FOR THE DISTRICT OF MARYLAND

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| PAUL FISCHER, *et al.*, | ) | |
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| Plaintiffs, | ) | |
| | ) | |
| v. | ) | Civil Action No. 1:11cv02191-WMN |
| | ) | |
| DONALD BERWICK, *et al.*, | ) | |
| | ) | |
| Defendants. | ) | |
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MEMORANDUM OF POINTS AND AUTHORITIES IN
SUPPORT OF DEFENDANTS' MOTION TO DISMISS

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**TABLE OF CONTENTS**

## TABLE OF AUTHORITIES

### FEDERAL CASES

**STATUTES**

**RULES AND REGULATIONS**



**MISCELLANEOUS**

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INTRODUCTION AND SUMMARY

Each year, the Secretary of Health and Human Services engages in notice-and-comment rulemaking to develop a physician fee schedule setting the amounts that Medicare and co-paying Medicare beneficiaries will together offer to pay for different physician services in the following calendar year. 42 U.S.C. § 1395w-4; *see*, *e.g.*, Final Rule with Comment Period, Physician Fee Schedule Rule for Calendar Year 2012, http://ofr.gov/OFRUpload/OFRData/2011-28597_PI.pdf (issued and displayed online and at the office of the Federal Register, Nov. 1, 2011; to be published in print *Federal Register*, Nov. 28, 2011) (hereinafter "2012 Final Rule with Comment Period"); 75 FED. REG. 73,583 (Nov. 29, 2010) (final rule for calendar year 2011); Complaint ¶ 41. One component used in setting the fee for a given physician service is the "relative value" of the service compared to other physician services. 42 U.S.C. § 1395w-4(b)(1).

Plaintiffs are primary care physicians. Complaint ¶¶ 7-12. Their Complaint focuses on a committee created by the nonparty American Medical Association ("AMA"), the AMA/Specialty

Society Relative Value Scale Update Committee ("AMA RUC"). The AMA RUC makes recommendations to the Secretary for revisions of relative values. Much of the Complaint sets out in detail plaintiffs' view that the AMA RUC's membership and procedures are inappropriately skewed against recommending that primary care services be given the higher relative values (and therefore higher relative payments) that plaintiffs argue are warranted. Complaint ¶¶ 45-47, 52-55, 61, 73-78.

The nonparty AMA contends that the AMA RUC's recommendations to the Secretary constitute the AMA's exercising its First Amendment right to petition the government. Complaint ¶ 51. Plaintiffs, on the other hand, contend either or both 1) that the Secretary controls the AMA RUC, *id*. ¶¶ 89, 91; or 2) that the AMA RUC controls the Secretary's rulemaking process, *id*. ¶¶ 97-99. If the former, plaintiffs contend that the AMA RUC is a Federal Advisory Committee ("FAC") that is not properly constituted under the Federal Advisory Committee Act, 5 U.S.C. app. §§ 1-16 ("FACA"); if the latter, plaintiffs contend that the Secretary has unconstitutionally surrendered her authority to the AMA RUC.

The complaint should be dismissed for three independently sufficient reasons. First, the Court lacks subject matter jurisdiction. Plaintiffs acknowledge that the FACA does not provide a private cause of action, Complaint ¶ 22, so they seek to use the Administrative Procedure Act ("APA") to challenge the proposed rulemaking for the 2012 fee schedule, Complaint ¶ 26. But agency action is generally reviewable under the APA only if it is either "final agency action" (which a proposed rule is not) or the action is "made reviewable by statute." 5 U.S.C.§ 704. Even final agency actions can be made unreviewable by statute. And here, Congress has directed that "[t]here shall be no administrative or judicial review under section 1395ff of this title or otherwise" of the

Secretary's "determination of relative values." 42 U.S.C. § 1395w-4(*i*)(1)(B). This provision bars plaintiffs' challenges to the determinations of relative values, including their challenges to the means by which those determinations were made. *See American Soc'y of Cataract & Refractive Surgery v. Thompson*, 279 F.3d 447 (7th Cir. 2002).

Second, the Complaint fails to state a claim upon which relief can be granted. The AMA RUC is run by the AMA, not by the Secretary, and is not a federal advisory committee, *de facto* or otherwise. *American Soc'y of Dermatology v. Shalala*, 962 F. Supp. 141, 147 (D.D.C. 1996), *aff'd mem.*, 116 F.3d 941 (D.C. Cir. 1997). And FACA does not apply in the first place to the Secretary's process for validating and appropriately adjusting relative values. Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 3134(b)(1)(A), 124 Stat. 119, 435 (2010), *to be codified at* 42 U.S.C. § 1395w-4 note. Plaintiffs' attempts to clothe their grievances in constitutional garb fail as well. The AMA RUC's recommendations are obviously influential, but the Secretary just as obviously maintains the final decisionmaking authority. Indeed, in one recent instance acknowledged by plaintiffs (Complaint ¶ 71) she rejected over half of the AMA RUC's recommendations. Nor does the fee schedule take plaintiffs' property without due process. The schedule, after all, sets the amounts that the federal government will offer to physicians who choose to participate in Medicare, but who are free to choose not to participate. They have no "property interest in receiving [Medicare] payments in an amount different from that set forth in the Secretary's . . . fee schedule." *Painter v. Shalala*, 97 F.3d 1351, 1357 (10th Cir. 1996).

Third, the AMA is "a person[ ] required to be joined if feasible," Rule 19(a), Fed. R. Civ. Proc., that plaintiffs have failed to join. Considering plaintiffs' claims without the AMA's

participating may as a practical matter impair the AMA's interests or leave defendants subject to a substantial risk of incurring inconsistent obligations in the cross-fire between plaintiffs, who want to end or diminish what they see as the AMA RUC's inordinate influence, and the AMA, which claims a First Amendment right to have its views given meaningful consideration.

