No. 98-1109

In the Supreme Court of the United States

DONNA E. SHALALA, SECRETARY OF HEALTH AND HUMAN SERVICES, ET AL., PETITIONERS

v.

ILLINOIS COUNCIL ON LONG TERM CARE, INC.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SEVENTH CIRCUIT

BRIEF FOR THE PETITIONERS

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QUESTION PRESENTED

Whether 42 U.S.C. 405(h), incorporated into the Medicare Act by 42 U.S.C. 1395ii, permits skilled nursing facilities participating in the Medicare program to bring anticipatory, pre-enforcement lawsuits under 28 U.S.C. 1331 and 1346 (1994 & Supp. III 1997) to challenge the validity of Medicare program enforcement regulations and guidelines notwithstanding the Medicare Act's provision of an express, post-enforcement mechanism for administrative and judicial review.

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OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1a-12a) is reported at 143 F.3d 1072. The memorandum and order of the district court (Pet. App. 13a-21a) is unreported.

JURISDICTION

The judgment of the court of appeals was entered on May 8, 1998. A petition for rehearing was denied on August 13, 1998 (Pet. App. 22a-23a). On November 2 and December 4, 1998, Justice Stevens extended the time within which to file a petition for a writ of certiorari, first to December 12, 1998, and then to January 10, 1999, a Sunday. The petition was filed on Monday, January 11, 1999, and was granted on April 19, 1999. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATUTORY AND REGULATORY PROVISIONS INVOLVED

Pertinent statutory and regulatory provisions are set forth in the appendix to this brief.

STATEMENT

The Health Insurance for the Aged Act, commonly known as the Medicare Act, Pub. L. No. 89-97, 79 Stat. 290, codified as amended, 42 U.S.C. 1395 *et seq.*, provides insurance for covered in-patient hospital and post-hospital services, 42 U.S.C. 1395x(m), including skilled nursing care. 42 U.S.C. 1395f(b)(1), 1395i-3, 1395x(v)(1)(A).[1] To receive payment for services provided to Medicare beneficiaries, a skilled nursing facility must enter into a provider agreement with the Secretary of Health and Human Services (HHS), and meet "requirements of participation" relating to beneficiary health, safety, and care. See 42 U.S.C. 1395i-3(a) to (d). Respondent, a trade association that represents nursing facilities participating in the Medicare program in Illinois, brought this suit to challenge the methods by which the Secretary assesses compliance with Medicare's health, safety, and quality-of-care requirements and selects remedies when noncompliance is detected. The question before the Court is whether a federal district court may entertain such a preenforcement challenge under the general grant of federal-question jurisdiction contained in 28 U.S.C. 1331, notwithstanding the Medicare Act's provision of express postenforcement mechanisms for judicial review.

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[1] Such coverage is provided through Part A of the program. Part B of Medicare is a voluntary supplementary insurance program covering physicians' charges and other medical services. 42 U.S.C. 1395k, 1395*l*, 1395x(s). The recently enacted Part C of Medicare authorizes beneficiaries to obtain covered Medicare services through Health Maintenance Organizations and other "managed care" arrangements. Balanced Budget Act of 1997, Pub. L. No. 105-33, Tit. IV, § 4001, 111 Stat. 276-327. Only Part A of the program is at issue here.

1. The Social Security Act was passed in 1935 to provide retirement and related benefits for the elderly. See ch. 531, 49 Stat. 620. Four years later, Congress amended the Act by adding express provisions for administrative and judicial review. See Social Security Act Amendments of 1939, ch. 666, 53 Stat. 1360; see S. Rep. No. 734, 76th Cong., 1st Sess. 51 (1939); H.R. Rep. No. 728, 76th Cong., 1st Sess. 42 (1939). Those provisions now appear (as amended) at 42 U.S.C. 405(b), (g) and (h).

Section 405(b) provides that any individual who is dissatisfied with an agency determination is entitled to "notice and opportunity for a hearing with respect to" the determination. 42 U.S.C. 405(b). Section 405(g), in turn, provides that anyone dissatisfied with a "final decision * * * made after a hearing to which he was a party may * * * obtain a review of such decision by" filing an action in district court. 42 U.S.C. 405(g). Finally, 42 U.S.C. 405(h) renders the administrative and judicial review procedures under Section 405(b) and (g) exclusive. It declares:

> The findings and decisions of the Commissioner of Social Security after a hearing shall be binding upon all individuals who were parties to such hearing. No findings of fact or decision of the Commissioner of Social Security shall be reviewed by any person, tribunal, or governmental agency except as herein provided. No action against the United States, the Commissioner of Social Security, or any officer or employee thereof shall be brought under sections 1331 or 1346 of title 28 to recover on any claim arising under this subchapter.

42 U.S.C. 405(h). (Section 1331 of Title 28 accords federal courts general federal-question jurisdiction, and 28 U.S.C. 1346 provides jurisdiction over cases in which the United States is a defendant.)

In 1965, Congress amended the Social Security Act by adding Title XVIII—the Medicare Act—to furnish medical

insurance for the elderly and disabled. Pub. L. No. 89-97, § 102, 79 Stat. 291, codified as amended at 42 U.S.C. 1395 *et seq.*; see p. 1, *supra*. Rather than enact separate provisions for review of Medicare claims, Congress incorporated the hearing and judicial review mechanisms of 42 U.S.C. 405(b), (g), and (h) into the Medicare program.[2] For example, 42 U.S.C. 1395ff(a) and (b) provide that any "individual dissatisfied with" the determination by the Secretary of Health and Human Services respecting either his "entitle[ment]" to or the "amount" of benefits under Medicare is entitled to "a hearing thereon * * * to the same extent as is provided in Section 405(b) * * * and to judicial review of the Secretary's final decision after such hearing as is provided in Section 405(g)." 42 U.S.C. 1395ff(a) and (b).

The Medicare Act makes those same hearing and judicial review provisions applicable to decisions affecting institutions, such as skilled nursing facilities, that provide services to Medicare beneficiaries. For example, nursing facilities may receive reimbursement under Medicare only if they have a provider agreement with the Secretary and they meet statutory requirements relating to patient health, safety, and care; they must be certified as meeting statutory requirements on average once a year. 42 U.S.C. 1395i-3(b) to (d), 1395cc. If a provider wishes to dispute a determination

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[2] Although 42 U.S.C. 405(b), (g), and (h) refer to the "Commissioner of Social Security," Congress declared that, in applying those provisions to the Secretary's decisions under Medicare, any reference to the Commissioner of Social Security shall be construed as a reference to the Secretary. See 42 U.S.C. 1395cc(h), 1395ii. As originally enacted, Section 405(b), (g), and (h) referred directly to the Secretary, but Congress changed those provisions so they would refer instead to the Commissioner of Social Security in 1994, when Congress established the Social Security Administration as a separate agency and made it responsible for administration of the social security program. See Social Security Independence and Program Improvements Act of 1994, Pub. L. No. 103-296, § 106(d), 108 Stat. 1476.

concerning compliance or certification—or termination or non-renewal of its provider agreement—42 U.S.C. 1395cc(h) provides that it may do so through the hearing and review procedures under 42 U.S.C. 405(b) and (g).[3] It thus states:

> [A]n institution or agency dissatisfied with a determination by the Secretary that it is not a provider of services or a determination described in subsection (b)(2) of this section shall be entitled to a hearing thereon by the Secretary (after reasonable notice) to the same extent as provided in section 405(b) [of Title 42], and to judicial review of the Secretary's final decision after such hearing as is provided in section 405(g) [of Title 42].

42 U.S.C. 1395cc(h). The determinations "described in subsection (b)(2)" include, among other things, a determination "that the provider fails to comply substantially with the provisions of [its provider agreement or] with the provisions of [the Medicare Act] and regulations thereunder."[4] Different provisions of the Medicare Act added after 1965 similarly channel other decisions affecting Medicare providers, including decisions determining provider reimbursement or imposing civil money penalties for violations, through spe-

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[3] Originally, 42 U.S.C. 1395cc(h) appeared as subsection (c) of 42 U.S.C. 1395ff. See 42 U.S.C. 1395ff(c) (1976). When the Act was amended in 1987 (see pp. 7-8, *infra*), the provision was moved to its current location in 42 U.S.C. 1395cc(h).

[4] A finding that a facility fails to meet statutory or regulatory standards for health or safety, and that imposes certain remedies as a result, might also be considered a determination that the facility "is not a provider of services." See 42 U.S.C. 1395i-3(a)(3) (defining provider of services as a facility that meets statutory and regulatory requirements); *Michigan Ass'n of Homes & Servs. for the Aging, Inc.* v. *Shalala*, 127 F.3d 496, 501 & n.3 (6th Cir. 1997).

cific statutory mechanisms for administrative and judicial review.[5]

Finally, the Medicare Act makes 42 U.S.C. 405(h)—the provision of Title II of the Social Security Act that declares the Secretary's decisions to be binding, prohibits review of any decision except as provided in the Act itself, and deprives federal courts of jurisdiction under 28 U.S.C. 1331 and 1346—applicable to the Medicare program. Specifically, Section 1395ii declares that "[t]he provisions of * * * subsections (a), (d), (e), (h), (i), (j), (k), and (*l*) of section 405 of this title, shall also apply with respect to this subchapter to the same extent as they are applicable with respect to [Title II]."

2. Notwithstanding the Medicare program's health and safety requirements for provider participation, a 1986 survey by the Institute of Medicine of the National Academy of Sciences found that, in many "government certified nursing homes, individuals * * * receive very inadequate —sometimes shockingly deficient—care that is likely to hasten the deterioration of their physical, mental, and emotional health." H.R. Rep. No. 391, 100th Cong., 1st Sess., Pt. 1, at 452 (1987). A Government Accounting Office survey also

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[5] Under Part A, initial reimbursement determinations affecting participating providers are made by fiscal intermediaries operating under contract with the Health Care Financing Administration (HCFA). 42 U.S.C. 1395h. Pursuant to 42 U.S.C. 1395*oo*(a), which was enacted in 1972, Pub. L. No. 92-603, § 243(a), 86 Stat. 1420, a provider that "is dissatisfied with a final determination" and timely files objections meeting amount-in-controversy requirements may obtain a hearing before the Provider Reimbursement Review Board (PRRB). The decisions of the PRRB are final (although the Secretary has the right to affirm, reverse, or modify them within 60 days); and, pursuant to 42 U.S.C. 1395*oo*(f), judicial review is available in district court. See *Your Home Visiting Nurse Servs., Inc.* v. *Shalala*, 119 S. Ct. 930, 932-933 (1999). Where the Secretary imposes civil money penalties under 42 U.S.C. 1320a-7a, a hearing is available under 42 U.S.C. 1320a-7a(c)(2), and review in the court of appeals is available under 42 U.S.C. 1320a-7a(e). See Medicare and Medicaid Amendments of 1981, Pub. L. No. 97-35, Tit. XXI, § 2105, 95 Stat. 789.

reported widespread deficiencies, *ibid.*, and testimony before Congress confirmed (sometimes in grim detail) extensive problems, such as unsanitary conditions, pervasive neglect, and instances of serious abuse. See generally 1 *Nursing Home Care—The Unfinished Agenda: Hearing Before the Senate Special Comm. on Aging*, 99th Cong., 2d Sess. (1986) (*1986 Hearing*).[6] As one observer summarized, Medicare's compliance regime had "failed, * * * somewhat dismally, to assure a decent level of patient care" to nursing facility residents. *Id.* at 2. That failure, Congress concluded, was in part the product of a system that focused on the facility's theoretical capacity to provide care, *i.e.*, paper qualifications and physical characteristics, rather than on the actual care provided to beneficiaries. H.R. Rep. No. 391, *supra*, Pt. 1, at 466-467. And it resulted in part from the limited effectiveness of the only enforcement remedy available to the Secretary—termination of the provider agreement permitting the facility to participate in the Medicare program. That regime led to a "yo-yo" effect, under which facilities with serious health, safety, and quality-of-care deficiencies would remedy them just in time to avoid termination, but fall into noncompliance once again immediately thereafter. *Id.* at 471.[7]

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[6] For example, surveyors and others found nursing home residents lying in their own feces or urine for extended periods of time, covered with flies and dried food, and ridden with bedsores, despite complaints from visiting relatives. *1986 Hearing* 8-9, 61, 64, 800. There were reports of patients dying when facilities failed to pay attention to their medical needs. See, *e.g.*, *id.* at 110 (patient died of starvation after facility failed to ensure feeding tube provided sufficient calories); *id.* at 73-74 (patient died from absence of medical attention for severe cramps and vomiting). And there were disturbingly frequent reports of brain-impaired and comatose patients being raped and sexually abused. *Id.* at 105-106.

[7] As the House Report explained, nursing homes knew "in advance that they [would] not be penalized" by termination even "if caught with serious deficiencies as long as they correct[ed] them sufficiently" after inspection. As a result, the deterrent value of that remedy was relatively slight. H.R. Rep. No. 391, *supra*, Pt. 1, at 471.

Congress responded in 1987 by comprehensively reforming the requirements of participation for skilled nursing facilities, altering the manner in which compliance is enforced, and expanding the range of available remedies. See Omnibus Budget Reconciliation Act of 1987 (OBRA), Pub. L. No. 100-203, §§ 4201-4218, 101 Stat. 1330-160 to 1330-221. Among other things, OBRA requires that skilled nursing facilities be subjected to inspection without prior notice on average once a year. 42 U.S.C. 1395i-3(g)(2)(A)(i) and (iii). Although surveys are generally under the control of state agencies, 42 U.S.C. 1395i-3(g)(1)(A),[8] federal law governs the qualifications of survey team members, prescribes survey methods and procedures, and requires the use of federal forms. 42 U.S.C. 1395i-3(g)(2)(C); see also 42 C.F.R. 488.26(c), 488.314. Survey information must be made available to the public, 42 U.S.C. 1395i-3(g)(5)(A), and information about some types of substandard care must be provided to certain state officials, licensing boards, and physicians, 42 U.S.C. 1395i-3(g)(5)(B) to (C); see also 42 C.F.R. 488.325. The statute also directs the Secretary to develop enforcement criteria and to minimize the time between the detection of deficiencies and the imposition of a remedy. 42 U.S.C. 1395i-3(h)(2)(B).

When a survey agency detects a deficiency, it must recommend a remedy to the Secretary, who can approve the remedy or select a different one. 42 U.S.C. 1395i-3(h)(1). If the facility substantially complies with health, safety, and quality of care requirements—that is, if "any identified deficiencies pose no greater risk to resident health or safety

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[8] State agencies conduct the surveys pursuant to contracts with the Secretary, see 42 U.S.C. 1395i-3(g)(1)(A), 1395aa, but the Secretary may survey public nursing facilities operated by state or local governments and may survey any other facility if she has reason to question the facility's compliance with the statute, 42 U.S.C. 1395i-3(g)(3)(D), or it is necessary to assess survey agency performance, 42 U.S.C. 1395i-3(g)(3)(A).

than the potential for causing minimal harm," 42 C.F.R. 488.301—no remedy is imposed.[9] Where substantial compliance is not found, however, the Secretary may impose a remedy from an expanded list of options; she may direct the creation of a plan for correcting violations, impose civil money penalties, deny further reimbursement for services rendered after the deficiency is discovered, appoint temporary management, or terminate a facility's right to participate in Medicare. 42 U.S.C. 1395i-3(h)(2); 42 C.F.R. 488.406. In general, the remedies selected depend on the seriousness of the violations. See 42 U.S.C. 1395i-3(h)(2)(B); see also 42 C.F.R. 488.408 (grouping violations into 3 categories). Thus, the Secretary's regulations require survey agencies to determine whether the violations have already resulted in actual harm to residents, the potential for harm the violations pose, the degree of that potential harm, and whether the violations place residents in "immediate jeopardy," *i.e.*, whether the violations have "caused, or [are] likely to cause, serious injury, harm, impairment, or death to a resident." 42 C.F.R. 488.301, 488.404(b)(1). The survey agency also must consider whether the violations are isolated, form a pattern, or are widespread. 42 C.F.R. 488.404(b)(2). Other factors relevant to remedy selection include the relationship among deficiencies and the facility's compliance history. 42 C.F.R. 488.404(c). In general, the Secretary is expected to use available enforcement mechanisms to "bring substandard facilities into compliance with [federal] quality of care re-

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[9] The regulations governing nursing home surveys and remedies for violations apply to both the Medicaid program, which is administered jointly by the States and the Secretary, and the Medicare program, which is administered by the Secretary (although state agencies conduct Medicare nursing home surveys for the Secretary under contract). See 42 C.F.R. 488.300, 488.400. Some of the regulations therefore refer to enforcement actions taken by the State as well as by HCFA on behalf of the Secretary. See, *e.g.*, 42 C.F.R. 488.402(b).

quirements or to exclude them from the program." H.R. Rep. No. 391, *supra*, Pt. 1, at 452.

Where relatively serious violations grouped under the heading "substandard quality of care" are found,[10] the agency must evaluate the facility's operations in greater depth and identify the policies and procedures that caused the deficiency. 42 U.S.C. 1395i-3(g)(2)(B). Nursing facilities that are subjected to such an extended survey because of substandard care lose their eligibility to conduct a certified nurse-aide training program for two years, 42 U.S.C. 1395i-3(f)(2)(B)(iii), and three consecutive findings of substandard quality of care trigger automatic sanctions, such as a denial of payment for new admissions until the facility achieves, and can demonstrate that it is able to maintain, substantial compliance, 42 U.S.C. 1395i-3(h)(2)(E); 42 C.F.R. 488.414.

Nursing homes must be afforded written notice of deficiencies noted in any survey, of the remedy (if any) to be imposed, and of appeal rights. 42 C.F.R. 488.330, 488.402(f). A facility that disagrees with the survey may invoke an informal dispute-resolution process before the survey agency. That process must afford the nursing facility a prompt and meaningful opportunity to refute any findings of deficient care. 42 C.F.R. 488.331.[11] Whether or not the facility in-

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[10] "Substandard quality of care" exists where serious violations of the statutory requirements most directly related to medical care and the residents' quality of life either (1) create immediate jeopardy to resident health and safety, (2) constitute a pattern of or widespread actual harm that falls short of immediate jeopardy, or (3) pose a widespread potential for more than minimal harm even if no actual harm has yet occurred. 42 C.F.R. 488.301.

[11] Under the prior regulatory scheme, many States had successfully employed various types of informal appeal procedures to handle compliance disputes. 59 Fed. Reg. 56,116, 56,224 (1994). Because those procedures had proven effective and efficient, the Secretary directed all States to establish similar processes. *Id.* at 56,224-56,225. Although the regulations give the States discretion concerning the form and content of

vokes the informal dispute resolution process, any facility subjected to a remedy for noncompliance is entitled to a hearing before an administrative law judge (ALJ). See 42 U.S.C. 1395cc(h); 42 C.F.R. 498.1(a)-(b), 498.3(a), 498.3(b)(12). At that hearing, the facility may be represented by counsel, call witnesses, and present evidence. 42 C.F.R. 498.40-498.78. Any nursing facility dissatisfied with the resulting "decision may request Departmental Appeals Board review." 42 C.F.R. 498.5(c). Where civil money penalties are imposed, the decision of the Departmental Appeals Board is subject to judicial review through a petition to the court of appeals. 42 U.S.C. 1395i-3(h)(2)(B)(ii); 42 U.S.C. 1320a-7a(e); see also 42 U.S.C. 1395cc(h)(2). In 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). 42 U.S.C. 1395cc(h)(1). See generally pp. 4-6 & n.5, *supra*.

3. Respondent filed this action in the United States District Court for the Northern District of Illinois in 1996 seeking injunctive and declaratory relief with respect to the implementing regulations the Secretary issued in 1995. The complaint does not challenge the Secretary's substantive standards governing resident health, safety, and care. J.A. 17, 22, 36-37 (¶¶ 1, 16, 64). Instead, respondent broadly challenges the procedures and remedies used in enforcing those standards.

More specifically, respondent alleges that the Secretary's regulations concerning the characterization of the seriousness of violations are unconstitutionally vague. J.A. 18, 29-32, 43-45 (¶¶ 3B, 37-50, 84-88). According to respondent,

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such procedures, the process as a whole must afford nursing homes a meaningful opportunity to refute findings of deficient care. 42 C.F.R. 488.331(a)(1). If the provider successfully rebuts a survey finding, the State must remove the deficiency from its findings and rescind any proposed enforcement action based on that determination. 42 C.F.R. 488.331(c). Similar procedures are also available with respect to federally-conducted surveys. 42 C.F.R. 488.331(a)(2).

critical terms such as "minimal harm," "immediate jeopardy," "pattern," and "widespread," are not defined with sufficient particularity. See J.A. 30-31 (¶¶ 42-44). Respondent further claims that, because of that asserted vagueness, remedies are not imposed in a consistent fashion. J.A. 18, 36-38, 45, 46 (¶¶ 3C, 64-68, 89-91, 94).

