UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

POWER MOBILITY COALITION	:
	: Case No. 05cv2027 (RBW)
	:
Plaintiff	:
v.	:
	:
MICHAEL O. LEAVITT, Secretary United States Department of Health and Human Services, and MARK B. McCLELLAN, Administrator, Centers for Medicare and Medicaid Services,	:
	:
Defendants.	:
	:

MEMORANDUM OPINION[1]

The plaintiff, Power Mobility Coalition (the "Coalition"), "is a national, non-profit association whose membership includes manufacturers and suppliers of motorized scooters and power wheelchairs." Complaint for Declaratory and Injunctive Relief ("Compl.") ¶ 4. On behalf of its memberships, the plaintiff request that this Court issue a preliminary injunction that would enjoin the enforcement of the new regulations promulgated by the Department of Health and Human Services ("HHS") through its Interim Final Rule entitled Conditions for Payment of Power Mobility Devices, Including Power Wheelchairs and Power-Operated Vehicles, ("PMD payment rule"), 70 Fed. Reg. 50,940, and adopted on August 26, 2005 (to be codified at 42 C.F.R. pt. 410). Plaintiff's Motion for Preliminary Injunctive Relief ("Pl.'s Mot."), [D.E. # 3] at 1; Compl. at 1. The plaintiff's jurisdictional basis for filing this action in this Court are 28 U.S.C. §§ 1331, 1361, 2201-2202 (2000) and the Administrative Procedure Act, 5 U.S.C. §§

[1]This memorandum opinion is being issued to supplement the oral ruling made at that October 25, 2005 hearing on the Plaintiff's Motion for Preliminary Injunctive Relief.

701-706 (2000). Compl. at 2. The plaintiff alleges that the Interim Final Rule, which became effective on October 25, 2005, was issued without notice and the opportunity for comment, and will radically change the procedures for obtaining reimbursement for motorized wheelchairs and scooters (known as power mobility devices or PMDs) under the Medicare program. Pl.'s Mot. at 1; Compl. at 2. The plaintiff also contends that the rule is arbitrary, capricious, and not in accordance with law in violation of the Administrative Procedure Act, 5 U.S.C. §§ 553, 706, and the Medicare Act, 42 U.S.C. §§ 1395hh(b), 1395(m)(j)(2) (2000). Compl. at 1-2.

Specifically, the plaintiff proclaims that "[u]nder current Medicare procedures, which reflect specific congressional direction, claimants submit a standardized form to HHS that contains information tailored to identify whether a beneficiary's motorized wheelchair or scooter is reimbursable under the program." Pl.'s Mot. at 1-2. However, according to the plaintiff, the new regulations eliminate this standardization approach and establish a highly discretionary, and much more costly system, in which the plaintiff's members are required to collect and review patients' medical records to determine whether the records establish eligibility for the use of PMDs to the satisfaction of HHS. Id. at 2.

On the other hand, the defendants opine that "[t]he new rule is not defective because it has been first issued as an interim final rule with a comment period rather than as a notice of proposed rulemaking." Defendants' Memorandum in Opposition to Plaintiff's Motion for Preliminary Injunction ("Defs.' Opp'n") at 2-3. They contend that "[the rule] is exempt from the notice and comment requirements of the APA because portions of it merely conform agency regulations to Congressional commands . . . ." Id. Moreover, argues the defendants, "the Secretary properly found that good cause justified issuing the balance, which is needed to combat

fraud and protect the integrity of the Medicare program." Id. at 3. In addition, the defendants' contend that the "[p]laintiff's claim that the rule is arbitrary and capricious is also meritless . . . [because] the rule is entirely consistent with the Medicare Act." Id. at 3.

For the reasons discussed below, the plaintiff's motion is denied.

I. Background

The Medicare Act was established under Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395-1395hhh, and provides for the payment of covered medical care services, equipment, and supplies provided to eligible aged and disabled persons. Defs.' Opp'n at 3. The statute consists of three main parts; however, this case involves only Part B, as the plaintiff is an association that represents durable medical equipment ("DME") "suppliers." Id. (citing 42 U.S.C. § 1395x(d); 42 C.F.R. § 400.202.). Part B of the Medicare Act provides supplementary medical insurance for covered medical services, such as doctors' visits, diagnostic testing, and covered medical supplies, such as DME. Id. (citing 42 U.S.C. §§ 1395j to 1395w-4, 42 C.F.R. Part 410.)[2] In administering Part B, the Administrator of the Center for Medicare and Medicaid Services ("CMS") acts through private fiscal agents called "carriers." Id. at 1; 4 (citing 42 U.S.C. § 1395u; 42 C.F.R. Part 421, Subparts A and C, and 42 C.F.R. § 421.5(b)). Carriers are private entities, generally insurance companies, that contract with the Secretary of Health and Human Services ("the Secretary") to perform a variety of functions, such as making coverage determinations in accordance with the Medicare Act, applicable regulations, the Medicare Part B Supplier Manual, the publicly available Program Integrity Manual ("PIM"), the regional Durable

[2]Part A authorizes payment for covered inpatient hospital care and related services, 42 U.S.C. §§ 1395c to 1395i-5; 42 C.F.R. Part 409, and Part C authorizes beneficiaries to obtain services through HMOs and other "managed care" arrangements, 42 U.S.C. §§ 1395w-21 to 1395w-28, 42 C.F.R. Part 422.1. Defs.' Opp'n at 2.

