IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

PAUL FISCHER, M.D., ROBERT CLARK, D.O., LESLIE POLLARD, M.D., EDWIN SCOTT, M.D., ROBERT SUYKERBUYK, M.D., and REBECCA TALLEY, M.D., in care of CENTER FOR PRIMARY CARE, P.C. 363 North Belair Rd. Evans, GA 30809 Plaintiffs, v. DONALD BERWICK, M.D. in his official capacity as ADMINISTRATOR, CENTERS FOR MEDICARE & MEDICAID SERVICES 7500 Security Boulevard, Baltimore, MD 21244, and KATHLEEN SEBELIUS, in her official capacity as SECRETARY OF THE UNITED STATES, DEPARTMENT OF HEALTH AND HUMAN SERVICES, 200 Independence Avenue, S.W. Washington, D.C. 20201 Defendants.	)	Case No. COMPLAINT

COMPLAINT

1. Plaintiffs Paul Fischer, M.D., Robert Clark, D.O., Leslie Pollard, M.D., Edwin Scott, M.D., Robert Suyberkuyk, M.D., and Rebecca Talley, M.D. ("Plaintiffs"), by and through undersigned counsel, bring this action against the Centers for Medicare and Medicaid Services ("CMS") through its agent Defendant Donald Berwick, M.D. ("Dr. Berwick"), the Acting Administrator of CMS, and the Department of Health and Human Services ("HHS") through its agent Defendant Kathleen Sibelius, United States Secretary ("the Secretary"), to challenge the failure of CMS to comply with the Federal Advisory Committee Act ("FACA"), 5 U.S.C. App. § 1 *et seq.*, the Administrative Procedure Act ("APA"), 5 U.S.C. § 551, *et seq.*, the Patient Protection and Affordable Care Act ("ACA"), Pub. L. No. 111-148, 124 Stat. 119 (2010), the Mandamus Act, 28 U.S.C. § 1361, the Delegation Clause of the United States Constitution, U.S. Const. art. I, § 1, and the Due Process Clause of the Fifth Amendment to the United States Constitution. U.S. Const. amend. V.

2. Plaintiffs seek a declaratory judgment that Defendants are in violation of the APA and FACA for utilizing the American Medical Association Specialty Society Relative Value Scale Update Committee ("AMA RUC") as an

unchartered and unofficial Federal Advisory Committee ("FAC") in that CMS directly manages, utilizes, and relies upon the AMA RUC in the relative valuation process that forms the basis of the Physician Fee Schedule ("PFS"). Plaintiffs further seek a declaratory judgment that Defendants have violated FACA by failing to ensure that the AMA RUC meetings are open to the public, failing to allow public petitioning of the AMA RUC, failing to provide public access to records of the AMA RUC meetings, and failing to ensure that the AMA RUC is constituted of members that have a balanced representation of views.

3. Plaintiffs further seek a declaratory judgment that Defendants are in violation of the APA for failing to ensure that agency actions are not arbitrary, capricious, or an abuse of discretion in violation of the Due Process Clause of the Fifth Amendment to the United States Constitution. Plaintiffs further seek declaratory judgment that Defendants are in violation of the United States Constitution for abrogating duties that were delegated to the Defendants by Congress and unlawfully sub-delegating them to the AMA RUC. Plaintiffs further seek declaratory judgment that Defendants are in violation of the ACA for failing to ensure the accuracy of the PFS. Plaintiffs seek injunctive relief enjoining Defendants from utilizing advice

from the AMA RUC in the promulgation of the PFS until Defendants comply fully with FACA, the APA, the ACA and the Constitution. Plaintiffs also seek Mandamus ordering Defendants to fulfill their duties under FACA and the APA.

JURISDICTION

4. This Court has jurisdiction over actions arising under the Constitution and laws of the United States (here FACA, the APA, the ACA, the Mandamus Act, the Due Process Clause, and the Delegation Clause) pursuant to 28 U.S.C. § 1331. This Court also has jurisdiction over agency actions which adversely affect or aggrieve a party within the meaning of relevant statutes (here FACA and the APA) pursuant to 5 U.S.C. § 702.

5. This Court may exercise mandamus jurisdiction over an action compelling an officer of the United States to perform their duty pursuant to 28 U.S.C. § 1361.

6. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(e) in that a substantial part of the events or omissions giving rise to this claim occurred in this district. Venue is proper in this court pursuant to 5 U.S.C. § 703 which provides for judicial review of an agency action where no other review is available.

PARTIES

7. Plaintiff Paul Fischer, M.D., is an aggrieved party and is a primary care physician at the Center for Primary Care, P.C. ("CPC") in Augusta, Georgia. Dr. Fischer started practicing family medicine as the only doctor in the farm community of Weeping Water, Nebraska. Dr. Fischer moved from there to the Medical College of Georgia, where he led the research team that studied the influence of tobacco advertising. This research lead to the pivotal study which showed that children as young as age five recognized the Camel cigarettes' "Old Joe" cartoon character as well as they did Mickey Mouse. In 1993, Dr. Fischer founded the CPC, a cutting edge primary care medical practice in Augusta, Georgia. This practice now provides care to one fourth of that community's population and it has led the national transformation of primary care in the areas of practice organization, physician payment, electronic medical records, and the development of a "medical home." Dr. Fischer is a member of the Institute of Medicine. He spends most of his time caring for his patients. Dr. Fischer has been directly harmed in his ability to carry out his professional duty to provide primary care to his patients as a result of Defendants' violations of federal law.

8. Plaintiff Robert Clark, D.O., is an aggrieved party and is a primary care physician at the Center for Primary Care. Dr. Clark is a first generation family physician from Chester County, Pennsylvania. Dr. Clark started his Family medicine career in Fayetteville, North Carolina at Cape Fear Valley Medical Center. There, he was part of a program designed to grow primary care in the Fayetteville area. In 1995, Dr. Clark joined the CPC in Augusta, Georgia. Since then, Dr. Clark has maintained an active private practice while becoming heavily involved in the leadership of the CPC. 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. Additionally, during Dr. Clark's tenure as CEO, the number of physicians employed by the CPC has increased from 14 to 23. 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. Dr. Clark has been directly harmed in his ability to carry out his professional duty to provide primary care to his patients as a result of Defendants' violations of federal law.

9. Plaintiff Leslie Pollard, Jr., M.D., is an aggrieved party and is a primary care physician at the Center for Primary Care. Dr. Pollard grew up in Augusta,

Georgia, and knew from the time his grandmother was diagnosed with multiple myeloma that he wanted to become a physician. Dr. Pollard determined that he wanted to become a family doctor in order to provide care for entire families, from the newborns to the adults. Dr. Pollard places a high value on his ability to get to know his patients and the family dynamics affecting their care. Dr. Pollard attended Xavier University of Louisiana for his undergraduate degree. Dr. Pollard received his medical degree from Morehouse School of Medicine and completed his family medicine residency at the University of North Carolina at Chapel Hill. After finishing his residency, Dr. Pollard wanted to be a small town doctor. He started a rural solo practice in Statesboro, Georgia, where he became an active member of the community. Dr. Pollard was a member of Rotary International and served as a board member to East Georgia Regional Hospital, Ogeechee Technical College, Bulloch County Board of Health and Ogeechee Area Hospice. After 6 years as a solo practitioner, Dr. Pollard left his practice and joined the CPC. Since joining the group, he has been medical director for his office and President of the CPC. Dr. Pollard is currently the treasurer for the CPC. Dr. Pollard has been directly harmed in

his ability to carry out his professional duty to provide primary care to his patients as a result of Defendants' violations of federal law.

10. Plaintiff Edwin Scott, M.D. is an aggrieved party and is a primary care physician with the Center for Primary Care. Dr. Scott was raised outside of Burlington, North Carolina, on his family's farm. Dr. Scott's family has a long tradition of primary care as both his father and his grandfather were rural family doctors. Dr. Scott attended The University of North Carolina at Chapel Hill, where he received his undergraduate degree in 1986 and went on to receive his medical degree in 1990. He then spent three years in residency training at the Medical College of Georgia in Augusta, Georgia. Except for one year during which he was in private practice in Hope Mills, North Carolina, Dr. Scott has practiced in Augusta since the end of his residency. Dr. Scott is Board Certified in Family Medicine. In his spare time, he is an avid mountain biker. Dr. Scott has been directly harmed in his ability to carry out his professional duty to provide primary care to his patients as a result of Defendants' violations of federal law.

