

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
DEPARTMENTAL APPEALS BOARD

**DECISION OF MEDICARE APPEALS COUNCIL**  
**Docket Number: M-11-2121**

**In the case of**

The Scooter Store  
\_\_\_\_\_  
(Appellant)

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

Noridian Administrative  
Services L.L.C. - DME MAC  
Jurisdiction D  
\_\_\_\_\_  
(Contractor)

**Claim for**

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

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

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(ALJ Appeal Numbers)

The Administrative Law Judge (ALJ) issued a decision, dated May 10, 2011, which addressed Medicare coverage for power wheelchairs and accessories the appellant supplied to two beneficiaries, A.R. and L.W.<sup>1</sup> The ALJ determined the wheelchairs and accessories were not medically reasonable and necessary and thus not covered under section 1862(a)(1) of the Social Security Act (Act). The ALJ further found that the appellant was liable for the cost of the non-covered items under section 1879 of the Act. 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

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<sup>1</sup> To maintain privacy, the Council will refer to the beneficiaries by their initials throughout this action. Their full names and HICNs, as well as the ALJ appeal numbers and the specific dates of service at issue, are listed in the attachment to this action.

review, unless the appellant is an unrepresented beneficiary.<sup>2</sup> 42 C.F.R. § 405.1112(c). The Council enters the appellant's request for review and supplemental brief into the record as exhibits (Exhs.) MAC-1 and MAC-2, respectively.

In its request for review dated July 11, 2011, the appellant requested the opportunity to present oral argument before the Council. Exh. MAC-1, at 1-2. A party does not have a right to a hearing before the Council. 42 C.F.R. § 405.1108(a). Under the standards set forth in 42 C.F.R. § 405.1124(a), the Council does not find that oral argument is warranted in this case because the case does not present an important question of law, policy, or fact, that cannot be readily decided based on written submissions alone. Thus, the Council denies the appellant's request for oral argument, or a hearing, in the alternative.

The Council has considered the administrative record and exceptions set forth in the appellant's request for review and supplemental brief. The Council concurs with the ALJ's conclusion that Medicare does not cover the wheelchairs and accessories at issue. The Council further agrees that the appellant remains liable for the non-covered charges. However, the Council modifies the ALJ's decision to expand the rationale for upholding the denial of coverage, and to address the appellant's exceptions.

#### **BACKGROUND AND PROCEDURAL HISTORY**

The appellant requests the Council's review of the ALJ's denial of coverage for a power wheelchair and accessories furnished to two beneficiaries. The Durable Medical Equipment Medicare Administrative Contractor (DME MAC) initially denied the claims. The appellant appealed the denial of medical coverage for the power wheelchairs. On redetermination, the DME MAC denied coverage of the beneficiaries' claims and found the supplier liable for the non-covered costs, pursuant to section 1879 of the Act. On reconsideration, the Qualified Independent Contractor (QIC) upheld the DME MAC's denial and liability determination. The ALJ affirmed the QIC's coverage decision, citing, *inter alia*, section 280.3 of the National Coverage Determinations (NCD) Manual, *Mobility Assistive Equipment (MAE)*,

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<sup>2</sup> The ALJ's decision involved the claims of five beneficiaries. The ALJ's decision was favorable to one beneficiary and unfavorable to the remaining four beneficiaries. In its request for review, however, the appellant only appealed the unfavorable decisions of A.R. and L.W. The Council will limit its review to the appeals of these two beneficiaries.

CMS Pub. 100-03 (Effective May 5, 2005), Local Coverage Determination (LCD) L23598, *Power Mobility Devices*, and LCD L11462, *Wheelchair Options/Accessories*.<sup>3</sup>

## COVERAGE DISCUSSION

### Introduction

Medicare is a defined benefit program. Medicare Part B covers the cost of "wheelchairs . . . used in the home" under the durable medical equipment (DME) benefit. Act § 1861(n), (s)(6). Wheelchairs "may include a power-operated vehicle that may be appropriately used as a wheelchair, but only where the use of such a vehicle is determined to be necessary on the basis of the individual's medical and physical condition," and the vehicle meets safety requirements that the Secretary established. Act § 1861(n).

Section 1862(a)(1)(A) of the Act bars coverage of items and services that are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. Section 1833(e) of the Act provides that no claim for Medicare coverage may be paid, unless "there has been furnished such information as may be necessary to determine the amounts due such provider." Similarly, the implementing regulation provides that the supplier "must furnish sufficient information to the intermediary or carrier to determine whether payment is due and the amount of payment."<sup>4</sup> 42 C.F.R. § 424.5(a)(6). Thus, the statute and regulations clearly place the burden of substantiating a claim for payment on the entity making the claim, by requiring the appellant to provide documentation explaining why the device is medically necessary for each particular beneficiary. In accord, section 556 of the Administrative Procedure Act places the burden of proof on the appellant as the proponent of coverage. 5 U.S.C. § 556.

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<sup>3</sup> The ALJ's decision references two LCDs for Power Mobility Devices, L23598 (issued by Noridian Administrative Services) and L27239 (issued by National Government Services, Inc.). For this decision, Noridian Administrative Services served as the DME MAC for A.R. and L.W. The Council will limit its discussion regarding both beneficiaries to LCD L23598.

<sup>4</sup> As a part of contractor reform pursuant to the Medicare Prescription Drug, Improvement and Modernization Act of 2003, carriers and intermediaries have been replaced by Medicare Administrative Contractors who perform similar claims-processing functions.

The appellant is a nationwide supplier of DME, including power mobility devices (PMDs) such as scooters and wheelchairs. Typically, in the ordinary course of business, the appellant will first conduct an interview with a beneficiary who is interested in a PMD. After interviewing the beneficiary, the appellant will then supply a treating physician or other treating practitioner with a form, or template, that the treating source completes after conducting a face-to-face examination. A form that the Texas Academy of Family Physicians (TAFP) created is the appellant's preferred form.<sup>5</sup> The treating source returns the form to the appellant, often with some other medical records.

Although the appellant has phrased its various arguments about the sufficiency of the medical documentation in different ways, in essence, the appellant seeks a declaration that the TAFP form (or any other form the appellant chooses to supply), completed in full or in part in some manner by the treating source, will serve as sufficient evidence of medical necessity, even without other documentation from the beneficiary's medical record. In particular, in its request for review and supplemental brief to the Council, the appellant asks the Council to consider all the evidence in the appeal and overturn the ALJ decisions regarding the beneficiaries.<sup>6</sup> Exh. MAC-1, at 3. In affirming the ALJ's conclusion that Medicare does not cover any of the power wheelchairs and accessories at issue, the Council will address the appellant's substantive arguments more fully below. We conclude that the determination of medical necessity, including the sufficiency of the evidence, is reserved to the Secretary. The TAFP form on its face, and without elaboration and corroboration, does not elicit all necessary information to determine that a PMD is medically reasonable and necessary, as required by the governing LCDs.

#### *The Appellant Has Not Demonstrated Good Cause to Submit New Evidence*

As a preliminary matter, the Council must address the appellant's submission of additional documentation with its supplemental brief. The additional documents consist of:

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<sup>5</sup> The appellant's headquarters are in Texas.

<sup>6</sup> Alternatively, the appellant requests that the Council remand the cases to another ALJ and require that ALJ to consider the medical evidence in the file. As the Council will render a decision in this appeal, no need exists to remand the case to another ALJ.