Medical Equipment Regional Carriers ("DMERCs," "DMER carriers," or "carriers") manual, and other guidance materials. Id. Carriers also determine reimbursement rates and allowable payments, conduct audits of the claims submitted for payment, and adjust payments and payment requests. Id. Once a carrier receives a claim for services rendered, the carrier pays the Medicare beneficiary on the basis of an itemized bill, and pays the Medicare supplier based on an assignment of benefits executed by the beneficiary. Id. (citing 42 U.S.C. § 1395u(b)(3)(B)). These carrier functions are prescribed by regulation, i.e., 42 C.F.R. § 421.200. Id. at 4. DMER carriers process claims for DME (including PMDs) payments within designated regions of the country.[3]

As indicated, Part B coverage extends to DME products, including wheelchairs used in the patient's "home," which includes institutions other than hospitals or skilled nursing facilities. Id. at 7 (internal citations omitted). Customized wheelchairs are covered so long as they are "uniquely constructed or substantially modified for a specific beneficiary according to the description and orders of a physician." Id. (quoting 42 C.F.R.§ 414.224(a)). All Medicare coverage is limited to services that are medically "reasonable and necessary" for the diagnosis or treatment of illness. Id. (quoting 42 U.S.C. § 1395y(a)(1)(A), 42 C.F.R. § 411.15(k)(1)).

Under the prior regulation that the new regulation replaces, suppliers had to submit a form, known as a Certificate of Medical Necessity ("CMN"), to the regional Medicare DMER carriers for payment for certain DME items. Id. at 7 (citing 42 U.S.C. § 1395m(j)(2)(B) (defining the CMN)). In addition to the CMN, the Secretary has always required suppliers to furnish

[3]Carriers have other responsibilities such as issuing bulletins to medical providers and suppliers, detailing coverage requirements, explaining limitations of coverage definitions, and medical necessity definitions, along with other pertinent matters. Defs.' Opp'n at 4 (citation omitted).

information sufficient to support payments authorized under Medicare Part B. Id. at 7-8 (citing 42 U.S.C. § 1395*l*(e) 2000). This requirement continues under the new rule. Id. at 7. "Consistent with these mandates, the Secretary – through the regional carriers – issued several directives advising suppliers that they were required in some instances to provide medical documentation in addition to the CMNs in order to substantiate compliance with the 'reasonable and necessary' requirement of the Act." Id. at 8 (citing Declaration of John F. Warren ("Warren Decl.") dated October 25, 2005, Exhibit ("Ex.") A (DMERCs' instructions to carriers)).[4]

"In 2003, Congress enacted the Medicare Prescription Drug, Improvement, and Modernization Act of 2003," ("Medicare Modernization Act" or"MMA"), id. at 9, which is codified in 42 U.S.C. § 1395m(a)1(E). Title III of that Act, entitled "Combatting Waste, Fraud, and Abuse," seeks to address and ameliorate fraud related to, inter alia, Medicare claims for PMDs. H.R. Conf. Rep. 108-391 at 575, reprinted in 2003 U.S.C.C.A.N. 1808, 1944 (discussing "'those covered items for which there has been a proliferation of use, consistent findings of charges for covered items that are not delivered, or consistent findings of falsification of documentation to provide for payment of such covered items' (emphasis in original))."[5] Defs.' Opp'n at 10. In pertinent part, the Act provides:

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[4]"The CMN itself is a limited, standard document, that requests (1) identifying information about the supplier and the beneficiary, (2) a description of the DME supplied, and (3) other administrative information "other than information relating to the beneficiary's medical condition, which could be provided by the supplier, and limited medical information required to be completed by a physician." Defs.' Opp'n at 8. The CMN is considered limited because oftentimes more than the CMN is needed in order for Medicare to pay the claim. For example, "[a] valid certification by a physician may be a CMN, where permitted, or a prescription or a physician order for an item of DME." Id. And "PMDs are a distinct, and expensive form of DME. [Thus,] [o]nly a small subset of Medicare beneficiaries who are eligible for payment for a wheelchair of some sort are eligible for reimbursement of a power operated wheelchair." Id. at 9.

[5]"The Act followed, and responded to, a proliferation of fraud and abuse in the PMD market. Indeed, 'DMERCs and the [HHS] Office of the Inspector General have identified fraud cases involving power wheelchairs that were not supplied, not medically necessary, or both.'" Id. at 10 (citation omitted).

E) Clinical conditions for coverage

(I) In general

The Secretary shall establish standards for clinical conditions for payment for covered items under this subsection.

. . . .

(ii) Requirements

The standards established under clause (i) shall include the specification of types or classes of covered items that require, as a condition of payment under this subsection, a face-to-face examination of the individual by a physician (as defined in section 1395x®)(1) of this title, a physician assistant, nurse practitioner, or a clinical nurse specialist (as those terms are defined in section 1395x(aa)(5)) of this title and a prescription for the item.

(iii) Priority of establishment of standards

In establishing the standards under this subparagraph, the Secretary shall first establish standards for those covered items for which the Secretary determines there has been a proliferation of use, consistent findings of charges for covered items that are not delivered, or consistent findings of falsification of documentation to provide for payment of such covered items under this part.

(iv) Standards for power wheelchairs

Effective on the date of the enactment of this subparagraph, in the case of a covered item consisting of a motorized or power wheelchair for an individual, payment may not be made for such covered item unless a physician (as defined in section 1395x®)(1)), a physician assistant, nurse practitioner, or a clinical nurse specialist (as those terms are defined in section 1395x(aa)(5)) has conducted a face-to-face examination of the individual and written a prescription for the item.

(v) Limitation on payment for covered items

Payment may not be made for a covered item under this subsection unless the item meets any standards established under this subparagraph for clinical condition of coverage.

