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

REPLY BRIEF FOR THE PETITIONERS

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This case concerns the timing—not the availability—of judicial review. Respondent does not dispute that the Medicare Act provides comprehensive mechanisms for administrative and judicial review. Nor does respondent deny that one of those mechanisms entitles any nursing home that is "dissatisfied with a determination * * * that it is not a provider of services," or that it does not "substantially comply" with the Secretary's health, safety and quality-of-care regulations, to a hearing as provided in 42 U.S.C. 405(b), and to judicial review as provided in 42 U.S.C. 405(g). 42 U.S.C. 1395cc(h)(1) and (b)(2); Resp. Br. 7. Respondent argues, however, that that mechanism is not exclusive—despite Congress's declaration that it "intended that the remedies provided by th[o]se review procedures shall be exclusive." S. Rep. No. 404, 89th Cong., 1st Sess. Pt. 1, at 54-55 (1965).

That contention is foreclosed by 42 U.S.C. 405(h), incorporated into the Medicare Act by 42 U.S.C. 1395ii. The second sentence of Section 405(h) declares that "[n]o findings of fact or decision of the [Secretary] shall be reviewed by any person, tribunal, or governmental agency except as herein provided." And the third sentence adds that "[n]o action * * * shall be brought under section 1331 or 1346 of title 28 to recover on any claim arising under this subchapter."

"[T]he 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 of all 'claim[s] arising under' the Medicare Act." *Heckler* v. *Ringer*, 466 U.S. 602, 614-615 (1984) (emphasis added). Simply put, where (as here) plaintiffs "have an adequate remedy in § 405(g) * * *[,] § 405(g) is the only avenue for judicial review," *Ringer*, 466 U.S. at 617—even if the plaintiffs challenge a rule or policy of general applicability, as in *Ringer* itself, *id.* at 613-616, 620-621, 624-626, and in *Salfi* as well, see Gov't Br. 34-35.

A. 1. Respondent and its amici argue that Section 405(h) applies only to "individual claims for benefits." See Resp. Br. 15, 16, 17, 21, 25. See also Am. Hosp. Ass'n (AHA) Br. 9, 12, 18; Am. Health Care Ass'n (AHCA) Br. 8. To the extent respondent and its amici suggest that Section 405(h) applies only to claims for monetary payments, this Court has already rejected that contention. In *Ringer*, the plaintiffs and the dissent contended that Section 405(h) "precludes only actions" in "which the claimant seeks payment of benefits"; it does not extend, they argued, to suits (like *Ringer*) that challenge generally applicable policies and seek only declaratory and injunctive relief. See 466 U.S. at 635 (dissenting opinion). They, like respondent, also sought to distinguish this Court's decision in *Salfi* as a benefits case. *Ibid.* This Court, however, rejected those arguments. "[T]here is no indication in *Salfi*," the Court explained, "that our holding in any way depended on the fact that the claimants there sought an award of benefits." 466 U.S. at 623. "Furthermore," the Court continued, "today we explicitly hold that our conclusion that the claims of [the respondents] are barred by § 405(h) is in no way affected by the fact that those respondents did not seek an award of benefits." *Ibid.*

Moreover, as we have explained (Gov't Br. 39-42), respondent's proposal to limit Section 405(h)'s preclusive scope to "amount," "benefits," or "reimbursement" claims has no

basis in the text of Section 405(h). The court of appeals suggested (Pet. App. 6a) that such a limit might be found in Section 405(h)'s third sentence, which bars federal-question jurisdiction over suits "to recover" on a claim arising under the Medicare Act. That argument is not only inconsistent with *Ringer*, but also incorrect as a textual matter. As we have pointed out (and respondent and its amici do not dispute), the word "recover" in legal contexts has never been limited to monetary recoveries. Gov't Br. 39. Moreover, the attempt to limit Section 405(h)'s preclusive effect to suits for benefits or payments cannot be reconciled with the fact that Congress expressly incorporated Section 405(h) into numerous Medicare provisions that do not involve the adjudication of claims for payments—including provisions that, like 42 U.S.C. 1395cc(h) here, deal with the imposition of remedies for noncompliance. See Gov't Br. 39-40 & n.21. Nor can it be reconciled with the statutory structure, as construing Section 405(h) to reach only benefits determinations would make the third sentence of Section 405(h) superfluous in light of the second. See p. 5, *infra*; Gov't Br. 40.[1]

Although the foregoing arguments appear in our opening brief, respondent and its amici make no attempt to answer them. In fact, notwithstanding their repeated use of phrases like "benefits claims" and "amount determinations," they ultimately concede that 42 U.S.C. 405(h)'s preclusive scope extends beyond suits seeking monetary payments. Resp. Br. 18, 19, 20 (conceding that Section 405(h)'s preclusion extends to non-monetary "provider status" claims, *i.e.*, suits challenging the termination of providers from the program)[2];

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[1] In any event, respondent's suit—which seeks invalidation of regulations that might render its members ineligible to participate in (and therefore to receive payments under) Medicare, and seeks an injunction to prohibit "any ban on payment as a remedy for any deficiency," J.A. 52—is inextricably intertwined with payment claims. See Gov't Br. 34-35, 41-42.