(1) a statement of Dr. Neal Robinson, dated November 17, 2011; (2) the Curriculum Vitae of Dr. Neal Robinson; and (3) case summaries that Dr. Robinson prepared for the two beneficiaries. See Exh. MAC-2. 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). The appellant initially asserts that the Council should consider Dr. Robinson's case summaries, since they highlight "the significant medical documentation that has been improperly dismissed and ignored by the ALJ in each of these cases . . . [and] also demonstrate that medical necessity has been established." Exh. MAC-2, at 3.

Dr. Robinson was retained by appellant's counsel to "address the medical issues in each case." Exh. MAC-2, at 2 n. 4. In addition, the appellant states that Dr. Robinson's statement provides "expert opinion as a physician on physician use of forms as medical records."<sup>7</sup> Exh. MAC-2, at 3. The appellant also submitted Dr. Robinson's curriculum vitae to qualify him as medical expert. Pursuant to 42 C.F.R. § 405.1122(a), the appellant requests the admission of Dr. Robinson's written statement because it specifically addresses and responds to the ALJ's primary rationale for denial in those cases. The appellant argues that good cause exists to admit the proffered evidence, as it will be useful to make "medical necessity determinations based on a record that [the ALJ] refused to develop completely." *Id.*

The Council concludes that good cause does not exist to admit the new evidence. The QIC decision advised the appellant that all evidence must be submitted before the ALJ level. See, e.g., A.R. Exh. 3, at 110; L.W. Exh. 3, at 110. In addition, the Council does not agree with the appellant's assertion that it had "no way to anticipate at prior levels of review that [the ALJ] would dismiss and exclude evidence in a manner contrary to statute, regulation, sound medical practice and prior decisions from almost every ALJ who had heard Appellant's cases previously." Exh. MAC-2, at 3. The redetermination decision advised the appellant that the use of supplier generated forms is not CMS approved and that the TAFP form is not a substitute for the comprehensive medical record. See, e.g., A.R. Exh. 3,

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<sup>7</sup> The Council notes that Dr. Robinson acknowledged a professional affiliation with the Florida Academy of Family Physicians who created a form similar to the TAFP form. See Statement of Dr. Neal Robinson at 2. The exact nature of Dr. Robinson's affiliation is not clear.

at 146; L.W. Exh. 3, at 146. The new evidence that appellant seeks to admit addresses a denial basis brought out in the redetermination. The new opinion evidence could have been, and should have been, adduced at the ALJ level.<sup>8</sup> The Council therefore finds that no good cause exists to admit the documents discussed above at this late stage in the proceedings and excludes them from the record, pursuant to the regulation at 42 C.F.R. § 405.1122(c)(2).<sup>9</sup>

Documentation of Medical Necessity, Including the Face-to-Face Examination, is Required

The authorities discussed below outline a comprehensive scheme for the submission of medical documentation required to establish that a PMD is medically reasonable and necessary. In the request for review and supplemental brief, the appellant asserted that the statute and regulation clearly specify that the face-to-face examination represents the event where medical necessity is determined. The Council has reviewed the ALJ's decision and finds that the ALJ neither violated the statute and regulation nor undermined the process established with regard to face-to-face examinations. That the ALJ assigned "little to no" probative value to the TAFP form in these cases does not mean that the ALJ disregarded the face-to-face examination. Rather, the ALJ recognized the need for proper documentation when conducting a face-to-face examination, noting that the TAFP form as completed was insufficient to properly document the face-to-face examination.

The statute and regulations, as well as regulatory history, set forth explicit instructions regarding documentation to establish medical necessity. Section 302(a)(2) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), Pub. L. 108-173 (effective October 25, 2005), amended the

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<sup>8</sup> Further, the case summaries are cumulative, as they "are based entirely on the documentation already in the record and therefore constitute argument on existing evidence." Exh. MAC-2, at 3.

<sup>9</sup> In its request for review, the appellant also seeks to admit a letter from a physician that testified before another ALJ, regarding the use of forms. MAC-1, at 10-11. The appellant also requests the inclusion of hearing tapes from two prior hearings that were held in October 2010 before the same ALJ in this case and in June 2010 before another ALJ. *Id.* at 4, 11. The Council does not look outside the record to take administrative notice of evidence in previous cases. Further, the appellant would have to demonstrate good cause for not submitting this information earlier in the course of this proceeding, and has not done so.

Social Security Act to add to the coverage requirements for power mobility devices. The statute requires that:

in the case of a covered item consisting of a motorized or power wheelchair for an individual, payment may not be made for such covered item unless a physician (as defined in section 1861(r)(1)), a physician assistant, nurse practitioner, or a clinical nurse specialist (as those terms are defined in section 1861(aa)(5)) has conducted a face-to-face examination of the individual and written a prescription for the item.

Act § 1834(a)(1)(E)(iv). By its terms, this section does not address the documentation requirements of the face-to-face examination. As with any other item or service for which Medicare coverage is sought, the appellant bears the burden of demonstrating through sufficient evidence that medical necessity is met under the general standards noted *supra* at page 3.

The Centers for Medicare & Medicaid Services (CMS) issued the final regulation implementing this statutory provision, with an effective date of June 5, 2006. Medicare Program; Conditions for Payment of Power Mobility Devices, including Power Wheelchairs and Power-Operated Vehicles, Final Rule, 71 Fed. Reg. 17,021 (Apr. 5, 2006).<sup>10</sup> The rule restates and further explains the requirements concerning the face-to-face evaluation by the physician or treating practitioner. In addition to conducting the face-to-face examination and writing a prescription for the device within 45 days of the exam, the physician or other treating practitioner must provide:

supporting documentation, including pertinent parts of the beneficiary's medical record (for example, history, physical examination, diagnostic tests, summary of findings, diagnoses, treatment plans and/or other information as may be appropriate) that supports the medical necessity for the power mobility device,

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<sup>10</sup> The final rule made only a few changes to the provisions of the interim final regulation. Medicare Program; Conditions for Payment of Power Mobility Devices, including Power Wheelchairs and Power-Operated Vehicles, Interim Final Rule with Comment Period, 70 Fed. Reg. 50,940 (Aug. 26, 2005). Most significant, the final rule extended the time that the prescription and supporting documentation must be received by the supplier from thirty to forty-five days from the date of the face-to-face examination. 71 Fed. Reg. at 17,027.

which is received by the supplier within 45 days after the face-to-face examination.

42 C.F.R. § 410.38(c)(2)(iii).

The final rule recognizes the additional burden on physicians of completing a face-to-face examination, and providing supporting documentation. Thus, the rule provides that:

[p]ayment for the history and physical examination will be made through the appropriate evaluation and management (E&M) code corresponding to the history and physical examination of the patient. Due to the MMA requirement that the physician or treating practitioner create a written prescription and this regulation's requirement that the physician or treating practitioner prepare pertinent parts of the medical record for submission to the DME supplier, we established an add-on G Code G0372 (used in addition to an E&M code for the examination) to recognize the additional work and resources required to document the need for the PMD. Prescribing physicians or treating practitioners who submit the required supporting documentation may submit a claim for payment for the add-on G code.

*Id.* at 17,022.

At the same time, the final rule explains that it is intended to move away from having treating sources merely complete forms, such as a certificate of medical necessity (CMN).

