No. _____

In The
Supreme Court of the United States

COUNTY OF SANTA CRUZ, *et al.*,

Petitioners,

v.

SYLVIA MATHEWS BURWELL, Secretary of the Department of Health and Human Services,

Respondent.

On Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Ninth Circuit

PETITION FOR WRIT OF CERTIORARI

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QUESTIONS PRESENTED

Since 2001, the Centers for Medicare and Medicaid Services ("CMS") has intentionally diverted reimbursements totaling almost $5 billion from physicians in urban counties to fund windfall overpayments to physicians in rural counties, despite CMS' admissions that doing so is in excess of its authority, despite the resulting curtailed access to medical care for Medicare's elderly and disabled beneficiaries in those urban counties, and despite the resulting overcharges of almost $1 billion to beneficiaries in those rural counties. Physicians and beneficiaries in 38 states and 85% of the counties across the country are harmed by this disparate treatment, the nature and scope of which are not in dispute. The decisions of the court of appeals afford no remedy, and CMS plans no cure.

1. Whether CMS' excuse of administrative burden can justify the widespread disparate treatment of similarly situated physicians where that rationale is contradicted by the administrative record.

2. Whether CMS' disparate treatment of similarly situated physicians can survive rational basis scrutiny where CMS has admitted that it has no authority to underpay some areas in order to raise payments to other areas.

3. Whether 42 U.S.C. § 1395w-4(i) impliedly bars judicial review of the definition of payment localities employed in Medicare Part B where Congress did not adopt an express bar contained in an early version of the statute.

PARTIES TO THE PROCEEDINGS

County of Santa Cruz, County of Sonoma, County of San Diego, County of Marin, County of Santa Barbara, County of San Luis Obispo, County of Monterey, Theodore M. Mazer, M.D., and Wolbers and Poree Medical Corporation, Petitioners here, were Plaintiffs and Appellants below.

Sylvia Mathews Burwell, Secretary of the United States Department of Health and Human Services (and her predecessors in office, Kathleen Sebelius and Michael O. Leavitt), Respondent here, was the Defendant and Appellee below.

RULE 29.6 DISCLOSURE

Petitioner Wolbers and Poree Medical Corporation is a California corporation, with no parent or subsidiary, and no publicly held company owns 10% or more of its stock.

TABLE OF CONTENTS

TABLE OF CONTENTS – Continued

TABLE OF CONTENTS – Continued

TABLE OF AUTHORITIES

Page

CASES

TABLE OF AUTHORITIES – Continued

TABLE OF AUTHORITIES – Continued

CONSTITUTION

STATUTES

TABLE OF AUTHORITIES – Continued

TABLE OF AUTHORITIES – Continued

REGULATIONS

RULES

OTHER AUTHORITIES

TABLE OF AUTHORITIES – Continued

INTRODUCTION

Petitioners County of Santa Cruz, County of Sonoma, County of San Diego, County of Marin, County of Santa Barbara, County of San Luis Obispo, County of Monterey, Theodore M. Mazer, M.D., and Wolbers and Poree Medical Corporation respectfully petition for a writ of certiorari to review the judgment of the United States Circuit Court of Appeals for the Ninth Circuit in this matter.

Since 1996, CMS has not adjusted the payment locality structure used in Medicare Part B to measure "local" costs despite subsequent significant changes in demographics and relative costs within and among localities, despite numerous requests to restructure localities, and despite a number of studies showing the wisdom of adopting alternative locality configurations. Because CMS has not maintained its own payment accuracy standards, payments to physicians in 85% of the counties in the nation no longer reflect the actual cost of providing medical services. By the end of 2015, underpayments to physicians in 260 urban counties will total $5 billion, overpayments to physicians in 2419 rural counties will total $5 billion, and overcharges to Medicare beneficiaries in those rural counties will total $1 billion.

OPINIONS BELOW

The August 1, 2014, opinion of the court of appeals (App. A, *infra*) is unreported, but is available at 2014 WL 3766538, at *1.

The April 26, 2013, order of the district court granting the Secretary's motion to dismiss or for summary judgment (App. B, *infra*) is unreported, but is available on the Northern District of California's Pacer website as Document 147 in Case 3:07-cv-02888-MJJ.

The September 29, 2010, order of the court of appeals (App. C, *infra*) is unreported, but is available in the Federal Appendix at 99 Fed. Appx. 174.

The March 11, 2008, order of the district court granting the Secretary's motion to dismiss (App. D, *infra*) is unreported, but is available on the Northern District of California's Pacer website as Document 57 in Case 3:07-cv-02888-MJJ.

The October 9, 2014, order of the court of appeals denying Petitioners' motion for rehearing or rehearing *en banc* (App. E, *infra*) is unreported, but is available on the Ninth Circuit's Pacer website as Document 45 in Case 13-16297.

JURISDICTION

The judgment of the court of appeals was entered on August 1, 2014. A timely petition for rehearing or

rehearing *en banc* was denied on October 9, 2014. This Court has jurisdiction under 28 U.S.C. § 1254(1).

Petitioners are "suppliers" of medical and other health services to Medicare beneficiaries under Medicare Part B as that term is defined in 42 U.S.C. § 1395x(d). They have accepted assignments from Medicare beneficiaries in order to receive payment directly from CMS (or the "Agency") for all items or services furnished to the beneficiaries that are at issue in this action, and have consistently submitted timely claims to CMS for payment for those services.

Petitioners satisfied the jurisdictional requirement of presentment in accordance with *Shalala v. Illinois Council on Long Term Care, Inc.*, 529 U.S. 1, 15 (2000) by submitting a detailed claim on behalf of themselves and others similarly situated to the Secretary's local administrator in March and May 2007 that raised constitutional and statutory challenges to the Secretary's failure to modify the payment localities where "local" costs are measured for use in the physician fee schedule. *Califano v. Yamasaki*, 442 U.S. 682, 697-701 (1979); *Weinberger v. Salfi*, 422 U.S. 749, 764 (1975); *Briggs v. Sullivan*, 886 F.2d 1132, 1139 (9th Cir. 1989). On May 11, 2007, CMS' local administrator denied the claim on the grounds that "it cannot grant, reject, or take any official action upon the submission, because the submission is not a cognizable request for action by a carrier."

Any administrative review of the issues raised by Petitioners' claim is precluded by regulation. As

counsel for the Secretary conceded during oral argument before the Ninth Circuit in 2008, "If they are challenging the definition of fee schedule areas . . . there would have been no administrative . . . review." *See* 42 C.F.R. § 405.926, subds. (a) and (c) (precluding any appeal within the Agency from a decision that involves actions that are not "initial determinations"); 67 Fed. Reg. 69312, 69321, 69345 (11/15/2002) ("Changes to the Medicare Claims Appeals Procedures").

Thus, Petitioners satisfied the exhaustion requirement as well because the Secretary has no administrative review process by which Petitioners may obtain a final determination of their claim under 42 U.S.C. § 405(h) which could then be reviewed by a court under 42 U.S.C. § 405(g).

Therefore, as no administrative review of the issues raised by Petitioners is possible under 42 U.S.C. § 405, and to the extent that the May 2007 denial of the claim constitutes a final determination by the Secretary that she does not have the authority to act on Petitioners' claim, subject matter jurisdiction over Petitioners' action can be exercised pursuant to 42 U.S.C. § 405(g). *Weinberger,* 422 U.S. at 764-67; *Mathews v. Eldridge*, 424 U.S. 319, 329-32 (1976); *Briggs*, 886 F.2d at 1139.

STATUTORY PROVISIONS INVOLVED

Relevant provisions of 42 U.S.C. § 1395w-4, relied upon by the court of appeals to find that judicial

review of Petitioners' claims is precluded, are reproduced in Appendix F.

Relevant provisions of the 1989 legislative history of 42 U.S.C. § 1395w-4(i)(1) are reproduced in Appendices G and H.

The regulation authorizing the Secretary to create or modify fee schedule areas, 42 C.F.R. § 414.4, is reproduced in Appendix I.

STATEMENT

A. Statutory Background

When Medicare was created in 1966, payment rates to physicians under Medicare Part B were determined by local administrators, usually insurance companies, who made those determinations based on the "reasonable rates" for similar services within 240 coverage areas.

Effective in 1992, the Omnibus Budget Reconciliation Act of 1989, Public Law No. 101-239 ("1989 OBRA"), created the nationwide physician fee schedule system that CMS currently uses to establish fees for physicians' services employing the formula set forth in 42 U.S.C. § 1395w-4.[1]

[1] Appendix J, pp. 71-a to 77-a, contains an explanation of the formula and variables CMS uses in computing reimbursements to physicians under Medicare Part B.

Generally, payments to physicians under Section 1395w-4 are to be based on the cost of providing medical care in the various "fee schedule areas" or "localities." However, the 1989 OBRA did not include a definition of how the boundaries of those areas were to be defined. Instead, Congress deferred that decision pending further study:

> "For 1990 and 1991, these fee schedule areas would be the current carrier locales, because the capacity does not currently exist to use other areas. However, the Committee believes that it would be more appropriate to use either statewide fee schedule areas or to use metropolitan statistical areas along with combined non-MSA areas. Further analysis on these, and possibly other alternatives, will be undertaken by the PPRC and the Secretary, so that a decision can be made at a later date. The bill states that the Secretary will make a decision prior to 1992, but it is the Committee's expectation that the Congress is likely to make such a decision before that date."[2]

H.R. Conf. Report No. 101-247, 345 (9/20/1989); *see also* H.R. Conf. Report No. 101-386, 743 (11/21/1989).

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[2] Established in 1985, the Physician Payment Review Commission ("PPRC") was the body that advised Congress on issues affecting the Medicare program until the Medicare Payment Advisory Committee ("MedPAC") was established by the Balanced Budget Act of 1997, Public Law No. 105-33.

Despite the expressed intentions of the 101st Congress, the 1966 definition of "fee schedule" has never been deleted or modified. "Fee schedule area" is defined by statute in 42 U.S.C. § 1395w-4(j)(2) as "a locality used under section 1395u(b) of this title for purposes of computing payment amounts for physicians' services." This provision refers to an artifact of the "reasonable charge" system of the original Medicare Act that provides:

> "In determining the reasonable charge for services for purposes of this paragraph, there shall be taken into consideration the customary charges for similar services generally made by the physician or other person furnishing such services, as well as the prevailing charges in the locality for similar services."

42 U.S.C. § 1395u(b)(3). This sentence has not been modified since Medicare was first implemented in 1966 as Sec. 1842(b)(3), part of the Social Security Amendments Act of 1965, Public Law No. 89-97.

In 2014, after years of intense lobbying efforts by the California Medical Association (the "CMA"), Congress added 42 U.S.C. § 1395w-4(e)(6), changing the locality structure for California to an MSA-based structure with the resulting modifications to payment amounts to be phased in over a 6-year period beginning in 2017. *See* App. F, pp. 64-a to 66-a.

B. Regulatory Background

In 1991, the Agency recognized "the lack of consistency among current localities and the fact that significant demographic and economic changes may have occurred since the existing localities were established [in 1966]." 56 Fed. Reg. 25792, 25832 (6/5/1991). Based on its stated belief that it was not precluded from doing so, the Agency assumed sole responsibility for redefining the locality structure. *Id.*, at 25833.

Between 1995 and 1996, the Agency undertook a detailed consideration of a number of alternative locality structures for Medicare Part B, but rejected most based on their failure to meet the payment accuracy standards the Agency established. Those accuracy standards included the acceptable levels of: (1) underpayments and overpayments; (2) differences between county and locality Geographic Adjustment Factors ("GAFs"); (3) "boundary differences" between the GAFs of adjoining counties in separate localities; and (4) cost homogeneity among counties within a locality.[3] 61 Fed. Reg. 34614, 34617 (7/2/1996).

Ultimately, the Agency adopted the "5% iterative method" because: (1) it "ensures that the statewide or residual [Fee Schedule Area or "FSA" or "locality"]

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[3] Generally, a GAF measures the cost of providing medical services within a county or fee schedule area relative to the national average of 1.000. Thus, a GAF of 1.188 shows that costs in that particular locality are 18.8% higher than the national average, and a GAF of 0.900 shows that costs in that locality are 10% lower than the national average.

has relatively homogeneous input prices"; (2) it addresses "the problems" of "unwarranted boundary differences and large higher-price areas not being separate FSAs in small States"; (3) "it more consistently defines homogeneous residual State FSAs"; (4) it "reduces unwarranted boundary differences"; and (5) it "would attain the goal of simplifying the payment areas and reducing payment differences among areas while maintaining accuracy in tracking input prices." 61 Fed. Reg. 34614, 34617-20 (7/2/1996); 61 Fed. Reg. 59490, 59494-97 (11/22/1996).

CMS implemented the 5% iterative methodology used to revise the payment localities in the following manner. It used then-current localities as building blocks with 22 existing statewide localities remaining statewide localities. For the remaining states, CMS then ranked the GAFs for the localities and counties within each of the remaining states from highest to lowest. If the GAF of the highest ranking locality within a state was 5% higher than the weighted average of the GAFs of the remaining localities, that locality became a distinct locality. The process was repeated or "iterated" until the remaining locality with the highest GAF did not exceed that 5% threshold. The remaining localities were then combined into a "Rest of State" locality where payment levels would be based on average costs within that Rest of State locality. If a particular state did not have any locality that exceeded the 5% threshold, that state became a single-state locality. According to CMS, "This ensures

that the statewide or residual State locality has relatively homogeneous resource costs." 61 Fed. Reg. 59490, 59494 (11/22/1996).

