DEPARTMENT OF HEALTH AND HUMAN SERVICES DEPARTMENTAL APPEALS BOARD

DECISION OF MEDICARE APPEALS COUNCIL

In the case of	Claim for Supplementary Medical
Maximum Comfort, Inc.	Insurance
(Appellant)	
* * * *	* * * *
(Beneficiary)	(HICN)
CIGNA - DMERC Region D	* * * *
(Carrier/Intermediary/PRO/HMO)	(Docket Number)

By notices dated March 21, 2001 and November 20, 2001, the Medicare Appeals Council advised the appellant that it had decided, on its own motion, to review Administrative Law Judge F. Lamont Liggett's January 23, 2001 decision and Administrative Law Judge Joseph F. De Pietro's September 25, 2001 decision because they contain errors of law (20 C.F.R. §§ 404.969 and 404.970, by reference of 42 C.F.R. § 405.856).

The Council has considered the records which were before the Administrative Law Judges, the February 28, 2001 and November 1, 2001 memoranda with attached documents submitted by the Centers for Medicare and Medicaid Services (CMS), and the briefs and other correspondence submitted by appellant's counsel.¹ All correspondence submitted to the Council pertaining to both hearing decisions has been entered into a master record sequentially as Exhibit MAC-1 et seq..

¹ During the period that the equipment at issue was supplied, CMS was named the Health Care Financing Administration. For the sake of simplicity, we refer to the agency as CMS throughout this decision.

I. <u>Procedural History</u>

A. The H. Group

Judge Liggett issued a fully favorable decision on January 23, 2001, for a group of cases with B.H. designated as the lead beneficiary (hereinafter "the H. group"). The decision was issued without a hearing. In his decision, the Administrative Law Judge found that the power-operated wheelchairs and accessories which were provided to the Medicare beneficiaries between January 1, 1998 and January 22, 1999 were covered equipment. These items had been previously paid by the carrier but were later found non-covered as a result of a post-payment The 19 claims at issue before the Administrative Law review. Judge were part of a statistical sample in which 30 claims were selected from a frame of 236 claims for similar equipment. The results of the review of those 30 claims were projected onto the universe of claims submitted by the supplier, resulting in a calculated overpayment of \$548,555.04. The appeal to the Administrative Law Judge consisted of the 19 sampled claims in which overpayments were found; the carrier determined that the remaining 11 claims in the sample met the coverage requirements.²

The Administrative Law Judge found that the claims addressed in this decision were covered largely on the conclusion that the supplier reasonably relied on certificates of medical necessity (CMNs) provided by the beneficiaries' physicians, who also The Administrative Law Judge concluded ordered the equipment. that there were no Medicare regulations or manual provisions in effect during the period at issue which would have required a supplier of durable medical equipment to obtain or make available to the carrier any medical records of an individual beneficiary; the supplier was required only to obtain an order and a CMN from the physician. Thus, the Administrative Law Judge concluded that when either (a) a physician did not produce medical records supporting the need for the supplier's equipment in response to the carrier's post-payment request, or (b) the medical records which were provided did not contain sufficient material

² Initially, the Council took own motion review of all of the claims forwarded to us. In a subsequent action issued July 9, 2001, we vacated the portion of our own motion review notice pertaining to two of the 19 beneficiaries whose claims were adjudicated in the hearing decision. Accordingly, this decison pertains to the 17 remaining claims in the H. group.

information, the wheelchairs and accessories should nonetheless be covered and, in any event, the supplier was not liable for any overpayment.

CMS referred the hearing decision to the Council for possible review by a memorandum dated February 28, 2001 (Exh. MAC-1). By notice dated March 21, 2001, the Council advised the supplier that it would review the cases under its own motion authority and would advise the supplier under separate cover of the specific grounds for review and the proposed action (Exh. MAC-2). The Council subsequently advised the supplier of the specific grounds for review in a notice of proposed remand issued on July 19, 2001. The primary basis for review was that the Administrative Law Judge's decision did not resolve adequately the type of documentation the supplier was required to provide to support its claims for durable medical equipment. The Council noted that one of the reasons it proposed to remand the case was that the Administrative Law Judge had issued a decision without holding an oral hearing and the record did not indicate that the supplier had waived its statutory right to that hearing.

