No. 98-1109

IN THE SUPREME COURT OF THE UNITED STATES

DONNA A. SHALALA, SECRETARY OF HEALTH AND HUMAN SERVICES, ET AL.,
Petitioner

v.

ILLINOIS COUNCIL ON LONG TREM CARE, INC.,
Respondent

BRIEF FOR THE AMERICAN HOSPITAL ASSOCIATION AS AMICUS CURIAE IN SUPPORT OF RESPONDENT ILLINOIS COUNCIL ON LONG TERM CARE, INC.

Filed August 23, 1999

QUESTION PRESENTED

Whether 42 U.S.C. § 405(h), incorporated into the Medicare Act by 42 U.S.C. § 1395ii, eliminates jurisdiction under 28 U.S.C. §§ 1331 and 1346 over an action asserting constitutional and statutory challenges to Medicare regulations where the contentions alleged cannot be considered in the administrative review process and are collateral to an individual claim.

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INTEREST OF THE AMICUS CURIAE

The American Hospital Association ("AHA") files this *amicus curiae* brief in support of Respondent Illinois Council on Long Term Care, Inc. ("Long Term Care").[1] AHA, a not-for-profit association founded in 1898, is the primary national membership organization for hospitals and health care institutions in the United States. Its membership includes approximately 4,500 hospitals and other institutions, as well as over 35,000 personal members. AHA's mission is to advance the health of individuals and communities; the AHA leads, represents, and serves health care provider organizations that are accountable to the community and committed to health improvement.

This case asks the Court to construe the Health Care for the Aged Act, commonly known as the Medicare Act, 42 U.S.C. § 1395, *et seq.* Virtually every institutional member of AHA is a Medicare provider. Many members provide long-term care services in addition to patient acute care. The purpose behind Medicare closely tracks the mission of AHA. The purpose of Part A of the Medicare Act is to provide "basic protection against the costs of hospital, related post-hospital, home health services, and hospice care" for those persons over sixty-five, disabled over twenty-four months, or suffering from end stage renal disease. 42 U.S.C. § 1395c. The purpose of Part B is described as "a voluntary insurance program to provide

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[1] AHA has obtained the written consent of the parties pursuant to Supreme Court Rule 37.2(a) and has filed copies of letters evidencing such consent together with this Brief.

Pursuant to Supreme Court Rule 37.6, AHA states that counsel for AHA authored this Brief in whole. No person or entity, other than AHA and its members, has made a monetary contribution to the preparation or submission of the Brief.

medical insurance benefits" for elderly and disabled individuals. 42 U.S.C. § 1395g. Given the similarities between the mission of AHA and the purpose of Medicare, AHA has a deeply-rooted interest in ensuring that the Medicare Act is correctly interpreted and applied.

Moreover, as participants in the Medicare program, AHA's members must comply with its regulatory standards for health, safety, and quality of patient care. AHA's members may therefore find themselves subject to enforcement measures taken by the Secretary ("Secretary") of Health and Human Services ("HHS"). If she finds a violation, the Secretary may impose civil money penalties, deny further reimbursement for treating Medicare beneficiaries, and terminate a hospital's right to participate in Medicare. Therefore, it is imperative to AHA's members that the Secretary administer the Medicare Act in a manner that is clear, fair, and faithful to the intent of Congress.

STATEMENT OF THE CASE

This case concerns whether hospitals, nursing homes, and other participants in the Medicare program may seek pre-enforcement relief in federal court from facially invalid rules and regulations promulgated under the Medicare Act, or whether they must endure a long, complex, and costly administrative review process, entirely unrelated to their constitutional and statutory claims, before doing so. The Medicare program represents a massive undertaking by the federal government. Medicare's beneficiaries number in excess of 38 million individuals, representing approximately fourteen percent of the population of the United States. Timothy S. Jost, *Governing Medicare*, 51 ADMIN. L. REV. 39, 40 (1999). Hundreds of managed care plans; thousands of hospitals, skilled nursing facilities, home health agencies, and hospices; and

hundreds of thousands of physicians and other practitioners provide health care services for these beneficiaries. *Id.* The Secretary runs the Medicare program through the Health Care Financing Administration ("HCFA"). In 1996, HCFA administered a Medicare budget of $196.6 billion. *Id.* at 82.

The Medicare program consists of two separate insurance programs. "Hospital Insurance," established by Part A of Title XVIII, provides certain benefits covering inpatient hospital, nursing facility, home health, and hospice services. "Supplementary Medical Insurance," established by Part B of Title XVIII, provides benefits in the areas of outpatient hospital visits, physician services, durable medical equipment, and diagnostic tests.

The Medicare Act itself is highly intricate and complex, currently consuming 430 pages in the United States Code. The statute and the regulations promulgated by the Secretary under that statute comprise a complicated and often seemingly contradictory maze for the reimbursement of covered health care services to Medicare beneficiaries. As one court of appeals commented, the statute and regulations of the Medicare program "are among the most completely impenetrable texts within human experience." *Rehabilitation Ass'n of Virginia, Inc. v. Kozlowski*, 42 F.3d 1444, 1450 (4th Cir. 1994).

In order to be eligible to receive payment for services rendered to Medicare beneficiaries, health care providers, such as hospitals, must enter into provider agreements and satisfy "Conditions for Participation" relating to beneficiary health, safety, and care. 42 U.S.C. § 1395x(e); 42 C.F.R. Part 482. The Secretary enters into agreements with "state survey agencies" ("SSA") to conduct inspections or "surveys" of participating hospitals to determine compliance with the Conditions of Participation and other

requirements.[2] *See* 42 U.S.C. § 1395aa. Although the SSA conducts the survey and makes a recommendation, the Secretary renders the final determination regarding certification. The Secretary has published instructions that an SSA must employ to conduct these surveys, including a detailed set of procedures known as the "State Operations Manual" ("SOM"). If the SSA finds noncompliance with a Condition of Participation – in other words, a deficiency – it reports that fact in writing to the facility in a "Statement of Deficiencies." The regulations require that a facility submit a written "Plan of Correction" that indicates the corrective action that the facility plans to take for each deficiency. 42 C.F.R. § 488.28. The SOM provides for the "monitoring" of a hospital to determine whether the hospital actually implements the corrective action and whether the corrective action is effective. *See* SOM § 3254.

