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 OF AMICI CURIAE AMERICAN HEATH CARE ASSOCIATION, NATIONAL SUBACUTE CARE ASSOCIATION, AND NATIONAL ASSOCIATION FOR THE SUPPORT OF LONG TERM CARE, IN SUPPORT OF RESPONDENT

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 unrelated to an individual claim.

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THE INTEREST OF *AMICI CURIAE*[1]

The American Health Care Association, the National Subacute Care Association, and the National Association for the Support of Long Term Care. (collectively, "*Amici*") are national trade associations representing the interests of nursing homes, state nursing home trade associations, and entities providing items or services to nursing homes. The nursing homes represented by *Amici* are certified to participate in the Medicare or Medicaid programs, or both. An integral part of the mission of each association is to influence the government to invest in the well-being of the elderly and disabled, to assure access to long-term care services, and to achieve sound legislative and regulatory policies that support the efforts of the provider community to deliver professional and compassionate care to nursing facility residents.

Respondent Illinois Council on Long Term Care, Inc. ("Illinois Council") challenges the regulations and manual that the Secretary of the Department of Health and Human Services ("Secretary"), through the Health Care Financing Administration ("HCFA"), uses to survey skilled nursing facilities ("SNFs") for compliance with Medicare certification requirements and to impose remedies in the event of a facility's alleged failure to comply with such certification requirements. Contrary to the intent of Congress in enacting the Omnibus Budget Reconciliation Act of 1987, Pub. L. No. 100-203, 101 Stat. 1330 ("OBRA 1987"), *Amici's* members' experience demonstrates that the Medicare survey, certification, and enforcement system is

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[1] The parties have consented to the submission of this brief. Their letters of consent have been filed with the clerk of court. No counsel for a party authored this brief in whole or in part, and no person or entity, other than *amici curiae*, its members, or its counsel, made a monetary contribution to the preparation or submission of this brief.

fatally flawed, often leading to citations for minor imperfections or administrative infractions that do not affect resident care, and punitive rather than remedial sanctions. Moreover, when erroneous deficiencies are cited, facilities are precluded or significantly discouraged from appealing those citations and correcting their compliance records -- despite public disclosure of every facility's deficiency record at the facility, on the internet, and by state survey agencies.

Amici and the long-term care facilities, trade associations, and providers of items and services to long-term care facilities that they represent have a profound interest in ensuring for both themselves and facility residents that the Medicare survey, certification, and enforcement procedures are applied consistently among providers and that wrongful agency survey and enforcement actions can be heard and remedied without diverting resources from caregiving or unduly disrupting resident care. The inconsistent, arbitrary, and capricious application of survey standards and enforcement remedies undermines daily facility operations, resident care, and the ability of every Medicare beneficiary to choose a quality long-term care provider. Moreover, because the current survey and enforcement system does not permit a facility to challenge many abusive survey and enforcement determinations and procedures, a facility is powerless, in its individual capacity, to bring justice to a fundamentally flawed administrative system.

This case presents an important opportunity to challenge an administrative system that would otherwise never be subject to judicial scrutiny. *Amici* have a strong interest in the outcome of this case, and they support Respondent's efforts to challenge the systemic administrative inequities in the Secretary's nursing home survey and enforcement scheme.

SUMMARY OF ARGUMENT

Power tends to corrupt and absolute power corrupts absolutely.[2]

This case is about power: the power of an administrative agency to act without regard to its statutory authority or the Constitution; the power of an agency to act subject only to a review system of its own creation that deliberately insulates the agency's acts from judicial review. In essence, this case is about the "absolute power" that corrupts so absolutely.

Given the extraordinary power of the Secretary in this context, we argue that, in the limited circumstances presented in this case, a federal district court has the power, pursuant to 28 U.S.C. §§ 1331 and 1346, to hear Respondent's constitutional and statutory challenge to HCFA's nursing facility survey and enforcement regulations. This Court should not permit the otherwise watchful eye of the judiciary to ignore the abuses, excesses, and injustices that inevitably occur when an agency possesses absolute discretion unfettered by judicial review.

I. Respondent's constitutional and statutory challenges to the Secretary's Medicare survey and enforcement system for SNFs is not barred by 42 U.S.C. § 405(h), as incorporated into the Medicare Act by 42 U.S.C. § 1395ii, which provides that federal courts do not have jurisdiction under 28 U.S.C. §§ 1331 and 1346 with respect to actions brought to "recover on any claim arising under" the Medicare Act. The issues presented in this case are simply not a "claim" within the meaning of section 405(h).

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[2] Bartlett, John, *Familiar Quotations* 615 (Emily M. Beck, ed., 15th ed. 1980).

Section 405(h) applies only to claims brought by individual providers or beneficiaries to recover Medicare benefits or reimbursement, or to challenge the termination or denial of a provider agreement. Because this is not a claim within the meaning of section 405(h), there is no administrative remedy to exhaust, and the United States Court of Appeals for the Seventh Circuit correctly held that the district court had subject matter jurisdiction over this important challenge.

II. Pre-enforcement judicial review of Respondent's challenge is warranted under this Court's decision in *Bowen v. Michigan Academy of Family Physicians* because the Secretary has promulgated a review scheme that is calculated to prohibit or strongly discourage judicial review of Respondent's challenge.

