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UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF CALIFORNIA

MAXIMUM COMFORT, INC., a  
California corporation,

NO. CIV. S-03-1584 LKK/PAN

Plaintiff,

v.

O R D E R

TOMMY G. THOMPSON, Secretary of  
Health and Human Service of the  
United States,

**TO BE PUBLISHED**

Defendant.

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Plaintiff filed this complaint against the Secretary of the United States Department of Health and Human Services, Tommy G. Thompson ("Secretary"), seeking judicial review of a final administrative decision made by the Medicare Appeals Council ("MAC") of the Department of Health and Human Services. The matter comes before the court on the parties' cross-motions for summary judgment. I decide the motions on the basis of the papers and pleadings filed herein and after oral argument.

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1 I.

2 BACKGROUND

3 Plaintiff, Maximum Comfort, is a California corporation in the  
4 business of selling, leasing, and renting durable medical equipment  
5 ("DME"). Plaintiff supplies DME, including motorized wheelchairs,  
6 to Medicare and Medicaid beneficiaries throughout  
7 California, Oregon and Nevada. Medicare reimburses Maximum Comfort  
8 for qualifying DME supplied to its beneficiaries. To receive  
9 reimbursement, plaintiff must first submit invoices to and receive  
10 approval from CIGNA Healthcare, a private fiscal agent that has  
11 contracted with Medicare to process claims.

12 The dispute in this case concerns reimbursement claims for  
13 numerous motorized wheelchairs provided by plaintiff to Medicare  
14 beneficiaries. CIGNA initially approved the claims for the  
15 motorized wheelchairs and Medicare accordingly provided plaintiff  
16 with reimbursement payments. After CIGNA conducted an audit,  
17 however, it concluded that the wheelchairs did not qualify for  
18 coverage and that Medicare had therefore overpaid plaintiff.  
19 Consequently, CIGNA began recouping the payments for the  
20 disqualified claims by offsetting plaintiff's Medicare account.  
21 Plaintiff challenged CIGNA's decision and exhausted the appeals  
22 process. In the final administrative hearing, the MAC concluded  
23 that the wheelchairs could not be paid for by Medicare because  
24 plaintiff had insufficiently documented the medical necessity of  
25 the wheelchairs.

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1 **A. PROCEDURAL HISTORY**

2 This case was first heard by this court on October 20,  
3 2003, pursuant to plaintiff's motion for a preliminary injunction.  
4 On October 22, the court issued an order explaining that the  
5 parties had failed to address certain critical issues and directed  
6 them to file supplemental briefing. In that same order, the court  
7 enjoined the defendant from "[r]ecouping, offsetting or otherwise  
8 collecting from plaintiff any alleged overpayments for any of the  
9 beneficiaries which are the subject of this action from any amounts  
10 due and owing to plaintiff and from failing to pay such amount when  
11 due." Order at 3. The parties filed their supplemental briefing  
12 and then filed cross-motions for summary judgment. In due course,  
13 a hearing was set and oral argument was heard on the cross-motions.  
14 This opinion disposes of all of the pending matters before the  
15 court.

16 **B. THE MEDICARE PROGRAM**

17 The Medicare Act, established under Title 18 of the Social  
18 Security Act, 42 U.S.C. §§ 1395-1395gg, pays for covered medical  
19 care provided to eligible aged and disabled persons. The Medicare  
20 Program is administered by the Centers for Medicare and Medicaid  
21 Services ("CMS"), a component of the United States Department of  
22 Health and Human Services ("HHS").<sup>1</sup>

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24 \_\_\_\_\_  
25 <sup>1</sup> CMS was formerly known as the Health Care Financing  
26 Administration ("HCFA"). See 66 Fed. Reg. 36583, 36584 (July 12,  
2001).

1           The Medicare Act consists of three main parts: Part A, which  
2 generally authorizes payment for covered inpatient hospital care  
3 and related services, 42 U.S.C. §§ 1395c to 1395i-5, 42 C.F.R. Part  
4 409; Part B, which provides supplementary medical insurance for  
5 covered medical services and equipment, 42 U.S.C. §§ 1395j to  
6 1395w-4, 42 C.F.R. Part 410; and Part C, which authorizes  
7 beneficiaries to obtain covered services through HMOs and other  
8 "managed care" arrangements, 42 U.S.C. §§ 1395w-21 to 1395w-28, 42  
9 C.F.R. Part 422.

10           This case involves Part B of the Medicare Act. Part B  
11 resembles "a private medical insurance program that is subsidized  
12 in major part by the federal government."<sup>2</sup> Schweiker v. McClure,  
13 456 U.S. 188, 190 (1982). Coverage under this part extends to DME,  
14 including wheelchairs used in a patient's home. 42 U.S.C.  
15 §§ 1395k, 1395x(s), 1395x(n); 42 C.F.R. § 410.38(a)-(c). As with  
16 private medical insurance programs, the statute and its  
17 implementing regulations establish conditions and limitations on  
18 the coverage of services and equipment, 42 U.S.C. §§ 1395k, 1395l,  
19 1395x(s), and provide for exclusions from coverage. 42 U.S.C.  
20 § 1395y(a)(2)-(16); 42 C.F.R. § 411.15(a)-(j). In all cases,  
21 Medicare coverage is limited to services that are medically  
22 "reasonable and necessary" for the diagnosis or treatment of  
23 illness. 42 U.S.C. § 1395y(a)(1)(A); 42 C.F.R. § 411.15(k)(1).

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25           <sup>2</sup> Part B participants pay monthly premiums that are deposited  
26 along with federal appropriations in the Federal Supplementary  
Medical Insurance Trust Fund which finances Part B. See 42 U.S.C.  
§§ 1395j, r, s, t, w.

1 **C. MEDICARE CARRIERS**

2 In administering Part B, CMS acts through private fiscal  
3 agents called "carriers." 42 U.S.C. § 1395u; 42 C.F.R. Part 421,  
4 Subparts A and C; 42 C.F.R. § 421.5(b). Carriers are entities  
5 that, under contract with the Secretary, perform a variety of  
6 functions including making coverage determinations, determining  
7 reimbursement rates and allowable payments, conducting audits of  
8 the claims submitted for payment, and rejecting or adjusting  
9 payment requests. Claims for DME, prosthetics, and orthotics are  
10 processed by designated regional carriers called Durable Medical  
11 Equipment Regional Carriers ("DMERCs"). 42 U.S.C. §§ 1395m, 1395u;  
12 42 C.F.R. § 421.210. At all relevant times, the DMERC for Maximum  
13 Comfort was CIGNA HealthCare ("CIGNA").