The payment locality structure created in 1996 is made up of 15 single-county localities where payments are made based on costs of providing medical care within each single-county locality, and 74 multi-county or statewide localities where payments are made based on the average costs of providing medical care within the counties making up those localities. In California, for example, there are six single-county localities, while all of the Petitioner Counties excepting Marin are part of a 47-county "Rest of California" locality. Marin County is part of a 3-county locality.

In 1996, the Secretary created both a method for future locality revisions and an expectation that such revisions would occur when the 5% "threshold" was exceeded. In the 1996 Proposed Rule, the Secretary invited commenters who felt their particular area, which would become a part of a residual "rest-of-state" area under the Secretary's proposal to "submit data to show that their area costs exceed the costs of other areas in the residual payment area by the 5-percent threshold." 61 Fed. Reg. 34614, 34621 (7/2/1996). Then, in response to commenters who asked if Medicare planned to change localities on a periodic basis to recognize future cost changes, the Secretary stated:

> "While we do not plan to routinely revise payment areas as we implement new GPCIs, we will review the areas in multiple locality States if the newer GPCI data indicates dramatic relative cost changes among areas."

61 Fed. Reg. 59490, 59497 (11/22/1996).

In 2001, representatives from Sonoma County and Santa Cruz County met with CMS administrators and demonstrated that reimbursement levels to physicians in those counties no longer fell within the 5% iterative standard. Since 2003, the Secretary has repeatedly acknowledged the existence of the systemic payment inaccuracies in the Federal Register.

Between 2001 and 2012, eleven (11) detailed studies by and for CMS have examined the cause and scope of payment inaccuracies in counties across the country: (1) CMS from 2001 to 2003; (2) CMS and the CMA from 2004 to 2006; (3) the CMA's comprehensive study in January 2006; (4) MedPAC's March 2007 Report to Congress on "Medicare Payment Policy"; (5) the GAO's June 2007 Report to Congress, "Geographic Areas Used to Adjust Physician Payments for Variation in Practice Costs Should Be Revised";[4] (6) the

[4] Published within days of the filing of Petitioners' initial complaint, the 2007 GAO Report virtually tracks the factual underpinnings of that complaint. The GAO found there were a total of 447 counties with "large payment differences" (a payment difference of 5% or more between the county-specific GAF and the locality GAF for the locality of which the county was a part), a disproportionate number of which were located in five states – California, Georgia, Minnesota, Ohio, and Virginia.

March 2008 report on the locality structure prepared by RTI and the Urban Institute for CMS; (7) CMS' 2008 studies of alternative locality configurations; (8) Acumen's 2008 and 2010 studies for CMS reviewing alternative locality structures; (9) the 2011 study performed by the Institute of Medicine ("IOM") for CMS, "Geographic Adjustment in Medicare Payment – Phase I: Improving Accuracy"; (10) the IOM's 2012 "Geographic Adjustment in Medicare Payment – Phase II: Implications for Access, Quality, and Efficiency"; and (11) the 2012 "evaluation" of the IOM studies performed by Acumen for CMS. Each of these studies is contained in the administrative record.

In its response to CMS' proposed rule for 2008, MedPAC pointedly criticized CMS' failure to modify the locality structure:

> "Some organizations that represent physicians have raised an issue that the structure of the payment localities often causes payments under the [Physician Fee Schedule] to inaccurately reflect the local costs of providing care. This can cause physicians in some areas to be systematically underpaid while others are overpaid, creating payment equity issues. The underlying factor for the payment inaccuracies is that many localities encompass geographic areas with very different costs of providing care. This appears to occur for two reasons: many localities are too large to accurately track geographic differences in costs of care and many are based on geographic entities established in 1966

> and have not been adjusted to reflect changes in economic and demographic conditions."

Of critical importance to this case are the detailed studies of the GAO and the IOM. The GAO's 2007 study concluded:

> "We have identified three alternative approaches to the current payment localities that, if uniformly applied to all states, could be used to improve payment accuracy while generally imposing a minimal amount of additional administrative burden. This is consistent with the goal that CMS has stated in setting the geographic boundaries of payment localities."

In 2010, with a goal of improving the Medicare payment system, the Secretary and the U.S. Congress sought advice from the IOM on the accuracy of methods used to ensure that Medicare payment fees and rates reflect differences in input costs across geographic areas.[5]

The IOM found:

> "There is little economic justification for using the 89 current physician payment areas. In fact, the current areas are inaccurate

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[5] The 2011 IOM Report was intentionally timed to allow the Secretary to implement its recommendations on January 1, 2013. However, the recommendations in the 2011 IOM Report have never been implemented, and CMS' rule for calendar year 2015 does not mention any intent to do so. *See* 79 Fed. Reg. 40318 (7/11/2014); 79 Fed. Reg. 67548 (11/13/2014).

> compared with the 441 metropolitan statistical areas (MSAs). They fail to differentiate geographic areas within payment areas where physicians face significant variation in their wages."

The IOM concluded that "long-term administrative simplification, reduced administrative burden, and improved consistency within the Medicare program" would result if CMS used MSAs to measure costs for physicians under Medicare Part B, the same geographic localities it already uses for hospitals under Part A. The reduced administrative burden would result because CMS would only be gathering one set of data for both Part A and Part B. Since the Office of Management and Budget regularly updates MSAs, that would also "relieve" CMS of the "administrative burden of redefining labor markets in response to claims that they are outdated." The IOM further concluded that using MSAs would advance CMS' goal of improving payment accuracy.

There is nothing in the administrative record of this case that contradicts the findings of the GAO and the IOM Reports that no significant administrative burden would result from a modification of the locality structure. Despite commissioning Acumen in 2012 to conduct a study of the IOM's 2011 study, the Secretary has not implemented the locality modification to MSAs recommended by the IOM.

C. Factual Background

The Secretary has not adjusted the payment locality structure since 1996 despite the fact that shifting demographics have increased costs of providing medical services in 260 counties to a point where those counties should have become single-county localities under the Secretary's own payment accuracy standards. As a result, suppliers in high-cost counties within the multi-county and statewide localities are being underpaid, and suppliers in 2419 low-cost counties within the multi-county and statewide localities are being overpaid.[6] As a further result, Medicare beneficiaries in the 2419 low-cost counties are being overcharged on their 20% co-pay, and beneficiaries in the 260 high-cost counties suffer from dangerous delays in and, at times, complete lack of access to health care.

"Boundary differences" in many counties now exceed the 1996 payment accuracy standards that defined boundary differences of 11% and over as "inappropriate," and boundary differences of 5% and over as "severe." 61 Fed. Reg. 34614, 34617-20 (7/2/1996). For example, physicians in Santa Cruz County are paid at the lowest rates in California, rates that are up to 20% less than those for physicians in

[6] In 1996, CMS determined that suppliers receiving payments that were 6.29% under their costs would be "substantially underpaid," and suppliers receiving payments that were 3.38% above their costs would be "substantially overpaid." 61 Fed. Reg. 34614, 34617 (7/2/1996).

neighboring Santa Clara and San Mateo Counties for providing the exact same services. In stark contrast, Santa Cruz hospitals are paid under Medicare Part A at the highest rate in the nation.

Through the end of 2015, the Secretary will have underpaid suppliers in those 260 high-cost counties by almost $5 billion and beneficiaries in those 2419 low-cost counties will have been overcharged on their co-pay by almost $1 billion.

Petitioners' factual allegations relating to the existence, scope, and cause of these massive cost reimbursement inequities are fully supported by the administrative record. The Secretary has never challenged those allegations.

D. Initial Proceedings In The District Court

In 2007, the Petitioner Counties submitted a detailed claim to CMS for additional reimbursement on behalf of themselves and a class of similarly situated suppliers based on the failure to adjust the locality structure. That claim was denied on May 11, 2007.

On June 4, 2007, the Petitioner Counties filed their initial class action complaint asserting constitutional and statutory claims relating to the Secretary's failure to revise the "fee schedule areas." The complaint alleged the failure violated the Counties' equal protection and due process rights, and that 42 U.S.C. § 1395w-4 and 42 C.F.R. § 414.4 are unconstitutional as applied to the Counties because they deprived

them of property and equal protection. The Counties' statutory claims asserted that the Secretary's failure to revise the fee schedule areas violated various provisions of the Administrative Procedures Act. 5 U.S.C. § 706, subds. (1), (2)(A), and (2)(C). The complaint also alleged that CMS had improperly delegated the authority to modify the locality structure to state medical associations.

On March 11, 2008, the district court dismissed the constitutional claims on the ground that the Counties lacked standing because they were not "persons" under the Fifth Amendment, dismissed the APA claims on the ground that they were impliedly barred by 42 U.S.C. § 1395w-4(i)(1), and granted leave to amend the claim for unlawful delegation.

On April 9, 2008, the district court entered an order granting Petitioners' request to enter judgment on the constitutional and APA claims, and staying the amendment of the unlawful delegation claim pending appeal.

Petitioners filed a timely notice of appeal.

E. Initial Decision Of The Court Of Appeals

The court of appeals granted Petitioners' unopposed motion to expedite oral argument based on Petitioners' showing that access to medical care in the Petitioners' counties was curtailed due to the Secretary's failure to modify the locality structure.

On September 29, 2010, the court of appeals issued a divided memorandum opinion affirming the dismissal of the Counties' APA claims and due process claims, and reversing the judgment on Petitioners' equal protection claims.

The majority affirmed the dismissal of the APA claims finding that "the challenge to the Fee Schedule necessarily involves a challenge to the geographic adjustment factors" and judicial review was therefore barred because 42 U.S.C. § 1395w-4(i)(1)(D) bars review of the "establishment of geographic adjustment factors under subsection (e)." App. C, p. 19-a. The majority also affirmed the dismissal of the Counties' due process claim "because the Counties do not have a property right to any particular payment by Medicare. *See Erickson v. U.S. ex rel. Dept. of Health and Human Services*, 67 F.3d 858, 862 (9th Cir. 1995)."

Finally, a different majority found, at least for purposes of the equal protection claims, that the Counties are persons, and remanded for a consideration of whether the Secretary's decision not to revise the fee schedule areas is supported by a rational basis, an issue that the district court had not reached.

F. Proceedings In The District Court On Remand

On February 18, 2011, Petitioners filed a First Amended Complaint that only included claims for violation of their equal protection rights and unlawful delegation. The First Amended Complaint added

Theodore M. Mazer, M.D., and the Wolbers and Poree Medical Corporation as named plaintiffs.

Over several months, the parties compiled an extensive administrative record dating back to 1989 and comprised of over 180,000 pages relating to Petitioners' claims. Responding to the Secretary's motion to dismiss or for summary judgment, Petitioners moved for leave to take discovery under Fed. R. Civ. P. 56(d).

Without a hearing, on December 4, 2012, the district court denied Petitioners' motion to take discovery, and granted the Secretary's motion to dismiss Petitioners' First Amended Complaint, dismissing Petitioners' claim for unlawful delegation without leave to amend, and giving Petitioners leave to amend their equal protection claims.

On January 17, 2013, Petitioners filed their Second Amended Complaint. On April 26, 2013, the district court granted the Secretary's motion to dismiss or in the alternative for summary judgment, again without a hearing. The district court held that Petitioners had failed "to meet their burden to show that the Secretary's failure to alter the geographic localities is not supported by a rational basis." Relying on *Guidace v. Jackson*, 726 F.Supp. 632 (E.D. Va. 1989) the district court also held that in "balancing competing interests, the decision to maintain the status quo was reasonable and does not violate equal protection." Finally, the district court found that Petitioners had failed to show that the Secretary had acted with discriminatory purpose.

Judgment was entered on April 26, 2013, and Petitioners filed a timely notice of appeal.

G. Final Decision Of The Court Of Appeals

Once again, the court of appeals granted Petitioners' unopposed motion to expedite oral argument based on Petitioners' showing that access to medical care for beneficiaries in the Petitioners' counties was being curtailed due to the Secretary's failure to modify the locality structure.

On appeal, the Secretary did not contest or address a number of significant points raised in Petitioners' opening brief, including:

- Petitioners have standing.
- Congress' overriding purpose in the Medicare scheme is reasonable (not excessive or unwarranted) cost reimbursement.
- There are three classes of Medicare Part B suppliers who are being disparately treated by the Secretary – one that is being reimbursed accurately, one that is being under-reimbursed, and one that is being over-reimbursed.
- Beginning in 2001 and due to changing economic and demographic conditions, suppliers in 260 urban counties have been underpaid based on the Secretary's own payment accuracy standards established in 1996.

- Overpayments to suppliers in 2419 rural counties are being funded by the underpayments to suppliers in 260 urban counties.
- The Secretary's failure to modify the locality structure results in excessive charges to beneficiaries in 2419 counties.
- There is no support in the administrative record for the proposition that modifying the locality structure will create a significant administrative burden, and the only evidence in the administrative record is directly contrary to that position.

