

DeWALL ENTERPRISES, INC., Plaintiff, vs. TOMMY THOMPSON, et al., Defendants.

8:02CV69

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEBRASKA

206 F. Supp. 2d 992; 2002 U.S. Dist. LEXIS 11619

June 26, 2002, Decided

DISPOSITION: **[**1]** Defendants' motion to dismiss denied and Plaintiff's motion for preliminary injunction granted.

CASE SUMMARY

PROCEDURAL POSTURE: Defendant Secretary of Health and Human Services moved to dismiss plaintiff company's action, seeking a preliminary injunction related to payments under the Medicare Act, 42 U.S.C.S. § 1395 et seq.

OVERVIEW: The Secretary asserted the court lacked subject matter jurisdiction because exhaustion of administrative remedies was a jurisdictional prerequisite to suit under the Medicare Act. The court found the company was denied an opportunity for meaningful review. The company sought and obtained numerous adjudications in its favor on the exact issue now before the court, and the Secretary did not challenge the determinations through the appeals process but simply ignored the determinations. Thus, invocation of federal question jurisdiction was proper, even absent exhaustion of administrative remedies. In any case, the company could show exhaustion sufficient to invoke jurisdiction under 42 U.S.C.S. § 405(g). The company satisfied the nonwaivable requirement that a claim for benefits be presented to the Secretary. Further, mandamus jurisdiction was appropriate, if not compelled. As to the motion for preliminary injunction, the company showed irreparable injury; the company could point to the Secretary's 11-year history of consistently following his own regulations, at many points of which the company was faced with economic ruin injury. The other injunction elements were also met.

OUTCOME: The court granted the company's motion for a preliminary injunction and denied the Secretary's motion to dismiss.

CORE TERMS: secretary, carrier, exhaustion, regional, Medicare Act, judicial review, mandamus, coding, orthotic, billing; administrative remedies, claimant, manual, jacket, supplier, posture, preliminary injunction, guidelines, overpayment, protector, Social Security Act, medical equipment, administrative procedures, prosthetic, durable, coded, matter jurisdiction, final decision, irreparable harm, reimbursement

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Public Health & Welfare Law > Social Security > Medicare > Coverage > Part A
Public Health & Welfare Law > Social Security > Medicare > Providers > Reimbursement >
General Overview
Public Health & Welfare Law > Social Security > Medicare > Providers > Types > Hospitals

HN1 ↓ Part A of the Medicare Act, 42 U.S.C.S. § 1395 et seq., provides insurance for hospital and related services. 42 U.S.C.S. § 1395c et seq. Part B of the Medicare Act establishes a voluntary program of supplemental medical insurance covering expenses not covered by the Part A program, such as reasonable charges for physicians' services, medical supplies, and laboratory tests. 42 U.S.C.S. § 1395j et seq. The Medicare Act authorizes the Secretary of Social Security to determine what claims are covered by the Medicare Act in accordance with the regulations prescribed by him. 42 U.S.C.S. § 1395ff(a). Payments for Part B expenses are made by private insurance carriers under contract to the Department of Health and Human Services, 42 U.S.C.S. § 1395u. These carriers are authorized to administer the payment of qualifying claims and act on behalf of the Secretary in this regard. The Secretary authorizes regional carriers to administer claims for durable medical equipment, prosthetic and orthotics and other supplies. 42 U.S.C.S. § 1395m(a)(12). The carrier determines whether the item is covered and the level of reimbursement in accordance with regulatory guidelines. 42 U.S.C.S. §§ 1395m(h) and 1395u(a).

Administrative Law > Judicial Review > General Overview
Civil Procedure > Jurisdiction > Subject Matter Jurisdiction > General Overview
Public Health & Welfare Law > Social Security > Medicare > Appeals Process & Judicial Review

HN2 ↓ The Social Security Act provides for judicial review in federal district court of any final decision of the Secretary of Social Security made after a hearing. 42 U.S.C.S. § 405(g). Section 405(g), as adapted to the Medicare Act, 42 U.S.C.S. § 1395 et seq., by 42 U.S.C.S. § 1395ff(b)(1), creates federal jurisdiction over final agency decisions in administrative Medicare appeals. A related provision, 42 U.S.C. § 405 (h), limits judicial review as follows: no finding of fact or decision of the Secretary shall be reviewed by any person, tribunal, or governmental agency except as herein provided and no action against the Secretary shall be brought under 28 U.S.C.S. § 1331 to recover on any claim arising under the Social Security Act. 42 U.S.C.S. § 1395ii makes § 405(h) applicable to the Medicare Act to the same extent as it applies to the Social Security Act.

Civil Procedure > Jurisdiction > Subject Matter Jurisdiction > General Overview
Healthcare Law > Business Administration & Organization > Judicial Review > General Overview
Public Health & Welfare Law > Social Security > Medicare > Appeals Process & Judicial Review

HN3 ↓ The provisions of 42 U.S.C.S. § 405(h), as incorporated into the Medicare Act, 42 U.S.C.S. § 1395 et seq., through 42 U.S.C.S. § 1395ii, operate as a complete bar to federal question jurisdiction for claims under the Medicare Act unless application of § 405(h) would not simply channel review through the agency, but would mean no review at all. Accordingly, § 1395ii will not be interpreted to apply the statutory bar of § 405(h) where application of § 405(h) would foreclose review. In order to determine whether this narrow exception applies, the court must determine whether a claimant is simply being required to seek review first through the agency or is being denied altogether the opportunity for judicial review.

