IN THE UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA
FORT LAUDERDALE DIVISION

Case No. 09-62034-Civ-Dimitrouleas

AMERICAN COLLEGE OF
CARDIOLOGY , et al.,

Plaintiffs,

vs.

KATHLEEN SEBELIUS, as SECRETARY,
U.S. DEPT. HHS,

Defendant.
____/

REPLY IN SUPPORT OF PLAINTIFFS' MOTION
FOR PRELIMINARY INJUNCTION

I. Introduction

The Opposition filed by Defendant (hereinafter, "CMS") improperly attempts to shield CMS's unlawful action from any judicial scrutiny whatsoever by asserting that this Court must defer to CMS's administrative expertise and that this Court lacks jurisdiction to review CMS's compliance with federal statutes. Distressingly, CMS has overstated its discretion and understated this Court's authority to review CMS's violation of federal law. There is no federal statute that excuses CMS's violation of federal law, nor is there any federal statute that precludes this Court from providing injunctive relief vitally important to protect the safety of Medicare beneficiaries. Furthermore, CMS in a strident but ineffective manner, attempts to dismiss the significant evidence submitted by Plaintiffs in support of their motion for a preliminary injunction. As explained in greater detail herein, the evidence presented by Plaintiffs' Motion

for Preliminary Injunction, and the evidence to be presented at the January 13, 2010 hearing, demonstrate that Plaintiffs have satisfied all the elements needed for a preliminary injunction. Accordingly, Plaintiffs' Motion for Preliminary Injunction should be granted.

II. **This Court Has Jurisdiction to Hear Plaintiffs' Claims**

In order to accept CMS's position that Plaintiffs' claims are not subject to judicial review, this Court would have to accept the proposition that CMS has unbridled discretion to use any practice expense data it desires, or to use no data at all, despite a mandate from Congress directing CMS to use data that meet statutory standards. Such a proposition is not supported by the language of the Medicare statute, is inconsistent with any of the jurisprudence applicable to the facts of this case, and would unconstitutionally abridge plaintiffs' right to judicial review and the judiciary's prerogative to review the acts of the executive branch. Therefore, this Court should not accept the Government's position that jurisdiction is lacking with regard to the Plaintiffs' claims.

A. **Judicial Review Is Not Precluded By 42 U.S.C. § 1395w-4(c)**

CMS asserts that the Court lacks jurisdiction pursuant to 42 U.S.C. § 1395w-4(i)(1). Defendant's Memorandum in Opposition to Plaintiffs' Motion for Preliminary Injunction (hereafter cited to as "DE 18") at 14. Jurisdiction is proper in this case because Plaintiffs are not complaining of any action or inaction on the part of CMS that is insulated from judicial review under 42 U.S.C. § 1395w-4(i)(1). CMS's efforts to deny Plaintiffs judicial recourse to address the substantial defects in the PPIS data, on the basis of 42 U.S.C. § 1395w-4(i)(1), should therefore be rejected.

A federal statute that denies judicial review of federal agency decisions raises serious Constitutional questions. *Bowen v. Michigan Academy of Family Physicians*, 476 U.S. 667, 681

n. 12 (1986). Accordingly, statutes purporting to preclude judicial review should be narrowly construed and enforced only when the Congressional intent to insulate agency action is clear and unambiguous. *See id*. at 670; *Sharkey v. Quarantillo*, 541 F.3d 75, 84 (2d Cir. 2008) ("statutory limitations on judicial review should be interpreted narrowly in light of the APA's strong presumption in favor of judicial review"); *Belles v. Schweiker*, 720 F.2d 509, 512 (8th Cir. 1983).

In this case, strictly construing the language in 42 U.S.C. § 1395w-4(i)(1) demonstrates that it does not apply to *every* action of CMS however marginally related it may be to the issuance of a Medicare physician fee schedule. Rather, this section is clear that judicial review is precluded only as to specifically enumerated claims:

> (1) Restriction on administrative and judicial review.—There shall be no administrative or judicial review … of—
>
> (A) the determination of the adjusted historical payment basis (as defined in subsection (a)(2)(D)(i)),
>
> (B) the determination of relative values and relative value units under subsection (c), including adjustments under subsections (c)(2)(F), (c)(2)(H), and (c)(2)(I) and section 13515(b) of the Omnibus Budget Reconciliation Act of 1993,
>
> (C) the determination of conversion factors under subsection (d), including without limitation a prospective redetermination of the sustainable growth rates for any or all previous fiscal years,
>
> (D) the establishment of geographic adjustment factors under subsection (e), and
>
> (E) the establishment of the system for the coding of physicians' services under this section.

CMS asserts that judicial review is barred by Section 1395w-4(i)(1)(B) because Plaintiffs' claims purportedly relate to "the determination of relative values and relative value

units [("RVUs")] under 42 U.S.C. § 1395w-4(c)."[1] DE 18 at 7. However, Plaintiffs' claims do not challenge CMS's computation of RVUs under subsection (c) of the statute. Thus, Plaintiffs' claims do not fall within Section 1395w-4(i)(1)(B) or any of the five enumerated provisions of Section 1395w-4(i)(1). The bar on judicial review does not apply to every claim involving RVUs, but rather, only applies to claims challenging "the determination of relative values and relative value units under subsection (c)" of the statute. *See* 42 U.S.C. § 1395w-4(i)(1)(B).

