III. CONCLUSION

For the reasons stated herein, the Court denies the Defendant's motions for judgment of acquittal and a new trial. An order in accordance with this opinion shall be entered.

James STEWART, et al.

v.

Louis W. SULLIVAN, M.D., et al.

Civ. A. No. 92–417.

United States District Court,
D. New Jersey.

Oct. 26, 1992.

Physician and patients brought action for declaratory and injunctive relief, challenging "so-called" policy of Secretary of Department of Health and Human Services (HHS) that allegedly prohibited physicians and Medicare patients from entering into private contracts for treatment on case-by-case basis and from choosing not to subject claim for reimbursement under Medicare Part B. Secretary filed motion to dismiss, and plaintiffs filed cross motion for summary judgment. The District Court, Politan, J., held that: (1) physician and patients satisfied injury in fact requirement for constitutional standing; (2) plaintiffs were not required in the first instance to present their claim to Secretary or his delegate; and (3) bulletins and advisory letters from Health Care Financing Administration (HCFA) did not demonstrate that Secretary had clearly articulated policy on issue of private contracting, and, therefore, action was not ripe for review.

Secretary's motion granted; plaintiffs' cross motion denied.

1. Federal Civil Procedure ⇐103.2

Plaintiff has satisfied constitutional standing requirement when plaintiff's allegations, if true, demonstrate that plaintiff is in fact injured by action he is seeking to have reviewed.

2. Social Security and Public Welfare ⇐241.45

Physician satisfied injury in fact test for constitutional standing to challenge alleged policy of Secretary of Department of Health and Human Services (HHS) prohibiting physicians and Medicare patients from entering into private contracts for treatment on case-by-case basis and from choosing not to submit claim for reimbursement under Medicare Part B, where physician alleged that Secretary had articulated broad policy that would subject physician to sanctions for entering into private agreements with patients. Social Security Act, §§ 1831–1848, as amended, 42 U.S.C.A. §§ 1395j to 1395w–4.

3. Social Security and Public Welfare ⇐241.45

Patients satisfied injury in fact requirement for constitutional standing to challenge alleged policy of Secretary of Department of Health and Human Services (HHS) prohibiting physicians and Medicare patients from entering into private contracts for treatment on case-by-case basis and from choosing not to submit claims for reimbursement under Medicare Part B, where patients claimed that because of Secretary's alleged policy, the physician of their choice would ultimately withdraw her services. Social Security Act, §§ 1831–1848, as amended, 42 U.S.C.A. §§ 1395j to 1395w–4.

4. Social Security and Public Welfare ⇐241.45

In determining whether plaintiff is required to present claim under Medicare Part B to Secretary of Department of Health and Human Services (HHS) or his delegate before bringing claim in court, amounts/methodology distinction is applicable, under which exhaustion before Secretary is required only with respect to challenges to amounts and not to challenges to methodology of Secretary in making determinations. Social Secu-

rity Act, §§ 205(g, h), 1831–1848, as amended, 42 U.S.C.A. §§ 405(g, h), 1395j to 1395w–4.

5. Social Security and Public Welfare ⇐241.45

Physician and patients, by framing their complaint against Secretary of Department of Health and Human Services (HHS) as challenge to articulated policy of Secretary to sanction doctors who engage in private contracting with Medicare Part B patients, made challenge to methodology by which Secretary would make sanction determination, as opposed to challenge to determination itself, and, thus, physician and patients were not required to first present claim to Secretary or delegate before bringing action in district court seeking declaratory and injunctive relief. Social Security Act, §§ 205(g, h), 1831–1848, as amended, 42 U.S.C.A. §§ 405(g, h), 1395j to 1395w–4.

6. Social Security and Public Welfare ⇐241.45

Bulletins and advisory letters from Health Care Financing Administration (HCFA) demonstrated that physician and patients failed to establish existence of articulated policy from Secretary of Department of Health and Human Services (HHS) on issue of private contracting, and, therefore, ripeness requirement was not satisfied with respect to action by physician and patients for declaratory and injunctive relief challenging Secretary's alleged policy prohibiting physicians and Medicare patients from entering into private contracts for treatment on case-by-case basis and from choosing not to submit claim for reimbursement under Medicare Part B. Social Security Act, §§ 1831–1848, as amended, 42 U.S.C.A. §§ 1395j to 1395w–4.

7. Social Security and Public Welfare ⇐241.30

Under Medicare Act, Secretary of Department of Health and Human Services (HHS), rather than private insurance carriers under contract with Secretary, has enforcement power to bring sanction proceedings against doctor. Social Security Act, § 1848(g)(1), (g)(4)(B)(ii), as amended, 42 U.S.C.A. § 1395w–4(g)(1), (g)(4)(B)(ii).

8. Social Security and Public Welfare ⇐241.45

No undue hardship would be suffered by physician and patients in withholding review of their action for declaratory and injunctive relief from alleged policy of Secretary of Department of Health and Human Services (HHS) prohibiting physicians and Medicare patients from entering into private contract for treatment on case-by-case basis and from choosing not to subject to claim for reimbursement under Medicare Part B; physician and plaintiffs had not established determination by Secretary that physicians who engage in private contracting engage in knowing and willful violations of Medicare Act, which would be prerequisite for imposition of sanctions on physician. Social Security Act, § 1848(g), as amended, 42 U.S.C.A. § 1395w–4(g).

