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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

PAUL FISCHER, M.D., *et.al*.,	*	
	*	
Plaintiffs,	*	
	*	**Case No. 1:11-cv-02191 (WMN)**
v.	*	
	*	
DONALD BERWICK, M.D. *et al.*,	*	
	*	
Defendants.	*	

PLAINTIFFS' OPPOSITION TO DEFENDANTS' MOTION TO DISMISS

INTRODUCTION AND SUMMARY

Defendants provide three reasons why the Complaint should be dismissed: (1) lack of subject matter jurisdiction because the 2012 Physician Fee Schedule was not final at the filing of the Complaint; (2) failure to state a claim because the AMA RUC is not a Federal Advisory Committee; and (3) failure to name the AMA as a Rule 19 necessary party. None of these arguments require dismissal, so the motion should be denied.

First, there is subject matter jurisdiction because the 2012 Physician Fee Schedule is now final, and the Court can take judicial notice of its finality. Medicare Program; Payment Policies Under the Physician Fee Schedule, 76 Fed. Reg. 73,026 (Nov. 28, 2011) (to be codified at 42 CFR pts. 410, 414, 415, *et al*.). However, even if this was not the case, plaintiffs here challenge a unique situation – the process for establishing the Physician Fee Schedule - which is both capable of repetition, and has proved to be repetitive, but would otherwise evade judicial review absent the Court recognizing the well-recognized exception to the mootness doctrine.

Second, Plaintiffs allege with sufficient factual detail, that the AMA RUC is a *de facto* FAC. This is the crux of Plaintiffs' case. Though Defendants disagree with this allegation

(summarily concluding that, "is not a federal advisory committee, *de facto* or otherwise"), the motion to dismiss is not the vehicle by which to dispute a properly alleged claim. By citing to case law from cases reviewing other FACs in the 1990s, Defendants attempt to *prove* their defense before discovery has taken place *in this case.* This is simply premature, as even the authority cited by Defendants supports the proposition that whether a group of persons advising the federal government is a FAC is a fact-intensive inquiry, subject to evaluation at the time the action is brought.

Third, the AMA is not a necessary party. However, even if it was, it is so closely tied to and aligned with the Defendants that its interests will be protected by them. Moreover, if at any time the Court believes that the AMA is a necessary party, it can easily be joined to the suit or it can intervene on its own. The absence of the AMA at this preliminary stage does not necessitate dismissal of the lawsuit, which Defendants appear to concede.

Defendants' substantive arguments for dismissing this case are baseless or inaccurate. Their procedural arguments only underscore their acknowledgement that the Physician Fee Schedule,[1] a schedule that controls physician pay nationally, is dictated by a small, stealthy and conflicted body of the AMA, the Relative Value Update Committee ("RUC"), acting arbitrarily – as even the RUC Chair has admitted – under the direct supervision of Defendants. Dr. Paul Fischer and the other named plaintiffs, primary care physicians, have all suffered direct injury as a result of Defendants' unlawful use of the RUC, and have a valid, timely and meritorious action. Plaintiffs' efforts to correct this injury through the direct petitioning of CMS have fallen "upon deaf ears," despite their extensive efforts, time, expense, and good faith. This forum and this

[1] At times referred to herein as "PFS."

case are therefore not only proper, but necessary to repairing a legally broken, and judicially indefensible manner of establishing physician payment schedules in the country.

STATEMENT OF THE CASE

This action is not brought by a national physician interest group or lobbying organization. Rather, Plaintiffs are six primary care physicians personally harmed by and concerned about Medicare's ongoing unlawful process for determining physician payment under the Physician Fee Schedule, which took effect on January 1, 2012. Plaintiffs do not challenge the *results* or *amounts* set forth in the Physician Fee Schedule, but rather, the *process* and *methodology* by which those results were obtained, an action that is wholly proper under established Supreme Court precedent. In so doing, Plaintiffs seek the Court to carry through with the analysis and evaluation begun by the United States District Court of the District of Columbia in *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)), in light of significant new evidence which can and must be heard by the Court. Using *Shalala* as a springboard, Plaintiffs add allegations regarding the unlawful actions of CMS and HHS, (including in issuing the most recent PFS), and in conjunction and combination with the AMA RUC, to corrupt the system of physician payments in America, to the detriment of physicians, Medicare beneficiaries, and indeed, all persons who seek medical care under the auspices of the AMA controlled and CMS collusive Physician Fee Schedule. The end result of this collusion is a dramatic overuse of unnecessary procedures by RUC-favored specialists upon patients who lack access to the most basic care and protection of primary care physicians.

Plaintiff Paul Fischer, M.D.[2], and five of his colleagues (Robert Clark, D.O.[3], Leslie Pollard, Jr., M.D.[4], Edwin Scott, M.D.[5], Robert Suykerbuyk, M.D.[6] and Rebecca Talley, M.D.[7]) are the plaintiffs in this action, and practice medicine at the Center for Primary Care, P.C.

[2] Plaintiff Dr. Fischer started practicing family medicine as the only doctor in the farm community of Weeping Water, Nebraska, and then pursued a career in Academic Medicine at the Medical College of Georgia. In 1993, he founded the CPC, and it now provides care to one fourth of the Augusta, Georgia population. CPC has led the national transformation of primary care in the areas of practice organization, physician payment, electronic medical records, and the development of a Medicare certified "medical home." Dr. Fischer has achieved membership in the prestigious Institute of Medicine as a result of his groundbreaking research concerning the effects of tobacco-related marketing on children.

[3] Plaintiff Robert Clark, D.O., started his Family medicine career in Fayetteville, North Carolina at Cape Fear Valley Medical Center. In 1995, Dr. Clark joined the CPC in Augusta, Georgia. Dr. Clark became CEO of the CPC in 2004. Under his leadership, the CPC instituted an electronic medical record system which links all of the CPC's offices and imaging services. Pursuant to his continued belief in "comprehensive care for family practice," Dr. Clark helped lead the CPC to become a certified Medical Home in 2010.

[4] Dr. Pollard was raised in Augusta, Georgia, and as a result of his family experiences with cancer, determined early to become a family doctor in order to provide care for families, from newborns to the adults. After six years as a rural solo family physician in Statesboro, Georgia, where he became an active member of the community, Dr. Pollard joined the CPC in order to support his practice and has served as both President and Treasurer.

[5] Dr. Scott was raised on a family farm near Burlington, North Carolina. Both his father and his grandfather were rural family doctors. After a year in private practice in Hope Mills, North Carolina, Dr. Scott has practiced in Augusta.

[6] Dr. Suykerbuyk is a primary care physician with the CPC. After attending college under the Army GI bill, Dr. Suykerbuyk earned a military scholarship to study medicine. Dr. Suykerbuyk was deployed in the Balkans and later in global terrorism missions, earning several military awards. He left active duty in order to join the CPC, established an office in underserved South Carolina, and transitioned CPC from paper an integrated lab, with electronic medical records and communications. Currently, Dr. Suykerbuyk is a Lt. Colonel in the Army medical corps.

[7] Dr. Talley is a primary care physician with the CPC. Her father was the family doctor for a small town in North Carolina. After medical school, Dr. Talley returned to the south to join the CPC in 1999. Since then, she has worked full-time at her practice which involves caring for patients in the office and at nursing homes. Dr. Talley has special interest in women's health. Dr. Talley's husband is also a family physician. She has been named one of the nations "Best Doctors" as a result of her primary care work and service to the profession.

("CPC") in Augusta, Georgia. Each is an accomplished physician and all have the unifying desire to better serve their patients.

CMS and HHS use Relative Value Units ("RVUs") to implement Congressional intent to value physician services through a resource-based relative value scale ("RBRVS").[8] (Compl. at ¶14.) "CMS establishes RVUs for physicians' work, practice expense, and malpractice insurance."[9] By statute, RVUs must be created to provide a single fee for a physicians "work, practice expense, and malpractice [costs]" for the services covered by Medicare.[10] These RVUs must be reevaluated at least every five years. As Defendants concede, in order to create and evaluate RVUs, CMS has relied heavily upon the AMA RUC. (Compl. at ¶14.)

The Social Security Act ("SSA") was intended "to provide for the general welfare by establishing a system of Federal old-age benefits, and by enabling the several States to make more adequate provision for aged persons, blind persons, dependent and crippled children, maternal and child welfare, public health, and the administration of their unemployment compensation laws."[11] SSA establishes health insurance for the elderly and disabled, which is overseen by CMS and HHS.[12] SSA also provides a method of physician payment for services under "Part B" of the Medicare program.[13] Physicians are paid the actual charge of the service as submitted by the physician or the fee for the service as established by statute, whichever is lower.[14] (Compl. at ¶¶36, 37.)

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[8] Omnibus Budget Reconciliation Act of 1989, tit. VI, Pub. L. No. 101-239, 103 Stat. 2106. Statutory provisions in this section are footnoted where possible.
[9] 42 C.F.R. § 414.22.
[10] 42 U.S.C. § 1395w-4(c)(2).
[11] Social Security Act, Pub. L. No. 74-271 (1935), codified as 42 U.S.C. ch. 7 (as amended).
[12] 42 U.S.C. § 1395 *et seq*.
[13] 42 U.S.C. § 1395w-4 *et seq.*
[14] 42 U.S.C. § 1395w-4(a)(1).