In this case, Plaintiffs do not allege a claim arising under subsection (c) of the statute. Instead, Plaintiffs allege that CMS's use of invalid and unreliable PPIS data regarding cardiology practice expenses for the 2010 PFS Rule violated the clear mandates of federal law found in Section 212 of the Balanced Budget Refinement Act of 1999 ("BBRA") (Pub. Law 106-113). *See*, *e.g.,* Compl. ¶¶21-26. Plaintiffs further allege that CMS's use of the PPIS data was arbitrary and capricious, and that CMS denied access to the PPIS data, thereby denying Plaintiffs a meaningful opportunity to comment during the rulemaking process, in violation of the Administrative Procedure Act and Section 212 of the BBRA. *See, e.g.,* Compl. ¶ 104.

Section 212 of the BBRA, entitled "Use of Data Collected by Organizations and Entities in Determining Practice Expense Relative Values," requires CMS to obtain practice expense data using "sound data practices":

> "Secretary … shall establish by regulation (after notice and opportunity for public comment) a process (including data collection standards) under which the Secretary *will* accept for use and *will* use, to the maximum extent practicable and consistent with ***sound data practices***, data collected or developed by entities and organizations (other than the

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[1] Section 1395w-4(c), in pertinent part, requires CMS to divide the relative values into three components – work, practice expense, and malpractice; requires CMS to develop a methodology for combining the three components into a single relative value for each service; requires CMS to periodically review and adjust the relative values; requires CMS to compute RVUs for each of the components of a physician's service; and requires CMS to determine a work percentage, practice expense percentage, and malpractice percentage of each physician's service.

> Department of Health and Human Services) to supplement the data normally collected by that Department in determining the practice expense component under …42 U.S.C. 1395w-4(c)(2)(C)(ii) for purposes of determining relative values for payment for physicians' services under the fee schedule under section …1395w-4" (emphasis added).

Importantly, the mandates in Section 212 of the BBRA are not duplicative of or incorporated into CMS's statutory obligations under Section 1395w-4(c)(2)(C), but rather, stand alone and supplement CMS's responsibilities under Section 1395w-4(c)(2)(C). Indeed, the fact that Section 212 expressly refers to Section 1395w-4 indicates that Congress intended to bind CMS to compliance with both statutes and did not intend Section 1395w-4(i) to preempt or supersede Section 212. One federal statute should not be construed to preempt another federal statute absent an express indication that Congress intended such a result. *See U.S. v. Norquay*, 905 F.2d 1157, 1160 (8th Cir. 1990) ("we are mindful of our duty to regard each statute as effective whenever possible, absent a clearly expressed Congressional intent to the contrary"), *citing Ruckelshaus v. Monsanto Co*., 467 U.S. 986, 1018 (1984). Thus, this Court is not barred from reviewing CMS's compliance with Section 212.

Furthermore, Plaintiffs are ***not*** challenging CMS's actions under any of the relevant provisions of subsection 1395w-4(c)[2], to wit:

- Subsection (c)(1) requires CMS to divide the relative values into three components – work, practice expense, and malpractice. Plaintiffs are not challenging CMS's division of the relative values into components.
- Subsection (c)(2)(A) requires CMS to develop a methodology for combining the three components into a single relative value for each service. Plaintiffs are not challenging CMS's methodology for combining the components.
- Subsection (c)(2)(B) requires CMS to periodically review and adjust the relative values. Plaintiffs are not challenging CMS's obligation to review or adjust the relative values.
- Subsection (c)(2)(C) requires CMS to compute RVUs for each of the components of a physician's service. Subsection (c)(2)(C) requires CMS to determine the practice expense

[2] The remaining subsections of Section 1395w-4(c) are not discussed here as they are not relevant (nor are they alleged by the Government to be relevant) to the issue in this case, namely whether CMS's use of the PPIS data to determine practice expenses for cardiology services was lawful.

RVUs for 2010 based entirely on practice expense resources. Plaintiffs are not challenging CMS's obligation to determine the 2010 RVUs or the 2010 practice expense RVUs based on practice expense resources.

- Subsection (c)(3) requires CMS to determine a work percentage, practice expense percentage, and malpractice percentage of each physician's service. Plaintiffs are not challenging CMS's obligation to determine percentages of the components of cardiology services.

Thus, Plaintiffs are not raising any claim under Section 1395w-4(c), which delegates to CMS limited discretion regarding the manner in which it computes RVUs. Plaintiffs' claims do not involve a challenge to CMS's computation of RVUs, nor do Plaintiffs seek to compel CMS to perform particular computations or even use a particular methodology. Rather, Plaintiffs are challenging CMS's unlawful use of the defective PPIS cardiology practice expense data, in violation of the mandates of Section 212 of the BBRA and the APA. While CMS has limited discretion regarding the computation of RVUs, CMS does not have the discretion to compute RVUs using data that violate statutory requirements, nor may the Government assert that CMS's violation of those statutory requirements is shielded from judicial review.

CMS's Opposition ignores the fact that, for the purpose of determining the practice expense component of the RVUs, *Section 212 of the BBRA is a statutory obligation of CMS separate and apart from 42 U.S.C. § 1395w-4(c).* CMS must satisfy the legislative mandates of *both* Section 212 of the BBRA and 42 U.S.C. § 1395w-4(c) before it may lawfully impose payment rates on physicians and Medicare beneficiaries. In this case, CMS has failed to comply with its obligations to determine practice expenses using a valid, reliable survey of data, pursuant to the clear unambiguous mandates of Section 212 of the BBRA.

Moreover, CMS, by denying Plaintiffs access to the PPIS data during the rulemaking process, has failed to comply with the notice-and-comment rulemaking requirements set forth in 5 U.S.C. § 553. Indeed, Section 212(a) of the BBRA expressly commands CMS to provide

"notice and opportunity for public comment" regarding CMS's process for practice expense data collection. There is nothing in Section 1395w-4(i)(1) that precludes judicial review of CMS's violation of APA rulemaking requirements simply because CMS's rule relates to physician fees schedules.