Kent Masterson Brown, Brown & Brown, Lexington, KY, Richard Forest, Island Heights, NJ, for plaintiffs.

Susan J. Steele, Asst. U.S. Atty., Michael Chertoff, U.S. Atty., Newark, NJ, Stuart E. Gerson, Asst. Atty. Gen., Sheila M. Lieber, Peter Robbins, Dept. of Justice, Washington, DC, for Federal defendant.

POLITAN, District Judge.

This matter comes before the court on defendant's, Louis M. Sullivan, M.D., Secretary of the United States Department of Health and Human Services, motion to dismiss plaintiffs' complaint pursuant to Rules 12(b)(1) and 12(b)(6) of the Federal Rules of Civil Procedure. Plaintiffs have filed a cross-motion for summary judgment pursuant to Rule 56 of the Federal Rules of Civil Procedure. Based upon the reasons set forth below, defendant's motion to dismiss is **GRANTED** and plaintiffs' motion for summary judgment is **DENIED.**

The plaintiffs in this case are Lois J. Copeland, M.D. (the "doctor" or "plaintiff-physician"), and five of her regular patients, James Stewart, Joan Kennedy Taylor, Trudy Drucker, Warren Klose and Connie Streich, ("patients" or "plaintiff-patients"). The five plaintiff-patients are all fully-enrolled benefi-

ciaries under Parts A and B of the Medicare program. Doctor Copeland is a non-participating physician of Medicare Part B. Plaintiffs challenge on several grounds a so-called policy of the Secretary that allegedly prohibits physicians and Medicare patients from entering into private contracts for treatment on a case-by-case basis whereby the requirements of the Medicare Act would be disregarded. First, plaintiffs allege that the policy violates various provisions of the Medicare Act and that the Medicare Act authorizes beneficiaries to contract privately for medical services. Such private contracting would not require a claim to be submitted to Medicare on behalf of the beneficiaries and would be allowed on a case-by-case basis as the beneficiary may choose. Second, plaintiffs allege that the policy is invalid for failure to comply with the notice-and-comment provisions of the Administrative Procedure Act, 5 U.S.C. § 553. Alternatively, plaintiffs claim that the policy violates various provisions of the United States Constitution and is an unconstitutional infringement on the privacy rights of the plaintiff-patients. Additionally, plaintiffs filed a verified amended complaint wherein they challenge so much of 42 U.S.C. § 1395w–4 as authorizes such a policy prohibiting private contracting arrangements as an unconstitutional delegation of legislative power to the Secretary in violation of Article I, § 1 and the Fifth Amendment to the United States Constitution. The plaintiffs have named as defendants both Louis Sullivan, the Secretary of the United States Department of Health and Human Services ("HHS"), and Medical Service Association of Pennsylvania d b a Pennsylvania Blue Shield, the medicare intermediary responsible for overseeing the program in New Jersey and under contract with the Secretary. An understanding of the plaintiffs' claims requires a brief overview of the structure of the Medicare program.

I. STRUCTURE OF MEDICARE

The Medicare program consists of two parts. Part A is a mandatory program that insures the elderly and disabled against the costs of hospital and certain post-hospital care. 42 U.S.C. §§ 1395 to 1395i–4. Under Part A, payment by Medicare for services rendered by a hospital or other institution may only be made to the institution and the institution may not bill the patient.

Part B is a voluntary program that provides supplemental coverage for other health-care costs, including physicians' services. 42 U.S.C. §§ 1395j to 1395w–4. Medicare beneficiaries purchase Part B coverage through monthly premiums. 42 U.S.C. §§ 1395j, 1395r, 1395s. These premiums, together with a contribution from the federal government, are placed in the Federal Supplementary Medicare Insurance Trust Fund. 42 U.S.C. § 1395t, from which Part B claims are paid. 42 U.S.C. § 1395j. The claims are processed by private insurance carriers under contract with the Secretary. 42 U.S.C. § 1395u. These carriers are commonly referred to as intermediaries. The Health Care Financing Administration ("HCFA"), a division of HHS, is responsible for entering into contracts with carriers to administer Part B of the Medicare program. HCFA also oversees the carriers' administration of the program. The carriers are required to administer the Medicare Part B program in accordance with the Medicare statutes and regulations, as well as the instructions and policies of the Secretary.

The provisions of Part B apply only to Medicare beneficiaries "who elect to enroll" in the program. 42 U.S.C. § 1395j. The manner of enrollment by eligible beneficiaries is prescribed in regulations promulgated by the Secretary. Within two months before a beneficiary becomes entitled to Part A benefits, he is sent a notice informing him that he will be automatically enrolled in Part B unless he declines in writing. 42 C.F.R. § 407.17(a), (b)(1), (2). Also, during specified periods, other beneficiaries may enroll by filing a written request with the Social Security Administration ("SSA") or HCFA. 42 C.F.R. § 407.22. Disenrollment occurs either by failure to pay premiums, 42 C.F.R. § 407.27(d) or by filing written notice with SSA or HCFA of his desire to disenroll. Neither the statutes nor the regulations expressly address the issue of whether disenrollment on a partial or service-by-service basis is acceptable under the Medicare program.

