

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION**

PREMIER MEDICAL SUPPLIES, INC.

Plaintiff,

v.

MICHAEL O. LEAVITT, Secretary of the
Department of Health and Human Services
et al.,

Defendants.

Case No. 1:07-CV-3809

JUDGE PATRICIA A. GAUGHAN

DEFENDANTS' MOTION FOR A PROTECTIVE ORDER

Defendants in the above-captioned action respectfully move this Court for a protective order to prevent impermissible discovery or, in the alternative, an order to stay discovery pending resolution of the issues of law presented in defendants' pending motion to dismiss. In support of this motion, defendants respectfully refer the Court to the accompanying memorandum of points and authorities.

Dated: April 21, 2008

Respectfully submitted,

JEFFREY BUCHOLTZ
Acting Assistant Attorney General

SHEILA M. LIEBER
Assistant Director, Federal Programs Branch

/s/ Stephen J. Buckingham

STEPHEN J. BUCKINGHAM

Trial Attorney

Department of Justice, Federal Programs Branch

20 Massachusetts Avenue, N.W., Room 7109

Washington, D.C. 20530

Tel: 202-514-4805

Fax: 202-616-8470

Attorneys for Defendants

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION**

PREMIER MEDICAL SUPPLIES, INC.

Plaintiff,

v.

MICHAEL O. LEAVITT, Secretary of the
Department of Health and Human Services
et al.,

Defendants

Case No. 1:07-CV-3809

JUDGE PATRICIA A. GAUGHAN
MAGISTRATE JUDGE BAUGHMAN

**MEMORANDUM IN SUPPORT OF DEFENDANTS’
MOTION FOR A PROTECTIVE ORDER**

INTRODUCTION

Through this motion, defendants Michael O. Leavitt, Secretary of the Department of Health and Human Services (“the Secretary”), and Kerry Weems, Acting Administrator of the Centers for Medicare and Medicaid Services, respectfully request a protective order to prevent impermissible discovery or, in the alternative, an order to stay discovery pending resolution of the issues of law presented in defendants’ pending motion to dismiss.

Plaintiff’s claims challenge the validity of agency regulations. These challenges arise under the Administrative Procedure Act (“APA”) and the Regulatory Flexibility Act (“RFA”). It is axiomatic that judicial review under the APA is limited to the administrative record produced by the agency. Judicial review of the procedural requirements created by the RFA is also restricted to the administrative record. Consequently, plaintiff should not be permitted to commence discovery on any of its claims.

FACTUAL AND STATUTORY OVERVIEW

Premier's Complaint challenges the legality of and manner in which the Secretary has implemented a subsection of the Part B supplementary medical insurance program,¹ specifically, section 302 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA" or "the Act"). See Compl. ¶¶ 81-83; 42 U.S.C. § 1395w-3 (2003) (directing the Secretary to establish a competitive bidding program by which suppliers compete for contracts to supply durable medical equipment, prosthetics, orthotics and supplies ("DMEPOS") to Medicare beneficiaries in designated areas). For the past several years, Medicare has paid for "durable medical equipment . . . using a different fee schedule for each class of covered items." H.R. Rep. No. 108-391, at Title III § 302 (2003) (Conf. Rep.). Following an investigation into the DMEPOS fee schedule payment system, Congress concluded that the existing fee schedule was too expensive for both taxpayers and Medicare beneficiaries and that it did not provide adequate value for what Medicare paid. H.R. Rep. No. 108-178 (II), at Title III, § 302 (2003).

Accordingly, Congress authorized a demonstration project to test whether a competitive acquisition program would be a more efficient method of paying for DMEPOS. Id. The competitive acquisition demonstrations were successful and Congress found that both taxpayers and Medicare beneficiaries "saved significantly and quality standards were higher under the demonstration." Id. Congress also found that in the demonstration projects "three-quarters of the [DMEPOS] winners were small businesses and beneficiary satisfaction remained high." Id.

In 2003, Congress enacted the Medicare DMEPOS competitive bidding program ("the

¹ Medicare Part B covers health care services such as physician visits, outpatient diagnostic tests, and durable medical equipment. *See* 42 U.S.C. § 1395k(a)(1).

competitive bidding program” or “the program”) as part of the MMA. See 42 U.S.C. § 1395w-3; 42 C.F.R. § 414.400 et seq. The MMA requires the Secretary to “establish and implement programs under which competitive acquisition areas are established throughout the United States for contract award purposes for the furnishing under this part of competitively priced [DMEPOS] items and services[.]” 42 U.S.C. § 1395w-3(a)(1). Under the program, the Secretary is required to conduct “a competition among entities supplying items and services,” id. at § 1395w-3(b)(1), wherein suppliers submit bids, offering to furnish items or services for a set price. Id. at § 1395w-3(b)(6)(B).

