-FFM Gordian Medical, Inc. v. Kathleen Sebelius Doc. 66

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA O

CIVIL MINUTES - GENERAL

Case No.	CV 10-3933CAS (FFMx)	Date	March 9, 2012
Title	GORDIAN MEDICAL, INC. v. KATHLEEN SEBELIUS, ETC.		

Present: The Honorable	CHRISTINA A. SNYDER	
CATHERINE JEANG	Not Present	N/A
Deputy Clerk	Court Reporter / Recorder	Tape No.

Attorneys Present for Plaintiffs:	Attorneys Present for Defendants:
Not Present	Not Present

Proceedings: (In Chambers:) Bench Trial

I. INTRODUCTION

On May 25, 2010, plaintiff Gordian Medical, Inc. filed suit against Kathleen Sebelius, in her official capacity as Secretary of the Department of Health and Human Services ("defendant" or the "Secretary"). Plaintiff filed a first amended complaint ("FAC") on January 14, 2011. Plaintiff seeks judicial review of a final decision by the Secretary, through the Medicare Appeals Council ("MAC"), to deny plaintiff's claims for Medicare reimbursement for composite dressings plaintiff provides to Medicare beneficiaries.

On October 3, 2011, plaintiff filed its opening trial brief. On October 31, 2011, the Secretary filed her opening trial brief and opposition to plaintiff's opening trial brief.[1] On November 28, 2011, plaintiff filed its opposition to the Secretary's opening trial brief and

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[1] Contemporaneously with her opening trial brief and opposition to plaintiff's opening trial brief, the Secretary filed objections to extra-record evidence offered by plaintiff. Specifically, the Secretary objects to evidence offered to advance plaintiff's argument that the Secretary improperly invalidated the Healthcare Common Procedure Coding System ("HCPCS") billing codes at issue in this case. For the reasons stated below, the Court finds that plaintiff did not pursue this argument through the proper administrative channels. As a result, there is no need to "inquire outside the administrative record . . . to explain the agency's action" because the record "includes everything that was before the agency pertaining to the merits of the decision." Animal Defense Council v. Hodel, 840 F.2d 1432, 1436 (9th Cir. 1988), as amended, 867 F.2d 1244 (1989). Therefore, the Court sustains the Secretary's objections.

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reply to the Secretary's opposition. On December 12, 2011, the Secretary filed her reply to plaintiff's opposition. On January 6, 2012, the Court held a bench trial at which the Court requested supplemental briefing from each party.[2] The parties each filed supplemental briefs on January 13, 2012, and replied on January 20, 2012. After considering the arguments set forth by both parties, the Court finds and concludes as follows.

II. BACKGROUND

Plaintiff is a Medicare enrolled supplier of wound care supplies, including non-bordered composite dressings. FAC ¶¶ 7–8. Plaintiff's dressings are eligible for federal reimbursement under Part B of the Medicare Act, 42 U.S.C. §§ 1395j–1395w-4. FAC ¶ 11. To obtain reimbursement, Medicare suppliers submit claims to a Durable Medical Equipment Medicare Administrative Contractor ("DME-MAC"), that are agents of the Centers for Medicare & Medicaid Services ("CMS"). FAC ¶ 15. The United States is divided into four geographic jurisdictions ("A" through "D"), each of which is assigned a DME-MAC. Id. During the relevant time period, the Statistical Analysis Durable Medical Equipment Regional Carrier ("SADMERC") – a CMS agent and contractor – offered guidance to Medicare suppliers on the proper billing codes for covered supplies. FAC ¶¶ 19–20. In December 2004 and April 2006, the SADMERC assigned billing codes to plaintiff's composite dressings, qualifying those dressings for Medicare reimbursement. FAC ¶ 25.

Beginning in 2004, DME-MACs began denying a high percentage of plaintiff's reimbursement claims based on a purported lack of medical necessity. FAC ¶ 27. Almost all of the DME-MACs denials were reversed on appeal by Administrative Law Judges ("ALJs"). Id. Plaintiff alleges that the DME-MACs, faced with the prospect of continuing reversals in the administrative appeals process, devised a strategy that would allow them to deny plaintiff's claims while shielding their decisions from administrative

[2] Specifically, the Court ordered the parties to address whether a durable medical equipment supplier could administratively appeal the agency's instruction that claims for composite surgical dressings without adhesive borders should be billed under three HCPCS Level II codes, which differed from the three HCPCS codes that plaintiff used in this case.

review. FAC ¶ 29. Plaintiff alleges that Medicare program contractors published a "Policy Article" unilaterally changing the definition of "composite dressings" to require, without medical justification, that the dressings have a physical adhesive border. FAC ¶¶ 30–33. Thereafter, Medicare contractors invalidated the billing codes that applied to plaintiff's dressings, and stopped reimbursing claims under the old codes in a manner that precluded further administrative review. FAC ¶¶ 34–54. Plaintiff alleges that these changes were contrary to established procedures for revising definitions and changing billing codes. FAC ¶¶ 30–49. As a result, plaintiff claims to have been denied reimbursement totaling $4,928,189.95. FAC ¶ 50.