The Patient Protection and Affordable Care Act ("ACA") was signed into law on March 23, 2010. (Compl. at ¶38.) The ACA, *inter alia*, expands Medicaid coverage and provides for the increase of Medicaid payments to primary care physician payments to the same level as current Medicare primary care physician payments. *Id.*

The ACA also provides for the identification of "misvalued" codes in the PFS. (Compl. at ¶39.) Section 3134 of the ACA amended the SSA to include two new subsections which address the reevaluation of potentially misvalued codes.[15] One of the new subsections of the SSA, 42 U.S.C. § 1395w-4(c)(2)(K), states that "[t]he Secretary shall . . . periodically identify services as being potentially misvalued . . . [and] review and make appropriate adjustments to the relative values established under this paragraph for services identified as being potentially misvalued." *Id.* Another new subsection, 42 U.S.C. § 1395w-4(c)(2)(L), further states that "[t]he Secretary shall establish a process to validate relative value units under the fee schedule." *Id.* Plaintiffs do not contend that the Secretary's periodic identification of "misvalued" codes is a process subject to FACA, but rather this case is solely about the annual promulgation of the Physician Fee Schedule. Indeed, demonstrating the pure lobbyist force of the AMA, the periodic "review" now mandated by ACA is solely an internal process designed to contain, but not resolve, the very abuses that this case is designed to correct. (Compl. at *e.g.*, ¶¶63, 64, 67.)

The SSA prescribes the system of payment for physician services.[16] Under this payment system, physicians are paid the smaller amount of either the cost of the service or the "fee schedule amount" for the service, that is, the amount established by the fee schedules produced by CMS every year.[17] (Compl. at ¶¶37, 41.) That fee schedule is created by CMS using a

[15] ACA, Pub. L. No. 111-148 at § 3134.
[16] 42 U.S.C. § 1395w-4.
[17] 42 U.S.C. §§ 1395w-4(a)(1)(A)-(B).

calculation based, in substantial part, on the RVU of the service.[18] RVUs are assigned to categories of physician services corresponding to the AMA's Current Procedural Terminology ("CPT") codes. (Compl. at ¶42.) The RVU of each physician service is calculated based on three separate components: the physician work unit, the practice expense ("PE") unit and the malpractice unit.[19] (Compl. at ¶42.) The reimbursement value for each type of physician service, as published in the proposed 2012 PFS, is calculated by first multiplying the RVU with a geographic adjustment factor and then multiplying the result with a conversion factor, updated yearly, which converts the RVU for each service to a dollar amount.[20] (Compl. at ¶42.)

CMS is charged with developing these RVUs.[21] (Compl. at ¶43.) In so doing, CMS must utilize RBRVS, a valuation system developed at Harvard University under the direction of Dr. William Hsiao, adopted by Congress in 1991, and effective as of January 1, 1992. RBRVS has been termed a "regulatory capture" system.[22] (Compl. at ¶43.)

From the inception of RBRVS, CMS (previously known as Health Care Finance Administration ("HCFA")), at the urging of the AMA, utilized the AMA RUC to value medical services under RBRVS, at the urging of the AMA. (Compl. at ¶44.) However, CMS and HHS did not at that time charter the AMA RUC as a Federal Advisory Committee pursuant to FACA.

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[18] 42 U.S.C. § 1394w-4(b)(1)(A).
[19] 42 U.S.C. § 1395w-4(c)(2)(A)(i).
[20] 42 U.S.C. § 1395w-4(b)(1)(A)-(C).
[21] 42 C.F.R. § 414.22.
[22] *See also* THE OXFORD HANDBOOK OF HEALTH ECONOMICS 65-66 (Sherry Glied & Peter C. Smith eds., Oxford University Press 2011), "regulatory capture" refers to "the process by which regulatory agencies eventually come to be dominated by the very industries they were charged with regulating. Regulatory capture happens when a regulatory agency, formed to act in the public's interest, eventually acts in ways that benefit the industry it is supposed to be regulating, rather than the public." Definition of "Regulatory Capture," Investopedia.com, http://www.investopedia.com/terms/r/regulatory-capture.asp#axzz1iVNG8Wbw (last visited Jan. 4, 2012). *See also* http://en.wikipedia.org/wiki/Regulatory_Capture and http://www.slate.com/articles/news_and_politics/prescriptions/2009/09/the_fix_is_in.html

CMS and HHS have taken no affirmative actions since 1992 to establish the AMA RUC as a lawful FAC, despite the efforts of various Administrators of CMS to curtail AMA's abusive practices.

The AMA RUC has met, and continues to meet, several times a year to debate relative values based upon input from surveys distributed to specialty societies. Although the AMA RUC sends out as many as 1000 physician surveys, it requires as few as 30 survey responses in order to value a physician service. (Compl. at ¶45.) This process results in survey biases that inherently favor procedural specialties, resulting in chronic overuse, and often abuse, of procedures such as stents, as this Court has evaluated. *See, e.g.*, *Baublitz v. Peninsula Reg. Med. Ctr.*, 2010 U.S. Dist. LEXIS 81791, 10-819-WMN (D. Md., Aug 10, 2010). Prominent Harvard Scholar, Robert Goodson, M.D., has described this phenomenon as the "unintended consequences" of the resource based relative valuation system. (Compl. at ¶78.)

The AMA RUC consists of 26 voting members and a Chairperson, representing various medical specialty societies. (Compl. at ¶46.) The RUC also includes non-voting members from groups such as the AMA CPT Editorial Panel. *Id.* The AMA benefits directly and substantially from its unusual agreement with the federal government giving it quasi-governmental status to the exclusive intellectual property rights to the CPT code set. (Compl. at ¶¶51-52.) Although the specialty societies are separate entities from the AMA, the AMA RUC only offers voting seats to specialty societies that are associated with the AMA. (Compl. at ¶46.) While AMA has sought to keep its RUC membership secret, in response to investigations undertaken by organizations such as the Wall Street Journal and the Center For Public Integrity, AMA released a list of the 2011 AMA RUC members. (Compl. at ¶47.) Of the AMA RUC's total members, 23 are appointed by national specialty societies. Only 3 of the seats rotate on a 2 year basis while

the other members have no term limits, and 11 members have been on the RUC for 8 years or more. (Compl. at ¶47.) One member of the AMA RUC, the representative of the American College of Surgeons, has been a member since 1991. *Id.*

The public is not invited to the AMA RUC meetings and has no input into the agenda for AMA RUC meetings. (Compl. at ¶48.) The public does not have any way to access the proceedings of the AMA RUC meetings through transcript or recording, or even minutes of the proceedings. *Id.* Invitations to attend AMA RUC meetings may only be issued by the Chairperson. Up to 300 persons have been known to attend the AMA RUC meetings, generally located in exclusive resorts or vacation destinations. (Compl. at ¶49.) Attendees at the RUC must sign a confidentiality agreement prohibiting them from discussing the content of the meetings. *Id.* Individuals who have violated those confidentiality agreements have been sanctioned by the AMA, and the RUC has sought to silence other critics of their practices and secrecy. *Id.*

The AMA RUC meetings are attended by multiple officials from CMS. (Compl. at ¶50.) CMS appoints advisors to the AMA RUC, AMA and a number of specialty societies have provided benefits to certain government attendees at those meetings, and indeed one CMS official has served on the AMA CPT Editorial Panel. (Compl. at ¶50.) While the AMA contends that its RUC meetings simply constitute the exercise of its First Amendment right to petition the government (Compl. at ¶51), and though Defendants suggest that a new family medicine task force gives Plaintiffs equal standing, (Defs' Mot. at 8), the facts belie AMA's position. Indeed, the AMA RUC is a volunteer, sole source contractor to HHS, which effectively blocks other interests from asserting their First Amendment rights. Moreover, operating in the

cloak of secrecy and quasi-governmental prestige, it actively works to deny the rights of other physicians to participate in the relative valuation process.

AMA also contends that it is does the government a service (proving Plaintiffs' point in this matter), since it pays the costs of the proceedings, which it estimates at six million dollars annually. (Compl. at ¶51.) However, AMA directly benefits from the results of the proceedings, since CMS has ceded to the AMA the rights to publish the code sets that result from their valuation by the AMA RUC and the AMA CPT Editorial Panel. (Compl. at ¶51.) Indeed, AMA obtains profits in excess of fifty million dollars annually through its copyright royalties and other monies (through sale of inventory) annually as a result of the sale, licensing, and other exploitation of the intellectual property in those code sets. *Id. Thus, it can fairly be said that the AMA RUC is no humble petitioner, but is indeed a sole-sourced contractor of the Federal Government, determining life, death, and payment decisions for the country.* Specialty societies that agree to be part of the AMA RUC process and their members also benefit financially as a result of their membership and participation in the AMA RUC. (Compl. at ¶52.) A liberal estimate is that only 22 percent of physicians (and far less of practicing physicians) in the United States – including M.D.s and D.O.s – belong to the AMA. *Id.* When the AMA established the RUC, the original membership was based on the American Board of Medical Specialties ("ABMS") in order "to include all major specialties, primarily defined as the 24 Member Boards of the ABMS." (Compl. at ¶53.) Since that time, the AMA RUC determines which specialty groups have a seat on the AMA RUC by using criteria they set.[23] (Compl. at ¶54.)

[23] These include:

1. The specialty is an American Board of Medical Specialties (ABMS) specialty.
2. The specialty comprises 1% of physicians in practice.
3. The specialty comprises 1% of physician Medicare expenditures.
4. Medicare revenue is at least 10% of mean practice revenue for the specialty.