Respondent also alleges that the Secretary's regulations are inconsistent with due process because they limit the scope of administrative review. J.A. 18-19, 32-36, 47-49 (¶¶ 3D-3E, 51-63, 95-101). In particular, respondent complains that administrative review of survey findings is not available if no remedy is imposed, J.A. 34-35, 48-49 (¶¶ 59, 99, 101), or as to matters such as the surveyors' characterization of the level of noncompliance (except where it affects the permissible range of civil penalties) and the remedy selected, J.A. 34, 48-49 (¶¶ 57-58, 101). See generally 42 C.F.R. 498.3(b)(12) and (13), (d)(10) and (11). Respondent also protests the absence of a prior hearing before certain remedies, such as termination of the provider agreement, are imposed. J.A. 18-19 (¶ 3D).[12] Finally, the complaint alleges that a manual used by state survey inspectors to review facilities for compliance—the State Operations Manual or SOM—is a substantive rule that was promulgated outside the notice-and-comment rulemaking process required by the Administrative Procedure Act (APA), 5 U.S.C. 553. J.A. 18, 26-28, 46 (¶¶ 3A, 30-36, 92-94).

Respondent seeks an order declaring that (1) the Secretary's regulations are unconstitutionally vague, (2) the State Operations Manual was promulgated in violation of the APA,

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[12] Respondent also complains that, under current regulations, no administrative review is available where a finding of "substandard quality of care" causes the facility (automatically) to lose approval for its nurse-aide training program but no other remedy is imposed. J.A. 33 (¶¶ 54-55); see 42 C.F.R. 498.3(b)(12) and (d)(10)(ii). We have been informed by the Department of Health and Human Services that it is currently reviewing that exclusion.

and (3) the administrative appeal procedures provided under the current regulations are inadequate. J.A. 51 (¶¶ A, C, D). Respondent also seeks an injunction precluding the Secretary from (1) disclosing survey results where "substandard quality of care" is found; (2) imposing or collecting civil money penalties; and (3) imposing "upon [respondent's] Medicare members any ban on payment as a remedy for any deficiency." J.A. 52 (¶¶ E, F, G). Subject matter jurisdiction is premised on 28 U.S.C. 1331, 1346, and 2201. J.A. 22 (¶ 14); Pet. App. 13a, 15a.

The district court dismissed the complaint for lack of subject matter jurisdiction. Pet. App. 13a-21a. The court pointed out that, under 42 U.S.C. 405(h), a federal district court may not assert jurisdiction under 28 U.S.C. 1331 or 1346 with respect to claims arising under the Medicare Act. In this case, the court reasoned, respondent's claims clearly arise under the Medicare Act, and it therefore could not assert jurisdiction under 28 U.S.C. 1331 and 1346. Pet. App. 15a-18a.

The district court also rejected respondent's reliance on *Bowen* v. *Michigan Academy of Family Physicians*, 476 U.S. 667 (1986). See Pet. App. 18a-19a. In *Michigan Academy*, this Court held that 28 U.S.C. 1331 gave a federal district court jurisdiction over a facial challenge to the validity of Medicare regulations governing the methodology for calculating payments under Part B of the Medicare program. At the time *Michigan Academy* was decided, the Medicare Act (through 42 U.S.C. 1395ff (1982)) provided for a hearing and judicial review, under 42 U.S.C. 405(b) and (g), of decisions regarding the amount of payment (if any) due for particular services under Part A of the Medicare program, but not under Part B, see 476 U.S. at 674 n.5, and the Court had already held in *United States* v. *Erika, Inc.*, 456 U.S. 201, 207-208 (1982), that Congress thereby had completely foreclosed judicial review of administrative decisions concerning the amount of benefits payable under Part B. In *Michigan*

Academy, however, the Court, relying on the "strong presumption that Congress intends judicial review of administrative action," held that the Medicare Act does not preclude "challenges mounted against the *method* by which [the] amounts [of Part B benefits] are to be determined rather than [challenges to] the [amount] *determinations* themselves." 476 U.S. at 670, 675.

In light of the statutory framework and this Court's analysis, the district court in this case concluded that *Michigan Academy* was premised on the fact that the plaintiffs there had "no other avenue of judicial review" to challenge the Secretary's regulations. Pet. App. 18a. Here, in contrast, the Medicare Act itself provides an avenue through which respondent's members can challenge the relevant enforcement procedures any time they are applied to the members themselves. *Ibid.* Moreover, the district court continued, Congress amended the Medicare Act shortly after the Court's decision in *Michigan Academy*, and the amendment now provides administrative and judicial review under 42 U.S.C. 405(b) and (g) for the sort of Part B methodology challenges that were at issue in that case. See Omnibus Budget Reconciliation Act of 1986, Pub. L. No. 99-509, § 9341(a)(1), 100 Stat. 2037 (codified at 42 U.S.C. 1395ff(1)). Because both Part A and Part B participants "now have an avenue of judicial review," the district court explained, "the concern * * * in *Michigan Academy*"—that agency action would be altogether immune from judicial review—"no longer exists." Pet. App. 18a.

The district court further found that respondent had not satisfied the prerequisites for judicial review under 42 U.S.C. 405(g) (as made applicable here by 42 U.S.C. 1395cc(h)(1)), including the non-waivable requirement that all claims be presented to the Secretary, and the waivable requirement that administrative remedies be exhausted. Pet. App. 18a-19a. Here, the court observed, respondent

"ha[d] not alleged or shown any attempt at presentment of [its] claims to the Secretary." *Id.* at 19a.[13]

4. The court of appeals vacated and remanded. Pet. App. 1a-12a. It acknowledged that this Court's decisions in *Heckler* v. *Ringer*, 466 U.S. 602 (1984), and *Weinberger* v. *Salfi*, 422 U.S. 749 (1975), "treat th[e] language [of 42 U.S.C. 405(h)] as channeling all claims to benefits through the administrative forum, no matter what legal theory underlies the claim." Pet. App. 4a. Relying on *Michigan Academy*, however, the court of appeals concluded that Section 405(h) addresses only provider claims relating to a "request for reimbursement," *ibid.*, and does not apply to an "anticipatory challenge to implementing regulations," *id.* at 5a.

The court of appeals agreed that "the 1986 amendments [to Part B]," which now provide an avenue of judicial review of Part B amount determinations and regulations through Section 405(g), might well "remove the practical support" for a distinction between "pre-enforcement challenges to Medicare regulations * * * and requests for reimbursement." Pet. App. 5a. It also recognized that "*Michigan Academy* [had] emphasized * * * the presumption that Congress has allowed some avenue of judicial review, and the Justices [had] read the statutes then in effect with that presumption in mind." *Ibid.* But the court of appeals noted that Congress had not amended 42 U.S.C. 405(h) or 1395ii. The court therefore considered itself "obliged to follow" *Michigan Academy*, which it read as permitting pre-enforcement review of regulations notwithstanding 42 U.S.C. 405(h), even where (unlike in *Michigan Academy*) Congress has provided for judicial review under 42 U.S.C. 405(g). See Pet. App. 6a-7a.[14]

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[13] The district court also dismissed respondent's claims brought under the *Medicaid* program. Pet. App. 19a-20a. The status of those claims is not at issue here. See note 14, *infra*.

[14] The court of appeals affirmed on ripeness grounds dismissal of respondent's vagueness challenge to the Secretary's regulations, Pet. App.

The Secretary's petition for rehearing with suggestion of rehearing en banc was denied, although three judges voted to grant rehearing en banc. Pet. App. 22a-23a & n.2.

SUMMARY OF ARGUMENT

A. The Medicare Act establishes detailed mechanisms for obtaining judicial review of claims that arise under the Act. Of particular significance here, it provides for judicial review of a regulation after the regulation has been applied to the party seeking to challenge it, the party has presented its claim to the Secretary, and the Secretary has issued a final decision. Where the Act itself provides an express mechanism for obtaining judicial review, that mechanism is exclusive. That is clear not merely from the reticulated nature of the Act's review mechanisms, but also from the text of 42 U.S.C. 405(h), which, as incorporated into the Medicare program by 42 U.S.C. 1395ii, declares that "[n]o findings of fact or decision of the [Secretary] shall be reviewed by any person, tribunal, or governmental agency except as * * * provided" in the Medicare Act itself, and that "[n]o action against the United States, the [Secretary], or any officer or employee thereof shall be brought under sections 1331 or 1346 of title 28 to recover on any claim arising under this subchapter." As the Senate Report accompanying the Medicare Act explained, "[i]t is intended that the remedies provided by these review procedures shall be exclusive." S. Rep. No. 404, 89th Cong., 1st Sess., Pt. 1, at 55 (1965).

B. The court of appeals' decision permitting federal-question jurisdiction over "pre-enforcement" challenges to

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10a-11a, and this Court denied respondent's conditional cross-petition for a writ of certiorari seeking review of that holding. See 119 S. Ct. 1459 (1999). The court of appeals also reinstated respondent's claims on behalf of its Medicaid-only members with respect to the Secretary's Medicaid regulations. Pet. App. 7a-8a. Our certiorari petition did not seek review of that aspect of the court of appeals' judgment. See Pet. i, 5.

the validity of Medicare regulations under 28 U.S.C. 1331, notwithstanding the availability of post-enforcement review, is at odds with the plain language of Section 405(h) and is inconsistent with *Heckler* v. *Ringer*, 466 U.S. 602 (1984); *Weinberger* v. *Salfi*, 422 U.S. 749 (1975), and *Mathews* v. *Eldridge*, 424 U.S. 319 (1976). Those precedents hold that where, as here, the plaintiff's standing and the substantive basis for the plaintiff's suit are based on the Social Security Act (including its Medicare title), review is available only as provided by the Act itself.

Nor is the court of appeals' decision supported by *Bowen* v. *Michigan Academy of Family Physicians*, 476 U.S. 667 (1986). Unlike this case, *Michigan Academy* involved Medicare claims for which there was no avenue of judicial review under the Medicare Act. As a result, precluding general federal-question jurisdiction over those claims would have left the plaintiffs with no means of securing judicial review of substantial questions concerning the administration of the Medicare program—a result that the Court found to be inconsistent with the strong presumption that Congress intends final agency action to be subject to judicial review. Thus, contrary to the decision below, *Michigan Academy* does not authorize federal-question jurisdiction over pre-enforcement challenges to Medicare regulations where, as here, the Medicare Act itself affords fully adequate means of judicial review.

C. Although respondent attempts to justify bypass of the Medicare Act's otherwise exclusive mechanisms by claiming that its statutory and constitutional claims cannot be raised in administrative proceedings, those claims can be raised on judicial review of the Secretary's final decision. This Court, moreover, has repeatedly rejected the suggestion that a party can bypass the otherwise exclusive mechanisms for review provided by the Social Security Act simply because it raises constitutional or other issues that would not ordinarily be addressed in the administrative process. "[T]he plain

words of the third sentence of 405(h) do not preclude constitutional challenges. They simply require that [the challenges] be brought under jurisdictional grants contained in the Act, and thus in conformity with the same standards which are applicable to nonconstitutional claims arising under the Act." *Salfi*, 422 U.S. at 762.

ARGUMENT

RESPONDENT'S PRE-ENFORCEMENT JUDICIAL CHALLENGE TO THE SECRETARY'S ENFORCEMENT GUIDELINES AND REMEDIES IS BARRED BY THE MEDICARE ACT

By incorporating 42 U.S.C. 405(g) and (h) into the Medicare Act through 42 U.S.C. 1395cc(h) and 1395ii, Congress established a specific and exclusive mechanism for obtaining judicial review of claims "arising under" the Medicare Act. Those provisions require a nursing facility or other participant in the Medicare program to challenge the Secretary's regulations and policies after they have been applied to that participant, thereby ensuring that challenges are of manageable proportions and are framed by a concrete, factual setting. And they route all challenges through the administrative process as a pre-condition to judicial review, thereby permitting the development of a factual record, allowing for refinement of legal issues, enabling the agency to apply its expertise to the specific issues raised, and affording the Secretary the opportunity to resolve the dispute on other grounds.

In this case, respondent seeks to bypass Medicare's established mechanisms for obtaining review by bringing an anticipatory challenge under 28 U.S.C. 1331 to the Secretary's regulations in the abstract, without reference to any specific enforcement action. That effort, however, cannot be reconciled with the Medicare "statute's language, structure, * * * purpose, [and] legislative history," especially given that the Act itself provides an opportunity for "meaningful

review." *Thunder Basin Coal Co.* v. *Reich*, 510 U.S. 200, 207 (1994). Indeed, the text of Section 405(h) prohibits such an effort in unmistakeable terms.

A. WHERE THE MEDICARE ACT PROVIDES A MECHANISM FOR OBTAINING JUDICIAL REVIEW, THAT MECHANISM IS EXCLUSIVE

1. a. The Medicare Act provides a highly "reticulated statutory scheme, which carefully details the forum and limits of review" of the Secretary's determinations. *Bowen* v. *Michigan Academy of Family Physicians*, 476 U.S. 667, 675 (1986). With respect to each of a number of categories of claims, the Act channels the claims through administrative and then judicial review *after* the Secretary has taken action (reimbursement, enforcement, etc.) directed at the person seeking review. Thus, individuals who are dissatisfied with entitlement and payment determinations, 42 U.S.C. 1395ff(a) and (b), providers aggrieved by reimbursement decisions, 42 U.S.C. 1395*oo*(a) and (f), and entities subjected to civil money penalties, 42 U.S.C. 1320a-7a(c)(2) and (e), all are afforded the opportunity for a hearing after the Secretary's initial determination, and for judicial review once the Secretary reaches a final decision. See also pp. 3-6, *supra*.

That same general scheme applies to nursing facilities seeking to challenge the Secretary's guidelines and remedies for enforcing the Medicare program's requirements for participation. In particular, any nursing facility or other provider "dissatisfied with a determination by the Secretary that it is not a provider of services" or a determination that it does not "substantially comply" with the Secretary's health, safety, and quality-of-care requirements "is entitled to a hearing thereon by the Secretary (after reasonable notice) to the same extent as provided in section 405(b) * * * and to judicial review of the Secretary's final decision after such hearing as is provided in section 405(g) [of Title 42]." 42 U.S.C. 1395cc(h)(1) and (b)(2); see pp. 4-5, *supra*.

Likewise, under 42 U.S.C. 1395i-3(h)(2)(B)(ii), a facility against which civil penalties have been assessed is entitled to a hearing, and judicial review in the court of appeals, as provided by 42 U.S.C. 1320a-7a(c)(2) and (e).

The provision of such a "detailed structure" for post-enforcement administrative and judicial review is, by itself, strong evidence that Congress intended to make that structure exclusive. See *Thunder Basin*, 510 U.S. at 207; *United States* v. *Erika, Inc.*, 456 U.S. 201, 208 (1982) (concluding that evidence of exclusivity is particularly strong "[i]n the context of" the Medicare Act's "precisely drawn provisions"). See also *Board of Governors of the Fed. Reserve Sys.* v. *MCorp Fin., Inc.*, 502 U.S. 32, 43-44 (1991); *United States* v. *Fausto*, 484 U.S. 439, 448-449 (1988); *Whitney Nat'l Bank* v. *Bank of New Orleans & Trust Co.*, 379 U.S. 411, 420 (1965). By contrast, when Congress intends to permit pre-enforcement review notwithstanding specific post-enforcement review mechanisms, it typically enacts express statutory provisions so providing. See, *e.g.*, *Harrison* v. *PPG Indus.*, 446 U.S. 578, 592-593 (1980). It has not done so here.[15]

b. Congress, in any event, has expressly provided that the post-enforcement mechanisms for judicial review in the Medicare Act are exclusive. When Congress provided for judicial review of Social Security decisions by enacting 42 U.S.C. 405(g), it paired that provision with 42 U.S.C. 405(h) to preclude judicial review by other means. And when Congress made 42 U.S.C. 405(g) applicable to compliance determinations under the Medicare program in 1965, it also made Section 405(h) applicable by enacting 42 U.S.C.

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[15] *Abbott Laboratories* v. *Gardner*, 387 U.S. 136 (1967), is not to the contrary. There, the Court permitted pre-enforcement review of an agency regulation absent express statutory authority, but only after determining that a statutory savings clause and the legislative history reflected Congress's intent to preserve an established practice of exercising equitable jurisdiction over pre-enforcement challenges to similar agency actions. *Id.* at 142-144. See also *Thunder Basin*, 510 U.S. at 212.

1395ii. As incorporated into the Medicare Act, Section 405(h) provides:

> The findings and decisions of the [Secretary] after a hearing shall be binding on all individuals who were parties to such hearing. No findings of fact or decision of the [Secretary] shall be reviewed by any person, tribunal, or governmental agency except as herein provided. No action against the United States, the [Secretary], or any officer or employee thereof shall be brought under sections 1331 or 1346 of title 28 to recover on any claim arising under this subchapter.

As this Court has observed, "the first two sentences of § 405(h) * * * assure that administrative exhaustion will be required," *Weinberger* v. *Salfi*, 422 U.S. 749, 757 (1975), while the third sentence "provides that § 405(g), to the exclusion of 28 U.S.C. § 1331, is the sole avenue for judicial review for *all* 'claim[s] arising under' the Medicare Act." *Heckler* v. *Ringer*, 466 U.S. 602, 614-615 (1984) (emphasis added). Section 405(h) thus "require[s] the exhaustion of available administrative procedures, * * * foreclose[s] jurisdiction under the general grant of federal-question jurisdiction, 28 U.S.C. § 1331, and * * * route[s] review through § [405(g)]." *Califano* v. *Sanders*, 430 U.S. 99, 103 n.3 (1977); see also *id.* at 110 (Stewart, J., concurring) ("I can see no reason in this case why the second sentence of § [405(h)] should not be read to mean exactly what it says—that the decision before us is reviewable under § [405(g)] or not at all.").[16]

c. To the extent the text and structure of the Medicare Act could leave any doubt, the legislative history erases it. The 1965 Senate Report that accompanied the Medicare Act,

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[16] As noted above, where civil money penalties are imposed as a sanction for noncompliance, a hearing and judicial review are available to the extent provided for by 42 U.S.C. 1320a-7a. See 42 U.S.C. 1395i-3 (h)(2)(B)(ii). Where 42 U.S.C. 1320a-7a applies, 42 U.S.C. 405(h) applies too. See 42 U.S.C. 1320a-7(f)(3).

immediately after discussing the various methods for obtaining administrative and judicial review under the Act, declares: "It is intended that the remedies provided by these review procedures *shall be exclusive*." S. Rep. No. 404, 89th Cong., 1st Sess., Pt. 1, at 54-55 (1965) (emphasis added). A clearer expression of Congress's intent is difficult to imagine.

d. Finally, requiring nursing facilities like respondent's members to seek judicial review under Section 405(g) after first seeking relief in the administrative process is fair and sensible. It does not deny nursing facilities the opportunity for judicial review; it merely postpones review until such time as the claim has arisen in a specific, factual context, the matter has been presented to the Secretary, and the Secretary has issued a final decision. See *Salfi*, 422 U.S. at 762. Moreover, channeling Medicare claims through the statutorily-provided mechanisms for administrative and judicial review serves important policy goals. First, by requiring that challenges be brought in the context of a specific enforcement action, the Act ensures that "the scope of the controversy [will be] reduced to more manageable proportions, and its factual components fleshed out, by some concrete action applying the regulation to the claimant's situation in a fashion that harms or threatens to harm him." *Lujan* v. *National Wildlife Fed'n*, 497 U.S. 871, 891 (1990); see *Reno* v. *Catholic Soc. Servs., Inc.*, 509 U.S. 43, 58-59 (1993) (noting, for similar reasons, that mere passage of a statute and issuance of regulations do not give a complainant a ripe claim absent agency action "applying the regulation to him"). Second, the process required by Section 405(g) and (h) promotes the interest in administrative efficiency by protecting the agency from the "potential for overly casual * * * judicial intervention in an administrative process" that is responsible not only for protecting the health and safety of thousands of Medicare beneficiaries residing in nursing homes, but also for resolving "millions of claims" a year. *Ringer*, 466 U.S. at 627; see also *Salfi*, 422 U.S. at 765.

Third, channeling claims through the administrative process promotes judicial economy. It permits the agency "to correct its own errors, to afford the parties and the courts the benefit of its experience and expertise, and to compile a record which is adequate for judicial review." *Salfi*, 422 U.S. at 765; accord *Ringer*, 466 U.S. at 619 n.12. Further, it may avert the need for judicial review altogether, as it "assures the Secretary the opportunity prior to * * * litigation to ascertain, for example, that the particular claims involved are neither invalid for other reasons nor allowable under other provisions of the Social Security Act." *Salfi*, 422 U.S. at 762.

