DEPARTMENT OF HEALTH AND HUMAN SERVICES
DEPARTMENTAL APPEALS BOARD

DECISION OF MEDICARE APPEALS COUNCIL
Docket Number: M-11-12

In the case of	**Claim for**
Gordian Medical, Inc., d/b/a American Medical Technologies (Appellant)	Supplementary Medical Insurance Benefits (Part B)
**** (Beneficiaries)	**** (HIC Numbers)
Cigna Government Services, National Heritage Insurance Company (NHIC), and Noridian Administrative Services (Contractor)	**** (ALJ Appeal Number)

On August 5, 2010, the Administrative Law Judge (ALJ) issued a decision "partially favorable" to the appellant, concerning Medicare coverage for various surgical dressings furnished to multiple beneficiaries from December 2007 through January 2009.[1] The decision concerned a universe of 812 claims, from which the ALJ randomly selected 50 claims for review. In one instance, the ALJ determined that Medicare covered all of the items at issue. In four instances, the ALJ determined that Medicare covered some, but not all, of the items at issue. In the remaining forty-five instances, the ALJ determined that Medicare did not cover any of the surgical dressings furnished to the beneficiaries. The ALJ extrapolated these results to the universe. The ALJ also found that the appellant remained liable for the non-covered items. The appellant has asked the Medicare Appeals Council (Council) to review this action.

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

[1] To maintain privacy, the Council will refer to the beneficiaries by their initials. The beneficiaries' full names and HICNs, as well as the specific dates of service at issue, are listed on Attachment A to this action.

review, unless the appellant is an unrepresented beneficiary. 42 C.F.R. § 405.1112(c). We enter the appellant's timely-filed request for review dated October 1, 2010, and the accompanying brief (Br.), into the record as exhibit (Exh.) MAC-1.

The Council has considered the administrative record and exceptions set forth in the appellant's request for review. As explained more fully below, we reverse the ALJ's decision and deny Medicare coverage for all of the items at issue.

BACKGROUND

The appellant seeks Medicare coverage for various surgical dressings it furnished to residents of long-term care facilities[2] and billed utilizing HCPCS codes that included: foam dressings (A6209, A6210, A6212); gauze (A6222); collagen dressings (A6021); specialty absorptive dressings (A6210); conforming dressings (A6446, A6253); alginate dressings (A6197); tape (A4452); hydrogel dressings (A6242, A6248); transparent film (A6257); and composite dressings (A6200, A6201, A6203).[3]

Initially and on redetermination, the Durable Medical Equipment (DME) Medicare Administrative Contractors (MACs), Cigna Government Services, National Heritage Insurance Company (NHIC), and Noridian Administrative Services, denied the claims. On reconsideration, the Qualified Independent Contractor (QIC), RiverTrust Solutions, Inc., also denied the claims. The QIC explained that the appellant had not submitted sufficient medical evidence to establish that the items at issue were medically reasonable and necessary for each beneficiary's condition under Medicare Part B. *See, e.g.,* Stat Sample Exh. 1, at 18-20; Stat Sample Exh. 2, at 30-31.[4]

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[2] The ALJ noted that one of the sample claims is for items furnished when the beneficiary was in a skilled nursing facility but had exhausted his part A benefits. Thus, the "supplier [was] eligible to bill Part B." Dec. at 42; Stat Sample Ex. 12.

[3] 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).

[4] We refer to the individual beneficiary files as Stat Sample Exhibits. There are also Master File Exhibits.

With respect to certain claims for borderless composite surgical dressings claimed under codes A6200 and A6201, the contractors also determined that the claims were unallowable based on policy articles A24114 (Cigna) and A23664 (NHIC). *See, e.g.,* Stat Sample Exh. 8, at 29; Stat Sample Exh. 16, at 20; Stat Sample 17, at 33. The policy articles provide that codes for composite dressings without adhesive border, A6200-A6202, "are invalid for claim submission."

The contractors held the appellant, and not the individual beneficiaries, liable for the non-covered items pursuant to section 1879 of the Social Security Act (Act). In multiple instances, the contractors noted, Medicare had made an overpayment for the surgical dressings. *See, e.g.*, Stat Sample Exh. 2, at 30; Stat Sample Exh. 9, at 31. In those instances, the contractors determined that the appellant was not "without fault" in creating the overpayment, and thus, was not entitled to a waiver of Medicare's recovery pursuant to section 1870 of the Act. See, e.g., Stat Sample Ex. 36, at 31.