[2] Respondent relies (Br. 20-21) on the fact that the 1965 legislative history, when stating that the statutory review procedures are exclusive, mentions only benefits determinations and "determinations regarding * * * eligibility to participate in the program." In 1965, however, those

Am. Ass'n of Homes & Servs. for the Aging (AAHSA) Br. 30 ("the issue is not whether payment of an 'amount' of money is at stake").

2. Respondent and its amici also argue that Section 405(h) is preclusive only with respect "to *individual* claims * * * for which there is an administrative hearing and a final decision." Resp. Br. 16, 19, 20, 29 (emphasis added). According to them, Section 405(h) distinguishes "between challenges to individualized determinations, which must be brought through established administrative channels," and "broad-based" pre-enforcement "challenges to the Secretary's rules and regulations governing such determinations, which may be brought directly in district court." AMA Br. 5-6; see Resp. Br. 29 (distinguishing between "statutory or constitutional challenges to a regulation or policy" and "an individual claim of entitlement").

That proposed distinction likewise has no textual basis. Section 405(h)'s second sentence does channel review of individual claims through special statutory review mechanisms. It declares that "[n]o * * * decision of the [Secretary] shall be reviewed * * * except as herein provided," 42 U.S.C. 405(h), and "decisions" of the Secretary are generally individualized determinations, see *Bowen* v. *Michigan Academy*, 476 U.S. 667, 679 n.8 (1986). But it would be inconsistent with the reasons for that exhaustion requirement, and with the very existence of a special statutory review procedure, to permit a party to separate out one legal issue that may bear on an administrative adjudication and present that issue in a separate anticipatory suit. In any event, the third sentence of Section 405(h) declares that "no action * * * to recover on any claim arising under" the Medicare Act shall be brought under Section 1331. Nothing

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were the only categories that existed; terminating a provider's participation was the *only* remedy the Secretary could impose for noncompliance. Gov't Br. 7. It follows that the statutory mechanism for judicial review is exclusive with respect to the additional remedies Congress authorized in 1986 as well.

in that "sweeping and direct" language "limit[s]" its "reach * * * to decisions of the Secretary" or other individualized or fact-based claims. *Salfi*, 422 U.S. at 762. To the contrary, by its plain terms, the third sentence of Section 405(h) precludes district courts from exercising federal-question jurisdiction over "any claim" arising under the Medicare Act, whether it is characterized as "individual" or as a broad-based challenge to regulations, policies, or a provision of the Act. Moreover, because Section 405(h)'s second sentence precludes review of individual determinations ("decisions" of the Secretary) except through the special review mechanisms in the Act, respondent's "treatment of the third sentence of § 405(h) not only ignore[s] that [third] sentence's plain language, but also relegate[s] it to a function which is already performed by other statutory provisions." *Id.* at 758-750 & n.6.

For similar reasons, respondent (Br. 30) and its amici (AHA Br. 17-19; AAHSA Br. 30; AMA Br. 17-19) err in relying on *McNary* v. *Haitian Refugee Center, Inc.*, 498 U.S. 479 (1991), *Reno* v. *Catholic Social Services, Inc.*, 509 U.S. 43 (1993), *Johnson* v. *Robison*, 415 U.S. 361 (1974), and *Traynor* v. *Turnage*, 485 U.S. 535 (1988), to support their argument that Section 405(h) distinguishes between individual claims and more generalized challenges to rules and regulations. None of the statutes in those cases contained a sweeping preclusion provision comparable to the third sentence of Section 405(h).[3] And in each of those cases, this Court relied on the fact that, absent review under 28 U.S.C. 1331, there would have been no mechanism for judicial review of sub-

[3] In *Robison*, 415 U.S. at 367, and *Traynor*, 485 U.S. at 541, the statute barred review of "decisions of the Administrator," and in *McNary* and *Catholic Social Services*, the statute barred "judicial review of a determination respecting an application for adjustment of status," 498 U.S. at 491; 509 U.S. 53, 60. Indeed, in *McNary*, the Court emphasized that the "critical words" of the provision there referred "only to review 'of *a* determination respecting an *application*"—a "single act" respecting an "individual application"—and did not extend to more general challenges to "a group of decisions or a practice or procedure." 498 U.S. at 491-492.

stantial constitutional claims. *Robison*, 415 U.S. at 366-367, 373-374; *Traynor*, 485 U.S. at 542-544; *McNary*, 498 U.S. at 484, 486; *Catholic Soc. Servs.*, 509 U.S. at 63-65.

It was on those very grounds that this Court in *Salfi* distinguished *Robison* and refused to import into Section 405(h) a distinction between individualized claims and broad-based constitutional challenges to the Act itself. Whereas the statute in *Robison* precluded review only of a "decision of the administrator," the Court explained, "[t]he language of § 405(h) is quite different. Its reach is not limited to decisions of the Secretary * * *. Rather, it extends to any 'action' seeking 'to recover on any * * * claim'" arising under the Act. 422 U.S. at 761-762. Moreover, the Court explained, in *Robison* "absolutely no judicial consideration of the issue would be available" if the statute were read as precluding the suit. *Id.* at 762. Here and in *Salfi*, by contrast, Section 405(h) does not "preclude constitutional" challenges, but "simply require[s] that [such challenges] be brought under the jurisdictional grants contained in the" Act itself, "and thus in conformity" with all other "claims arising under the Act." 422 U.S. at 762; Gov't Br. 44-46, 47-48.[4]