11. Plaintiff Robert Suykerbuyk, M.D., is an aggrieved party and is a primary care physician with the Center for Primary Care. After attending college under the Army GI bill, Dr. Suykerbuyk earned a military scholarship to

study medicine. Dr. Suykerbuyk was the first member of his family to graduate from college. Upon the completion of his medical degree, Dr. Suykerbuyk completed a Residency at Eisenhower Army Medical Center. After his residency was finished, Dr. Suykerbuyk stayed on at Eisenhower Army Medical Center as teaching staff and helped train future family doctors. Dr. Suykerbuyk was deployed in support of the war in the Balkans and later in support of the global war on terrorism. He has earned several military awards for his service. Dr. Suykerbuyk left active duty in order to join the CPC. Since that time, he has helped establish a new CPC office in an underserved area of South Carolina and has worked successfully to transition the CPC from paper charts to a fully integrated lab, electronic patient communication, and electronic medical records system. Currently, Dr. Suykerbuyk is a Lt. Colonel in the medical corps of the Army reserves and has a busy home life with his wife and five kids. Dr. Suykerbuyk has been directly harmed in his ability to carry out his professional duty to provide primary care to his patients as a result of Defendants' violations of federal law.

12. Plaintiff Rebecca Talley, M.D., is an aggrieved party and is a primary care physician with the Center for Primary Care. Dr. Talley has always had roots

in family practice. Her father was the family doctor for a small town in North Carolina and Dr. Talley worked in his office most of her life, working her way up from wallpaper hanger to physician's assistant. Dr. Talley attended Wake Forest School of Medicine, spent her residency years in Pittsburgh, and returned to the south to join the CPC in 1999. Since then, Dr. Talley 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 and is certified in bone densometry. Additionally, she serves as medical director for her office. Dr. Talley's husband is also a family physician and they have a daughter, who does not yet work in her office but probably will someday. Dr. Talley has been directly harmed in her ability to carry out her professional duty to provide primary care to her patients as a result of Defendants' violations of federal law.

13. Defendant Kathleen Sibelius is the United States Secretary of the Department of Health and Human Services and is sued in her official capacity only. HHS is a Federal Agency within the meaning of 5 U.S.C. App. § 3 and 5 U.S.C. § 701. HHS has its headquarters in Washington, D.C. and branches in Maryland. The Secretary is charged with the responsibility of implementing the provisions of the Social Security Act, as amended, 42

U.S.C. ch. 7 ("SSA"). The Secretary administers the Medicare program through CMS, an agency within HHS.

14. Defendant Donald Berwick, M.D., is the Acting Administrator of CMS and is sued in his official capacity only. CMS is a Federal Agency within the meaning of 5 U.S.C. App. § 3 and 5 U.S.C. § 701. CMS is under the control of HHS. CMS and HHS use Relative Value Units ("RVUs") to implement Congressional intent to value physician services through a resource-based relative value scale ("RBRVS"). Omnibus Budget Reconciliation Act of 1989, tit. VI, Pub. L. No. 101-239, 103 Stat. 2106. "CMS establishes RVUs for physicians' work, practice expense, and malpractice insurance." 42 C.F.R. § 414.22. 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. 42 U.S.C. § 1395w-4(c)(2). These RVUs must be reevaluated at least every five years. *Id.* In order to create and evaluate RVUs, CMS has relied heavily upon the AMA RUC, to the extent that the AMA RUC now has become a *de facto* Federal Advisory Committee and therefore must be regulated according to FACA.

STATUTORY AND REGULATORY FRAMEWORK

The Federal Advisory Committee Act

15. FACA was passed by Congress in an effort to control the formation, management and termination of committees that advised officers and agencies of the Executive branch of the Federal government, and to keep these committees to a minimum number. 5 U.S.C. App. § 2(a), (b)(2)-(4). In passing FACA, Congress sought to ensure that advisory committees are solely advisory in nature and that the work they produce will be open to the government and to the general public. 5 U.S.C. App. § 2(b)(5)-(6). One of the purposes of FACA was to address the "concern that some interests had come to enjoy unchecked and perhaps illicit access to federal executive decisionmakers." Steven P. Croly & William F. Funk, *The Federal Advisory Committee Act and Good Government*, 14 Yale J. on Reg. 451, 453 (1997).

16. FACA imposes a number of requirements on committees that provide advice or recommendations to government agencies. 5 U.S.C. App. § 1 *et seq*. A FAC is an advisory committee that is "established or utilized by one or more agencies, in the interest of obtaining advice or recommendations." 5 U.S.C. App. § 3(2)(C).

17. Under FACA, a charter must be filed for each FAC that lists the following.

(A) the committee's official designation;
(B) the committee's objectives and the scope of its activity;
(C) the period of time necessary for the committee to carry out its purposes;
(D) the agency or official to whom the committee reports;
(E) the agency responsible for providing the necessary support for the committee;
(F) a description of the duties for which the committee is responsible, and if such duties are not solely advisory, a specification of the authority for such functions;
(G) the estimated annual operating costs in dollars and man-years for such committee;
(H) the estimated number and frequency of committee meetings;
(I) the committee's termination date, if less than two years from the date of the committee's establishment; and
(J) the date the charter is filed.

5 U.S.C. App. § 9(c). This charter must be filed before the FAC can act.

18. Additionally, FACs are subject to the following requirements.

A. The membership of a FAC must be "fairly balanced in terms of the points of view represented." 5 U.S.C. App. § 5(b)(2).

B. The recommendations of a FAC cannot be "inappropriately influenced by the appointing authority or by any special interest, but will instead be the result of the advisory committee's independent judgment." 5 U.S.C. App. § 5(b)(3).

C. FAC meetings "shall be open to the public" and "[i]nterested persons shall be permitted to attend, appear before, or file statements with" a FAC (unless the head of the agency to which the FAC reports closes

the meeting in accordance with the Government in Sunshine Act, 5 U.S.C. § 552b(c)). 5 U.S.C. App. § 10(a)(1)-(3).

D. The "records, reports, transcripts, minutes, appendixes, working papers, drafts, studies, agenda, or other documents which were made available to or prepared for or by" a FAC must be "available for public inspection." 5 U.S.C. App. § 10(b).

E. A FAC "shall make available to any person . . . copies of transcripts" of its meetings. 5 U.S.C. App. § 11(a).

F. FACs must maintain detailed minutes of their meetings with a record "of the persons present . . . of matters discussed and conclusions reached, and copies of all reports received, issued or approved by" the FAC. 5 U.S.C. App. § 10(c).

G. FACs are reviewable by the Administrator of General Services to determine "whether such committee is carrying out its purpose . . . [and whether] the responsibilities assigned to it should be revised." 5 U.S.C. App. § 7(b).

H. FACs are overseen by an Advisory Committee Management Officer, established by the agency being advised by the FAC, who has control over "the establishment, procedures, and accomplishments" of the

FAC. The Management Officer is also responsible for assembling and maintaining the reports and records of the FAC. 5 U.S.C. App. § 8(b).

19. Although FACA originally was intended to control advisory committees established by Congress, the law has evolved through legal precedent to cover committees that provide advice to a federal agency without formal registration as a FAC. These committees are termed "*de facto* FACs" and can be ordered to comply with FACA by the Federal Court. The Supreme Court has recognized that groups utilized by federal agencies can become *de facto* FACs. *See Pub. Citizen v. U.S. Dep't of Justice*, 491 U.S. 440 (1989).

20. *De facto* FACs are those committees under the "actual management or control" of a federal agency, *Wash. Legal Found. v. U.S. Sentencing Comm'n*, 17 F.3d 1446, 1450 (D.C. Cir. 1994), or those committees "utilized by a department or agency in the same manner as a Government-formed advisory committee." *Pub. Citizen*, 491 U.S. at 457 (citing Exec. Order No. 11007, 27 FR 1875 (Feb. 26, 1962)).

21. To be considered a *de facto* FAC, an advisory committee must have an established structure that is not "an unstructured arrangement in which the government seeks advice from what is only a collection of individuals who

do not significantly interact with each other", but instead is a "formal group of a limited number of private citizens who are brought together to give publicized advice as a group." *Ass'n of Am. Physicians and Surgeons, Inc. v. Clinton*, 997 F.2d 898, 915 (D.C. Cir. 1993). No court has specifically evaluated these factors with regard to the AMA RUC. *Cf. American Society of Dermatology v. Shalala*, 962 F. Supp. 141, 147 (D.D.C. 1996), *aff'd* 116 F.3d 941 (D.C. Cir. 1997) (applying factors to other AMA committees but not to the AMA RUC).

22. The FACA statute, 5 U.S.C. App. § 1 *et seq.*, does not provide for a private cause of action. *See Judicial Watch, Inc. v. U.S. Dep't of Commerce*, 736 F. Supp. 2d 24, 30 (D.D.C. 2010) (citing *Alexander v. Sandoval*, 532 U.S. 275, 286 (2001)). Plaintiffs do not seek relief under FACA, but instead seek relief pursuant to the APA for violation of FACA. *See Judicial Watch, Inc.*, 736 F. Supp. 2d at 30-31 (holding that plaintiff may bring FACA claims pursuant to the APA).

The Administrative Procedures Act

23. The APA prescribes standards for agency rulemaking, 5 U.S.C. § 551 *et seq.*, and adjudications. 5 U.S.C. § 701 *et seq*. Under the APA, "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." 5 U.S.C. § 702.