The appellant requested an ALJ hearing. Master File Exh. 1. After a pre-hearing conference and with the appellant's consent, the ALJ commissioned an independent statistical expert to produce a statistical sample of 50 beneficiaries from a universe of 812 claims. Dec. at 1-2; *see also* Master File Exh. 12 (Order dated April 15, 2010 and April 20, 2009 pre-hearing CD). The ALJ conducted a consolidated hearing on April 21, 2010,[5] with Michael D. Watson, the appellant's Vice President of Governmental Affairs, Kristi M. Jorritsma, certified wound care specialist, and Laura L. Bolton, Ph.D., a scientific consultant, on behalf of the appellant. Dec. at 1-2; Hearing CD. Richard Whitten, M.D., Medical Director of Noridian Administrative Services, also appeared at the hearing. *Id.*

On August 5, 2010, the ALJ issued a decision in which he performed an individualized analysis for each of the 50 sample claims. *See* Dec. at 18-121. In one instance, the ALJ granted coverage for all of the surgical dressings furnished to an individual beneficiary. Dec. at 18-20 (beneficiary A.A., sample number 1). In four instances, the ALJ determined that Medicare

[5] The ALJ scheduled the hearing for April 21, 2010 and for April 22, 2011, "if needed." Master File Exh. 9, at 83. The ALJ decision states that the hearing was held on both April 21, and April 22, 2010. On review of the record, we find that the hearing was held and concluded on April 21, 2010, and that the decision's reference to proceedings on April 22, 2010 was in error, though harmless.

covered only a portion of the dressings furnished to a particular beneficiary, with coverage limited by quantity and/or type of dressing. *See, id.,* at 22-24 (beneficiary L.B., sample number 3); 48-49 (beneficiary J.F., sample number 15); 107-109 ((beneficiary A.S., sample number 44); and 109-110 ((beneficiary M.S., sample number 45). In the remaining forty-five instances, the ALJ determined that Medicare did not cover any of the surgical dressings furnished to the beneficiaries. *See, e.g., id.* at 20-22 (beneficiary Y.B.); 24-26 (beneficiary M.B.).

The ALJ then forwarded his findings to the independent statistical expert responsible for the sample, who determined that an extrapolation percentage of 11.6 percent applied to the universe of claims. Dec. at 120; Master File Exhs. 22-23. Based on the extrapolation percentage, the ALJ concluded the appellant was entitled to payment for 11.6 percent of the total amount at issue in the universe. Dec. at 121.

Before the Council, the appellant asserts that all of the claims should be allowed. The Appellant contends that the documentation it submitted from each beneficiary's medical record is sufficient for reimbursement of the claims at issue under Medicare Part B. The appellant argues that the ALJ "inaccurately portrayed the availability of wound documentation in long-term care facilities," mischaracterized Ms. Jorritsma's testimony on that issue, and inaccurately described appellant's operational model and employee compensation system. Br. at 2-3, 12, 17, 20. The appellant further contends that the ALJ inappropriately gave substantial deference to the policy article relating to composite dressings without adhesive borders billed under codes A6200, A6201 and A6202. Further, the appellant argues, Medicare should cover foam dressings at a frequency of change of more than three times per week and in the absence of moderate to heavy exudate. The Council addresses the appellant's contentions below.

DISCUSSION

For the reasons explained more fully below, the Council reverses those portions of the ALJ's decision that were favorable to the appellant to deny Medicare coverage for *all* of the surgical dressings at issue.

New Evidence

As a preliminary matter, the Council must address the appellant's submission of additional documentation with its request for review, identified as Exhibit B to its brief. Exhibit B purports to contain an example of "the documentation typically maintained by [long-term care facilities]," specifically, weekly skin assessments maintained by one of the long-term care facilities "in which certain of Appellants beneficiaries reside." Br. at 14.

When an appellant submits new evidence with its request for review, it must show good cause for submitting the documentation at this late stage in the appeal proceedings. *See* 42 C.F.R. §§ 405.966(a)(2), 405.1018, 405.1122(c). Here, the appellant states that the new evidence responds to the ALJ's assertion that in certain instances "daily or weekly medical documentation" is required to establish that the items supplied were reasonable and necessary, and to counter the assumption that such documentation is readily available. Br. Exh. C (Statement of Good Cause). The appellant contends that there is good cause to admit the evidence because "the adequacy of Appellant's documentation was not challenged in any of the first three stages of appeal for the claims at issue," and the need to introduce the evidence "has arisen for the first time in connection with the ALJ stage of this appeal." *Id.*