Under Part B, physicians are either "participating" or "nonparticipating." Each year the physician elects his status in Medicare. 42 U.S.C. § 1395u(b)(4). Participating physicians agree to accept an assignment of each beneficiary's claim and to charge no more than the amount specified by the Secretary for the particular service as full payment for services rendered. The carrier then pays the physician 80% of the Medicare amount and the patient is liable to the doctor for the 20% balance. Nonparticipating physicians may choose on a claim-by-claim basis, either to bill the patient directly for the service requiring the patient then to be reimbursed by Medicare, or to accept an assignment of the patient's claim in the same manner as a participating physician. Prior to a series of reforms enacted by Congress in the 1980s, nonparticipating physicians on unassigned claims were free to charge the patients whatever rates they chose. Any excess above the Medicare prescribed fee would have to be contributed by the patient.

Pursuant to the "Omnibus Budget Reconciliation Act of 1989," Pub.L. 101–239 (December 19, 1989), physicians currently are prohibited from charging Part B patients in excess of a limiting charge established by the Secretary under 42 U.S.C. § 1395w–4(g)(2). 42 U.S.C. § 1395w–4(g)(1). "If a nonparticipating physician knowingly and willfully bills on a repeated basis for physicians' services ... an actual charge in excess of the limiting charge ... the Secretary may apply sanctions against" the physician. 42 U.S.C. § 1395w–4(g). Such discretionary sanctions include exclusion from Medicare for up to five years, 42 U.S.C. § 1395u(j)(2)(A), and civil monetary penalties and assessments of up to $2,000.00 per offense and twice the amount charged or claimed for the Medicare item or service provided. 42 U.S.C. § 1395u(j)(2)(B); 42 U.S.C. § 1320a–7a(a).

When services are furnished "for which payment is made under this part," a claim form must be submitted regardless of whether the claim is assigned or unassigned. 42 U.S.C. § 1395w–4(g)(4)(A). If the physician fails to submit a claim to the Medicare carrier on behalf of the beneficiary when one is required to be submitted the Secretary may impose sanctions. 42 U.S.C. § 1395w–4(g)(4)(B)(ii). A sanction may be imposed only where the physician acts "knowingly and willfully" and only in an amount "not to exceed $2,000." 42 U.S.C. § 1395u(p)(3)(A). If the knowing and willful violation also occurs "in repeated cases," however, the physician may be subject to the same exclusionary and monetary penalties that apply to repeated, knowing and willful violations of the limiting charge. 42 U.S.C. § 1395u(p)(3)(B).

The procedures for imposing an exclusionary sanction are set forth in 42 U.S.C. § 1320a–7, *as incorporated in* 42 U.S.C. § 1395u(j)(2). Among other things, the physician is "entitled to reasonable notice and opportunity for a hearing," conducted by an administrative law judge, to the same extent as Social Security claimants are entitled to a hearing under 42 U.S.C. § 405(b). 42 U.S.C. § 1320a–7(f)(1), (2). A physician dissatisfied with the Secretary's final decision is entitled to judicial review in the district court pursuant to 42 U.S.C. § 405(g). 42 U.S.C. § 1320a–7(f)(1). The provisions of 42 U.S.C. § 405(h), which preclude 28 U.S.C. § 1331 general federal question jurisdiction over Social Security claims, apply equally to the exclusionary determinations of the Secretary. 42 U.S.C. § 1320a–7(f)(3).

The administrative procedures governing the imposition of a civil monetary penalty are set forth in 42 U.S.C. § 1320a–7a(c)–(*l*), *as incorporated in* 42 U.S.C. §§ 1395u(j)(2), 1395u(p)(3). Generally, the procedures provide that the Secretary can initiate a proceeding with the concurrence of the Attorney General. The physician has the right to a full blown hearing on the record. An adverse determination by the Secretary is reviewable in the United States Court of Appeals for the Circuit in which the person resides, or in which the claim was presented. 42 U.S.C. § 1320a–7(f)(3).

II. FACTS GIVING RISE TO THIS LITIGATION

In 1991, Dr. Copeland was approached by five of her patients, the plaintiff-patients in this case, and asked whether she could provide routine medical services for them on a private contractual basis without claims for

payment being submitted to Medicare. The plaintiff-patients wished to pay for such services out of their own funds and requested that Dr. Copeland not submit claims for reimbursement to Medicare on their behalf. After inquiring into this matter, Dr. Copeland received two bulletins distributed by Medicare carriers under contract with the Secretary. *See* Plaintiffs' complaint, exhibits A and B. Exhibit A states in relevant part:

> Some physicians have contacted Medicare and requested they be removed from the program. As long as covered services are provided, however, a provider must abide by all Medicare rules and regulations pertaining to those services. The law cannot be bypassed by having patients sign a disclaimer stating that services provided to them should not be billed to Medicare.