Based upon these criteria, the AMA RUC awarded a permanent seat to the American Academy of Neurology in 1997 but has refused to award Gastroenterology and Geriatric Medicine groups a permanent seat. *Id.* That Medicare, an agency *dedicated* to the funding of physician services for the aged and disabled, and is in turn funded by taxpayer dollars, permits Geriatric physicians to be excluded from the RUC is beyond regulatory malfeasance and constitutes a virtual abdication of its regulatory authority.

A specialty society can only become a permanent voting member of the RUC after first becoming a board member of ABMS. (Compl. at ¶55.) ABMS has not admitted a new specialty society as a member board since the admission of Medical Genetics in 1991. *Id.* Thus, although the AMA's website lists 116 "National Medical Specialty Societies" that have representation in the AMA's House of Delegates, their main policy-making body, only 23 of these societies have a voting membership on the AMA RUC. *Id.*

Three voting members of the AMA RUC hold "rotating seats," the purported purpose of which is to give other specialty societies access; however, these rotating seats have been held by only eleven different specialty societies since the RUC's creation in 1991. (Compl. at ¶55.) Given the lack of representation on the AMA RUC of the majority of American physicians and specialty societies, the specialty societies on the AMA RUC have a significant advantage over other stakeholders in establishing and maintaining robust values for their work and practice expenses. *Id.*

Significant financial ties exist between various medical industry/pharmaceutical companies and the AMA RUC members. (Compl. at ¶56.) And, as this Court has seen, the

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5. The specialty is not meaningfully represented by an umbrella organization, as determined by the RUC.

dramatic overuse of procedures has led to outright criminality and Medicare Fraud, well-documented not only by the government but by leading health care scholars. (Compl. at ¶¶56-58.) This presents potential conflicts of interests, as some companies which have compensated the AMA RUC members for consulting and other services have direct interests in the outcome of the AMA RUC decisions. *Id.* However, the RUC claims to have no responsibility, as would members of an official Federal Advisory Board, to report any potential conflicts of interest. *Id.* Many of the current RUC members have financial or consulting ties to companies in the medical and insurance industries, including, to identify a few, Pfizer, Medtronics, Johnson & Johnson, Aetna, United Healthcare, Blue Cross and Blue Shield, and numerous medical device companies that serve the surgical specialties. (Compl. at ¶57.) Some of these companies have been involved in recent criminal matters and settlements, including, for example, for off-label marketing to physicians and surgeons. (Compl. at ¶58.)

Over time, CMS' inability to control the AMA RUC's inflation of certain specialty code values to the detriment of others, such as primary care, has led CMS to become increasingly contentious with the AMA and has directed the AMA RUC to place items upon their agenda. (Compl. at ¶60.) However, as of the proposed July 19, 2011 Physician Fee Schedule for 2012, CMS conceded that those efforts have not resulted in significant movement by the AMA RUC, particularly in the areas of the proper valuation of primary care and in the overvaluation of various procedures. *Id.*

With increasing disparities in specialty payments and physician compensation, and with increasing criticism from Congress and its Medicare Payment Advisory Committee beginning in its 2006 Report to Congress, on June 19, 2008, then Acting CMS Administrator Kerry Weems drafted a letter on behalf of CMS and HHS to Dr. William Rich, who was then Chair of the

AMA RUC. (Compl. at ¶61.) In that letter, Weems conceded that CMS had accepted the vast majority of AMA RUC valuations, but noted the very inequality at issue here.[24]

Weems conceded the arbitrariness of AMA RUC's processes and outright failure to correct certain valuations, such as 2900 codes valued in the Harvard Study but never reevaluated for twenty years. (Compl. at ¶62.) He then provided the AMA RUC with a roadmap, directing them to evaluate highly utilized, low-intensity procedures in the one hundred fastest growing services with annual costs over a million dollars, attaching a list of those codes from an analysis of actual CMS 2004-2007 data.[25]

Other former CMS officials have derided the RUC evaluation system, such as Former Administrator Thomas Scully, who describes the RUC as "indefensible" and that "[i]t's not healthy to have the interested party essentially driving the decision-making process." (Compl. at ¶63.) Indeed, even the RUC admits its process is corrupt, as RUC Chair Barbara Levy has stated: "[w]e assume that everyone is inflating everything when they come in. They are anteing to fight for the best possible values for their specialties." (Compl. at ¶64.) Even Congressional advisors and experts agree, including Dr. Robert Berenson, Chair of the MedPAC and a former

[24] He noted that this acceptance had resulted in a history of AMA RUC overvaluation of certain codes, and that the present coding valuations "disadvantages primary care" and "created distortions in our payment system that makes moving to value driven health more difficult." (Compl. at ¶61.) He also noted that "Congress has considered establishment of a separate advisory committee to the Secretary solely for the purpose of identifying overvalued procedures. In lieu of legislation on this issue, we encourage AMA RUC and others to place renewed emphasis on identifying overvalued procedures." *Id.*

[25] If there were any question before this action as to CMS' management involvement in the RUC (such as expressed by the Court in *American Society of Dermatology v. Shalala* (5 years previously), Weems' directives, and CMS' subsequent actions, put that to rest.

American College of Physicians representative to the RUC,[26] and John A. Patti, M.D., the chair of the American College of Radiology Board of Chancellors.[27] These experts and commentators have described Defendants' delegation of their duty to establish RVUs to the AMA. (Compl. at ¶66.)

Despite Plaintiffs' dedicated efforts, resulting in a meeting at CMS with its payment officials and RUC representative physicians responsible for the Physician Fee Schedule, CMS chose not to distance itself from AMA, but rather to invest itself further, and "dig in" to a fully flawed process. (Compl. at ¶67.) Indeed, in the 2012 PFS, CMS not only points to the disparities in primary care values as compared to procedural values, but directs the AMA RUC to undertake a full-scale review of primary care. (Compl. at ¶68.) *See also, e.g.*, 2012 PFS, at 91-95; Mot. Dismiss, at 19.

Despite their full and unequivocal admission of grossly improper valuations, Defendants' delegation of such high impact and financially significant tasks to the RUC demonstrates their abdication of statutorily-mandated responsibility of determining RVUs to the RUC. Defendants have stated that the AMA RUC's recommendations are often found to be overvalued and to rely

[26] Dr. Berenson has written,"[e]very specialty society requested up values and never came in requesting down values." (Compl. at ¶65.) When Dr. Berenson suggested the RUC obtain assistance in identifying overvalued RVUs, "[he] was roundly jeered." *Id.* As Dr. Berenson has said, "[i]f we are spending $70 billion on physician payments, surely we can find a way to rely on real data to inform the values rather than relying on self-interested estimates." *Id.*

[27] Dr. Patti has acknowledged the AMA RUC's control over RVUs. (Compl. at ¶66.) In the proposed 2012 PFS, CMS proposed a reduction in the reimbursement rate for a physician interpreting MRI or CT scans, such that a physician interpreting multiple scans would be paid 50% less for reading the second and following scans, radiologists spoke out against the plan. *Id.* According to Dr. Patti**,** "[t]his [50% reduction in payment] is a bold attempt by CMS to reduce physician payments without specific authorizing legislation, and to usurp the function of the AMA Relative Value Update Committee without any supporting evidence." *Id.*

on false assumptions. (Compl. at ¶71.) In the proposed 2012 PFS, Defendants included a list of 40 codes with site-of-service anomalies[28] that CMS had directed the AMA RUC to reevaluate in 2010. *Id.* Of those 40 codes, CMS adopted the AMA RUC's recommended reevaluations of only 19. *Id.* The reevaluations of the remaining 21 codes were rejected because the AMA RUC recommended work values based on inpatient hospital visits even though the codes were being reevaluated based on the shift of these procedures to outpatient procedures. *Id.* Although these codes were recommended for reevaluation based *entirely* on the shift in the procedures from inpatient to outpatient procedures, the AMA RUC failed to adjust their recommendations accordingly. Defendants decreased the work RVU, visits and time related to those codes to reflect actual outpatient practices before publishing the new value in the 2012 PFS. *Id.*

The AMA RUC's failure to properly evaluate RVUs with regard to primary care has had a devastating effect upon the provision of primary care services in America (including family medicine, general internal medicine, and pediatrics), as well as a devastating effect upon the nation's health and health care spending. (Compl. at ¶73.) This result is largely and directly due to the fact that unlike an official Federal Advisory Committee, which by law must have balanced representation and transparency, the composition of the AMA RUC *de facto* FAC is highly biased towards procedural specialties, and particularly surgical specialties. *Id.* Indeed, only two seats on the AMA RUC actually represent primary care. In addition, the seat for internal medicine, which directs an increasingly small percentage of its specialists to primary care, is filled by an oncologist who also works for the American Cancer Society. *Id.* In general, the "cognitive" medical disciplines, those involving complex tasks of evaluation, discernment, medical management, and comprehensive patient care, are drastically underrepresented on the

[28] Site-of-service anomalies arise when a procedure is performed as an outpatient procedure but the code still reflects payment and hospital visits associated with an inpatient procedure.