During oral argument, counsel for the Secretary was repeatedly asked to identify any evidence of resulting administrative burden in the record. Counsel was unable to do so, and suggested that she would "go back and check with the agency and look at the record again" and then "get back" to the court of appeals. Tellingly, counsel never did "get back" to the court of appeals on the issue.

In its brief decision, the court of appeals stated that it had conducted a "highly deferential" review of the record under *Kahawaiolaa v. Norton*, 386 F.3d 1271 (9th Cir. 2004), and had relied upon *Armour v. City of Indianapolis*, ___ U.S. ___, 132 S.Ct. 2073, 2083 (2012), to find the Secretary's justification of "administrative burden" sufficient to survive that "highly deferential" review.

REASONS FOR GRANTING THE PETITION

A. The Petition Raises Issues Of National Importance

This Petition for Certiorari raises issues of national importance, affecting physicians, other "suppliers" of medical services, and beneficiaries under Medicare Part B.[7]

The disparate treatment caused by CMS' stubborn refusal to adjust the locality boundaries is widespread, and affects physicians, other suppliers, and beneficiaries in 38 states and 85% of the counties across the United States. The undisputed facts in the administrative record show that since 2001 CMS has knowingly – and admittedly without authority to do so – underpaid physicians in 260 urban counties in order to provide overpayments to physicians in 2419 rural counties.

The monetary effects alone are staggering. From 2001 through the end of 2015, the total underpayments to physicians in those 260 urban counties will total nearly $5 billion, with physicians in the 2419 rural counties receiving windfall overpayments of

[7] "Supplier" also includes physician assistants, nurse practitioners, clinical nurse specialists, nurse midwives, dentists, podiatrists, optometrists, chiropractors, clinical psychologists, clinical social workers, physical therapists, occupational therapists, and entities such as a county or corporation that employ and bill for medical services performed by individuals under Medicare Part B.

$5 billion. Beneficiaries in the 2419 rural counties will have been overcharged on their co-pay by nearly $1 billion.

Of graver concern are the effects on public health. Because the current locality structure does not accurately reimburse physicians in the 260 urban counties for the actual costs of providing medical care, there is a growing scarcity of physicians and other suppliers who will treat Medicare patients in the affected urban counties because they simply cannot afford to do so if Medicare rates are below the cost of providing the care.

Even while holding that judicial review of the selection of localities was prohibited, Judge McKeown acknowledged, "The Counties certainly have well-documented reasons to object to the lag between their payment levels under the current Fee Schedule Areas and their real costs to provide care." App. C, p. 24-a.

B. The Decision Denying Petitioners' Equal Protection Claims Conflicts With Decisions Of This Court, Other Courts, And The "Overriding Purpose" Of Medicare

1. The Court of Appeals Did Not Perform A Proper Review Of The Administrative Record

The final decision of the court of appeals denying Petitioners' equal protection claims was distressingly brief. The court of appeals failed to properly examine the administrative record that actually contradicts

the existence of any substantial administrative burden that might result from a modification of the locality structure.

Even under the most "highly deferential" standard of review, Petitioners are entitled to refute a presumption of rationality by showing that the governmental entity's rationale for disparate treatment of similarly situated classes of persons is irrational, false, or pretextual. *Heller v. Doe*, 509 U.S. 312, 320-21 (1993) (rational basis review requires finding "some footing in the realities of the subject addressed by the legislation"). In *Romer v. Evans*, 517 U.S. 620, 632-33 (1996), this Court reaffirmed that there must be a "sufficient factual context" that allows a court to ascertain that "the classification bears a rational relationship to an independent and legitimate legislative end." *See Kelo v. City of New London, Conn.*, 545 U.S. 469, 491 (2005) ("a court applying rational-basis review under the Equal Protection Clause must strike down a government classification that is clearly intended to injure a particular class of private parties, with only incidental or pretextual public justifications"), citing *City of Cleburne, Tex. v. Cleburne Living Center, Inc.,* 473 U.S. 432, 446-47, 450 (1985), and *Department of Agriculture v. Moreno,* 413 U.S. 528, 533-36 (1973).

The only two cases relied upon by the Panel – *Kahawaiolaa*, 386 F.3d 1271, and *Armour*, 132 S.Ct. 2073 – do not compel a different approach.

In *Kahawaiolaa*, 386 F.3d at 1279-83, the court conducted a lengthy and detailed review of the legislative and administrative underpinnings of the regulation at issue, and ultimately concluded that the plaintiffs had not met their burden "to negative every conceivable basis which might support it." *Id.*, at 1280. The same cannot be said in this case where the administrative record only supports Petitioners' position.

In *Armour*, 132 S.Ct. at 2080-84, this Court conducted an extensive examination of the administrative record, and found that the petitioners had not been able to show that the "administrative burden is too insubstantial to justify the classification." *Id.*, at 2083. The majority's opinion in *Armour* was specifically limited to the circumstances of the case, and expressly disclaimed any intention to hold that "administrative considerations" can always justify even tax differences. *Ibid*.

There are critical differences between the circumstances in this case and the circumstances in *Armour* where the City of Indianapolis conducted a detailed cost-benefit analysis before concluding that it would take too long and cost too much to collect certain unpaid assessments. In contrast, Petitioners made an uncontradicted showing that any administrative burden would be "too insubstantial to justify the classification." The GAO found that there would only be an initial "minimal amount" of administrative burden that would result in ***any*** locality reconfiguration. As the 2011 IOM Report pointed out, shouldering the

slight burden of some initial costs would advance the Agency's goals of improving payment accuracy and would result in long-term cost savings if the Agency were to align the locality structures of Part B and Part A. It bears repeating that in the courts below the Secretary never contradicted or even challenged these findings of the GAO and the IOM, and, when specifically questioned by Judge Bea, her counsel was absolutely unable to identify any specific administrative burden that might result.

This case deals with CMS' channeling of reimbursements for providing medical services owed to one group in order to make windfall overpayments to another group in a manner that CMS admits is beyond its authority. In *Armour*, the City of Indianapolis decided to forego collection of tax revenue it was owed due to the costs and complications involved in collecting that revenue.

Yet another critical difference lies in the comparative income and expenses of CMS and the City of Indianapolis. According to the "2010 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds," in 2009 CMS received a total income of $222.9 billion, and expended $62.5 billion just for Medicare Part B. Similar figures for the City of Indianapolis are not known, but it should be a matter not subject to dispute that the City's income and expenses were less by several orders of magnitude. The Secretary's justification of some unspecified and never quantified "administrative burden" needs to be

viewed in the context of CMS' massive income and expenditure figures.

The GAO and IOM reports demonstrate that any administrative burden that might result from an adjustment of the payment locality structure would be minimal at the outset and would be eliminated over the long-term. These undisputed facts are sufficient to support a determination ***in favor*** of Petitioners for purposes of summary judgment. *See Copelin-Brown v. New Mexico State Pers. Office*, 399 F.3d 1248, 1255 (10th Cir. 2005) (administrative burden did not withstand rational basis review where defendant failed "to present any facts showing that the regulation in question eased administrative burdens").

2. The Final Decision Of The Court Of Appeals Ignores The "Overriding Purpose" Of Medicare And Conflicts With Key Decisions Of This Court

This Court has recognized that "the Legislature's overriding purpose in the Medicare scheme [is] reasonable (not excessive or unwarranted) cost reimbursement." *Regions Hospital v. Shalala*, 522 U.S. 448, 459-60 (1998). A necessary corollary is the avoidance of inadequate cost reimbursement. The final decision of the court of appeals ignores this overriding purpose.

Stephen Zuckerman of the Urban Institute, one of the nation's foremost experts on Medicare payment systems, wrote in 2004:

> "The goal of the Medicare fee schedule was to create a payment system for physician services in which fees varied with resource costs. . . . The fundamental reason that policymakers vary physician fees across geographic areas is to adjust for differences in input prices faced by physicians that are beyond their control. . . . Adjustments for input price differences can be seen as promoting fairness by acknowledging cost differences across areas."

As detailed above, the Secretary established payment accuracy standards in 1996 in the process of creating the current locality structure. Due to changing demographics and economics, those standards are no longer being met, but the Secretary has offered no real explanation for ignoring those standards.

In *Kaiser Foundation Hospitals v. Sebelius*, 828 F.Supp.2d 193, 203 (D.D.C. 2011), aff'd, 708 F.3d 226, 233 (D.C. Cir. 2013), the court held that where, as here, the Secretary failed to provide sufficient reasons for changing a previously stated position on reimbursement levels, the failure was arbitrary and constitutionally infirm even in the face of additional administrative burdens that would result:

> "[I]n this case, the Secretary maintains that it is perfectly reasonable to allow the error to affect reimbursement levels far into the

> future. The only real difference between the miscalculation in [*Regions*] and the purported error here is that perpetuation of the mistake in *Regions* would have resulted in a financial loss to the agency, whereas in this case, the agency stands to gain. This seems to be the very definition of treating like situations differently. Since the Secretary has failed to provide sufficient reasons for her change of position, the Court finds that her decision in this case was arbitrary."

While the payment errors in this case do not benefit the Secretary or CMS, they allow the Secretary to make windfall overpayments to a favored group at the expense of another. This blatant and overt economic favoritism cannot withstand rational basis review. *See Atlantic Coast Line R. Co. v. North Carolina Corp. Comm'n*, 206 U.S. 1, 25-26 (1907); *Merrifield v. Lockyer,* 547 F.3d 978, 990-92 (9th Cir. 2008); *Craigmiles v. Giles*, 312 F.3d 220, 225 (6th Cir. 2002); *Cornwell v. Hamilton*, 80 F.Supp.2d 1101, 1117-18, fn. 50 (S.D. Cal. 1999).

The constitutionality of the Secretary's action or inaction is measured not by the circumstances in 1996, but within the context of the changes in economic conditions that began in 2001 and continue to the present. In *United States v. Carolene Products, Co.*, 304 U.S. 144, 153 (1938), this Court held that the "constitutionality of a statute predicated upon the existence of a particular state of facts may be challenged by showing to the court that those facts have ceased to exist." *See* also *Nashville C. & St.L. Ry. v.*

Walters, 294 U.S. 405, 415 (1935) ("A statute valid when enacted may become invalid by change in the conditions to which it is applied").

In *Shelby County, Alabama v. Holder*, ___ U.S. ___, 133 S.Ct. 2612 (2013), this Court applied a rational basis standard to invalidate the preclearance requirement of the Voting Rights Act. This Court concluded that Congress could have updated the formula, but that its "failure to act" left the Court no choice but to declare that the old formula "could no longer be used as a basis" for the federal preclearance requirement. *Shelby County*, 133 S.Ct. at 2631. In short, a federal formula that once had been rational was deemed irrational because it no longer "speaks to current conditions." In *Shelby County*, Congress was on notice that the preclearance coverage formula was out of date and likely irrational, much as the Secretary has been on notice in this case since 2001. *Shelby County*, 133 S.Ct. at 2625-26.

This Court should require the Secretary to ensure that the Medicare Part B locality structure speaks to current conditions and furthers, rather than impedes, the "overriding purpose" of Medicare.

3. The Final Decision Of The Court Of Appeals Conflicts With Decisions Of Other Courts

The final decision of the court of appeals fails to weigh the Secretary's attempted justification within the context of the Medicare Act and flatly conflicts

with decisions of other courts that have addressed a similar issue in the context of cases involving public health issues.

There are substantial and obvious policy differences between the City of Indianapolis' decision to forego collection of a portion of the City's tax revenue based on a detailed cost-benefit analysis and a decision in this case involving substantial public health issues to improperly channel Medicare reimbursements owed to one group in order to make unearned windfall payments to another. Thus, the goals and purposes of Medicare – not those of a city tax collection policy – must be examined in order to properly assess Petitioners' equal protection claims because "[t]he State may not rely on a classification whose relationship to an asserted goal is so attenuated as to render the distinction arbitrary or irrational." *Cleburne*, 473 U.S. at 446.

"[I]n taxation, even more than in other fields, legislatures possess the greatest freedom in classification." *Madden v. Kentucky*, 309 U.S. 83, 88 (1973).[8] In contrast to cases involving tax issues, the government's purported justification of administrative burden is routinely given short shrift in equal protection and other cases involving public health issues. In

[8] As the dissent observed in *Armour*, the Equal Protection Clause requires "rough equality" even in tax cases, citing *Allegheny Pittsburgh Coal Co. v. Commission of Webster Cty.,* 488 U.S. 336, 343-44 (1989), and *Hillsborough v. Cromwell,* 326 U.S. 620, 623 (1946). *Armour*, 132 S.Ct. at 2084-85.

Sowell v. Richardson, 319 F.Supp. 689, 691 (D.S.C. 1970), the court found:

> "The purpose of the [Medicare] Act was to insure that adequate medical care was available to the aged throughout this country. Neither the courts nor the Secretary should, in the interest of minimizing costs so interpret the provisions of the Act as to frustrate its purpose."