Plaintiffs' complaint, exhibit A. Exhibit B essentially reiterates the statement in Exhibit A. In addition to the two bulletins, Dr. Copeland received a copy of a letter, dated October 15, 1991, authored by Gail R. Wilensky, then Administrator of the HCFA. The letter states in pertinent part:

> We expect that almost all patients who have Part B coverage will choose to use that coverage regardless of their financial means. We are very aware of past problems patients experienced in completing Medicare claims forms. However, with the advent of the requirement that the physician submit the claim, the patient is relieved from coping with any complexities in the Medicare claims process. We are not aware of any instances where a patient has initiated agreements with a physician to the effect that Medicare will not be billed for the physicians' services. Furthermore, such an agreement initiated by a physician would be invalid. In the rare event, however, that a patient, for his or her own reasons, and entirely independently, chooses not to use Part B coverage, the law does not require the submission of a claim by the physician.
>
> * * * * * *
>
> Where patients have Part B enrollment, a patient can choose not to use Part B coverage for certain physician services. However, by law the physician is still required to follow certain Medicare requirements other than the claims submission requirement. This would include the limiting charge provision applicable to a nonparticipating physician when assignment is not accepted, or advance written notice to the patient when the physician furnishes services which are not considered reasonable and necessary under Medicare guidelines.

Affidavit of Camilla G. Taylor, pps. 4–5.

Although not addressed in plaintiffs' complaint and not discussed at oral argument, plaintiffs also submitted to this court the affidavit of Joseph M. Scherzer, M.D., a resident and citizen of Arizona. Doctor Scherzer stated that upon inquiring of the HCFA as to whether he could privately contract with his patients who are enrolled in Medicare, he received in response a letter from Eugene L. Chinn, Chief, Contractor Operations Division Manager, at HCFA's Region 14. This letter stated in pertinent part:

> Frequently, when a physician and a patient, that is Medicare eligible, enter into a private pay only agreement, a contract or written agreement is prepared and signed. These arrangements are usually called a Private Agreement and are designed to exclude the Medicare program. The Health Care Financing Administration (HCFA) does not pursue or promote the use of private agreements. However, HCFA would not be bound by a private agreement if the Medicare beneficiary complained or files a claim for the service provided under the private agreement.

Affidavit of Joseph M. Scherzer, M.D. p. 2, ¶ 5.

III. DISCUSSION

The bulletins issued by the intermediaries and the Wilensky letter were the impetus of the instant action. *See* Transcript of proceedings, 9/14/92, at T–6, L.23 to T–7, L.14 (hereinafter "T-page"). Plaintiffs seek a Declaration of Rights and Injunctive Relief challenging a policy which allegedly precludes the plaintiffs from privately contracting for medical services on a case-by-case basis and choosing not to submit a claim for reimbursement under Part B of Medicare.

In other words, plaintiffs wish to partially disenroll in Medicare at their option. In the instance of disenrollment, the Medicare Act would be side-stepped completely and a claim form would never be submitted on behalf of the beneficiary. In addition, as clarified at oral argument, plaintiffs seek a determination that the physician would not be bound by the fee limitation requirement of the Medicare Act and would be able to charge whatever she wished. *See* T-56, L.08–L.24. The plaintiffs contend that the bulletins and the Wilensky letter in addition to the defense put forth by the Secretary in this action constitute a clearly articulated policy of the Secretary interpreting the Medicare Act as prohibiting such private agreements and threatening sanctions against a physician who enters into such agreements.

a. Standing

[1] I first address the issue of standing. To satisfy the constitutional requirement of standing, the plaintiffs must identify a "direct threatened injury traceable to the challenged action." *Colonial Penn Ins. Co. v. Heckler*, 721 F.2d 431, 434 (3d Cir.1983); *see also Valley Forge Christian College v. Americans United for Separation of Church and State, Inc.*, 454 U.S. 464, 102 S.Ct. 752, 70 L.Ed.2d 700 (1982). This requirement is commonly referred to as the "injury in fact" requirement. *See Association of Data Processing Service Organizations, Inc. v. Camp*, 397 U.S. 150, 90 S.Ct. 827, 25 L.Ed.2d 184 (1970). The relevant inquiry is "whether, assuming justiciability of the claim, the plaintiff has shown an injury to himself that is likely to be redressed by a favorable decision." *Simon v. Eastern Kentucky Welfare Rights Org.*, 426 U.S. 26, 38, 96 S.Ct. 1917, 1924, 48 L.Ed.2d 450 (1976). Thus, where plaintiff's allegations, if true, demonstrate that plaintiff is in fact injured by the action he is seeking to have reviewed, then plaintiff has satisfied the constitutional standing requirement. *See id.; see also Warth v. Seldin*, 422 U.S. 490, 498, 95 S.Ct. 2197, 2205, 45 L.Ed.2d 343 (1975) ("the standing question is whether the plaintiff has 'alleged such a personal stake in the outcome of the controversy' as to warrant *his* invocation of federal court jurisdiction") (emphasis supplied).

[2] The Secretary first argues that both the patients and the physician lack standing to challenge the alleged policy of the Secretary. The substance of the government's argument with respect to Dr. Copeland is that absent actual sanctions or a threat of sanctions against the doctor, she has not satisfied the injury in fact requirement of standing. In accordance with the *Simon* case, however, for the purpose of determining the standing question, I must accept as true plaintiffs' allegation that the Secretary has articulated a broad policy that would subject Dr. Copeland to sanctions for entering into private agreements with her patients. I am satisfied that, if such a policy exists, the alleged threat of pecuniary and exclusionary sanctions is sufficient to satisfy the injury in fact test. The injury suffered by the doctor is traceable to the alleged policy and a favorable decision to plaintiffs by this court on the validity of the policy would redress the injury.