We conclude that good cause does not exist to admit the new evidence. The insufficiency of the documentation submitted in support of each claim was a stated basis for the DME-MAC and QIC decisions below. For example, the DME-MAC redetermination in the claim for surgical dressings furnished to beneficiary Y.B. stated that "no medical documentation on the initial assessment and the ongoing progress of the wound has been provided. Since the medical records requested were not provided for this claim, it is appropriately denied and no payment will be made." Stat Sample Exh. 2, at 19. Moreover, the DME-MAC advised the appellant that if it wished to appeal to the QIC, any additional evidence must be submitted with its request for QIC review. *Id.* at 17. The DME-MAC also advised the appellant that it would not be able to submit any new evidence to the ALJ or on further appeal unless it could demonstrate good cause for withholding the evidence from the QIC. *Id.* In numerous instances, the contractors issued separate requests for contemporaneous clinical documentation from the beneficiaries' medical records, including office notes and progress notes, to evaluate the

claims. *See, e.g.,* Stat Sample Exh. 2, at 46; Stat Sample Exh. 10, at 45; Stat Sample Exh. 12, at 15-17; Stat Sample Exh. 41, at 11-14,.

In the reconsideration decisions, the QIC provided a detailed explanation of the documentation necessary to support the claimed items and why the documentation submitted by the appellant was insufficient. *See, e.g., Stat Sample Exh. 2,* at 30-31. The QIC stated that "neither a physician's order, nor a certificate of medical necessity, nor a durable medical information form . . . nor physician attestation by itself provides sufficient documentation of medical necessity . . . . There must be information in the patient's medical record that supports the medical necessity for the item and substantiates the answers on the [filled-in forms]." *Id.* at 31. Thus, there is no merit in appellant's claim that the sufficiency of the medical documentation to support the claims was raised for the first time at the ALJ level of appeal. We therefore find that there is not good cause to admit Exhibit B to the appellant's brief at this late stage in the proceedings and exclude it from the record, pursuant to the regulation at 42 C.F.R. § 405.1122(c)(2).

Statistical Sample Methodology and Application

The ALJ, with the consent of the appellant, decided to use statistical sampling as a technique of adjudication and manner of proof. *See* Dec. at 2. As noted by the ALJ:

> To efficiently resolve the large number of similar cases, John A***, Ph.D., a statistical expert, was appointed to obtain a random sample of fifty (50) cases from the universe of eight-hundred twelve (812) claims via pre-hearing request. . . . Further, the Appellant consented to the admission of the pre-extrapolation statistical results. . . . The fifty (50) sample cases now represent the entire universe of eight-hundred twelve (812), from which they were randomly selected. The Appellant, as well as the [Centers for Medicaid & Medicare Services (CMS)] contractors were timely notified of these results and provided the list of the universe, as well as, the sample results.

Id. (citing Master File Exhs. 12, 20.)

The appellant has not raised any contentions with respect to the use of this methodology for determining whether Medicare coverage is appropriate for each of the 812 claims at issue. Therefore, the Council has similarly limited its review to the 50 sample cases and used this methodology as a framework for the present case. 42 C.F.R. §§ 405.1112(b), 405.1112(c).

Medical Record Documentation

When the Council reviews an ALJ decision, it undertakes a *de novo* review. 42 C.F.R. § 405.1100(c). Before the Council, the appellant asserts generally that the form of the documentation submitted in support of each claim is sufficient for reimbursement under Medicare Part B. Therefore, the Council has reviewed whether the medical evidence is sufficient in each of the cases in the sample.

For each claim, the appellant submitted the beneficiary's facility admission record; an appellant-generated form entitled "Nursing Facility Patient Wound Care Order Sheet" (Order), signed and dated by the beneficiary's treating physician; a wound care evaluation form (Evaluation), also apparently generated by the appellant and dated on, or within several days prior to, the date of service at issue; and an invoice or proof of delivery. *See, e.g.,* Stat Sample Exh. 1, at 38-41; Stat Sample Exh. 2, at 47-50; Br. at 11. In many of the sample cases, the appellant also provided Evaluations, at monthly intervals, for several months prior to the dates of service at issue. *See, e.g.,* Stat Sample 4, at 41-44. The appellant argues that this documentation meets the requirements of the Social Security Act, regulations and the applicable Local Coverage Determinations (LCDs). Furthermore, the appellant contends, the adequacy of this documentation "has been repeatedly litigated, in dozens of cases in the Medicare appeals system, and has been consistently upheld." Br. at 3. According to the appellant, to deny the claims based on the insufficiency of the medical documentation would thus "inject a bizarre potential for randomness into this matter . . . ." *Id.* at 9.