A. The Secretary's regulations preclude providers from appealing a number of significant determinations that go to the heart of whether a facility is deemed to provide quality care. For example, a facility may not appeal a deficiency citation for which no enforcement penalty or remedy is imposed -- despite the significant future ramifications of such citations, including widespread public disclosure of such deficiencies at the facility, by state survey agencies, and on the internet, and the use of such deficiencies to justify harsher enforcement remedies or "PPF" designation after a subsequent survey. The Secretary's review scheme also prohibits providers from appealing the Secretary's choice of remedy, regardless of the harshness of the remedy relative to the underlying deficiency or the inconsistency with which various remedies are imposed among providers on a local or regional basis. Further, providers generally are unable to appeal a determination regarding the "level of noncompliance," which is determined in part based on vague terms that purport to define the degree of harm that was or could be caused by the deficiency.

B. The Secretary's administrative review system prohibits providers from challenging the validity of the regulations with which they must comply. Constitutional or statutory challenges may not be raised in the informal dispute resolution procedure authorized for contesting survey findings. Moreover, the Secretary's administrative review procedures preclude administrative law judges ("ALJs") from addressing such challenges. Consequently, on the small chance that a provider has appealed a determination for which the Secretary's regulations permit an appeal, and the provider has finally reached federal court after exhausting its administrative remedies, there is no record for a court to review with respect to the constitutional or statutory challenge. In cases where a provider has challenged the imposition of a civil monetary penalty and must appeal directly to the federal circuit court of appeals, the appellate court is hindered by both the lack of an appropriate record and the inability to perform the fact-finding to create such a record.

C. Even when administrative or judicial review is available, such review is strongly discouraged by the Secretary and, as a practical matter, remains unavailable. The Secretary successfully prevents providers from pursuing their claims by advocating strict pleading requirements, which have no basis in the regulations. In addition, the time-consuming nature of the administrative review process further discourages providers from raising important constitutional and statutory challenges, especially since the Secretary's review scheme does not provide for expedited review of such collateral issues, which the HCFA Departmental Appeals Board ("DAB") and ALJs have no authority to decide. It is unjust and nonsensical to require providers to appeal constitutional and statutory issues on a piecemeal basis while the entire industry suffers during the intervening years from the illegal and unconstitutional practices and policies of the Secretary and when the end

result could be accomplished swiftly and efficiently in a single challenge by Respondent.

III. Pre-enforcement judicial review of Respondent's case should be permitted because such review does not violate the purposes of the doctrine of exhaustion of administrative remedies. In this case, pre-enforcement judicial review does not constitute premature interference with agency process because the administrative review body has no authority to address statutory or constitutional challenges. Moreover, such challenges are not within the realm of agency expertise, and the parties cannot compile a record to assist later judicial review. Judicial economy, on the other hand, dictates that Respondent's case be addressed immediately in a single ruling, thereby precluding the Secretary from violating the Constitution and exceeding her statutory authority to the detriment of this nation's long-term care providers and the residents to whom they provide care.

ARGUMENT

I. The Medicare Act Does Not Bar Pre-Enforcement Judicial Review Of A Statutory Or Constitutional Challenge

The Social Security Act jurisdictional bar, which is codified at 42 U.S.C. § 405(h) and made applicable to the Medicare program by 42 U.S.C. § 1395ii, provides that federal courts do not have subject matter jurisdiction with respect to any action "*to recover on any claim* arising under" the Medicare Act (emphasis added). Section 405(h) further provides that no finding of fact or decision of the Secretary may be reviewed by any tribunal except as provided in the Medicare Act. Section 405(g) permits aggrieved parties to obtain judicial review in federal district court of any "final decision" of the Secretary made after a hearing, thus requiring claimants to exhaust administrative remedies. 42 U.S.C. § 405(g).

For two simple and straightforward reasons, section 405 does not require exhaustion of administrative remedies for a statutory or constitutional challenge such as that raised here by Illinois Council. First, section 405(h) applies only to individual or provider actions to recover on a claim for Medicare *benefits or reimbursement*. Second, section 405(h) does not preclude pre-enforcement judicial review of constitutional and statutory claims -- even if those claims directly or indirectly involve Medicare benefits or reimbursement -- where delayed judicial review is not available.

A. Section 405(h) Applies Only To Claims For Benefits Or Reimbursement

Section 405(h) provides for judicial review of "findings of fact" and decisions of the Secretary made after a hearing. A critical reading of the context of section 405 confirms that such a hearing clearly was intended to adjudicate only claims for payment of benefits. In section 405(a), the Commissioner of Social Security is authorized to adopt procedures for establishing "the right to *benefits*" under Title II of the Social Security Act. In section 405(b)(1), the Commissioner is directed to make findings of fact and decisions regarding "the rights of any individual applying for a *payment*" under Title II. Section 405(b)(3)(A) sets forth the consequences for failure to timely request review of an adverse determination with respect to an individual's "application for any *benefit*" under Title II. Section 405(g) provides that an individual may obtain judicial review of the Secretary's final decision made after a hearing "irrespective of the *amount in controversy*." Finally, section 405(i) sets forth the procedure for authorizing payment of benefits after the Commissioner or a district court has found an individual eligible for such benefits.

The language of section 405 also evidences an intent that the hearing, exhaustion, and judicial review procedures

only apply to claims brought by individual beneficiaries or providers. Indeed, the seminal cases in which this Court has interpreted sections 405(h) and 405(g) have involved individual claims for benefits or reimbursement. *E.g.*, *Weinberger v. Salfi*, 422 U.S. 749 (1975) (Social Security survivor benefits); *Mathews v. Eldridge*, 424 U.S. 319 (1976); *Heckler v. Ringer*, 466 U.S. 602 (1984) (Medicare reimbursement for a surgical procedure). The availability of review under section 405 of provider agreement terminations[3] provides further evidence that section 405 is limited to review of individual provider determinations and not major constitutional and statutory challenges to agency practices and procedures.