CMS's interpretation of Section 1395-w-4(i)(1) would permit CMS to ignore the express mandates of: (1) Section 212 of the BBRA – a statutory provision *not* incorporated into any provision of Section 1395w-4, and that also governs CMS's development of payment rates for cardiology services, and (2) the rulemaking requirements of the APA. If CMS's argument were accepted, CMS would have unfettered discretion to develop Medicare payment rates without any judicial review or other oversight to ensure the agency's compliance with federal law. Moreover, under CMS's flawed interpretation of the statute, Plaintiffs would have no right to redress in this Court or any court even though CMS decided to develop payment rates for cardiologists using data that was kept from the public and developed payment rates based on practice expense data that failed to meet applicable standards. This is not the law, and CMS's arguments against jurisdiction in this case must be rejected.

CMS's jurisdictional challenge relies upon *American Society of Cataract and Refractive Surgery v. Thompson*, 279 F.3d 447 (7th Cir. 2002). In that case, plaintiff medical societies challenged CMS's "transition formula" for physician practice expenses, which CMS determined under 42 U.S.C. § 1395w-4(c). *See American Society of Cataract and Refractive Surgery,* 279 F.3d at 449-50. The Seventh Circuit concluded that claim was not subject to judicial review. *Id.* at 452. Likewise, in *American Society of Anesthesiologists v. Shalala*, 90 F. Supp.2d 973 (N.D. Ill. 2000), the plaintiff-physicians' action included a challenge to CMS's "exclusion of actual expenses in her determination of the practice expense relative value units." *Id.* at 974 n. 1. The

court found that the plaintiffs' claims challenged the "subject matter of the selfsame Subsection (c) that is insulated from judicial review…." *Id* at 976. Thus, the case law indicates that the critical inquiry is whether a plaintiff's claim challenges CMS's computation of practice expenses conducted pursuant to Section 1395w-4(c).

In stark contrast to the cases cited by CMS, Plaintiffs' claims herein do *not* challenge CMS's transition formula, exclusion of practice expenses, or any other computation performed by CMS pursuant to Section 1395w-4(c). Plaintiffs are challenging CMS's use of data that was gathered and tabulated from a source outside the agency, but for which CMS is responsible to ensure that it met sound data practices. CMS wrongly claims it can shirk this responsibility with impunity. Thus, the jurisdiction bar Section 1395w-4(i)(1) does not apply to this particular case.

Finally, it must be recognized that the cases relied upon by the Government were limited to plaintiff-physicians asserting that Medicare reimbursement under a physician fee schedule was unlawfully reduced. In applying Section 1395w-4(i)(1), some federal courts have stated that if physicians are not satisfied by rates paid under the physician fee schedule, physicians may opt not to provide services to Medicare beneficiaries. *See e.g. Painter v. Shalala*, 97 F.3d 1351, 1357-58 (10th Cir. 1996). Here, by contrast, Plaintiffs claim that the unlawful rates issued by CMS will result in the elimination of medically necessary cardiology services to Medicare beneficiaries. *See e.g.* Compl. ¶¶ 77-86. Medicare beneficiaries faced with the loss of access to cardiology services do not have the "option" of forgoing medically necessary services. Thus, the cases relied upon by the Government are inapposite to Plaintiffs' claims in this proceeding.

In short, Section 1395w-4(i)(1) does not preclude judicial review of Plaintiffs' claims. Thus, Plaintiffs' claims are properly within this Court's jurisdiction.

B. **Judicial Review Is Not Precluded By 42 U.S.C. § 405(h)**

CMS incorrectly asserts that 42 U.S.C. § 405(h), as incorporated into the Medicare statute by 42 U.S.C. § 4395ii, defeats this Court's jurisdiction over Plaintiffs' claims. DE 18 at 9-11. The Supreme Court has held that, as a general rule, Section 405(h) requires claims under the Medicare Act to be channeled through the administrative review process. *Shalala v. Illinois Council on Long Term Care*, 529 U.S. 1, 12-13 (2000). However, the Supreme Court's decision in *Illinois Council* has expressly recognized an important exception to the general rule: Section 405(h) 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." *Id*. at 16-17, *citing Bowen v. Michigan Academy of Family Physicians*, 476 U.S. 667, 681 (1986).

Following *Illinois Council*, the so-called "*Michigan Academy*" exception has been applied in instances where, like here, the application of Section 405(h) would mean "no review at all." *See, e.g., Binder & Binder v. Barnhart*, 481 F.3d 141, 149 (2d Cir. 2007) (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) (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 23, 30 (D.D.C. 2002) (denial of jurisdiction would leave plaintiff without "adequate proxy in the administrative review process"); *Sharp Healthcare v. Leavitt*, 555 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) 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”).

As Plaintiffs have clearly stated, the reduction in payment for cardiology services under the PFS Rule will immediately result in the loss of cardiology services to Medicare beneficiaries. Comp. ¶ 81. Put bluntly, CMS’s PFS Rule will lead to medically necessary cardiology services not being delivered, thus there will be ***no*** claim for Medicare reimbursement that could even hypothetically be “channeled” through an administrative process. As the Government acknowledges, “physicians need only provide a service to a Medicare beneficiary after January 1, 2010; have that claim processed; and, if dissatisfied with their payment, file an appeal with an ALJ…” DE 18 at 11 n. 4. Of course, the Government’s suggestion misses the point: the PFS Rule will immediately result in lost access to medically necessary services, and there is no administrative mechanism thus far invented by CMS that would permit a beneficiary to challenge the amount of payment for services that never were delivered.