2. Consistent with the text, structure, history, and purposes of the Social Security Act's review provisions, the Court repeatedly has recognized that, where those provisions create a mechanism for judicial review, that mechanism is exclusive. In *Salfi*, for example, the Court held that a federal district court lacked jurisdiction under 28 U.S.C. 1331 to hear a constitutional challenge to a provision of the Social Security Act that rendered the plaintiffs ineligible for certain benefits. The language of Section 405(h), the Court held, is "sweeping and direct"; it states "that *no* action shall be brought under § 1331" with respect to any claim "arising under" the Social Security Act. 422 U.S. at 757. The Court in *Salfi* also rejected the argument that Section 405(h) does not apply if the suit can be characterized as "arising under" the Constitution. Where "the Social Security Act * * * provides both the standing and the substantive basis for the presentation of their constitutional contentions," the Court held, the plaintiffs' action is a suit "arising under" the Act within the meaning of Section 405(h), even if the suit could be said to arise under the Constitution as well. 422 U.S. at 760-761. Consequently, where such claims are asserted, Section 405(h) precludes federal courts from exercising jurisdiction over them pursuant to 28 U.S.C. 1331; instead, judicial review is available only through the mechanisms

provided by the Social Security Act itself. 422 U.S. at 760-761.

Seven years later, the Court again stressed the exclusivity of the Act's review mechanisms in *United States* v. *Erika, Inc.*, 456 U.S. 201 (1982). There, a company that had provided services to Medicare beneficiaries sought to challenge the amount of reimbursement it received under Part B of the Medicare program. At that time, the Act provided for judicial review of decisions under both Part A and Part B where the "dispute relates to * * * eligibility to participate," but provided for judicial review of determinations concerning the "amount" of payment only with respect to claims under Part A. See 456 U.S. at 207-208. "In the context of the statute's precisely drawn provisions" and supporting legislative history, the Court explained, the omission of an express provision for judicial review of Part B "amount determinations" furnished "persuasive evidence that Congress deliberately intended to foreclose further review" of such determinations. *Id.* at 208. Thus, even though treating the Medicare program's review provisions as exclusive in *Erika* rendered the administrative determination at issue there completely unreviewable, the Court held them to be exclusive.

More recently, in *Heckler* v. *Ringer*, 466 U.S. 602 (1984), this Court once again concluded that 42 U.S.C. 405(g) provides the exclusive mechanism for obtaining judicial review of the Secretary's implementation and enforcement of the Medicare Act. In *Ringer*, one of the named plaintiffs, Freeman Ringer, sought to challenge an agency rule that precluded reimbursement for an operation he wished to undergo. Because Ringer had not undergone that procedure, he could not file a claim for reimbursement and challenge the Secretary's decision denying the claim under 42 U.S.C. 405(g). Accordingly, he brought a "pre-enforcement" action in district court requesting a declaratory judgment that the pertinent Medicare regulation was invalid.

466 U.S. at 621-623. This Court held that the Medicare Act itself, in 42 U.S.C. 405(g) (as incorporated by 42 U.S.C. 1395ff(b)), affords the exclusive basis for obtaining jurisdiction over such a claim, and that federal courts could not exercise jurisdiction under 28 U.S.C. 1331. The Court stated: "The third sentence of 42 U.S.C. § 405(h), made applicable to the Medicare Act by 42 U.S.C. § 1395ii, provides that § 405(g), to the exclusion of 28 U.S.C. § 1331, is the sole avenue for judicial review for *all* 'claim[s] arising under' the Medicare Act." 466 U.S. at 614-615 (emphasis added; footnote omitted).

Finally, just last Term, in *Your Home Visiting Nurse Services, Inc.* v. *Shalala*, 119 S. Ct. 930, 935 (1999), this Court reaffirmed its holding in *Ringer*, again declining to permit judicial review of claims under the Medicare program except as provided in the Act itself. There, a provider sought judicial review of a refusal to reopen its reimbursement claim. "[J]udicial review under the federal-question statute, 28 U.S.C. § 1331," the Court explained, "is precluded by 42 U.S.C. § 405(h), applicable to the Medicare Act by operation of § 1395ii, which provides that '[n]o action against . . . the [Secretary] or any officer or employee thereof shall be brought under section 1331 . . . of title 28 to recover on any claim arising under this subchapter." 119 S. Ct. at 935. The provider's claim, the Court further concluded, "'arises under' the Medicare Act within the meaning of [Section 405(h)] because 'both the standing and the substantive basis for the presentation' of the claim are the Medicare Act." *Ibid.* (quoting *Ringer*, 466 U.S. at 615 (some internal quotation marks omitted)).

3. The exclusivity of the review procedures established by Section 405(g) is further reinforced by the Administrative Procedure Act (APA), 5 U.S.C. 702-704. Section 10(b) of the APA states that, where Congress has provided a "special statutory review proceeding relevant to the subject matter," complainants must use that "form of proceeding for judicial

review," unless it is "inadequa[te]." 5 U.S.C. 703. Moreover, Section 10(c) of the APA bars resort to its general provisions for judicial review of agency action unless "there is no other adequate remedy in a court." 5 U.S.C. 704.

As Attorney General Clark explained shortly after the APA's enactment, "[t]he net effect [of Section 10], clearly intended by the Congress, is to provide for a dovetailing of the general provisions of the [APA] with the particular statutory provisions which the Congress has moulded for special situations." *Attorney General's Manual on the Administrative Procedure Act* 95 (1947).[17] The APA thus "'does not provide additional judicial remedies in situations where the Congress has provided special and adequate review procedures.'" *Bowen* v. *Massachusetts*, 487 U.S. 879, 903 (1988) (quoting *Attorney General's Manual*, *supra*, at 101).

4. The foregoing principles foreclose respondent's suit here. Respondent seeks to challenge the Secretary's regulations and guidelines governing the enforcement of Medicare's health, safety, and quality-of-care requirements for nursing homes. But respondent does not seek review of a specific, concrete "determination" or application of those regulations. See J.A. 22 (¶ 16) (Respondent "does not challenge the specific application of the 1995 Regulations and the SOM to any one facility, but challenges instead their lawfulness and their use" generally). Nor does respondent assert that jurisdiction is proper under the mechanisms for judicial review provided by the Medicare Act itself. To the contrary, respondent omits any reference to those provisions in its complaint, relying only on the more general jurisdictional grants contained in 28 U.S.C. 1331 and 1346. J.A. 22 (¶ 14).

Respondent thus is attempting to bypass the express statutory mechanisms for judicial review provided by the

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[17] The Court has accorded the *Attorney General's Manual* deference in construing the APA. See, *e.g.*, *Darby* v. *Cisneros*, 509 U.S. 137, 148 n.10 (1993).

Medicare Act. But such a bypass is precisely what Section 405(h) prohibits, for it makes Section "405(g) * * * the sole avenue for judicial review for *all* 'claim[s] arising under' the Medicare Act." *Ringer*, 466 U.S. at 615 (emphasis added). Respondent nowhere disputes that its claims "arise under" the Act within the meaning of Section 405(h).[18]

Permitting respondent to bypass the mechanisms for review provided by the Medicare Act in this case, moreover, would give rise to the very dangers that the Medicare Act seeks to avoid. Because respondent seeks to raise its claims in the abstract rather than in connection with a specific application of the regulations, "the scope of the controversy" has not been "reduced to more manageable proportions," *Lujan*, 497 U.S. at 891; instead, it remains unwieldy and unmanageable, a broad-ranging attack on virtually every aspect of the Secretary's compliance regime. The correspondingly broad relief respondent seeks also creates a serious risk that premature judicial interference could have devastating consequences for the program. In essence, respondent asks the district court to invalidate the Secretary's entire compliance enforcement program, J.A. 51 (¶¶ A-D), and to bar the Secretary from assessing civil

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[18] Indeed, respondent concedes that its "claims on behalf of its Medicare members arise under * * * the provisions of the Social Security Act pertaining to Medicare, 42 U.S.C. § 1395 *et seq.*" J.A. 22 (¶ 14). Respondent's standing, which derives from its members' participation in the Medicare program, clearly derives from the Act; absent the Act, respondent would have no complaint and no basis for bringing suit. See *Salfi*, 422 U.S. at 760-761. Likewise, the "substantive basis for the presentation" of respondent's claims originates in the Act. Respondent, by this lawsuit, seeks to bar the Secretary from enforcing regulations alleged to be inconsistent with the Act, to prevent the Secretary from cutting off reimbursement otherwise provided by the Act, and to bar the imposition of remedies alleged to be contrary to the Act. J.A. 51-53 (¶¶ A-H). To suggest that such an action "does not arise under the Act" is "to ignore both the language and the substance of the complaint and the judgment" that respondent seeks. *Salfi*, 422 U.S. at 761.

penalties, withholding payments, or imposing other sanctions, even where blatant and dangerous violations of the program's health, safety, and quality-of-care criteria are detected, J.A. 52 (¶¶ F-H). That relief would deprive the Secretary of access to the very remedies Congress thought necessary when it enacted OBRA to reform enforcement in 1987, and would bring enforcement to a virtual standstill in Illinois. See pp. 6-9, *supra*. Requiring respondent's members to challenge a discrete instance of enforcement of the regulations under the Medicare Act's review provisions will dramatically reduce the risk of such a grave intrusion on a federal program critical to the health of thousands of Medicare beneficiaries. See *Ringer*, 466 U.S. at 627 (Medicare Act remedies protect the agency from the "potential for overly casual * * * judicial intervention in" important administrative processes); *Salfi*, 422 U.S. at 765 (review mechanisms avoid "premature interference with agency processes, so that the agency may function efficiently").

Likewise, because respondent's challenge is purely anticipatory, it suffers from the absence of a factual record and concrete context that would make it fit for judicial review. Indeed, for that reason, the court of appeals held that respondent's void-for-vagueness claim was not "ripe" under ordinary APA principles. See Pet. App. 10a-11a. Compare *Salfi*, 422 U.S. at 765 (administrative process helps create a record and thereby render the case "fit" for judicial review); *Ringer*, 466 U.S. at 619 (similar). A similar absence of requisite facts—such as the nature of the nursing patient interests at stake in individual cases, *e.g.*, whether there is immediate jeopardy to their lives requiring prompt action—makes adjudication of respondent's procedural due process claims cumbersome, if not impossible, as well. J.A. 32-46 (¶¶ 51-63).

Nor can it be claimed that there is a need here for immediate review outside of ordinary processes. Respondent does not assert that its members are required by allegedly improper regulations to refrain from engaging in otherwise

lawful conduct. Cf. *Lujan*, 497 U.S. at 891 (rules requiring the complainant "to adjust [its] conduct immediately" may be ripe). To the contrary, respondent disavows any challenge to the substantive health, safety, and quality-of-care standards that govern its members' day-to-day operations. Instead, respondent claims that its members cannot tell *what sanction*, if any, otherwise clearly proscribed conduct will draw. See pp. 11-12, *supra*. Such an argument hardly provides compelling grounds for bypassing the express post-enforcement review process provided by the Medicare Act. Would-be criminals normally cannot bring declaratory judgment actions seeking to halt enforcement of criminal laws simply because they cannot tell in advance what their sentence will be if they commit a crime; any arbitrariness in sentencing must be raised through ordinary criminal processes only after an allegedly arbitrary sentence is imposed. The same should be true of would-be violators of the (unchallenged) substantive health, safety, and quality-of-care requirements that protect Medicare beneficiaries from abuse and injury.

B. *MICHIGAN ACADEMY* DOES NOT PERMIT FEDERAL COURTS TO EXERCISE GENERAL FEDERAL-QUESTION JURISDICTION OVER RESPONDENT'S SUIT

The court of appeals disputed none of the preceding analysis. Nowhere did the court dispute that the text, structure, purposes and legislative history of the Medicare Act all demonstrate that, where the Act provides a mechanism for obtaining judicial review, that mechanism is exclusive. Nor did the court of appeals express any doubt that respondent's members would be able to obtain judicial review of their claims—in a concrete factual setting—through the procedures provided by the Medicare Act itself. Indeed, the court of appeals agreed that, in a long line of cases stretching from *Salfi* to *Ringer*, this Court has rejected efforts to bypass the

mechanisms for judicial review provided by the Medicare Act, and has held that 42 U.S.C. 405(h) precludes federal courts from exercising jurisdiction with respect to such claims under 28 U.S.C. 1331. See Pet. App. 2a-3a.

1. Nonetheless, the court of appeals concluded that *Michigan Academy* allowed the district court to exercise jurisdiction over respondent's pre-enforcement action. In *Michigan Academy*, the plaintiffs challenged the validity of reimbursement regulations under Part B of the Medicare program. At that time, the relevant provision of the Medicare Act, 42 U.S.C. 1395ff(b)(1) (1982), expressly provided for judicial review of disputes concerning the "amount" of reimbursement (if any) payable under Part A, but not under Part B. See 476 U.S. at 674-675. And in *Erika*, the Court had held that that omission, together with the relevant legislative history, established that Congress had intended to preclude judicial review of Part B claims challenging the amount of reimbursement. See 456 U.S. at 207-208.

In *Michigan Academy*, the government argued that Congress's failure to include a provision for judicial review of Part B claims, other than those relating to basic eligibility under the program, indicated that Congress intended to preclude judicial review of *all* issues under Part B except those relating to eligibility. Relying on the "strong presumption that Congress did not mean to prohibit all judicial review" of agency decisions, 476 U.S. at 672, the Court rejected that argument. While the Court found evidence that Congress had deliberately foreclosed any challenge to the amount of benefits awarded in a particular case, it found no evidence that Congress intended to preclude more general "challenges mounted against the *method* by which [the] amounts [of Part B benefits] are to be determined rather than [challenges to] the [amount] *determinations* themselves." *Id.* at 675. In particular, the legislative history provided "specific evidence of Congress' intent to foreclose review" with respect to "amount determinations," *i.e.*, claims concerning the mone-

tary sum of benefits due, but provided no indication of a similar intent to foreclose judicial review of more general "methodology" claims, which might involve "statutory and constitutional challenges to the Secretary's administration of Part B of the Medicare program." *Id.* at 680. Because the government had not produced "clear and convincing evidence" sufficient to overcome the "strong presumption that Congress did not mean to preclude judicial review" entirely, *id.* at 681, the Court held that "methodology" claims were not precluded even though "amount" claims were.

In this case, the court of appeals read *Michigan Academy* as broadly "hold[ing] that [42 U.S.C.] § 1395ii," which incorporates 42 U.S.C. 405(h) into the Medicare program, "does not foreclose Medicare providers' anticipatory challenge[s] to implementing regulations" under 28 U.S.C. 1331. Pet. App. 4a, 6a. In particular, the court of appeals interpreted *Michigan Academy* as holding that Section 405(h) "addresses only 'amount determinations' * * * —that is, calculations of reimbursements.'" Pet. App. 4a; see also *id.* at 6a. Thus, in the court of appeals' view, pre-enforcement challenges are permissible under *Michigan Academy* whether or not such claims could be adjudicated after a final administrative decision under the mechanisms for judicial review provided by the Medicare Act itself. That reading of *Michigan Academy* is incorrect.

a. Whatever the continuing vitality of *Michigan Academy* in the particular context in which it arose, in light of later amendments to the Medicare Act (see pp. 36-37, *infra*), that decision has no bearing where, as here, the question is not *whether* judicial review will be available, but *when* it will be available. See *National Kidney Patients Ass'n* v. *Sullivan*, 958 F.2d 1127, 1133 (D.C. Cir. 1992) ("[T]he Court in *Michigan Academy* was concerned not with timing, but with reviewability *vel non*."), cert. denied, 506 U.S. 1049 (1993). The Court's reasoning in *Michigan Academy* literally begins with, 476 U.S. at 670, ends with, *id.* at 681, and is steeped

throughout with, see *id.* at 672, the presumption that Congress intends judicial review to be available. See also *id.* at 681 n.12 (noting that finding review to be available "avoids the 'serious constitutional question' that would arise if [the Court] construed § 1395ii to deny a judicial forum for constitutional claims arising under Part B"). That presumption, however, is not "implicate[d]" where, as here, the Medicare Act itself provides for judicial review of a regulation once it is applied in a concrete, factual context. See *Thunder Basin*, 510 U.S. at 207 n.8, 212-214 ("Because court of appeals review is available, this case does not implicate the strong presumption that Congress did not mean to prohibit all judicial review. *Bowen* v. *Michigan Academy*."); *MCorp*, 502 U.S. at 44 n.16 (similar analysis). See also *McNary* v. *Haitian Refugee Ctr., Inc.*, 498 U.S. 479, 498 (1991) ("Inherent in our [*Michigan Academy*] analysis was the concern that * * * [there] would be 'no review at all of substantial statutory and constitutional challenges to the Secretary's administration of Part B of the Medicare program.'") (quoting *Michigan Academy*, 476 U.S. at 680).

Moreover, *Michigan Academy* relied heavily on the legislative history of the relevant statutory provision, which provided "specific evidence" that Congress intended to foreclose judicial review entirely only with respect to so-called "amount" determinations under Part B. 476 U.S. at 680. But whether or not Congress intended judicial review to be *available* at all for *Part B* benefit "amount" determinations has no bearing on the question here, which is merely the *timing* of judicial review of nursing home regulations under *Part A*. The relevant legislative history in this context, moreover, makes it abundantly clear that, while Congress did not intend to foreclose judicial review of claims like respondent's entirely, it did intend that such review would occur exclusively through the post-enforcement mechanisms provided in the Medicare Act itself. Immediately after describing the mechanisms for judicial review provided by the

Medicare Act, the Senate Report states: "It is intended that the remedies provided by these review procedures shall be exclusive." S. Rep. No. 404, *supra*, Pt. 1, at 55.

Finally, the distinction between post-decision "amount" claims on the one hand and pre-enforcement actions on the other has no logical place in the context of enforcement actions under 42 U.S.C. 1395cc(h). The Court's opinion in *Michigan Academy* drew that distinction based on the language of 42 U.S.C. 1395ff (1982), which addressed review of "amount" claims under Part A, but was (at that time) silent about review of such claims under Part B. 476 U.S. at 674-675. Here, the relevant provision of the Medicare Act is not 42 U.S.C. 1395ff, but 42 U.S.C. 1395cc(h), which incorporates 42 U.S.C. 405(b) and (g). Unlike Section 1395ff, Section 1395cc(h) does not mention "amount" claims, and in fact it does not deal with reimbursement requests or such "amount" claims at all. Instead, it addresses challenges to noncompliance determinations. (Reimbursement or "amount" claims relating to nursing facilities would arise instead under 42 U.S.C. 1395*oo*.) It simply makes no sense to incorporate an amount/methodology distinction from *Michigan Academy* into Section 1395cc(h), which deals with neither reimbursement amounts nor the method by which they are calculated.

Thus, neither *Michigan Academy*'s reasoning, nor the statutory language and legislative history it cited, has any bearing on cases like this one, in which barring review under 28 U.S.C. 1331 would not preclude judicial review altogether, but rather would channel it through the specific mechanisms provided by the Medicare Act. It therefore should be unsurprising that every court of appeals to have considered the matter—with the exception of the panel decision below—has concluded that *Michigan Academy* does not permit pre-enforcement judicial review under 28 U.S.C. 1331 where the Medicare Act itself provides for post-enforcement review. See, *e.g.*, *National Kidney Patients Ass'n*, 958 F.2d

at 1133 (because *Michigan Academy* rested "largely on the presumption of reviewability," it does not govern where agency action "will not go unreviewed," but review instead "simply awaits *initial* administrative determination in a concrete setting"); *St. Francis Med. Ctr.* v. *Shalala*, 32 F.3d 805, 812 (3d Cir. 1994) ("Since a provider seeking Part A payments has these avenues of review available under the Medicare Act, the presumption that Congress did not intend to foreclose judicial review, which was central to the decision in *Michigan Academy*, is inapplicable."), cert. denied, 514 U.S. 1016 (1995); *Michigan Ass'n of Homes & Servs. for the Aging, Inc.* v. *Shalala*, 127 F.3d 496, 501 (6th Cir. 1997) (*Michigan Academy* permits review despite 405(h) "when there is no other avenue of judicial review.").

b. Reading *Michigan Academy* as the court of appeals did here—as drawing a program-wide distinction between pre-enforcement suits challenging regulations on the one hand, and suits seeking to challenge "amount" determinations on the other—would also place *Michigan Academy* in irreconcilable conflict with the Court's prior decision in *Ringer*, which held that "§ 405(g), to the exclusion of 28 U.S.C. § 1331, is the sole avenue for judicial review for *all* 'claim[s] arising under' the Medicare Act." *Ringer*, 466 U.S. at 615 (emphasis added). As we have pointed out above (see pp. 24-25, *supra*), one of the named plaintiffs in *Ringer* sought pre-decisional, declaratory relief with respect to a Medicare rule. Moreover, the plaintiff in *Ringer* did not challenge a determination concerning the "amount" of reimbursement (if any) he was due for a particular claim. Instead, he sought to challenge a rule that, if he *had* submitted a claim, might have required denial of that claim. See 466 U.S. at 613. The Court nevertheless held that Section 405(h) precluded the exercise of general federal-question jurisdiction over such a pre-enforcement challenge. The Court reached an identical result in *Salfi*. There, the plaintiffs sought injunctive relief prohibiting the Secretary

from relying on allegedly unconstitutional provisions (App. at 12-13, *Weinberger* v. *Salfi*, 422 U.S. 439 (1975) (No. 74-214)). But the Court held that Section 405(h) precluded federal district courts from entertaining their challenges under 28 U.S.C. 1331, and required that they instead file a claim and seek review through the mechanisms provided by the Social Security Act itself. 422 U.S. at 764.

