[PUBLISH]

IN THE UNITED STATES COURT OF APPEALS

FOR THE ELEVENTH CIRCUIT

FILED
U.S. COURT OF APPEALS
ELEVENTH CIRCUIT
NOVEMBER 3, 2006
THOMAS K. KAHN
CLERK

No. 05-16935

D. C. Docket No. 04-02610-CV-T-26EAJ

GULFCOAST MEDICAL SUPPLY, INC.,

Plaintiff-Appellant,

versus

SECRETARY, DEPARTMENT OF HEALTH
AND HUMAN SERVICES,

Defendant-Appellee.

Appeal from the United States District Court
for the Middle District of Florida

(November 3, 2006)

Before BLACK and HULL, Circuit Judges, and RYSKAMP,[*] District Judge.

PER CURIAM:

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[*]Honorable Kenneth L. Ryskamp, United States District Judge for the Southern District of Florida, sitting by designation.

Appellant Gulfcoast Medical Supply (Gulfcoast) is a Florida-based supplier of durable medical equipment (DME), including motorized wheelchairs. Appellee, the Secretary of Health and Human Services (Secretary), administers the federal Medicare program. The Secretary determined that Medicare had overpaid Gulfcoast for wheelchairs Gulfcoast supplied to Medicare beneficiaries between September 8, 2001, and February 14, 2002. Gulfcoast sought judicial review of the Secretary's decision in the United States District Court for the Middle District of Florida, and the district court affirmed.

This appeal presents an issue of first impression in this and all circuit courts: whether, under Part B of the Medicare Act, a DME supplier unequivocally establishes that such equipment is medically "reasonable and necessary" (and therefore covered by Part B of the Act) by submitting a "certificate of medical necessity," or whether the Secretary may require the supplier to submit additional evidence of medical necessity.[1] We find the Secretary has discretion to require additional submissions, and we therefore affirm.

I. BACKGROUND

[1] We note that two district courts have addressed the issue: *MacKenzie Medical Supply, Inc. v. Leavitt*, 419 F. Supp. 2d 766 (D. Md. 2006) and *Maximum Comfort, Inc. v. Thompson*, 323 F. Supp. 2d 1060 (E.D. Cal. 2004).

Part B of the Medicare Act is a federally subsidized, voluntary enrollment health insurance program. 42 U.S.C. §§ 395j to 1395w-4. Part B pays a substantial portion of the health costs incurred by those enrolled in the program, including the costs of DME such as wheelchairs. 42 U.S.C. § 1395x(n); 42 C.F.R. § 410.38(a)-(c). The program is administered by the Center for Medicare and Medicaid Services (CMS), a division supervised by the Secretary. *See generally United States v. R&F Properties of Lake County, Inc.*, 433 F.3d 1349, 1351 (11th Cir. 2005).

Part B coverage extends only to those medical services that are medically "reasonable and necessary" for the beneficiary. 42 U.S.C. § 1395y(a); 42 C.F.R. § 411.15(k)(1). In order to administer, validate, and pay claims made under Part B, CMS contracts with regional, private insurance carriers who act as claims processors. 42 U.S.C. § 1395u; *see R&F Properties*, 433 F.3d at 1351. Upon receipt of a claim for payment, the carrier decides whether the claimed services "were medically necessary, whether the charges are reasonable, and whether the claim is otherwise covered by Part B." *Schweiker v. McClure*, 456 U.S. 188, 191, 102 S. Ct. 1665, 1667 (1982); *see* 42 U.S.C. §§ 1395*l*, 1395y(a); 42 C.F.R. § 405.803. Among other requirements, Medicare will not pay a claim unless a

physician certifies that the medical services were medically required. 42 U.S.C. § 1395n(a)(2)(B)

To facilitate claims processing, the Medicare Act permits DME suppliers to distribute to physicians a "certificate of medical necessity" (CMN). 42 U.S.C. § 1395m(j)(2)(A). The Medicare Act defines the 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. . . . " 42 U.S.C. § 1395m(j)(2)(B). Pursuant to the Medicare Act, suppliers of medical services are permitted to fill in certain portions of the CMN in advance to make it easier for physicians to complete the remainder of the CMN. Specifically, suppliers are permitted to include on the CMN (1) identifying information about the supplier and the beneficiary, (2) a description and product code for the medical equipment supplied, and (3) other administrative information not related to the beneficiary's medical condition. 42 U.S.C. § 1395m(j)(2)(A). The partially completed form reduces the administrative burden on physicians, who need only supply the medical information on the CMN.

For reasons of administrative efficiency, carriers typically authorize payment on claims immediately upon receipt of the claims, so long as the claims do not contain glaring irregularities. Later, carriers conduct post-payment audits to verify that the payments were proper. *See* 42 U.S.C. § 1395u; 42 C.F.R. § 421.200(a)(2).