See In re Medicare Reimbursement Litig., 414 F.3d 7, 12 (D.C. Cir. 2005) ("even if the delay increased HCFA's administrative burden, the additional 'burden [would] not outweigh the public's substantial interest in the Secretary following the law.'"); *West Virginia Univ. Hosps. Inc. v. Casey*, 885 F.2d 11, 29 (3d Cir. 1989), aff'd on other grounds, 499 U.S. 83 (1991) ("Pennsylvania's excuse of administrative burden does not, in this case, provide a rational basis for [the hospital's] grossly diminished reimbursement rates."); *Children's Seashore House v. Waldman*, 197 F.3d 654, 662 (3d Cir. 1999) (following *Casey*); *Samaritan Health Center v. Heckler*, 636 F.Supp. 503, 518 (D.D.C. 1985) ("The burden on the Secretary will not be great, and the equities favor a result that requires the Secretary to perform the duty that Congress had assigned to her.").

When viewed in the context of the purpose of the Medicare scheme, the insubstantial phantasm of administrative burden cannot justify the Secretary ignoring the public health consequences of failing to accurately reimburse physicians for the costs of services

they have advanced. Inadequate reimbursement coupled with the galling knowledge that the savings realized by the Secretary are being used to make windfall overpayments to others amounts to begging physicians to stop treating Medicare beneficiaries, a result that could not be further from the "overriding purpose" of Medicare. When properly viewed in the context of that purpose, "administrative burden" cannot serve as a rational basis for maintaining a locality structure that lowers reimbursement rates for one group in order to provide artificially inflated and unearned windfalls to another.

C. Rational Basis Review Cannot Support The Agency's Admittedly *Ultra Vires* Actions

An especially troublesome aspect of this case is that even though CMS has repeatedly admitted that it has no authority to reduce payments to physicians in some areas in order to fund unearned higher payments to physicians in other areas, the final decision of the court of appeals will allow CMS to continue exceeding its authority.

In 1996, CMS stated, "Arbitrarily taking away money from a high cost area merely to redistribute it to other areas would violate our criteria and underpay the high cost area while overpaying the low cost areas." 61 Fed. Reg. 59490, 59496 (11/22/1996). In rejecting the CMA's 2007 proposal to modify the locality structure in California, CMS made a similar admission: "We have no authority to reduce the

GPCIs of some localities in a State to offset higher payments to other localities." 72 Fed. Reg. 66222, 66248 (11/27/2007). CMS also admitted in 2007 that it had "no authority to assign or retain GPCIs that do not represent the actual values for a locality." *Id.* at 66247-48.

CMS' admissions are correct. *See New York v. F.E.R.C.*, 535 U.S. 1, 18 (2002) ("[A]n agency literally has no power to act unless and until Congress confers power upon it."). Nothing in the Medicare Act authorizes the Secretary to channel supplemental payments to rural counties. Congress itself has provided for increased payments to underserved areas of the country in a number of other sections of the Medicare Act by:

(1) providing bonus payments and other incentives for those practicing in "Health Professional Shortage Areas" (42 U.S.C. §§ 254c, *et seq.*, and 42 C.F.R. §§ 51c.102, *et seq.*);

(2) setting a floor for Alaska's work GPCI at 1.5 (42 U.S.C. § 1395w-4(e)(1)(G));

(3) setting a 1.0 practice expense GPCI floor for the five "Frontier States" (North Dakota, South Dakota, Montana, Idaho, and Nevada) (42 U.S.C. § 1395w-4(e)(1)(I));

(4) setting a 1.00 work GPCI floor for all localities (42 U.S.C. § 1395w-4(e)(1)(E)); and

(5) providing that the work GPCIs reflect only one-quarter of the relative cost differences compared to the national average (42 U.S.C. § 1395w-4(e)(1)(A)(iii)).

Between 2004 and 2013, CMS regularly invoked a four-part mantra to justify the delay in implementing locality reconfiguration to cure the payment disparities that had arisen since 1996: (1) the fact that "winners and losers" or a "significant redistribution" would result; (2) the need for "support of a State medical association"; (3) the need for further study; and (4) administrative burden. *See*, *e.g.*, 75 Fed. Reg. 40039, 40086-87 (7/13/2010).

Each of these rationales is, in reality, a pretext to justify the *ultra vires* act of channeling supplemental payments to rural areas. The concern for "losers" should a locality reconfiguration be accomplished is a truly misplaced concern for so-called "losers" who will only be "losers" if they stop receiving windfall overpayments at the expense of others. The desire to obtain "support" of state medical associations is equally irrational because it requires realizing the pipedream of obtaining the support of members of those associations who will be "losers" when their windfall overpayments are eliminated. After eleven detailed studies over fifteen years, asserting the "need for further study" verges on the absurd. As discussed, *supra*, administrative burden is a phantasm contradicted by the administrative record.

It should be too plain to be contested that CMS' admittedly *ultra vires* actions cannot survive rational basis review because a governmental entity does not have a legitimate purpose to regulate beyond the authority conferred by its enabling legislation. *See Atlantic Coast Line,* 206 U.S. at 25-26.

D. The Legislative History Shows That Congress Did Not Intend To Prohibit Judicial Review Of The Selection Of Fee Schedule Areas

The initial decision of the court of appeals wrongfully precludes judicial review of Petitioners' claims under the Administrative Procedures Act. App. C, pp. 19-a to 23-a. As enacted, 42 U.S.C. § 1395w-4(i)(1) expressly prohibits administrative and judicial review of the determination of the key cost variables used in the physician fee schedule formula to calculate reimbursement rates under Medicare Part B. The majority decision of the court of appeals held that 42 U.S.C. § 1395w-4(i)(1) also impliedly prohibits judicial and administrative review of "the selection of fee schedule areas" where those "local" cost variables are measured. That decision cannot stand for a number of reasons.

First, the legislative history of the statute does not support the construction imposed by the court of appeals. That legislative history of 42 U.S.C. § 1395w-4(i)(1) shows that an earlier version of the 1989 OBRA included a provision that expressly prohibited judicial

or administrative review of the "selection of fee schedule areas." However, that provision was deleted from the final version of the bill.

Initially, the House version of the 1989 OBRA prohibited judicial or administrative review of: "(e) the ***selection*** of fee schedule areas under subsection (c)(3)(B) [sic]." 135 Cong. Rec. H5984-05 at H6023 (9/27/1989); App. G, p. 68-a.[9] The later Senate version deleted that prohibition and substituted: "(e) the establishment
of the system for the coding of physicians' services under this section." 135 Cong. Rec. S13911-04 at S13928-29 (10/24/1989); App. H, p. 69-a; *see also* 135 Cong. Rec. at H6105.

The only inference that can be reasonably drawn from the legislative history is that Congress considered prohibiting judicial review of the selection of localities but decided against it. "Where Congress includes limiting language in an earlier version of a bill but deletes it prior to enactment, it may be presumed that the limitation was not intended." *Russello v. United States,* 464 U.S. 16, 23-24 (1983); *see United States v. Naftalin*, 441 U.S. 768, 773 (1979) ("The short answer is that Congress did not write the statute that way.").

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[9] Subsection (c)(3)(***B***) dealt with "anesthesia services." The intended reference was presumably to subsection (c)(3)(***C***), which defined "fee schedule areas." 135 Cong. Rec. at H6023, App. G, p. 68-a; *see* Order, at App. D, p. 41-a, fn. 3.

Second, the majority's opinion misconstrues the nature of the relationship between the locality structure and the "establishment of geographic adjustment factors under [42 U.S.C. § 1395w-4(e)]" when it found Petitioners' challenge to the locality structure "necessarily involves a challenge to the geographic adjustment factors." Localities are geographic areas where costs are measured. Those areas ***are not*** statutorily defined. The "establishment" of the GAFs is how costs relative to the national average are measured and combined by the fee schedule formula (i.e., what specific costs, cost proxies, comparisons, and/or adjustments should be used). That process ***is*** statutorily defined in 42 U.S.C. § 1395w-4(e). As Judge Reinhardt stated in dissent, "Whereas GAFs are tools that the HHS secretary uses to adjust payments for Medicare services, fee schedule areas are geographic entities that GAFs measure." App. C, p. 21-a.

Third, that majority's construction finds that there is no administrative or judicial review of each of the fee schedule formula variables ***and*** the locations in which they are measured. That construction is inherently flawed because had that been Congress' intent, all that Congress would have needed to do is prohibit "review of the amounts of reimbursement payments under Medicare Part B," and the discrete prohibitions in the subsections of 42 U.S.C. § 1395w-4(i)(1) would then be "mere surplusage." *See Marbury v. Madison*, 1 Cranch 137, 174 (1803).

The bar on judicial review must be read in context and not in isolation. *Koons Buick Pontiac GMC,*

Inc. v. Nigh, 543 U.S. 50, 60 (2004). In other parts of the Medicare Act, Congress has specifically precluded judicial review of the definition of geographic localities:

(1) 42 U.S.C. § 1395ww(d)(10)(C)(iii)(II) – the "reclassification" of localities for hospitals;

(2) 42 U.S.C. § 1395*l*(m)(4)(A) – the "identification" of a "Health Professional Shortage Area";

(3) 42 U.S.C. § 1395*l*(u)(4)(D)(i) – the "identification" of counties and areas as "Physician Shortage Areas";

(4) 42 U.S.C. § 1395m(l)(12)(B)(v) – the "identification" of "qualified rural areas"; and

(5) 42 U.S.C. § 1395w-3b(g)(3) – the "establishment" of "qualified acquisition areas."

Within the Medicare Act, Congress has also expressly prohibited judicial review of ***all aspects*** of payment determinations in the following instances:

(1) 42 U.S.C. § 1395*l*(i)(2)(D)(v) – certain surgical services;

(2) 42 U.S.C. § 1395*l*(t)(12) – hospital outpatient department services;

(3) 42 U.S.C. § 1395m(l)(5) – ambulance services;

(4) 42 U.S.C. § 1395u(b)(10)(D) – cataract surgery procedures;

(5) 42 U.S.C. § 1395w-3a(g) – certain drugs and biologicals;

(6) 42 U.S.C. § 1395w-3b(g) – other drugs;

(7) 42 U.S.C. § 1395rr(b)(12)(H) – end stage renal disease treatments;

(8) 42 U.S.C. § 1320a-1(f) – certain planning activities; and

(9) 42 U.S.C. § 1395hhh(i) – "any determination made by the Secretary" with respect to Medicare's Health Care Infrastructure Improvement Program.

These express prohibitions of judicial review of localities and payment amounts in other sections of the Medicare Act demonstrate that it is proper to infer that Congress intended to permit rather than to prohibit courts from reviewing challenges to the determination of the fee schedule areas used in Medicare Part B. "[W]here Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion." *Kucana v. Holder*, 558 U.S. 233, 249 (2010) (multiple quotes omitted); *Russello*, 464 U.S. at 23.

Fourth, the 1989 OBRA did not include a methodology for fixing the boundaries of the fee schedule areas where "local" costs were to be measured. It is highly improbable that the 101st Congress chose to

impliedly preclude any review of fee schedule areas where it indicated that it wished to study the locality structure more closely, directed the Secretary to do the same, and left it up to a future Congress to define those boundaries. *See* H.R. Conf. Report No. 101-247, 345 (9/20/1989); H.R. Conf. Report No. 101-386, 743 (11/21/1989).

Finally, there is a "strong presumption" that Congress intends judicial review of administrative actions that can only be overcome by clear and convincing evidence of contrary intent. *Traynor v. Turnage*, 485 U.S. 535, 542 (1988); *Gutierrez de Martinez v. Lamagno*, 515 U.S. 417, 424 (1995). The Secretary certainly has not carried that heavy burden.

For these reasons, the only proper interpretation of the scope of the bar of judicial review found in 42 U.S.C. § 1395w-4(i)(1) is that it extends only to those specific formulaic elements of the physician fee schedule that are listed in subdivision (i)(1), and does not extend to the selection of localities.

CONCLUSION

The remedies Petitioners seek are revision of the antiquated locality structure and reimbursement at rates consistent with the Secretary's own payment accuracy standards. The court of appeals' rulings foreclose all ability to ever challenge the Secretary's configuration of the payment locality structure for

Medicare Part B, whether under the APA or on constitutional grounds.

As a result, the court of appeals has endowed the Secretary with absolute discretion to continue to economically favor one group over another as she has done since 2001 in a manner that CMS has repeatedly admitted it has no authority to employ. The rulings force a Hobson's choice on medical care providers in the affected counties – either continue to be paid by Medicare at rates below the cost of providing medical care or stop providing medical care to beneficiaries in the Medicare program. Such an outcome is antithetical to the goals of the Medicare program and directly harms Medicare's vulnerable beneficiaries, the elderly and infirm.

For all of the foregoing reasons, Petitioners respectfully request that their petition for a writ of certiorari be granted.

January 7, 2015

Respectfully submitted,

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APPENDIX A: OPINION OF THE COURT OF APPEALS (AUGUST 1, 2014)

UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

County of Santa Cruz v. Burwell, No. 13-16297,

2014 WL 3766538, at *1 (9th Cir. Aug. 1, 2014)

COUNTY OF SANTA CRUZ; County of Sonoma; County of San Diego; County of Marin; County of Santa Barbara; County of San Luis Obispo; County of Monterey; Theodore M. Mazer, M.D.; Wolbers and Poree Medical Corporation,

Plaintiffs–Appellants,

v.

Sylvia M. BURWELL,* Secretary, Department of Health and Human Services,

Defendant–Appellee.