This is one of those atypical cases that falls squarely within the exception to Section 405(h) and, therefore, this Court may properly exercise jurisdiction over Plaintiffs’ claims.

III. Plaintiffs Are Entitled To A Preliminary Injunction

Having spent the majority of its brief attacking this Court’s jurisdiction, CMS offers little more than perfunctory arguments against the merits of Plaintiffs’ request for injunctive relief. As addressed below, the arguments made by CMS against injunction are weak and unavailing.

A. Plaintiffs Are Likely to Succeed on The Merits

1 CMS is Not Entitled to Deference When It Acts in a Manner That is Arbitrary, Capricious and Contrary to Its Federal Statutory Duties

Plaintiffs do not dispute that CMS is entitled to limited deference. However, as stated by the Supreme Court, “deference to the Secretary […] has important limits: A regulation cannot

stand if it is arbitrary, capricious, or manifestly contrary to the statute." *Ragsdale v. Wolverine World Wide*, 535 U.S. 81, 86 (2002) (internal quotations omitted). An agency rule is "arbitrary and capricious if the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins.*, 463 U.S. 29, 43 (1983). Under circumstances that were very similar to the present case, the Eleventh Circuit reversed a CMS rule when CMS "failed to give the facts" underlying the study cited in support of its rule, "failed to discuss adequately the [study's] flaws," and "did not consider reasonably obvious alternatives." *Lloyd Noland Hosp. and Clinic v. Heckler*, 762 F.2d 1561, 1567 (11th Cir. 1985). Thus, CMS's departure from its previous rule on the basis of a clearly flawed study was "arbitrary and capricious." *Id.* at 1568.

The Eleventh Circuit's precedent is compelling and controlling on this point. Furthermore, Plaintiffs note that the Eleventh Circuit is in good company in holding that CMS may not justify a rule on the basis of obviously flawed survey data. As noted by the Fourth Circuit in a similar case:

> We note at the outset that the challenged regulation has spawned extensive litigation, and that to date, six other circuits have considered challenges to its validity. All but one have found the rule invalid; and the one remanded with expression of doubt as to validity. See DeSoto General Hospital v. Heckler, 766 F.2d 182 (5th Cir.1985) (affirming district court judgment insofar as it invalidated the new rule); Lloyd Noland Hospital and Clinic v. Heckler, 762 F.2d 1561 (11th Cir.1985) (affirming district court judgment invalidating the new rule); St. James Hospital v. Heckler, 760 F.2d 1460 (7th Cir.1985) (affirming district court judgment invalidating the new rule); Humana of Aurora, Inc. v. Heckler, 753 F.2d 1579 (10th Cir.1985) (reversing a district court judgment upholding the new rule); Abington Memorial Hospital v. Heckler, 750 F.2d 242 (3d Cir.1984) (affirming district court judgment invalidating the new rule); and Walter O. Boswell Memorial Hospital v. Heckler, 749 F.2d 788 (D.C.Cir.1984) (raising serious questions regarding the Secretary's rulemaking, but ultimately remanding because

the parties failed to submit a complete administrative record for consideration by the district court).

Bedford County Memorial Hosp. v. HHS, 769 F.2d 1017, 1019 -1020 (4th Cir. 1985).

As with *Lloyd Nolan* and the related cases, here CMS has failed to explain its decision to use the PPIS data in the face of compelling substantive critiques of the PPIS data, which were raised by both public comments to the proposed rule and the findings of CMS's own consultant. In addition, CMS has failed to consider an obvious alternative to the flawed PPIS data, *i.e.*, the SS data, which satisfies applicable survey standards, is consistent with sound data practices and has been used by CMS until CMS switched to the PPIS for the 2010 physician fee schedule. Therefore, CMS's rulemaking is arbitrary and capricious and clearly exceeds the deference that should be afforded by this Court.

2. PPIS is Not Representative of Cardiology Practice Expenses

CMS defends the representativeness of the PPIS cardiology practice expense data by claiming that there is no "gold standard" for survey data. DE 18 at 24-26, citing Lewin Report at 7. CMS's assertion misses the point. Regardless of whether there is a "gold standard," the Supplemental Survey ("SS") is clearly more representative than the PPIS with respect to cardiology practice expenses.

CMS's opposition memorandum fails to confront the conclusion of CMS's own consultant (Lewin) that "benchmark data available to us suggest that the SS PE more closely approximate the cardiology practice populations that the PPIS PE at least as evidence by other benchmarks." Lewin Report (Exhibit 3 to Plaintiffs' Motion for Preliminary Injunction) at 7. Dr. Henry Miller confirmed Lewin's conclusion and testified that the representativeness of the SS relative to the cardiologist population made the SS clearly superior to the PPIS. Miller Decl. (Exhibit 12 to Plaintiffs' Motion for Preliminary Injunction) at ¶ 27. The superiority of the SS is

further corroborated by the fact that the SS data is consistent with the other available benchmarks, *i.e*., MedAxiom and MGMA, while the PPIS data deviates significantly from all other benchmarks for determining practice expenses. Miller Decl. at ¶ 22.[3]

Thus, leaving aside the notion of a "gold standard," the critical fact that CMS fails to confront is that it elected to use the PPIS despite undisputed evidence in the rulemaking record that the SS practice expense data for cardiology was clearly more representative than the PPIS data. CMS's decision is arbitrary and capricious, in violation of the APA. The issue is not CMS's failure to use a "gold standard." The salient point is that CMS clearly failed to use sound data practices in collecting practice expense data for cardiology services, in violation of federal law.