24. Courts may review agency actions "made reviewable by statute and final agency actions." 5 U.S.C. § 704. Plaintiffs can obtain judicial relief for unlawful agency actions that are "arbitrary, capricious, an abuse of discretion or otherwise not in accordance with law; contrary to constitutional right . . . [or] without observance of procedure required by law." 5 U.S.C. § 706(2).

25. In order for a plaintiff to have standing under the APA, the plaintiff must be "suffering legal wrong because of agency action," 5 U.S.C. § 702, and the agency action must be final. 5 U.S.C. § 704. Final agency actions are those where "the agency has completed its decision-making process, and . . . the result of that process is one that will directly affect the parties." *Franklin v. Massachusetts*, 505 U.S. 788, 797 (1992).

26. Defendants have relied and continue to rely upon the AMA RUC to make critical national policy determinations with regard to physician payment for primary care. This reliance continues despite twenty years of the AMA RUC's failures to adequately address the disparity between payments and reimbursements to primary care physicians as opposed to specialist

physicians. Due to Defendants' virtually uniform adoption of the AMA RUC recommendations, the July 19, 2011 publication of the proposed 2012 Physician Fee Schedule, CMS & HHS, *Medicare Program; Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2012*, 42 CFR pts. 410, 414, 415, 495 (2011) ("2012 PFS"), constitutes an agency action that is effectively final, and in any event, capable of repetition, but evading review. *Roe v. Wade*, 410 U.S. 113, 125 (1973) (quoting *S. Pac. Terminal Co. v. ICC*, 219 U.S. 498, 515 (1911)).

The Delegation Clause

27. Article 1, section 1 of the United States Constitution vests "[a]ll Legislative Powers herein granted . . . in a Congress of the United States." U.S. Const. art. I, § 1. Congress, in turn, may delegate to federal agencies the authority to administer specific statutes if it establishes "by legislative act an intelligible principle to which the person or body authorized to act is directed to conform." *Loving v. United States*, 517 U.S. 748, 771 (1996) (citing *J. W. Hampton, Jr., & Co.* v. *United States*, 276 U.S. 394, 409, 72 L. Ed. 624, 48 S. Ct. 348 (1928)) (alterations omitted).

28. Federal agencies, however, cannot lawfully sub-delegate their entire authority to administer statutes. *See Nat'l Park and Conservation Ass'n v.*

Stanton, 54 F. Supp. 2d 7, 18 (D.D.C. 1999). Sub-delegation of power occurs when an agency allows another party to determine whether statutory requirements are met or allows the other party to have final reviewing authority. *The Fund for Animals v. Kempthorne*, 538 F.3d 124, 133 (2d Cir. 2008).

29. Although Defendants are presumed to have the authority to delegate powers to subordinate federal officers or agencies, *see United States v. Giordano*, 416 U.S. 505, 512–13 (1974), there is no such presumption that Defendants can delegate authority to non-federal agencies or outside parties. *See U.S. Telecom Ass'n v. F.C.C.*, 359 F.3d 554, 565 (D.C. Cir. 2004). Agency delegations are particularly subject to constitutional review where the party to which authority is delegated may present conflicts of interest inconsistent with the principals of good governance. *See Nat'l Ass'n of Regulatory Utils. Comm'rs v. F.C.C.*, 737 F.2d 1095, 1143 n.41 (D.C. Dir. 1984) ("[O]ne of the rationales against excessive delegation [is] the harm done thereby to principles of political accountability.").

The Due Process Clause

30. The Fifth Amendment to the United States Constitution declares that no person can be deprived of "life, liberty or property without due process of

law." U.S. Const. amend. V. Due process is "the protection of the individual against arbitrary action." *Ohio Bell Tel. Co. v. Pub. Utils. Comm'n of Ohio*, 301 U.S. 292, 302 (1937). An agency action may be "such a hazard of arbitrary decisionmaking that it should be held violative of due process of law." *Wolff v. McDonnell*, 418 U.S. 539, 571 (1974).

31. A due process claim encompasses both procedural due process and substantive due process. "[T]he right to procedural due process is applicable only to state action which impairs a person's interest in either liberty or property." *Jeffries v. Turkey Run Consol. School Dist.*, 492 F.2d 1, 4 (7th Cir. 1974). A plaintiff's right to substantive due process requires "that state action which deprives him of life, liberty, or property must have a rational basis- that is to say, the reason for the deprivation may not be so inadequate that the judiciary will characterize it as 'arbitrary.'" *Id.* at 3-4.

The Mandamus Act

32. The Mandamus Act provides district courts with the ability to require federal officers or employees to perform their statutorily mandated duties. "The district courts shall have original jurisdiction of any action in the nature of mandamus to compel an officer or employee of the United States or any agency thereof to perform a duty owed to the plaintiff." 28 U.S.C. § 1361.

33. Congress used the word "shall" throughout FACA when describing the duties of an agency utilizing a FAC, thus these "discrete, non-discretionary duties qualify as relief in the nature of mandamus." *Judicial Watch, Inc. v. U.S. Dept. of Commerce*, 736 F.Supp.2d 24, 30 (D.D.C. 2010) (holding that plaintiff could bring a claim for FACA violations under the Mandamus Act). Mandamus is appropriate as Defendants continue to rely on the AMA RUC's advice and recommendations regarding RVUs but have failed to charter the AMA RUC as a FAC or to follow the guidelines established in FACA for the management and transparency of a FAC.

34. The ACA mandates that "[t]he Secretary shall establish a process to validate relative value units under the fee schedule." Patient Protection & Affordable Care Act, Pub. L. No. 111-148, § 3134, 124 Stat 119 (2010). Mandamus as to Defendants' duties under ACA is appropriate as Congress directed the Secretary of HHS to act using the word "shall." Defendants have failed to faithfully fulfill their statutorily mandated duty pursuant to the ACA by utilizing RVUs recommended by the AMA RUC when Defendants themselves have admitted that the present AMA RUC-based evaluation system creates "distortions" in the payment system.

35. 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." 42 U.S.C. § 1395w-4(c)(2)(B)(iii). Defendants have violated the spirit and the letter of the law by relying so heavily on the American Medical Association ("AMA") for recommendations regarding RVUs. To the extent that Defendants claim their reliance on the AMA RUC is simply a fulfillment of their statutory duty, the statute specifically dictates that the Secretary consult with *organizations*, more than one, and Defendants reliance on the AMA, and through them the AMA RUC, effectively obviates the need to consult with other groups with regard to revaluing RVUs.

GENERAL ALLEGATIONS

The Social Security Act and the Patient Protection and Affordable Care Act

36. The SSA, passed in 1935 and amended substantially since that time, 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." Social Security Act, Pub. L. No. 74-271 (1935), codified as 42 U.S.C. ch. 7 (as amended).

37. The SSA establishes health insurance for the elderly and disabled, which is overseen by CMS and HHS. 42 U.S.C. § 1395 *et seq*. The SSA also provides a method of physician payment for services under "Part B" of the Medicare program. 42 U.S.C. § 1395w-4 *et seq*. 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. 42 U.S.C. § 1395w-4(a)(1).

38. The ACA was signed into law on March 23, 2010 by President Barack Obama. Kaiser Family Foundation, *Focus on Health Reform: Summary of New Health Reform Law*, 1, April 15, 2011, *at* http://www.kff.org/healthreform/upload/8061.pdf. 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.* at 2.

39. The ACA also provides for the identification of misvalued codes in the PFS. Section 3134 of the ACA amended the SSA to include two new subsections which address the reevaluation of potentially misvalued codes. ACA, Pub.

L. No. 111-148 at § 3134. 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.*

Medicare and Physician Payment

40. Title XVIII of the SSA establishes health insurance for the elderly and disabled. 42 U.S.C. § 1395 *et seq.* This health insurance is commonly known as Medicare and is overseen by HHS and CMS.

41. The SSA prescribes the system of payment for physician services. 42 U.S.C. § 1395w-4. 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. 42 U.S.C. §§ 1395w-4(a)(1)(A)-(B).

42. The fee schedule is created by CMS using a calculation based, in substantial part, on the RVU of the service. 42 U.S.C. § 1394w-4(b)(1)(A). RVUs are

assigned to categories of physician services corresponding to the AMA's Current Procedural Terminology ("CPT") codes. 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. 42 U.S.C. § 1395w-4(c)(2)(A)(i). 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. 42 U.S.C. § 1395w-4(b)(1)(A)-(C).

43. CMS is charged with developing these RVUs. 42 C.F.R. § 414.22. 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, Wikipedia, *Resource-Based Relative Value Scale*, http://en.wikipedia.org/wiki/Resource-Based_Relative_Value_Scale (July 21, 2011), where "independent regulators . . . side with the interests of the industry they are supposed to regulate rather than with the interests of the general public or the consumers whom they are supposed to protect."

Economics-Dictionary.com, *regulatory capture*, http://www.economics-dictionary.com/definition/regulatory-capture.html (July 21, 2011).