When the carrier discovers that an overpayment has occurred, the carrier may suspend or recoup payment. 42 C.F.R. § 405.371(a).

A supplier dissatisfied with the carrier's resolution of a claim may appeal the decision through a designated administrative appeals process. 42 U.S.C. § 1395ff(b)(1)(A) (incorporating by reference the appeals process under the Social Security Act, 42 U.S.C. § 405(b)); *see also* 42 C.F.R. § 405.801. After exhausting this administrative process, the supplier may seek judicial review by a federal district court. 42 U.S.C. § 1395ff(b)(1)(A) (incorporating by reference the judicial review available under the Social Security Act, 42 U.S.C. § 405(g)).

II. FACTS

Gulfcoast is a Florida-based supplier of DME, including motorized wheelchairs. At all relevant times, the Medicare carrier administering Part B claims in Gulfcoast's region was Palmetto Government Benefits Administrators (Palmetto).

After receiving consumer complaints and suspicious results from statistical analyses of Gulfcoast's claims, Palmetto decided to audit Gulfcoast. In June 2002, Palmetto surveyed 30 randomly selected beneficiaries out of the 102 beneficiaries who received a certain type of power wheelchair from Gulfcoast between

September 8, 2001, and February 14, 2002. Palmetto requested medical records of all 30 beneficiaries and interviewed 20 of the beneficiaries (or their caregivers).

Based on its audit, Palmetto determined that a number of the patients for whom Gulfcoast had submitted claims for Medicare reimbursement of DME did not meet the necessary criteria. For example, Palmetto found that services for 22 of the beneficiaries were not supported by documents in their medical records and that at least half of those whose records were examined did not need a power wheelchair. Palmetto ultimately concluded that Gulfcoast had been overpaid by $280,573.68. A Medicare fair hearing officer affirmed the overpayment assessment.

Gulfcoast appealed the carrier's decision before an administrative law judge (ALJ). Gulfcoast argued that because it submitted a CMN signed by a physician for each of the challenged claims, Palmetto lacked discretion to reject those claims on the basis of additional evidence. The ALJ rejected Gulfcoast's argument and found that the 30 audited claims reflected a "pattern of erroneous billing." The ALJ determined that overpayments were correctly assessed in 17 cases, but incorrectly in 6 others,[2] and therefore ordered that the total be recalculated by the

[2]Of the 30 claims audited by Palmetto, 6 were initially allowed by Palmetto. Therefore, before the ALJ for consideration were 24 claims. The ALJ dismissed one claim and adjudicated the remaining 23 claims.

carrier. Gulfcoast appealed to the United States District Court for the Middle District of Florida, which affirmed.

III. DISCUSSION

The facts established by the administrative record and outlined above are not in dispute, and the sole issue before us is a question of law.[3] Gulfcoast argues that as a matter of statutory construction, Part B of the Medicare Act does not give carriers or the Secretary discretion to require a supplier to submit additional medical documentation beyond the CMN to prove medical reasonableness and necessity. Rather, according to Gulfcoast, the CMN signed by a physician is legally sufficient to validate a claim under Plan B. Thus, because Gulfcoast submitted a signed CMN for each of the disputed claims, Gulfcoast contends that the Secretary lacked discretion to reject those claims on the basis of the additional records procured and interviews conducted by the carrier, Palmetto.

Gulfcoast's argument relies almost entirely on the Medicare Act's definition of a "certificate of medical necessity" as "a form or other document containing information required by the carrier to be submitted to show that an item is

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[3]Pursuant to 42 U.S.C. § 405(g), judicial review of the Secretary's decision regarding a claim for Medicare benefits is limited to "whether there is substantial evidence to support the findings of the . . . [Secretary], and whether the correct legal standards were applied." *Wilson v. Barnhart,* 284 F.3d 1219, 1221 (11th Cir. 2002); *see* 42 U.S.C. § 1395ff(b)(1)(A) (incorporating into Medicare Act the standard of review set forth in 42 U.S.C. § 405(g)). We review *de novo* the district court's determination of whether substantial evidence supports the ALJ's decision. *Wilson*, 284 F.3d at 1221.

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). Gulfcoast argues that this statutory provision unambiguously mandates that a CMN alone establishes the reasonableness and necessity of medical equipment, leaving the Secretary no discretion to require a supplier to submit additional proof of medical necessity. Gulfcoast asks us to follow a California district court's ruling 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 § 1395(j)(2)(B)." *Maximum Comfort, Inc. v. Thompson*, 323 F. Supp. 2d 1060, 1067-68 (E. D. Cal. 2004). 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.

