**PUBLISHED**

# UNITED STATES COURT OF APPEALS

## FOR THE FOURTH CIRCUIT

MACKENZIE MEDICAL SUPPLY, INCORPORATED,
*Plaintiff-Appellant,*

v.

MICHAEL O. LEAVITT, in his capacity as Secretary of Health and Human Services,
*Defendant-Appellee,*

and

TOMMY G. THOMPSON, in his capacity as Secretary of the United States Department of Health and Human Services,
*Defendant.*

No. 06-1630

Appeal from the United States District Court
for the District of Maryland, at Baltimore.
Andre M. Davis, District Judge.
(1:04-cv-02807-AMD)

Argued: September 25, 2007

Decided: October 31, 2007

Before TRAXLER, Circuit Judge,
HAMILTON, Senior Circuit Judge, and
Robert J. CONRAD, Jr., Chief United States District Judge for the Western District of North Carolina, sitting by designation.

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Affirmed by published opinion. Senior Judge Hamilton wrote the opinion, in which Judge Traxler and Judge Conrad joined.

## COUNSEL

**ARGUED:** David C. Frederick, KELLOGG, HUBER, HANSEN, TODD, EVANS & FIGEL, P.L.L.C., Washington, D.C., for Appellant. Howard S. Scher, UNITED STATES DEPARTMENT OF JUSTICE, Civil Division, Appellate Section, Washington, D.C., for Appellee. **ON BRIEF:** Derek T. Ho, KELLOGG, HUBER, HANSEN, TODD, EVANS & FIGEL, P.L.L.C., Washington, D.C., for Appellant. Peter D. Keisler, Assistant Attorney General, Rod J. Rosenstein, United States Attorney, Anthony J. Steinmeyer, UNITED STATES DEPARTMENT OF JUSTICE, Civil Division, Appellate Section, Washington, D.C., for Appellee.

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## OPINION

HAMILTON, Senior Circuit Judge:

In this action, MacKenzie Medical Supply, Inc. (MacKenzie) seeks to set aside the Secretary of the United States Department of Health and Human Services' (the Secretary) determination that it overpaid MacKenzie $508,747.57 in Medicare reimbursement payments for 135 power wheelchairs that MacKenzie provided to Medicare recipients between September 1, 1998 and February 28, 1999. According to the Secretary, MacKenzie is liable for the overpayment because a post-payment audit revealed that insufficient medical documentation existed to establish the medical necessity of providing each power wheelchair at issue. In its defense, MacKenzie argued that the documentation that it submitted for reimbursement, in the form of certificates of medical necessity (CMN), as the term CMN is defined in 42 U.S.C. § 1395m(j)(2)(B), sufficed to qualify for reimbursement. Rejecting MacKenzie's argument, the district court granted summary judgment in favor of the Secretary. MacKenzie appealed, and we affirm.

### I.

The Medicare Act (the Medicare Act), 42 U.S.C. § 1395 *et seq.*, establishes a federally subsidized health insurance program for eligi-

ble aged and disabled persons. Akin to private health insurance programs, the Medicare Act and its implementing regulations promulgated by the Secretary set forth conditions and limitations on the coverage of medical services and equipment. *See* 42 U.S.C. §§ 1395k, 1395l, 1395x(s), 1395y(a)(1)-(22), 1395ff(a); 42 C.F.R. § 411.15(a)-(r). Of relevance on appeal, Part B coverage under the Medicare Act extends to durable medical equipment (DME), including power wheelchairs used in the medicare recipient's home (including institutions used as his home other than hospitals or skilled nursing facilities). 42 U.S.C. §§ 1395k(a)(2)(B), 1395x(n), and 1395x(s)(6); 42 C.F.R. § 410.38(a)-(c).