Consequently, if the court of appeals' construction of *Michigan Academy* were correct—that it limits Section 405(h)'s preclusive effect to "amount" determinations and prevents its application to pre-enforcement regulatory challenges—then *Michigan Academy* would have overruled *Ringer* and *Salfi sub silentio*. That reading, we submit, is implausible given the seminal and far-reaching significance of *Salfi* and *Ringer*, as well as the strong presumption, rooted in considerations of stare decisis, that where this Court intends to overrule precedents it says so expressly. See *Rodriguez de Quijas* v. *Shearson/American Express, Inc.*, 490 U.S. 477, 484 (1989); *Agostini* v. *Felton*, 521 U.S. 203, 237 (1997). For the same reason, the courts of appeals have uniformly refused to conclude that *Michigan Academy* overruled *Ringer* and *Salfi*. Instead, they have concluded that *Michigan Academy* controls over *Ringer* and *Salfi* only where—unlike here—the Medicare statute itself provides no mechanism for judicial review and, as a result, applying 42 U.S.C. 405(h) to bar suit under 28 U.S.C. 1331 would preclude judicial review altogether. *National Kidney Patients Ass'n*, 958 F.2d at 1132; *Farkas*, 24 F.3d at 860; *American Academy of Dermatology*, 118 F.3d at 1500.[19]

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[19] The court of appeals likewise erred in asserting that *McNary* v. *Haitian Refugee Center*, 498 U.S. 479, 497-498 (1991), "reiterated [the] conclusion that § 1395ii [which incorporates Section 405(h)] does not affect regulatory challenges that are detached from any request for reimbursement." Pet. App. 5a. *McNary* was not a Medicare case; it concerned whether Congress intended to foreclose judicial review of certain claims concerning the immigration status of agricultural workers. In addressing

c. For similar reasons, subsequent statutory amendments have eliminated the basis for continuing application of the result in *Michigan Academy* even in the specific context in which it arose: challenges to the methods used to calculate the amount of reimbursement due on claims under Part B of the Medicare program. As the district court explained below, Pet. App. 18a, Congress amended Section 1395ff in 1986 (months after *Michigan Academy* was decided) to provide for administrative and judicial review (under 42 U.S.C. 405(b) and (g)) of carrier determinations concerning "amount" determinations under Part B. Pub. L. No. 99-509, § 9341(a)(1)(B), 100 Stat. 2037. In light of that amendment and its legislative history, the courts of appeals have uniformly agreed that district courts now lack jurisdiction under 28 U.S.C. 1331 to review all benefit-related claims arising under Part B, including the type of "methodology" disputes at issue in *Michigan Academy*. Instead, all such claims, like their counterparts under Part A, must be brought through the review mechanisms provided by the Medicare Act itself. See *National Kidney Patients Ass'n*, 958 F.2d at 1132 ("[T]he special treatment of part B [methodology claims], based on the pre-October 1986 statutory

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that issue, *McNary* cited *Michigan Academy* for the proposition that statutes barring review of a final administrative decision are not sufficient to preclude "collateral" challenges to regulations that *would otherwise be unreviewable*. Thus, far from supporting the court of appeals' view that *Michigan Academy* sanctions immediate review of pre-enforcement claims without regard to whether review would be available after exhaustion of administrative remedies, *McNary* stressed the difference between *postponement* of judicial review and *foreclosure*, and noted that the distinction is central to *Michigan Academy*'s holding. "Inherent in our [*Michigan Academy*] analysis," the *McNary* Court explained, "was the concern that absent such a construction of the judicial review provisions of the Medicare statute, there would be 'no review at all of substantial statutory and constitutional challenges to the Secretary's administration of Part B of the Medicare program.'" 498 U.S. at 498 (quoting *Michigan Academy*, 476 U.S. at 680).

differences, cannot survive the elimination of those differences."); *American Academy of Dermatology*, 118 F.3d at 1500 ("[T]he amount/methodology distinction established in *Michigan Academy* is no longer viable."); *Martin* v. *Shalala*, 63 F.3d 497, 503 (7th Cir. 1995) ("[T]he *Michigan Academy* distinctions drawn between 'amount of payment' and 'validity of the statute and regulations' challenges are no longer meaningful or necessary."); *Farkas*, 24 F.3d at 860 (amount/methodology distinction no longer "good law"); *Abbey* v. *Sullivan*, 978 F.2d 37, 42 (2d Cir. 1992) (*Michigan Academy*'s distinction "relegat[ed] to irrelevancy").

2. Although conceding the lack of "practical support" for the result it reached, Pet. App. 5a, the court of appeals nonetheless read Part III of the Court's opinion in *Michigan Academy*—the only portion addressed to 42 U.S.C. 1395ii, which incorporates 42 U.S.C. 405(h) into the Medicare program—as providing a broadly applicable limit on the preclusive scope of Section 405(h). In particular, the court of appeals interpreted Part III as holding that Section 405(h), as incorporated into Medicare, precludes review of "only 'amount determinations.'" Pet. App. 6a. That reasoning is flawed from premise to conclusion.

As an initial matter, the construction of Sections 1395ii and 405(h) the court of appeals purported to draw from *Michigan Academy* is not supported by that decision. This Court did not hold that Section 405(h) has no effect on any claim other than one involving the amount of reimbursement. Rather, again relying on the presumption that Congress intends agency action to be reviewable, 476 U.S. at 680, 681, the Court simply rejected the "extreme position" that Congress, by incorporating 42 U.S.C. 405(h) into the Medicare Act, "intended no review at all of substantial statutory and constitutional challenges to the Secretary's administration of Part B of the Medicare program." 476 U.S. at 680. Nowhere did the Court reject the distinctly more moderate position that, in those circumstances where the

Medicare Act does provide mechanisms for judicial review, Section 405(h) channels all challenges to the Secretary's actions through those mechanisms.

In fact, far from offering a broadly applicable construction of Section 405(h), the Court in *Michigan Academy* expressly declined to "pass on the meaning of § 405(h) in the abstract," instead choosing to decide only that Section 405(h) "d[id] not apply" to preclude review of the particular claims at issue there. And to the extent the Court did identify generally applicable constructions of Section 405(h), both of the constructions it identified would bar the pre-enforcement action respondent seeks to bring here. The broader of the two interpretations (which represented the government's position in that case) was that Section 405(h) "by its terms prevents any resort to the grant of general federal-question jurisdiction contained in 28 U.S.C. 1331." 476 U.S. at 679. That construction would surely bar respondent's claim, which rests explicitly on 28 U.S.C. 1331. The narrower view identified by the Court was that Congress enacted Section 405(h) "to make clear that whatever specific procedures it provided for judicial review of final action by the Secretary were exclusive, and could not be circumvented by resort to the general jurisdiction of the federal courts." 476 U.S. at 679. That position too—although previously rejected by this Court in *Salfi* as excessively narrow[20]—would bar respondent's suit here, since the issues respondent seeks to raise on behalf of its members all may be raised after enforcement action is taken against a member, under the "specific procedures * * * for judicial review" provided by the Medicare Act.

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[20] "Nor can it be argued that the third sentence of § 405(h) simply serves to prevent a bypass of the § 405(g) requirements by filing a district court complaint alleging entitlement prior to applying for benefits through administrative channels." *Salfi*, 422 U.S. at 759 n.6.

3. Nor does the court of appeals' decision find support in the text of 42 U.S.C. 405(h). The court of appeals found it significant that the third sentence of 42 U.S.C. 405(h) bars the exercise of general federal-question jurisdiction over suits "to recover" on a claim arising under the Medicare Act, apparently reading "to recover" as meaning to obtain a monetary recovery. See Pet. App. 6a. That reasoning, however, does not take respondent's suit outside of Section 405(h).

a. To begin with, the court of appeals' reading of the phrase "to recover" is unnecessarily starchy. "Section 405(h) does not apply on its own terms" to challenges to the Secretary's enforcement of health, safety and quality-of-care requirements, "but instead is incorporated *mutatis mutandis*"—that is, with necessary changes in details and meaning, *Black's Law Dictionary* 1019 (6th ed. 1990)—"by § 1395ii." *Michigan Academy*, 476 U.S. at 680. In legal contexts, moreover, the phrase "to recover" does not refer only to the recovery of a monetary award. Instead, it means "to prevail" or "to obtain relief." See *Black's Law Dictionary* 1275-1276 (6th ed. 1990) ("In a narrower sense, to be successful in a suit, * * * to have judgment, to obtain a favorable or final judgment."); *Webster's Third New International Dictionary* 1898 (1981) ("to gain by legal process; to obtain a final judgment in one's favor: to succeed in a lawsuit or proceeding"); *Random House Dictionary of the English Language* 1613 (2d ed. 1987) ("to obtain by judgment in a court of law or by legal proceedings").

That Congress used the words "to recover" in that broader sense in Section 405(h)—and did not by that phrase intend to limit Section 405(h)'s application to "amount" determinations—is evident from the fact that Congress incorporated Section 405(h) into numerous parts of the Medicare program where "amount" determinations, as such, do not arise. For example, Congress expressly incorporated Section 405(h) into 42 U.S.C. 1320a-7 and 1320c-5, which address

the circumstances under which Medicare providers can or must be excluded from the program. See 42 U.S.C. 1320a-7(f)(3). Since neither of those provisions deals with "amount" determinations—instead, like 42 U.S.C. 1395cc(h) here, they deal with eligibility to participate in Medicare—it would be illogical to construe Section 405(h) as "affect[ing]" only "amount determinations" of claims for reimbursement. Congress cannot be presumed to have specifically incorporated Section 405(h) in that setting with the understanding that so doing would have no effect at all.[21]

Construing Section 405(h) as "affect[ing] only 'amount determinations,'" Pet. App. 6a, moreover, would make the second sentence in Section 405(h) mere surplusage. An amount determination is by its very nature a reimbursement decision by the Secretary. Judicial review of such amount determinations through means other than those provided by the Medicare Act itself, however, is already precluded by the *second* sentence of Section 405(h), which states that "[n]o * * * decision of the [Secretary] shall be reviewed by any person, tribunal, or governmental agency except as herein provided." The court of appeals' construction thus makes the third sentence of Section 405(h) superfluous in light of the second sentence.

The court of appeals' ruling ignores the text and purpose of the second sentence of Section 405(h) in another respect as well. Whatever the words "to recover" might mean in the

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[21] That Congress specifically meant Section 405(h) to apply to suits, like respondent's, that seek to avoid sanctions is also made clear by its incorporation into 42 U.S.C. 1320a-7a and 1320a-8, which authorize the Secretary to impose civil money penalties and other sanctions for misconduct. See 42 U.S.C. 1320a-7(f)(3) ("The provisions of section 405(h) * * * shall apply with respect to sections 1320a-7a [and] 1320a-8."). Under the court of appeals' theory, Section 405(h) in that context would not bar an anticipatory suit seeking to prevent the Secretary from collecting a civil penalty, since such a suit would not be an "amount" claim seeking reimbursement from the Secretary, but rather a pre-enforcement suit.

third sentence of Section 405(h), those words do not appear in the second sentence, which bars "any person, tribunal or governmental agency" from reviewing *any* "decision" of the Secretary, except as provided in the Medicare Act.[22]

b. In any event, respondent's suit is a suit "to recover" under Medicare even if some nexus to monetary recovery were necessary to trigger Section 405(h). By this suit, respondent seeks to preclude enforcement of the requirements that govern its members' participation in Medicare, and thus their eligibility for payment. See 42 U.S.C. 1395i-3(a) to (d); 42 C.F.R. 483.1-483.75; pp. 2, 12, *supra*. Respondent even prays for an injunction prohibiting the Secretary from imposing "upon [respondent's] Medicare members any ban on payment as a remedy for any deficiency." J.A. 52 (¶¶G, H). As the district court aptly observed (Pet. App. 17a):

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[22] The Secretary's regulations and guidelines are not themselves "decisions" of the Secretary within the meaning of the second sentence of 42 U.S.C. 405(h). See *Michigan Academy*, 476 U.S. at 679 n.8. But respondent cannot avoid the force of Section 405(h)'s second sentence by arguing that it is not challenging a "decision" of the Secretary here. If that argument were accepted, any plaintiff could bypass the Medicare Act's exhaustion requirements at will by filing a declaratory judgment action in federal court at a time when its claims are least ripe for review—when enforcement may not even be contemplated and the Secretary therefore has not yet issued any "decision." For the same reason, this Court rejected that argument in *Ringer*, 466 U.S. at 621. There, the lead plaintiff contended that Section 405(h) did not preclude his lawsuit because his request had neither "blossomed into a 'claim' cognizable under § 405(g)," nor resulted in a decision by the Secretary. The Court held that to allow plaintiffs "to bypass the exhaustion requirements of the Medicare Act by simply bringing declaratory judgment actions in federal court" in any instance where the Secretary has not yet issued an individualized decision would "undercut Congress' carefully crafted scheme for administering the Medicare Act." See 466 U.S. at 621. Accordingly, it held that Ringer's claim was barred even though the regulation he sought to challenge had not yet resulted in a "decision" by the Secretary on a claim for benefits.

> [A]t the heart of [respondent's] case, is a claim for benefits. This is evidenced by the relief sought by [respondent]. [Respondent] seeks continuation of Medicare payments and reimbursement for past due payments incurred by the patients at the nursing homes. Thus, the issue here is whether or not the nursing homes are entitled to benefits.

For that reason, respondent's claim is essentially indistinguishable from the lead plaintiff's claim in *Ringer* and *Salfi*. Just as Freeman Ringer sought to bring a pre-enforcement challenge to the Secretary's rule barring payment for the treatment he wanted, *Ringer*, 466 U.S. at 614-615, respondent here brought a pre-enforcement challenge to regulations that could deny payments to its members if noncompliance is found. See p. 41, *supra*. And just as *Salfi* sought (as an alternative to monetary relief) a declaratory judgment that the statutory provisions were unconstitutional and injunctive relief prohibiting the Secretary from applying those provisions to deny him payment in administrative proceedings (App. at 12-13, *Weinberger* v. *Salfi*, *supra*), respondent makes an identical request with respect to the regulations at issue here. Since Ringer's and Salfi's anticipatory lawsuits challenging payment-barring statutes and regulations under 28 U.S.C. 1331 were precluded by Section 405(h) as suits "to recover on a claim arising under" the Act, respondent's action must be barred by Section 405(h) as well.[23]

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[23] To the extent there are differences between *Ringer* and this case, *Ringer* provided the more compelling case for bypass of administrative remedies. The lead plaintiff in *Ringer* wished to undergo surgery that, under the Secretary's guidelines, was not covered by Medicare. Because Ringer allegedly could not afford to pay for the surgery himself and (he contended) no surgeon would perform the surgery in light of the noncoverage guideline, Ringer contended that he could not have the surgery, submit a claim, and challenge the Secretary's resulting decision through the Medicare Act's judicial review procedures; instead, to have the surgery, he needed an anticipatory ruling. See 466 U.S. at 629 (Stevens,

Even as an original matter, moreover, the court of appeals' theory would place an implausible gloss on the statutory scheme as a whole. It ignores the fact that Congress deliberately paired Section 405(g) with Section 405(h), with the obvious purpose of excluding through the latter, at a minimum, all issues that could be raised under the former. And it turns the normal priorities for access to judicial review on their head. Under the court of appeals' approach, the party with the least need for immediate access to judicial review—the party bringing an abstract, facial challenge to regulations that may not be applied to it—has immediate access to the courts, while the party with a greater need, *i.e.*, a party to whom the regulations have actually been applied and that is facing imminent enforcement proceedings and remedies, cannot bring suit until it exhausts administrative remedies. It is singularly unlikely that Congress intended to allocate access to the courts in that manner.

C. RESPONDENT'S CLAIMS CONCERNING THE ADEQUACY OF THE MEDICARE ACT'S REVIEW MECHANISMS ARE WITHOUT MERIT

In its brief in opposition, respondent attempted to defend the judgment of the court of appeals on different grounds. In particular, respondent argued that the issues it sought to raise in district court do not fall within Section 405(h)'s preclusive scope because they would not be addressed in a hearing under 42 U.S.C. 405(b); given that no such hearing is available, respondent argued, providing judicial review only after exhaustion of administrative remedies "is the practical equivalent of total denial of judicial review." See Br. in Opp. 13; see also *id.* at 9-10. The court of appeals did not address those arguments, and they are, in any event, without merit.

1. Respondent is, as an initial matter, incorrect in asserting that its members can obtain no relief at all with re-

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J., dissenting). Respondent's institutional members could not make any such assertion of personal hardship.

spect to any of its claims. For example, respondent contends that the State Operations Manual, which is used by survey agencies when reviewing nursing facilities for compliance, is invalid because it was "promulgated without the required notice and comment procedures required by the Administrative Procedures Act for substantive regulations." J.A. 18, 27-28, 46 (¶¶ 3A, 32-36, 94A-94B); see Br. in Opp. 2. Any nursing facility that is subjected to a remedy for a violation because of the Manual, however, can challenge the finding of a violation in administrative proceedings. Because ALJs and the Departmental Appeals Board are not bound by the Manual, see *Shalala* v. *Guernsey Mem'l Hosp.*, 514 U.S. 87, 99 (1995),[24] such a nursing home could obtain complete relief. Moreover, a claim of a violation of the APA's notice-and-comment requirements can in any event be addressed on judicial review, after exhaustion, under 42 U.S.C. 405(g). See *Ringer*, 466 U.S. at 614-616 (claim that regulations and instructions to intermediaries violate APA notice-and-comment requirements reviewable under Section 405(g) after exhaustion of administrative remedies).[25]

To be sure, some of the other issues respondent seeks to raise, such as its constitutional contentions and its challenges to the Secretary's regulations, ordinarily would not be the

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[24] See, *e.g.*, *Furlong* v. *Shalala*, 156 F.3d 384, 388-389, 394 (2d Cir. 1998) (noting that ALJs had, in over 100 cases, declined to apply a particular manual provision); see also *Ringer*, 466 U.S. at 607-608 (even though HCFA had concluded that a particular surgical procedure was not "reasonable and necessary" within the meaning of the Medicare Act and had issued instructions to fiscal intermediaries not to approve claims for that procedure, ALJs "were consistently ruling in favor of individual * * * claimants" with respect to that procedure; only later did HCFA issue a formal ruling that bound ALJs).

[25] Of course, interpretive rules, general statements of policy, and rules of agency organization, procedure, or practice in the Manual are exempt from APA notice-and-comment requirements. 5 U.S.C. 553(b)(A); *Guernsey Mem'l Hosp.*, 514 U.S. at 99.

subject of an administrative hearing. Neither the Departmental Appeals Board nor individual ALJs are free to depart from statutory and regulatory requirements. But that does not mean that Section 405(h) ceases to apply. To the contrary, Section 405(h) requires all claims "arising under" the Medicare Act to be brought through the mechanisms provided by the Medicare Act itself; nowhere does it exclude individual issues that would not be addressed in the administrative process. That, in fact, is precisely the holding of *Salfi*, 422 U.S. at 760-762. There, the plaintiffs sought to challenge the constitutionality of a provision of the Social Security Act, a challenge that could not be resolved in the administrative process. This Court held that the language of Section 405(h), "which is sweeping and direct," does not limit its preclusive effect "to decisions of the Secretary on issues of law or fact. Rather, it extends to any 'action' seeking 'to recover on any * * * claim'—irrespective of whether resort to judicial processes is necessitated by discretionary decisions of the Secretary or by * * * nondiscretionary application of allegedly unconstitutional statutory restrictions." *Id.* at 757, 762. As the Court summarized: "[T]he plain words of the third sentence of § 405(h) do not preclude constitutional challenges. They simply require that [the challenges] be brought under jurisdictional grants contained in the Act, and thus in conformity with the same standards which are applicable to nonconstitutional claims arising under the Act." *Id.* at 762.

This Court likewise has applied Section 405(h) to preclude federal courts from exercising federal-question jurisdiction over procedural and due process claims like respondent's. In *Ringer*, for example, the Court "disagree[d] in particular with [the court of appeals'] apparent conclusion that simply because a claim somehow can be construed as 'procedural,' it is cognizable in federal district court by way of federal-question jurisdiction." 466 U.S. at 614. Instead, "the inquiry in determining whether § 405(h) bars federal-question jurisdic-

tion must be whether the claim 'arises under' the Act, not whether it lends itself to a 'substantive' rather than a 'procedural' label." *Id.* at 615.