*Sylvia M. Burwell is substituted for her predecessor as Secretary of the Department of Health and Human Services.

No. 13–16297. Argued and Submitted June 10, 2014. Filed Aug. 1, 2014.

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Appeal from the United States District Court for the Northern District of California, Jeffrey S. White, District Judge, Presiding. D.C. No. 3:07–cv–02888–JSW.

Before: O'SCANNLAIN, FERNANDEZ, and BEA, Circuit Judges.

MEMORANDUM**

**This disposition is not appropriate for publication and is not precedent except as provided by 9th Cir. R. 36–3.

*1 The California counties of Santa Cruz, Sonoma, San Diego, Marin, Santa Barbara, San Luis Obispo, and Monterey, as well as Theodore M. Mazer and Wolbers & Poree Medical Corp.,

(collectively "Plaintiffs"), brought this action against the Secretary of the Department of Health and Human Services ("the Secretary"). Plaintiffs claim that the Secretary's failure to revise the "fee schedule areas," which determine the fees paid to the Plaintiffs for providing Medicare services, violated Plaintiffs' equal protection rights, and that 42 U.S.C. § 1395w–4(j)(2) (the "Fee Schedule" statute) and the regulation implementing this statute, 42 C.F.R. § 414.4, are unconstitutional as applied to Plaintiffs because the Fee Schedule statute and the related regulation deprived Plaintiffs of equal protection.

The district court granted the Secretary's motion to dismiss for failure to state a claim for relief or, in the alternative, for summary judgment. We AFFIRM. Under our "highly deferential" rational basis review of such government classification under the equal protection component of the Due Process Clause, *Kahawaiolaa v. Norton*, 386 F.3d 1271, 1279–80 (9th Cir.2004), the Secretary's decision to maintain the status quo in the fee schedule areas structure can be supported on the basis of minimizing administrative cost and burden. See *Armour v. City of Indianapolis*, —— U.S. ——, 132 S.Ct. 2073, 2083, 182 L.Ed.2d 998 (2012).

AFFIRMED.

APPENDIX B: ORDER OF THE DISTRICT COURT (APRIL 26, 2013)

Case 3:07-cv-02888-MJJ Document 147

Filed 04/26/2013

IN THE UNITED STATES
DISTRICT COURT
FOR THE NORTHERN DISTRICT
OF CALIFORNIA

SANTA CRUZ COUNTY, et al.,

Plaintiffs,

v.

KATHLEEN SEBELIUS, Secretary of the United States Department of Health and Human Services,

Defendant.

_____/

No. C07-02888 MJJ

ORDER GRANTING DEFENDANT'S MOTION TO DISMISS OR FOR SUMMARY JUDGMENT

Now before the Court is the motion to dismiss or, in the alternative, for summary judgment filed by Defendant. Having carefully reviewed the parties' papers, considered their arguments and the

relevant legal authority, the Court hereby grants Defendant's motion to dismiss or for summary judgment.[1]

Fn. 1 The Court DENIES Plaintiffs' request to file a sur-reply.

BACKGROUND

Defendant moves to dismiss Plaintiffs' second amended complaint ("SAC") or, in the Alternative, for summary judgment. Plaintiffs' only remaining claims are those for violation of equal protection. The Court will address additional facts as necessary in the remainder of this Order.

ANALYSIS

A. Applicable Legal Standards.

When a defendant moves to dismiss a complaint or claim for lack of subject matter jurisdiction the plaintiff bears the burden of proving that the court has jurisdiction to decide the claim. *Thornhill Publ'n Co. v. Gen. Tel. & Elecs. Corp.*, 594 F.2d 730, 733 (9th Cir. 1979). A motion to dismiss for lack of subject matter jurisdiction under Federal Rule of Civil Procedure 12(b)(1) may be "facial or factual." *Safe Air for Everyone v. Meyer*, 373 F.3d 1035, 1039 (9th Cir. 2004).

A facial attack on the jurisdiction occurs when factual allegations of the complaint are taken as true. *Fed'n of African Am. Contractors v. City of Oakland*, 96 F.3d 1204, 1207 (9th Cir. 1996). The plaintiff is then entitled to have those facts

construed in the light most favorable to him or her. *Id.* A factual attack on subject matter jurisdiction occurs when defendants challenge the actual lack of jurisdiction with affidavits or other evidence. *Thornhill*, 594 F.2d at 733. In a factual attack, plaintiff is not entitled to any presumptions or truthfulness with respect to the allegations in the complaint, and instead must present evidence to establish subject matter jurisdiction. *Id.*

A motion to dismiss is proper under Federal Rule of Civil Procedure 12(b)(6) where the pleadings fail to state a claim upon which relief can be granted. The Court construes the allegations in the complaint in the light most favorable to the non-moving party and all material allegations in the complaint are taken to be true. *Sanders v. Kennedy*, 794 F.2d 478, 481 (9th Cir. 1986). However, even under the liberal pleading standard of Rule 8(a)(2), "a plaintiff's obligation to provide the 'grounds' of his 'entitle[ment] to relief' requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (citing *Papasan v. Allain*, 478 U.S. 265, 286 (1986)).

Pursuant to *Twombly*, a plaintiff must not merely allege conduct that is conceivable but must instead allege "enough facts to state a claim to relief that is plausible on its face." *Id.* At 570. "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S.662, 678 (2009) (citing *Twombly*, 550 U.S. at

556). "The plausibility standard is not akin to a probability requirement, but it asks for more than a sheer possibility that a defendant has acted unlawfully.... When a complaint pleads facts that are merely consistent with a defendant's liability, it stops short of the line between possibility and plausibility of entitlement to relief." *Id.* (quoting *Twombly*, 550 U.S. at 557) (internal quotation marks omitted). If the allegations are insufficient to state a claim, a court should grant leave to amend, unless amendment would be futile. *See, e.g., Reddy v. Litton Indus., Inc.*, 912 F.2d 291, 296 (9th Cir. 1990); *Cook, Perkiss & Liehe, Inc. v. N. Cal. Collection Serv., Inc.*, 911 F.2d 242, 246-47 (9th Cir. 1990).

Summary judgment is proper when the "pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c). "In considering a motion for summary judgment, the court may not weigh the evidence or make credibility determinations, and is required to draw all inferences in a light most favorable to the non-moving party." *Freeman v. Arpaio*, 125 F.3d 732, 735 (9th Cir. 1997).

The party moving for summary judgment bears the initial burden of identifying those portions of the pleadings, discovery, and affidavits that demonstrate the absence of a genuine issue of material fact. *Celotex Corp. v. Cattrett*, 477 U.S. 317, 323 (1986). An issue of fact is "genuine" only if there is sufficient evidence for a reasonable fact

finder to find for the non- moving party. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248-49 (1986). A fact is "material" if it may affect the outcome of the case. *Id.* at 248. If the party moving for summary judgment does not have the ultimate burden of persuasion at trial, that party must produce evidence which either negates an essential element of the non-moving party's claims or that party must show that the non-moving party does not have enough evidence of an essential element to carry its ultimate burden of persuasion at trial. *Nissan Fire & Marine Ins. Co. v. Fritz Cos.*, 210 F.3d 1099, 1102 (9th Cir. 2000). Once the moving party meets its initial burden, the non-moving party must go beyond the pleadings and, by its own evidence, "set forth specific facts showing that there is a genuine issue for trial." Fed. R. Civ. P. 56(e).

In order to make this showing, the non-moving party must "identify with reasonable particularity the evidence that precludes summary judgment." *Keenan v. Allan*, 91 F.3d 1275, 1279 (9th Cir. 1996). In addition, the party seeking to establish a genuine issue of material fact must take care adequately to point a court to the evidence precluding summary judgment because a court is "'not required to comb the record to find some reason to deny a motion for summary judgment.'" *Carmen v. San Francisco Unified School Dist.*, 237 F.3d 1026, 1029 (9th Cir. 2001) (quoting *Forsberg v. Pacific Northwest Bell Telephone Co.*, 840 F.2d 1409, 1418 (9th Cir. 1988)). If the non-moving party fails to point to evidence precluding summary judgment, the moving party is entitled to judgment as a matter of law. *Celotex*, 477 U.S. at 323.

B. Defendant's Motion.

1. Plaintiffs' Equal Protection Claims.[2]

Fn.2 In their motion to dismiss Plaintiffs' first amended complaint, Defendant argued that a provision within the Medicare statute, 42 U.S.C. § 1395w-4(i)(1)(D), bars judicial review of Plaintiffs' constitutional equal protection claims. The Court rejected this argument, concluding that there was no clear and convincing evidence that Congress intended to preclude review of constitutional claims. To the extent Defendants are again arguing that judicial review of Plaintiffs' constitutional equal protection claims is barred, Defendant failed to first move for leave to file a motion for reconsideration. Therefore, the Court will not consider this argument. To the extent Defendant argues that judicial review of Plaintiffs' claims is barred because Defendant has construed Plaintiffs' claims as ones falling under the Medicare Act, the Court has already held that Plaintiffs cannot bring a statutory claim.

Equal Protection jurisprudence is "concerned with governmental classifications that 'affect some groups of citizens differently than others.'" *Enquist v. Oregon Dept. of Agriculture*, 553 U.S. 591, 601 (2008) (quoting *McGowan v. Maryland*, 366 U.S. 420, 425 (1961)). The Equal Protection Clause generally requires that similarly situated individuals be treated similarly. *City of Cleburne, Texas v. Cleburne Living Center*, 473 U.S. 432, 439 (1985). Because Plaintiffs have not alleged that they are members of a protected class, they must allege that they were "intentionally treated differently from others similarly situated and that there is no rational basis for the difference in

treatment." *Village of Willowbrook v. Olech*, 528 U.S. 562, 564 (2000).

In dismissing Plaintiffs' first amended complaint, the Court found that despite Plaintiffs' claims label, their claims were premised on the statutory scheme and alleged that the Medicare statute was not properly followed. Upon review of Plaintiffs' SAC, the Court finds that Plaintiffs' equal protection claims are still premised on the Medicare statute. Plaintiffs deleted the statutory references, but the substance of Plaintiffs' allegations remain essentially unchanged. For example, Plaintiffs had alleged that "Pursuant to 42 U.S.C. § 1395w-4(b), [Centers for Medicare and Medicaid Services ("CMS")] had a duty ..." Now Plaintiffs just allege that CMS has the same duty, but omit the source of that duty. (See SAC ¶ 291.) Although Plaintiffs have artfully deleted some references to the Medicare statute, the Court finds that their equal protection claims are still premised on this statute. Therefore, the Court grants Defendant's motion to dismiss.

However, assuming *arguendo* that Plaintiffs' did successfully allege an equal protection claim, they still fail to demonstrate that Defendant lacks a rational basis for its conduct in opposition to Defendant's motion for summary judgment. Rational basis review is "a paradigm of judicial restraint" and "is not a license for courts to judge the wisdom, fairness, or logic of legislative choices." *FCC v. Beach Communications, Inc.*, 508 U.S. 307, 313-14 (1993); see also *Kahawaiolaa v. Norton*, 386 F.3d 1271, 1279 (9th Cir. 2004) (describing rational basis review as "highly deferential"). "Nor does it

authorize 'the judiciary [to] sit as a superlegislature to judge the wisdom or desirability of legislative policy determinations made in areas that neither affect fundamental rights nor proceed along suspect lines.'" *Heller*, 509 U.S. at 319 (quoting *Dukes*, 427 U.S. at 303).

"'[T]he burden of establishing the unconstitutionality of a statute rests on him who assails it.'" *Baker v. Carr*, 369 U.S. 186, 266 (1962) (quoting *Metropolitan Casualty Ins. Co. v. Brownell*, 294 U.S. 580, 584 (1935)). The burden is to "'negative every conceivable basis which might support it,' whether or not the basis has a foundation in the record." *Heller*, 509 U.S. at 320-21 (quoting *Lehnhausen v. Lake Shore Auto Parts Co.*, 410 U.S. 356, 364 (1973)). "A classification does not fail rational-basis review because it 'is not made with mathematical nicety or because in practice it results in some inequality.'" *Id.* at 321 (quoting *Dandridge v. Williams*, 397 U.S. 471, 485 (1970)). "The problems of government are practical ones and may justify, if they do not require, rough accommodations – illogical, it may be, and unscientific." *Id.* (citing *Metropolis Theatre Co. v. City of Chicago*, 228 U.S. 61, 69-70 (1913)). "A statutory discrimination will not be set aside if any state of facts reasonably may be conceived to justify it." Id. (citing *McGowan v. Maryland*, 366 U.S. 420, 426 (1961)).

Plaintiffs fail to meet their burden to show that the Secretary's failure to alter the geographic localities is not supported by a rational basis.[3] Although Plaintiffs disagree with the reasons proffered by the Secretary, they have not shown

that the justifications are at least arguable. The Secretary has explained that while the agency has been considering making changes to the existing payment localities, removing high-cost counties from a locality would result in lower geographic practice cost indicies ("GPCIs") for the remaining counties due to the budget neutrality requirement. See 70 Fed. Reg. 45764, 45783. Due to this redistributive effect, the agency has refrained from making changes to payment localities unless there is evidence of statewide support for the proposed change. Id. Although the California Medical Association ("CMA") did propose a change, the proposed change would have minimized the lowered locality payments to the negatively affected payment localities by redistributing payments from the existing and newly created higher payment localities. The Secretary determined that it did not have the authority under the statue to modify the GPCIs in this manner. Id.

