United States Court of Appeals For the First Circuit

No. 07-2476

PUERTO RICAN ASSOCIATION OF PHYSICAL MEDICINE AND REHABILITATION, INC.; DOCTORS MARIA PALOU, LAURA PLAZA AND MIGUEL CARDONA; AND PATIENTS ROSITA MENDOZA-VEGA AND JOHN DOE,

Plaintiffs, Appellants,

v.

UNITED STATES OF AMERICA; TRIPLE S OF PUERTO RICO; CENTERS FOR MEDICARE AND MEDICAID SERVICES; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES,

Defendants, Appellees.

APPEAL FROM THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF PUERTO RICO

[Hon. José Antonio Fusté, U.S. District Judge]

Before

Boudin, Chief Judge,

Lynch, Circuit Judge,

and Keenan, * Senior District Judge.

Rafael E. Silva-Almeyda with whom <u>Silva-Almeyda Law Offices</u>, <u>René Arrillaga-Armendáriz</u> and <u>Arrillaga & Arrillaga</u> were on brief for appellants.

<u>Marcus H. Christ, Jr.</u>, Office of the General Counsel, Department of Health and Human Services, with whom <u>Daniel Meron</u>, General Counsel, <u>Carol Bennett</u>, Acting Associate General Counsel,

*Of the Southern District of New York, sitting by designation.

<u>Jeffrey S. Bucholtz</u>, Acting Assistant Attorney General, <u>Rosa E.</u> <u>Rodríquez-Vélez</u>, United States Attorney, and <u>Barbara C. Biddle</u>, Appellate Staff, Civil Division, Department of Justice, were on brief for appellees.

March 26, 2008

BOUDIN, <u>Chief Judge</u>. The Puerto Rico Association of Physical Medicine and Rehabilitation ("PRAPMR") is a group of medical doctors practicing in Puerto Rico. It, and several doctors and patients, sued to challenge a regulation restricting Medicare reimbursement for physical therapy services. The district court dismissed the case, relying on statutory provisions that preclude all actions "brought under section 1331 or 1346 of Title 28 to recover on any claim arising under" the Medicare Act. 42 U.S.C. §§ 405(h), 1395ii (2000). This appeal followed.

The federal Medicare program has several components. At issue here is Medicare Part B, which offers voluntary supplemental health insurance for "aged and disabled individuals who elect to enroll under such program." 42 U.S.C. § 1395j. Enrolled beneficiaries are entitled to recover reimbursement (usually partial) for covered medical costs; they may alternatively assign reimbursement rights to their physicians or other health care providers, who may then pursue the claims. 42 C.F.R. § 422.574(b).

Among the medical costs covered by Medicare are those for services "furnished as an incident to a physician's professional service, of kinds which are commonly furnished in physicians' offices and are commonly either rendered without charge or included in the physicians' bills." 42 U.S.C. § 1395x(s)(2)(A). But under a regulation promulgated by the Secretary of Health and Human Services in 2004, physical therapy services provided in this

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"incident-to" fashion can only be reimbursed if the individual providing the therapy meets certain educational and training requirements. 42 C.F.R. §§ 410.60(a)(3)(iii), 484.4. The regulation means that medical doctors may no longer bill Medicare for physical therapy services provided in their offices by, for example, athletic trainers who lack the approved, specialized training in physical therapy.

The regulation implemented a statutory prohibition, enacted by Congress in 1997, that precludes payment for physical therapy services provided "incident to" a doctor's services unless such services "meet the standards and conditions" that the Secretary is authorized to impose to govern physical therapy services provided independently, <u>e.g.</u> in a physical therapist's private office. 42 U.S.C. § 1395y(a) (20); <u>see also id.</u> § 1395x(p). Essentially, the new regulations require that whether therapy is billed as "incident to" a doctor's services or as an independent medical service, those providing the therapy meet the same qualifications.

In March 2006, some eight months after the regulation took effect, PRAPMR submitted a self-styled "Administrative Appeal" to the Centers for Medicare and Medicaid Services ("CMS"), the agency that administers Medicare on behalf of the Secretary. The submission argued that the regulation was arbitrary, unauthorized by statute and unconstitutional; CMS responded, advising the

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doctors that their letter had "no legal bearing on CMS" and suggesting that they "pursue whatever other administrative processes are available." PRAPMR then filed this suit in Puerto Rico's federal district court, premised on federal question jurisdiction, 28 U.S.C. § 1331 (2000), seeking declaratory and injunctive relief on the same medley of statutory and constitutional grounds.