It is no surprise, then, that this Court has strictly enforced the exhaustion requirements for reimbursement or benefit claims brought by individuals. In *Heckler v. Ringer*, 466 U.S. at 614, this Court interpreted section 405(h) to preclude immediate judicial review of individual or provider claims that are "inextricably intertwined" with a benefit or reimbursement claim for which administrative remedies have not been exhausted. Where, at bottom, the claim at issue is one for reimbursement, this Court has required exhaustion of administrative remedies. *Id.*

This case, however, is very different from its predecessors. Illinois Council is not a provider certified to participate in the Medicare program. It has not sought to disguise a termination decision or claim for reimbursement as a constitutional issue in an effort to circumvent the

[3] 42 U.S.C. § 1395cc(h)(1) provides that an institution dissatisfied with a determination by the Secretary that it is not a provider of services or with the Secretary's determination to terminate its provider agreement shall be entitled to a hearing to the same extent as is provided in Section 405(b) and to judicial review of the Secretary's final decision after a hearing.

jurisdictional bar. *Cf. Ringer*, 466 U.S. at 614 (disagreeing with the notion that claims construed as "procedural" in nature are cognizable in federal district court by way of federal question jurisdiction). Respondent's request for relief would not, if granted, require merely "ministerial details" to be performed before receiving payment of reimbursement or reinstatement of its Medicare certification. *See id.* at 615. In sum, Respondent does not raise a routine or "quite minor matter" for judicial consideration. *See Bowen v. Michigan Academy of Family Physicians*, 476 U.S. 667, 677 (1986) (noting Congressional intent "to avoid overloading the courts with 'quite minor matters'").

Further, this case was not even brought by an individual provider, but by an association representing the interests of nursing facilities in Illinois. It asserts important constitutional and statutory issues that section 405, with its emphasis on individual claims, is not designed to address. Respondent challenges the legality of systemic agency practices and procedures which are dealt with most efficiently in a single case, thereby preventing a flood of similar litigation throughout the country. *See Michigan Academy* 476 U.S. at 680 n.11 (noting that regulatory challenge would not open the floodgates to millions of claims because the broad challenge at issue was not a "quite minor matter" properly confined to administrative review). As noted subsequently herein, Respondent's case cannot be meaningfully addressed in the administrative process, nor can the violation of its members' constitutional rights be adequately remedied retroactively upon judicial review.

In a nutshell, this case simply does not present a claim within the meaning of section 405(h). The challenged regulations do not constitute a "decision of the Secretary," which section 405(h) excepts from review by any tribunal. As this Court noted in *Michigan Academy*, a contrary conclusion "would ignore the contextual definition of 'decision' in the first sentence [of section 405(h)] as those

determinations made by the Secretary after a hearing." 476 U.S. at 679 n.8. This Court recognized that where, as here, judicial review is not available as a legal or practical matter, a regulatory challenge is not subject to section 405(h) because *there is no administrative remedy to exhaust*. *Id.*

B. Section 405(h) Does Not Preclude Pre-Enforcement Judicial Review Of Collateral Constitutional And Statutory Challenges

Nothing in section 405 or the remainder of the Social Security Act explicitly precludes pre-enforcement review of actions brought to challenge the unconstitutional or otherwise unlawful practices and policies of an administrative agency. As this Court has recognized on more than one occasion, there exists a "strong presumption that Congress intends judicial review of agency action." *E.g., Michigan Academy*, 476 U.S. at 670; *McNary v. Haitian Refugee Ctr. Inc.*, 498 U.S. 479, 496 (1991). Accordingly, not all statutory or regulatory challenges involving the Medicare Act are barred by section 405(h) or are required to proceed through administrative review.

Although judicial review historically has been denied where a provider or beneficiary has failed to exhaust administrative remedies, this Court has permitted immediate judicial review for constitutional claims that were collateral to a claim for payment. *Eldridge*, 424 U.S. 319 (1976). In *Mathews v. Eldridge*, this Court held that the district court had jurisdiction to decide a constitutional issue that was collateral to a claim for disability benefits, despite the fact that the respondent had not exhausted his administrative remedies. *Id.* at 331. This Court found that the respondent raised a colorable constitutional claim that justified immediate review because a denial of disability benefits "would damage him in a way not recompensable through retroactive payments." *Id.* Accordingly, this Court waived

the respondent's obligation to exhaust his administrative remedies. *Id.* at 331-32. The exhaustion requirement may similarly be waived if it would be futile to pursue administrative remedies. *Salfi*, 422 U.S. at 767 (noting that exhaustion may be futile where the only issue to be resolved is a matter of constitutional law beyond the Secretary's competence to resolve).

Immediate judicial review also has been permitted where review of "substantial statutory and constitutional challenges" to the Secretary's administration of the Medicare program would be otherwise foreclosed. *Michigan Academy*, 476 U.S. at 680; *see also McNary*, 498 U.S. 479 (permitting constitutional challenge to agency practices and procedures where meaningful judicial review was unavailable as a practical matter). In *Michigan Academy*, an association of family physicians and several individual physicians challenged the validity of a regulation governing the methodology for determining physician reimbursement under Medicare Part B. At the time *Michigan Academy* was decided, the Medicare statute explicitly authorized judicial review of determinations regarding the amount of payments under Part A but not under Part B. This Court rejected the government's assertion that Congress contemplated administrative review of "trivial" monetary claims, but intended no review of statutory and constitutional challenges. 476 U.S. at 680. Recognizing instead the "strong presumption" that Congress intends judicial review of agency action, this Court held that the respondents' claims were not barred by section 405(h). *Id.* at 670.

