

**In the
Supreme Court of the United States**

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

v.

OHIO HOSPITAL ASSOCIATION, ET AL.,
Respondents.

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

**BRIEF IN OPPOSITION TO
PETITION FOR 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 relief in a federal district court under the general federal jurisdiction 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, as such policies are being applied in the context of investigations under the False Claims Act, 31 U.S.C. § 3729.

PARTIES TO THE PROCEEDINGS AND
STATEMENT PURSUANT TO RULE 29.6

The petitioner is Donna E. Shalala, Secretary, Health and Human Services. The respondents are two trade associations, the Ohio Hospital Association and the American Hospital Association.*

The Ohio Hospital Association and the American Hospital Association are unrelated to each other and neither has a parent or publicly held company owning any portion of its stock.

* This action was initially filed by the Ohio Hospital Association. During the course of these proceedings, the association changed its name to "OHA: The Association for Hospitals and Health Systems" but has since changed it back to "Ohio Hospital Association." At all stages, the case has been captioned under the original "Ohio Hospital Association" name.

TABLE OF CONTENTS

Question Presented	i
Parties to the Proceedings.....	ii
Table of Contents	iii
Table of Cited Authorities.....	iv
Statutory Provisions Involved.....	1
Statement of the Case	1
Reasons for Denying the Petition	13
Conclusion.....	26
Appendix	1a

TABLE OF CITED AUTHORITIES

	Page(s)
CASES:	
<i>Bowen v. Michigan Academy of Family Physicians</i> , 476 U.S. 667 (1986).....	<i>passim</i>
<i>Heckler v. Ringer</i> , 466 U.S. 602 (1984).....	15, 16, 20, 21, 22
<i>Lawrence v. Chater</i> , 516 U.S. 163 (1996).....	24, 25
<i>Lords Landing Village Condominium Council v. continental Ins. Co.</i> , 520 U.S. 893 (1997).	25,26.
<i>Shalala v. Illinois Council on Long Term Care, Inc.</i> , 120 S. Ct. 1084 (2000).....	<i>passim</i>
<i>Stutson v. United States</i> , 516 U.S. 193 (1996).....	25, 26
<i>Weinberger v. Salfi</i> , 422 U.S. 749 (1975).....	15, 16, 20, 21, 22.
STATUTES AND REGULATIONS:	
31 U.S.C. § 3729 (1994).....	<i>passim</i>
31 U.S.C. § 3729(a) (1994).....	<i>passim</i>
42 U.S.C. § 405 (b).....	<i>passim</i>
42 U.S.C. § 405(g) (1994).....	<i>passim</i>
42 U.S.C. § 405(h) (1994).....	<i>passim</i>
42 U.S.C. § 1395h (1994 & Supp. IV 1998).....	5
42 U.S.C. § 1395ii (1994)	1
42 C.F.R. § 405.841-.842 (1999).....	5
42 C.F.R. § 405.1895(d) (1999).....	5
MISCELLANEOUS	
American Medical Association, Physicians’ Current Procedure Terminology Guide (1989-1995).	10, 11
Medicare Hospital Manual, Health Care Financing Admin. Pub. 10, § 437(J) (1996).....	12
Provider Reimbursement Manual, Health Care Financing Admin. Pub. 15, §§ 2931, 2932 (1985).	5

STATUTORY PROVISIONS INVOLVED

1. 42 U.S.C. § 405(g). See Pet. App. at 37a-38a.
2. 42 U.S.C. § 405(h). See Pet. App. at 39a.
3. 42 U.S.C. § 1395ii. See Pet. App. at 42a-43a.
4. Administrative Procedures Act, 5 U.S.C. § 553 (1994)
5. False Claims Act, 31 U.S.C. § 3729 (1994) is set forth in the appendix to this brief. See App., *infra*, 1a.
6. Medicare Act, 42 U.S.C. § 1395 *et seq.*

STATEMENT OF THE CASE

Contrary to Petitioner's assertion, this case is not about the scope of Petitioner's authority pursuant to the Health Insurance for the Aged Act, commonly known as the Medicare Act. 42 U.S.C. § 1395 *et seq.* Rather, this case is about whether Petitioner can, on the one hand, elect to eschew the administrative scheme available to her under the Medicare Act to pursue alleged reimbursement irregularities using the False Claims Act (31 U.S.C. § 3729 (1994)) and then, on the other hand, claim the protection of that same administrative scheme in order to deny Respondents a meaningful judicial review of her actions.

The issue before the Court is whether jurisdiction in federal court is available to review Department of Health and Human Services regulations that were never the subject of a rule-making proceeding under the Administrative Procedure Act (5 U.S.C. § 553 (1994)), and where Petitioner has never initiated administrative proceedings to recoup the alleged overpayments she now demands.

