UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

ATLANTIC UROLOGICAL ASSOCIATES, P.A., *et al*.,	)	
Plaintiff,	)	
v.	)	**Civil Action No. 08-141 (RMC)**
MICHAEL O. LEAVITT, Secretary, Department of Health and Human Services,	)	
Defendant.	)	

MEMORANDUM OPINION

Plaintiffs brought this suit against Michael Leavitt, in his official capacity, as Secretary of the Department of Health and Human Services ("the Secretary" or "HHS") challenging the HHS's Final Order, 73 Fed. Reg. 404 (Jan. 3, 2008), which relates to Medicare billing of laboratory testing services. The Final Order delays for one year the application of the November 2007 Anti-Markup Rule[1] to services other than anatomic pathology diagnostic testing service. 73 Fed. Reg. 404 (Jan. 3, 2008). Plaintiffs include: (1) three urology physician group practices (the "Physician Groups")[2] that own and operate pathology laboratories; (2) Dr. Sam Michaels, a self-

[1] On November 27, 2007, the Centers for Medicare and Medicaid Services ("CMS"), on behalf of the Secretary, issued the final Anti-Markup Rule, 72 Fed. Reg. 66,222, 66,306. This rule, effective for services rendered after January 1, 2008, limited Medicare payment for the professional component of diagnostic testing services provided in a "centralized building" that does not qualify as the "same building" under the physician self-referral exception (also known as the "Stark Law"), 42 C.F.R. § 411.355(b).

[2] The Physician Groups are Atlantic Urological Associates, P.A.; Urology Center of Alabama, P.C.; and Urology Care, Inc.

employed pathologist who performs testing services for other physician groups; (3) Uropath, LLC, a limited liability company that manages various pathology laboratories; and (4) Uropath's Director of Clinical Operations, Rebecca Page. Plaintiffs seek to enjoin and invalidate the Final Order.

Plaintiffs move for a preliminary injunction; HHS opposes and also moves to dismiss for lack of jurisdiction. In order to permit time for briefing and oral argument on the complex issues involved, the parties consented to an Interim Order, entered February 8, 2008. The Interim Order set a briefing schedule (with briefing completed on March 19, 2008) and a hearing on March 28, 2008. The Interim Order further provided that Secretary would not apply the Anti-Markup Rule, as amended by the Final Rule, until April 1, 2008, as follows:

> [The Secretary] will not apply the final anti-markup rule, 72 Fed. Reg. 66,222 (Nov. 27, 2007), as amended by 73 Fed. Reg. 404 (Jan. 3, 2008), to claims submitted between February 1 and April 1, 2008, seeking Medicare reimbursement for anatomic pathology diagnostic testing services that are furnished in a centralized building that does not qualify as the "same building" under the physician self-referral exception at 42 C.F.R. § 411.355(b). Such claims shall remain subject to all other Medicare requirements. In the event the Court subsequently affirms the anti-markup rule as applied to anatomic pathology diagnostic testing services, the Secretary *shall not* recoup any Medicare payments made for any such claims submitted from February 1 to April 1, 2008, based on failure to comply with the provision governing payment for such services furnished in a centralized building that does not qualify as the "same building" under the physician self-referral exception.

Interim Order filed Feb. 8, 2008 [Dkt. #12] (emphasis added).

At the March 28, 2008, oral argument, the Court told the parties that it needed more than a weekend to decide the issues presented and invited the Secretary to extend the Interim Order. On March 31, 2008 at 12:10, the Secretary filed a Proposal to Extend Interim Agreement, indicating that it would extend the agreement not to apply the Anti-Markup Rule by thirty days, from April 1

to May 2, 2008. Critically, however, the Secretary indicated that "it reserves the right to recoup any Medicare payments in excess of the amounts that would be permissible under the anti-markup rule for any such claims submitted between April 2 to May 2, 2008." Def.'s Proposal to Extend Interim Agreement [Dkt. #23] at 1. In other words, the Secretary would have the Final Rule take effect. Because the Secretary insists on retaining the right to recoupment, the Court finds that, for the purpose of delaying a ruling on the Plaintiffs' motion for preliminary injunction, the Secretary has not sufficiently waived its right to implement the Anti-Markup Rule. Accordingly, as explained below, the Court will grant Plaintiffs' motion for a preliminary injunction.