[3] The plaintiff-patients claim that because the alleged policy of the Secretary prohibits private contracting out of Medicare on a case-by-case basis, Dr. Copeland, the physician of their choice, will ultimately withdraw her services.[1] The patient-plaintiffs argue that pursuant to the policy, in order to maintain the physician of their choice, the patients would have to disenroll completely from Medicare. Complete disenrollment would allegedly leave the patients without any health care coverage. *See Affidavit of J. Patrick Rooney*, Chairman of the Board of Golden Rule Insurance Company (stating that no private coverage outside of medicare exists for patients over sixty-five years of age). The government contends that the patients have suffered no injury sufficient to satisfy the injury in fact requirement. I disagree. If I accept plaintiffs' allegations as true, I am satisfied that "[f]oregoing all Medicare benefits in exchange for care from

1. Although the assertion that Dr. Copeland would withdraw her services was not specifically pleaded in the plaintiffs' complaint or presented in plaintiffs' motion papers, this position was advanced by the plaintiffs at oral argument. T-51, L.06–L.23; T-48, L.10–L.18.

a physician of their choice" is an injury in fact sufficient to confer standing upon the plaintiff patients.[2] *See American Soc. of Cataract & Ref. Surgery v. Bowen*, 725 F.Supp. 606, 610 (D.D.C.1989) (citing *New York State Ophthalmological Society v. Bowen*, 854 F.2d 1379, 1385 (D.C.Cir.1988), *reh'g denied en banc*, 861 F.2d 1283 (D.C.Cir. 1988), *cert. denied*, 490 U.S. 1098, 109 S.Ct. 2448, 104 L.Ed.2d 1003 (1989) stating "a provision that, as a practical matter, conditions access to a desired service or exemption from an approval requirement on a patient's 'voluntary' decision to give up a valuable benefit is tantamount to a direct penalty imposed on the patient who chooses the service").

b. Exhaustion

Having determined that both the plaintiff-patients and plaintiff-physician have standing to challenge the so-called policy of the Secretary, I next address the Secretary's claim that this court lacks subject matter jurisdiction to hear the challenge because plaintiffs have failed to exhaust their administrative remedies. The Secretary bases this argument on the prerequisites to judicial review of determinations of the Secretary as established by 42 U.S.C. § 405(g), (h). The resolution of this "jurisdictional issue requires a choice between two lines of precedent." *National Kidney Patients Ass'n v. Sullivan*, 958 F.2d 1127, 1130 (D.C.Cir.1992). The Secretary relies on the *Heckler v. Ringer*, 466 U.S. 602, 613–16, 104 S.Ct. 2013, 2020–22, 80 L.Ed.2d 622 (1984), *Weinberger v. Salfi*, 422 U.S. 749, 95 S.Ct. 2457, 45 L.Ed.2d 522 (1975) line. Plaintiffs rely the *Bowen v. Michigan Academy of Family Physicians*, 476 U.S. 667, 106 S.Ct. 2133, 90 L.Ed.2d 623 (1986) line.

The *Ringer* line construes 42 U.S.C. § 405(g), (h) as requiring a plaintiff in the first instance to present a claim to the Secretary or his delegate. This presentment requirement is unwaivable. After presentment the plaintiff is required to exhaust his administrative remedies. The exhaustion requirement may be excused only where (1) the plaintiff's claim is a procedural challenge "wholly" collateral to the substantive issues, (2) the plaintiff's injury cannot be retroactively corrected through a favorable final decision in the administrative process, or (3) exhaustion would be futile. *Ringer*, 466 U.S. at 619, 104 S.Ct. at 2024.

[4] The *Michigan Academy* line narrowed the scope of the *Ringer* line by "articulating a distinction between the method by which Part B amounts are determined and the *determinations* themselves." *American Ambulance Service v. Sullivan*, 911 F.2d 901, 905 (3rd Cir.1990) (emphasis supplied). Under *Michigan Academy*, a plaintiff's challenge to the methodology of the Secretary in making determinations, including "challenges to the validity of the Secretary's instructions and regulations, are cognizable in courts of law." *See id.* at 905 (quoting *Michigan Academy*, 476 U.S. at 680, 106 S.Ct. at 2141).[3]

[5] Although the subject matter of the instant case deals not with an issue regarding coverage or an amount determination, but with the statutory duties of the physician, 42 U.S.C. § 1320a–7(f)(1), (3) made the limitations of § 405(h) applicable to the re-

2. Plaintiff-patients also claim that they suffer injury in fact because the claim submission requirement violates their right to privacy. Because I found standing on the ground of foregoing all health care coverage in order to get treatment from the physician of their choice, I will not address this issue.