The Medicare program is administered by the Center for Medicare & Medicaid Services (CMS), a division of the United States Department of Health and Human Services (HHS) supervised by the Secretary. *Gulfcoast Medical Supply, Inc. v. Secretary, HHS*, 468 F.3d 1347, 1349 (11th Cir. 2006). At all times relevant to this appeal, in administering Part B, CMS, under the authority of the Secretary, acted through private fiscal contractors called "carriers."[1] 42 U.S.C. § 1395u. Carriers performed a variety of functions, such as making coverage determinations in accordance with the Medicare Act and agency guidance. 42 C.F.R. §§ 405.803, 421.200. Carriers also conducted audits of the claims submitted for payment, and adjusted payments and payment requests. *Id.*; 42 C.F.R. § 421.214. Carriers paid Medicare suppliers on the basis of assignments of benefits executed by the Medicare beneficiaries. 42 U.S.C. § 1395u(b)(3)(B); 42 C.F.R. §§ 424.55, 802.

During the relevant time period, certain carriers, called DME Regional Carriers (DME Regional Carriers), processed DME claims within designated regions of the country. 42 U.S.C. § 1395u; 42 C.F.R. § 421.210. During the relevant time period, the DME Regional Carrier for Region C, which includes Maryland, was Palmetto Gov-

[1]Pursuant to § 911 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (Dec. 8, 2003), with an effective date of October 1, 2005, most of the carrier responsibilities have been transferred to entities now labeled medicare administrative contractors. *See* 42 U.S.C. § 1395kk-1 and Historical and Statutory Notes for such section. *See also* 42 U.S.C. § 1395u(a).

ernment Benefits Administrators (Palmetto). Notably, the Region C DMEPOS[2] Supplier Manual (Autumn 1998) included the following guidelines for coverage of the power wheelchairs at issue here:

> 1. The patient's condition is such that without the use of a wheelchair the patient would otherwise be bed or chair confined; and,
>
> 2. The patient's condition is such that a wheelchair is medically necessary and the patient is unable to operate a wheelchair manually; and,
>
> 3. The patient is capable of safely operating the controls for the power wheelchair.

(J.A. 156-57). The same manual further provided that "[a] patient who requires a power wheelchair usually is totally nonambulatory and has severe weakness of the upper extremities due to a neurologic or muscular disease/condition." (J.A. 157). In all cases, Medicare Part B coverage is limited to services that are medically "reasonable and necessary" for the diagnosis or treatment of illness. 42 U.S.C. § 1395y(a)(1)(A).

Pursuant to 42 U.S.C. § 1395l(e), payment on a DME claim under Part B cannot be made "unless there has been furnished such information as may be necessary in order to" support payment of the claim. To facilitate claims processing for DME, the Medicare Act permits DME suppliers to distribute CMNs to physicians. 42 U.S.C. § 1395m(j)(2)(A); *Gulfcoast Medical Supply, Inc.*, 468 F.3d at 1349. The Medicare Act defines CMN as "a form or other document containing information required by the carrier to be submitted to show that an item is [medically] reasonable and necessary for the diagnosis or treatment of illness or injury . . . ." 42 U.S.C. § 1395m(j)(2)(B).

CMS has approved a one-page CMN specifically for power wheelchairs, on which the DME supplier is permitted to provide the follow-

[2]DMEPOS refers to the category of DME in the form of prosthetics or orthotics.

ing information: (1) identification of the supplier and the beneficiary; (2) a description of the medical equipment; (3) the product code identifying such equipment; and (4) "[a]ny other administrative information (other than information relating to the beneficiary's medical condition) identified by the Secretary." 42 U.S.C. § 1395m(j)(2)(A)(i). Section B of the form also asks a series of questions related to the mobility and medical condition of the beneficiary, which the beneficiary's treating physician or a third party, but not the DME supplier, is permitted to answer. The only part of the form required to be completed by the treating physician is the attestation portion of the form whereby the treating physician certifies via his signature and date that "the medical necessity information in Section B is true, accurate and complete, to the best of my knowledge, and I understand that any falsification, omission, or concealment of material fact in that section may subject me to civil or criminal liability." (J.A. 222).