The court of appeals specifically found that the "Secretary has never initiated a rulemaking proceeding under the Administrative Procedure Act to formalize the billing standards she now espouses," and that she never "initiated administrative proceedings to recoup the alleged overpayments" she attempted to collect by resort to the threat of False Claims Act prosecutions. Pet. App. at 2a. Indeed, she never challenged the reimbursement

practices of Ohio hospitals when claims were submitted or afterward, and only *later* "came to believe that the methodology used by the hospitals in calculating their reimbursement claim was improper in certain respects." Pet. App. at 5a. Petitioner thus *paid* the hospitals' claims and never invoked *her* administrative remedy of recoupment.

Having been paid on their unchallenged claims, the individual hospitals had no wrong to remedy and no adverse decision to appeal. Yet they were subjected to what the court of appeals described as the "heavy-handed" (Pet. App. at 1a) threat of False Claims Act prosecution if they did not acquiesce to Petitioner's post-hoc decision that her prior interpretation of reimbursement rules was no longer adequate.

Faced with the jurisdictional impossibility of administrative review, Petitioner would have the hospitals be content with the Hobson's choice either to pay money "on terms they consider unjust," (Pet. App. at 2a) or to defend their unbundling practices as a defense to False Claims Act prosecution, and risk the full panoply of civil, criminal, and disbarment penalties an unsuccessful defense could entail. According to Petitioner, this type of "judicial review" is merely a question of "timing" and not of "availability." Pet. at 20-24.

But the court of appeals correctly held that this is no review at all. Pet. App. at 12a. The court said that "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 taken." Pet. App. at 5a. Because the individual hospitals had no remedies under 42 U.S.C. § 405(b), they had no basis for judicial review under 42 U.S.C. § 405(g).

For these reasons, the decision of the Sixth Circuit comports perfectly with this Court's intervening decision in *Shalala v. Illinois Council on Long Term Care*, 120 S. Ct. 1084 (2000). The December 29, 1999 decision below, authored by the honorable David A. Nelson, followed the

precedent established by this Court in *Bowen v. Michigan Academy of Family Physicians*, 476 U.S. 667 (1986). Observing a split among courts interpreting and applying *Michigan Academy*, this Court accepted certiorari in *Illinois Council* 120 S. Ct. at 1091. Although the decision in *Illinois Council* was issued on February 29, 2000, the decision in the case at hand followed the interpretation of *Michigan Academy* which was adopted by this Court in *Illinois Council*. Thus, as a result of *Illinois Council*, the decision below does not create a conflict among the circuits on the jurisdictional issue in this case.

Moreover, after requesting and receiving a 30-day extension in which to file its rehearing petition, Petitioner was able to present the court below with this Court's decision in *Illinois Council*, as well as her arguments as to why the subsequent decision merited reconsideration of the case at hand. After directing Respondents to brief the issues raised in the petition for rehearing and further considering the issue, the court of appeals denied Petitioner's request for rehearing. The court of appeals correctly determined that its original decision properly followed the interpretation of *Michigan Academy* which was subsequently affirmed by this Court in *Illinois Council*. Accordingly, the petition should be denied.

As stated, the summary of Medicare statutes and regulations and the history of the case presented by Petitioner are sufficiently accurate and will not be disputed by Respondents in this response. Pet. at 2-11. Missing from this discussion, however, is a description of the facts and circumstances facing Respondents' member hospitals with False Claims Act investigations initiated by Petitioner outside of the Medicare Act. Thus, the following explanation, which was clearly understood by the courts below (Pet. App. at 4a-7a, 18a-23a), is necessary for the Court's consideration of the petition.

1. Hospitals that are eligible Medicare “providers” provide medical services to Medicare beneficiaries. They then submit bills for these services to the Medicare program’s designated

agent, usually an insurance company and commonly referred to as a fiscal intermediary. 42 U.S.C. § 1395h (1994 & Supp. IV 1998). The petition accurately describes the fiscal intermediary's statutory responsibilities before paying a hospital for a claim submitted. Pet. at 3, n.2. Through the fiscal intermediary, Petitioner has an opportunity to review all claims for Medicare reimbursement at the time they are submitted. In addition, the fiscal intermediary has the opportunity to review claims on an ongoing basis and to challenge improper claims by exercising its right to "re-open" past claims that have been paid.¹ This right to re-open exists for three years from when the claim was paid, unless fraud is suspected, in which case there is no statute of limitations. 42 C.F.R. § 405.1895(d) (1999).

The petition describes the administrative and judicial review mechanisms available for "anyone dissatisfied with an initial determination" by Petitioner or her agents. Pet. at 4-5. Indeed, administrative procedures exist under the Medicare program to give hospitals an opportunity to challenge the *denial* of submitted claims and to give the fiscal intermediary or Petitioner an opportunity to audit or revise initial payment determinations. Neither of these triggers to administrative review exist in the case at hand.