Similarly, in *McNary*, this Court held that two organizations and several individuals could bring a due process challenge to Immigration and Naturalization Service ("INS") amnesty determination procedures where respondents "would not, as a practical matter, be able to obtain, meaningful judicial review." 498 U.S. at 496. The statute at issue expressly provided that judicial review of

adverse amnesty determinations could only occur in the context of deportation or exclusion proceedings. This Court also held that the relevant jurisdictional bar did not preclude the respondents' claims because they did not seek review on the merits of an amnesty determination. *Id.* at 494.

For a variety of reasons, meaningful judicial review of the claims in *McNary* was not possible. Applicants for amnesty were precluded from developing an adequate record for judicial review. *Id.* at 496. In addition, because review of an adverse amnesty determination could only be reviewed in the context of a deportation proceeding, an undocumented alien seeking review of such a determination would have to voluntarily surrender for deportation, thus virtually assuring that no review would be had. Finally, this Court recognized that the forum for judicial review -- the federal circuit courts of appeal -- would lack the fact-finding and record-developing capabilities of a district court.

As discussed below, the case at bar fits squarely into the exception this Court has delineated for those collateral issues for which meaningful judicial review is otherwise foreclosed.

II. Immediate Judicial Review Of Respondent's Challenge Is Warranted Under *Michigan Academy* Because Such A Challenge Is Otherwise Incapable Of Receiving Meaningful Review

Respondent's legal challenges are incapable of receiving meaningful administrative or judicial review because the Secretary has promulgated an unprecedented review scheme that either completely prohibits review or strongly discourages providers from seeking review of certain determinations. Contrary to the Secretary's assertion

that judicial review is merely delayed,[4] the fact is that, for a variety of reasons, review is nearly impossible to obtain. Consequently, the inconsistencies in the survey and enforcement process, which OBRA 1987 was designed in part to address,[5] continue to persist. Efforts to challenge or address these inconsistencies divert valuable facility staff and resources from caregiving, and frustrate facility attempts to comply with applicable standards and to provide quality resident care. Ultimately, these inconsistencies prevent beneficiaries from receiving a fair and accurate assessment of the quality of care at a particular facility.

Congress could not have intended such a result, and it is disingenuous for the Secretary to suggest otherwise when it is she, and not Congress, who has precluded review of critical agency determinations. Although we do not dispute that section 405(g) sets forth the exclusive review mechanism for the vast majority of provider disputes, this case presents a exception to that review process. A decision to the contrary would be tantamount to writing a "blank check[ ] drawn to the credit of some administrative officer or board." *Michigan Academy*, 476 U.S. at 671 (quoting S. Rep. No. 752, 79th Cong., 1st Sess. 26 (1945)). Failure to allow pre-enforcement judicial review of the Secretary's regulations and manual provisions would similarly be giving the Secretary *carte blanche* to issue deficiencies and to impose remedies without giving providers, in many cases, the ability to challenge the agency action.

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[4] Petitioner's Brief ("Pet. Brf.") at 38.

[5] Omnibus Budget Reconciliation Act of 1987, Pub. L. No. 100-203, § 4202, 101 Stat. 1330-174 (codified at 42 U.S.C. § 1395i-3(g)(2)(D) (requiring implementation of programs to reduce inconsistencies in survey results)).

A. Medicare Regulations Prohibit Review Of Respondent's Constitutional Challenge

The administrative review mechanisms set forth in section 405(g) are incapable of addressing statutory, regulatory, or constitutional challenges. When a provider undergoes a survey and is cited for deficiencies, it may dispute these deficiencies directly with the surveyors pursuant to the informal dispute resolution procedure authorized by 42 C.F.R. § 488.331(a). However, providers may use that procedure only to refute survey findings; the validity of the regulations that form the basis for a survey deficiency cannot be challenged. *See id.* Moreover, the failure of HCFA or the state agency to complete informal dispute resolution in a timely manner will not delay any enforcement action, and the facility is expressly precluded from seeking any such delay. *Id.* § 488.331(b).

In addition, in hearing a facility's appeal of the imposition of civil money penalties ("CMPs"), ALJs have no authority to determine the validity of the underlying federal statutes or regulations or to enjoin any act of the Secretary. 42 C.F.R. § 1005.4(c)(1), (4); *Care Inn of Gladewater*, No. A-98-61, DAB 1680 (March 2, 1999), *reprinted in* Medicare and Medicaid Guide (CCH) ¶ 120,041; *Birchwood Manor Nursing Ctr.*, No. A-98-66, DAB 1669 (Sept. 4, 1998). Moreover, there is no "expedited review" procedure to permit immediate judicial review of survey, certification, and enforcement determinations that involve solely the validity of a statute or regulation. *Cf.* 42 U.S.C. § 1395oo(f)(1) (authorizing judicial review of reimbursement determinations made by fiscal intermediaries if such determinations involve questions of law or regulation and the ALJ determines on its own motion or on the provider's motion that it is without authority to decide such questions).