Premier filed its Complaint on December 13, 2007, challenging the substance of the competitive bidding program enacted by Congress and its implementation by the Secretary. Compl. ¶¶ 50-80. Premier seeks a declaration that section 302 of the MMA is itself unlawful, Compl. ¶¶ 81-83, and a preliminary and permanent injunction ordering the cessation of the DMEPOS competitive bidding program. Compl. ¶ 84.

ARGUMENT

Rule 26(c) of the Federal Rules of Civil Procedure gives this Court broad discretion to “make any order which justice requires to protect a party or person from annoyance, embarrassment, oppression, or undue burden or expense.” This discretion includes the ability to enter an order “that discovery or disclosure not be had” at all. Fed. R. Civ. P. 26(c)(1). In addition, the Court has the “discretion to defer discovery or other proceedings,” *Air Line Pilots Ass'n v. Miller*, 523 U.S. 866, 879 n.5 (1998), as part of its inherent authority “to control the disposition of the causes on its docket with economy of time and effort for itself, for counsel, and for litigants.” *Id.* (quoting *Landis v. North American Co.*, 299 U.S. 248, 254-55 (1936)). This

Court should exercise that authority here to deny discovery entirely.

I. To the Extent They Survive, Claims 2 and 3 of Plaintiff’s Complaint Must be Considered Under the Administrative Procedure Act

Plaintiff expressly captions only one of its claims as arising under the Administrative Procedure Act (“APA”). Compl. ¶¶ 73-80 (“Claim 4”). Plaintiff asserts two claims, however, which must be evaluated based on the standard of review contained in the APA. In Claim 2, plaintiff alleges that, in promulgating the regulations implementing the DMEPOS competitive bidding program, defendants failed to evaluate and analyze the impact of the program on the ability of small suppliers to meet the needs of beneficiaries, in violation of section 302 of the MMA. Compl. ¶¶ 62-68 (labeled “Claim 2 -Section 302 of the MMA”). In Claim 3, plaintiff alleges that portions of the final regulations promulgated by defendants are not “logical outgrowths” of the proposed regulations and, therefore, those portions should have been subjected to an additional public comment process in accordance with section 902 of the MMA. Compl. ¶¶ 69-72 (labeled “Claim 3 - Section 902 of the MMA”).

Plaintiff does not couch Claim 2 or Claim 3 in any express waiver of sovereign immunity or statutory cause of action and the MMA does not provide a cause of action for the challenges raised in those claims. A suit against the head of a federal agency, such as the Secretary, is a suit against the United States as sovereign. *Hawaii v. Gordon*, 373 U.S. 57, 58 (1963) (per curiam). It is “axiomatic that the United States may not be sued without its consent and that the existence of consent is a prerequisite for jurisdiction.” *United States v. Mitchell*, 463 U.S. 206, 212 & n.9 (1983) (citing *United States v. Sherwood*, 312 U.S. 584, 586 (1941)). “[T]he terms of [the government’s] consent to be sued in any court define that court’s jurisdiction to entertain suit.”

Sherwood, 312 U.S. at 586. Such consent cannot be implied, but must be “‘unequivocally expressed’ in the statutory text” and strictly construed in favor of the government. *Dep't of the Army v. Blue Fox, Inc.*, 525 U.S. 255, 261 (1999) (quoting *Lane v. Pena*, 518 U.S. 187, 192 (1996)). The bar of sovereign immunity applies even when, as here, only injunctive and declaratory relief is sought. *See, e.g., Vanover v. Hantman*, 77 F. Supp. 2d 91, 99 (D.D.C. 1999) (finding that a “claim for injunctive relief is . . . subject to the sovereign immunity of the United States and its officers unless such immunity is waived by the [APA]”). In the absence of a waiver of sovereign immunity, the courts lack jurisdiction over claims against the United States. *See Mitchell*, 463 U.S. at 212 (when an act gives a court jurisdiction over certain claims, sovereign immunity is waived as to those claims).