CMS' experience has been that the CMN does not reliably accomplish its original purpose with regard to PMDs. The CMN did not serve to help physicians better document their patients' clinical needs for a PMD, it did not serve to ensure that beneficiaries always received appropriate equipment, and it did not serve as an effective deterrent to fraud and abuse. We believe the beneficiaries' physician or treating practitioner is in the best position to evaluate and document the beneficiary's clinical condition and PMD medical needs, and good medical practice requires that this evaluation be adequately documented. Thus, to minimize the documentation requirements for providers while assuring that documentation is adequate,

physicians and treating practitioners will now prepare written prescriptions (as required by MMA sec. 302 and this regulation) and submit copies of relevant existing documentation from the beneficiary's medical record, rather than having to transcribe medical record information onto a separate form such as a CMN.

*Id.* at 17,024.

CMS further noted:

[a]s we stated in the interim final rule, we believe that recently published new coverage criteria for mobility assistive devices, including PMDs, provides guidance on what Medicare will consider when determining coverage, and that physicians, treating practitioners and suppliers will better know how to properly evaluate and document a beneficiary's clinical condition. Therefore, we determined that the practical utility of a CMN, given the function-based approach to coverage, was questionable, and that the continued use of a CMN for power wheelchairs or power-operated vehicles would no longer be required.

*Id.* at 17,027.

In providing the documentation specified above, the final rule noted that the physician or treating practitioner should only select those portions of the medical record that clearly demonstrate medical necessity for the power mobility device (PMD). *Id.* at 17,022. The final rule further set forth:

[i]n addition to the prescription for the PMD, the physician or treating practitioner must provide to the supplier supporting documentation which will include pertinent parts of the medical record that clearly support the medical necessity for the PMD in the beneficiary's home. Pertinent parts from the documentation of the beneficiary's PMD evaluation may include the history, physical examination, diagnostic tests, summary of findings, diagnoses, and treatment plans. The physician or treating practitioner should select only those parts of the medical record that clearly demonstrate medical necessity for the PMD. The parts of the medical record selected should be sufficient to delineate the history of events that led

to the request for the PMD; identify the mobility deficits to be corrected by the PMD; and document that other treatments do not obviate the need for the PMD, that the beneficiary lives in an environment that supports the use of the PMD and that the beneficiary or caregiver is capable of operating the PMD. In most cases, the information recorded at the face-to-face examination will be sufficient. However, there may be some cases where the physician or treating practitioner has treated a patient for an extended period of time and the information recorded at the face-to-face examination refers to previous notes in the medical record. In this instance, those previous notes would also be needed.

*Id.* at 17,022-23.

CMS also specifically rejected comments that asked that CMS create more specific guidelines that would outline all the documents needed from the patient's medical record or create a template (for example, a standard set of questions) to capture the information that CMS determines is medically necessary to justify the prescription. CMS stated that it "believes the current documentation requirements provide suppliers with a comprehensive picture of a patient's history, physical examination and functional assessment describing the patient's mobility limitation and his/her physical and mental ability to operate a PMD." *Id.* at 17,024.

Further, CMS stated:

[a]s noted in previous responses, there is no set volume of documentation (for example, number of pages or number of sections from a record) that, taken alone without regard to substantive content, will guarantee that the beneficiary's clinical condition meets the conditions for payment. Similarly, there is no type of document that, taken alone without regard to substantive content, will guarantee that the beneficiary's clinical condition meets the conditions for payment. It would be misleading to suggest otherwise.

. . .

It is important to remember that the submission of any particular piece or combination of medical record documentation does not guarantee that the substantive clinical information contained therein establishes the medical need for the device. If the beneficiary's clinical condition does not meet the conditions for payment, the accurate medical record, regardless of completeness, volume and detail, would not support coverage by Medicare. Conversely, if the beneficiary's clinical condition is such that the conditions for payment are met, that might be adequately documented in a variety of ways from the available portions of the medical record.

*Id.*

In addition, the physician or practitioner should provide information to the supplier as necessary. This is consistent with section 1842(p)(4) of the Act, which requires that:

[i]n the case of an item or service defined in [subsection 1861(s) paragraph (6), durable medical equipment, among others] ordered by a physician or a practitioner . . . but furnished by another entity, if the Secretary (or fiscal agent of the Secretary) requires the entity furnishing the item or service to provide diagnostic or other medical information in order for payment to be made to the entity, the physician or practitioner shall provide that information to the entity at the time that the item or service is ordered by the physician or practitioner.

The regulations thus require that the supplier "maintain the prescription and the supporting documentation provided by the physician." 42 C.F.R. § 410.38(c)(5)(i). The regulations further specify that the supplier must submit additional documentation beyond the prescription and supporting documentation to "support and/or substantiate the medical necessity for the power mobility device." 42 C.F.R. § 410.38(c)(5)(ii). The final rule further clarifies this requirement, stating:

[u]pon request, suppliers must submit additional documentation if the PMD prescription and supporting documentation are not sufficient to determine that the PMD is reasonable and necessary. Additional documentation may include physician office records,

hospital records, nursing home records, home health agency records, records from other healthcare professionals, and test reports. This documentation does not need to be submitted with every claim, but must be made available to CMS or its agent upon request.

71 Fed. Reg. at 17,023.

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

[f]or any [durable medical equipment, prosthetics, orthotics, or supplies] item 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 [certificate of medical necessity (CMN)] or [DME information form (DIF)], 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 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 (MPIM), Ch. 5 at § 5.7 (emphasis supplied).<sup>11</sup>

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<sup>11</sup> All CMS manuals are available at <http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/index.html> (last visited May 11, 2012).

The TAFP Form Qualifies as a CMN

Section Act § 1834(j)(2)(B) of the Act states that "the term 'certificate of medical necessity' means a form or other document containing information required by the carrier to be submitted to show that an item is reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member."

The United States Court of Appeals for the Ninth Circuit has interpreted this section of the Act thusly:

[t]he second subsection [Act § 1834(j)(2)(B)], provides that "[f]or purposes of this paragraph, the term 'certificate of medical necessity' means a form or other document containing information required by the carrier to be submitted to show that an item is reasonable and necessary . . . ." (emphasis added). The most logical reading of this sentence is that it is intended only to define the certificate of medical necessity for the purposes of applying the restrictions outlined in [Act § 1834(j)(2)(A)]. The subsection does not state that the certificate of medical necessity is the sole vehicle for claims reimbursement, nor does it state that a completed certificate establishes, by itself, a right to reimbursement. . . We reject, therefore, Maximum Comfort's view that [Act § 1834(j)(2)] precludes the Secretary from requiring additional evidence, beyond the certificate, to establish medical necessity for the equipment supplied.

*Maximum Comfort v. Secretary of Health & Human Services*, 512 F.3d 1081, 1087-88 (9th Cir. 2007), cert. denied, 129 S. Ct. 115 (Oct. 6, 2008) (No. 07-1507).

While the term CMN was originally applied to forms developed by CMS contractors, the definition of the form includes similar forms developed by suppliers, such as the appellant or other third parties, and given to treating sources for completion, for the purpose of establishing medical necessity. The TAFP form includes "information required by the carrier to be submitted to show that an item is reasonable and necessary." The TAFP form, like many other forms which qualify as a CMN, at best represents a template to guide the user in providing medical facts. The law is well-settled that the Secretary may require medical

documentation, in addition to a CMN, to support medical reasonableness and necessity for the claimed DME. See *Maximum Comfort*, 512 F.3d at 1087-88; 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).

The Council finds that the TAFP form, as a type of CMN, does not establish medical necessity, and additional documentation is required to support medical necessity.

*NCD 280.3 Requires the Use of Clinical Criteria to Establish that a PMD is Medically Reasonable and Necessary*

An NCD is a determination by the Secretary of whether a particular item or service is covered nationally under Medicare. 42 C.F.R. § 405.1060(a). Both ALJs and the Council are bound by statutes, regulations, NCDs, and CMS Rulings. 42 C.F.R. §§ 405.1060(a)(4), 405.1063.