2. This case challenges a comprehensive investigation being conducted by Petitioner under the authority of the False Claims Act, 31 U.S.C. § 3729 (1994) (and outside of the Medicare Act) into certain billing and coding practices of Ohio hospitals. This investigation was launched initially in Ohio and targeted over 150 of the approximately 185 general acute care hospitals in

¹ Even after a hospital has received reimbursement without adjustment from the fiscal intermediary, the intermediary, the Health Care Financing Administration or Petitioner has the right to reopen an otherwise final reimbursement decision. 42 C.F.R. § 405.841-.842 (1999). "Reopening" allows Petitioner or her agents the opportunity to "reexamine or question the correctness of a determination or decision otherwise final." Provider Reimbursement Manual, Health Care Financing Admin. Pub. 15, §2931 (1985). Any correction made upon re-opening is deemed to be a separate and distinct determination for which the effected provider is entitled to available administrative remedies. *Id.* at §2932. Critical to the jurisdictional issue at hand, no re-opening occurred here.

the state. It has since been called the "Ohio Hospital Project" by both government and industry representatives.

The Ohio Hospital Project is an investigation of Medicare claims submitted by hospitals for certain outpatient laboratory tests performed over a period of six prior years. During that time, hospitals performed the tests and submitted claims for reimbursement from Medicare. Of particular importance to the jurisdictional issue at hand, the fiscal intermediary carried out the responsibilities described above and in the petition *and paid the claims now being investigated*. Because the claims were paid in full, hospitals were not "dissatisfied" and accordingly did not exercise, or have the right to exercise, any administrative or judicial review mechanisms afforded by the Medicare program. Moreover, neither Petitioner nor her agents have invoked any administrative procedures under the Medicare program to recoup allegedly improper payments to hospitals.

In the case at hand, and entirely separate from the normal process for the review of Medicare claims described previously, Petitioner directed the fiscal intermediary in Ohio to perform a retroactive review of outpatient laboratory claims submitted by hospitals during a twenty-nine month period beginning in 1992 and ending in 1994. The results of this review, which formed the basis for the Ohio Hospital Project, were shared with the Department of Justice. In addition to the fiscal intermediary, the Office of Inspector General, the Health Care Financing Administration (agencies which are a part of the Department of Health and Human Services administered by Petitioner) and the Federal Bureau of Investigation ("FBI") participated in the process, all in conjunction with Petitioner. At the behest of Petitioner and her agents, hospitals began receiving notices that they were under investigation in June 1995. C.A. App. 3 (Compl. ¶ 9).

Such notice took two forms. Some hospitals received an unannounced visit from agents of the FBI. FBI agents notified hospital representatives that they were under investigation and faced the possibility of civil or criminal sanctions, including imprisonment. Then the agents immediately commenced an on-site investigation replete with interviews of hospital staff. Pet. App. at 5a. Other hospitals received notification of the investigation through letters from United States Attorneys from the northern or southern districts of Ohio. Many of the letters in the northern district of Ohio were very similar to that which is attached as Exhibit A to Respondents' complaint and contained the following statement:

...We have identified certain claims which may constitute the submission of false claims in violation of the False Claims Act, 31 U.S.C. §3729 *et seq.* This 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.

C.A. App. 3-4, 29 (Compl. ¶¶ 9-12 and Exh. A). Letters from the U.S. Attorney for the southern district of Ohio similarly cited the False Claims Act. Pet. App. at 5a-6a. C.A. App. 49-50 (Plaintiff's Mem. Contra Mot. to Dismiss, Exh. 1). These letters give the hospital the choice of participating in a "self-disclosure program" (i.e., negotiate a settlement) or face a False Claims Act suit. Pet. App. at 6a. Because of the severe and substantial penalties under the False Claims Act (described by the court of appeals as "draconian," Pet. App. at 1a-2a) and the very real possibility that unintentional coding and billing mistakes may have occurred over the six year period of investigation, many Ohio hospitals concluded that they had no choice but to participate in the self-disclosure program.

The False Claims Act investigations are not part of the Medicare program. Hospitals are afforded no opportunity to obtain a review of their False Claims Act allegations within the administrative hearing process designed for Medicare claims. Indeed, hospitals would welcome the ability to "channel" their claims through Medicare's administrative process.

Instead, hospitals were forced to "negotiate" a settlement under the False Claims Act, which provides maximum penalties of \$10,000 per claim, triple damages and liability for the cost of the government's legal fees. 31 U.S.C. § 3729(a) (1994). In the context of this negotiation, hospitals have no meaningful process to challenge the legal validity of Petitioner's position with respect to certain of the coding and billing issues being investigated — those which are now the subject of this lawsuit. Absent an administrative review process or jurisdiction over an action such as this, Petitioner is free to force hospitals, under threat of a False Claims Act prosecution, to give in to government demands which are based upon plainly erroneous legal standards.

