FOR PUBLICATION

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

MAXIMUM COMFORT INC., *Plaintiff-Appellee,* v. SECRETARY OF HEALTH AND HUMAN SERVICES; MICHAEL O. LEAVITT,* *Defendants-Appellants.*	No. 05-15832 D.C. No. CV-03-01584-LKK OPINION

Appeal from the United States District Court
for the Eastern District of California
Lawrence K. Karlton, Senior Judge, Presiding

Argued and Submitted
June 13, 2007—San Francisco, California

Filed December 21, 2007

Before: Mary M. Schroeder, William C. Canby, Jr. and
M. Margaret McKeown, Circuit Judges.

Opinion by Judge Canby

*Michael O. Leavitt is substituted for his predecessor, Tommy G. Thompson, as Secretary of Health and Human Services. Fed. R. App. P. 43(c)(2).

COUNSEL

Howard S. Scher, Assistant United States Attorney, Civil Division, Washington, D.C., for the defendants-appellants.

David C. Frederick, Kellogg, Huber, Hansen, Todd, Evans & Figel, P.L.L.C., Washington, D.C., for the plaintiff-appellee.

OPINION

CANBY, Circuit Judge:

Appellant, the Secretary of Health and Human Services, administers the federal Medicare program. Appellee Maximum Comfort, Inc. supplies power-operated wheelchairs to Medicare beneficiaries. The Secretary determined that Maximum Comfort was not entitled to reimbursement for equipment it supplied to certain Medicare beneficiaries, because the company did not establish sufficiently that the power wheelchairs were medically necessary. Maximum Comfort sought judicial review of the Secretary's determination, and the district court reversed. The Secretary now appeals.

The primary question before us is whether Maximum Comfort, by submitting for each wheelchair a "certificate of medical necessity"[1] signed by a physician, established conclusively that the wheelchair was medically necessary, thus precluding the Secretary from requiring additional documentation. Like the other two circuit courts that have addressed the question, we conclude that the applicable provisions of the Medicare Act do not make the certificate conclusive, and that the Secretary may require additional documentation to establish medical necessity. *See MacKenzie Medical Supply, Inc. v. Leavitt*, No. 06-1630, 2007 WL 3173302 (4th Cir. Oct. 31, 2007); *Gulfcoast Medical Supply, Inc. v. Secretary, HHS*, 468 F.3d

[1]The parties and the decisions under review all use the initials CMN in place of "certificate of medical necessity." For ease of comprehensible reading, we will avoid use of the initials except where inclusion in quoted material compels it. In the same spirit, we avoid entirely the use of DME for "durable medical equipment."

1347 (11th Cir. 2006). We accordingly reverse the decision of the district court.

I. BACKGROUND: PART B OF THE MEDICARE ACT

The Medicare Act, established under Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395-1395hhh, provides coverage for certain medical services to eligible aged and disabled people. The Medicare Program is administered by the Centers for Medicare and Medicaid Services, on behalf of the Department of Health and Human Services. Part B of the Medicare Act provides supplementary medical insurance for, *inter alia*, covered medical supplies, including durable medical equipment such as power-operated wheelchairs. 42 U.S.C. §§ 1395j–1395w-4.

In administering Part B, the Centers act through private entities, such as insurance companies, called "carriers."[2] Claims for durable medical equipment are processed by designated regional carriers. *See* 42 U.S.C. §§ 1395m(a)(12), 1395u. Upon receipt of a claim for such equipment, the carrier pays the Medicare beneficiary on the basis of an itemized bill, or pays the Medicare supplier on the basis of an assignment of benefits from the beneficiary. 42 U.S.C. § 1395u(b)(3)(B).

In order for the beneficiary, and therefore the equipment supplier, to be reimbursed for a claim, Medicare requires the beneficiary's physician to certify that the services provided were medically required. 42 U.S.C. § 1395n(a)(2); *see also* 42 U.S.C. § 1395y(a)(1)(A) (Medicare coverage is limited to services that are medically "reasonable and necessary"). In connection with the processing of claims, an equipment supplier "may distribute to physicians" a "certificate of medical necessity," which the statute defines as "a form or other document

[2]These carriers also are referred to as "medicare administrative contractors" in recent amendments to the Medicare Act. *See* Pub. L. No. 108-173, 117 Stat. 2066, 2384 (2003).