Administrative Law > Judicial Review > Reviewability > Exhaustion of Remedies
Civil Procedure > Justiciability > Exhaustion of Remedies > Administrative Remedies
Public Health & Welfare Law > Social Security > Disability Insurance & SSI Benefits > Judicial Review > General Overview

HN4 ↓ Subject matter jurisdiction based upon exhaustion of administrative remedies is a question of law.

Administrative Law > Judicial Review > General Overview
 Healthcare Law > Business Administration & Organization > Judicial Review > Exhaustion of Remedies
 Public Health & Welfare Law > Social Security > Medicare > Providers > Reimbursement > General Overview

HNS By granting the right to obtain judicial review of any final decision in 42 U.S.C.S. § 405(g), the statute makes it clear that federal judicial review of Medicare reimbursement decisions is available once the Secretary of Social Security renders a final decision. Generally, a provider who fails to exhaust its administrative remedies will be precluded from seeking relief in federal court. Exhaustion is required in order to prevent premature interference with agency processes, to permit the agency to function efficiently and so that it may have an opportunity to correct its own errors, to afford the parties and the courts the benefit of its experience and expertise, and to compile a record which is adequate for judicial review.

Civil Procedure > Justiciability > Exhaustion of Remedies > Administrative Remedies
 Public Health & Welfare Law > Social Security > Medicare > General Overview

HN6 Finality, for purposes of 42 U.S.C.S. § 405(g), has two components: a nonwaivable requirement that a claim be presented for administrative review, and a waivable requirement that all administrative remedies be fully pursued. Waiver of exhaustion allows an administrative claim essentially to leapfrog over the otherwise required administrative procedures and go straight to court. A claimant may find an exception to the exhaustion requirement if: (1) the claim involves a legitimate constitutional claim, (2) irreparable harm would result from exhaustion, or (3) further administrative procedures would be futile.

Administrative Law > Judicial Review > Reviewability > Exhaustion of Remedies
 Civil Procedure > Justiciability > Exhaustion of Remedies > Administrative Remedies
 Civil Procedure > Justiciability > Exhaustion of Remedies > Failure to Exhaust

HN7 As a general matter of administrative law, it is well established that where the pursuit of administrative remedies would be futile, failure to exhaust such remedies should be excused. In other words, if the agency's hostile attitude makes it impossible for the litigant to obtain the relief he seeks or renders it highly improbable that he will obtain such relief, exhaustion will not be required. Also, when an administrative appeal would be futile and little more than a formality, exhaustion will not be required. Thus, the doctrine of exhaustion of administrative remedies is not a strict jurisdictional requirement, but rather a flexible concept which must be tailored to the circumstances of the particular case. The vitality of the "waiver of exhaustion" doctrine in the Social Security context, as part of the "entirely collateral" exception, survives the Illinois Council decision when a litigant satisfies the nonwaivable and nonexcusable requirement of initial presentment of its claim to the appropriate agency.

Administrative Law > Judicial Review > Remedies > Mandamus
 Civil Procedure > Remedies > Writs > Common Law Writs > Mandamus
 Governments > Courts > Authority to Adjudicate

HN8 The federal mandamus statute, 28 U.S.C.S. § 1361, gives district courts power to compel an officer of the United States or any agency thereof to perform a duty

owed to the plaintiff, after exhaustion of all other avenues of relief, if the duty is clear, certain, and nondiscretionary. Mandamus jurisdiction in cases involving the Medicare Act, 42 U.S.C.S. § 1395 et seq., is approved in the Eighth Circuit.

Administrative Law > Agency Adjudication > Presiding Officers > Duties & Powers
Public Health & Welfare Law > Social Security > Medicare > General Overview

HN9 The Secretary of Social Security's duty to decide eligibility for an amount of payments under Part B of the Medicare Act, 42 U.S.C.S. § 1395 et seq., may be discretionary.

Civil Procedure > Remedies > Injunctions > Preliminary & Temporary Injunctions

HN10 The extraordinary remedy of a preliminary injunction should not be granted unless the movant has demonstrated: (1) the threat of irreparable harm to it; (2) the state of the balance between this harm and the injury that granting the injunction will inflict on other parties; (3) the probability that it will succeed on the merits; and (4) the public interest. No single factor is determinative, although the failure to demonstrate the threat of irreparable harm is, by itself, a sufficient ground upon which to deny a preliminary injunction.

COUNSEL: For DEWALL ENTERPRISES, INC., plaintiff: Timothy J. Pugh, MCGRATH, NORTH LAW FIRM, Omaha, NE.

For DEWALL ENTERPRISES, INC., plaintiff: Kent Masterson Brown, Christopher J. Shaughnessy, BROWN LAW FIRM, Lexington, KY.

For TOMMY THOMPSON, HEALTH AND HUMAN SERVICES, ADMINASTAR FEDERAL, Inc., BLUE CROSS AND BLUE SHIELD OF SOUTH CAROLINA, CONNECTICUT GENERAL LIFE INSURANCE COMPANY, HEALTHNOW NEW YORK, Inc., defendants: Robert L. Homan, ASSISTANT UNITED STATES ATTORNEY, Omaha, NE.