3. This lawsuit focuses on those specific coding and billing standards for which there was no legal basis for Petitioner's position that the claims were false or even improper.

Respondents' complaint seeks declaratory and injunctive relief as follows:

1. A declaration that the billing and coding policies discussed in the complaint did not exist during the periods for which the Ohio Hospital Project is now seeking recoupment.
2. A declaration that such billing and coding policies were not properly promulgated.
3. A declaration that such billing and coding policies cannot be enforced retroactively.
4. A declaration that in the absence of a properly promulgated rule, hospitals could not have possessed the intent required under the False Claims Act; and
5. An injunction prohibiting Petitioner or her agents from attempting to recoup overpayments based on billing and coding policies which did not exist and were not properly promulgated.

Pet. App. at 17a-18a. C.A. App. 26-27 (Compl., Prayer ¶¶ A-F).

As referenced in the letter from the U.S. Attorney, Petitioner and her agents allege that hospitals are "unbundling" tests. Pet. at 5-6. The term "unbundling" is recognized to mean billing the components of a profile of tests individually when the rules require that such component tests, when performed simultaneously, must be billed under one, more comprehensive code. For example, if tests for glucose, sodium, potassium and chloride were

performed simultaneously, the rules require that these tests be billed under one code representing a four-test profile rather than the four individual codes representing each of the tests. Typically, the reimbursement for the four-test profile will be less than the total reimbursement of the four individual tests.

Certain blood chemistry tests did have rules that required that they be “bundled” together and billed as a profile when performed simultaneously. Until October 1996, Medicare instructions directed hospitals to bill procedures according to the American Medical Association's Physicians' Current Procedure Technology (or "CPT") Guide (the court of appeals described this manual as the "Rosetta Stone" for billing codes, Pet. App. at 4a). The CPT manual identified a specific list of nineteen blood chemistry codes that should be billed as multi-test profiles rather than individually. At all pertinent times, the CPT manual preface to this list read as follows:

The following list contains those tests that can be and are frequently done as groups and combinations ("profiles") on automated multichannel equipment. *For any combination of tests among those listed immediately below, use the appropriate number 80002-80019.* Groups of the tests listed here are distinguished from multiple tests performed individually for immediate or "stat" reporting.

American Medical Association, Physicians' Current Procedure Terminology Guide (1989-95) (emphasis added). C.A. App. 51-64 (Plaintiff's Mem. Contra Mot. to Dismiss, Exh. 2). The CPT manual then listed the nineteen codes that should be bundled together when performed simultaneously. *At no time prior to 1996 did that list include three tests which are the subject of Respondents' lawsuit: creatine-kinase (CPK), gammaglutamyltransferase (GGT) and triglycerides.* Thus, hospitals had no basis to believe that any or all of these three tests should have been bundled when performed simultaneously together or with any other tests on that list.

To illustrate one of the issues being challenged in this lawsuit, if a hospital performed five tests, four of which were on the above-referenced list of the nineteen tests to be bundled

together (e.g., sodium, glucose, potassium and chloride) and one of which was not on the list (e.g., CPK), it would bill the four-test profile using CPT code 80004 and it would also bill the CPT code for CPK (82550). This billing was totally appropriate based on the instructions and guidance available to hospitals at the time. In the Ohio Hospital Project, Petitioner has taken the unfounded position that the five tests performed should have been bundled together into a five-test profile (CPT code 80005) which should have been the only code billed, notwithstanding the glaring absence of CPK from the list in the CPT manual. Petitioner alleges that the separate billing of the CPK test constitutes a "false claim" in the amount of the reimbursement of that code (\$9.69). In fact, Petitioner alleges that every time the hospital separately billed CPK, each such occurrence constituted a separate false claim with statutorily-prescribed liability of \$5,000 to \$10,000 per claim.

Notably, the claim when originally presented clearly showed the separate codes for the four-test profile and the CPK. It was paid fully by the fiscal intermediary as presented, and was not subsequently adjusted or subjected to the reopening procedures available to Petitioner. As an approved claim, there was no authority or reason for a hospital to invoke the Medicare administrative processes for this claim. By her own choice, Petitioner has pursued recoupment of this claim outside of the Medicare program.

In the billing and coding issues that are the subject of Respondents' action, Petitioner and her agents are demanding reimbursement in compliance with billing policies that did not exist until the Ohio Hospital Project investigations.² Moreover, Petitioner and her agents are applying the new policies retroactively to each of the past six years. Most disturbingly,

² In fact, the Medicare Hospital Manual was amended effective October 1, 1996 to reflect Petitioner's new interpretation of the billing and coding issues which are the subject of this action. Medicare Hospital Manual, Health Care Financing Admin. Pub. 10, § 437(J), as revised by Transmittal 698, effective October 1, 1996.