In this case, CMS issued an NCD concerning mobility assistive equipment, which includes PMDs. The NCD predates, but is not superseded by, the regulations. Medicare NCD Manual (MNCDM) § 280.3.A (eff. May 5, 2005).<sup>12</sup> According to the NCD, "MAE is reasonable and necessary for beneficiaries who have a personal mobility deficit sufficient to impair their participation in mobility-related activities of daily living (MRADLs) such as toileting, feeding, dressing, grooming, and bathing" within the home. MNCDM § 280.3.B. The NCD defines a mobility limitation as one that prevents the beneficiary from accomplishing MRADLs entirely, places the beneficiary at a heightened risk of morbidity or mortality as a result of attempting to participate in the MRADL, or prevents the beneficiary from completing the MRADL in a reasonable time. MNCDM § 280.3.B.1. The NCD requires the use of a sequential assessment process, based on *clinical criteria*, to determine whether a beneficiary requires and can benefit from a mobility assistive device and, if so, what type of device. For example, the NCD requires consideration of whether a cane or walker can resolve the beneficiary's functional mobility deficit and whether the beneficiary typically has the upper extremity function to propel a manual wheelchair to participate in MRADLs. *Id.* at 280.3.B.5, 280.3.B.7. However, the NCD does not provide detailed documentation requirements.

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<sup>12</sup> The preamble to the interim final rule makes clear that the requirements of the NCD apply in conjunction with the requirements of the regulation for coverage of power mobility devices such as POVs. 70 Fed. Reg. at 50,943.

*The Governing LCDs Require Medical Evidence, In Addition to Forms Given to a Treating Source by the Supplier, to Establish Medical Necessity*

A LCD means a decision by a contractor whether to cover a particular item or service on a contractor-wide basis in accordance with section 1862(a)(1) of the Act. 42 C.F.R. § 400.202. Neither an ALJ nor the Council is bound by contractor LCDs 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." 42 C.F.R. § 405.1062(a). An ALJ or the Council must explain the reason for not following such a policy in a specific case. 42 C.F.R. § 405.1062(b). Any decision to disregard a policy "applies only to the specific claim being considered and does not have precedential effect." *Id.*

As noted above, LCD L23598 applies to the instant case.<sup>13</sup> The LCD reiterates the coverage requirements in the NCD, as well as the statutory requirement for a face-to-face examination and subsequent order. The LCD adds detailed documentation requirements. With regard to the face-to-face examination, the LCD provides:

[t]he evaluation should be tailored to the individual patient's conditions. The history should paint a picture of the patient's functional abilities and limitations on a typical day. It should contain as much objective data as possible. The physical examination should be focused on the body systems that are responsible for the patient's ambulatory difficulty or impact on the patient's ambulatory ability.

A date stamp or equivalent must be used to document the date that the supplier receives the report of the face-to-face examination. The written report of this examination must be available upon request.

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<sup>13</sup> LCD L11462 also applies regarding wheelchair options/accessories. It states, in pertinent part:

[o]ptions and accessories for wheelchairs are covered if the patient has a wheelchair that meets Medicare coverage criteria and the option/accessory itself is medically necessary. . . . If these criteria are not met, the item will be denied as not medically necessary.

*Physicians shall document the examination in a detailed narrative note in their charts in the format that they use for other entries. The note must clearly indicate that a major reason for the visit was a mobility examination.*

*Many suppliers have created forms which have not been approved by CMS which they send to physicians and ask them to complete. Even if the physician completes this type of form and puts it in his/her chart, this supplier-generated form is not a substitute for the comprehensive medical record as noted above. Suppliers are encouraged to help educate physicians on the type of information that is needed to document a patient's mobility needs.*

Physicians shall also provide reports of pertinent laboratory tests, x-rays, and/or other diagnostic tests (e.g., pulmonary function tests, cardiac stress test, electromyogram, etc.) performed in the course of management of the patient. Upon request, suppliers shall provide notes from prior visits to give a historical perspective of the progression of the disease over time and to corroborate the information in the face-to-face examination.

LCD L23598 (emphasis added).

*The Council Will Not Review the Per Se Validity of the LCD*

The appellant's arguments suggest that the Council ought to review the validity of the LCD itself. See Exh. MAC-2 at 9-11. However, the Council has no authority to perform such review. The regulations at 42 C.F.R. Part 426 provide a process for reviewing the validity of LCDs before ALJs of the Civil Remedies Division of the Departmental Appeals Board, at the request of an aggrieved beneficiary. The review of an LCD is distinct from the claims appeal process in 42 C.F.R. Part 405, subpart I, under which the present case arose. See Act § 1869(f)(2)(A); 42 C.F.R. Part 426, Subparts C and D. CMS further noted, in the final rule dated April 5, 2006, that, to the extent any commenters believe that the LCDs addressing PMDs do not reflect the provisions of the final rule, the commenters should raise these comments through the LCD issuance process. CMS would not use a regulation to ask the Durable Medical Equipment Regional Carriers to clarify any guidance. 71 Fed. Reg. at 17,026.

The DME MAC Guidance Letters Further Explain Why the TAFP Form is Alone Insufficient to Establish Medical Necessity

All four DME MACs have provided further guidance on the use of forms to document medical necessity. A link to the guidance letter in fact appears on the same TAFP internet page as the TAFP form at issue here. The appellant takes exception to the ALJ's inclusion of a letter entitled, "Power Wheelchairs and Power Operated Vehicles - Documentation Requirements," which is linked to the TAFP website, as evidence that the Texas Academy of Family Physicians itself believes the form alone does not establish medical necessity. In pertinent part, the letter sets forth:

[y]ou should record the visit and examination in your usual medical record-keeping format. Many suppliers provide forms for you to complete. Suppliers often try to create the impression that these documents are a sufficient record of the in-person visit and medical evaluation. Based upon our auditing experience, most of them are not. This is usually because **these documents do not record a complete medical examination and thus do not provide enough detailed information to adequately describe the medical necessity for the power mobility device in the patient's home.**

There are numerous sources that have developed forms. Many are home-grown by the individual supplier, some have been created by equipment manufacturers or other industry sources, and some have even been developed by medical groups, e.g., the Texas Academy of Family Physicians and Florida Academy of Family Physicians.

*While there is no specific prohibition against the use of a form to facilitate record-keeping, any instrument you choose must be a complete and comprehensive record of your in-person visit and the examination that was performed. **Documents such as the Texas or Florida Academy of Family Physicians forms that are designed to simply gather selected bits of information to be used for reimbursement purposes are insufficient to meet the statutory requirements. Even if you complete this type of form and include it in the patient's chart, it does not provide sufficient documentation of a comprehensive assessment of a patient's mobility***

**needs. You should perform a complete examination and document the results of the face-to-face examination in the same format that you use for other entries in your patient records.**

Dec. at 28-29 (*citing* Oct. 2008 letter from National Government Services)(underlined, bold face emphasis added in ALJ decision, italic emphasis added here).