JUDGES: JOSEPH F. BATAILLON, United States District Judge.

OPINION BY: JOSEPH F. BATAILLON

OPINION

[*993] MEMORANDUM OPINION AND ORDER

The matters before the court are 1) the motion of the plaintiff, DeWall Enterprises, Inc. (DeWall), for preliminary injunction and a writ of mandamus, Filing No. 2; and 2) the motion of defendants Healthnow New York, Inc., Connecticut General Life Insurance Company, ▼ Blue Cross and Blue Shield of South Carolina, ▼ Adminastar Federal, Inc., Health and Human Services, and Tommy Thompson, Secretary (collectively, "the Secretary") to dismiss for lack of subject matter jurisdiction and for failure to state [*2] a claim, Filing No. 22. ¹ A hearing on the above matters was held on June 18, 2002.

----- Footnotes -----

¹ Although numerous defendants are named in the complaint, the Secretary of the United States Department of Health and Human Services is the real party in interest in the action. See 42 U.S.C. § 1395u and 42 C.F.R. § 421.5(b). Under the Medicare scheme, fiscal intermediaries are agents of the Secretary charged with relevant duties under the Medicare Act and its regulations and, as such, may properly be bound by a judgment against the Secretary. *Monmouth Med. Ctr. v.*

Thompson, 347 U.S. App. D.C. 214, 257 F.3d 807, 813 (D.C. Cir. 2001).

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I. BACKGROUND

This action involves payments to a supplier under Title XVIII of the Social Security [*994] Act, commonly known as the Medicare Act, which establishes a federally subsidized health insurance program to be administered by the Secretary. 42 U.S.C. § 1395, *et seq.* ^{HN1} Part A of the Medicare Act provides insurance [**3] for hospital and related services. 42 U.S.C. § 1395c, *et seq.* Part B of the Medicare Act establishes a voluntary program of supplemental medical insurance covering expenses not covered by the Part A program, such as reasonable charges for physicians' services, medical supplies, and laboratory tests. 42 U.S.C. § 1395j, *et seq.* The Medicare Act authorizes the Secretary to determine what claims are covered by the Act "in accordance with the regulations prescribed by him." 42 U.S.C. § 1395ff(a). Payments for Part B expenses are made by private insurance carriers under contract to the Department of Health and Human Services, 42 U.S.C. § 1395u. These carriers are authorized to administer the payment of qualifying claims and act on behalf of the Secretary in this regard. *Id.* The Secretary authorizes regional carriers to administer claims for durable medical equipment, prosthetic and orthotics and other supplies. 42 U.S.C. § 1395m(a)(12). The carrier determines whether the item is covered and the level of reimbursement in accordance with regulatory guidelines. [**4] 42 U.S.C. §§ 1395m(h) and 1395u(a).

Plaintiff DeWall Enterprises, Inc. manufactures a spinal orthosis, or orthotic body jacket/back brace called the "DeWall Posture Protector" that consists of a custom-fitted molded plastic jacket or vest with elastic inserts. Defendants are the Secretary of Health and Human Services and several regional carriers who administer claims for such equipment under Medicare Part B.

A. Facts

In 1991 DeWall became a "participating supplier of durable medical equipment" under Part B of the Medicare program under 42 U.S.C. section 1395u(h). As such, he was provided with the Durable Medical Equipment Prosthetics, Orthotics and Supplies Supplier Manual (Manual). DeWall submitted claims to Medicare's Health Care Financing Administration (HCFA) ² using the HCFA Common Procedure Coding System. The codes are established by the HCFA in consultation with insurer groups. Code L0430 is described in the Manual as: "a [thoracic-lumbar support orthosis], anterior-posterior-lateral control, with interface material, custom-fitted." Code L0300 is described as "Thoracic-lumbar-sacral-orthosis (TLSO), flexible (dorso-lumbar [**5] surgical support)." Code L0315 is described in the Manual as "TLSO flexible dorso-lumbar surgical support, elastic type, with rigid posterior panel." The regional carriers determine what code is applicable to a given product. When DeWall began marketing its product in 1990, it was advised that its product fell under Code L0340. See Pl. Exs. 4, 12 at 7.

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² The HCFA is now known as the Centers for Medicare and Medicaid Services (CMS) but will be referred to in this case as the HCFA.

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In September 1991, Adminastar, a regional carrier, denied a claim for the DeWall posture protector submitted under Code L0430. Adminastar suggested that Code L0315 be used for billing Medicare. See Pl. Ex. 12. DeWall contested this determination before a carrier-appointed hearing officer, who determined that L0430 was, in fact, the proper code. *Id.* at 7.