AMA RUC, and this process results in direct harm to their ability to obtain the valuations to which their services are entitled. *Id.*

Experts evaluating the effect of the AMA RUC's processes, independent bodies such as the MedPAC, and CMS itself recognize that the AMA RUC process is perversely incentivizing physicians to enter higher paying procedural specialties, to the detriment of the nation's health.[29] (Compl. at ¶74.) MedPAC recently admitted that the physician payment system is ineffective and biased towards specialist proceduralists. *Id.*

The broken system is harmful to far more than just the Plaintiffs. Due to the RUC's influence, the current system embodies lucrative financial incentives that drive the over-utilization of procedures, placing patients at unnecessary health risk, and creating unnecessary financial burdens/risk for purchasers. Meanwhile, the drastic shortage of primary care physicians in the United States results in those physicians experiencing chronic overwork, rationing of primary care, unnecessary referrals to "proceduralists" or other specialists, severe strains upon emergency room care for conditions readily treatable through primary care, and in many localities, the complete absence of access to the benefits of primary care such as early and regular evaluation, treatment of multiple complex conditions in a medical home environment, evaluation of lifestyle conditions that impact the diagnosis and treatment of diseases and illnesses, dependable management and follow-up for chronic conditions including diabetes, heart disease, and obesity, provision of accurate information to counter the barrage of

[29] The current Chair of the MedPac, Dr. Robert Berenson, has also spoken harshly of the physician fee schedule. (Compl. at ¶75.) According to Dr. Berenson, the physician fee schedule "leads to the wrong mix of services and the wrong mix of doctors . . . [and] produces increased spending for Medicare and for the rest of the system." *Id.*

pharmacological, procedural, or internet based-misinformation, monitoring of family hereditary conditions, and diagnosing rare disease. (Compl. at ¶76.)

The progenitor of the RBRVS methodology, Dr. Hsiao of Harvard, has publicly distanced himself from the AMA RUC process, noting that the AMA RUC's use of specialty society survey data was "almost guaranteed to inflate values." (Compl. at ¶77.) In his original study and analysis, Dr. Hsiao specifically identified the core primary care codes – the evaluation and management codes – as an issue that the government would need to address going forward, since they represented such a small percentage of the submitted codes and the analytical model of RBRVS did not readily transfer to the time-and patient-intensive model for providing primary care. *Id.* Independent studies, such as that of John Goodson, M.D., have identified the irrational disparities that result from the AMA RUC based system.[30] (Compl. at ¶78.)

Plaintiffs have been harmed as a direct result of the undervaluing of primary care physicians and Defendants' failure to oversee the process establishing the RVUs and the Physician Fee Schedule. (Compl. at ¶¶79, 80.) Plaintiffs face a scarcity of new doctor candidates for hire, limited openings for new patients, a decreasing ability to serve the needs of existing Medicare and Medicaid patients, increasingly shortened patient visits, increasingly complex diagnoses within these shortened visits, and an inability to serve the needs of the 30 million newly-eligible Medicaid enrollees in the Augusta market. (Compl. at ¶80.) Plaintiffs also must address the well-documented impacts of the usage of certain unnecessary specialty and outpatient procedures upon their patients' health. (Compl. at ¶80.) With the number of

[30] Dr. Goodson contends that the AMA RUC is the "primary advisor to CMS for all work RVU decisions" and that by listening to the AMA RUC and maintaining specialty care incentives, CMS has "fueled health care inflation." *Id.*

Medicare beneficiaries expected to double in the next 35 years,[31] and with the associated crushing burden on the health care budget, the sum total of the harms not only to Plaintiffs but to the "patient public" are patent and can be proscribed.

STANDARD OF REVIEW

Defendants move to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6), which permits dismissal only if Plaintiffs have failed to state a claim upon which relief can be granted. The Defendants also move to dismiss pursuant to FRCP 12(b)(7) for failure to join a party under FRCP 19. It is settled that the burden of proof rests on the party moving to dismiss to support their claim that dismissal can be granted at this early stage solely upon the law, as applied to the facts alleged in the complaint. *I R Construction Products Company, Inc. v. D.R. Allen & Son, Inc.*, 737 F. Supp. 895 (W.D.N.C. 1990). All well pleaded allegations in the complaint are to be accepted as true and all reasonable factual inferences are to be construed in favor of the Plaintiffs.

The issue at this stage then is "whether the plaintiff is entitled to offer evidence to support the claims." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544 (2007). The motion may not be granted unless "it appears certain" that the Plaintiffs cannot prove *any set of facts* entitling them to relief. *Edwards v. City of Goldsboro*, 178 F.3d 231, 244 (4th Cir. 1999) (discussing F.R.C.P. 12(b)(6))(emphasis added). Not surprisingly, the Defendants spend no time addressing the standard for a motion to dismiss – most likely because they cannot meet this burden.

[31] In 2008, 45.2 million people were covered by Medicare, and that number is expected to reach 79.2 million people by the year 2030. The total number of Medicare beneficiaries approximately doubled over the last 35 years and is expected to double again over approximately the next 35 years. *The 2009 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds*, May 12, 2009, at pp. 36-37, available at http://www.cms.gov/ReportsTrustFunds/downloads/tr2009.pdf.

The sole purpose of a motion to dismiss is to determine the sufficiency of the complaint. *Id.* at 243. Federal Rule of Civil Procedure 12(b) should be read in conjunction with FRCP 8(a)(2), which requires only "a short and plain statement of the claim showing that the pleader is entitled to relief. Importantly, a motion to dismiss "does not resolve contests surrounding the facts, the merits of a claim, or the applicability of defenses." *Edwards*, at 243. So long as the complaint gives fair notice of its bases and the reasons supporting them, it is deemed to be sufficient. *See Erickson v. Pardus*, 551 U.S. 89, 93 (2007).

Plaintiffs have articulated detailed allegations concerning the unlawfulness of Defendants' actions in promulgating the Physician Fee Schedule. That Defendants dispute these allegations should result in this matter proceeding to discovery and ultimately determined on its merits.

ARGUMENT

I. Judicial Review Of The Secretary's Determination Of Relative Value Is Not Barred By Statute.

A. The Claims Are Not Barred By The APA Or The FACA.

Defendants argue that that the Court lacks subject matter jurisdiction because they mistakenly conclude that no final agency action has occurred and that consequently, Plaintiffs may not bring claims under the APA and/or the FACA. (Mot. Dismiss at. 8-9.) As the Complaint makes clear, Plaintiffs do not seek relief under FACA, but rather under the APA. (Compl. at ¶22.)

The APA provides that a person "suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action within the meaning of a relevant statute, is entitled to judicial review thereof." 5 U.S.C. § 702. Defendants do not dispute that Plaintiffs have the right to bring FACA claims under the APA. *See Judicial Watch, Inc. v. U.S. Dep't of*

Commerce, 736 F. Supp. 2d 24, 30-31 (D.D.C. 2010) (recognizing that FACA claims may be brought under the APA). They merely argue that review under the APA requires final agency action. Final agency action has occurred in this case and even if final agency action had not yet occurred, the Complaint would still not be completely barred by the APA.

Defendants' argument on finality is moot because, as anticipated by the Plaintiffs and in keeping with the 20 year tradition of almost unquestioned adoption of AMA RUC proposed recommendations, (Compl. at ¶¶ 43, 90, 92), the 2012 fee schedule was adopted and published in the Federal Register on November 28, 2011 and became effective in January 1, 2012. Medicare Program; Payment Policies Under the Physician Fee Schedule, 76 Fed. Reg. 73,026 (Nov. 28, 2011) (to be codified at 42 CFR pts. 410, 414, 415, *et al*.). The Court may, and should, take judicial notice of this final rule as it may with all records and reports of administrative bodies. *Mack v. South Bay Beer Distributors, Inc.*, 798 F.2d 1279, 1282 (9th Cir. 1986). *See also, American Maritime Assoc. v. United States*, 766 F.2d 545, 554 (D.C. Cir. 1985) (stating "we take judicial notice of the fact that the final rule reaffirms the findings discussed in the interim rulemaking and basically adopts the interim rule's bid augmentation regulation"); 44 U.S.C. § 1507 (mandating judicial notice of the Federal Register); *United States v. Coffman*, 638 F.2d 192, 194 (10th Cir. 1980) (judicial notice should be taken of relevant contents of Federal Register); *Pueblo of Sandia v. United States*, 50 F.3d 856, 861 n. 6 (10th Cir. 1995) (court may take judicial notice of post-decision document).

However, even if, *arguendo*, the final rule had not yet been adopted and published, the Complaint would still be viable. In advancing their finality argument, Defendants rely upon *Flue-Cured*. (Mot. Dismiss at 9.) In that case, which involved a unique statute that expressly precluded the EPA from taking regulatory action, the Fourth Circuit held that a report issued by

the EPA was not a "final action" that was reviewable under the APA and set forth a finality analysis involving inquiry of two issues: 1) "the action must mark the 'consummation' of the agency's decision-making process-it must not be of a merely tentative or interlocutory nature; and 2) the action must be one by which 'rights or obligations have been determined,' or from which 'legal consequences will flow.'" *Flue-Cured*, 313 F.3d, at 858 (citing *Bennett v. Spear*, 520 U.S. 154 (1997)).[32]

Defendants' Motion to Dismiss, which preceded the adoption of the 2012 PFS as a final rule, claims that the Secretary's 2012 Fee Schedule was not final agency action because it was merely "proposed." (Mot. Dismiss at 9.) Indeed, though it is now final, the Complaint does not state that the 2012 fee schedule was a final rule at the time the Complaint was filed. (Compl. at ¶¶ 26, 95.) Instead, this is a unique situation in that every year a new Rule is proposed and finalized. It is noteworthy that the history of almost 20 years of the "virtually uniform adoption" of the AMA RUC proposed recommendations, which "constitutes an agency action that is effectively final, and in any event, capable of repetition, but evading review." (Compl. at ¶26.) Litigation takes years. If Plaintiffs had filed suit under the 2011 PFS, the Government would claim that by the time the issue was litigated, the 2011 PFS was moot as it would be replaced by its 2012 counterpart. Likewise, when Plaintiffs sued under the proposed 2012 PFS (which is now final), the Government attempts to play a procedural game of "gotcha" by claiming that when the Complaint was filed, the agency rule was not yet final, so it is incapable of review. This Catch 22 philosophy means that Plaintiffs could *never* obtain meaningful review because

[32] Of course, now that the 2012 PFS is a final agency action, the *Flue-Cured* analysis is buttressed since it is the consummation of the agency's decision-making process that gives rise to legal consequences, rights or obligations. Because the agency action carries direct and appreciable legal consequences, it is reviewable under the APA. *Flue-Cured Tobacco Cooperative Stabilization Corp v. EPA*, 313 F.3d 852, 858 (4th Cir. 2002).

there is always a new rule waiting in the wings to moot out the previous one and threaten meaningful litigation.