The American Medical Association's Specialty Society Relative Value Scale Update Committee ("AMA RUC")

44. 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. However, CMS and HHS did not at that time charter the AMA RUC as a Federal Advisory Committee pursuant to FACA. Upon information and belief, CMS and HHS have taken no affirmative action to establish the AMA RUC as a lawful FAC since 1992.

45. Upon information and belief, the AMA chartered the AMA RUC in 1991, after having provided technical assistance to Dr. Hsiao and his team to draft the first delineation of RVUs published through his report. *See* American Medical Association, *History of the RBRVS*, *at* http://www.ama-assn.org/ama/pub/physician-resources/solutions-managing-your-practice/coding-billing-insurance/medicare/the-resource-based-relative-value-scale/history-of-rbrvs.page. 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. Numerous experts have attacked

this survey methodology as inherently biased and arbitrary and capricious in yielding accurate or reliable outcomes. Upon information and belief, although the AMA RUC sends out as many as 1000 physician surveys, the AMA RUC requires as few as 30 survey responses in order to value a physician service. Carlos J. Lavernia & Brian Parsley, *Medicare Reimbursement: An Orthopedic Primer*, 21 J. Anthroplasty Supp. 2 6, 8 (2006); *see also* AMA/Specialty Society, *2011 RVS Update Process*, at 7, *at* http://www.ama-assn.org/resources/doc/rbrvs/ruc-update-booklet.pdf ("The societies are required to survey at least 30 practicing physicians.").

46. The AMA RUC consists of 26 voting members and a Chairperson, representing various medical specialty societies. The RUC also includes non-voting members from groups such as the AMA CPT Editorial Panel. Upon information and belief, 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.

47. Although the AMA RUC membership has been a well-kept secret in the past, the AMA, presumably in response to articles published by the Wall Street Journal and other publications which published the AMA RUC membership list, has released a list of the 2011 AMA RUC members. Anna

Wilde Mathews, *Dividing the Medicare Pie Pits Doctor Against Doctor*, April 7, 2011, *at* http://online.wsj.com/article/SB10001424052702303341904575576480649488148.html. Currently, out 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. Upon information and belief, one member of the AMA RUC, the representative of the American College of Surgeons, has been a member since 1991. *Id.*

48. The public is not invited to the AMA RUC meetings. The public does not have any input into the agenda for AMA RUC meetings. 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.

49. Invitations to attend AMA RUC meetings may only be issued by the Chairperson, currently, Barbara Levy, M.D. Up to 300 persons have been known to attend the AMA RUC meetings, generally located in exclusive resorts or vacation destinations. Attendees at the AMA RUC meetings must sign a confidentiality agreement prohibiting them from discussing the

content of the meetings. Upon information and belief, persons violating those confidentiality agreements have been sanctioned by the AMA.

50. The AMA RUC meetings are attended by multiple officials from CMS. CMS appoints advisors to the AMA RUC. Upon information and belief, AMA and a number of specialty societies have provided benefits to certain government attendees at those meetings.

51. The AMA contends that the AMA RUC meetings simply represent its exercise of its First Amendment right to petition the government. The AMA also contends that it is doing the government a service, since it pays the costs of the proceedings, which it estimates at six million dollars annually. 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. Upon information and belief, the AMA obtains profits of approximately 56 million dollars in copyright royalties and extensive 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. *See* AMA Form 990 (2009).

52. Specialty societies that agree to be part of the AMA RUC process, and their members, benefit financially as a result of their membership and participation in the AMA RUC. Only 22 percent of physicians in the United States – including M.D.s and D.O.s – belong to the AMA.

53. When the AMA established the AMA RUC in 1991, 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." AMA House of Delegates, *The RUC: Recent Activities to Improve the Valuation of Primary Care Services*, Report 14 of the Board of Trustees (A-08), available at http://www.ama-assn.org/resources/doc/rbrvs/rucbotreport.pdf ("AMA Report 14").

54. Since that time, the AMA RUC determines which specialty groups have a seat on the AMA RUC by using the following criteria:

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

Id. at 9. Based on 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.* at 10.

55. Upon information and belief, a specialty society can only become a permanent voting member of the AMA RUC if they first become a board member of ABMS. *Id.* ABMS has not admitted a new specialty society as a member board since the admission of Medical Genetics in 1991. American Board of Medical Specialties, *Approval of New Member Boards, at* http://www.abms.org/About_ABMS/ABMS_History/Extended_History/Approving_New_Boards.aspx. 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, AMA, *The Delegates, at* http://www.ama-assn.org/ama/pub/about-ama/our-people/house-delegates/the-delegates.page?, only 23 of these societies have a voting membership on the AMA RUC. Three voting members of the AMA RUC hold "rotating seats," the purpose of which is to give other specialty societies access to the AMA RUC; however, these rotating seats have been held by only eleven different specialty societies since the creation of the AMA RUC in 1991. AMA Report 14, at 14. 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.

56. Upon information and belief, significant financial ties exist between various medical industry/pharmaceutical companies and the AMA RUC members. 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. However, upon information and belief, the AMA RUC claims to have no responsibility, as would members of an official Federal Advisory Board, to report any potential conflicts of interest.

57. Upon information and belief, current AMA RUC members have financial or consulting ties to companies including Pfizer, Medtronics, Johnson & Johnson, Aetna, Conceptus, Vivacare, AMS, Covidien, Halt Medical, Gynesonics, Idoman Medical, Sanofi-Aventis, Americhoice by United Healthcare, Blue Cross and Blue Shield, Advanced Renal Technologies, Network 15, Baxter Home Dialysis, Fresenius, Neose Technologies, Jazz Pharmaceuticals, Glaxo-SmithKline, Photomedex, Vivacare Dermatology,

DermFirst, Logical Image, Eli-Lilly, Bayer, Retrosence Therapeutics, ThromboGenics Ltd., Allergan, Opthalmic Mutual Insurance Company , Neurotech, Nu-Vue Technologies, Optimedica, and Alcon Laboratories.

58. Some of these companies have been involved in recent criminal matters and settlements, including, for example, for off-label marketing to physicians and surgeons. *See, e.g.*, Press Release, U.S. Dep't of Justice, *Justice Department Announces Largest Health Care Fraud Settlement in Its History: Pfizer To Pay $2.3 Billion for Fraudulent Marketing* (Sept. 2, 2009) *at* http://www.justice.gov/usao/ma/news/Pfizer/Pfizer%20-%20PR%20%28Final%29.pdf; Press Release, U.S. Dep't of Justice, *Two Johnson & Johnson Subsidiaries to Pay Over $81 Million to Resolve Allegations of Off-Label Promotion of Topamax* (Apr. 29, 2010) *at* http://www.justice.gov/opa/pr/2010/April/10-civ-500.html; Press Release, U.S. Dep't of Justice, *Allergan Agrees to Plead Guilty and Pay $600 Million to Resolve Allegations of Off-Label Promotion of Botox®* (Sept. 1, 2010) *at* http://www.justice.gov/opa/pr/2010/September/10-civ-988.html; Press Release, U.S. Attorney's Office, *Eastern District of New York, Jazz Pharmaceuticals Agrees to Pay $20 Million to Resolve Criminal and Civil*

Allegations In "Off-Label" Marketing Investigation (Jul. 13, 2007) *at* http://www.justice.gov/usao/nye/pr/2007/2007jul13a.html.

59. The public has no opportunity to have input into the agenda for the AMA RUC meetings. Nor does the public have the opportunity to suggest that the AMA RUC reevaluate RVUs for procedures and treatments that are over-valued or under-valued. This results in the AMA RUC's agendas being opaque and lacking in coherency, organization or structure, even to CMS.

60. 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 direct the AMA RUC to place items upon their agenda, but as of the proposed July 19, 2011 Physician Fee Schedule for 2012, CMS concedes 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.

61. With increasing disparities in specialty payments and physician compensation, and with increasing criticism from Congress and its Medicare Payment Advisory Committee, 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. In that letter, he

conceded that CMS had accepted the vast majority of AMA RUC valuations. However, he then 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." 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."

62. Although the 2008 CMS letter should have served as a clarion call to the AMA RUC to improve its processes, it had little effect. Administrator Weems pointed out dramatic examples of the arbitrariness of the AMA RUC's process and its failure to correct or even consider certain valuations, such as 2900 codes, originally valued in the Harvard Study nearly twenty years prior, which had never been reevaluated. He also provided the AMA RUC with a roadmap for correcting their evaluations, directing them to evaluate highly utilized, low-intensity procedures in the one hundred fastest growing services with annual costs over a million dollars. To assist the

process, he attached a list of those codes from a CMS analysis of 2004 – 2007 data. Finally, he directed the AMA RUC to review practice expense RVUs. Upon information and belief, despite entrusting themselves with ensuring the accuracy of the nation's physician payment processes, and despite a mandate that codes be reviewed every five years for overvaluation, the AMA RUC had never before undertaken these most basic evaluative tasks directed by Administrator Weems.