Finally, in *Mathews* v. *Eldridge*, 424 U.S. 319 (1976), the plaintiff alleged that the procedures the Secretary employed under the Act violated procedural due process. Even though the plaintiff's claims were "collateral" to the merits—they challenged the process provided, not the substantive result—and the plaintiff made a colorable claim that the post-deprivation review provided through administrative remedies would be inadequate, this Court held that "[t]he only avenue for judicial review" of such claims "is 42 U.S.C. 405(g)." *Id.* at 327. Section 405(g), the Court explained, permits adequate review of even completely collateral claims so long as the "final decision" requirement is properly applied.[26]

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[26] The Court held that the "final decision" requirement of Section 405(g)—like the "final decision" requirement of 28 U.S.C. 1291—is sufficiently flexible to permit expedited review of collateral claims in limited, appropriate circumstances. According to the Court, an otherwise interim decision by the Secretary may be considered "final" within the meaning of Section 405(g) and thus immediately reviewable, even where the plaintiff has not fully pursued all administrative remedies, if: (1) a claim for benefits has been properly presented to the Secretary, 424 U.S. at 328-329, (2) the challenge on which review is sought is "entirely collateral to" the merits of the plaintiff's substantive claim, 424 U.S. at 330, and (3) full relief with respect to that challenge could not be afforded after exhaustion of administrative remedies. *Mathews*, 424 U.S. at 331-332. See also *Bowen* v. *City of New York*, 476 U.S. 467, 483-486 (1986) (excusing failure to exhaust in "unique" circumstances involving secret agency policy).

In *Mathews* itself, the Court held that the plaintiff could seek immediate judicial review under 42 U.S.C. 405(g) to assert a constitutional right to a pre-deprivation hearing, once he had presented his claim to the Secretary and the Secretary had made an initial determination to terminate his benefits without that full hearing, because the plaintiff could not obtain relief on his claim that he had a right to a *pre*-deprivation hearing in an action for judicial review *after* the deprivation had taken effect. 424 U.S. at 331-333. That holding, however, does not assist respondent. First, respondent does not assert that jurisdiction is proper

2. The text and structure of the Medicare Act confirm the correctness of that result. As the Court recognized in *Ringer* and *Salfi*, nothing in Section 405(h) limits its application to issues that might be addressed by an ALJ in the administrative process; its sweeping language instead extends to "all 'claim[s] arising under' the Medicare Act." *Ringer*, 466 U.S. at 615. Nor can such a limit be inferred from the scope of review provided by Section 405(g). Whereas the hearing provided by Section 405(b) might have a limited scope, the review provided by Section 405(g) is not limited to those issues cognizable before an ALJ. For example, far from restricting the reviewing court to an examination of whether "the findings * * * as to any fact" are "supported by substantial evidence," 42 U.S.C. 405(g), Section 405(g) expressly permits the reviewing court to address "the validity of [the] regulations" themselves, *ibid.*—an issue an ALJ could not address.

Other provisions of the Medicare Act, moreover, confirm that Congress intended to channel all claims through the administrative process as a prerequisite to judicial review under Section 405(g) and parallel Medicare provisions, even where individual legal issues bearing on those claims—

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under Section 405(g); it relies on the general federal-question statute, 28 U.S.C. 1331, instead. J.A. 22 (¶ 14); Pet. App. 13a, 15a. Second, the collateral order rule described in *Mathews* excuses the plaintiff from fully pursuing available administrative remedies, but it does not excuse the other jurisdictional prerequisites for review under Sections 405(g) and 1395cc(h), such as the requirement that the plaintiff actually present its claim to the Secretary, see *Salfi*, 422 U.S. at 764; *Ringer*, 466 U.S. at 617-618; *Mathews*, 424 U.S. at 328, and that it be "dissatisfied with a determination" of the Secretary, 42 U.S.C. 405(g), 1395cc(h)(2). Here, the district court expressly found that respondent "has not alleged or shown any attempt at presentment of [its] claims to the Secretary," *id.* at 19a, and respondent has never challenged that finding. That failure is fatal to jurisdiction under 42 U.S.C. 405(g), since the requirements of presentation and dissatisfaction with a determination are not waivable. See *Ringer*, 466 U.S. at 617.

including challenges to the Act or regulations—would not be addressed in the administrative process. For example, 42 U.S.C. 1395*oo*(f)(1) permits the Provider Reimbursement Review Board (PRRB) to facilitate judicial review on an expedited basis by certifying "that it is without authority to decide" a "question of law or regulations relevant to the matters in controversy." Once such a certification is made in a case otherwise properly before the PRRB, 42 U.S.C. 1395*oo*(a), an action for judicial review on that question may be filed immediately; it need not await the PRRB's resolution of issues that *are* within its competence to decide, as would otherwise be required by *Salfi* and *Ringer*. See 42 U.S.C. 1395*oo*(f)(1); *Bethesda Hosp. Ass'n* v. *Bowen*, 485 U.S. 399, 406-407 (1988). If matters outside the PRRB's competence to decide were not required to be channeled into the special statutory procedure for administrative and judicial review together with issues that are—and such issues instead could be presented outside that procedure in district court under 28 U.S.C. 1331—the expedited review provision in 42 U.SC. 1395*oo*(f)(1) would be entirely unnecessary. It is, of course, inappropriate to construe a statute so as to make any of its provisions superfluous. *Moskal* v. *United States*, 498 U.S. 103, 109-110 (1990). Similarly, in the case of individuals who seek administrative and judicial review of individual benefit claims under 42 U.S.C. 1395ff(b) (which incorporates 42 U.S.C. 405(g)), the Act specifically contemplates that judicial review of national coverage determinations of general applicability will be available under 42 U.S.C. 405(g), even though such determinations cannot be reviewed by an ALJ. See 42 U.S.C. 1395ff(b)(3).[27]

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[27] See also 42 U.S.C. 1395ff(b)(4) (barring judicial review of a regulation or instruction relating to a method of determining the amount of payments under Part B if the regulation or instruction was issued prior to January 1, 1981). Judicial review similarly would be available with respect to the Secretary's choice of remedies to be imposed on a particular facility,

3. Because even issues that would not be addressed in a hearing can be reviewed by a court under 42 U.S.C. 405(g) after exhaustion, respondent's reliance on *Thunder Basin*, 510 U.S. at 207, is misplaced. Quoting *Thunder Basin*, respondent notes that whether "a statute is intended to preclude initial judicial review" depends in part on "whether the claims can be afforded meaningful review" through the mechanisms provided by statute. Br. in Opp. 13. Respondent then contends that the issues it seeks to raise "cannot be meaningfully addressed or reviewed in the administrative process." Br. in Opp. 13. But the question is not whether its contentions will be "meaningfully addressed * * * *in the administrative process*." It is whether they will be meaningfully addressed through the statutory mechanism for administrative *and* judicial review as a whole, with an emphasis on the latter. See 510 U.S. at 212-213 (inquiry particularly important "where a finding of preclusion could foreclose all meaningful *judicial* review") (emphasis added). In fact, in *Thunder Basin* itself, this Court held that the statutory review mechanism was meaningful, adequate, *and* exclusive "[e]ven if" the administrative agency would not or

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and the characterization of seriousness of violations to the extent it influenced the choice of remedies, even though those issues are, by regulation, outside the scope of ALJ and Departmental Appeals Board review. (The ALJ, of course is *not* precluded from addressing whether and how many violations occurred.) See 42 C.F.R. 498.3(d)(10)-(11) (excluding the choice of remedy and disputes concerning the agency's characterization of the scope and severity of the violations from the administrative review process, except where the range of civil money penalties would be affected). The standard of review applied to such remedy-related claims, however, is extraordinarily deferential. See *Butz* v. *Glover Livestock Comm'n Co.*, 411 U.S. 182, 185-186 (1973) ("[W]here Congress has entrusted an administrative agency with the responsibility of selecting the means of achieving the statutory policy 'the relation of remedy to policy is peculiarly a matter for administrative competence,'" and the agency's choice of remedies may not be overturned unless "unwarranted in law or * * * without justification in fact.").

could not adjudicate the statutory and constitutional claims at issue there, because those issues ultimately would "be meaningfully addressed" on judicial review. *Id.* at 215. The same is true of the issues respondent seeks to raise here.

4. At bottom, respondent's suit for anticipatory relief is nothing more than an effort to bypass the reticulated mechanisms for administrative and judicial review provided by the Medicare Act itself. Seeking to avoid the necessity of bringing challenges in the context of specific violations, and attempting to evade the requirements that individual claims be presented to the Secretary and administrative remedies be exhausted, respondent filed the current facial challenge to the Secretary's regulations in an effort to obtain far-reaching and intrusive relief. But it was precisely such circumvention of the statutory processes (and the resulting potential for unnecessary and damaging intrusion into the administration of programs affecting millions of people) that this Court rejected in *Salfi*, in *Mathews*, and in *Ringer*, and that Sections 405(g) and 405(h) were designed to prevent. Those provisions simply do not permit a nursing facility to split off one legal issue bearing on the merits of a challenge to a compliance determination and present that issue in an independent action for declaratory or injunctive relief under 28 U.S.C. 1331. Of course, "[i]n the best of all worlds, immediate judicial access * * * might be desirable" for particular challenges in particular cases. *Ringer*, 466 U.S. at 627. But this is not such a case and, even if it were, "Congress, in § 405(g) and § 405(h), struck a different balance, refusing declaratory relief and requiring that administrative remedies be exhausted before judicial review of the Secretary's decisions takes place." *Ibid.* Because the court of appeals' judgment fails to respect that statutory balance, it should be reversed.

CONCLUSION

The judgment of the court of appeals should be reversed.

Respectfully submitted.

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JULY 1999

APPENDIX A

STATUTORY PROVISIONS

1. Section 405(g) of Title 42, United States Code, provides:

(g) Judicial review

Any individual, after any final decision of the Commissioner of Social Security made after a hearing to which he was a party, irrespective of the amount in controversy, may obtain a review of such decision by a civil action commenced within sixty days after the mailing to him of notice of such decision or within such further time as the Commissioner of Social Security may allow. Such action shall be brought in the district court of the United States for the judicial district in which the plaintiff resides, or has his principal place of business, or, if he does not reside or have his principal place of business within any such judicial district, in the United States District Court for the District of Columbia. As part of the Commissioner's answer the Commissioner of Social Security shall file a certified copy of the transcript of the record including the evidence upon which the findings and decision complained of are based. The court shall have power to enter, upon the pleadings and transcript of the record, a judgment affirming, modifying, or reversing the decision of the Commissioner of Social Security, with or without remanding the cause for a rehearing. The findings of the Commissioner of Social Security as to any fact, if supported by substantial evidence, shall be conclusive, and where a claim has been denied by the Commissioner of Social Security or a decision is rendered under subsection (b) of this section which is adverse to an individual who was a party to the hearing before the Commissioner of Social Security, because of failure of the claimant or such individual

to submit proof in conformity with any regulation prescribed under subsection (a) of this section, the court shall review only the question of conformity with such regulations and the validity of such regulations. The court may, on motion of the Commissioner of Social Security made for good cause shown before the Commissioner files the Commissioner's answer, remand the case to the Commissioner of Social Security for further action by the Commissioner of Social Security, and it may at any time order additional evidence to be taken before the Commissioner of Social Security, but only upon a showing that there is new evidence which is material and that there is good cause for the failure to incorporate such evidence into the record in a prior proceeding; and the Commissioner of Social Security shall, after the case is remanded, and after hearing such additional evidence if so ordered, modify or affirm the Commissioner's findings of fact or the Commissioner's decision, or both, and shall file with the court any such additional and modified findings of fact and decision, and a transcript of the additional record and testimony upon which the Commissioner's action in modifying or affirming was based. Such additional or modified findings of fact and decision shall be reviewable only to the extent provided for review of the original findings of fact and decision. The judgment of the court shall be final except that it shall be subject to review in the same manner as a judgment in other civil actions. Any action instituted in accordance with this subsection shall survive notwithstanding any change in the person occupying the office of Commissioner of Social Security or any vacancy in such office.

2. Section 405(h) of Title 42, United States Code, provides:

(h) Finality of Commissioner's decision

The findings and decision of the Commissioner of Social Security after a hearing shall be binding upon all individuals who were parties to such hearing. No findings of fact or decision of the Commissioner of Social Security shall be reviewed by any person, tribunal, or governmental agency except as herein provided. No action against the United States, the Commissioner of Social Security, or any officer or employee thereof shall be brought under section 1331 or 1346 of title 28 to recover on any claim arising under this subchapter.

3. Section 1320a-7 of Title 42, United States Code, provides in relevant part:

§ 1320a-7. Exclusion of certain individuals and entities from participation in Medicare and State health care programs

(a) Mandatory exclusion

The Secretary shall exclude the following individuals and entities from participation in any program under subchapter XVIII of this chapter and shall direct that the following individuals and entities be excluded from participation in any State health care program (as defined in subsection (h) of this section):

(1) Conviction of program-related crimes

* * * * *

(2) Conviction relating to patient abuse

* * * * *

(b) Permissive exclusion

The Secretary may exclude the following individuals and entities from participation in any program under subchapter XVIII of this chapter and may direct that the following individuals and entities be excluded from participation in any State health care program:

(1) Conviction relating to fraud

* * * * *

(2) Conviction relating to obstruction of an investigation

* * * * *

(3) Conviction relating to controlled substance

* * * * *

(f) Notice, hearing, and judicial review

(1) Subject to paragraph (2), any individual or entity that is excluded (or directed to be excluded) from participation under this section is entitled to reasonable notice and opportunity for a hearing thereon by the Secretary to the same extent as is provided in section 405(b) of this title, and to judicial review of the Secretary's final decision after such hearing as is provided in section 405(g) of this title, except that, in so applying such sections and section 405(*l*) of this title, any reference therein to the Commissioner of Social Security or the Social Security Administration shall be considered a reference to the Secretary or the Department of Health and Human Services, respectively.

(2) Unless the Secretary determines that the health or safety of individuals receiving services warrants the exclusion taking effect earlier, any individual or entity that is the subject of an adverse determination under subsection (b)(7) of this section shall be entitled to a hearing by an administrative law judge (as provided under section 405(b) of this title) on the determination under subsection (b)(7) of this section before any exclusion based upon the determination takes effect.

(3) The provisions of section 405(h) of this title shall apply with respect to this section and sections 1320a-7a, 1320a-8, and 1320c-5 of this title to the same extent as it is applicable with respect to subchapter II of this chapter, except that, in so applying such section and section 405(*l*) of this title, any reference therein to the Commissioner of Social Security shall be considered a reference to the Secretary.

4. Section 1320a-7a of Title 42, United States Code, provides in relevant part:

§ 1320a-7a. Civil monetary penalties

* * * * *

(c) Initiation of proceeding; authorization by Attorney General, notice, etc., estoppel, failure to comply with order or procedure

* * * * *

(2) The Secretary shall not make a determination adverse to any person under subsection (a) or (b) of this section until the person has been given written notice and an opportunity for the determination to be made on the record after a hearing at which the person is entitled to be represented by counsel, to present witnesses, and to cross-examine witnesses against the person.

* * * * *

(e) Review by courts of appeals

Any person adversely affected by a determination of the Secretary under this section may obtain a review of such determination in the United States Court of Appeals for the circuit in which the person resides, or in which the claim was presented, by filing in such court (within sixty days following the date the person is notified of the Secretary's determination) a written petition requesting that the determination be modified or set aside. A copy of the petition shall be forthwith transmitted by the clerk of the court to the Secretary, and thereupon the Secretary shall file in the Court[1] the record in the proceeding as provided in section 2112 of title 28. Upon such filing, the court shall have

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[1] So in original. Probably should not be capitalized.

jurisdiction of the proceeding and of the question determined therein, and shall have the power to make and enter upon the pleadings, testimony, and proceedings set forth in such record a decree affirming, modifying, remanding for further consideration, or setting aside, in whole or in part, the determination of the Secretary and enforcing the same to the extent that such order is affirmed or modified. No objection that has not been urged before the Secretary shall be considered by the court, unless the failure or neglect to urge such objection shall be excused because of extraordinary circumstances. The findings of the Secretary with respect to questions of fact, if supported by substantial evidence on the record considered as a whole, shall be conclusive. If any party shall apply to the court for leave to adduce additional evidence and shall show to the satisfaction of the court that such additional evidence is material and that there were reasonable grounds for the failure to adduce such evidence in the hearing before the Secretary, the court may order such additional evidence to be taken before the Secretary and to be made a part of the record. The Secretary may modify his findings as to the facts, or make new findings, by reason of additional evidence so taken and filed, and he shall file with the court such modified or new findings, which findings with respect to questions of fact, if supported by substantial evidence on the record considered as a whole, shall be conclusive, and his recommendations, if any, for the modification or setting aside of his original order. Upon the filing of the record with it, the jurisdiction of the court shall be exclusive and its judgment and decree shall be final, except that the same shall be subject to review by the Supreme Court of the United States, as provided in section 1254 of title 28.

5. Section 1395i-3(h) of Title 42, United States Code, provides:

(h) Enforcement process

(1) In general

If a State finds, on the basis of a standard, extended, or partial extended survey under subsection (g)(2) of this section or otherwise, that a skilled nursing facility no longer meets a requirement of subsection (b), (c), or (d) of this section, and further finds that the facility's deficiencies—

(A) immediately jeopardize the health or safety of its residents, the State shall recommend to the Secretary that the Secretary take such action as described in paragraph (2)(A)(i); or

(B) do not immediately jeopardize the health or safety of its residents, the State may recommend to the Secretary that the Secretary take such action as described in paragraph (2)(A)(ii).

If a State finds that a skilled nursing facility meets the requirements of subsections (b), (c), and (d) of this section, but, as of a previous period, did not meet such requirements, the State may recommend a civil money penalty under paragraph (2)(B)(ii) for the days in which it finds that the facility was not in compliance with such requirements.

(2) Secretarial authority

(A) In general

With respect to any skilled nursing facility in a State, if the Secretary finds, or pursuant to a recommendation of the State under paragraph (1) finds, that a skilled nursing facility no longer meets a requirement of subsection (b), (c),

(d), or (e) of this section, and further finds that the facility's deficiencies—

(i) immediately jeopardize the health or safety of its residents, the Secretary shall take immediate action to remove the jeopardy and correct the deficiencies through the remedy specified in subparagraph (B)(iii), or terminate the facility's participation under this subchapter and may provide, in addition, for one or more of the other remedies described in subparagraph (B); or

(ii) do not immediately jeopardize the health or safety of its residents, the Secretary may impose any of the remedies described in subparagraph (B).

Nothing in this subparagraph shall be construed as restricting the remedies available to the Secretary to remedy a skilled nursing facility's deficiencies. If the Secretary finds, or pursuant to the recommendation of the State under paragraph (1) finds, that a skilled nursing facility meets such requirements but, as of a previous period, did not meet such requirements, the Secretary may provide for a civil money penalty under subparagraph (B)(ii) for the days on which he finds that the facility was not in compliance with such requirements.

(B) Specified remedies

The Secretary may take the following actions with respect to a finding that a facility has not met an applicable requirement:

(i) Denial of payment

The Secretary may deny any further payments under this subchapter with respect to all individuals entitled to benefits under this subchapter in the facility or with respect to such individuals admitted to the facility after the effective date of the finding.

(ii) Authority with respect to civil money penalties

The Secretary may impose a civil money penalty in an amount not to exceed $10,000 for each day of noncompliance. The provisions of section 1320a-7a of this title (other than subsections (a) and (b)) shall apply to a civil money penalty under the previous sentence in the same manner as such provisions apply to a penalty or proceeding under section 1320a-7a(a) of this title.

(iii) Appointment of temporary management

In consultation with the State, the Secretary may appoint temporary management to oversee the operation of the facility and to assure the health and safety of the facility's residents, where there is a need for temporary management while—

(I) there is an orderly closure of the facility, or

(II) improvements are made in order to bring the facility into compliance with all the requirements of subsections (b), (c), and (d) of this section.

The temporary management under this clause shall not be terminated under subclause (II) until the Secretary has determined that the facility has the management capability to ensure continued compliance with all the requirements of subsections (b), (c), and (d) of this section.

The Secretary shall specify criteria, as to when and how each of such remedies is to be applied, the amounts of any fines, and the severity of each of these remedies, to be used in the imposition of such remedies. Such criteria shall be designed so as to minimize the time between the identification of violations and final imposition of the remedies and shall provide for the imposition of incrementally more severe fines for repeated or uncorrected deficiencies. In addition, the

Secretary may provide for other specified remedies, such as directed plans of correction.

(C) Continuation of payments pending remediation

The Secretary may continue payments, over a period of not longer than 6 months after the effective date of the findings, under this subchapter with respect to a skilled nursing facility not in compliance with a requirement of subsection (b), (c), or (d) of this section, if—

(i) the State survey agency finds that it is more appropriate to take alternative action to assure compliance of the facility with the requirements than to terminate the certification of the facility,

(ii) the State has submitted a plan and timetable for corrective action to the Secretary for approval and the Secretary approves the plan of corrective action, and

(iii) the facility agrees to repay to the Federal Government payments received under this subparagraph if the corrective action is not taken in accordance with the approved plan and timetable.