To the extent that Claims 2 and 3 challenge the regulations in question as contrary to law, assuming the Court enjoys jurisdiction over these claims, the Court should view these claims as APA challenges. 5 U.S.C. § 706(2)(A) (providing the Court with the authority to set aside agency action which is “arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law”); *cf. Sierra Club v. Slater*, 120 F.3d 623, 630-31 (6th Cir. 1997) (finding that the National Environmental Policy Act does not authorize a private right of action, but a plaintiff can bring a NEPA challenge through the APA). As explained in detail below, challenges to agency action under section 706 of the APA are restricted to the administrative record. *See Florida Power & Light Co. v. Lorion*, 470 U.S. 729, 743-744 (1985).

II. Discovery Is Not Appropriate Under The Administrative Procedure Act

Review of plaintiff’s APA claims is restricted to the administrative record. *Sierra Club*, 120 F.3d at 638. Under the APA, “courts confine their review to the administrative record,

which includes all materials compiled by the agency that were before the agency at the time the decision was made.” *Id.* (internal quotations and citations omitted). In reviewing agency action under the APA, “[t]he task of the reviewing court is to apply the appropriate APA standard of review, 5 U.S.C. § 706, to the agency decision based on the record the agency presents to the reviewing court.” *Id.*² (citing *Citizens to Preserve Overton Park, Inc., v. Volpe*, 401 U.S. 402, 420 (1971)). Thus, “the focal point for judicial review should be the administrative record already in existence, not some new record made initially in the reviewing court.” *Camp v. Pitts*, 411 U.S. 138, 142 (1973). It is well-established that the Court’s review of agency action under the APA must focus on the record before the agency. *Florida Power & Light Co.*, 470 U.S. at 743-744; *Camp*, 411 U.S. at 142; *see also* 5 U.S.C. § 706(2).

The APA limitation to record review reflects the fundamental tenet governing judicial review of Executive Branch actions generally that “[i]n the absence of clear evidence to the contrary, courts presume that [public officers] have properly discharged their official duties.” *United States v. Armstrong*, 517 U.S. 456, 464 (1996) (quoting *United States v. Chemical Found.*, 272 U.S. 1, 14-15 (1926)); *accord United States Postal Serv. v. Gregory*, 534 U.S. 1, 10 (2001). This presumption of regularity precludes discovery unless plaintiff makes a “strong showing of bad faith or improper behavior.” *Citizens to Preserve Overton Park*, 401 U.S. at 420.

Accordingly, under the APA a district court acts as a court of review, not as the initial,

² The APA provides that agency action may be set aside only if it was arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law. 5 U.S.C. § 706(2). This standard of review includes substantial deference to agency decision-making. *See, e.g., Medical Rehabilitation Services, P.C. v. Shalala*, 17 F.3d 828, 831 (6th Cir. 1994).

independent decision maker.³ As the Supreme Court has held, “[t]he APA specifically contemplates judicial review on the basis of the agency record compiled in the course of informal agency action in which a hearing has not occurred. The factfinding capacity of the district court is thus typically unnecessary to judicial review of agency decisionmaking.” *Florida Power & Light Co.*, 470 U.S. at 744. Thus, in a challenge to administrative action under the APA, the administrative record cannot normally be supplemented. *Sierra Club*, 120 F.3d at 638; *Florida Power & Light Co.*, 470 U.S. at 744; *Camp*, 411 U.S. at 140-42. In accordance with the settled standard and scope of review on APA claims, the Sixth Circuit has consistently rejected attempts to engage in discovery to supplement the administrative record. *See, e.g., Csekinek v. I.N.S.* 391 F.3d 819, 830-31 (6th Cir. 2004); *Kroger Co. v. Regional Airport Authority of Louisville and*

³ As the D.C. Circuit has explained, a court’s inquiry under the APA, 5 U.S.C. § 706(2)(a), is a question of law, not fact:

The district court sits as an appellate tribunal, not as a court authorized to determine in a trial-type proceeding whether the Secretary’s study was factually flawed. Appellants imply that their claims that the Secretary acted arbitrarily and capriciously, or refused to consider material in the record, are similar to factual allegations – allegations they are entitled to “prove” as if the complaint alleged that the Secretary, driving her car negligently, had run into one of their hospitals. Based on this misunderstanding, appellants contend that the district court erred in dismissing their complaint under Rule 12(b)(6) because the court actually considered whether their “allegations” were true and thus improperly determined the “merits” of the dispute. Such a conclusion, according to appellants, might be appropriate on a motion for summary judgment, but certainly not on a motion to dismiss – the latter is meant to test only the sufficiency of the complaint.

Appellants, however, overlook the character of the questions before the district court when an agency action is challenged. The entire case on review is a question of law, and only a question of law. And because a court can fully resolve any purely legal question on a motion to dismiss, there is no inherent barrier to reaching the merits at the 12(b)(6) stage.