3. It should be noted that *Michigan Academy* and *Ringer* were decided prior to a 1986 amendment to the Medicare Act when judicial review was only available for Part A claims. The 1986 amendment provided for judicial review of Part B claims upon final decision by the Secretary. The D.C. Circuit has concluded that this amendment mooted the need for the methodology/amounts distinction and held that even challenges to the Secretary's methodology now require exhaustion. With the 1986 amendment, Part B claims will not go unreviewed: judicial review simply awaits the initial administrative determination in a concrete setting. *National Kidney Patients Ass'n v. Sullivan*, 958 F.2d 1127, 1133 (D.C.Cir.1992).

Inasmuch as the Third Circuit in *American Ambulance Service v. Sullivan*, 911 F.2d 901, 902 n. 2 (3d Cir.1990) acknowledged the 1986 amendment to the Medicare Act, but continued to employ the amounts/methodology distinction, I conclude that I must still follow the amounts/methodology distinction.

view of exclusionary sanctions. Thus, the *Michigan Academy* and *Ringer* discussions concerning § 405(h) are applicable to the case before me. I must decide whether plaintiffs, by framing their complaint as a challenge to an articulated policy of the Secretary to sanction doctors who engage in private contracting with Medicare Part B patients, have made a challenge to the methodology by which the Secretary makes a sanction determination or a challenge to a determination itself.

I am convinced that plaintiffs' challenge to the so-called policy of the Secretary falls within the directive of *Michigan Academy*. The plaintiffs in this case are not challenging a sanction imposed by the Secretary. Indeed, plaintiffs are challenging a policy whereby the plaintiff-physician is allegedly subjected to sanctions. It is the validity of such an alleged policy that is in issue, not a disputed factual determination in which the Secretary imposed sanctions. Recognizing general federal question jurisdiction under 28 U.S.C. § 1331 to address such a challenge to a policy of the Secretary does not frustrate the meaning and purpose of § 405(h). *Michigan Academy* made clear that in enacting § 405(h), the Congressional purpose was to " 'avoid overloading the courts' with 'trivial matters', a consequence which would 'unduly tax' the federal court system with 'little real value' to be derived by participants in the program." *Michigan Academy*, 476 U.S. at 667, 106 S.Ct. at 2133 (quoting 118 Cong.Rec. 33992 (1972) (remarks of Sen. Bennett)). I do not think that a challenge to a policy of the Secretary is a challenge that Congress would consider a trivial matter burdening the federal courts. Assuming an articulated policy, such a policy would be integral to the way in which the Secretary analyzes a sanction proceeding. Thus, if the policy is invalid so would be the Secretary's methodology. *American Ambulance*, at 906.

c. Ripeness

[6] The final threshold issue that I must address is ripeness. It is here where plaintiffs' case must fail. The purpose of the ripeness doctrine is:

> to prevent the courts, through avoidance of premature adjudication, from entangling themselves in abstract disagreements over administrative policies, and also to protect the agencies from judicial interference until an administrative decision has been formalized and its effects felt in a concrete way by the challenging parties.

Pacific Gas & Elec. v. Energy Resources Comm'n, 461 U.S. 190, 200, 103 S.Ct. 1713, 1720, 75 L.Ed.2d 752 (1983) (quoting *Abbott Laboratories v. Gardner*, 387 U.S. 136, 148–49, 87 S.Ct. 1507, 1515–16, 18 L.Ed.2d 681 (1967), *overruled on other grounds by Califano v. Sanders*, 430 U.S. 99, 97 S.Ct. 980, 51 L.Ed.2d 192 (1977)); *see also American Medical Ass'n v. Bowen*, 857 F.2d 267, 272 (5th Cir.1988) (ripeness "doctrine discourages the litigation of contingent events that either may not occur at all or, at least, may not occur as anticipated"). In addressing the ripeness issue, I must evaluate "the fitness of the issues for judicial decision and the hardship to the parties of withholding court consideration." *Pacific Gas & Elec.*, 461 U.S. at 201, 103 S.Ct. at 1720.

The plaintiffs in their briefs and at oral argument claim to be challenging an articulated policy of the Secretary "which specifically prohibits Medicare patient-beneficiaries from paying for such services entirely out of their own funds and requesting their physician not to submit a claim for Medicare Part B benefits to the Secretary on their behalf." *See* Plaintiffs' brief at 2. As evidence of this articulated policy the plaintiffs proffered the two bulletins attached to their complaint and the advisory letters issued by the HCFA in response to questions concerning private contracting.[4]

The plain reading of the bulletins and the two advisory letters from HCFA clearly demonstrate that plaintiffs have failed to establish the existence of an articulated policy from the Secretary on the issue of private

4. Plaintiffs also contend that the defense put forth by defendants against the merits of plaintiffs' case indicates the existence of a policy and the imminence of sanctions. I disagree. The government's reply brief made clear that their argument on the merits presumes that this court has found that the policy exists. *See* Government reply brief at 12 n. 9.

contracting. The various documents themselves are not in accord and none of them explicitly recounts the policy as alleged by plaintiffs. The letter from Mr. Chinn indicates no objection by HCFA to such private contracting. In the event that the patient changes his or her mind and submits a claim, however, HCFA would not be bound by a private agreement. The Gail Wilensky letter states that possibly in the situation where the private agreement is totally the idea of the patient and not influenced at all by the physician, the doctor may not be required to submit a claim. However, other medicare requirements, including the fee limiting charge, would have to be followed.

