No. 00-558

In the Supreme Court of the United States

DONNA E. SHALALA, SECRETARY,
HEALTH AND HUMAN SERVICES, PETITIONER

v.

OHA: THE ASSOCIATION FOR HOSPITALS
AND HEALTH SYSTEMS, ET AL.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SIXTH CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

Whether 42 U.S.C. 405(h), as incorporated by 42 U.S.C. 1395ii into the Medicare Act, 42 U.S.C. 1395 *et seq.*, bars respondents from seeking declaratory relief in a federal district court under the general federal question statute, 28 U.S.C. 1331, to challenge the validity of the Secretary of Health and Human Services' purported billing policies for certain diagnostic tests.

PARTIES TO THE PROCEEDINGS

The petitioner is Donna E. Shalala, Secretary, Health and Human Services. The respondents are two organizations, OHA: The Association for Hospitals and Health Systems,* and the American Hospital Association.

* At the time that this litigation was commenced, OHA was known as the "Ohio Hospital Association."

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PETITION FOR A WRIT OF CERTIORARI

The Solicitor General, on behalf of Donna E. Shalala, Secretary of Health and Human Services, respectfully petitions for a writ of certiorari to review the judgment of the United States Court of Appeals for the Sixth Circuit in this case.

OPINIONS BELOW

The opinion of the court of appeals (App., *infra*, 1a-16a) is reported at 201 F.3d 418. The opinion of the district court (App., *infra*, 17a-34a) is reported at 978 F. Supp. 735.

JURISDICTION

The judgment of the court of appeals was entered on December 29, 1999. A petition for rehearing was denied on May 11, 2000. App., *infra*, 35a-36a. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATUTORY PROVISIONS INVOLVED

Pertinent statutory provisions are set forth in the appendix to this petition. See App., *infra*, 37a-43a.

STATEMENT

This case involves the Health Insurance for the Aged Act, commonly known as the Medicare Act, Pub. L. No. 89-97, Tit. I, 79 Stat. 290, codified as amended, 42 U.S.C. 1395 *et seq.* Part B of Medicare is a voluntary supplemental insurance program that covers certain physician's charges and other medical services, including outpatient diagnostic laboratory services. 42 U.S.C. 1395j to 1395w-4, 1395x(s) (1994 & Supp. IV 1998). Under Part B, the Health Care Financing Administration (HCFA) pays for such care and related services if they are provided by a hospital or provider that has entered into a "provider agreement" with the Secretary. 42 U.S.C. 1395d(a), 1395x(u), 1395cc (1994 & Supp. IV 1998); 42 C.F.R. 400.202.[1]

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[1] Medicare Part A provides insurance for inpatient hospital and post-hospital services, 42 U.S.C. 1395x(m) (1994 & Supp. IV 1998), including skilled nursing care, 42 U.S.C. 1395f(b)(1), 1395x(v)(1)(A); 1395i-3 (1994 & Supp. IV 1998). The recently enacted Part C of Medicare authorizes beneficiaries to obtain Medicare services through Health Maintenance Organizations and other "managed care" arrangements. Balanced Budget Act of 1997, Pub. L. No. 105-33, Tit. IV, Subtit. A, Ch. 1, § 4001, 111 Stat. 275-327.

1. The Medicare Act provides a statutory system for processing Part B claims for payment. Under the Act, claims are processed in the first instance by private insurance companies—called "carrier[s]" or "fiscal intermediar[ies]"—that act as agents for the Secretary. 42 U.S.C. 1395h(a), 1395u(a); 42 C.F.R. 421.5(c). Hospitals are generally required to submit reimbursement claims on behalf of Part B beneficiaries, including claims relating to outpatient laboratory tests, using the appropriate billing codes from the American Medical Association Physicians' Current Procedural Terminology (CPT) Guide. See App., *infra*, 8a, 19a. The fiscal intermediaries in turn provide reimbursement for laboratory services according to a "fee schedule" calculated by the Secretary under a statutory formula. See 42 U.S.C. 1395*l*(h)(1)(A) and (h)(2) (1994 & Supp. IV 1998); 42 U.S.C. 1395*l*(1)(C).[2] A beneficiary or provider dissatisfied with an initial determination regarding reimbursement, whether as to eligibility or amount, is entitled to review of that determination, 42 C.F.R. 405.807-405.812, and a hearing before the fiscal intermediary's hearing officer, 42 C.F.R. 405.822-405.823. An intermediary may, after approving a hospital's claim, reopen the claim to determine whether or

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[2] Certain statutory requirements must be satisfied before an intermediary may pay a claim. No payment may be made for any item or service, including a diagnostic laboratory test, that is not "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." 42 U.S.C. 1395y(a)(1). In addition, payments for "medical and other health services," 42 U.S.C. 1395k(a)(2)(B) (1994 & Supp. IV 1998), including diagnostic laboratory tests, may be made only to qualifying providers, and "only if * * * a physician certifies * * * that * * * such services are or were medically required." 42 U.S.C. 1395n(a)(2)(B).

not an overpayment has been made, and may issue a revised determination to recoup any overpayment. 42 U.S.C. 1395gg(b); 42 C.F.R. 405.841-405.842.

The Social Security Act provides that anyone dissatisfied with an initial determination may seek an administrative hearing as provided 42 U.S.C. 405(b), and may obtain "judicial review" of the agency's "final decision" following such a hearing, 42 U.S.C. 405(g). Expressly incorporating that provision into Medicare, 42 U.S.C. 1395ff(b)(1) provides a system of administrative and then judicial review for Medicare beneficiaries and providers.[3] In particular here, Section 1395ff(b)(1) provides that anyone dissatisfied with the fiscal intermediary's determination (including a determination made on reopening, see 42 C.F.R. 405.842(b)) may seek a hearing before an administrative law judge as provided for in 42 U.S.C. 405(b), so long as the disputed claim or claims exceed a specified amount, see 42 U.S.C. 1395ff(b)(2) (1994 & Supp. IV 1998). See also 20 C.F.R. 404 Subpts. J and R.[4] Section 1395ff(b)(1)(C), in turn, "entitle[s]" any beneficiary or a provider representing a

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[3] Until 1986, Section 1395ff did not provide for judicial review of Part B determinations by insurance carriers concerning the *amount* of payment. Only determinations under Part A, and Part B eligibility determinations, could be the subject of a hearing before an ALJ and judicial review. See *United States* v. *Erika, Inc.*, 456 U.S. 201, 207-208 (1982). In 1986, however, Congress amended Section 1395ff to make the administrative and judicial review provisions of the Social Security Act—*i.e.*, 42 U.S.C. 405(b) and (g)—applicable to both Part A claims and Part B carrier determinations, subject to amount-in-controversy limitations. See Omnibus Budget Reconciliation Act of 1986, Pub. L. No. 99-509, Tit. IX, Pt. 3, § 9341(a)(1)(B), 100 Stat. 2037.

[4] By regulation, the beneficiary or provider is also entitled to review of the ALJ's decision by the agency Appeals Council. 20 C.F.R. 404.967.

beneficiary who was a party to the hearing provided for in 42 U.S.C. 405(b) "to judicial review of the Secretary's *final decision* after such hearing," as provided for in 42 U.S.C. 405(g). See 42 U.S.C. 1395ff(b)(1)(C) (emphasis added).

Section 405(h) of the Social Security Act, incorporated into the Medicare Act by 42 U.S.C. 1395ii, makes that mechanism for judicial review exclusive. It provides, among other things, that "[n]o action against * * * the [Secretary] * * * shall be brought under [28 U.S.C. 1331 or 1346 (1994 & Supp. IV 1998)] to recover on any claim arising under [the Medicare Act]." 42 U.S.C. 405(h).

2. In late 1994, the United States Attorneys' Offices in Ohio began an investigation into whether hospitals in Ohio had submitted fraudulent requests for Medicaid and Medicare reimbursement for certain outpatient laboratory services, in violation of the False Claims Act, 31 U.S.C. 3729.[5] The investigation sought to determine whether providers billed for services that were not reasonable and necessary, or billed twice for a single service. In addition, the investigation focused on a practice known as "unbundling." Because laboratories frequently perform certain diagnostic laboratory tests as a group, Medicare guidelines require that providers bill simultaneously conducted tests as a group, using the "bundled" code representing that group of tests. See App., *infra*, 19a.[6] Because reim-

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[5] Under the False Claims Act, a person who knowingly presents a false or fraudulent claim for payment to an officer or employee of the United States Government is liable to the government for damages and civil penalties. 31 U.S.C. 3729(a)(1).

[6] AMA's CPT guide lists "19 different codes for automated tests that should be 'bundled' together for billing purposes, when performed simultaneously." App., *infra*, 19a.

bursement for bundled tests is lower than if the tests are billed separately, billing a group of tests as a series of individual tests can be used to increase reimbursement. *Ibid.* The United States Attorneys' Offices sent letters to the hospitals being investigated, inviting them to participate in a voluntary self-disclosure program to uncover information that would assist the government in making the relevant prosecutorial determinations and to provide the basis for possible prelitigation settlement negotiations. *Id.* at 5a-6a.

Respondents are non-profit trade associations whose members include hospitals in Ohio that have entered into provider agreements with the Secretary pursuant to the Medicare Act. They brought this action in the United States District Court for the Northern District of Ohio in response to the above-described investigation, seeking declaratory and injunctive relief against the Secretary.[7] According to the complaint, from 1989 to June 1994, hospitals in Ohio customarily "unbundled" the claims they submitted for reimbursement of certain outpatient chemistry tests—that is, the hospitals billed certain tests under individual CPT codes rather than using a group code—and the fiscal intermediary reimbursed the hospitals for those individual tests "without comment or disallowance." App., *infra*, 19a-20a; C.A. App. 12 (Compl. ¶¶ 25, 27). See also App.,

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[7] The investigation involved hospitals in both the Northern and Southern Districts of Ohio. We have been informed by the United States Attorney's Office for the Northern District, where this lawsuit was filed, that the investigation has been concluded and that settlements were reached with 98 hospitals. No court actions were ever filed in connection with those matters. The United States Attorney's Office for the Southern District reports that, of 75 hospitals under investigation, 52 have reached settlements with the government.

infra, 7a-8a. The complaint further alleged that, beginning in June 1995, hospitals in Ohio "were informed through the U.S. Attorney's office that the Secretary has taken the position that at all times since 1989, [the subject tests] were supposed to have been bundled and billed [as a group]." C.A. App. 13 (Compl. ¶ 28); see App., *infra*, 20a-21a.