Of relevance in the present appeal, the Secretary has issued a directive advising Region C DME suppliers that medical documentation in addition to a physician's order for DME may be necessary in order to substantiate compliance with the "reasonable and necessary" requirement of the Medicare Act. Specifically, Region C's Medicare Advisory (September 1996) advised Region C suppliers that:

> It is the primary responsibility of those supplying beneficiaries with durable medical equipment, prostheses, orthoses and supplies (DMEPOS) to assure claims billed to Medicare have the proper documentation accurately reflecting the beneficiary's medical condition as it relates to the Medicare coverage criteria by which claims are adjudicated by the Durable Medical Equipment Regional Carrier (DMERC). *Even if a supplier has a physician order on file, failure of the patient's medical records to substantiate the condition for which Medicare approves reimbursement subjects the supplier to liability for repayment of that reimbursement to the Medicare program, and possibly to civil and criminal penalties.* Therefore, it is to the benefit of suppliers, Medicare beneficiaries and the Medicare Trust Fund that physicians be well informed about their role in evaluating, ordering and documenting the need of DMEPOS for their

> Medicare patients. The better informed the physician about DMERC Regional Medical Review Policies (RMRPs) and Medicare's coverage criteria for DMEPOS, the less likely the supplier's frustration at filling orders for items that will not be, or should not have been, reimbursed.

(J.A. 249) (emphasis added).

During the period at issue, September 1, 1998, through February 28, 1999, MacKenzie submitted to Palmetto, for reimbursement, claims for a total of 135 power wheelchairs. MacKenzie supported each claim solely with a completed CMN, which claims Palmetto initially approved and made payment.

In April 1999, Palmetto initiated a post-payment audit because: (1) MacKenzie had submitted an extremely high volume of claims for power wheelchairs; (2) more than 30% of the Medicare payments received by MacKenzie during the time period used the same referring physician; and (3) of the 135 beneficiaries receiving power wheelchairs from MacKenzie during the relevant time period, 115 did not previously have any prior wheelchair, such as a manual wheelchair, which failed to indicate a progression of a medical condition that might medically lead to the use of a power wheelchair. These concerns resulted in an audit by a medical investigator of a random sample of thirty out of the 135 claims, twenty-nine of which failed to satisfy the requirements for medical necessity.

The medical investigator requested all relevant medical records from MacKenzie and the treating physicians and concluded that for twenty-one of the beneficiaries, "the information and progress notes supplied are not sufficiently specific to warrant powered mobility within the confines of a home or apartment. While powered mobility might help extend the distance the beneficiary might be able to travel beyond the boundaries of the home, it must be needed for mobility within the home to be considered medically necessary by Medicare." (J.A. 198-99). The audit report further noted that no physicians' surveys or progress notes were received with respect to eight beneficiaries as requested during the audit, and those claims were denied since "medical necessity could not be established." (J.A. 293).

Based on these findings, CMS approved a request by Palmetto to suspend payment to MacKenzie effective July 20, 1999. Palmetto determined the total overpayment for the sample to be $114,448.96 and, from that sample, projected the total amount of overpayment to be $508,747.57. On November 2000, Palmetto notified MacKenzie by letter that it had been overpaid by $508,747.57.

MacKenzie then proceeded to exhaust its administrative remedies in challenge to the overpayment notice. 42 U.S.C. § 1395ff(b)(1)(A). First, MacKenzie requested reconsideration by a hearing officer through Palmetto's internal appeal process, arguing the Secretary lacked the authority to deny any DME claim supported by a completed CMN. The hearing officer rejected MacKenzie's argument and upheld the overpayment determination. MacKenzie then appealed to an administrative law judge (ALJ), who upheld the hearing officer. The ALJ also determined that, because MacKenzie ignored guidelines provided in various Palmetto issuances "which advised suppliers that if clinical records were not available to support a CMN, payment could be denied," (J.A. 79), MacKenzie was not without fault, and, therefore, was not entitled to a waiver of liability under Medicare Part B's safe harbor provision. MacKenzie subsequently appealed the ALJ's decision to the Medicare Appeals Council, which upheld the ALJ's decision.

Having exhausted its administrative remedies with the Secretary, MacKenzie filed the present action in federal court, seeking judicial review of the Secretary's final overpayment determination. *See* 42 U.S.C. § 1395ff(b)(1)(A) (providing for judicial review of final decisions by the Secretary regarding reimbursement claims under Medicare Part B upon exhaustion of administrative remedies). MacKenzie challenged the Secretary's final decision on three grounds: (1) the Secretary's position was erroneous that he could condition approval of a DME claim upon the provision of medical documentation beyond a completed CMN; (2) requiring it to provide any documentation in addition to a CMN in order to support a DME claim violated the Paperwork Reduction Act of 1995, 44 U.S.C. § 3501 *et seq.*; and (3) 42 U.S.C. §§ 1395gg(c) and 1395pp(a) entitled it to waiver of repayment.