When the deficiencies pose an "immediate and serious threat to patient health or safety," SSA monitoring begins immediately and termination procedures commence. *See* SOM § 3274; *see also* 42 C.F.R. § 489.53. A finding of an "immediate and serious threat to patient health or safety" is essential to this "fast-track" termination. No statute, however, defines this standard, although the SOM contains instructions to SSAs regarding the finding. SOM § 3010A. The Secretary's regulations provide for an opportunity to appeal HCFA's decision to an administrative law judge ("ALJ"). *See* 42 C.F.R. § 498.1, *et seq*. *See generally* 42 U.S.C. § 1395cc(h); 42 C.F.R.

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[2] Under certain circumstances, accreditation by certain third-party organizations can substitute for this survey process. 42 U.S.C. §§ 1395x(e), 1395bb; 42 C.F.R. § 488.5. Many hospitals participate in the Medicare program through accreditation by the Joint Commission on Accreditation of Healthcare Organizations.

§ 489.53(d). However, any relief obtained by the provider through an appeal often comes too late – after the Secretary's actions have caused irreparable injury and sometimes after a facility has been closed. A hearing on the merits often is not available until after the termination has been completed.

Moreover, during this hearing process, the ALJ cannot entertain constitutional or statutory challenges to the Secretary's rules and regulations, or challenges to the propriety of the hearing and appeal process itself. *See Bowen v. Michigan Academy of Family Physicians*, 476 U.S. 667, 676 n.6 (1986) (Medicare manual specifically prohibits administrative law judge from commenting on constitutionality of Medicare Act or regulations); HHS CARRIER'S MANUAL § 12016 ("The HO [Hearing Officer] may not overrule the provisions of law or interpret them in a way different than HCFA does when he disagrees with their intent; nor may he use hearing decisions as a vehicle for commentary upon the legality, constitutional or otherwise, of any provision of the Act or regulations."); Petitioner's Brief at 44-45 ("constitutional contentions" and "challenges to the Secretary's regulations, ordinarily would not be the subject of an administrative hearing. Neither the Department Appeals Board nor individual ALJs are free to depart from statutory and regulatory requirements."). The administrative review process accordingly does not result in the creation of any "administrative record" for such claims.

In 1987, Congress amended the Social Security Act with the Omnibus Budget Reconciliation Act ("ORBA"), Pub. L. No. 100-203 (1987). The amendments, among other things, require stricter guidelines and penalties for nursing facilities not satisfying minimum health and safety standards. 42 U.S.C. § 1395i-3. In this case, Long

Term Care points out that after the Secretary implemented these new regulations, the percentage of nursing homes in Illinois found out of compliance with the requirements of Medicare and Medicaid jumped from 6% to nearly 70%. (Respondent's Brief in Opposition ("Res. Br.") at 2) Long Term Care alleges that this drastic change occurred because the new regulations are vague and leave too much discretion to the individual inspectors. (*Id.*) The Secretary has also proposed voluminous regulations concerning the conditions for the participation of hospitals. *See* 62 Fed. Reg. 66726 (Dec. 19, 1997). If implemented, hospitals and the trade associations that represent them, like the AHA, likewise may have constitutional or statutory challenges to those regulations.

Once they become eligible to participate in Medicare, providers submit claims for reimbursement for the provision of health care services. HCFA does not itself evaluate the millions of claims submitted by Medicare providers; federal contractors administer most of the program. "Fiscal Intermediaries," generally state Blue Cross programs, process and pay claims under Part A, and "Carriers," usually insurance companies, process and pay Part B claims. 42 U.S.C. §§ 1395u(a) to (b), 1395u(b)(3), 1395ff; 42 C.F.R. §§ 405.710, 405.821 to .850. A hospital or other provider dissatisfied by an adverse benefit determination by a fiscal intermediary or carrier concerning a Part A claim in excess of $1000 or a Part B claim in excess of $500, respectively, is entitled to a hearing before a hearing officer designated by the fiscal intermediary or carrier. 42 U.S.C. § 1395ff(a); 42 C.F.R. §§ 405.1809 to .1833 (intermediary hearing procedures), 42 C.F.R. §§ 405.801 to .874 (Part B appeals); *see also* 42 C.F.R. §§ 405.724, 405.856, 405.1875, 417.632 (regarding appeal rights to HHS's Departmental Appeals Board). Providers must submit

disputed Part A claims in excess of $10,000 to the Provider Reimbursement Review Board ("PRRB"). 42 U.S.C. § 1395oo; 42 C.F.R. §§ 405.1835 to .1873. HCFA's Administrator, in his or her sole discretion, may review any decision rendered by the PRRB. 42 C.F.R. § 405.1875; *see infra* discussion regarding the average cost and length of a PRRB appeal. Once the Secretary has reached a "final decision" with respect to either an eligibility or amount determination, Section 405(g) authorizes a health care provider to seek review by initiating an action in federal district court. 42 U.S.C. § 405(g).

SUMMARY OF ARGUMENT

As this Court has recognized, the Medicare Act involves a "reticulated statutory scheme," which comprehensively details the rights and duties of the beneficiaries, providers, and other participants in the program. *Bowen v. Michigan Academy of Family Physicians*, 476 U.S. 667, 675 (1986). When the Act prescribes an exclusive administrative mechanism for reviewing the Secretary's decisions, as it admittedly does for disputes involving individual benefit determinations, it says so explicitly. *See* 42 U.S.C. §§ 1395h, 1395u(a) to (b), 1395ff, 1395oo. However, as this Court recognized in *Michigan Academy*, nothing in the language of the Medicare Act, its legislative history, or its "statutory scheme" bars a constitutional or statutory challenge to the Secretary's rules and regulations where the challenge is unrelated, or "collateral," to an individual benefit determination.