14 One of the carrier's duties is to conduct post-payment audits  
15 to ensure that payments are made in accordance with applicable  
16 Medicare payment criteria. When payment is made erroneously, an  
17 "overpayment" is assessed and "recouped" from subsequent payments  
18 due to the DME supplier.<sup>3</sup> 42 C.F.R. § 421.200(a)(2); see also 42  
19 U.S.C. §§ 1395g(a), 1395l(j), 1395gg(b)(1); 42 C.F.R. §§ 405.370,  
20 405.371(a)(1), (2), 405.350. The Act provides for relief from  
21 liability for a supplier when it is determined that the  
22 supplier "did not know, and could not reasonably have been expected  
23 to know, that payment would not be made for a service in question."

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25 <sup>3</sup> Recoupment is defined as "[t]he recovery by Medicare of any  
26 outstanding Medicare debt by reducing the present or future  
Medicare payments and applying the amount withheld to the  
indebtedness." 42 C.F.R. § 405.370.

1 42 U.S.C. § 1395pp(a).

2 **D. DURABLE MEDICAL EQUIPMENT SUPPLIERS**

3 Private businesses selling health care items and products may  
4 enter into agreements with the Secretary to become participants in  
5 the Medicare program. See 42 U.S.C. § 1395u(h)(1). Once  
6 participants, these business, identified by Medicare as suppliers,  
7 can provide hardware to Medicare beneficiaries. Beneficiaries  
8 execute an assignment of benefits to the supplier so that it may  
9 be reimbursed for the service by Medicare.<sup>4</sup> See 42 U.S.C.  
10 § 1395u(b)(3)(B). A prerequisite for receipt of reimbursement is  
11 submitting a Certificate of Medical Necessity (CMN) to the Carrier.  
12 See 42 U.S.C. § 1395m(j)(2)(A).

13 **II.**

14 **FACTS**

15 On April 3, 2000, CIGNA audited 30 of the 236 power-operated  
16 wheelchair claims submitted by plaintiff from its Redding store  
17 between January 1, 1998 and January 22, 1999. Administrative  
18 Record (A.R.) Vol. 6 at 1585. This audit, identified as the "Hayes  
19 group" audit,<sup>5</sup> resulted in a determination that plaintiff failed  
20 to provide sufficient medical information, including patients'

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22 <sup>4</sup> Under an assignment agreement, the beneficiary transfers  
23 his right to payment to the supplier. A supplier who accepts  
24 assignment agrees to accept, as full satisfaction, the amount the  
25 carrier determines to be the reasonable charge. See 42 U.S.C.  
26 § 1395u(b)(3)(B)(ii); 42 C.F.R. § 424.55.

<sup>5</sup> Brenda Hayes was the designated lead Medicare beneficiary  
in the Administrative Law Judge's review of this group of claims  
audit, referred to as the 'Hayes group' claims throughout the  
record.

1 medical records, to substantiate the medical necessity of 22  
2 reimbursement claims. As a result, CIGNA concluded that Maximum  
3 Comfort was overpaid a total of \$ 640,457.01.<sup>6</sup> Id. at 1595. CIGNA  
4 subsequently received additional documentation from the plaintiff,  
5 reducing the number of problematic claims to 19 and the overpayment  
6 amount to \$ 548,555.04. Id. at 1634.

7 On September 14, 2000, CIGNA notified plaintiff that it  
8 conducted a second audit of a sample number of the 182 Medicare  
9 claims submitted by plaintiff from its Sacramento store between  
10 July 1, 1998 and July 2, 1999. A.R. Vol. 5 at 1275. This second  
11 audit, known as the "Torres group,"<sup>7</sup> resulted in a determination  
12 that plaintiff was overpaid \$237,229.11. A.R. Vol. 4 at 1180.<sup>8</sup>  
13 CIGNA determined that the claims did not qualify for reimbursement  
14 because, although plaintiff submitted the required CMN for each  
15 claim in the Hayes and Torres groups, it failed to provide  
16 *additional* medical documentation to establish the medical necessity  
17 and reasonableness of the motorized wheelchairs. A.R. Vol. 5 at  
18 1251; A.R. Vol. 6 at 1585.

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21 <sup>6</sup> CIGNA used a method it refers to as "extrapolation" to  
22 project the overpayments of the 22 claims to the balance of the 236  
claims to arrive upon an original overpayment assessment of  
\$640,457.01.

23 <sup>7</sup> Elizabeth Torres was the designated lead Medicare  
24 beneficiary in the Administrative Law Judge's review of this group  
of claims, referred to as the "Torres group" throughout the record.

25 <sup>8</sup> The original overpayment assessment was in the amount of  
26 \$308,383.50, but was subsequently reduced to \$237,229.11. A.R.  
Vol. 4 at 1181; A.R. Vol. 5 at 1275-1279.

1 Plaintiff challenged both of the overpayment assessments  
2 through CIGNA's in-house administrative appeals process, but did  
3 not prevail. A.R. Vol. 3 at 572; A.R. Vol. 5 at 1335; see 42  
4 C.F.R. §§ 405.815, 405.821. It then appealed CIGNA's decisions.  
5 A.R. Vol. 1 at 20, 22; see 42 C.F.R. § 405.855. Two different  
6 Administrative Law Judges (ALJs) issued almost identical decisions  
7 in plaintiff's favor, concluding that, as a supplier, plaintiff  
8 was only required to submit a CMN to establish the medical  
9 necessity and reasonableness of each wheelchair it provided. They  
10 further concluded that the Secretary did not have the authority to  
11 require that Maximum Comfort provide patient medical records to  
12 support medical necessity. A.R. Vol. 2 at 00451; A.R. Vol. 4 at  
13 4.

14 By notices dated March 21 and November 20, 2001, the MAC  
15 notified plaintiff of its determination to review the ALJs'  
16 decisions. A.R. Vol. 1 at 21-22; see 20 C.F.R. § 404.969. The  
17 MAC's purpose in reviewing the ALJs' decisions was to determine the  
18 type of documentation plaintiff was required to obtain and keep to  
19 support the medical reasonableness and necessity of the DME it  
20 supplied to Medicare beneficiaries. A.R. Vol. 1 at 21, 24.

