F.R. §§ 411.406(e)(1),(3).

Medicare issued, among other guidance, MBPM, Ch. 15, § 290, LCD 9708 and the Podiatry Specialty Manual. All detailed the documentation and coverage requirements for Medicare Part B payment, including the requirements for nursing home medical records. Thus, the appellant could reasonably been expected to know that Medicare would not pay for services at issue. The records lack evidence that the appellant notified the beneficiaries that Medicare might not cover the services at issue.

Section 1870 of the Act allows for a waiver of recoupment of an overpayment to a supplier if it is without fault in incurring the overpayment. The Medicare Financial Management Manual (MFMM) (Pub. 100-06) states that a supplier is without fault if it exercised reasonable care in billing and accepting Medicare payment. MFMM, Ch. 3, § 90. The MFMM further explains that the supplier 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.

The appellant's allegation that it was not at fault with respect to payment for noncovered services because it was not aware of the Medicare coverage and documentation provisions is not a basis for finding it without fault if, as here, the appellant had constructive knowledge of the contractor's policies. *Id.* at § 90.1.H. Accordingly, the appellant could reasonably been expected to know that Medicare would not pay for services at issue and no waiver of recoupment of the overpayments is warranted.

FINDINGS

The Council has considered the full record and the exceptions in the appellant's request for review, and hereby modifies and reverses the ALJ's decision accordingly:

- 1) For all beneficiaries except beneficiaries C.Bro., A.G., M.H., L.I. and L.M., the Council finds that the appellant's exceptions present no basis for changing the ALJ's conclusions that the podiatry services at issue are not covered by Medicare. The Council modifies the ALJ's decisions to present additional support, including medical

testimony of Drs. Goldsmith, Luvison and Ramoska, as to why the claims are not covered by Medicare.¹⁴

- 2) The Council reverses the ALJ's favorable Medicare coverage determinations for beneficiaries C.Bro., A.G., M.H. and L.M.. The Council finds that, in these cases, the beneficiaries' medical documentation lacks support for Medicare coverage.
- 3) The Council reverses the ALJ's unfavorable finding for the debridement service, claimed using HCPCS/CPT code 11721, for beneficiary L.I.. The Council finds that the record supports Medicare coverage for this service on the date at issue.
- 4) The Council further finds that the appellant could reasonably been expected to know that Medicare would not pay for services at issue and was not "without fault" in creating the overpayments. Thus the Council finds that the appellant is liable under section 1879, and that no waiver of recoupment of the overpayment is warranted under section 1870.

MEDICARE APPEALS COUNCIL

/s/ Clausen J. Krzywicki
Administrative Appeals Judge

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

Date: May 20, 2011

¹⁴ The Council notes that because the claims have multiple deficiencies, beneficiaries are listed in multiple categories. See Appendix B for a detailed listing of each beneficiary and the categories for which the associated podiatric claims are denied, except beneficiaries L.I. and L.M. who received individual review.