A. Section 405(h) of the Social Security Act, 42 U.S.C. § 405(h), incorporated into the Medicare Act by 42 U.S.C. §§ 1395cc, 1395ff, and 1395ii, sets forth the limitations that Congress placed on judicial review under the Medicare Act. By its plain terms, Section 405(h) does not place any limitation on challenges to a regulation not

connected with a hearing on an individual claim for benefits under the Medicare Act. The legislative history of the 1965 Medicare Act and its amendments reinforce this conclusion and makes clear that Congress created an administrative review process to handle only the "trivial" and "quite minor" matters of individual eligibility and benefit determinations, which might otherwise flood the Courts. Congress did not intend for the administrative review process to address constitutional and statutory challenges to regulations that might affect substantial portions, or even all, of the health care field.

B. The Court should adhere to its holding in *Bowen v. Michigan Academy of Family Physicians*, 476 U.S. 667 (1986). In that case, the Court held that the language and legislative history of the Medicare Act and its amendments showed that Congress intended only to foreclose review of individual "amount determinations" and did not intend to bar review of "substantial statutory and constitutional challenges to the Secretary's administration" of the Medicare program. 476 U.S. at 680. *Michigan Academy* did not create a judicial "exception" to the statute, which this Court can now repeal, but instead determined Congress's intent concerning the Medicare Act. The amendments that Congress made to the Medicare Act in 1986 did nothing to change the relevant statutory language or legislative history. Congress's inaction in the face of the Court's decision in *Michigan Academy* suggests that the Court correctly determined Congress's intent in that case.

C. Public policy strongly supports reaffirmation of the Court's holding in *Michigan Academy*. Requiring constitutional and statutory challenges to the Secretary's regulations to endure the long, complex, and costly administrative review process serves only to allow the government to engage in a "war of attrition" to avoid

resolution of those claims. The administrative review process will not permit the development of a relevant factual record or allow for the refinement of issues because administrative hearing bodies cannot hear constitutional or statutory claims, nor can they comment on the constitutionality or validity of the rules and regulations involved. Moreover, the administrative review process does not provide for any participation by trade associations, leaving institutions like AHA unable to adequately advance their members' interests. Finally, as this Court recognized in *Michigan Academy*, 476 U.S. at 680 n.11, allowing immediate judicial review of such constitutional and statutory claims will not open the floodgates to millions of Medicare claims, but rather would make for a more efficient system by allowing the federal courts to determine the validity of a standard, often in a single case.

ARGUMENT

I. UNDER THE MEDICARE ACT, A FEDERAL DISTRICT COURT HAS JURISDICTION TO HEAR CONSTITUTIONAL AND STATUTORY CLAIMS WHICH ARE COLLATERAL TO AN INDIVIDUAL CLAIM FOR BENEFITS UNDER THE ACT.

A. THE LANGUAGE OF SECTION 405(h) SHOWS THAT CONGRESS DID NOT INTEND TO BAR FEDERAL DISTRICT COURT JURISDICTION OVER COLLATERAL CLAIMS.

The Medicare Act provides that an individual "dissatisfied with any determination" concerning his eligibility for the program, "the amount of benefits," or "any other denial of a claim for benefits" is entitled to a hearing "to the same extent as provided in [42 U.S.C. § 405(b)] and to judicial review of the Secretary's final decision after such hearing as provided in [42 U.S.C.

§ 405(g)]." 42 U.S.C. §§ 1395ff(a) and (b). The Act also provides that if a provider wishes to dispute a determination concerning compliance or certification under the Medicare Act, the provider is entitled to the hearing and review procedures under 42 U.S.C. §§ 405(b) and 405(g). 42 U.S.C. § 1395cc(h). *See also* 42 U.S.C. § 1395ii.

Section 405(g) authorizes a party to seek judicial review "after any final decision of the [Secretary] made after a hearing to which he was a party." 42 U.S.C. § 405(g). The next section, Section 405(h) states:

> 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 government agency except as herein provided. No action against the United States, the [Secretary], or any other officer or employee thereof shall be brought under section 1331 or 1346 of Title 28 to recover on any claim arising under this subchapter.

42 U.S.C. § 405(h). The Secretary contends that these provisions provide an "exclusive mechanism for obtaining judicial review of claims 'arising under' the Medicare Act," (Brief for the Petitioners ("Pet. Br.") at 18), including pre-enforcement challenges to her regulations under the Constitution and statutes of the United States. However, as this Court recognized in *Bowen v. Michigan Academy of Family Physicians*, 476 U.S. 667 (1986), nothing in the language of 405(h), its legislative history, or the statutory framework of Medicare bars such pre-enforcement challenges.

1. The Court should begin with the language of Section 405(h). As the Court has explained, the "lodestar is the language of the statute." *United States v. Erika, Inc.*, 456 U.S. 201, 206 (1982). Nothing in the language of

Section 405(h) bars pre-enforcement judicial review of a challenge that is collateral to a claim for benefits under the Medicare Act, such as the claims brought by Long Term Care.

The first sentence of Section 405(h) makes the "findings and decision of the [Secretary] after a hearing" binding on the parties to the hearing. It does not otherwise limit judicial review. The second sentence limits judicial review of the "findings of fact and decisions of the Secretary" to the mechanisms established by the Medicare Act. This limitation, however, does not apply to pre-enforcement challenges that are collateral to a claim for benefits. The first sentence defines the terms "findings of fact" and "decision" as determinations made by the Secretary after a hearing. This Court has held that these terms have the same meaning in the second sentence. *Michigan Academy*, 476 U.S. at 679 n.8 (identifying "the contextual definition of 'decision' in the first sentence [of Section 405(h)] as those determinations made by 'the Secretary after a hearing' "). *See generally, Mathews v. Eldridge*, 424 U.S. 319, 328 (1976) (the term "final decision" requires that "a claim for benefits shall have been presented to the Secretary"). A pre-enforcement challenge to a regulation on constitutional or statutory grounds, which is collateral to a claim for benefits, does not seek review of any "finding of fact" or "decision" of the Secretary made "after a hearing." Rather, it seeks review of a rule or regulation before any hearing or decision. The plain language of the second sentence of 405(h) therefore does not bar judicial review of such a pre-enforcement challenge.