The appellant asserts that the letter, which was promulgated in October 2008, lacks the force of law, does not bind the ALJ, and lacks the authority of the LCD. Exh. MAC-1, at 11. Further, the appellant asserts that the letter was outdated, as another DME MAC issued a revised version of the letter, dated September 2010.<sup>14</sup>

The September 2010 version of the letter, however, mirrors the October 2008 letter. In pertinent part, it states:

[y]ou should record the visit and mobility evaluation in your usual medical record-keeping format. Many suppliers provide forms for you to complete. Suppliers often try to create the impression that these documents are a sufficient record of the in-person visit and medical evaluation. Based upon our auditing experience, most of them are not. That is because they typically contain check-off boxes or space for only brief answers and thus do not provide enough detailed information about the patient's ambulatory abilities and limitations to allow the Medicare contractor to determine if coverage criteria have been met. *Forms such as those developed by the Texas or Florida Academy of Family Physicians are designed to gather selected bits of information and are almost always insufficient. What is required is a thorough narrative description of your patient's current condition, past history, and pertinent physical examination that clearly describes their mobility needs in the home and why a cane, walker, or*

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<sup>14</sup> The Council believes that the ALJ included the correct version of the letter in her decision. The date of service of the power wheelchairs provided to the beneficiaries occurred in March 2010, well before the issuance of the revised September 2010 letter, which is found at: <http://www.tafp.org/Media/Default/Downloads/practice%20resources/mobility-eval-ltr.pdf>. As such, the October 2008 letter was in effect on the dates of service at issue in this case. The October letter is found at: <http://cecommunications.info/mobility/data/downloads/ngs-deardoctor.pdf>.

*optimally configured manual wheelchair is not sufficient to meet those needs.*

Letter from Noridian Administrative Services, Inc. (Sept. 2010) (Underline in original, italic emphasis added here).

Although it is true that these guidance letters lack the force of law, do not strictly bind the ALJ, and lack the authority of the LCD, that does not mean that they are bereft of value. The letters nonetheless present a reasoned interpretation of the LCD by the contractor charged by law with creating and implementing the LCD. They are entitled to deference to the extent that they are consistent with the Act, regulations, CMS manuals, NCD and the LCDs, and have the power to persuade. They are also relevant to knowledge for limitation on liability purposes under 42 C.F.R. § 411.406(e), as they constitute written bulletins or guides from the DME MAC.

We conclude that the letters satisfy all of these criteria. The letters provide constructive notice to users that the information provided on the form failed to provide a complete and comprehensive record of the face-to-face visit. Further, the evidence supports the ALJ's determination that, by linking the DME MAC's letter to its website, the TAFP "recognized that the face-to-face form was not sufficient and directed physicians to perform a complete examination and to document the results of a face-to-face examination in the same format used for the other entries in the patient records."<sup>15</sup> Dec. at 29.

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<sup>15</sup> In addition to Noridian's letter, the TAFP website currently includes a video on the use of the form, which emphasizes that the form is not sufficient on its own to demonstrate medical necessity under the LCD. For example, slide 33 states, "[m]ake sure you document the examination in a detailed narrative note in your clinical notes in the same format that you use for other entries. The note must clearly indicate that a major reason for the face to face visit was a mobility examination." Slide 31 emphasizes that, rather than just checking boxes, it is important to clearly describe how the symptoms affect your patient's mobility. "So when you check a box on this guide, also provide verbose details, legibly written on a separate sheet of paper." Further, slide 18 provides, "LCD stipulates that physicians provide two documents to justify the medical necessity for a powered mobility device. Clinical notes documenting the face-to-face evaluation in a detailed narrative note that charts in the format that they use for other entries, and a '7-Element Prescription.'" The video can be found at: <http://cecommunications.info/mobility/player.html>. (last visited May 11, 2012).

The TAFP Form Alone is Insufficient to Establish Medical Necessity

The Council concurs that the use of the TAFP form during the face-to-face examination is not sufficient alone to establish that medical necessity exists for beneficiaries to receive a power wheelchair under Medicare. The appellant's assertion that the TAFP form, or any other form it chooses to supply to treating sources, should be accepted as sufficient evidence, flies in the face of the detailed statutory, regulatory and CMS guidance regarding documentation of medical necessity cited above.

As noted above, the face-to-face examination is required by statute, and may represent the primary documentation of medical necessity. Medicare makes separate payment for this examination, and additional payment for any additional documentation submitted. The LCD reasonably requires that the face-to-face examination be recorded in a detailed narrative note in the same format as the treating source uses for other entries, for all the reasons identified in the preamble to the final rule. That detailed narrative note should address the criteria in the LCD, many of which are repeated in summary fashion without significant clinical elaboration in the TAFP form. Documentation as to the medical necessity of a power mobility device is insufficient if recorded solely on the TAFP form. A blank TAFP form has no value. The form's value is only derived to the extent that it contains useful information. The generalized check-the-block questions are not designed to solicit specific, clinically meaningful information. Without elaboration, the form does not provide an objective, clinical assessment of the beneficiaries' physical ability and condition, such as the beneficiaries' ability to perform mobility-related activities of daily living, as Medicare coverage criteria requires.

Moreover, the TAFP form template is not in the same format as other medical information in the patient records, as required by the LCD. Accordingly, other medical records, beyond the TAFP form, are necessary to corroborate the information on the TAFP form and support medical reasonableness and necessity for the claimed power mobility device.

The ALJ's holding seeks to ensure that the face-to-face examination properly determines whether a beneficiary qualified for a power wheelchair. The ALJ recognized the need for proper

documentation when conducting a face-to-face examination, noting that the TAFP form was insufficient to properly document the face-to-face examination. The appellant asserts that the ALJ's decision "directly conflicts with CMS's regulation which specifically does not require any medical record format." Exh. MAC-1, at 6. The appellant points to language in the preamble of the final rule that stated CMS was "not requiring that the SOAP [subjective, objective, assessment, plan] format be used or that the descriptions be of a certain length for documentation in the beneficiary's medical record, as treating practitioners use a variety of methods depending on their professional training and the context of the clinical encounter." *Id.* (citing 71 *Fed. Reg.* at 17,028).

However, the appellant fails to quote the sentence immediately following its quoted sentence, which states "[w]hatever the length or format or accumulated volume of the documentation materials, its substance must clearly establish that the device dispensed was fully consistent with Medicare's coverage criteria." In other words, while no specific format is required for a medical record, the record must clearly demonstrate that the power mobility device is medically necessary. Thus, the format of the TAFP form is not the issue; rather, the information on the TAFP form fails to establish medical necessity, as Medicare requires. Appellant attempts to turn the regulatory scheme on its head by insisting that the forms it chooses to give the treating source, and only those forms, are alone sufficient to establish that the PMD supplied is medically reasonable and necessary.

Moreover, the ALJ did not establish the format in which the physician/treating practitioner must document medical necessity. Instead, as the italicized excerpt in LCD L23598 set forth above demonstrates, the ALJ relied on the pertinent LCD as a guide in deciding what type of documentation is required to determine the medical necessity of the power mobility device. The LCD clearly indicates that forms, such as the TAFP form, do not substitute for the comprehensive medical record that the ALJ held was required to document medical necessity.

The italicized portion in LCD L23598 set forth above also discusses supplier generated forms. The appellant particularly focuses on semantics as to whether the TAFP form was "supplier-generated." Exh. MAC-1, at 8. The appellant argues that the TAFP forms are not "supplier-generated" and do not fall "under the purview of the LCD[']s prohibition against supplier-

generated forms." Dec. at 29. Even if the appellant did not create the form, it supplied the form to the treating source for completion. The record does not suggest that the treating sources regularly use the form to document examination of patients, except as the form is supplied to them for purposes of prescribing a scooter. Even if the form is construed not to meet the strict definition of "supplier-generated" in the sense that the supplier did not create the form from scratch, the Council finds that it constitutes, for all intents and purposes, a *de facto* supplier-generated form because the supplier gives this form to treating sources, directly or indirectly, to complete as evidence of the face-to-face examination. Accordingly, the LCD should apply to the TAFP form, and the Council finds that the ALJ provided appropriate deference to the relevant provisions of the LCD, as the regulations require. We are not persuaded that the appellant has shown that it would be error to defer to the LCD.