The complaint alleged that the Secretary's "mandate" that the hospitals bundle certain outpatient laboratory tests was invalid, and was implemented without a rulemaking proceeding in violation of the Medicare Act, 42 U.S.C. 1395hh, and the Administrative Procedure Act (APA), 5 U.S.C. 553. App., *infra*, 29a; C.A. App. 25 (Compl. ¶¶ 83, 85). It further alleged that the Secretary's purported threat to bring charges against the hospitals under the False Claims Act violated the Fifth Amendment, and that the Secretary's "use of the False Claims Act in this manner is contrary to the purpose and intent standard" of that Act. App., *infra*, 24a-25a; C.A. App. 25-26 (Compl. ¶¶ 87-90). Respondents sought an injunction barring the Secretary from "enforcing" her alleged position with respect to appropriate coding and billing for certain outpatient laboratory tests. *Id.* at 26 (Compl., Prayer ¶ E). Respondents also requested a declaratory judgment that the Secretary's "position" with respect to appropriate coding and billing is "incorrect," and a declaration that the "position" was promulgated in violation of the APA's and the Medicare Act's rulemaking provisions. App., *infra*, 29a; C.A. App. 26 (Compl., Prayer ¶¶ A-B).[8]

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[8] Although the investigation targeted providers' reimbursement claims for outpatient laboratory tests under both the Medicaid and Medicare programs, respondents sought relief only with respect to the hospitals' Medicare claims. In addition,

The district court dismissed the complaint for lack of subject matter jurisdiction. App., *infra*, 17a-34a. Addressing respondents' False Claims Act issues first, the district court held that "plaintiffs cannot obtain a judgment declaring that it is, or would be, improper for *the Secretary* to threaten their member hospitals with prosecution under the False Claims Act, as the law is clear that only the Attorney General has the power to pursue a prosecution." *Id.* at 26a. The court further held that it could not enjoin the Attorney General, who was not named as a defendant in the case, with respect to her exercise of prosecutorial discretion under the False Claims Act. *Id.* at 28a-29a.

Turning next to respondents' challenge to the Secretary's alleged billing policies for certain outpatient laboratory tests, the district court explained that the Medicare Act, through 42 U.S.C. 1395ff (1994 & Supp. IV 1998) and 42 U.S.C. 1395ii, incorporates the administrative and judicial review provisions of 42 U.S.C. 405(g) and (h). App., *infra*, 30a. Under Section 405(g), the court explained, judicial review is not available until the matter has been presented to the Secretary and the Secretary has reached a "final decision." *Ibid.* Section 405(h), the court further observed, precludes courts from entertaining any claim "arising under" the Medicare Act based on the general federal question statute,

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although the investigation concerned a wide variety of hospital outpatient laboratory billing practices, the complaint focused on a very limited range of laboratory test billings that respondents aver should not be subject to investigation or prosecution under the False Claims Act. See C.A. App. 9, 24, 29-32 (Compl. ¶¶ 12, 78-82 & Exh. A). Indeed, the panel decision here notes that "plaintiffs have as much as admitted that some reimbursement claims of types not placed in issue here might well have violated the False Claims Act." App., *infra*, 7a.

28 U.S.C. 1331. App., *infra*, 30a. "Thus," the court concluded, "for claims 'arising under' the Medicare Act, the Secretary must reach a 'final decision' before a plaintiff may obtain judicial review." *Ibid.*

The district court further concluded that respondents' claims "arise under" the Medicare Act. App., *infra*, 30a-31a. Under *Heckler* v. *Ringer*, 466 U.S. 602, 615 (1984), and *Weinberger* v. *Salfi*, 422 U.S. 749, 760-761 (1975), the court pointed out, a claim arises under the Medicare Act if "both the standing and the substantive basis for the presentation of the claims is the" Medicare Act. App., *infra*, 30a (internal quotation marks omitted). "In this case," the district court continued, "the standing and substantive basis for [respondents' challenges] is clearly the Medicare Act," as those claims allege that the "Secretary promulgated her billing policies in violation" of the Medicare Act and the APA. *Id.* at 31a. "At bottom," the court further explained, "this is a request for an adjudication of the propriety of past payment of benefits, which *Ringer* holds is a claim that arises under the Medicare Act." *Id.* at 31a-32a. Accordingly, the district court held that it did not "have jurisdiction over [respondents'] claims" under 28 U.S.C. 1331. *Id.* at 32a.[9]

The district court expressly rejected respondents' argument that they have no other avenue of judicial review. App., *infra*, 32a-33a. It explained:

> [T]he hospitals could eventually obtain judicial review by "calling the Secretary's bluff," as follows:

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[9] In light of the district court's conclusion that it lacked subject matter jurisdiction to grant the relief sought by respondents, the court found it unnecessary to address the Secretary's argument that respondents lacked standing to bring suit on behalf of their member hospitals. App., *infra*, 18a n.1.

> (1) refusing to settle to avoid prosecution; (2) presenting their defenses to a False Claims Act lawsuit; and (3) winning that lawsuit based on lack of scienter, as they allege they would. This course of action would force the Secretary to either file an administrative recoupment action, or forego reclamation of her "excessive reimbursements." In the end, the hospitals would either avoid recoupment, or be in a position to obtain judicial review of a recoupment decision, and the policy underlying it.

Id. at 33a.

3. The court of appeals affirmed in part, and reversed and remanded in part. The court of appeals agreed with the district court that only the Attorney General has the discretion and authority to pursue a False Claims Act prosecution. App., *infra*, 15a. And it further agreed that the district court lacked jurisdiction to enjoin a potential prosecution by the Attorney General, who was not named as a defendant in the suit, through an order directed at the Secretary. *Ibid.* Accordingly, the court of appeals affirmed dismissal of the False Claims Act counts of the complaint "for essentially the reasons stated by the district court." *Ibid.*

The court of appeals held, however, that Section 405(h), as incorporated into Medicare by 42 U.S.C. 1395ii, did not preclude the district court from exercising federal question jurisdiction over respondents' statutory and regulatory challenges to the Secretary's purported billing policies. App., *infra*, 8a-14a. The court did not dispute that there is an administrative process through which providers may challenge reimbursement determinations. But it concluded that "[t]he hospitals had no opportunity to invoke these

administrative procedures in connection with the disputes that led to the filing of the instant lawsuit, the Secretary never having taken the type of administrative action from which administrative appeals could be prosecuted." *Id.* at 5a.

The court also distinguished this Court's decisions in *Salfi* and *Ringer*, upon which the Secretary and the district court had relied. App., *infra*, 11a-12a.

> In both *Salfi* and *Ringer*, it is important to understand, individual claimants were seeking a judgment directing the payment of benefits. * * * In the case at bar, by contrast, the plaintiffs are not seeking a judgment directing the payment of benefits. Unlike the plaintiffs in *Salfi* and *Ringer*, neither the plaintiff hospital associations nor the individual hospitals they represent have any remedies under § 405(b). And no judicial remedy is available to them under § 405(g), of course.

Ibid. The court of appeals also concluded that this case resembles *Bowen* v. *Michigan Academy of Family Physicians*, 476 U.S. 667 (1986). App., *infra*, 12a.[10]

The Secretary sought rehearing, citing this Court's decision in *Shalala* v. *Illinois Council on Long Term Care, Inc.*, 120 S. Ct. 1084 (2000), which was decided after the court of appeals issued the decision in this case. The court called for a response, and respondents argued that *Illinois Council* is inapplicable because respondents could not invoke administrative processes.

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[10] The court of appeals declined to address the other jurisdictional arguments (lack of standing and ripeness) urged by the Secretary, preferring to "leave it to the district court to deal with these matters in the first instance on remand." App., *infra*, 16a.

The petition for rehearing was denied. App., *infra*, 35a-36a.

REASONS FOR GRANTING THE PETITION

In *Shalala* v. *Illinois Council on Long Term Care, Inc.*, 120 S. Ct. 1084 (2000), this Court addressed the preclusive scope of 42 U.S.C. 405(h), as incorporated into the Medicare Act by 42 U.S.C. 1395ii. Section 405(h), the Court held, channels virtually all challenges to the Secretary's Medicare policies and regulations—whether or not the challenges concern the "amount" of benefits payable—through the specific judicial review mechanisms provided by the Medicare Act itself, and ordinarily precludes district courts from entertaining pre-enforcement challenges under the general federal question jurisdiction statute, 28 U.S.C. 1331. See 120 S. Ct. at 1092, 1094. In addition, the Court clarified the relationship among its earlier decisions construing Section 405(h), including *Heckler* v. *Ringer*, 466 U.S. 602, 615 (1984); *Weinberger* v. *Salfi*, 422 U.S. 749, 760-761 (1975), and *Bowen* v. *Michigan Academy of Family Physicians*, 476 U.S. 667 (1986). See 120 S. Ct. at 1095-1097. In particular, the Court clarified that the "exception" to Section 405(h)'s preclusive scope recognized in *Michigan Academy* is applicable only if applying Section 405(h) would not merely delay judicial review, but instead would preclude judicial review altogether. *Id.* at 1096-1097.

The court of appeals' decision in this case, which was rendered before *Illinois Council*, addresses the same issues, but reaches a different result. Construing Section 405(h) and this Court's decisions in *Ringer*, *Salfi*, and *Michigan Academy*, the decision appears to hold that Section 405(h) is inapplicable where the case does not concern an "amount" determination. App.,

infra, 11a-12a, 13a. Moreover, the decision relies on *Michigan Academy* to hold that Section 405(h) is inapplicable, without finding that, absent review now, judicial review would be permanently foreclosed. *Id.* at 12a. Because the decision below was issued without benefit of this Court's decision in *Illinois Council*—and because its reasoning and result cannot be reconciled with *Illinois Council*—the petition should be granted, the judgment of the court of appeals vacated, and the case remanded for further consideration in light of *Illinois Council.*

1. The Medicare Act provides a highly "reticulated statutory scheme, which carefully details the forum and limits of review" of the Secretary's determinations. *Michigan Academy*, 476 U.S. at 675. In general, the Social Security Act provides that anyone dissatisfied with an agency determination may seek a hearing as provided 42 U.S.C. 405(b), and may obtain "judicial review" of the agency's "final decision" following such a hearing, 42 U.S.C. 405(g). By incorporating the hearing and judicial review provisions of Section 405(b) and (g) with respect to each of a number of categories of Medicare claims, the Medicare Act channels the claims through administrative processes and provides for judicial review *after* the Secretary has taken final action. Of particular relevance here, the Act accords a beneficiary or other party aggrieved by an individual entitlement or payment determination the right to request an agency hearing, as provided in 42 U.S.C. 405(b), and to seek judicial review of the Secretary's final decision, as provided under 42 U.S.C. 405(g). 42 U.S.C. 1395ff(b)(1).

Congress also provided that, with respect to claims arising under Medicare, those post-enforcement mechanisms for judicial review would be 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 various types of determinations under the Medicare program in 1965, it made Section 405(h) applicable through 42 U.S.C. 1395ii. As incorporated into the Medicare Act, Section 405(h) provides:

> The findings and decision of the [Secretary] after a hearing shall be binding upon all individuals who were parties to such hearing. No findings of fact or decision of the [Secretary] shall be reviewed by any person, tribunal, or governmental agency except as herein provided. No action against the United States, the [Secretary], 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.

42 U.S.C. 405(h). As this Court has observed, "the first two sentences of § 405(h) * * * assure that administrative exhaustion will be required," *Salfi*, 422 U.S. at 757, 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." *Ringer*, 466 U.S. at 614-615.