The Secretary recognizes that her "regulations and guidelines are not themselves 'decisions' of the Secretary within the meaning of the second sentence" of Section 405(h), but argues that applying Section 405(h) as written would allow "any plaintiff" to "bypass the Medicare

Act's exhaustion requirements at will by filing a declaratory judgment action." (Pet. Br. at 41 n.22) In making this argument, she relies on the Court's decision in *Heckler v. Ringer*, 466 U.S. 602 (1984). (*Id.*) *Ringer*, however, involved substantially different facts from those presented here. In that case, Ringer sought to overturn a regulation which denied benefits for an operation that he had not yet had. The Court accordingly viewed the lawsuit as seeking to recover on a claim of benefits, even though Ringer had not yet formally made such a claim: "Although it is true that Ringer is not seeking the immediate payment of benefits, he is clearly seeking to establish a right to future payments should he ultimately decide to proceed with [the] surgery." *Ringer*, 466 U.S. at 621. In contrast to *Ringer*, the constitutional and statutory claims brought by Long Term Care in this case are admittedly unrelated – in other words, collateral – to any particular claim for benefits. Immediate judicial review of claims unrelated or collateral to an individual claim for benefits will not allow participants in the Medicare Program to bypass the administrative review mechanisms. The second sentence of Section 405(h) therefore does not limit a federal district court's jurisdiction over those claims. *See Thunder Basin Coal Co. v. Reich*, 510 U.S. 200, 212 (1994) ("This Court previously has upheld district court jurisdiction over claims considered 'wholly "collateral" ' to a statute's review provisions and outside of the agency's expertise . . . . ") (citing cases).

2. The third sentence of Section 405(h) likewise does not bar a lawsuit seeking judicial review of the Secretary's regulations, but instead precludes only actions "to recover on any claim arising under this subchapter." The court of appeals correctly read the third sentence to cover only those cases seeking to recover on individual benefit

claims, and not a pre-enforcement challenge to a regulation as invalid that seeks only equitable relief: "[P]re-enforcement review of a regulation's validity is not an action to 'recover on' a claim, even when per [*Weinberger v. Salfi*, 422 U.S. 522 (1975)] a constitutional objection to the regulation is a 'claim arising under this subchapter.' " 143 F.3d at 1075-76. The language of Section 405(h) thus makes clear that Congress sought only to ensure that actions seeking to establish an individual's right to benefits go through the administrative review process.

3. The Secretary cannot suggest that the silence of Sections 405(g) and (h) concerning collateral challenges means that Congress intended to preclude judicial review of those challenges. As this Court has explained, it "customarily" refuses "to treat such silence 'as a denial of authority to [an] aggrieved person to seek appropriate relief in the federal courts.' " *Reno v. Catholic Social Servs., Inc.*, 509 U.S. 43, 56-57 (1993) (quoting *Stark v. Wickard*, 321 U.S. 288, 309 (1944)); *see also, Abbott Lab. v. Gardner*, 387 U.S. 136, 141 (1967) (" 'The mere fact that some acts are made reviewable should not suffice to support an implication of exclusion as to others. The right to review is too important to be excluded on such slender and indeterminate evidence of legislative intent.' ") (quoting LOUIS L. JAFFE, JUDICIAL CONTROL OF ADMINISTRATIVE ACTION 357 (1965)). Put another way, if Congress had intended to bar pre-enforcement constitutional and statutory challenges, "it could easily have used broader language." *McNary v. Haitian Refugee Ctr., Inc.*, 498 U.S. 479, 494 (1991).

4. The language of Section 405(g) reinforces the conclusion that Section 405(h) applies only to individual claims for benefits. Section 405(g) provides, in part, that the "findings of the [Secretary] as to any fact, if supported by substantial evidence, shall be conclusive." The

use of a substantial evidence standard, which is inapplicable to constitutional or statutory challenges, suggests that Congress did not intend the Medicare Act's review provisions to apply to such pre-enforcement challenges to the Secretary's regulations where the challenge is collateral or unrelated to a particular claim for benefits. *See McNary*, 498 U.S. at 493 (abuse of discretion standard "lends substantial credence" to conclusion that the Immigration Reform and Control Act does not apply to challenges to the Immigration and Nationalization Services' practices and procedures); *Lindahl v. Office of Personnel Mgmt.*, 470 U.S. 768, 779 n.12 (1985) ("The juxtaposition of the finality language with the language concerning OPM's determinations of 'the facts' of disability arguably suggests that the finality language does not extend to procedural or legal questions."). The language of Sections 405(g) and (h) thus does not bar claims such as those brought by Long Term Care.

B. THE LEGISLATIVE HISTORY HIGHLIGHTS THAT CONGRESS INTENDED ONLY TO PRECLUDE JUDICIAL REVIEW OF INDIVIDUAL AMOUNT DETERMINATIONS AND NOT COLLATERAL CHALLENGES.

The legislative history of the Medicare Act, which this Court reviewed extensively in *Michigan Academy*, underscores that Congress intended to require only that plaintiffs seeking to recover on individual benefits claims proceed through the administrative review process, not that constitutional challenges to regulations endure the same process. By establishing the administrative review mechanisms of Section 405(g), Congress intended only to protect the federal courts from the flood of "trivial" and "quite minor" individual benefit claims that otherwise might result. *See Michigan Academy*, 476 U.S. at 680. It did

not intend to restrict access to the federal courts for challenges to the regulations that might substantially and immediately impact hundreds or thousands of providers and beneficiaries at the same time.