In unique litigation circumstances like this, where a situation is "capable of repetition, yet evading review," courts have historically drawn conclusions of "nonmootness." *Roe v. Wade*, 410 U.S. 113, 125 (1973) (quoting *S. Pac. Terminal Co. v. ICC*, 219 U.S. 498, 515 (1911) (citing *Moore* v. *Ogilvie*, 394 U.S. 814, 816 (1969); *Carroll* v. *Princess Anne*, 393 U.S. 175, 178-179 (1968); *United States* v. *W. T. Grant Co.*, 345 U.S. 629, 632-633 (1953)). *See also, Boise City Irrigation & Land Co. v. Clark*, 131 F. 415 (9th Cir. 1904) (involving a situation where the period for which a municipal ordinance fixed a water rate expired pending the litigation as to its legality, it was contended that the case had become moot. The court disagreed, stating: "But the courts have entertained and decided such cases heretofore, partly because … of the necessity or propriety of deciding some question of law presented which might serve to guide the municipal body when again called upon to act in the matter."). Such is the case here. Since it is the *process and methodology* that are under attack, as opposed to the amounts or results of the 2011 PFS, the same method and procedure are going to be repeated and unless reviewed by this Court, are going to continue to evade review. Like in *Boise City*, this Court needs to weigh in to "guide" the Defendants "when again called upon to act" in the future.

In any event, whether Plaintiffs challenge prior agency action, such as the 2011 Physician Fee Schedule promulgation, promulgation of the proposed Physician Fee Schedule of 2012, or the now final Physician Fee Schedule of 2012, this is a case that is both capable and proven of repetition, and otherwise not subject to review. (Compl. at ¶135.) It is also a classic case in the mode of *Bowen v. Acad. Of Family Physicians*, discussed further *infra*, where the Supreme Court recognized that Congress could not have "intended no review at all of substantial statutory and

constitutional challenges to the Secretary's administration of Part B of the Medicare program." 476 U.S. 667, 680 (1986). As such, the utilization of the PFS and the effects toward policy and methodology that involve statutory and/or constitutional concerns regarding the administration and promulgation of Medicare policy and laws merit judicial review in the federal courts. *Id.* at 680-81.

In the end, in this unseemly and conflicted regulatory capture scheme, the only stakeholders NOT entitled to a "dog in the fight" are physicians such as those in primary care doctors and geriatric medicine. Thus, even while Medicare beneficiaries have avenues of review and appeals to challenge both individual nonpayment decisions and national non-coverage decisions, Defendants seek to fully deny Plaintiffs the most basic aspects of due process in light of their substantial and acknowledged property interests in treating Medicare beneficiaries at a reasonable and equitable rate of return. As such, while CMS repeatedly recognizes the primary care shortage, Defendants nonetheless deny that Plaintiffs have any rights to object to the process through which those shortages are effectuated through a corrupt promulgation of the Physician Fee Schedule. It is the *process* that is challenged and it is the process that should and can be reviewed.

B. The Medicare Immunity Statute Does Not Bar This Action.

Defendants argue that the Court lacks subject matter jurisdiction because 42 U.S.C. § 1395w-4(*i*)(1)(B) bars challenges to the Secretary's determinations of relative values and/or that Plaintiffs' claims are barred because they did not avail themselves of the remedies afforded by the Medicare "claims" process. (Mot. Dismiss, at 3, 13-14.) Moreover, Defendants rely heavily on *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 *Painter v. Shalala*, 97 F.3d 1351, 1355 (10th Cir. 1996) to

arrive at a most troublesome conclusion that "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." (Mot. Dismiss at 11.)

These are specious and distracting arguments. The implications of Defendants' disturbing statement are that questions of fair governance, policy, legitimate constitutional concerns and rule making processes are foreclosed to the very groups they affect. Such a result violates the letter and spirit of the APA and FACA. (Compl. at ¶¶ 26, 29.) Defendants' statement is inconsistent with case law regarding Medicare Immunity (which Defendants fail to cite), that hold that "courts should not interpret section 1395ii as requiring such a problematic foreclosure of review in all circumstances." *Furlong v. Shalala*, 238 F.3d 227 (2d Cir. 2001).

In *Furlong*, the Second Circuit considered a suit brought by a group of anesthesiologists challenging the validity of Medicare regulation with respect to varying appeal rights between "assigned" and "non-assigned" physicians and the reduction in amount that anesthesiologists could charge for certain types of procedures. *Id.* Embarking on an analysis of *Bowen ("Michigan Academy")* and *Shalala v. Illinois Council on Long Term Care*, 529 U.S. 1 (2000),[33] the court observed that claims regarding "methodology," "process," "policy," "good government," "transparency," and unfortunately, even about corruption, *may not* be foreclosed from judicial review. The court differentiated:

[33] Stating, "the legislative history of both the statute establishing the Medicare program and the 1972 amendments thereto provides specific evidence of Congress' intent to foreclose review only of 'amount determinations' -- i.e., those [matters] . . . remitted finally and exclusively to adjudication by private insurance carriers in a 'fair hearing.' By the same token, matters which Congress did not delegate to private carriers, such as **challenges to the validity of the Secretary's instructions and regulations, are cognizable in courts of law**." *Shalala v. Ill. Council on Long Term Care*, 529 U.S. 1, 16-17 (U.S. 2000). (Emphasis supplied.)

> We are convinced that plaintiffs' claims are challenges to agency policy (or, in the language of *Michigan Academy*, "methodology claims") rather than challenges to the calculation of benefits. We described this distinction in our opinion in *Abbey v. Sullivan*, 978 F.2d 37, 42 (2d Cir. 1992), stating that '**federal jurisdiction exists where there is a challenge to the validity of an agency rule or regulation**, but jurisdiction is lacking where the claim is merely that the insurance carrier misapplied or misinterpreted valid rules and regulations'…

Furlong, 238 F.3d at 234. (Emphasis supplied.) *See also, Vermont Assembly of Home Health Agencies, Inc. v. Shalala*, 18 F.Supp.2d 355 (D.Vt. 1998) (stating that " while disputes involving the calculation of an amount due should be left to administrative determination, the courts have subject matter jurisdiction over a challenge to 'a rule of general applicability'"); *Walsh v. McGee*, 899 F. Supp. 1232, 1237 (S.D.N.Y. 1995) (noting that the court has jurisdiction over challenges to validity of Medicare rules or regulations).

Once it is recognized that this case brings methodology claims, it is clear that Defendants' reliance on cases such as *Painter v. Shalala*, 97 F.3d 1351, 1355 (10th Cir. 1996), which precluded judicial review of the conversion factor multiplicand of the fee schedule, are simply inapplicable. (Mot. Dismiss at 10.) Even a cursory review of the Complaint reveals that the Plaintiffs' contention in no way centers on individual disconcert over "amount determinations." Indeed, Plaintiffs have taken no position on and claim no stake in the results of the 2012 Physician Fee Schedule. Their concern is one of fair process and equitable policy. ***Plaintiffs have not sued for money damages***. They seek no direct monetary award associated with this lawsuit and they do not seek a review of the amounts assigned to their practice area in the 2012 PFS. Instead, this suit demands a level playing field and requirement that a lawful and fair process be followed. Since this is the classic challenge to process and methodology, as opposed to an "amount claim," the claims are reviewable and this Court has subject matter jurisdiction even in the absence of a final rule. *Furlong*, 238 F.3d at 232-238.

Moreover, Defendants inaccurately claim that Plaintiffs are always required to channel complaints through the Medicare claims process and that "there is … always an opportunity to persuade the Secretary to revise the relative values… ." (Mot. Dismiss at 13, 15.) In making these assertions, Defendants rely on *Shalala v. Illinois Council on Long Term Care*, 529 U.S. 1, 5, 12-13 (2000), which requires certain claims under the Medicare Act to be channeled through the administrative review process. (Mot. Dismiss, at 13-14.) Defendants fail to recognize that the Supreme Court's decision in *Illinois Council* expressly carved out an exception to this general rule stating that 42 U.S.C. § 1395*ii* does not bar judicial review of claims "where its application to a particular category of cases…would not lead to a channeling of review through the agency, but would mean no review at all." 529 U.S., at 16-17 (citing *Bowen*, 476 U.S., at 681. *See also, e.g.*, *Binder & Binder v. Barnhart*, 481 F.3d 141, 149 (2d Cir. 2007) (recognizing that the court has jurisdiction where "no alternative means to review a federal claim arising under the Social Security Act"); *Action Alliance of Senior Citizens v. Leavitt*, 438 F.3d 852, 859-60 (D.C. Cir. 2007) (recognizing that the district court had jurisdiction where "the Medicare statute [provided] no avenue of review of" plaintiff's claim); *Am Lithotripsy Soc'y v. Thompson*, 215 F.Supp.2d 1121, 1123 (S.D. Cal. 2008) (exercising jurisdiction where plaintiff otherwise would have "no appeal rights"); *National Ass'n of Psychiatric Health Sys. V. Shalala*, 120 F.Supp.2d 33, 39 (D.D.C. 2000) (holding that Section 405(h), made applicable to Medicare by § 1395*ii*, did not bar judicial review where plaintiffs, "as a practical matter, [did] not have the option of incurring a minor penalty and receiving an administrative hearing before proceeding to federal court"). In the end, the analysis in *Illinois Council* does not bar this Complaint; indeed, it allows it.

