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 AMERICAN ASSOCIATION OF HOMES AND SERVICES FOR THE AGING AS AMICUS CURIAE IN SUPPORT OF RESPONDENTS

Filed August 13, 1999

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INTEREST OF AMICUS

The American Association of Homes and Services for the Aging (AAHSA), a national nonprofit membership association, submits this brief in support of respondent with the written consent of both parties. AAHSA and its forty affiliated state associations represent over 5,000 not-for-profit facilities and organizations providing services to over 1,000,000 aging and disabled individuals. Seventy percent of AAHSA member organizations have religious sponsors. Others are sponsored by private foundations, fraternal organizations, government agencies, unions and community groups. Approximately 3,500 of AAHSA's members are nursing homes and continuing care retirement communities with skilled nursing care components, 85% of which participate in Medicaid, Medicare or in both programs.

This case involves the availability of meaningful judicial review of the system developed by the Secretary of Health and Human Services (the Secretary of HHS) to enforce nursing home compliance with Medicaid and Medicare conditions of program participation. AAHSA provided information used in developing the 1986 report of the Institute of Medicine ("IOM"), *Improving the Quality of Care in Nursing Homes (IOM Study)*, and has for over ten years provided extensive comment on proposed federal implementing rules, communicated regularly with the Health Care Financing Administration of HHS ("HCFA") and participated extensively in committees and task forces surrounding the adoption of standards and procedures designed to implement the OBRA reforms. Additionally, AAHSA participated as *amicus curiae* before the federal district court in *Michigan Ass'n of Homes and Services for the Aging, Inc. v. Shalala*, No. 95-75278 *(MAHSA v. Shalala)*, and sponsored the appeal and rehearing petition filed in the Sixth Circuit in *MAHSA v. Shalala*, 127 F.3d 496 (6th Cir. 1997), "an essentially identical case" that conflicts with the decision of the Seventh Circuit below. *Illinois Council on Long Term Care, Inc. v. Shalala*, 143 F.3d 1072, 1074 (7th Cir. 1998) (Pet. App. 1a-2a).

In sum, AAHSA's members are vitally effected by the Secretary's implementation of the OBRA enforcement scheme and significantly impacted in their operations if the system is not administered in a fair, understandable and consistent fashion.

STATEMENT

A. The Genesis Of The Current Nursing Home Survey and Enforcement Standards

By adding sections 1819 and 1919 to the Social Security Act (the Act or SSA) the Omnibus Budget Reconciliation Act of 1987 (OBRA) changed the emphasis on Medicaid and Medicare program participation for long term care providers from a physical-plant and process based approach to one oriented towards resident outcomes. OBRA §§4201, 4211, 101 Stat. 1330-160 to 1330-221, codified at 42 USC 1395i-3, 1396r. *See* 53 Fed. Reg. 22850 (June 17, 1988). The OBRA reforms were an outgrowth both of the IOM study which was commissioned by the Secretary in 1985 and of a class action initiated in 1983 to challenge the survey and enforcement system that predated the OBRA amendments. *See In re Estate of Smith v. O'Halloran*, 557 F.Supp. 289 (D.Colo. 1983), *rev'd sub nom In re Estate of Smith v. Heckler*, 747 F.2d 583 (10th Cir. 1984) (recognizing jurisdiction and compelling adoption of rules); *on remand sub nom In re Estate of Smith v. Bowen*, 656 F.Supp. 1093 (D.Colo. 1987) (ordering publication of survey and enforcement standards as rules on remand); *In re Estate of Smith v. Bowen*, 675 F.Supp. 586 (D. Colo. 1987) (holding Secretary in technical contempt for use of Manuals to establish key survey parameters) (collectively, *Smith* litigation). *Smith* contested the Secretary's failure to adopt nationally uniform and consistently applied patient-outcome oriented conditions of Medicaid program participation and enforcement for nursing homes. Assuming plenary jurisdiction, the court in *Smith* criticized the fact that:

> None of the survey forms and guidelines was published in the Rule, and no details were given concerning the criteria for assessing . . . the patients . . . [or] for determining deficiencies. As a result, there is confusion and uncertainty about the components of the . . . system.

656 F. Supp. at 1097.

The court determined that "uniform guidelines are imperative" to achieving uniform enforcement policies, that the "failure

of the Rule to include the specifics of the . . . survey system" also raises a "procedural due process concern" (*id.*), and that "[t]he refusal of the Secretary to be bound [through the rulemaking process] by specific procedures, guidelines and forms is a dereliction of his duty . . . ." *Id.* at 1096. In July 1987, the Secretary published a proposed rule to "specify clear requirements in the regulations that State surveyors could follow" in order to purge the contempt citation entered in *Smith*. 52 Fed. Reg. 24752 (July 1, 1987). These rules were finalized in 1988. 53 Fed. Reg. 22850 (June 17, 1988).

The district court ultimately authorized the Secretary to supplant the rules adopted in response to its prior orders with similar but more comprehensive rules mandated by OBRA. *Id.* In 1991 HCFA adopted final regulations to implement the new substantive standards imposed by OBRA. *See* 56 Fed. Reg. 48826 (Sept. 26, 1991), *adopting* 42 C.F.R. Part 483. These established clinical outcome and quality of [redacted] oriented standards of care which centrally require nursing homes to structure their services to "attain or maintain the highest practical mental, physical, and psychosocial well being of each resident," 42 U.S.C. 1395i-3(b)(2) [Medicare], 1396r(b)(2) [Medicaid]; 42 C.F.R. Part 483 [both]. These substantive requirement have been in effect for nearly a decade, and have not been challenged by respondent.

Under the pre-OBRA system, surveyors determined whether or not facilities were in "substantial compliance" with the standards of participation, and the only remedies for non- compliance were termination of a facility's participation or a ban on payment for new Medicare or Medicaid admissions. Facilities that regained substantial compliance were not subject to sanction. In addition to requiring new outcome-oriented participation standards, OBRA obligated the Secretary to develop a revised enforcement scheme that included an array of "intermediate sanctions" for facilities found to be out of compliance by state or federal surveyors for survey violations that do not pose immediate jeopardy to the nursing home's residents. 42 U.S.C. 1395i-3(h)(1), (2), 1396r(h)(1), (2). Among these are State-imposed plans of correction, the imposition of temporary facility management or State monitors, and civil monetary penalties (CMPs). 42 U.S.C. 1395i-3(h)(1), (2), 1396r(h)(1), (2).

Cognizant of the *Smith* litigation, Congress specifically ordered the Secretary to enact these sanctions and remedies "through regulations" and otherwise to ensure that "each State and the Secretary shall . . . reduce inconsistency in the application of survey results among surveyors." 42 U.S.C. 1395i-3(g)(1)(D), 1396r(g)(1)(D); 42 U.S.C. 1395i-3(h)(2)(B), 1396r(g), (h)(2)(b).[1] Congress imposed an October 1, 1988 deadline for the Secretary to promulgate complementary survey and enforcement regulations containing "specific criteria" and "guidelines" to govern the application of the remedies added by OBRA by State survey agencies. 42 U.S.C. 1396r(h)(2)(A), (B). Congress further specified that the Secretary's failure to timely enact enforcement rules "shall not relieve a State of the responsibility for establishing such remedies" as are required by OBRA effective October 1, 1989. Pub. L. No. 100-203, §4213, 101 Stat. 1330, *codified* at 42 U.S.C. 1396r(h)(2)(B).