Because ALJs do not have the authority to address constitutional or statutory challenges, providers have no opportunity to develop a record on such issues for later judicial review. This is especially critical in those cases involving the imposition of CMPs because judicial review of this type of penalty is available only in a federal court of appeals. As a general matter, fact-finding and record developing capabilities are not within the expertise of the court of appeals. In contrast, these tasks are germane to the federal district courts. For this and other reasons, this Court found in *McNary* that restricting judicial review to the courts of appeals for a particular amnesty determination of the INS was the "practical equivalent of a total denial of judicial review of generic constitutional and statutory claims." 498 U.S. at 497.

The Secretary's reliance on *Thunder Basin Coal Co. v. Reich*, 510 U.S. 200 (1994), is misplaced. *See Pet. Brf.* at 20, 32, and 49. *In Thunder Basin*, this Court held that a pre-enforcement regulatory challenge was precluded by the administrative review scheme of a federal mining act that provided for review of statutory and constitutional issues by an independent commission. *Id.* at 216. This Court found that such claims could receive meaningful administrative review because the reviewing body was an independent entity and not the agency itself, which is clearly not the case here. *Id.* at 215. This Court also was persuaded by the availability of subsequent review in the federal court of appeals. However, because the independent commission had the authority to review constitutional or regulatory challenges, it was capable of building an adequate record for appellate court review.

As in *McNary*, Illinois Council seeks review of unlawful practices and policies adopted by a federal agency in administering a federal program. As in *McNary*, the inability of courts of appeals to review or develop a record that adequately reflects the manner in which HCFA

administers the survey and enforcement process is a severe impediment to adequate and meaningful judicial review.

B. The Challenged Regulations Prohibit All Review Of Significant Survey And Enforcement Actions

When a nursing facility is surveyed by a state agency[6] and cited for one or more deficiencies, the state agency may recommend that the Secretary impose one or more remedies. The recommended remedies depend on the scope and severity of the deficiency citations, but may include, among other things, state monitoring, denial of payment, CMPs, temporary management, and termination of the provider agreement. 42 U.S.C. § 1395i-3(h); 42 C.F.R. §§ 488.406, 488.408. The challenged regulations prohibit review of a number of very significant survey and enforcement determinations, including the following: issuance of deficiencies without the imposition of a remedy; the government's choice of remedy; and determinations regarding the level of noncompliance. These determinations have a fundamental impact on facility operations and the Secretary's assessment of the quality of care provided at a facility. Thus, these determinations are not "quite minor matters" -- they address the very purpose of the survey and enforcement system.

1. Issuance Of Deficiencies Without Imposition Of A Remedy

In some cases, surveyors cite deficiencies based upon findings at the facility, but HCFA does not impose a remedy, either because the deficiency was found to be corrected

[6] Pursuant to 42 U.S.C. § 1395i-3(g)(1), states are responsible for certifying skilled nursing facility compliance with Medicare standards.

promptly or it did not rise to the scope or severity for which a remedy was deemed appropriate. *See* 59 Fed. Reg. 56,116, 56,164 (Nov. 18, 1994) ("there are situations in which a remedy might not be necessary because the facility corrected the practice which led to the abuse."). In such cases, the determination that a deficiency existed is not appealable -- even if the provider vigorously disputes the accuracy of the citation and seeks only to correct its compliance record.[7] Further, where HCFA or the state agency threatens to impose a remedy that is ultimately not imposed, a provider is nevertheless powerless to appeal the citation. *Ruth Taylor Inst.*, No. C-96-100, DAB-CR430 (Aug. 21, 1996) *reprinted in* Medicare & Medicaid Guide (CCH) ¶ 44,760. The only way a facility may challenge a deficiency citation for which no remedy is imposed is to refuse to submit a plan of correction and to refuse to correct the alleged deficiency, thereby risking termination of its Medicare provider agreement -- hardly an acceptable option.

While the Secretary apparently believes that it is reasonable to preclude review on the grounds that the absence of a remedy equates to the absence of any harm, the reality is that such determinations can and do have significant future ramifications. First, every Medicare and Medicaid certified nursing home in the country must post its statement of deficiencies in a location that is easily

[7] 42 C.F.R. § 498.3(d)(1); *Schowalter Villa*, No. C-98-493, DAB-CR568 (Jan. 25, 1999); *reprinted in* Medicare & Medicaid Guide (CCH) ¶ 120,037, *aff'd*, DAB-1688 (App. Div. May 5, 1999); *Rafael Convalescent Hosp.*, No. C-96-292, DAB-CR444 (Nov. 19, 1996), *reprinted in* Medicare & Medicaid Guide (CCH) ¶ 45,008, *aff'd*, DAB-1616 (App. Div. Mar. 24, 1997), *app. filed* at Doc. No. 97-1967 (N.D. Cal. May 23, 1997); *Arcadia Acres, Inc.*, No. C-96-160, DAB-CR424 (June 26, 1996), *reprinted in* Medicare & Medicaid Guide (CCH) ¶ 44,513; *aff'd*, No. A-96-183, DAB-AD1607 (Jan. 22, 1997) *reprinted in* Medicare & Medicaid Guide (CCH) ¶ 45,140; *Fort Tyron Nursing Home*, No. C-96-173 (July 3, 1996).

accessable to its residents (*e.g.*, in the lobby). 42 C.F.R. § 483.10(g)(1); U.S. Department of Health and Human Services, Medicare/Medicaid State Operations Manual, HCFA Pub. 7 Rev. 1 (3/98) App. PP-25 (hereinafter, "HCFA Pub. 7"). By statute, statements of deficiencies must also be disclosed to the public by HCFA and state survey agencies.[8] 42 U.S.C. § 1395i-3(g)(5). Moreover, statements of deficiencies now are publicly disclosed on HCFA's internet website.[9] The website publicizes all deficiencies for which a home was cited, including isolated deficiencies that constitute no actual harm. Provider comments regarding the deficiencies are not provided on the website, and although the website contains a column to identify the date a facility has corrected a deficiency, those dates frequently are missing. The widespread public availability of inaccurate, unbalanced, or misleading deficiency data -- at the facility itself, from the state survey agency, and on the internet -- serves to harm the facility and mislead those beneficiaries or family members who seek accurate information on a facility's compliance record.