In August 1995, another regional carrier, Cigna, advised DeWall that it had determined [*995] that the DeWall posture had been "billed using incorrect codes" and sought reimbursement [**6]

of over \$ 445,000 in alleged Medicare overpayments. See Pl. Ex. 5. DeWall sought review and, after a Medicare Part B hearing, Cigna determined that "no reimbursement can be made for the DeWall Posture Protector using the procedure codes that DeWall is currently billing under." *Id.* DeWall then requested a hearing before an administrative law judge. A hearing was held before ALJ Robert H. Burgess on April 10, 1996. *Id.* The ALJ issued his decision on April 13, 1997. *Id.*

The issue presented to the ALJ was "whether Medicare claims submitted by DeWall between 1990 and 1995 were properly coded, pursuant to . . . the Medicare carrier's Manual." *Id.* at 2. The ALJ "could find no substantial evidence" showing that DeWall had "failed to provide a body jacket having the essential characteristics contemplated by code L0430." *Id.* at 3. Accordingly, the ALJ found that "DeWall properly billed the basic device under L0430." Pl. Ex. 5. The secretary did not appeal that determination.³

----- Footnotes -----

³ The record further shows that Cigna failed to pay approximately \$ 170,000 worth of claims following the decision of ALJ Burgess. United States Senator Chuck Hagel intervened on DeWall's behalf requesting immediate attention to the matter, noting "the money is needed immediately to prevent closing of his company as Mr. DeWall has exhausted his ability to borrow additional funds during this year-long dispute as to the correct HCPCS coding for the DeWall Posture Protector." See Pl. Ex. 7.

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[**7] In October 1995, Palmetto, as the regional carrier, advised DeWall that certain L0300 codes should be used to bill Medicare, rather than L0430. See Pl. Ex. 12 at 8-9. DeWall then applied to the HCPCS Alpha-numeric panel for the creation and issuance of a new HCPCS code for the device. That request was denied, but the regional carrier advised DeWall and others that the device had been reviewed and that L0430 was the proper code. See Pl. Exs. 9, 12 at 10-11. In February 1996, Palmetto issued a memorandum noting that its regional administrator's "decision still remains to code L0430." See Pl. Ex. 8.

Meanwhile, Palmetto had conducted an audit in 1995 and had determined that DeWall had been overpaid \$ 101,000 for billing under an improper code. See Pl. Ex. 12 at 8-11. DeWall requested review by Palmetto and the overpayment determination was overturned. *Id.* at 9. The medical review director found that the claims had been correctly billed under code L0430 and found that recoupment of overpayment was not warranted. See Pl. Ex. 12 at 8-11, Pl. Ex. 10.

On January 11, 1996, regional carrier Adminastar determined that L0430 was not the proper code and demanded repayment of \$ [**8] 60,000 from DeWall. DeWall again requested an administrative hearing before an ALJ. See Pl. Ex. 11. At the hearing the issues presented were: 1) whether DeWall knowingly used improper billing codes from January 1993 through July 1995; and 2) whether, if DeWall had not knowingly used improper billing codes, whether DeWall was otherwise entitled to receive the full amount from Adminastar. *Id.* at 1.

In a sharply worded opinion, harshly critical of the regional carriers involved, ALJ Byron A. Samuelson found, "the Appellant did, in fact, use the correct billing code for its products and did not engage in any fraudulent billing practices." *Id.* at 6. The ALJ noted, "remarkably," that the regional carrier had failed to refund \$ 60,000 to DeWall, had denied DeWall a hearing, had then adjusted the overpayment demand, again without a [*996] hearing, and continued to wrongfully withhold DeWall's funds. *Id.* at 4. Again, the secretary did not appeal this determination.

In May 1998, Palmetto again requested a refund for overpayment to DeWall in the amount of \$ 64,000. DeWall again sought review before an administrative law judge. In October 2000, ALJ Emily Cameron Shattil issued her opinion. [**9] Pl. Ex. 12. The general issue was whether Medicare had overpaid DeWall and the amount of the overpayment, and "the specific issue is whether DeWall properly coded its back brace when it filed claims for payment by Medicare." *Id.* at 1. Noting that "the descriptions for Codes L0315 and L0430 are materially unchanged from July 1995 through autumn 1998," the ALJ found that "the plain language of the [Durable Medical

Equipment Prosthetic Orthotic Supplies] Supplier Manuals and Revisions supports the finding that DeWall properly used L0430 in claims for Medicare payment." *Id.* at 3. The ALJ further noted that "DeWall has now established in four separate instances that the proper code is being used, but this has been at the cost of nearly destroying his company . . . this result does not advance the purposes of the Medicare program." *Id.* at 13. The Secretary did not appeal this determination.

In the most recent chapter of this saga, DeWall was informed by letter dated January 25, 2001, that a Coding Verification Re-Review had been initiated. Pl. Ex. 14. On April 9, 2001, DeWall was informed by the HCFA, via its intermediary, Palmetto, that the proper code for Medicare billing [**10] on the DeWall Posture Protector was L0300 or L0999 (miscellaneous). Pl. Ex. 15. The letter informed DeWall that if he disagreed with the decision, he could apply through the Alpha-numeric workgroup for a new code for the product. *Id.* In a letter dated July 6, 2001, the Secretary rejected DeWall's challenge to the recoding in reliance on the ALJ decisions by stating that the decisions "are not precedent-setting." Pl. Ex. 17. DeWall then filed this action for declaratory and injunctive relief.