This Court's cases establish that a claim "arises under" the Social Security Act within the meaning of Section 405(h) —and review under 28 U.S.C. 1331 is therefore precluded in favor of review through 42 U.S.C. 405(g)—if the Act "provides both the standing and the substantive basis for the presentation" of the plaintiff's contentions. *Salfi*, 422 U.S. at 760-761; *Ringer*, 466 U.S. at 615; *Mathews* v. *Eldridge*, 424 U.S. 319, 327 (1976). Those cases draw no distinction between claims turning on specific facts and legal claims of

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[4] Respondent seems to argue (Br. 24) that Section 405(g) does not permit judicial review of regulations except those relating to the claimant's "burden of proof." That assertion is incorrect. See, *e.g.*, *Califano* v. *Yamasaki*, 442 U.S. 682 (1979) (reviewing, under 42 U.S.C. 405(g), the validity of regulations providing that hearings are available only after an initial "recoupment" determination); *Sullivan* v. *Everhart*, 494 U.S. 83 (1990) (reviewing "netting" regulations under 42 U.S.C. 405(g)).

more systemic import. Indeed, the plaintiffs in *Salfi* represented a class of plaintiffs and sought broad-based relief with respect to general practices. They requested and obtained from the district court declaratory relief and a nationwide injunction against statutory duration-of-relationship requirements alleged to be unconstitutional. 422 U.S. at 754-755. This Court nonetheless held that Section 405(h) precluded them from bringing their challenge under 28 U.S.C. 1331, in circumvention of 42 U.S.C. 405(g). 422 U.S. at 765.[5]

Nor can the distinction proposed by respondent and amici be defended under the theory that "collateral" claims are exempted from 42 U.S.C. 405(h)'s preclusive scope. Resp. Br. 29-30; AMA Br. 24; AAHSA Br. 10; AHCA Br. 10-11. Even if we assume, *arguendo*, that respondent's claims are "collateral" to the merits of enforcement actions that might be brought against its members, this Court has specifically held that "[t]he only avenue for judicial review" of collateral claims "is 42 U.S.C. 405(g)." *Eldridge*, 424 U.S. at 327, 330-332; *Bowen* v. *City of New York*, 476 U.S. 467, 483-486 (1986).[6]

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[5] Respondent suggests that because 42 U.S.C. 405(b)—which, as incorporated into 42 U.S.C. 1395cc(h), provides a right to an administrative hearing—is focused on individualized fact-bound disputes, Section 405(h) should be so read as well. But Congress chose to provide for administrative and judicial review under the special statutory review procedures only in connection with claims arising out of specific enforcement actions precisely to ensure that adjudication would take place in a concrete, factual setting; permitting abstract pre-enforcement challenges in district court outside the special statutory mechanism would defeat that purpose. The text of Section 405(h)'s third sentence, its legislative history, and *Ringer* and *Salfi* are all, in any event, directly contrary to respondent's position. See pp. 2-5, *supra*. Respondent and its amici also argue that 42 U.S.C. 405(b) provides for administrative review only with respect to *monetary* issues (*i.e.*, benefits claims). See Resp. Br. 15-16; AHCA Br. 7. But the review provided by Section 405(b), as incorporated *mutatis mutandis* into the particular aspect of the Medicare program at issue here, cannot be limited to monetary claims, since Section 1395cc(h) gives providers a right to a Section 405(b) hearing on matters that do not involve requests for payment, as respondent concedes (Br. 16, 20).

[6] *Eldridge* and *City of New York* held that collateral claims could be raised through Section 405(g) itself without complete exhaustion because

Finally, the "individual" claim gloss that respondent seeks to place on Section 405(h)'s plain language is implausible. Under respondent's view, providers with the least need for immediate judicial review—those that do not face imminent enforcement proceedings and instead assert only abstract facial challenges—would have immediate access to the courts, while a provider subjected to an enforcement action would have to exhaust administrative remedies. See Gov't Br. 43. Respondent's construction also defeats the purposes of the statutory design. By requiring claims to arise in the concrete factual setting of a specific enforcement action, the Act ensures that controversies are of manageable proportions, that constitutional issues can be avoided if possible, and that judicial review does not prematurely or unduly interfere with this important federal program. It is precisely such an unmanageable broadside attack—a suit that demands constitutional adjudication in the abstract and that requests a broad injunction against the use of the very remedies Congress found to be essential to enforcement of Medicare's health, safety, and quality-of-care regulations—that respondent has brought here. See Gov't Br. 26-28.[7]

Section 405(g)'s requirement of a "final" decision—like the "final decision" requirement of 28 U.S.C. 1291—permits immediate review of collateral legal issues in exceptional circumstances once a claim has been presented to the Secretary. See Gov't Br. 46-47 n.26; cf. *Cohen* v. *Beneficial Indus. Loan Corp.*, 337 U.S. 541 (1949). In *Eldridge* and *City of New York*, moreover, the Court held that a collateral issue can be raised under 42 U.S.C. 405(g) without complete exhaustion only if (1) a claim has been presented to the Secretary, and (2) relief on the collateral issue could not be afforded after exhaustion. 424 U.S. at 331-332; 476 U.S. at 483. If respondent were correct that claims can be brought under 28 U.S.C. 1331 merely because they are in some sense "collateral"—without presentment to the Secretary and without a showing of irreparable injury—then those requirements would be superfluous.