The appellant also asserts that the ALJ "inaccurately portrayed the quality and quantity of wound documentation in long-term care facilities." Br. at 12. The ALJ indicated that daily or weekly physician or nursing notes reflecting the status of the wounds is required, and should be available, to determine whether the dressings claimed were reasonable and necessary. The appellant argues that there "is simply no additional

documentation in the beneficiaries' medical records that is reliably available." Br. at 12. According to the appellant, physician and nursing notes for beneficiaries in long-term care facilities are inferior to, and less frequently obtained than, the documentation kept in skilled nursing and acute care facilities. The appellant asserts that the wound evaluations and order forms it submitted are sufficient to meet all requirements for reimbursement. *Id.* at 13-14. The appellant also contends that the ALJ "inappropriately required documentation for prior, unrelated dates of service." Br. at 15.

The appellant further argues that the ALJ mischaracterized Ms. Jorritsma's testimony relating to the professional standards of wound care documentation. According to the ALJ's decision, Ms. Jorritsma testified that "the status of a wound is documented every time a nurse or physician examines it" and that "the documentation should note how long a wound has existed, whether it is improving and whether the prescribed dressing and wound care protocol is working." Dec. at 3. The ALJ stated that Ms. Jorritsma noted that "a one-time snapshot of the wound is not sufficient and there should be support in the medical documentation, for the type of dressing prescribed." *Id.* The appellant contends that Ms. Jorritsma "was referring to wounds in an acute care setting, not a long-term care setting" and that she did not state that "a onetime snapshot of the wound is not sufficient" to support a surgical dressing claim. Br. at 17-18.

The Council is not persuaded by the appellant's contentions. The Council has reviewed whether the medical evidence is sufficient in each of the cases in the sample. As noted, in support of each claim the appellant has submitted a facility admission form for each beneficiary, an invoice or proof of delivery, an Evaluation, and an Order. *See, e.g.,* Stat Sample Exh. 1, at 38-41; Stat Sample Exh. 2, at 47-50; Stat Sample Exh. 5, at 36-43. In many instances, the appellant also provided monthly Evaluations from several months prior to the dates of service at issue. *See, e.g.,* Stat Sample 4, at 41-44. In addition, the appellant also included, for each claim sample, a summary prepared by appellant's Medical Director of the information provided on the documentation. We find that, with respect to the instances where the ALJ granted coverage for all or some of the surgical dressings furnished to individual beneficiaries, the ALJ erred in concluding that this documentation was sufficient to support the claims up to the

frequency limits set forth in the applicable LCDs.[6] As detailed below, we conclude that none of the sample claims were supported by sufficient medical evidence to establish that the items furnished were reasonable and necessary under Medicare Part B.

Under sections 1832(a)(2)(B), 1861(s)(6) and 1862(a)(1)(A) of the Act, Medicare Part B covers durable medical equipment that is reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. Under section 1833(e) of the Act, "[n]o payment shall be made to any provider of services or other person under this part unless there has been furnished such information as may be necessary in order to determine the amounts due such provider or other person. . . ."

CMS has set forth the following guidance regarding documentation in a beneficiary's medical record:

> For any [durable medical equipment, prosthetics, orthotics, or supplies] to be covered by Medicare, the patient's medical record must contain sufficient documentation of the patient's medical condition to substantiate the necessity for the type and quantity of items ordered and for the frequency of use or replacement (if applicable). The information should include the patient's diagnosis and other pertinent information including, but not limited to, duration of the patient's condition, clinical course (worsening or improvement), prognosis, nature and extent of functional limitations, other therapeutic interventions and results, past experience with related items, etc. If an item requires a CMN [certificate of medical necessity] or DIF [DMA information forms], it is recommended that a copy of the completed CMN or DIF be kept in the patient's record. However, neither a physician's order nor a CMN nor a DIF nor a supplier prepared statement nor a

[6] The contractors' LCDs L11449, L11460, and L11471 ("LCD for Surgical Dressings") in effect January 1, 2008, are available online at http://coverage.cms.fu.com/mcd_archive/viewlcd.asp?lcd_id=11449&lcd_version=41&show=all; http://coverage.cms.fu.com/mcd_archive/viewlcd.asp?lcd_id=11460&lcd_version=36&basket=lcd%3A11460%3A36%3ASurgical+Dressings%3ADME+MAC%3ANoridian+Administrative+Services+%2819003%29%3A; and http://coverage.cms.fu.com/mcd_archive/viewlcd.asp?lcd_id=11471&lcd_version=36&basket=lcd%3A11471%3A36%3ASurgical+Dressings%3ADME+MAC%3ANHIC%7C%7C+Corp%2E+%2816003%29%3A. (Last visited July 21, 2011.)