The Secretary shall establish guidelines for approval of corrective actions requested by States under this subparagraph.

(D) Assuring prompt compliance

If a skilled nursing facility has not complied with any of the requirements of subsections (b), (c), and (d) of this section, within 3 months after the date the facility is found to be out of compliance with such requirements, the Secretary shall impose the remedy described in subparagraph (B)(i) for all individuals who are admitted to the facility after such date.

(E) Repeated noncompliance

In the case of a skilled nursing facility which, on 3 consecutive standard surveys conducted under subsection (g)(2) of this section, has been found to have provided substandard quality of care, the Secretary shall (regardless of what other remedies are provided)—

(i) impose the remedy described in subparagraph (B)(i), and

(ii) monitor the facility under subsection (g)(4)(B) of this section,

until the facility has demonstrated, to the satisfaction of the Secretary, that it is in compliance with the requirements of subsections (b), (c), and (d) of this section, and that it will remain in compliance with such requirements.

(3) Effective period of denial of payment

A finding to deny payment under this subsection shall terminate when the Secretary finds that the facility is in substantial compliance with all the requirements of subsections (b), (c), and (d) of this section.

(4) Immediate termination of participation for facility where Secretary finds noncompliance and immediate jeopardy

If the Secretary finds that a skilled nursing facility has not met a requirement of subsection (b), (c), or (d) of this section, and finds that the failure immediately jeopardizes the health or safety of its residents, the Secretary shall take immediate action to remove the jeopardy and correct the deficiencies through the remedy specified in paragraph (2)(B)(iii), or the Secretary shall terminate the facility's participation under this subchapter. If the facility's participation under this subchapter is terminated, the State shall provide for the safe

and orderly transfer of the residents eligible under this subchapter consistent with the requirements of subsection (c)(2) of this section.

(5) Construction

The remedies provided under this subsection are in addition to those otherwise available under State or Federal law and shall not be construed as limiting such other remedies, including any remedy available to an individual at common law. The remedies described in clauses (i),[2] and (iii) of paragraph (2)(B) may be imposed during the pendency of any hearing.

(6) Sharing of information

Notwithstanding any other provision of law, all information concerning skilled nursing facilities required by this section to be filed with the Secretary or a State agency shall be made available by such facilities to Federal or State employees for purposes consistent with the effective administration of programs established under this subchapter and subchapter XIX of this chapter, including investigations by State medicaid fraud control units.

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[2] So in original. The comma probably should not appear.

6. Section 1395cc of Title 42, United States Code, provides in relevant part:

§ 1395cc. Agreements with providers of services

* * * * *

(b) Termination or nonrenewal of agreements

(1) A provider of services may terminate an agreement with the Secretary under this section at such time and upon such notice to the Secretary and the public as may be provided in regulations, except that notice of more than six months shall not be required.

(2) The Secretary may refuse to enter into an agreement under this section or, upon such reasonable notice to the provider and the public as may be specified in regulations, may refuse to renew or may terminate such an agreement after the Secretary—

(A) has determined that the provider fails to comply substantially with the provisions of the agreement, with the provisions of this subchapter and regulations thereunder, or with a corrective action required under section 1395ww(f)(2)(B) of this title,

(B) has determined that the provider fails substantially to meet the the applicable provisions of section 1395x of this title, or

(C) has excluded the provider from participation in a program under this subchapter pursuant to section 1320a-7 of this title or section 1320a-7a of this title.

(3) A termination of an agreement or a refusal to renew an agreement under this subsection shall become effective on the same date and in the same manner as an

exclusion from participation under the program under this subchapter becomse effective under section 1320a-7(c) of this title.

* * * * *

(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 it is not a provider of services or with a determination described in subsection (b)(2) of this section shall be entitled to a hearing thereon by the Secretary (after reasonable notice) to the same extent as is provided in section 405(b) of this title, and to judicial review of the Secretary's final decision after such hearing as is provided in section 405(g) of this title, except that, in so applying such sections and in applying section 405(*l*) of this title thereto, any reference therein to the Commissioner of Social Security or the Social Security Administration shall be considered a reference to the Secretary or the Department of Health and Human Services, respectively.

(2) An institution or agency is not entitled to separate notice and opportunity for a hearing under both section 1320a-7 of this title and this section with respect to a determination or determinations based on the same underlying facts and issues.

7. Section 1395ii of Title 42, United States Code, provides:

§ 1395ii. Application of certain provisions of subchapter II

The provisions of sections 406 and 416(j) of this title, and of subsections (a), (d), (e), (h), (i), (j), (k), and (*l*) of section 405 of this title, shall also apply with respect to this subchapter to the same extent as they are applicable with respect to subchapter II of this chapter, except that, in applying such provisions with respect to this subchapter, any reference therein to the Commissioner of Social Security or the Social Security Administration shall be considered a reference to the Secretary or the Department of Health and Human Services, respectively.

APPENDIX B

REGULATORY PROVISIONS

1. Section 488.301 of Title 42, Code of Federal Regulations, provides:

§ 488.301 Definitions.

As used in this subpart—

Abbreviated standard survey means a survey other than a standard survey that gathers information primarily through resident-centered techniques on facility compliance with the requirements for participation. An abbreviated standard survey may be premised on complaints received; a change of ownership, management, or director of nursing; or other indicators of specific concern.

Abuse means the willful infliction of injury, unreasonable confinement, intimidation, or punishment with resulting physical harm, pain or mental anguish.

Deficiency means a SNF's or NF's failure to meet a participation requirement specified in the Act or in part 483, subpart B of this chapter.

Dually participating facility means a facility that has a provider agreement in both the Medicare and Medicaid programs.

Extended survey means a survey that evaluates additional participation requirements subsequent to finding substandard quality of care during a standard survey.

Facility means a SNF or NF, or a distinct part SNF or NF, in accordance with § 483.5 of this chapter.

Immediate family means husband or wife; natural or adoptive parent, child or sibling; stepparent, stepchild, step-

brother, or stepsister; father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law; grandparent or grandchild.

Immediate jeopardy means a situation in which the provider's noncompliance with one or more requirements of participation has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident.

Misappropriation of resident property means the deliberate misplacement, exploitation, or wrongful, temporary or permanent use of a resident's belongings or money without the resident's consent.

Neglect means failure to provide goods and services necessary to avoid physical harm, mental anguish, or mental illness.

Noncompliance means any deficiency that causes a facility to not be in substantial compliance.

Nurse aide means an individual, as defined in § 483.75(e)(1) of this chapter.

Nursing facility (NF) means a Medicaid nursing facility.

Partial extended survey means a survey that evaluates additional participation requirements subsequent to finding substandard quality of care during an abbreviated standard survey.

Skilled nursing facility (SNF) means a Medicare nursing facility.

Standard survey means a periodic, resident-centered inspection which gathers information about the quality of

service furnished in a facility to determine compliance with the requirements for participation.

Substandard quality of care means one or more deficiencies related to participation requirements under § 483.13, Resident behavior and facility practices, § 483.15, Quality of life, or § 483.25, Quality of care of this chapter, which constitute either immediate jeopardy to resident health or safety; a pattern of or widespread actual harm that is not immediate jeopardy; or a widespread potential for more than minimal harm, but less than immediate jeopardy, with no actual harm.

Substantial compliance means a level of compliance with the requirements of participation such that any identified deficiencies pose no greater risk to resident health or safety than the potential for causing minimal harm.

Validation survey means a survey conducted by the Secretary within 2 months following a standard survey, abbreviated standard survey, partial extended survey, or extended survey for the purpose of monitoring State survey agency performance.

2. Section 488.330 of Title 42, Code of Federal Regulations, provides:

§ 488.330 Certification of compliance or non-compliance.

(a) *General rules*—(1) *Responsibility for certification.* (i) The State survey agency surveys all facilities for compliance or noncompliance with requirements for long term care facilities. The survey by the State survey agency may be followed by a Federal validation survey.

(A) The State certifies the compliance or noncompliance of non-State operated NFs. Regardless of the State entity doing the certification, it is final, except in the case of a complaint or validation survey conducted by HCFA, or HCFA review of the State's findings.

(B) HCFA certifies the compliance or noncompliance of all State-operated facilities.

(C) The State survey agency certifies the compliance or noncompliance of a non-State operated SNF, subject to the approval of HCFA.

(D) The State survey agency certifies compliance or noncompliance for a dually participating SNF/NF. In the case of a disagreement between HCFA and the State survey agency, a finding of noncompliance takes precedence over that of compliance.

(ii) In the case of a validation survey, the Secretary's determination as to the facility's noncompliance is binding, and takes precedence over a certification of compliance resulting from the State survey.

(2) *Basis for certification.* (i) Certification by the State is based on the survey agency findings.

(ii) Certification by HCFA is based on either the survey agency findings (in the case of State-operated facilities), or, in the case of a validation survey, on HCFA's own survey findings.

(b) *Effect of certification*—(1) *Certification of compliance.* A certification of compliance constitutes a determination that the facility is in substantial compliance and is eligible to participate in Medicaid as a NF, or in Medicare as a SNF, or in Medicare and Medicaid as a dually participating facility.

(2) *Certification of noncompliance.* A certification of noncompliance requires denial of participation for prospective providers and enforcement action for current providers in accordance with subpart F of this part. Enforcement action must include one of the following:

(i) Termination of any Medicare or Medicaid provider agreements that are in effect.

(ii) Application of alternative remedies instead of, or in addition to, termination procedures.

(c) *Notice of certification of noncompliance and resulting action.* The notice of certification of noncompliance is sent in accordance with the timeframes specified in § 488.402(f), and resulting action is issued by HCFA, except when the State is taking the action for a non-State operated NF.

(d) *Content of notice of certification of noncompliance.* The notice of certification of noncompliance is sent in accordance with the timeframes specified in § 488.402(f) and includes information on all of the following:

(1) Nature of noncompliance.

(2) Any alternative remedies to be imposed under subpart F of this part.

(3) Any termination or denial of participation action to be taken under this part.

(4) The appeal rights available to the facility under this part.

(5) Timeframes to be met by the provider and certifying agency with regard to each of the enforcement actions or appeal procedures addressed in the notice.

(e) *Appeals.* (1) Notwithstanding any provision of State law, the State must impose remedies promptly on any provider of services participating in the Medicaid program—

(i) After promptly notifying the facility of the deficiencies and impending remedy or remedies; and

(ii) Except for civil money penalties, during any pending hearing that may be requested by the provider of services.

(2) HCFA imposes remedies promptly on any provider of services participating in the Medicare or Medicaid program or any provider of services participating in both the Medicare and Medicaid programs—

(i) After promptly notifying the facility of the deficiencies and impending remedy or remedies; and

(ii) Except for civil money penalties, during any pending hearing that may be requested by the provider of services.

(3) The provisions of part 498 of this chapter apply when the following providers request a hearing on a denial of participation, or certification of noncompliance leading to an enforcement remedy (including termination of the provider agreement), except State monitoring:

(i) All State-operated facilities;

(ii) SNFs and dually participating SNF/NFs; and

(iii) Any other facilities subject to a HCFA validation survey or HCFA review of the State's findings.

(4) The provisions of part 431 of this chapter apply when a non-State operated Medicaid NF, which has not received a HCFA validation survey or HCFA review of the State's findings, requests a hearing on the State's denial of participation, termination of provider agreement, or certification of noncompliance leading to an alternative remedy, except State monitoring.

(f) *Provider agreements.* HCFA or the Medicaid agency may execute a provider agreement when a prospective provider is in substantial compliance with all the requirements for participation for a SNF or NF, respectively.

(g) *Special rules for Federal validation surveys.* (1) HCFA may make independent certifications of a NF's, SNF's, or dually participating facility's noncompliance based on a HCFA validation survey.

(2) HCFA issues the notice of actions affecting facilities for which HCFA did validation surveys.

(3) For non-State-operated NFs and non-State-operated dually participating facilities, any disagreement between HCFA and the State regarding the timing and choice of remedies is resolved in accordance with § 488.452.

(4) Either HCFA or the survey agency, at HCFA's option, may revisit the facility to ensure that corrections are made.

3. Section 488.331 of Title 42, Code of Federal Regulations, provides:

§ 488.331 Informal dispute resolution.

(a) *Opportunity to refute survey findings.* (1) For non-Federal surveys, the State must 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.

(2) For Federal surveys, HCFA offers 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.

(b)(1) Failure of the State or HCFA, as appropriate, to complete informal dispute resolution timely cannot delay the effective date of any enforcement action against the facility.

(2) A facility may not seek a delay of any enforcement action against it on the grounds that informal dispute resolution has not been completed before the effective date of the enforcement action.

(c) If a provider is subsequently successful, during the informal dispute resolution process, at demonstrating that deficiencies should not have been cited, the deficiencies are removed from the statement of deficiencies and any enforcement actions imposed solely as a result of those cited deficiencies are rescinded.

(d) *Notification.* Upon request, HCFA does and the State must provide the facility with written notification of the informal dispute resolution process.

4. Subpart F (Sections 488.400-488.456) of Title 42, Code of Federal Regulations, provides:

Subpart F—Enforcement of Compliance for Long-Term Care Facilities with Deficiencies

SOURCE: 59 FR 56243, Nov. 10, 1994, unless otherwise noted.

§ 488.400 Statutory basis.

Sections 1819(h) and 1919(h) of the Act specify remedies that may be used by the Secretary or the State respectively when a SNF or a NF is not in substantial compliance with the requirements for participation in the Medicare and Medicaid programs. These sections also provide for ensuring prompt compliance and specify that these remedies are in addition to any others available under State or Federal law, and, except for civil money penalties, are imposed prior to the conduct of a hearing.

§ 488.401 Definitions.

As used in this subpart—

New admission means a resident who is admitted to the facility on or after the effective date of a denial of payment remedy and, if previously admitted, has been discharged before that effective date. Residents admitted before the effective date of the denial of payment, and taking temporary leave, are not considered new admissions, nor subject to the denial of payment.

Plan of correction means a plan developed by the facility and approved by HCFA or the survey agency that describes the actions the facility will take to correct deficiencies and specifies the date by which those deficiencies will be corrected.

[59 FR 56243, Nov. 10, 1994; 60 FR 50118, Sept. 28, 1995]

§ 488.402 General provisions.

(a) *Purpose of remedies.* The purpose of remedies is to ensure prompt compliance with program requirements.

(b) *Basis for imposition and duration of remedies.* When HCFA or the State chooses to apply one or more remedies specified in § 488.406, the remedies are applied on the basis of noncompliance found during surveys conducted by HCFA or by the survey agency.

(c) *Number of remedies.* HCFA or the State may apply one or more remedies for each deficiency constituting noncompliance or for all deficiencies constituting noncompliance.

(d) *Plan of correction requirement.* (1) Except as specified in paragraph (d)(2) of this section, regardless of which remedy is applied, each facility that has deficiencies with respect to program requirements must submit a plan of correction for approval by HCFA or the survey agency.

(2) *Isolated deficiencies*. A facility is not required to submit a plan of correction when it has deficiencies that are isolated and have a potential for minimal harm, but no actual harm has occurred.

(e) *Disagreement regarding remedies.* If the State and HCFA disagree on the decision to impose a remedy, the disagreement is resolved in accordance with § 488.452.

(f) *Notification requirements*—(1) Except when the State is taking action against a non-State operated NF, HCFA or the State (as authorized by HCFA) gives the provider notice of the remedy, including the—

(i) Nature of the noncompliance;

(ii) Which remedy is imposed;

(iii) Effective date of the remedy; and

(iv) Right to appeal the determination leading to the remedy.

(2) When a State is taking action against a non-State operated NF, the State's notice must include the same information required by HCFA in paragraph (f)(1) of this section.

(3) *Immediate jeopardy—2 day notice.* Except for civil money penalties and State monitoring imposed when there is immediate jeopardy, for all remedies specified in § 488.406 imposed when there is immediate jeopardy, the notice must be given at least 2 calendar days before the effective date of the enforcement action.

(4) *No immediate jeopardy—15 day notice.* Except for civil money penalties and State monitoring, notice must be given at least 15 calendar days before the effective date of the enforcement action in situations in which there is no immediate jeopardy.

(5) *Latest date of enforcement action.* The 2 and 15-day notice periods begin when the facility receives the notice, but, in no event will the effective date of the enforcement action be later than 20 calendar days after the notice is sent.

(6) *Civil money penalties.* For civil money penalties, the notices must be given in accordance with the provisions of §§ 488.434 and 488.440.

(7) *State monitoring.* For State monitoring, no prior notice is required.

[59 FR 56243, Nov. 10, 1994; 60 FR 50118, Sept. 28, 1995]

§ 488.404 Factors to be considered in selecting remedies.

(a) *Initial assessment.* In order to select the appropriate remedy, if any, to apply to a facility with deficiencies, HCFA and the State determine the seriousness of the deficiencies.

(b) *Determining seriousness of deficiencies.* To determine the seriousness of the deficiency, HCFA considers and the State must consider at least the following factors:

(1) Whether a facility's deficiencies constitute—

(i) No actual harm with a potential for minimal harm;

(ii) No actual harm with a potential for more than minimal harm, but not immediate jeopardy;

(iii) Actual harm that is not immediate jeopardy; or

(iv) Immediate jeopardy to resident health or safety.

(2) Whether the deficiencies—

(i) Are isolated;

(ii) Constitute a pattern; or

(iii) Are widespread.

(c) *Other factors which may be considered in choosing a remedy within a remedy category.* Following the initial assessment, HCFA and the State may consider other factors, which may include, but are not limited to the following:

(1) The relationship of the one deficiency to other deficiencies resulting in noncompliance.

(2) The facility's prior history of noncompliance in general and specifically with reference to the cited deficiencies.

§ 488.406 Available remedies.

(a) *General.* In addition to the remedy of termination of the provider agreement, the following remedies are available:

(1) Temporary management.

(2) Denial of payment including—

(i) Denial of payment for all individuals, imposed by HCFA, to a—

(A) Skilled nursing facility, for Medicare;

(B) State, for Medicaid; or

(ii) Denial of payment for all new admissions.

(3) Civil money penalties.

(4) State monitoring.

(5) Transfer of residents.

(6) Closure of the facility and transfer of residents.

(7) Directed plan of correction.

(8) Directed in-service training.

(9) Alternative or additional State remedies approved by HCFA.

(b) *Remedies that must be established.* At a minimum, and in addition to termination of the provider agreement, the

State must establish the following remedies or approved alternatives to the following remedies:

(1) Temporary management.

(2) Denial of payment for new admissions.

(3) Civil money penalties.

(4) Transfer of residents.

(5) Closure of the facility and transfer of residents.

(6) State monitoring.

(c) *State plan requirement.* If a State wishes to use remedies for noncompliance that are either additional or alternative to those specified in paragraphs (a) or (b) of this section, it must—

(1) Specify those remedies in the State plan; and

(2) Demonstrate to HCFA's satisfaction that those remedies are as effective as the remedies listed in paragraph (a) of this section, for deterring noncompliance and correcting deficiencies.

(d) *State remedies in dually participating facilities.* If the State's remedy is unique to the State plan and has been approved by HCFA, then that remedy, as imposed by the State under its Medicaid authority, may be imposed by HCFA against the Medicare provider agreement of a dually participating facility.

[59 FR 56243, Nov. 10, 1994; 60 FR 50118, Sept. 28, 1995]

§ 488.408 Selection of remedies.

(a) *Categories of remedies.* In this section, the remedies specified in § 488.406(a) are grouped into categories and applied to deficiencies according to how serious the noncompliance is.

(b) *Application of remedies.* After considering the factors specified in § 488.404, as applicable, if HCFA and the State choose to impose remedies, as provided in paragraphs (c)(1), (d)(1) and (e)(1) of this section, for facility noncompliance, instead of, or in addition to, termination of the provider agreement, HCFA does and the State must follow the criteria set forth in paragraphs (c)(2), (d)(2), and (e)(2) of this section, as applicable.

(c) *Category 1.* (1) Category 1 remedies include the following:

(i) Directed plan of correction.

(ii) State monitoring.

(iii) Directed in-service training.

(2) HCFA does or the State must apply one or more of the remedies in Category 1 when there—

(i) Are isolated deficiencies that constitute no actual harm with a potential for more than minimal harm but not immediate jeopardy; or

(ii) Is a pattern of deficiencies that constitutes no actual harm with a potential for more than minimal harm but not immediate jeopardy.

(3) Except when the facility is in substantial compliance, HCFA or the State may apply one or more of the remedies in Category 1 to any deficiency.

(d) *Category 2.* (1) Category 2 remedies include the following:

(i) Denial of payment for new admissions.

(ii) Denial of payment for all individuals imposed only by HCFA.

(iii) Civil money penalties of $50-3,000 per day.