## STATEMENT OF THE CASE

### 1. The Annual Physician Fee Schedule Rulemaking Process and Relative Values

Each year, the Secretary of Health and Human Services engages in a massive notice-and-comment rulemaking to develop a physician fee schedule setting the amounts that Medicare and co-paying Medicare beneficiaries will together offer to pay for different physician services rendered to the beneficiaries in the following calendar year. 42 U.S.C. § 1395w-4; *see*, *e.g.*, 2012 Final Rule with Comment Period; 75 FED. REG. 73,583 (Nov. 29, 2010) (final rule for calendar year 2011); Complaint ¶ 41. Otherwise qualified physicians may choose to participate in the Medicare program, and, if they do so choose, are required to accept as full payment for each service rendered the lower of their actual charges or the amount set forth in the fee schedule. 42 U.S.C. § 1395w-4(a)(1); Complaint ¶ 37.

Generally speaking, the payment for each service is calculated as a product of the 1) "relative value for the service"; 2) the "conversion factor"; and 3) the "geographic adjustment factor." 42 U.S.C. § 1395w-4(b)(1). This case concerns the calculation of the relative values. *See* Complaint ¶ 2. The relative value of a given service is based on a combination of three components, the "work component," the "practice expense component," and the "malpractice component." 42 U.S.C. § 1395w-4(c)(1), (2).

The "relative" in "relative value" is a straightforwardly literal description of how the term operates. Under the statutory formula, a relatively complicated, time-consuming, or difficult physician service with a relative value of, say 20, will have a price 20 times that of a simpler service with a relative value of 1. Relative values are also relative in another sense. Congress has directed that changing the relative values not significantly change the absolute amount that the Medicare program will pay out in either an upward or downward direction, but, within a fairly small margin ($20 million nationwide), must instead be budget neutral. *See* 42 U.S.C. § 1395w-4(c)(2)(B)(II); Complaint ¶ 42. Thus, raising the number assigned as the relative value of some procedures will not significantly raise federal expenditures, but will instead lower the amounts paid for other procedures whose relative value numbers, even if unchanged, will be lower relative to the raised-value procedures. By the same token, the budget-neutrality constraint means that government cannot cut its overall expenditures by lowering some relative values, for that will merely cause an increase in the relative value of other services. The conversion factor – an across-the-board multiplicand in calculating the payment for each service – is changed if necessary to preserve budget neutrality in light of changes in relative value units. *See* 2012 Final Rule with Comment Period at 646-47 (increasing 2012 conversion factor to offset reduction of expenditures that would otherwise result from changes in relative value units). For physicians, this makes the calculation of relative values and relative value units a zero-sum game, in which increased payment for some procedures translates into offsetting decreases for others.

As with several other Medicare calculations that are intended to be budget-neutral for the government and zero-sum for the community of providers, Congress has specified that "[t]here shall

be no administrative or judicial review under section 1395ff of this title or otherwise" of the Secretary's "determination of relative values." 42 U.S.C. § 1395w-4(*i*)(1)(B).

There is, however, an opportunity every year for the Secretary to revisit the relative values and, in particular, to obtain feedback from the physician community on the appropriateness of relative values. In Section 3134 of the Affordable Care Act, Congress has, moreover, recently tasked the Secretary with periodically identifying "potentially misvalued" services and validating relative value units. Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 3134(a), 124 Stat. 119, 434-435 (2010), *to be codified at* 42 U.S.C. § 1395w-4(c)(2)(K), (L); Complaint ¶¶ 34, 39. In doing so, the Secretary may, *inter alia*, "use existing processes to receive recommendations on the review and appropriate adjustment of potentially misvalued services." Section 3134(a) (to be codified at 42 U.S.C. § 1395w-4(c)(2)(K)(iii)).

2. The AMA RUC's Role In Recommending Changes In Relative Values

One of the organizations from which the Secretary receives such recommendations is the AMA RUC, a committee created by the nonparty American Medical Association. Complaint ¶¶ 2, 45. The AMA RUC has 26 voting members (and a few non-voting members) drawn from many different medical specialties. *Id*. ¶¶ 46-47; American Medical Association, RUC Members 2011, http://www.ama-assn.org/resources/doc/rbrvs/ruc-members-current.pdf (last visited, October 21, 2011).[1] They meet "several times a year to debate relative values based upon input from surveys"

[1] The Complaint itself contains citations to the AMA's website for a description of the AMA RUC, *e.g*., Complaint ¶¶ 45, 53-55, which makes it appropriate for the Court to consider the AMA's own description of the AMA RUC (which, on this point at least, is quite similar to plaintiffs') even with respect to defendants' Rule 12(b)(6) motion. In any event, citations in this brief to information on the AMA website, particularly for points on which the AMA's views do differ from plaintiffs', are

distributed to medical specialty societies and by them to their physician members. Complaint ¶ 45. The AMA thereafter arrives at recommendations concerning possible changes that CMS might make to relative values. Complaint ¶¶ 69-71.

According to plaintiffs, AMA RUC membership "is highly biased toward procedural specialties, and particularly surgical specialties," and away from what plaintiffs describe as "the 'cognitive' medical disciplines" that they practice; this allegedly results in a "failure" of the AMA RUC to "properly evaluate RVUs with regard to primary care." *Id*. ¶ 73; *see id*. ¶¶ 46-47, 52,-55. The AMA, on the other hand, flatly denies that the AMA RUC is "dominated by proceduralists who do not understand the challenges faced by primary care physicians." *AMA/Specialty Society RVS Update Committee*. http://www.ama-assn.org/resources/doc/rbrvs/toptenthings.pdf (last visited, Nov. 10, 2011). According to the AMA's public website, the AMA contends that it "advocates for fair and accurate valuation for all physician services"[2] and that, through the AMA RUC, the AMA is "simply . . . exercis[ing] its First Amendment right to petition the government," Complaint ¶ 51.

With thousands of medical procedures to understand and evaluate, AMA RUC members make a substantial commitment of professional time and energy ("it takes 'a year of doing it before you get

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primarily intended to support defendants' motion, under Rule 12(b)(7), that the AMA is a party to be joined if feasible. To show that an absent party may claim an interest in the controversy between the existing parties, a Rule 12(b)(7) motion may point to material, such as the absent party's own statements, outside the pleadings. *E.g*., 5C Charles Alan Wright & Arthur R. Miller, FEDERAL PRACTICE AND PROCEDURE 68 (3d ed. 2004).