Second, by statute, deficiencies characterized as substandard quality of care[10] on three consecutive annual

[8] In some cases, the state survey agency must disclose deficiencies to the state's long-term care ombudsman and must notify a resident's treating physician and the state's nursing home administrator licensing board of the facility's noncompliance. 42 U.S.C. § 1395i-3(g)(5).

[9] The website is located at www.medicare.gov/nursing/home.asp.

[10] "Substandard quality of care" is defined as one or more deficiencies related to the requirements of participation for resident behavior and facility practices, quality of life, or quality of care that constitute (i) immediate jeopardy to residents, (ii) a pattern of or widespread actual harm that is not immediate jeopardy, or (iii) a widespread potential for more than minimal harm but less than immediate jeopardy with no actual harm. 42 C.F.R. § 488.301.

surveys require a ban on payment for new admissions. 42 U.S.C. § 1395i-3(h)(2)(D). If no remedy is imposed for two limited substandard quality of care citations, and the facility receives a third such citation, the ban on payment for new admissions is imposed automatically. Thus, a very significant penalty can be imposed on a facility when the underlying deficiencies cannot be challenged.

Third, past deficiency citations, regardless of their scope or severity, often affect which enforcement remedy the government chooses to impose after a subsequent survey. In choosing a remedy, HCFA and state agencies are authorized to consider a facility's history of noncompliance, both in general and with respect to the specific deficiencies cited in the current survey. 42 C.F.R. § 488.404(c)(2). There is no limit on the number of years of deficiency data that HCFA can consider in determining the enforcement remedy. Thus, unrelated deficiency citations that occurred several years earlier can be used to justify a more severe penalty against a provider that is now powerless to contest the underlying deficiencies at issue.

Fourth, past deficiencies for which no remedy was imposed can cause a facility to be designated a "poor performing facility" ("PPF"). *See, e.g., Baltic Country Manor*, No. C-96-295 (Dec. 11, 1996), *reprinted in* Medicare & Medicaid Guide (CCH) ¶ 45,038. A PPF is defined in the HCFA State Operations Manual as "a facility with a history of going in and out of compliance or a facility that has no system in place to monitor its own compliance." HCFA Pub. 7 § 7304B. Unlike facilities without such a designation, PPFs have no opportunity to correct deficiencies prior to the recommendation of the imposition of CMPs or other remedies. *Id.* A facility may be designated a PPF if significant noncompliance is found during the current survey

and Level A deficiencies[11] were identified in one of the facility's two most recent standard surveys.[12] HCFA currently is developing criteria for identifying poor performing nursing home chains, and it has recommended that states designate a facility as a PPF if another facility within the same chain -- regardless of its location or its separate corporate or licensure status -- has been designated a PPF.[13] Thus, PPF designation, especially when based on citations that cannot be appealed by a provider, has a particularly detrimental "domino effect" on other facilities within the same chain that suffer from even relatively minor deficiencies. Chain facilities would have no ability to appeal a related facility's PPF designation or the deficiencies that formed the basis for that designation.

The Secretary's Departmental Appeals Board ("DAB"), which hears provider appeals of adverse survey and enforcement determinations, has refused to permit appeals of prior, uncontested deficiencies that served as a basis for PPF designation. In *Baltic Country Manor*, No. C-96-295 (Dec. 11, 1996), *reprinted in* Medicare & Medicaid Guide (CCH) ¶ 45,038, a facility was designated a PPF based on the results of a February 1996 survey and its two previous surveys in 1994 and 1995. The facility was never

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[11] A Level A deficiency is the least serious type of deficiency. A Level A deficiency results in no actual harm, and although it must be corrected, it is not even required to be addressed in a facility's plan of correction.

[12] Standard surveys must be conducted at least once every 15 months. 42 U.S.C. §1395i-3(g)(2)(A)(iii)(I).

[13] Memorandum from Richard P. Brummel, Acting Director, Disabled and Elderly Health Programs Group, Center for Medicaid and State Operations, to Associate Regional Administrators and State Agency Directors (Sept. 22, 1998).

provided a hearing on the 1994 and 1995 survey deficiencies, which were corrected without the imposition of a CMP, and it therefore sought to contest those deficiencies on the grounds that they contributed to HCFA's imposition of a CMP in the 1996 survey. The ALJ rejected the facility's argument, prohibiting the facility from contesting the earlier deficiencies in an effort to challenge its designation as a PPF. Moreover, the ALJ held that the facility's PPF designation could not be appealed because it was not a reviewable "initial determination" as defined at 42 C.F.R. § 498.3(b).

Significantly, despite the serious consequences of the PPF designation and its relationship to nonappealable deficiency citations, the designation is not authorized by statute or regulation. It was promulgated without public notice or comment and appears only in the State Operations Manual, which is published by HCFA to provide guidance to surveyors. In the case at bar, Illinois Council has challenged the validity of the State Operations Manual on the grounds that it should have been promulgated under the Administrative Procedure Act. As is quite evident in *Baltic Country Manor*, HCFA likes to have its cake and eat it, too -- it will require providers to exhaust administrative remedies, but it then uses informal manual guidance to conveniently circumvent the fair hearing procedures that provide the only forum for review of HCFA and state surveyor actions.

