PRECEDENTIAL

Filed October 17, 2003

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

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No. 03-1268

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THE UNIVERSITY OF MEDICINE AND DENTISTRY OF NEW JERSEY; THE COOPER HEALTH SYSTEM; UNIVERSITY PHYSICIAN ASSOCIATES OF NEW JERSEY, INC.

v.

DANA CORRIGAN, ACTING INSPECTOR GENERAL, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES*

The University of Medicine and Dentistry of New Jersey; The Cooper Health System; University Physician Associates of New Jersey, Inc.,
Appellants

*(Pursuant to Rule 43(c), F.R.A.P.)

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On Appeal from the United States District Court
for the District of New Jersey
D.C. Civil Action No. 99-cv-05046
(Honorable Harold A. Ackerman)

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Argued April 23, 2003

Before: SCIRICA, *Chief Judge*,** AMBRO and WEIS, *Circuit Judges*

(Filed: October 17, 2003)

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** Judge Scirica began his term as Chief Judge on May 4, 2003.

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## OPINION OF THE COURT

SCIRICA, *Chief Judge*.

This is an action seeking an injunction against a planned Medicare audit of New Jersey teaching hospitals by the inspector general of the Department of Health and Human Services. The District Court held that it did not have standing to consider plaintiffs' claims under the Administrative Procedures Act, 5 U.S.C. § 704, and that plaintiffs failed to state a due process claim. The District Court also granted defendant's motion to enforce subpoenas related to the audit. We will affirm.

### I.

A. *Medicare Billing.*

The underlying dispute in this case involves Medicare billing at teaching hospitals. The parties differ on when physicians could bill for work performed by interns and residents under Health and Human Services regulations in effect before July 1996. Plaintiffs contend defendant's planned audit of their billing records would use an improper standard and should be enjoined.[1]

The Medicare program is the responsibility of the United States Department of Health and Human Services. Within the department, the program is administered by the Centers for Medicare and Medicaid Services, the successor to the Health Care Financing Administration. The processing of bills submitted by the healthcare providers for particular services rendered has been contracted out to several insurance companies known as "carriers." Because

1. Plaintiffs are the University of Medicine and Dentistry of New Jersey and two corporations associated with it: the Cooper Health System, a non-profit corporation that owns and operates a teaching hospital affiliated with the university; and University Physician Associates of New Jersey, Inc., a non-profit corporation that processes bills and Medicare payments for university faculty members. The claims of all parties are based on the proposed audit of the university's teaching hospitals.

the carriers handle the billing and payment, they have initial responsibility for ensuring compliance with the statutes and regulations governing Medicare billing of individually billable services.[2]

Medicare payments to healthcare providers fall under two categories. Medicare Part A covers general hospital expenses, including residents' and interns' salaries. Part B covers payments made on a fee-for-service basis, reimbursing direct care by physicians, among other services. Consequently, at teaching hospitals, most services performed by residents are covered under Part A, which reimburses the hospitals for residents' salaries, but does not reimburse them on the basis of particular services they provide. 42 U.S.C. § 1395x(b)(6). Physicians providing care to patients, by contrast, are reimbursed under Part B based on the service performed and in line with reimbursement paid to physicians for services outside of teaching hospitals.

But this distinction is not so easily drawn. Physicians can also bill Medicare for services in which residents and interns participate, so long as the physician is sufficiently involved in the provision of services. The appropriate standard for determining when physicians may bill under Part B for work performed by residents and interns is the subject of the underlying dispute in this case.

In 1968, HHS promulgated regulations for Part B reimbursement of services performed at teaching hospitals. The regulations authorized payment to an "attending physician" for services "of the same character, in terms of the responsibilities to the patient that are assumed and fulfilled, as the services he renders to his other paying patients" if the physician "provides personal and identifiable direction to interns or residents who are participating in the care of his patient." 20 C.F.R. § 405.521 (1968). Notwithstanding, "[i]n the case of major surgical procedures and other complex and dangerous procedures

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2. Payments for other kinds of costs, i.e., not on a fee-for-service basis, are made by "intermediaries"—private entities contracted by HHS for processing payments under Medicare Part A. Like the carriers, their Part B analogues, intermediaries have a certain amount of responsibility for ensuring compliance with Medicare requirements. 42 U.S.C. § 1395h.

or situations, such personal and identifiable direction must include supervision in person by the attending physician." *Id*.

In 1980, Congress amended the statute, largely adopting the standard HHS stated in its regulations, but omitting the specific references to surgery and other hazardous procedures. The statute now provides that if a physician "renders sufficient personal and identifiable physicians' services to the patient to exercise full, personal control over the management of the portion of the case for which the payment is sought, [and] the services are of the same character as the services the physician furnishes to patients not entitled to benefits under this subchapter," the physician may bill for the services under Part B. 42 U.S.C. § 1395u(b)(7)(A)(i)(I).