In response to the proposed notice, the Council first received a letter from Ms. Valerie Eastwood of the law firm Duane, Morris & Heckscher dated August 8, 2001, requesting oral argument and a request for an extension of time to provide additional documentation. Subsequently, the Council received additional correspondence and telephone communications from Bartley S. Fleharty of the law firm Wells, Small, Selke & Graham objecting to the proposed remand. The supplier's counsel appeared to take conflicting positions concerning whether the H. Group should be remanded to the Administrative Law Judge for a hearing or decided by the Council without a hearing. Therefore, the Council sent a letter to both attorneys dated December 7, 2001, requesting that the supplier designate a lead counsel in the case and clarify which action, either remand or a decision by the Council, it was seeking. The Council explained that because the supplier had a statutory right to an oral hearing before an Administrative Law Judge, the Council would not entertain any further proceedings unless the supplier waived its right to an oral hearing before an Administrative Law Judge. The Council requested that the attorneys reply jointly.

Mr. Fleharty responded to the Council in a December 19, 2001 letter; however, he did not answer fully the questions the Council had raised. The Council did not receive a response from Ms. Eastwood. The Council subsequently learned that Ms. Eastwood and the firm of Duane, Morris & Hecksher no longer represent the supplier.

B. The T. Group

Judge De Pietro issued a fully favorable decision on September 25, 2001, for a group of cases with E.T. designated as the lead beneficiary (hereinafter "the T. group"). Similar to Judge Leggitt's disposition of the H. group, Judge De Pietro did not offer the supplier a hearing, concluding that all of the poweroperated wheelchairs and accessories at issue were covered under Medicare. These items, which were provided to Medicare beneficiaries from July 1, 1998 through July 2, 1999, were, like the H. group, the subject of a post-payment review. The 18 claims at issue before the Administrative Law Judge were part of a statistical sample in which 63 claims were selected from a frame of 182 claims. The results of the review of those 63 claims were projected onto the universe of claims, resulting in a calculated overpayment of \$308,383.50. The appeal to the Administrative Law Judge consisted of 21 sampled claims in which overpayments were found;³ the carrier had determined that the supplier had not been overpaid for the remaining claims.

In a decision nearly identical to the H. group decision, the Administrative Law Judge found the claims at issue covered based largely on the conclusion that the supplier reasonably relied on the CMNs provided by the beneficiaries' physicians who ordered the equipment, regardless of whether additional medical records were produced to support the need for the equipment. By a memorandum dated November 1, 2001, CMS referred the case to the Council for possible review (Exh. MAC-7). By notice dated November 20, 2001, the Council advised the supplier that it would review the case under its own motion authority and would provide the supplier the specific grounds for review and the proposed action under separate cover (Exh. MAC-9).⁴

⁴In three separate actions issued September 17, 2002, November 5, 2002 and December 3, 2002, we vacated the portion

³In a letter dated April 6, 2001, the supplier's representative requested a hearing before an Administrative Law Judge for 21 claims. Two of those claims, for beneficiaries *** and ***, were handled in a separate Administrative Law Judge decision dated January 24, 2002, that is not currently before the Council. A third claim, that of beneficiary ***, was apparently decided on the merits by the Administrative Law Judge; the administrative record does not reveal how the claim was resolved. Since the supplier has not raised the disposition of the *** claim as an issue before the Council, we do not address it in this decision.

C. H. and T. Groups-Subsequent Proceedings Before the Council

On December 31, 2002, the Council issued a letter addressing both the H. and T. groups. With respect to the H. group, the Council again advised the appellant that because the Administrative Law Judges had issued a favorable decision without affording the appellant an opportunity for a hearing, it could not entertain further proceedings unless the supplier waived its right to an oral hearing. The letter further informed the appellant that if the Council did not receive such a waiver, the H. group would be remanded to an Administrative Law Judge in accordance with its earlier proposed remand order.

The December 31, 2002 letter also provided for the T. group the Council's grounds for own motion review, as required by 20 C.F.R. § 404.973. The Council stated that the sole basis for review was identical to the primary issue in the H. Group, i.e., the type of documentation the supplier was required to provide to support its claims for durable medical equipment. The Council noted that the specific reasons it proposed to remand the H. group were again present in the T. group, namely, the Administrative Law Judge had issued a decision without holding an oral hearing and the record did not indicate that the supplier had waived its statutory right to that hearing.

The supplier's representative responded to the Council in a letter dated January 17, 2003. As to the H. Group, the supplier waived its right to an oral hearing before the Administrative Law Judge and requested that the Council entertain further proceedings before it, either by briefing or oral argument. As to the T. group, the supplier requested that the claims be stayed until a decision had been rendered by the Council in the H. group, noting that if the Council found favorably for the supplier in the H. group, the Council could then rule accordingly in the T. group.