> Fn. 3 Plaintiffs again argue that the Secretary's decision should be evaluated under the arbitrary and capricious standard under the Administrative Procedure Act ("APA"), citing *Ursack Inc. v. Sierra Interagency Black Bear Group*, 639 F.3d 949, 956 (9th Cir. 2011). The Court already rejected this argument. In the Order dismissing Plaintiffs' first amended complaint, the Court noted that although the court in *Ursack* states that the rational basis and the arbitrary and capricious standard are analogous, the court proceeded to evaluate the plaintiff's equal protection claim under the framework of an equal protection analysis. *Id.* at 958. This Court will do the same.
>
> Plaintiffs also improperly seek to increase the standard of review, by citing to cases regarding selective

> enforcement and cases where a statutory command was violated. (Opp. at 10 (citing to *Squaw Valley Dev. Co. v. Goldberg*, 375 F.3d 936 (9th Cir. 2004) and 20-21 (citing to *Servin-Espinosa v. Ashcroft*, 309 F.3d 1193 (9th Cir. 2002) and *Allegheny Pittsburgh Coal Co. v. Cnty Com'n of Webster Co., W. Va*, 488 U.S. 336 (1989). However, selective enforcement and violations of statutory commands are not at issue here. Therefore, those cases are inapplicable.

The Secretary proposed removing just Santa Cruz and Sonoma Counties from the Rest of California locality, but this proposed change met with much opposition and was not supported by a majority of the commenters. *Id.*; see also 70 Fed. Reg. 70116, 70152. While the agency noted the concerns of practitioners in Santa Cruz and Sonoma Counties, the agency also "acknowledge[d] the concerns of those in the Rest of California payment locality about the negative payment impact of removing the GPCI data for Santa Cruz and Sonoma Counties, and the lack of support from the CMA for an administrative solution to these payment concerns." *Id.* The Secretary is seeking to balance these two competing interests. *Id.*

Although Plaintiffs vehemently disagree with the choices the Secretary has made, balancing between competing interests constitutes a rational basis for the Secretary's decision to not alter the geographic localities. Notably, Plaintiffs are not challenging the Secretary's initial creation of the geographic localities. Instead, Plaintiffs are challenging the Secretary's failure to make changes to the geographic localities in light of changed

circumstances. See *Guidace v. Jackson*, 726 F. Supp. 632 (E.D. Va. 1989).

In *Guidace*, the plaintiffs challenged Virginia's maintenance of the original locality groupings for purpose of payments under Aid to Families with Dependent Children ("AFDC"). In 1974, Virginia created three different groupings. The plaintiffs did not challenge the initial groupings or Stafford County's initial placement within those groupings. However, due to the changed cost-of-living in Stafford County since the initial groupings, the plaintiffs challenged the continued maintenance of the original groupings. *Id.* at 636-37. The court noted that there were no statutory or regulatory requirements which required states to periodically adjust groupings due to changes in the costs-of-living. *Id.* at 637. The defendant argued that due to limited funds, if it moved all of the localities that need to be shifted into a higher grouping, it would have needed to reduce the AFDC benefits for all recipients in the state. Instead, the defendant chose to maintain the status quo. *Id.* at 639. The Court held that such choice was reasonable and did not violate equal protection. *Id.*

Similarly, here, due to the requirement to maintain budget neutrality, any changes made to Plaintiffs' geographic locality would negatively impact the remaining areas in the Rest of California locality. In balancing competing interests, the decision to maintain the status quo was reasonable and does not violate equal protection.

The Court finds that Plaintiffs' equal protection challenge fails for another reason. Plaintiffs must "plead and prove that the defendant acted with discriminatory purpose." *Ashcroft*, 556 U.S. at 676. To show such discriminatory purpose, Plaintiffs must do more than show Defendant's "awareness of the consequences." Id. Rather, Plaintiffs must show Defendant's "undertaking a course of action "because of,' not merely 'in spite of,' [the action's] adverse effects upon an identifiable group.'" *Id.* (quoting *Personnel Admin. of Mass. v. Feeney*, 442 U.S. 256, 279 (1979). Here, Plaintiffs have not submitted any evidence of intentional discrimination. At most, Plaintiffs have shown that Defendant is aware that suppliers in high-cost counties are seeking to alter the geographic localities and contend that suppliers in these counties are not being adequately reimbursed. What Plaintiffs have not shown is any intent by Defendant to maintain the status quo "because of," and not merely "in spite of" the adverse effects on Plaintiffs.

Accordingly, the Court grants Defendant's motion to dismiss, and assuming arguendo Plaintiffs state an equal protection constitutional claim, the Court grants Defendant's motion for summary judgment.

CONCLUSION

For the foregoing reasons, the Court GRANTS Defendant's motion to dismiss or, in the alternative, for summary judgment.

IT IS SO ORDERED.

Dated: April 26, 2013

s/ JEFFREY S. WHITE
UNITED STATES DISTRICT JUDGE

APPENDIX C: ORDER OF THE COURT OF APPEALS (SEPTEMBER 29, 2010)

County of Santa Cruz v. Sebelius,
99 Fed.Appx. 174
(9th Cir. September 29, 2010)

UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

COUNTY OF SANTA CRUZ; County of Sonoma; County of San Diego; County of Marin; County of Santa Barbara; County of San Luis Obispo; County of Monterey, on behalf of themselves and all others similarly situated,

Plaintiffs–Appellants,

v.

Kathleen SEBELIUS,

Defendant–Appellee.

No. 08–16389. Argued and Submitted April 13, 2009. Filed Sept. 29, 2010.

*175 Colleen Duffy–Smith, Morgan Duffy–Smith & Tidalgo, Michael Gannon Reedy, McManis Faulkner, San Jose, CA, Dario De Ghetaldi, Corey Luzaich Pliska De Ghetaldi & Nastari LLP, Millbrae, CA, Dana Maureen McRae, Santa Cruz, CA, for Plaintiffs–Appellants.

Catherine Y. Hancock, Peter Robbins, Esquire, Michael Raab, U.S. Department of Justice, Washington, DC, for Defendant–Appellee.

Appeal from the United States District Court for the Northern District of California, Jeffrey S. White, District Judge, Presiding. D.C. No. 3:07–cv–02888–JSW.

Before: REINHARDT, NOONAN and McKEOWN, Circuit Judges.

MEMORANDUM*

*This disposition is not appropriate for publication and is not precedent except as provided by 9th Cir. R. 36–3.

Various counties of the state of California ("the Counties") brought this action against the Secretary of the Department of Health and Human Services ("the Secretary") raising constitutional and statutory claims in connection with reimbursement under Medicare. The Counties' constitutional claims asserted that Secretary's failure to revise the "fee schedule areas" that determine the fees paid to the Counties for providing Medicare services violated the Counties' equal protection and due process rights, and that 42 U.S.C. § 1395w–4(1)(2) (the "Fee Schedule" statute) and the regulation implementing this statute, 42 C.F.R. § 414.4, are unconstitutional as applied to the Counties because they deprived them of property and equal protection. The Counties' statutory claims asserted that the Secretary's failure to revise the fee schedule areas violated various provisions of the

Administrative Procedure Act and the Medicare Act.

The district court dismissed the Counties' constitutional claims on the ground that the Counties did not qualify as persons under the Fifth Amendment, and thus lacked standing. The court dismissed the Counties' statutory claims on the ground that they are barred by statute. We affirm the district court's dismissal of the Counties' statutory and due process claims, and remand the Equal Protection claims.

We affirm the district court's dismissal of the Counties' statutory claims. The Medicare statute bars judicial review of the "establishment of geographic adjustment factors under subsection (e)." 42 U.S.C. § 1395w–4(i)(1)(d). The challenge to the Fee Schedule necessarily involves a challenge to the geographic adjustment factors. The district court appropriately concluded that it lacked jurisdiction over *176 the statutory claims related to the fee schedule areas.

We also affirm the district court's dismissal of the Counties' due process claims. We conclude that, at least for purposes of the claim before us, the counties are persons. Nonetheless, the Counties' due process claims fail because the Counties do not have a property right to any particular payment by Medicare. *See Erickson v. U.S. ex rel. Dept. of Health and Human Services*, 67 F.3d 858, 862 (9th Cir.1995).

Finally, we remand the Counties' Equal Protection claims. Because we conclude, at least for

purposes of this claim, that the Counties are persons, we move to considering whether the Secretary's decision not to revise the fee schedule areas is supported by a rational basis. The district court did not reach this issue. In response to our request for supplemental briefing on rational basis, the Secretary relied on the rationality of the 1996 revision of the fee schedule, while the Counties pointed to demographic changes that made the 1996 schedule irrational. We cannot decide this issue on the complaint and the briefs alone. Accordingly, we remand the Equal Protection claims to the district court for further proceedings.

For the forgoing reasons, the judgment of the district court is AFFIRMED in part, REVERSED in part, and REMANDED. The parties shall bear their own costs on appeal.

REINHARDT, Circuit Judge, concurring in part and dissenting in part.

I concur in the remand of the Equal Protection claim and agree that Counties are persons for purposes of the Counties' constitutional claims.

I dissent from the majority's affirmance of the district court's dismissal of the Counties' statutory claims because, in my view, 42 U.S.C. § 1395w–4(i)(1)(D) does not bar judicial review of fee schedule areas. The statute does not explicitly bar such review. The majority does not dispute this fact, but decides instead that it implicitly bars review of fee schedule areas because it bars review of geographic adjustment factors (GAFs)

subcomponents, and fee schedule areas constitute GAF subcomponents.

The statute's plain language, legislative history, and purpose show the error in the majority's reasoning. Congress explicitly enumerated several areas of Medicare for which judicial review is prohibited (including conversion factors, adjusted historical payment basis, and more important to the case before us, the establishment of GAFs), but it did not include fee schedule areas in this list. Because Congress omitted fee schedule areas from the factors enumerated in the statutory bar, it is reasonable to infer from its action that Congress intended to permit rather than to prohibit courts from reviewing challenges to the determination of fee schedule areas. Congress also explicitly enumerated several subcomponents of the GAFs, (including procedure codes for physicians' services and relative value unites), but it did not include fee schedule areas as a subcomponent. Nor can fee schedule areas simply be assumed to be subcomponents of GAFs, as the majority believes. Whereas GAFs are tools that the HHS secretary uses to adjust payments for Medicare services, fee schedule areas are geographic entities that GAFs measure. See 42 U.S.C. § 1395w–4(j)(2) (defining a fee schedule area as "a locality used ... for purposes of computing payment amounts for physicians' services").

Legislative history also supports the proposition that Congress did not intend that § 1395w–4(i)(1)(D) bar judicial review of fee schedule areas. The Senate deleted a prohibition against judicial review of fee *177 schedule areas from the

earlier House version of the statute that became the 1989 Omnibus Budget Reconciliation Act. Compare 135 Cong. Rec. H5984–05 at H6023 with 135 Cong. Rec. S13911–04 at S13928–29. The Supreme Court has held that in comparing earlier versions of a statute with the final version, courts may infer that Congress intentionally omitted items that were included in the earlier versions but omitted from the final version. *See Russello v. United States*, 464 U.S. 16, 23–24, 104 S.Ct. 296, 78 L.Ed.2d 17 (1983).

Finally, analysis of statutory purpose supports judicial review of fee service areas. Because GAFs are overhauled frequently, but fee service areas are not, a bar to judicial review helps to ensure efficient administrative handling of GAF changes, but provides no such help with respect to fee service areas. The statute requires that the HHS Secretary review GAF indices every three years and update the fee schedule annually, but imposes no such requirement for regular review or designation of fee schedule areas. 42 U.S.C. § 1395w–4(b)(1) & (e)(1)(c). In the absence of a congressional mandate, the HHS Secretary has in fact updated the fee schedule areas just once, over eleven years ago. A bar on judicial review could hardly be said to promote efficiency or timeliness with respect to a matter that is so infrequently the subject of review or change. In fact, should the setting of fee schedules on the basis of such unmodified area determinations have the disparate and unfair effect alleged by the plaintiffs on the compensation received by physicians and hospitals, it would seem to demonstrate that Congress could not have intended that the failure of HHS to

establish fair and reasonable boundaries for fee schedule areas should go permanently unreviewed by the courts.

For the foregoing reasons, I dissent from the majority's conclusion that Congress intended that 42 U.S.C. § 1395w–4(i)(1)(D) bar judicial review of fee schedule areas.

I also dissent from the court's failure to remand the Due Process claim on the ground that the Counties do not have a "property right" to Medicare payments. This issue is a close and important one that was not adequately briefed or argued by the parties, nor decided by the district court. Rather than decide that issue here, without adequate consideration, I would remand it to the district court for an initial and thorough review.

McKEOWN, Circuit Judge, concurring in part and dissenting in part:

I join in affirming dismissal of the Counties' statutory claims. I concur in the judgment dismissing the due process claims. I do not concur in the conclusion that the counties are persons for purposes of this suit. This novel question requires more nuanced consideration and, in my view, it is unnecessary to decide the issue in this case. I write separately to respectfully dissent from remand of the Equal Protection claim.