Petitioner and her agents are alleging that these are "false claims," meaning that hospitals submitted them knowing them to be false notwithstanding the above-described lack of guidance. Hospitals typically process tens of thousands of laboratory claims in a year. With each claim being investigated constituting a separate false claim, at a mandatory penalty of between \$5,000 and \$10,000 per claim regardless of the amount of claim, hospitals faced significant potential liability through the Ohio Hospital Project.

REASONS FOR DENYING THE PETITION

Contrary to Petitioner's assertion, the court of appeals' decision in this case is unquestionably consistent with the holding in *Illinois Council*. The court of appeals found as follows: "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." Pet. App. at 5a. In *Illinois Council* this Court held that "it is more plausible to read *Michigan Academy* as holding that § 1395ii does not apply [42 U.S.C.] § 405(h) where application of § 405(h) would not simply channel review through the agency, but would mean no review at all." *Illinois Council*, 120 S. Ct. at 1096-97. Petitioner argues that the court of appeals' decision reaches a "different result" than this Court's decision in *Illinois Council* but that is because this is a different case from *Illinois Council*. Instead, it is a case which resembles *Michigan Academy*.

Petitioner contends the court of appeals did not have the benefit of the decision in *Illinois Council* and, therefore, seeks relief in the form of an order which would grant certiorari, vacate Judge Nelson's opinion and remand to the court of appeals for reconsideration of the case in light of *Illinois Council*. Judicial economy is served by this relief when a potentially determinative intervening event occurs *that the court of appeals did not have an opportunity to*

consider. In this case, however, the court of appeals did have an opportunity to consider this Court's decision in *Illinois Council*. In fact, Petitioner received an extension in which to file a petition for rehearing and was able to brief her arguments concerning the applicability of *Illinois Council* to the court of appeals. Further, the court directed Respondents to respond to Petitioner's petition. These circumstances clearly do not support the relief requested by Petitioner in this case.

1. The gist of Petitioner's request for certiorari is that the court of appeals' decision in the case at hand cannot be reconciled with this Court's February 29, 2000 decision in *Illinois Council*. On the contrary, the case at hand can easily be reconciled with *Illinois Council* as falling squarely within the exception in *Michigan Academy*, which exception clearly survives after the precedent of *Illinois Council*.

The issue before the Court is whether Respondents' member hospitals have "no review at all" absent jurisdiction over this cause of action. The court of appeals reached the unmistakable conclusion that Respondents' members had no opportunity for administrative review, thereby warranting an exception to the preclusive effect of Section 405(h). Denying jurisdiction to Respondents in the case at hand would not "channel" the claims of Respondents' members to any administrative agency or process. Rather, those claims would never be heard by any administrative forum. Under those circumstances, the court of appeals' decision is squarely in line with this Court's decisions in *Michigan Academy* and *Illinois Council*.

In *Illinois Council*, an association of nursing homes brought a challenge to Medicare regulations that specified enforcement actions to be taken if it is found that a nursing home violates substantive standards. Under the applicable statutes and regulations, a nursing home dissatisfied with any enforcement action has the opportunity for administrative and judicial review. *Illinois Council*, 120 S. Ct. at 1097-98. Like the case at hand, the issue before the Court

was whether Section 405(h) precluded the association's legal challenge. Unlike the case at hand, the association's members had an opportunity for administrative and judicial review.

The Court in *Illinois Council* analyzed the Section 405(h) bar previously examined in *Michigan Academy*, *Weinberger v. Salfi*, 422 U.S. 749 (1975) and *Heckler v. Ringer*, 466 U.S. 602 (1984). First, the Court recognized in *Salfi* and *Ringer* that Section 405(h) required "the 'channeling' of virtually all legal attacks through the agency." *Illinois Council*, 120 S. Ct. at 1093. Further, *Salfi* and *Ringer* confirmed that Section 405(h) "forecloses distinctions" based upon the nature of the relief sought. *Id.* At 1094. For purposes of applying Section 405(h), then, the only distinction which mattered after *Salfi* and *Ringer* was the availability of administrative review, i.e., the *Michigan Academy* exception.

In *Michigan Academy*, a group of physicians challenged the validity of a regulation authorizing different reimbursement rates for similar services. As in the case at hand, the physicians had no access to the courts under Section 405(g).³ In a unanimous decision, this Court affirmed jurisdiction over the action, finding the preclusive effect of Section 405(h) inapplicable. *Michigan Academy*, 476 U.S. at 680. In analyzing the statutory scheme and legislative history, the Court stated, "We begin with the strong presumption that Congress intends judicial review of administrative action." *Id.* at 670. The Court found the presumption supported by legislative history (*Id.* at 670-73) and permitted federal question jurisdiction, thereby establishing *Michigan Academy* as an exception to the Section 405(h) bar and to the precedents of *Salfi* and *Ringer*.