The October 1988 deadline passed without new survey rules being promulgated, and enforcement of the revised substantive standards was channeled into the existing survey enforcement scheme. Eventually the Secretary published proposed enforcement rules in 1992, 57 Fed. Reg. 39278 (Aug. 28, 1992), and issued final regulations which became effective July 1, 1995. and are the subject of this action, 59 Fed. Reg. 56116 (Nov. 10, 1994). These rules were accompanied by the issuance of HCFA Pub. 7, State Operations Manual (SOM), Transmittals 273 and 274 (June 1995), which also are challenged by respondent.

B. Conduct of Nursing Home Surveys and Appeals Under Current Standards

1. Medicaid Versus Medicare

This case pertains predominately if not exclusively to the Medicaid program compliance. Long term care under Medicare is only an adjunct of the Part A hospital benefit, and generally extends only to admissions that follow a three (3) day or longer

1. In contrast, Congress authorized the Secretary to establish "guidelines" for setting minimum standards to be incorporated in the States' Medicaid appeal procedures. 42 U.S.C. 1396r(f)(3).

hospitalization and require highly skilled nursing or rehabilitative post-hospital care by licensed professionals. 42 U.S.C. 1395d(a)(2)(A), (b)(2). In contrast, Title XIX broadly authorizes coverage of long term care for aged and impoverished individuals, and requires participating states to cover nursing facility services. 42 U.S.C. 1396d(a)(i)(4)(A),1396a(a)(10)(A).

Nursing homes may participate in Medicaid, Medicare or both programs. Under OBRA, separate but parallel amendments were made to Titles XVIII and XIX of the Act, and the Secretary implemented regulatory standards common to both programs. 42 U.S.C. 1395i-3, 1396r; 42 C.F.R. 483.1. According to statistics derived from HCFA's Online Survey Certification and Reporting (OSCAR) database, approximately 13% of all nursing homes (2,259) participate only in Medicaid, 8% (1,448) participate only in Medicare, and 78% (13,552) are "dually certified." Cowles Research Group, *Nursing Home Statistical Yearbook* (AAHSA 1998), at 130 (Table V-1). In 1998, 1,014,534 nursing home beds were certified under Medicaid only as compared with 57,458 certified under Medicare only and 654,442 "dually certified." *Id.* at 136 (Table V-4). Approximately *71.9%* of all *patient days* in nursing home facilities are covered by Medicaid, which is by far the largest single payer for long term care, whereas Medicare covers only *8%* of *patient days*. HCIA, Inc. and Arthur Anderson, LLP, *Guide to the Nursing Home Industry* (1997).

2. Inconsistent Enforcement Of The Standards

A State agency typically conducts "surveys" to assess a facility's compliance with Part 483 of CFR Title 42 under the Medicaid program and serves simultaneously under agreement with the Secretary as the Medicare survey agency for facilities that are "dually certified." 42 U.S.C. 1395aa; 42 C.F.R. 488.7, 488.330.[2] Both the action below and *MAHSA v. Shalala* were initiated in response to indications that the survey and enforcement system implemented in 1995 was rife with confusion and was being

2. HCFA also conducts surveys to assess compliance by state-owned nursing homes, and either independently or to validate survey findings by their state counterparts regarding Medicare compliance. *See* 42 C.F.R. 488.7, 488.330.

administered in a manner that varied widely from one state (and region) to the next.

After the revised enforcement system was launched in Illinois in 1995, the reported rate of substantial compliance with the OBRA standards dropped precipitously from seventy percent (*70%*) to six percent (*6%*). *Illinois Council,* 143 F.3d at 1074. Within HHS Region 5, which includes Illinois, Michigan and four other states, five percent (*5%*) of the facilities in Wisconsin were found to provide substandard care as compared with thirty-four percent (*34%*) of those in Minnesota. JA 79. Other HCFA statistics before the court in *MAHSA* reflected that even though the underlying conditions of participation were unchanged, six percent (*6%*) of Michigan facilities were cited for providing substandard quality care (SQC) in 1994, in contrast with over sixty percent (*60%*) upon the implementation of the new enforcement rules and manuals. Within Region 5, *100%* of facilities found out-of-compliance on a standard survey were found in substantial compliance upon resurvey, compared with *43%* of facilities in Michigan. JA 83.

Similarly, HCFA State Implementation Reports introduced in *MAHSA* reflect that SQC citations ranged anywhere from three percent (*3%*) up to twenty-three percent (*23%*) among the ten (10) HHS regions. According to HCFA's calendar year 1998 data, level "G" citations — significant because they can brand facilities as "poor performers" under recent HCFA transmittals (as discussed below) — were assigned to *2.44%* of providers in Oklahoma compared with *41.81%* in Connecticut, *2.7%* in West Virginia, and *31.28%* in Tennessee. *1998 Nursing Home Statistical Yearbook, supra* at Table IV-5. Citations of Level "F" deficiencies ("widespread" violations with the potential for causing more than minimum harm) ranged from *.88%* of facilities in Arizona up to *12.91%* of all facilities in New Jersey — a fifteen fold difference.

3. Choice Of Remedy Under OBRA

Under 42 C.F.R. 488.406, eight (8) potential remedies, in addition to "termination" of the provider agreement (including six (6) that States are obligated to adopt) may be applied against a

facility found out of substantial compliance with any federal condition(s) of participation.[3] Remedies are subdivided into Categories 1 through 3, with the severity of the mandatory or optional sanctions increasing by Category. 42 C.F.R. 488.408. Selection of the appropriate penalty Category derives from the combination of the "scope" and "severity" rankings assigned to the deficiencies identified by the surveyors. This determination in turn derives exclusively from the surveyors' use of a scope and severity "Grid" published in the HCFA Pub. 7 State Operations Manual (SOM), a copy of which is reproduced at JA 66.

The imposition of no remedy, or of a Category 1, 2 or 3 remedy under the Grid turns on a combination of whether the *scope* of a given deficiency is viewed as "isolated," a "pattern" or "widespread," and on the *severity* of the violation. There are four *severity* categories, including: (1) "no actual harm with a potential for minimal harm"; (2) "no actual harm with a potential for more than minimal harm that is not immediate jeopardy"; (3) "actual harm that is not immediate jeopardy"; or (4) "immediate jeopardy to resident health or safety." With the exception of a finding of "immediate jeopardy," none of the scope or severity criteria has been defined. Instead, interpretations have evolved in the field and through the periodic issuances by HCFA to State surveyors of transmittals or information in "question and answer" format, some of which have modified or reversed HCFA's previous informal guidance. *See, e.g.*, JA 73-74. As the chief surveyor for the Michigan State agency attested in *MAHSA*, the vaguely worded, evolving, and conflicting approaches taken by HCFA in its informal development of these standards resulted in a situation where "our own people are unable to agree on the scope and severity after very intelligent, very professional discussion."

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3. These include: (1) temporary management; (2) denial of payment; (3) civil monetary penalties; (4) state monitoring; (5) transfer of residents; (6) closure of the facility with transfer of residents; (7) directed plan of correction; (8) directed in-service training; and (9) termination of provider agreement.