CMS suggests that any lack of representativeness in the PPIS of cardiology practice expense that is attributable to the extremely low response rate among cardiologists is the fault of cardiologists, and not a basis for attacking the PPIS. DE 18 at 28 n. 14. There is no factual support for the assertion that cardiologists were substantially less responsive to the PPIS relative

[3] CMS attempts to dodge the impact of Dr. Miller's testimony by asserting that Dr. Miller's expert opinion is outside the rulemaking record. DE 18 at 26-27. That assertion, however, is incorrect. Dr. Miller's opinions were included as part of Plaintiff ACC's comments filed with CMS on December 28, 2009. Exhibit 2 to Plaintiffs' Motion for Preliminary Injunction. Alternatively, CMS asserts that Dr. Miller's report submitted during the comment period is untimely because it was submitted during the comment period allowed after the final rule was adopted, rather than while the rule was in the proposed phase. DE 18 at 26-27. After CMS adopted the PFS Rule on November 25, 2009, it permitted public comments on the final rule through December 29, 2009. 74 Fed. Reg. 61738 (Nov. 25, 2009). Dr. Miller's opinions were timely delivered to CMS before the December 29, 2009 deadline. CMS fails to cite any authority for the proposition that Dr. Miller's comments submitted during the extended comment period cannot be part of the rulemaking record. Finally, it is important to note that the flaws in the PPIS were raised by the ACC in its comments to the proposed rule (Exhibit 1 to Plaintiffs' Motion for Preliminary Injunction), as well as by many other physician groups. CMS notes the criticism of PPIS in the final rule. *See e.g*. 74 Fed. Reg. 61738, 61750 (Nov. 25, 2009). Thus, CMS cannot claim any "surprise" regarding the criticism of the PPIS data. CMS simply chose to ignore the public comments on the proposed rule before CMS adopted the final rule.

to other medical specialties, and the assertion is wrong. The statistical mean response rate was 142 responses and the cardiologists response rate was in line with other groups. The response rate, which was a phenomenon across all specialties included in the PPIS, is attributable to the defects in the PPIS as a survey tool. Miller Decl. ¶¶ 20-27.

CMS asserts that the PPIS does not need to meet a precision standard. DE 18 at 29. However, CMS fails to refute the statement of Dr. Henry Miller that a survey which is not subjected to an appropriate precision standard is statistically invalid. Miller Decl. at ¶ 28. CMS contends that the PPIS of cardiology practice expenses had a precision level of 15%. DE 18 at 29. However, a 15% precision level is inadequate to have statistical validity, and at 15% precision, the PPIS was clearly inferior to the SS, which had a far more accurate precision level of 5%. Miller Decl. at ¶ ¶ 16, 28.[4] Therefore, CMS's decision to use the PPIS practice expense data for cardiology services is arbitrary and capricious, in violation of the APA.

In sum, the PPIS fails to satisfy survey standards regarding the representativeness and precision of physician practice expense data. The PPIS fails to comply with sound data practices, as confirmed by Dr. Henry Miller.

Section 212 of the BBRA, entitled "Use of Data Collected by Organizations and Entities in Determining Practice Expense Relative Values," requires CMS to obtain practice expense data using "sound data practices":

> "Secretary … shall establish by regulation (after notice and opportunity for public comment) a process (including data collection standards) under which the Secretary *will* accept for use and *will* use, to the maximum extent practicable and consistent with ***sound***

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[4] While the PPIS data for cardiology practice expenses barely satisfied the 15% precision standard that CMS established as a maximum permissible level, the practice expense data for other specialties exceeded the allowable precision standard. For example, radiology had a precision level of 22%. Lewin Report at 4. Thus, Plaintiffs noted in their motion for preliminary injunction that the PPIS did not satisfy CMS's precision standard with respect to all medical specialties, a fact that CMS is reluctant to acknowledge. DE 18 at 29.

> ***data practices***, data collected or developed by entities and organizations (other than the Department of Health and Human Services) to supplement the data normally collected by that Department in determining the practice expense component under …42 U.S.C. 1395w-4(c)(2)(C)(ii) for purposes of determining relative values for payment for physicians' services under the fee schedule under section …1395w-4" (emphasis added).

CMS's decision to use the PPIS data for cardiology practice expenses violates CMS's obligation under Section 212 of the BBRA to use survey data that complies with "sound data practices." Moreover, CMS decided to use the PPIS data in the face of evidence from its own consultant (Lewin), as well as public comments, that the SS data met all applicable survey standards and was clearly superior to the PPIS data. CMS claims that it did not have access to the PPIS (DE 18 at 31), a questionable assertion given the fact that CMS retained and paid the American Medical Association to conduct the PPIS on behalf of CMS. CMS highlights a comment from the AMA that it neither endorses nor disputes any individual specialty survey results, noting that the survey was conducted in what it asserted was a fair and equitable manner across specialties. DE 18 at 10. It is an essential point that the data were collected using specialty-specific methods and are being used in a specialty-specific manner. If CMS did not seek or have access to the data it was using to set specialty-specific PE/HR, and if the AMA did not endorse it, how can anyone be assured it was collected and used in a manner consistent with sound data practices? It appears each of CMS and the AMA is "washing its hands" of any responsibility to offer this assurance as required by law. In any event, CMS acknowledges that it did not have access to the raw survey data from the PPIS. DE 18 at 31. CMS's use of the PPIS data that it did not – and could not- validate for compliance with CMS's statutory obligation to use sound data practices, is the epitome of arbitrary and capricious agency action. Accordingly, Plaintiffs are likely to prevail on the merits.

B. Plaintiffs Will Suffer Irreparable Injury

Ignoring the central impetus for seeking injunctive relief, and all actions taken by the Plaintiffs before filing their Complaint, CMS simplistically argues that Plaintiffs' claims address nothing more than the distribution of federal dollars, and is untimely. As addressed below, these arguments are wrong.