This Court has addressed Section 405(h)'s preclusive scope on a number of occasions. In *Salfi*, 422 U.S. at 757, the Court addressed whether Section 405(h) precluded a pre-enforcement constitutional challenge to a statutory provision that, if valid, would have denied the plaintiffs the benefits they sought. Although the plaintiffs contended that Section 405(h) did not apply to constitutional challenges, the Court concluded other-

wise. The "sweeping and direct" language of Section 405(h), the Court held, "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. The Court summarized: "[T]he plain words of the third sentence of § 405(h) do not preclude constitutional challenges. They simply require that [such challenges] be brought under jurisdictional grants contained in the Act," *i.e.*, after a final decision of the Secretary, pursuant to 42 U.S.C. 405(g). 422 U.S. at 762.

In *Ringer*, 466 U.S. at 614-615, the Court again concluded Section 405(h) generally makes exclusive the mechanisms for judicial review provided by the Medicare Act itself. In that case, one of the named plaintiffs, Freeman Ringer, sought to challenge an agency rule that precluded reimbursement for an operation he wished to undergo. *Id.* at 621. Because Ringer had not undergone the procedure, he could not file a claim for reimbursement, which was a prerequisite for seeking an administrative hearing under 42 U.S.C. 405(b), and for seeking judicial review under 42 U.S.C. 405(g). 466 U.S. at 621, 623. Accordingly, he brought a pre-enforcement action in district court, requesting a declaratory judgment that the pertinent Medicare regulation was invalid. *Id.* at 621-623. This Court held that the Medicare Act itself, by incorporating 42 U.S.C. 405(g) through 42 U.S.C. 1395ff(b) (1994 & Supp. IV 1998), afforded the exclusive basis for jurisdiction over such a claim, and that federal courts could not exercise jurisdiction under 28 U.S.C. 1331. "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 ex-

clusion 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).

In *Michigan Academy*, however, this Court recognized a limit on Section 405(h)'s preclusive scope. In that case, the plaintiffs sought to challenge the validity of certain Part B reimbursement practices. At that time, however, there was no statutory mechanism for bringing such a challenge under the Medicare Act itself.[11] To the contrary, this Court had construed the Medicare Act, 42 U.S.C. 1395ff(b)(1) (1982 & Supp. II 1984), as precluding judicial review of Part B disputes regarding the "amount" of reimbursement. See *United States* v. *Erika, Inc.*, 456 U.S. 201, 207-208 (1982). Relying on the "strong presumption that Congress did not mean to prohibit all judicial review" of agency policies and regulations, *Michigan Academy*, 476 U.S. at 672, the Court held that—although challenges to individual "amount" determinations were barred—neither the statutory structure nor Section 405(h) precluded the plaintiffs from bringing a challenge to the Secretary's regulations where the Medicare Act provided no alternative mechanism for obtaining judicial review after a final determination. The government, the Court concluded, had not produced the "clear and convincing evidence" needed to overcome the "strong presumption that Congress did not mean to prohibit all judicial review" of Part B payment practices. *Id.* at 681.

The courts of appeals subsequently arrived at somewhat divergent results in construing *Michigan Acad-*

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[11] Congress enacted a judicial review provision for such claims in 1986. See note 3, *supra*.

emy. See *Illinois Council*, 120 S. Ct. at 1091. Accordingly, last Term, in *Illinois Council*, this Court again considered Section 405(h)'s preclusive scope. *Ibid.* In *Illinois Council*, an association representing skilled nursing facilities sought to invalidate certain Medicare regulations and policies as having been promulgated in violation of "the Administrative Procedure Act's demands for 'notice and comment,'" as inconsistent with the Medicare Act, and as a denial of due process. *Id.* at 1090. The Seventh Circuit in *Illinois Council* acknowledged that "*Ringer* and *Salfi* treat [Section 405(h)'s] language as channeling all claims to benefits through the administrative forum, no matter what legal theory underlies the claim." 143 F.3d 1072, 1075 (7th Cir. 1998). But it read *Michigan Academy* as creating a broad exception to Section 405(h)'s preclusive scope, and to the earlier holdings of *Salfi* and *Ringer* as well. In particular, it read *Michigan Academy* as making Section 405(h) applicable only to Medicare "amount determinations," *i.e.*, "calculations of reimbursements by the fiscal intermediaries." 143 F.3d at 1075.

Reversing, this Court rejected that reading of Section 405(h). Section 405(h), the Court explained, "demands the 'channeling' of virtually all legal attacks through the agency," thereby assuring "the agency greater opportunity to apply, interpret, or revise policies, regulations, or statutes without possibly premature interference by different individual courts." 120 S. Ct. at 1093. After reviewing its decisions in *Salfi* and *Ringer*, the Court further explained that it could not "accept a distinction that limits the scope of § 405(h) to claims for monetary benefits." *Id.* at 1094. Neither the language nor the purposes of Section 405(h), the Court explained, provides any "reason to distinguish among" claims based on whether or not they seek money, and

"Section 1395ii's blanket incorporation of that provision into the Medicare Act as a whole certainly contains no such distinction." *Ibid.* "Nor for similar reasons," the Court concluded, "can we here limit those provisions to claims that involve 'amounts.'" *Ibid.*

The Court also rejected the Seventh Circuit's reading of *Michigan Academy*. The opinion in *Michigan Academy*, the Court explained, does "not limit the scope of § 405(h) itself to instances where a plaintiff, invoking § 1331, seeks review of an 'amount determination.'" 120 S. Ct. at 1095. Instead, the Court observed, *Michigan Academy* construed Section 1395ii as making Section 405(h) applicable except "where its application to a particular category of cases * * * would not lead to a channeling of review through the agency, but would mean no review at all." *Id.* at 1096. The contrary interpretation of *Michigan Academy* would have "overturned or dramatically limited this Court's earlier precedents, such as *Salfi* and *Ringer*," and "would, moreover, have created a hardly justifiable distinction between 'amount determinations' and many other similar HHS determinations." *Ibid.* Further, the Court explained, "we do not understand why Congress * * * would have wanted to compel Medicare patients, but not Medicare providers, to channel their claims through the agency." *Ibid.* Accordingly, the Court concluded, "it is more plausible to read *Michigan Academy* as *holding* that § 1395ii does not apply § 405(h) where application of § 405(h) would not simply channel review through the agency, but would mean no review at all." *Id.* at 1096-1097.

2. The holding and reasoning of *Illinois Council* bear strongly on the proper resolution of this case, which the court of appeals decided before *Illinois Council* was announced. This case, like *Illinois Coun-*

cil, concerns whether Section 405(h) precludes an industry association from bringing an anticipatory declaratory judgment action, under 28 U.S.C. 1331, to invalidate the Secretary's policies and regulations. Compare App., *infra*, 7a-8a, 29a (challenge to Secretary's position on coding as not "properly promulgated" and inconsistent with Medicare Act), with 120 S. Ct. at 1090 (challenge to Secretary's regulations and manual because they allegedly "were not promulgated consistent" with the APA and allegedly "violate statutory requirements"). Moreover, the court of appeals in this case, like the Seventh Circuit in *Illinois Council*, distinguished *Ringer* and *Salfi*, finding this case to be more similar to its understanding of *Michigan Academy*. App., *infra*, 10a-12a.

Illinois Council has now clarified the preclusive scope of Section 405(h), and explains the relationship among *Salfi*, *Ringer*, and *Michigan Academy*. And much of the court of appeals' reasoning—as well as the result it reached—cannot be squared with *Illinois Council*. First, the court of appeals appears to have limited Section 405(h)'s applicability to cases involving benefits or "amount" determinations. It distinguished *Salfi* and *Ringer* on that basis:

> In both *Salfi* and *Ringer*, it is important to understand, individual claimants were seeking a judgment directing the *payment of benefits*. * * * In the case at bar, by contrast, the plaintiffs *are not seeking a judgment directing the payment of benefits*.

App., *infra*, 11a-12a (emphasis added). And the court of appeals further declared that Section 405(h), "viewed within the context in which it was drafted and made applicable to Medicare, simply seeks to preserve the integrity of the administrative process Congress de-

signed to deal with challenges *to amounts determinations*." *Id.* at 13a (internal quotation marks omitted). That analysis cannot be reconciled with *Illinois Council*, which refused to "accept a distinction that limits the scope of § 405(h) to claims for monetary benefits." 120 S. Ct. at 1094. See also *ibid.* ("Nor for similar reasons can we here limit those provisions to claims that involve 'amounts'."); *id.* at 1095 (*Michigan Academy* does "not limit the scope of § 405(h) itself to instances where a plaintiff, invoking § 1331, seeks review of an 'amount determination.' ").[12]

Second, the court of appeals confused the *timing* of judicial review with its *availability*—a distinction that is critical under *Illinois Council.* As *Illinois Council* explains, parties may seek review of statutory or constitutional issues under the general federal question statute, 28 U.S.C. 1331, if applying Section 405(h) to preclude such a course would not merely delay review, but instead "would mean no review at all." 120 S. Ct. at 1097. *Michigan Academy*, the Court further concluded, is to be read "as *holding* that § 1395ii does not apply § 405(h) where application of § 405(h) would not simply

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[12] The court of appeals' decision also suggests that Section 405(h) applies only to Medicare patients, and not to the providers who serve them. See App., *infra*, 12a (Section 405(h) does "not proscribe judicial review . . . where the challenge was made by a party other than a claimant for benefits."). This Court, in *Illinois Council*, rejected that distinction as well. See 120 S. Ct. at 1096 ("[W]e do not understand why Congress * * * would have wanted to compel Medicare patients, but not Medicare providers, to channel their claims through the agency."). Moreover, under the Medicare Act, payment for outpatient diagnostic laboratory tests furnished by a hospital to a Medicare beneficiary may be made "*only* to providers." 42 U.S.C. 1395n(a)(2)(B) (emphasis added).

channel review through the agency, but would mean no review at all." *Id.* at 1096-1097.

In this case, neither the court of appeals nor the district court found that the administrative process would be unavailable to respondents' members if the agency actually applied the challenged policies or regulations to them, whether in an initial determination regarding reimbursement or after re-opening prior payment determinations to recoup overpayments. App., *infra*, 4a. See also pp. 3-5, *supra*. Nor did either court dispute that respondents' members would be able to obtain judicial review of any final agency decision. To the contrary, the district court expressly concluded that respondents members "could eventually obtain judicial review." App., *infra*, 33a.[13] As a result, this is not a case in which invoking Section 405(h) would have the effect of precluding judicial review altogether; instead, it would channel review through the administrative process established by the Medicare Act itself.