There is a fundamental reason why we do not need to address the "Counties as persons" argument. The Complaint identifies no cognizable Equal Protection claim as the government offers a

viable rationale for its approach to the Fee Schedule Areas. The Counties certainly have well-documented reasons to object to the lag between their payment levels under the current Fee Schedule Areas and their real costs to provide care. But the Secretary's stated reasons for maintaining the current Fee Schedule Areas, based on the 1996 revision, pass the "highly deferential" review applicable under the Equal Protection Clause. *See Kahawaiolaa v. Norton*, 386 F.3d 1271, 1279–80 (9th Cir.2004). The Secretary stated that the Fee Schedule *178 Areas established in the 1996 revision best met the goal of the revision process, which was to simplify payment areas and reduce disparities among geographic areas, while maintaining accuracy in tracking price differences across areas. The Secretary further declared that a solution has not yet been found that would better remedy the issue of geographic variations in costs without creating negative redistributive impacts and an increased administrative burden. The Secretary's rationale for not revising the 1996 Fee Schedule Areas is sufficient to pass our review. "In the end, we must commit this question to Congress to apply its wisdom in deciding" whether to alter the requirements for updating the Fee Schedule Areas. *Id.* at 1283.

For these reasons, I dissent from remand of the Equal Protection claim, and would affirm the district court's dismissal of that claim.

APPENDIX D: ORDER OF THE DISTRICT COURT GRANTING DEFENDANT'S MOTION TO DISMISS (MARCH 11, 2008)

Case 3:07-cv-02888-MJJ Document 57
Filed 03/11/2008

IN THE UNITED STATES
DISTRICT COURT
FOR THE NORTHERN DISTRICT
OF CALIFORNIA

SANTA CRUZ COUNTY,

Plaintiff,

v.

MICHAEL O. LEAVITT,

Defendant.

_____/

No. C07-02888 MJJ

ORDER GRANTING DEFENDANT'S MOTION TO DISMISS

INTRODUCTION

Before the Court is Defendant Michael O. Leavitt's ("Defendant") Motion To Dismiss. (Docket No. 40.) For the following reasons, the Court

GRANTS Defendant's Motion. The Court **DISMISSES** Plaintiffs' statutory claims (the fifth, sixth, and seventh causes of action) for lack of subject matter jurisdiction under 42 U.S.C. § 1395w-4(i)(1)(D). The Court **DISMISSES** Plaintiffs' Fifth Amendment due process and equal protection claims (the first, second, third and fourth causes of action) for failure to state a claim because the named Plaintiffs, which are all political subdivisions of the State of California, do not qualify as "persons" within the meaning of the Fifth Amendment. Finally, the Court **DISMISSES WITH LEAVE TO AMEND** Plaintiffs' unlawful delegation claim (the eighth cause of action) because Plaintiffs have not adequately pleaded the claim in a manner that demonstrates it has a constitutional basis that might confer subject matter jurisdiction on this Court.

FACTUAL BACKGROUND

Plaintiffs, several California counties that provide Part B Medicare services, contend that changing demographics have resulted in relative cost changes that meet or exceed the regulatory thresholds for modifying "fee schedule areas" or "localities" established by Medicare in 1996. The fee schedule controlling payments to physicians providing Part B Medicare services is determined by a formula set forth in 42 U.S.C. § 1395w-4. The formula consists of three core components calculated together in a multi-step process. One of these core components is the "geographic adjustment factor", which takes into account the variance in costs for doctors working in different parts of the country. A geographic adjustment

factor is established for every "fee schedule area" in the United States on the basis of the relative costs of practicing medicine, the relative costs of malpractice insurance, and the relative value of physician work effort in the different fee schedule areas. The term "fee schedule area" is defined as "a locality" used "for purposes of computing payment amounts for physicians' services", under the payment regime that preceded the present fee schedule regime. 42 U.S.C. § 1395w-4(j)(2).

Plaintiffs contend that Medicare has refused to implement its own policy to revise the affected localities and redraw the "fee schedule areas" to reflect the true economic costs of the services provided by Plaintiffs. Plaintiffs' putative class action complaint asserts eight causes of action challenging Defendant's determination and application of the fee schedule areas. Plaintiffs seek declaratory and injunctive relief, as well as more than $2.4 billion in compensation for underpayments under Part B Medicare reimbursement.

Plaintiffs' complaint asserts eight causes of action. The first, second, third and fourth causes of actions assert various equal protection and due process claims grounded in the Fifth Amendment. The fifth, sixth and seventh causes of action assert statutory claims grounded in the Administrative Procedure Act and the Medicare Act. The eighth cause of action asserts that Medicare has unlawfully delegated its duty to reconfigure Part B payment localities to state medical associations.

Defendant now moves to dismiss Plaintiff's claims on Rule 12(b)(1) and 12(b)(6) grounds.

LEGAL STANDARD

A. Rule 12(b)(1).

Rule 12(b)(1) authorizes a party to move to dismiss a claim for lack of subject matter jurisdiction. Federal courts are courts of limited jurisdiction; thus, the Court presumes lack of jurisdiction, and the party seeking to invoke the court's jurisdiction bears the burden of proving that subject matter jurisdiction exists. *See Kokkonen v. Guardian Life Ins. Co.*, 511 U.S. 375, 377 (1994). A party challenging the court's jurisdiction under Rule 12(b)(1) may do so by raising either a facial attack or a factual attack. *See White v. Lee*, 227 F.3d 1214, 1242 (9th Cir. 2000).

A facial attack is one where "the challenger asserts that the allegations contained in a complaint are insufficient on their face to invoke federal jurisdiction." *Safe Air for Everyone v. Meyer*, 373 F.3d 1035, 1039 (9th Cir. 2004). In evaluating a facial attack to jurisdiction, the Court must accept the factual allegations in plaintiff's complaint as true. *See Miranda v. Reno*, 238 F.3d 1156, 1157 n.1 (9th Cir. 2001). For a factual attack, in contrast, the Court may consider extrinsic evidence. *See Roberts v. Corrothers*, 812 F.2d 1173, 1177 (9th Cir. 1987). Further, the court does not have to assume the truthfulness of the allegations, and may resolve any factual disputes. *See White*, 227 F.3d at 1242. Thus, "[o]nce the moving party has converted the motion to dismiss into a factual

motion by presenting affidavits or evidence properly before the court, the party opposing the motion must furnish affidavits or other evidence necessary to satisfy its burden of establishing subject matter jurisdiction." *Savage v. Glendale Union High Sch.*, 343 F.3d 1036, 1039 n.2 (9th Cir. 2003).

In the Ninth Circuit, "[j]urisdictional dismissals in cases premised on federal-question jurisdiction are exceptional, and must satisfy the requirements specific in *Bell v. Hood*, 327 U.S. 678 [] (1946)." *Sun Valley Gas., Inc. v. Ernst Enters.*, 711 F.2d 138, 140 (9th Cir. 1983); *see Safe Air for Everyone*, 373 F.3d at 1039. The *Bell* standard provides that jurisdictional dismissals are warranted "where the alleged claim under the [C]onstitution or federal statute clearly appears to be immaterial and made solely for the purpose of obtaining federal jurisdiction or where such a claim is wholly insubstantial and frivolous." 327 U.S. at 682-83. Additionally, the Ninth Circuit has admonished that a "[j]urisdictional finding of genuinely disputed facts is inappropriate when 'the jurisdictional issue and substantive issues are so intertwined that the question of jurisdiction is dependent on the resolution of factual issues going to the merits' of an action." *Sun Valley*, 711 F.2d at 139. The jurisdictional issue and the substantive issues are intertwined where "a statute provides the basis for both the subject matter jurisdiction of the federal court and the plaintiff's substantive claim for relief." *Safe Air for Everyone*, 373 F.3d at 1039 (quoting *Sun Valley*, 711 F.2d at 139).

B. Rule 12(b)(6).

A motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6) tests the legal sufficiency of a claim. *Navarro v. Block*, 250 F.3d 729, 732 (9th Cir. 2001). Because the focus of a Rule 12(b)(6) motion is on the legal sufficiency, rather than the substantive merits of a claim, the Court ordinarily limits its review to the face of the complaint. *See Van Buskirk v. Cable News Network, Inc.*, 284 F.3d 977, 980 (9th Cir. 2002). In considering a Rule 12(b)(6) motion, the Court accepts the plaintiff's material allegations in the complaint as true and construes them in the light most favorable to the plaintiff. *See Shwarz v. United States*, 234 F.3d 428, 435 (9th Cir. 2000). Generally, dismissal is proper only when the plaintiff has failed to assert a cognizable legal theory or failed to allege sufficient facts under a cognizable legal theory. *See SmileCare Dental Group v. Delta Dental Plan of Cal., Inc.*, 88 F.3d 780, 782 (9th Cir. 1996); *Balisteri v. Pacifica Police Dep't*, 901 F.2d 696, 699 (9th Cir. 1988); *Robertson v. Dean Witter Reynolds, Inc.*, 749 F.2d 530, 534 (9th Cir. 1984). In pleading sufficient facts, however, a plaintiff must suggest his or her right to relief is more than merely conceivable, but plausible on its face. *See Bell Atlantic Corp. v. Twombly*, 127 S.Ct.1955, 1974 (2007).

ANALYSIS

I. Statutory Claims Under The APA And The Medicare Act Must Be Dismissed For Lack Of Subject Matter Jurisdiction.

As a threshold matter, Defendant contends that this Court lacks subject matter jurisdiction over Plaintiffs' statutory claims brought under the APA and the Medicare Act because Congress has precluded judicial review of the configuration of fee schedule areas. The central dispute between the parties is whether the configuration of fee schedule areas, the agency action challenged by Plaintiffs here, falls within the scope of 42 U.S.C. § 1395w-4(i)(1)(D), which precludes any judicial review of "the establishment of geographic adjustment factors." Defendant contends that the configuration of fee schedule areas is a sub-component of establishing geographic adjustment factors, and therefore is outside the scope of judicial review pursuant to 42 U.S.C. § 1395w-4(i)(1)(D). Plaintiffs disagree, and contend that because the configuration of fee schedule areas is not expressly enumerated in so many words in 42 U.S.C. § 1395w-4(i)(1), Congress did not intend to prevent judicial review of how the Defendant determines and applies the fee schedule areas.

After carefully considering the parties' arguments, the Court finds that 42 U.S.C. § 1395w-4(i)(1)(D) has placed the configuration of fee schedule areas outside the scope of this Court's jurisdiction for purposes of Plaintiff's statutory claims.

A. 42 U.S.C. § 1395w-4(i)(1) Is A Clear Prohibition Upon Judicial Review.

The relevant statute, 42 U.S.C. § 1395w-4(i)(1), provides:

> There shall be no administrative or judicial review under section 1395ff of this title or otherwise of—
>
> (A) the determination of the adjusted historical payment basis (as defined in subsection (a)(2)(D)(I) of this section),
>
> (B) the determination of relative values and relative value units under subsection (c) of this section, including adjustments under subsections (c)(2)(F), (c)(2)(H), and (c)(2)(I) of this section and section 13515(b) of the Omnibus Budget Reconciliation Act of 1993,
>
> (C) the determination of conversion factors under subsection (d) of this section, including without limitation a prospective redetermination of the sustainable growth rates for any or all previous fiscal years,
>
> (D) the establishment of geographic adjustment factors under subsection (e) of this section, and

> (E) the establishment of the system for the coding of physicians' services under this section.

(Emphasis added.)

As several courts have found, 42 U.S.C. § 1395w-4(i)(1) is a clear and comprehensive "no review" provision that directly targets all three core components of the overall formula for Part B fee reimbursement. *See Am. Med. Ass'n v. Thompson*, 2001 WL 619510 at *4 (N.D. Ill. May 29, 2001) ("AMA") ("the 'no review' provision in this statute is clear and comprehensive"); *see also Am. Soc'y of Dermatology v. Shalala*, 962 F. Supp. 141, 145 (D.D.C. 1996); *Am. Soc'y of Cataract and Refractive Surgery v. Thompson*, 279 F.3d 447, 453 (7th Cir. 2002). 42 U.S.C. § 1395w-4 "could not be a more clear prohibition of judicial review." *Soc'y of Dermatology*, 962 F. Supp. at 146; see also *Painter v. Shalala*, 97 F.3d 1351, 1356 (10th Cir. 1996) ("the 'no review provision' clearly indicates Congress' intent to preclude administrative and judicial review"). 42 U.S.C. § 1395w- 4(i)(1) unequivocally precludes judicial review of any element listed in subsections (A) through (E), including one of the core components of the fee schedule: "the establishment of geographic adjustment factors."

B. The Sole Use For "Fee Schedule Areas" In The Statutory Scheme Is To Help Establish And Calculate Geographic Adjustment Factors.

A review of the statutory scheme for Part B Medicare payments, located at 42 U.S.C. § 1395j-

1395w-4, makes clear that the sole purpose for the existence of "fee schedule areas" is to define local geographic areas that form the basis for calculating the "geographic adjustment factors" that adjust Medicare reimbursement based on geographic variations in the costs and resources required to furnish medical items and services.