(2) HCFA applies one or more of the remedies in Category 2, or, except for denial of payment for all individuals, the State must apply one or more of the remedies in Category 2 when there are—

(i) Widespread deficiencies that constitute no actual harm with a potential for more than minimal harm but not immediate jeopardy; or

(ii) One or more deficiencies that constitute actual harm that is not immediate jeopardy.

(3) HCFA or the State may apply one or more of the remedies in Category 2 to any deficiency except when—

(i) The facility is in substantial compliance; or

(ii) HCFA or the State imposes a civil money penalty for a deficiency that constitutes immediate jeopardy, the penalty must be in the upper range of penalty amounts, as specified in § 488.438(a).

(e) *Category 3.* (1) Category 3 remedies include the following:

(i) Temporary management.

(ii) Immediate termination.

(iii) Civil money penalties of $3,050-$10,000 per day.

(2) When there are one or more deficiencies that constitute immediate jeopardy to resident health or safety—

(i) HCFA does and the State must do one or both of the following:

(A) Impose temporary management; or

(B) Terminate the provider agreement;

(ii) HCFA and the State may impose a civil money penalty of $3,050-$10,000 per day, in addition to imposing the remedies specified in paragraph (e)(2)(i) of this section.

(3) When there are widespread deficiencies that constitute actual harm that is not immediate jeopardy, HCFA and the State may impose temporary management, in addition to Category 2 remedies.

(f) *Plan of correction.* (1) Except as specified in paragraph (f)(2) of this section, each facility that has a deficiency with regard to a requirement for long term care facilities must submit a plan of correction for approval by HCFA or the State, regardless of—

(i) Which remedies are imposed; or

(ii) The seriousness of the deficiencies.

(2) When there are only isolated deficiencies that HCFA or the State determines constitute no actual harm

with a potential for minimal harm, the facility need not submit a plan of correction.

(g) *Appeal of a certification of noncompliance.* (1) A facility may appeal a certification of noncompliance leading to an enforcement remedy.

(2) A facility may not appeal the choice of remedy, including the factors considered by HCFA or the State in selecting the remedy, specified in § 488.404.

[59 FR 56243, Nov. 10, 1994; 60 FR 50118, Sept. 28, 1995]

§ 488.410 Action when there is immediate jeopardy.

(a) If there is immediate jeopardy to resident health or safety, the State must (and HCFA does) either terminate the provider agreement within 23 calendar days of the last date of the survey or appoint a temporary manager to remove the immediate jeopardy. The rules for appointment of a temporary manager in an immediate jeopardy situation are as follows:

(1) HCFA does and the State must notify the facility that a temporary manager is being appointed.

(2) If the facility fails to relinquish control to the temporary manager, HCFA does and the State must terminate the provider agreement within 23 calendar days of the last day of the survey, if the immediate jeopardy is not removed. In these cases, State monitoring may be imposed pending termination.

(3) If the facility relinquishes control to the temporary manager, the State must (and HCFA does) notify the facility that, unless it removes the immediate jeopardy, its provider

agreement will be terminated within 23 calendar days of the last day of the survey.

(4) HCFA does and the State must terminate the provider agreement within 23 calendar days of the last day of survey if the immediate jeopardy has not been removed.

(b) HCFA or the State may also impose other remedies, as appropriate.

(c)(1) In a NF or dually participating facility, if either HCFA or the State finds that a facility's noncompliance poses immediate jeopardy to resident health or safety, HCFA or the State must notify the other of such a finding.

(2) HCFA will or the State must do one or both of the following:

(i) Take immediate action to remove the jeopardy and correct the noncompliance through temporary management.

(ii) Terminate the facility's participation under the State plan. If this is done, HCFA will also terminate the facility's participation in Medicare if it is a dually participating facility.

(d) The State must provide for the safe and orderly transfer of residents when the facility is terminated.

(e) If the immediate jeopardy is also substandard quality of care, the State survey agency must notify attending physicians and the State board responsible for licensing the facility administrator of the finding of substandard quality of care, as specified in § 488.325(h).

[59 FR 56243, Nov. 10, 1994; 60 FR 50118, Sept. 28, 1995]

§ 488.412 Action when there is no immediate jeopardy.

(a) If a facility's deficiencies do not pose immediate jeopardy to residents' health or safety, and the facility is not in substantial compliance, HCFA or the State may terminate the facility's provider agreement or may allow the facility to continue to participate for no longer than 6 months from the last day of the survey if—

(1) The State survey agency finds that it is more appropriate to impose alternative remedies than to terminate the facility's provider agreement;

(2) The State has submitted a plan and timetable for corrective action approved by HCFA; and

(3) The facility in the case of a Medicare SNF or the State in the case of a Medicaid NF agrees to repay to the Federal government payments received after the last day of the survey that first identified the deficiencies if corrective action is not taken in accordance with the approved plan of correction.

(b) If a facility does not meet the criteria for continuation of payment under paragraph (a) of this section, HCFA will and the State must terminate the facility's provider agreement.

(c) HCFA does and the State must deny payment for new admissions when a facility is not in substantial compliance 3 months after the last day of the survey.

(d) HCFA terminates the provider agreement for SNFs and NFs, and stops FFP to a State for a NF for which participation was continued under paragraph (a) of this

section, if the facility is not in substantial compliance within 6 months of the last day of the survey.

[59 FR 56243, Nov. 10, 1994; 60 FR 50118, Sept. 28, 1995]

§ 488.414 Action when there is repeated substandard quality of care.

(a) *General.* If a facility has been found to have provided substandard quality of care on the last three consecutive standard surveys, as defined in § 488.305, regardless of other remedies provided—

(1) HCFA imposes denial of payment for all new admissions, as specified in § 488.417, or denial of all payments, as specified in § 488.418;

(2) The State must impose denial of payment for all new admissions, as specified in § 488.417; and

(3) HCFA does and the State survey agency must impose State monitoring, as specified in § 488.422, until the facility has demonstrated to the satisfaction of HCFA or the State, that it is in substantial compliance with all requirements and will remain in substantial compliance with all requirements.

(b) *Repeated noncompliance.* For purposes of this section, repeated noncompliance is based on the repeated finding of substandard quality of care and not on the basis that the substance of the deficiency or the exact tag number for the deficiency was repeated.

(c) *Standard surveys to which this provision applies.* Standard surveys completed by the State survey agency on or after October 1, 1990, are used to determine whether the threshold of three consecutive standard surveys is met.

(d) *Program participation.* (1) The determination that a certified facility has repeated instances of substandard quality of care is made without regard to any variances in the facility's program participation (that is, any standard survey completed for Medicare, Medicaid or both programs will be considered).

(2) Termination would allow the count of repeated substandard quality of care surveys to start over.

(3) Change of ownership. (i) A facility may not avoid a remedy on the basis that it underwent a change of ownership.

(ii) In a facility that has undergone a change of ownership, HCFA does not and the State may not restart the count of repeated substandard quality of care surveys unless the new owner can demonstrate to the satisfaction of HCFA or the State that the poor past performance no longer is a factor due to the change in ownership.

(e) *Facility alleges corrections or achieves compliance after repeated substandard quality of care is identified.* (1) If a penalty is imposed for repeated substandard quality of care, it will continue until the facility has demonstrated to the satisfaction of HCFA or the State that it is in substantial compliance with the requirements and that it will remain in substantial compliance with the requirements for a period of time specified by HCFA or the State.

(2) A facility will not avoid the imposition of remedies or the obligation to demonstrate that it will remain in compliance when it—

(i) Alleges correction of the deficiencies cited in the most recent standard survey; or

(ii) Achieves compliance before the effective date of the remedies.

§ 488.415 Temporary management.

(a) *Definition.* Temporary management means the temporary appointment by HCFA or the State of a substitute facility manager or administrator with authority to hire, terminate or reassign staff, obligate facility funds, alter facility procedures, and manage the facility to correct deficiencies identified in the facility's operation.

(b) *Qualifications.* The temporary manager must—

(1) Be qualified to oversee correction of deficiencies on the basis of experience and education, as determined by the State;

(2) Not have been found guilty of misconduct by any licensing board or professional society in any State;

(3) Have, or a member of his or her immediate family have, no financial ownership interest in the facility; and

(4) Not currently serve or, within the past 2 years, have served as a member of the staff of the facility.

(c) *Payment of salary.* The temporary manager's salary—

(1) Is paid directly by the facility while the temporary manager is assigned to that facility; and

(2) Must be at least equivalent to the sum of the following—

(i) The prevailing salary paid by providers for positions of this type in what the State considers to be the facility's geographic area;

(ii) Additional costs that would have reasonably been incurred by the provider if such person had been in an employment relationship; and

(iii) Any other costs incurred by such a person in furnishing services under such an arrangement or as otherwise set by the State.

(3) May exceed the amount specified in paragraph (c)(2) of this section if the State is otherwise unable to attract a qualified temporary manager.

(d) *Failure to relinquish authority to temporary management*—(1) *Termination of provider agreement.* If a facility fails to relinquish authority to the temporary manager as described in this section, HCFA will or the State must terminate the provider agreement in accordance with § 488.456.

(2) *Failure to pay salary of temporary manager.* A facility's failure to pay the salary of the temporary manager is considered a failure to relinquish authority to temporary management.

(e) *Duration of temporary management.* Temporary management ends when the facility meets any of the conditions specified in § 488.454(c).

§ 488.417 Denial of payment for all new admissions.

(a) *Optional denial of payment.* Except as specified in paragraph (b) of this section, HCFA or the State may deny payment for all new admissions when a facility is not in

substantial compliance with the requirements, as defined in § 488.401, as follows:

(1) *Medicare facilities.* In the case of Medicare facilities, HCFA may deny payment to the facility.

(2) *Medicaid facilities.* In the case of Medicaid facilities—

(i) The State may deny payment to the facility; and

(ii) HCFA may deny payment to the State for all new Medicaid admissions to the facility.

(b) *Required denial of payment.* HCFA does or the State must deny payment for all new admissions when—

(1) The facility is not in substantial compliance, as defined in § 488.401, 3 months after the last day of the survey identifying the noncompliance; or

(2) The State survey agency has cited a facility with substandard quality of care on the last three consecutive standard surveys.

(c) *Resumption of payments: Repeated instances of substandard quality of care.* When a facility has repeated instances of substandard quality of care, payments to the facility or, under Medicaid, HCFA payments to the State on behalf of the facility, resume on the date that—

(1) The facility achieves substantial compliance as indicated by a revisit or written credible evidence acceptable to HCFA (for all facilities except non-State operated NFs against which HCFA is imposing no remedies) or the State (for non-State operated NFs against which HCFA is imposing no remedies); and

(2) HCFA (for all facilities except non-State operated NFs against which HCFA is imposing no remedies) or the State (for non-State operated NFs against which HCFA is imposing no remedies) believes that the facility is capable of remaining in substantial compliance.

(d) *Resumption of payments: No repeated instances of substandard quality of care.* When a facility does not have repeated instances of substandard quality of care, payments to the facility or, under Medicaid, HCFA payments to the State on behalf of the facility, resume prospectively on the date that the facility achieves substantial compliance, as indicated by a revisit or written credible evidence acceptable to HCFA (under Medicare) or the State (under Medicaid).

(e) *Restriction.* No payments to a facility or, under Medicaid, HCFA payments to the State on behalf of the facility, are made for the period between the date that the—

(1) Denial of payment remedy is imposed; and

(2) Facility achieves substantial compliance, as determined by HCFA or the State.

[59 FR 56243, Nov. 10, 1994; 60 FR 50119, Sept. 28, 1995]

§ 488.418 Secretarial authority to deny all payments.

(a) *HCFA option to deny all payment.* If a facility has not met a requirement, in addition to the authority to deny payment for all new admissions as specified in § 488.417, HCFA may deny any further payment for all Medicare residents in the facility and to the State for all Medicaid residents in the facility.

(b) *Prospective resumption of payment.* Except as provided in paragraphs (d) and (e) of this section, if the facility achieves substantial compliance, HCFA resumes payment prospectively from the date that it verifies as the date that the facility achieved substantial compliance.

(c) *Restriction on payment after denial of payment is imposed.* If payment to the facility or to the State resumes after denial of payment for all residents, no payment is made for the period between the date that—

(1) Denial of payment was imposed; and

(2) HCFA verifies as the date that the facility achieved substantial compliance.

(d) *Retroactive resumption of payment.* Except when a facility has repeated instances of substandard quality of care, as specified in paragraph (e) of this section, when HCFA or the State finds that the facility was in substantial compliance before the date of the revisit, or before HCFA or the survey agency received credible evidence of such compliance, payment is resumed on the date that substantial compliance was achieved, as determined by HCFA.

(e) *Resumption of payment—repeated instances of substandard care.* When HCFA denies payment for all Medi-

care residents for repeated instances of substandard quality of care, payment is resumed when—

(1) The facility achieved substantial compliance, as indicated by a revisit or written credible evidence acceptable to HCFA; and

(2) HCFA believes that the facility will remain in substantial compliance.

§ 488.422 State monitoring.

(a) A State monitor—

(1) Oversees the correction of deficiencies specified by HCFA or the State survey agency at the facility site and protects the facility's residents from harm;

(2) Is an employee or a contractor of the survey agency;

(3) Is identified by the State as an appropriate professional to monitor cited deficiencies;

(4) Is not an employee of the facility;

(5) Does not function as a consultant to the facility; and

(6) Does not have an immediate family member who is a resident of the facility to be monitored.

(b) A State monitor must be used when a survey agency has cited a facility with substandard quality of care deficiencies on the last 3 consecutive standard surveys.

(c) State monitoring is discontinued when—

(1) The facility has demonstrated that it is in substantial compliance with the requirements, and, if imposed

for repeated instances of substandard quality of care, will remain in compliance for a period of time specified by HCFA or the State; or

(2) Termination procedures are completed.

[59 FR 56243, Nov. 10, 1994; 60 FR 50119, Sept. 28, 1995]

§ 488.424 Directed plan of correction.

HCFA, the State survey agency, or the temporary manager (with HCFA or State approval) may develop a plan of correction and HCFA, the State, or the temporary manager require a facility to take action within specified timeframes.

§ 488.425 Directed inservice training.

(a) *Required training.* HCFA or the State agency may require the staff of a facility to attend an inservice training program if—

(1) The facility has a pattern of deficiencies that indicate noncompliance; and

(2) Education is likely to correct the deficiencies.

(b) *Action following training.* After the staff has received inservice training, if the facility has not achieved substantial compliance, HCFA or the State may impose one or more other remedies specified in § 488.406.

(c) *Payment.* The facility pays for directed inservice training.

[59 FR 56243, Nov. 10, 1994; 60 FR 50119, Sept. 28, 1995]

§ 488.426 Transfer of residents, or closure of the facility and transfer of residents.

(a) *Transfer of residents, or closure of the facility and transfer of residents in an emergency.* In an emergency, the State has the authority to—

(1) Transfer Medicaid and Medicare residents to another facility; or

(2) Close the facility and transfer the Medicaid and Medicare residents to another facility.

(b) *Required transfer when a facility's provider agreement is terminated.* When the State or HCFA terminates a facility's provider agreement, the State arranges for the safe and orderly transfer of all Medicare and Medicaid residents to another facility.

[59 FR 56243, Nov. 10, 1994; 60 FR 50119, Sept. 28, 1995]

§ 488.430 Civil money penalties: Basis for imposing penalty.

(a) HCFA or the State may impose a civil money penalty for the number of days a facility is not in substantial compliance with one or more participation requirements, regardless of whether or not the deficiencies constitute immediate jeopardy.

(b) HCFA or the State may impose a civil money penalty for the number of days of past noncompliance since the last standard survey, including the number of days of immediate jeopardy.

§ 488.432 Civil money penalties: When penalty is collected.

(a) *When facility requests a hearing.* (1) A facility must request a hearing on the determination of the noncompliance that is the basis for imposition of the civil money penalty within the time specified in one of the following sections:

(i) Section 498.40 of this chapter for a

(A) SNF;

(B) Dually participating facility;

(C) State-operated NF; or

(D) Non-State operated NF against which HCFA is imposing remedies.

(ii) Section 431.153 of this chapter for a non-State operated NF that is not subject to imposition of remedies by HCFA.

(2) If a facility requests a hearing within the time specified in paragraph (a)(1) of this section, HCFA or the State initiates collection of the penalty when there is a final administrative decision that upholds HCFA's or the State's determination of noncompliance after the facility achieves substantial compliance or is terminated.

(b) *When facility does not request a hearing.* If a facility does not request a hearing, in accordance with paragraph (a) of this section, HCFA or the State initiates collection of the penalty when the facility—

(1) Achieves substantial compliance; or

(2) Is terminated.

(c) *When facility waives a hearing.* If a facility waives its right to a hearing in writing, as specified in § 488.436, HCFA or the State initiates collection of the penalty when the facility—

(1) Achieves substantial compliance; or

(2) Is terminated.

(d) Accrual and computation of penalties for a facility that—

(1) Requests a hearing or does not request a hearing are specified in § 488.440;

(2) Waives its right to a hearing in writing, are specified in §§ 488.436(b) and 488.440.

(e) The collection of civil money penalties is made as provided in § 488.442.

[59 FR 56243, Nov. 10, 1994; 60 FR 50119, Sept. 28, 1995]

§ 488.434 Civil money penalties: Notice of penalty.

(a) *HCFA notice of penalty.* (1) HCFA sends a written notice of the penalty to the facility for all facilities except non-State operated NFs when the State is imposing the penalty.

(2) *Content of notice.* The notice that HCFA sends includes—

(i) The nature of the noncompliance;

(ii) The statutory basis for the penalty;

(iii) The amount of penalty per day of noncompliance;

(iv) Any factors specified in § 488.438(f) that were considered when determining the amount of the penalty;

(v) The date on which the penalty begins to accrue;

(vi) When the penalty stops accruing;

(vii) When the penalty is collected; and

(viii) Instructions for responding to the notice, including a statement of the facility's right to a hearing, and the implication of waiving a hearing, as provided in § 488.436.

(b) *State notice of penalty.* (1) The State must notify the facility in accordance with State procedures for all non-State operated NFs when the State takes the action.

(2) The State's notice must—

(i) Be in writing; and

(ii) Include, at a minimum, the information specified in paragraph (a)(2) of this section.

[59 FR 56243, Nov. 10, 1994; 60 FR 50119, Sept. 28, 1995]

§ 488.436 Civil money penalties: Waiver of hearing, reduction of penalty amount.

(a) *Waiver of a hearing.* The facility may waive the right to a hearing, in writing, within 60 days from the date of the notice imposing the civil money penalty.

(b) *Reduction of penalty amount.* (1) If the facility waives its right to a hearing in accordance with the procedures specified in paragraph (a) of this section, HCFA or the State reduces the civil money penalty amount by 35 percent.

(2) If the facility does not waive its right to a hearing in accordance with the procedures specified in paragraph (a) of this section, the civil money penalty is not reduced by 35 percent.

[59 FR 56243, Nov. 10, 1994; 62 FR 44221, Aug. 20, 1997]

§ 488.438 Civil money penalties: Amount of penalty.

(a) *Amount of penalty.* The penalties are within the following ranges, set at $50 increments:

(1) *Upper range—$3,050-$10,000.* Penalties in the range of $3,050-$10,000 per day are imposed for deficiencies constituting immediate jeopardy, and as specified in paragraph (d)(2) of this section.

(2) *Lower range—$50-$3,000.* Penalties in the range of $50-$3,000 per day are imposed for deficiencies that do not constitute immediate jeopardy, but either caused actual harm, or caused no actual harm, but have the potential for more than minimal harm.

(b) *Basis for penalty amount.* The amount of penalty is based on HCFA's or the State's assessment of factors listed in paragraph (f) of this section.

(c) *Decreased penalty amounts.* Except as specified in paragraph (d)(2) of this section, if immediate jeopardy is removed, but the noncompliance continues, HCFA or the State will shift the penalty amount to the lower range.

(d) *Increased penalty amounts.* (1) Before the hearing, HCFA or the State may propose to increase the penalty amount for facility noncompliance which, after imposition of a lower level penalty amount, becomes sufficiently serious to pose immediate jeopardy.

(2) HCFA does and the State must increase the penalty amount for any repeated deficiencies for which a lower level penalty amount was previously imposed, regardless of whether the increased penalty amount would exceed the range otherwise reserved for non-immediate jeopardy deficiencies.

(3) Repeated deficiencies are deficiencies in the same regulatory grouping of requirements found at the last survey, subsequently corrected, and found again at the next survey.

(e) *Review of the penalty.* When an administrative law judge or State hearing officer (or higher administrative review authority) finds that the basis for imposing a civil money penalty exists, as specified in § 488.430, the administrative law judge or State hearing officer (or higher administrative review authority) may not—

(1) Set a penalty of zero or reduce a penalty to zero;

(2) Review the exercise of discretion by HCFA or the State to impose a civil money penalty; and

(3) Consider any factors in reviewing the amount of the penalty other than those specified in paragraph (f) of this section.