³ The statutory scheme then in place for "Part B" claims did not offer the same opportunities for administrative and judicial review as were available under "Part A" of the Medicare Act. See Pet. at 4, n.3.

In *Illinois Council*, a 5-4 decision, the majority and dissent strongly disagreed as to the proper interpretation to be given to *Michigan Academy*.⁴ Under either interpretation, however, federal jurisdiction in the case at hand is appropriate. The majority interpreted *Michigan Academy* to hold that Section 405(h) does not apply "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." *Illinois Council*, 120 S. Ct. at 1095-1096. The majority confirmed *Michigan Academy*'s status as an exception to the Section 405(h) bar in cases where no administrative review was available to which the legal challenges should be channeled.⁵ However, the facts in *Illinois Council* differ from the case at hand in that the nursing homes had available administrative processes through which their legal challenges could be channeled.

In the same way, the court of appeals applied the facts at hand to *Michigan Academy* and adhered to the interpretation of *Michigan Academy* subsequently adopted by the *Illinois Council* majority. The court of appeals noted that Petitioner's arguments focused solely on the third sentence of Section 405(h), "ignoring the context in which that sentence appears." Pet. App. at 10a. Section 405(h) begins, "The findings and decision of the [Secretary] *after a hearing* shall be binding upon all individuals who were parties to such *hearing*." 42 U.S.C. 405(h) (1994) (emphasis added). The court found that Respondents' member hospitals "had no opportunity to invoke these administrative procedures." Pet. App. at 5a. Indeed, the only "agency action" under the Medicare program was an action to pay the hospitals' claims in full as originally submitted.

⁴ The Seventh Circuit Court of Appeals had interpreted *Michigan Academy* in line with Justice Thomas' dissent. *Illinois Council*, 120 S. Ct. at 1108.

⁵ The dissent in *Michigan Academy* also supports a finding of jurisdiction in the case at hand. Justice Thomas' dissent interprets *Michigan Academy* to permit pre-enforcement judicial review to any challenge of the validity of the Secretary's instructions or regulations, which is consistent with the cause of action initiated by Respondents herein. *Illinois Council*, 120 S.Ct. at 1103-1114.

In evaluating the case at hand, it must be emphasized that the availability of administrative and judicial review to Respondents' members is entirely within the control of Petitioner. Petitioner paid Respondents' members' claims in full upon initial presentation; from this determination in their favor, hospitals cannot and would not seek administrative review.⁶ Through the Ohio Hospital Project, Petitioner now seeks recoupment for claims she alleges were improperly paid. Rather than exercise administrative options within the Medicare statutory and regulatory scheme to recoup such claims, Petitioner has sought to recoup the claims through False Claims Act investigations. If Petitioner intends to rely on Section 405(h) as the exclusive process for review, *her* claims must be "channeled" through the administrative process. By her choice of forum, Petitioner should not now be permitted to shield her action from judicial review.

From her arguments, it appears Petitioner believes that some administrative process is available to Respondents' members through which Respondents' claims should be "channeled." For instance, Petitioner relies upon *Salfi* for the proposition that Section 405(h) "extends to any 'action' seeking 'to recover on any ... claim' " and "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)." Pet. at 15. Respondents' members are not seeking "to recover" any claim because the claims they submitted were paid in full; only Petitioner is seeking to recover on such claims. Indeed, the "final decision of the Secretary" discussed by Petitioner was a decision

⁶ In this context, footnote 14 of the petition (Pet. at 22, n.14) is particularly disingenuous. Petitioner correctly points out that "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 the purposes of recoupment of any previously-paid claim." Petitioner then cites authority as to why hospitals cannot force Petitioner to re-open the claims. The cases cited were instances in which providers sought to force Petitioner to re-open cost reports so that the provider could obtain *additional* reimbursement or cost allowance. In the case at hand, however, hospitals have no reason to seek reopening for claims which have been paid in full. The cited authority is inapposite. Indeed, it is Petitioner who has effectively reopened the claims through the False Claims Act investigations and outside the review mechanism

of full payment in favor of the hospitals. *Salfi* cannot be applied to the case at hand as Petitioner believes.

Petitioner states that neither of the courts below “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.” Pet. at 21. This statement captures the root of Respondents’ concern. The problem here is that the agency *has not and will not* “actually [apply] the challenged policies to [Respondents]” either in an initial determination or in a re-opening of prior payment determinations. There will not be any challenge to the “initial determinations” of claims here because all of the disputed claims have already been paid. Furthermore, Petitioner has made it clear, by both her actions and words since the inception of the Ohio Hospital Project, that she has no intention to re-open the paid claims in dispute here. Pet. at 22, n. 14.