Nonetheless, the court of appeals found it significant that the hospitals have not yet had an "opportunity to invoke these administrative procedures in connection with the disputes that led to the filing of the instant lawsuit, the Secretary never having taken the type of administrative action from which administrative appeals could be prosecuted." App., *infra*, 5a. See also App., *infra*, 12a (distinguishing *Salfi* and *Ringer* on the ground that, "[u]nlike the plaintiffs in *Salfi* and *Ringer*, neither the plaintiff hospital associations nor the individual hospitals they represent" currently "have

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[13] Nor did the court dispute that, if a False Claims Act suit were brought against one or more of respondents' members, those members could obtain a judicial determination of the validity of the claims against them in that suit.

any remedies under § 405(b)" or the present ability to seek judicial review under § 405(g)). *Illinois Council*, however, makes it clear that a *current* inability to obtain judicial review through the Medicare Act does not render Section 405(h) inapplicable, so long as judicial review of any adverse administrative decision would be available. Here, judicial review—although deferred until such time as the Secretary actually applies the disputed policies to one of respondents' members in administrative proceedings—eventually would be available, as the district court expressly found.[14]

Indeed, in that respect, this case is identical to *Illinois Council* and *Ringer*. In both of those cases, at least one of the parties seeking immediate review under 28 U.S.C. 1331 could not, at the time the suit was brought, invoke the mechanisms for administrative and judicial review provided by the Medicare Act itself. In *Illinois Council*, for example, the relevant Medicare provision (42 U.S.C. 1395cc (1994 & Supp. IV 1998)) made the right to administrative and then judicial

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[14] Respondents' member hospitals have been paid for the outpatient laboratory tests at issue here, and the hospitals have received no notice of any proposed reopening of any claim for purposes of recoupment of any previously-paid claim. As this Court has held, the Secretary's decision *not to reopen* a reimbursement determination is committed to agency discretion by law. See *Your Home Visiting Nurse Servs., Inc.* v. *Shalala*, 525 U.S. 449 (1999). Thus, to the extent this action is attempting to force the Secretary, in effect, to reopen, it is contrary to *Your Home*. If any recoupment action were taken by the Secretary, respondents would then be entitled to challenge any revised determination that meets the amount-in-controversy requirements through the same administrative process described above, see pp. 3-5, *supra*, followed by judicial review as provided by the Medicare Act. See 42 C.F.R. 405.841-405.842, 405.842(b); 42 U.S.C. 405(g), 1395ii.

review contingent on an initial determination of non-compliance by the Secretary; as a result, the affected providers could not challenge the regulations except by violating them and incurring a sanction, something they were not inclined to do. 120 S. Ct. at 1097 (review available only if facility is "dissatisified . . . with a *determination*" that "the provider fails to comply substantially") (quoting 42 U.S.C. 1395cc(b)(2)(A), 1395cc(h)); *id.* at 1098 (only way to "test the lawfulness of" the regulations was to refuse to comply and incur a sanction). This Court, however, concluded that, because the providers could eventually raise their challenges if the disputed regulations were applied to them, Section 405(h) precluded review.

Similarly, in *Ringer*, judicial review was available only *after* the individual had undergone the medical procedure, submitted a claim for payment, and obtained a final determination from the Secretary. See 466 U.S. at 605, 621. Because one of the plaintiffs, Freeman Ringer, sought to challenge an agency rule that precluded reimbursement for an operation that he had not yet undergone, he had no claim to submit and could not invoke the administrative or judicial process. See *id.* at 621, 623. Indeed, Ringer claimed that, because no physician would perform the operation in light of the Secretary's announced policy of not paying for it, anticipatory judicial review was necessary. *Id.* at 625 (noting contention that there are many "people, like Ringer, who desire some kind of controversial operation but who are unable to have it because their surgeons will not perform the surgery without knowing in advance whether they will be" paid for it). This Court nevertheless held that Section 405(h), as incorporated into Medicare by 42 U.S.C. 1395ii, bars recourse to an anticipatory declaratory judgment action under 28 U.S.C.

1331. 466 U.S. at 622 ("Because Ringer has not given the Secretary an opportunity to rule on a concrete claim for reimbursement, he has not satisfied the nonwaivable exhaustion requirement of § 405(g)," and there also "is no jurisdiction pursuant to § 1331.").

Nowhere did the court of appeals in this case explain why a different result is appropriate here. As this Court explained in *Illinois Council*, the question is whether the hardship asserted by the plaintiff "turns what appears to be simply a channeling requirement into *complete* preclusion of judicial review." 120 S. Ct. at 1098. In *Illinois Council*, "the Council ha[d] not shown anything other than potentially isolated instances of the inconveniences sometimes associated with the postponement of judicial review." *Id.* at 1099. Similarly, in this case, respondents have merely identified the difficulties their member hospitals might face due to a delay of judicial review. Indeed, the only difficulties asserted by respondents relate to potential future suits against one or more of their members under the False Claims Act. But, as the district court pointed out, those difficulties are no different than those faced by any person confronting potential liability under the False Claims Act. App., *infra*, 28a. In addition, because the only hardship respondents identify stems from the possibility of a False Claims Act suit, at bottom their action is an effort attempt to obtain pre-enforcement relief for use in any False Claims Act suit that may eventually be filed. But as the district court and court of appeals agreed, respondents are not entitled to injunctive or declaratory relief against the Secretary for use in a potential False Claims Act prosecution by the Attorney General. App., *infra*, 15a, 27a.

3. Because the court of appeals' decision was decided without the benefit of this Court's decision in *Illinois Council*—and is inconsistent with that decision— this Court should grant the petition, vacate the judgment below, and remand the case for reconsideration in light of *Illinois Council*. The fact that the court of appeals denied the Secretary's petition for rehearing after this Court issued its decision in *Illinois Council* does not make that course any less appropriate. This Court "ha[s] never held lower court briefing to bar [the Court's] review and vacatur where the lower court's order shows no sign of having applied the precedent[] that [was] briefed." *Lawrence* v. *Chater*, 516 U.S. 163, 170 (1996); cf. *Lords Landing Village Condominium Council* v. *Continental Ins. Co.*, 520 U.S. 893, 896-897 (1997) (per curiam) (appeals court's "ambiguous" statement that petitioner's request to stay or recall mandate based on intervening precedent was "without merit" did not establish that court "actually considered and rejected" petitioner's argument concerning intervening precedent). Here, the Sixth Circuit's order denying rehearing does not offer any justification for leaving its decision in place, despite the inconsistency of its reasoning with *Illinois Council*, and it identifies no ground for distinguishing *Illinois Council*. Indeed, the order does not state that the court actually considered the applicability of *Illinois Council* to this case.[15]

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[15] The court of appeals' order suggests that, although the court requested a response to the Secretary's rehearing petition, it did *not* specifically consider this Court's decision in *Illinois Council*. The court's order denying rehearing, which echoes the standard Sixth Circuit language for such orders, states that "the issues raised in the petition were fully considered upon the original submission and decision of the case." App., *infra*, 36a. It is simply not possible that the court of appeals "fully considered" this

Accordingly, an order granting the petition, vacating the judgment below, and remanding the case is proper.

CONCLUSION

The Court should grant the petition for a writ of certiorari, vacate the judgment of the court of appeals, and remand the case to the court of appeals for further consideration in light of *Shalala* v. *Illinois Council on Long Term Care, Inc.*, 120 S. Ct. 1084 (2000).

Respectfully submitted.

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OCTOBER 2000

Court's decision in *Illinois Council* when the case was originally submitted and decided, since *Illinois Council* was announced months after the panel issued its decision.

APPENDIX A

UNITED STATES COURT OF APPEALS
FOR THE SIXTH CIRCUIT

No. 97-4217

OHIO HOSPITAL ASSOCIATION
AND AMERICAN HOSPITAL ASSOCIATION,
PLAINTIFFS—APPELLANTS

v.

DONNA E. SHALALA, SECRETARY OF HEALTH AND
HUMAN SERVICES, DEFENDANT-APPELLEE

[Argued: Oct. 27, 1998
Decided and Filed: Dec. 29, 1999
Rehearing and Suggestion for Rehearing En Banc
Denied May 11, 2000]

BEFORE: NELSON, CLAY, and JOHN R. GIBSON*,
Circuit Judges.

OPINION

DAVID A. NELSON, Circuit Judge.

Employing tactics that the district court characterized as "heavy-handed," the Secretary of Health and Human Services has threatened a number of Ohio

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* The Honorable John Gibson, Circuit Judge of the United States Court of Appeals for the Eighth Circuit, sitting by designation.

hospitals with draconian penalties under the False Claims Act if the hospitals do not disgorge double the amount of alleged overpayments received under the Medicare program for performing certain outpatient laboratory tests.

The hospitals contend that at the time they submitted reimbursement claims for the tests in question, the billing standards by which they routinely measured the amount of their claims were consistent with the rules and regulations of the Department of Health and Human Services. After several years in which the hospitals' billing standards are said to have been tacitly approved by the Secretary, however, the Secretary changed her mind as to the propriety of these standards.

The Secretary has never initiated a rulemaking proceeding under the Administrative Procedure Act to formalize the billing standards she now espouses. Neither has she initiated administrative proceedings to recoup the alleged overpayments. Instead, as part of a sweeping investigation called the "Ohio Hospital Project," the Secretary has allegedly used the Federal Bureau of Investigation and other elements of the Department of Justice to coerce the hospitals into retroactively accepting revised standards and paying the Secretary large sums of money under threat of having to pay much more if the hospitals decline to enter into settlement agreements on the Secretary's terms.

Unwilling to settle on terms they considered unjust, and threatened with False Claims Act litigation entailing risks they considered unacceptable, the hospitals,

through trade associations of which they are members, brought the present declaratory judgment action against the Secretary. The plaintiffs sought a judicial determination as to the legality of the billing standards in question and of the Secretary's alleged misuse of the False Claims Act.

The Secretary moved for dismissal on jurisdictional grounds. Among other things, she contended that

— she is not subject to suit for her alleged misuse of the False Claims Act because, as between the Secretary and the Attorney General, discretion to sue under the Act is vested solely in the Attorney General, and

— jurisdiction to grant declaratory relief as to the propriety of the billing standards is barred by an express statutory preclusion of federal-question jurisdiction over any claim arising under the Medicare Act. See 42 U.S.C. § 405(h), as incorporated in the Medicare Act by 42 U.S.C. § 1395ii.

Agreeing with both of these contentions, the district court dismissed the case in its entirety. See *Ohio Hospital Ass'n v. Shalala*, 978 F. Supp. 735 (N.D. Ohio 1997). Upon review, we conclude that the court was right to accept the first contention but wrong to accept the second. The dismissal order will therefore be vacated and the case will be remanded for further proceedings.

I

Part I of the district court's opinion contains an extensive and very helpful recital of the factual background. *Shalala*, 978 F. Supp. at 736-38. This recital is unchallenged on appeal, and we incorporate it here. In brief outline, the salient facts are these. The Medicare Act, as codified at 42 U.S.C. §§ 1395 *et seq.*, established a health insurance program ("Medicare") for the aged and disabled. The members of the plaintiff associations are Ohio hospitals that have entered into agreements with the Secretary to provide services, on a cost-reimbursable basis, to patients covered by Medicare.

The hospitals' applications for reimbursement are submitted to designated "fiscal intermediaries"—usually insurance companies—that handle the paperwork for the Secretary. To obtain reimbursement, the hospitals must assign "billing codes" to the services they have provided. (The Rosetta Stone for the billing codes is found in an American Medical Association publication called "Physicians' Current Procedural Terminology," or "CPT.") In paying for services rendered by the hospitals, the fiscal intermediaries use a reimbursement rate set by the Secretary for each CPT billing code.