1. The PFS Rule Will Lead to A Loss of Cardiology Services

The PFS Rule will impose a drastic reduction in Medicare payments for cardiology services as a result of its reliance on the defective PPIS cardiology practice expense data. The drastic rate reductions to be imposed under the PFS Rule for 2010 will bring Medicare payments below operating costs. Lourie Decl. at ¶8.

As a result of the Medicare payment cuts to be imposed under the PFS Rule effective January 15, 2010, cardiologists will take drastic measures. Some cardiologists will be forced to curtail services to their Medicare patients. Some will discontinue all non-emergency services to Medicare patients. Some will discontinue certain diagnostic services to Medicare patients. Erb Decl. at ¶11; Lourie Decl. at ¶9. This reduction in services provided by cardiologists in private practice will force Medicare beneficiaries to seek those services from hospitals on an outpatient basis. This shift will result in the absence of community based services in some communities and substantial delays in others. thus resulting in delay in obtaining outpatient cardiology services. Moreover, the significantly higher cost to Medicare beneficiaries of obtaining those services in a hospital will lead beneficiaries to avoid or substantially delay seeking medically necessary cardiology services. Seigel Decl. at ¶9. Given the serious nature of many cardiac diseases, delay in receiving cardiac diagnostic testing and other cardiology services poses a significant threat to patient safety. Erb Decl. at ¶12; Lourie Decl. at ¶6.

CMS asserts that Plaintiffs' evidence of immediate, irreparable injury is "speculative." DE 18 at 34. That assertion ignores the evidence presented by Plaintiffs. While CMS asserts (based on pure speculation) that the rate cuts for cardiology services are not significant enough to cause a loss of cardiology services (DE 18 at 35), cardiologists have testified under oath that the rate cuts are large enough to force them to immediately curtail cardiology services. For example, Dr. Lourie testified that:

> If the 2010 Physician Fee Schedule goes into effect, *I will immediately* take a number of actions in response to these inadequate payment rates. First, I will be *forced to discontinue providing echocardiograms and nuclear imaging studies*. Second, I also will be unable to afford to leave my office to go to a local hospital to perform these diagnostic tests, or to provide evaluation and management services to patients in the hospital. Moreover, I will no longer be able to take call from the local hospital emergency rooms. Finally, I will shift toward a primary care practice and phase out cardiology services as soon as possible consistent with the needs of my patients.

Lourie Decl. at ¶ 9 (emphasis added). Other physicians have provided similar testimony. Erb Decl. at ¶ 11. The imminent loss of medically necessary cardiology services for Medicare beneficiaries is not speculative; it clearly constitutes irreparable injury. *See Independent Living Center,* 572 F.3d at 658 (law imposing Medicaid rate cuts leading to denial of necessary medical care creates irreparable injury to plaintiff-beneficiaries); *McLaughlin*, 801 F. Supp. at 644 (plaintiff faces irreparable injury if Medicaid program not enjoined from denying plaintiff access to medically necessary treatment); *Mt. Sinai Medical Center*, 425 F. Supp. at 8 (curtailment of medical services that would result from reduction in Medicare payment constitutes irreparable injury*); see also Doe 1-13 by and through Doe Sr. 1-13 v. Chiles*, 136 F.3d 709, 721-23 (11th

Cir. 1998) (affirming injunction against state Medicaid agency that delayed beneficiaries' access to health care services).[5]

2. Plaintiffs' Request for Preliminary Injunction is Timely

CMS argues that Plaintiffs' request for an injunction should be denied because "Plaintiffs… waited 59 days" after the final rule became available for inspection to file their claim for injunctive relief. DE 18 at 36. The only support CMS provides for its position is a series of cases, none from an Eleventh Circuit Court, in which courts found that a delay by the party seeking an injunction weighed against the granting of the injunction. *Id.* at 36-37. Notably, in not one of the cases cited by CMS is there any discussion or evidence of the efforts made by the party seeking the injunction to resolve the dispute through avenues other than injunctive relief or of the party seeking the injunction providing an explanation for the asserted delay. Where a party seeking an injunction has been diligent in seeking a remedy other than injunctive relief and/or has an explanation for the delay in seeking an injunction, the delay will not weigh against the granting of the injunction. *Jacksonville Coalition for Voter Protection v. Hood*, 351 F.Supp. 2d 1326, 1328, 1332 (M.D. Fla. 2004) (granting an injunction where there was over a two month delay in seeking injunctive relief); *Moltan Co. v. Eagle-Picher Industries, Inc.*, 55 F.3d 1171, 1176 (6th Cir. 1995) (affirming the grant of an injunction where there was almost a two year delay in seeking injunctive relief); *Powell v. Home Depot U.S.A., Inc.*, 2009

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[5] CMS asserts that it considered the differences between the surveys for cardiology expenses and determined that to minimize the impact. CMS relies heavily on its argument that CMS transitioned the new PE/HR over four years. DE 18 at 10-11. However, CMS fails to acknowledge that one of the most significant tests used for early diagnosis of cardiac disease, nuclear stress tests, for example, which are performed in the majority of cardiology practices, was not transitioned and the full impact is being borne in the 2010 PFS. The lack of transition for nuclear stress testing will result in an immediately imposed, negative decrease of the reimbursement for this test in 2010. The impact and the result of this decrease, as confirmed by Drs. Seigel and Erb, is directly related to the discontinuation of these services in physician offices.