21 On June 11, 2003, the MAC issued its opinion reversing the  
22 ALJs' decisions that a CMN is the only required medical necessity  
23 documentation and reinstating the denial of reimbursement. Citing  
24 § 1834(j)(2)(B) of the Social Security Act, 42 U.S.C. §  
25 1395m(j)(2)(B), the MAC recognized that Congress established that  
26 "a CMN is a form containing information to assist the carrier in

1 determining whether an item is medically reasonable and necessary."  
2 A.R. Vol. 1 at 26. It limited the significance of that definition,  
3 however, claiming that such language was included only in reference  
4 to certain restrictions Congress placed on the type of information  
5 that suppliers could provide on the CMN. Id. at 26-27. It then  
6 stated that it could not conclude that Congress intended the CMN  
7 to be the sole mechanism establishing the coverage of DME, or that  
8 the Secretary, through his Carriers, cannot establish additional  
9 medical documentation requirements. Id. Based on that reasoning,  
10 it concluded that, although plaintiff provided a CMN for each  
11 claim, it was also required to submit any other medical necessity  
12 documentation as prescribed by the Secretary or his delegates.

13 The MAC then turned to several manuals and newsletters issued  
14 by CIGNA to DME suppliers to determine what medical necessity  
15 documents plaintiff was required to provide during the period in  
16 question. Adverting to various sections of those materials, it  
17 determined that the manuals and newsletters contained  
18 pronouncements requiring that plaintiff keep on file and submit  
19 beneficiaries' medical records and making it "responsible for  
20 [reviewing the records and] making a judgment as to whether the  
21 service [was] medically necessary."<sup>9</sup> A.R. Vol. 1 at 28. Because  
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23 <sup>9</sup> The MAC relied upon language in a March 1997  
24 newsletter, the "DMERC Dialogue - Region D," providing that  
25 "a supplier, by virtue of its furnishing a DMEPOS item to a  
26 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

1 plaintiff only provided a CMN, the MAC concluded that it failed to  
2 meet all documentation requirements. Accordingly, the MAC  
3 determined that plaintiff had not provided the required  
4 documentation to establish that the wheelchairs were reasonable and  
5 medically necessary as contemplated by the Act, and that it had  
6 therefore been overpaid by Medicare. A.R. Vol. 1 at 17-39.

7 **III.**

8 **STANDARDS**

9 The Medicare Act provides for judicial review of final  
10 decisions by the Secretary of Health and Human Services  
11 regarding benefits paid under Medicare B. See 42 U.S.C.  
12 § 1395ff(a), (b). The reviewing court may affirm, modify, or  
13 reverse the final decision of the Secretary. 42 U.S.C. § 405(g)  
14 (incorporated by reference in 42 U.S.C. § 1395ff(b)(1)(a)).

15 Review of the Secretary's decision is governed by the  
16 Administrative Procedure Act, 5 U.S.C. §§ 701-706, which  
17 provides that the Agency's decision will be set aside only if it  
18 is "arbitrary, capricious, an abuse of discretion, or otherwise  
19 not in accordance with law . . . or unsupported by substantial  
20 evidence." 5 U.S.C. § 706(2)(A), (E); see also French Hosp. Med.  
21 Ctr. v. Shalala, 89 F.3d 1411, 1416 (9th Cir. 1996). Because  
22 the parties agree that the facts are restricted to the

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payment on the basis that the item is not reasonable and  
necessary." A.R. Vol. 1 at 28 (emphasis added).

1 administrative record,<sup>10</sup> the sole issue is one of law., i.e.  
2 whether the MAC's determination of the scope of a provider's  
3 obligation relative to documenting medical necessity is legally  
4 proper.

5 A court's review of an agency's construction of a statute  
6 which it is charged with administering involves a now familiar  
7 two step process. First, it must determine whether the statute  
8 speaks directly to the issue; if so, no further construction  
9 is required. Chevron U.S.A. Inc. v. Natural Resources Defense  
10 Council Inc., 467 U.S. 842. That is because, "[i]f the intent  
11 of Congress is clear, that is the end of the matter; for the  
12 court, as well as the agency, must give effect to the  
13 unambiguously expressed intent of Congress." Id. On the other  
14 hand, if the court concludes that "the statute is silent or  
15 ambiguous," it must determine "whether the agency's answer is  
16 based on a permissible construction of the statute." Id.

17 The manner in which the agency supplies construction of the  
18 statute is within its discretion. Cnty. Hosp. of Monterey  
19 Peninsula v. Thompson, 323 F.3d 782, 790 (9th Cir. 2003). Thus,  
20 it is not necessary that the agency promulgate regulations, but  
21 it may properly determine benefits under the Medicare Act by

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23 <sup>10</sup> While there are limited circumstances in which the  
24 District Court may receive information extrinsic to the  
25 administrative record, see Occidental Engineering Co. v. INS, 753  
26 F.2d 766, 769-70 (9th Cir. 1985) (citing Citizens to Preserve  
Overton Park v. Volpe, 401 U.S. 402, 415 (1971)), in the matter at  
bar, there has been no indication by any party that receipt of  
extrinsic evidence and de novo fact-finding by the court is  
appropriate.

1 relying upon both the rule making and the adjudicative process.  
2 Id. "It is, thus, well settled that, if the Secretary fills a  
3 gap that he is authorized to fill, his resolution in the course  
4 of formal adjudication of the kind we review is controlling  
5 unless arbitrary, capricious, or manifestly contrary to the  
6 statute." Id.<sup>11</sup> While an agency may construe statutes through  
7 the adjudicative process, due process may restrain retroactive  
8 application of a construction which adversely affects a  
9 provider's right to reimbursement. See Covey v. Hollydale  
10 Mobilehome Estates, 116 F.3d 830 (9th Cir. 1997).

#### 11 IV.

#### 12 ANALYSIS

13 The issue tendered is whether the Secretary may require  
14 that plaintiff, as a DME supplier, obtain and submit medical  
15 documentation in addition to the CMN to prove the medical  
16 necessity and reasonableness of the motorized wheelchairs it  
17 supplied to Medicare beneficiaries.<sup>12</sup>

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19 <sup>11</sup> "A decision is arbitrary and capricious if the agency  
20 'has relied on factors which Congress has not intended it to  
21 consider, entirely failed to consider an important aspect of the  
22 problem, offered an explanation for its decision that runs counter  
23 to the evidence before the agency, or is so implausible that it  
24 could not be ascribed to a difference in view or the product of  
25 agency expertise.'" O'Keefe's, Inc. v. United States Consumer  
26 Prod. Safety Comm'n, 92 F.3d 940, 942 (9th Cir. 1996) (quoting  
Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co., 463  
U.S. 29, 43 (1983)).

24 <sup>12</sup> A second issue was whether plaintiff was required to make  
25 an independent determination of medical necessity. While that  
26 issue is discussed in the body of this opinion, as the court  
understands it, the MAC's determination of overpayment essentially  
rested upon the failure to obtain documentation beyond the CMN.