C. Impact of Adverse Survey Findings and Scope of Available Review

1. Use Of The Grid And SQC Standards

Penalties and remedial procedures are materially affected by the substantive rule under which a given deficiency is cited.[4] Where a surveyor assigns a deficiency under 42 C.F.R. 483.13 (resident behavior and facility practices), §483.15 (quality of life) or §483.25 (quality of care) to box F, H, I, J, K or L[5] of the Grid, the nursing facility is automatically classified as one that provides "substandard quality of care" (SQC). 42 C.F.R. 488.301. If a deficiency under a subpart of §483 other than the three listed above is cited, a facility is equally subject to penalties based on the scope and severity of its noncompliance, but the SQC designation is inapplicable. Whenever a facility is found by surveyors to render substandard quality care, the regulations mandate that notices of that designation be disseminated, *inter alia*, to all of the attending physicians of individuals admitted to the faculty, and to state boards that license the facility's administrator. 42 C.F.R. 488.325(g), (h). SQC findings in three consecutive surveys subject a facility to immediate, mandatory termination from Medicare and/or Medicaid and denial of Medicare or Medicaid payment. 42 C.F.R. 488.414.

2. Loss Of Nurse-Aide Training Rights

As a condition of Medicare and Medicaid program participation, nursing homes are obligated by OBRA to ensure that all of their nurse-aides complete a nurse-aide training and competency evaluation program (NATCEP). 42 U.S.C. 1395i-3(b)(5), 1396r(f)(2). Nurse-aides, which comprise the majority of nursing

4. Under guidance published in the SOM, each regulation containing a condition of participation is subdivided into constituent elements referred to as "F Tags," each of which is assigned a number. After a survey is concluded, the survey agency issues a report in which each deficiency citation is identified by "F Tag" and scope and severity level assigned to that F Tag (i.e., category "A" through "L" on the Grid, JA 66).

5. For example, an "F" citation means that there is a failure to abide by an element of a condition of participation that is "widespread" and that has caused no actual harm, but has the potential to cause more than "minimal harm" but not "immediate jeopardy."

facility staff, may not be retained unless they are trained and certified within four months of employment. Facilities generally conduct their own NATCEPs under authority of 42 U.S.C. 1395i-3(f)(B), 1396r(f)(B). When a facility is "found" to provide SQC during a "standard survey," it is reflexively subjected to an "extended survey" and automatically barred from conducting nurse-aide training for a two-year period. 42 U.S.C. 1395i-3(g)(2)(B), and 1396r(g)(2)(B); 42 C.F.R. 483.151(b)(2); SOM §7210. Facilities "locked out" of conducting NATCEPs must procure training for all new employees from outside sources, if possible. If an alternative program is not locally available, and new staff cannot be trained and certified, the facility is subject to termination.

3. "Poor Performer" Status

Without the benefit of rulemaking, HCFA adopted the concept of a "poor performing" facility. SOM §7304.B. Any facility cited for a deficiency categorized as SQC in any two out of three surveys is labeled a "poor performer," and, as a result, automatically denied the opportunity to correct deficiencies by a "date certain" and thereby avoid the imposition of penalties. *Id.* By memorandum issued to State Agency Directors and HCFA Associate Regional Directors on September 22, 1998, HCFA unilaterally announced that in order "[t]o strengthen enforcement, the mandatory 'poor performing facility' criteria are being revised" and expanded to reach facilities cited for level "G" deficiencies "at the previous standard survey or any intervening survey." Through a second transmittal issued the same day, the Secretary urged States to treat all facilities within a nursing home chain as "poor performers" if another facility within the same chain — including one that is separately operated, licensed and incorporated, and located in a different geographic region — is found to be a poor performer. Because the Secretary did not mandate the uniform use of this approach, even under the SOM, application of this standard will necessarily vary from state to state. *Contrast* 42 U.S.C. 1396r(g), (h)(2)(B) and 1395i-3(g)(3)(D), (h)(2)(B).

4. Appeal And IDR Processes

Although it comprehensively amended the conditions of participation and enforcement rules, OBRA did not similarly amend

the provisions of the Act to address or limit administrative and judicial review. No new provisions were engrafted onto Title XIX. The language formerly codified in §1395ff(c), and recodified at §1395cc(h)(1) without substantive change by OBRA, states:

> (h) **Dissatisfaction with determination of Secretary; appeal by institutions or agencies; single notice and hearing.** (1) Except as provided in paragraph (2), an institution or agency dissatisfied with a determination by the Secretary that is not a provider of services or with a determination described in subsection (b)(2) shall be entitled to a hearing thereon by the Secretary (after reasonable notice) to the same extent as is provided in section 205(b), and to judicial review of the Secretary's final decision after such hearing as is provided in section 405(g).
>
> (2) An institution or agency is not entitled to separate notice and opportunity for a hearing under both section 1128 [42 U.S.C.§1320a-7] and this section with respect to a determination or determinations based on the same underlying facts and issues.

By regulation the Secretary independently has provided for administrative appeals before an ALJ from the imposition of certain of the sanctions delineated in 42 C.F.R. 488.406 in addition to terminations. 42 C.F.R. 431.151, 498.3(d). Unless a facility actually is subjected to one of the remedies listed in 42 C.F.R. 488.406 that the Secretary has categorized as a "determination subject to appeal," there is no right under the rules to an adjudicative hearing to contest the deficiency citation even if the citation also triggers a SQC or poor performer designation. 42 C.F.R. 431.151, 431.153(b), 498.3(d). No right to appeal exists from citations resulting in the installation of a State monitor. Where her rules permit an appeal, the Secretary has with minor exception[6]

6. The only exception applies to level of scope or severity findings that shift a violation from a lower to a higher "range" of civil monetary. 42 C.F.R. 431.153(b)(4). CMPs in the range of $50 to $3,000 per day may be imposed in the absence of "immediate jeopardy," while noncompliance that constitutes immediate jeopardy is subject to penalties ranging from $3,050 to $10,000 per day. 42 C.F.R. 488.408. A provider may challenge the level of the deficiency citation to the extent it impacts the permissible "range" of monetary penalties,

prohibited the provider from contesting the scope or severity of a deficiency and limited review to the question of whether the acts or omissions cited comprise a deficiency *vel non*. Additionally, where an appeal is permitted, the filing of an appeal generally does not stay the immediate imposition of a sanction. 42 C.F.R. 431.153(e)(2), (f)(1),(2).

Under 42 C.F.R. 488.331, the Secretary requires the State agency to "offer a facility an informal opportunity, at the facility's request, to dispute survey findings upon the facility's receipt of the official statement of deficiencies." This informal dispute resolution (IDR) process amounts to reconsideration by the same surveyors that levied the deficiency citation in the first place. IDR may be limited to a paper review, and "cannot delay the effective date of any enforcement action against the facility." 42 C.F.R. 488.331(b)(1), (2). Under rules found only in the SOM, HCFA has further prohibited facilities from contesting the surveyor's selection of remedies or the assignment of a given "scope" or "severity" level, even in the context of the IDR process. SOM §7212. There is no right to obtain review from an adverse disposition of an IDR request.

SUMMARY OF ARGUMENT

I.A. Although the Secretary relies heavily on *Heckler v. Ringer*, 466 U.S. 602 (1984), and *Thunder Basin Coal Co. v. Reich*, 510 U.S. 200 (1994), in contending that the lack of immediate judicial review of the Secretary's compliance with the APA or the Due Process Clause will be ameliorated by subsequent judicial review, administrative or judicial review is unavailable in most cases, even on a post-deprivation basis. Title XVIII directs the Secretary to provide appeals only when the State agency (or HCFA) has "terminated" or refused to renew a facility's Medicare certification or where a civil monetary penalty has been assessed. By regulation the Secretary has provided for administrative appeals from the actual imposition of certain of the seven other

under a narrow "clearly erroneous" standard of review. 42 C.F.R. 431.153(b)(4), (j), 498.3(d)(13). Accordingly, even in CMP cases, the scope and severity may not be challenged unless a facility is cited under level "D," "G" or "J" of the Grid, JA 66.

sanctions included within 42 C.F.R. 488.408. At the same time, the Secretary has refused to allow an adjudicative appeal from certain sanctions, such as orders appointing State monitors to oversee operations and otherwise severely limited providers' appeal rights.