In dismissing the suit, the district court agreed with the agency that any challenge to the regulation must be channeled through a multi-step administrative review process before a federal court may pass on it. A patient or provider may, under a statutorily prescribed regime, seek administrative review wherever a claim for reimbursement for a service is rejected, 42 U.S.C. § 1395ff(b)(1)(A); and, if the agency outcome is adverse, obtain federal court review. <u>Id.</u> § 405(g). The district court ruling meant that the regulation could be challenged but only through this statutory "exhaustion of remedies" procedure.

There is no uniform rule governing when and how agency action can be judicially reviewed; the proper process depends, <u>inter alia</u>, on which agency is involved, what type of claim is pressed, statutory provisions and court-created doctrine. For example, courts have constructed doctrines requiring that administrative remedies be exhausted before judicial review is sought, <u>Myers v. Bethlehem Shipbuilding Corp.</u>, 303 U.S. 41, 50-51

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(1938), and that claims be "ripe" for review, <u>Abbott Labs.</u> v. <u>Gardner</u>, 387 U.S. 136, 148-49 (1967), although both rules are subject to multiple exceptions. <u>E.g.</u>, <u>McCarthy</u> v. <u>Madigan</u>, 503 U.S. 140, 147-48 (1992) (futility exception); <u>Abbott Labs.</u>, 387 U.S. at 149 (hardship exception).

In the case of the Medicare Act, Congress has enacted a statute that "reaches beyond ordinary administrative law principles of 'ripeness' and 'exhaustion of administrative remedies'." <u>Shalala v. Ill. Council on Long Term Care, Inc.</u>, 529 U.S. 1, 12 (2000). Under 42 U.S.C. § 405(h), which in terms relates to the Social Security program but is incorporated <u>mutatis mutandis</u> into the Medicare Act, <u>id.</u> § 1395ii, neither federal question nor federal defendant jurisdiction is available for suits "to recover on any claim arising under" the Act. Separate provisions, <u>id.</u> §§ 405(g), 1395ff(b)(1)(A), allow for judicial review once a specified agency appeals process is completed.

Were we writing on a blank slate, the scope of section 405(h) would raise interesting questions. But we are not: the Supreme Court has interpreted broadly the section 405(h) bar, holding that a claim "arises under" the Social Security or Medicare Act if "the standing and the substantive basis" for the claim derive from that statute. <u>Weinberger</u> v. <u>Salfi</u>, 422 U.S. 749, 760-61 (1975); <u>see also Heckler</u> v. <u>Ringer</u>, 466 U.S. 602, 615 (1984).

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The provision thus mandates the "'channeling' of virtually all legal attacks through the agency." <u>Ill. Council</u>, 529 U.S. at 13.

Although PRAPMR's suit challenges a regulation and does not directly request payment for a specific service, it seeks at its heart the extension of Medicare benefits; accordingly, it would appear barred by section 405(h) as construed by the Supreme Court. The regulation being challenged is simply a limitation on the claims that Medicare will pay and so foreshadows the denial of such claims. The government concedes that--if a specific claim is denied on account of the regulation--the regulation may be challenged in court on review of the denial of a specific claim after administrative remedies are exhausted. <u>See Ill. Council</u>, 529 U.S. at 23 (so holding).

PRAPMR responds with heavy reliance on the Supreme Court's decision in <u>Bowen</u> v. <u>Michigan Academy of Family Physicians</u>, 476 U.S. 667 (1986). When that case was decided, the Medicare Act did not provide for <u>any</u> judicial review of determinations made under Medicare Part B, and the Court refused to assume that Congress "intended no review at all of substantial statutory and constitutional challenges to the Secretary's administration" of that program. <u>Id.</u> at 680. Invoking the canon of constitutional avoidance, the Court distinguished "amount" challenges (<u>i.e.</u>, factbased challenges to particular decisions) from "methodology"

challenges (<u>i.e.</u>, legal attacks on statutes, regulations and the like), and permitted the latter to proceed directly to court. Id.