In response to these actions, on February 25, 2008, plaintiff filed suit against the Secretary in the United States District Court for the District of Columbia in Am. Med. Tech. v. Johnson, 598 F. Supp. 2d 78, 83 (D.D.C. 2009).[3] FAC ¶ 55. On February 25, 2009, the court dismissed plaintiff's lawsuit for lack of subject matter jurisdiction due to the Medicare statute's jurisdictional exclusivity and exhaustion requirements. Am. Med. Tech. v. Johnson, 598 F. Supp. 2d at 83. The court determined that plaintiff could have obtained administrative review under 42 C.F.R. § 405.924(b)(12) by "submitt[ing] claims for reimbursement using the new codes rather than the old ones."[4] Id. at 82. The court held that 42 C.F.R. § 405.926(c), which precludes appeals of "[a]ny issue regarding the computations of the payment amount of program reimbursement of general applicability . . . such as the establishment of a fee schedule," would not bar judicial review because plaintiff would be challenging the approach the Medicare contractors used in invalidating the old codes and issuing the new ones. Id. at 83.

Thereafter, plaintiff availed itself of the administrative appeals process and sought administrative review of its claims for non-bordered composite dressings by filing certain claims using the new codes, and additional claims using the original codes. FAC ¶ 59. Plaintiff alleges that its entire universe of claims for composite dressings are at various stages of administrative appeal. Id. The claims for non-bordered composite dressings

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[3] Plaintiff was then referred to by the name of its predecessor, American Medical Technologies, Inc. FAC ¶ 7.

[4] 42 C.F.R. § 405.924(b)(12) provides that any issue "having a present or potential effect on the amount of benefits to be paid" may be appealed.

that are the subject of the Secretary's final decision and that are the subject of this case were filed using the original codes for non-bordered composite dressings. FAC ¶ 60. Specifically, plaintiff used the original billing codes for dressings supplied to nine patient-beneficiaries during the three-month period between December 2007 and February 2008. Administrative Record ("AR") 11.

Reimbursement for the claims at issue was originally denied by a Medicare contractor. Id. Plaintiff requested reconsideration of the denials by the Qualified Independent Contractor ("QIC"). FAC ¶ 61. The QIC also denied Medicare coverage of these claims. Id. Plaintiff then sought review by an ALJ, who ultimately concluded that the claims were not covered by Medicare. FAC ¶ 62. The ALJ did not address the validity, reasonableness or enforceability of the revised definition of "composite dressing" or the changed billing codes. Id. Plaintiff appealed to the final level in the administrative appeals process by seeking review in the Medicare Appeals Council ("MAC"). FAC ¶ 63. The MAC held that "[n]either an ALJ nor the Council have the authority to review . . . the [Medicare contractors'] invalidation of [billing] codes, or any CMS action or inaction with respect to coding issues." AR 6. Accordingly, the MAC held that plaintiff's claims for non-bordered composite dressings billed under the original codes were not covered items under Medicare. AR 7.

Plaintiff then filed this suit seeking relief under the Medicare statute and the Administrative Procedure Act ("APA"), 5 U.S.C. §§ 551 et seq. and 701 et seq.

III. LEGAL STANDARD

Subject matter jurisdiction over plaintiff's challenge to the Secretary's final decision is based upon the Medicare statute, 42 U.S.C. § 1395ff(b)(1)(A), which authorizes judicial review "as provided in [42 U.S.C. §] 405(g)." On review, the Secretary's findings "as to any fact, if supported by substantial evidence, shall be conclusive . . . " See 42 U.S.C. § 405(g). The Court must affirm the findings of the Secretary "if they are supported by 'substantial evidence' and if the proper legal standards were applied." Mayes v. Masanari, 276 F.3d 453, 458–59 (9th Cir. 2001). "'Substantial evidence' is more than a mere scintilla but less than a preponderance; it is such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." Id. at 459 (internal quotation and citation omitted). In applying the substantial evidence standard, "a reviewing court may not substitute its own judgment for

that of the agency." Memorial, Inc. v. Harris, 655 F.2d 905, 912 (9th Cir. 1980) (citing Citizens to Improve Overton Park v. Volpe, 401 U.S. 402, 416 (1971)). "Substantial evidence exists if there is 'such relevant evidence as a reasonable mind might accept as adequate to support a conclusion.' A finding supported by substantial evidence must be affirmed by a reviewing court even if it is possible to draw two inconsistent conclusions from the evidence." Id. (quoting Consolo v. Federal Mar. Comm'n, 383 U.S. 607, 620 (1996)).

