

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

**AMERICAN MEDICAL
TECHNOLOGIES,**

Plaintiff,

v.

**CHARLES E. JOHNSON,¹ Acting
Secretary, United States Department of
Health and Human Services,**

Defendant.

Civil Action No. 08-00319 (JDB)

MEMORANDUM OPINION

American Medical Technologies ("plaintiff") is a Medicare supplier claiming that contractors for defendant U.S. Department of Health and Human Services ("defendant" or "the Secretary") unlawfully changed the Medicare reimbursement process, thereby harming plaintiff. The Secretary has filed a motion to dismiss for lack of subject matter jurisdiction pursuant to Federal Rule of Civil Procedure 12(b)(1). He argues that under the Medicare statute, plaintiff was required to present these claims within an administrative review mechanism before filing suit in federal court. For the reasons explained below, the Secretary's motion to dismiss is granted.

BACKGROUND

Plaintiff is a privately-owned supplier of composite dressings. Compl. ¶ 7. The dressings

¹ Former Secretary Michael O. Leavitt was named as the original defendant in this case. Pursuant to Federal Rule of Civil Procedure 25(d), the Court automatically substitutes his successor, acting Secretary Charles E. Johnson, as the new defendant.

are covered under Part B of the Medicare statute, 42 U.S.C. §§ 1395j-1395w-4. To obtain reimbursement, plaintiff -- like other enrolled Medicare suppliers -- must submit claims to a Durable Medical Equipment Medicare Administrative Contractor ("DME-MAC"). The United States is divided into four geographic jurisdictions ("A" through "D"), each of which is assigned a DME-MAC. Id. ¶ 11. DME-MACs reimburse Medicare suppliers pursuant to billing codes and fee schedules set by another of the Secretary's contractors, the Statistical Analysis Durable Medical Equipment Regional Carrier ("SADMERC"). Id. ¶ 15. In December 2004 and April 2006, SADMERC assigned billing codes to plaintiff's composite dressings, thereby qualifying those dressings for reimbursement. Id. ¶ 20.

Reimbursement for plaintiff's dressings got off to a rocky start. DME-MACs routinely denied plaintiff's reimbursement claims and those denials were almost always reversed upon appeal. Id. ¶ 22. Plaintiff alleges that the DME-MACs -- frustrated that the denials were being reversed on appeal -- then unilaterally revised the definition of "composite dressings," invalidated the billing codes that applied to plaintiff's dressings and replaced them with new codes, and stopped reimbursing claims submitted under the old codes. Id. ¶¶ 24-25, 29. Plaintiff alleges that these changes violated established procedures for revising definitions and billing codes. Id. ¶¶ 25-42. Plaintiff claims to have had 1,714 claims denied from October 1, 2006 to October 31, 2007, totaling \$741,442 in improperly disallowed reimbursements. Id. ¶ 45. Two jurisdictions in particular -- "B" and "C" -- have denied plaintiff's requests for reimbursement under the old billing codes for use of an invalid code. Id. ¶¶ 46, 48.

Plaintiff filed suit on February 25, 2008, alleging jurisdiction pursuant to 28 U.S.C. § 1331. Id. ¶ 4. Plaintiff alleges that the DME-MACs' actions violate the Administrative Procedures Act, 5 U.S.C. §§ 701-706, and seeks monetary, injunctive, and declaratory relief.

The Secretary filed this Rule 12(b)(1) motion to dismiss for lack of subject matter jurisdiction on August 29, 2008.

STANDARD

Under Fed. R. Civ. P. 12(b)(1), the plaintiff bears the burden of establishing that the court has jurisdiction. Grand Lodge of Fraternal Order of Police v. Ashcroft, 185 F. Supp. 2d 9, 13 (D.D.C. 2001) (a court has an "affirmative obligation to ensure that it is acting within the scope of its jurisdictional authority"); see also Pitney Bowes, Inc. v. United States Postal Serv., 27 F. Supp. 2d 15, 18 (D.D.C. 1998). A court must accept as true all the factual allegations contained in the complaint when reviewing a motion to dismiss pursuant to Rule 12(b)(1), and the plaintiff should receive the benefit of all favorable inferences that can be drawn from the alleged facts. See Leatherman v. Tarrant Cty. Narcotics Intelligence & Coordination Unit, 507 U.S. 163, 164, (1993); EEOC v. St. Francis Xavier Parochial Sch., 117 F.3d 621, 624-25 n. 3 (D.C. Cir. 1997). However, "the court need not accept inferences drawn by plaintiffs if such inferences are unsupported by the allegations set out in the complaint. Nor must the court accept legal conclusions cast in the form of factual allegations." Kowal v. MCI Commun. Corp., 16 F.3d 1271, 1276 (D.C. Cir. 1994). Furthermore, "'plaintiff[s]' factual allegations in the complaint . . . will bear closer scrutiny in resolving a 12(b)(1) motion' than in resolving a 12(b)(6) motion for failure to state a claim." Grand Lodge, 185 F. Supp. 2d at 13-14 (quoting 5A CHARLES ALAN WRIGHT & ARTHUR R. MILLER, FEDERAL PRACTICE AND PROCEDURE § 1350).²

² A court may consider material other than the allegations of the complaint in determining whether it has jurisdiction to hear the case. See Jerome Stevens Pharmaceuticals, Inc. v. FDA, 402 F.3d 1249, 1253-54 (D.C. Cir. 2005); Coalition for Underground Expansion v. Mineta, 333 F.3d 193, 198 (D.C. Cir. 2003); St. Francis Xavier Parochial Sch., 117 F.3d at 624-25 n. 3. The Court finds no need to review extra-pleading materials to resolve the pending motion.

