

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF TEXAS
DALLAS DIVISION

NATIONAL ATHLETIC TRAINERS' ASSOCIATION, INC., a Texas Non-Profit Corporation,)	
)	
Plaintiff,)	CIVIL ACTION NO.
)	
VS.)	3:05-CV-1098-G
)	
UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, ET AL.,)	
)	
Defendants.)	

JUDGMENT

This judgment is entered pursuant to F.R. Civ. P. 58 and the memorandum opinion and order of this date. For the reasons stated in that memorandum opinion and order, it is **ORDERED** that this case is **DISMISSED**, at the plaintiff's cost, for lack of subject matter jurisdiction.

July 21, 2005.



A. JOE FISH
CHIEF JUDGE

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF TEXAS
DALLAS DIVISION

NATIONAL ATHLETIC TRAINERS')	
ASSOCIATION, INC., a Texas Non-)	
Profit Corporation,)	
)	
Plaintiff,)	
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VS.)	
)	
UNITED STATES DEPARTMENT OF)	
HEALTH AND HUMAN SERVICES,)	
ET AL.,)	
)	
Defendants.)	

CIVIL ACTION NO.
3:05-CV-1098-G

MEMORANDUM OPINION AND ORDER

Before the court is the motion of the defendants, the United States Department of Health and Human Services (“H.H.S.”), Michael O. Leavitt, Secretary, H.H.S. (the “Secretary”), and Mark McClellan, MD, Administrator, Centers for Medicare and Medicaid Services (“CMS”) (collectively, the “defendants”), to dismiss the application of the plaintiff, the National Athletic Trainers’ Association, Inc. (“NATA”), for a temporary restraining order, for

preliminary and permanent injunctive relief, and for a declaratory judgment. For the reasons discussed below, the defendants' motion is granted.

I. BACKGROUND

A. Procedural History

On May 27, 2005, NATA initiated this action, seeking injunctive and declaratory relief in connection with the implementation of new regulations promulgated by the Secretary. *See generally* Plaintiff's Application for Temporary Restraining Order, Request for Preliminary and Permanent Injunctive Relief, and Complaint for Declaratory Judgment ("Complaint"). On June 3, 2005, this court issued an order, incorporating an agreement of the parties, staying implementation of the revised Medicare regulations at issue until such time as the court issues a ruling on NATA's request for preliminary injunctive relief or until July 22, 2005, whichever occurs first. Order, filed June 3, 2005, at 2-3. This order also established a schedule for the parties to submit proposed findings of fact and conclusions of law relating to the request for preliminary injunctive relief. *Id.* at 3-4.

On June 23, 2005, the defendants filed this motion to dismiss. In an effort to provide the parties with a timely resolution of this dispute, the court agreed to use its best efforts to rule on the motion to dismiss and, if necessary, the motion for preliminary injunctive relief before the deadline of July 22, 2005 agreed on by the parties.

B. Statutory and Regulatory Background

Medicare, enacted in 1965 as Title XVIII of the Social Security Act, is a health insurance program for the elderly and disabled. 42 U.S.C. § 1395 *et seq.* The Medicare Program is divided into three parts, Parts A, B, and C. *Id.* Included in Medicare Part B's coverage are "services and supplies . . . furnished as an incident to a physician's professional service, of kinds which are commonly furnished in physicians' offices and are commonly either rendered without charge or included in the physicians' bills. . . ." 42 U.S.C. § 1395x(s)(2)(A). Medicare regulations provide that "[s]ervices of nonphysicians that are covered as incident to a physician's service are paid as if the physician had personally furnished the service." 42 C.F.R. § 414.34(b). The regulations further provide that "Medicare Part B pays for physicians' services, including . . . therapy." 42 C.F.R. § 410.20(a).

In 1997, Congress, as part of the Balanced Budget Act of 1997, amended section 1862(a) of the Social Security Act, 42 U.S.C. § 1395y(a), by adding paragraph 20. As a result of the amendment, the statute provides in relevant part:

(a) Notwithstanding any other provision of [the Medicare Act], no payment may be made under part A or part B of [the Medicare Act] for any expenses incurred for items or services --

* * *

(20) in the case of outpatient occupational therapy services or outpatient physical therapy services furnished as an incident to a physician's professional services (as described in section 1395x(s)(2)(A) of this title), that do

not meet the standards and conditions (other than any licensing requirement specified by the Secretary) under the second sentence of section 1395x(p) of this title (or under such sentence through the operation of section 1395x(g) of this title) as such standards and conditions would apply to such therapy services if furnished by a therapist

42 U.S.C. § 1395y(a)(20); Pub. L. No. 105-33 § 4541(b) (1997). At the time

§ 1395y(a)(20) was enacted, the second sentence of § 1395x(p) provided:

[t]he term “outpatient physical therapy services” also includes physical therapy services furnished an individual by a physical therapist . . . who meets licensing and other standards prescribed by the Secretary in regulations . . . , if the furnishing of such services meets such conditions relating to health and safety as the Secretary may find necessary.¹

42 U.S.C. § 1395x(p) (1997). The language of § 1395x(p) has remained unchanged since 1997.

On November 15, 2004, the Secretary issued a final rule entitled 42 CFR Parts 403, 405, 410, et. al. Medicare Program: Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005; Final Rule (the “Final Rule”). 69 Fed. Reg. 66,235 (Nov. 15, 2004). Among other revisions, the Final Rule modified those portions of the Medicare regulations pertaining to therapy services which are included under the “incident to” coverage of Medicare Part B. *Id.* The relevant

¹ This provision in the second sentence of § 1395x(p) is made applicable to outpatient occupational therapists by § 1395x(g). 42 U.S.C. § 1395x(g). Throughout this opinion, the court may sometimes refer only to physical therapy or physical therapist(s); unless otherwise noted, however, such references are intended to include occupational therapy or occupational therapist(s).

provisions of the Final Rule at issue authorize payment for occupational therapy and physical therapy services which are provided “incident to” a physician’s professional services only if therapy services are provided by an occupational or physical therapist who meets the qualifications provided by 42 C.F.R. § 484.4. *Id.* at 66,421-66,422 (revising 42 C.F.R. §§ 410.26(c)(2), 410.59(a)(3)(iii), 410.60(a)(3)(iii)) (the “New Rules”). The New Rules provide:

§ 410.26 Services and supplies incident to a physician’s professional services: Conditions.

* * *

(c) Limitations

* * *

(2) Physical therapy, occupational therapy and speech-language pathology services provided incident to a physician’s professional services are subject to the provisions established in § 410.59(a)(3)(iii), § 410.60(a)(3)(iii), and § 410.62(a)(3)(iii).

42 C.F.R. § 410.26(c)(2) (2005).

§ 410.59 Outpatient occupational therapy services: Conditions.

(a) Basic rule. Except as specified in paragraph (a)(3)(iii) of this section, Medicare Part B pays for outpatient occupational therapy services only if they are furnished by an individual meeting the qualifications in § 484.4 of this chapter for an occupational therapist or by an appropriately supervised occupational therapy assistant but only under the following conditions:

* * *

(3) They are furnished--

* * *

(iii) By, or incident to the service of, a physician, physician assistant, clinical nurse specialist, or nurse practitioner when those professionals may perform occupational therapy services within the scope of State law. When an occupational therapy service is provided incident to the service of a physician, physician assistant, clinical nurse specialist, or nurse practitioner, by anyone other than a physician, physician assistant, clinical nurse specialist, or nurse practitioner, the service and the person who furnishes the service must meet the standards and conditions that apply to occupational therapy and occupational therapists, except that a license to practice occupational therapy in the State is not required.

42 C.F.R. 410.59(a)(3)(iii) (2005).

§ 410.60 Outpatient physical therapy services:
Conditions.

(a) Basic rule. Except as specified in paragraph (a)(3)(iii) of this section, Medicare Part B pays for outpatient physical therapy services only if they are furnished by an individual meeting the qualifications in § 484.4 of this chapter for a physical therapist or by an appropriately supervised physical therapy assistant but only under the following conditions:

* * *

(3) They are furnished--

* * *

(iii) By, or incident to the service of, a physician, physician assistant, clinical nurse specialist, or nurse practitioner when those professionals may perform physical therapy services under State law. When a physical therapy service is provided incident to the service of a physician,

physician's assistant, clinical nurse specialist, or nurse practitioner, by anyone other than a physician, physician assistant, clinical nurse specialist, or nurse practitioner, the service and the person who furnishes the service must meet the standards and conditions that apply to physical therapy and physical therapists, except that a license to practice physical therapy in the State is not required.

42 C.F.R. 410.60(a)(3)(iii) (2005).

An occupational or physical therapist is qualified under 42 C.F.R. § 484.4 if he or she meets certain educational or experience-based requirements. 42 C.F.R. § 484.4. These qualifications do not include any licensing requirements. *Id.* The effect of the implementation of the New Rules is summarized in the revisions to section 230.5 of the Medicare Benefit Policy Manual, which provides in relevant part:

Qualifications of Auxiliary Personnel.

* * *

Medicare is authorized to pay only for services provided by those trained specifically in physical therapy, occupational therapy, or speech-language pathology. That means that the services of athletic trainers, massage therapists, recreation therapists, kinesiotherapists, low vision specialists or any other profession may not be billed as therapy services.