[2] http://www.ama-assn.org/ama/pub/physician-resources/solutions-managing-your-practice/coding-billing-insurance/medicare/the-resource-based-relative-value-scale.page (last visited Nov. 10, 2011).

a good idea of what is going on'") to work that has been described as "'beyond tedious.'" Complaint ¶ 64 (quoting former AMA RUC member Dr. Neil Brooks).

Other medical groups are also free to make recommendations to the Secretary. Recently the American Academy of Family Physicians formed a task force to provide recommendations concerning relative values. According to plaintiffs' public website concerning this case, "interesting[ly]" the Secretary "has agreed to send an observer," to the Family Physicians' task force, "which conveys a level of regard that has previously been shown only for the RUC." http://replacetheruc.org/2011/08/12/a-legal-challenge-to-cms-reliance-on-the-ruc/ (last visited Nov. 10. 2011).

The Secretary accepts many of the AMA RUC's recommendations. But she also rejects many. In the final rule with comment period for calendar year 2012, the Secretary agreed with 68 percent of the AMA RUC's recommendations for the work component of various services' relative values. 2012 Final Rule with Comment Period at 507-08. Plaintiffs note another instance in which the Secretary rejected 21 of 40 AMA RUC recommendations. Complaint ¶ 71.

## ARGUMENT

### I. Judicial Review Of The Secretary's Determination Of Relative Values Is Barred By Statute

#### A. There Is No Private Right Of Action Under FACA

Plaintiffs acknowledge that the statute on which they principally rely, FACA, does not provide any private right of action. Complaint ¶ 22; *accord, e.g.*, *Utah Ass'n of Counties v. Bush*, 316 F. Supp. 2d 1172, 1184 (D. Utah. 2004), *appeal dismissed*, 455 F.3d 1094 (10th Cir. 2006). Plaintiffs must therefore find some other basis for this action. They seek to do so by arguing that

they challenge agency action that is reviewable under the APA and then argue that one reason that agency action is invalid is that the agency violated the FACA in the course of deciding upon that reviewable action. Complaint ¶ 26. But, as we show next, there is no reviewable agency action at issue here.

### B. The Secretary's Proposed 2012 Physician Fee Schedule Is Not Final Agency Action Potentially Subject To Review

Plaintiffs seek APA review of the agency's July 19, 2011, proposed 2012 Physician Fee Schedule. Complaint ¶ 26. But the APA generally allows for review only of "final agency action." 5 U.S.C. § 704 (emphasis supplied). A proposed rule is not a final agency action. As a general matter, to be final agency action, an action must satisfy two conditions: "First, the action must mark the 'consummation' of the agency's decisionmaking process – it must not be of a merely tentative or interlocutory nature. And second, the action must be one by which 'rights or obligations have been determined,' or from which 'legal consequences will flow.'" *Bennett v. Spear*, 520 U.S. 154, 177-78 (1997) (internal citations omitted); *accord, e.g., Flue-Cured Tobacco Cooperative Stabilization Corp. v. EPA*, 313 F.3d 852, 858 (4th Cir. 2002). A proposed rule satisfies neither condition, let alone both. A proposed rule is not the consummation of anything; that is the function of the final rule. Nor do plaintiffs identify any rights, obligations, or legal consequences that will or ever did flow from the proposed rule. That too is the domain of the final rule.

Of course, even a non-final action can be reviewed if it is "made reviewable by statute." 5 U.S.C. § 704. No statute, however, makes a proposed determination of relative values reviewable.

C. Judicial Review Of Final Agency Action Determining Relative Values is Barred By 42 U.S.C. § 1395w-4(*i*)(1)(B)

Instead, there is a statute that makes even the final determination of relative values unreviewable: "There shall be no administrative or judicial review under section 1395ff of this title or otherwise" of the Secretary's "determination of relative values and relative value units." 42 U.S.C. § 1395w-4(*i*)(1)(B). Thus, even now that a final determination of relative values for the 2012 fee schedule has been issued, that agency action is not subject to judicial review.[3] "[I]t would be difficult for Congress to have written paragraph (B) in clearer terms prohibiting such a challenge." *American Soc'y of Cataract & Refractive Surgery v. Thompson*, 279 F.3d 447, 453 (7th Cir. 2002); *see Painter v. Shalala*, 97 F.3d 1351, 1355 (10th Cir. 1996) (similar observation about paragraph (C), precluding judicial review of the conversion factor multiplicand of the fee schedule). The statute leaves "no room for employing" the presumption that judicial review is generally available "where, as here, Congress has been so *explicit* in stating a prohibition against judicial review – federal courts are not, after all, superlegislatures entitled to invoke a generalized presumption to trump an express 'hands off' direction from Congress." *American Soc'y of Anesthesiologists v. Shalala*, 90 F. Supp. 2d 973, 975 (N.D. Ill. 2000) (emphasis original). And this is true whether plaintiffs paint their vehicle of review as the APA or the Medicare Act or mandamus or (in the words of the statute) "otherwise." *See Painter* (rejecting jurisdiction under, *inter alia*, mandamus theory and the "*ultra vires*"doctrine).

Plaintiffs cannot evade this preclusion of judicial review by asserting that they are seeking review, not of the determination of relative values itself, but of the (allegedly) erroneous method by

[3] Plaintiffs have not in any event supplemented their complaint to allege the publication of the final rule and to challenge that final agency action.

which the Secretary reaches that determination, in particular the alleged over-reliance on the AMA RUC. Even if that were a complete characterization of the lawsuit (it's not[4]), it would not make plaintiffs' claims reviewable. After all, any claim that the ultimate determination of relative values is wrong necessarily involves some proximate argument that the method of getting there took one or more wrong turns. Allowing plaintiffs to disavow challenging the ultimate "determination" of relative values as long as they take the trivial step of putting their claims in the always available verbal garb of a challenge to the method used in arriving at the determination would impermissibly ignore Congress' decision that judicial review of the determination of relative values is not permitted. As Judge Shadur explained in the *Anesthesiologists* case:

> [I]t 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'" (Mem. 8, emphasis in original).
>
> . . . . 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.