During year-end cost reviews, the Secretary has an opportunity to consider all payments made by the fiscal intermediaries and to adjust any payments found to be in error. If a hospital disagrees with any such adjustment, it may invoke established administrative procedures to challenge the Secretary's position.

The hospitals had no opportunity to invoke these administrative procedures in connection with the disputes that led to the filing of the instant lawsuit, the Secretary never having taken the type of administrative action from which administrative appeals could be prosecuted. The disputes did not arise in connection with year-end adjustments, but in connection with an investigation instigated, presumably, by the Secretary and spearheaded by the offices of the United States Attorneys for the Northern and Southern Districts of Ohio.

The investigation turned on reimbursement of the hospitals for outpatient laboratory tests. Although, as noted above, the reimbursements in question were not challenged by the Secretary during her year-end reviews, the Secretary came to believe that the methodology used by the hospitals in calculating their reimbursement claims was improper in certain respects. The Secretary apparently communicated her concerns to the Attorney General, and the investigation—the "Ohio Hospital Project"—followed.

Some of the hospitals were first apprised of the investigation when agents of the Federal Bureau of Investigation appeared on their premises, unannounced, and began interviewing hospital staffers. The FBI agents said that they were conducting an investigation that might lead to the imposition of civil or criminal sanctions, including imprisonment.

Other hospitals were notified of the investigation through letters signed by an Assistant United States Attorney. In the Northern District of Ohio, at least, the typical letter opened with a paragraph stating that

the hospital might have used "two or more CPT billing codes in lieu of one inclusive code" when seeking reimbursement for outpatient laboratory services; that such code usage might have constituted "the submission of false claims in violation of the False Claims Act, 31 U.S.C. §§ 3729 et seq.;" and that "[t]his statute allows the United States to recover three times its actual damages plus a civil penalty of not less than $5,000 or more than $10,000 for each false claim submitted."

The letters went on to offer an opportunity to participate in a "self- disclosure program" under which the hospitals would

- examine the reimbursement applications they had submitted in past years and flag those involving the use of CPT billing codes in a manner now asserted to be improper;
- execute an agreement (on a form enclosed with the letter) tolling the statute of limitations; and
- pay "an amount which is twice the actual overpayment . . . ."

Recipients of these letters were warned that if they did not wish to participate in the self-disclosure program, "then this office will proceed in the normal course with a review of your institution's activities and seek the appropriate remedy."

The remedy mentioned in the letters—treble damages plus a penalty of $5,000 to $10,000 for each individual item determined to be a False Claims Act violation—seems, not surprisingly, to have caused the

hospitals real concern. The plaintiffs have as much as admitted that some reimbursement claims of types not placed in issue here might well have violated the False Claims Act. With respect to the particular categories of reimbursement at issue here, however, the hospitals insist that the standards under which the amounts billed were determined—standards that, for example, made it permissible to use one CPT billing code for the creatine-kinase component of a seven-chemical automated laboratory test and a "bundled" CPT billing code for the remaining six components of the test, see *Shalala*, 978 F. Supp. at 737—were permissible under the Secretarial guidance in effect at the time reimbursement was obtained. The hospitals were obviously unhappy about the prospect of having to disgorge twice the amount of "overpayments" that they did not view as overpayments at all in order to limit their exposure to full statutory penalties for actual violations of the False Claims Act. With no administrative remedies available to them, the hospitals caused their trade associations to file the instant declaratory judgment action.

II

In Counts I and II of their complaint the plaintiffs allege that the Secretary has implemented a number of specified positions on outpatient lab test billing standards "in the absence of any rule or regulation supporting any such position;" that the positions so implemented "represent a change in existing law or policy and affect[] existing substantive rights of Ohio hospitals;" and that the Secretary's actions are in violation of her statutory duty under the Medicare Act (42 U.S.C. § 1395hh) and the Administrative Procedure

Act (5 U.S.C. § 553) to promulgate regulations on matters of this sort. In the prayer for relief associated with these counts, the plaintiffs seek a declaration that the positions taken by the Secretary are "without basis under existing law" and constitute "substantive rules which have not been properly promulgated . . . ." The plaintiffs also ask that the Secretary be enjoined from enforcing the challenged positions.

Responding to the plaintiffs' complaint with a motion to dismiss under Rule 12(b)(1), Fed. R. Civ. P., the Secretary argued that federal-question jurisdiction over Counts I and II is precluded by 42 U.S.C. § 405(h), a Social Security Act provision incorporated in the Medicare Act by 42 U.S.C. § 1395ii. We shall turn to the language of § 405(h) presently, but first we need to take a brief look at the subsections leading up to it.

The subsections preceding § 405(h) spell out procedures under which applications for social security benefits are adjudicated. Under 42 U.S.C. § 405(b), to begin with, "[t]he Commissioner of Social Security is directed to make findings of fact, and decisions as to the rights of any individual applying for [Social Security benefits] . . . ." Upon request, the Commissioner must accord a dissatisfied applicant (or affected family members) an evidentiary hearing. *Id.* Once the Commissioner has issued a final decision after a hearing to which the individual was a party, 42 U.S.C. § 405(g) provides, the individual "may obtain a review of such decision by a civil action commenced [in a United States District Court] . . . ." And 42 U.S.C. § 405(h)—the section on which the Secretary relies here—then provides as follows:

> "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.*"[1] (Emphasis supplied.)

The Medicare Act, in turn, provides that individuals claiming Medicare benefits shall be entitled both to evidentiary hearings before the Secretary and to judicial review of the Secretary's final decision in the same way that applicants for Social Security benefits are entitled to hearings and judicial review under §§ 405(b) and (g). See 42 U.S.C. § 1395ff. Similarly, § 1395ii makes the provisions of § 405(h) and other designated subsections applicable with respect to the Medicare subchapter "to the same extent as they are applicable with respect to subchapter II of this chapter [the Social Security subchapter], except that, in applying such provisions with respect to this subchapter, any

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[1] The sections of Title 28 referred to in the third sentence give the federal district courts original jurisdiction over civil actions arising under the laws of the United States and certain actions against the United States for the recovery of money. The subchapter referred to as "this subchapter" is Subchapter II of Chapter 7, captioned "FEDERAL OLD-AGE, SURVIVORS, AND DISABILITY INSURANCE BENEFITS." The Medicare subchapter Subchapter XVIII—is captioned "HEALTH INSURANCE FOR AGED AND DISABLED."

reference therein to the Commissioner of Social Security . . . shall be considered a reference to the Secretary. . . ."

When we read §§ 1395 and 405 together, then, we find that after providing for the adjudication of Medicare claims in the same way that Social Security claims are adjudicated, Congress has said this with respect to Medicare claims:

> The findings and decision of the Secretary after a hearing shall be binding upon all individuals who were parties to such hearing. No findings of fact or decision of the Secretary shall be reviewed by any person, tribunal, or governmental agency except as herein provided. No action against the United States, the Secretary, 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.

Focusing solely on the third sentence, and ignoring the context in which that sentence appears, the Secretary argues here, as she did before the district court, that insofar as Counts I and II of the complaint are concerned, the plaintiffs' declaratory judgment action is an action "to recover on [a] claim arising under this subchapter." In this connection the Secretary relies heavily upon *Weinberger v. Salfi*, 422 U.S. 749, 95 S. Ct. 2457, 45 L.Ed.2d 522 (1975), and *Heckler v. Ringer*, 466 U.S. 602, 104 S. Ct. 2013, 80 L.Ed.2d 622 (1984). That reliance, we believe, is misplaced.

Weinberger v. Salfi arose out of Social Security claims asserted by the widow and step-child of a

deceased wage earner. The claims were denied administratively on the strength of a statutory "duration-of-relationship" rule. Instead of obtaining a final decision on the claims after an evidentiary hearing and challenging the constitutionality of the duration-of-relationship rule in judicial review proceedings under 42 U.S.C. § 405(g), the claimants sought to bring their constitutional challenge in a class action that invoked federal-question jurisdiction under 28 U.S.C. § 1331. A three-judge federal district court accepted jurisdiction on the theory that the third sentence of § 405(h) "amounted to no more than a codification of the doctrine of exhaustion of administrative remedies." *Salfi*, 422 U.S. at 757, 95 S. Ct. 2457. The Supreme Court rejected this reading of § 405(h) as "entirely too narrow," *id.*, and held that the district court had no jurisdiction over the class action.

Heckler v. Ringer was an action by individual Medicare claimants who sought coverage for a type of surgical procedure that the Secretary determined was not "reasonable and necessary" within the meaning of the Medicare Act. Instead of challenging the Secretary's determination in § 405(g) proceedings brought after issuance of a final decision under § 405(b), the claimants sued the Secretary for declaratory and injunctive relief on the basis of (*inter al.*) 28 U.S.C. § 1331. Again the Supreme Court held that jurisdiction was barred by the third sentence of § 405(h); the only avenue for judicial review, the Court concluded, was that provided by § 405(g).

In both *Salfi* and *Ringer*, it is important to understand, individual claimants were seeking a judgment directing the payment of benefits. The Supreme Court

emphasized this fact in explaining, in both cases, why it concluded that the actions had been brought "to recover on . . . claim[s] arising under" the Social Security Act or the Medicare Act within the meaning of the third sentence of § 405(h). In the case at bar, by contrast, the plaintiffs are not seeking a judgment directing the payment of benefits. Unlike the plaintiffs in *Salfi* and *Ringer*, neither the plaintiff hospital associations nor the individual hospitals they represent have any remedies under § 405(b). And no judicial remedy is available to them under § 405(g), of course.

In this respect the instant case resembles *Michigan Academy of Family Physicians v. Blue Cross and Blue Shield of Michigan*, 757 F.2d 91 (6th Cir. 1985), *aff'd. sub nom. Bowen v. Michigan Academy of Family Physicians*, 476 U.S. 667, 106 S. Ct. 2133, 90 L.Ed.2d 623 (1986). There a group of physicians wished to challenge the validity of a regulation authorizing different reimbursement rates for similar services. The physicians had no access to the courts under § 405(g); unless they could invoke federal-question jurisdiction under 28 U.S.C. § 1331, they had no way of obtaining judicial review. Relying on *Ringer*, the Secretary contended that the third sentence of § 405(h) left the plaintiffs without any judicial remedy at all. We rejected the Secretary's argument, holding (see 757 F.2d at 94) that *Ringer* "did not proscribe judicial review . . . where the challenge was made by a party other than a claimant for benefits." The Supreme Court, expressing itself as "most reluctant" to read § 405(h) as prohibiting all judicial review of the action complained of by the physicians, affirmed. *Bowen*, 476 U.S. at 680-82, 106 S. Ct. 2133.