ANALYSIS

The Secretary rests on a single argument in support of his motion to dismiss: the Court lacks subject matter jurisdiction over this case because of the Medicare statute's jurisdictional exclusivity and exhaustion requirements. Under those requirements, the Secretary contends, federal courts lack subject matter jurisdiction over cases like this one until a claim has been presented within an extensive system of administrative review and all administrative appeals have been exhausted. The Secretary argues that plaintiff has not presented his claims within the requisite administrative review mechanism, so this case must be dismissed for lack of subject matter jurisdiction. Plaintiff counters that it could not have pursued administrative appeals any further than it did, and hence this case is excepted from Medicare's jurisdictional exclusivity and exhaustion requirements.

The requirements that form the basis of the Secretary's motion to dismiss come from § 405 of the Medicare statute. See 42 U.S.C. § 405.³ Section 405(h) divests federal courts of jurisdiction over claims "arising under" the Medicare statute.⁴ Section 405(g), on the other hand, provides that a plaintiff may seek judicial review after the Secretary has made a "final decision." Read together, §§ 405(g) and (h) require "presentment" (i.e., initiation of administrative review) and "exhaustion" (i.e., completion of that review) of claims before a federal court has subject matter jurisdiction over a case arising under the Medicare statute. See Nat'l Kidney Patients

³ The relevant portions of § 405 are incorporated into the Medicare statute by 42 U.S.C. § 1395ii. See Shalala v. Illinois Council on Long Term Care, Inc., 529 U.S. 6, 9 (2000).

⁴ Plaintiff does not dispute that this case arises under the Medicare statute.

Ass'n v. Sullivan, 958 F.2d 1127, 1130 (D.C. Cir. 1992).

Section 405 has been the subject of several Supreme Court opinions. The most recent, Illinois Council, made it clear that the jurisdictional exclusivity and exhaustion requirements demand an expansive reading. There, the Supreme Court held that the presentment and exhaustion requirements apply to all types of claims -- the requirements call for "the 'channeling' of virtually all legal attacks through the agency." 529 U.S. at 13-14; see also Nat'l Kidney, 958 F.2d at 1129, 1133-34 (holding that § 405 applies to disputes over the methods used to determine reimbursement just as it applies to disputes over reimbursement amount determinations). The Supreme Court recognized that this broad reading "comes at a price, namely, occasional individual, delay-related hardship." Illinois Council, 529 U.S. at 13. But "in the context of a massive, complex health and safety program such as Medicare . . . paying this price seems justified." Id. The Supreme Court explained that this result was demanded both by the expansive language of § 405 and the numerous cases interpreting it, beginning with Weinberger v. Salfi, 422 U.S. 749 (1975), and Heckler v. Ringer, 466 U.S. 602 (1984).

But the Supreme Court's holding in Illinois Council was complicated by one case. In Bowen v. Michigan Academy of Family Physicians, 476 U.S. 667, 675 (1986), the Supreme Court had held that certain challenges to the method by which reimbursement is determined are not subject to the § 405 presentment and exhaustion requirements. The Court in Illinois Council noted the concern expressed in Michigan Academy that a broad reading of the exclusivity and exhaustion requirements -- as then written -- "would not lead to a channeling of review through the agency, but would mean no review at all." Illinois Council, 529 U.S. at 17. A total absence of review of challenges to methodology would give rise to a "serious constitutional question." Id.

(quoting Michigan Academy, 476 U.S. at 681 n.12 (internal quotations and ellipsis omitted)).

The Illinois Council Court narrowly interpreted Michigan Academy to reconcile it with the Salfi-Ringer line of cases. The holding in Michigan Academy had already been undermined because changes to the Medicare statute meant that challenges to methodology could now be channeled through the Medicare administrative review mechanism. See Nat'l Kidney, 958 F.2d at 1132. Hence, the "serious constitutional question" that had animated the decision in Michigan Academy had already been addressed. Moreover, Illinois Council held that a narrow reading was required because a broad one would mean that Michigan Academy overruled (or dramatically limited) the Salfi-Ringer cases sub silentio -- something the Supreme Court does not normally do. See Illinois Council, 529 U.S. at 18. The Illinois Council Court thus concluded that Michigan Academy only provides an exception to the presentment and exhaustion requirements "where application of § 405(h) would not simply channel review through the agency, but would mean no review at all." Id. at 19.