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[4] Getting a different schedule with higher rates for the kinds of services plaintiffs provide is the ultimate remedial point of the suit. *See, e.g.*, Complaint ¶¶ 73-86. And in fact the Complaint does expressly seek to enjoin use of the physician fee schedule, *e.g.*, Complaint ¶ 102(D). The Complaint qualifies this demand by having the schedule invalidated only "to the extent that the" agency relied on the AMA RUC. But as a practical matter, that is no qualification as all: The payment rate for one service is necessarily based on its weight relative to all the others, so if the values for some rates are invalid, it throws off the payment rates for all the services. *See Cataract & Refractive Surgery*, 279 F.3d at 454. Such an injunction would therefore seem to affect any and all payments by Medicare to physicians, since it would leave no valid physician fee schedule in place.

90 F. Supp. 2d at 976. *See Cataract & Refractive Surgery*, 279 F.3d at 452 (rejecting view that statute "does not foreclose review of a systemic challenge to the Secretary's interpretation"). In a case decided just last year, a group of physicians sought, as here, to challenge the Secretary's reliance on information submitted to the Secretary by physicians. *American College of Cardiology v. Sebelius*, No. 09-62034-CIV (S.D. Fla. Apr. 27, 2010) (copy attached). The court rejected an argument that, despite the ban on reviewing the determination on relative values, it could nevertheless review whether the Secretary could rely on the physician-submitted data in determining relative values. *Id*. at 5-6. Such a hair-shredding interpretation of § 1395w-4(*i*) would render it "virtually ineffectual." *Id*. at 5. In short, it is not just the destination, but also the road to getting there that is unreviewable. *See also Painter*, 97 F.3d at 1356 (statute precludes review of "manner" in which the conversion factor was determined)

It also does not matter that plaintiffs attempt to characterize some of their arguments as constitutional claims. Claiming a "due process" right to have what plaintiffs contend is a correct rate is just another way of restating a right to have the determination of the relative values reviewed. Even if physicians have a property right in receiving payment for Medicare services they render after agreeing to accept Medicare, that does not imply (what plaintiffs must argue) that they have "a legitimate property interest in having their reimbursements calculated in a particular manner." *Painter*, 97 F.3d at 1357. They do not. As *Painter* explained, because the fees that Medicare will offer to pay for physician services are set before the services are rendered, physicians may "decide whether to become a participating or non-participating physician for a particular year, and to decide whether to treat Medicare patients at all during a particular year." *Id*. In light of that statutory

framework, plaintiffs do not have a property interest in receiving Medicare payments in an amount different from that set forth in the offer embodied in the Secretary's fee schedule. *Id*.; *accord*, *Cataract & Refractive Surgery*, 279 F.3d at 454-55; *American Soc'y of Dermatology v. Shalala* , 962 F. Supp. 141, 146 (D.D.C. 1996), *aff'd mem.*, 116 F.3d 941 (D.C. Cir. 1997). The claim that the Secretary has unlawfully delegated her authority to the AMA RUC is likewise unreviewable. *Id*., 962 F. Supp. at 145-46.[5]

D. To The Extent, If Any, That Judicial Review Of Any Of Plaintiffs' Claims Is Not Barred By 42 U.S.C. § 1395w-4(*i*)(1)(B), The Court Nonetheless Lacks Jurisdiction Unless And Until Such Claims Have Been Channeled Through The Medicare Claim Process

Even if one or another aspect of plaintiffs' claim were somehow outside the scope of section 1395w-4(*i*)(1)(B)'s bar on "administrative or judicial review," plaintiffs are required to first "channel" those claims through the administrative claim process before seeking judicial review. They do not allege that they have done so.

The Medicare Act has "a set of special statutory provisions that creates a separate, virtually exclusive, system of administrative and judicial review for denials of Medicare claims." *Shalala v. Illinois Council on Long Term Care*, 529 U.S. 1, 5 (2000). Thus, 42 U.S.C. § 405(h), made

[5] The district court in *Dermatology*, on the other hand, thought that judicial review of FACA claims was not barred by § 1395w-4(*i*)(1)(B). 962 F. Supp. at 147. That issue is not presented here since plaintiffs concede that the FACA does not provide them a private right of action. In any event, that holding of the *Dermatology* district court was made without benefit of the later explanations of § 1395w-4(*i*)(1)'s scope in *Painter* and *Cataract & Refractive Surgery*. The D.C. Circuit's non-precedential affirmance in *Dermatology* reached the merits only on the "*arguendo*" assumption "that despite 42 U.S.C. § 1395w-4(*i*)(1)(B), there is judicial review over appellants' claims relating to" FACA. *American Soc'y of Dermatology v. Shalala*, 116 F.3d 941, 1997 WL 206144, at *1 (D.C. Cir. 1997).

applicable to Medicare by 42 U.S.C. § 1395*ii*, "channels most, if not all, Medicare claims through this special review system." *Illinois Council*, 529 U.S. at 8. Plaintiffs' claims, at bottom, are Medicare claims. They claim that as primary physicians they should be paid more by the Medicare program. Complaint ¶¶ 76-86. For any Medicare reimbursement claim they have been assigned, they could thus present that claim for increased payment through the administrative process. But, until they have finished that process (which they do not claim to have even started), the Court has no jurisdiction to entertain an out-of-channel end-run on the administrative process. And it does not matter that plaintiffs may argue that the issues they seek to raise are only "'potential future'" claims, or are "'collateral'" to any claims for benefits, or turn on "'general legal'" rather than "'fact-specific'" considerations; even potential future, collateral, and non-fact-specific general legal claims must be channeled through the administrative process. *Illinois Council*, 529 U.S. at 13-14. Constitutional arguments likewise must be channeled through the Medicare administrative process. *Id*. at 11; *see generally United States v. Clintwood Elkhorn Mining Co.*, 553 U.S. 1, 9 (2008) ("Congress has the authority to require administrative exhaustion before allowing a suit against the Government, even for a constitutional violation").