HHS's regulations were changed in 1992, but continued to authorize payment to a teaching physician only when the attending physician "furnishes personal and identifiable direction to interns or residents who are participating in the care of the patient." 42 C.F.R. § 405.521(b)(1) (1992). And the regulations continued to require that the physician "personally supervise" the residents and interns in the case of major surgery or other dangerous procedures.

Between 1992 and 1996, the Health Care Financing Administration began to interpret the phrase "furnishes personal and identifiable direction" as requiring the physician to be physically present when and where the resident or intern provides the billed service in order to be eligible for Part B payment. This interpretation led to widespread complaints from healthcare providers, many of whom claimed that it amounted to a change in the regulation. A physician could provide "personal and identifiable direction," it was claimed, without being physically present when the resident performed the billed care. The university contends that in response to these comments, the Health Care Financing Administration agreed to refrain from imposing such a requirement until there was a new rule clarifying the agency's position.

In December 1995, HHS adopted a new rule governing physicians at teaching hospitals that took effect July 1,

1996. The rule now provides, "If a resident participates in a service furnished in a teaching setting, physician fee schedule payment is made only if a teaching physician is present during the key portion of any service or procedure for which payment is sought." 42 C.F.R. § 415.170.

Because the carriers are initially responsible for enforcing the billing standards, the carriers themselves often issue clarifying instructions to the healthcare providers, furnishing a source of information about Medicare billing requirements in addition to the statute and regulations.

B. *The Inspector General.*

The Office of Inspector General of HHS, along with inspector generalships for other federal administrative agencies and departments, is governed by the Inspector General Act of 1978, 5 U.S.C. App. 3.[3] Offices of Inspector General are designed to be "independent and objective units" separate from their respective departments and agencies. 5 U.S.C. App. 3 § 2. They are directed to "conduct and supervise audits and investigations relating to the programs and operations" of their respective agencies. *Id.* Their primary task is to prevent fraud and abuse within such programs and operations. The Office of Inspector General of HHS is thus an independent office with a primary function to investigate fraud and abuse within the Medicare program.

The Inspector General Act grants inspectors general broad discretion to determine which investigations and audits are necessary to its mission, authorizing them "to make such investigations and reports relating to the administration of the programs and operations of the applicable establishment as are, in the judgment of the Inspector General, necessary or desirable." 5 U.S.C. App. 3 § 2.

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3. The inspector general for HHS (then the Department of Health, Education, and Welfare) was created by statute in 1976. Pub L. No. 94-505. The Inspector General Act is similar in relevant respects to the original statute.

C. *The PATH Audits.*

The HHS inspector general's auditing of teaching hospitals for overbilling began with an audit of the University of Pennsylvania Health System's Medicare billing records from 1989 to 1994. The audit disclosed three purported deficiencies in the University of Pennsylvania Health System's billing. First, the inspector general reported a substantial amount of billing by physicians for work performed by residents. Second, the audit revealed a certain amount of "upcoding"—billing for procedures more complex than were actually performed. And finally, the inspector general contended that documentation was inadequate for many of the billed items. The University of Pennsylvania Health System paid $30 million to settle any potential False Claims Act charges.

Following that audit, the inspector general (then June Gibbs Brown) decided to expand the investigation to determine if these practices were widespread. The result was the Physicians at Teaching Hospitals ("PATH") initiative, under which the inspector general selected a large number of teaching hospitals nationwide for audits looking for the alleged problems discovered in the University of Pennsylvania audit.

The PATH initiative was launched in 1996, the same year the new HHS regulations expressly adopted a physical presence requirement. PATH audits—including the one now challenged—were directed at billing in the years before the rule change. The operative rules for these audits, therefore, are primarily the rules as amended in 1992, which spoke of "personal and identifiable direction," but did not expressly state that a physician's presence was required. 42 C.F.R. § 404.521(b)(1) (1992).

PATH audits are of two types. "PATH I" audits are those performed by the Office of Inspector General at its expense. A healthcare provider can choose, however, to hire an independent auditor to perform the audit, reporting the results to the inspector general. This is a "PATH II" audit.

A number of healthcare providers and medical professional organizations objected to the initiative, claiming the PATH audits amounted to retroactive

application of the 1996 rules. The inspector general contended instead that the rules had always required the physical presence of the physician for Part B payments, even though it was not stated as clearly as under the new rule.

HHS responded to the controversy by issuing the so-called "Rabb letter." Harriet Rabb, the general counsel of HHS, issued a letter clarifying her views concerning the PATH audits. Rabb, of course, worked for HHS, not the independent Office of Inspector General. Accordingly, her letter is not a policy statement from the Office of Inspector General. Rather, it expressed Rabb's understanding of the standards the Office of Inspector General would apply in determining when a PATH audit would be conducted.