In the vast majority of cases (over *96%*), administrative appeal rights are rescinded before any adjudication can occur. "Regardless of which penalty is proposed," a facility independently is obligated to submit a plan to remediate the deficiencies cited by the surveyors regardless of whether it agrees or disagrees with the allegations and may be automatically terminated from the programs if it fails or refuses to do so. 42 C.F.R. 488.402(d)(1). If, however, the Plan of Correction is timely and adequate, the proposed "sanction" is withdrawn and the right to appeal from the underlying deficiency citation (and any other consequences that attach to it) that otherwise exists under the rules is "rescinded" in most instances. *See Country Club Center II v. HCFA*, DAB No. C-96-111 (Aug. 28, 1996), *reprinted in* (CCH) Medicare & Medicaid Guide ¶44,778. However, the adverse findings become a permanent part of the facility's record, and, depending on the scope and severity assigned, may prompt a designation that the facility provides substandard quality care or is a "poor performer" which sets another chain of adverse administrative actions into play.

Even where an adjudicative appeal is allowed, the Secretary has limited the issue and evidence that may be considered to whether a deficiency exists *vel non*, and has *prohibited* facilities from challenging the surveyor's scope or severity determinations or choice of a particular remedy. 42 C.F.R. 488.331(b). Consequently, the very issues that are at the core of respondent's complaint may not be considered in an administrative proceeding, and, except for an extremely narrow band of cases in which an individual provider actually has been fined or terminated, there is never any right to obtain subsequent judicial review under the Act itself. As a result, and "as a practical matter," the approach constructed by the Secretary affords the vast majority of facilities and individuals subject to the new system no "meaningful opportunity" for contesting the inherent limits in the process, or the legality of the Manual provisions and rules that drive the new

enforcement system. Accordingly, this case is controlled not by *Ringer*, but by *Bowen v. Michigan Academy of Family Physicians*, 476 U.S. 667 (1986) (*Michigan Academy*).

I.B. The Secretary's position is all the more indefensible because it would foreclose most providers from obtaining judicial review of substantial constitutional claims. It is no small irony for the Secretary to insist that eventual judicial review will satisfy Due Process requirements where one of respondent's most fundamental concerns is that the Secretary's enforcement and review system inherently denies facilities (and their administrators) Due Process because it is calculated to preclude even post-deprivation review. Unappealable deficiency citations that result in an SQC designation simultaneously trigger the mandatory dissemination of damaging public notices that the facility provides substandard quality services. These notices go to the treating physicians who often refer their patients to the facility, among others, and seriously damage morale and the reputation of the home within its community. These harms are exacerbated by the Secretary's recent launch of an Internet web site in which this information is posted for review by two hundred million Americans.

Although the level and timing of penalties to which a facility may be subject are based on the facility's past performance, facilities are not only denied the right to a contemporaneous appeal for most citations, but the Secretary has further prohibited them from contesting deficiencies cited during earlier surveys even when they later serve to transform the facility into a "repeat offender" and aggravate sanctions. Until weeks ago, the Secretary had also denied appeal rights from deficiency citations that automatically prompt the revocation of a facility's right to conduct training and competency programs for their nurse-aides — the procurement of which is a mandatory condition of Medicaid and Medicare participation — for two years. This is akin to withdrawing a license, and the economic and practical problems caused by such lock-outs has now essentially been conceded by the Secretary, 64 Fed. Reg. 39934, 39935 (July 23, 1999). Such deprivations may not be inflicted without affording a facility Due Process of law. *Paul v. Davis*, 424 U.S. 693, 700 (1976); *Board of Regents v. Roth*, 408 U.S. 564, 573 (1972).

The only protection afforded against erroneous deprivations in these instances is a highly informal dispute resolution process before the same state survey agency that imposed the deficiency, which may be limited to a paper review and includes no right to make a record or to or examine witnesses. Even in this context the Secretary has prohibited the consideration of the scope or severity of the alleged violation or the choice of penalty. Particularly given the absence of any subsequent right to obtain judicial review, *Zimmerman v. Burch*, 494 U.S. 113 (1990), respondent has made out more than a colorable claim that this approach does not afford Due Process.

II. This Court's analysis must "begin with the strong presumption that Congress intends judicial review of administrative action" which can be overcome only by "clear and convincing evidence" to the contrary. *Michigan Academy*, 476 U.S. at 670. *Accord McNary v. Haitian Refugee Ctr., Inc.*, 498 U.S. 479, (1991) (*McNary*). For several reasons, the Secretary cannot sustain this burden.

A. The provisions on which the Secretary would rest the preclusion of judicial review under §1331 were incorporated from Title II of the Act under a pre-OBRA provision of Title XVIII that pertains only to review of terminations of individual facilities from the Medicare program or refusals to renew Medicare certifications. No comparable review-limiting provisions exist under Title XIX, and the rules and guidelines challenged by respondent overwhelmingly impact Medicaid (not Medicare) program participation. In direct contrast with Medicaid, which (at 71.9% of all resident days) is the single largest payer, Medicare coverage of long term care is extremely narrow.

The limited incorporated bar on the exercise of federal jurisdiction under 42 U.S.C. 1395ii for facilities that seek prematurely to challenge a proposed Medicare termination in district court is a scant basis to conclude that Congress clearly intended to bar all manner of systemic challenges under the APA and the Due Process Clause to rules that principally impact Medicaid program participation. *See Woodstock/Kenosha Health Ctr. v. Secretary of HHS*, 713 F.2d 285 (7th Cir. 1983). The Secretary's position also is refuted by the legislative history.

Although the Secretary would ignore this fact, the Act was amended to impose specific duties and rulemaking requirements upon the Secretary in "direct[] response to the district court's opinion in [the *Smith*] case." *Estate of Smith v. Heckler*, 747 F.2d at 590 n.3. Congress had every opportunity to limit or preclude judicial review when it comprehensively amended the Act in 1987 (and in many years since). Instead, in enacting the OBRA reforms Congress took direct cognizance of the "Court order" in *Smith* compelling HCFA to "revis[e] the current survey process." H.R. Rep. No. 100-391(I), 100th Cong. 1st Sess. at 452, *reprinted in* 1987 U.S.C.C.A.N. 2313-1 at 2313-272. This recognition, coupled with the omission of any review-limiting provisions pertaining to the new intermediate sanction rules, is tantamount to a congressional endorsement of jurisdiction.

B. As the lower court recognized, the Medicare provisions on which the Secretary would rely to preclude any systemic judicial review of the survey and enforcement system are designed only to prevent premature judicial review of fact-specific penalty determinations by facilities for which the Act provides an on-record post-deprivation hearing before an ALJ. This case is a generalized systemic challenge to the rules that establish the overall processes for enforcement and review and the claims held reviewable below "arise under" the APA and the Due Process clause, not the SSA. Rather than *Ringer* or *Thunder Basin Coal Co.*, this case is accordingly governed by *Michigan Academy* and *McNary*, which underscore "the critical difference" between a collateral challenge to the rules and processes by which decisions are made, and a challenge to a sanction imposed or payment due in "an individual [case]." 498 U.S. at 497.