In considering Gulfcoast's contention that the Secretary's actions were contrary to the Medicare Act, we are mindful that "considerable weight should be accorded to an executive department's construction of a statutory scheme it is entrusted to administer." *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 844, 104 S. Ct. 2778, 2782 (1984). Under *Chevron*'s

two-step approach, we first ask "whether Congress has directly spoken to the precise question at issue," removing the interpretation of the statutory provision from the agency's discretion. *Id.* at 842, 104 S. Ct. at 2781. Only if the statute "is silent or ambiguous with respect to the specific issue" will we proceed to *Chevron*'s second step and ask "whether the agency's [interpretation] is based on a permissible construction of the statute." *Id.* at 842-43, 104 S. Ct. at 2781-82.

Gulfcoast insists that the Secretary's position fails on the first step of the *Chevron* analysis. According to Gulfcoast, § 1395m(j)(2)(B) unambiguously removes from the Secretary any discretion to request additional medical necessity documentation beyond a CMN. *See Maximum Comfort*, 323 F.Supp.2d at 1075 (asserting that § 1395m(j)(2)(B) the plain language of the Medicare Act requires that "any and all information required from suppliers to make a medical necessity determination must be contained in a CMN").

Contrary to Gulfcoast's assertion and the holding in *Maximum Comfort*, the Medicare statute does not unambiguously preclude the Secretary from requiring a supplier to submit information beyond a CMN to prove medical reasonableness and necessity. 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 fails to draw our attention to any other section of the Medicare Act that states, or even suggests, that the Secretary may not require that a supplier supplement a CMN with other documentation. Thus, Gulfcoast's argument asks us to construe § 1395m(j)(2)(B), a definition subsection of the Act, as performing a substantive function not delineated elsewhere. As persuasively reasoned by the district court in *MacKenzie Medical Supply, Inc. v. Leavitt*, 419 F. Supp. 2d 766, 771 (D. Md. 2006), the subsection that defines "certificate of medical necessity" is an unlikely place for Congress "to mandate that the CMN serve as the exclusive and final documentation required for proof of medical necessity."

In fact, neither § 1395m(j)(2) nor any other provision even requires that a supplier submit a CMN to the carrier. Section 1395m(j)(2)(A) provides that a medical equipment supplier "may distribute" a CMN to physicians, and then restricts the information the supplier may complete on a CMN. In other words, a CMN is an optional pre-payment tool designed primarily to reduce paperwork and

to streamline the processing of claims. Section 1395m(j)(2)(A) restricts the supplier's ability to fill out a CMN in advance, no doubt in order to ensure that CMNs are not abused. It would be incoherent to construe §1395m(j)(2), a subsection restricting the use of CMNs and clearly indicating that they are voluntary, to also make CMNs the exclusive means for proving medical necessity. *See also* 42 U.S.C. § 1395x(n) (stating that Part B coverage extends to power wheelchairs "where the use of such a vehicle is determined to be necessary on the basis of the individual's medical and physical condition" but making no mention of CMNs as proof of such necessity).

To the contrary, the auditing provisions of Part B convince us that Congress unambiguously contemplated the Secretary's authority to require suppliers to submit medical documentation beyond a CMN to prove medical reasonableness and necessity. The Act empowers carriers to "make such audits of the records of providers of services as may be necessary to assure that proper payments are made under this part." 42 U.S.C. § 1395u(a)(1)(C); *see also* 42 C.F.R. § 421.200(e) (requiring that "[t]he carrier must audit the records of providers to whom it makes Medicare Part B payments, to assure that payments are made properly"). If, as Gulfcoast suggests, the carriers and the Secretary have no discretion to request any evidence of medical necessity apart from the CMNs already submitted by the

suppliers, such audits would be rendered useless. Moreover, were we to adopt Gulfcoast's position, the Secretary would effectively lack the discretion to deny any claim so long as a supplier could find a physician–even a dishonest or incompetent one–to sign a CMN. Accordingly, we agree with the district court, and we conclude that when the Medicare Act is read as a whole, it unambiguously permits carriers and the Secretary to require suppliers to submit evidence of medical necessity beyond a CMN.

However, even if the Medicare Act were ambiguous on this issue, the Secretary's interpretation of its authority under the Medicare Act is permissible. Section 1395ff(a) affords the Secretary discretion to make determinations with respect to benefits under Part B of the Act. 42 U.S.C. § 1395ff(a). Given the Secretary's discretion under § 1395ff(a), as well as the language of § 1395(m)(j)(2) and the carriers' authority to conduct post-payment audits pursuant to § 1395(a)(1)(C), Palmetto and the Secretary acted reasonably in assuming the authority to require additional documentation from Gulfcoast. Because Medicare is a "complex and highly technical regulatory program," judicial deference to the Secretary's discretionary decisions in this area is all the more warranted. *Sarasota Mem'l Hosp. v. Shalala*, 60 F.3d 1507, 1511 (11th Cir. 1995).

AFFIRMED.