63. Former CMS officials have derided the AMA RUC based evaluation system. Former Administrator Thomas Scully, J.D. for example, has publicly stated that the AMA RUC system is "indefensible" and that "[i]t's not healthy to have the interested party essentially driving the decision-making process." 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/SB10001424052748704657304575540440173772102.html ("Mathews & McGinty").

64. Former AMA RUC member Dr. Neil Brooks referred to the AMA RUC process as "beyond tedious" and "opaque" and added that it takes "a year of doing it before you get a good idea of what is going on." Joe Eaton, *Little Known AMA Group has Big Influence on Medicare Payments*, The Center

for Public Integrity, Oct. 27, 2010, at http://www.kaiserhealthnews.org/Stories/2010/October/27/AMA-center-public-integrity.aspx ("Eaton"). Current AMA RUC Chair Barbara Levy stated that "[w]e assume that everyone is inflating everything when they come in. They are wanting to fight for the best possible values for their specialties." *Id.*

65. According to Dr. Robert Berenson, vice-chair of the MedPAC and a former American College of Physicians representative to the AMA RUC, "[e]very specialty society requested up values and never came in requesting down values." *Id.* 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.*

66. Other members of the physician community have also noted Defendants' delegation of their duty to establish RVUs to the AMA. For example, John A. Patti, M.D., the chair of the American College of Radiology Board of Chancellors, has acknowledged the AMA RUC's control over RVUs. 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. Charles Fiegl, *Medicare proposes 50% cut for some imaging fees in 2012*, Am. Medical News, July 18, 2011, *at* http://www.ama-assn.org/amednews/2011/07/18/gvl10718.htm. 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.*

67. Although CMS unduly relies upon the AMA RUC to carry out its statutory duties to accurately value the Physician Fee Schedule (duties that are only reinforced by the ACA), and although the obvious perversion of the current process suggests an "emperor has no clothes" phenomenon, CMS has chosen in its recent proposed fee schedule not to distance itself from AMA, but rather to invest itself further. CMS has failed to realize that twenty years of AMA RUC control over the physician fee schedule has resulted in a process that is irrational, arbitrary, and absolutely destined to lead to the continued devastation of primary care.

68. Indeed, in the proposed 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. *See* 2012 PFS, at 91-92. CMS has essentially directed the AMA RUC to review the disparity that the AMA RUC created. Although the ACA requires Defendants to "validate" the accuracy of RVUs, the PFS demonstrates that Defendants have not validated the accuracy and instead continue to choose to utilize the AMA RUC, despite twenty years of inadequate and inaccurate valuations.

69. Examples of Defendants' continued use of the AMA RUC are provided in the proposed 2012 PFS, where CMS directs the AMA RUC to undertake tasks that are part of its own statutory, non-delegable mandate, including the following:

A. Defendants direct the AMA RUC to "conduct a comprehensive review of all E/M [(evaluation and management)] codes" to address the evolving nature of primary care in preventing and managing chronic diseases. 2012 PFS, at 91. Defendants provided the AMA RUC with a 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. *Id.* at 91-92.

B. Defendants direct the AMA RUC to conduct a review of "high PFS expenditure procedural codes," not reviewed since 2006, that had costs of "greater than $10 million at the specialty level" in 2010. *Id.* at 94. Defendants again provided a deadline of July 2012 for the first half of the review. *Id.* at 95.

C. Defendants direct the AMA RUC to review "direct PE inputs and work values" for a number of computer tomography ("CT scan") codes. *Id.* at 98. Defendants had previously directed the AMA RUC to value the direct PE inputs for these codes, and had adopted the AMA RUC recommended values in 2011. *Id.* at 97. However, the AMA RUC recommended values resulted in a disparity between the new codes and old codes. The AMA RUC's recommendations caused the new codes for CT scans of half of the body to cost *more* than an identical scan of the entire body. *See id.* at 98. "Specifically, the PE RVUs for the codes that describe CT scans without contrast for either body region are greater than the PE RVUs for . . . a CT scan of both body regions." *Id.* Defendants thus refer the partial and full body scan codes back to the AMA RUC for further evaluation. *Id.*

D. Defendants direct the AMA RUC to review both the direct PE inputs and work values of a tissue pathology code. *Id.* at 100. The code had previously been valued, but "the AMA RUC relied upon an atypical clinical vignette in identifying the direct PE inputs" for the code. *Id.* at 99. Although "the typical cost for the service amount is approximately $18," the previous AMA RUC-recommended value resulted in a "national payment rate of $69.65 for the technical component of the service" in 2011. *Id.* at 100.

E. Defendants direct the AMA RUC to compare two new in situ hybridization testing codes for urine with old codes for the same testing of a large range of bodily fluids. *See id.* at 101-02. The old codes are billed once for each time a "probe" is done, while billing once with the new code accounts for up to four probes. *Id.* at 101. According to the proposed 2012 PFS, under the old code, a test with three probes would be billed at 18.84 RVUs, while a similar test under the new code using 4 probes would be billed at 13.47 RVUs. *Id.* As CMS believes the new code to be appropriately valued, Defendants direct the AMA RUC to compare the new and old codes to determine the appropriate valuation of the old code. *Id.*

F. Defendants direct the AMA RUC "to make recommendations regarding the appropriateness of creating nonfacility direct PE inputs" for a variety of codes. *Id.*

G. Defendants direct the AMA RUC to review ultrasound equipment, on which the price ranges "from $1,304.33 to $466,492.00." *Id.* at 103. Defendants also direct a review of the description and price of the ultrasound equipment as listed in the direct practice expense database and the use of that price in direct PE inputs for other codes. *Id.*

H. Finally, Defendants direct the AMA RUC to reevaluate the relative prices of two cholecystectomy CPT codes for similar procedures. *Id.* at 104. Initially, Defendants thought the value difference between the codes to be warranted, but clinical review showed that there was no need for the increased number office visits paid for under the second code and Defendants determined a review was in order. *Id.*

70. These direct assignments from Defendants to the AMA RUC show that Defendants have not only delegated their statutorily mandated responsibility of valuing RVUs to the AMA RUC, but also have done so with full knowledge that the AMA RUC regularly provides RVUs that are improperly valued.

71. Further, Defendants themselves have stated that the AMA RUC's recommendations are often found to be overvalued and to rely on false assumptions. In the proposed 2012 PFS, Defendants included a list of 40 codes with site-of-service anomalies that CMS had directed the AMA RUC to reevaluate in 2010. *Id.* at 106. (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.) Of those 40 codes, CMS adopted the AMA RUC's recommended reevaluations of only 19. *Id.* at 107. 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 proposed 2012 PFS. *Id.*

72. If there were any prior doubt, CMS' announced continuation – in a proposed federal rule – of its intention to continue its intertwined relationship with the

AMA, despite their lack of accuracy, balance, or re-evaluation of codes renders the AMA RUC a *de facto* FAC, with CMS and HHS as the intentional facilitators of that illegal relationship. Nothing in the SSA or ACA permits CMS to conduct its business in a manner so contrary to the letter and spirit of the Federal Advisory Committee Act.

The AMA RUC's Influence on Primary Care in the United States

73. 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. 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 is highly biased towards procedural specialties, and particularly surgical specialties. 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. In general, the "cognitive" medical disciplines, those involving complex tasks

of evaluation, discernment, medical management, and comprehensive patient care, are drastically underrepresented on the AMA RUC, and this process results in direct harm to their ability to obtain the valuations to which their services are entitled.

74. 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. MedPAC recently admitted that the physician payment system is ineffective and biased towards specialist proceduralists.

> Medicare's payment system for physician and other health professional services is flawed in many ways: It continues to call for unrealistically steep fee cuts, it inherently rewards volume over quality and efficiency, and it favors procedural services over primary care, which has serious implications for the nation's future primary care workforce.

MedPAC, *Report to the Congress: Medicare and the Health Care Delivery System*, at 3 (June 2011).

75. The current Vice-chair of the MedPac, Dr. Robert Berenson, has also spoken harshly of the physician fee schedule. 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." Eaton, *supra*.

76. 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 pharmacological, procedural, or internet based-misinformation, monitoring of family hereditary conditions, and diagnosing rare disease.

77. Indeed, 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." Mathews & McGinty, *supra*. 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 since the analytical model of RBRVS did not readily transfer to the time- and patient-intensive model for providing primary care.

78. Moreover, independent studies, such as that of John Goodson, M.D., have identified the irrational disparities that result from the AMA RUC based system. John Goodson, *Unintended Consequences of Resource-Based Relative Value Reimbursement*, 298 J.A.M.A 2308 (2007). 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.*

Defendants' Reliance on the AMA RUC Has Caused and Continues to Cause Irreparable Harm to Plaintiffs

79. If Plaintiffs, all of whom are Primary Care Physicians, are denied the relief they seek, irreparable harm will continue to occur to their ability to carry out their professional duties and to the health and well-being of their patients. Harms will also flow to the greater Medicare population as a result of the

economic impact of decreased availability of primary care and the continued over-utilization of procedures and even medical interventions that have been proved unnecessary.