2. The petition takes editorial license with the court of appeals' opinion to distort its true meaning. Petitioner claims “the court of appeals confused the *timing* of judicial review with its *availability*.” Pet. at 20. Petitioner suggests that the court of appeals believed there would be administrative procedures available to Respondents’ members at some later date. For instance, Petitioner claims in her brief:

[T]he 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 any remedies under § 405(b)” or the present ability to seek judicial review under § 405(g)).

created by Congress. Petitioner should not be permitted shelter from federal court review of her action under these circumstances.

Pet. at 21-22. However, the court of appeals' opinion is unmistakably clear in recognizing that there is no administrative procedure available to Respondents.

The court of appeals stated, "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." Pet. App. at 5a. The court later stated, "[u]nlike 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." Pet. App. at 12a. The opinion makes no reference to the "timing" of administrative review. The court is entirely unambiguous in recognizing that in this situation channeling review through the agency means no review at all.

Petitioner further claims that the "court of appeals appears to have limited Section 405(h)'s applicability to cases involving benefits or 'amount' determinations." Pet. at 19. Petitioner quotes from the opinion where the court of appeals purportedly distinguished *Salfi* and *Ringer* on an "amount determination" basis. However, a further reading of that paragraph in the opinion makes it clear that the court of appeals did not base its decision on whether this was a claim for benefits. On the contrary, the court of appeals referred to "amount determinations" to illustrate the unavailability of administrative review and remedies in this situation. It is that lack of administrative review that formed the basis for the court of appeals' opinion.

The opinion states in relevant part:

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 . . . claims[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.

Pet. App. at 11a-12a, emphasis added. The court of appeals has only highlighted the fact that a claimant seeking payment of benefits quite clearly has administrative channels he or she must traverse before any judicial review can take place. It is true that in both *Salfi* and *Ringer* the plaintiffs were attempting to collect Medicare benefits. However, in both cases there was an established administrative procedure by which the plaintiffs should have sought relief. It is the latter point (and the *unavailability* of such procedures in the case at hand) which formed the basis for the court's decision.

3. Petitioner contends the court of appeals did not have the benefit of, and did not fully consider, this Court's decision in *Illinois Council*. Pet. at 25. Accordingly, she requests an order granting the petition for certiorari, vacating the lower court's decision, and remanding for further proceedings (often referred to as a "GVR" order). Pet. at 25. It is clear, however, that the court of appeals did consider *Illinois Council* and Petitioner's arguments, as well as a separate brief requested from Respondents. Accordingly, this case is not appropriate for a GVR order.

To assess the "intervening event" analysis of the GVR request, the Court should consider the proceedings below. The court of appeals issued its decision on December 29, 1999. On February 3, 2000, Petitioner requested a 30-day extension in which to file a petition for rehearing, which motion was granted by the court of appeals by order dated February 7, 2000. On February 29, 2000, this Court issued its decision in *Illinois Council*. Petitioner filed her Petition for Rehearing *En Banc* on March 14, 2000. The crux of Petitioner's rehearing request was premised upon this Court's decision in *Illinois Council*. The court of appeals could have ruled on the petition for rehearing as filed but instead, by letter dated March 22, 2000, directed

Respondents to file a response to the petition for rehearing. Such response was filed with the court of appeals on April 5, 2000. Again, the primary issue addressed in Respondents' response was the effect of this Court's decision in *Illinois Council*. Under these circumstances, it is difficult to believe that the court of appeals did not fully consider the decision in *Illinois Council*.

Petitioner contends that the court of appeals' order denying rehearing did not specifically consider this Court's decision in *Illinois Council*. Pet. at 25, n.15. The court of appeals' order reads as follows:

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.

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.

Pet. App. at 35a-36a. Based on what was before it, the court of appeals concluded that *Illinois Council* was not applicable to the facts at hand. Indeed, the *issues* raised in *Illinois Council* were fully considered upon the original submission and decision of this case because this case properly relies on *Michigan Academy*. As discussed *supra*, the court of appeals' decision and examination of *Michigan Academy* were not improper in light of this Court's decision in *Illinois Council*.

This Court has said that a GVR order is appropriate:

“[w]here intervening developments, or recent developments that we have reason to believe the court below did not fully consider, reveal a reasonable probability that the decision below rests upon a premise that the lower court would reject if given the opportunity for further consideration, and where it appears that such a redetermination may determine the ultimate outcome of the litigation[.]”

Lawrence v. Chater, 516 U.S. 163, 167 (1996). The intervening development in the case at hand – the decision in *Illinois Council* – was fully considered by the court of appeals. Moreover, and

especially in light of the court's disposition of the rehearing request, there is no reasonable probability that the court of appeals would change its decision upon further consideration. To direct Judge Nelson's panel (which included a visiting judge⁷) to reconvene for further briefs and oral argument under these circumstances is an unnecessary diversion of judicial resources.