In the letter, Rabb acknowledged that "the standards for paying teaching physicians under Part B of Medicare have not been consistently and clearly articulated by [the Health Care Financing Administration, now the Centers for Medicine and Medicaid Services] over a period of decades." Letter of Harriet S. Rabb, HHS General Counsel, at 4 (July 11, 1997). Nevertheless, Rabb concluded that the inspector general's interpretation, even if not clearly stated before 1996, was the correct one. Because of the ambiguity, Rabb stated that clear statements by the carriers "would be controlling." *Id*. Thus, if the carriers had issued materials clearly stating a physical presence requirement, the providers would bound by it. Rabb concluded that many, though not all, carriers had expressly stated that physical presence was required for teaching physicians to receive compensation under Medicare Part B.

Given this, Rabb stated her understanding that carrier notification would be a necessary requirement for initiation of a PATH audit: "[T]he OIG will undertake PATH audits only where carriers, before December 30, 1992, issued clear explanations" that Part B payments would be made only "when the teaching physicians either personally furnished services to Medicare beneficiaries or were physically present when the services were furnished by interns or residents." *Id*. at 5. An audit would go forward only after the Office of Inspector General had "obtained carrier materials showing that clear instructions on the need for teaching physicians

to be physically present were given to the institutions or physicians served by that carrier." *Id.* at 5-6. If the Office of Inspector General obtained such materials, a hospital would "have the opportunity to show, as a matter of fact, that it or the teaching physicians at the institution received guidance from the carrier which the hospital views as contradictory to the standard referenced above." *Id.* at 6.

Importantly, the letter states, "The decision whether clear guidance was given by carriers to teaching hospitals and physicians will be made by OIG. That determination is, necessarily, a fact bound one and will have to be made particularly and in each instance." *Id.*

In short, Rabb—speaking on behalf of HHS, not the inspector general—stated the Office of Inspector General would begin a PATH audit only if it was convinced, after a hospital had an opportunity to respond, that the hospital had received clear instructions from its carrier of the physical presence requirement.

D. *This Case.*

When the Office of Inspector General informed of its intention to initiate a PATH audit, the University of Medicine and Dentistry of New Jersey initially elected to have a PATH II audit performed by an independent auditor at its expense. But it never went forward with the audits and instead filed this action to enjoin the audits.

The university contends the audits are unlawful for several reasons. First, it argues the inspector general lacks the power to conduct PATH audits, as they are properly the function of HHS. It also argues the Office of Inspector General did not comply with the terms of the Rabb letter, concluding the University of Medicine and Dentistry was auditable without its having received clear notice from its carrier. And because it lacked prior notice of the standard the Office of Inspector General intends to apply in its audit, the university contends the initiation of the audits is arbitrary and capricious and violates its due process rights.

Because of the university's refusal to go forward with the audit, the inspector general issued administrative subpoenas for the relevant records. The university refused

to comply with the subpoenas. Consequently, the inspector general filed a motion to enforce the subpoenas in the District Court.

The District Court rejected the university's claims, primarily on the basis of its finding a lack of subject-matter jurisdiction for lack of finality and ripeness. It also granted the inspector general's motion to enforce the administrative subpoenas. The university appealed.

## II.

The university's challenge to the PATH audits comes to us in two forms. First, because the university has resisted the administrative subpoenas issued by the inspector general, the inspector general brought an action seeking enforcement of those subpoenas. The university appeals the District Court's order enforcing the subpoenas. Second, the university seeks injunctive relief against the audits. Under both sets of claims, the university seeks to block the initiation of the PATH audits. But the audits themselves would appear to be an early stage in an investigation that may or may not lead to enforcement actions. Because of this, the District Court determined that review of most of the university's claims was premature. As we discuss, we hold that the District Court lacked jurisdiction to consider these claims at this stage in the proceedings, but that it had jurisdiction over the inspector general's motion to enforce the subpoenas.

### A.

With respect to the subpoenas, the District Court found—correctly—that it had jurisdiction to enforce the subpoenas. Under the Inspector General Act, each inspector general "is authorized . . . to require by subpena [sic] the production of all . . . documentary evidence necessary in the performance of the functions assigned by this Act, which subpena, in the case of contumacy or refusal to obey, shall be enforceable by order of any appropriate United States district court." 5 U.S.C. app. § 6(a)(4); *see also* 28 U.S.C. § 1345 ("[T]he district courts shall have original jurisdiction of all civil actions, suits or proceedings commenced by the

United States, or by any agency or officer thereof expressly authorized to sue by Act of Congress.").

Although orders enforcing, or refusing to quash, subpoenas issued in the trial context are ordinarily not considered final orders subject to appeal (unless a contempt order is entered, which is itself a final order subject to appeal), orders enforcing administrative subpoenas are subject to appellate review. "These orders are considered 'final' for purposes of 28 U.S.C. § 1291 because there is no ongoing judicial proceeding that would be delayed by an appeal." *In re Subpoena Duces Tecum*, 228 F.3d 341, 345-46 (4th Cir. 2000); see also *FDIC v. Wentz*, 55 F.3d 905 (3d Cir. 1995) (reviewing order enforcing administrative subpoena); *NLRB v. Frazier*, 966 F.2d 812, 815 (3d Cir. 1992) (reviewing quashal). "[W]e will affirm an order enforcing an agency's subpoena unless we conclude that the district court has abused its discretion." *Wentz*, 55 F.3d at 908.