1. The Medicare Act was amended in 1972. The remarks of Senator Bennett, "as those of the sponsor of the language ultimately enacted, are an authoritative guide to the statute's construction." *North Haven Bd. of Educ. v. Bell*, 456 U.S. 512, 526-27 (1982). *See also Grove City College v. Bell*, 465 U.S. 555, 567 (1984) (same). Senator Bennett's introductory remarks make clear that Congress intended to restrict access to the courts only for "trivial" and "quite minor matters" concerning amount determinations:

> The situations in which medicare decisions are appealable to the courts were intended in the original law to be greatly restricted in order to avoid overloading the courts with quite minor matters. The law refers to "entitlement" as being an issue subject to court review and the word was intended to mean eligibility to any benefits of medicare but not to decisions on a claim for payment for a given service.
>
> If judicial review is made available where any claim is denied, as some court decisions have held, the resources of the Federal court system would be unduly taxed and little real value would be derived by the enrollees. The proposed amendment would merely clarify the original intent of the law and prevent the overloading of the courts with trivial matters because the intent is considered unclear.

118 Cong. Rec. 33992 (1972).

2. After closely examining Senator Bennett's remarks, as well as the remainder of the Medicare Act's 1965 and 1972 legislative history, the *Michigan Academy*

Court concluded that they accurately reflected the intent of Congress:

> The legislative history of both the statute establishing the Medicare program and the 1972 amendments thereto provides specific evidence of Congress' intent to foreclose review only of "amount determinations" – i.e., those "quite minor matters," remitted finally and exclusively to adjudication by private insurance carriers in a "fair hearing." By the same token, matters which Congress did not delegate to private carriers, such as challenges to the validity of the Secretary's instructions and regulations, are cognizable in courts of law.

476 U.S. at 680 (quoting 118 Cong. Rec. 33992 (1972) (footnote omitted)). The challenge to the Secretary's regulations and guidelines brought by Long Term Care is thus "cognizable in courts of law."

3. The Secretary's discussion of this legislative history is incorrect. The Secretary thrice quotes the same fourteen words from the Senate Report accompanying the 1965 Medicare Act in support of her argument that Long Term Care's challenges must be brought within the mechanism outlined in Section 405(g): " 'It is intended that the remedies provided by these review procedures shall be exclusive.' " (Pet. Br. at 16, 22, 33) (quoting S. Rep. No. 89-404, at 55 (1965)) However, as this Court has previously recognized, the language relied upon by the Secretary does not address challenges to the methods by which the Secretary arrives at her decisions:

> That Congress did not preclude review of the method by which Part B awards are computed (as opposed to the computation) is borne out by the very legislative history we found persuasive in *Erika*. The Senate Committee Report on the original 1965 legislation reveals an intention to preclude "judicial review of a determination concerning the amount of benefits under part B where claims will probably be for substantially smaller amounts than under part A."

Michigan Academy, 476 U.S. at 676-77 (quoting S. Rep. No. 89-404, at 54-55 (1965)). Long Term Care's suit does not contest any benefit or eligibility determination by the Secretary and therefore the limitation of judicial review referenced by the Secretary's legislative history does not address the challenge brought by Long Term Care.

C. NOTHING IN THE STATUTORY SCHEME SUGGESTS AN INTENTION TO BAR CHALLENGES THAT ARE COLLATERAL TO AN INDIVIDUAL CLAIM FOR BENEFITS.

The Court may find an intention of Congress to preclude judicial review of an agency's rules and regulations when such an intent is " 'fairly discernable in the statutory scheme.' " *Thunder Basin*, 510 U.S. at 207 (quoting *Block v. Community Nutrition Inst.*, 467 U.S. 340, 351 (1984) (citation omitted)). The statutory scheme of the Medicare Act, however, does not suggest any intention to preclude pre-enforcement constitutional or statutory challenges that are collateral to an award of benefits.

1. As this Court has recognized in analyzing the scope of judicial review of the decisions of other federal agencies, "the factual 'question' " of an individual's entitlement to benefits "is quite distinct from questions of what laws and procedures the [agency] must apply in administering" the agency's responsibilities. *Lindahl*, 470 U.S. at 779. *See also McNary*, 498 U.S. at 493 (distinguishing between denials of individual applications and collateral challenges to INS procedures and practices); *Traynor v. Turnage*, 485 U.S. 535, 542-45 (1988) (statutory prohibition of judicial review of Veterans Administration benefit

determinations did not preclude jurisdiction over collateral statutory claim); *Michigan Academy*, 476 U.S. at 678-680 (distinguishing between challenges to the amount of Medicare payments and challenges to the method by which the Secretary determines such amounts); *Bowen v. City of New York*, 476 U.S. 467, 484 (1986) (challenge to procedure used by Social Security Administration "is materially distinguishable from one in which a claimant sues in district court, alleging mere deviation from the applicable regulations in his particular administrative proceeding"). Congress's decision to route individual claims concerning the amount of benefits through an administrative review process therefore does not suggest a similar intent concerning constitutional and statutory challenges to the Secretary's regulations.

2. The Secretary argues that when the Medicare Act provides a mechanism for obtaining review, that mechanism is exclusive. (Pet. Br. at 23-26) This argument misses the point. By its terms, Section 405(g) provides only for administrative review of individual amount determinations. It does not provide for review of constitutional and statutory challenges to the Secretary's regulations and guidelines. Nor, as a practical matter, are such claims reviewable. As the Secretary admits, Long Term Care's "constitutional contentions and its challenges to the Secretary's regulations, ordinarily would not be the subject of an administrative hearing. Neither the Department Appeals Board nor individual ALJs are free to depart from statutory and regulatory requirements." (Pet. Br. at 44-45) Congress instead designed the administrative review process to handle those "quite minor matters" related to the determination of benefits in individual cases. By the same token, matters for which Congress did not establish a review process, such as challenges to the

validity of the Secretary's regulations, are accordingly cognizable in courts of law.