42 U.S.C. A. § 1395m(a)(1)(E) (West Supp. 2005).[6] In response to the enactment of the Medicare Modernization Act ("MMA"), on August 26, 2005, the CMS adopted the Interim Final Rule, which is being challenged in this action. Defs. Opp'n at 11. The rule had a 90 day comment period that expired on November 25, 2005, at 5:00 p.m. Id. at 11. The rule is an attempt to conform the CMS's regulations to 42 U.S.C. § 1395m(a)(1)(E) of the MMA. Id. at 11-12. The rule imposes two requirements. First, "a face-to-face examination of the [beneficiary] must be conducted by a physician, a physician assistant, a nurse practitioner or a clinical nurse specialist." Id. at 12. Second, "payment may not be made for a power wheelchair unless the physician or treating practitioner has written a prescription for the item." Id. Additionally, "[u]nder the new system envisioned by the PMD payment rule, physicians and treating practitioners will be compensated for the required face-to-face examination, and for the additional work necessary to complete a written prescription and prepare pertinent parts of the medical record." Id. (citing PMD payment rule, 70 Fed. Reg. at 50,941).[7] According to the defendants, "the PMD payment rule commits to regulation [the] CMS's longstanding requirement that, as part of a medical review, a supplier is required to produce documentation from the beneficiary's medical record that demonstrates the medical necessity of an item or service." Id. Although "the rule eliminates the requirement of a CMN [it does] require[] a written prescription, and also requires a supplier have

[6]It is this Court's practice to cite solely the United States Code. However, the Medicare Modernization Act of 2003 is not yet codified in the United States Code or any supplement thereto, but rather is only codified in the annotated version of the United States Code. Accordingly, with respect to the MMA, this Court will have to cite the annotated version of the United States Code throughout this opinion.

[7]"By permitting treating practitioners to conduct the face-to-face examination, [the MMA] effectively removed [the] CMS' [previous] regulatory requirement that a beneficiary must be seen by a specialist in physical medicine, orthopedic surgery, neurology, or rheumatology in order to receive a power-operated vehicle, also known as a scooter." Defs.' Opp'n at 12 (citing Warren Decl. ¶ 28).

the supporting documentation before submitting a claim." Id. "The PMD payment rule does nothing, however, to alter the administrative review procedures . . . that are available to a supplier dissatisfied with a claim denial or other decision of the Secretary." Id. at 12-13.

II. Analysis

A. Preliminary Injunction Factors

1. Likelihood of Success on the Merits

The plaintiff claims that a preliminary injunction against enforcement of the new rule is warranted because there is a strong likelihood that its challenge to the rule will succeed on the merits. Pl.'s Mot. at 11. The plaintiff cites two reasons for its purported likelihood of success on the merits: (1) the Secretary unlawfully failed to follow notice and comment rulemaking procedures in promulgating the rule, id. at 12-19, and (2) the rule is arbitrary, capricious and contrary to law. Id. at 19-24. The defendants disagree with both positions, Defs.' Opp'n at 27-42, and also argues that this Court does not have jurisdiction over the plaintiff's claims, id. at 20-26.

As its initial position, the defendants contend that the plaintiff has failed to meet "its burden to establish subject matter jurisdiction because jurisdiction of its underlying claim in this Court is barred by statute." Id. at 20. Specifically, the defendants posit that § 405(h) of the Medicare Act, 42 U.S.C. § 405(h), "bars subject matter jurisdiction over all claims arising under the Medicare statute absent two requirements: presentment of a claim to the Secretary, which may not be waived, and exhaustion of administrative remedies, which is waivable by the Secretary." Id. at 21 (citing 42 U.S.C. § 405(h), incorporated into the Medicare Act by 42 U.S.C. § 1395ii). They further contend "that even if the Court could consider the plaintiff's underlying APA claims, [the] [p]laintiff is not likely to prevail." Id. at 20.

a. Jurisdiction Under the Medicare Act

"The Medicare Act establishes a comprehensive remedial scheme, providing both administrative hearing rights for aggrieved providers . . . and judicial review of the Secretary's final decisions." Lifestar Ambulance Serv., Inc. v. United States, 365 F.3d 1293, 1295 (11th Cir. 2004) (citing Heckler v. Ringer, 466 U.S. 602, 605-06 & n.1 (1984) (quoting 42 U.S.C. § 405(g)). Section 405(g) of the Medicare Act states, in pertinent part:

> (g) Judicial review
>
> Any individual, after any final decision of the Commissioner of Social Security made after a hearing to which he was a party, irrespective of the amount in controversy, may obtain a review of such decision by a civil action commenced within sixty days after the mailing to him of notice of such decision or within such further time as the Commissioner of Social Security may allow. Such action shall be brought in the district court of the United States for the judicial district in which the plaintiff resides, or has his principal place of business, or, if he does not reside or have his principal place of business within any such judicial district, in the United States District Court for the District of Columbia . . . .

42 U.S.C. § 405(g) (2000). The Medicare statute "'demands the 'channeling' of virtually all legal attacks through the [HHS] before a health care provider may seek judicial review of a claim arising under the Medicare statute.'" Lifestar, 365 F.3d at 1296 (quoting Shalala v. Ill. Council on Long Term Care, 529 U.S. 1, 13 (2000). "This 'nearly absolute channeling requirement' serves important governmental interests in administrative efficiency and judicial economy," and "assures the agency greater opportunity to apply, interpret, or revise policies, regulations, or statutes." Id. (quoting Ill. Council, 529 U.S. at 2). "Section 405(h) purports to make exclusive the judicial review method set forth in § 405(g)." Illinois Council, 529 U.S. at 10. Section 405(h) of the Medicare Act provides:

> The findings and decision of the [Secretary] after a hearing shall be binding upon all individuals who were parties to such hearing. No findings of fact or decision of the [Secretary] shall be reviewed by any person, tribunal, or governmental agency except as herein provided. No action against the United States, the [Secretary], or any officer or employee thereof shall be brought under section 1331 [authorizing federal jurisdiction over federal questions] or 1346 [authorizing federal jurisdiction over claims against the United States as defendant] of title 28 to recover on any claim arising under [the Medicare Act].