The future ramifications inherent in the citation of deficiencies for which no remedies are imposed are further compounded by the absurdity of many deficiencies. Examples of unreasonable deficiencies include the following:

(i) A deficiency was cited for use of non-certified staff to make beds, transport patients in wheelchairs, label a pair of glasses for a resident, and organize a patient's clothing, all of which the

surveyor believed constituted a "direct caregiving activity."

(ii) A D-level deficiency (*i.e.*, an isolated deficiency resulting in no actual harm but with the potential for more than minimal harm and less than immediate jeopardy) was cited because the activity goals for a blind resident who was very interested in sailing and related hobbies "did not include any activities that involved sailing or nautical issues" and because the facility failed to provide a table for the resident to use for building model ships.

(iii) A G-level deficiency (*i.e.*, a deficiency causing actual harm to a resident) was imposed for violating a resident's dignity by causing him or her to wait in line for a whirlpool bath.

(iv) A G-level citation was imposed for failure to provide notice to the resident's physician of a change in the resident's condition, even though the facility phoned the physician and the physician personally examined the resident the next day.

Far too often, facilities receive citations for clerical or documentation issues even where there is no allegation of any adverse impact on resident health and safety. In other instances, surveyors impose their own subjective view as to whether the resident was, or could have been, harmed by the facility's conduct, even where the resident and family members expressed no concern. It is unconscionable that providers can be subject to harsh enforcement remedies, "PPF" status, and the widespread public disclosure of their compliance records on the basis of unrelated or absurd

deficiencies for which administrative and judicial review is completely foreclosed.

2. Government's Choice Of Remedy

A nursing facility may not challenge the particular remedy imposed on it by HCFA. 42 C.F.R. § 498.3(d)(11), (14) . The DAB frequently has refused to review HCFA's choice of remedy. For example, in *Somers Manor Nursing Home, Inc.*, No. C-96-054, DAB-CR420 (June 4, 1996), *reprinted in* Medicare & Medicaid Guide (CCH) ¶ 44,517, the facility had been advised incorrectly by the state agency that a particular deficiency had been deemed corrected. Unfortunately, the state agency failed to notify the facility of its erroneous advice in sufficient time to permit the facility to correct the deficiency before the applicable deadline. HCFA nevertheless imposed the remedy of denial of payment for new admissions. The ALJ held that HCFA was not estopped from imposing this severe penalty and noted that ALJs have no authority to review the government's choice of remedy. Similar cases abound. *E.g.*, *Beverly Health & Rehabilitation-Springhill*, No. A-99-19, DAB-CR553 (Oct. 27, 1998) *reprinted in* Medicare & Medicaid Guide (CCH) ¶ 120,033; *Orchard Grove Extended Care Ctr.*, No. C-97-555, DAB-CR541 (July 20, 1998), *reprinted in* Medicare & Medicaid Guide (CCH) ¶ 120,006; *Brighton Pavilion*, No. C-96-081, DAB-CR510 (Dec. 10, 1997). Consequently, providers may be subject to excessively harsh remedies, and similarly situated providers may receive very different remedies for the same infractions. Nevertheless, providers have no mechanism to challenge the arbitrary nature of remedy determinations.

3. Level Of Noncompliance Determinations

The severity or level of noncompliance affects HCFA's choice of remedy. The state agency determines the level of noncompliance by considering (i) whether a facility's deficiencies constitute actual harm or immediate jeopardy and (ii) whether the deficiencies are isolated or constitute a pattern or are widespread. 42 C.F.R. § 488.404(b) The remedies are divided into three groups, Categories 1, 2, and 3, with the least severe remedies (*e.g.*, directed plan of correction) in Category 1 and the most severe remedies (*e.g.*, immediate termination) in Category 3.

CMPs may be imposed as Category 2 or Category 3 remedies. Depending on the severity of the deficiency, a CMP may range from $50 - $3,000 per day or from $3,050 - $10,000 per day. 42 C.F.R. § 488.438(a).[14] The penalty amount is based on the facility's history of noncompliance (including repeat deficiencies, the facility's financial condition, and the facility's degree of culpability). *Id.* § 488.438(b).

A nursing facility may not challenge a finding as to the level of noncompliance, unless a successful challenge on the issue would (i) affect the range of CMP amounts that

[14] The Secretary recently issued a regulation which purports to establish CMPs "per instance" of noncompliance. 64 Fed. Reg. 13,354 (Mar. 18, 1999) (codified at 42 C.F.R. §§ 488.402 *et seq.*). The American Health Care Association has challenged the Secretary's authority to issue this rule on the grounds that "per instance" CMPs violate the Medicare and Medicaid statutes and the Administrative Procedure Act. *American Health Care Ass'n v. Shalala*, Case No. 1:99 CV 01207 (D. D.C. May 18, 1999).

[15] The loss of approval to provide nurse aide training programs is a Category 1 remedy. 42 C.F.R. § 488.408(c).

HCFA could collect, or (ii) affect a finding of substandard quality of care that results in the facility's loss of approval to provide in-house nurse aide training programs.[15] 64 Fed. Reg. 39,934 (July 23, 1999).