Finally, Defendants are quick to presume that "Constitutional arguments likewise must be channeled through the Medicare administrative process." (Mot. Dismiss, at 14.) The Supreme Court in *Illinois Council* only mentioned in passing that constitutionality of interrelated regulations or statutory provisions should be channeled through the Medicare administrative process. Plaintiffs are doing far more than merely challenging the constitutionality of regulations or statutory provisions. Plaintiffs are attempting to compel the Secretary to use her statutorily delegated authority to provide a more holistic rule making and promulgation process rather than re-delegating and relying almost exclusively on the self-interested AMA RUC for rules that will ultimately govern all physician payments under Medicare.

Moreover, Defendants' citation to *United States v. Clintwood Elkhorn Mining Co.*, 553 U.S. 1, 9 (2008) does little to advance their presumption that all Constitutional arguments must be channeled through the Medicare administrative process. (Mot. Dismiss, at 14.) In *Clintwood*, the Supreme Court only stated that Congress *can* authorize administrative exhaustion for Constitutional violations, not that it was indeed a requirement. *Clintwood*, 553 U.S. at 9.

In summary, Defendants' argument that the Court lacks subject matter jurisdiction because no final action has occurred with regard to the 2012 PFS is moot because the 2012 Fee Schedule became effective on January 1, 2012. Furthermore, Defendants incorrectly presume that 42 U.S.C. § 1395w-4(*i*)(1)(B) bars *all* challenges to the Secretary's determinations of relative values and that *all* challenges of such nature must be pursued through the Medicare "claims" process. In fact, case law regarding the application of the Medicare Immunity Statute to claims that go toward fundamental questions and concerns of the methodology, policy, and rule support jurisdiction in this matter.

II. The Complaint States A Valid Claim For Relief.

A. The Mandamus Act Compels The Secretary Under PPACA and The SSA To Consult And Solicit Recommendations From Non-AMA RUC Physician Groups In The Annual Making And Promulgation Of The Physician Fee Schedule.

Defendants' first argument relies exclusively on the application of FACA to the relative value *revaluation* process. In making this argument, Defendants completely misinterpret the Complaint and fail to understand that it does not assert the application and relevance of FACA to the Secretary's relative value *revaluation* process and/or her review of misvalued codes. Defendants point to the Affordable Care Act § 3134 (b), 124 Stat. at 435, which exempts the application of the FACA to the Secretary's duty to "establish a process to validate relative values under the fee schedule" in § 3134(a). (Mot. Dismiss at 16.) In making this apparent connection, Defendants fail to fully comprehend the nature of Plaintiffs' allegations and the rulemaking, review, and validation process CMS utilizes when compiling and revising the annual physician fee schedule. It is not the revaluation process that is challenged, rather, it is the improper re-delegation of the *rulemaking* process to the AMA RUC.

Indeed, in ¶34 of the Complaint, Plaintiffs provide a citation to the Affordable Care Act, but this is not meant to suggest that the Secretary (under § 3134(a)) has a statutory mandate to follow the FACA with respect to the validation and review of relative values under the fee schedule. In fact, nowhere in ¶34 is there mention of the Secretary's possible subjugation to the FACA in her "yearly work in re-examining and validating relative value units." (Mot. Dismiss at 17.) Section II.A of the Motion to Dismiss seems to miss the mark entirely.

A review of ¶¶ 32-35 of the Complaint (entitled the "Mandamus Act") to which Section II.A of the Motion to Dismiss relates, reveals Plaintiffs' argument that the Mandamus Act and Congress' added desire to expressly delegate to the Secretary the RVU validation and

revaluation process with respect to the Fee Schedule under the ACA, taken together, mean that there are certain, non-delegable duties assigned to the Secretary, and subsequently, to CMS. (Compl. at ¶34.) The next paragraph (¶35) expands on this by articulating that the SSA "*also* mandates that '[t]he Secretary, in making adjustments [to RVUs], shall consult with the Medicare Payment Advisory Commission and organizations representing physicians.'" (Compl. at ¶35 *citing* 42 U.S.C. § 1395w-4(c)(2)(B)(iii)). Both the ACA and this provision in the SSA point to one purpose of the ACA, which is to bring more rationality to the payment system and repair inequities through the delegation of RVU processes under the fee schedules to the Secretary. The use of the word "shall" in the relevant ACA and the SSA provisions, is demonstrative of Congress' intent to delegate to the Secretary the role of forming RVUs with the recommendations of a variety of representative physician groups, reviewing, and validating the physician fee schedules produced by CMS. (Compl. at ¶¶59, 67, 92.)

Moreover, Plaintiffs use §3134(a) stating, that the "Secretary shall establish a process to validate relative values under the fee schedule," merely as an example of the additional delegation to the Secretary with respect to the RVU revaluation process through the ACA. The Complaint does not challenge the Secretary's review of misvalued RVUs, validation of relative values, and/or adjustments in §3134(a).

Rather, the crux of Plaintiffs' claim is that Defendants "violated the spirit and the letter of the law by relying so heavily on the [AMA] for *recommendations* regarding RVUs." (Compl. at ¶35.) Plaintiffs are referring to the improper re-delegation by CMS to the AMA RUC of the rulemaking process. Plaintiffs challenge the virtually exclusive reliance and adoption of the AMA RUCs recommendations which make up the rulemaking and rule setting process that have

now culminated in the 2012 Physician Fee Schedule governing all physician practices. (Compl. at ¶¶ 68, 69.)

There is a clear difference between the annual recommendation and rulemaking process and the validation and review process found in §3134(a). Therefore, Defendants are not wrong to state that the validation and review process of misvalued codes is exempt from the FACA under §3134(b). However, the initial recommendation and annual rule making process would not be subject to §3134(b). In fact, an application of §3134(b) would be unnecessary as Plaintiffs are not relying on the ACA for asserting a violation of the FACA, but instead are pursuing claims under the Mandamus Act. As such, Defendants' arguments regarding §3134(b) are irrelevant, and do not require dismissal.

B. The AMA RUC Is A *De Facto* FAC Subject To Regulation Under The FACA.

Although the AMA RUC has not formally been deemed a Federal Advisory Committee within the meaning of the FACA, that is not a basis for dismissing the Complaint. For, at this stage, a court does not consider whether a plaintiff will ultimately prevail; rather, the issue is "whether the plaintiff is entitled to offer evidence to support the claims." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544 (2007). The Complaint alleges that the AMA RUC is a *de facto* FAC and this allegation is sufficient at this stage. The claims here may be unique, but they are well supported and state a valid cause of action.

Generally, Defendants fail to recognize the subtleties of the allegations. The Plaintiffs do not allege that the AMA RUC is a formally recognized FAC subject to the requirements of the FACA. Rather, Plaintiffs allege that the purpose and functioning of the AMA RUC so closely

resembles a FAC that *it should be* subject to regulation under the FACA,[34] and that not subjecting it to the FACA regulations results in the violation of "the spirit and the letter of the law by relying so heavily on the AMA for recommendations regarding RVUs." (Compl. at ¶35 *citing* SSA, 42 U.S.C. § 1395w-4(c)(2)(B)(iii)). **This distinction may be somewhat subtle, but it is critical.**

Without any facts in the record, and in an attempt to skip to the summary judgment stage before discovery, Defendants prematurely conclude that the AMA RUC is *clearly not* a FAC. (Mot. at 17, 20 *citing American Soc'y of Dermatology v. Shalala* 962 F. Supp. 141, 147 (D.D.C. 1996)). Even if this argument were not premature, which it is, Defendants vastly overstate the holding. First, *American Soc'y of Dermatology* is distinguishable factually and procedurally.[35] Second, *American Soc'y of Dermatology* did not hold that the AMA RUC was "clearly not" a FAC. Rather, in granting the Secretary's motion for summary judgment in that case, the court very generally referred to a collective group of AMA committees in 1996 as *only one* scenario in which the nature and functioning of a committee would not satisfy the "utilized by one or more agencies" requirement in accordance with FACA §3. *American Soc'y of Dermatology*, 962 F. Supp. 141, 147.

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[34] *See* Compl. at ¶92 ("Defendants' actions violate the Federal Advisory Committee Act because, *inter alia*, they rely heavily on the recommendations of the AMA RUC when the AMA RUC is not a chartered FAC, has an unbalanced membership which is closely tied to special interest groups, and withholds information from and closes its meetings to the public.") and Compl. at ¶19 (observing that the Supreme Court recognized that groups utilized by federal agencies can become *de facto* FACs).

[35] Unlike this Complaint, the plaintiffs in *American Soc'y of Dermatology* did not seek a mandamus ordering defendants to fulfill delegated duties under the SSA and the ACA (which was obviously not implemented and therefore unaddressed by the plaintiffs and the court). Moreover, it was not until the summary judgment stage that the court made its pronouncement regarding the existence of a FAC in that case.