Transmittal 34, Change Request 3648, CMS Manual System, Pub. 100-02, Chapter 15, Sections 220 and 230 Therapy Services, *attached as* Exhibit F-3 to Appendix to Plaintiff's Proposed Findings of Fact and Conclusions of Law in Support of its Request for Preliminary Injunction and Request for Evidentiary Hearing ("Appendix to Plaintiff's Proposed Findings") at 126. The implementation of the policy above

was delayed, per the parties' agreement, until resolution of the application for preliminary injunctive relief or July 22, 2005, whichever occurs first.

II. ANALYSIS

The defendants assert two grounds for dismissal: (1) that the court lacks subject matter jurisdiction over this case because the plaintiff does not have standing to challenge the implementation of the relevant provisions, and (2) that the court lacks subject matter jurisdiction over this case because the plaintiff has failed to exhaust all of its available administrative remedies. Defendants' Brief in Support of the Motion to Dismiss Plaintiff's Application and Complaint for Injunctive and Other Relief ("Motion to Dismiss") at 3-4.

A. Subject Matter Jurisdiction -- The Legal Standard

Federal courts are courts of limited jurisdiction. See *Kokkonen v. Guardian Life Insurance Company of America*, 511 U.S. 375, 377 (1994); *Owen Equipment and Erection Company v. Kroger*, 437 U.S. 365, 374 (1978). A federal court may exercise jurisdiction over cases only as expressly provided by the Constitution and laws of the United States. See U.S. CONST. art. III §§ 1-2; see also *Kokkonen*, 511 U.S. at 377. Federal law gives the federal district courts original jurisdiction over "all civil actions arising under the Constitution, laws, or treaties of the United States." 28 U.S.C. § 1331. A party seeking relief in a federal district court bears the burden of establishing the subject matter jurisdiction of that court. *United States v. Hays*, 515

U.S. 737, 743 (1995); *McNutt v. General Motors Acceptance Corporation of Indiana, Inc.*, 298 U.S. 178, 189 (1936); *Langley v. Jackson State University*, 14 F.3d 1070, 1073 (5th Cir.), *cert. denied*, 513 U.S. 811 (1994).

Rule 12(b)(1) of the Federal Rules of Civil Procedure authorizes the dismissal of a case for lack of jurisdiction over the subject matter. *See* FED. R. CIV. P. 12(b)(1). A motion to dismiss pursuant to Rule 12(b)(1) for lack of subject matter jurisdiction must be considered by the court before any other challenge because “the court must find jurisdiction before determining the validity of a claim.” *Moran v. Kingdom of Saudia Arabia*, 27 F.3d 169, 172 (5th Cir. 1994) (internal citation omitted); *see also* *Ruhrgras AF v. Marathon Oil Company*, 526 U.S. 574, 577 (1999) (“The requirement that jurisdiction be established as a threshold matter . . . is inflexible and without exception”) (citation and internal quotation marks omitted).

On a Rule 12(b)(1) motion, which “concerns the court’s ‘very power to hear the case . . . [,] the trial court is free to weigh the evidence and satisfy itself as to the existence of its power to hear the case.’” *MDPhysicians & Associates, Inc. v. State Board of Insurance*, 957 F.2d 178, 181 (5th Cir.) (quoting *Williamson v. Tucker*, 645 F.2d 404, 413 (5th Cir.), *cert. denied*, 454 U.S. 897 (1981)), *cert. denied*, 506 U.S. 861 (1992). In ruling on a motion to dismiss under Rule 12(b)(1), the court may rely on: “1) the complaint alone; 2) the complaint supplemented by undisputed facts; or 3) the complaint supplemented by undisputed facts and the court’s resolution of

disputed facts.” *MCG, Inc. v. Great Western Energy Corporation*, 896 F.2d 170, 176 (5th Cir. 1990) (citing *Williamson*, 645 F.2d at 413).

B. Prudential Standing -- Zone of Interest

NATA brings this action under the Administrative Procedure Act (“APA”). Complaint ¶ 11. Section 10(a) of the APA provides that “[a] person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action within the meaning of the relevant statute, is entitled to judicial review thereof.” 5 U.S.C. § 702. The Supreme Court of the United States has interpreted this section “to impose a prudential standing requirement in addition to the requirement, imposed by Article III of the Constitution, that a plaintiff have suffered a sufficient injury in fact.” *National Credit Union Administration v. First National Bank & Trust Company*, 522 U.S. 479, 488 (1998). “For a plaintiff to have prudential standing under the APA, ‘the interest sought to be protected by the complainant [must be] arguably within the zone of interests to be protected or regulated by the statute . . . in question.’” *Id.* (citing *Association of Data Processing Service Organizations, Inc. v. Camp*, 397 U.S. 150, 153 (1970)).