Under the Administrative Procedure Act, the reviewing court must affirm the agency's determination unless it is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law." 5 U.S.C. § 706(2)(A). "A decision is arbitrary and capricious if the agency 'has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.'" Motor Vehicle Mfr.'s Ass'n v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983)).

IV. DISCUSSION

A. Scope of this Review

The Court first considers whether subject matter jurisdiction in this case extends beyond the MAC's final decision concerning plaintiffs' claims as to nine beneficiaries during the three-month period between December 2007 and February 2008.

According to plaintiff, its "entire universe of claims" are at issue in this action. Pl. Op. Brf. at 11 n. 8. Plaintiff further argues that because it submitted evidence beyond the claims for the nine beneficiaries analyzed by the ALJ, the Court has jurisdiction over all of plaintiff's claims. Pl. Opp'n Brf. at 2.

The Secretary responds that plaintiffs allegations of subject matter jurisdiction over all of its claims are not supportable given that the MAC's final decision was limited to the claims of only nine patient-beneficiaries during the period between December 2007 and February 2008. Def. Op. Brf. at 9 (citing A.R. at 3–11). According to the Secretary, except for the claims specifically addressed by the MAC's final decision, plaintiff's

request for relief for the remainder of the universe of its claims exceeds the narrow scope of the Court's jurisdiction pursuant to § 405(g). Id.

The Medicare Statute provides for "judicial review of the Secretary's final decision . . . as is provided in section 405(g) of this title." 42 U.S.C. § 1395ff(b)(1)(A). The Ninth Circuit has held that "[f]ederal courts have jurisdiction over provider reimbursement disputes only to the extent provided by 42 U.S.C. § 1395oo(f)(1)." Anaheim Mem'l Hosp. v. Shalala, 130 F.3d 845, 853 (9th Cir. 1997). See also Rhode Island Hosp. v. Califano, 585 F.2d 1153, 1158 (1st Cir. 1978) (noting that § 1395oo(f) is the "functional equivalent of § 405(g)). Accordingly, a party can secure judicial review of a particular claim under the Medicare statute only if there is a final agency decision on the matter in question. Importantly, the "final decision" requirement in 42 U.S.C. § 405(g) is a "statutorily developed jurisdictional prerequisite," not "simply a codification of the judicially developed doctrine of exhaustion." Weinberger v. Salfi, 422 U.S. 749, 766 (1975). As the Ninth Circuit has explained, the exclusive jurisdictional prerequisites of the Medicare statute consist of two requirements: "a nonwaivable requirement that 'a claim for benefits shall have been presented to the Secretary;'" and a final decision or exhaustion requirement, which "a district court cannot waive . . . for equitable or other policy reasons." Queen of Angels/Hollywood Presbyterian Medical Ctr. v. Shalala, 65 F.3d 1472, 1482 (9th Cir. 1995).

In this case, the Court's jurisdiction pursuant to § 405(g) does not extend beyond the claims of the nine beneficiaries which were finally denied by the MAC in its March 24, 2010 decision.[5] See, e.g., Heckler v. Ringer, 466 U.S. at 610 (finding no jurisdiction under § 405(g)); Pacific Coast Med. Enter. v. Harris, 633 F.2d 123, 137–38 (9th Cir. 1980) (no § 1395oo(f) jurisdiction); Western Med. Enter. v. Heckler, 783 F.2d 1376, 1380 (9th Cir. 1986) (same).

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[5] Because plaintiff alleges that most of its claims are still pending in the administrative appeals process, FAC ¶ 59, it cannot be said that the Secretary has in any sense "waived further exhaustion" as to whether those claims satisfy the applicable coverage requirements. Heckler v. Ringer, 466 U.S. 602, 618 (1984).

B. Whether the MAC Should have Decided Issues Regarding HCPCS Coding Procedures

According to plaintiff, the Secretary abused her discretion by failing to adhere to Congressional mandates and her own public notice and comment procedures regarding the revisions of HCPCS codes. Pl. Op. Brf. at 16–22. Plaintiff argues that the ALJ and MAC erroneously ignored plaintiff's procedural objections because of the mistaken belief that those objections could be heard in the Local Coverage Determination ("LCD") appeals process. Pl. Opp'n Brf. at 4 (citing A.R. 9).