The bulletins from the carriers come closest to reflecting the policy alleged by plaintiffs. The bulletins make the broad statement that the law cannot be bypassed by entering into private contracts in which patients disclaim the coverage. Again, this statement does not "specifically prohibit Medicare patient-beneficiaries from paying for such services out of their own funds and requesting their physician not to submit a claim for Medicare Part B benefits to the Secretary on their behalf." Assuming, however, that the prohibitions alleged by the plaintiffs are the "law" to which the bulletins refer, then one may make the argument that the bulletins do enunciate the policy as challenged by plaintiffs.

Notwithstanding this possibility, plaintiffs have not placed any evidence in the record identifying the source of the bulletins such that they can be attributed to the Secretary. In their complaint plaintiffs allege that the bulletins were "prepared by the Defendant, Louis W. Sullivan, M.D., Secretary of the United States Department of Health and Human Services, and sent to health care providers." *See* Plaintiffs' complaint at 19 ¶ 30. At oral argument plaintiffs' attorney responded when questioned about the origin of the bulletins, that they "come from intermediaries of the Secretary." T–38, L.13–L.14.[5] At oral argument the government took the position that it did not know the origin of the bulletins. T–38, L.1–L.5.

[7] Given the confusion as to the origin of these bulletins, the lack of any evidence in the record attributing the statements in the bulletins to the Secretary, and the inconsistencies reflected in the HCFA letters, I cannot possibly conclude that the Secretary has clearly articulated a policy on the issue of private contracting. These bulletins may be nothing more than the intermediaries' interpretation of what the law may or may not be and not a statement by the Secretary as to his intentions regarding the proposed issue. Under the Medicare Act, the Secretary has enforcement power to bring sanction proceedings against the doctor. 42 U.S.C. § 1395w–4(g)(1) (violation of limiting charge); 42 U.S.C. § 1395w–4(g)(4)(B)(ii) (violation of claims submission requirement). The intermediaries do not have such power. Accordingly, such a statement coming from an organization which does not have enforcement power cannot be interpreted as a ripe threat against the doctors. *Compare American Federation of Gov. Employees v. O'Connor*, 747 F.2d 748, 749 (D.C.Cir.1984) (case not ripe for review where plaintiffs present general question not wedded to the facts of a particular case and where plaintiffs offer advisory letters from entity with no enforcement power as the basis of their challenge), *with Colonial Penn Insurance v. Heckler*, 721 F.2d 431, 439–40 (3d Cir.1983) (case ripe for judicial review where "it is apparent to a statistical and almost metaphysical certainty that claims will be pressed against" the plaintiff).

From my review of the documents submitted by the plaintiffs in their attempt to identify the Secretary's policy, it is clear to me that the challenge to the alleged policy of the Secretary is not fit for judicial decision. This is not a case where the Secretary has clearly stated his position on a posed issue. The Secretary has not promulgated any rules or regulations either formally or informally espousing the policy alleged by plaintiffs. *See Colonial Penn*, at 439. Nor have plaintiffs

5. Interestingly, neither of the bulletins come from the actual intermediary joined as a defendant in this case.

demonstrated that the bulletins supplied by the carriers were issued on behalf of or at the direction of the Secretary. *See Association of American Physicians v. Bowen*, 909 F.2d 161, 163 (6th Cir.1990) (plaintiffs succeeded in challenge to letters issued by the carrier, "on behalf of the Secretary of Health and Human Services," as violative of the Medicare Act).[6] Nor have plaintiffs demonstrated that the documents represent statements of the Secretary intended to have the force of law such that conformity to them in the administrative process would be expected. *See Abbott Labs*, 387 U.S. at 150–51, 87 S.Ct. at 1516–17 (Secretary's intentions clearly definitive where regulations were "promulgated in a formal manner after announcement in the Federal Register and consideration of comments by interested parties"). *See also American Ambulance Service v. Sullivan*, 911 F.2d 901 (3d Cir.1990) (ripeness not in issue where plaintiffs challenge provisions in Secretary's Carrier Manual[7] and HCFA Regional Medicare letter).

Plaintiffs cite *Whitney v. Heckler*, 780 F.2d 963 (11th Cir.1986) in support of their argument that this claim is ripe for judicial review. In *Whitney*, plaintiffs challenged as unconstitutional a provision of the Medicare Act that placed a temporary freeze on the fees non-participating physicians may charge their Medicare patients. In addressing the question of ripeness, the court concluded that "because this appeal raises a facial attack on the constitutionality of § 2306 and presents a purely legal question, we will never be in a better position to decide this issue." *Id.* at 968–69 n. 6. This case is clearly distinguishable. Here, the plaintiffs attack an alleged policy of the Secretary. Plaintiffs have failed, however, to establish that such a policy exists. Not until the Secretary has taken a position on this issue, will plaintiffs case be fit for judicial review.

[8] I also must evaluate the hardship to the parties of withholding court consideration. *Pacific Gas & Elec.*, 461 U.S. at 201, 103 S.Ct. at 1720. For reasons similar to those that lead me to conclude that plaintiffs' claim was not fit for judicial review, I am satisfied that no undue hardship is suffered by the plaintiffs in withholding such review. The *Whitney* court stated that "it is well established that an issue is ripe for judicial review when the challenging party is placed in the dilemma of incurring the disadvantages of complying or risking penalties for noncompliance." *Whitney*, at 969.

