IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

PAUL FISCHER, M.D. et al.	*	
	*	
v.	*	
	*	Civil Action No. WMN-11-2191
DONALD BERWICK, M.D. et al.	*	
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MEMORANDUM

Before the Court is Defendants' Motion to Dismiss. ECF No. 10. The motion is fully briefed. Upon a review of the papers and the applicable case law, the Court determines that no hearing is necessary, Local Rule 105.6, and that the motion will be granted.

Plaintiffs are six physicians in an Augusta, Georgia primary care practice. Named as defendants are Donald Berwick, M.D., Administrator of the Centers for Medicare and Medicaid Services (CMS), and Kathleen Sebelius, Secretary of the United States Department of Health and Human Services (HHS) (hereinafter, "the Secretary"). Plaintiffs bring this action challenging the method by which the Secretary formulates the Physician Fee Schedule (PFS) paid to health care providers for various procedures under the Medicare program. Specifically, Plaintiffs challenge what they see as the dominating influence of the American Medical Association's Relative Value Update

Committee (RUC) on the process of calculating "relative value units," which are a major component of the fee structure. Because certain medical specialties are disproportionately represented on RUC, Plaintiffs maintain that primary care providers, like themselves, are undercompensated under the PFS. Beyond the harm to their own practices, Plaintiffs maintain that the over-reliance on RUC in formulating the PFS has lead to the overuse of unnecessary procedures by RUC-favored specialists and a "devastating effect upon the nations' health and health care spending." Compl. ¶ 73.

Plaintiffs assert in their Complaint that RUC's influence is so dominating in the process that it functions as a de facto Federal Advisory Committee (FAC). As such, the functioning of RUC should be, in Plaintiffs' view, subject to the provisions of the Federal Advisory Committee Act, 5 U.S.C. app. §§ 1-16 (FACA). In addition to their claim alleging a violation of FACA, Plaintiffs maintain that Defendants' over reliance on the recommendations of RUC constitutes an unlawful violation of the Delegation Clause of the United States Constitution. Plaintiffs also assert that, because Defendants' continued reliance on data and recommendations from RUC constitutes arbitrary decision making that denies Plaintiffs income that they would otherwise have obtained, Defendants are violating the Due Process Clause of the Fifth Amendment.

Plaintiffs are not seeking monetary relief in this action. Instead, they seek a declaratory judgment that Defendants are violating FACA, the Administrative Procedures Act (APA), 5 U.S.C. § 551 et seq., and the Patient Protection and Affordable Care Act (ACA), Pub. L. No. 111-148, 124 Stat 119 (2010). They further seek an order enjoining Defendants from utilizing RUC in the formulation of the PFS until such time as Defendants fully comply with FACA, the APA, the ACA and the Constitution. Finally, Plaintiffs seek Mandamus ordering Defendants to fulfill their duties under FACA and the APA.

Defendants have moved to dismiss the Complaint in its entirety on a number of grounds. First, Defendants argue that this Court lacks subject matter jurisdiction over this action. Because it was a "proposed" fee schedule that was challenged in the Complaint,[1] Defendants contend that this proposed schedule was not a "final agency action" subject to review under the APA. In addition, Defendants assert that Congress has made even final agency actions regarding the determination of relative value units unreviewable by the courts. See 42 U.S.C. § 1395w-4(i)(1)(B). In addition to the jurisdictional challenge, Defendants argue that the Complaint fails to state a claim upon which relief can be granted. Finally, Defendants argue that the

[1] Since the filing of the Complaint, the final PFS has been issued.

American Medical Association is a party that should be joined in this action under Rule 19(a) of the Federal Rules of Civil Procedure.

For the reasons that follow, the Court finds that Plaintiffs' Complaint seeks judicial review that is barred under 42 U.S.C. § 1395w-4(i)(1)(B) and, thus, the Court need not reach Defendants' alternative arguments.

Medicare, Title XVIII of the Social Security Act, is a federal health insurance program for the aged and disabled. This action relates to Part B of Medicare, a voluntary supplemental insurance program that covers payments for physician's services and other healthcare services. See id. § 1395j – 1395w-4. Fees paid to physicians who elect to participate in the program are capped by the annual PFS which sets the fees for hundreds of types of specific services. Payment amounts under the PFS are calculated by multiplying (1) the relative value of a service; (2) the conversion factor for the particular year; and (3) the geographic adjustment factor applicable to the locality in which the service was provided. See id. § 1395w-4(b)(1). This case relates to the determination of the first component, the relative value of a service, which is calculated by combining three subcomponents, each of which is measured in terms of relative value units ("RVUs"). The three subcomponents are (1) the work component; (2) the practice

expense component; and (3) the malpractice component. See 42 U.S.C. §§ 1395w-4(c)(1).