“The ‘zone of interest’ test is a guide for deciding whether, in view of Congress’ evident intent to make agency action presumptively reviewable, a particular plaintiff should be heard to complain of a particular agency decision.” *Clarke v. Securities Industry Association*, 479 U.S. 388, 399-400 (1987). In determining whether a

plaintiff may bring an action under the APA, “[t]he proper inquiry is simply ‘whether the interest sought to be protected by the complainant is *arguably* within the zone of interests to be protected . . . by the statute.’” *National Credit Union Administration*, 522 U.S. at 492 (internal citation omitted) (emphasis in original). “The test is not meant to be especially demanding; in particular, there need be no indication of congressional purpose to benefit the would-be plaintiff.” *Clarke*, 479 U.S. at 399-400 (footnote omitted). In fact, the Fifth Circuit has stated that “[u]nder the ‘zone of interests’ test, we liberally construe Congressional acts to favor a plaintiff’s standing to challenge administrative actions.” *Corrosion Proof Fittings v. Environmental Protection Agency*, 947 F.2d 1201, 1209 (5th Cir. 1991) (citing *Warth v. Seldin*, 422 U.S. 490, 501 (1975)). However,

[i]n cases where the plaintiff is not itself the subject of the contested regulatory action, the test denies a right of review if the plaintiff’s interests are so marginally related to or inconsistent with the purposes implicit in the statute that it cannot reasonably be assumed that Congress intended to permit the suit.

Clarke, 479 U.S. at 399-400.

[I]n applying the “zone of interests” test, [the court] do[es] not ask whether, in enacting the statutory provision at issue, Congress specifically intended to benefit the plaintiff. Instead, [the court] first discern[s] the interests “arguably . . . to be protected” by the statutory provision at issue; [the court] then inquire[s] whether the plaintiff’s interests affected by the agency action in question are among them.

National Credit Union Administration, 522 U.S. at 492.

NATA argues that the New Rules are contrary to Congress' intent in enacting 42 U.S.C. § 1395y(a)(20) in 1997. Complaint ¶¶ 3, 20-22, 38. Again, that section provides:

Notwithstanding any other provision of [the Medicare Act], no payment may be made under part A or part B of [the Medicare Act] for any expenses incurred for items or services --

* * *

(20) in the case of outpatient occupational therapy services or outpatient physical therapy services furnished as an incident to a physician's professional services (as described in section 1395x(s)(2)(A) of this title), that do not meet the standards and conditions (other than any licensing requirement specified by the Secretary) under the second sentence of section 1395x(p) of this title (or under such sentence through the operation of section 1395x(g) of this title) as such standards and conditions would apply to such therapy services if furnished by a therapist

42 U.S.C. § 1395y(a)(20).

The Supreme Court has stated that the plaintiff must establish that “the injury he complains of . . . falls within the ‘zone of interests’ sought to be protected by the statutory provision whose violation forms the legal basis for his complaint.” *Lujan v. National Wildlife Federation*, 497 U.S. 871, 883 (1990). “The relevant statute, of course, is the statute whose violation is the gravamen of the complaint.” *Id.* at 886. The Court has further explained that “the meaning of the zone of interests test is to be determined not by reference to the overall purpose of the Act in question . . . , but by reference to the particular provision of law upon which the plaintiff relies.”

Bennett v. Spear, 520 U.S. 154, 175-76 (1997). Accordingly, the overall purpose behind Congress' enactment of Medicare in the Social Security Act of 1965, is relevant only to the extent it assists the court in determining the intent underlying enactment of § 1395y(a)(20). *Grand Council of Crees (of Quebec) v. Federal Energy Regulatory Commission*, 198 F.3d 950, 956 (D.C. Cir. 2000).

Thus, in determining whether NATA has prudential standing to bring this action under the APA, the court must first determine what interests are arguably protected by § 1395y(a)(20). Then, the court must discern whether NATA's alleged interests fall within those protected by § 1395y(a)(20).

1. *Interests Arguably Protected by § 1395y(a)(20)*

The language of § 1395y(a)(20) indicates that Medicare will only pay for those services that “*meet the standards and conditions (other than any licensing requirement specified by the Secretary) under the second sentence of [42 U.S.C.] § 1395x(p) . . . as such standards and conditions would apply to such therapy services if furnished by a therapist . . .*” 42 U.S.C. § 1395y(a)(20) (emphasis added). The second sentence of § 1395x(p) provides: “[t]he term ‘outpatient physical therapy services’ also includes physical therapy services furnished an individual by a physical therapist . . . *who meets licensing and other standards prescribed by the Secretary in regulations . . . , if the furnishing of such services meets such conditions relating to health and safety as the Secretary may find necessary.*” 42 U.S.C. § 1395x(p) (emphasis added).