1 **A. THE PARTIES' CONTENTIONS**

2 The Secretary asserts that the MAC correctly concluded that  
3 he is vested with the authority to promulgate rules regarding  
4 the type of documentation required to determine the medical  
5 necessity of DME. He maintains that neither the Medicare Act  
6 nor the implementing regulations establish the CMN as the sole  
7 document to demonstrate that an item is medically reasonable and  
8 necessary. Def's Br. in Supp. of Mot. for Summ J. at 15.

9 Rather, he argues, "Congress has granted the Secretary very  
10 broad discretion to determine the documentation required to  
11 establish medical necessity . . . ." Id. at 2. He asserts that  
12 it was pursuant to this authority that he required that "[a] CMS  
13 must be substantiated by the patient's relevant medical  
14 records." Def's Supplemental Br. at 4.

15 The Secretary argues that the court must give deference to  
16 the MAC's decision because the medical necessity documentation  
17 requirements were created under his authority and are not  
18 "inconsistent with the statute or regulations or . . . an  
19 unreasonable implementation of them." Def's Br. in Opp'n. to  
20 Pl's Mot. for Prelim. Inj. at 16. Accordingly, he claims  
21 plaintiff was properly required to obtain the beneficiaries'  
22 medical records, review them, and make a judgment as to whether  
23 the wheelchairs at issue were medically necessary.

24 Plaintiff, on the other hand, argues that the MAC's  
25 decision improperly imposed documentation requirements, and  
26 maintains that its only obligation under the Medicare Act to

1 show that the wheelchairs it provided were medically necessary  
2 was to keep on file and provide a CMN. Pl's Br. in Supp. of  
3 Mot. for Summ. J. at 4. Plaintiff insists that it abided by  
4 this requirement when it sought reimbursement for the motorized  
5 wheelchairs by providing CIGNA with a CMN for each claim.

6 Plaintiff advances two arguments to support its contention  
7 that the Secretary's underlying decision is unfounded. First,  
8 it contends that the Secretary simply does not have the  
9 authority to create rules or regulations requiring medical  
10 necessity documentation in addition to the CMN. Pl's Br. in  
11 Supp. of Mot. for Summ. J. at 3. Second, it asserts that, even  
12 if the Secretary did have the authority, any such rules would  
13 not be binding upon it because CIGNA did not provide it with  
14 adequate notice of the new documentation requirements.

15 **B. THE SECRETARY'S AUTHORITY**

16 The resolution of this case turns on whether Congress has  
17 directly spoken on medical necessity documentation requirements,  
18 or whether it explicitly or implicitly delegated the task to the  
19 Secretary, vesting him with discretion to establish the  
20 challenged requirements. As I explain below, a review of the  
21 statute demonstrates that, contrary to the Secretary's  
22 contentions, there is no gap left by Congress for the Secretary  
23 to fill regarding medical necessity documentation.

24 To resolve the issues in dispute, I must "look first to the  
25 plain language of the statute, construing the provisions of the  
26 entire law, including its object and policy, to ascertain the

1 intent of Congress." Carson Harbor Vill. Ltd. v. Unocal Corp.,  
2 270 F.3d 863, 877 (9th Cir. 2001) (en banc) (internal citations  
3 omitted). As the High Court instructed, "the meaning of a  
4 statute must, in the first instance, be sought in the language  
5 in which the act is framed, and if that is plain, . . . the sole  
6 function of the courts is to enforce it according to its  
7 terms.'" Id. at 878 (quoting Caminetti v. United States, 242  
8 U.S. 470, 485 (1917)).

9 Put directly, here Congress addressed the issue of medical  
10 necessity documentation in 42 U.S.C. § 1395m(j). That section  
11 provides that a "'certificate of medical necessity' means a form  
12 or other document containing information required by the carrier  
13 to be submitted to show that an item is reasonable and necessary  
14 for the diagnosis or treatment of illness or injury or to  
15 improve the functioning of a malformed body member." 42 U.S.C.  
16 § 1395m(j)(2)(B).<sup>13</sup> The Secretary's contention that Congress

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18 <sup>13</sup> The Act also specifies what the CMN shall contain:

- 19 (2) Certificates of medical necessity  
20 (A) Limitation on information provided by suppliers on certificates  
21 of medical necessity  
22 (i) In general  
23 Effective 60 days after October 31, 1994, a supplier of medical  
24 equipment and supplies may distribute to physicians, or to  
25 individuals entitled to benefits under this part, a certificate of  
26 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

1 provided him with the authority to decide what documentation may  
2 be required to determine the medical necessity of DME conflicts  
3 with the plain meaning of § 1395m(j)(2)(B). That section  
4 plainly specifies that Congress intended that whatever  
5 information may be required by carriers from suppliers to show  
6 the medical necessity and reasonableness of DME must be  
7 contained in a CMN. As I explain below, the CMN complies with  
8 § 1395m(j)(2)(B); moreover, any deficiency in the CMN now in use  
9 is easily corrected administratively.

10 The CMN is created and approved by CMS and is comprised of  
11 four sections. Section A solicits identifying information of  
12 the supplier, beneficiary, and physician, as well as other  
13 administrative information. A.R. Vol. 4 at 860-861. Section B  
14 contains a series of questions to be completed by the

15 \_\_\_\_\_  
16 relating to the beneficiary's medical condition) identified by the  
17 Secretary.

18 (ii) Information on payment amount and charges  
19 If a supplier distributes a certificate of medical necessity  
20 containing any of the information permitted to be supplied under  
21 clause (I), the supplier shall also list on the certificate of  
22 medical necessity the fee schedule amount and the supplier's charge  
23 for the medical equipment or supplies being furnished prior to  
24 distribution of such certificate to the physician.

25 (iii) Penalty  
26 Any supplier of medical equipment and supplies who knowingly and  
willfully distributes a certificate of medical necessity in  
violation of clause (I) or fails to provide the information  
required under clause (ii) is subject to a civil money penalty in  
an amount not to exceed \$1,000 for each such certificate of medical  
necessity so distributed. The provisions of section 1320a-7a of  
this title (other than subsections (a) and (b) of such section)  
shall apply to civil money penalties under this subparagraph in the  
same manner as they apply to a penalty or proceeding under section  
1320a-7a(a) of this title.

42 U.S.C. § 1395m(j)(2)(A).

1 beneficiary's ordering physician. According to the instructions  
2 for completing the CMN, Section B "is used to gather clinical  
3 information to determine medical necessity." Id. at 861.  
4 Section C of the CMN requires the supplier to provide a  
5 narrative description of the equipment and the cost thereof.  
6 Id. Finally, section D provides for the physician's attestation  
7 and signature. Id. at 860. The instructions explain that the  
8 physician's signature "certifies the items ordered are medically  
9 necessary for [the] patient." Id. at 861.<sup>14</sup> The CMN thus  
10 complies with Congress' mandate that whatever clinical  
11 information the carrier determines is required to determine the  
12 medical necessity of motorized wheelchairs must be gathered  
13 using the CMN. Given the above, no room is left for requiring  
14 further documentation.