ARGUMENT

I. THE APPEALS SYSTEM ADOPTED BY THE SECRETARY PROVIDES NO AVENUE FOR JUDICIAL REVIEW AND TOTALLY FORECLOSES REVIEW OF CONSTITUTIONAL ISSUES IN THE VAST MAJORITY OF CASES

A. The Secretary's Argument That The Instant Claims Must Be Channeled Through The Administrative Process Intentionally Ignores The Substantial Lack Of Administrative Appeal Rights

Relying heavily on *Heckler v. Ringer*, 466 U.S. 602 (1984), and *Thunder Basin Coal Co. v. Reich*, 510 U.S. 200 (1994), the Secretary contends that 42 U.S.C. 405(h), as incorporated into Title XVIII (Medicare) by 42 U.S.C. 1395ii and 1320a-7, precludes respondent from invoking federal question jurisdiction to challenge the Secretary's regulatory scheme under the APA or the Constitution without first exhausting administrative remedies. This argument is inextricably linked to the Secretary's insistence that these claims ultimately will be preserved for judicial review under 42 U.S.C. 1395ii and 405(g) once the administrative appeal process has been exhausted. That premise, however, is simply false: in most cases and for most of the issues raised below, there are no administrative (let alone judicial) remedies available to facilities. Consequently, the real issue presented is not whether *eventual* judicial review is meaningful or adequate as the Secretary asserts (*see* Pet. Br. at 49-50), but whether the Secretary may lawfully deprive nursing homes of *any* mechanism to obtain judicial review.

This litigation is a systemic challenge to shortcomings in the enforcement and review scheme that extend far beyond termination cases and are largely beyond the compass of ~~§1395cc(h)~~ §1395cc(h). Section 1395cc(h) provides for an adjudicative proceeding only in the limited instances where a provider has been terminated or excluded from the Medicare program, or assessed a CMP. By regulation, the Secretary has provided for post-deprivation adjudicative proceedings for certain other penalties included in

§488.406. However, the right to an adjudicative appeal is limited to situations where a provider actually has been subjected to those sanctions. 42 C.F.R. 498.3(b)(12) (Medicare), 431.151(a), incorporated by 42 C.F.R. 488.330(e)(4) (Medicaid). *See, e.g., Arcadia Acres, Inc. v. HCFA*, DAB-AD-1607 (Jan. 22, 1997), *reprinted in* (CCH) Medicare & Medicaid Guide ¶45,140; *Rafeal Convalescent Hosp. v. HCFA*, DAB-CR-444 (Nov. 19, 1996), *reprinted in* (CCH) Medicare & Medicaid Guide ¶45,241; *Waterman Convalescent Hosp. v. HCFA*, DAB-AB-1548 Docket No. A-96-22 (Nov. 13, 1995).

In no case will an appeal lie from "the imposition of State monitoring, the loss of the approval for a nurse-aide training program," or a deficiency finding by a surveyor requiring the submission of a plan of correction (POC). 42 C.F.R. 431.153(b). In other cases the right to appeal is more apparent than real. Any provider found not in "substantial compliance" with substantive program conditions (i.e., is cited for any deficiency under Part 483 that places in Grid boxes "D" through "L," JA 66) is legally obligated to submit a POC for approval by HCFA or the State survey agency "regardless of which remedy" has been proposed, and terminated from the programs if it fails or refuses to do so. 42 C.F.R. 488.402(d)(1). If, however, the POC is found acceptable because the provider has corrected the alleged deficiencies (even though it simultaneously contests the citation), the proposed sanction is not imposed (unless the facility has already been branded a "poor performer" as a result of prior surveys). At that point, the right to appeal is "rescinded" under the regulations. *See Country Club Center II v. HCFA*, DAB No. C-96-111 (Aug. 28, 1996), *reprinted in* (CCH) Medicare and Medicaid Guide ¶45,240; *University Towers Medical Pavilion v. HCFA*, DAB-CR-436 (Sept. 12, 1996), *reprinted in* (CCH) Medicare & Medicaid Guide ¶44,778.

Stated otherwise, the Secretary has created a "Catch 22." Facilities are obligated to undertake prompt corrective action notwithstanding the pendency of an appeal from a deficiency citation, and regardless of whether they dispute the underlying deficiency citation. As a practical matter, a facility cannot meaningfully preserve its appeal rights by declining to submit a POC (as the Sixth Circuit appeared to conclude in *MAHSA*), since it is

independently subject to termination for *failing* to submit a POC. A facility that takes steps "required" by regulation and timely corrects the alleged deficiencies loses the right to challenge the underlying citation, which is permanently etched into its record. As a result, it is saddled with the permanent deficiency citations, the loss of nurse-aide training rights, and the issuance of damaging notices to licensing boards and to treating and referring physicians.

A facility thus deprived of the right to challenge the deficiency citation also remains subject to enhanced and accelerated sanctions in future surveys under the poor performer rule adopted informally through the SOM, or the repeat offender standards the Secretary has adopted for SQC facilities. Under a complementary rule adopted solely through the SOM, the Secretary has further decreed that providers that become subject to enhanced or accelerated penalties as a result of (nonappealable) deficiency citations in prior survey cycles may *not later challenge* the earlier citations, even when they serve to compound a sanction under the repeat offender standards. SOM §§7303, 7304(A), 7320. This would be analogous to subjecting a person to a higher minimum penalty or longer prison term under federal sentencing guidelines based on recidivism in the absence of any right to contest the prior offenses. Even the agency's Departmental Appeal Board has described this limitation as constitutionally suspect. *Fort Tryon Nursing Home v. HCFA*, DAB CR-425 (July 3, 1996), *reprinted in* (CCH) Medicare and Medicaid Guide ¶44, 514.

While the Secretary's review of the regulatory scheme essentially ignores all cases for which no administrative appeal (let alone judicial review) actually is available, these represent the *vast majority* of cases. Governmental statistics illustrate that 21,351 nursing home surveys occurred from July 1, 1995 through January 1, 1996 (8711 "standard surveys" plus 12,640 "complaint surveys"). JA 77. Penalties ranging from State monitoring to termination were proposed in 14,386 cases. JA 78. These culminated in the actual imposition of a sanction that would enable the facility to pursue an administrative appeal in 523 instances (629 remedies imposed, including 106 cases resulting in "State monitoring" for which no appeal is permitted under 42 C.F.R. 498.3(d)(10)(iii)). Accordingly, the right to challenge the surveyors' findings before an administrative law judge, along with any eventual right to judicial review following the "exhaustion" of administration remedies under Title XVIII, was actually extended in only 3.6% of the nationwide surveys in which deficiencies were cited (523/14,386). Conversely, there was *no right* to an adjudicative appeal in *over 96%* of such cases.

The Secretary acknowledges that the legality or constitutionality of her rules may not be considered by an ALJ or on appeal to the DAB, but suggests that the eventual right to obtain review in federal court under the SSA will cure this problem. For example, the Secretary states that the imposition of a CMP gives rise to direct appellate review under §1395cc(h)(2), and, on the putative basis of §1395cc(h)(1), that "*[i]n all other cases*, 'judicial review of the Secretary's final decision' is available in district court as provided in 42 U.S.C. 405(g)." Pet. Br. at 11 (emphasis added). That representation is misleading.