B.

As the Supreme Court has said of the Federal Trade Commission and Internal Revenue Service, an agency ordinarily "can investigate merely on suspicion that the law is being violated, or even just because it wants assurance that it is not." *United States v. Powell*, 379 U.S. 48, 57 (1964) (IRS); *United States v. Morton Salt Co.*, 338 U.S. 632, 642-643 (1950) (FTC); *see also Wentz*, 55 F.3d at 908 (FDIC). The power to effectively investigate HHS and the participants in the Medicare program is fundamental to the HHS inspector general's mission. *Cf. Fed. Maritime Comm'n v. Port of Seattle*, 521 F.2d 431 (9th Cir. 1975) ("It is beyond cavil that the very backbone of an administrative agency's effectiveness in carrying out the congressionally mandated duties of industry regulation is the rapid exercise of the power to investigate the activities of the entities over which it has jurisdiction and the right under the appropriate conditions to have district courts enforce its subpoenas."). In the ordinary course, judicial proceedings are appropriate only after the investigation has led to enforcement, because "[j]udicial supervision of agency decisions to investigate might hopelessly entangle the courts in areas that would

prove to be unmanageable and would certainly throw great amounts of sand into the gears of the administrative process." *SEC v. Wheeling-Pittsburgh Steel Corp.*, 648 F.2d 118, 127 n.12 (3d Cir. 1981) (quoting *Dresser Industries, Inc. v. United States*, 596 F.2d 1231, 1235 n.1 (5th Cir. 1979)).

For these reasons, judicial review of administrative subpoenas is "strictly limited." *FTC v. Texaco*, 555 F.2d 862, 871-72 (D.C. Cir. 1997) (en banc). "The ultimate inquiry . . . is whether the enforcement of the administrative subpoena would constitute an abuse of the court's process." *Wheeling-Pittsburgh*, 648 F.2d at 125. A district court should enforce a subpoena if the agency can show "that the investigation will be conducted pursuant to a legitimate purpose, that the inquiry is relevant, that the information demanded is not already within the agency's possession, and that the administrative steps required by the statute have been followed. The demand for information must not be unreasonably broad or burdensome." *Wentz*, 55 F.3d at 908 (citing *Powell*, 379 U.S. at 57-58; *Morton Salt*, 338 U.S. at 652).

C.

The University of Medicine and Dentistry of New Jersey contends the subpoenas were not "issued pursuant to a legitimate purpose" because the inspector general lacks the authority to conduct PATH audits in the absence of evidence of fraud or abuse. And the university avers that the inspector general admitted to them that she had no evidence of Medicare fraud at the university hospitals.

As noted, the Inspector General Act creates Offices of Inspector General "to prevent and detect fraud and abuse in . . . programs and operations" of their respective departments and agencies. 5 U.S.C. App. 3 § 2. To accomplish these ends, the statute specifically authorizes inspectors general "to conduct and supervise audits and investigations relating to [these] programs and operations." *Id.* Furthermore, the Act grants inspectors general a degree of discretion in determining when such audits and investigations are appropriate: "In addition to the authority

otherwise provided by this Act, each Inspector General, in carrying out the provisions of the Act, is authorized . . . to make such investigations and reports relating to the administration of the programs and operations of the applicable establishments as are, in the judgment of the Inspector General, necessary or desirable." *Id.* § 6, 6(a)(2).

Here, the inspector general determined that the PATH audits are necessary or desirable for the purposes of preventing and detecting fraud and abuse in teaching hospitals' Medicare Part B billing. Accordingly, at first blush, the PATH audits would seem to fall comfortably within the Inspector General Act's broad grant of authority.

That authority is subject to certain limitations, however. Section 9 of the Act contains a restriction on the ability of the inspectors general to perform program operating responsibilities.[4] The Act permits the transfer of departmental functions that the head of the agency "may determine are properly related to the functions of the Office [of Inspector General] and would, if so transferred, further the purposes of this Act." The Act specifically provides, however, that no such transfer shall include "program operating responsibilities." 5 U.S.C. App. 3 § 9.