In response, the Secretary first contends that this court lacks jurisdiction. He further argues that the action is premature because DeWall has not filed a claim that has been denied. He also argues that DeWall has not presented evidence to warrant injunctive relief. In support of the motion, the Secretary has submitted evidence showing that, in 1999 the Office of the Inspector General (OIG) issued a report entitled "Medicare Payments for Orthotic Body Jackets," for the purpose of "determining whether or not Medicare inappropriately pays for orthotic body jackets under Code L0430." Def. Ex. 1 attached to the Declaration of Jennifer Hutter. The OIG found in its report that "lack of uniformity [**11] and standardization may account for some upcoding," noting that "the complex Medicare coding system combined with vague, outdated guidance has created a lack of uniformity and standardization in coding." *Id.* at 10. It recommended that "the HCFA should review and revise the Medicare Coding Guidelines." *Id.* at 16. The American Orthotic and Prosthetic Association, invited to comment, suggested a revised definition of "body jacket" for the coding guidelines. *Id.* at 31. The Health Care Financing Administration declined to follow the recommendations of the OIG to revise the coding guidelines, and instead instructed the regional carriers to compile product lists. *Id.* at 24. The HCFA noted, "we do not believe it is feasible for HCFA and the AOPA to formally enter into a joint effort to develop brace guidelines on brace codes. The requirements of the Federal Advisory Committee Act require federal agencies to conduct any [*997] consultations with outside organizations in an open forum. As a result, if we work with AOPA to develop guidelines, it may be necessary for us to work with other groups that may have differing views than AOPA on what constitutes appropriate coding guidance." [**12] *Id.*

In order to compile such a product list, the regional carrier requested information from the top 30 suppliers billing under L0430. DeWall is not one of these top suppliers. In her declaration, Jennifer Hutter, who oversees all product reviews, acknowledged that since 1995, the regional carriers had coded one aspect of the DeWall device as L0430. Def. Ex., Declaration of Jennifer Hutter, at P 14. In its review, it requested and obtained further information about the device from DeWall and then, in consensus with the four regional carriers, coded DeWall's device as either L0430 or L0999 (miscellaneous). *Id.* at P 19. In her declaration, Ms. Hutter declares that she agrees with the consensus coding of L0300 for the DeWall device. *Id.* at P 22. Hutter states that the DeWall product cannot be coded L0430 because it is "not a molded body jacket," noting that "it does have molded plastic pieces, but does not provide full circumferential coverage with a rigid component." *Id.* at P 21.

II. DISCUSSION

A. Motion to Dismiss - Subject Matter Jurisdiction

DeWall premises jurisdiction on 28 U.S.C. § 1331 (federal question jurisdiction) [**13] and 28 U.S.C. § 1361 (mandamus jurisdiction), asserting that he has been denied constitutional rights to due process under the Fifth Amendment. He further contends that he has exhausted

administrative remedies so as to invoke jurisdiction under 42 U.S.C. §§ 405(g) and 1395ii (the Social Security and Medicare Acts).

In his motion to dismiss, the Secretary asserts that this court lacks subject matter jurisdiction because exhaustion of administrative remedies is a jurisdictional prerequisite to suit under the Medicare statute. It asserts that, "although it is unclear from the face of the complaint which action the plaintiff is challenging, it appears to be the July 6, 2001 decision by the agency not to classify the DeWall device as L0430." The Secretary contends that the challenge will be ripe for review under the Medicare statute only after the plaintiff has actually been refused payment for a claim under that code and has challenged that refusal through the administrative process. ⁴ It further argues that mandamus jurisdiction is unavailable for claims arising under the Medicare statute except as provided in that statute.

- - - - - Footnotes - - - - -

4 In connection with this argument, the Secretary contends that such an avenue of review is available to DeWall and points to DeWall's familiarity with such administrative procedures based on his past appeals.

- - - - - End Footnotes - - - - -

[**14] ~~HN2~~ The Social Security Act provides for judicial review in federal district court of "any final decision of the [Secretary] made after a hearing. . . ." 42 U.S.C. § 405(g). Section 405(g), as adapted to the Medicare Act by 42 U.S.C. § 1395ff(b)(1), creates federal jurisdiction over final agency decisions in administrative Medicare appeals. *Midland Psychiatric Assoc., Inc. v. United States*, 145 F.3d 1000, 1003 (8th Cir. 1998). A related provision, 42 U.S.C. § 405(h), limits judicial review as follows: "no finding of fact or decision of [the Secretary] shall be reviewed by any person, tribunal, or governmental agency except as herein provided" and no action against the Secretary "shall be brought under section 1331 . . . of title 28 to recover on any claim arising under" the Social Security Act. 42 U.S.C. § 405(h). Section 1395ii makes [*998] § 405(h) applicable to the Medicare Act "to the same extent as" it applies to the Social Security Act. 42 U.S.C. § 1395ii.

~~HN3~~ The provisions of 42 U.S.C. § 405(h), as incorporated into the Medicare ^[**15] Act through § 1395ii, thus operate as a complete bar to federal question jurisdiction for claims under the Medicare Act unless "application of 405(h) would not simply channel review through the agency, but would mean no review at all." *Shalala v. Illinois Council on Long Term Care, Inc.*, 529 U.S. 1, 16, 146 L. Ed. 2d 1, 120 S. Ct. 1084 (2000) (clarifying the scope of explaining the exception to the 405(h) bar carved out in *Bowen v. Michigan Academy of Family Physicians*, 476 U.S. 667, 679-81, 90 L. Ed. 2d 623, 106 S. Ct. 2133 (1986)). Accordingly, 1395ii will not be interpreted to apply the statutory bar of § 405(h) where application of § 405(h) would foreclose review. *Id.*, 529 u.s. at 19 (noting "§ 1395ii is a channeling requirement, not a foreclosure provision"). In order to determine whether this narrow exception applies, the court must determine whether a claimant is simply being required to seek review first through the agency or is being denied altogether the opportunity for judicial review. *See Cathedral Rock of North College Hill v. Shalala*, 223 F.3d 354, 361 (6th Cir. 2000).