Lest there be any mistake: In defendants' view, § 1395w-4(*i*)(1)(B) by its express terms does not permit <u>either</u> "administrative or judicial review" of the determination of relative values. For the same reasons that judicial review is barred by that provision, in defendants' view, administrative review through the Medicare claims process is thus barred as well. But plaintiffs cannot have it both ways. To whatever extent they contend that their claim is outside the scope of that bar on judicial review, then it would be equally outside the co-extensive bar on administrative review. Thus,

assuming *arguendo* that judicial review is not entirely foreclosed with respect to plaintiffs' arguments, their claims cannot be presented for judicial review until they have first been channeled through the administrative review process. As there is no allegation that the claims have been so channeled, this Court lacks jurisdiction. *See Anesthesiologists*, 90 F. Supp. 2d at 976 n.2 (Secretary's contention that claims not subject to § 1396w-4(*i*)(1)(B) bar on review must be channeled through claims process "also appears to have a good deal of force," though not deciding issue because § 1396w-4(*i*)(1)(B) was a complete bar).

We note that, though there is no judicial review of relative value units, plaintiffs are not left without redress, beginning, of course, with the self-help option of declining the Secretary's offer by refusing to accept Medicare patients. And, even more so than most other ratemaking proceedings, a physician fee schedule "is not an order for all time," *FPC v. Hope Natural Gas Co*., 320 U.S. 591, 615 (1944). Indeed, here each rulemaking will govern only a single year's payments, and there is thus always an opportunity to persuade the Secretary to revise the relative values for the next year. Congress too, as demonstrated by Section 3134 of the Affordable Care Act, pays close attention to the relative values. Thus, if the fee schedule were not offering a sufficient monetary incentive for a particular type of physicians to serve Medicare patients, there is every reason to believe that the administrative ratemaking process or congressional oversight or both would respond to the problem.[6]

[6] Even the very names of the leading cases reflect the responsiveness of the relative value process to changing conditions or concerns. A decade ago, in *Cataract & Refractive Surgery*, societies of surgeons and other specialists were challenging the Secretary's rules for giving too <u>low</u> a relative value to surgical and other specialized services, the opposite of plaintiffs' current claim that such services are given too high a relative value.

II. The Complaint Fails To State A Claim Upon Which Relief Can Be Granted

A. The Federal Advisory Committee Act Does Not Apply To The Relative Value Revaluation Process

Plaintiffs stress that in subsection 3134(**a**) of the Affordable Care Act Congress extensively revisited the relative value process and required that the "'Secretary shall establish a process to validate relative values under the fee schedule.'" Complaint ¶ 34, *quoting* Affordable Care Act § 3134(a), 124 Stat. 119, 435. *See also* Complaint ¶¶ 38-39. Plaintiffs emphasize the "shall" and conclude that the Secretary therefore has a statutory mandate to follow the Federal Advisory Committee Act. *See id*. ¶ 34.

Congress decided otherwise. In the very next subsection, § 3134(**b**), Congress provided: "[T]he provisions of the Federal Advisory Committee Act (5 U.S.C. App.) shall not apply to this section or the amendment made by this section." 124 Stat. at 435 (to be codified at 42 U.S.C. § 1395w-4 note).

"[T]his section and the amendment made by this section" reach the entirety of the relative value determination process. As plaintiffs point out, Complaint ¶ 34, section 3134 requires the Secretary to "establish a process to validate relative value units under the fee schedule." 124 Stat. at 435 (to be codified at 42 U.S.C. § 1395w-4(c)(2)(L)(i)). It also provides that the Secretary "may use" the "existing processes to receive recommendations on the review and appropriate adjustment of potentially misvalued services." *Id*. at 435 (to be codified at 42 U.S.C. § 1395w-4(c)(2)(K)(iii)(I)). She may conduct surveys, studies, and analysis, and use analytic contractors to identify and analyze services and conduct surveys and data collection. *Id*. (to be codified at 42 U.S.C. § 1395w-4(c)(2)(K)(iii)(II), (III)).

This recent congressional decision that the Secretary's yearly work in re-examining and validating relative value units "shall not" be subject to FACA precludes plaintiffs' statutory claim that FACA applies to the "existing processes" and other provisions set forth in section 3134 that are used in the Secretary's determinations of relative values.

B. The AMA RUC Is Not A Federal Advisory Committee

Even if Congress had not already decided that the Federal Advisory Committee Act shall not apply to the relative value decisionmaking process, plaintiffs' FACA claims would still lack merit. The AMU RUC is not a Federal Advisory Committee. *American Soc'y of Dermatology v. Shalala* , 962 F. Supp. 141, 147 (D.D.C. 1996), *aff'd mem.*, 116 F.3d 941 (D.C. Cir. 1997).

Although the FACA applies to committees that are, *inter alia*, "utilized" by federal agencies, 5 U.S.C. app. § 3(2), "utilized" is a "wooly verb" that should not be read to convert every organization that gives advice, including organizations that give useful, requested, and relied-upon advice, into Federal Advisory Committees. *Public Citizen v. United States Dep't of Justice*, 491 U.S. 440, 452-53 (1989). The FACA was never intended to prohibit federal agencies from seeking input from interested groups, the views of the NAACP, for example, on civil rights issues, or the American Bar Association on judicial appointments. *See id.* Nor does FACA require that the American Medical Association convert its internal committees into Federal Advisory Committees merely by choosing to offer useful and wanted advice on subjects of manifest interest to its members. *See Dermatology*, 962 F. Supp. at 147. FACA has thus been given a narrow construction consistent with its "principal purpose . . . to enhance the public accountability of advisory committees established by the Executive Branch and to reduce wasteful expenditures on them." *Public Citizen*, 491 U.S. at 459.