*The Medical Documentation in These Cases Does Not Establish Medical Necessity*

The medical record for both beneficiaries contain, among other things: a prescription that sets forth the date that the face-to-face examination occurred; the face-to-face examination; and the power mobility device evaluation (TAFP form). The Council has reviewed the evidence *de novo*, and agrees with the ALJ that the documentation in the record does not meet Medicare coverage requirements for the power wheelchair and accessories provided to both beneficiaries.

In particular, the documentation in these cases does not address each beneficiary's functional or mobility limitations in detail. The documentation did not specifically address any of the following criteria set forth in the applicable LCD that was required to determine the medical necessity for a power mobility device:

1. What is this patient's mobility limitation and how does it interfere with the performance of activities of daily living?
2. Why can't a cane or walker meet this patient's mobility needs in the home?
3. Why can't a manual wheelchair meet this patient's mobility needs in the home?

4. Does this patient have the physical and mental abilities to transfer into a POV and to operate it safely in the home?
5. Why can't a POV (scooter) meet this patient's mobility needs in the home?
6. Does this patient have the physical and mental abilities to operate a power wheelchair safely in the home?

LCD L23598.

The Council finds that the medical documentation of record is insufficient to substantiate the medical necessity for the power wheelchair and accessories under the applicable regulations and guidance. The documentation for both beneficiaries lacks quantifiable measurable data, such as arm and leg strength, endurance, or range of motion, which substantiates the necessity of the power wheelchair.<sup>16</sup> For example, in describing both beneficiaries' physical limitations, the person completing the form checked "moderate," "partially," or "severe" for every criterion under that section. The form required that a description accompany these responses; however, no further description was provided for L.W., while the description on A.R.'s form does not provide any objective evidence supporting the characterization. See A.R. Exh. 3, at 129; L.W. Exh. 3, at 136. The TAFP form thus failed to provide any further substantive or meaningful information to determine whether medical necessity existed.<sup>17</sup> In addition, the medical

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<sup>16</sup> The Council finds, however, that some valuable information may be gleaned from the TAFP form both in favor of, and against, medical necessity. For example, in the case of A.R., on page 3 of the TAFP form, under the section "Ambulatory Status in Relation to Mobility Related Activities of Daily Living (MRADL) in Home," it notes that A.R. can safely walk 15 feet without a mobility aid and without stopping. A.R. Exh. 3, at 88. The next entry notes that this distance allows "the patient to independently accomplish ALL MRADL in the home in a safe and timely fashion." *Id.* Based on this entry, the form provides some value, which combined with other medical documentation, supports the conclusion that the power wheelchair was not medically necessary.

<sup>17</sup> For beneficiary L.W., responses on the form appear internally inconsistent. On page 1 of the TAFP form, the person filling out the form indicated that no significant edema existed by marking "no." L.W. Exh. 3, at 138. On page 4, the box next to "[p]atient has significant edema of lower extremities that requires having an elevated leg rest" is checked. *Id.* at 132. Moreover, the Council notes that the handwriting on the form appears different, depending on the page. *Id.* at 133, 136-37. The Council also notes that one version of page 1 in the record lists two dates of evaluation, January 10, 2010 and January 22, 2010, which had initials next to it. *Id.* at 139. This

documentation does not establish that a manual wheelchair could not meet either beneficiary's mobility needs.

As previously noted, the appellant fails to provide an objective, clinical assessment of the beneficiaries' ability to perform mobility-related activities of daily living, as Medicare coverage criteria require. The Council also questions why multiple copies of the TAFP form exist in the record for both beneficiaries. Further, the documentation does not establish the need for the device in either instance under the algorithmic process set out in the applicable NCD. For all these reasons, the Council concludes that the power wheelchair and accessories furnished to the beneficiaries are not reasonable and necessary and are not covered by Medicare.

*The Treating Physician Rule Does Not Apply*

The appellant asserted that the "Medicare program does not authorize a supplier of medical equipment to supersede the judgment of the beneficiary's treating physician/clinician." Exh. MAC-1, at 13. Further, the appellant contended that, for each beneficiary, the treating physician conducted a face-to-face examination and documented the medical necessity for the equipment provided, on the TAFP form. Accordingly, Scooter Store relied on the treating physician's documentation in providing the beneficiaries with the power wheelchairs based on medical necessity.

In essence, the appellant asserts that the "treating physician rule" applies to this case and argues that the ALJ, by denying coverage for the power wheelchairs and accessories, erred because Congress empowered the treating physician to determine medical necessity. The appellant also asserts that the Secretary must defer to the treating source's determination of what evidence is necessary to establish that a PMD is medically reasonable and necessary. Scooter Store, therefore, relied on the treating physician's documentation in providing the beneficiaries with the power wheelchairs based on medical necessity. Contrary to the appellant's argument, however, the treating physician rule has not been explicitly extended to Medicare cases. And the treating source is not the ultimate arbiter of what documentation is needed to establish medical necessity. Medicare also does not require a supplier to

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contradictory and internally inconsistent information leads the Council to question the validity and reliability of the TAFP form for L.W.

dispense a PMD, if the supplier believes that the supporting documentation is inadequate. 71 Fed. Reg. at 17,027.

As the Supreme Court noted, the treating physician rule was originally developed by the Courts of Appeals as a means to control disability determinations made by Social Security ALJs. *Black & Decker Disability Plan v. Nord*, 538 U.S. 822, 829 (2003). The Court observed that the rule had not attracted universal adherence outside the social security disability context, even in other public and private benefit contexts. *Id.* at 830 n.3.<sup>18</sup> The Court specifically declined to extend the rule to claims for disability benefits arising under ERISA, noting that the Secretary of Labor had issued no regulations on this matter, despite a grant of authority to promulgate necessary or appropriate regulations. The Court held that adoption of the treating physician rule was best left to Congress or the superintending administrative agency. *Id.* at 832. Here too, the Secretary of Health and Human Services has full authority under sections 1871 and 1872 of the Act to adopt rules and regulations regarding the nature and extent of proofs and evidence, but has issued no regulation endorsing the treating physician rule.

The Court of Appeals for the Second Circuit was influential in the development of the treating physician rule in Social Security disability cases.<sup>19</sup> For Medicare cases, however, the Second Circuit has stated that "[t]he Medicare statute unambiguously vests final authority in the Secretary, and no one else, to determine whether a service is reasonable and necessary, and thus whether reimbursement should be made." *State of New York o/b/o Bodnar v. Secretary*, 903 F.2d 122, 125 (2d Cir. 1990). The court further found "no contradiction,

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<sup>18</sup> The Supreme Court also noted that treating physicians may have an incentive to favor their patient. *Black & Decker*, 538 U.S. at 832. Judge Posner has pragmatically observed that "the fact that the claimant is the treating physician's patient also detracts from the weight of that physician's testimony, since, as is well known, many physicians (including those most likely to attract patients who are thinking of seeking ... benefits) will often bend over backwards to assist a patient in obtaining benefits." *Hofslein v. Barnhart*, 439 F.3d 375, 377 (7th Cir. 2006).