The court finds that this is a case where an aggrieved ^[**16] claimant is not simply required to seek administrative review in the first instance; he is being denied an opportunity for meaningful review. *See, e.g., McNary v. Haitian Refugee Ctr., Inc.* 498 U.S. 479, 497, 112 L. Ed. 2d 1005, 111 S. Ct. 888 (1991) (finding agency practice that ensured review of INS actions only if an alien voluntarily surrendered himself for deportation tantamount to a complete denial of judicial review for most undocumented aliens). DeWall has sought and obtained numerous adjudications in his favor on the exact issue now before the court. It is uncontroverted that neither the device at issue nor the code definitions have changed since these adjudications. The Secretary has not challenged the determinations through the appeals process available to it, but has simply ignored the determinations. Under this system, district court review is available only if DeWall loses. By failing to appeal adverse decisions, but then refusing to follow the dictates of those decisions, the

Secretary has, in practice, denied any judicial review to DeWall.

The facts presented here, spanning eleven years of litigation, amount to a total preclusion of review and not [**17] a mere postponement--these are not the "potentially isolated instances of inconvenience sometimes associated with the postponement of review." See *Illinois Council*, 529 U.S. at 23. The Secretary admits that there is nothing to prevent the same thing from happening again should DeWall follow administrative procedures in connection with any potential claims.⁵ DeWall is caught in an endless loop wherein he achieves an illusory victory in administrative proceedings but has no recourse to enforce that victory.

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⁵ Moreover, DeWall contends he is constrained from filing a claim under Code L0430 by the possibility of inviting prosecution for Medicare fraud. The Secretary stated at the hearing that DeWall could "probably" assert that there was a good faith dispute about the issue, but the court understands DeWall's reluctance to pursue the tactic.

----- End Footnotes-----

The circumstances presented in this case show that DeWall has been denied review and that invocation of federal question jurisdiction is proper, even absent [**18] exhaustion of administrative remedies. The jurisdictional bar of 405(h) does not apply to DeWall's claim and this court has jurisdiction [**999] under 28 U.S.C. § 1331. See, e.g., *Furlong*, 238 F.3d 227 at 234-35.⁶

----- Footnotes -----

⁶ The Secretary's reliance on *Hatcher v. Heckler*, 772 F.2d 427, 432 (8th Cir. 1985) as support for the proposition that this court lacks jurisdiction is misplaced. *Hatcher* applied to the Medicare Part B payments statute before it was amended. See *Illinois Council*, 529 U.S. at 38 n.7 (J. Thomas, dissenting) ("Congress amended § 1395ff after *Michigan Academy* to make express provision for administrative and judicial review of Part B benefits claims). See also, *Furlong*, 238 F.3d at 232 ("the Medicare Act was amended in 1987 to afford individuals challenging Part A determinations the same appeals procedures as individuals challenging Part A determinations"). The Secretary's reliance on *Painter v. Shalala*, 97 F.3d 1351 (10th Cir. 1996), is similarly inapposite as it is premised on specific statutory language not applicable to this case. *Id.* at 1356.

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[**19] Alternatively, even if jurisdiction is not premised on section 1331, the court finds DeWall can show exhaustion sufficient to invoke the jurisdiction of this court under 42 U.S.C. § 405(g). **HN4** Subject matter jurisdiction based upon exhaustion of administrative remedies is a question of law. *Bueford v. Resolution Trust Corp.*, 991 F.2d 481, 484 (8th Cir. 1993). **HN5** By granting the right to obtain judicial review of any final decision in section 405(g), the statute makes it clear that federal judicial review of Medicare reimbursement decisions is available once the Secretary renders a final decision. *Heckler v. Ringer*, 466 U.S. 602, 605, 80 L. Ed. 2d 622, 104 S. Ct. 2013 (1984) ("judicial review of claims arising under the Medicare Act is available only after the Secretary renders a 'final decision' on the claim"). Generally, a provider who fails to exhaust its administrative remedies will be precluded from seeking relief in federal court. See *Weinberger v. Salfi*, 422 U.S. 749, 764, 45 L. Ed. 2d 522, 95 S. Ct. 2457 (1975). Exhaustion is required in order to prevent premature interference with agency processes, to permit [**20] the agency to function efficiently and so that it may have an opportunity to correct its own errors, to afford the parties and the courts the benefit of its experience and expertise, and to compile a record which is adequate for judicial review. *In Home Health, Inc. v. Shalala*, 272 F.3d 554, 559-60 (8th Cir. 2001).