The Council responded to the supplier's representative in a letter dated March 5, 2003. The Council denied the supplier's request for a stay in the T. group, reasoning that since the

of our own motion review notice pertaining to 8 of the 18 beneficiaries whose claims were adjudicated in the hearing decision. Accordingly, this decision pertains to the 10 remaining claims.

issues were the same in both cases, in the interests of judicial economy, we would follow the same process in both cases. The Council again gave the supplier the opportunity to request that both sets of cases be remanded to the Administrative Law Judge for an oral hearing. We also declined the supplier's request for oral argument, but provided an opportunity for additional briefing of the pertinent issues in the cases.

The supplier's representative notified the Council in a letter dated March 12, 2003, that his client requested that both the H. group and T. group proceed simultaneously to decision by the Council, and expressly waived the right to an oral hearing before an Administrative Law Judge in the T. group as well. The supplier submitted a brief to the Council on March 20, 2003, addressing the pertinent issues in the cases (Exh. MAC-26).

<u>II.</u> <u>Substantive Issues</u>

A. Need for Supporting Medical Documentation

The central issues in these cases are: 1) what documentation, if any, a supplier of power-operated wheelchairs and accessories was required (in 1998 and early 1999) to obtain and keep on file in support of the medical reasonableness and necessity of the equipment it supplied; 2) whether it was appropriate for CMS to establish an overpayment for claims with a valid CMN but with no underlying medical documentation; and 3) whether the supplier had notice of the documentation requirements.

1. The Social Security Act

Both Administrative Law Judges concluded that:

[S]ections of the [Social Security] Act clearly show that a supplier can use a CMN to submit information to a carrier to verify that an item is reasonable and necessary for the treatment of an injury or to improve the functioning of a malformed body member.

(H. Dec. at 5, T. Dec. at 5).

To support their conclusion, they cited to §§ 1862(a)(1)(A) and 1834(j)(2)(A)&(B) of the Social Security Act. Section 1862(a)(1) states:

[N]o payment may be made under part A or part B for any expenses incurred for items or services which ... 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 1834(j)(2)(A) provides the circumstances under which a supplier of medical equipment and supplies may distribute a CMN to physicians. Section 1834(j)(2)(B) states that:

For 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 for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

(Emphasis added.)

The above provisions are the primary basis for the Administrative Law Judges' ultimate conclusion that the CMNs demonstrated the items supplied in these cases were medically reasonable and necessary, that there were no additional medical documentation requirements, and, therefore, the power-operated wheelchairs and accessories were Medicare covered items.

The Administrative Law Judges also supported their conclusion that a certificate of medical necessity alone is sufficient documentation to demonstrate an item is medically reasonable and necessary by referring to § 4152 of the Omnibus Budget Reconciliation Act of 1990 (P.L. 101-508) (hereafter: OBRA '90) as follows:

Section 4152 of [OBRA '90] provides documentation requirements for durable medical equipment items. This provision applies to all suppliers of durable medical equipment and supplies. Claims for DME and related supplies can be paid only if the items meet the Medicare definition of covered DME and are found to be medically necessary. The determination of medical necessity is made using documentation written by the beneficiary's physician. This documentation <u>can</u> include medical records, plans of care, discharge plans, prescriptions, <u>and/or</u> forms explicitly designed to facilitate the documentation of medical necessity. <u>Such forms are referred to as certificates of medical</u> <u>necessity</u>. (*** decision, page 4. Emphasis in original.) To the extent that the above paragraph is intended to describe the provisions of § 4152 of OBRA' 90, it is misleading. Section 4152 does not discuss the role of the CMN or the type of documentation required to establish medical necessity for DME. Rather, the thrust of the section, in pertinent part, was to restrict the manner in which suppliers submitted DME claims by directing the Secretary to establish prior approval rules for potentially overused items and prohibiting suppliers from distributing medical necessity forms to physicians.

The appellant does not address the significance of the above legislation. Rather, it argues that because the CMN has been defined by Congress as a medical necessity document, suppliers should be able to rely on it as evidence that the item in question is covered. To support this contention, the appellant cites to § 1834(j)(2)(B) of the Social Security Act, which contains the definition of a CMN (Exh. MAC-26 at 12-13).