3. To support her argument, the Secretary points repeatedly to this Court's characterization of the Medicare Act's statutory scheme as "reticulated." (Pet. Br. at 16, 19, 50). This "reticulated" scheme, however, does not suggest that the Court should route collateral challenges to regulations though the administrative review process. To the contrary, the reticulated nature of the Medicare Act is precisely what led this Court to earlier conclude that challenges mounted directly against the Secretary's regulations are not barred, because such challenges are nowhere addressed in the Act:

> The reticulated statutory scheme, which carefully details the forum and limits of review of "any determination . . . of . . . the amount of benefits under Part A," and of the "amount . . . of payment" of benefits under Part B, simply does not speak to challenges mounted against the method by which such amounts are to be determined rather than the determinations themselves.

Michigan Academy, 476 U.S. at 675 (quoting 42 U.S.C. §§ 1395ff(b)(1)(C) and 1395u(b)(3)(C)). The Medicare Act's statutory scheme thus does not support foreclosing claims, such as Long Term Care's, that the plain language of Sections 1495(g) and (h) does not address.

II. NOTHING IN THE 1986 AMENDMENTS TO THE MEDICARE ACT ALTERED THE LANGUAGE OR LEGISLATIVE HISTORY OF SECTION 405(g) AND 405(h). THE COURT THEREFORE SHOULD ADHERE TO ITS DECISION IN *MICHIGAN ACADEMY*.

In *Michigan Academy*, individual doctors and an association of family physicians filed suit to challenge the

statutory and constitutional validity of 42 C.F.R. § 405.504(b). 476 U.S. at 668. The challenged regulation authorized the payment of benefits in different amounts for similar physicians' services. *Id.* The Secretary argued that Section 405(h) barred judicial review of all questions affecting the payment of benefits under the Medicare program. *Id.* at 669. After carefully reviewing the Medicare Act's legislative history, *Michigan Academy* held that "Congress intended to bar judicial review only of determinations of the amount of benefits to be awarded under Part B." *Id.* at 678.

A. Shortly after *Michigan Academy* was decided, Congress amended the Medicare Act to provide for judicial review of Part B benefit determinations to the same extent as Part A, thereby overruling the holding of *United States v. Erika, Inc.*, 456 U.S. 201 (1982). The Secretary argues that the 1986 amendment served to eliminate the "exception" to Section 405(h)'s limits on federal jurisdiction created by *Michigan Academy*. (*See* Pet. Br. at 36-37) The court of appeals, however, correctly identified the fatal flaw in the Secretary's argument – namely, that the 1986 amendments did not change the language of Section 405(g) and (h). 143 F.3d at 1075-76. Nor did the legislative history of the 1986 amendment indicate any intention to alter the result reached in *Michigan Academy*.

The Court therefore has no reason to reconsider its analysis of Section 405(h) in *Michigan Academy*. To the contrary, Congress's failure to amend the controlling statutory language relied upon in *Michigan Academy* suggests Congress's implied assent to the continued application of that interpretation to the Medicare Act. " 'Congress is presumed to be aware of an administrative or judicial interpretation of a statute and to adopt that interpretation when it reenacts a statute without change.' " *Lindahl*, 470 U.S. at 782 n.15 (quoting *Lorillard v. Pons*, 434 U.S. 575, 580 (1978)). *See also Cannon v. University of Chicago*, 441 U.S. 677, 696-697 (1979) ("It is always appropriate to assume that our elected representatives, like other citizens, know the law . . . . "); *Garrett v. United States*, 471 U.S. 773, 793-94 (1985) ("It is not a function of this Court to presume that 'Congress was unaware of what it accomplished.' ") (citation omitted).

The court of appeals, moreover, correctly rejected the Secretary's characterization of *Michigan Academy* as establishing an "exception" to Section 405(h): "*Michigan Academy* does not say that a presumption of judicial review justifies an 'exception' to § 1395ii. It says, rather, that § 1395ii, read in light of its 1972 legislative history, affects only 'amount determinations.' " 143 F.3d at 1075 (citing *Michigan Academy*, 476 U.S. at 678-81). As this Court has acknowledged, it does not possess the authority to craft an "exception" to validly enacted legislation. "To allow otherwise 'would confer on the judiciary discretionary power to disregard the considered limitations of the law it is charged with enforcing.' " *Bank of Nova Scotia v. United States*, 487 U.S. 250, 254 (1988) (quoting *United States v. Payner*, 447 U.S. 727, 737 (1980)). As the Court lacked the power to craft an "exception" to the Medicare Act in 1986 when it decided *Michigan Academy*, it cannot judicially repeal any such "exception" now.

B. This Court also recognized the continuing validity of *Michigan Academy* after the 1986 amendment in *McNary v. Haitian Refugee Ctr., Inc.*, 498 U.S. 479 (1991). In *McNary*, the Court rejected the Commissioner of Immigration and Naturalization's reliance on *Heckler v. Ringer*, 466 U.S. 602 (1984), and expressly found that *Michigan Academy* applied to permit a collateral challenge to the Commissioner's regulations despite a jurisdictional limitation established by 8 U.S.C. § 1160(e)(1) for cases involving "a determination respecting an application for

adjustment of status." *McNary*, 498 U.S. at 494-99. *See also Thunder Basin*, 510 U.S. at 213 (citing *Michigan Academy* with approval)

C. In support of her argument, the Secretary relies upon a host of Supreme Court decisions: *Your Home Visiting Nurse Servs., Inc. v. Shalala*, 119 S. Ct. 930 (1999); *Heckler v. Ringer*, 466 U.S. 602 (1984); *United States v. Erika, Inc.*, 456 U.S. 201 (1982); *Califano v. Sanders*, 430 U.S. 99 (1977); *Mathews v. Eldridge*, 424 U.S. 319 (1976); and *Weinberger v. Salfi*, 422 U.S. 749 (1975). Each of these cases, however, concerns an attempt to recover on a claim for benefits under the Medicare Act as opposed to a collateral challenge to the Secretary's regulations. *Your Home* addressed the efforts of a Medicare provider to reopen its reimbursement determination. 119 S. Ct. at 933. *Ringer* involved a dispute over the payment of claims; in particular, challenges "to the payment of Medicare benefits for a surgical procedure known as bilateral carotid body resection." 466 U.S. at 604-05. *Erika*, which arose prior to the 1986 amendments, addressed whether federal court jurisdiction existed to "review determinations by private insurance carriers of the amount of benefits payable under Part B of the Medicare statute." 456 U.S. at 202. *Sanders* addressed a denied claim for disability benefits brought by an individual allegedly suffering from epilepsy and blackout spells. 430 U.S. at 102. *Eldridge* involved a challenge brought after the termination of Social Security disability benefit payments. 424 U.S. at 323. Last but not least, *Salfi* concerned the denial of insurance benefits under the Social Security Act. 422 U.S. at 753-54. None of those cases therefore is inconsistent with the Court's holding in *Michigan Academy*.