PRAPMR's claim is, under that dichotomy, a "methodology" attack. But only a few months after <u>Michigan Academy</u>, Congress provided explicitly that Part B determinations <u>can</u> be challenged in court after administrative remedies have been exhausted. Omnibus Budget Reconciliation Act of 1986, Pub. L. No. 99-509, § 9341(a)(1), (b), 100 Stat. 1874, 2037-38 (codified at 42 U.S.C. § 1395ff). So, as clarified in <u>Illinois Council</u>, <u>Michigan Academy</u> means only that section 405(h) does not apply if "its application to a particular category of cases . . . would not lead to a channeling of review through the agency, but would mean no review at all." Ill. Council, 529 U.S. 1, 17 (2000).¹

That PRAPMR seeks to challenge an administrative regulation rather than a particular factual determination thus does not matter. The precedents "foreclose distinctions based upon the 'potential future' versus the 'actual present' nature of the claim, the 'general legal' versus the 'fact-specific' nature of the

¹There was initial uncertainty as to whether the <u>Michigan</u> <u>Academy</u> exception retained its full force after the amendments. Most circuits said no, given that the decision's rationale had been entirely undermined, <u>see Fanning v. United States</u>, 346 F.3d 386, 397-98 (3d Cir. 2003), <u>cert. denied</u>, 542 U.S. 919 (2004), but one court insisted that "inferior courts are not authorized to declare the reasoning of [Supreme Court] opinions outdated." <u>Ill. Council on Long Term Care, Inc. v. Shalala</u>, 143 F.3d 1072, 1076 (7th Cir. 1998). On review, that uncertainty was resolved by the Supreme Court.

challenge," and so on. <u>Ill. Council</u>, 529 U.S. at 13-14. What does matter is whether PRAPMR can, at some point, using some process, obtain judicial review of its claims. <u>Accord Am. Chiropractic</u> <u>Assoc., Inc.</u> v. <u>Leavitt</u>, 431 F.3d 812, 816 (D.C. Cir. 2005). PRAPMR insists that barring its federal law suit would mean "no review at all" for its claims, <u>Ill. Council</u>, 529 U.S. at 17, "because there has been no payment claim denials yet." But this is not a denial of review, merely its postponement until a payment claim has been denied.

Appellants complain that, in the meanwhile, the supply of therapists may dry up, and doctors may be unwilling to supply (or patients unwilling to accept) services that do not qualify, fearing that they may be asked to reimburse the agency later. But the doctors and therapists certainly have ample economic incentive to frame and support a test case. Appellants could provide service to a couple of patients through therapists who do not qualify, submit claims for reimbursement, and candidly admit in their filings that their only challenge is to the regulation.

We therefore need not decide whether or when irreparable injury "turns what appears to be simply a channeling requirement into <u>complete</u> preclusion of judicial review," <u>Ill. Council</u>, 529 U.S. at 22-23, nor whether <u>Illinois Council</u>'s exception applies to statutory as well as constitutional claims; but it should be remembered that the litigation process itself imposes risks and

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unrecoverable costs and there is little doubt that Congress can, in the context of a complex administrative scheme, preclude preenforcement challenges without creating a hardship exception. <u>Cf.</u> <u>Nat'l Private Truck Council, Inc.</u> v. <u>Okla. Tax Comm'n</u>, 515 U.S. 582, 591 (1995) (no federal right to declaratory or injunctive relief from unconstitutional state taxes if state law offers <u>ex</u> <u>post</u> refund).

Further, the problem of irreparable injury does not only affect one side. It is likely that section 405's insistence on exhaustion owes something to the fear that the Secretary's decisions restricting payment might otherwise be promiscuously enjoined at great cost to the government. Channeling review makes certain that the agency determinations are thoroughly developed through the administrative process and that payments are not compelled until judicial review has been undertaken.

At oral argument, PRAPMR suggested that the agency was approving noncompliant claims notwithstanding the regulation, but government counsel said he was unaware of any program of deliberate non-enforcement. We need not consider whether a pattern of conduct designed to frustrate test cases brought to challenge the regulation would trigger the "no review at all" exception of <u>Illinois Council</u>; neither in the district court nor on appeal have the appellants offered anything more than speculation or even provided the legal analysis necessary to develop such an argument.

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Finally, PRAPMR argues that the submission of its selfstyled "Administrative Appeal" to the agency should somehow change the analysis. But it concedes that it has not appealed any Medicare claim denial, and that is the only way, under the statute and regulations, 42 U.S.C. § 1395ff(b)(1)(A); 42 C.F.R. § 405.801, to initiate the multi-step appeal process that culminates in federal court review. We add only that it is in the government's interest, as well as the appellants', to get such a claim served up promptly.

Affirmed.