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). Suppliers may include on the certificate only certain information, such as identifying information about the supplier, the beneficiary, the equipment being supplied, and other administrative information unrelated to the beneficiary's medical condition. *Id.* The remaining information is completed by the beneficiary's physician. If the Secretary requires a supplier of durable medical equipment to provide diagnostic or other medical information in order for payment to be made, the physician "shall provide that information to the entity at the time that the item [ ] is ordered . . . ." 42 U.S.C. § 1395u(p)(4).

"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." *Gulfcoast*, 468 F.3d at 1349. Carriers later may conduct audits to ensure that payments were made in accordance with Medicare criteria. If the carrier discovers that payments were made for equipment not covered by the Medicare Act, it may assess an overpayment and recoup the overpaid amount from the supplier. 42 C.F.R. § 405.371(a). Suppliers, however, may be excused from liability for repayments when they did not have reason to know the equipment they supplied would not be covered by Medicare. 42 U.S.C. § 1395pp. Suppliers also may appeal carriers' claim resolutions through a designated administrative appeals process, 42 U.S.C. § 1395ff(b)(1)(A), and, after exhausting the administrative appeals process, may seek judicial review in federal court pursuant to the Administrative Procedure Act. *Id.*; 42 U.S.C. § 405(g).

II. FACTS

In 1998 and 1999, Maximum Comfort provided numerous power-operated wheelchairs to Medicare beneficiaries in Cali-

fornia, Oregon, and Nevada. CIGNA Healthcare, the designated regional carrier, initially approved the claims for these power-operated wheelchairs, and Medicare accordingly reimbursed Maximum Comfort. CIGNA then conducted an audit of 30 of the 236 power-operated wheelchair claims submitted by Maximum Comfort in 1998 and early 1999. CIGNA concluded that Maximum Comfort had failed to substantiate the medical necessity of 22 of the 30 claims at issue, and concluded from this sample that Maximum Comfort had been overpaid $640,457.01. This amount was reduced to $548,555.04 once Maximum Comfort provided CIGNA with additional documentation. CIGNA then conducted a second audit, examining 182 Medicare claims submitted by Maximum Comfort from mid-1998 to mid-1999. CIGNA concluded that Maximum Comfort was overpaid $237,229.11, again because it failed to provide documentation establishing the medical necessity and reasonableness of the wheelchairs.[3]

Maximum Comfort unsuccessfully appealed both overpayment assessments through CIGNA's in-house administrative process. The examining officer upheld CIGNA's overpayment assessments, finding that the certificates submitted by Maximum Comfort failed to demonstrate the medical necessity of power wheelchairs, and that either Maximum Comfort failed to seek additional documentation of medical necessity

[3]The applicable regional supplier's manual provides that a power wheelchair is covered by Medicare when all of the following criteria are met:

1) The patient's condition is such that without the use of a wheelchair, he would 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 the wheelchair manually, and;

3) The patient is capable of safely operating the controls for the power wheelchair.

DMERC Region D Supplier Manual, Ch. IX, p. 52.

or the beneficiaries' physicians had not responded to requests for additional documentation.[4]

Maximum Comfort then appealed CIGNA's decisions to two Administrative Law Judges ("ALJs") pursuant to 42 C.F.R. § 405.855. The ALJs ruled in Maximum Comfort's favor, finding that (1) for each of the claims at issue, the beneficiary's treating physician had completed a valid certificate of medical necessity certifying that a power wheelchair was reasonable and necessary for the diagnosis or treatment of the beneficiary's injury or the functioning of a malformed body member; and (2) the wheelchairs furnished by Maximum Comfort were medically reasonable and necessary and met the requirements for coverage under Part B of the Medicare Act. In reaching finding (2), the ALJs concluded that a certificate of medical necessity alone sufficed to prove the medical necessity of durable medical equipment.

The Medicare Appeals Council *sua sponte* reviewed the ALJs' decisions and reversed both of them. The Council concluded that Congress did not intend the certificate to be the only mechanism through which suppliers could establish coverage for durable medical equipment, and that nothing prevented the Secretary from imposing additional documentation requirements on equipment suppliers. The Council found that the certificates in issue failed to establish medical necessity, and that Maximum Comfort consequently was not entitled to reimbursement.

The Council also found that certain manuals and newsletters issued by CIGNA instructed Maximum Comfort to retain supporting documentation substantiating its equipment claims in case of an audit. As a result, the Council concluded that

[4]In other cases not at issue in this appeal, the officer found that both the certificates of medical necessity and the additional medical documentation submitted to CIGNA did not sufficiently demonstrate the medical necessity of power wheelchairs.