Section 1395cc(h)(1) makes judicial review available "to the same extent as provided in section 405(b) of this title" for "a determination described in subsection (b) of this section." Since subsection (b)(2) relevantly pertains only to a determination of the Secretary to "terminate" a provider agreement, the logical import of the Secretary's argument is that *no review is available in district court* following an administrative hearing that does *not* result in a "termination." Unreviewable cases include those, *inter alia*, where payments have been denied for Medicare recipients. Out of the 523 instances in which an administrative appeal actually was available, only twenty-one (21) involved terminations. JA 78. Accordingly, if we understand the Secretary's position, only .14% of cases involving deficiency citations leading to proposed sanction (21/14,386) would *ever* qualify for review in which challenges to the legality and constitutionality of the rules and Manuals might be advanced in district court.[7]

7. 42 U.S.C. 1395i-3(h)(2)(B)(ii), read in conjunction with §1320a-7a(e), separately provides for direct review in the United States Court of Appeals for cases in which a civil monetary penalty has been imposed upon a facility after a hearing. If direct appeals to the U.S. Courts of Appeals were added to terminations, a total of 0.7% of the cases in which deficiencies were cited (115/14,386) eventually became eligible for judicial review.

The fact that a small percentage of facilities ultimately might be entitled to contest a remedy that has been applied to them, and that an even smaller number might be entitled to subsequent judicial review in which the legality of the underlying rules might be challenged does nothing to protect or preserve the rights of the vast majority of providers afforded no viable avenue for seeking relief against the flaws in the system. This includes facilities that are branded as substandard, deprived of the ability to conduct nurse-aide training and certification, or mandatorily subjected to increased penalties as recidivists due to deficiency citations which they may never challenge on their behalves. Indeed, it is doubtful that a facility that obtains the right to review under 42 U.S.C. 1395cc(h) and §405 of the SSA because it actually has been terminated (or subjected to CMPs) following an administrative determination would even possess standing (let alone the incentive) to challenge the system's denial of hearing rights to other parties or its impact on other providers that have gone before it. *See Singleton v. Wulff*, 428 U.S. 106, 113 (1976); *Barrows v. Jackson*, 346 U.S. 249, 255 (1953).

In the limited instances where an administrative appeal right exists, severe limitations on the scope of review undermine its meaningfulness. Although a provider actually subjected to a sanction is afforded [redacted] the right to a post-deprivation administrative hearing, the Secretary has by regulation which binds the ALJ and DAB members *limited* the issues and the evidence that may be considered to whether or not an alleged act or omission constitutes a deficiency (i.e., non-compliance with a substantive standard) *prohibited* providers from contesting the "scope or severity" the surveyors attach to a violation based on the unexplicated standards embodied in 42 C.F.R. 488.404 and the Grid. 42 C.F.R. 431.151(b), (c), (e); 498.3(d)(12).[8] Even in the highly informal context of IDR, the Secretary prohibits consideration of

8. A lone partial exception to the Secretary's ban on challenging the scope and severity assigned to a violation under the Grid applies to CMP cases. *See supra* at 10 n. 6. Even then, the Secretary has systemically discouraged appeals by offering a 35% "discount" of CMPs for facilities that agree to waive their rights to a hearing within 60 days of their receipt of notice of the penalty. 42 C.F.R. 488.436.

the scope and severity assessment or choice of penalty imposed by HCFA or the State agency. 42 C.F.R. 488.331(b); SOM §7212(c)(2).

Accordingly, neither the legality of the very standards that lie at the heart of the complaint in this case (and in *MAHSA v. Shalala*) nor the facts that go to the level of a deficiency citation or choice of penalty may be considered when cases proceed to an administrative appeal. *See e.g., Beverly Health & Rehabilitation - Springhill v. HCFA*, DAB-CR-553 (Oct. 27, 1998), *reprinted in* (CCH) Medicare & Medicaid Guide ¶120,033; *Brighton Pavilion v. HCFA*, DAB-CR-510 (Dec. 10, 1997). This additionally prevents facilities as a "practical matter" from obtaining "meaning judicial review" of "the types of claims raised in this litigation." *McNary*, 498 U.S. 476 at 496-97 (1991). *Contrast Thunder Basin Coal Co.*, 510 U.S. at 781-82 (meaningful post-deprivation hearing eventually is available to address the same claims over which plaintiff sought to obtain immediate review); *Reno v. Catholic Soc. Servs.*, 509 U.S. 43, 60, 62 (1993) (meaningful judicial review includes "the opportunity to build an administrative record on which judicial review might be based").[9]

B. The Secretary's Appeal Rules Preclude Judicial Review of Colorable Constitutional Claims

The Secretary's approach is all the more invidious because it absolutely prevents providers from advancing substantial constitutional claims. As this Court has instructed:

> When constitutional questions are in issue, the availability of judicial review is presumed, and we will not read a statutory scheme to take the "extraordinary" step of foreclosing jurisdiction unless Congress' intent

9. In *Catholic Soc. Servs.*, the Court held that *McNary* supported the exercise of federal question jurisdiction over challenges to the "front-desk" treatment of an application under the IRA that would preempt subsequent review, and remanded the matter for consideration of whether this approach had been applied to class members. As noted in Justice O'Conner's concurring opinion, ripeness is far more of an issue where a party seeks to challenge the application of a benefit-granting rule that has not yet been applied to him, then it is in a suit challenging a duty-creating rule (such as the present case). 509 U.S. at 68.

> to do so is manifested by " 'clear and convincing' " evidence. [*Weinberger v. Salfi*], 422 U.S. [749] at 762; *Johnson v. Robison*, 415 U.S.361, 366-6 (1974).

Califano v. Sanders, 430 U.S. 99, 109 (1977). *Accord Bartlett v. Bowen*, 816 F.2d 695, 699 (D.C. Cir. 1987). *Parker v. Califano*, 644 F.2d 1199, 1201 (6th Cir. 1981) (reversing denial of jurisdiction under §405 of Due Process challenge to adequacy of "notice and opportunity to be heard"). The right to immediate judicial review is particularly worthy of protection where it includes a Due Process based challenge to the adequacy of the very notice and hearing procedures the Secretary has promulgated. *See Himmler v. Califano*, 611 F.2d 137, 148 (6th Cir. 1979).

It is no small irony for the Secretary to insist that eventual judicial review will cure any Due Process concerns where one of respondent's central complaints is that the Secretary has totally foreclosed the right to any review in most instances and for most facilities impacted by the enforcement scheme. Findings that serve to compound, heighten and accelerate the imposition of present and future sanctions are unappealable as are most determinations of the scope or severity of the violation, despite the ratcheting effect they have on present and future sanctions. With the limited exception of a highly informal IDR conducted by the surveyors, the system includes no right to contest deficiency findings that mandate the conclusion that a facility provides substandard care. This finding, in turn, irreversibly triggers the issuance of notices to, *inter alia*, the physicians who treat and refer nursing home residents, and must certify individuals for admission to a skilled nursing facility under the Secretary's rules. *See* 42 C.F.R. 488.325(g), (h). Moreover, in *MAHSA v. Shalala*, the Secretary candidly admitted for the record that the severe restrictions placed on provider appeal rights were motivated by administrative convenience and cost considerations. *See Vlandis v. Kline*, 412 U.S. 441, 450 (1973); *Stanley v. Illinois*, 405 U.S. 645, 656 (1972) ("the Constitution recognizes higher values than speed and efficiency").[10]

10. On March 18, 1999, the Secretary issued a final rule with comment period which narrows the category of cases in which the imposition of a civil monetary penalty may be deferred pending corrective action that might serve to abate the penalty, and authorizes the immediate imposition of a CMP based on a set of criteria that include the "facility's history of prior offenses." 64 Fed. Reg. 13354, 13357 (Mar. 18, 1999). This further compounds the impact of the regulatory limitations the Secretary has placed on provider appeals.