Marshall County Health Care Authority v. Shalala, 988 F.2d 1221, 1226 (D.C. Cir. 1993).

Jefferson County, 286 F.3d 382, 386-87 (6th Cir. 2002); *Cumberland Reclamation Co. v. Secretary, U.S. Dept. of Interior*, 925 F.2d 164, 167 (6th Cir. 1991).

This case presents no reason to stray from the well-established rule that judicial review of agency action under the APA is limited to the administrative record produced by the agency and, therefore, discovery is inappropriate. *See Florida Power & Light Co.*, 470 U.S. at 744. The Court should, accordingly, permit no discovery on plaintiff's APA claims. *Cf. American Textile Manufacturers Inst. v. Donovan*, 452 U.S. 490, 539 (1981) (agency action must be upheld under the APA, if at all, solely on the basis articulated by the agency itself).

III. Discovery Is Not Appropriate Under The Regulatory Flexibility Act

Similarly, the Court's review of plaintiff's claim under the Regulatory Flexibility Act ("RFA"), Compl. ¶¶ 58-61, is restricted to the administrative record. *See* 32 Wright & Koch, *Federal Practice and Procedure* § 8187 ("Judicial review of the analysis required by the [RFA] may be reviewed only as part of the whole record of the rulemaking."); *see also* 5 U.S.C.A. § 611(b) ("In an action for the judicial review of a rule, the regulatory flexibility analysis for such rule . . . shall constitute part of the entire record of agency action in connection with such review"). The RFA amended the APA in an effort "to encourage Federal agencies to utilize innovative administrative procedures in dealing with individuals, small businesses, small organizations, and small government bodies that would otherwise be unnecessarily adversely affected by Federal regulations." S. Rep. No. 96-868 (1980), reprinted in 1980 U.S.C.C.A.N. 2788. The RFA requires agencies to publish an "initial regulatory flexibility analysis" at the time a proposed rule is published, and a "final regulatory flexibility analysis" at the time a final rule is published. 5 U.S.C. §§ 603, 604. "Judicial review is available only of the final analysis."

Ranchers Cattleman Action Legal Fund United Stockgrowers of America v. U.S. Dept. of Agriculture, 415 F.3d 1078, 1100-1101 (9th Cir. 2005) (citing 5 U.S.C. § 611). Congress limited judicial review of RFA compliance to “agency compliance with the requirements of sections 601, 604, 605(b), 608(b), and 610 *in accordance with chapter 7* [of the APA].” 5 U.S.C. § 611(a)(1) (emphasis added).

It is well-established that the RFA is “purely procedural” in nature. *United States Cellular Corp. v. FCC*, 254 F.3d 78, 88 (D.C. Cir. 2001). The RFA “does not alter the substantive mission of the agencies under their own statutes; rather, the Act creates procedural obligations to assure that the special concerns of small entities are given attention in the comment and analysis process when the agency undertakes rule-makings that affect small entities.” *Little Bay Lobster Co., Inc. v. Evans*, 352 F.3d 462, 470 (1st Cir. 2003); *see also* 5 U.S.C. § 606 (“The requirements of [5 U.S.C. §§ 603-04] do not alter in any manner standards otherwise applicable by law to agency actions.”). Section 604 of the RFA “requires nothing more than that the agency file a [final regulatory flexibility analysis] demonstrating a ‘reasonable, good-faith effort to carry out [the RFA’s] mandate.’” *United States Cellular Corp.*, 254 F.3d at 88 (citing *Alenco Communications, Inc. v. FCC*, 201 F.3d 608, 625 (5th Cir. 2000)). Thus, “[l]ike the Notice and Comment process required in administrative rulemaking by the APA, the analyses required by the RFA are essentially procedural hurdles.” *Envtl. Defense Ctr., Inc. v. United States EPA*, 344 F.3d 832, 879 (9th Cir.2003). Determination of whether an agency has complied with the requirements of the RFA, therefore, is limited to the administrative record. *Tafas v. Dudas*, 530 F. Supp. 2d 786, 799 (E.D. Va. 2008) (finding the evidence contained in the existing administrative record “sufficient for [the] Court to determine whether the [agency] made a

‘reasonable, good-faith effort’ to comply with the RFA's procedural requirements”); *Ranchers Cattleman Action Legal Fund United Stockgrowers of America v. U.S. Dept. of Agriculture*, 415 F.3d 1078, 1102 (9th Cir. 2005).