15 Despite the Congressional specification of the function of  
16 the CMN, the Secretary cites to 42 U.S.C. § 405(a) to support  
17 his position that he properly required plaintiff to provide  
18 beneficiaries' medical records. I cannot agree.

19 Section 405(a) provides that the Secretary "shall have full  
20 power and authority to make rules and regulations and to  
21 establish procedures" to carry out the provisions of the Act.  
22 42 U.S.C. § 405(a). This authority, however, does not mean that

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24 <sup>14</sup> The physician's signature "certifies that the medical  
25 necessity information . . . is true, accurate and complete, . . .  
26 and [that the physician] understand[s] that any falsification,  
omission, or concealment of material fact in [section B] may  
subject [the physician] to civil or criminal liability." A.R. Vol.  
4 at 861.

1 he has the authority to create rules that are at odds with the  
2 plain language of the statute. Pub. Employees Ret. Sys. of Ohio  
3 v. Betts, 492 U.S. 158, 171 (1989) ("[N]o deference is due to  
4 agency interpretations at odds with the plain language of the  
5 statute itself."). Section 405(a) cannot be read to permit the  
6 Secretary to create requirements that undermine both the plain  
7 text of the statute and Congressional intent.

8 Defendant presents three arguments in support of his  
9 contention. None are persuasive. First, the Secretary argues  
10 that because he is vested with the authority to determine what  
11 criteria must be met for an item to be medically reasonable and  
12 necessary, he must also be vested with the authority to  
13 determine the mechanisms by which suppliers prove that criteria.  
14 Second, he submits that the CMN is not sufficient to provide the  
15 required information to demonstrate medical necessity because  
16 Congress restricted the type of information that suppliers may  
17 provide on it. Lastly, he argues that the plaintiff was  
18 required to submit additional medical necessity information  
19 because the CMN does not request enough information to address  
20 all the criteria for motorized wheelchairs. I address each  
21 argument in turn.

22 The premise of the Secretary's chief argument is that he is  
23 authorized to determine the type of medical necessity  
24 documentation by virtue of his authority to determine medical  
25 necessity criteria. Defendant correctly asserts that Congress  
26 granted him broad discretion over the criteria required to prove

1 medical necessity and reasonableness. Nonetheless, as I note  
2 below, Congress did not provide the Secretary with the same  
3 discretion regarding the type of documentation which suppliers  
4 must provide.

5 Congress vested exclusive and final authority in the  
6 Secretary to decide what criteria must be met for a particular  
7 item or service to qualify as medically necessary, and  
8 accordingly, to be reimbursable under Medicare. 42 U.S.C.  
9 § 1395ff(a); 42 U.S.C. § 1395y(a)(1)(A). 42 U.S.C. § 1395x(n)  
10 provides that power-operated wheelchairs may be covered "where  
11 the use of such a vehicle is determined to be necessary on the  
12 basis of the individual's medical and physical condition . . .  
13 as the Secretary may prescribe." In Heckler v. Ringer, the High  
14 Court emphasized that "[t]he Secretary's decision as to whether  
15 a particular medical [item] is 'reasonable and necessary'" is  
16 "clearly" within his discretion. 466 U.S. 602, 617 (1984).

17 Exercising this authority, the Secretary has promulgated  
18 regulations establishing criteria to be used in determining the  
19 medical necessity and reasonableness of motorized wheelchairs.  
20 Section 410.38 of Title 42 of the C.F.R. provides that  
21 wheelchairs must be used in the patient's home or in an  
22 institution that is used as a home, that power-operated  
23 wheelchairs must be "necessary on the basis of the individual's  
24 medical and physical condition," and "[m]eet any safety  
25 requirements specified by CMS." 42 C.F.R. 410.38. The  
26 Secretary asserts that the Carrier's manuals and newsletters

1 contain further medical necessity criteria.<sup>15</sup> Def's Br. in Supp.  
2 of Mot. for Summ. J. at 6. Specifically, he points to the  
3 "DMERC Region D Supplier Manual" issued in December of 1993  
4 which provides that power-operated wheelchairs are covered if:  
5 (1) the beneficiary would otherwise be bed or chair confined,  
6 (2) the wheelchair is medically necessary and the patient is  
7 unable to operate the wheelchair manually, and (3) the  
8 beneficiary is capable of safely operating the power wheelchair.  
9 Id.; A.R. Vol. 1 at 52.<sup>16</sup>

10 The Secretary reasons that, because he has prescribed  
11 medical necessity criteria for wheelchairs, "providers and  
12 suppliers must follow the uniform . . . documentation  
13 requirements set forth in [the] carrier issuances . . . ."  
14 Def's Br. in Supp. of Mot. for Summ. J. at 15. He avers that  
15 his discretion to determine the medical necessity of an item  
16 "includes the right to determine the level of documentation  
17 necessary to substantiate that an item of durable medical  
18 equipment furnished to a Medicare beneficiary is reasonable and  
19 medically necessary." Def's Br. in Opp'n to Pl's Mot. for  
20 Prelim. Inj. at 5. This analytical leap has some initial  
21 appeal, and if Congress was silent, might well be persuasive.

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22  
23 <sup>15</sup> The MAC's decision did not discuss the legal sufficiency  
24 or weight of the Carrier manuals and newsletters. Given the  
court's disposition, I need not address that issue.

25 <sup>16</sup> Plaintiff, quite properly, does not dispute the  
26 Secretary's authority or ability to prescribe the medical necessity  
criteria for the motorized wheelchairs it provided to Medicare  
beneficiaries.

1 The fact is, however, that the argument simply cannot stand in  
2 light of the fact that Congress has directly spoken to the  
3 issue. Put another way, while it is clear that Congress vested  
4 the Secretary with the discretion to determine medical necessity  
5 criteria, it does not inexorably follow that Congress  
6 concurrently granted him the authority to determine the type of  
7 documentation required to satisfy that criteria. Indeed, it is  
8 clear that Congress did not do so.

9 It is true that Congress explicitly provided the Secretary  
10 with authority to determine medical necessity criteria.  
11 Importantly, however, Congress not only omitted similar language  
12 pertaining to medical necessity documentation, it determined  
13 this issue itself in creating and defining the CMN, thereby  
14 leaving no gap for the Secretary to fill.