Respondent here and plaintiffs in *MAHSA* alleged and demonstrated that branding a facility as substandard, combined with targeted dissemination of that information by a government agency, damages its reputation in the community[11] *and* carries tangible financial consequences and other burdens in the form of curtailed admissions, collateral review by state agencies that license nursing home administrators, added training costs, and barriers to hiring staff. Government may not prompt such deprivations without satisfying Due Process requirements. *See Paul v. Davis*, 424 U.S. 693, 700 (1976); *Board of Curators v. Horowitz*, 435 U.S. 78 (1978); *Board of Regents v. Roth*, 408 U.S. 564, 573 (1972) (due process requires opportunity to refute public dissemination of contested information that stigmatizes or impinges on reputation or which may foreclose other business or employment opportunities). Provisions of the Act must be construed, if reasonably possible, in a manner that avoids Constitutional infringements, *see DeBartolo Corp. v. Florida Coast Bldg. and Constr. Trades Council*, 485 U.S. 568, 574 (1988); *Gomez v. United States*, 490 U.S. 858, 864 (1989), which further ~~mitigates~~ militate against the Secretary's expansive reading of §1395ii.

The reputational plus financial injury — from which the Secretary provides no meaningful way to obtain review in most cases — is compounded by the fact that the Secretary has not only required the public posting and distribution of deficiency reports, 42 C.F.R. 488.325, but has by recent administrative decree created an Internet website entitled "Nursing Home Compare" (http://www.medicare.gov/ nursing/home.asp), through which the unappealable deficiency citations and substandard care designations are disseminated to millions of consumers and professional peers of facility administrators. Widespread dissemination of a potentially inaccurate characterization about the quality of care a

11. As Michigan's State survey chief attested in *MAHSA v. Shalala*, "when a facility is designated" a poor performer, "morale is just devastated and key people are disenchanted because . . . it certainly portrays the facility in a less than flattering manner in the community."

nursing facility renders can be particularly devastating when the facility is a non-profit entity operated by a religious order or fraternal organization.

In addition to triggering repeat offender status and the widespread dissemination of damaging information without the benefit of a prior *or* subsequent adjudicative process, the surveyors' assignment of a given scope and severity level to an alleged deficiency can cause a two-year revocation of a facility's federal authorization to conduct NATCEP programs for their unlicensed staff. Training and certification is a mandatory condition of Medicaid and Medicare program participation. Revocation of the right to provide such training is analogous to the revocation of a license and thereby additionally warrants Due Process protection. *See generally Barry v. Barchi*, 443 U.S. 55 (1979) (state's suspension of a horse trainer's license implicates deprivation of a property interest protected by the Due Process Clause and requires a post-suspension hearing); *Bell v. Burson*, 402 U.S. 513, 539 (1971) (whether the entitlement to a driver's license is a right or a privilege, the State's termination of a license whose "continued possession may become essential in the pursuit of a livelihood" is subject to due process protection). Adequate protection against errors and their injuries is not afforded by the IDR process, particularly given the absence of any right to a name-clearing adjudication or subsequent judicial review in which the effects of the SQC citation might be reversed even after the information has been disseminated. *See Roth*, 408 U.S. at 573. To say the least, respondent has raised a colorable Due Process claim, especially given the absence of any subsequent right to judicial review to protect against erroneous deprivations flowing from the lack of an administrative adjudication. *See Zimmerman v. Burch*, 494 U.S. 113 (1990).

After filing her brief on the merits, the Secretary published an "interim final rule" that will in the future enable providers to separately appeal from SQC determinations that cause a facility to lose the approval of its nurse-aide training and evaluation program. 64 Fed. Reg. 39934 (July 23, 1999). In liberalizing the appeal procedures, the Secretary observed:

> Facilities have had the ability to challenge the loss of their nurse aide training program only if they were challenging the imposition of a remedy that was appealable. . . . We believe, however, that we should acknowledge the arguments that have been advanced by individual facilities as to the magnitude of the loss to them when they are unable to train nurse aides themselves. *Facilities have alerted us to the difficulty they sometimes have in finding qualified nurse aides once they are unable to train their own. . . . Turnover in these positions is high,* thereby placing increased pressures on facilities to maintain staff they need to furnish essential services to faculty residents. *Thus, the loss of an ability to train nurse aides can have significant consequences for a facility.* (*Id.* at 39935; emphasis added.)

This belated partial repair of the problem strongly reinforces respondent's arguments that the historic refusal to provide an appeal from citations prompting this remedy offends due process. Unfortunately, this rule is too little and too late for those providers subjected to a NATCEP lock-out prior to its effective date, and it offers no relief to any provider subject to enhanced penalties for deficiency citations that do not also trigger a lock-out.

II. THE SECRETARY CANNOT SATISFY HER BURDEN OF DEMONSTRATING THAT CONGRESS INTENDED TO PRECLUDE JUDICIAL REVIEW OF THE MATTERS RAISED IN RESPONDENT'S COMPLAINT

This Court's analysis must "begin with the strong presumption that Congress intends judicial review of administrative action," *Michigan Academy*, 476 U.S. at 670. *Accord McNary*, 498 U.S. at 496, 498. *See also Colorado River Water Conservation District v. United States*, 424 U.S. 800, 817 (1976) (there is a "virtually unflagging obligation of federal courts to exercise the jurisdiction given them"); *Wilcox v. Consolidated Gas Co.*, 212 U.S. 19, 40 (1908). That presumption may be overcome only by "clear and convincing evidence" that Congress intended to preclude jurisdiction. *Michigan Academy* at 670, 680, *citing Abbott Labs. v. Gardner*, 387 U.S. 136, 141 (1967); *McNary, supra.* The secretary cannot sustain that burden here.

A. *The Narrow Review-Limiting Provisions Incorporated Under Title XVIII Of The Act Do Not Evince A Clear and Convincing Intent To Abrogate Systemic Review of Rules Principally Applied Under Title XIX*

The Secretary treats this case as though it exclusively involves the Medicare program. This is not surprising given the Secretary's reliance on review-limiting provisions of the Act — including 42 U.S.C. 1395cc(h) and 1395ii, which in turn incorporate 42 U.S.C. 405(g), (h) from Title II — that apply exclusively to Medicare, and the fact that Title XIX, 42 U.S.C. 1396 *et seq.*, "lacks any comparable restriction." *Illinois Council*, 143 F.3d at 1047. Consequently, the Secretary is reduced to arguing that the incorporation by reference of narrow jurisdiction-limiting provisions in the Medicare Act is "clear and convincing" proof that Congress intended to preclude systemic legal challenges to program rules whose principal impact is under Medicaid, where no provision of law limits or precludes review. That proposition is even more of a stretch in view of the fact that Medicare coverage extends to only a small fraction of nursing home residents (*8%*) as compared with Medicaid (*72%*) (*see* page 5, *supra*), and it turns the presumption in *favor* of jurisdiction on its head. *See Woodstock Kenosha Health Ctr. v. Secretary of HHS*, 802 F.2d 870 (7th Cir. 1983). It is also contrary to the legislative history.