Maximum Comfort knew or should have known that its claims were deficient and therefore it was not entitled under 42 U.S.C. § 1395pp to a waiver of its repayment liability.

Maximum Comfort then brought this action challenging the Appeal Council's decision pursuant to the Administrative Procedure Act. *See* 42 U.S.C. §§ 405(g), 1395ff(b). On cross-motions for summary judgment, the district court ruled in favor of Maximum Comfort. The court found that the plain language of § 1395m(j)(2)(A)(i) establishes that "any and all information required from suppliers to make a medical necessity determination must be contained in a CMN." *Maximum Comfort, Inc. v. Thompson*, 323 F. Supp. 2d 1060, 1075 (E.D. Cal. 2004). The court further found that the Secretary could not require suppliers of durable medical equipment to obtain additional documentation of medical necessity. *Id*. at 1074-75. As a result, the district court permanently enjoined the Secretary from collecting overpayments from Maximum Comfort in connection with the audited claims. *Id*. at 1075. This appeal followed.

III. DISCUSSION

A. Whether the certificate of medical necessity is conclusive proof of medical necessity

The first question before us is one of statutory construction: whether the Medicare Act requires the Secretary to base his decision that an item of durable medical equipment is or is not "medically reasonable and necessary" solely on the contents of a certificate of medical necessity, or whether the Secretary may request additional documentation from a supplier of durable medical equipment. The two-step approach of *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984), governs our inquiry. We first ask whether the Medicare Act speaks directly to the question presented. "If the intent of Congress is clear, that is the end of the matter," and this court must give effect to Congress's

expressed intent. *Id*. at 842-43. If, on the other hand, the Medicare Act is silent or ambiguous with respect to the question presented, then this court asks "whether the [Secretary's] answer is based on a permissible construction of the statute." *Id*. at 843.

We begin with the statute's plain language. *See Botosan v. Paul McNally Realty*, 216 F.3d 827, 831 (9th Cir. 2000). The provisions on which Maximum Comfort (and the district court) relied state:

> **(2) Certificates of medical necessity**
>
> **(A) Limitation on information provided by suppliers on certificates of medical necessity**
>
> **(i) In general**
>
> "[A] supplier of medical equipment and supplies may distribute to physicians . . . 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 bene-

> ficiary's medical condition) identified by the Secretary.
>
> . . .
>
> **(B) Definition**
>
> 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.

42 U.S.C. § 1395m(j)(2)(A) & (B).

[1] Maximum Comfort draws from these provisions a command that the Secretary must accept the certificate of medical necessity as conclusive for purposes of reimbursing the equipment supplier. For reasons that parallel the reasoning of the Fourth Circuit in *MacKenzie*, 2007 WL 3173302 at *6-7, and the Eleventh Circuit in *Gulfcoast*, 468 F. 3d at 1351-52, we reject this interpretation of § 1395m(j)(2). The language of the statute contains no such command or limitation. The first provision, § 1395m(j)(2)(A)(I), states that "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 . . . ." (emphasis added). This subsection permits (but does not require) the supplier to distribute certificates to physicians or patients. It also limits the information suppliers may furnish in the certificate of medical necessity, but does not purport to explain the effect to be given a completed certificate or suggest that a completed certificate is sufficient and conclusive proof of medical necessity. *See MacKenzie*, 2007 WL 3173302 at *6.

[2] The second subsection, § 1395m(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 § 1395m(j)(2)(A).[5] 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. *See MacKenzie*, 2007 WL 3173302 at *6; *Gulfcoast*, 468 F.3d at 1351.

[3] We reject, therefore, Maximum Comfort's view that § 1395m(j)(2) precludes the Secretary from requiring additional evidence, beyond the certificate, to establish medical necessity for equipment supplied. Not only do the plain words of § 1395m(j)(2) fail to impose any such restraint upon the Secretary, but reading such a limitation on the Secretary's powers into that provision would be inconsistent with § 1395y(a), which states:

> *Notwithstanding any other provision of this subchapter*, no payment may be made under Part A or Part B of this subchapter for any expenses incurred for items or services —
>
> (1)(A) 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 . . . .