The defendants assert that “the intent [of the bill that became § 1395y(a)(20)] was to establish ‘a consistent standard for the delivery of services to ensure quality patient care.’” Motion to Dismiss at 9. This asserted intent is derived from comments made by the two members of Congress who introduced the bill that produced § 1395y(a)(20). *Id.* Additionally, the defendants offer the intent of Congress in establishing the Medicare program -- “‘more adequate and feasible health insurance protection’ designed to ‘contribute toward making economic security in old age more realistic, a more nearly attainable goal for most Americans.’” *Id.* at 8 (citing S. Rep. No. 89-404 (1965)).

On the other hand, NATA argues that “[i]t is apparent that in enacting § 1395y(a)(20), Congress sought to ensure and protect a physician’s ability to use auxiliary personnel, including athletic trainers, to perform medically necessary and properly documented incident to therapy services.”² Plaintiff’s Response to

² NATA further argues that the New Rules are contrary to 42 U.S.C. § 1395. *See* Response at 6. Section 1395 states:

Nothing in [the Medicare Act] shall be construed to authorize any Federal officer or employee to exercise any supervision or control over the practice of medicine or the manner in which medical services are provided, or over the selection, tenure, or compensation of any officer or employee of any institution, agency, or person providing health services. . . .

(continued...)

Defendants' Motion to Dismiss ("Response") at 6.

"The parties apparently agree that one impetus for the enactment of section 1395y(a)(20) was the 1994 HHS Office of Inspector General (OIG) Report [(the "1994 OIG Report")] entitled 'Physical Therapy in Physician's Offices[,] March 1994 OEI-02-90-00590." Motion to Dismiss at 10 n. 4; *see also* Response at 5. The 1994 OIG Report recommended that existing physical therapy coverage guidelines for other settings be applied to such services performed in physicians' offices. 1994 OIG Report at ii, *attached as* Exhibit F-1 to Appendix to Plaintiff's Proposed Findings at 48. Among the issues addressed in the 1994 OIG Report were concerns of professional associations, carriers, physicians and physical therapists over what services truly constituted physical therapy, possible excessive therapy services, and the persons actually performing these services. 1994 OIG Report at 11-13, Exhibit F-1 to Appendix to Plaintiff's Proposed Findings at 61-63.

It appears to the court -- after examining the language of the statute, the legislative intent asserted by the defendants, and the 1994 OIG Report -- that the overriding impetus behind the enactment of § 1395y(a)(20) was the standard and quality of therapy care provided to Medicare beneficiaries "incident to" a physician's

²(...continued)

42 U.S.C. § 1395. However, NATA's complaint and its response (with the exception of two sentences regarding § 1395) focus on section § 1395y(a)(20) as the foundation for its claim under the APA. Accordingly, the issue at hand is what interests are arguably protected by § 1395y(a)(20), not § 1395. *See Lujan*, 497 U.S. at 883, 886.

services. Thus, the interests arguably protected by the statute are (1) the interests of the Medicare beneficiary as it relates to the quality of care she may receive and (2) the interests of the physician in ensuring that therapeutic care provided “incident to” his services is of an acceptable standard and quality. The second interest is slightly different from the protected interest urged by NATA, *see* Response at 6, in that the court is not convinced that physicians have a protected interest in utilizing “auxiliary personnel” to perform therapy services. However, the court does recognize that the interests protected by § 1395y(a)(20) are not limited to those of Medicare beneficiaries. The court must now consider whether NATA’s alleged interests fall within the interests protected by § 1395y(a)(20).

2. *NATA’s Alleged Interests*

NATA asserts an interest in ensuring that its members be allowed to provide therapeutic services “incident to” a physician’s services. Response at 6. Additionally, NATA maintains that its “interest in seeing that physicians are permitted to utilize non-therapist personnel in performing medically necessary incident to services, especially when it is the services of athletic trainers that physicians choose to utilize” falls within the zone of interests protected by § 1395y(a)(20). *Id.* at 7.

In support of their position that NATA’s interests are incongruent with those protected by § 1395y(a)(20), the defendants rely heavily on *TAP Pharmaceuticals v. United States Department of Health and Human Services*, 163 F.3d 199 (4th Cir. 1998).