The Council agrees that a CMN is a form containing information to assist the carrier in determining whether an item is medically reasonable and necessary. But we do not find persuasive the supplier's argument that § 1834(j)(2)(B) of the Act establishes the CMN as the sole mechanism for establishing coverage of durable medical equipment (DME) or that the Secretary, through his Medicare contractors, cannot establish additional medical documentation requirements for determining coverage of various DME items. As noted above, OBRA '90 prohibited suppliers from completing any portion of the CMN. The Social Security Amendments of 1994 (P.L. 103-432) modified this restriction by allowing suppliers of DME to complete the portion of the CMN that identifies the supplier, the beneficiary to whom the DME is being furnished, the type of DME being supplied, its product code, if any, and any other administrative information identified as necessary by the Secretary other than information related to the beneficiary's medical condition.⁵ Suppliers who violate these

⁵ The current text of § 1834(j)(2)(A)(i) of the Act reflects these revisions.

restrictions are subject to civil monetary penalties. It is for the purpose of applying these provisions that the term "certificate of medical necessity" is defined in § 1834(j)(2)(B).

Furthermore, in examining the legislative history of the development of the CMN, it becomes even clearer that Congress encouraged the Secretary to develop uniform CMNs to prevent supplier misconduct. In developing the Federal Program Improvement Act of 1992, the House of Representatives issued House Report No. 102-486(I), which referred in its introduction "[p]rovisions in the bill dealing with the Medicare Program to (Title I) [that] will reduce fraud, waste, and abuse in the areas of durable medical equipment..." In this vein, the Act would have required the Secretary to develop one or more standardized certificates of medical necessity for durable medical equipment.⁶ In House Report No. 103-7, which described the 1992 Comprehensive Oversight Initiative of the Committee on Ways and Means, Congress again stated that a focus of the initiative was investigation of fraud, waste and abuse in the Medicare program. Out of these investigations, the Committee made several recommendations to stem abusive marketing practices by DME suppliers, including requiring CMS to develop standardized certificates of medical necessity. This requirement was later included in the Omnibus Reconciliation Act of 1993 (P.L. 103-66). In summary, neither the above legislative history of the CMN or the text of § 1834(j)(2) of the Act supports a conclusion that the primary purpose of the CMN is to eliminate the need for any supporting medical documentation to establish medical necessity.

2. Contractor Issuances

The hearing decisions cite several DMERC⁷ issuances referenced in the appellant's brief to the Administrative Law Judges, which, read in isolation, could suggest that a supplier of wheelchairs was required to obtain and keep in its files only an order or prescription for the equipment and a CMN. However, the decisions ignore several other provisions concerning post-pay audits that address the liability of a supplier if such documents are later found to be incorrect or inadequate and/or it is later determined that the equipment was not medically necessary.

⁶The bill was vetoed by the President on November 5, 1992.

⁷DMERC stands for "Durable Medical Equipment Regional Carrier."

The appellant specifically states in its brief to the Council that Maximum Comfort at all times complied with the DMERC's documentation requirements for the supplies at issue. The appellant further argues that during the dates of service, the DMERC required a CMN to document the medical necessity of the supplies and that no other specific documentation was required or recommended to suppliers (Exh. MAC-26 at 6). The Council finds that the totality of the DMERC issuances do not support either the Administrative Law Judges' or the appellant's interpretations of these issuances.

In its February 28, 2001 and November 1, 2001 memoranda to the Council, CMS referred to a March 1997 carrier newsletter concerning the duty of a DME supplier to either look behind the order and CMN for evidence of medical reasonableness and necessity or to assume liability if such equipment is later found to be non-covered:

Some suppliers have questioned the DMERC's authority to hold a supplier responsible for verifying through information obtained from the ordering physician that billed DMEPOS items were medically necessary prior to Medicare Part B allowing reimbursement to the supplier for the item. There is no specific requirement that a supplier verify through the ordering physician that the billed items are medically necessary. However, a supplier, by virtue of its furnishing a DMEPOS item to a Medicare beneficiary, is responsible for making a judgment as to whether the service is medically necessary and, for assigned claims, for informing the beneficiary prior to furnishing the item, of the likelihood of Medicare denial of payment on the basis that the item is not reasonable and necessary. If the supplier fails to verify the medical necessity of ordered items, and the items are subsequently determined to be not medically necessary, the supplier may be held liable for payment under the limitation on liability provision in section 1879 of the Social Security Act.