80. 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. 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 established Medicaid patients under ACA as a result of Defendants' actions. Plaintiffs also must address the well-documented impacts of the usage of certain unnecessary specialty and outpatient procedures upon their patients' health.

81. Defendants' undervaluing of primary care physicians has resulted in a decreased candidate pool for primary care physician positions. The undervaluing of primary care has resulted in a life-time earning gap of 3.5 million dollars between primary care physicians and specialists. As a result, medical students are discouraged from pursuing a career in primary care and

Plaintiffs are unable to hire enough physicians to meet their current and projected demands for primary care physicians.

82. Further, as a result of this new primary care physician shortage, Plaintiffs are harmed by Defendants' actions because they cannot meet the primary care physician needs of their communities. Plaintiffs currently serve close to the maximum number of primary care patients that can be served given the number of physicians employed by the Center for Primary Care. As with primary care physicians around the country, the number of potential patients that need primary care physicians far outweighs the capacity of physicians to service those patients. As a result, millions of new Medicaid patients will be left without primary care physicians and will be forced to seek the subpar and overly expensive care available to them in emergency departments.

83. As a result of Defendants' actions in undervaluing primary care, Plaintiffs are forced to spend shorter and shorter lengths of time with each patient. The disparity between the actual cost of an office visit and the Medicare/Medicaid reimbursement rates has forced Plaintiffs to shorten the office visits in an effort to decrease costs. As a result, Plaintiffs are forced to forego building a trusting, care-improving relationship with their patients in

favor of treating their most obvious ills and moving on to the next patient in order to keep the actual visit costs on par with reimbursement levels.

84. Defendants' actions have resulted in Plaintiffs being faced with increasingly complex issues within these shortened office visits. CMS has admitted that "the focus of primary care has evolved from an episodic treatment-based orientation to a focus on comprehensive patient-centered care management in order to meet the challenges of preventing and managing chronic disease." 2012 PFS, at 91. According to Dr. John Goodson, "[a]ttaining the expected health benefits from early and effective treatment of symptomatic and asymptomatic illness will not be achievable without increasing the number of generalists." Goodson, 298 J.A.M.A. at 2308. However, Defendants have prohibited Plaintiffs from moving towards this comprehensive patient-centered care by undervaluing their efforts. Instead of being able to offer sensitive, attentive care, Plaintiffs are forced to treat each visit as an issue-oriented situation where specific illnesses identified by the patient are dealt with in as little time as possible.

85. Further, Defendants' actions have resulted in the creation of a primary care environment where Plaintiffs are unable to treat all of their patients' needs. Upon information and belief, although primary care codes exist for the

preventative medicine counseling a patient and addressing a patient's risk factors for disease, these codes are not reimbursed by Medicare. Plaintiffs are frequently required to shortchange their patients by addressing only the most pressing needs because at length counseling sessions will not be reimbursed. This has harmed the Plaintiffs' ability to interact with their patients and to build a true doctor-patient relationship that would provide for a higher level of primary care.

86. Defendants have further harmed Plaintiffs by creating a payment system that encourages unnecessary procedures. Plaintiffs are frequently asked to handle the post-operative care of patients who have undergone unnecessary procedures recommended and performed by specialists. These procedures often result in follow-up visits, pain management consultations and consultations over the need for further (unnecessary) surgery with Plaintiffs.

FIRST CLAIM FOR RELIEF

(Relief requested under the Administrative Procedures Act for an agency violation of the Federal Advisory Committee Act (5 U.S.C. App. § 1 *et seq.*).)

87. Plaintiffs hereby incorporate by reference Paragraphs 1 – 86 as if fully set forth herein.

88. FACA prohibits the utilization of the advice or recommendations of a committee by a federal agency unless that committee has been appropriately

chartered, has a fairly-balanced membership, and maintains its records and meetings open to the public. A group is a *de facto* FAC if it is under the "actual management or control" of a federal agency, *Am. Soc'y of Dermatology v. Shalala*, 962 F. Supp. 141, 147 (D.D.C. 1996) (citing *Wash. Legal Found. v. U.S. Sentencing Comm'n*, 17 F.3d 1446, 1450 (D.C. Cir. 1994)), and if the group is "a limited number of private citizens who are brought together to give publicized advice as a group." *Am. Soc'y of Dermatology*, 962 F. Supp. at 148.

89. The AMA RUC has become a *de facto* FAC based on CMS' and HHS' regular reliance on the recommendations of the AMA RUC and CMS' exertion of control over the AMA RUC. Further, the AMA RUC falls on the structured end of the *Clinton* continuum which triggers FACA, where a committee is "a formal group of a limited number of private citizens who are brought together to give publicized advice as a group. That model would seem covered by the statute regardless of other fortuities such as whether the members are called 'consultants.'" *Clinton*, 997 F.2d at 915. The AMA RUC certainly does not fall at the unstructured end of the *Clinton* continuum which depicts "an unstructured arrangement in which the government seeks advice from what is only a collection of individuals who do not significantly

interact with each other. That model . . . does not trigger FACA," and is not representative of the AMA RUC's interaction with CMS. *Id.* The AMA RUC is a structured committee consisting of 26 voting members and a Chairperson who regularly meet and give their advice as a group to CMS.

90. CMS and HHS rely on the advice of the AMA RUC to establish the Physician Fee Schedule and AMA RUC Chairperson Barbara Levy has previously stated that CMS adopts as much as 95% of the AMA RUC's proposed RVUs without alteration.

91. CMS and HHS have exerted control over the AMA RUC by assigning reviews of certain RVU codes and now, under the proposed PFS, by actually directing the conduct, management and timetables for valuations.

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.

93. Plaintiffs have been and will continue to suffer legal wrongs because of the agency action described herein, including Defendants' continued insistence

on adopting the AMA RUC-recommended RVUs with minimal change into the proposed Physician Fee Schedule.

94. As these actions by Defendants in permitting the Physician Fee Schedule to pass into law with recognized undervaluation of primary care codes are ongoing, and this pattern is likely to continue into the future, as evidenced by the proposed 2012 PFS, Plaintiffs have no effective remedy other than through this action that would provide the requested relief.

95. This action is ripe because although the Physician Fee Schedule is not final, Defendants' violations are capable of repetition and evading review, CMS anticipates releasing the final version of the 2012 PFS on November 15, 2011 and the PFS becomes effective law on January 1, 2012, precluding any opportunity for meaningful federal review after the release.

RELIEF REQUESTED

WHEREFORE, Plaintiffs respectfully request this Court to grant the following relief:

A. Enter judgment for Plaintiffs and against Defendants on the first claim of this complaint;

B. Declare pursuant to 28 U.S.C. § 2201 that Defendants have violated the Administrative Procedures Act by unlawfully utilizing the

American Medical Association Specialty Society Relative Value Scale Update Committee (AMA RUC) as a *de facto* Federal Advisory Committee without implementing the statutory mandates of FACA (5 U.S.C. App. § 1 *et seq.*);

C. Order Defendants to charter the AMA RUC as a FAC and to open the AMA RUC procedures to the public according to FACA mandates;

D. Enjoin Defendants from implementing the PFS to the extent that Defendants rely improperly on the AMA RUC as a *de facto* FAC;

E. Award Plaintiffs their costs of their suit herein incurred;

F. Award Plaintiffs their attorneys' fees pursuant to 28 U.S.C. § 2412 and/or any other appropriate source; and

G. Provide such other and further relief as the Court deems proper.

SECOND CLAIM FOR RELIEF

(Relief requested under the Administrative Procedures Act and independently for an agency violation of the Delegation Clause of the United States Constitution (U.S. Const. art I, § 1).)

96. Plaintiffs hereby incorporate by reference Paragraphs 1 – 95 as if fully set forth herein.

97. The Delegation Clause of the United States Constitution vests all legislative power in the United States Congress, which can designate authority to

federal agencies. However, federal agencies cannot sub-delegate their power to non-federal agencies. When a federal agency gives a non-federal agency or group final reviewing authority over the responsibilities of the federal agency, it violates the Delegation Clause.

98. CMS and HHS are responsible for the development of RVUs and the mandatory 5-year review of the RVUs. CMS and HHS have improperly delegated their authority to establish RVUs and conduct periodic reviews to the AMA RUC.

99. Defendants' actions violate the Delegation Clause in that CMS and HHS have allowed the AMA RUC to establish RVUs, a duty delegated directly to Defendants. For example, in the proposed 2012 PFS, "CMS accepted the RUC- recommended work values and direct PE inputs, without refinement, for the two new cytopathology codes that describe in situ hybridization testing using urine samples." 2012 PFS, at 101. This "acceptance" has occurred over 90 percent of the time, according to independent evaluations and Chairperson Levy.