HN6 Finality, for purposes of 405(g), has two components: a nonwaivable requirement that a claim be presented for administrative review, and a waivable requirement that all administrative remedies be fully pursued. *Midland Psychiatric*, 145 F.3d at 1003. Waiver of exhaustion allows an administrative claim essentially to leapfrog over the otherwise required administrative procedures

and go straight to court. See, e.g., *Bowen v. City of New York*, 476 U.S. 467, 482, 90 L. Ed. 2d 462, 106 S. Ct. 2022 (1986). A claimant "may find an exception to the exhaustion requirement if: (1) the claim involves a legitimate constitutional claim, (2) irreparable harm would result from exhaustion, or (3) further administrative procedures would be futile." *In Home Health*, 272 F.3d at 559-60. ⁷

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⁷ *HN7* As a general matter of administrative law, it is well established that where the pursuit of administrative remedies would be futile, failure to exhaust such remedies should be excused. *Arkla Exploration Co. v. Texas Oil & Gas Corp.*, 734 F.2d 347, 355 (8th Cir.1984). In other words, if the agency's hostile attitude makes it impossible for the litigant to obtain the relief he seeks or renders it highly improbable that he will obtain such relief, exhaustion will not be required. *Id.* Also, "when an administrative appeal would be futile and little more than a formality, exhaustion will not be required." *Sioux Valley Hospital v. Bowen*, 792 F.2d 715, 724 (8th Cir.1986). Thus, "the doctrine of exhaustion of administrative remedies is not a strict jurisdictional requirement, but rather a flexible concept which must be tailored to the circumstances of the particular case." *South Dakota v. Andrus*, 614 F.2d 1190, 1192 n. 1 (8th Cir. 1980). The vitality of the "waiver of exhaustion" doctrine in the Social Security context, as part of the "entirely collateral" exception, survives *Illinois Council* when a litigant satisfies the nonwaivable and nonexcusable requirement of initial presentment of its claim to the appropriate agency. See *Cathedral Rock*, 223 F.3d at 367-68 (Batchelder, J., concurring).

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[**21] [*1000] This court has no trouble finding that DeWall has satisfied the "nonwaivable requirement that 'a claim for benefits shall have been presented to the Secretary.'" ⁸ *Heckler v. Ringer*, 466 U.S. at 617 (quoting *Mathews v. Eldridge*, 424 U.S. 319, 328, 47 L. Ed. 2d 18, 96 S. Ct. 893 (1976)). It is clear that DeWall has presented a colorable constitutional claim, has been irreparably injured, and further attempts at exhaustion will be futile. See, e.g., *Cathedral Rock*, 223 F.3d at 361.

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⁸ This can be achieved either by viewing DeWall's last abortive attempt at review, culminating in the Secretary's letter of July 6, 2001, as exhaustion, or by viewing the previous attempts, involving the exact same issue, as exhaustion. The court can also deem the Secretary's actions as a waiver by the Secretary in view of his admission that DeWall will likely face the same result on his next round of appeal.

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Additionally, under the facts of this case, the court finds mandamus jurisdiction [**22] is appropriate, if not compelled. *HNS* The federal mandamus statute, 28 U.S.C. § 1361, gives district courts power to "compel an officer of the United States or any agency thereof to perform a duty owed to the plaintiff," after exhaustion of all other avenues of relief, "if the duty is clear, certain, and nondiscretionary." See *Hatcher v. Heckler*, 772 F.2d 427, 432 (8th Cir.1985). Contrary to the Secretary's assertions, the Supreme Court has avoided deciding "whether mandamus relief is altogether unavailable to review claims under the Medicare Act." See, e.g., *Your Home Visiting Nurses' Servs., Inc. v. Shalala*, 525 U.S. 449, 457 n.3, 142 L. Ed. 2d 919, 119 S. Ct. 930 (1999). Mandamus jurisdiction in cases involving the Medicare Act, however, is approved in this circuit. *Belles v. Schweiker*, 720 F.2d 509, 512 (1983); see also *Schoolcraft v. Sullivan*, 971 F.2d 81, 87-88 (8th Cir. 1992).

Although *HN9* the Secretary's duty to decide eligibility for an amount of payments under Part B of Medicare may be discretionary, see *Hatcher*, 772 F.2d at 432, the duties challenged in this case are not. [**23] DeWall challenges the Secretary's duty, absent an appeal of an ALJ's order, to follow the mandate of that order to a situation involving the same claimant, the same device and the same regulation. The facts in this case present a situation where "a party with the incentive to appeal an order has failed to do so at one stage, and seeks to ignore the order at another." *Furlong*, 238 F.3d at 235 n.4 (discussing applicability of the law of the case doctrine). At issue here is not the Secretary's duty to construe agency policy--it has already had three cracks at this--but to consistently apply that policy to claims involving the same claimant, the same device, and

the same definition of procedure code. Although the Secretary may be free to change that definition in its procedure code manual, until he does so, he is compelled to follow his earlier interpretations with respect to this plaintiff. The court thus finds mandamus jurisdiction is proper.