15 "In construing a statute, we begin with the understanding  
16 that Congress says in a statute what it means and means in a  
17 statute what it says there." In re Price, 353 F.3d 1135, 1140  
18 (9th Cir. 2004) (internal quotations and citations omitted). It  
19 is plain from the Medicare Act that Congress meant for the  
20 Secretary to determine medical necessity and that the required  
21 information to make that determination be contained in a CMN.  
22 Accordingly, the plain language of the statute forecloses the  
23 Secretary's first argument.

24 I now examine the Secretary's second argument tendered in  
25 support of his position. That argument asserts that §1833(e) of  
26 the Act, 42 U.S.C. § 1395l(e), provides the Secretary with the

1 authority to create the disputed medical necessity documentation  
2 requirements in his discretion. Again, I cannot agree.

3 Section 13951(e) provides that "[n]o payment shall be made  
4 to any provider of services . . . under this part unless there  
5 has been furnished such information as may be necessary in order  
6 to determine the amounts due such provider . . . ." 42 U.S.C. §  
7 13951(e). The Secretary asserts that the MAC correctly  
8 concluded that the requirement that a DME supplier maintain  
9 "'medical documentation[,] in addition to the CMN in the  
10 supplier's records, . . . is consistent with §1833(e) of the  
11 Act, which requires suppliers to furnish sufficient information  
12 to support payments under Part B.'" Def's Br. in Opp'n to Pl's  
13 Prelim. Inj. at 15; A.R. Vol. 1 at 29. The Secretary asserts  
14 that the statute implicitly grants him the discretionary  
15 authority to create medical necessity documentation requirements  
16 in order to determine whether a particular item may be  
17 reimbursed. The Secretary's focus on the opening language of  
18 the section is too narrow. As the balance of the statute  
19 demonstrates, the statute's provision addresses "determin[ing]  
20 the amounts due such provider . . . ." 42 U.S.C § 13951(e)  
21 (emphasis added). Read in its entirety, it is apparent that  
22 this section concerns information which the Secretary may  
23 require to ascertain the monetary amount due for covered items,  
24 and has no bearing on the determination of medical necessity.

25 The Secretary's reliance on Cnty. Hosp. of Monterey  
26 Peninsula v. Thompson, 323 F.3d 782 (9th Cir. 2003), to

1 demonstrate that § 13951(e) provides him with discretion to  
2 create medical necessity documentation requirements is  
3 unavailing. That decision addressed the means of ascertaining  
4 the amount due a provider. The Circuit quite correctly  
5 concluded that the plain text made it clear that "Congress  
6 expected the Secretary to resolve" billing issues and the  
7 requirements placed on providers relative to that issue had been  
8 properly created pursuant to his discretionary power. Id. at  
9 789. The court explained that §§ 1395g(a) and 1395x(v)(1)(A) of  
10 Title 42 of the United States Code explicitly provided the  
11 Secretary with such authority. Id. at 789-790. Those two  
12 sections provide that the Secretary shall determine the  
13 reimbursement amount of a given service by, inter alia,  
14 considering the cost actually incurred to the provider and  
15 establishing methods to be used in computing the amount of  
16 payment.<sup>17</sup> In sum, the portion of the Act addressed in Cnty.

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17  
18 <sup>17</sup> 42 U.S.C. § 1395x(v)(1)(A) provides, in relevant  
part, that:

19 The reasonable cost of any services shall be the cost  
20 actually incurred, excluding therefrom any part of incurred  
21 cost found to be unnecessary in the efficient delivery of  
22 needed health services, and shall be determined in accordance  
23 with regulations establishing the method or methods to be  
24 used, and the items to be included, in determining such costs  
25 for various types or classes of institutions, agencies, and  
26 services; . . . the Secretary shall consider, among other  
things, the principles generally applied by national  
organizations or established prepayment organizations (which  
have developed such principles) in computing the amount of  
payment, to be made by persons other than the recipients of  
services, to providers of services on account of services  
furnished to such recipients by such providers. . . . Such

1 Hosp. instructs the Secretary to create regulations regarding  
2 the determination of the amount due to providers for services  
3 and the methods by which to make that determination. The Ninth  
4 Circuit's opinion, limited to the issue of billing requirements,  
5 is clearly distinct from the question presented here. Indeed,  
6 Cnty. Hosp. indirectly supports the plaintiff's position.

7       The sections of the statute at issue in Cnty. Hosp. are

8 \_\_\_\_\_  
9 regulations shall (i) take into account both direct and  
10 indirect costs of providers of services (excluding therefrom  
11 any such costs, including standby costs, which are determined  
12 in accordance with regulations to be unnecessary in the  
13 efficient delivery of services covered by the insurance  
14 programs established under this subchapter) in order that,  
15 under the methods of determining costs, the necessary costs  
16 of efficiently delivering covered services to individuals  
17 covered by the insurance programs established by this  
18 subchapter will not be borne by individuals not so covered,  
19 and the costs with respect to individuals not so covered will  
20 not be borne by such insurance programs, and (ii) provide for  
21 the making of suitable retroactive corrective adjustments  
22 where, for a provider of services for any fiscal period, the  
23 aggregate reimbursement produced by the methods of  
24 determining costs proves to be either inadequate or  
25 excessive.

26 42 U.S.C. § 1395g(a) provides that:

      The Secretary shall periodically determine the amount  
which should be paid under this part to each provider of  
services with respect to the services furnished by it, and  
the provider of services shall be paid, at such time or times  
as the Secretary believes appropriate . . . and prior to  
audit or settlement by the General Accounting Office, from  
the Federal Hospital Insurance Trust Fund, the amounts so  
determined, with necessary adjustments on account of  
previously made overpayments or underpayments; except that no  
such payments shall be made to any provider unless it has  
furnished such information as the Secretary may request in  
order to determine the amounts due such provider under this  
part for the period with respect to which the amounts are  
being paid or any prior period.

1 akin to § 1395l(e), relied upon by the Secretary here. Like  
2 §§ 1395g(a) and 1395x(v)(1)(A), § 1395l(e) also explicitly  
3 provides the Secretary discretion to determine the monetary  
4 amount due to a supplier for qualifying DME. Significantly,  
5 however, while Congress vested the Secretary with authority  
6 over medical necessity criteria and billing requirements, it  
7 did not include language in the Act delegating the same  
8 authority concerning medical necessity documentation, but  
9 chose to speak on that subject itself. Unlike billing  
10 matters, Congress did not leave a gap for the Secretary to  
11 fill regarding medical necessity documentation; instead, it  
12 specifically provided that whatever information is required  
13 to determine the medical necessity of DME is to be contained  
14 in a CMN. The Secretary's contention that § 1395l(e)  
15 provides him with discretion to create the requirement in  
16 question is based on an impermissible reading of the statute.