42 U.S.C. § 405(h) (2000) (emphasis in original). As the second sentence of § 405(h) states, "[n]o findings of fact or decision of the [Secretary] shall be reviewed by any person, tribunal, or governmental agency except as herein provided." Id. (quoting § 405(h)). And, the third sentence, which is at issue here, states that "[n]o action against the United States, the [Secretary], or any officer or employee thereof shall be brought under section 1331 or 1346 of title 28 to recover on any claim arising under this subchapter." Id. (emphasis in original). Thus, "[t]he third sentence of 42 U.S.C. § 405(h), made applicable to the Medicare Act by 42 U.S.C. § 1395ii, provides that § 405(g), to the exclusion of 28 U.S.C. § 1331, is the sole avenue for judicial review for all 'claim[s] arising under' the Medicare Act." Heckler, 466 U.S. at 614-15 (footnote omitted) (citing Weinberger v. Salfi, 422 U.S. 749, 760-61 (1975)).

The plaintiff agrees that "when a plaintiff brings a claim relating to Medicare under the general federal-question jurisdictional statute, 28 U.S.C. § 1331, the claim must first proceed through the administrative process . . . ." Plaintiff's Reply in Support of its Motion for Preliminary Injunctive Relief ("Pl.'s Reply") at 3. However the plaintiff claims that this prerequisite to judicial review is not applicable if "doing so 'would not simply channel review through the agency, but would mean no review at all.'" Id. (citing Illinois Council, 529 U.S. at 19 (interpreting Bowen v. Mich. Acad. of Family Physicians, 476 U.S. 667 (1986)) (internal footnote

omitted). The plaintiff notes that "[t]he test [, in making this determination,] is whether the plaintiff would 'as a practical matter be able to obtain meaningful judicial review' of agency regulations if he is required to exhaust the administrative process in the first instance." Id. (quoting McNary v. Haitian Refugee Ctr., Inc., 498 U.S. 479, 496 (1991). The plaintiff represents that "its members have sought relief from the Rule through informal administrative channels, but because the Rule is not yet in effect, [the] CMS has not rendered any claim-denials under the Rule that would trigger the administrative review process."[8] Id. at 3-4. The plaintiff further contends that "[t]he process of appealing a carrier's disallowance of a PMD claim commonly takes two to three years." Id. 4. The plaintiff therefore concludes that "[f]orcing Coalition members to [comply with the] administrative process would deny them access to meaningful judicial review" because "HHS's administrative processes cannot provide any review of the Coalitions's claim that the Rule has been promulgated in violation of the APA's notice-and-comment requirements." Id. And according to the plaintiff, "[n]o subordinate Medicare contractor, ALJ, or administrative body could require the Secretary to undertake a notice-and-comment proceeding. Id. Consequently, argues the plaintiff, "[b]y the time a challenge to [the] CMS's denial of a claim for reimbursement cleared the futile administrative process and could be reviewed in court, the

[8] "A Medicare supplier dissatisfied with the resolution of a claim must present its grievance through the designated administrative appeals process and exhaust the administrative remedies available to it." Def.'s Opp'n at 5 (citing 42 U.S.C. § 1395u(b)(3)(C); 42 U.S.C. § 1395ff(b)) (incorporating by reference 42U.S.C. § 405(b)); see also 42 C.F.R. §§ 405.801 et seq., 405.901 et seq (describing the administrative appeals process for Part B). "The Medicare Act's review scheme is established through four statutory provisions: 42 U.S.C. § 405(b), 42 U.S.C. § 405(g), 42 U.S.C. § 405(h), and 42 U.S.C. § 1395cc(h)." Id. at 6. "Section 405(b) provides that any individual dissatisfied with a determination of the Secretary is entitled to 'notice and opportunity for a hearing with respect to' the determination." Id. (quoting 42 U.S.C. § 405(b)). "Once this administrative process is exhausted, judicial review of the Secretary's 'final decision' is available as provided in 42 U.S.C. § 405(g) (incorporated by reference in 42 U.S.C. § 1395ff(b)(1)(a)), which provides that anyone dissatisfied with a 'final decision . . . made after a hearing to which he was a party may obtain . . . review of such decision by' filing an action in federal district court." Id. (citing 42 U.S.C. § 405(g)). "Section 405(h) renders the administrative and judicial review procedures under Section 405(b) and (g) exclusive." Id.

Secretary would have issued a permanent rule to replace or modify the challenged interim rule." Id. (citation omitted).