In affirming our court's judgment, as the Court of Appeals for the Eleventh Circuit observed in *United States ex rel. Body v. Blue Cross and Blue Shield of Alabama, Inc.*, 156 F.3d 1098, 1109 (11th Cir. 1998), the *Bowen* Court recognized "that subsection 405(h), viewed within the context in which it was drafted and made applicable to Medicare, simply seeks to preserve the integrity of the administrative process Congress designed to deal with challenges to amounts determinations by dissatisfied beneficiaries, not to serve as a complete preclusion of all claims related to benefits determinations in general." Expanding on this theme earlier in its opinion, the Eleventh Circuit explained its thinking as follows:

> "Taken alone, the third sentence of the subsection appears to be a plenary revocation of federal-question jurisdiction for Medicare-related cases. Taken in context, however, it is quite clear that the provision is intended to prevent circumvention of the administrative process provided for the adjudication of disputes between Medicare beneficiaries and the government (or agents of the government such as fiscal intermediaries). The provision takes away general federal-question jurisdiction over claims by Medicare beneficiaries, forcing them to pursue their claims in a hearing under subsection 405(b) and then, if necessary, in an appeal under the specific grant of jurisdiction contained in subsection 405(g). Thus, the third sentence is the final piece in an administrative scheme designed to give the administrative process the first opportunity to resolve disputes over eligibility or the amount of benefits awarded under the Act.

> "Nothing in subsection 405(h), however, or in the rest of section 405, suggests that the third sentence of subsection 405(h) eliminates federal-question jurisdiction over all actions implicating the Medicare Act, regardless of the availability—or unavailability—of administrative and judicial review within the Medicare administrative scheme. Subsection 405(h) prevents beneficiaries and potential beneficiaries from evading administrative review by creatively styling their benefits and eligibility claims as constitutional or statutory challenges to Medicare statutes and regulations. It does not create two class of claims 'arising under' Medicare: those that may be brought administratively and then appealed under the grant of jurisdiction in subsection 405(g), and those that are not subject to administrative review and are therefore not reviewable *at all*. Actions such as Body's, which do not seek payment from the government and could not be brought under section 405, are therefore not barred by subsection 405(h)." *Body*, 156 F.3d at 1103-04 (footnotes omitted).

As the Eleventh Circuit went on to demonstrate very persuasively, nothing in *Salfi* or *Ringer* dictates a contrary conclusion. See *Body*, 156 F.3d at 1105-07. The Eleventh Circuit's logic seems sound to us, and we adopt it here. That logic clearly compels the conclusion that the district court ought to have rejected the Secretary's § 405(h) argument in the case at bar.

III

In Counts III and IV of their complaint the plaintiffs seek relief on the grounds that "[the] Defendant

Secretary, through the U.S. Attorney's Office and the U.S. Department of Justice, has threatened and continues to threaten Ohio hospitals that charges will be brought against them under the False Claims Act for Outpatient Laboratory Testing charges unless the hospitals enter into settlements that impose penalties for violations of billing rules that were not in existence at the time the bills were submitted;" that such use of the U.S. Attorney's Office and the Department of Justice "deprives hospitals of their property without due process of law in violation of the Fifth Amendment of the United States Constitution;" and that "use of the False Claims Act in this manner is contrary to the purpose and intent standard of the False Claims Act, 18 U.S.C. § 287 and 31 U.S.C. § 3729."

The district court dismissed Counts III and IV on the ground that the United States cannot file a False Claims Act suit against a defendant through the Secretary of Health and Human Services; it can do so only through the Attorney General, and the Attorney General has not been named as a party here. Although the hospitals allege that the Secretary is the moving force behind the threatened False Claims Act prosecutions, the district court noted that "it is still only the Attorney General who has the discretion and authority to ultimately pursue a False Claims Act prosecution." *Shalala,* 978 F. Supp. at 739 n. 5. The district court concluded that it had no equitable jurisdiction to control the exercise of the Attorney General's discretion through an order directed to the Secretary of Health and Human Services. We agree. The dismissal of Counts III and IV will be affirmed for essentially the reasons stated by the district court at *Shalala,* 978 F. Supp. at 738-740.

The Secretary presents various arguments on appeal that were not addressed by the district court. The most prominent is an argument that the plaintiff hospital associations lack standing to sue on behalf of their members. We shall leave it to the district court to deal with these matters in the first instance on remand.

For the reasons stated, the judgment appealed from is **AFFIRMED** in part and **REVERSED** in part. The case is **REMANDED** to the district court for further proceedings not inconsistent with this opinion.

APPENDIX B

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

No. 1:96-CV-2165

OHIO HOSPITAL ASSOCIATION, ET AL., PLAINTIFFS

v.

DONNA E. SHALALA, SECRETARY OF
HEALTH AND HUMAN SERVICES, DEFENDANT

[Filed: Sept. 18, 1997]

MEMORANDUM & ORDER

O'MALLEY, District Judge.

Plaintiffs Ohio Hospital Association and American Hospital Association bring this action on behalf of their member hospitals against Donna E. Shalala, in her capacity as Secretary of Health and Human Services. Plaintiffs assert that the Secretary is improperly and retroactively enforcing new coding and billing standards in connection with Medicare reimbursement for certain medical laboratory tests. Plaintiffs seek to enjoin the Secretary from continuing this enforcement, and also seek a judgment from this Court declaring that: (1) the Secretary did not properly promulgate the

new standards; (2) the Secretary cannot retroactively enforce them; and (3) the government cannot hold plaintiffs' member hospitals liable under the False Claims Act.

The Secretary moves to dismiss plaintiffs' complaint on several grounds, including lack of jurisdiction (docket no. 9).[1] For the reasons stated below, the motion to dismiss is **GRANTED** and this case is dismissed.

I.

The parties generally agree that the following alleged factual background is accurate. Pursuant to 42 U.S.C. § 1395, *et seq.*, the federal Medicare program reimburses qualified hospitals for the cost of providing certain covered medical care to eligible patients. Plaintiffs' member hospitals are all qualified Medicare "providers," which have entered into agreements with the Secretary regarding the provision of services and reimbursement. Regarding reimbursement, the Medicare statute provides that the Secretary shall set out fee schedules for diagnostic laboratory tests provided to outpatients by provider hospitals. 42 U.S.C. § 1395l(h). These fee schedules set out the precise amount of reimbursement Medicare will pay for any particular lab test. Provider hospitals are directed to submit their claims for lab test reimbursement using specific billing codes.

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[1] The Secretary has also attacked plaintiffs' standing to bring this action on behalf of their member hospitals. In light of the conclusions reached in this opinion, the Court finds it unnecessary to address the question of standing.

When doctors at the provider hospitals order performance of diagnostic lab tests upon an outpatient, the doctors often order the tests as a group, especially when the tests are automated. For example, a doctor will often order a "Chem 7," which is comprised of seven separate automated chemical tests to determine the following ingredient levels in a patient's blood: chloride, cholesterol, potassium, sodium, creatinine, glucose, and creatine-kinase. Because doctors so frequently order certain automated lab tests as a group, Medicare regulations provide that the provider hospitals must also bill some of these tests as a group, rather than individually. Typically, reimbursement for the tests, when billed as a group, is lower than if the tests had been billed individually.

To give direction to the provider hospitals regarding which diagnostic lab tests should be billed as a group, the Secretary published, several years ago, a "Medicare Hospital Manual." The Medicare Hospital Manual stated that "National Guidelines for [hospital laboratories] on what tests are available in automated batteries are being developed. Until completed, use [billing] codes found in CPT-4, [the American Medical Association Current Procedure Terminology manual]." In turn, the CPT-4 listed 19 different codes for automated tests that should be "bundled" together for billing purposes, when performed simultaneously.

During the period from 1989 to 1996, of the seven tests that comprise a Chem-7, six were included in the list of 19 "bundled" tests contained in the CPT-4; the creatine-kinase test was not on the list. Thus, when a provider hospital billed Medicare for performance of a Chem-7 upon an outpatient, the hospital would

normally submit to Medicare two billing codes: one for the creatine-kinase test (code 82550, creatine-kinase test only), and one for the other six tests combined (code 80006, 6 clinical chemistry tests combined). Medicare regularly accepted this type of statement and provided reimbursement.[2]

Plaintiffs allege that, despite this long-term practice, in 1996 the Secretary joined forces with the office of the United States Attorney General to investigate the billing practices of hospitals, including plaintiffs' members. During this investigation, the Secretary took the position that the hospitals should have bundled all seven of the tests contained in the Chem-7 and submitted only one billing code—code 80007 (7 clinical chemistry tests combined). The Secretary suggested that the hospitals purposely failed to bundle all seven tests together in order to submit higher bills to Medicare for reimbursement, seeking to manipulate the system so as to increase their Medicare receipts.

The Secretary addressed certain other of the member hospitals' billing practices in similar fashion. Thus, plaintiffs point to several other specific examples of billing practices the Secretary now attacks as insufficiently "bundled," despite having tacitly approved those practices through unquestioned reimbursements over the seven year period from 1989 through 1996. Again, the Secretary has taken the position that the hospitals' billing practices were not only improper, but

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[2] Reimbursement was actually provided by a "fiscal intermediary," which contracts with the government to make initial determinations regarding coverage and payment.

were undertaken intentionally in order to inflate Medicare reimbursements beyond those properly due.

In the context of this broad-scale investigation, the Secretary wrote letters to various member hospitals stating that their claims for reimbursement "may constitute the submission of false claims in violation of the False Claims Act." The Secretary then suggested that the hospitals could avoid prosecution by the Attorney General for violation of the False Claims Act if they cooperated with the Secretary in an investigation of their billing practices over the prior six years. This "cooperation" included repaying Medicare for the "excess reimbursement" the member hospitals allegedly received by virtue of their unbundled billing practices, plus penalties.

Plaintiffs assert that, in practice, the Secretary has followed up her letters to the member hospitals (in which she suggested they may have violated the False Claims Act) by: (1) conducting an audit of each hospital's billings; (2) identifying "errors" based on the hospital's alleged failure to properly bundle test procedures when billing for them; (3) computing the damages the government could recover under a False Claims Act lawsuit (which the Secretary notes in her letters to the hospitals include both a penalty of up to $10,000 *per* false claim, plus triple the amount of actual damages); and (4) inviting the hospital to pay a penalty of something less than the damages available under the False Claims Act, to avoid legal prosecution. Plaintiffs assert this practice is highly unfair, because: (1) their bundling of claims was correct under then-applicable guidelines; and (2) even though they would not be found liable under the False Claims Act, they cannot risk rejecting the

Secretary's invitation to settle, because the damages available under the False Claims Act are so overwhelming.

Plaintiffs have brought this action in an attempt to thwart (or at least slow down) the Secretary's heavy-handed approach to this investigation, and in the hopes of finding an even-handed forum within which to dispute the Secretary's views of their long-standing billing practices. Plaintiffs assert that, without this lawsuit, their member hospitals have no avenue to challenge the Secretary's actions: if the Secretary pursued normal administrative "recoupment" procedures to reclaim her alleged payments of "excess reimbursement," the hospitals could challenge the Secretary's alleged change in position through administrative remedies; by skipping normal recoupment procedures and instead threatening a False Claims Act lawsuit, plaintiffs claim the Secretary has robbed the hospitals of any way to challenge the Secretary's position. Plaintiffs point out, moreover, that the Secretary is demanding payments in excess of those normally available through a recoupment procedure by using the threat of a False Claims Act action to "extort" not just the return of Medicare payments previously received, but the payment of additional sums as well.