That purpose may be accomplished without expanding coverage of the Act to "privately organized committees that received no federal funds." *Id*. Thus, FACA "'does not apply . . . *to advisory committees not directly established by or for such agencies*.'" *Id*. at 462, *quoting* H.R. CONF. REP. No. 92-1403, at 10 (1972) (emphasis supplied by Supreme Court).

Under this standard, the AMA RUC is clearly not an advisory committee. *Dermatology*, 962 F. Supp. at 147. First, as even the complaint acknowledges, the AMA RUC was not established by the Secretary. It was established by the AMA. Complaint ¶¶ 45, 53-55. Nor can plaintiffs show that the Secretary has "*actual management or control* of the" AMA RUC. *Dermatology*, 962 F. Supp. at 147 (emphasis original). To the contrary, plaintiffs acknowledge (indeed complain) that it is the AMA that appoints and controls the AMA RUC members, Complaint ¶¶ 46-47, and the AMA that unilaterally decides who may attend AMA RUC meetings, *id*. ¶¶ 48-49. In fact, plaintiffs themselves affirmatively allege that the Secretary does not have the ability to control the AMA RUC. Complaint ¶ 60. In short, "the AMA committees are run by the AMA." *Dermatology*, 962 F. Supp. at 147.

In an attempt to support a contention that the AMA RUC is nevertheless under the control of the Secretary, plaintiffs argue that, in a series of instances in the 2012 proposed rule, the agency "direct[ed]" the AMA RUC to undertake various reviews. Complaint ¶ 69. Even if this were true, it would fall short of supporting plaintiffs' FACA claim because "'[e]ven significant influence' over a committee does not constitute the degree of control required to qualify as utilization in the FACA context." *Judicial Watch v. United States Dep't of Justice*, 736 F. Supp. 2d 24, 34 (D.D.C. 2010) (quoting *Washington Legal Found. v. United States Sentencing Comm'n.*, 17 F.3d 1446, 1451 (D.C. Cir. 1994)). But in any event, plaintiffs' argument distorts the actual language of the proposed rule.

In none of the instances cited by plaintiffs did the Secretary in fact "direct" the AMA RUC to do anything. In each instance the Secretary instead "request[ed]" or "ask[ed]" the AMA RUC to undertake some review.[7]

The Secretary does not control or purport to direct or control the AMA RUC. She would not have to "ask" for and "request" reviews if she did.[8]

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[7] *Compare* Complaint ¶ 69(A) ("Defendants direct the AMA RUC to 'conduct a comprehensive review of all E/M [evaluation and management] codes'") *with* 75 FED. REG. at 42,793 ("we are requesting that the AMA RUC conduct . . .); *compare* Complaint ¶ 69(B) ("Defendants direct the AMA RUC to conduct a review of 'high PFS expenditure procedural codes'" *with* 75 FED. REG. at 42,794 ("we . . . are requesting that the AMA RUC review . . . "); *compare* Complaint ¶ 69(C) ("Defendants direct the AMA RUC to review 'direct PE inputs and work values'") *with* 75 FED. REG. at 42,795 ("Therefore, we are requesting that the AMA RUC review both the direct PE inputs and work values"); *compare* Complaint ¶ 69(D) ("Defendants direct the AMA RUC to review both the direct PE inputs and work values of a tissue pathology code") *with* 75 FED. REG. at 42,795 ("we are asking that the AMA RUC review . . ."); *compare* Complaint ¶ 69(E) ("Defendants direct the AMA RUC to compare two new in situ hybridization testing codes . . .") *with* 75 FED. REG. at 42,796 ("Therefore, we are asking the AMA RUC to review . . ."); *compare* Complaint ¶ 69(F) ("Defendants direct the AMA RUC to 'make recommendations regarding the appropriateness of creating nonfacility direct PE inputs") *with* 75 FED. REG. at 42,796 ("we are asking the RUC to make recommendations regarding the appropriateness of creating nonfacility direct PE inputs"); *compare* Complaint ¶ 69(G) ("Defendants direct the AMA RUC to review ultrasound equipment . . .") *with* 75 FED. REG. at 42,796 ("we are asking the AMA RUC to review the ultrasound equipment . . . . and we hope that the RUC will continue to address issues relating to equipment . . ."); *compare* Complaint ¶ 69(H) ("Finally, defendants direct the AMA RUC to reevaluate the relative prices of two cholecystectomy CPT codes") *with* 75 FED. REG. at 42,796 ("we are asking the AMA RUC to review these two cholecystectomy codes").

[8] A committee can also be a FAC if it is a "quasi-public organization in receipt of public funds, such as the National Academy of Sciences," *Public Citizen*, 491 U.S. at 460, an "archetypal example . . . because the NAS, although organized as a private corporation, was created and funded by Congress." *Judicial Watch*, 736 F. Supp. 2d at 34. Plaintiffs do not appear to contend, and could not persuasively contend, that the AMA or its RUC committee is such a quasi-public organization. *See Public Citizen*, 491 U.S. at 460-61 (ABA Standing Committee on the Judiciary not a quasi-public organization).

Accordingly, the AMA RUC is not a Federal Advisory Committee, *Dermatology*, 962 F. Supp. at 147, and would not be subject to the FACA even if that FACA did apply to the relative value determination process.