The plaintiff relies on McNary v. Haitian Refugee Ctr., Inc. 498 U.S. 479 (1991) to support its position that it would not "be able to obtain meaningful judicial review of agency regulations if [] required to exhaust the administrative process in the first instance." Pl.'s Reply at 3 (citation omitted). There, the plaintiffs challenged the procedural mechanism by which applicants were selected for an amnesty program administered by the Immigration and Naturalization Service ("INS") for special agricultural workers ("SAW"s). 498 U.S. at 483. This amnesty program was initiated by the Immigration Reform and Control Act of 1986 ("Reform Act"), 8 U.S.C. § 1324a (1991). Id. at 481. "The Reform Act amended the Immigration and Nationality Act ("INA"), creating, inter alia, the [SAW] amnesty program for specified alien farm workers." Id. Section 210(e)(1) of the INA bars judicial review "of a determination respecting an application [for amnesty under the SAW program]" except in the context of judicial review of a deportation order, a review which is conducted by the courts of appeals. Id. at 889. Despite the immigration statute's bar of § 1331 challenges to any INS "'determination respecting an application for adjustment of status'" under the SAW program, the district court "accepted jurisdiction" and permitted a § 1331 challenge to be pursued. Id. at 488. The Supreme Court affirmed, nothing that its conclusion turned on the specific language of the statute at issue. Id. at 494. The full text of § 210(e) of the INA, as set forth in 8 U.S.C. § 1160(e), reads as follows:

> (e) Administrative and judicial review
> (1) Administrative and judicial review
> There shall be no administrative or judicial review of a determination respecting an application for adjustment of status under this section except in accordance with this subsection.

> (2) Administrative review
>
> (A) Single level of administrative appellate review
>
> The Attorney General shall establish an appellate authority to provide for a single level of administrative appellate review of such a determination.
>
> (B) Standard for review
>
> Such administrative appellate review shall be based solely upon the administrative record established at the time of the determination on the application and upon such additional or newly discovered evidence as may not have been available at the time of the determination.
>
> (3) Judicial review
>
> (A) Limitation to review of exclusion or deportation
>
> There shall be judicial review of such a denial only in the judicial review of an order of exclusion or deportation under section 1105a of this title.
>
> (B) Standard for judicial review
>
> Such judicial review shall be based solely upon the administrative record established at the time of the review by the appellate authority and the findings of fact and determinations contained in such record shall be conclusive unless the applicant can establish abuse of discretion or that the findings are directly contrary to clear and convincing facts contained in the record considered as a whole.

Haitian Refugee Ctr., 498 U.S. at 486. The defendants' jurisdictional demur rested on "their view that the respondents' constitutional challenge [was] an action seeking 'judicial review of a determination respecting an application for adjustment of status' and that district court jurisdiction over the action [was] therefore barred by the plain language of § 210(e)(1) of he amended INA." Id. at 491. The Supreme Court concluded that "[t]he critical words in § 210 (e)(1), however, describe the provision as referring only to review 'of a determination respecting an application' for SAW status." Id. at 492 (emphasis in original). Thus, noted the Court, reference to "'a determination' describe[d] a single act rather than a group of decisions or a practice or procedure employed in making decisions." Id. Indeed, the language of § 210(e)(3) further clarifies that "the only judicial review permitted is in the context of a deportation proceeding, it refers to 'judicial

review of such a denial' – again referring to a single act, and again making clear that the earlier reference to 'a determination respecting an application' describes the denial of an individual application." Id. (internal citation omitted). Thus, the Supreme Court agreed with both the "District Court's and the Court of Appeals' reading of [§ 210(e)(1)] as describing the process of direct review of individual denials of SAW status, rather than as referring to general collateral challenges to unconstitutional practices and policies used by the agency in processing applications." Id. Accordingly, concluded the Court, if the plaintiffs were not allowed to pursue their claims in the District Court, they "would not as a practical matter be able to obtain 'meaningful judicial review' of their application denials or of their objections to INS procedures nothwithstanding the review provisions of § 210(e) of the amended INA." Id. at 496. And the Supreme Court identified three reasons why the statutory scheme of § 210(e) "would preclude review of [the plaintiffs'] application denials if [it] were to hold that the District Court lacked jurisdiction to hear [the plaintiffs'] challenge." Id. (emphasis added).

First, the Court noted that judicial review of an agency decision is confined to the administrative record, which is made in the initial proceeding at the decision making level. Id. And, one of the plaintiff's central attacks on INS procedures was that it did "not allow applicants to assemble adequate records." Id. Therefore, the Court agreed with the District Court's finding that

> because of the lack of recordings or transcripts of [legalization office] interviews and the inadequate opportunity for SAW applicants to call witnesses or present other evidence on their behalf, the administrative appeals unit of the INS, in reviewing decisions of legalization offices and regional processing facilities, and the courts of appeals, in reviewing SAW denials in the context of deportation proceedings, have no complete or meaningful basis upon which to review application determinations.

Id. Second, "because there [was] no provision for direct judicial review of the denial of SAW status . . . , most aliens denied SAW status can ensure themselves review in courts of appeals only if they voluntarily surrender themselves for deportation." Id. And, as the Supreme Court noted, "that price is tantamount to a complete denial of judicial review for most undocumented aliens." Id. at 497. Third, "even in the context of a deportation proceeding, it is unlikely that a court of appeals would be in a position to provide meaningful review of the type of claims raised in th[e] litigation." Id. The Court reasoned that "[n]ot only would a court of appeals reviewing an individual SAW determination . . . not have an adequate record as to the pattern of INS' allegedly unconstitutional practices, but it would also lack the factfinding and record-developing capabilities of a federal district court." Id. For these three reasons, the Supreme Court concluded that "restricting judicial review to the courts of appeals as a component of the review of an individual deportation order is the practical equivalent of a total denial of judicial review of generic constitutional and statutory claims." Id. (emphasis added). Moreover, the Court found that "[t]he language of § 210(e)(3)(B) thus lends substantial credence to the conclusion that the Reform Act's review provision does not apply to challenges to INS' practices and procedures in administering the SAW program." Id. at 493-94. Accordingly, the Supreme Court concluded that "challenges to the procedures used by INS do not fall within the scope of § 210(e)[, but] [r]ather . . . § 210(e) applies only to review of denials of individual SAW applications." Id. at 494. Therefore, "[b]ecause [the] respondents' action [did] not seek review on the merits of a denial of a particular application, the District Court's general federal-question jurisdiction under 28 U.S.C. § 1331 to hear [the] action remain[ed] unimpaired by § 210(e)." Id.