In opposition, the Secretary argues that plaintiff's focus on the LCD is misplaced because the MAC's final denial of coverage was not based on the LCD but was instead based on a July 2007 HCPCS Quarterly Update. Def. Reply Brf. at 6. The Secretary further contends that insofar as plaintiff wished to challenge the procedure by which the HCPCS Quarterly Update invalidated the original billing codes, the proper avenue was for plaintiff to file its claims under the new codes and then challenge the rate at which they were paid. Rep. Tr. Of Proceedings Jan. 6, 2012, at 18:24–19:6.

In its supplemental brief, plaintiff argues that the changes made to the HCPCS codes through the July 2007 Quarterly Update cannot be reviewed under Health and Human Services' administrative appeal process. According to plaintiff, regardless of whether it files claims under the old codes or the new codes, plaintiff cannot raise procedural challenges as to the Secretary's various policy statements through the administrative claims appeal process. Pl. Post Trial Brf. at 2. Further, plaintiff argues that no right of administrative appeal would have existed for claims paid under the new codes because those would have been paid as fully favorable claims at the administrative level. Id. at 3. In such case, plaintiff argues that the only issue that it could appeal would be the amount of payment received. Plaintiff maintains that this is significant because Health and Human Services' regulations preclude challenge to "payment amounts or methodologies" in administrative claim appeals. Id. at 4 (citing 42 C.F.R. § 426.325(b)(7); 20 C.F.R. § 404.946 ("The issues before the administrative law judge include all the issues brought out in the initial, reconsidered, or revised determination that were not decided entirely in your favor.")).

In her supplemental brief, the Secretary argues that plaintiff's challenge to the HCPCS billing instruction could have been raised as "part and parcel" of a

reimbursement appeal. Def. Post Trial Brf. at 1. In support of this argument, the Secretary notes that the Medicare statute allows for full administrative review of both the Medicare contractor's "'initial determination of the amount of benefits available,'" and "'[a]ny other initial determination . . . that payment may not be made.'" Id. (quoting 42 U.S.C. § 1395ff(a)(1)(B), (C), (b)(1)(A)). According to the Secretary, plaintiff could also appeal an initial determination concerning whether items or services furnished "'are covered'" and "'[a]ny other issues having a present or potential effect on the amount of benefits to be paid under Part A or Part B.'" Id. at 1–2 (quoting 42 C.F.R. § 405.924(b)(1), (12)). Further, the Secretary maintains that had plaintiff used the new HCPCS codes, plaintiff could have argued that it had been underpaid because the fee schedule amounts for those codes are less than those for the original codes. Id. at 4.

The Court finds that plaintiff could have challenged the procedure by which the original HCPCS codes were invalidated by bringing its claims under the new codes, and therefore that the MAC's determination that it could not reach plaintiff's procedural arguments was not arbitrary and capricious.[6] In American Medical Technologies, 598 F.Supp.2d at 82, plaintiff's predecessor-in-interest contested the Secretary's assertion that it could have submitted claims for reimbursement using the new HCPCS codes rather than the olds codes, and that 42 C.F.R. § 405.924(b)(12) provided "a vehicle for administrative appeal" of the HCPCS billing instructions. The court rejected the supplier's "counter[,] that the Secretary's proposal is unworkable." Specifically, the court held:

> If plaintiff were to appeal from an initial determination using the new billing codes, however, it would *not* be raising an 'issue regarding the computation of payment amount." Rather, plaintiff would be raising an issue regarding the approach the

[6] It is irrelevant that plaintiff could not challenge the MAC's denial of coverage through the LCD appeals process. This is so because the MAC's final denial of coverage was not based on an LCD but was instead based on the July 2007 HCPCS Quarterly Update. A.R. 7. While the MAC also discussed the Medicare contractor's LCD for Surgical Dressings and its interpreting Policy Article, it did so solely in response to plaintiff's complaints about the "reconsideration" of its claims by the QIC and the ensuing rejection of plaintiff's claims by the ALJ. A.R. 8–9. The MAC's statements about the LCD and Policy Article were therefore unnecessary to its decision.

> contractors used in invalidating the old codes and issuing the new ones. Hence, the Court is persuaded that . . . § 405.924(b)(12) would provide plaintiff with a vehicle for administrative review and moreover, review would not be barred by § 405.926(c).