The Secretary does not deny that her position regarding the member hospitals' billing practices is different today than it was in the past. Nor does the Secretary deny that her approach to this investigation (and the approach of those counsel who represent her)

has been somewhat heavy-handed.[3] The Secretary simply argues that this Court is without jurisdiction to question or interfere with her investigation and/or her negotiations with the individual member hospitals, and that this action must, therefore, be dismissed. Despite understandable concern over the Secretary's and Attorney General's investigative tactics, the Court is compelled to agree that this action must be dismissed for lack of subject matter jurisdiction.

II.

There are two general categories into which Rule 12(b)(1) motions to dismiss for lack of subject matter jurisdiction fall: facial attacks and factual attacks. Fed. R. Civ. P. 12(b)(1); *United States v. Ritchie*, 15 F.3d 592, 598 (6th Cir. 1994), *cert. denied*, 513 U.S. 868, 115 S. Ct. 188, 130 L.Ed.2d 121 (1994). A facial attack challenges the sufficiency of the pleading itself. On such a motion, the Court must take all of the material allegations in the complaint as true and construe them in the light most favorable to the nonmoving party. *Id.* (citing *Scheuer v. Rhodes*, 416 U.S. 232, 235-37, 94 S. Ct. 1683, 1686-87, 40 L.Ed.2d 90 (1974)). In contrast, a factual attack, as is made here, challenges the factual existence of subject matter jurisdiction.

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[3] Indeed, if the Attorney General's threatened False Claims Act prosecution was criminal in nature, the actions of government counsel could be in breach of the mandatory ethical standards contained in the Ohio Code of Professional Responsibility. *See* D.R. 7-105(A) ("A lawyer shall not threaten to present criminal charges solely to obtain an advantage in a civil matter"). Plaintiffs do not argue the False Claims Act lawsuits threatened against the hospitals are criminal in nature, although they do argue the combined actions of the Secretary and Attorney General are confiscatory.

On this form of motion, the Court's inquiry is limited to determining whether the challenged pleadings set forth allegations sufficient to show the Court that it has jurisdiction over the subject matter; "no presumptive truthfulness applies to the factual allegations, and the court is free to weigh the evidence and satisfy itself as to the existence of its power to hear the case." *Id.* (internal citations omitted); *RMI Titanium Co. v. Westinghouse Elec. Corp.*, 78 F.3d 1125, 1135 (6th Cir. 1996). In reviewing such a motion, a district court is to probe the facts and assess the validity of its own jurisdiction. In doing so, the Court has wide discretion to consider affidavits and documents outside the complaint, and may even conduct a limited evidentiary hearing if necessary. *Ohio Nat'l Life Ins. Co. v. United States*, 922 F.2d 320, 325 (6th Cir. 1990). In connection with this analysis, the plaintiff bears the burden of demonstrating that the Court has and may appropriately exercise jurisdiction over the subject matter. *RMI Titanium Co.*, 78 F.3d at 1134. The Court may examine evidence of its power to hear a case, and must make any factual findings to determine whether it has jurisdiction. *Kroll v. United States*, 58 F.3d 1087, 1090 (6th Cir. 1995); *Rogers v. Stratton Inds., Inc.*, 798 F.2d 913, 915 (6th Cir. 1986). The Court's examination of this evidence does not convert a 12(b)(1) motion into a Rule 56 motion. *Rogers*, 798 F.2d at 915.

III.

A. The False Claims Act.

In Counts III and IV of the plaintiffs' complaint, the plaintiffs claim that: (1) the Secretary has violated the Fifth Amendment by "inappropriately us[ing] . . . the U.S. Attorney's Office and the U.S. Department of

Justice to coerce [the hospitals] into making substantial payments to [Medicare] to avoid" prosecution under the False Claims Act; and (2) the Secretary's "use of the False Claims Act in this manner is contrary to the purpose and intent standard" contained in the Act. Complaint at ¶¶ 88, 90. As remedy for these claims, plaintiffs seek:

> [a] declaration that the Secretary's actions to enforce her position with respect to the appropriate coding and billing for certain Outpatient Laboratory Tests for the period of 1989 to the present constitutes a violation of the Fifth Amendment of the United States Constitution[; and]
>
> [a] declaration that the Secretary's use and interpretation of the False Claims Act as a means to enforce her position with respect to appropriate coding and billing for certain Outpatient Laboratory Tests for the period of 1989 to the present is improper as being contrary to the intent and language of the False Claims Act.

Id. at 21, prayer ¶¶ C, D. In response, the Secretary argues this Court cannot issue the requested declarations because there exists no viable legal theory to support them, and thus the plaintiffs' claims are not within the Court's equitable jurisdiction. The Court agrees.

It is clear that only the United States, acting through the Attorney General, can file a False Claims Act suit against a defendant; the Secretary cannot. *See* 31 U.S.C. § 3730(a) ("If the Attorney General finds that a person has violated or is violating [the False Claims Act], the Attorney General may bring a civil action

under this section against the person"); *Martin J. Simko Constr., Inc. v. United States*, 852 F.2d 540, 547 (Fed. Cir. 1988) (the Attorney General's authority to bring suit under the False Claims Act is exclusive; "no other agency is empowered to act under that statute").[4] Thus, plaintiffs cannot obtain a judgment declaring that it is, or would be, improper for *the Secretary* to threaten their member hospitals with prosecution under the False Claims Act, as the law is clear that only the Attorney General has the power to pursue a prosecution.[5]

Plaintiffs attempt to sidestep this problem by arguing they are not directly trying to prevent the Attorney General from proceeding against the hospitals under the False Claims Act, should the Attorney General so desire; rather, they seek only a declaration that the hospitals did not have the requisite intent to be held liable under the False Claims Act, and that the Secretary's threat of prosecution is therefore improper. Simply, plaintiffs seek to have the Court undercut the Secretary's negotiating tactics, taken in the wake of her investigation of the hospital's coding and billing practices, by neutralizing her threat of a False Claims Act prosecution.

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[4] Although 31 U.S.C. § 3730(b) allows private parties to bring False Claims Act actions, "[t]he action shall be brought in the name of the Government." The only governmental actor authorized to bring a False Claims Act action is the Attorney General.

[5] Even though the hospitals allege it is really the Secretary who is the moving force behind the threatened False Claims Act prosecutions—indeed, the Secretary has allegedly rejected some of the settlements worked out by the Attorney General—it is still only the Attorney General who has the discretion and authority to ultimately pursue a False Claims Act prosecution.

This tactic is unavailing. The true purpose of the requested declaration is for the hospitals "to hold [it] in readiness for use should the [Attorney General] attempt at any future time to apply any part of the [False Claims] statute to [them]." *Public Service Comm'n of Utah v. Wycoff Co.*, 344 U.S. 237, 245, 73 S. Ct. 236, 241, 97 L.Ed. 291 (1952). This purpose "exceeds any permissible discretionary use of the Federal Declaratory Judgment Act." *Id.* The hospitals' assertion that they did not "knowingly" submit a "false" claim to the government, and thus cannot be held liable under the False Claims Act for improper billing, is properly tendered as a defense to a False Claims Act suit. It is not properly tendered as the basis for what would essentially be an advisory opinion in this case, to the effect that "if the Attorney General ever brings a False Claims Act lawsuit against the member hospitals, then the suit must fail because the Attorney General cannot prove an element of the claim, and therefore the Secretary's threat that the hospitals might be liable under the False Claims Act is of no merit."

It is true that each hospital faces the difficult choice of deciding to either: (1) settle with the Secretary in exchange for an agreement that the government will not bring a False Claims Act action against it; or (2) face the possibility of losing a False Claims Act action and suffering a huge damages award.[6] This

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[6] Indeed, plaintiffs claim its members have been placed in an impossible position by the Secretary. They believe their billing practices were appropriate and, even if not, were undertaken in good faith—facts which would defeat any False Claims Act suit against them. Like any litigation, however, they recognize that a trier of fact might disagree with them. Because the risk of loss in a False Claim Act case carries potentially devastating penalties,

dilemma, however, is faced to some degree by every litigant. Every defendant in a False Claims Act action must face a

> choice between potentially enormous civil fraud penalties and foregoing their right to have their [challenges] heard before the Court. * * * While [this] choice [may be] difficult and painful, it is far from unique. All parties to potential litigation, when offered a settlement, must weigh the odds of prevailing upon a claim and potential gains against possible liabilities. The choice is never easy, but it is not unfair or inequitable.

Largen v. United States, 1995 WL 556621 at *10 (M.D. Fla. July 14, 1995). Invocation of the Court's equity jurisdiction in these circumstances is simply not appropriate.

Whether the Attorney General ever chooses to pursue a member hospital for violation of the False Claims Act is a matter of prosecutorial discretion. *Bordenkircher v. Hayes*, 434 U.S. 357, 364, 98 S. Ct. 663, 668, 54 L.Ed.2d 604 (1978) ("the decision whether or not to prosecute, and what charge to file or bring before a grand jury, generally rests entirely in [the prosecutor's] discretion"). If faced with such a lawsuit, a hospital will have the opportunity to raise any and all defenses, including lack of intent. This Court cannot exercise its equitable jurisdiction to declare in advance that a particular hospital's defenses are valid, or that the Secretary's False Claims Act threat is empty. "An

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however, unlike most litigation or even an administrative recoupment action, it is a risk the hospitals feel they cannot take—even if they believe their chances of prevailing would be great.

injunction against threatened legal action will not issue if the party will have an adequate opportunity to fully present his defenses and objections in the legal action he seeks to enjoin." *Travis v. Pennyrile Rural Elec. Co-op.*, 399 F.2d 726, 729 (6th Cir. 1968). Because the Court does not have equitable jurisdiction over Counts III and IV of the plaintiffs' complaint, the Secretary's motion to dismiss these claims is granted.

B. The Secretary's Policies.

In Counts I and II of plaintiffs' complaint, plaintiffs claim that: (1) "the Secretary's mandate as to the manner in which [member hospitals] must [bundle coding and billing of certain lab tests] has been implemented in the absence of any rule or regulation supporting such position;" and (2) this action is in violation of the Secretary's "statutory duty to promulgate . . . regulations regarding Outpatient Laboratory Testing," as set out in 42 U.S.C. § 1395*hh* and 5 U.S.C. § 533. Complaint at ¶¶ 78, 83, 85. As remedy for these claims, plaintiffs seek:

> [a] declaration that the Secretary's position with respect to the appropriate coding and billing for certain Outpatient Laboratory Tests is incorrect and without basis under existing law; and
>
> [a] declaration that the Secretary's position with respect to the appropriate coding and billing for certain Outpatient Laboratory Tests constitutes substantive rules which have not been properly promulgated pursuant to 42 U.S.C. § 1395hh and 5 U.S.C. § 533.