In contrast to the narrow statutory provision at issue in Haitian Refugee Center, the

Supreme Court has characterized the Medicare Act's § 405(h) bar to § 1331 jurisdiction as "sweeping and direct" and applicable to "all 'claim[s] arising under the' Medicare Act." Weinberger v. Salfi, 422 U.S. 749, 757 (1975). Indeed the Medicare Act provides a "comprehensive remedial scheme," for "both administrative hearing rights for aggrieved providers . . . , and judicial review of the Secretary's final decisions." Lifestar, 365 F.3d at 1295 (citing Ringer, 466 U.S. at 605-06 (quoting 42 U.S.C. § 405(g)). This case is therefore more akin to Heckler v. Ringer. There, four individuals brought a § 1331 action challenging the policy decision of the Secretary of HHS not to provide Medicare Part A reimbursement to individuals who had undergone a particular medical procedure. 466 U.S. at 609. Specifically, the respondents challenged the Secretary's procedure for reaching the decision not to cover the procedure, and the Secretary's alleged failure to comply with the rulemaking requirements of the APA in issuing the instructions and the rule. Id. at 614. Although the relief sought by the respondents to redress their "procedural" objections was the invalidation of the Secretary's then existing policy, and a "substantive" declaration that the expenses of the procedure were reimbursable under the Medicare Act, the Court concluded that "all aspects of [the plaintiffs'] claim for benefits should be channeled first into the administrative process which Congress has provided for the determination of claims for benefits." Id. The Court reasoned that "to be true to the language of the statute, the inquiry in determining whether § 405(h) bars federal-question jurisdiction must be whether the claim 'arises under' the Act, not whether it lends itself to a 'substantive' rather than 'procedural' label." Id. at 615. The Court reiterated that § 405(h) applies where "both the standing and the substantive basis for the presentation" of a claim is the Medicare Act. Id. at 615 (quoting Salfi, 422 U.S. at 760-761).

Similarly, in the earlier case of Weinberger v. Salfi, the Supreme Court construed the "claim arising under" language of the Social Security Act "quite broadly to include any claims in which both the standing and the substantive basis for the presentation of the claims [was] the Social Security Act." 422 U.S. at 760-61. In Salfi, a mother and daughter, filing on behalf of themselves and a class of individuals, brought a § 1331 action challenging the constitutionality of a statutory provision that, if valid, would deny them Social Security benefits. Id. at 753-54. At the time the action was filed, the mother and daughter had not exhausted their administrative remedies. Id. at 755. The Supreme Court held that § 405(h) was a bar to § 1331 jurisdiction for all members of the class because "it [was] the Social Security Act which provides both the standing and the substantive basis for the presentation of the constitutional contentions." Id. at 760-761. The Court explained that the reach of the language of § 405(h) "is not limited to decisions of the Secretary on issues of law or fact[, but] [r]ather, it extends to any 'action' seeking 'to recover on any (Social Security) claim' – irrespective of whether resort to judicial processes is necessitated by discretionary decisions of the Secretary or by [the Secretary's] nondiscretionary application of allegedly unconstitutional statutory restrictions." Id. at 762. Moreover, the Court found that "the plain words of the third sentence of § 405(h) do not preclude constitutional challenges[, t]hey simply require that they be brought under jurisdictional grants contained in the Act, and thus in conformity with the same standards which are applicable to nonconstitutional claims arising under the Act." Id.

From a reading of these cases, in addition to the clear language of § 405(h), this Court concludes that it cannot entertain § 1331 jurisdiction in this case unless and until the plaintiff exhausts its administrative remedies. As discussed above, "[s]ection 405(h) purports to make

exclusive the judicial review method set forth in § 405(g)." Illinois Council, 529 U.S. at 13. With respect to the plaintiff's contention that "[f]orcing Coalition members to [comply with] th[e] administrative process would deny them access to meaningful judicial review" because "HHS's administrative processes cannot provide any review of the Coalitions's claim that the Rule has been promulgated in violation of the APA's notice-and-comment requirements," Pl.'s Reply at 4, this contention is simply unfounded. "[U]nder the PMD payment rule a supplier whose claim for reimbursement is denied can appeal that denial, including a challenge to the underlying rule . . . ." Defs.' Opp'n at 24 (citing 42 U.S.C. § 1395u(b)(3)(C); 42 U.S.C. § 1395ff(b) (incorporating by reference 42 U.S.C. § 405(b) (providing for judicial review of the Secretary's final decision after a hearing pursuant to section 405(g) of this title has been conducted); 42 C.F.R. §§ 405.801 et seq., 405.901 et seq. (delineating the administrative appeals process for Part B). As discussed earlier, in Ringer, the relief the plaintiff sought there was the redress of their "procedural" objections through the invalidation of the Secretary's policy that was in effect at that time, and a "substantive" declaration that the expenses for the medical procedure at issue were reimbursable under the Medicare Act. Ringer, 466 U.S. at 614. However, the Court concluded that "all aspects of [the plaintiffs'] claim for benefits should be channeled first into the administrative process which Congress has provided for the determination of claims for benefits." Id. And Illinois Council is particularly instructive on this point because the plaintiffs there also complained, inter alia, that a "manual and other agency publications create[d] legislative rules that were not promulgated consistent with the APA's demands for 'notice and comment' and a statement of 'basis and purpose[.]" 529 U.S. at 7. There, the plaintiffs, as does the plaintiff here, complained that "procedural regulations unlawfully limit[ed] the extent to which the agency itself [would]