WL 3855174, *13 (S.D. Fla. 2009) (recognizing that a delay in seeking injunctive relief can be excused by an explanation). Here, Plaintiffs were diligent in pursuing their claim and any delay in Plaintiffs filing their Complaint was not due to Plaintiffs sitting on their rights, but rather, was due to Plaintiffs' attempts to resolve this dispute through means other than seeking an injunction.

Both *Moltan Co.* and *Jacksonville Coalition* demonstrate that any delay by Plaintiffs in seeking injunctive relief should not weigh against the grant of injunctive relief. In *Moltan Co.* a party seeking an injunction waited almost two years to file for an injunction and the party against whom the injunction was sought argued that this delay should have barred the injunction. 55 F.3d at 1176. The Court dismissed this argument because the party seeking the injunction did not "'sit' on it rights" but rather actively sought to resolve the dispute by discussing the issue with the other party, filing complaints with state agencies and contacting the customers of the other party. *Id.* The Court held that it would "not penalize [the party seeking the injunction] for attempting to use other avenues to resolve the dispute" and upheld the issuance of a preliminary injunction. *Id.*

A similar result was reached in *Jacksonville Coalition*. In *Jacksonville Coalition*, the plaintiffs sought an injunction to require a Florida county to have additional early polling venues. 351 F.Supp. 2d at 1329. The defendants argued that the injunction should be denied based on the plaintiffs' delay in filing for injunctive relief in light of the proximity to the election. *Id.* at 1332. Particularly, the plaintiffs' motion was filed on October 19, 2004 at a point when early voting was almost half over and plaintiffs admitted that they were aware in "July/early August" of the number of early polling venues the county planned and yet still waited until October 19 to file for injunctive relief. *Id.* at 1328, 1332. Despite the plaintiffs delay in seeking injunctive

relief the Court refused to weigh the delay against the plaintiffs' right to injunctive relief.

Specifically, the Court held:

> While Plaintiffs were aware of the situation by mid-August, Plaintiffs did not file suit earlier because they were engaged in the great American tradition of negotiating…. Plaintiffs were first involved in discussions with state and local officials at the Supervisor of Elections office. Then, when it was determined that such discussions were fruitless, Plaintiffs turned to their politicians, including the City Council and Mayor, to request financial and public support for early voting sites. These attempts were made in hopes of reaching an amicable solution without engaging the judicial branch of the government. **The Court will not punish Plaintiffs for their decision to try other governmental channels before seeking judicial redress given that Plaintiffs filed suit in a timely fashion once other channels partial "came up dry."**

Id. at 1332. (emphasis added).

The situation here is analogous to those in *Moltan Co.* and *Jacksonville Coalition*. Here, the Plaintiffs pursued all avenues available to them, other than injunctive relief, in attempt to prevent the use of the defective survey data in the PFS Rule. As will be demonstrated at the hearing, as soon as Plaintiffs became aware that CMS intended to rely on defective survey data in setting the Medicare payment rates for cardiology services under the PFS Rule, the Plaintiffs took immediate action. The Plaintiffs held meetings with the Secretary and various senior members of CMS, sought legislative remedies; and met with counsel for CMS. Once CMS issued the final rule, Plaintiffs efforts to prevent the use of the defective data only intensified. In the time between the issuance of the final rule and Plaintiffs filing for injunctive relief, Plaintiffs met with numerous Representatives and Senators, continued communicating with CMS both in person and in writings and took steps to bring the issue to the public's attention. Plaintiffs did everything in their power to find a resolution to this dispute without judicial involvement. It was only after Plaintiffs determined that their efforts were to no avail, that Plaintiffs sought injunctive relief. Those efforts were unsuccessfully, but Plaintiffs did not "sit on [their] rights" and only

filed for injunctive relief once it was determined that Plaintiffs pursuit of other avenues of relief was "fruitless." *Id.*; *Moltan Co.*, 55 F.3d at 1176. As both the *Moltan Co.* and the *Jacksonville Coalition* courts recognized, Plaintiffs should not be penalized for attempting to pursue other avenues of relief before seeking judicial redress. In short, Plaintiffs' request for injunctive relief is timely.

C. <u>The Balance of Relative Harms Favors the Granting of Injunctive Relief</u>

CMS asks this Court to excuse CMS's failure to follow the law because allegedly "giving plaintiff cardiologists the additional Medicare dollars they seek would correspondingly reduce the fees that the Secretary has determined are appropriate for other physicians who treat Medicare beneficiaries." DE 18 at 3. More to the point, Defendants seek to avoid the consequences of their own unlawful actions by claiming a parade of horribles - "enormous administrative burden and confusion [--] would ensue if plaintiffs were given the relief they seek and an entirely new Medicare physician fee schedule were required to be developed at this late date – an exercise that could take months." *Id.* CMS has already acknowledged that inaccurate fee schedule reimbursement disrupts the health care delivery system and determined all physician claims should be held while the problem is fixed. *See* Exhibit 4 to Plaintiffs' Motion for Preliminary Injunction. There is no valid basis upon which CMS can argue that there is no harm when it delays the implementation of a Medicare rate cut, but there are devastating consequences when Plaintiffs request a preliminary injunction to allow the flaws in the PPIS data to be corrected.

"With the audacity of someone possessing the mistaken belief that they occupy a position of unchecked power, Defendants implicitly argue that they are above the law. Essentially, Defendants complain that their own failure to follow the law regarding the [development of the

practice expense component for cardiology in the] fee schedule …. will cause them future difficulties if they are forced at this time to follow the law." *Lifestar Ambulance Srv. Inc. v. United States,* 211 F.R.D. 688 (M.D. Ga. 2003), *vacated and remanded on other grounds*, 365 F.3d 1293 (11th Cir. 2004). The federal court first presented with these specious, self-serving, unsupported arguments from CMS soundly rejected them, and this Court should reject them as well.