The hospitals rely on this section in attempting to establish a distinction between "routine compliance audits" and "fraud investigations." The administration of the Medicare program is the responsibility of HHS (carried out by the Centers for Medicare and Medicaid Services, an agency within HHS). HHS's direct role with respect to Part B payments at teaching hospitals, however, is one of oversight. Most of the direct interaction with the healthcare providers is done by the carriers, who process the bills submitted by the healthcare providers. The carriers are responsible for ensuring, in the first instance, that the bills they receive comply with the statutory and regulatory requirements of the Medicare program, subject to the oversight of the Centers for Medicare and Medicaid Services. Indeed, 42 U.S.C. § 1395u(a) provides that "the Secretary shall to the extent possible enter into . . . contracts [to] . . . make such audits of the records of

4. The 1976 Act contained a similar limitation.

providers of services as may be necessary to assure that proper payments are made under this part." Thus, HHS, through the carriers, is statutorily responsible for routine compliance audits, which are core "program operating responsibilities," according to the university. And because the PATH audits are routine compliance audits, the university contends the authority to conduct them cannot be transferred to the inspector general unless it is acting on a specific allegation of fraud or abuse.

The university does not challenge the inspector general's authority to investigate healthcare providers directly under the right circumstances. While a primary purpose of the inspectors general is to investigate the operations of their federal departments internally, they are charged with preventing fraud and abuse in the programs of their departments as well. The providers are participants in the Medicare program, and through that program they receive federal funds. Thus, they are not merely regulated by HHS, they are part of the Medicare program. As such, they are within the range of legitimate targets of the inspector general's efforts "to prevent and detect fraud and abuse" in the Medicare program. *Cf. Inspector Gen. of the U.S. Dept. of Agric. v. Glenn*, 122 F.3d 1007, 1011 (11th Cir. 1997) ("While we agree that the [Inspector General Act]'s main function is to detect abuse within agencies themselves, the IGA's legislative history indicates that Inspectors General are permitted and expected to investigate public involvement with the programs in certain situations."). The university concedes this, but contends the inspector general's authority to investigate healthcare providers arises only after the inspector general has received a referral from a carrier, or is otherwise responding to a specific allegation of fraud.

If the carriers uncover any evidence that gives rise to a suspicion of fraud on the part of healthcare providers, they are directed to refer the case to the Office of Inspector General for a fraud investigation. Medicare Program Integrity Manual, ch. 3 § 10.1. ("Carriers . . . have a duty to identify cases of suspected fraud and to make referrals of all such cases to the OIG, regardless of dollar thresholds or subject matter."). But in the absence of a specific allegation

of fraud, according to the university, an audit is simply a routine matter of ensuring compliance with the regulations, a responsibility central to the basic mission of HHS itself. HHS directs and oversees the carriers' routine auditing of healthcare providers. And because this is routine work performed by HHS (through the carriers), permitting the inspector general to perform such functions would amount to a transfer of "program operating responsibilities."

At bottom, the university contends the inspector general cannot perform such audits because HHS can and does[5] perform those audits in the ordinary course of business. But we see no basis for concluding that the inspector general's authority cannot overlap with that of the department. As the Court of Appeals for the Fifth Circuit stated, "Section 9(a)(2) prohibits the transfer of 'program operating responsibilities,' and not the duplication of functions or the copying of techniques. No transfer of operating responsibility occurs and the IG's independence and objectivity is not compromised when the IG mimics or adapts agency investigatory methods or functions in the course of an independent audit or investigation." *Winters Ranch Partnership v. Viadero*, 123 F.3d 327, 334 (5th Cir. 1997). The inspector general's mandate to prevent and detect fraud and abuse is not limited by HHS's—or its agents'—own efforts to prevent and detect fraud and abuse.

If the department fails to perform a function that is within its responsibilities, and the inspector general takes on those responsibilities, then it may be correct to speak of "transfer" of program operating responsibilities. *See, e.g.*, *id.* at 334; *Burlington N. R.R. Co. v. Office of Inspector General, R.R. Retirement Bd.*, 983 F.2d 631 (5th Cir. 1993) (finding impermissible transfer of authority where the inspector general audited railroad employers for tax compliance when the board had declined to do so). For in such a case, the department might be said to be abdicating

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5. HHS itself does not appear to perform any compliance audits. According to plaintiffs, these are the responsibility of the carriers, acting as contractors for the department. We need not determine what effect, if any, the fact that these audits are not, strictly speaking, functions of the department itself may have on the analysis.

its own responsibilities, which is arguably one of the concerns animating § 9(a)(2)'s prohibition on transfers of program operating responsibilities. But this is not a concern here.

Furthermore, that HHS can and does perform routine compliance audits does not necessarily make them "program operating responsibilities." Routine compliance audits, routine as they be, are nonetheless investigatory in nature, and are directed at enforcing the rules under which the providers operate. They need not be seen as part of the "operation" of the Medicare program. In any event, the statute contemplates the transfer of any duties that may assist the inspector general in its mission, so long as they are not "program operating responsibilities." Presumably, this would include a range of responsibilities the department might perform, that do not constitute program operating responsibilities. Thus, the fact that the department can and does perform some of these tasks would not alone prevent their transfer to the Office of Inspector General.