Pursuant to the Medicare Act, the imposition of sanctions by the Secretary is discretionary. 42 U.S.C. § 1395w–4(g). The discretionary sanctions for violating the fee limiting provisions are only authorized where the physician acts "knowingly and willfully on a repeated basis." *Id.* Similar preliminary requirements exist for the Secretary to exercise his discretion in imposing sanctions for violation of the claims submission requirement. *Id.* As concluded above, plaintiffs have not established a determination by the Secretary that doctors who engage in private contracting whereby claim forms are not submitted and the fee limitation provision is not followed have engaged in knowing and willful violations of the Medicare statute. Inasmuch as such a determination is a prerequisite to the Secretary's exercise of discretion in imposing sanctions, it is difficult for me to conclude that Dr. Copeland is facing the real

6. Plaintiffs' attorney cited this case at oral argument as an example of a case where a policy directive could trigger judicial review. *See* T–14, L.6–L.25. Although I agree that *Association of American Physicians* presents a situation where the court took judicial review of a policy directive, the facts of that case were much different than the facts of the instant case. In that case physicians received letters from a carrier written "on behalf of the Secretary" informing them that they were in violation of the Medicare statute and might face sanctions because they were billing Medicare patients for clinical diagnostic laboratory tests on a non-assignment basis in contravention to the Act. In the instant case, plaintiffs present no evidence that the statements in the bulletins or the letters from HCFA were made "on behalf of the Secretary." In fact the government contends that those documents merely enunciate an interpretation of what the law may be by the parties that issued the documents. *See* T–36, L.4 to T–38, L.5.

7. The Carrier's Manual is a set of instructions prepared and periodically revised by the Secretary of Health and Human Services for circulation to the private insurance carriers under contract with the Secretary to administer the Part B program.

dilemma of complying or being sanctioned that was the concern of the *Whitney* court. *See American Medical Ass'n v. Bowen*, 857 F.2d 267, 272 (5th Cir.1988) (no case or controversy where physician not personally threatened with sanctions); *see also Abbott Labs.* 387 U.S. at 151–53, 87 S.Ct. at 1516–18, (case ripe for judicial review where regulations are clear-cut and effective immediately upon publication and plaintiffs risk serious criminal and civil penalties).

d. Plaintiffs' constitutional attack on the statute

In their verified amended complaint, plaintiffs make a constitutional attack on the validity of 42 U.S.C. § 1395w–4. Plaintiffs claim that to the extent that § 1395w–4 authorizes the alleged policy of the Secretary prohibiting private contracting on a case-by-case basis without filing any claims for payment and requiring beneficiaries to disenroll and threatening sanctions against the physician if such private contracting is done, the statute constitutes an unconstitutional delegation of legislative power to the defendants in violation of Article I, § 1, and the Fifth Amendment to the United States Constitution.

From my reading of the verified amended complaint, plaintiffs' papers and the position taken by plaintiffs at oral argument, I understand plaintiffs' constitutional attack to be predicated on a finding by this court that the statutory provision being challenged authorizes the alleged policy. Inasmuch as I have concluded that plaintiffs' challenge to the alleged policy of the Secretary is not ripe for determination because plaintiffs have failed to establish the existence of such a policy, I find that it is unnecessary to address plaintiffs' constitutional attack on the statute.

IV. CONCLUSION

Rule 12(b)(6) of the Federal Rules of Civil Procedure provides for dismissal of an action for failure to state a claim upon which relief can be granted. In the instant case, plaintiffs claim to be challenging a clearly articulated policy of the Secretary prohibiting private contracting on a case-by-case basis and threatening sanctions against doctors who enter into such arrangements. Plaintiffs argue that such a policy is in contravention to the Medicare Act and to various provisions of the United States Constitution. In addition, plaintiffs challenge, as an unconstitutional delegation of legislative authority, a provision of the Act to the extent that it is found to authorize such a policy. I have concluded that plaintiffs' claims are not ripe because plaintiffs have not established that the Secretary has clearly articulated a policy on private contracting. Accordingly, plaintiffs have failed to state a claim upon which relief can be granted. Based upon the foregoing discussion, defendant's motion to dismiss is **GRANTED** and plaintiffs' cross-motion for summary judgment is **DENIED.**

SO ORDERED.

WEST KEY NUMBER SYSTEM

ANALYTICAL MEASUREMENTS, INC.; (a NJ corporation held in trust by Ella May Paully and Theresa Scarinzi), and Ella May Paully (individually), Plaintiffs,

v.

The KEUFFEL & ESSER COMPANY; the Azon Corporation; Selective Insurance Company; the Orion Group; the Aetna Casualty & Surety Company; and John Does I through X, Defendants.

Civ. No. 89–2512.

United States District Court,
D. New Jersey.

Feb. 9, 1993.

Owners of property upon which photosensitive paper coating factory had been operated brought action to obtain contribution from corporation which operated plant, corporate officer and various others for cleanup of site, and corporation and various others asserted cross claims against corporate offi-