I. FACTS

The Final Order challenged here delays for one year the application of the Anti-Markup Rule[3] to services other than anatomic pathology diagnostic testing service. 73 Fed. Reg. 404 (Jan. 3, 2008). Medicare Part B provides supplementary insurance coverage for physician and outpatient services, including diagnostic laboratory tests. 42 U.S.C. 1395x(s)(3). CMS published a notice of proposed rulemaking on July 12, 2007. 72 Fed. Reg. 38,122. This notice included an anti- markup rule regarding Medicare Part B payments for diagnostic testing services purchased from an outside provider or provided in a "centralized building." CMS was concerned that diagnostic testing services provided in a "centralized building" were overutilized and thus resulted in high costs to the Medicare program. *See* 72 Fed. Reg. 38,179. After receiving and reviewing numerous comments, on November 27, 2007, CMS published the final Anti-Markup Rule. The Anti-Markup Rule limited payment for anatomic pathology diagnostic testing services performed at a "site other

[3] CMS, on behalf of the Secretary, issued the Anti-Markup Rule. CMS administers the Medicare program on behalf of the Secretary. The Medicare program is the federal health insurance program for individuals age 65 and older and for the disabled. *See* 42 U.S.C. §§ 1395-1395hhh.

than the office of the billing physician or other supplier"[4] to the lesser of: (1) the performing supplier's net charge to the billing physician or other supplier; (2) the billing physician or other supplier's actual charge; or (3) the fee schedule amount for the test that would be allowed if the performing supplier billed directly. 73 Fed. Reg. at 405; 42 C.F.R. § 4.14.50(a)(1).

Shortly thereafter, CMS received "informal" comments and published another rule, the Final Rule at issue here. The Final Rule delayed until January 1, 2009, the applicability of the Anti- Markup Rule *except* as to (1) the technical component of a diagnostic test,[5] and (2) anatomic pathology diagnostic testing services furnished in a "centralized building." CMS indicated, "[b]ecause anatomic pathology diagnostic testing arrangements precipitated our proposal for revision of the anti-markup provisions and remain our core concern, we are not delaying the date of applicability with respect to anatomic pathology diagnostic testing services." 73 Fed. Reg. at 405. At this juncture, the Secretary has submitted no administrative record reflecting the making of the January 2008 Final Rule. There is nothing in the record before the Court describing the nature or content of the "informal" comments that led to the Final Rule.

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[4] The Final Rule clarified that a "site other than the office of the billing physician or other supplier" meant a "centralized building" that does not qualify as the "same building" under the physician self-referral exception (also known as the "Stark Law"), 42 C.F.R. § 411.355(b).

[5] Payment for diagnostic testing consists of a "technical component," the amount paid to the person or entity that performs the test, and a "professional component," the amount paid to the physician for interpreting the test. A limitation on payment for purchased technical component of diagnostic tests has been in effect since 1992 under 42 C.F.R. § 414.50. Thus, CMS contends that the Final Rule did not delay implementation of the Anti-Markup Rule as it applies to the professional component and non-purchased technical components of anatomic pathology diagnostic testing services. Plaintiffs make it clear that they challenge the Final Rule with respect to its application to both the professional and non-purchased technical components of anatomic pathology diagnostic testing services. Pls.' Opp. at 5-6. They do not challenge the application of the Anti-Markup Rule as applied to the technical component of a diagnostic test.