The RVUs are revised each year by CMS. According to the Complaint, RUC has met each year since 1991 to "debate relative values based upon input from surveys distributed to specialty societies." Compl. ¶ 45. RUC then makes recommendations to the Secretary of HHS. Although Plaintiffs acknowledge that the Secretary rejects some of those recommendations, see id. ¶ 71, Plaintiffs assert that most RUC recommendations are routinely adopted into the final PFS.

Accepting as true that RUC plays a major role in the formation of the PFS and also accepting as true that this role unfairly skews the PFS toward certain medical professions and procedures, the Court, nonetheless, finds that Congress has precluded courts from reviewing, not only the final relative values and RVUs, but also the method by which those values and units are generated. Section 1395w-4(i)(1) of Section 42 of the United States Code provides:

> There shall be no administrative or judicial review under section 1395ff of this title or otherwise of--
>
> (A) the determination of the adjusted historical payment basis (as defined in subsection (a)(2)(D)(i) of this section),
>
> (B) the determination of relative values and relative value units under subsection (c) of this section, including adjustments under subsections (c)(2)(F), (c)(2)(H), and (c)(2)(I) of this section and section

> 13515(b) of the Omnibus Budget Reconciliation Act of 1993,
>
> (C) the determination of conversion factors under subsection (d) of this section, including without limitation a prospective redetermination of the sustainable growth rates for any or all previous fiscal years,
>
> (D) the establishment of geographic adjustment factors under subsection (e) of this section, and
>
> (E) the establishment of the system for the coding of physicians' services under this section.

42 U.S.C. § 1395w-4(i)(1) (emphasis added).

Several courts have examined this prohibition on judicial review in the context of challenges similar to that presented by Plaintiffs here. In American Society of Cataract and Refractive Surgery v. Thompson, 279 F.3d 447 (7th Cir. 2002), eleven national medical societies and associations brought a statutory and constitutional challenge to an HHS regulation implementing a new system for calculating "practice expense RVUs." Specifically, the plaintiffs challenged the formula by which the practice expense RVUs would be calculated during a congressionally mandated four year transition period. They asserted that the formula adopted by the Secretary was "arbitrary, capricious, and contrary to law in violation of the Medicare Act, the Administrative Procedure Act, and the Due Process Clause of the Fifth Amendment." Id. at 450.

In holding that the plaintiffs' claims were barred under § 1395w-4(i)(1)(B), the Seventh Circuit began with the observation that there is a "strong presumption that Congress intends a judicial review of administrative action" and "only upon a showing of 'clear and convincing evidence' of a contrary legislative intent should the courts restrict access to judicial review." Id. at 452. "While we acknowledge that respondents bear a heavy burden to overcome the strong presumption that Congress did not mean to prohibit all judicial review of administrative action, we also recognize that "all presumptions used in interpreting statutes, may be overcome by, inter alia, specific language or specific legislative history that is a reliable indicator of congressional intent, or a specific congressional intent to preclude judicial review that is fairly discernible in the detail of the legislative scheme." Id. (quotations omitted).

The plaintiffs in Thompson, like Plaintiffs here, argued that while § 1395w-4(i)(1)(B) precludes administrative and judicial review of the Secretary's determination of specific RVUs assigned to specific services, "this provision does not foreclose systemic challenge to the Secretary's interpretation of Congress's nondiscretionary instructions for establishing components of the physician fee schedule." Id. (emphasis added). In rejecting that argument, the Seventh Circuit noted

that the regulation challenged by the plaintiffs was "an integral part of the relative value determination." Id. at 453. As such, the Court concluded that "[i]t would be difficult for Congress to have written paragraph (B) in clearer terms prohibiting such a challenge." Id.

The court went on to explain the rationale for such a comprehensive bar of judicial review:

> the payment scheme in Part B of the Medicare Act supports our determination that Congress intended to bar judicial review of petitioners' challenge. RVUs are used to calculate the physician's fee schedule. The fee schedule is updated yearly and each year's schedule is established by November 1 of the preceding year. See 42 U.S.C. § 1395w-4(b)(1). As respondents highlight, this tight time frame demands that the Secretary's decisions regarding the RVUs be made quickly and efficiently. Further, Congress directed that adjustments in the RVU component of the fee schedule be made in a budget neutral fashion, see 42 U.S.C. §§ 1395w-4(c)(2)(B)(ii), (c)(2)(F), 1395w-4 note, requiring increases for some services to be offset by decreases in others. While petitioners acknowledge that a favorable decision would be disruptive, we believe, as respondents persuade us to, that to ensure finality so that the Secretary can make any necessary budget neutrality adjustments, claims such as petitioners' claim must be precluded from judicial review.