> physician attestation by itself provides sufficient documentation of medical necessity, even though it is signed by the treating physician or supplier. There must be information in the patient's medical record that supports the medical necessity for the item and substantiates the answers on the CMN (if applicable) or DIF (if applicable) or information on a supplier prepared statement or physician attestation (if applicable).

CMS, Pub. 100-08, Medicare Program Integrity Manual, Ch. 5 at § 5.7.[7] This guidance was reiterated in the QIC reconsideration determinations for the claims at issue. *See, e.g.,* Stat Sample Exh. 1, at 19-20; Stat Sample Exh. 2, at 30-31.

The applicable LCDs, L11460 (Noridian Administrative Services); L11449 (CIGNA Government Services); and L11471 (NHIC) ("LCD for Surgical Dressings"), detail the types of documentation contemplated: "It is expected that the patient's medical records will reflect the need for the care provided. The patient's medical records include the physician's office records, hospital records, nursing home records, home health agency records, records from other healthcare professionals and test reports." Further, the LCDs state: "Current clinical information which supports the reasonableness and necessity of the type and quantity of surgical dressings provided must be present in the patient's medical records." *Id.* Thus, clinical documentation sufficient to satisfy the LCD's coverage criteria may take several different forms. The LCD makes clear that Medicare may require additional, supporting clinical documentation beyond the appellant's Evaluation and Order forms to support coverage.

The appellant asserts that there is simply no additional documentation in the beneficiaries' medical records that is reliably available. Exh. MAC-1 at 12. At the same time, the appellant paradoxically admits that there may be "skin sheets" or nursing notes that document that a dressing was changed. *Id.* at 14-15. The appellant also cites state survey guidance which states that, at least daily, staff should evaluate and document

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[7] All CMS manuals are available at http://www.cms.gov/Manuals/IOM/list.asp (last visited July 22, 2011).

identified changes in wound conditions. *Id.* at 29-30. Thus, it is reasonable to assume that long-term care facilities would maintain such clinical records detailing wound evaluations and care performed by physicians, nurses, and other treating health care professionals to substantiate the need for the type and quantity of items ordered, as well as for the frequency of use or replacement.

The hearing testimony of the appellant's own witness supports this reasonable assumption. Specifically, certified wound care specialist, Kristi Jorritsma testified:

> It's very important, I think, *in all settings, whether it be long-term care or acute care or wound clinics*, [or] podiatry offices *that they keep very good daily, most of the time I see daily logs of what the wound is doing in terms of progressing towards healing*. And pretty much a standard of care for what I see is documenting daily and then if there is not progression towards healing within a one- to two-week period, choosing an alternative dressing or alternative way of treatment. . . . In my experience [doctors] look at the notes on a daily basis or if it's weekly if they're in the facility and let's say there is a change on day three, and he's only in the facility once a week, then it's the responsibility of the specialist seeing the wound daily to contact the doctor and let him know of the change so that he can make recommendations appropriately. . . . In long term care . . . we do typically see [a prescribing period of] 30 days, they look at the wounds for a month . . . *but that's not to say that there's not constant ongoing assessments to determine what the wound needs to heal*.

Hearing CD at 1:42:45 – 1:48:30 (emphasis added). Based on this testimony, we reject the appellant's contention that the ALJ mischaracterized Ms. Jorritsma's testimony about the professional standards of care for assessing and documenting wounds and wound treatment in nursing homes and other long-term care settings. While Ms. Jorritsma did not specifically state that "a one-time snapshot" of a wound would fail to meet the standard of care, the ALJ reasonably used this language to accurately summarize Ms. Jorritsma's testimony that wounds should be assessed on a constant, ongoing basis and that there should be documentation to support those assessments.

The appellant has not submitted any contemporaneous clinical evidence from the beneficiaries' medical records to support the claims. The record does not contain any primary, corroborating, daily or weekly documentation showing the clinical course (worsening or improvement) of the wounds, the day-to-day care of the wounds, or the totality of the beneficiaries' conditions to substantiate the need for the types and quantities of dressings ordered.[8] The forms that the appellant did submit provide the Council with, at most, monthly snapshots of a beneficiary's condition without any daily or weekly longitudinal information as to the clinical course of the wounds. This limited documentation is insufficient to satisfy the coverage criteria set forth in the LCDs and to establish medical necessity.