The university relies on a seemingly contrary decision reached by the Court of Appeals for the District of Columbia Circuit. In *Truckers United for Safety v. Mead*, 251 F.3d 183 (D.C. Cir. 2001), the court held the Office of Inspector General for the Department of Transportation had overstepped its statutory authority when it engaged in a joint operation with the Office of Motor Carriers (an office within DOT) to investigate trucking records. The program was designed "to create a greater deterrence to motor carrier violations of the Federal Motor Carrier Safety Regulations." *Id.* at 187. The inspector general subpoenaed a variety of records seeking, inter alia, to uncover falsification of hours of service logs.

The court viewed the investigation "as part of enforcing motor carrier safety regulations—a role which is central to the basic operations of the agency." *Id.* at 189. On the court's view, the inspector general was not engaged in an audit investigation, rather, he "merely lent his search and seizure authority to standard OMC enforcement investigations." *Id.* The court concluded that the "actions of the IG were ultra vires." *Id.* at 190.

Here, by contrast, there is no suggestion that the PATH audits are aimed at anything other than the inspector general's (admittedly broad) view of what constitutes fraud and abuse in the Medicare program. The inspector general is charged with preventing and detecting, by audit and investigation, fraud and abuse in the Medicare program. There is no statutory basis for imposing an additional requirement that the inspector general begin such an audit or investigation only after she has received a referral or other allegation of fraud. And this is especially true given the broad discretion the inspector general enjoys when determining audits and investigations are appropriate.

D.

In sum, the PATH audits are of a kind that is squarely within the broad authority of the inspector general to audit providers for the purpose of preventing fraud and abuse within the Medicare program. The PATH audits do not represent a "transfer" of "program operating responsibilities." The important issue here is not whether the inspector general is doing something that HHS itself (or its agents) might also do, but whether the PATH audits are within the authority granted the inspector general by the Inspector General Act. For the reasons discussed, we hold that they are.

There is no dispute that the subpoenas at issue are relevant to the inspector general's purpose, that the inspector general lacks the information it seeks, that statutory procedures have been followed, or that the demand for information is not unreasonably broad or burdensome. *See Wentz*, 55 F.3d at 908. Consequently, the subpoenas are lawful and we will affirm the District Court's order to enforce them.

III.

In addition to opposing the inspector general's motion to enforce its subpoenas, the University of Medicine and Dentistry of New Jersey seeks to enjoin the PATH audits for several reasons. The District Court declined to consider the

merits of these claims, deciding it lacked jurisdiction over these claims. We agree.

The District Court found a lack of jurisdiction on two related grounds. First, it held it lacked jurisdiction to review the agency action under the Administrative Procedures Act, 5 U.S.C. § 704, because the decision to initiate the audit was not "final." It also concluded, for similar reasons, that the case was not sufficiently "ripe" at this point to permit judicial review.

Ripeness and finality in this context are closely related. Finality is an element in the test for ripeness. *Nat'l Park Hospitality Assoc. v. Dept. of the Interior*, 123 S. Ct. 2026, 2032 (2003); *Abbott Labs. v. Gardner*, 387 U.S. 136, 149 (1967). And as we have noted, "the Court's treatment of the finality issue has involved an inquiry into the broader question of whether a given action is ripe for judicial review." *CEC Energy Co. v. Public Serv. Comm'n*, 891 F.2d 1107, 1110 (3d Cir. 1989). We will address finality within the context of an assessment of ripeness.

A.

Determining whether a dispute over agency action is ripe involves a two-part inquiry. We must assess "(1) the fitness of the issues for judicial decision and (2) the hardship to the parties of withholding court consideration." *Nat'l Park Hospitality Assoc.*, 123 S. Ct. at 2030; *Abbott Labs.*, 387 U.S. at 149. The fitness question, in turn, requires an assessment of whether the issues presented are "purely legal," whether the agency action is final for purposes of section 10 of the Administrative Procedures Act,[6] and whether "further factual development would 'significantly advance our ability to deal with the legal issues presented.' " *Nat'l Park Hospitality Assoc.*, 123 S. Ct. at 2028 (quoting *Duke Power Co. v. Caroline Envtl. Study Group, Inc.*, 438 U.S. 59 (1978)); *Abbott Labs.*, 387 U.S. at 149.

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6. Under section 10(c) of the Administrative Procedures Act, federal courts have jurisdiction to review "final agency action for which there is no other adequate remedy," 5 U.S.C. § 704, unless the action "is committed to agency discretion by law." § 701(a)(2).

While there are some factual disputes in this case, the main issue—whether the inspector general has the authority to initiate audits of the providers under the announced standard—is primarily legal. Further factual development does not seem necessary to resolve these issues. But we believe the case is not sufficiently "fit" for judicial review, because the action of the inspector general was not a final one for these purposes.