Id. at 83 (emphasis in original).

The reasoning of American Medical Technologies applies equally to this case. Here, plaintiff ignored the agency's directive to use the new HCPCS billing codes, and instead billed under the superseded codes it preferred. Had plaintiff billed using the new codes and then argued that it was underpaid, the MAC could have decided the merits of plaintiff's challenge to the agency's billing instructions. Because plaintiff did not do so, the Court finds that the MAC did not act arbitrarily and capriciously by concluding that it lacked the authority to review the procedures by which the HCPCS codes were adopted.

The regulations upon which plaintiff relies do not compel a contrary result. While 42 C.F.R. § 426.325(b)(4), (12) does in some circumstances remove from review "contractor bulletin articles, education materials, website frequently asked questions" and "any other policy that is not an LCD or NCD[,]" plaintiff overlooks the regulation's caveat that such review only is precluded "under this part." 42 C.F.R. § 426.325(b). The "part" referred to is Part 426 of Title 42 of the Code of Federal Regulations, which provides for administrative and judicial review of facial challenges to the lawfulness of a national coverage determination ("NCD") or LCD. Id. § 426.100. This case does not involve an NCD or a facial challenge to an LCD. Instead, plaintiff's administrative appeal was based exclusively on the review provisions for individual benefit claims. Therefore, the Court agrees with the Secretary that the provisions of § 426 concerning appeals of NCDs and LCDs are inapplicable. Plaintiff's reliance on 42 C.F.R. § 426.325(b)(7) is misplaced for the same reason. Finally, 20 C.F.R. § 404.946 is also inapposite. That provision is part 20 C.F.R § 404(J), which governs appeals of claims for Social Security retirement and disability benefits, and is inapplicable to this case for two reasons. First, for Medicare purposes 20 C.F.R. § 404(J) applies only to initial determinations and redeterminations by the Social Security Administration as to whether a person is entitled to Medicare benefits. ALJ hearings on Medicare entitlement issues are governed instead by 42 C.F.R. § 405.904. Second, this case involves only issues of Medicare coverage and payment for the Part B benefit claims of a supplier; there are no issues concerning any person's entitlement to Medicare benefits.

C. Whether the Secretary's Denial of Coverage Was Supported by Substantial Evidence

The Court finds that the Secretary's decision to deny coverage was supported by substantial evidence, and therefore must be affirmed. Mayes, 276 F.3d at 458–59.

Plaintiff argues that the Secretary committed "clear error" by confusing Policy Articles with Local Coverage Determinations. Pl. Op. Brf. At 13. According to plaintiff, the ALJ's confusion of Policy Article A24114 with an LCD was critical because the ALJ specifically declined to review certain issues because plaintiff had failed to pursue an administrative remedy through the LCD appeals process. Id. (citing A.R. 206). Plaintiff contends that the applicable LCD at the time the ALJ made his determination provided that the original codes were still valid for non-bordered composite dressings, and therefore that there was nothing in the LCD for plaintiff to challenge through the LCD process. Id.

In opposition, the Secretary argues that the MAC did not rely upon a Policy Article, but instead properly relied upon CMS' July 2007 HCPCS Quarterly Update, which provides that composite dressing claims billed under the applicable "HCPCS codes are non-covered by Medicare, effective July 1, 2007." Def. Op. Brf. at 11 (citing CMS Transmittal 1388 at 5). According to the Secretary, the MAC found that the dates of service for the claims at issue were "well within the range of dates of service to be denied coverage specified in the HCPCS Quarterly Update." Id. (quoting A.R. 7).

The Court agrees with the Secretary that the MAC did not base its decision on a Policy Article or LCD, but instead based the denial of coverage on the July 2007 HCPCS Quarterly Update. See A.R. 7. The Quarterly Update provides that composite dressing claims are non-covered by Medicare. Accordingly, the MAC's decision that the surgical dressings for nine beneficiaries that plaintiff billed under the original codes were not covered items under Medicare is supported by substantial evidence in the administrative record. In this respect, any error by the ALJ or the MAC regarding the effect of Policy Article A24114 has no bearing on this case. See Yassini v. Crosland, 618 F.2d 1356, 1362 (9th Cir. 1980) (holding that a "hypertechnical" violation is not grounds to invalidate an agency action).

V. CONCLUSION

In accordance with the foregoing, the Court finds for the Secretary. The Court directs the Secretary to submit within **ten (10)** days proposed findings of fact and conclusions of law that are consistent with this order. The Secretary is further directed to submit a courtesy copy to the Court.

IT IS SO ORDERED.

00:00
CMJ