<u>See</u> DMERC Dialogue - Region D, March 1997, pp. 7-8 (Exh. MAC-31). This newsletter was issued several months prior to the dates of service at issue in this case.

In addition to the above newsletter notification, chapter IX of the DMERC Region D Supplier Manual, (Exh. MAC-30), contains sections regarding the coverage of Motorized/Power Wheelchair Bases and Wheelchair Options/Accessories. Both sections, issued in December 1993, state that the supplier should "[r]efer to the Documentation and CMN sections of the DMERC supplier manual for more information on orders, CMN's, medical records, and supplier documentation" with regard to documentation for prescribing wheelchairs and accessories. (pp. IX-53 and IX-102, Rev. 12/93.)

The Supplier Manual documentation chapter (Exh. MAC-29) states, in pertinent part, that-

It is expected that the physician's evidence of medical necessity for all DME items will be on file at the supplier's office and available for carrier review. Retention of hardcopy documentation of medical necessity is important for both paper and electronically submitted claims.

(p. VII-4, Rev. 12/93.) The manual further states, in a paragraph entitled "Supplier Requirements," that -

Physician records must corroborate the supplier's information. The supplier must have on file medical documentation for each DME item.

(p. VII-5, Rev. 12/93.) In addition, the DMERC Supplier Manual provisions in effect at the time informed suppliers that original CMNs are audited periodically to validate that they have been completed and transmitted to the DMERC correctly. (p. VII-2, Rev. 12/93.) A DMERC Dialogue newsletter (dated July 1995, p. 8)(Exh. MAC-28) informed suppliers that "[s]upporting documentation will be requested and reviewed from the selected suppliers by the CMN validation auditors."

Each of the above-quoted provisions had been published prior to, and was in effect during, the periods of delivery of the DME items at issue in these claims. Although these issuances were discussed in both CMS' memoranda to the Council, which we proffered to the appellant with our initial notice of review, and the Council's proposed remand order of July 19, 2001, the appellant has not addressed any of these manual provisions or the newsletter in its brief to the Council.

We find that the manual provisions and newsletter described above required the DME supplier to maintain medical documentation in addition to the CMN in the supplier's records, and that such a requirement is consistent with § 1833(e) of the Act, which requires suppliers to furnish sufficient information to support payments under Part B. In addition, as noted in CMS' memoranda to the Council, the DMERC's coverage guidelines themselves put suppliers on notice that it might be necessary to obtain additional documentation beyond the CMN to ensure that a power wheelchair meets the requirements for coverage. Specifically, the CMN does not solicit information concerning all of the coverage criteria listed in the DMERC's supplier manual. For example, although the coverage manual states that the patient's condition must be such that without the use of a wheelchair, the patient would otherwise be bed or chair confined, there is no question on the CMN that specifically addresses this coverage element. Therefore, since the supplier cannot determine whether the beneficiary meets this aspect of the coverage criteria based on the CMN alone, it had to have known that additional documentation would be required to make a complete coverage determination.⁸

3. The Treating Physician Rule

The appellant argues that "the treating physician rule" as articulated by the United States Court of Appeals for the Second Circuit should apply to the case at hand. The appellant contends that the rule supports appellant's position that it demonstrated sufficient documentation of medical necessity by submitting a CMN signed by the patient's physician (Exh. MAC-26 at 10).

The treating physician rule was developed in the context of Social Security disability cases.⁹ Under the rule as articulated by the Second Circuit,

[t]he treating source's opinion on the subject of medical disability ... is (1) binding on the factfinder unless contradicted by substantial evidence and (2) entitled to some extra weight, even if contradicted by substantial evidence, because the treating source is

⁸ Although CMS's point concerning this aspect of the coverage criteria is well taken, it also begs the question why a question soliciting this information was not included in the CMN.

⁹ The application, if any, and scope of the treating physician rule in Social Security disability and Medicare adjudication has been developed by the courts and the executive branch for nearly twenty years. To facilitate an understanding of our ruling in this matter we have appended to this decision a brief history of the treating physician rule, with specific reference to the rule as developed in the Second Circuit. See Appendix I.

inherently more familiar with a claimant's medical condition than are other sources.

Schisler v. Bowen 851 F.2d 43, 47 (2d Cir. 1988).