Id. at 21, prayer ¶¶ A, B. In response, the Secretary argues this Court cannot issue the requested declara-

tions because: (1) the Medicare Act itself generally states that a plaintiff cannot bring suit to recover on a claim "arising under" the Act; (2) the only exception to this rule is for judicial review of a "final decision" of the Secretary, after completion of administrative review; and (3) there has been no administrative review or final decision of the Secretary in this case, so this Court has no jurisdiction to resolve the plaintiffs' claims, which "arise under" the Act. Again, the Court agrees with the position of the Secretary.

By way of 42 U.S.C. §§1395ff and 1395ii, the Medicare Act incorporates the method of judicial and administrative review found in 42 U.S.C. §§ 405(h) and 405(g). Section 405(h) states 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. No action against the United States, the [Secretary] or any officer or employee thereof shall be brought under section 1331 or 1346 of Title 28 to recover on any claim arising under [the Medicare Act]." Section 405(g) states that "[a]ny individual, after any final decision of the [Secretary] 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 . . . " Thus, for claims "arising under" the Medicare Act, the Secretary must reach a "final decision" before a plaintiff may obtain judicial review.

The Supreme Court has "construed the 'claim arising under' language of section 405(h) broadly to include any claims in which 'both the standing and the substantive basis for the presentation' of the claims is the [Medicare] Act." *Heckler v. Ringer*, 466 U.S. 602, 615, 104 S. Ct. 2013, 2022, 80 L.Ed.2d 622 (quoting *Weinberger v.*

Salfi, 422 U.S. 749, 760-61, 95 S. Ct. 2457, 2464, 45 L.Ed.2d 522 (1975)). In *Ringer*, the plaintiffs

> arguably . . . assert[ed] objections to the Secretary's "procedure" for reaching her decision . . . to issue a generally applicable rule . . . . and they challenged her alleged failure to comply with the rulemaking requirements of the [Administrative Procedure Act]. . . . [T]hose claims are "inextricably intertwined" with [plaintiffs'] claims for benefits . . . . [T]he relief that [plaintiffs] seek to redress their supposed "procedural" objections is the invalidation of the Secretary's current policy and a "substantive" declaration from her [regarding Medicare reimbursement]. We conclude that all aspects of respondents' claim for benefits should be channeled first into the administrative process which Congress has provided for the determination of claims for benefits.

Id. at 614, 104 S. Ct. at 2021.

In this case, the standing and substantive basis for Count I is clearly the Medicare Act, as Count I alleges the Secretary promulgated her billing policies in violation of the Act. The same is true of Count II, which, like the Ringer plaintiffs, alleges the Secretary violated the Administrative Procedure Act. Plaintiffs ask this Court to rule that: (1) their member hospitals correctly bundled the billing codes for their lab tests; (2) the hospitals received the correct reimbursement for those lab tests; and (3) the Secretary's change in position is improper. At bottom, this is a request for an adjudication of the propriety of past payment of benefits, which *Ringer* holds is a claim that arises under the Medicare Act. Accordingly, this Court does not

have jurisdiction over these claims.[7] To the extent this conclusion is contrary to the holding of *Cedars-Sinai Med. Ctr. v. Shalala*, 939 F. Supp. 1457 (C.D. Cal. 1996) (appeal pending), the Court finds that case unpersuasive.[8]

Plaintiffs argue that their claims cannot "arise under" the Medicare Act because no administrative remedies exist to resolve their claims. That is, the Secretary has not administratively *denied* any of their claims for reimbursement, and has not sought to *recoup* reimbursements through the administrative process; thus, there exists no decision of the Secretary to appeal through the administrative process. Instead, the Secretary is enforcing her allegedly new reimbursement and billing policy by threatening the member hospitals with False Claims Act prosecution, leaving the hospitals without a forum for review of the Secretary's policy position. Plaintiffs' argue that this lack of any means for administrative review shows that their claims do not arise under the Medicare Act.

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[7] The plaintiffs also argue that, even if their claims "arise under" the Medicare Act, the Court should exercise jurisdiction because: (1) as a practical matter the hospitals have exhausted all administrative remedies; or (2) the Court should waive the exhaustion requirement. In the face of the clear mandate of section 405(h), neither of these arguments is convincing.

[8] The *Cedars-Sinai* court held that a certain role [sic] promulgated by the Secretary was a "substantive rule," not an "interpretive rule," and, thus, that the Secretary's rule had to be "promulgated in accordance with the rule-making requirements of the APA." *Cedars-Sinai*, 939 F. Supp. at 1464. This Court believes the *Cedars-Sinai* conclusion is contrary to *Ringer*, which the Cedars-Sinai court never cited.

This argument ultimately fails because the hospitals could eventually obtain judicial review by "calling the Secretary's bluff," as follows: (1) refusing to settle to avoid prosecution; (2) presenting their defenses to a False Claims Act lawsuit; and (3) winning that lawsuit based on lack of scienter, as they allege they would. This course of action would force the Secretary to either file an administrative recoupment action, or forego reclamation of her "excessive reimbursements." In the end, the hospitals would either avoid recoupment, or be in a position to obtain judicial review of a recoupment decision, and the policy underlying it.[9]

There is no question that this route to obtain judicial review, which the Secretary forces upon the hospitals, is extremely onerous. Despite the very real possibility that the Secretary's position regarding the hospitals' billing practices is wrong, the practical barriers of challenging the Secretary leave the hospitals with little choice and no bargaining room. Still, that the Secretary's actions seem heavy-handed does not confer jurisdiction upon this Court to hear the plaintiffs' claims.[10]

In sum, the Court concludes that plaintiffs have not carried their burden of proving the existence of federal jurisdiction over any of the claims asserted in this

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[9] That the hospitals could ultimately obtain judicial review through this process also suggests that the plaintiffs' members have an adequate remedy at law, so that equitable relief is inappropriate.

[10] As discussed at oral argument, plaintiffs may resort to Congress to address the arguable unfairness created by 42 U.S.C. § 405(h). Resort to this Court on that point, however, is inappropriate.

action. Accordingly, the Secretary's motion to dismiss for lack of jurisdiction is **GRANTED**.

IT IS SO ORDERED.

ORDER

For the reasons set forth in this Court's Memorandum & Order of this date, the Secretary's motion to dismiss for lack of jurisdiction is **GRANTED** and this case is dismissed.

IT IS SO ORDERED.

APPENDIX C

UNITED STATES COURT OF APPEALS
FOR THE SIXTH CIRCUIT

No. 97-4217

OHIO HOSPITAL ASSOCIATION, ET AL.,
PLAINTIFFS-APPELLANTS

v.

DONNA E. SHALALA, SECRETARY OF HEALTH AND
HUMAN SERVICES, DEFENDANT-APPELLEE

[Filed: May 11, 2000]

ORDER

Before: NELSON, CLAY, and GIBSON,* Circuit Judges.

The court having received a petition for rehearing en banc, and the petition having been circulated not only to the original panel members but also to all other active judges of this court, and no judge of this court having requested a vote on the suggestion for rehearing en banc, the petition for rehearing has been referred to the original panel.

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* Hon. John R. Gibson, Senior United States Circuit Judge for the Eighth Circuit Court of Appeals sitting by designation.

The panel has further reviewed the petition for rehearing and concludes that the issues raised in the petition were fully considered upon the original submission and decision of the case. Accordingly, the petition is denied.

ENTERED BY ORDER OF THE COURT

/s/ LEONARD GREEN
LEONARD GREEN, Clerk

APPENDIX D

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 1395ff of Title 42, United States Code, provides in relevant part:

§ 1395ff. Determinations of Secretary

(a) Entitlement to and amount of benefits

The determination of whether an individual is entitled to benefits under part A or part B of this subchapter, and the determination of the amount of benefits under part A or part B of this subchapter, and any other determination with respect to a claim for benefits under part A of this subchapter or a claim for benefits with respect to home health services under part B of this subchapter shall be made by the Secretary in accordance with regulations prescribed by him.

(b) Appeal by individuals; provider representation of beneficiaries

(1) Any individual dissatisfied with any determination under subsection (a) of this section as to—

(A) whether he meets the conditions of section 426 or section 426a of this title, or

(B) whether he is eligible to enroll and has enrolled pursuant to the provisions of part B of this subchapter or section 1395i-2 of this title,

(C) the amount of benefits under part A or part B of this subchapter (including a determination where such amount is determined to be zero), or

(D) any other denial (other than under part B of subchapter XI of this chapter) of a claim for benefits under part A of this subchapter or a claim for benefits with respect to home health services under part B of this subchapter,

shall be entitled to 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 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. Sections 406(a), 1302, and 1395hh of this title shall not be construed as authorizing the Secretary to prohibit an individual from being represented under this subsection by a person that furnishes or supplies the individual, directly or indirectly, with services or items solely on the basis that the person furnishes or supplies the individual with such a service or item. Any person that furnishes services or items to an individual may not represent an individual under this subsection with respect to the issue described in section 1395pp(a)(2) of this title unless the person has waived any rights for payment from the beneficiary with respect to the services or items involved in the appeal. If a person fur-

nishes services or items to an individual and represents the individual under this subsection, the person may not impose any financial liability on such individual in connection with such representation.

(2) Notwithstanding paragraph (1)(C) and (1)(D), in the case of a claim arising—

(A) under part A of this subchapter, a hearing shall not be available to an individual under paragraph (1)(C) and (1)(D) if the amount in controversy is less than $100 and judicial review shall not be available to the individual under that paragraph if the amount in controversy is less than $1,000; or

(B) under part B of this subchapter, a hearing shall not be available to an individual under paragraph (1)(C) and (1)(D) if the amount in controversy is less than $500 (or $100 in the case of home health services) and judicial review shall not be available to the individual under that paragraph if the aggregate amount in controversy is less than $1,000.

In determining the amount in controversy, the Secretary, under regulations, shall allow two or more claims to be aggregated if the claims involve the delivery of similar or related services to the same individual or involve common issues of law and fact arising from services furnished to two or more individuals.

(3) Review of any national coverage determination under section 1395y(a)(1) of this title respecting whether or not a particular type or class of items or services is covered under this subchapter shall be subject to the following limitations:

(A) Such a determination shall not be reviewed by any administrative law judge.

(B) Such a determination shall not be held unlawful or set aside on the ground that a requirement of section 553 of title 5 or section 1395hh(b) of this title, relating to publication in the Federal Register or opportunity for public comment, was not satisfied.

(C) In any case in which a court determines that the record is incomplete or otherwise lacks adequate information to support the validity of the determination, it shall remand the matter to the Secretary for additional proceedings to supplement the record and the court may not determine that an item or service is covered except upon review of the supplemented record.

(4) A regulation or instruction which relates to a method for determining the amount of payment under part B of this subchapter and which was initially issued before January 1, 1981, shall not be subject to judicial review.

(5) In an administrative hearing pursuant to paragraph (1), where the moving party alleges that there are no material issues of fact in dispute, the administrative law judge shall make an expedited determination as to whether any such facts are in dispute and, if not, shall determine the case expeditiously.

4. 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.