C. Plaintiffs' Constitutional Claims Lack Merit

Plaintiffs' claim that they have been deprived of property without due process lacks merit. Because the fees that Medicare will offer to pay for physician services are set before the services are rendered, a physician may "decide whether to become a participating or non-participating physician for a particular year, and to decide whether to treat Medicare patients at all during a particular year." *Painter*, 97 F.3d at 1357. Plaintiffs therefore do not have a property interest in receiving Medicare payments in an amount different from that set forth in the offer of payment embodied in the Secretary's fee schedule. *Id*.; *Cataract & Refractive Surgery*, 279 F.3d at 454-55; *American Soc'y of Dermatology v. Shalala* , 962 F. Supp. 141, 146 (D.D.C. 1996), *aff'd mem*., 116 F.3d 941 (D.C. Cir. 1997); *Pharmacist Political Action Comm. v. Harris*, 502 F. Supp. 1235, 1243 (D. Md. 1980) ("no taking of property without just compensation has occurred on this record. There is no compulsion to participate in the program. . . . [I]f the individual pharmacist disagrees with the Secretary's determination, he can cease participating in the program"); *cf. Ram v. Heckler*, 792 F.2d 444, 447 (4th Cir. 1986) (once physician does choose to participate, he or she has property interest when faced with involuntary termination from program).[9]

[9] "[T]he fact that Medicare patients comprise a substantial percentage of [plaintiffs'] practices does not render their participation 'involuntary.'" *Whitney v. Heckler*, 780 F.2d 963, 972 n.12 (11th Cir. 1986).

Even if plaintiffs had some property right in being able to insist on receiving a different offer than the one the Secretary has decided to make through the Fee Schedule, it surely does not violate physicians' due process rights when the Secretary does consider the recommendations of the nation's leading association of physicians in the course of deciding the Medicare Physician Fee Schedule. There is no allegation that the Secretary will not consider plaintiffs' reasoned views as well. Plaintiffs may not like the substantive outcome, but due process is not impugned by a decisionmaker's willingness to consider recommendations, even if plaintiffs disagree with recommendations that others offer.

To be sure, the matter might be different if the Secretary was not merely considering the AMA's recommendations but was also, as plaintiffs try to allege, delegating her authority to decide the relative values to the AMA. That claim, however, is also without merit. While the Secretary may not delegate "core governmental power" to a private party, it does not violate the nondelegation principle for one or more private parties to play an "*advisory* role[ ]." *Pittston Co. v. United States*, 368 F.3d 385, 395 (4th Cir. 2004) (emphasis original).

The AMA RUC's role is advisory. It should not be surprising that, as with other instances where private parties have expertise relevant to an agency decision, the agency should listen to such advice and give it considerable weight. The relative values are of interest to the physician community that the AMA represents. And, in light of what is alleged to be the "'tedious'" and time-consuming work required to make recommendations on the relative values, Complaint ¶ 64, there are likely to be few other commenters who will have the interest and ability to provide as detailed and expert comments and analysis. Thus, if (as plaintiffs allege) many of the AMA RUC's recommen-

dations are accepted, it should come as no surprise and does no violence to any constitutional principle. As the Third Circuit noted in rejecting a prior nondelegation challenge to Medicare decision-making, "even [*A.L.A. Schechter Poultry Corp. v. United States*, 295 U.S. 495 (1935)], which is perhaps the furthest extension of the hostility to delegations of authority to nonpublic organizations, acknowledges that Congress may seek private assistance in 'matters of a more or less technical nature.' 295 U.S. at 537." *Cospito v. Heckler*, 742 F.2d 72, 88 n.25 (3d Cir. 1984). In *Cospito*, the plaintiffs argued that a hospital's loss of Medicare certification followed from its loss of accreditation by the private co-defendant Joint Commission on Accreditation of Hospitals. The court explained that a nondelegation claim was not viable, even though in that case the Secretary's decertification did follow the private party's decision, *see id*. at 75-77, because the Secretary retained "ultimate authority over the decertification decisions." *Id*. at 88.

The Secretary likewise retains "ultimate authority" here to decide the relative values. Given the expertise of the AMA RUC and the willingness of its members to engage in the tedium of examining relative values, it is understandable that many of its recommendations end up being accepted. *See* Complaint ¶ 90 (citing AMA RUC's claim that at times it has been successful in having the agency adopt "as much as 95%" of its recommendations). Indeed, it would be surprising if the Secretary did <u>not</u> pay close attention, and give considerable weight, to the recommendations of the nation's leading association of physicians when promulgating the Physician Fee Schedule. Nevertheless, the Secretary also rejects many of the AMA RUC recommendations. In the final rule with comment period for calendar year 2012, the Secretary agreed with only 68 percent of the AMA RUC's recommendations for the work component of various services' relative values. 2012 Final

Rule with Comment Period at 507-08. And even plaintiffs note another recent instance in which the Secretary rejected 21 of 40 AMA RUC recommendations. Complaint ¶ 71. The Secretary obviously takes the advice of the AMA RUC seriously, as its expertise warrants, but just as obviously retains ultimate authority to accept or reject that advice and to decide for herself what the relative values shall be. Under these circumstances, there is no unconstitutional delegation of authority. *See, e.g*, *Cospito*; *Riverbend Farms v. Madigan*, 958 F.2d 1479, 1488 (9th Cir. 1992) (no constitutional violation where "[a]lthough the Secretary [of Agriculture] normally follows the NOAC's suggestions, he retains the authority to depart from or ignore them altogether"); *Noblecraft Indus. Inc. v. Secretary of Labor*, 614 F.2d 199, 203 (9th Cir. 1980) ("OSHA in practice did not surrender to ANSI all its standard-making function. As was the case here, it selected among the ANSI standards with apparent discrimination.")

III. The American Medical Association Is A Party That Must Be Joined If Feasible

The American Medical Association is a party that must be joined if feasible to this action in which plaintiffs seek to compel a reduction in what plaintiffs argue is the AMA's inordinate influence.