provide the administrative review channel leading to judicial review . . . ." 529 U.S. at 23. However, the Supreme Court explained that the plaintiffs were "free . . . after following the special review route that the statutes prescribe, to contest in court the lawfulness of any regulation or statue upon which an agency determination depends." Id. The Court went on to explain that "[t]he fact that the agency might not provide a hearing for that particular contention, or may lack the power to provide one . . . is beside the point because it is the 'action arising under' the Medicare Act that must be channeled through the agency." Id. (citing Salfi, 422 U.S. at 762, 764) (other citation omitted). In other words, "[a]fter the action has been channeled, the court will consider the contention when it later reviews the action." Id. "And a court reviewing an agency determination under § 405(g) has adequate authority to resolve any statutory or constitutional contention that the agency does not, or cannot decide . . . ." Id.[9] Accordingly, this Court does not have federal question jurisdiction in this situation under 28 U.S.C. § 1331 because § 405(h) of the Medicare Act prohibits judicial review of the plaintiff's claim, absent presentment of its claim to

[9]The plaintiff also asserts that this Court has jurisdiction pursuant to the general mandamus statute, 28 U.S.C. § 1361, the Declaratory Judgment Act, 28 U.S.C. § 2201-2202, and the Administrative Procedure Act., 5 U.S.C. § 701-706. Compl. at 2. However, it is clear that no writ of mandamus could properly issue in this case. The common-law writ of mandamus, as codified in 28 U.S.C. § 1361, is intended to provide a remedy for a plaintiff only if he has exhausted all other avenues of relief and only if the defendant owes it a clear nondiscretionary duty. Ringer, 466 U.S. at 617 (citations omitted). Here, the plaintiff clearly has an adequate means in § 405(g) for challenging all aspects of its claims arising under the Medicare Act, including any objections it has to the alleged failure to provide notice and the opportunity to comment, or to the new rule itself, if either ultimately should play a part in the Secretary's denial of the plaintiff's claims. Thus, § 405(g) is the only avenue for judicial review of their claims. Moreover, neither the APA nor the Declaratory Judgment Act provide an independent grant of subject matter jurisdiction for review of agency action. See, e.g., Schilling v. Rogers, 363 U.S. 666, 677 (1990) (Declaratory Judgments Act is not an independent source of federal jurisdiction. The availability of such relief presupposes the existence of a judicially remediable right.); Califano v. Sanders, 430 U.S. 99, 104 (1977) (The APA does not provide an independent grant of subject matter jurisdiction).

the Secretary and exhaustion of its other administrative remedies.[10]

2. Irreparable Harm

The plaintiff claims that "members of the Coalition would suffer irreparable injury if the injunction is not granted." Pl.'s Mot. at 11. Specifically the plaintiff alleges that "[t]he Rule will inflict irrecoverable, severe, and immediate economic loss upon Coalition members who depend upon timely and reliable Medicare reimbursement in their businesses." Id. at 25. The plaintiff claims that the documentation requirments of the new Rule (1) abolishes the CMN and (2) fails to provide meaningful criteria by which suppliers can reliably predict whether the CMS and its contractors have documentation that adequately supports prescriptions for PMDs. Id. at 27. In other words, according to the plaintiff, suppliers will be unable to make any educated prediction about whether they will be reimbursed for the cost of providing a PMD pursuant to a doctor's prescription. Id. Moreover, the plaintiff contends that the increased record-gathering and maintenance costs associated with the new rule, and related delays in obtaining reimbursement, and the uncertainty about whether claims will be paid is likely to put Coalition members out of business. Id. at 28 (citation omitted). The plaintiff also opines that the losses that will be sustained by these suppliers will be irreparable because lost sales on mobility devices and denied claims for reimbursement cannot be recouped from patients. Id. (citation omitted).

On the other hand, according to the defendants, the plaintiff's motion should be denied because it has not shown imminent, certain and irreparable injury. Defs.' Opp'n at 14-15.

[10]With respect to the plaintiff's position that "[t]he process of appealing a carrier's disallowance of a PMD claim commonly takes two to three years," Pl.'s Reply at 4, counsel for the defendant represented, at oral argument, that the delay would not be as long as the plaintiff has indicated. Counsel also noted that the Secretary has the option of waiving the exhaustion of administrative remedies in order to expedite judicial review, if necessary.

Moreover, putting aside the plaintiff's evidentiary deficiencies, the defendants argue that the plaintiff's "central claim is not credible [because its members] will not be imminently and certainly forced out of business if they abide by the PMD payment rule and its documentation requirements, i.e., if they must obtain prescriptions rather than a CMN and Medicare continues its longstanding policy of relying on medical record evidence." Id. at 15 (footnote omitted). The defendants contend that the underlying opinion of the economists upon which the plaintiffs rely for this proposition "is, on its face, pure speculation based on false assumptions." Id. at 16 (citation omitted). For example, opines the defendants, "the economists [sic] claim that the PMD payment rule injects 'subjectivity' into the claims process in an effort to reject more claims, despite the rules clear purpose and effort to reject more PMD claims only in the sense that it seeks to ferret out fraudulent claims." Id. at 15 & footnote 11 (citing Warren Decl.) (emphasis in original) Additionally, according to the defendants, the plaintiff's assertion that the CMS's documentation requirements necessitate the submission of a 362-500 word essay on each patient is also erroneous because "there is no such requirement." Id. at 17 (emphasis in original).