[7] Respondent's argument (Br. 21-22) that the Declaratory Judgment Act, 28 U.S.C. 2201, and the Administrative Procedure Act, 5 U.S.C. 702-704, authorize suit under 28 U.S.C. 1331 is also unavailing. The Declaratory Judgment Act creates a remedy; it is not an independent jurisdictional grant. *Skelly Oil Co.* v. *Phillips Petroleum Co.*, 339 U.S. 667, 671

B. In the end, respondent and its amici rely primarily not on the text of Section 405(h) but rather on *Michigan Academy*, which they construe as creating an across-the-board distinction between "amount claims," to which Section 405(h) concededly applies, and "methodology claims," to which it allegedly does not. See Resp. Br. 33-40; AMA Br. 12-21, 24-30. But they do not dispute that *Michigan Academy* expressly declined to provide a generalized construction of Section 405(h), see 476 U.S. at 680, or that the two alternative constructions it did identify both would bar respondent's extra-statutory pre-enforcement suit. Gov't Br. 38. Respondent and amici likewise do not dispute that the Court in *Michigan Academy* derived its "amount/methodology" distinction from the language of 42 U.S.C. 1395ff(b)(1), a provision that is not applicable here, and that the provision that is applicable in this case, 42 U.S.C. 1395cc(h), does not support that distinction and has nothing to do with "amount" claims in any event. Gov't Br. 33.

More fundamentally, respondent and its amici do not dispute that *Michigan Academy* relied heavily on the presumption that Congress intends judicial review to be available in some manner—and the canon that statutes should be construed to avoid serious constitutional questions—because, absent review under 28 U.S.C. 1331, the Secretary's interpretation of Part B payment obligations would have been absolutely unreviewable. Gov't Br. 31-32. Nor, finally, do

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(1950). It therefore cannot create jurisdiction under 28 U.S.C. 1331 where 42 U.S.C. 405(h) withdraws it, and the Court in *Ringer* specifically rejected the contention that a declaratory judgment action can be used to circumvent the special statutory review procedure in Section 405(g). See 466 U.S. at 621-622. Likewise, the APA does not create subject-matter jurisdiction; it merely creates a cause of action. *Califano* v. *Sanders*, 430 U.S. 99, 106 (1977). Moreover, that cause of action is unavailable on its own terms where, as here, Congress has provided a "special statutory review proceeding relevant to the subject matter" if that mechanism is adequate. 5 U.S.C. 703; Gov't Br. 25-26. Here, the special statutory mechanism—quite aside from being rendered exclusive by the Medicare Act itself, 42 U.S.C. 405(h)—is fully adequate. See pp. 14-20, *infra.*

they dispute that the Court relied extensively on legislative history indicating that Congress did not intend to foreclose judicial review altogether. *Id.* at 32-33. Since the question here is not the *reviewability* of the Secretary's regulations and policies but rather its *timing*, neither the rules of construction nor the legislative history on which *Michigan Academy* relied applies to this case. 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); Gov't Br. 31-34 (additional cases).

For that reason, respondent and its amici's reliance on selective quotes from *Michigan Academy* is unavailing. Respondent, for example, relies on *Michigan Academy*'s observation that "[t]he legislative history * * * provides specific evidence of Congress' intent to foreclose review only of 'amount determinations'—*i.e.*, those 'quite minor matters,' remitted finally and exclusively to adjudication by private insurance carriers in a 'fair hearing,'" and the statement that "matters which Congress did not delegate to private carriers, such as challenges to the validity of the Secretary's instructions and regulations, are cognizable in courts of law." Resp. Br. 35-36. But again, the question here is not whether Section 405(h) "foreclose[s]" such challenges altogether. It is whether Congress, by providing for review through 42 U.S.C. 405(g), and barring recourse to alternative mechanisms through 42 U.S.C. 405(h), required challenges to rules and policies to be routed through the express statutory mechanism for administrative and judicial review.[8] *Ringer*

[8] Citing this Court's statement that "matters which Congress did not leave to be determined in a 'fair hearing' conducted by the carrier—including challenges to the validity of the Secretary's instructions and regulations—are not impliedly insulated from judicial review by 42 U.S.C. 1395ff," respondent also argues that *Michigan Academy* makes judicial review available under 28 U.S.C. 1331 for any issue that an ALJ would not address under 42 U.S.C. 405(b). Resp. Br. 35. That result would be flatly inconsistent with *Salfi*, where the Court held that a challenge to the constitutionality of the Act, which could not be resolved by an ALJ,

squarely held that it did. See p. 2, *supra*.[9] Simply put, Congress paired Section 405(g) with Section 405(h) for the obvious purpose of excluding through the latter, at a minimum, those claims that could be raised under the former. Since claims like respondent's—unlike the claims at issue in *Michigan Academy* when that case was decided—can be raised under Section 405(g), Section 405(h) precludes their assertion here.