Petitioner argues that prior decisions of this Court support a GVR under these circumstances where the effects of the "intervening event" were already briefed to the court of appeals. In those cases, however, there was "uncertainty as to what the court below 'might ... have relied on.'" *Lawrence*, 516 U.S. at 170. In *Stutson v. United States*, 516 U.S. 193, 195-196 (1996), the Court found an "exceptional combination of circumstances" to support a GVR order to consider recent Supreme Court precedent that was briefed by the parties.⁸ Such circumstances do not exist in the case at hand, however. In *Lords Landing Village Condominium Council of Unit Owners v. Continental Insurance Co.*, 520 U.S. 893 (1997), the court of appeals' decision was issued on August 6, 1996, rehearing was denied on September 3, 1996 and the court's mandate was issued on September 11, 1996. On September 17, 1996, petitioner moved the court of appeals to recall its mandate based on a newly-discovered July 26, 1996 state court decision relating to a state law point decided by the court of appeals. This Court issued a GVR order concluding that the court of appeals believed it was procedurally precluded from considering the motion filed after issuance of its mandate. *Lords Landing*, 520 U.S. at 897. Unlike *Stutson* and *Lords Landing*, there is no ambiguity about what the court of appeals considered in the present case.

⁷ Honorable John R. Gibson, Senior United States Circuit Judge for the Eighth Circuit Court of Appeals, sitting by designation.

⁸ The petitioner's appeal of a criminal conviction was denied as untimely in a summary affirmance by the court of appeals. In petitioning this Court, the government repudiated its legal position advanced below with respect to the Supreme Court precedent at issue, and all six courts of appeals that had addressed the applicability of the precedent reached conclusions different from the court in that case. The

CONCLUSION

For the foregoing reasons, Respondents respectfully request that this Court deny the Petition for a Writ of Certiorari.

Respectfully Submitted,
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incarcerated defendant, through no fault of his own, had no plenary consideration of his appeal. *Stutson*, 516 U.S. at 195.

APPENDIX

The False Claims Act, Section 3729 of Title 31, United States Code, provides:

- (a) Liability for certain acts.--Any person who--
- (1) knowingly presents, or causes to be presented, to an officer or employee of the United States Government or a member of the Armed Forces of the United States a false or fraudulent claim for payment or approval;
 - (2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government;
 - (3) conspires to defraud the Government by getting a false or fraudulent claim allowed or paid;
 - (4) has possession, custody, or control of property or money used, or to be used, by the Government and, intending to defraud the Government or willfully to conceal the property, delivers, or causes to be delivered, less property than the amount for which the person receives a certificate or receipt;
 - (5) authorized to make or deliver a document certifying receipt of property used, or to be used, by the Government and, intending to defraud the Government, makes or delivers the receipt without completely knowing that the information on the receipt is true;
 - (6) knowingly buys, or receives as a pledge of an obligation or debt, public property from an officer or employee of the Government, or a member of the Armed Forces, who lawfully may not sell or pledge the property; or
 - (7) knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Government,

is liable to the United States Government for a civil penalty of not less than \$5,000 and not more than \$10,000, plus 3 times the amount of damages which the Government sustains because of the act of that person, except that if the court finds that--

- (A) the person committing the violation furnished officials of the United States responsible for investigating false claims violations with all information known to such person about the violation within 30 days after the date on which the defendant first obtained the information;
- (B) such person fully cooperated with any Government investigation of such violation; and

(C) at the time such person furnished the United States with the information about the violation, no criminal prosecution, civil action, or administrative action had commenced under this title with respect to such violation, and the person did not have actual knowledge of the existence of an investigation into such violation;

the court may assess not less than 2 times the amount of damages which the Government sustains because of the act of the person. A person violating this subsection shall also be liable to the United States Government for the costs of a civil action brought to recover any such penalty or damages.

(b) Knowing and knowingly defined.--For purposes of this section, the terms "knowing" and "knowingly" mean that a person, with respect to information--

- (1) has actual knowledge of the information;
- (2) acts in deliberate ignorance of the truth or falsity of the information; or
- (3) acts in reckless disregard of the truth or falsity of the information,

and no proof of specific intent to defraud is required.

(c) Claim defined.--For purposes of this section, "claim" includes any request or demand, whether under a contract or otherwise, for money or property which is made to a contractor, grantee, or other recipient if the United States Government provides any portion of the money or property which is requested or demanded, or if the Government will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded.

(d) Exemption from disclosure.--Any information furnished pursuant to subparagraphs (A) through (C) of subsection (a) shall be exempt from disclosure under section 552 of title 5.

(e) Exclusion.--This section does not apply to claims, records, or statements made under the Internal Revenue Code of 1986.