The *American Soc'y of Dermatology* Court did not explicitly hold that the AMA RUC is not a FAC. It simply interpreted a decision by the Supreme Court to hold that an entity is a FAC if it can be shown that a federal agency "has actual management or 'utilizes'" the committees in question. *Id. citing Public Citizens v. United States Dept. of Justice*, 491 U.S. 440 (1989). Though the *American Soc'y of Dermatology* Court rejected a literal reading of the term "utilize," it did so in considering specific types of committees that merely volunteer information and "give information," which implies intermittent or even casual participation by an entity and/or solicitation for recommendations by a federal agency. Indeed, the Court distinguishes that "[t]he RUC and the RUC Advisory Committee clearly furnish advice or recommendations to the HCFA" while the Secretary "disputes whether the CPT Editorial Panel and its Advisory Committee furnish" such advice and/or recommendations. *American Soc'y of Dermatology*, 962 F. Supp. 141, 147. But, all of this analysis is premature. In the end, the Court reviewed the evidence before it *at the summary judgment stage* and held that under the circumstances presented, the collective group of AMA committees was not a FAC. The Court did not specifically hold that the AMA RUC committee is not, and could never be deemed, a FAC. As such, that case is not dispositive at this initial stage and does not warrant dismissal of the Complaint before discovery.

Additionally, in relying too heavily on the Supreme Court's interpretation of the term "utilized" under FACA §3 in *Public Citizens v. U.S. Dep't of Justice*, 491 U.S. 440 (1989), Defendants fail to address and draw the fine distinction between the mere periodic recommendation provided by the American Bar Association (ABA) Committee on judicial nominations in that case, and the close, institutional relationship, collaboration, delegation and reliance between the AMA RUC, CMS, and HHS as alleged in this Complaint.

In *Public Citizens*, the Court qualified the term "utilize" by holding that the ABA Committee on judicial nominations is not an "advisory committee" because it merely gives "*information*" to the President. 491 U.S. 440 (1989). In that case, the Court rejected a literal reading of the word "utilize" and concluded that an advisory committee comes within the confines of FACA if it is "utilized by a department or agency in the same manner as a Government-formed advisory committee." *Id.* at 456-57. The "same manner" analysis extends to conclude that "only committees directed to make recommendations on an identified governmental policy for which specified advice was being sought are subject to FACA." *See Sofamor Danek Group, Inc. v. Gaus*, 61 F.3d 929, 936, n. 4 (D.C. Cir. 1995), *cert. denied*, 116 S.Ct. 910 (1996) *citing Nader v. Baroody*, 396 F.Supp. 1231, 1234 (D.D.C. 1975).

Furthermore the definition has been broadened even more and *Public Citizen* has been interpreted to provide that a committee qualifies as an advisory committee that is "utilized" under FACA when they are *amenable* to *any* management by an official, or "by [any] semiprivate entity the Federal Government helped bring into being." *See Food Chem. News v. Young*, 900 F.2d 328 (D.C. Cir. 1990) *cert. denied*, 498 U.S. 846 (1990) (quoting *Public Citizen*, 491 U.S. at 457-58).

The allegations in the Complaint go far beyond merely alleging "information" as was the case in *Public Citizens*. Plaintiffs allege here that the AMA RUC is solicited, almost exclusively, by the Secretary to provide advice and recommendations regarding RVUs under the Fee Schedule. (Compl. at ¶26.) First, the AMA RUC can be found, at least, to be amenable to "any management by an official" because CMS directs the AMA RUC to undertake tasks outlined expressly in the proposed 2012 Physician Fee Schedule. (Compl. at ¶69.) The Complaint provides several examples of the tasks expressly delegated by CMS and HHS to the AMA RUC

in preparation for reviewing and revising RVUs in the Physician Fee Schedules that are to be promulgated in 2013. (Compl. at ¶69.) In one instance, CMS expressly directs the AMA RUC to complete reviews by the "deadline of July 2012 for the first half of the review (to allow inclusion in the 2013 PFS), and a deadline of July 2013 for the second half." (Compl. at ¶69 (A) *citing* 2012 PFS, at 91-92.)

What this implies is that CMS and HHS work closely with the AMA RUC by exercising control through the setting of the subject of review, agendas, and timetables. The AMA RUC is subject to FACA because it is expressly "directed to make recommendations" on the setting of RVUs, which CMS is charged with developing. (Compl. at ¶43 *citing* 42 C.F.R. § 414.22, to influence federally mandated physician fee schedules.) *See also Sofamor*, 61 F.3d 929 at 936, n.4. No other committees have such a collaborative relationship with CMS and HHS in the advisement and setting of fee schedules. (Compl. at ¶67.)

Instead of attempting to home in on the differences between the workings and relationship of the AMA RUC and other groups, the Defendants attempt to draw an unwarranted analogy between the function of the AMA RUC and public interest groups such as the NAACP or the American Bar Association on judicial appointments. (Mot. Dismiss at 17.) Additionally, Plaintiffs' claim that the AMA RUC is a *de facto* FAC subject to the FACA should not be dismissed because courts have found that the application of the term "utilize" in *Public Citizens* and its progeny, though providing some guidance, is "not dispositive" in every case. *Ctr. For Arms Control and Non-Proliferation v. Lago*, 2006 WL 3328257 at *5 (D.D.C. 2006). "Congress did not intend for FACA to apply to every formal and informal consultation between the President or an Executive agency and a group rendering advice." *Id.* citing *Sofamor*, 61 F.3d at 933.

Lastly, Defendants rely heavily upon the supposition that RUC is a "necessary evil" of sorts because the work in appraising relative values is "tedium" and must be zero sum, and budget neutral. (Mot. Dismiss at 5, 22.) However, this "tedium" is responsible for the distribution of *billions of dollars* in federal funds each year.[36] Indeed, if "tedium" were a proper rationale for federal agencies to cede their rulemaking authority to private bodies with self-interest in the results, the federal government would simply cease to exist. Here, the AMA RUC is more than a "necessary evil" and is doing more than "rendering advice." Defendant directs and delegates to the AMA RUC to review, assess, and set out RVUs for almost unquestioned manifestation into the federal physician fee schedules. (Compl., at ¶69.) Accordingly, the AMA RUC so closely resembles a FAC that it should be subject to the FACA, and disagreement as to this point is not grounds for dismissal under Rule 12(b)(6).

C. Plaintiffs' Due Process Claims Are Cognizable.

Defendants cannot challenge that Plaintiffs have a due process interest in this matter, cognizable and well-supported by the Complaint, and subject to discovery. For, although a physician's decision to participate in the Medicare program is voluntary, the Fourth Circuit has held that the "expectation of continued participation in the Medicare program is a property interest protected by the due process clause of the fifth amendment." *Ram v. Heckler*, 792 F.2d 444, 447 (4th Cir. 1986). The sound analysis[37] of cases like *Ram* concludes that if physicians are

[36] Anna Mathews and Tom McGinty, *Physician Panel Prescribes the Fees Paid by Medicare*, Wall St. J., Oct. 26, 2010, at http://online.wsj.com/article/SBI10001424052748704657304575540440173772102.html

[37] Using the same analysis, courts have found a property interest in the continued participation in the Medicaid program. *Bowens v. N.C. Dep't of Human Resources*, 710 F.2d 1015, 1018-1019 (4th Cir. N.C. 1983) (holding, "we therefore conclude that at the time of his suspension Dr. Bowens had a property right in continued participation in the Medicaid program entitling him to be terminated only for cause."); *Greenspan v. Klein*, 442 F. Supp. 860, 861 (D.N.J. 1977) (court assumed that a physician had a property interest in the continued participation in the Medicaid

already a part of the Medicare program, then they have a property interest to continue to be a part of that program. *Bowens v. North Carolina Dept. of Human Resources*, 710 F.2d 1015, 1018 (4th Cir. 1983) ("the regulations created a property interest in continued participation in the program unless terminated for cause.").

In fact, this Court has termed this property interest as a "continued expectation to run a business." In *Ivy Hall Geriatric & Rehabilitation Ctr., Inc. v. Shalala*, 50 F. Supp 2d (D. Md. 1999) the Court found that a property interest in approval of a nurse aide training and competency evaluation program was:

> appropriately characterized as a continued expectation to run its business at a particular reduced cost absent some minimal level of justification for the loss of that expectation. The government may not, without *some form of process*, interfere with [that] legitimate business expectancy.

Ivy Hall, 50 F. Supp. 2d at 456. Plaintiffs' business expectancy and property interest are jeopardized here as a result of Defendants' continued use of survey data collected by conflicted, self-interested specialty societies, which data the RUC concedes are overinflated and which are based upon statistically unsound methodology and validity. Through Defendants' actions, Plaintiffs and other primary care physicians have been denied income that they would otherwise have obtained, were the primary care codes accurately

valued. (Compl., at ¶106.)

Curiously, the case that Defendants cite, *Pittston Co. v. United States*, 368 F.3d 385, 390 (4th Cir. 2004), supports the denial of their Motion. In *Pittson*, the plaintiffs challenged the constitutionality of the Coal Act and its application following a related Supreme Court

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program); *Hathaway v. Mathews*, 546 F.2d 227, 229 (7th Cir. 1976); *Case v. Weinberger*, 523 F.2d 602, 606 (2d Cir. 1975) (holding that operators of nursing homes have a property interest in the continued participation in the Medicaid program entitling them to the protection of the due process clause.)

decision,[38] including that the Coal Act unconstitutionally violated nondelegation and separation of powers principles by placing governmental powers in the hands of the trustees of the common trust fund. *Pittson* proceeded through discovery not only upon the due process claims but also upon the delegation claims raised by plaintiffs. While Defendants provide one small sound bite from *Pittson* (Mot. Dismiss, at 21), it was only after discovery was completed that the court engaged in its lengthy and detailed analysis regarding the delegation at issue. *Pittson*, 368 F.3d 385, 393-398. This Court will not undergo the same comprehensive analysis if Defendants' Motion is granted.