This judicial rule was incorporated in a Social Security Ruling in 1988. However, in 1991 the Social Security Administration replaced this ruling with a regulation, codified at 20 C.F.R. § 404.1527, which, as acknowledged by the Second Circuit, varies to some extent from the court's original rule. <u>Schisler v.</u> <u>Sullivan</u>, 3 F.3d 563 (2d Cir. 1993) (finding new regulation "binding" on courts even though it gives less deference to unsupported treating source opinions than court's rule).

Contrary to the appellant's assertions, however, neither the Second Circuit's treating physician rule nor 20 C.F.R. § 404.1527 has ever been extended to apply to Medicare claims adjudication. By its terms, the codified version of the treating physician rule does not apply in Medicare cases. Moreover, even before the rule was codified, the Second Circuit declined to decide whether the judicially crafted rule applied in Medicare cases. <u>State of New</u> York o/b/o Holland v. Sullivan, 927 F.2d 57, 60 (2d Cir.1991); State of New York o/b/o Stein v. Secretary of Health and Human Services, 924 F.2d 431, 433-34 (2d Cir.1991). Rather, the Second Circuit remanded both the Holland and Stein cases to the Secretary to explain the weight the Department gives to the opinion of the treating physician when making Medicare Part A inpatient hospital coverage determinations. In response, CMS issued Ruling 93-1. The ruling concluded:

[N]o presumptive weight should be assigned to the treating physician's medical opinion in determining the medical necessity of inpatient hospital or SNF services under section 1862(a)(1) of the Act.

With this Ruling, CMS stated that the treating physician rule, as articulated by the Second Circuit, does not apply in inpatient hospital and SNF cases. The Ruling also specifically states that it "does not by omission or implication endorse the application of the treating physician rule to those types of services that are not discussed in this Ruling." However, Ruling 93-1 has never been specifically extended to cover other types of Medicare services.

Nonetheless, the appellant urges application of the Second Circuit's former rule in this case, relying on the following language of the District Court for the Eastern District of New York in <u>Gartman v. Secretary, Department of Health and Human</u> <u>Services</u>, 633 F. Supp. 671, 680-81 (E.D.N.Y. 1986):

[the treating physician rule] may well apply with even greater force in the contest of Medicare reimbursement. The legislative history of the Medicare statute make clear the essential role of the attending physician in the statutory scheme: 'The physician is to be the key figure in determining utilization of health services.' [Internal citations omitted.]

We note that this district court opinion preceded the case law cited above, including <u>Holland</u> and <u>Stein</u>. We find that neither the <u>Gartmann</u> decision nor <u>Klementowski v. Secretary, Department</u> <u>of Health and Human Services</u>, 801 F. Supp. 1022 (W.D.N.Y. 1992) another district court decision also cited by the appellant, provide authority for applying to Medicare adjudication the Second Circuit's treating physician rule, particularly since, as described in Appendix I., that rule is no longer in effect in the Second Circuit for the disability cases in which it arose.

Finally, even if the codified treating physician rule issued by the Social Security Administration were extended to Medicare cases, it would not provide any relief to the appellant. 20 C.F.R. § 404.1527 states that SSA will give controlling weight to a treating physician's opinion if it is "...well-supported by medically acceptable clinical and laboratory diagnostic techniques and is not inconsistent with the other substantial evidence in your case record." Since the appellant maintains that they need only provide a valid CMN to support medical necessity, it is difficult to determine how this rule could be applied. Nor does the CMN provide the other information that the regulation identifies as significant to determining the weight to be given the physician's opinion, such as the nature and extent of the treatment relationship.¹⁰

¹⁰ On May 27, 2003, the Supreme Court of the United States decided in <u>Black & Decker Disability Plan v. Nord</u> 538 U.S. _____ (2003), that the Court of Appeals for the Ninth Circuit erred in applying its treating physician rule developed in Social Security cases to a disability decision made under a benefit plan governed by the Employee Retirement Income Security Act of 1974 (ERISA). In reaching this conclusion, the Court noted that neither the ERISA statute nor the Department of Labor's regulations requires plan administrators to give special deference to the opinions of treating physicians.

B. Paperwork Reduction Act

The appellant also argues that CMS's Paperwork Reduction Act submissions demonstrate that the CMN form was developed by CMS as a legal document used to determine medical necessity. The Council does not disagree with this description. As the Supporting Statement for Paperwork Reduction Act Submissions states:

Certificates of Medical Necessity provide a mechanism for suppliers of Durable Medical Equipment, defined in 42 U.S.C. § 1395x(n), and Medical Equipment and Supplies defined in 42 U.S.C. § 1395j(5), to demonstrate that the item being provided meets the criteria for Medicare Coverage.