Although some level of compliance determinations are now subject to review, virtually all such determinations have a significant effect on the facility, especially financially. Moreover, level of compliance determinations are not imposed in a consistent manner among providers because so many of the terms used to define the levels of compliance are vague (*e.g.*, "actual harm," "more than minimal harm," "widespread actual harm that is not immediate jeopardy," "widespread potential for more than minimal harm, but less than immediate jeopardy with no actual harm"). Illinois Council has challenged the vagueness of these regulations, but no individual provider could ever bring such a challenge in the current administrative review process. The vagueness of the standards by which providers are judged -- and judged harshly -- should not be left to chance interpretation by individual HCFA officials or state surveyors.

C. Even When Administrative Or Judicial Review Is Available, The Secretary's Procedural Or Other Requirements Strongly Discourage Such Review

The Secretary has created such significant incentives for providers to waive their appeal rights that meaningful review is effectively precluded. For example, the Secretary's strict pleading requirements -- with no support in the regulations -- are one way that the Secretary prevents providers from challenging deficiencies imposed under the facility survey, certification, and enforcement system. According to applicable regulations, a request for hearing is only required to identify the "specific issues, and the findings of fact and conclusions of law with which the affected party disagrees; and . . . specify the basis for

contending that the findings and conclusions are incorrect." 42 C.F.R. § 498.40(b). However, on HCFA's motions for summary affirmance of the remedy imposed, hearing requests specifying the issues using notice pleading rules have been deemed insufficient. *E.g., Care Inn of Gladewater*, DAB-1680 (requesting review of "the alleged noncompliance with certification requirements that lead to the threatened enforcement"); *Birchwood Manor Nursing Ctr.*, No. A-98-66, DAB 1669 (Sept. 4, 1998) *reprinted in* Medicare & Medicaid Guide (CCH) ¶ 120,023 (requesting a hearing to "contest the remedies, certification issues, and any and all remedies and adverse actions recommended as a result of the . . . survey").

In addition, the time-consuming nature of the administrative review process further discourages providers from appealing adverse determinations. As noted above, there is no expedited review process for the issues raised by Respondent in this case. Moreover, appeals are not prioritized in any way (except for those involving the imposition of immediate provider termination). Consequently, a broad regulatory or statutory challenge such as this -- even if it were subject to administrative review, which *Amici* do not concede -- will be reviewed with all other appeals on a "first-in-first-out" basis. Given the amount of time required to obtain a decision from the DAB, providers frequently decide not to appeal at all, or they discontinue the appeal process at the DAB level. Our research revealed only two cases involving a constitutional or regulatory challenge to HCFA practices and policies that was reviewed in federal court: *Rafael Convalescent Hosp. v. Shalala*, No. C 97-1967 FMS, 1998 WL 196469 (N.D. Cal. Apr. 15, 1998) (denying government's motion for summary judgment with respect to provider's allegations that regulations were not promulgated in accordance with Administrative Procedure Act and that HCFA failed to follow internal guidelines before sanctioning provider); and *Ivy Hall Geriatric & Rehabilitation Ctr., Inc. v. Shalala*, No.

CIV. AMD 98-2666, 1999 U.S. Dist. LEXIS 8677 (D. Md. May 25, 1999) (granting defendant's motion for summary judgment regarding constitutionality of appeal procedures for revocation of facility's authorization to conduct nurse aide training programs).

III. Permitting Pre-Enforcement Judicial Review Of Respondent's Case Is Consistent With The Purposes Of The Doctrine Of Exhaustion Of Administrative Remedies

The purpose of the doctrine of exhaustion of administrative remedies is to (i) prevent premature interference with agency process, (ii) to afford the agency an opportunity to correct its own errors, (iii) to provide the parties and the courts the benefit of agency expertise, and (iv) to compile a record for judicial review. *Salfi*, 422 U.S. at 765 (1975). None of the purposes of the doctrine would be satisfied if this Court were to require Respondent's members to contest individually, and in piecemeal fashion, the regulatory scheme at issue in this case.

First, pre-enforcement judicial review of regulatory challenges does not constitute premature interference with agency process, where, as here, the administrative agency has no authority to address statutory or constitutional issues. As this Court recognized in *Mathews v. Eldridge*, it is unrealistic to expect that the Secretary would consider substantial changes in the current administrative review system at the behest of a single provider raising a constitutional challenge in an adjudicatory context. 424 U.S. at 330. The futility of exhaustion in such a case is obvious.

Second, Respondent's challenge is not within the scope of administrative expertise. Constitutional and statutory challenges are considered to be within the scope of judicial competence. *Salfi*, 422 U.S. at 767; *Thunder Basin Coal Co.*, 510 U.S. at 215.

Third, the parties cannot compile a record to assist later judicial review when the administrative review process precludes consideration of regulatory and statutory challenges. Because the administrative review process does not address the broad challenge at issue here, this Court should not relegate review of this matter to a process that cannot produce an adequate record for review. *See McNary*, 498 U.S. at 493. The adequacy of the record for review is particularly critical in this case, where, as here and in *McNary*, some administrative determinations are appealed directly to a circuit court of appeals.

Finally, denying jurisdiction in this case and requiring Respondent's members to individually appeal what could be accomplished in a single ruling serves only (at best) to consume the resources of an already overburdened administrative appeal system At worst, Respondent's legitimate constitutional and statutory challenges will never receive meaningful review, and the Secretary will possess the absolute power -- unfettered administrative discretion -- that corrupts so absolutely.

CONCLUSION

The judgment of the Court of Appeals for the Seventh Circuit should be affirmed.

Respectfully submitted,

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