The Secretary makes much of this Court's holding in *Ringer* denying jurisdiction to one of the named plaintiffs, Freeman Ringer. (Pet. Br. at 24-25) Ringer brought suit to

challenge an agency rule that barred reimbursement for an operation he wished to undergo. Since Ringer had not yet had the surgery, his claim, the Secretary argues, is a " 'pre-enforcement' action" the same as Long Term Care's action, and therefore *Ringer* bars Long Term Care's action. (*Id.* at 24) The Secretary, however, ignores this Court's observation that "[a]lthough it is true that Ringer is not seeking the immediate payment of benefits, he is clearly seeking to establish a right to future payments should he ultimately decide to proceed with [the] surgery." 466 U.S. at 621. Ringer's claim therefore was not collateral to an award of benefits, as are the claims brought by Long Term Care in this case, but instead was "inextricably intertwined with what we hold is in essence a claim for benefits and [therefore] § 1331 jurisdiction over all their claims is barred by § 405(h)." *Id.* at 624.

This case stands in stark contrast to *Ringer*. As the Secretary acknowledges, this case does not involve any "reference to any specific enforcement action." (Pet. Br. at 18) Long Term Care instead charges that the SOM used by inspection teams was adopted in violation of the Administrative Procedure Act and that the administrative appeals process under the Secretary's new regulations is so restrictive that it violates due process. Long Term Care also alleges that the Secretary's regulations are unconstitutionally vague, but the court of appeals dismissed this challenge after finding that it was not ripe for decision. The complaint in this case does not involve an effort to recover on a claim under the Medicare Act. It instead seeks relief from the uncertain punitive arm which hangs over its members, meting out punishment at a markedly increased rate since the challenged SOM and enforcement measures took effect, and for reasons and to a degree shrouded from view. Under the plain language of Section

405(h), as well as this Court's decision in *Michigan Academy*, those claims may proceed in federal court.

III. PUBLIC POLICY SUPPORTS THE ALLOWANCE OF CONSTITUTIONAL AND STATUTORY CHALLENGES TO REGULATIONS WHICH ARE COLLATERAL TO AN INDIVIDUAL CLAIM FOR BENEFITS.

The Medicare Act's rules and regulations provide for a lengthy, complicated, and costly administrative review process that does next to nothing to assist in the determination of constitutional and statutory challenges to the Secretary's rules and regulations. The only purpose served by forcing such constitutional and statutory challenges through this process is to allow the government to engage in a "war of attrition," with the hope that the "protracted delay" would discourage providers "from pursuing valid claims against the government." *See* Phyllis E. Bernard, *Empowering the Provider: A Better Way to Resolve Medicare Hospital Payment Disputes*, 49 ADMIN. L. REV. 269, 300 (1997). The Court should not require constitutional and statutory claims to proceed along such a tortuous route before being heard in a court of law.

A. Although Long Term Care's allegations here concern appeals through the Department Appeals Board of the HHS, the Court's decision in this case will likely impact not only that process, but also the other administrative review schemes established by the Secretary under the Medicare Act. One such appeals process that AHA and its members often must deal with is appeals through the PRRB. Although AHA has not located any data concerning the time and expense associated with appeals through the Department Appeals Board, the statistics concerning appeals through the PRRB underscore just

how onerous and long the process is, and how the Secretary's position is unfair and unjust.

In 1994, the PRRB commonly set hearing dates four years in advance, into 1998. *See Empowering the Provider*, 49 ADMIN. L. REV. at 281-82. Although procedures existed by which a provider could seek an expedited hearing, few took advantage of this route. *Id.* at 282. As one commentator has noted, this "long waiting period could easily be perceived as a means of rationing justice." *Id.* at 300. The legal and accounting costs of proceeding through the review process could "easily" amount to between $25,000 and $100,000. *Id.* at 279-80. The Administrator of HCFA may review a decision of the PRRB and may affirm, reverse, modify, or remand the case. 42 C.F.R. §§ 405.1871(b), 405.1875(g). Between 1975 and 1989, the Administrator reversed approximately one-half of the PRRB decisions that were favorable to providers. 49 ADMIN. L. REV. at 287 (citing David Holthaus, *First Step in Medicare Appeal Can Be A Long One*, HOSPITALS, May 5, 1989, at 40). " '[T]he fact that HCFA reviews all board decisions and reverses many of them, diminishes the importance of the board and often makes arguing before it an exercise in futility.' " *Id.* at 286 (quoting *First Step*, at 40).

A provider who believes that the Secretary's rules and regulations violate constitutional or statutory limitations therefore lacks any realistic opportunity to seek judicial review through the PRRB under the Secretary's proposed construction of Sections 405(g) and 405(h). The provider must spend tens of thousands of dollars and many years proceeding through a process that admittedly cannot address the issues that the provider has raised. In the meantime, in order to have standing to bring its

claim, the provider must bear the burden of the Secretary's decision. The administrative review process therefore does not provide meaningful judicial review of constitutional and statutory challenges to the Secretary's rules and regulations. *See McNary*, 498 U.S. at 496-97 (the fact that undocumented aliens may challenge the INS's review procedures only if the surrender themselves for deportation "is tantamount to a complete denial of judicial review for most undocumented aliens").