In *TAP Pharmaceuticals* (“TAP”), the Fourth Circuit held that a drug manufacturer (“TAP”) lacked prudential standing because its interest in selling its drugs was not within the interests protected by the Medicare statute in question -- “providing ‘reasonable and necessary’ medical services.” *Id.* at 208. The court stated that “when Congress passes a statute regulating a defined class, its intention to limit the class must be given the same respect as its intention to regulate it.” *Id.* at 207. Thus, the court held “that where a statute defines a group that is subject to its provisions, a party asserting commercial interests satisfies the zone of interests test only if its interests put it in the same position as a member of the subject group or a commercial competitor of such a member.” *Id.* at 208. According to the Fourth Circuit, TAP did not compete with Medicare Part B beneficiaries or medical professionals, each of whom was subject to the statute at issue. *Id.* Rather, TAP competed with other drug manufacturers, a group not regulated by the statute. *Id.*

The defendants argue that the facts of this action and those in *TAP* are analogous. Motion to Dismiss at 13. According to the defendants, both TAP and NATA assert a “purely economic interest,” and neither NATA nor TAP is “a beneficiary of the Medicare statute nor a competitor of an entity that is regulated by that statute.” *Id.*

The Fourth Circuit’s holding in *TAP* has been criticized by the District of Columbia (“D.C.”) Circuit. In *Amgen, Inc. v. Smith*, 357 F.3d 103 (D.C. Cir. 2004),

the D.C. Circuit noted that it had previously rejected an approach similar to that taken in *TAP* -- limiting standing to “regulated firms, their competitors, and other firms whose interests put them in the ‘same position.’” *Id.* at 110. Instead, the D.C. Circuit noted that its earlier approach in *Mova Pharmaceutical Corporation v. Shalala*, 140 F.3d 1060, 1075 (D.C. Cir. 1998), “that focuses . . . on whether a party ‘in practice can be expected to police the interests that the statute protects,’” was more flexible and “faithful” to the Supreme Court’s zone of interest analysis in *Clarke* and *National Credit Union Administration*. *Id.* The court further noted that there was no reason to limit the “parties whose interests sufficiently align with some statutory schemes to confer prudential standing” to commercial competitors of regulated parties and those in the “same position.” *Id.* Moreover, the court observed that a plaintiff does not lack prudential standing merely because its asserted interests are commercial in nature. *Id.* at 109.

NATA argues that the D.C. Circuit’s approach in *Mova* and *Amgen* is more attuned to the guidance provided by the Supreme Court. Response at 10. This court agrees.

Obviously, NATA is not itself the subject of § 1395y(a)(20); the issue before the court, therefore, is whether NATA’s interest in ensuring its members are allowed to perform therapy services under Medicare Plan B is “so marginally related to or inconsistent with the purposes implicit in [§ 1395y(a)(20)] that it cannot reasonably

be assumed that Congress intended to permit the suit.” See *Clarke*, 479 U.S. at 399-400. In making this determination, the court must ask if NATA is a party “who in practice can be expected to police the interests that [§ 1395y(a)(20)] protects.” See *Mova Pharmaceutical Corporation*, 140 F.3d 1075.

As stated above, the interests protected by § 1395y(a)(20) primarily address the standards and quality of therapy services provided “incident to” a physician’s services. NATA asserts that “it is more than reasonable to presume that athletic trainers -- commonly used by physicians to provide incident to services -- should be expected to police the interests of a statute that directly affects their ability to provide such services.” Response at 7 (citing *Mova Pharmaceutical Corporation*, 140 F.3d at 1075).

NATA focuses on the interests of the physician protected by § 1395y(a)(20), arguing that NATA “has an interest in seeing that physicians are permitted to utilize non-therapist personnel in performing medically necessary incident to services, especially when it is the services of athletic trainers that physicians choose to utilize.” Response at 7. As stated above, the court does not completely agree with NATA’s argument that § 1395y(a)(20) protects a physician’s interest in selecting whoever she chooses to perform “incident to” therapy services. Nevertheless, the court concludes that personnel who, for approximately seven years, were deemed by the Secretary to adequately perform “incident to” therapy services in a manner that met the

appropriate standards and quality required by § 1395y(a)(20), can be expected to police the physicians' interests protected by that statute. The interests of NATA members in providing "incident to" therapy services -- which they were allowed to do under § 1395y(a)(20) for seven years -- are not so marginally related to or inconsistent with the purposes implicit in § 1395y(a)(20). Accordingly, NATA satisfies the prudential standing requirement to bring this action under the APA.

C. Exhaustion of Administrative Remedies

The defendants also argue that dismissal is appropriate because NATA "has not and cannot show that [its] members have met the jurisdictional prerequisites which must be satisfied before claims arising under the Medicare statute can be brought in district court." Motion to Dismiss at 15.

Generally, claims arising under the Medicare Act must first proceed through all available administrative avenues for review before a district court has jurisdiction to hear the plaintiff's claim. *Rencare, Ltd. v. Humana Health Plan of Texas, Inc.*, 395 F.3d 555, 557 (5th Cir. 2004). "42 U.S.C. § 405(h), made applicable to the Medicare Act by 42 U.S.C. § 1395ii, provides that § 405(g) is the sole avenue for judicial review of all 'claims arising under' the Medicare Act." *Id.* A district court has jurisdiction only over final decisions by the Commissioner of Social Security, and generally, until such a final decision is rendered, an action arising under the Medicare Act may not be brought in any federal court. 42 U.S.C. §§ 405(g), (h).