2. The amount/methodology distinction drawn by *Michigan Academy* in any event has been superseded by statute even in the specific context in which that case arose. In 1986, shortly after *Michigan Academy* was decided, Congress amended 42 U.S.C. 1395ff to provide an express mechanism by which providers can challenge Part B reimbursement determinations in court, and thereby raise their Part B "methodology" claims as well. Since then, the courts of appeals have unanimously agreed that *Michigan Academy*'s holding that "methodology" claims can be raised outside of express statutory mechanisms has been superseded. Gov't Br. 36-37.[10] The legislative history of the 1986 amend-

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nevertheless had to be brought under Section 405(g). See 422 U.S. at 760-764. Read in context, the sentence respondent quotes from *Michigan Academy* merely states that Congress, by omitting any special mechanism by which Part B "methodology" claims could be asserted first in an administrative forum and *then* in court, had not clearly indicated its intent to foreclose judicial review of such claims altogether. The Court was not addressing the very different question of whether, when Congress *does* provide for administrative and then judicial review, Section 405(h) renders that mechanism exclusive.

[9] As the District of Columbia Circuit has observed, a broad construction of *Michigan Academy* like respondent's would "require a decision that *Michigan Academy* either overruled *Ringer* * * * or assumed that it was only an 'amount' case, not a methodology dispute. The latter would be a stretch, however, as *Ringer* revolved around the legality of the Secretary's policy statement expressing her *generic* approach to BCBR * * * operations." *National Kidney Patients Ass'n*, 958 F.2d at 1132.

[10] The AMA (Br. 20) and respondent (Br. 38) point out that Congress did not amend 42 U.S.C. 1395ii, or 42 U.S.C. 405(h), in 1986. As the AMA recognizes (Br. 14-15), in *Michigan Academy* this Court construed the scope of 42 U.S.C. 1395ii and 405(h) in light of 42 U.S.C. 1395ff, reading

ment, which explains that it was designed to bring review of Part B claims into line with review of Part A claims, H.R. Rep. No. 727, 99th Cong., 2d Sess. 95 (1986), supports that conclusion; the courts of appeals (like this Court in *Ringer*) have long recognized that, with respect to Part A claims, the Medicare Act's special review mechanism is exclusive.[11]

Respondent and its amici seek to bolster their argument that *Michigan Academy* has continuing vitality with respect

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them as not foreclosing review when neither Section 1395ff nor any other provision of the Act provided a mechanism for review. Congress has since amended Section 1395ff to provide for judicial review of Part B claims, thereby rendering inapplicable to Part B "methodology" claims the limitation on the reach of Section 405(h) and 1395ii the Court identified in *Michigan Academy*. When Congress amends one set of provisions, the effect of related statutory provisions may be altered as well. See, *e.g.*, *Clark* v. *Uebersee Finanz-Korporation, A.G.*, 332 U.S. 480, 489 (1947). Respondent likewise errs in asserting (Br. 37-38) that *Michigan Academy* must still be good law because this Court has cited it for various propositions—in non-Medicare cases—since the 1986 amendment. This Court often cites a prior case for a particular principle even after the statute that case interpreted has been amended in a way that may overturn the specific result reached. See, *e.g.*, *McKennon* v. *Nashville Banner Publ'g Co.*, 513 U.S. 352, 360-361 (1995) (citing *Price Waterhouse* v. *Hopkins*, 490 U.S. 228 (1989), even though it was superseded by statute, see *Landgraf* v. *USI Film Prod.*, 511 U.S. 244, 251 (1994)); *Seminole Tribe* v. *Florida*, 517 U.S. 44, 54 n.7, 55-56 (1996) (citing *Atascadero State Hosp.* v. *Scanlon*, 473 U.S. 234 (1985), even though the statute was amended in response to *Atascadero*, see *Lane* v. *Peña*, 518 U.S. 187, 198 (1996)).

[11] See *National Kidney Patients*, 958 F.2d at 1132; *St. Francis Med. Ctr.* v. *Shalala*, 32 F.3d 805, 812-813 (3d Cir. 1994), cert. denied, 514 U.S. 1016 (1995); *Westchester Mgm't Corp.* v. *HHS*, 948 F.2d 279, 282 (6th Cir. 1991), cert. denied, 504 U.S. 909 (1992). Notwithstanding those decisions, amicus AMA contends (Br. 13 & n.9, 22) that *Michigan Academy* permits both Part A and Part B "methodology" claims to be asserted under 28 U.S.C. 1331. That argument is foreclosed by *Ringer* insofar as Part A is concerned. Moreover, the AMA cites not one decision that so concludes under Part A, and never explains how the reasoning of *Michigan Academy*—which rests almost solely on the fact that review of Part B methodology claims would have been entirely unavailable absent review under 28 U.S.C. 1331, see 476 U.S. at 670-674, 678-681—could be applicable to Part A methodology claims, which could always be raised in the context of a specific reimbursement determination.

to Part B "methodology" challenges by quoting Representative Wyden's assertion that the 1986 amendment "strengthens the rights established by * * * Bowen versus Michigan Academy." Resp. Br. 38 (quoting 132 Cong. Rec. 32,978 (1986)). But that isolated statement does not support respondent's position.[12] Even though the 1986 amendment superseded *Michigan Academy*'s specific holding that Part B methodology challenges may be brought under 28 U.S.C. 1331, it strengthened the right to insist on a proper methodology by establishing a special (and exclusive) statutory mechanism by which physicians can challenge the individual reimbursement decisions in which the Secretary applies her methodology. Under *Michigan Academy*, in contrast, physicians could not challenge individual determinations, and thus could not avoid losses from even a wholly unlawful methodology except by obtaining a declaratory judgment before the Secretary actually applied that methodology.