(f) *Factors affecting the amount of penalty.* In determining the amount of penalty, HCFA does or the State must take into account the following factors:

(1) The facility's history of noncompliance, including repeated deficiencies.

(2) The facility's financial condition.

(3) The factors specified in § 488.404.

(4) *The facility's degree of culpability. Culpability* for purposes of this paragraph includes, but is not limited to, neglect, indifference, or disregard for resident care, comfort or safety. The absence of culpability is not a mitigating circumstance in reducing the amount of the penalty.

§ 488.440 Civil money penalties: Effective date and duration of penalty.

(a) *When penalty begins to accrue.* The civil money penalty may start accruing as early as the date that the facility was first out of compliance, as determined by HCFA or the State.

(b) *Duration of penalty.* The civil money penalty is computed and collectible, as specified in §§ 488.432 and 488.442, for the number of days of noncompliance until the date the facility achieves substantial compliance, or, if applicable, the date of termination when—

(1) HCFA's or the State's decision of noncompliance is upheld after a final administrative decision;

(2) The facility waives its right to a hearing in accordance with § 488.436; or

(3) The time for requesting a hearing has expired and HCFA or the State has not received a hearing request from the facility.

(c) The entire accrued penalty is due and collectible, as specified in the notice sent to the provider under paragraphs (d) and (e) of this section.

(d) When a facility achieves substantial compliance, HCFA does or the State must send a separate notice to the facility containing—

(1) The amount of penalty per day;

(2) The number of days involved;

(3) The total amount due;

(4) The due date of the penalty; and

(5) The rate of interest assessed on the unpaid balance beginning on the due date, as provided in § 488.442.

(e) In the case of a terminated facility, HCFA does or the State must send this penalty information after the—

(1) Final administrative decision is made;

(2) Facility has waived its right to a hearing in accordance with § 488.436; or

(3) Time for requesting a hearing has expired and HCFA or the state has not received a hearing request from the facility.

(f) *Accrual of penalties when there is no immediate jeopardy.* (1) In the case of noncompliance that does not pose immediate jeopardy, the daily accrual of civil money penalties is imposed for the days of noncompliance prior to the notice specified in § 488.434 and an additional period of no longer than 6 months following the last day of the survey.

(2) After the period specified in paragraph (f)(1) of this section, if the facility has not achieved substantial compliance, HCFA terminates the provider agreement and the State may terminate the provider agreement.

(g) *Accrual of penalties when there is immediate jeopardy.* (1) When a facility has deficiencies that pose immediate jeopardy, HCFA does or the State must terminate the provider agreement within 23 calendar days after the last day of the survey if the immediate jeopardy remains.

(2) The accrual of the civil money penalty stops on the day the provider agreement is terminated.

(h) *Documenting substantial compliance.* (1) If an on-site revisit is necessary to confirm substantial compliance and the provider can supply documentation acceptable to HCFA or the State agency that substantial compliance was achieved on a date preceding the revisit, penalties only accrue until that date of correction for which there is written credible evidence.

(2) If an on-site revisit is not necessary to confirm substantial compliance, penalties only accrue until the date of

correction for which HCFA or the State receives and accepts written credible evidence.

§ 488.442 Civil money penalties: Due date for payment of penalty.

(a) *When payments are due*—(1) *After a final administrative decision.* A civil money penalty payment is due 15 days after a final administrative decision is made when—

(i) The facility achieves substantial compliance before the final administrative decision; or

(ii) The effective date of termination occurs before the final administrative decision.

(2) *When no hearing was requested.* A civil money penalty payment is due 15 days after the time period for requesting a hearing has expired and a hearing request was not received when—

(i) The facility achieved substantial compliance before the hearing request was due; or

(ii) The effective date of termination occurs before the hearing request was due.

(3) *After a request to waive a hearing.* A civil money penalty payment is due 15 days after receipt of the written request to waive a hearing when—

(i) The facility achieved substantial compliance before HCFA or the State received the written waiver of hearing; or

(ii) The effective date of termination occurs before HCFA or the State received the written waiver of hearing.

(4) *After substantial compliance is achieved.* A civil money penalty payment is due 15 days after substantial compliance is achieved when—

(i) The final administrative decision is made before the facility came into substantial compliance;

(ii) The facility did not file a timely hearing request before it came into substantial compliance; or

(iii) The facility waived its right to a hearing before it came into substantial compliance;

(5) *After the effective date of termination.* A civil money penalty payment is due 15 days after the effective date of termination, if before the effective date of termination—

(i) The final administrative decision was made;

(ii) The time for requesting a hearing has expired and the facility did not request a hearing; or

(iii) The facility waived its right to a hearing.

(6) In the cases specified in paragraph (a)(4) of this section, the period of noncompliance may not extend beyond 6 months from the last day of the survey.

(b) *Deduction of penalty from amount owed.* The amount of the penalty, when determined, may be deducted from any sum then or later owing by HCFA or the State to the facility.

(c) *Interest*—(1) *Assessment.* Interest is assessed on the unpaid balance of the penalty, beginning on the due date.

(2) *Medicare interest.* Medicare rate of interest is the higher of—

(i) The rate fixed by the Secretary of the Treasury after taking into consideration private consumer rates of interest prevailing on the date of the notice of the penalty amount due (published quarterly in the Federal Register by HHS under 45 CFR 30.13(a)); or

(ii) The current value of funds (published annually in the Federal Register by the Secretary of the Treasury, subject to quarterly revisions).

(3) *Medicaid interest.* The interest rate for Medicaid is determined by the State.

(d) *Penalties collected by HCFA.* Civil money penalties and corresponding interest collected by HCFA from—

(1) Medicare-participating facilities are deposited as miscellaneous receipts of the United States Treasury; and

(2) Medicaid-participating facilities are returned to the State.

(e) *Collection from dually participating facilities.* Civil money penalties collected from dually participating facilities are deposited as miscellaneous receipts of the United States Treasury and returned to the State in proportion commensurate with the relative proportions of Medicare and Medicaid beds at the facility actually in use by residents covered by the respective programs on the date the civil money penalty begins to accrue.

(f) *Penalties collected by the State.* Civil money penalties collected by the State must be applied to the protection of the health or property of residents of facilities that the State or HCFA finds noncompliant, such as—

(1) Payment for the cost of relocating residents to other facilities;

(2) State costs related to the operation of a facility pending correction of deficiencies or closure; and

(3) Reimbursement of residents for personal funds or property lost at a facility as a result of actions by the facility or by individuals used by the facility to provide services to residents.

[59 FR 56243, Nov. 10, 1994; 60 FR 50119, Sept. 28, 1995]

§ 488.444 Civil money penalties: Settlement of penalties.

(a) HCFA has authority to settle cases at any time prior to a final administrative decision for Medicare-only SNFs, State-operated facilities, or other facilities for which HCFA's enforcement action prevails, in accordance with § 488.330.

(b) The State has the authority to settle cases at any time prior to the evidentiary hearing decision for all cases in which the State's enforcement action prevails.

§ 488.450 Continuation of payments to a facility with deficiencies.

(a) *Criteria.* (1) HCFA may continue payments to a facility not in substantial compliance for the periods specified in paragraph (c) of this section if the following criteria are met:

(i) The State survey agency finds that it is more appropriate to impose alternative remedies than to terminate the facility;

(ii) The State has submitted a plan and timetable for corrective action approved by HCFA; and

(iii) The facility, in the case of a Medicare SNF, or the State, in the case of a Medicaid NF, agrees to repay the Federal government payments received under this provision if corrective action is not taken in accordance with the approved plan and timetable for corrective action.

(2) HCFA or the State may terminate the SNF or NF agreement before the end of the correction period if the criteria in paragraph (a)(1) of this section are not met.

(b) *Cessation of payments.* If termination is not sought, either by itself or along with another remedy or remedies, or any of the criteria set forth in paragraph (a)(1) of this section are not met or agreed to by either the facility or the State, the facility or State will receive no Medicare or Federal Medicaid payments, as applicable, from the last day of the survey.

(c) *Period of continued payments.* If the conditions in paragraph (a)(1) of this section are met, HCFA may continue payments to a Medicare facility or to the State for a Medicaid facility with noncompliance that does not constitute immediate jeopardy for up to 6 months from the last day of the survey.

(d) *Failure to achieve substantial compliance.* If the facility does not achieve substantial compliance by the end of the period specified in paragraph (c) of this section,

(1) HCFA will—

(i) Terminate the provider agreement of the Medicare SNF in accordance with § 488.456; or

(ii) Discontinue Federal funding to the SNF for Medicare; and

(iii) Discontinue FFP to the State for the Medicaid NF.

(2) The State may terminate the provider agreement for the NF.

[59 FR 56243, Nov. 10, 1994; 60 FR 50119, Sept. 28, 1995]

§ 488.452 State and Federal disagreements involving findings not in agreement in non-State operated NFs and dually participating facilities when there is no immediate jeopardy.

The following rules apply when HCFA and the State disagree over findings of noncompliance or application of remedies in a non-State operated NF or dually participating facility:

(a) *Disagreement over whether facility has met requirements.* (1) The State's finding of noncompliance takes precedence when—

(i) HCFA finds that a NF or a dually participating facility is in substantial compliance with the participation requirements; and

(ii) The State finds that a NF or dually participating facility has not achieved substantial compliance.

(2) HCFA's findings of noncompliance take precedence when—

(i) HCFA finds that a NF or a dually participating facility has not achieved substantial compliance; and

(ii) The State finds that a NF or a dually participating facility is in substantial compliance with the participation requirements.

(3) When HCFA's survey findings take precedence, HCFA may—

(i) Impose any of the alternative remedies specified in § 488.406;

(ii) Terminate the provider agreement subject to the applicable conditions of § 488.450; and

(iii) Stop FFP to the State for a NF.

(b) *Disagreement over decision to terminate.* (1) HCFA's decision to terminate the participation of a facility takes precedence when—

(i) Both HCFA and the State find that the facility has not achieved substantial compliance; and

(ii) HCFA, but not the State, finds that the facility's participation should be terminated. HCFA will permit continuation of payment during the period prior to the effective date of termination not to exceed 6 months, if the applicable conditions of § 488.450 are met.

(2) The State's decision to terminate a facility's participation and the procedures for appealing such termination, as specified in § 431.153(c) of this chapter, takes precedence when—

(i) The State, but not HCFA, finds that a NF's participation should be terminated; and

(ii) The State's effective date for the termination of the NF's provider agreement is no later than 6 months after the last day of survey.

(c) *Disagreement over timing of termination of facility.* The State's timing of termination takes precedence if it does not occur later than 6 months after the last day of the survey when both HCFA and the State find that—

(1) A facility is not in substantial compliance; and

(2) The facility's participation should be terminated.

(d) *Disagreement over remedies.* (1) When HCFA or the State, but not both, establishes one or more remedies, in addition to or as an alternative to termination, the additional or alternative remedies will also apply when—

(i) Both HCFA and the State find that a facility has not achieved substantial compliance; and

(ii) Both HCFA and the State find that no immediate jeopardy exists.

(2) *Overlap of remedies.* When HCFA and the State establish one or more remedies, in addition to or as an alternative to termination, only the HCFA remedies apply when both HCFA and the State find that a facility has not achieved substantial compliance.

(e) Regardless of whether HCFA's or the State's decision controls, only one noncompliance and enforcement decision is applied to the Medicaid agreement, and for a dually participating facility, that same decision will apply to the Medicare agreement.

§ 488.454 Duration of remedies.

(a) Except as specified in paragraph (b) of this section, alternative remedies continue until—

(1) The facility has achieved substantial compliance, as determined by HCFA or the State based upon a revisit or after an examination of credible written evidence that it can verify without an on-site visit; or

(2) HCFA or the State terminates the provider agreement.

(b) In the cases of State monitoring and denial of payment imposed for repeated substandard quality of care, remedies continue until—

(1) HCFA or the State determines that the facility has achieved substantial compliance and is capable of remaining in substantial compliance; or

(2) HCFA or the State terminates the provider agreement.

(c) In the case of temporary management, the remedy continues until—

(1) HCFA or the State determines that the facility has achieved substantial compliance and is capable of remaining in substantial compliance;

(2) HCFA or the State terminates the provider agreement; or

(3) The facility which has not achieved substantial compliance reassumes management control. In this case, HCFA

or the State initiates termination of the provider agreement and may impose additional remedies.

(d) If the facility can supply documentation acceptable to HCFA or the State survey agency that it was in substantial compliance, and was capable of remaining in substantial compliance, if necessary, on a date preceding that of the revisit, the remedies terminate on the date that HCFA or the State can verify as the date that substantial compliance was achieved and the facility demonstrated that it could maintain substantial compliance, if necessary.

[59 FR 56243, Nov. 10, 1994; 60 FR 50119, Sept. 28, 1995]

§ 488.456 Termination of provider agreement.

(a) *Effect of termination.* Termination of the provider agreement ends—

(1) Payment to the facility; and

(2) Any alternative remedy.

(b) *Basis for termination.* (1) HCFA and the State may terminate a facility's provider agreement if a facility—

(i) Is not in substantial compliance with the requirements of participation, regardless of whether or not immediate jeopardy is present; or

(ii) Fails to submit an acceptable plan of correction within the time-frame specified by HCFA or the State.

(2) HCFA and the State terminate a facility's provider agreement if a facility—

(i) Fails to relinquish control to the temporary manager, if that remedy is imposed by HCFA or the State; or

(ii) Does not meet the eligibility criteria for continuation of payment as set forth in § 488.412(a)(1).

(c) *Notice of termination.* Before terminating a provider agreement, HCFA does and the State must notify the facility and the public—

(1) At least 2 calendar days before the effective date of termination for a facility with immediate jeopardy deficiencies; and

(2) At least 15 calendar days before the effective date of termination for a facility with non-immediate jeopardy deficiencies that constitute noncompliance.

(d) *Procedures for termination.* (1) HCFA terminates the provider agreement in accordance with procedures set forth in § 489.53 of this chapter; and

(2) The State must terminate the provider agreement of a NF in accordance with procedures specified in parts 431 and 442 of this chapter.

5. Section 498 of Title 42, Code of Federal Regulations, provides in relevant part:

§ 498.1 Statutory basis.

(a) Section 1866(h) of the Act provides for a hearing and for judicial review of the hearing for any institution or agency dissatisfied with a determination that it is not a provider, or with any determination described in section 1866(b)(2) of the Act.

(b) Section 1866(b)(2) of the Act lists determinations that serve as a basis for termination of a provider agreement.

(c) Sections 1128(a) and (b) of the Act provide for exclusion of certain individuals or entities because of conviction of crimes related to their participation in Medicare and section 1128(f) provides for hearing and judicial review for exclusions.

(d) Section 1156 of the Act establishes certain obligations for practitioners and providers of health care services, and provides sanctions and penalties for those that fail to meet those obligations.

* * * * *

(i) Section 1819(h) of the Act—

(1) Provides that, for SNFs found to be out of compliance with the requrements for participation, specified remedies may be imposed instead of, or in addition to, termination of the facilitity's Medicare provider agreement; and

(2) Makes certain provisions of section 1128A of the Act applicable to civil money penalties imposed on SNFs.

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§ 498.3 Scope and applicability.

(a) *Scope.* This part sets forth procedures for reviewing initial determinations that HCFA makes with respect to the matters specified in paragraph (b) of this section, and that the OIG makes with respect to the matters specified in paragraph (c) of this section. It also specifies, in paragraph (d) of this section, administrative actions that are not subject to appeal under this part.

(b) *Initial determinations by HCFA.* HCFA makes initial determinations with respect to the following matters:

(1) Whether a prospective provider qualifies as a provider.

(2) Whether an institution is a hospital qualified to elect to claim payment for all emergency hospital services furnished in a calendar year.

(3) Whether an institution continues to remain in compliance with the qualifications for claiming reimbursement for all emergency services furnished in a calendar year.

(4) Whether a prospective supplier meets the conditions for coverage of its services as those conditions are set forth elsewhere in this chapter.

(5) Whether the services of a supplier continue to meet the conditions for coverage.

(6) Whether a physical therapist in independent practice or a chiropractor meets the requirements for coverage of his

or her services as set forth in subpart D of part 486 of this chapter and § 410.22 of this chapter, respectively.

(7) The termination of a provider agreement in accordance with § 489.53 of this chapter, or the termination of a rural health clinic agreement in accordance with § 405.2404 of this chapter, or the termination of a Federally qualified health center agreement in accordance with § 405.2436 of this chapter.

(8) HCFA's cancellation, under section 1910(b) of the Act, of an ICF/MR's approval to participate in Medicaid.

(9) Whether, for purposes of rate setting and reimbursement, an ESRD treatment facility is considered to be hospital-based or independent.

(10) Whether to deny payment under § 409.19 or § 409.64 of this chapter, pertaining to cardiac pacemakers and the pacemaker registry.

(11) Whether a hospital, skilled nursing facility, home health agency, or hospice program meets or continues to meet the advance directives requirements specified in subpart I of part 489 of this chapter.

(12) With respect to an SNF or NF, a finding of noncompliance that results in the imposition of a remedy specified in § 488.406 of this chapter, except the State monitoring remedy, and the loss of the approval for a nurse-aide training program.

(13) The level of noncompliance found by HCFA in an SNF or NF but only if a successful challenge on this issue would affect the range of civil money penalty amounts that HCFA could collect. (The scope of review during a hearing

on imposition of a civil money penalty is set forth in § 488.438(e) of this chapter.)

(14) The effective date of a Medicare provider agreement or supplier approval.

(c) *Initial determinations by the OIG.* The OIG makes initial determinations with respect to the following matters:

(1) The termination of a provider agreement in accordance with Part 1001, Subpart C of this title.

(2) The suspension, or exclusion from coverage and the denial of reimbursement for services furnished by a provider, practitioner, or supplier, because of fraud or abuse, or conviction of crimes related to participation in the program, in accordance with Part 1001, Subpart B of this title.

(3) The imposition of sanctions in accordance with Part 1004 of this title.

(d) *Administrative actions that are not initial determinations.* Administrative actions that are not initial determination (and therefore not subject to appeal under this part) include but are not limited to the following:

(1) The finding that a provider or supplier determined to be in compliance with the conditions or requirements for participation or for coverage has deficiencies.

(2) The finding that a prospective provider does not meet the conditions of participation set forth elsewhere in this chapter, if the prospective provider is, nevertheless, approved for participation in Medicare on the basis of special access certification, as provided in subpart B of part 488 of this chapter.

(3) The refusal to enter into a provider agreement because the prospective provider is unable to give satisfactory assurance of compliance with the requirements of title XVIII of the Act.

(4) The finding that an entity that had its provider agreement terminated may not file another agreement because the reasons for terminating the previous agreement have not been removed or there is insufficient assurance that the reasons for the exclusion will not recur.

(5) The determination not to reinstate a suspended or excluded practitioner, provider, or supplier because the reason for the suspension or exclusion has not been removed, or there is insufficient assurance that the reason will not recur.

(6) The finding that the services of a laboratory are covered as hospital services or as physician's services, rather than as services of an independent laboratory, because the laboratory is not independent of the hospital or of the physician's office.

(7) The refusal to accept for filing an election to claim payment for all emergency hospital services furnished in a calendar year because the institution—

(i) Had previously charged an individual or other person for services furnished during that calendar year;

(ii) Submitted the election after the close of that calendar year; or

(iii) Had previously been notified of its failure to continue to comply.

(8) The finding that the reason for the revocation of a supplier's right to accept assignment has not been removed or there is insufficient assurance that the reason will not recur.

(9) The finding that a hospital accredited by the Joint Commission on Accreditation of Hospitals or the American Osteopathic Association is not in compliance with a condition of participation, and a finding that that hospital is no longer deemed to meet the conditions of participation.

(10) With respect to an SNF or NF-

(i) The finding that the SNF's or NF's deficiencies pose immediate jeopardy to the health or safety of its residents;

(ii) Except as provided in paragraph (b)(13) of this section, a determination by HCFA as to the facility's level of noncompliance; and

(iii) The imposition of State monitoring or the loss of the approval for a nurse-aide training program.

(11) The choice of alternative sanction or remedy to be imposed on a provider or supplier.

(12) The determination that the accreditation requirements of a national accreditation organization do not provide (or do not continue to provide) reasonable assurance that the entities accredited by the accreditation organization meet the applicable long-term care requirements, conditions for coverage, conditions of certification, conditions of participation, or CLIA condition level requirements.

(13) The determination that requirements imposed on a State's laboratories under the laws of that State do not provide (or do not continue to provide) reasonable assurance

that laboratories licensed or approved by the State meet applicable CLIA requirements.

(14) The choice of alternative sanction or remedy to be imposed on a provider or supplier.

(15) A decision by the State survey agency as to when to conduct an initial survey of a prospective provider or supplier.

(e) *Exclusion of civil rights issues.* The procedures in this subpart do not apply to the adjudication of issues relating to a provider's compliance with civil rights requirements that are set forth in Part 489 of this chapter. Those issues are handled through the Department's Office of Civil Rights.