100. Plaintiffs have been and will continue to suffer legal wrongs because of the agency action described herein, including Defendants' continued insistence on relying on the AMA RUC to carry out their delegated duties.

101. As these actions by Defendants in permitting the Physician Fee Schedule to pass into law with recognized undervaluation of primary care codes are ongoing, and this pattern is likely to continue into the future, as evidenced by the proposed 2012 PFS, Plaintiffs have no effective remedy other than through this action that would provide the requested relief.

102. This action is ripe because although the Physician Fee Schedule is not final, Defendants' violations are capable of repetition and evading review, CMS anticipates releasing the final version of the 2012 PFS on November 15, 2011 and the PFS becomes effective law on January 1, 2012, precluding any opportunity for meaningful federal review after the release.

RELIEF REQUESTED

WHEREFORE, Plaintiffs respectfully request this Court to grant the following relief:

A. Enter judgment for Plaintiffs and against Defendants on the second claim of this Complaint;

B. Declare pursuant to 28 U.S.C. § 2201 that Defendants' reliance upon the AMA RUC data to be an unconstitutional delegation of Agency power in violation of the Delegation Clause of the United States Constitution, Article I, section 1;

C. Order Defendants to comply with the mandates of 42 U.S.C § 1395 *et seq.*, including the amendments made by the ACA, and rescind their delegation of their mandatory statutory power to the AMA RUC;

D. Enjoin Defendants from implementing the Physician Fee Schedule to the extent that Defendants rely on the AMA RUC to perform their own non-delegable duty;

E. Award Plaintiffs the costs and expenses of their suit herein incurred;

F. Award Plaintiffs their attorneys' fees pursuant to 28 U.S.C. § 2412 and/or any other appropriate source; and

G. Order such other further legal and equitable relief as this Court may deem just and proper.

THIRD CLAIM FOR RELIEF

(Relief requested under the Administrative Procedures Act and independently for an agency violation of the Due Process Clause of the Fifth Amendment of the United States Constitution (U.S. Const. amend. V).)

103. Plaintiffs hereby incorporate by reference Paragraphs 1 – 102 as if fully set forth herein.

104. The Fifth Amendment to the United States Constitution prohibits arbitrary decision-making that is so unjustifiable as to be a violation of Plaintiffs' rights not to be deprived of property without due process of law.

105. CMS and HHS admit that their own data demonstrates that the primary care "evaluation and management codes" are undervalued and that the present AMA RUC-based evaluation system creates "distortions" in the payment system.

106. Defendants violate the Due Process Clause of the Fifth Amendment to the United States Constitution by their continued use of survey data collected by conflicted, self-interested specialty societies, which data the RUC chairman concedes are known to be 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.

107. Plaintiffs have been and will continue suffer legal wrongs because of the agency action described herein, including Defendants' continued insistence in the proposed Physician Fee Schedule that they will continue to utilize the AMA RUC in evaluating primary care.

108. As these actions by Defendants in permitting the Physician Fee Schedule to pass into law with recognized undervaluation of primary care codes are ongoing, and this pattern is likely to continue into the future, as evidenced

by the proposed 2012 PFS, Plaintiffs have no effective remedy other than through this action that would provide the requested relief.

109. This action is ripe because although the Physician Fee Schedule is not final, Defendants' violations are capable of repetition and evading review, CMS anticipates releasing the final version of the 2012 PFS on November 15, 2011 and the PFS becomes effective law on January 1, 2012, precluding any opportunity for meaningful federal review after the release.

RELIEF REQUESTED

WHEREFORE, Plaintiffs respectfully request this Court to grant the following relief:

A. Enter judgment for Plaintiffs and against Defendants on the third claim of this Complaint;

B. Declare Defendants' conduct with regard to their continued use of the AMA RUC-collected data, that was known to be improperly collected and not representative of the actual value of physician services, to be so lacking in rationality and arbitrary and capricious as to violate Plaintiffs' due process rights under the United States Constitution;

C. Order the Defendants to correct its Constitutional violations against Plaintiffs in a manner consistent with the duty to impose remedies

narrowly tailored to cure based upon the scope of the proved violations;

D. Enjoin Defendants from implementing the Physician Fee Schedule to the extent that Defendants relied arbitrarily and capriciously on data known to be improperly collected and not representative of the actual value of physician services;

E. Award Plaintiffs the costs and expenses of their suit herein incurred;

F. Award Plaintiffs their attorneys' fees pursuant to 28 U.S.C. § 2412 **and/or any other appropriate source**; and

G. Order such other further legal and equitable relief as this Court may deem just and proper.

FOURTH CLAIM FOR RELIEF

(Relief requested under the Mandamus Act (28 U.S.C. § 1361) for an agency violation of the Patient Protection and Affordable Care Act (Pub. L. no. 111-148, 124 Stat 119 (2010)) for failure to carry out a non-delegable duty to ensure the accuracy of the Physician Fee Schedule and under the Federal Advisory Committee Act (5 U.S.C. App. § 1 *et seq.*) for failure to follow the requirements regarding a utilized advisory committee.)

110. Plaintiffs hereby incorporate by reference Paragraphs 1 – 109 as if fully set forth herein.

111. The Affordable Care Act requires that Defendants carry out their non-delegable duty to ensure the accuracy of the Physician Fee Schedule. FACA requires that Defendants perform ministerial duties including providing access to FAC meetings, documents, and meeting minutes.

112. CMS and HHS admit that their own data demonstrates that the primary care "evaluation and management codes" are undervalued and that the present AMA RUC-based evaluation system creates "distortions" in the payment system.

113. Defendants' actions violate the ACA in that Defendants, in the proposed PFS, re-delegate authority to review the primary care codes to the AMA RUC, who already has demonstrated an inability and unwillingness to appropriately value those codes over twenty years, resulting in numerous harms, including a nationwide shortage of primary care physicians.

114. Defendants' actions violate FACA in that Defendants rely on advice and recommendations provided by the AMA RUC without chartering the AMA RUC as a FAC or meeting the other requirements of FACA for an advisory committee.

115. Plaintiffs have been and will continue to suffer legal wrongs because of the agency action described herein, including Defendants' continued insistence

in the proposed Physician Fee Schedule that they will continue to utilize the AMA RUC in evaluating primary care.

116. As these actions by Defendants in permitting the Physician Fee Schedule to pass into law with recognized undervaluation of primary care codes are ongoing, and this pattern is likely to continue into the future, as evidenced by the proposed 2012 PFS, Plaintiffs have no effective remedy other than through this action that would provide the requested relief.

117. This action is ripe because although the Physician Fee Schedule is not final, Defendants' violations are capable of repetition and evading review, CMS anticipates releasing the final version of the 2012 PFS on November 15, 2011 and the PFS becomes effective law on January 1, 2012, precluding any opportunity for meaningful federal review after the release.

RELIEF REQUESTED

WHEREFORE, Plaintiffs respectfully request this Court to grant the following relief:

A. Enter judgment for Plaintiffs and against Defendants on the fourth claim of this Complaint;

B. Declare pursuant to 28 U.S.C. § 2201 that Defendants failure to do their duties as described in the APA and FACA is contrary to law and invalid under the Mandamus Act;

C. Order Defendants to comply with the Mandamus Act by carrying out their statutorily delegated duties under the ACA and FACA, to the extent not already provided for by the Relief requested in Claims 1-3;

D. Enjoin Defendants from implementing the Physician Fee Schedule to the extent that Defendants rely on the AMA RUC in violation of their statutorily mandated duty;

E. Issue a Writ of Mandamus ordering Defendants to comply with their statutorily mandated duties;

F. Award Plaintiffs the costs and expenses of their suit herein incurred;

G. Award Plaintiffs their attorneys' fees pursuant to 28 U.S.C. § 2412 and/or any other appropriate source; and

H. Order such other further legal and equitable relief as this Court may deem just and proper.

FIFTH CLAIM FOR RELIEF

(Relief requested under the Administrative Procedures Act for an agency violation of the Patient Protection and Affordable Care Act (Pub. L. no. 111-148, 124 Stat 119 (2010)) for failure to carry out a non-delegable duty to ensure the accuracy of the Physician Fee Schedule.)

118. Plaintiffs hereby incorporate by reference Paragraphs 1 – 117 as if fully set forth herein.

119. The Affordable Care Act requires that Defendants carry out their non-delegable duty to ensure the accuracy of the Physician Fee Schedule.

120. CMS and HHS admit that their own data demonstrates that the primary care "evaluation and management codes" are undervalued and that the present AMA RUC-based evaluation system creates "distortions" in the payment system.

121. Defendants' actions violate the ACA because there is no rational basis or scientific evidence of any kind for the discriminatory treatment of physicians who provide primary care as opposed to physicians who provide procedural specialties.

122. Plaintiffs have been and will continue to suffer legal wrongs because of the agency action described herein, including Defendants' continued insistence in the proposed Physician Fee Schedule that they will continue to utilize the AMA RUC in evaluating primary care.