On cross-motions for summary judgment, the district court granted summary judgment in favor of the Secretary, thereby upholding the Secretary's final decision. This timely appeal followed.

II.

Our review of the Secretary's final decision in this case, like the district court, is to be based solely on the administrative record, and the Secretary's findings of fact, if supported by substantial evidence, shall be conclusive. 42 U.S.C. § 1395ff(b)(1)(A) (incorporating 42 U.S.C. § 405(g) by reference). Moreover, because the Secretary is charged with administering the Medicare Act, we substantially defer to the Secretary's construction of any ambiguous language in the Act, if the Secretary's construction "is based on a permissible construction of the statute." *Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 843 (1984).

MacKenzie first argues that the plain language of Part B of the Medicare Act provides that a completed CMN is always sufficient to entitle a DME supplier to reimbursement on a DME claim under Part B. Thus, because MacKenzie submitted a completed CMN for each of the power wheelchair claims at issue, MacKenzie contends the Secretary lacked the authority to reject those claims on the basis of the additional medical records procured and those requested but not procured. MacKenzie argues that 42 U.S.C. § 1395m(j)(2)(A)(i) and (j)(2)(B), when read in combination, unambiguously dictate this result. Moreover, MacKenzie argues that any other reading would undermine Congress' purpose in creating the CMN to streamline the DME claim process.

The first of the statutory subsections relied upon by MacKenzie provides:

> **(2) Certificates of medical necessity**
>
> > **(A) Limitation on information provided by suppliers on certificates of medical necessity.**
> >
> > **(i) In general**

> Effective 60 days after October 31, 1994, a supplier of medical equipment and supplies *may* distribute to physicians, or to individuals entitled to benefits under this part, a certificate of medical necessity for commercial purposes which contains no more than the following information completed by the supplier:
>
> > **(I)** An identification of the supplier and the beneficiary to whom such medical equipment and supplies are furnished.
> >
> > **(II)** A description of such medical equipment and supplies.
> >
> > **(III)** Any product code identifying such medical equipment and supplies.
> >
> > **(IV)** Any other administrative information (other than information relating to the beneficiary's medical condition) identified by the Secretary.

42 U.S.C. § 1395m(j)(2)(A)(i) (underscore emphasis added). The second of the two statutory subsections relied upon by MacKenzie supplies the definition of the term "certificate of medical need" as found in the just quoted passage:

> **(B) Definition**
>
> For purposes of this paragraph, the term "certificate of medical need" 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.

42 U.S.C. § 1395m(j)(2)(B) (emphasis added).

With respect to case law in support of its position, MacKenzie relies upon a district court case from the Eastern District of California, *Maximum Comfort, Inc. v. Thompson*, 323 F. Supp. 2d 1060 (E.D.Cal. 2004). The *Maximum Comfort* court held that "[t]he Secretary's contention that Congress provided him with the authority to decide what documentation may be required to determine the medical necessity of DME conflicts with the plain meaning of § 1395m(j)(2)(B)." *Id.* at 1067-68. According to the *Maximum Comfort* court, § 1395m(j)(2)(B) "plainly specifies that Congress intended that whatever information may be required by carriers from suppliers to show the medical necessity and reasonableness of DME must be contained in a CMN." *Id.* at 1068.