As noted by both parties, one exception exists to the requirement that challenges arising under the Medicare Act must first be channeled through the administrative appeals process. In *Shalala v. Illinois Council on Long Term Care, Inc.*, 529 U.S. 1 (2000), the Supreme Court held that “§ 1395ii does not apply § 405(h) where application of § 405(h) would not simply channel review through the agency, but would mean no review at all.” *Id.* at 19 (limiting its earlier holding in *Bowen v. Michigan Academy of Family Physicians*, 476 U.S. 667 (1986)). The defendants assert, and the court agrees, that the *Michigan Academy* exception applies in two circumstances: (1) “where there is no avenue for administrative review at all,” Motion to Dismiss at 21 (citing *Furlong v. Shalala*, 238 F.3d 227, 234 (2d Cir. 2001), and (2) “where the party with a right to pursue a claim has no incentive to assert the issues of concern to the plaintiff,” *Id.* (citing *American Lithrotripsy Society v. Thompson*, 215 F. Supp. 2d 23, 29-30 (D.D.C. 2002), and *American Chiropractic Association v. Shalala*, 131 F. Supp. 2d 174, 177 (D.D.C. 2001) (hereinafter *American Chiropractic II*)).

NATA argues that it lacks any avenues of administrative review so that this court has subject matter jurisdiction over its complaint. Response at 12-13. Because athletic trainers are not providers or beneficiaries, NATA contends, they have no means of initiating administrative appeals of denied claims. According to NATA, it “cannot seek review through the applicable administrative channels . . . [and it is]

entitled to judicial review of the New Rules.” *Id.* at 13. In support of this position, NATA cites *Buchanan v. Apfel*, 249 F.3d 485 (6th Cir. 2001). In *Buchanan*, the court found a nonparty to agency proceedings to fall within the *Michigan Academy* exception. *Id.* at 489-90. The plaintiff in *Buchanan* was an attorney challenging the constitutionality of the method used by the Commissioner of Social Security to calculate his attorney fees. *Id.* at 487-88. The court held that “[t]he language of § 405(h) indicates that Congress never contemplated a situation where someone other than a party pursuing entitlement benefits would seek review of a colorable claim that the Commissioner engaged in a statutory or constitutional violation.” *Id.* at 490.

Buchanan is somewhat analogous to the instant case. Like the plaintiff in *Buchanan*, NATA is not a party pursuing entitlement benefits, but is instead seeking review of a colorable claim that Secretary engaged in a statutory violation. The defendants argue, however, that the *Michigan Academy* exception does not apply “where the plaintiff itself lacks such an administrative remedy but another party does have that administrative appeal right and has an incentive to raise the issues of concern to the plaintiff.” Motion to Dismiss at 21-22 (citing *American Chiropractic II*, 131 F. Supp. 2d at 176). The court agrees with this argument.

In *American Chiropractic II*, the court held that Medicare enrollees had an incentive to pursue some claims of interest to the American Chiropractic Association,

but not others, because “the enrollee’s interest would lie only in ensuring that the chiropractic treatment sought or received is covered by Medicare.” *American Chiropractic II*, 131 F. Supp. 2d at 177. Moreover, the court was concerned that there would be “no review at all” of certain claims of the American Chiropractic Association. *American Chiropractic Association v. Shalala*, 108 F. Supp. 2d 1, 9-12 (D.D.C. July 7, 2000) (hereinafter *American Chiropractic I*). In *American Chiropractic I & II*, the American Chiropractic Association challenged Medicare regulations and policy that allowed non-chiropractors to provide manual manipulations of the spine to correct a subluxation (“manual manipulations”). In *American Chiropractic I*, the court stated that the claims may not be subject to review because, as a practical matter, “it would be unnecessary to determine whether non-chiropractors may provide manual manipulations under the Medicare program in order to resolve an administrative claim brought by a chiropractor regarding coverage for a manual manipulation performed by that chiropractor,” and directed the parties to submit briefing on the *Michigan Academy* exception. *Id.* at 10-11. The court then determined that an enrollee would have no incentive to bring this claim in an administrative appeal because Medicare will cover manual manipulations performed by chiropractors and non-chiropractors. *American Chiropractic II*, 131 F. Supp. 2d at 177. Accordingly, because the enrollees had no incentive to pursue the American Chiropractic Association’s claims, no vehicle existed for presenting those claims for administrative

review before seeking judicial review. *Id.* In the instant case, however, there is an incentive to bring an administrative appeal because the New Rules provide that “incident to” therapy services furnished by athletic trainers will no longer be covered by Medicare. Thus, that portion of *American Chiropractic II* finding that the American Chiropractic Association’s claims were subject to “no review at all” is distinguishable.

