UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

OHIO HOSPITAL ASSOCIATION AND
AMERICAN HOSPITAL ASSOCIATION

Plaintiffs,

v.

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

Defendant.

Case No. 1:96CV 2165

JUDGE O'MALLEY

Memorandum & Order

Plaintiffs Ohio Hospital Association and American Hospital Association bring this action on behalf of their member hospitals against Donna E. Shalala, in her capacity as Secretary of Health and Human Services. Plaintiffs assert that the Secretary is improperly and retroactively enforcing new coding and billing standards in connection with Medicare reimbursement for certain medical laboratory tests. Plaintiffs seek to enjoin the Secretary from continuing this enforcement, and also seek a judgment from this Court declaring that: (1) the Secretary did not properly promulgate the new standards; (2) the Secretary cannot retroactively enforce them; and (3) the government cannot hold plaintiffs' member hospitals liable under the False Claims Act.

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

I.

The parties generally agree that the following alleged actual background is accurate. Pursuant to 42 U.S.C. §1395 et seq., the federal Medicare

program reimburses qualified hospitals for the cost of providing certain covered medical care to eligible patients. Plaintiffs' member hospitals are all qualified Medicare "providers," which have entered into agreements with the Secretary regarding the provision of services and reimbursement. Regarding reimbursement, the Medicare statute provides that the Secretary shall set out fee schedules for diagnostic laboratory tests provided to outpatients by provider hospitals. 42 U.S.C. §l3954-*l*(h). These fee schedules set out the precise amount of reimbursement Medicare will pay for any particular lab test. Provider hospitals are directed to submit their claims for lab test reimbursement using specific billing codes.

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

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

During the period from 1989 to 1996, of the seven tests that comprise a Chem-7, six were included in the list of 19 "bundled" tests contained in the CPT-4; the creatin-kinase test was not on the list. Thus, when a provider hospital billed Medicare for performance of a Chem-7 upon an outpatient, the hospital would normally submit to Medicare two billing codes: one for the creatine-kinase test (code 82550, creatine-kinase test only), and one for the other six tests combined (code 80006, 6 clinical chemistry tests combined). Medicare regularly accepted this type of statement and provided reimbursement.[2]

Plaintiffs allege that, despite this long-term practice, in 1996 the Secretary joined forces with the office of the United States Attorney General to investigate the billing practices of hospitals, including plaintiffs' members. During this investigation, the Secretary took the position that the hospitals should have bundled all seven of the tests contained in the Chem-7 and

submitted only one billing code - code 80007 (7 clinical chemistry tests combined). The Secretary suggested that the hospitals purposely failed to bundle all seven tests together in order to submit higher bills to Medicare for reimbursement, seeking to manipulate the system so as to increase their Medicare receipts.

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

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

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

Plaintiffs have brought this action in an attempt to thwart (or at least slow down) the Secretary's heavy-handed approach to this investigation, and in the hopes of finding an even-handed forum within which to dispute the Secretary's views of their long-standing billing practices. Plaintiffs assert that, without this lawsuit, their member hospitals have no avenue to challenge the Secretary's actions: if the Secretary pursued normal administrative "recoupment" procedures to reclaim her alleged payments

of "excess reimbursement," the hospitals could challenge the Secretary's alleged change in position through administrative remedies; by skipping normal recoupment procedures and instead threatening a False Claims Act lawsuit, plaintiffs claim the Secretary has robbed the hospitals of any way to challenge the Secretary's position. Plaintiffs point out, moreover, that the Secretary is demanding payments in excess of those normally available through a recoupment procedure by using the threat of a False Claims Act action to "extort" not just the return of Medicare payments previously received, but the payment of additional sums as well.

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

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

II.

There are two general categories into which Rule l2(b)(1) motions to dismiss for lack of subject matter jurisdiction fall: facial attacks and factual attacks. Fed. R. Civ. P. 12(b)(1); United States v. Ritchie, 15 F.3d 592, 598 (6th Cir. 1994), cert. denied, 513 U.S. 868 (1994). A facial attack challenges the sufficiency of the pleading itself. On such a motion, the Court must take all of the material allegations in the complaint as true and construe them in the light most favorable to the nonmoving party. Id. (citing Scheuer v. Rhodes 416 U.S. 232, 235-37(1974)). In contrast, a factual attack, as is made here, challenges the factual existence of subject matter jurisdiction.