Under Rule 19(a)(1) of the Federal Rules of Civil Procedure, a person must be joined in an action when "(A) in that person's absence, the court cannot accord complete relief among existing parties; or (B) that person claims an interest relating to the subject of the action and is so situated that disposing of the action in person's absence may (i) as a practical matter impair or impede the

person's ability to protect the interest: or (ii) leave an existing party subject to a substantial risk of incurring double, multiple, or otherwise inconsistent obligations because of the interest."[10]

The conflict between the plaintiffs' claims and the AMA's claimed interest is patent. Plaintiffs argue that the AMA has too much influence and seek to reduce that influence. Complaint ¶ 35. The AMA argues that what plaintiffs claim is the AMA's inappropriate influence is instead a straightforward exercise of its First Amendment rights to petition the government. Complaint ¶ 51. Plaintiffs seek "injunctive relief enjoining Defendants from utilizing advice from the AMA RUC," Complaint ¶ 3, advice the AMA claims it has a First Amendment right to give. To be sure, that last request for injunctive relief has an "until" qualifier, Complaint ¶ 3, but that qualification itself runs into an interest the AMA claims. Plaintiffs allege both that the Secretary cannot now direct the AMA RUC, Complaint ¶ 60, and that she already is controlling the RUC, *id.* ¶ 69. Whatever the outcome of that intramural dispute among the paragraphs of the Complaint over whether the Secretary already controls the AMA RUC, there is no doubt that plaintiffs contend that the Secretary <u>should</u> control the AMA RUC by requiring it to follow the procedures for a Federal Advisory Committee, Complaint ¶ 95(C), and "until" then should not accept its advice. Complaint ¶ 3. The AMA, on the other hand, claims an interest in being able to run its own committees as it sees fit. *See RBRVS: Resource-Based*

[10] "Rule 19 sets out separate tests for determining whether a party is 'necessary' and 'indispensable.' It is a two-step inquiry in which courts must first ask whether a party is necessary to a proceeding because of its relationship to the matter under consideration pursuant to Rule 19(a)." *Owens-Illinois, Inc. v. Meade*, 186 F.3d 435, 440 (4th Cir, 1999) (internal quotations omitted). Because plaintiffs have not set out under Rule 19(c) any "reasons for not joining" the AMA, at this time the Court need not proceed beyond that first step, whether the AMA should be joined if it is feasible to do so, and need not yet consider whether the AMA would be indispensable in the event that joinder is infeasible.

*Relative Value Scale*,

http://www.ama-assn.org/ama/pub/physician-resources/solutions-managing-your-practice/coding-billing-insurance/medicare/the-resource-based-relative-value-scale.page (last visited, Nov. 9, 2011). Plaintiffs do not like (to put it mildly) how the AMA is running its committee, and argue that the AMA RUC's governance is in dire need of fundamental reform. Complaint ¶¶ 44-59.[11]

In short, relief sought by plaintiffs includes at least three elements that would squarely clash with claimed interests of the AMA: Plaintiffs seek to reduce or eliminate the willingness of the Secretary to consider the AMA's views; plaintiffs seek to have the Secretary take over the running of the AMA RUC from the AMA; and plaintiffs seek to have the way in which the AMA's committee is governed changed from the way the AMA itself has chosen. Thus, under Rule 19(a)(2)(i), the AMA is a person who "claims an interest" in the "subject of the action," *i.e.*, how and by whom the AMA RUC committee should be governed and what weight the AMA's views should be given. It is equally obvious that "as a practical matter" that interest could at least be "impair[ed]" if the Court were to proceed to the merits without allowing the AMA to participate. "[I]n making the highly practical determination required" by Rule 19(a), "a court may draw reasonable, pragmatic inferences from the particular circumstances in the case to protect the absent party." *Picciotto v. Continental*

[11] Other relief sought by plaintiffs would cause even greater impairment to the AMA's interests (though it is hard to see how it would do plaintiffs any good either). Specifically, plaintiffs ask the Court to enjoin use of any fee schedule "to the extent" that the Defendant inappropriately relied on the AMA RUC. Complaint ¶ 95(D). Because the values for all services are indeed "relative," the "to the extent" modifier is, as a practical matter, meaningless or hopelessly indeterminate. There is no fee schedule that could be applied other than the Secretary's schedule. Invalidation of that schedule would thus leave the Secretary without any schedule on which to base Medicare payments to physicians.

*Cas. Co.*, 512 F.3d 9, 17 (1st Cir. 2008). Finally, under Rule 19(a)(1)(B)(ii), the Secretary would be subject to a "substantial risk of incurring . . . inconsistent obligations" if she were ordered to take over the AMA RUC (notwithstanding the AMA's view that it is entitled to run its own committees) or to refuse to hear advice the AMA contends it is constitutionally entitled to proffer.

Even if it were possible to hypothesize that ultimately some modest relief might be crafted that might somehow avoid both infringing on the AMA's interests and leaving the government subject to inconsistent obligations, that is not the test Rule 19(a) requires at the beginning of the case. The question is whether 1) "complete relief" (not some merely partial relief) might either 2) "as a practical matter" (not a metaphysical certainty) "impair or impede" (not destroy completely) an interest that the AMA "claims" (whether or not, in plaintiffs' view, or even in defendants' or the Court's view, the AMA's claim is correct), or 3) subject defendant to a "substantial risk" (not a certainty) of incurring "inconsistent obligations."[12] Under that test of Rule 19(a), it is evident that the Court should not in this case decide who should run the AMA RUC, how the AMA RUC should be run, and what weight should be given to the AMA RUC's views unless the AMA itself is made a party.

Rule 19 is "designed to accommodate the sort of complexities that may arise from a decree affecting numerous people in various ways." *Martin v. Wilks*, 490 U.S. 755, 767 (1989). If plaintiffs were to succeed in fundamentally changing the way the Physician Fee Schedule is generated, they would not be the only physicians in the country who would be affected. The Secretary ought not be

[12] *See, e.g., R-Delight Holding LLC v. Anders*, 246 F.R.D. 496, 503 (D. Md. 2007) (rejecting argument that plaintiff can "waive" or "accept" a "risk" of inconsistent obligations).

subject to being "whipsawed," *Schlumberger Indus.. v. National Sur. Corp*, 36 F.3d 1274, 1286 (4th Cir. 1994), by successive actions from different elements of the physician community with different views on who among them does the most relatively valuable work.

Conclusion

For the reasons stated above, defendants' motion to dismiss should be granted.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on November 10, 2011, I electronically submitted the foregoing document with the clerk of court for the U.S. District Court, District of Maryland, using the electronic case filing system of the court, and that service will accordingly be made through the Court's notice of electronic filing.

/s/ Brian G. Kennedy
Brian G. Kennedy