"[I]rreparable harm to the moving party is 'the basis of injunctive relief in the federal courts.'" Almurbati v. Bush, 366 F. Supp. 2d 72, 77-78 (D.D.C. 2005) (Walton, J.) (citing CityFed Financial Corp. v. Office of Thrift Supervision, 58 F.3d 738, 747 (D.C. Cir. 1995) (quoting Sampson v. Murray, 415 U.S. 61, 88 (1974)). Accordingly, a plaintiff's failure to meet its burden of establishing irreparable harm is sufficient, in itself, to deny emergency relief. CityFed Fin. Corp., 58 F.3d 738, 747. Moreover, "[t]o obtain injunctive relief, [a plaintiff] must show that the threatened injury is not merely 'remote and speculative.'" Almurbati, 366 F. Supp.2d at 78 (quoting Milk Indus. Found. v. Glickman, 949 F. Supp. 882, 897 (D.D.C. 1996)).

Thus, proving "irreparable" injury is a considerable burden, requiring proof that the movant's injury is "certain, great and actual – not theoretical – and imminent, creating a clear and present need for extraordinary equitable relief to prevent harm." Wisconsin Gas Co. v. FERC, 758 F.2d 669, 674 (D.C. Cir. 1985); Varicon Int'l v. OPM, 934 F. Supp. 440, 447 (D.D.C. 1996). "Even more important, the plaintiff[] must show that the injury will be impossible to correct or redress after it occurs[.]" Foundation Health Fed. Servs. v. United States, 1993 WL 738426, *2 (D.D.C. Sept. 23, 1993). And economic loss, in and of itself, generally does not constitute irreparable harm. Wisconsin Gas Co., 758 F.2d at 674; Varicon, 934 F. Supp. at 447. Rather, only economic loss that threatens the survival of a movant's business amounts to irreparable harm. Wisconsin Gas Co., 758 F.2d at 674; Holiday Tours, Inc., 559 F.2d at 843 n.3. But, again, such harm must be certain to occur in the near future as a direct result of the threatened action. Wisconsin Gas Co., 758 F.2d at 674; Varicon, 934 F. Supp. at 447.

Here, the plaintiff has not demonstrated that irreparable injury is "certain, great and actual – not theoretical – and imminent, creating a clear and present need for extraordinary equitable relief to prevent harm." Wisconsin Gas Co., 758 F.2d at 674. The plaintiff has presented the sworn declaration of Philip DiLernia, President of Cornell Healthcare Corp., d/b/a Mr. Mobility, who states that "[i]f the new rules take effect as planned by CMS, [he] anticipate[s] that Mr. Mobility will wind-down its operations and stop doing business as a supplier of mobility equipment in early 2006." Pl.'s Mot., Ex. 9 (Declaration of Philip DiLernia) ¶ 18. And the plaintiff has also provided the joint declaration of J. Gregory Sidak and Hal J. Singer ("Sidak &

Singer Decl.")[11] as support for its contention that "when the Secretary has promulgated a rule to reduce PMD reimbursement costs . . . the Secretary intends to deny more claims under the new procedures," despite the Secretary's pronouncement that "we anticipate that supplier denial rates will decline" under the new rule. Sidak and Singer Decl. ¶ 24. However, it is the Court's view, after hearing the arguments of counsel, that the plaintiff's claim of imminent irreparable harm is, at best, remote and speculative. The plaintiff's are basically predicting that many of their claims for reimbursement for PMDs will be denied, and consequently, they will be forced out of business. The plaintiffs make this prediction without having ever filed a claim for reimbursement and having the claim denied under the new rule, and without adhering to the claim presentment requirement and the exhaustion of available administrative remedies. Moreover, the plaintiff's complaint that elimination of the CMN will result in increased claim denials and place an additional burden on the providers is also unfounded.

As explained at oral argument, and in the brief submitted by counsel for the defendants, the additional burdens imposed by the new rule are primarily placed on the physicians and other practitioners who are required to conduct face-to-face examinations of potential beneficiaries, provide a written prescription for PMDs, and produce documentation from potential beneficiaries' medical records showing medical necessity for the use of PMDs. Defs.' Opp'n at 12. The only "additional burden" placed upon the providers of PMDs is the requirement that they have supporting documentation prior to submitting a claim to the CMS. Id. The plaintiff's complaint, at bottom, is therefore to its obligations to "maintain the prescription and the supporting

[11]Mr. Sidak is a visiting Professor of Law at the Georgetown University Law Center and the founder of Criterion Economics, an economic consulting firm. Hal J. Singer is the President of Criterion Economics.

documentation" and to make those documents available "to [the] CMS and its agents upon request." Pl.'s Mot. at 10. These requirements can hardly be considered significant or unreasonable. Although the plaintiff will have to find space to store this documentation, it would appear that maintaining this information may actually help facilitate claims reimbursement, rather than generate denials, when questions about the necessity for DMEs are raised. It is therefore the Court's conclusion that based on the entire record before the Court at this time, the plaintiff's claim of irreparable harm is far too speculative to merit injunctive relief. Accordingly, the plaintiff has not satisfied its burden of establishing irreparable harm.[12]

III. Conclusion

Based upon the foregoing analysis, the Plaintiff's Motion for Preliminary Injunctive Relief must be denied because (1) the plaintiff is not likely to succeed on the merits because this Court is barred by statute from having subject matter jurisdiction in this case and, (2) the plaintiff has not met its burden of establishing irreparable harm.

SO ORDERED this 25th day of October, 2005, nunc pro tunc.

REGGIE B. WALTON
United States District Judge

[12]Because "a plaintiff's failure to meet its burden of establishing irreparable harm is sufficient, in itself, to deny emergency relief," CityFed Fin. Corp., 58 F.3d at 747, this Court will not address the remaining two preliminary injunction factors.