Id. at 454.

Similarly, in American Society of Anesthesiologists v. Shalala, 90 F. Supp. 2d. 973 (N.D. Ill. 2000), five physicians' associations filed suit against the then Secretary of HHS, challenging the Secretary's "methodology" in determining the practice expense RVUs. Id. at 974. Specifically, the

plaintiffs took issue with the Secretary's exclusion of certain types of expenses in the determination of practice expense RVUs. While the plaintiffs conceded the "existence of the congressional directive barring judicial review," the argued that this bar was limited to the "six highly discretionary and infinitely debatable decisions" listed in sections (A) through (E) of § 1395w-4)i)(1), supra, i.e.: "the determinations of (1) the adjusted historical payment basis, (2) relative values, (3) relative value units, (4) conversion factors, and (6) the coding system for each procedure." Id. at 975-76. The plaintiffs argued that, in contrast, decisions as to what types of expenses must be considered in setting relative values are reviewable, non-discretionary matters. Id. at 976.

In rejecting that argument, the American Society of Anesthesiologists court observed:

> the obvious problem with that artificial construct is that it would impermissibly rewrite the statute. Again Subsection (i)(1)(B) expressly states that the congressional prohibition against judicial review extends to the totality of "the determination of relative values and relative value units under subsection (c) of this section." And it simply will not do for Associations to say "Oh, we're only challenging Secretary's 'decisions that must be made before the relative value and relative value unit determinations.'"
>
> . . . If Associations' position were accepted, the congressional mandate against court intervention would be totally frustrated, because the opportunity for parties such as Associations to launch in-court attacks on the individual strands — the specific items

> – that are both integral to and essential components of the congressionally-protected determinations that Secretary must make would defeat her ability to make the determinations themselves.

Id. (emphasis in original).

A recent decision of the United States District Court for the Southern District of Florida parallels more closely the case at bar. In American College of Cardiology v. Sebelius, Civ. No. 09-62034 (S.D. Fla. Apr. 26, 2010), several cardiology associations, individual cardiologists, and patients brought suit against the Secretary challenging her reliance on certain survey data used to determine a portion of the practice expense RVU. The plaintiffs criticized the use of this data on the ground, inter alia, that it was not made available to the public. Id. at *2. The plaintiffs also appear to have believed that the use of this data was inconsistent with "sound data practices" as mandated by Congress. Id. at *5 (citing Section 212 of the Balanced Budget Act of 1999, Pub. L. No. 106-113 (1999)). To avoid the bar of 1395w-4(i)(1), the plaintiffs argued that they were not seeking a review of the determination of relative value units, but were simply challenging the Secretary's reliance on this particular data. Id. at 3. Relying on Thompson and American Society of Anesthesiologists, inter alia, the court disagreed, holding that to allow judicial review of the determination of the components of the RVUs would

render § 1395w-4(i)(1) "virtually ineffectual." Id. See also, Painter v. Shalala, 97 F.3d 1351, 1355 (10th Cir. 1996) (holding that § 1395w-4(i)(1)(C) barred judicial review of the determination of conversion factors).

In opposing the motion to dismiss, Plaintiffs in this action largely ignore the significance of 1395w-4(i)(1). In their summary of the arguments made in Defendants' motion, Opp'n at 1-2, Plaintiffs omit any mention of this provision. Plaintiffs do not discuss or even cite Thompson, American Society of Anesthesiologists, or American College of Cardiology. Furthermore, Plaintiffs' argument that their claims are not barred is the same argument rejected by these courts, i.e., that they are not challenging the specific fees in the PFS, "but rather the process and methodology by which those results were obtained." Opp'n at 3; see also id. at 23 ("It is the process that is challenged and it is the process that should and can be reviewed.")(emphasis in original).[2]

While ignoring decisions under § 1395w-4(i)(1), Plaintiffs rely instead on decisions interpreting an entirely different

[2] In addition, Plaintiffs emphasize the fact that they are not seeking monetary damages. Opp'n at 25. Thompson, American Society of Anesthesiologists, or American College of Cardiology, however, were also cases that did not involve monetary damages.

provision of the Medicare Act, 42 U.S.C. § 1395ii.[3] In decisions under that provision, courts have recognized a distinction between "amount claims" and "methodology claims." See Furlong v. Shalala, 238 F.3d 227, 232 (2nd Cir. 2001) (Furlong II).[4] The decisions cited by Plaintiff, however, including Furlong II, the decision upon which Plaintiffs most heavily rely, had nothing to do with the determination of relative values, relative value units, or any of the other components used to calculate the PFS. Thus, the bar of § 1395w-4(i)(1) was not raised or considered in those decisions.