On this form of motion, the Court's inquiry is limited to determining whether the challenged pleadings set forth allegations sufficient to show the Court that it has jurisdiction over the subject matter; no presumptive truthfulness applies to the factual allegations, and the court is free to weigh the evidence and satisfy itself as to the existence of its power to hear the case." Id. (internal citations omitted); RMI Titanium Co. v. Westinghouse Elec. Corp., 78 F.3d 1125, 1135 (6th Cir. 1996). In reviewing such a motion, a district court is to probe the facts and assess the validity of its own jurisdiction. In doing so, the Court has wide discretion to consider affidavits and documents outside the complaint, and may even conduct a limited evidentiary hearing if necessary. Ohio Nat'l Life Ins. Co v. United States 922 F.2d 320, 325 (6th Cir. 1990). In connection with this analysis, the plaintiff bears the burden of

demonstrating that the Court has and may appropriately exercise jurisdiction over the subject matter. RMI Titanium Co., 78 F.3d at 1134. The Court may examine evidence of its power to hear a case, and must make any factual findings to determine whether it has jurisdiction. Kroll v. United States: 58 F.3d 1087, 1090 (6th Cir. 1995); Rogers v. Stratton Inds., Inc. 798 F.2d 913, 915 (6th Cir. 1986). The Court's examination of this evidence does not convert a 12(b0(1) motion into a Rule 56 motion. Rogers, 798 F.2d at 915.

III.

A. The False Claims Act

In Counts III and IV of the plaintiffs' complaint, the plaintiffs claim that: (1) the Secretary has violated the Fifth Amendment by "inappropriately us [ing]. . . the U.S. Attorney's Office and the U.S. Department of Justice to coerce [the hospitals] into making substantial payments to (Medicare] to avoid" prosecution under the False Claims Act; and (2) the Secretary's "use of the False Claims Act in this manner is contrary to the purpose and intent standard" contained in the Act. Complaint at ¶¶88, 90. As remedy for these claims, plaintiffs seek:

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

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

It is clear that only the United States, acting through the Attorney General, can file a False Claims Act suit against a defendant; the Secretary cannot. See 31 U.S.C. §3730(a) ("If the Attorney General finds that a person has violated or is violating [the False Claims Act], the Attorney General may bring a civil action under this section against the person"); Martin J. Simko Constr., Inc. v. United States, 852 F.2d 540, 547 (Fed. Cir. 1988) (the Attorney General's authority to bring suit under the False Claims Act is

exclusive; "no other agency is empowered to act under that statute").[4] Thus, plaintiffs cannot obtain a judgment declaring that it is, or would be, improper for the Secretary to threaten their member hospitals with prosecution under the False Claims Act, as the law is clear that only the Attorney General has the power to pursue a prosecution.[5]

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

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

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

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

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

Whether the Attorney General ever chooses to pursue a member hospital for violation of the False Claims Act is a matter of prosecutorial discretion. Bordenkircher v. Hayes, 434 U.S. 357, 364 (1978) ("the decision whether or not to prosecute, and what charge to file or bring before a grand jury, generally rests entirely in (the prosecutor's] discretion"). If faced with such a lawsuit, a hospital will have the opportunity to raise any and all defenses, including lack of intent. This Court cannot exercise its equitable jurisdiction to declare in advance that a particular hospital's defenses are valid, or that the Secretary's False Claims Act threat is empty. "An injunction against threatened legal action will not issue if the party will have an adequate opportunity to filly present his defenses and objections in the legal action he seeks to enjoin." Travis v. Pennyrile Rural Elec. Co-op., 399 F.2d 726, 729 (6th Cir. 1968). Because the Court does not have equitable jurisdiction over Counts III and IV of the plaintiffs' complaint, the Secretary's motion to dismiss these claims is granted.