Moreover, the appellant bears the burden of providing additional documentation to explain the special circumstances necessitating each beneficiary's use of additional or specialized surgical dressings. In this instance, the appellant has not met its burden. Instead of providing contemporaneous clinical documentation to support its claims, the appellant relied on the opinions of the beneficiaries' physicians as expressed on the limited, appellant-generated forms it submitted. The Council agrees with several United States Circuit Courts of Appeal who have held that forms, such as a certificate of medical necessity, signed by a physician, are not conclusive evidence that an item is medically reasonable and necessary within the meaning of section 1862(a)(1)(A) of the Social Security Act (Act). *See Maximum Comfort v. Secretary of Health & Human Services,* 512 F.3d 1081 (9th Cir. 2007); *accord MacKenzie Medical Supply,, Inc. v. Leavitt,* 506 F. 3d 341 (4th Cir. 2007); *Gulfcoast Medical Supply, Inc. v. Secretary, HHS,* 468 F. 3d 1347 (11th Cir. 2006). Thus, we find the appellant's assertions regarding the sufficiency of its documentation without merit.

Furthermore, we reject appellant's arguments that the Council should find the documentation submitted sufficient in light of prior ALJ and carrier decisions. As noted, the Council's review of the ALJ's decision is a *de novo* review. 42 C.F.R. § 405.1100(c). Prior decisions of ALJs and contractors are not precedential, nor are they binding on the Council.

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[8] Even assuming, *arguendo*, that some facilities may not maintain this information, the appellant has offered no explanation why the wound care protocols it develops for facilities do not include this documentation which it asserts is required by F-tag 314.

We also conclude that the ALJ's characterization of the appellant's employee compensation system does not provide a basis to allow the claims in dispute. In a footnote, the ALJ stated that the appellant's employees are placed on site at the facilities, make recommendations as to appropriate wound dressings, assist with evaluations and orders, and "function as commissioned salespersons." Dec. at 18, n.1. The appellant argues that its employees are certified wound care specialists, that they visit the facilities because they are required to do so under CMS quality standards, and that they are salaried employees, not commissioned salespersons. We conclude that any error in the ALJ's description of the appellant's business practices and employee compensation system was harmless. Regardless of the nature of its business operations, the appellant was required, yet failed, to furnish all of the required contemporaneous clinical documentation to support the medical necessity of the items claimed.

Composite Borderless Dressings Billed Under Codes A6200-A6201

The appellant also argues that the ALJ "inappropriately gave substantial deference" to a policy article in denying a number of claims involving composite dressings without adhesive borders. Br. at 18, *citing* Dec. at 35; *see, e.g.,* Stat Sample Exhs. 8, 9, 17. The policy articles referenced by the ALJ are A23903 (Noridian Administrative Services), A24114 (CIGNA Government Services), and A23664 (NHIC), which state that codes for composite dressings without an adhesive border (A6200, A6201, and A6202) are invalid for claim submission. The appellant contends that policy articles are "created by Medicare contractors," not subject to any administrative appeal process, are informational only, and "are not required to be given 'substantial deference' by ALJs." Br. at 19.

Authority to Review HCPCS Codes

The authority of an ALJ and the Council under the claims coverage and payment appeals process is bounded by the provisions of section 1869(a)(1) of the Act and the Secretary's delegations of authority. *See* 70 Fed. Reg. 36386 (June 23, 2005) and 60 Fed. Reg. 64065 (Dec. 13, 1995). An ALJ and the Council only have authority to review appeals of "initial determinations," as that term is defined in 42 C.F.R. § 405.924. Actions that are not initial determinations include any issue for which the CMS has sole responsibility; any issue regarding the computation of the payment amount of general

applicability for which the CMS or the contractor has the sole responsibility, such as actions regarding the establishment of a fee schedule under 42 C.F.R. part 414; and, claims submissions that do not meet the requirements for a Medicare claim. 42 C.F.R. § 405.926(a), (c), and (s).

Payment for surgical dressings is made under a fee schedule, as provided in section 1834(i) of the Act and 42 C.F.R. § 414.220(g). The HCPCS has been selected as the approved coding set for entities covered under the Health Insurance Portability and Accountability Act (HIPAA), for reporting outpatient procedures. Medicare Claims Processing Manual (MCPM), IOM 100-04, ch. 23, § 20. The CMS developed the 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). The HCPCS is updated annually to reflect changes in the practice of medicine and provision of health care, including codes that have been deleted during each year. MCPM, ch. 23., § 20.3.