B. Motion for Preliminary Injunction/Mandamus

HN10 The extraordinary remedy of a preliminary injunction should not be granted unless the movant has demonstrated: (1) the threat of irreparable harm to it; (2) the state **[**24]** of the balance between this harm **[*1001]** and the injury that granting the injunction will inflict on other parties; (3) the probability that it will succeed on the merits; and (4) the public interest. *Dataphase Systems, Inc. v. C L Systems, Inc.*, 640 F.2d 109, 113-14 (8th Cir. 1981) (en banc). No single factor is determinative, although the failure to demonstrate the threat of irreparable harm is, by itself, a sufficient ground upon which to deny a preliminary injunction. See *Adam-Mellang v. Apartment Search, Inc.*, 96 F.3d 297, 299 (8th Cir. 1996); see also *Modern Computer Sys., Inc. v. Modern Banking Sys., Inc.*, 871 F.2d 734, 738 (8th Cir. 1989) (en banc).

Applying those factors, the court first finds that DeWall has shown irreparable harm. He has shown more than a mere economic injury. See Pl. Ex. 12 (cataloging injuries to DeWall). DeWall can point to an eleven-year history of the Secretary's recalcitrance in consistently following his own interpretation of his own regulations. At many points in this history, DeWall has been faced with economic ruin injury and the court finds that he should not, once again, be forced to face this specter.

[25]** With regard to probability of success on the merits, the court finds that DeWall has shown such probable success under several theories. The heart of DeWall's challenge is a due process challenge to the Secretary's actions, which can be characterized as the classic "run-around," in the eleven-year history of this case. Since it is outside the ambit of Section 405(h), the court would undertake the traditional due process analysis under *Mathews v. Eldridge*, 425 U.S. at 335. See *Furlong*, 238 F.3d at 236-38. Let it suffice to say that the facts presented thus far satisfy the *Dataphase* standard for a showing of success on that claim. DeWall has also made a preliminary showing that the actions of the Secretary can be characterized as arbitrary and capricious in violation of the Administrative Procedure Act.

The Secretary's assertions that the ALJ's decisions are not afforded any preclusive effect are without merit. ⁹ The cases cited by the Secretary do not stand for any such proposition. See *Warder v. Shalala*, 149 F.3d 73 (1st Cir. 1998) (finding a Medicare rule an interpretive rather than legislative rule), and *Wilkins v. Sullivan*, 889 F.2d 135 (7th Cir. 1989) **[**26]** (finding a clarification of a rule by the Secretary was not a "change of course"). Nothing in those cases suggests that the Secretary is not bound by the agency's earlier determinations vis-a-vis the same claimant, the same device, and an unchanged procedure code. Notably, this action does not involve a rule change by the Secretary. Accordingly, the Secretary's rule-making authority is not at issue. Whether based on law of the case principles or equitable estoppel, the Secretary is simply not free to inconsistently interpret its own rules and regulations and to continue to run a claimant through a never-ending gauntlet in pursuit of his rights. DeWall has shown he is caught in the ultimate "catch-22" and it is up to this court as a last resort to protect such a claimant and to prevent the sort of bureaucratic legerdemain--incompetence at the least and outright trickery at the most--presented in this case. ¹⁰

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⁹ The court regards the Secretary's argument that the Secretary cannot be bound by the ALJ's decision because he was not a party to the lawsuit as wholly specious. Under contract with the Secretary, regional carriers do the work of the government on the Secretary's behalf. *Midland Psychiatric Assoc.*, 145 F.3d at 1003-04. The court similarly rejects the Secretary's contention that the decisions of the ALJs are dicta. Each ALJ decision addressed the precise issue of propriety of procedure Code L0430. **[**27]**

¹⁰ The court is particularly offended by the Secretary's cavalier contention at oral argument characterizing DeWall's

eleven-year struggle as operating "below the Secretary's radar."

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[*1002] The court further finds that the balance of harms weighs in favor of DeWall. The Secretary cannot be harmed by a consistent interpretation of its own regulations. The evidence presented by the Secretary regarding the OIG report of upcoding of orthotic body jackets was not aimed at a situation like that presented by DeWall. See Pl. Ex. 1. The undisputed evidence shows that DeWall has shown good faith in its dealings with the Secretary, but there has been no showing of any reciprocal good faith.

Moreover, the court finds the public interest favors DeWall. See, e.g., *Hatcher*, 772 F.2d at 432 n.9 (commenting on "the uniformity of result obviously needed in such a massive system of claims determination."). Whatever the merits of protecting the assets of the Medicare Trust Fund, they do not extend to disregarding Constitutional rights in the process. Under the circumstances, the court will not require [**28] DeWall to give security under Fed. R. Civ. P. 65(c). There has been no showing of costs or damages that the Secretary may incur in the event it is determined he has been wrongfully enjoined.

III. CONCLUSION

Accordingly, the Secretary's motion to dismiss will be denied and DeWall's motion for a preliminary injunction will be granted.

IT IS ORDERED that:

1. Defendants' motion to dismiss, Filing No. 22, is denied.
2. Plaintiff's motion for a preliminary injunction and mandamus relief, Filing No. 2, is granted.
3. The defendants are ordered to accept, process and pay Medicare Part B claims for the provision of the "DeWall Posture Protector" under Code L0430 as the proper HCPCS code under the relevant provisions of the Durable Medical Equipment Prosthetics, Orthotics and Supplies Supplier Manual, until further order of this court.
4. Trial of the merits of this action will be expedited; the matter is referred to the magistrate for progression of the case.
5. No security is required under Fed R. Civ. P. 65(c).


DATED this 26 day of June, 2002.

BY THE COURT:

JOSEPH F. BATAILLON

United States [**29] District Judge

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