II. ANALYSIS

A. Motion to Dismiss for Lack of Jurisdiction

Federal courts are courts of limited jurisdiction and the law presumes that "a cause lies outside this limited jurisdiction." *Kokkonen v. Guardian Life Ins. Co. of Am.*, 511 U.S. 375, 377 (1994). Because subject matter jurisdiction is an Article III as well as a statutory requirement, "no action of the parties can confer subject[]matter jurisdiction upon a federal court." *Akinseye v. District of Columbia*, 339 F.3d 970, 971 (D.C. Cir. 2003). On a motion to dismiss for lack of subject-matter jurisdiction pursuant to Rule 12(b)(1), the plaintiff bears the burden of establishing that the court has subject matter jurisdiction. *Evans v. B.F. Perkins Co.*, 166 F.3d 642, 647 (4th Cir. 1999); *see also McNutt v. Gen. Motors Acceptance Corp.*, 298 U.S. 178, 182-83 (1936).

Here, the Secretary seeks dismissal. The Secretary argues that Uropath lacks standing to bring this suit. *See Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-61 (1992). Moreover, the Secretary argues that *Shalala v. Illinois Council on Long Term Care*, 529 U.S. 449, 120 S. Ct. 1084 (1999) applies. *See Illinois Council,* 120 S. Ct. at 1093-94 (42 U.S.C. § 405(h) (incorporated into the Medicare Act by 42 U.S.C. § 3595ii) precludes review under 28 U.S.C. § 1331; claims under the Medicare Act must be channeled through HHS's administrative process before they can be heard in federal court). Plaintiffs counter that the exception to this rule, set forth in *Bowen v. Michigan Academy of Family Physicians*, 476 U.S. 667 (1986), applies. *Michigan Academy* permits federal question jurisdiction where the application of section 405(h) would not lead to channeling of review through the agency but would result in no review at all. *Id*. at 681 n.12.

The Court has not decided the jurisdictional issues, but it need not do so prior to entering a preliminary injunction. *See Belbacha v. Bush*, No. 07-5258 (D.C. Cir. Mar. 14, 2008)

(under the All Writs Act, the district court retains authority to preserve the status quo by issuing a preliminary injunction).

B. Motion for Preliminary Injunction

A preliminary injunction is "an extraordinary remedy that should be granted only when the party seeking the relief, by a clear showing, carries the burden of persuasion." *Cobell v. Norton*, 391 F.3d 251, 258 (D.C. Cir. 2004). A court must consider four factors in deciding whether to issue a preliminary injunction:

1. whether the movant has shown a substantial likelihood of success on the merits;

2. whether the movant would suffer irreparable injury if the injunction is not granted;

3. whether the issuance of a preliminary injunction would cause substantial harm to other interested parties; and

4. whether the public interest would be served by the issuance of an injunction.

Mova Pharm. Corp. v. Shalala, 140 F.3d 1060, 1066 (D.C. Cir. 1998). The foregoing factors should be balanced on a "sliding scale," i.e., a lesser showing on one factor can be surmounted by a greater showing on another factor. *CSX Transp., Inc. v. Williams*, 406 F.3d 667 (D.C. Cir. 2005). Even so, in order to justify intruding into the ordinary litigation process by issuing a preliminary injunction, it is critical that a movant 1) make a substantial showing of likelihood of success on the merits, *Am. Bankers Ass'n v. Nat'l Credit Union Admin.*, 38 F. Supp. 2d 114, 140 (D.D.C. 1999), and 2) make a showing of at least some injury. *CityFed Fin. Corp. v. Office of Thrift Supervision*, 58 F.3d 738, 746 (D.C. Cir. 1995).