We disagree. Contrary to MacKenzie's position and the similar holding of *Maximum Comfort*, 42 U.S.C. § 1395m(j)(2)(A)(i) and (j)(2)(B), when read in combination, do not unambiguously provide that a completed CMN is always sufficient to entitle a DME supplier to reimbursement on a DME claim. While the use of the permissive "may" in § 1395m(j)(2)(A)(i) certainly grants a DME supplier permission to distribute a partially completed CMN to a physician treating a Medicare patient, such language in no way mandates a DME supplier's entitlement to reimbursement on a DME claim solely upon the DME supplier's submission of such claim supported only by a fully completed CMN. *See Lopez v. Davis*, 531 U.S. 230, 241 (2001) (describing statute's use of "may" as permissive and contrasting it with Congress' use of a mandatory "shall" elsewhere in statute to impose discretionless obligations). The same holds true for the definition of CMN in § 1395m(j)(2)(B). In the words of the Eleventh Circuit, which has had occasion to address the same argument MacKenzie makes with respect to the statutory definition of CMN:

> First and foremost, § 1395m(j)(2)(B) does not state unequivocally that a CMN is the *only* documentation that may be required of suppliers to show medical necessity. Section 1395m(j)(2)(B) simply defines a CMN as "a form or other document" containing information showing medical necessity. On its face, the section simply does not contain any explicit or unambiguous words of exclusivity-Section 1395m(j)(2)(B) does not define a CMN as "*the* form" or "the

> *only* form" containing "*all* information" or "*exclusive* information" of medical necessity.

*Gulfcoast*, 468 F.3d at 1351 (emphasis in original). Given our analysis and MacKenzie's failure to point us to any other section of the Medicare Act even suggesting that the Secretary's hands are tied with respect to requiring additional medical documentation to establish the medically "reasonable and necessary" standard set forth in 42 U.S.C. § 1395y(a)(1)(A) in the case of a DME claim supported only by a fully completed DME, we reject MacKenzie's plain language argument.

Moreover, it follows that even if the Medicare Act were ambiguous on this issue, the Secretary's interpretation of § 1395m(j)(2)(A)(i) and (j)(2)(B) as not mandating that a completed CMN is always sufficient to entitle a DME supplier to reimbursement on a DME claim under Part B "is based on a permissible construction of the statute." *Chevron*, 467 U.S. at 843. This is especially so given that 42 U.S.C. § 1395ff(a) affords the Secretary discretion to make determinations with respect to DME claims under Part B of the Medicare Act, and 42 U.S.C. §§ 1395u(p)(4) and 1395ddd afford the Secretary (or the fiscal agent of the Secretary) auditing powers with respect to such claims under Part B.

Furthermore, the Secretary's reading of 42 U.S.C. § 1395m(j)(2)(A)(i) and (j)(2)(B) does not, as MacKenzie asserts, undermine Congress' legislative goal of standardization in creating the CMN. We agree with the Eleventh Circuit that the CMN is best viewed as "an optional pre-payment tool designed primarily to reduce paperwork and to streamline the processing of claims," *Gulfcoast*, 468 F.3d at 1352, not as a complete standardization of the DME-claim-process which eliminates all flexibility of the Secretary to require further support for DME claims initially made via a CMN. In short, MacKenzie could not overcome the deference we would owe to the Secretary's interpretation under *Chevron*.

In conclusion, the plain language of the Medicare Act does not support MacKenzie's position that a DME claim accompanied solely by a completed CMN is always sufficient to support payment. Moreover, even if the Medicare Act is ambiguous on this point, the Secretary's

reading of the statute is reasonable, and therefore, would be entitled to *Chevron* deference. Accordingly, the district court did not err in rejecting MacKenzie's plain language argument.

III.

We next address MacKenzie's challenge to the district court's rejection of its argument that, under the waiver mechanism set forth in 42 U.S.C. §§ 1395gg(c) and/or 1395pp(a), it is exempt from liability to repay any and all monies that it received for the power wheelchairs at issue in this case. MacKenzie's challenge is without merit.

First, MacKenzie cannot avail itself of the waiver mechanism provided in 42 U.S.C. § 1395gg(c), because § 1395gg(c) explicitly applies only to the waiver of "adjustment[s] as provided in subsection (b) of this section," *id.*, and the only adjustment contemplated by § 1395gg(b) is an adjustment of payments to individuals not suppliers or providers. *Visiting Nurses Ass'n of Southwestern Indiana, Inc. v. Shalala*, 213 F.3d 352, 355-59 (7th Cir. 2000) (holding overpayment waiver mechanism in § 1395gg(c) applies only to individual Medicare beneficiaries, not Medicare providers, in view of statutory and regulatory distinctions between individuals and providers). Rather, MacKenzie must proceed on its waiver argument under 42 U.S.C. § 1395pp(a), which statutory section allows a DME supplier such as itself to obtain a waiver of liability for overpayment receipt when coverage is later denied and the individual beneficiary of the DME at issue and the DME supplier both "did not know, and could not reasonably have been expected to know, that payment would not be made for such items . . . ."[3] *Id. See also Kraemer v. Heckler*, 737 F.2d 214, 216 (2d Cir. 1984) (noting individual/provider distinction between §§ 1395gg(b)-(c) and 1395pp(a)).