17       Lastly, I address the Secretary's claim that it may  
18 require that DME suppliers obtain and provide Medicare  
19 beneficiaries' medical records because "[i]t is not possible  
20 for a CMN to fully describe the medical necessity of DME."  
21 Def's Br. in Supp. of Mot. for Summ. J. at 15. The Secretary  
22 asserts that because "the Act places strict limitations on  
23 the kind of information a supplier may ask a physician to  
24 provide in a CMN," beneficiaries' medical records are  
25 necessary to substantiate the medical necessity of DME. Id.

26

1 at 15-16. Below, I explain why the argument fails.<sup>18</sup>

2 Part B of the Act places limits on suppliers' use of a  
3 CMN, but does not in any way restrict the type or amount of  
4 medical information that *physicians* may be required to  
5 include in it. See 42 U.S.C. § 1395m(j)(2)(A)(I).<sup>19</sup> While  
6 the statute provides that the *supplier* cannot complete the  
7 portion of the CMN relating to the beneficiary's medical  
8 condition, but is strictly limited to providing  
9 administrative information, nothing in that section supports  
10 the Secretary's argument that Congress limited the type of  
11 medical condition information in a CMN that may be provided  
12 by others.

13 The Secretary also argues that plaintiff must obtain,  
14 review, and provide medical records to prove the medical

15

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16 <sup>18</sup> I am compelled to observe that if the Secretary is right,  
17 his relief comes not from applying a construction of the statute  
18 which is inconsistent with its plain meaning; rather, his relief  
is to be sought by legislative action.

19 <sup>19</sup> The statute provides, in pertinent part that:

20 ". . . a supplier of medical equipment and supplies may  
21 distribute to physicians . . . a Certificate of Medical  
22 Necessity . . . which contains no more than the  
23 following information *completed by the supplier*: (I) An  
24 identification of the supplier and the beneficiary to  
25 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 . . ."

26 42 U.S.C. § 1395m(j)(2)(A)(i) (emphasis added).

1 necessity of power wheelchairs and other DME. According to  
2 the Secretary, Congress placed the limitations listed in  
3 § 1395m(j)(2)(A), and created penalties for violations of  
4 that section, because of concern with fraudulent and abusive  
5 practices by DME suppliers. Def's Br. in Supp. of Mot. for  
6 Summ. J. at 15-16; A.R. Vol. 1 at 27.<sup>20</sup> According to the  
7 Secretary, these policy considerations place limits on the  
8 medical information that a supplier may obtain from a  
9 physician on a CMN. On that basis, the Secretary contends  
10 that he must have the authority to create other documentation  
11 requirements so that he may determine when DME may be  
12 reimbursed by Medicare, while at the same time being mindful  
13 of Congressional intent to curb supplier fraud.

14 The argument is less than pellucid. I have already  
15 noted that the statute does not limit physician-supplied  
16 information. Moreover, it is unclear how such policy  
17 considerations allow or require that suppliers obtain medical  
18 records to support and make a judgment about the medical  
19 necessity of DME. The Secretary fails to explain why, if  
20 Congress was concerned with supplier misconduct, and  
21 accordingly strictly restricted suppliers to providing  
22 administrative information, it would agree to allow suppliers  
23 to "request copies of the customer's medical and clinical

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24  
25 <sup>20</sup> Indeed, Congress provided that suppliers who violate the  
26 restrictions enumerated in § 1395m(j)(2)(A)(i) are subject to  
monetary penalties of up to \$1,000 per violation. See 42 U.S.C.  
§ 1395m(j)(2)(A)(iii).

1 records substantiating the doctor's CMNs and review them for  
2 . . . completeness and reasonableness." Def's Br. in Opp'n  
3 to Pl's Prelim. Inj. at 12; A.R. Vol. 1 at 28-29. Indeed, it  
4 appears to this court that the Secretary's contention based  
5 on Congressional concern with suppliers' fraudulent practices  
6 is a non sequitur.

7 Given that Congress designated the vehicle by which  
8 suppliers are to provide the information requested by the  
9 Secretary to determine medical necessity, and that it took  
10 precautionary measures to prevent supplier misconduct, it  
11 seems implausible that Congress would allow suppliers to  
12 obtain and keep private medical records, second guess  
13 physicians' professional conclusions by making medical  
14 necessity judgments themselves, and then inform beneficiaries  
15 prior to furnishing an item of "the likelihood of Medicare  
16 denial of payment." See A.R. Vol. 1 at 28. Such  
17 requirements would likely lead to the very type of abuse that  
18 apparently concerned Congress. Finally, in this regard, I  
19 note that the Secretary's construction raises serious privacy  
20 concerns.<sup>21</sup> A construction raising constitutional questions,

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21  
22 <sup>21</sup> Individuals have a right protected under the Due Process  
23 Clause of the Fifth and Fourteenth Amendments in the privacy of  
24 personal medical information and records. Yin v. State of Cal.,  
25 95 F.3d 864 (9th Cir. 1996); see also Whalen v. Roe, 429 U.S. 589,  
26 599 (1977). Moreover, the Privacy Act, 5 U.S.C. § 552a, provides  
that, with certain exceptions, "no agency may disclose any record  
which is contained in a system of records . . . except pursuant to  
a written request by, or with the prior written consent of, the  
individual to whom the record pertains . . . ." 5 U.S.C. §  
552a(b); See also Cal. Civ. Code § 56.10(C) (requiring health care

1 or suggesting statutory conflict is, of course, to be  
2 avoided.

3       In a final effort to defend the challenged documentation  
4 requirements, the Secretary argues that the plaintiff was  
5 required to obtain medical records because the current CMN  
6 does not request enough information to provide information as  
7 to all of the medical necessity criteria for motorized  
8 wheelchairs. Def's Br. in Supp. of Mot. for Summ. J. at 17.  
9 According to the MAC, the CMN alone would not have allowed  
10 CIGNA to determine the medical reasonableness of the  
11 wheelchairs because the document fails to "solicit  
12 information concerning all the coverage criteria." A.R. Vol.  
13 1 at 30. Specifically, the MAC explained that, "although the  
14 coverage manual states that the patient's condition must be  
15 such that without the use of a wheelchair, the patient would  
16 otherwise be bed or chair confined, there is no question on  
17 the CMN that specifically addresses this coverage element."  
18 Id. The Secretary further argues that, because plaintiff was  
19 on notice of all of the coverage elements and the CMN did not  
20 inquire regarding all of them, it should have known that it  
21 needed to supply medical documentation in addition to the

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25 \_\_\_\_\_  
26 providers to hold a patient's medical information confidential  
unless the information falls under an enumerated exceptions).