Neither an ALJ nor the Council has the authority to review HCPCS definitions, as these definitions are integral to the computation of a payment amount of general applicability. The Council has no authority to review the PSC's invalidation of codes, or any CMS action or inaction with respect to coding issues. Further, the Council has no authority to review CMS's deletion of the code at issue from the fee schedule.

Medicare Coverage under the Billed Codes

In its July 2007 HCPCS Quarterly Update, the CMS announced that composite dressings under HCPCS codes A6200, A6201, and A6202 were no longer covered items under Medicare, effective July 1, 2007. *See* CMS Manual System, Pub. 100-4, Medicare Claims Processing Manual, Transmittal 1388 (Dec. 7, 2007), at 5.[9] The Transmittal elaborated:

> To reflect this change, the fee schedule amounts for codes A6200, A6201, and A6202 will be removed from the fee schedule file as part of this update. Contractors shall deny claims for the aforementioned HCPCS codes with dates of service July 1, 2007 through December 31, 2007.

[9] This document can be located on the internet at http://cms.hhs.gov/Transmittals/Downloads/R1388CP.pdf.

Id.[10] Further, Transmittal 1388 indicates that update revisions to the DMEPOS fee schedule were effective as of January 1, 2008. *Id.* at 1. Subsequently, the CMS deleted HCPCS codes A6200-A6202 from its 2008 Schedule for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS). *See* 2008 DMEPOS Fee Schedule (revised Feb. 11, 2008).[11]

In this case, the dates of service of the claims at issue are after the effective date for the denial of coverage for claims with codes A6200, A6201, and A6202, as specified in the HCPCS Quarterly Update. Thus, the Council finds that the surgical composite dressings claimed under HCPCS codes A6200 and A201 are not covered items under Medicare.

Deference to Policy Articles

The Council notes that the appellant accurately asserts that policy articles do not carry the same authoritative weight as an LCD. The regulation at 42 C.F.R. § 405.1062(a) states that:

> ALJs and the MAC are not bound by LCDs, LMRPs, or CMS program guidance, such as program memoranda and manual instructions, but will give substantial deference to these policies if they are applicable to a particular case.

Although a Policy Article is not an LCD, it is a long-standing practice to afford some deference to an associated interpretive article published by the contractor. In this case, the ALJ's deference to the Policy Article was harmless for the reasons discussed above, *i.e.,* the HCPCS codes at issue were invalidated by CMS in its July 2007, HCPCS Quarterly Update and subsequently deleted from the DME fee schedule. Thus, the CMS's July 2007, HCPCS Quarterly Update is the original source of the non-payment policy. The CMS undoubtedly has the authority to establish coding and payment policies.

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[10] CMS also distributed information about its decision not to cover composite dressing HCPCS codes A6200-A6202 in its December 2007 Medicare Learning Network (MM5803) and Provider Inquiry Assistance releases. *See, e.g.,* http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM5803.pdf.

[11] This document can be located at: http://www.cms.hhs.gov/DMEPOSFeeSched/LSDMEPOSFEE/. The file name is D08 JANR2.zip.

Foam Dressings

The appellant contends that the ALJ inappropriately deferred to the applicable LCDs in denying reimbursement for foam dressings. Br. at 27-32.[12] More specifically, the appellant asserts that the ALJ's findings regarding the foam dressings at issue are arbitrary, capricious, and unsupported by substantial evidence. *Id*. The appellant argues that the medical necessity of providing daily foam dressings has been "extensively litigated and consistently approved" in "dozens of cases in the Medicare appeals system." *Id.* at 23. The appellant asserts that the standard of care requires foam dressings to be changed daily, and that the relevant LCD is unreasonable in that it allows for reimbursement of foam dressings only up to three times per week. *Id.* The appellant further contends that "foam dressings can be supplied in the absence of moderate to heavy exudates levels, when required by the standard of care." *Id*. at 32.

The Council, and likewise, an ALJ, is not bound by LCDs but will give substantial deference to these policies if they are applicable to a particular case. 42 C.F.R. § 405.1062(a). However, if either declines to follow an LCD, it must explain the reasons why the policy was not followed. *Id*. The Council finds that the appellant has not presented any valid reason why the applicable LCD should not be afforded substantial deference in the instant case. The appellant makes generalized assertions regarding what it characterizes as the current standard of care for furnishing foam dressings. However, the appellant does not discuss any medical evidence contained in the beneficiaries' records; nor does the appellant explain why consideration of the advantages of foam dressings would support findings that these dressings were medically necessary for each of the beneficiaries in the sample claims, or that the LCD documentation requirements were satisfied.