Finally, respondent's argument that the 1986 amendment codifies the specific holding in *Michigan Academy* cannot be reconciled with the fact that identical changes were proposed in 1985, before *Michigan Academy* was decided. Nor can it be reconciled with the fact that, when those changes were proposed in 1985, Congress clearly understood that the new mechanism for review would be exclusive. Indeed, the amendment's proponents justified it by explaining that, absent the legislation, no review would be available at all.[13]

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[12] Such an isolated floor statement is entitled to little weight, *Weinberger* v. *Rossi*, 456 U.S. 25, 35 n.15 (1982), especially where (as here) the statement was inserted into the Congressional Record after the fact, see 132 Cong. Rec. at 32,707 (1986) (explaining significance of typeface); Congressional Quarterly, *How Congress Works* 101 (3d ed. 1998). See *Gustafson* v. *Alloyd Co.*, 513 U.S. 561, 580 (1995).

[13] See 131 Cong. Rec. 22,274, 22,275 (1985) (bill necessary to provide "judicial review of claims disputed by Medicare's beneficiaries," and "to guarantee * * * due process"); *id.* at 22,275 (bill necessary because "[f]or Part B beneficiaries, as well as providers, the Medicare statute and recent court decisions have effectively precluded judicial review of part B programs and claims"); *ibid.* (reform necessary because total preclusion of

C. Finally, abandoning the rationale of the court of appeals, respondent and its amici argue that the specific statutory mechanisms for review established by the Medicare Act are inadequate. But Congress, in establishing those mechanisms and rendering them exclusive, deemed them adequate under the vast Medicare program, and courts may not carve out exceptions to that statutory arrangement based on their own assessments of adequacy. In any event, respondent's and amici's complaints are without merit.

1. AAHSA asserts (Br. 16, 19) that Section 1395cc(h) provides no right to review at all except "in the limited instances where a provider has been terminated or excluded from the Medicare program, or assessed a [civil money penalty]." See also Resp. Br. 27. That assertion is incorrect. See Gov't Br. 5. Section 1395cc(h) provides for review where a provider is "dissatisfied" with a determination that the provider is "not a provider of services," such as where the Secretary decides to terminate it from Medicare, "or with a determination described in subsection (b)(2)." Subsection (b)(2) in turn describes several types of determinations, including a "determin[ation] 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." 42 U.S.C. 1395cc(b)(2). Section 1395cc(h) thus permits review not only when the provider is terminated or excluded from the program, but also when (because some other remedy is imposed) it is dissatisfied with a finding that it is not in substantial compliance with its provider agreement, the Act, or the Secretary's regulations.[14]

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review is potentially unconstitutional); *id.* at 17,232, 17,244 (bill would permit judicial review of Part B claims).

[14] AAHSA's contention that review is available only when a termination occurs also renders Section 1395cc(h)'s reference to "determinations described in subsection (b)(2)" mere surplusage, because Section 1395cc(h), even absent that reference, makes any decision to terminate a provider reviewable as a determination that the institution "is not a provider of services." See also Gov't Br. 5 n.4 (noting that phrase "not a provider of services" can be construed to include findings of non-

Respondent admits (Br. 7) that Section 1395cc(h) provides for administrative and judicial review of any finding of noncompliance where a remedy is imposed. See also AHA Br. 10. But it argues that review should be permitted under 28 U.S.C. 1331 because ALJs cannot rule on challenges to the Secretary's regulations and therefore would not develop a factual record, and because judicial review under 42 U.S.C. 405(g) is limited to the administrative record. See Resp. Br. 23-26; AHCA Br. 12, 15. That argument is without merit. First, facial challenges to regulations generally do not require a factual record beyond what was developed in the rulemaking proceeding, and an as applied challenge generally can be resolved on the basis of the administrative record. Second, although ALJs are bound by the Secretary's regulations and ought not rule on their validity, nothing precludes ALJs from accepting proffers of evidence relevant to such challenges in appropriate circumstances. Cf. 42 C.F.R. 498.61 (ALJ not bound by rules of evidence, including relevance). Third, district courts can "at any time" remand a case with an inadequate record and "order additional evidence to be taken." 42 U.S.C. 405(g); see *Sullivan* v. *Hudson*, 490 U.S. 877, 885 (1989). Fourth, it is well settled in administrative law generally that, if agency processes do not permit necessary record development for substantial constitutional claims, the district court may allow the parties to supplement the record.[15] Section 405(g) should not be construed to depart from that approach where constitutional

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compliance). The Secretary's construction of the hearing right provided by Section 1395cc(h) is entitled to deference. See, *e.g.*, *Your Home Visiting Nurse Servs.* v. *Shalala*, 119 S. Ct. 930, 933-934 (1999).