MacKenzie contends that it is entitled to a waiver of overpayment for the entire amount sought to be recovered by the Secretary, because it could not have known that reimbursement would be denied for lack of medical documentation in addition to the respective CMNs that it

[3]Apparently also aware of the distinction, the district court only specifically addressed MacKenzie's waiver of liability argument under 42 U.S.C. § 1395pp(a).

submitted. According to MacKenzie, its interpretation of 42 U.S.C. § 1395m(j)(2)(A)(i) and (j)(2)(B) as providing that a completed CMN is always sufficient to entitle a DME supplier to reimbursement was objectively reasonable at the time of reimbursement given the language of § 1395m(j)(2)(B) and the then lack of case law to the contrary.

None of MacKenzie's arguments warrant reversal on this issue. As our analysis in Part II demonstrates, the plain language of § 1395m(j)(2)(A)(i) and (j)(2)(B) in no way states that a CMN alone is sufficient to establish medical reasonableness and necessity under Part B. Moreover, Region C's Medicare Advisory Manual (1996) explicitly put MacKenzie on notice that medical documentation in addition to a physician's order (which is the nature of a CMN) may be required to support a DME claim. In light of these circumstances, the fact that no case law had been issued on the subject is beside the point. Finally, the ALJ, as the trier of fact, had the opportunity to judge the credibility of the witnesses on this point not us or the district court. In sum, there is no basis upon which to reverse the district court's upholding of the administrative denial of MacKenzie's claim that it is entitled to a waiver of liability for the overpayment that it received in connection with the power wheelchairs at issue.

## IV.

MacKenzie argued below and argues on appeal that the Paperwork Reduction Act of 1995 (PRA), 44 U.S.C. § 3501 *et seq.*, prevents the Secretary from requesting medical records in addition to CMNs to substantiate its DME claims for the power wheelchairs at issue. We reject MacKenzie's argument as without merit on the reasoning of the district court.

Under the PRA, the government is prohibited from sponsoring a collection of information unless certain procedures are followed, including an opportunity for public comment, approval from the Office of Management and Budget, and the display of a control number on the request. 44 U.S.C. §§ 3506(c)(2), 3507(a), (c). However, the government is exempted from the requirements of the PRA "during the conduct of—(ii) an . . . investigation involving an agency

against specific individuals or entities . . . ." 44 U.S.C. § 3518(c)(1)(B)(ii).

The district court concluded that this investigation exception applied to exempt the Secretary from the requirements of the PRA in investigating DME claims under Part B. Specifically, the district court reasoned:

> For one thing, although the word "audit" is not mentioned specifically in the exception to the PRA, an audit certainly must be considered to be a subset of an "investigation." *See Shell Oil Co. v. Babbitt*, 945 F. Supp. 792, 807 (D.Del. 1996) ("The PRA specifically exempts activities such as an [Minerals Management Service] audit from its requirements.").
>
> In addition, contrary to MacKenzie's argument, the Secretary has not issued an information request "to an entire class of individuals." Pl.'s Reply in Opp. to Def.'s Mot. for Summ. J. at 24. Rather, here the audit explicitly targeted MacKenzie because MacKenzie was submitting an unusually high rate of requests for power wheelchairs. A.R. 20, 1073-77. In addition, about 30 percent of payments from those requests come from a single doctor's referrals. *Id.* This request certainly falls under the investigatory exception to the PRA.(J.A. 303). We agree. Accordingly, we hold the investigatory exception to the requirements of the PRA squarely applies.

V.

For the above stated reasons, we affirm the district court's grant of summary judgment in favor of the Secretary.

*AFFIRMED*