123. As these actions by Defendants in permitting the Physician Fee Schedule to pass into law with recognized undervaluation of primary care codes are ongoing, and this pattern is likely to continue into the future, as evidenced by the proposed 2012 PFS, Plaintiffs have no effective remedy other than through this action that would provide the requested relief.

124. This action is ripe because although the Physician Fee Schedule is not final, Defendants' violations are capable of repetition and evading review, CMS anticipates releasing the final version of the 2012 PFS on November 15, 2011 and the PFS becomes effective law on January 1, 2012, precluding any opportunity for meaningful federal review after the release.

RELIEF REQUESTED

WHEREFORE, Plaintiffs respectfully request this Court to grant the following relief:

A. Enter judgment for Plaintiffs and against Defendants on the fifth claim of this Complaint;

B. Declare pursuant to 28 U.S.C. § 2201 that Defendants' failure to ensure the accuracy of the Physician Fee Schedule is contrary to law and invalid under the ACA;

C. Order Defendants to comply with the Affordable Care Act to the extent not already provided for by the Relief requested in Claims 1-4.

D. Enjoin Defendants from implementing the Physician Fee Schedule to the extent that Defendants rely on AMA RUC to perform their own non-delegable duty;

E. Award Plaintiffs the costs and expenses of their suit herein incurred;

F. Award Plaintiffs their attorneys' fees pursuant to 28 U.S.C. § 2412 and/or any other appropriate source; and

G. Order such other further legal and equitable relief as this Court may deem just and proper.

SIXTH CLAIM FOR RELIEF

(Relief requested under 28 U.S.C. § 2201, which authorizes the granting of Declaratory Judgment and 28 U.S.C. § 2202, which authorizes further relief based on such a Declaratory Judgment.)

125. Plaintiffs hereby incorporate by reference Paragraphs 1 – 124 as if fully set forth herein.

126. Declaratory Judgment is authorized by 28 U.S.C. § 2201 for an "actual controversy within [the] jurisdiction" of the Court. *Id.* Further relief based on such a declaration is authorized under 28 U.S.C. § 2202.

127. Defendants' actions violate FACA and the APA because Defendants directly manage, utilize, and rely upon the AMA RUC in the relative valuation process that forms the basis of the Physician Fee Schedule without chartering the AMA RUC as a federal advisory committee.

128. Defendants' actions have further violated FACA by failing to ensure that the AMA RUC meetings are open to the public, failing to allow public petitioning of the AMA RUC, failing to provide public access to records of the AMA RUC meetings, and failing to ensure that the AMA RUC is constituted of members that have a balanced representation of views.

129. Attendance at the AMA RUC meetings is controlled by Chairperson Barbara Levy and only members of the AMA RUC have access to their reports and meeting papers. The members of the AMA RUC have been shown to be connected to special interest groups which have a vested interest in the outcome of the AMA RUC decisions regarding the PFS.

130. Defendants are in violation of the APA for failing to ensure that agency actions are not arbitrary, capricious, or an abuse of discretion in violation of the Due Process Clause of the Fifth Amendment to the United States Constitution. CMS and HHS admit that their own data demonstrates that the primary care "evaluation and management codes" are undervalued and that

the present AMA RUC-based evaluation system creates "distortions" in the payment system, yet Defendants still rely on this payment system in preparing the PFS.

131. Defendants are in violation of the United States Constitution for abrogating duties that were delegated to the Defendants by Congress and unlawfully sub-delegating them to the AMA RUC. Congress has delegated the responsibility of establishing RVUs to CMS and HHS and Defendants have unlawfully delegated this duty to the AMA RUC.

132. Defendants are in violation of the ACA because there is no rational basis or scientific evidence of any kind for the discriminatory treatment of physicians who provide primary care as opposed to physicians who provide procedural specialties.

133. Plaintiffs have been and will continue to suffer legal wrongs because of the agency action described herein, including Defendants' continued insistence in the proposed Physician Fee Schedule that they will continue to utilize the AMA RUC in evaluating primary care.

134. As these actions by Defendants in permitting the Physician Fee Schedule to pass into law with recognized undervaluation of primary care codes are ongoing, and this pattern is likely to continue into the future, as evidenced

by the proposed 2012 PFS, Plaintiffs have no effective remedy other than through this action that would provide the requested relief.

135. This action is ripe because although the Physician Fee Schedule is not final, Defendants' violations are capable of repetition and evading review, CMS anticipates releasing the final version of the 2012 PFS on November 15, 2011 and the PFS becomes effective law on January 1, 2012, precluding any opportunity for meaningful federal review after the release.

136. Plaintiffs have an interest in the Physician Fee Schedule and are negatively affected by the continued use of the AMA RUC in evaluating primary care. There is an actual justiciable controversy, or antagonistic claims indicating inevitable litigation, and the Court's issuance of a declaratory judgment will serve to end the controversy.

RELIEF REQUESTED

WHEREFORE, Plaintiffs respectfully request this Court to grant the following relief:

A. Enter judgment for Plaintiffs and against Defendants on the sixth claim of this Complaint;

B. Declare pursuant to 28 U.S.C. § 2201 that Defendants' reliance on the AMA RUC as an unchartered and unofficial Federal Advisory

Committee in the formation of the Physician Fee Schedule is contrary to law and invalid under the APA and FACA;

C. Declare pursuant to 28 U.S.C. § 2201 that Defendants' utilization, reliance, and management of the AMA RUC in the formation of the Physician Fee Schedule is contrary to law and invalid under the APA and FACA;

D. Declare pursuant to 28 U.S.C. § 2201 that Defendants' failure to ensure that the AMA RUC meetings are open to the public, failure to allow public petitioning of the AMA RUC, failure to provide public access to records of the AMA RUC meetings, and failure to ensure that the AMA RUC is constituted of members that have a balanced representation of views is contrary to law and invalid under the APA and FACA;

E. Declare pursuant to 28 U.S.C. § 2201 that Defendants' failure to ensure that Agency actions are not arbitrary, capricious, or an abuse of discretion is contrary to law and invalid under the Due Process Clause of the Fifth Amendment to the United States Constitution;

F. Declare pursuant to 28 U.S.C. § 2201 that Defendants' abrogation of duties that were delegated to the Defendants by Congress and sub-

delegation of those duties to the AMA RUC is contrary to law and invalid under the Delegation Clause of the United States Constitution;

G. Declare pursuant to 28 U.S.C. § 2201 that Defendants' failure to ensure the accuracy of the Physician Fee Schedule is contrary to law and invalid under the ACA;

H. Order Defendants to comply with the Administrative Procedure Act to the extent not already provided for by the Relief requested in Claims 1-5;

I. Order Defendants to comply with the Federal Advisory Committee Act to the extent not already provided for by the Relief requested in Claims 1-5;

J. Order Defendants to comply with the Due Process Clause of the Fifth Amendment to the United States Constitution to the extent not already provided for by the Relief requested in Claims 1-5;

K. Order Defendants to comply with the Delegation Clause of the United States Constitution to the extent not already provided for by the Relief requested in Claims 1-5;

L. Order Defendants to comply with the Affordable Care Act to the extent not already provided for by the Relief requested in Claims 1-5;

M. Enjoin Defendants from implementing the Physician Fee Schedule to the extent that Defendants rely on the AMA RUC as an unchartered and unofficial Federal Advisory Committee;

N. Enjoin Defendants from implementing the Physician Fee Schedule to the extent that Defendants rely on the AMA RUC without making the AMA RUC meetings, papers, and reports open to the public;

O. Enjoin Defendants from implementing the Physician Fee Schedule to the extent that Defendants arbitrarily and capriciously rely on the AMA RUC's improperly valued RVU recommendations;

P. Enjoin Defendants from implementing the Physician Fee Schedule to the extent that Defendants rely on AMA RUC to perform their own non-delegable duty;

Q. Enjoin Defendants from implementing the Physician Fee Schedule to the extent that Defendants have not guaranteed its accuracy;

R. Award Plaintiffs the costs and expenses of their suit herein incurred;

S. Award Plaintiffs their attorneys' fees pursuant to 28 U.S.C. § 2412 and/or any other appropriate source; and

T. Order such other further legal and equitable relief as this Court may deem just and proper.

Respectfully submitted,

_____

Kathleen A. Behan
Maryland Bar No. 12481
BEHAN LAW
910 17th St., NW
Suite 800
Washington, D.C. 20006
(202) 223-9005
Kathleen.Behan@kablegal.com

and

_____

Timothy F. Maloney
Maryland Bar No. 03381
Jay P. Holland
Maryland Bar No. 06051
Veronica B. Nannis
Maryland Bar No. 15679
Joseph M. Creed
Maryland Bar No. 17134
Joseph, Greenwald & Laake, P.A.
6404 Ivy Lane, Suite 400
Greenbelt, MD 20770
Phone: (301) 220-2200
Fax: (301) 220-1214
tmaloney@jgllaw.com
jholland@jgllaw.com
vnannis@jgllaw.com
jcreed@jgllaw.com