[15] *American Trucking Ass'n* v. *United States*, 344 U.S. 298, 320 (1953) (The "right to introduce evidence to support the [constitutional] claim * * * may be enforced in the District Court, if the Commission bars an opportunity to do so."); cf. *Citizens to Preserve Overton Park, Inc.* v. *Volpe*, 401 U.S. 402, 415 (1971) (under APA, "there may be independent judicial factfinding" in adjudicatory actions when "agency factfinding procedures are inadequate" and "when issues that were not before the agency are raised in a proceeding to enforce nonadjudicatory action.").

claims are raised. Cf. *City of New York*, 476 U.S. at 473-474, 478 (noting district court trial on unique "secret policy" issue in suit under 42 U.S.C. 405(g)).[16]

Respondent complains that, because 42 U.S.C. 1395cc(h) provides for review only in the context of actual noncompliance findings, associational plaintiffs like respondent—which do not operate nursing homes and thus are not subject to noncompliance findings—cannot seek judicial review in their own right. Resp. Br. 32-33; AMA Br. 28-30. Because respondent's standing derives from and extends no further than that of its members, and because its members have an adequate remedy under 42 U.S.C. 1395cc(h), the fact that respondent cannot sue under that provision causes it no legally cognizable injury.[17] Respondent, moreover, can raise its issues in court by participating as amicus when one of its members seeks judicial review, and it can facilitate review by assuming a member's litigation costs.

2. Respondent's and amici's remaining arguments are directed not at the adequacy of the *statutory* review mecha-

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[16] In *McNary*, relied upon by respondent (Br. 25-26; see AHCA Br. 12), the record could not be developed in district court because judicial review was directed to the courts of appeals, 498 U.S. at 497. AHCA attempts (Br. 15) to make this case more like *McNary* by noting that review of civil money penalties is directly in the court of appeals. The scope of administrative review in the context of civil money penalties, however, is broader than in other contexts, 42 C.F.R. 498.3(b)(13), 488.438(e) and (f); p. 20, *infra*, and the statutory provision governing such appeals, 42 U.S.C. 1320a-7a(e) (as incorporated by 42 U.S.C. 1395i-3h(2)(B)(ii)), provides for remands for factfinding under appropriate conditions.

[17] For the same reason, respondent (Br. 33) and its amici (AAHSA Br. 2-4, 26-27) err in relying on *Nader* v. *Alleghany Airlines, Inc.*, 426 U.S. 290, 302 (1976), *Rosado* v. *Wyman*, 397 U.S. 396, 406 (1970), and *Estate of Smith* v. *Heckler*, 747 F.2d 583 (10th Cir. 1984). None of those cases held that an association that has no interests other than those of its members can bring suit outside of an otherwise exclusive statutory review procedure where that procedure provides the association's members with a way to obtain judicial review. To the contrary, in those cases, the statute provided neither the members nor a relevant association with an express mechanism for seeking review; the question therefore was whether Congress intended to bar review altogether.

nisms, but rather at the Secretary's implementation. In essence, they argue that the Secretary's regulations restrict the scope and availability of administrative review under 42 U.S.C. 1395cc(h) in a manner that renders it inadequate as a practical matter. See Resp. Br. 26-27; AAHSA Br. 16-25; AHCA Br. 14-27. Those contentions, however, can be raised on judicial review under 42 U.S.C. 405(g), as incorporated into 42 U.S.C. 1395cc(h). See, *e.g.*, *Eldridge*, *supra* (challenging regulations that did not provide a pre-deprivation hearing); *Califano* v. *Yamasaki*, 442 U.S. 682 (1979) (similar). And precisely those claims have been raised under 42 U.S.C. 405(g) in the context of specific enforcement actions. See, *e.g.*, *Rafael Convalescent Hosp.* v. *Shalala*, No. C-97-1967 FMS, 1998 WL 196469 (N.D. Cal. Apr. 15, 1998) (due process, vagueness, and APA challenges to regulations); *Beverly Health & Rehab. Serv.* v. *Shalala*, No. 99-09012 (N.D. Cal. complaint filed Sept. 3, 1999) (similar). Thus, far from justifying bypass of the special statutory mechanism for administrative and judicial review, respondent's and amici's attack on the regulations is precisely the sort of challenge that should be raised under that mechanism.

The claims of inadequacy are, in any event, without merit. Respondent and its amici complain that the Secretary's regulations do not provide for administrative review unless a remedy is imposed, 42 C.F.R. 498.3(b)(12), and that the Secretary ordinarily rescinds proposed remedies if a noncomplying provider files a plan of correction and cures the violation within a specified period of time. According to respondent and its amici, the Secretary's practice of requiring them to correct their violations immediately, and not providing for an appeal if, in light of the immediate correction, no remedy is imposed, "coerces" them into surrendering their right to administrative review. Resp. Br. 26-27; AAHSA Br. 17-18; AHCA Br. 17.

It is hard to see how the Secretary's decision *not* to impose penalties on a provider in a particular instance—*i.e.*, giving the provider a chance to correct deficiencies before

imposing remedies—could be a basis for complaint. The Secretary could impose remedies in all cases of noncompliance without providing an opportunity to correct (with the incidental effect of permitting immediate appeal of every noncompliance finding). But a practice of imposing penalties for all violations without opportunity for correction would not make nursing homes and other providers better off.