(Exh. MAC-26, appellant's exhibit 4 at 5-6.) However, the submissions cited by the appellant do not state that development of the CMN would eliminate the need for the supplier to maintain and/or submit additional documentation of medical necessity. In fact, in a portion of the submission entitled "Special Circumstances" that addressed record retention requirements, CMS stated that "[r]espondents retain medical records only in conjunction with copies of CMNs for more than three years." This statement demonstrates that CMS contemplated suppliers would be responsible for maintaining medical records in support of the submitted CMN. CMS's Paperwork Reduction Act submissions demonstrate that the CMN was created to assist CMS in consistent claims processing, to help reduce improper Medicare payments, and to facilitate electronic filing of claims to the benefit of both CMS and suppliers, but not to eliminate entirely the need for supporting medical documentation.

C. Technical Requirements

In CMS's referral memo of February 28, 2001 for the H. group, CMS alleges that the claims of beneficiaries *** and *** should also have been denied for failure to meet certain technical requirements for payment. The memorandum noted that although the carrier hearing officer's findings of non-coverage were based, in part, on the failure to meet these technical requirements, the Administrative Law Judge's decision did not address these issues.

With regard to beneficiary ***, CMS stated that there was no signature of this beneficiary, either on the claim or on file with the supplier, which authorized the supplier to bill Medicare for the power-operated wheelchair and accessories. The memo cited to §§ 42 C.F.R. 424.32(a)(3) and 42 C.F.R. 424.36(a) which collectively provide that a claim must be signed by the beneficiary or, if the beneficiary has died or become incapacitated, by the beneficiary's representative. CMS asserted that the appellant admitted this deficiency in a April 24, 2000 letter.

The administrative record does not contain either the claim form or the referenced April 24, 2000 letter. Without these documents the Council cannot make a determination concerning whether the appellant secured a claim form signed by the beneficiary or the beneficiary's representative. However, since the appellant has not submitted any medical documentation to support the CMN in this case, it is not otherwise factually distinguishable from that of the other claims addressed in this decision. Therefore, the Council has concluded it is not necessary to further develop the signature issue to resolve this claim.

With regard to the claim of beneficiary ***, CMS stated that certain sections of the CMN which are required to be filled out by a medical practitioner were, in fact, filled out by the beneficiary's wife. According to CMS, the CMN states, on the back in the instructions section, that section B is to be completed by a physician, clinician, or physician's employee. CMS alleges that this error in completing the form rendered the equipment non-covered. (The back of the CMN form is not reproduced in the record.) This issue is not addressed in the Administrative Law Judge's decision.

Section B of the CMN was clearly filled out by the beneficiary's wife, as her name and status as wife are listed in that section. Chapter VIII of the DMERC Region D Supplier Manual states:

Section B may be completed by the physician, the physician's employee or another clinician involved in the care of the patient (e.g., nurse, physical or occupational therapist, etc.) as long as that person is not the supplier (Exh. MAC-27).

(Emphasis in original.) The beneficiary's wife is not among those allowed to complete section B of the CMN.

Furthermore, the Council finds that the Administrative Law Judge's conclusion that the medical records provided supported the medical necessity of the power-operated wheelchair is not supported by the evidence of record. As noted above, one of the requirements that must be met to qualify for a power-operated wheelchair is that the patient's condition is such that without the use of a wheelchair the patient would otherwise be bed or chair confined (DMERC D Supplier Manual, Chapter IX). The clinical record for a visit to the prescribing physician, Dr. J.L.C., on January 26, 1999 states that the beneficiary is ambulating with a walker. Therefore, he would not have met the Medicare coverage requirements for a power-operated wheelchair.

D. Section 1879 of the Act, Limitation of Liability

Section 1879 of the Social Security Act provides for a limitation of liability for the supplier, in pertinent part, when it is determined that the supplies at issue were not medically reasonable and necessary, but the supplier did not know, and could not reasonably been expected to know, that the items would not be covered under Medicare. The Administrative Law Judges did not address limitation of liability under Section 1879 of the Act in their decisions.

The Council finds that the supplier in this case has not submitted sufficient information to establish that the poweroperated wheelchairs it provided to the beneficiaries were medically reasonable and necessary. The Council further finds that DMERC Dialogue - Region D, March 1997, and Chapter VII of the DMERC Region D Supplier Manual clearly required that the supplier maintain medical documentation to support the medical necessity for the items provided. Therefore, the Council concludes that the appellant knew or should have known that Medicare payment would not be made for the items in question, and therefore, the appellant's liability for the services at issue may not be waived under § 1879 of the Act.