No matter how decisive the inspector general's determination to initiate a PATH audit of the University of Medicine and Dentistry of New Jersey under its stated standard was, it was only a decision to initiate an investigation of the university's prior billing practices. Neither the university nor the other plaintiffs has been charged with fraud, nor has any kind of enforcement proceeding commenced. The hospitals are required neither to change their billing practices nor pay a penalty for past practices. All they are required to do is to cooperate with the audit—an audit the Office of Inspector General would perform at its expense if the university so chose.

Courts should hesitate to scrutinize decisions to initiate administrative audits and investigations for the same reasons they accord administrative entities broad leeway in issuing subpoenas. Subpoenas in this context are part of an investigation or audit, taken after the decision to investigate has been made, where there is a reason to believe the target of the subpoena may not cooperate without a legal requirement. It would be anomalous to demand a greater showing for the initiation of an investigation than is required for the issuance of subpoenas.

"An investigation, even one conducted with an eye to enforcement, is quintessentially non-final as a form of agency action." *Assoc. of Am. Med. Colls. v. United States*, 217 F.3d 770, 781 (9th Cir. 2000). In the ordinary course, an investigation is the beginning of a process that may or may not lead to an ultimate enforcement action. The decision to investigate is normally seen as a *preliminary* step—non-final by definition—leading toward the possibility of a "final action" in the form of an enforcement or other action. That path is highly uncertain. Here, as in most

actions, the possibility that no enforcement action may be taken is real for several reasons, not least of which is that the inspector general may change her mind on one or more issues along the way. "Judicial intervention into the agency process denies the agency an opportunity to correct its own mistakes and to apply its expertise." *FTC v. Standard Oil Co.*, 449 U.S. 232, 242 (1980).

B.

The university nevertheless contends that the initiation of the PATH audits is a final decision under the standards announced by the Supreme Court and this court. Even if the decision to *initiate* the audits is not deemed final, the hospitals argue the decision to employ a *standard* incorporating a physical-presence requirement was itself "final action" subject to judicial review.

We have listed several factors relevant to an assessment of finality in the administrative context, the most important of which for these purposes are "whether the decision represents the agency's definitive position on the question," "whether the decision has the status of law with the expectation of immediate compliance," and "whether the decision has immediate impact on the day-to-day operations of the party seeking review."[7] *CEC Energy*, 891 F.2d at 1110 (citing *Standard Oil*, 449 U.S. at 239-40; *Solar Turbines, Inc. v. Seif*, 879 F.2d 1073,1080 (3d Cir. 1989).

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7. In *CEC Energy*, we provided the following list of relevant factors:

> 1) whether the decision represents the agency's definitive position on the question; 2) whether the decision has the status of law with the expectation of immediate compliance; 3) whether the decision has immediate impact on the day-to-day operations of the party seeking review; 4) whether the decision involves a pure question of law that does not require further factual development; and 5) whether immediate judicial review would speed enforcement of the relevant act.

891 F.2d at 1110.

We recognize the decision involves a pure question of law that may not require further factual development. We have doubts that immediate judicial review would speed enforcement, but would reach the same result even if we concluded it might.

The decision to initiate the PATH audit represents a "definitive position" of the inspector general only in the narrowest sense. The decision is not likely to be reopened, but it is a decision only to investigate, which is by nature a preliminary one. It is the initiation of a process designed to make a determination as to plaintiffs' potential fraud and abuse in the Medicare program. Intermediate decisions made in the course of determining what position will ultimately be taken are not "determinative" in the appropriate sense. As the Court of Appeals for the Ninth Circuit stated:

> [O]n the facts before this court it is an open question whether the PATH audits will actually result in findings of abuse or fraud. . . . OIG could still modify its rather draconian view of the Act's requirements for Part B billing, and, for any number of reasons, the PATH audits may not reveal significant violations. Even if violations are found there are a panoply of administrative and judicial remedies open to the Secretary and DOJ, at least some of which we might be without jurisdiction review under 42 U.S.C. § 405(h) and [*Shalala v.* ]*Illinois Council* [*on Long Term Care, Inc.*, 529 U.S. 1, (2000)].

*Assoc. of Am. Med. Colls.*, 217 F.3d at 781.

The University of Medicine and Dentistry of New Jersey also contends the decision to initiate the audits "has the status of law with the expectation of immediate compliance," and "has immediate impact on the day-to-day operations of the party seeking review." *CEC Energy*, 891 F.2d at 1110. Instead of focusing on potential enforcement measures, the university contends the burdens of compliance with the audits themselves constitute the relevant effects. The university avers the decision requires that they immediately comply with the audits—a disruptive process it alleges would detract from providing healthcare and would cost over one million dollars.[8]

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8. This figure appears to be based on an assessment of a PATH II audit, which would be performed by a third party at the university's expense. A PATH I audit, which the university could have chosen, would be performed by the Office of Inspector General at its cost. Accordingly, it appears the university could choose a course substantially less costly than the one it selected.