IV. Even Assuming Discovery Is Appropriate, the Court Should Stay Any Discovery Until Plaintiff Establishes Subject Matter Jurisdiction In This Court

“[T]he requirement that jurisdiction be established as a threshold matter ‘springs from the nature and limits of the judicial power of the United States’ and is ‘inflexible and without exception.’” *Steel Co. v. Citizens for a Better Env’t*, 523 U.S. 83, 94-95 (1998) (quoting *Mansfield, C. & L.M. Ry. Co. v. Swan*, 111 U.S. 379, 382 (1884)). Thus, the “first and fundamental” question for this Court is that of jurisdiction. *Id.* at 94 (quoting *Great S. Fire Proof Hotel Co. v. Jones*, 177 U.S. 449, 453 (1900)). “Without jurisdiction the court cannot proceed at all in any cause,” other than to “announc[e] the fact and dismiss[]” the case. *Id.* (quoting *Ex parte McCardle*, 74 U.S. 506, 514 (1968)). But, as defendants explain in their motion to dismiss, plaintiff cannot establish jurisdiction its claims. *See* Defs.’ Mot. To Dismiss, Parts I, II, III.

A plaintiff bears the burden of demonstrating that its case meets the requirements of subject matter jurisdiction. *See Lujan v. Defenders of Wildlife*, 504 U.S. 555, 561 (1992). There is a presumption that a federal court lacks jurisdiction in a particular case until plaintiff meets that burden. *Renne v. Geary*, 501 U.S. 312, 316 (1991). Unless and until plaintiff makes that threshold showing, the “defendant[s] should not be put to the trouble and expense of any further proceeding, and the time of [the] court should not be occupied with any further proceeding.” *United Transport Serv. Employees of America, CIO v. Nat’l Mediation Bd.*, 179 F.2d 446, 454

(D.C. Cir. 1949).

Plaintiff has not met its burden. Plaintiff purports to challenge the regulations implementing the DMEPOS competitive bidding program. But, as defendants explain in their motion to dismiss, the MMA expressly precludes judicial review of the key aspects of the establishment and implementation of the program. *See* Defs.’ Mot. To Dismiss, Part I citing, *inter alia*, 42 U.S.C. § 1395w-3(b)(10). If the Court were to find that the statutory provision precluding administrative and judicial review did not apply in the context of this case, then administrative review would be available and plaintiff would be required to exhaust its administrative remedies prior to this Court’s exercise of jurisdiction over plaintiff’s claims. *See Weinberger v. Salfi*, 422 U.S. 749, 765 (1975). Finally, plaintiff has not established the constitutional requirements of standing and ripeness necessary to provide this Court with subject matter jurisdiction. *See* Defs.’ Mot. To Dismiss, Part II, III.

Until plaintiff meets its burden of establishing subject matter jurisdiction on its APA and RFA claims, there should be no further proceedings on those claims. *See, e.g., Ruhrgas AG v. Marathon Oil Co.*, 526 U.S. 574, 583 (1999) (“Article III generally requires a federal court to satisfy itself of its jurisdiction over the subject matter before it considers the merits of the case”).

CONCLUSION

For all of the foregoing reasons, this Court should grant defendants’ motion for a protective order.

Dated: April 21, 2008

Respectfully submitted,

JEFFREY BUCHOLTZ

Acting Assistant Attorney General

SHEILA M. LIEBER
Assistant Director, Federal Programs Branch

/s/ Stephen J. Buckingham
STEPHEN J. BUCKINGHAM
Trial Attorney
Department of Justice, Federal Programs Branch
20 Massachusetts Avenue, N.W., Room 7109
Washington, D.C. 20530
Tel: 202-514-4805
Fax: 202-616-8470
Attorneys for Defendants

OF COUNSEL:
LINDA KEYSER
MARCUS CHRIST
Attorneys
Department of Health and Human Services

CERTIFICATE OF SERVICE

I hereby certify that on this 21st day of April, 2008, a copy of foregoing Motion for Protective Order was filed electronically. Notice of this filing will be sent by operation of the Court's electronic filing system to all parties indicated on the electronic filing receipt. Parties may access this filing through the Court's system.

/s/ Stephen J. Buckingham
STEPHEN J. BUCKINGHAM
Trial Attorney
United States Department of Justice
Civil Division, Federal Programs Branch
20 Massachusetts Ave., NW Rm. 7119
Washington, D.C. 20530
Tel: (202) 514-3330
Fax: (202) 616-8470
Stephen.Buckingham@usdoj.gov