CMS urges this Court to ignore Congressional mandates that control in this case, and tries instead to hide behind alleged "budget neutrality" provisions as a basis to justify its failure to follow the law. But the "budget neutrality" provisions relied upon by CMS do not authorize the unlawful actions taken against the plaintiffs in this case. Defendants incorrectly claim that Congress limits the financial impact of any changes CMS may make to the RVUs on an annual basis to only $20,000,000. *See* DE 18 at 5[6]. This is not the law. Defendants have misrepresented to this Court the difference between the limitation imposed on annual growth in expenditures under the PFS (known as the "sustainable growth rate" or SGR adjustment, 42 U.S.C. §§ 1395w-4(d), (f)), and a minor limitation ($20 million, compared to the total estimated expenditures proposed under the 2010 PFS of $9.08 *billion*, *see* 74 Fed. Reg. 61,737, 62,001 (Nov. 25, 2009)) imposed on adjustments in RVUs made only as a result of, as CMS admits, "administrative policy changes" (DE 18 at 5) that may occur pursuant to a review of RVUs the Secretary is mandated to conduct at least every five years (42 U.S.C. §§ 1395w-4(c)(2)(B)(ii)(II)).

Contrary to CMS's allegations, the subsection of the statute on which CMS relies (42 U.S.C. § 1395w-4(c)(2)(B)(ii)(II)) does not require that annual changes to the PFS be "budget

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[6] In fact, the shifting of cardiology services into hospitals will increase costs to CMS to a greater degree than fixing its errors and using sound data.

neutral." Indeed, even under CMS's flawed interpretation, this provision permits net increases in Medicare payments under the fee schedule; it does not require a *quid pro quo* reduction in RVUs for every increase. To the extent, however, that *any* provision of the PFS limits increases in the payment amounts to physicians, it would be the SGR provisions that accomplish this. However, for the 2010 PFS, Congress has repealed the SGR provision and permitted the conversion factor that is applied to all RVUs to be *increased* from 2009, according to the Medicare Economic Index ("MEI"). *See* HR 3691 (Medicare Physician Payment Reform Act of 2009, amending 42 U.S.C. § 1395w-4(d)).

According to the 2010 PFS regulation issued by CMS on November 25, 2009, CMS's unlawful actions resulted in a net *decrease* in estimated Medicare expenditures under the 2010 PFS of more than $13 billion from 2009. 74 Fed. Reg. 61,737, 62,001, Table 54 (Nov. 25, 2009). Clearly, CMS has funds to pay for the costs of reprocessing claims [claims or data? Not sure what you are trying to say] correctly and undertaking an administratively compliant rulemaking process. "As a matter of public policy and equity [any] unexpected consequences . . . caused by Defendant's failure to follow the law should be borne by those who created the lamentable situation and not by innocent intended beneficiaries of the law." *Lifestar Ambulance Srv. Inc.,* 211 F.R.D. 688 (M.D. Ga. 2003), *vacated and remanded on other grounds*, 365 F.3d 1293 (11th Cir. 2004).

Furthermore, and as previously stated, Plaintiffs seek narrow relief, *i.e.*, temporarily suspending the use of the PFS Rule to set payment rates for cardiology services provided in 2010 and continuing the Medicare payment rates currently in effect for 2009, until the Court has a full opportunity to adjudicate Plaintiffs' claims. Temporarily enjoining a cut in Medicare payment rates for cardiology services would benefit the public by ensuring the continued availability of

medically necessary cardiology services to Medicare beneficiaries until the Court has a full opportunity to adjudicate Plaintiffs' claims herein. *See Independent Living Center*, 572 F.3d at 658-59 (affirming preliminary injunction based on "robust public interest in safeguarding access to health care"); *McLaughlin*, 801 F. Supp. at 644 (public interest served by injunction assuring Medicaid beneficiary's access to health care services); *Mt. Sinai Medical Center*, 425 F. Supp. at 8 (public interest served by injunction ensuring availability of health care services to Medicare beneficiaries).

By contrast, if the Court were to later determine that the Medicare payment rates for cardiology services under the PFS Rule are lawful, CMS could recoup any alleged "overpayments" by offsetting reductions in payments for cardiology services after a final adjudication in this case. *See* 42 C.F.R. § 405.371. Thus, a preliminary injunction would, at most, impose a modest administrative inconvenience upon CMS and Defendant's argument that the administrative burden demonstrates that the public would be better served without an injunction has been squarely rejected. *See Independent Living Center,* 572 F.3d at 657-58 (injury to plaintiffs if Medicaid rate reduction not enjoined outweighs Medicaid program's claim that injunction precluding rate reduction would impose financial hardship on program); *McLaughlin*, 801 F. Supp. at 644 (financial burden imposed on Medicaid program by granting injunction was "inconsequential" relative to irreparable injury to plaintiff if access to health care services denied); *Mt. Sinai Medical Center*, 425 F. Supp. at 8 (denial of injunctive relief, leading to curtailed health care services, outweighs harm to Medicare program caused by temporary restriction on reduction of Medicare payment to provider).

IV. **Conclusion**

For the foregoing reasons, and for the reasons stated in Plaintiffs' Motion, Plaintiffs' request for preliminary injunction should be granted.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on January 11, 2010, I electronically filed the foregoing document with the Clerk of the Court using CM/ECF. I also certify that the foregoing document is being served this day on all counsel of record or *pro se* parties identified on the attached Service List in the manner specified, either *via* transmission of Notices of Electronic Filing generated by CM/ECF or in some other authorized manner for those counsel or parties who are not authorized to receive electronically Notices of Electronic Filing.

/s/
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