The potential applicability of § 1395w-4(i)(1) was raised in the district court in an earlier phase of the Furlong litigation, see Furlong v. Shalala, Civ. No. 94-4817, 1996 WL 393526 (S.D.N.Y. 1996) (Furlong I), and the district court's

[3] Section 1395ii makes certain subsections of 42 U.S.C. § 405, including subsection 405(h), applicable to the Medicare Act. Section 405(h) provides that:

> The findings and decision of the [Secretary] after a hearing shall be binding upon all individuals who were parties to such hearing. No findings of fact or decision of the [Secretary] shall be reviewed by any person, tribunal, or governmental agency except as herein provided. No action against the United States, the Commissioner of Social Security, or any officer or employee thereof shall be brought under section 1331 or 1346 of Title 28 to recover on any claim arising under this subchapter.

[4] The Second Circuit in Furlong II noted that the status of the amount/methodology distinction was "somewhat unclear" after the Supreme Court's decision in Shalala v. Illinois Council on Long Term Care, Inc., 529 U.S. 1 (2000).

discussion is instructive here. The Furlong decisions arose out of the application of the "one-and-one-half rule" under which physicians performing multiple procedures were only compensated at a rate of one half of the Medicare-approved charge for the second procedure. Plaintiffs, a group of anesthesiologists, argued that the one-and-one-half rule should only be applied to surgical procedures and that the particular procedure at issue in that litigation was a medical procedure, not a surgical procedure.

In holding that § 1395w-4(i)(1) did not bar the plaintiffs' claims, the district court noted that the one-and-one-half rule was an "ancillary policy," "utilized after the relative values and relative value units are determined in order to implement their application." Id. at *8 (emphasis in original). The court noted that § 1395w–4(i)(1)(B), "does not state that it precludes judicial review of anything beyond the determinations of relative values and relative value units under subsection (c); it does not foreclose judicial review of all issues which may implicate subsection (c)." Id. The court found this omission "important because ancillary policies, such as the one and one-half rule, are not characterized as comprising part of the actual determination of relative values or relative value units." Id. Here, however, Plaintiffs' claims clearly

implicate part of the actual determinations of RVUs and, thus, do fall within the bar of § 1395w–4(i)(1).

Congress, of course, cannot bar review if that bar would be unconstitutional. The Thompson court examined that possibility and rejected it. The plaintiffs in Thompson, like Plaintiffs here, argued that without an opportunity for judicial review their due process rights would be violated. 279 F.3d at 454. To have a due process claim, however, one must first have a property interest in or "'legitimate claim of entitlement'" to the benefit at issue. Id. at 454-55 (quoting Bd. of Regents of State Colls. v. Roth, 408 U.S. 564, 577 (1972)). While physicians would have a property interest in being reimbursed for services rendered at the rate set out in the PFS, there is "no legitimate property interest in having reimbursements calculated in a particular manner." Id. at 455 (citing Painter, 97 F.3d at 1357-58). As the Painter court explained, because physicians can see ahead of time what Medicare will pay for particular services, they can decide each year whether they will be a participating physician for that particular year or whether to treat Medicare patients at all during that particular year. Painter, 97 F.3d at 1357. Once they choose to become a participating physician or choose to treat Medicare patients, they have no legitimate expectation to be compensated at any rate other than that set forth in the PFS. Id.

The cases cited by Plaintiffs in support of their due process claims are inapposite. See Opp'n at 35-36 (citing, inter alia, Ram v. Heckler, 792 F.2d 444, 447 (4th Cir. 1986); Bowens v. N.C. Dep't of Human Resources, 710 F.2d 1015, 1018-19 (4th Cir. 1983)). These cases arose after health care providers were suspended or terminated from participation in the Medicare program. In that context, courts have held that providers have a property interest in the "expectation of continued participation in the Medicare program." Ram, 792 F.2d at 447. Here, however, Plaintiffs' continued participation in the Medicare program has not been barred, but is conditioned only on Plaintiffs' decision as to whether to accept fees that are offered.

For these reasons, the Court finds that Plaintiffs' claims are barred by 42 U.S.C. § 1395w-4(i)(1). Accordingly, Defendants' motion to dismiss will be granted. A separate order consistent with this memorandum will be issued.

/s/
William M. Nickerson
Senior United States District Judge

DATED: May 9, 2012