Defendants seek to evade discovery and force the Court to adopt their conclusions at this initial stage. Contrary to the allegations and before any discovery, Defendants summarily conclude that "the AMA RUC's role is advisory" and "the Secretary obviously takes the advice of the AMA RUC seriously." (Mot. Dismiss, at 21, 23.) These are findings of fact to be made after discovery is completed like in *Pittson*, not conclusions that can be made before a thorough record is established. Moreover, that the *Pittston* Plaintiff Coal Companies did not prevail is simply not pertinent. What is relevant here is that Plaintiffs have a significant and fully pled due process and Constitutional claim to a violation of the Secretary's duties not to delegate mandatory authority, to fully execute the law, and to not intentionally and with actual knowledge act in an arbitrary and illegal manner to the detriment of Plaintiffs. Of course, to the extent that the Defendants assert and can prove that they acted reasonably and within their discretion, they will be able to mount evidence in their defense. However, these arguments and conclusions are

[38] *Eastern Enterprises v. Apfel*, 524 U.S. 498, 141 L. Ed. 2d 451, 118 S. Ct. 2131 (1998) (holding that the Coal Act was unconstitutional insofar as it imposed severe retroactive liability on a coal company that had not signed a labor agreement since 1964.).

premature. Plaintiffs are entitled to discovery on their well-pled allegations of Constitutional violations.

III. The AMA Is Not A Necessary Party Under FRCP 19(a).

Defendants argue that the AMA should be joined pursuant to Rule 19(a)(1) because not doing so would "impair the AMA's interests or leave defendants subject to a substantial risk of incurring inconsistent obligations …" (Mot. Dismiss at 4.) First, the AMA is not a mandatory necessary party because it is so closely tied to the Defendants such that its interests will be protected by them. Second, even if it is a necessary party, the AMA can make that determination for itself and can move to intervene.

Under Rule 19(a)(1) an entity shall be joined as a party when feasible and "(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 the 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 that interest."

Here, contrary to assertions made by Defendants, nonparticipation by the AMA in this case would not have the effect of impairing or impeding the AMA's ability to protect its interest in formulating the Resource Based Relative Value Scales for the Defendants. "A non-party is adequately represented by existing parties if: (1) the interests of the existing parties are such that they would undoubtedly make all of the non-party's arguments; (2) the existing parties are capable and willing to make such arguments; and (3) the non-party would offer no necessary element to the proceeding that existing parties would neglect." *Southwest Ctr. for Biological Diversity v. Babbitt*, 150 F.3d 1152, 1153-4 (9th Cir. 1998). The question, then, is whether

Defendants could adequately represent the AMA's claimed interest in running its RUC committee and presenting for use RBRVS to the Secretary. Moreover, the Defendants can adequately represent the AMA unless there is a conflict of interest between the two. *Southwest Ctr. for Biological Diversity*, 150 F.3d, at 1154.

No conflict has been claimed here because none exists. The Centers for Medicare and Medicaid Services (CMS) is a federal agency that "directly manages, utilizes, and relies upon the AMA RUC in the relative valuation process that forms the basis of the Physician Fee Schedule." (Compl., at ¶2.) Several officials from CMS attend AMA RUC meetings and therefore, have direct knowledge of the contents of such meetings. (Compl., at ¶50.) Far from being conflicted, the AMA and the Defendants are so closely aligned that the Defendants blindly accept as much as 95% of the AMA RUC's proposed RVUs without alteration. (Compl., at ¶90.)

Defendants fail to understand the heart of Plaintiffs' claim, which is that CMS and HHS have exclusively and therefore, improperly, relied upon and adopted the recommendations of the AMA RUC without utilizing proper administrative notice and rule-making channels in accordance with FACA and the APA. The effect of this reliance has been a one-sided agreement as to the fee schedules that govern all physicians. As such, the Defendants and the AMA share a strong interest in continuing their current framework and relationship. The extent of sub-delegation, vested involvement, and understanding between the Defendants and the AMA is demonstrative of Defendants' ability and willingness to "proceed to the merits" through the adequate representation of the AMA's coinciding interests in this matter. In summary, as a *de facto* FAC, the AMA is not a separate and independent entity, but instead merely an (improper) arm of the Federal Government and specifically HHS and CMS. As an arm of the Government, its interests are one and the same as the Governments' and can and will be protected by the

Government's attorneys here. Defendants defend the current scheme and make every argument in their Motion to Dismiss that would have been made by the AMA.

Defendants, without elaboration or explanation, state that failing to add the AMA as a necessary party would subject the Secretary to "inconsistent obligations." (Mot. Dismiss, at 26.) Inconsistent obligations arise only when a party to the case risks facing *conflicting* judgments so that compliance with one would conflict with the other. *Southern Co. Energy Mktg., L.P. v. Virginia Elec. & Power Co.*, 190 F.R.D. 182 (E.D. Va, 1999). Defendants only state that inconsistent obligations would arise if the Secretary were "ordered to take over the AMA RUC … or to refuse to hear advice of the AMA …", but fails to articulate how either of those potential judgments would conflict with her compliance to an unmentioned existing judgment and/or obligation.

Defendants have also proffered no definition of "whipsawed" within the context of this case and have subsequently failed to draw an analogy between the fact set involving coverage policies of multiple insurers in *Schlumberger Indus., v. National Sur. Corp*, 36 F.3d 1274, 1286 (4th Cir. 1994)[39] and the current case in which, in the event of a decision in favor of Plaintiffs, CMS and HHS would have to consider suggestions and proposals from different elements of the physician communities (not just the AMA) before adopting the "best" physician fee schedule—something the agencies are already required to do under the APA and FACA. Defendants do not articulate how the failure of joining the AMA would subject the Secretary to other adjudications

[39] In *Schlumberger Indus.*, the court drew a distinction between being factually and legally "whipsawed" finding that the "potential for 'whipsaw' arises from the fact that … different insurance policies issued to Sangamo covered different policy periods, and it manifests itself in three ways, based upon the three steps that a court presiding over some aspect of the controversy at hand would be expected to undertake." 36 F.3d at 1286.

as opposed to periods of notice and commenting by non-AMA related physician communities with varying views.

Moreover, Defendants appear to argue that because there could theoretically be "successive actions from different elements of the physician community with different views" from those of the Plaintiffs, the AMA is necessary. (Mot. Dismiss at 26-27.) This wildly misstates the facts and misinterprets Rule 19. First, the AMA only represents 22% of the country's physicians (Compl., at ¶52), so joining it would not end the possibility of other, successive views on the issue. Second, the "Rule does not require a court to join all persons whose interests might conceivably be affected by the decision in the case." *American Civil Liberties Union v. Board of Public Works*, 357 F. Supp. 877, 884 (D. Md. 1972). Third, any truly interested parties are free to move to intervene under FRCP 24. Lastly, it may very well be the case here that it is too early in the litigation to decide if the AMA is a necessary party.

> The Rules Advisory Committee recognizes that issues of joinder need not be decided during the preliminary proceeding of a suit, stating that 'the relationship of an absent person to the action, and the practical effects of an adjudication upon him and others, may not be sufficiently revealed at the pleading stage; in such a case it would be appropriate to defer decision until the action was further advanced.'

American Civil Liberties Union, 57 F. Supp. at 884 (citing 28 U.S.C.A., Rules 17 to 33 (Rule 19 note), Notes of Advisory Committee on the Rules). Therefore, the issue of the AMA's joinder need not be decided at this preliminary juncture.

In the end, Defendants' Motion alleges less than plausible grounds by which the AMA is a necessary party to this action. However, even if the AMA is deemed to be a necessary party, dismissal of the Complaint for this reason has not been requested and would not be the appropriate result. Defendants merely assert that the AMA is a necessary party under Rule 19(a). It is Rule 19(b) that governs the determination of whether the suit should be dismissed

when a necessary party *cannot* be joined. However, since there is nothing demonstrating that the AMA is not amenable to suit in this Court or could not be joined in the instant suit, the standards of 19(b) are inapplicable here. FRCP 19; *American Civil Liberties Union*, 357 F. Supp. at 884. If the AMA wants to protect its interest in maintaining total control over the Government's adoption of RVUs, then it should move the Court to intervene under FRCP 24 and explain its interests.

CONCLUSION

For the reasons stated herein, Plaintiffs respectfully request that Defendants' Motion to Dismiss be denied.

REQUEST FOR HEARING

Plaintiffs respectfully request a hearing on the Motion to Dismiss.

/s/
Veronica Nannis

Respectfully submitted,

/s/
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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

PAUL FISCHER, M.D., *et.al*.,	*	
	*	
Plaintiffs,	*	
	*	**Case No. 1:11-cv-02191 (WMN)**
v.	*	
	*	
DONALD BERWICK, M.D. *et al.*,	*	
	*	
Defendants.	*	

_____

ORDER

Upon consideration of Defendant's Motion to Dismiss (docket number 10), Plaintiffs' Opposition thereto and any hearing on the matter, it is this _____ day of _____, 2012, by the United States District Court for the District of Maryland:

ORDERED, that Defendant's Motion to Dismiss be and hereby is **DENIED**.

_____
William M. Nickerson,
United States District Court
for the District of Maryland

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