These burdens, however, are not the kind of burdens that support a finding of finality. In *Standard Oil*, the Supreme Court held the FTC's issuance of a complaint was not a final order in the face of a similar contention. The Court noted that the only legal effect of filing the complaint on defendant was the requirement that it participate in the proceeding by responding to the charges against it. The Court stated, "Although this burden certainly is substantial, it is different in kind and legal effect from the burdens attending what heretofore has been considered to be a final action." 449 U.S. at 242. The Court noted that "the expense and annoyance of litigation is part of the social burden of living under government." *Id.* at 244. There is no basis for treating the expense and annoyance of administrative audits and investigations any differently. *See CEC Energy*, 891 F.2d at 1110 (following *Standard Oil* and stating that the obligation to respond to the FTC's inquiries, even if substantial, is not a basis for finding finality). And because the audit at issue here is directed only at past conduct, the only effects plaintiffs will encounter are related to their participation in the investigatory process and actions that might be taken as a result—there is no direct effect on plaintiffs' "primary conduct." *See Nat'l Park Hospitality Assoc.*, 123 S. Ct. at 2031; *Toilet Goods Assn., Inc. v. Gardner*, 387 U.S. 158, 164 (1967).

We are cognizant of the special responsibilities entrusted to healthcare providers and the obstacles they face. The economics of healthcare are at a precarious juncture. Placing additional burdens—financial and otherwise—on already taxed hospitals may have serious consequences for access to healthcare, either by increasing its cost or by diminishing its availability. It is to be hoped that a decision to initiate a PATH audit will be made only after consideration of these consequences. But these considerations are, in the first instance, ones for the inspector general, who has been charged with uncovering fraud and has been given the authority to determine when audits are appropriate to that end.

Focusing not on the decision to initiate the audit, but to initiate the audit under a particular standard, the lack of finality is even more clear. For it seems unlikely that the

choice of which standard would be applied in assessing the billing data compiled would have a significant effect on the university during the audit. The relevant costs would seem to be associated with collecting the data, not applying any particular standard in interpreting it. The only apparent effect from that choice would come if and when it resulted in a conclusion about plaintiffs' compliance with the applicable standards. And as we have seen, we are not now in a position to assess what might or might not happen at the end of this process.

C.

For the foregoing reasons, the present dispute is not sufficiently "fit" for review at this time. Nor have the hospitals shown sufficient "hardship" to support a determination that the case is ripe for judicial consideration. Again, the only significant hardships resulting from the challenged decision are those related to compliance with a request for information reasonably directed at a legitimate purpose of the inspector general. This is a cost that plaintiffs—recipients of Medicare funding—must face as a "burden of living under government." *Standard Oil*, 449 U.S. at 244.

While the hospitals have raised profoundly serious questions about the wisdom and fairness of the PATH audits, the audits are within the broad authority of the inspector general, and any challenges are properly made when they have led to action against the hospitals and their employees, if any. Accordingly, we will affirm the judgment of the District Court.

AMBRO, Circuit Judge, *Concurring*:

The majority decides (1) generally that the Inspector General ("IG") of the federal Department of Health and Human Services ("HHS") has the authority to issue subpoenas in furtherance of an audit of appellants' teaching hospitals in determining compliance with certain Medicare requirements, and (2) specifically that the District Court lacks jurisdiction to enjoin the audit at issue here because the IG's decision merely to investigate by issuing subpoenas was neither final nor ripe for review. I agree as to (1) and concur in the result as to (2).

At the outset is a paradox. If there is no jurisdiction to consider appellants' attempt to block the Medicare audit, how does jurisdiction exist to enforce subpoenas to turn over documents for the audit? Stated conversely, if there is jurisdiction to review the enforcement of administrative subpoenas like those of the IG, should not jurisdiction also exist to review whether an audit (which the subpoenas attempt to implement) is allowed in appellants' case?

The majority handles this conundrum deftly. The IG has the power under the Inspector General Act of 1978 to investigate fraud and abuse involving Medicare. Inherent within its investigatory power is the authority to issue subpoenas. But a subpoena to an entity operating within the Medicare program merely begins an investigation lacking both the finality and ripeness of an enforcement action that may result from the investigation. Thus the general authority for the IG to issue subpoenas is not, for any particular entity, an action alleging noncompliance with Medicare.

But rather than deciding that specific enforcement of the IG's auditing powers is not final nor ripe for review, I simply would rely on 5 U.S.C. § 701(a)(2) of the Administrative Procedures Act ("APA"), which exempts from judicial review "agency action . . . committed to agency discretion by law." As § 6(a)(2) [5 U.S.C. app. 3, § 6(a)(2)] of the Inspector General Act authorizes the IG "to make such investigations . . . relating to the administration of the programs and operations of [HHS] as are, in the judgment of the [IG],

necessary or desirable," § 701(a)(2) applies. *Cf. Webster v. Doe*, 486 U.S. 592, 600 (1988).

A True Copy:
Teste:

*Clerk of the United States Court of Appeals*
*for the Third Circuit*