Instead, the appellant's arguments seem to invite the Council to review the validity of the LCD itself. *See* Br. at 27-33. However, the Council has no authority to perform any such review. The regulations at 42 C.F.R. Part 426 provide a process for reviewing the validity of LCDs. The review of an LCD is distinct from the claims appeal process in 42 C.F.R. Part 405,

[12] The appellant's brief refers only to LCD L11460, applicable to claims filed with DME-MAC Noridian Administrative Services. Corresponding LCDs L11449 and L11471 apply, respectively, to claims filed with CIGNA Government Services and NHIC.

subpart I, under which the present case arose. *See* Act at § 1869(f)(2)(A) and 42 C.F.R. Part 426, Subparts C and D.

The applicable LCDs provide, in pertinent part:

> Foam dressings are covered when used on full thickness wounds (e.g., stage III or IV ulcers) with moderate to heavy exudate. Usual dressing change for a foam wound cover used as a primary dressing is up to 3 times per week. When a foam wound cover is used as a secondary dressing for wounds with very heavy exudate, dressing change may be up to 3 times per week. . . .

The LCDs also state: "When claims are submitted for these dressings for changes greater than once every other day, the quality in excess of that amount will be denied as not medically necessary." Thus, the LCDs contemplate scenarios in which a provider may submit claims for greater quantities of dressings and for more frequent dressing changes than Medicare would cover. The appellant asserts that the LCDs are unreasonable because they do not cover everything required by a current standard of care. However, Medicare is a defined benefit program; it does not cover every service or item ordered by a physician. Thus, simply because an order was written for a particular quantity or type of dressing, does not, in itself, mean that the dressing is reasonable and necessary as contemplated by section 1862(a) of the Act.

The LCDs specify that the "medical necessity for more frequent change of dressing must be documented in the patient's medical record and submitted with the claim (see Documentation section)." The Documentation Requirements section of the LCDs requires that the "[c]urrent clinical information which supports the reasonableness and necessity of the type and quantity of surgical dressings provided must be present in the patient's medical records." As discussed above, the appellant has not provided such documentation to support the claims as billed. Thus, we find that the ALJ did not err in applying the relevant LCDs to the medical documentation in the record and concluding that Medicare does not cover the foam dressings furnished by the appellant as primary dressings.

The Council therefore concludes that all of the surgical dressings provided to the beneficiaries who comprised the sample were not reasonable and necessary, and thus, not covered by

Medicare. As both CMS and the appellant have consented to the use of statistical sampling in this case, we extrapolate our findings to the universe of claims and find that Medicare does not cover any of the surgical dressings furnished to the 812 beneficiaries in the universe of claims.

Limitation on Liability

The ALJ determined that the record did not contain any Advanced Beneficiary Notices (ABNs) and thus, the beneficiaries could not have been expected to know that Medicare would not cover the surgical dressings at issue. Dec. at 121. Conversely, the ALJ found that the appellant's liability could not be waived pursuant to section 1879 of the Act, and held the appellant liable for the non-covered charges in the claims universe. *Id.*

The appellant did not raise any exceptions to the ALJ's findings concerning its financial liability or the lack of ABNs. A supplier, such as the appellant, is deemed to have 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) and 411.406(e)(3). Thus, we concur with the ALJ's finding the appellant liable for the non-covered items without further discussion.

Finally, since multiple sample claims arose from overpayments, section 1870(b) of the Act may be applied to determine whether the appellant was without fault with respect to the overpayments. However, the appellant has not asserted that it is without fault. Although the ALJ did not address the applicability of section 1870(b) with respect to those claims, we conclude that the contractors did not err in determining that the appellant was not without fault with respect to the overpayments because it knew or should have known that the items would not be covered. *See* MCPM, Ch. 3, § 90.

CONCLUSION

For the reasons enumerated above, the Council concludes that Medicare does not cover any of the various surgical dressings at issue. We therefore reverse those portions of the ALJ's

decision which were favorable to the appellant and hold the appellant liable for the non-covered items under section 1879 of the Act.

MEDICARE APPEALS COUNCIL

/s/ Clausen J. Krzywicki
Administrative Appeals Judge

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

Date: August 8, 2011