In enacting OBRA, Congress took direct cognizance of the "Court Order" in *Smith* that had compelled HCFA to "revis[e] the current survey process." H.R. Rep. No. 100-391(I), 100th Cong. 1st Sess. at 452, *reprinted in* 1987 U.S.C.C.A.N. 2313-1 at 2313-272. Congress had every opportunity to amend Title XIX to mandate the exhaustion of administrative remedies or preclude the exercise of general federal question jurisdiction to challenge the newly adopted standards in radically revising the survey and enforcement scheme, but did not do so.[12] Instead, in comprehensively amending the Act to provide for new and expanded sanctions, Congress required the Secretary to utilize regulations and

12. These provisions were again amended in 1992, 1996 and 1997 by the Older Americans Act of 1992, Pub. L. No. 102-375, 106 Stat. 1195; the Nursing Home Facility Resident Reform Act, Pub. L. No. 104-315, 110 Stat. 3824; and the Balanced Budget Act of 1997, Pub. L. No. 105-33, 111 Stat. 251, respectively.

pursue national consistency in administration of the survey and enforcement scheme consistent with the judicial relief ordered in *Smith*. If anything, this recognition, coupled with the omission of any bar on the exercise of federal question jurisdiction in OBRA, is tantamount to a congressional ratification of juridical oversight. *See generally Davis v. Michigan Dept. of Treas.*, 489 U.S. 803, 811 (1989) (codification of a judicial determination as endorsement); *Lorilard v. Pons*, 434 U.S. 575, 580-81 (1978) (reenactment of law with awareness of judicial determination as ratification of the same); *Wilder v. Virginia Hosp. Ass'n*, 496 U.S. 498, 517 (1990). The Secretary's contrary approach would only further the very mischief Congress sought to address in enacting OBRA.

B. *Respondent's Claims Do Not "Arise Under" The Medicare Act*

Finally, as the Seventh Circuit recognized, the provisions on which the Secretary would rely to preclude systemic judicial review of the rules and guidelines under both programs were not intended to preclude the claims being advanced by the respondent even as they pertain exclusively to Medicare participation.

The Secretary contends that the claims at bar "arise under" the Medicare Act, and, based upon *Heckler v. Ringer*, asserts that §405(h) accordingly bars judicial review except to the extent it is specifically authorized by 42 U.S.C. 1395cc(h) and 405(g). *Ringer*, however, involved individual providers' efforts to obtain judicial review concerning claims-specific payments under Medicare. This Court observed that the result sought by plaintiffs in the form of a suit for declaratory relief was "inextricably intertwined" with a claim for benefits and, "at bottom" and "in substance," a judicial determination of a coverage issue that would be controlling of individual claims for payment of Medicare benefits. 466 U.S. at 614, 622, 624. *See also McNary*, 498 U.S. at 490, 494-95 (preclusion of jurisdiction attaches to cases involving "individual [claims] determinations" or which at their essence involve a "claim of entitlement to payment").

Accordingly, *Ringer* was limited to interdicting immediate judicial challenges to the amount being paid to providers for specific services in derogation of 42 U.S.C. 1395cc and 405(h). To the extent the phrase "arising under" the Act in § 405(h) is deemed synonymous with a claim that is not cognizable under

federal question jurisdiction, only individualized claims for relief are properly characterized as "arising under" Title XVIII under *Ringer* and in *Michigan Academy*.

Under 42 U.S.C. 1395cc(h)(1), the Medicare Act relevantly bars direct access to federal district court only to a facility challenging a determination that "it is no longer a provider." Section 1395cc(h) is the only provision that limits judicial review of matters relating to the OBRA survey and enforcement scheme. Originally codified at 42 U.S.C. 1395ff, §1395ii(h)(1) predates the adoption of "intermediate" sanctions and is a vestige from the pre-OBRA remedial scheme. By its plain terms, §1395cc(h) creates an entitlement to an on-record adjudicative hearing and subsequent judicial review for a facility that seeks review from a "final decision after [a] . hearing . provided [for] in section 405(g) of [Title 42]." As incorporated *mutatis mutandis* by §1395ii, §405(h) provides that "findings and decisions" concerning "individuals who were parties . . . [to] hearings" authorized by §405(b)(2) "shall be binding on all individuals who were parties to such hearings," and concomitantly prohibits the direct exercise of jurisdiction, under 28 U.S.C. 1331 or 1346 to "recover on any claim arising under" the Act. Unless the last sentence of §405(h) is read as if it is unconnected to the first two sentences of §405(h), the preclusion of §1331 review is inextricably interrelated to the types of matters and determinations to which §405(g) and §1395cc(h) apply. Certainly, that construction is heavily favored by the settled interpretive principle that establishes a presumption in *favor* of judicial review.

Unlike *Ringer*, this case does not involve an entity seeking to leap-frog over an ALJ or DAB hearing. Respondent does not challenge the adequacy of payment for particular services, or, for that matter, the imposition of a given sanction or penalty to any particular provider. Nor would a judgment predetermine the outcome of a specific result in any particular case. Rather, this is a collateral systemic challenge to the Secretary's use of Manuals to fashion important substantive standards, and to the severe restrictions the rules impose on providers' efforts to secure judicial review of adverse actions and determinations that for the most part do not involve "terminations" and which are not inextricably intertwined with an individualized claim for relief.

Respondent's position finds strong support in *McNary*. In *McNary* the Court examined a provision of the Immigration Reform and Control Act (IRA) that expressly authorized administrative review but foreclosed judicial review of certain adjudicative determinations by the Attorney General that might result in deportations. Plaintiffs sought to challenge the regulatory scheme the INS had adopted for processing deportation decisions on a systemic basis under the Act and the Due Process Clause. Relying heavily on this Court's analysis of §405 of the SSA in its "unanimous holding" in *Michigan Academy*, the Court found it "most unlikely" that the IRA's flat bars to administrative and judicial review in individual cases, 8 U.S.C. 1160(e), were intended to preclude a systemic challenge to aspects of the regulatory scheme on statutory or constitutional grounds. 498 U.S. at 496-98. Stressing that Congress abhors situations where there is "no review at all of substantial statutory and constitutional challenges to the Secretary's administration of . . . the Medicare program," the Court concluded that the review-limiting provisions of the IRA were aimed at individualized deportation determinations, not at the manner in which all claims are processed under the "newly . . . prescribed [regulatory] procedure" *Id.* at 495, 498. As *McNary* observed in looking to the analogous provisions of the Medicare Act, there is a "critical difference between an individual amount determination" and a challenge to the procedures for making such determinations." *Id.* at 498. As in *McNary*, respondent herein does "not seek a substantive declaration" about the merits of any particular penalty being applied to any particular facility.[13]

The Secretary expends much effort arguing that not all relevant provisions of the Medicare Act on which she relies pertain to determinations of "amounts," and asserting on that basis that the court below construed *Ringer* too narrowly and misapplied

13. *McNary* also emphasized that jurisdiction over collateral challenges to the hearing system itself was presumed even though individual relief might flow *indirectly* from such review: "Unlike the situation in *Heckler*, individual respondents in this action do not seek a substantive decision that they are entitled to SAW status. . . . Rather if . . . [they] prevail in this action, respondents would only be entitled to have their case files reopened and their applications reconsidered in light of the newly prescribed INS procedures." *Id.* at 495.

Michigan Academy to this case. As *McNary* recognized in analogizing to *Michigan Academy*, however, the issue is not whether payment of an "amount" of money is at stake, but whether the provisions that limit review involve the resolution of individualized claims for relief. Similarly, in revalidating the decision in *McNary*, the Court explained in *Reno v. Catholic Soc. Servs., Inc.*, that the statutory limitations imposed on judicial review under the statute at issue in *McNary* " 'describes the denial of an individual application [for relief] . . . and thus' applies only to review of denials of individual applications." 509 U.S. at 55, *quoting McNary*, 498 U.S. at 498, 494. *Accord Thunder Basin Coal Co.*, 510 U.S. at 771 ("petitioner's claims are "pre-enforcement" only because the company sued before a citation was issued").

CONCLUSION

The judgment of the Court of Appeals should be affirmed.

Respectfully submitted,

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