<sup>19</sup> The Social Security Administration later issued a detailed regulation describing how medical evidence, including opinion evidence, should be evaluated in the disability claims process. 56 Fed. Reg. 36,960 (Aug. 1, 1991); 20 C.F.R. § 404.1527. The Court of Appeals for the Second Circuit upheld the new regulation in *Schisler v. Sullivan*, 3 F.3d 563 (2d Cir. 1993) as a valid exercise of the Secretary's rulemaking authority.

however, between Congress's vision of the physician and the URC (utilization review committee) as gatekeepers initially determining eligibility and Congress's delegation to the Secretary of ultimate authority to determine whether the services provided a patient are covered by Medicare." *Id.* at 126.

In *State of New York o/b/o Stein v. Secy of HHS*, 924 F.2d 431 (2d Cir. 1991), the Second Circuit explicitly deferred ruling on the district court's application of the treating physician rule to coverage of an inpatient hospital rehabilitation admission. The court stated:

We are not prepared at this time to pass judgment upon the district court's holding that the case can be disposed of by applying the treating physician rule that is used in social security disability cases. Under this rule, "[t]he treating source's opinion on the subject of medical disability... is (1) binding on the fact-finder unless contradicted by substantial evidence, because the treating source is inherently more familiar with a claimant's medical condition than are other sources." [internal citation omitted.]. We believe it better practice to have the Secretary first advise us what role if any the attending physician rule played in the instant case and will play in future cases of this nature. After this has been done, a judicial determination can be made as to whether the Secretary's procedures in this regard meet statutory requirements.

*Id.* at 433-34.

In *State of New York o/b/o Holland v. Sullivan*, 927 F.2d 57 (2d Cir. 1991), the court reiterated that it would not apply the treating physician rule without first considering the Secretary's input: "[W]e will also follow *Stein* in leaving for the Secretary's initial consideration the issue of whether the treating physician rule, applicable to disability cases, [cite to *Schisler*], applies to Medicare coverage determinations." *Id.* at 60.

In response to these Second Circuit cases, CMS issued Ruling 93-1 (*eff.* May 18, 1993), to explain the agency's position on the treating physician rule. The Ruling provides that no presumptive weight should be assigned to a treating physician's medical opinion in determining the medical necessity of

inpatient hospital or skilled nursing facility services.<sup>20</sup> Rather, “[a] physician’s opinion will be evaluated in the context of the evidence in the complete administrative record.” Moreover, the Ruling adds parenthetically that it does not “by omission or implication” endorse the application of the “treating physician rule” to services not addressed in the Ruling, e.g., services other than Medicare Part A services. We note that the Second Circuit decisions did not address the weight to afford a treating physician’s opinion concerning durable medical equipment.

In *Arruejo v. Thompson*, 2001 WL 1563699 (E.D.N.Y. 2001), the district court declined to apply the treating physician rule to claims for physician services under Medicare Part B. And, in language that is particularly apt in the present case, the *Arruejo* court added:

Even if the rule were found to apply, it would not save plaintiffs’ claims. The treating physician rule, as noted above, is based on the premise that a treating physician has intimate familiarity with a patient’s specific medical circumstances, and operates on the assumption that evidence about the patient’s condition or diagnosis will be proffered. The regulatory scheme envisions a well-documented and supported basis for the conclusion and opinion of the treating physician. . . . In this way, the codified rule resembles the case law from which it was derived. [Citing *Friedman*, 819 F.2d at 46 and to § 1833(e) of the Act, requiring Medicare beneficiaries and their doctors to submit the necessary documentation to justify payment.] For these reasons, even if the treating physician rule were to be extended to Medicare cases, there is simply no basis for its application here. Plaintiffs did not submit medical records or other evidence to the ALJ showing the medical conditions of the patients who were [being treated], nor have they presented such evidence here. Rather, plaintiffs rely on the mere fact the treating physicians . . . requested the [services], without providing any patient-specific evidence of the reasons for those requests. This is simply not a sufficient showing to create a prima facie case of medical necessity under either case law or regulations.

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<sup>20</sup> By regulation, CMS Rulings are binding on ALJs and the Council. 42 C.F.R. §§ 401.108, 405.1063.

*Id.* at 14.

In the present case, as in *Arruejo*, the appellant has failed to provide documents that would support the conclusion and opinion of the treating physician. The mere fact that a physician completed and signed the TAFP form for the power wheelchairs at issue does not establish medical necessity. The ALJ's decision is consistent with the applicable LCD, which set forth the criteria and requirements needed to establish medical necessity. The LCD clearly articulated that, even if the physician completes a form similar to the TAFP form "and puts it in his/her chart, this supplier-generated form is not a substitute for the comprehensive medical record." LCD L23598 (emphasis in the original). Thus, even if the "treating physician rule" were applicable in this case, it would not result in a favorable coverage determination under the circumstances presented here.

*Prior Adjudications by Other ALJs are Not Precedential*

The appellant also argues that the ALJ's holding regarding the TAFP form contradicted federal law, sound medical practices, and prior precedent from other ALJs who had heard appellant's prior cases. Exh. MAC-2, at 2. The appellant appears to imply that the ALJ's decision in the present case is arbitrary and capricious because it differs from the results reached by other ALJs. By extension, the appellant implies that a decision by the Council upholding the ALJ's coverage denial would be arbitrary and capricious.

In reviewing matters that come before it, the Council undertakes *de novo* review. The United States Circuit Court of the Fourth Circuit recently held:

[i]t is undisputed that [the] lower-level decisions are not precedential and not binding on the [Council]. The Secretary's promulgated regulations make clear that a decision by a contractor or ALJ is only binding on the parties to that particular case, and that a decision is not binding once "a party files a written request for a MAC review that is accepted and processed." 42 C.F.R. § 405.984. Other circuits have considered analogous situations, and they all reach the shared conclusion that "[t]here is no authority for the proposition that a lower component of a government agency may bind the decision making of the highest level . . . [E]ven if these cases were found

to evince internal inconsistency at a subordinate level, the [agency] itself would not be acting inconsistently." *Community Care Found. v. Thompson*, 318 F.3d 219, 227 (D.C. Cir. 2003); see *Almy*, 749 F.Supp.2d at 326-28 (collecting cases).

*Almy v. Sebelius*, No. 10-2241, slip. op. at 21-22 (4th Cir. Apr. 26, 2012).

The Ninth Circuit further held that it is not "arbitrary and capricious of the [Council] to make final determinations that may have been at odds with prior coverage decisions that did not carry the full imprimatur of the Secretary's authority." *Almy*, No. 10-2241, slip. op. at 23-24. Therefore, the Council is not bound by earlier ALJ and contractor decisions, as it has been delegated authority to issue final coverage determinations on behalf of the Secretary. See also *Gordian Medical, Inc. v. Sebelius*, No. 8:10-cv-01202 CAS-FFM (C.D. Cal. Mar. 9, 2012 (holding prior favorable coverage decisions by an ALJ do not give rise to agency precedent), and 70 Fed. Reg. 11,420, 11,449 (Mar. 8, 2005) (noting Medicare administrative appeal decisions have no precedential value).