With regard to the first factor, Plaintiffs have shown a likelihood of success on the

merits. Under the Administrative Procedure Act ("APA"), 5 U.S.C. § 551 *et seq.*, a reviewing court must set aside an agency action that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A); *Tourus Records, Inc. v. Drug Enforcement Admin.*, 259 F.3d 731, 736 (D.C. Cir. 2001). In making this inquiry, the reviewing court "must consider whether the [agency's] decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment." *Marsh v. Oregon Natural Res. Council*, 490 U.S. 360, 378 (1989) (internal quotation marks and citation omitted). At a minimum, the agency must have considered relevant data and articulated an explanation establishing a "rational connection between the facts found and the choice made." *Bowen v. Am. Hosp. Ass'n*, 476 U.S. 610, 626 (1986); *see also Pub. Citizen, Inc. v. Fed. Aviation Admin.*, 988 F.2d 186, 197 (D.C. Cir. 1993) ("The requirement that agency action not be arbitrary or capricious includes a requirement that the agency adequately explain its result."). An agency action usually is arbitrary or 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 Mfrs. Ass'n of U.S. v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983); *see also County of Los Angeles v. Shalala*, 192 F.3d 1005, 1021 (D.C. Cir. 1999) ("Where the agency has failed to provide a reasoned explanation, or where the record belies the agency's conclusion, [the court] must undo its action.").[6]

[6] As the Supreme Court has explained, "the scope of review under the 'arbitrary and capricious' standard is narrow and a court is not to substitute its judgment for that of the agency." *Motor Vehicle Mfrs. Ass'n*, 463 U.S. at 43; *see Henley v. FDA*, 77 F.3d 616, 621 (2d Cir. 1996) ("we might not have chosen the FDA's course had it been ours to chart . . . [b]ut that is hardly the point.").

The law of this circuit is clear: "Once an agency gives its regulation an interpretation, it can only change that interpretation as it would formally modify the regulation itself: through the process of notice and comment rulemaking." *Paralyzed Veterans of Am. v. D.C. Arena L.P.*, 117 F.3d 579, 586 (D.C. Cir. 1997). This is because under the APA an agency's obligation to engage in notice and comment procedures before promulgating regulations also extends to amendments and repeals of regulations. *Paralyzed Veterans*, 117 F.3d at 586.

The Secretary issued the Final Rule without notice and comment. Further, while the Secretary admits that it issued the Final Rule pursuant to "informal" comment, no record indicating the nature and substance of such comments has been presented to the Court for review. The Court thus finds that this constitutes evidence in support of a finding of arbitrary and capricious rulemaking, evidence sufficient to support a preliminary injunction.

With regard to the second factor, Plaintiffs have demonstrated irreparable harm. Although the Secretary claims that this is merely a "benefits" case and that Plaintiffs can be made whole with a monetary damage award, such is not the case. Plaintiffs have shown that it is likely that Uropath and Dr. Michaels will lose their businesses if the Anti-Markup Rule goes into effect. The Physician Groups have shown that it is likely they will lose a substantial portion of their businesses and that they will be forced to close their laboratories. A preliminary injunction avoids such irreparable harm.

As for the third factor, there are no other interested parties who will be affected by

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Rather, the agency action under review is "entitled to a presumption of regularity" and the court must consider only whether the agency decision was based on relevant factors and whether there has been a clear error of judgment. *Citizens to Pres. Overton Park, Inc. v. Volpe*, 401 U.S. 402, 415 (1971), *abrogated on other grounds by Califano v. Sanders*, 430 U.S. 99 (1977).

the issuance of an injunction in this case. The Secretary will not be harmed as an injunction will merely maintain the status quo.

Finally, with regard to the public interest, public policy favors fair and open agency rulemaking. Therefore, issuance of a preliminary injunction is in the public interest.

III. CONCLUSION

In sum, Plaintiffs have shown a likelihood of success on the merits, and the Secretary will not suffer significant harm if the injunction is granted. The balance of harms favors the Plaintiffs, and public interest favors the issuance of an injunction. Accordingly, the Court will grant Plaintiffs' motion for preliminary injunction [Dkt. #5]. A memorializing order accompanies this Memorandum Opinion.

Date: March 31, 2008

_____/s/_____
ROSEMARY M. COLLYER
United States District Judge