1 CMN.<sup>22</sup>

2 The MAC is correct that the CMN used during the time in  
3 question, and currently in effect, DMERC form 2.03 A, does  
4 not make inquiries regarding all of the medical necessity  
5 criteria for motorized wheelchairs. See A.R. Vol. 4 at 860.  
6 That form asks only seven questions regarding the  
7 beneficiary's medical condition and does not inquire whether  
8 the patient would be bed or chair confined without a  
9 motorized wheelchair, a criterion that must be met for a  
10 wheelchair to be considered medically necessary for the  
11 beneficiary. Id. at 860. The Secretary essentially argues  
12 that his response to this "practical dilemma" is to require

13 \_\_\_\_\_  
14 <sup>22</sup> According to 42 C.F.R. § 411.406(e)(1)), a supplier  
15 will be presumed to know that an item was not reasonable and  
16 necessary where the supplier has received relevant CMS  
17 notices, including manual issuances or other written guides  
18 from the Medicare carrier. 42 C.F.R. § 411.406 provides  
19 that:

18 (e) Knowledge based on experience, actual notice, or  
19 constructive notice. It is clear that the provider,  
20 practitioner, or supplier could have been expected to have  
21 known that the services were excluded from coverage on the  
22 basis of the following:

21 (1) Its receipt of CMS notices, including manual issuances,  
22 bulletins, or other written guides or directives from  
23 intermediaries, carriers, or QIOs, including notification of  
24 QIO screening criteria specific to the condition of the  
25 beneficiary for whom the furnished services are at issue and  
26 of medical procedures subject to preadmission review by a  
QIO.

24 (2) Federal Register publications containing notice of  
25 national coverage decisions or of other specifications  
26 regarding noncoverage of an item or service.

(3) Its knowledge of what are considered acceptable standards  
of practice by the local medical community.

1 suppliers to obtain other medical documentation to provide  
2 proof of whatever criteria are not addressed in the CMN.

3         Although courts may go beyond the plain meaning of a  
4 statute if it leads to an "impracticable consequence," the  
5 problem complained of here is not a consequence of the  
6 statute, but of CMS' drafting of the CMN. As I now explain,  
7 because the "problem" is self-created and easily remedied, a  
8 proper construction of the statute does not at all produce an  
9 impracticable result, and the plain meaning must be honored.  
10 See Avendano-Ramirez v. Ashcroft, 365 F.3d 813, 816 (9th Cir.  
11 2004). That CMS has elected to limit the questions on the  
12 CMN does not mean that it is incapable of soliciting all of  
13 the necessary information required to make a medical  
14 necessity determination based on all the coverage criteria.  
15 Indeed, a prior version of the form demonstrates that CMS is  
16 capable of meeting Congress' directive by obtaining all of  
17 the required medical necessity information on a CMN. That  
18 version, DMERC form number 2.01, contained twenty questions  
19 covering a wide variety of medical coverage elements,  
20 including whether the patient would otherwise be bed or chair  
21 confined. Decl. of Tom Lambert, Exh. A. The solution to the  
22 current gap between medical necessity coverage criteria and  
23 the information solicited on the CMN is not to impose an  
24 impermissible requirement that the supplier obtain and review  
25 medical records, but to use a CMN similar to DMERC form  
26 number 2.01, seeking that information from the physician.

1 The Secretary cannot rest on a self-created problem to  
2 justify ignoring the plain words of the statute.

3 For the foregoing reasons, the court concludes that the  
4 plain language § 1395m(j)(2)(A)(i) supports the plaintiff's  
5 position that it may only use a CMN to provide the necessary  
6 information for the determination of medical necessity and  
7 reasonableness. The Secretary cannot require that DME  
8 suppliers, such as plaintiff, obtain Medicare beneficiaries'  
9 medical records and make a judgment as to whether the  
10 equipment is medically necessary and reasonable. It is clear  
11 from the plain text of the Medicare Act that, while Congress  
12 granted the Secretary broad discretion over medical necessity  
13 and billing criteria and procedures, it did not do the same  
14 regarding medical necessity documentation. Instead, Congress  
15 addressed that issue itself and established that any and all  
16 information required from suppliers to make a medical  
17 necessity determination must be contained in a CMN. Because  
18 the MAC's conclusion, and the Secretary's contentions,  
19 conflict with the plain language of the Medicare Act,  
20 plaintiff's motion for summary judgment must be granted.

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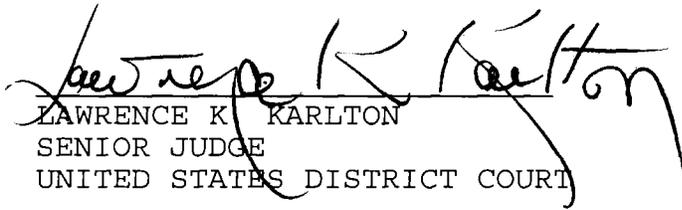
V.

**CONCLUSION**

For the foregoing reasons, the court hereby ORDERS as follows:

1. Plaintiff's motion for summary judgment and permanent injunction is GRANTED;
2. Defendant, and his agents, officers, employees, representatives, and all persons acting in concert or participating with him, are ENJOINED from recouping, offsetting or otherwise collecting from plaintiff any alleged overpayments for any of the beneficiaries which are the subject of this action from any amounts due and owing to plaintiff; and
3. Plaintiff is directed to SUBMIT a proposed judgment, including the amount of judgment and supporting calculations and documents, within twenty (20) days from the date this order is filed. Defendant shall file a statement of non-opposition or an opposition to the amounts set forth in the plaintiff's proposed judgment within twenty (20) days after the date recorded on the proof of service to the proposed judgment.

IT IS SO ORDERED.  
DATED: June 28, 2004.

  
LAWRENCE K. KARLTON  
SENIOR JUDGE  
UNITED STATES DISTRICT COURT

United States District Court  
for the  
Eastern District of California  
June 30, 2004

\* \* CERTIFICATE OF SERVICE \* \*

2:03-cv-01584

Maximum Comfort Inc

v.

Secretary of Health

---

I, the undersigned, hereby certify that I am an employee in the Office of the Clerk, U.S. District Court, Eastern District of California.

That on June 30, 2004, I SERVED a true and correct copy(ies) of the attached, by placing said copy(ies) in a postage paid envelope addressed to the person(s) hereinafter listed, by depositing said envelope in the U.S. Mail, by placing said copy(ies) into an inter-office delivery receptacle located in the Clerk's office, or, pursuant to prior authorization by counsel, via facsimile.

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