[5]The legislative history of this statute supports this interpretation. As the Appeals Council noted in its decision, § 1395m(j) was added to the statute to modify previous restrictions that, inter alia, prohibited suppliers from completing *any* portion of the certificate of medical necessity. *See* Social Security Amendments of 1994, Pub. L. No. 103-432, 108 Stat. 4398, 4416-19 (1994).

(emphasis added). By the terms of this provision, § 1395m(j)(2) as an "other provision of this subchapter" cannot limit the Secretary's duty imposed by § 1395y(a) to ensure that no payment is made for items that are not medically necessary.

[4] We conclude, therefore, that the Secretary's interpretation of the relevant provisions of the Medicare Act is correct, and that the Secretary may require, as a condition of reimbursement to an equipment supplier, information in addition to that provided by the certificate of medical necessity. If there could be any doubt about the meaning of § 1395m(j)(2) in light of § 1395y(a), however, the provision would at worst be silent or ambiguous with regard to the Secretary's power to require additional information. In that case, for reasons that should be apparent from our discussion of the statutory provisions in issue, the interpretation of the Secretary is certainly reasonable and entitled to deference under *Chevron*, 467 U.S. at 842-43. *See MacKenzie*, 2007 WL 3173302 at *7; *Gulfcoast*, 468 F.3d at 1352-53.

B. Whether Maximum Comfort was on notice that payment would be denied

[5] We now turn to whether Maximum Comfort is excluded from liability for repayment under 42 U.S.C. § 1395pp(a)(2), which provides that the company may not be denied reimbursement if it "did not know, and could not reasonably have been expected to know, that payment would not be made" for the durable medical equipment it supplied.[6] We may set aside

[6]Because the district court concluded that Maximum Comfort could rely on the certificate alone to establish medical necessity, it did not address Maximum Comfort's eligibility for limitation of liability under 42 U.S.C. § 1395pp(a)(2). We reach the issue, however, because we review de novo the district court's decision, *see Indep. Acceptance Corp. v. California*, 204 F.3d 1247, 1251 (9th Cir. 2000), and because the § 1395pp(a)(2) issue was decided by the Secretary and was presented to the district court for review.

the Secretary's conclusion that Maximum Comfort is not excused from liability under § 1395pp(a)(2) if it is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." *See Indep. Acceptance Corp. v. California*, 204 F.3d 1247, 1251 (9th Cir. 2000) (quoting 5 U.S.C. § 706(2)(A), (E)) (internal quotation marks omitted). Our review of the Secretary's decision is "highly deferential." *Id.*

[6] Under Health and Human Services regulations, Maximum Comfort is deemed to have constructive notice of manual issuances, bulletins, and other written guidelines and directives indicating that certain items of durable medical equipment will not be covered by Medicare. *See* 42 C.F.R. § 411.406(e). CIGNA's Supplier Manual states that physicians are required to maintain documentation of medical necessity beyond the certificate of medical necessity.[7] A March 1997 CIGNA newsletter makes clear that, because physicians are not subject to liability under the applicable statutes and regulations, it is the responsibility of the supplier to establish medical necessity "either through the ordering physician or through some other means." Region DMERC Dialogue Mar. 1977 p. 8. An earlier CIGNA newsletter, in a section entitled "Retaining CMN Records," states that, in the course of an audit, "[s]upporting documentation will be requested and reviewed from the selected suppliers by the CMN validation auditors." Region DMERC Dialogue July

[7]The manual states:

> The physician must be certain that the patient's *medical record* contains sufficient documentation of the patient's medical condition to substantiate the need for the items ordered . . . Although it is recommended that a copy of the completed CMN be kept in the patient's record, the CMN by itself does not provide sufficient documentation of medical necessity. There must be additional clinical information in the medical record. The physician must also obtain a copy of the order or have equivalent information in the record.

DMERC Region D Supplier Manual, Ch. VII, p. 3 (emphasis in original).

1995 p. 8. These documents provided Maximum Comfort with sufficient notice that the Secretary might require documentation of medical necessity in addition to the certificate of medical necessity and would deny the claim if the additional information were not forthcoming. *See* 42 U.S.C. § 1395pp(a)(2); *MacKenzie*, 2007 WL 3173302 at *7. We accordingly uphold the Secretary's conclusion that Maximum Comfort cannot avail itself of the liability-limiting provisions of § 1395pp(a)(2).

IV. CONCLUSION

The judgment of the district court is reversed, and the matter is remanded to the district court for further proceedings consistent with this opinion.

REVERSED AND REMANDED.