The defendants contend that if the court were to apply the *Michigan Academy* exception to NATA’s complaint, “such a holding would permit athletic trainers and other employees to end-run the carefully crafted administrative and judicial review scheme established by Congress,” “while virtually all providers, suppliers and beneficiaries -- the entities and individuals with a direct relationship to the Medicare program -- must channel their claims through the administrative review process.” Defendants’ Reply in Support of the Motion to Dismiss Plaintiff’s Application and Complaint for Injunctive and Other Relief (“Reply”) at 4 (citing *Block v. Community Nutrition Institute*, 467 U.S. 340 (1984)). According to the defendants, “[a]ny contention that the Secretary’s regulations violate the plain meaning of section 1395y(a)(20) can be raised by adversely affected physicians or beneficiaries through Medicare’s administrative appeals process.” Motion to Dismiss at 22. Physicians or beneficiaries may appeal through the Medicare administrative process claims that are denied as a result of the new rules. The defendants argue that “physicians have every incentive to appeal claims denied . . . [because of their] financial incentive to use lower

paid employees, including nurses and medical assistants, as well as athletic trainers, because they can retain the difference between the Medicare payment amount and their costs.” *Id.* at 22-23.

NATA counters that since neither physicians nor beneficiaries have any incentive to pursue an administrative claim asserting the interests of NATA, the *Michigan Academy* exception applies. Response at 14-16. While NATA recognizes that “physicians might theoretically save a modest amount of money if the New Rule[s were] never implemented,” it argues that any such financial incentive is outweighed by potential criminal and civil penalties for submitting fraudulent or false claims of incident to therapy service performed by non-therapists, including athletic trainers. Response at 14-15 (citing the Declaration of Marjorie J. Albohm (Exhibit A to Appendix to Plaintiff’s Response to Defendant’s Motion to Dismiss), which references several criminal provisions under Title 18 of the United States Code and the penalties provided thereunder). Severe penalties and sanctions have been held to remove any incentive a party may have to seek administrative review of a denial of claims in violation of the Medicare regulation. *American Lithotripsy Society*, 215 F. Supp. 2d at 29; *National Association of Psychiatric Health Systems v. Shalala*, 120 F. Supp. 2d 33, 38-39 (D.D.C. 2000).

In reply, the defendants maintain that the contention that physicians have no incentive to bring an action is without merit. Reply at 7. The defendants assert that

“Medicare has coding procedures that allow physicians and other suppliers to submit claims with specified modifiers when they want to indicate that the item or service is either statutorily non-covered, or is not a Medicare benefit, or when they expect Medicare will deny a service as not reasonable and necessary.” *Id.* (citing Medicare Claims Processing Manual, Chapter 23, Fee Schedule Administration and Coding Requirements, § 20.9.1.1.E (Coding for Non-Covered Services and Services Not Reasonable and Necessary), Exhibit S to Appendix to Defendants’ Response to Plaintiff’s Proposed Findings of Fact and Conclusions of Law). The defendants argue that “[b]y using the modifiers, physicians identify the claims as ones for which they are not expecting Medicare payment, and thus no realistic possibility of civil or criminal penalty exists because required elements of any cause of action cannot be established.” *Id.* It appears to the court that the existence and availability of these modifiers vitiates NATA’s argument that physicians would have no incentive to submit claims necessary to initiate the administrative appeals process. Moreover, it appears to the court that physicians themselves would have incentive to protect their interest in “utiliz[ing] non-therapist personnel in performing medically necessary incident to services, especially when it is the services of athletic trainers that physicians choose to utilize.” *See* Response at 7. Thus, judicial review of NATA’s claims is not completely foreclosed because physicians do have an administrative appeal right and have an incentive to raise the issue of who may provide therapy

services “incident to” their own professional services. See *American Chiropractic II*, 131 F. Supp. 2d at 176.

Accordingly, the court concludes that the *Michigan Academy* exception does not apply to the facts in this case, and the jurisdictional requirements of § 405(h) are applicable to bar NATA’s claims. As a result, this court does not have subject matter jurisdiction over NATA’s application for injunctive and declaratory relief.

III. CONCLUSION

For the reasons discussed above, the defendants’ motion to dismiss NATA’s application for injunctive and declaratory relief is **GRANTED**. Judgment will be entered dismissing NATA’s claims for lack of subject matter jurisdiction.

SO ORDERED.

July 21, 2005.



A. JOE FISH
CHIEF JUDGE