B. The Secretary's Policies.

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

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

Id. at 21, prayer ¶¶A, B. In response, the Secretary argues this Court cannot issue the requested declarations because: (1) the Medicare Act itself generally states that a plaintiff cannot bring suit to recover on a claim "arising under" the Act; (2) the only exception to this rule is for judicial review of a "final decision" of the Secretary, after completion of

administrative review; and (3) there has been no administrative review or final decision of the Secretary in this case, so this Court has no jurisdiction to resolve the plaintiffs' claims, which "arise under" the Act. Again, the Court agrees with the position of the Secretary.

By way of 42 U.S.C. §§1395*ff* and 1395*ii*, the Medicare Act incorporates the method of judicial and administrative review found in 42 U.S.C. §§405 (h) and 405(g). Section 405(h) states that "[n]o findings of fact or decision of the [Secretary] shall be reviewed by any person, tribunal, or governmental agency except as herein provided. No action against the United States, the [Secretary,] or any officer or employee thereof shall be brought under section 1331 or 1346 of Title 28 to recover on any claim arising under [the Medicare Act]." Section 405(g) states that" [a]ny individual, after any final decision of the [Secretary] made after a hearing to which he was a party, irrespective of the amount in controversy, may obtain a review of such decision by a civil action. . . ." Thus, for claims "arising under" the Medicare Act, the Secretary must reach a "final decision" before a plaintiff may obtain judicial review.

The Supreme Court has "construed the 'claim arising under' language of section 405(h) broadly to include any claims in which 'both the standing and the substantive basis for the presentation' of the claims is the [Medicare] Act." Heckler v. Ringer, 466 U.S. 602, 615 (quoting Weinberger v.Salfi, 422 U.S. 749, 760-61(1975)). In Ringer, the plaintiffs

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

Id at 614.

In this case, the standing and substantive basis for Count I is clearly the Medicare Act, as Count I alleges the Secretary promulgated her billing policies in violation of the Act. The same is true of Count II, which, like the Ringer plaintiffs, alleges the Secretary violated the Administrative Procedure Act. Plaintiffs ask this Court to rule that: (1) their member

hospitals correctly bundled the billing codes for their lab tests; (2) the hospitals received the correct reimbursement for those lab tests; and (3) the Secretary's change in position is improper. At bottom, this is a request for an adjudication of the propriety of past payment of benefits, which Ringer holds is a claim that arises under the Medicare Act. Accordingly, this Court does not have jurisdiction over these claims.[7] To the extent this conclusion is contrary to the holding of Cedars-Sinai Med Ctr. v. Shalala, 939 F. 1457 (C.D. Cal. 1996) (appeal pending), the Court finds that case unpersuasive.[8]

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

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

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

In sum, the Court concludes that plaintiffs have not carried their burden of proving the existence of federal jurisdiction over any of the claims asserted in this action. Accordingly, the Secretary's motion to dismiss for lack of jurisdiction is **GRANTED**.

IT IS SO ORDERED.

KATHLEEN McDONALD O'MALLEY
UNITED STATES DISTRICT JUDGE

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

OHIO HOSPITAL ASSOCIATION AND
AMERICAN HOSPITAL ASSOCIATION

Plaintiffs,

v.

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

Defendant.

Case No. 1:96CV 2165

JUDGE O'MALLEY

Order

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

IT IS SO ORDERED.

KATHLEEN McDONALD O'MALLEY
UNITED STATES DISTRICT JUDGE

Footnotes

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

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

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

4. Although 331 U.S.C. Section 3730(b) allows private parties to bring False Claims

Act actions, "[t]he action shall be brought in the name of the government." The only governmental actor authorized to bring a False Claims Act action is the Attorney General.

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

6. Indeed, plaintiffs claim its members have been placed in an impossible position by the Secretary. They believe their billing practices were appropriate and, even if not, were undertaken in good faith -- facts which would defeat any False Claims Act suit against them. Because the risk of loss in a False Claim Act case carries potentially devastating penalties, however, unlike most litigation or even an administrative recoupment action, it is a risk the hospitals feel they cannot take -- even if they believe their chances of prevailing would be great.

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

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

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

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