B. Moreover, adopting the Secretary's construction of Sections 405(g) and 405(h) would unfairly limit a trade association's ability to bring constitutional and statutory claims on behalf of its members. This Court has held that trade associations have standing to bring claims on behalf of their members. *See Hunt v. Washington State Apple Advertising Comm'n*, 432 U.S. 333, 342-43 (1977) (even in the absence of a direct injury to itself, an association may have standing solely as a representative of its constituents). However, this standing depends " 'in substantial measure on the nature of the relief sought.' " *Id.* at 343 (quoting *Warth v. Seldin*, 422 U.S. 490, 515 (1975)). An association has standing to bring a claim only if "neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit." *Hunt*, 432 U.S. at 343. Permitting trade associations, such as AHA, to bring such claims allows the cost of challenging an allegedly improper regulation to be more fairly shared by all of the members of the field affected by that regulation, rather than placing the entire burden of challenging the regulation on an individual institution.

Accepting the Secretary's position would effectively eliminate the ability of trade associations to bring such claims. The rules and regulations promulgated by the Secretary limit the parties to "the affected party and HCFA or OIG, as appropriate" and make no provision for

any involvement by a trade association. 42 C.F.R. § 498.42. Moreover, a trade association may not have standing even after the provider has endured the administrative review process because a court may consider an action to review the Secretary's determinations concerning a particular provider to be limited to "the participation of individual members in the lawsuit." *Hunt*, 432 U.S. at 343.

C. The preclusion of meaningful judicial review is particularly problematic where it would serve no meaningful purpose to force providers to go through the tortuous administrative review process in order to assert constitutional and statutory claims. The Secretary argues that routing all challenges "through the administrative review process as a pre-condition to judicial review" would permit "development of a factual record," allow "for refinement of legal issues, enabling the agency to apply its expertise to the specific issues raised" and afford "the Secretary the opportunity to resolve the dispute on other grounds." (Pet. Br. at 18) However, given the limitations upon the power of the administrative tribunals, requiring a provider to first endure the administrative review process will not serve any of these purposes.

The administrative review process will not result in the compilation of a detailed record to assist the courts in reviewing the constitutional and statutory claims. As explained *supra*, administrative law judges lack jurisdiction to address claims regarding the SOM and the Secretary's enforcement measures. *See* 42 C.F.R. § 405.860. *See also Michigan Academy*, 476 U.S. at 676 n.6 (Medicare Manual expressly prohibits the hearing officer from overruling or commenting on the legality or unconstitutionality of any Medicare Act provision or regulation). Because the administrative law judges cannot address

such claims, they cannot develop a factual record for such claims. Moreover, it is not clear what, if any, assistance further factual development will provide. *See Thomas v. Union Carbide Agric. Prods. Co.*, 473 U.S. 568, 581 (1985) ("The issue presented in this case is purely legal, and will not be clarified by further factual development.").

Nor will the administrative review process allow "for refinement of legal issues" by "enabling the agency to apply its expertise to the specific issues raised." (Pet. Br. at 18) Since neither the ALJ nor the various appeals boards can even "comment upon" constitutional or statutory challenges to the Secretary's rules or regulations, *Michigan Academy*, 476 U.S. at 676 n.6, the administrative review process does not provide any opportunity for the agency to provide its expertise on those issues. Moreover, even if the ALJ or appeals board could comment on such challenges, they would not bring any particular expertise in evaluating those constitutional and statutory claims, as those claims involve the expertise particularly within the providence of the courts. *See Sanders*, 430 U.S. at 109 ("Constitutional questions obviously are unsuited to resolution in administrative hearing procedures and, therefore, access to the courts is essential to the decision of such questions."). The courts will have to address the same undigested legal issues regardless of whether the Medicare provider has exhausted its administrative remedies. Permitting the federal courts to address constitutional and statutory arguments in the first instance will thus not create a "risk [of] premature judicial interference" nor run the risk of "devastating consequences," (Pet. Br. at 27), for the Medicare Program.

The Secretary's third argument, that requiring administrative review will allow the Secretary to resolve the matter "on other grounds," (Pet. Br. at 18), does not advance a legitimate public interest. It is not in the public

interest to avoid resolving whether the Secretary's rules and regulations violate constitutional or statutory provisions; to the contrary, it furthers the public interest to ensure that such claims are resolved promptly, in order to fairly and effectively implement the intent of Congress. However, as explained *supra*, the delay and expense exacted by the administrative review process frustrates this worthy objective.

Finally, contrary to the Secretary's suggestions, permitting federal courts to hear pre-enforcement constitutional and statutory challenges will not exhaust the resources of the court system. In fact, as this Court has recognized, a timely challenge to an unconstitutional or unlawful enforcement measure may result in substantial economies by forestalling the filing of a myriad of individual claims raising the same arguments. *See Michigan Academy*, 476 U.S. at 680 n.11 (" '[P]ermitting review only [of] . . . a particular statutory or administrative standard . . . would not result in a costly flood of litigation, because the validity of a standard can be readily established, at times even in a single case.' ") (quoting Note, *Congressional Preclusion of Judicial Review of Federal Benefit Determinations: Reasserting Separation of Powers*, 97 HARV. L. REV. 778, 792 (1984) (footnote omitted)).

Moreover, the federal courts have a well-established body of law to determine whether they can properly address and resolve a legal issue. As this Court has explained, *Abbott Labs*, 387 U.S. 136, 148-49 (1967), the ripeness doctrine serves "to prevent the courts, through avoidance of premature adjudication, from entangling themselves in abstract disagreements over administrative policies" as well as "to protect the agencies from judicial interference until an administrative decision has been formalized and its effects felt in a concrete way by the challenging parties." The court of appeals in this case

applied those principles in deciding which of Long Term Care's claims were ripe for adjudication, although Long Term Care disputes its ruling on some points. The decision of the court of appeals thus demonstrates that the Secretary's concern regarding the "serious risk that premature judicial interference could have devastating consequences for the [Medicare] program," (Pet. Br. at 27), is groundless.

CONCLUSION

For the reasons discussed above, the judgment of the court of appeals should be affirmed.

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Respectfully submitted,

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