Turning to the present case, plaintiff argues that the Michigan Academy exception applies to its claims such that this Court has federal question jurisdiction under 28 U.S.C. § 1331.

Plaintiff targets three allegedly unlawful acts by the Secretary:

- (1) revising the definition of non-bordered composite dressings;
- (2) invalidating [billing] Codes for non-bordered composite dressings;
- and (3) failing to provide an administrative remedy to challenge these actions for a portion of Plaintiff's claims for non-bordered composite dressings.

Pl.'s Mem. in Opp'n to the Mot. to Dismiss ("Pl. Opp.") at 1. According to plaintiff, none of these allegedly unlawful acts could have been presented to -- and therefore could have been exhausted through -- the Medicare administrative review mechanism. The claims that were not

reimbursed in Jurisdictions "B" and "C" were denied for use of an invalid code, a determination that is unappealable. See Compl. ¶¶ 46-48; 42 C.F.R. § 405.926(s) (providing that a determination that a claim is "incomplete, invalid, or do[es] not meet the requirements for a Medicare claim" is not appealable).

The Secretary insists that the complained-of wrongs could indeed have been redressed within the Medicare administrative review mechanism. When plaintiffs in the Medicare context do not avail themselves of administrative review, courts routinely consider whether the plaintiff could have sought administrative review before filing suit in court. In Illinois Council itself, the Supreme Court noted that it had no reason to doubt the tenability of an alternative approach -- suggested by the Secretary over the protestations of the plaintiff -- that the plaintiff could have taken to obtain administrative review. See 529 U.S. at 21. Here, the Secretary asserts that plaintiff could have submitted claims for reimbursement using the new codes rather than the old ones. See Def.'s Mem. in Supp. of the Mot. to Dismiss ("Def. Mem.") at 21-22. Had plaintiff used the new codes, it could have sought further administrative (and potentially judicial) review of the initial reimbursement determination. Def. Mem. at 22. The Secretary cites to 42 C.F.R. § 405.924(b)(12), which provides that any issue "having a present or potential effect on the amount of benefits to be paid" may be appealed. Because the promulgation of new billing codes has an "effect on the amount of benefits to be paid," the Secretary argues, plaintiff had a vehicle for an administrative appeal. As part of that appeal, plaintiff could have challenged the allegedly unlawful actions about which it now complains.

Plaintiff counters that the Secretary's proposal is unworkable. According to plaintiff, it would have been reimbursed had it used the new codes, but the reimbursement amounts would

have been lower. And under a different provision of the regulations, 42 C.F.R. § 405.926(c), plaintiff argues, disputes as to fee schedule amounts cannot be appealed. See Pl. Opp at 10-11.

But the regulation cited by plaintiff would not bar review under the approach suggested by the Secretary. To be sure, 42 C.F.R. § 405.926(c) precludes appeals of "[a]ny issue regarding the computation of the payment amount of program reimbursement of general applicability . . . such as the establishment of a fee schedule" 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 the payment amount." Rather, plaintiff would be raising an issue regarding the approach the contractors used in invalidating the old codes and issuing the new ones.⁵ Hence, the Court is persuaded that 42 C.F.R. § 405.924(b)(12) would provide plaintiff with a vehicle for administrative review and, moreover, review would not be barred by § 405.926(c).

Having determined that plaintiff could have availed itself of the Medicare administrative review mechanism, it follows that this Court lacks subject matter jurisdiction over this case. See Illinois Council, 529 U.S. at 13-14. Plaintiff protests that the Secretary's alternative would "force the Plaintiff to inflict upon itself the precise harm that [it] is seeking to avoid." Pl. Opp. at 10. But that "harm" is unavoidable given how broadly § 405 is written and must be applied under Illinois Council. Plaintiff was not precluded from raising its claims within the Medicare administrative review mechanism. The Secretary has outlined a workable approach that plaintiff

⁵ The Secretary assures the Court that even if § 405.926(c) were to apply here, it would not bar plaintiff's claims. See Def.'s Rep. in Supp. of the Mot. to Dismiss at 15-16. The purpose of § 405.926(c) is to bar the equivalent of facial challenges to generally applicable reimbursement programs. Id. Plaintiff's claim, however, would be the equivalent of an "as-applied" challenge because it seeks reimbursement for specific claims. The Secretary's interpretation of its own regulation is not "plainly erroneous or inconsistent with the regulation," so it is entitled to "substantial deference." See Thomas Jefferson Univ. v. Shalala, 512 U.S. 504, 512 (1994).

could have taken and plaintiff has not provided a persuasive reason why that approach could not work. Hence, plaintiff's claims do not fall within the Michigan Academy exception as narrowly construed by Illinois Council; instead, subject matter jurisdiction is foreclosed under §§ 405(g) and (h) as interpreted by the Supreme Court. Accordingly, the Secretary's motion to dismiss is granted and this case is dismissed without prejudice. A separate order accompanies this opinion.

/s/
JOHN D. BATES
United States District Judge

Date: February 25, 2009