Nor do the Secretary's regulations "coerce" providers into surrendering their appeal rights. Although amici are correct that nursing homes face the possibility of termination if they fail to submit a voluntary plan of correction and correct the deficiencies, AHCA Br. 17-19; AAHSA Br. 17-18, 22, see also 42 C.F.R. 488.456(b)(ii), terminations from the program are rare and generally reserved for the most egregious recidivist institutions. HHS has informed us that, between July 1995 and June 1996, only 25 of 13,166 nursing homes were terminated. More important, providers are not penalized for preserving their appeal rights. The remedy imposed on a facility that fails to submit a plan of correction or to correct a deficiency—and appeals the deficiency—is no different than the remedy the Secretary ordinarily would impose in the first instance, upon identifying the deficiency, if the Secretary did not give the facility an intervening opportunity to correct. Facilities thus do not face termination for failing to correct or submit a plan of correction in order to preserve their appeal rights; they face termination for noncompliance, and then only if the noncompliance is sufficiently dangerous to patient health to warrant that remedy.

Amici also argue that the regulations—by not providing for appeal of deficiency findings if the deficiencies are corrected and no remedy is imposed—cause providers to suffer more severe penalties in later enforcement actions based on findings that are unreviewable. AHCA Br. 19-21; AAHSA Br. 18, 22. The very administrative decisions they cite, however, refute that contention. In *Fort Tryon Nursing Home* v. *HCFA*, DAB No. CR425, 1996 WL 385660 (HHS July 3, 1996), for example, the Department Appeals Board ex-

plained that, although the challenged deficiency was not subject to administrative review because no remedy had been imposed, if HCFA later "determined to impose a remedy based on the finding of a new deficiency coupled with [the provider's] past compliance record, including the finding of deficiency on which [the provider] bases its current hearing request, then [the provider] would have a right to a hearing, *both* as to the existence of the new deficiency *and* as to the existence of the deficiency which is at issue here." (Emphasis added).[18]

Finally, AHCA complains (Br. 23) that the agency's characterization of the scope and severity of violations, and the agency's exercise of discretion in selecting remedies, are not subject to administrative review. But it does not deny that those issues are subject to *judicial* review. See Gov't Br. 48-49 n.27. See also *Thunder Basin Coal Co.* v. *Reich*, 510 U.S. 200, 215 (1994) (review mechanism exclusive "[e]ven if" the agency would not adjudicate certain claims, if those issues would "be meaningfully addressed" on judicial review). Moreover, the *factual* predicates for the scope and severity characterizations *are* within the scope of administrative review; only review of the characterization itself, divorced from the facts underlying it, is sometimes excluded from the hearing. See, *e.g.*, *Beverly Health & Rehab. Springhill* v. *HCFA*, DAB No. CR553, 1998 WL 839612 (HHS Oct.

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[18] Accord *Baltic Country Manor* v. *HCFA*, [1986-1987 Transfer Binder] Medicare & Medicaid Guide (CCH) ¶¶ 45,038, at 52,578 (Dec. 11, 1996) (to the extent HCFA bases civil money penalty amount on earlier noncompliance, provider can "contradict or make more accurate any history of noncompliance"). AAHSA also complains (Br. 17, 18) about the Secretary's general policy of imposing sanctions immediately on so-called poor-performing facilities without offering them an opportunity to correct. But the decision to proceed with enforcement actions against such facilities immediately, and to permit others to correct their mistakes without imposing a remedy, is a wholly legitimate (and essentially unreviewable) exercise of enforcement discretion. See *Heckler* v. *Chaney*, 470 U.S. 821, 830 (1985); cf. *Reno* v. *American-Arab Anti-Discrimination Committee*, 119 S. Ct. 936, 945 (1999).

27, 1998). And the characterizations of scope and severity *are* subject to administrative review if a successful challenge would alter the range of permissible remedies, such as where the provider claims that its performance constituted substantial compliance (in which case *no* remedy can be imposed).[19] Where civil money penalties are imposed, ALJs can consider the appropriateness of the penalty amount in light of the number and nature of the violations, even if the characterization of scope and severity is not itself reviewable. 42 C.F.R. 498.3(b)(13), 488.38(e)-(f).[20]

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For the foregoing reasons and those stated in the opening brief, the judgment of the court of appeals should be reversed.

SETH P. WAXMAN
Solicitor General

SEPTEMBER 1999

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[19] See 42 C.F.R. 498.3(d)(10)(ii) (barring review of characterization of "level of noncompliance"), 488.301 (defining "noncompliance" as the condition of not being in "substantial compliance).

[20] Amici also complain that, where deficiencies are found, the statute requires them to post the deficiencies in a public location, and the deficiencies are listed on HCFA's website, even if they are not subject to administrative review. AAHSA Br. 22; AHCA Br. 17-18. But nothing prevents providers from posting their responses as well. Moreover, if a provider truly wishes to contest the finding, it can avoid taking actions that will cause the Secretary to forbear enforcement, and challenge the finding through administrative review. Finally, if a provider believes that the Constitution or the Act requires administrative review where the only effect of the finding is informational, it can raise that claim under 42 U.S.C. 405(g). See p. 17, *supra*. Although respondent and its amici complain about administrative delay, the agency has an active process of adjudicating the most serious cases first, and claims of inordinate delay can, under appropriate circumstances, be raised under 42 U.S.C. 405(g) as well. See *Heckler* v. *Day*, 467 U.S. 104, 110 n.14 (1984).