E. Section 1870 of the Act, Waiver of Liability

Section 1870(b) of the Act provides for waiver of recovery of an overpayment to a provider or other person whenever it is determined that the person is without fault in incurring the overpayment. "Without fault" is described in the Medicare Carrier Manual § 7103 as follows:

Consider a physician without fault if he exercised reasonable care in billing for and accepting the payment; i.e.; he made full disclosure of all material facts, <u>and</u> on the basis of the information available to him, including, but not limited to, the Medicare regulations, he had reasonable basis for assuming that payment was correct or, if the physician had reason to question the payment, he promptly brought the question to your attention.

The Medicare Carriers Manual at § 7103.1 provides examples of situations where a person is not without fault. These include situations where the person furnished erroneous information, or failed to disclose facts that he knew or should have known were material to payment, and situations where the person billed for items or services which he should have known were not covered. A person should have known of a policy or rule if the policy is in the regulations, or was included in a general notice to the medical community.

The Council finds that the appellant had notice that the items would not be Medicare covered without additional medical documentation via the DMERC Dialogue - Region D, March 1997, and Chapter VII of the DMERC Region D Supplier Manual, as cited above. Therefore the appellant was not without fault in incurring the overpayment and is not entitled to waiver under § 1870 of the Act.

FINDINGS

After careful consideration of the entire record, the Medicare Appeals Council makes the following findings:

- 1. The Appellant provided power-operated wheelchairs and accessories to the beneficiaries in 1998 and early 1999.
- The Administrative Law Judges found that the furnished items met all of the requirements for coverage under Part B of Title XVIII of the Social Security Act.
- 3. With the exception of the *** claim, the administrative record does not contain any medical documentation supporting the certificates of medical necessity for the claims at issue.
- 4. The Council took own motion review of the cases on March 21, 2001 and November 1, 2001. In letters dated January 17, 2003 and March 12, 2003, the Appellant waived their right to an oral hearing before an Administrative Law Judge and requested the Council reach a final decision in the cases.
- 5. During the period at issue, a DMERC newsletter advised suppliers that they were responsible for making a judgment whether an item ordered by a physician was medically

necessary and, if the item was later found to not be medically necessary, the supplier may be held liable for the payment.

- 6. During the period at issue, the DMERC's Supplier Manual included a chapter on documentation which stated that a supplier must have on file medical documentation for each DME item.
- 7. The Appellant should have known that the supplies at issue would not be considered medically reasonable and necessary based on the DMERC's manual instructions and newsletter.
- 8. The Council is unable to ascertain whether the Appellant provided a beneficiary signed claim form for beneficiary *** because the primary evidence, the claim form is not contained within the administrative record.
- 9. The Appellant provided a power-operated wheelchair and accessories to beneficiary *** that was not medically reasonable and necessary under Section 1862(a)(1)(A) of the Social Security Act because the beneficiary was able to ambulate with a walker.
- 10. The Appellant supplied power-operated wheelchairs and accessories without supporting medical documentation to the following individuals, whose claims are found to be not medically reasonable and necessary under Section 1862(a)(1) of the Act:

[REDACTED]

- 11. Because the appellant had notice through the DMERC's newsletter and manual instructions that the items at issue would not be covered without documentation supporting the CMNs, it knew or should have known that Medicare payment would not be made for those items and, therefore, is liable under Section 1879 of the Act.
- 12. Because the appellant had notice through the DMERC's newsletter and manual instructions that the items at issue would not be covered without documentation supporting the CMNs, the appellant is not without fault in incurring the overpayment and is not entitled to waiver under Section 1870 of the Act.

DECISION

It is the decision of the Medicare Appeals Council that, as detailed above, Medicare coverage is denied for the poweroperated wheelchairs and accessories at issue because the medical documentation provided did not support that the items were medically reasonable and necessary under Section 1862(a)(1)(A) of the Social Security Act. The appellant's liability for the items at issue may not be waived under § 1879 or § 1870 of the Act.

MEDICARE APPEALS COUNCIL

/s/ M. Susan Wiley Administrative Appeals Judge

/s/ Clausen Krzywicki Administrative Appeals Judge

Date: June 11, 2003