*The Allegation that the ALJ was Biased is Not Well-Founded*

The ALJ convened a telephonic hearing with the parties on April 28, 2011 at 10:00 A.M. Eastern Time in Cleveland, Ohio.<sup>21</sup> Dec. at 1. The Council has audited the hearing CD, paying particular attention to the portions relevant to A.R. and L.W., and noted that the ALJ accepted all exhibits and testimony into the record. The Council did not identify any instance during the hearing in which the appellant was precluded from presenting its evidence or testimony, although the appellant asserts that the ALJ had previously "made clear [in prior hearings] that she personally does not consider the [TAFP] form a medical record and thus will ultimately give it little or no weight." See Exh. MAC-1, at 4. But, as the appellant acknowledges, the ALJ did not hew to this position during the hearing at issue. The Council concludes that the ALJ fully and fairly developed the record and gave the appellant ample opportunity to present its

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<sup>21</sup> The Council notes, however, that the date and time on the CDs (May 9, 2011 at 11:30 A.M.) in the case file did not correlate with the actual hearing date noted in the decision. In listening to the CDs, the Council confirmed that hearings on the CDs involved the parties and beneficiaries subject to this decision.

case.<sup>22</sup>

In addition, the appellant asserted that the failure to consider the TAFP form when making medical necessity determinations demonstrated that the beneficiaries subject to this appeal "did not receive a full and fair hearing." *Id.* at 2. The appellant also took issue with the ALJ's finding that the form is "inappropriately leading because it is 'premised on the fact that a beneficiary requires a power wheelchair.'" MAC-1, at 12. The appellant contends that the ALJ's reasoning assumes that "physicians/treating practitioners lack the professional wherewithal to answer these questions in accordance with their examinations." *Id.* The appellant's assertions in this regard go to the consistent theme in appellant's arguments that the ALJ's stance against the form demonstrated bias against the appellant in past proceedings.

At the outset, we note that the appellant did not object to the ALJ at the time of the hearing, as contemplated under 42 C.F.R. § 405.1026. The regulation further provides that, if the ALJ does not withdraw, the appellant may, after the ALJ has heard the case, present its objections to the Council. Thus, there is a question whether the appellant has even preserved an issue with respect to an allegation of bias for review.

We will nonetheless consider the allegation. The Council does not find any basis supporting the appellant's assertions. The ALJ found that the TAFP form "is premised on the fact that a beneficiary requires a power wheelchair . . . and concludes with a series of leading questions." Dec. at 29-30. The ALJ's interpretation of the form in this manner is reasonable. The purpose of the form is to determine whether medical necessity exists for a beneficiary to receive a power wheelchair. While the ALJ may view the form as containing leading questions to obtain a desired result, the ALJ's decision that the form has "little to no" probative value in determining medical necessity does not reflect partiality, prejudice, or bias. Mere disagreement with the ALJ's rulings is not evidence of bias. Nor would error alone, even if demonstrated, necessarily prove bias.

In fact, the appellant has not identified any specific evidence of bias before the Council in the conduct of the hearing or in

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<sup>22</sup> The Council addressed this contention, even though Appellant's argument appears to center around a different hearing that occurred on October 13-14, 2010. No mention is made of the April 28, 2011 hearing.

ALJ's decision, regarding the TAFP form, or arising from an extra-judicial source. Allegations that an ALJ is biased are a grave matter and should not be raised lightly and without foundation. The Council finds no evidence of bias on the part of the ALJ in either the record or the decision in this case.

OMB has Approved the Collection of Information Associated with 42 C.F.R. § 410.38(c)

The appellant asserts that the ALJ attempted to create a new documentation standard. See, e.g., Exh. MAC-1, at 8. However, OMB has repeatedly approved the information collection associated with the regulations at 42 C.F.R. § 410.38, under OMB No. 0938-0971. See, e.g., 74 Fed. Reg. 20,318 (May 1, 2009); 77 Fed. Reg. 13337-38 (Mar. 6, 2012). The ALJ did not create a new documentation standard that would require formal rulemaking, pursuant to the Administrative Procedure Act, and approval from the Office of Management Budget, as appellant claims. Further, approval of the collection of the information is OMB's concern, not the method by which the author records that information.

The appellant also contends that forms "are commonplace in the medical field," and the "healthcare industry continues to move toward a system of electronic medical records, now considered a priority of the President and Congress." Exh. MAC-1, at 2. Even if we accept this contention as true, the appellant's argument regarding the trend toward a system of electronic medical records is not pertinent, given the language of the final rulemaking and LCD discussed above. The medium of the record is not relevant; rather, the content of the actual information contained in the document with regard to medical necessity is determinative. It is paradoxical for appellant to assert that a regulation, which requires no specific form, should instead be interpreted as an endorsement of the appellant's chosen form, which it supplies directly or indirectly to treating sources. The Council concludes that these extraneous arguments do not go toward the question of whether the TAFP form, on its own, demonstrates medical necessity.

#### **LIMITATION ON LIABILITY**

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 non-coverage. See also 42 C.F.R. §§ 411.400, 411.404, 411.406. A

beneficiary is deemed to have knowledge of non-coverage if the supplier provides a notice to the beneficiary explaining why it believes that Medicare will not cover the item or service. 42 C.F.R. § 411.404(b). An Advanced Beneficiary Notice (ABN) must provide a sufficient explanation of a supplier's (or provider's) belief that an item would not be covered to enable a beneficiary to make an informed consumer decision whether to decline the item or pay for it personally. See Medicare Claims Processing Manual (MCPM), Pub. L. No. 100-04, Ch. 30, § 40.3.8.

A supplier is deemed to have knowledge of non-coverage, in part, when it informs the beneficiary before furnishing the services that the services are not covered. 42 C.F.R. § 411.406(d)(1). A supplier also has actual or constructive knowledge of non-coverage 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), (e)(3). In this case, the regulations, LCDs and other DME MAC issuances discussed above provide ample evidence for concluding that the appellant knew or should have known that the TAFP form alone may not be sufficient to document medical necessity.

The appellant also asserts that it is not liable because it should not be required to substitute its judgment for that of the treating physician who prescribed the device. Exh. MAC-1, at 13. CMS responded to similar comments in the preamble to the final rule, stating:

[w]e believe that it is the supplier's responsibility to provide a legible copy of the written prescription and any other required information as defined in this rule. CMS believes that a party engaged in healthcare-related businesses should ensure that its staff has adequate expertise to carry out its responsibilities, and should obtain the training necessary to achieve and maintain that level of expertise. The supplier should obtain as much documentation from the patient's medical record as it determines that it needs to assure itself that the coverage criteria for payment have been met. If the information in the patient's medical record does not adequately support the medical necessity for the item, then for assigned claims the supplier is liable for the dollar amount involved unless a properly executed

advance beneficiary notice (ABN) of possible denial has been obtained.

71 Fed. Reg. at 17,026.

In each instance, the ALJ determined that the appellant knew, or should have known, that the documentation was insufficient and that the services would not be covered. In addition, the ALJ found that the appellant failed to furnish the beneficiaries with notice that Medicare may not cover their power wheelchairs. As such, the appellant remained liable for the non-covered costs. See Dec. at 32-33, 38. The records in these cases do not contain any evidence to suggest that any beneficiary received prior written notice of Medicare's possible non-coverage. We therefore concur with the ALJ's general conclusions and reiterate that the beneficiaries are not liable for the non-covered items at issue.

Accordingly, the Council concludes that the appellant's liability in each case is not limited pursuant to section 1879 of the Act. The appellant remains liable for the cost of the non-covered items.

#### **DECISION**

The Council finds that Medicare will not cover the power wheelchairs and accessories provided to beneficiaries A.R. and L.W. under section 1862 (a)(1) of the Act. Further, the Council finds the appellant liable for the cost of the non-covered items under section 1879. The Council modifies the ALJ's decision accordingly.

MEDICARE APPEALS COUNCIL

/s/ Clausen J. Krzywicki  
Administrative Appeals Judge

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

Date: May 18, 2012