Payment for physician services under Part B is made according to a "fee schedule" published once a year. 42 U.S.C. § 1395w-4. Under the fee schedule, the amount Medicare pays for a particular type of physician's service is not uniform throughout the country. Rather, payment rates are adjusted for geographic variations in the costs and resources required to furnish medical items and services. This adjustment is accomplished through use of a "geographic adjustment factor", 42 U.S.C. § 1395w-4(e), which is determined according to a formula that includes a significant degree of judgment on the part of the Secretary. A geographic adjustment factor is established for every "fee schedule area" in the United States on the basis of the relative costs of practicing medicine, the relative costs of malpractice insurance, and the relative value of physician work effort in the different fee schedule areas. 42 U.S.C. §§ 1395w-4(e)(1)(a)(i), (ii) & (iii). The term "fee schedule area" is defined in the statutory scheme as "a locality" used "for purposes of computing payment amounts for physicians' services" under the payment regime that was replaced by the fee schedule. 42 U.S.C. § 1395w-4(j)(2).

It is evident from these statutory provisions that the establishment of fee schedule areas is a

subcomponent, and necessary precursor, to the establishment of geographic adjustment factors. The boundaries of fee schedule areas must be drawn before any geographic adjustment factors can be established under 42 U.S.C. § 1395w-4(e). Indeed, on the record before the Court, there does not appear to be any purpose for "fee schedule areas" in the statutory scheme other than for establishing geographic adjustment factors under 42 U.S.C. § 1395w-4(e). The only occasion to create or utilize fee schedule areas springs from the need to use to them to establish geographic adjustment factors that adjust Medicare reimbursement based on geographic variations in the costs and resources required to furnish medical items and services.

Although Plaintiffs contend the "the establishment of fee schedule areas is ancillary to the determination" of geographic adjustment factors (Opp. at 14:3-4), Plaintiffs fail to identify any other role that fee schedule areas play in the statutory scheme. When asked at oral argument, Plaintiffs were unable to identify any other role for "fee schedule areas" in the Medicare reimbursement system other than as a basis for calculating geographic adjustment factors. Moreover, Plaintiffs' ultimate purpose in challenging the boundaries of the fee schedule areas is clearly to force a recalculation of the geographic adjustment factors that apply to the Plaintiffs' provision of medical services. If Plaintiffs are not really challenging the "geographic adjustment factors" used to determine their Part B reimbursements then their lawsuit could not result in the relief that they seek, because it is only from impact of the fee schedule areas upon the determination of the

geographic adjustment factors that the physician fee schedule could be changed in the manner that Plaintiffs seek. The Court is not persuaded by Plaintiffs' contention that the establishment of fee schedule areas is an agency action that somehow has significance independent of the establishment of geographic adjustment factors.[1]

> Fn.1. The Court finds inapposite the fact that Congress directed the Secretary, on various timetables, to review and revise other components of the geographic adjustment factor, but did not establish any time frame for reviewing or revising fee schedule areas. This contrast does not render fee schedule areas independent of the "establishment of geographic adjustment factors" that is barred from judicial review, and does not change the fact that fee schedule areas must be determined and defined before the calculation of geographic adjustment factors can take place under 42 U.S.C. § 1895w-4(e.)

C. Because The Sole Purpose Of Configuring Fee Schedule Areas Is For Purposes Of Establishing Geographic Adjustment Factors, 42 U.S.C. § 1395w-4(i)(1)(D) Precludes Judicial Review Of How The Boundaries Are Drawn.

Given that the sole purpose for defining the boundaries of fee schedule areas in the statutory scheme is to aid the Secretary's establishment of geographic adjustment factors, the Court finds that 42 U.S.C. § 1395w-4(i)(1)(D) precludes judicial review, in connection with Plaintiffs' statutory claims, of how the fee schedule area boundaries are drawn.

Consistent with other courts that have considered judicial challenges to components of the fee schedule formula, this Court finds that it cannot read 42 U.S.C. § 1395w-4(i)(1) to allow litigants to challenge specific items that are "integral to and essential components of the congressional-protected determinations" because this would frustrate the congressional mandate and defeat the Secretary's ability to make the protected determination itself. *See Am. Soc'y of Anesthesiologists v. Shalala*, 90 F. Supp. 2d 973, 976 (N.D. Ill. 2000); *Dermatology*, 962 F. Supp. at 145-46; *Cataract*, 279 F.3d at 449. "It would not make much sense for Congress to preclude review of the three main components of the statutory formula but then to allow review of challenges to the various sub- components of that formula." *AMA*, 2001 WL 619510 at *4.

Here, because defining the boundaries of fee schedule areas has no function beyond aiding in the geographic factor calculation, it would strain common sense to say that the fee schedule areas are not a part of the determination of the geographic conversion factor that has been placed outside the scope of judicial review. See *AMA*, 2001 WL 619510 at *4; *Painter*, 97 F.3d 1351 at 1356. Plaintiffs' reliance on the doctrine of *expressio unis est exclusio alterius* is misplaced in this context, given that fee schedule areas are a necessary component of an item expressly listed in the "no review" provision. Courts have appropriately declined to carve out, for judicial review, individual pieces of the three core components expressly enumerated in the "no review" clauses of 42 U.S.C. § 1395w-4(i)(1). See *Cataract*, 279 F.3d at 452-53 (finding no judicial

review available for transition formula under 42 U.S.C. § 1395w-4(i)(1)(B) where formula was "an integral part of the relative value determination"); *AMA*, 2001 WL 61956 at *3-5 (finding no judicial review available for calculation that affects conversion factor rendered unreviewable by 42 U.S.C. § 1395w-4(i)(1)(C)); *Anesthesiologists*, 90 F. Supp. at 974-76 (finding no judicial review available for "individual strands" of the Secretary's determinations of relative value units protected under 42 U.S.C. § 1395w-4(i)(1)(B)). Here, to allow Plaintiffs to attack the boundaries of the "fee schedule areas" by means of claims brought under the APA or the Medicare Act would undermine the Secretary's ability to make the congressionally-protected determination, under 42 U.S.C. § 1395w-4(i)(1)(D), as to geographic adjustment factors. *Accord Anesthesiologists*, 90 F. Supp. 2d at 976.

In this Court's view, the wording of the no review clause found at 42 U.S.C. § 1395w- 4(i)(1)(D) is even broader than the no-review clauses at issue in *Cataract*, *AMA* and *Anesthesiologists*. Whereas those clauses precluded judicial review of "the determination of relative values and relative value units" and "the determination of conversion factors" , the no-review clause at issue here prevents review of "the establishment of geographic adjustment factors." Compare 42 U.S.C. §§ 1395w-4(i)(1)(B) & (C) with 42 U.S.C. § 1395w-4(i)(1)(D). The word "establishment" is a broader term that this Court reads to encompass not only the particular formulas used to calculate the geographic adjustment factors, but the establishment of particular geographic regions (fee schedule areas) across which the geographic adjustment factors are to be applied.[2]

Fn.2 The instant case is unlike *Furlong v. Shalala*, 1996 WL 393526 (S.D.N.Y. July 12, 1996), to which Plaintiff cites, because the configuration of fee schedule areas cannot be characterized as "ancillary" to the establishment of geographic adjustment factors, given that they must be configured before geographic adjustment factors can be established. The plaintiffs in *Furlong* were challenging a policy that was utilized after the calculation of the relevant core component of the Part B fee schedule. It was therefore more reasonable to argue in *Furlong* that the policy at issue was not part of the "determination of" or "establishment of" that core component.

Contrary to Plaintiffs' contention, the mere fact that "fee schedule areas" are formally defined in subsection (j) of U.S.C. § 1395w-4, rather than in subsection (e) which describes how geographic adjustment factors are to be determined, does not lend support to Plaintiffs' position that the prohibition upon judicial review of "the establishment of geographic adjustment factors under subsection (e) of this section" (42 U.S.C. § 1395w-4(i)(1)(D)) cannot extend to fee schedule areas.

The fee schedule areas are incorporated into subsection (e) for purposes of determining geographic adjustment factors and have no other purpose in the statutory scheme. *Cf. AMA*, 2001 WL 619510 at *4 ("The mere fact that the SGR calculation is set forth in a separate subsection does not prove much. Although the details of the SGR calculation are not set out in [the subsection directly referenced by the no-review clause], the

SGR calculation is incorporated into that subsection.").

D. The Legislative History Does Not Evidence An Intent By Congress To Permit Judicial Review Of The Boundaries Of Fee Schedule Areas.

In support of their narrow reading of the "no review" provision, Plaintiffs contend that the legislative history of 42 U.S.C. § 1395w-4(i)(1) demonstrates that Congress intended to allow judicial review of the boundaries of fee schedule areas. The Court finds this argument unpersuasive.

As an initial matter, the no-review provision is sufficiently clear in its directive that the Court need not resort to legislative history to interpret it. *See Circuit City Stores, Inc. v. Adams*, 532 U.S. 105, 119 (2001). But in any event, the Court disagrees with Plaintiffs' reading of the legislative record.

The initial House draft of the Omnibus Budget Reconciliation Act of 1989, which contained the statutory provision now found at 42 U.S.C. § 1395w-4(i)(1), expressly listed "the selection of fee schedule areas under subsection (c)(3)(B)" as one of the enumerated items not subject to judicial review. 135 Cong. Rec. H5984, H6023 (daily ed. Sept. 27, 1989). In contrast, the Senate version did not contain a similarly-worded prohibition. 135 Cong. Rec. S13911-04, S13928-29 (daily ed. Oct. 24, 1989). The final bill, as enacted, did not include the express prohibition on "the selection of fee schedule areas under subsection (c)(3)(B)" originally

contained in the House draft. Plaintiffs contend that this legislative record indicates that Congress contemplated shielding fee schedule areas from judicial review, but ultimately decided to allow them to be subject to judicial scrutiny. *Cf. Russello v. United States*, 464 U.S. 16, 23-24 (1983) ("Where Congress includes limiting language in an earlier version of a bill, but deletes it prior to enactment, it may be presumed that the limitation was not intended.")

The Court finds the inference regarding Congressional intent advanced by Plaintiffs is unwarranted. The specific reference to "the selection of fee schedule areas under subsection (c)(3)(B)" found in the House draft appears to have been a cross-reference to another provision in the House draft, found at subsection (c)(3)(C),[3] that required that fee schedule areas be redrawn according to one of two new methods to be chosen by the Secretary. 135 Cong. Rec. H5984, H6022 27 (daily ed. Sept. 27, 1989). The fact that this specific cross-reference did not make it into the final bill is more plausibly explained by the fact that the cross-referenced requirement that the Secretary redraw the boundaries also did not make it into the final bill, obviating any need for the specific reference.

> Fn.3 The House language's cross-reference to "subsection (c)(3)(B)" appears to include a typographical error, given that subsection (c)(3)(B) of the House draft referred to anesthesia services and bore no relation to fee schedule areas.

Accordingly, the Court finds that 42 U.S.C. § 1395w-4(i)(1)(D) bars judicial review of Plaintiffs'

fifth, sixth, and seventh causes of action, which are statutory claims premised on the APA and the Medicare Act.[4]

> Fn.4 At oral argument, Plaintiffs cited *Bedford County Memorial Hospital v. HHS*, 769 F.2d 1017 (4th Cir. 1985) in support of their contention that at least one theory of liability in Plaintiffs' statutory claims might survive even if 42 U.S.C. § 1395w-4(i)(1)(D) precludes judicial review of the boundaries of fee schedule areas. Having reviewed *Bedford*, the Court finds that it lends no support to Plaintiffs' contention. *Bedford* did not involve a statute barring judicial review and that court did not address any issues involving non-reviewability.

II. Plaintiffs' Due Process And Equal Protection Constitutional Claims Must Be Dismissed Because Plaintiffs Are Not "Persons" Within The Meaning Of The Fifth Amendment.

Plaintiffs' first, second, third and fourth causes of action assert due process and equal protection claims grounded in the Fifth Amendment of the U.S. Constitution. The question of whether Congress intended 42 U.S.C. § 1395w-4(i)(1)(D) to bar judicial review of such constitutional challenges – and, if so, whether such a prohibition of judicial review would itself violate due process or separation of powers principles – presents a thorny legal issue.[5] However, at least with respect to Plaintiffs' due process and equal protection claims, the Court need not resolve this jurisdictional issue because the claims must be dismissed for an independent reason. Plaintiffs, as political subdivisions of a State, are unable to assert either due process or

equal protection claims against the federal government.

> Fn.5 "Construing a statute to preclude constitutional review would 'raise serious questions concerning its constitutionality,' and therefore, whenever possible, statutes should be interpreted as permitting such review." *U.S. v. Emerson*, 846 F.2d 541, 544 (9th Cir. 1988) (quoting *Johnson v. Robison*, 415 U.S. 351, 366 (1974)).

A. As Political Subdivisions Of A State, The Plaintiff Counties Are Not "Persons"Entitled To Bring Fifth Amendment Due Process Claims.

Plaintiffs' due process claims necessarily arise under the Fifth Amendment because they are brought against the federal government. However, it has long been settled that States are not "persons" within the meaning of the Due Process clause of the Fifth Amendment. *See South Carolina v. Katzenbach*, 383 U.S. 301, 323-24 (1966); *Premo v. Martin*, 119 F.3d 764, 771 (9th Cir. 1997); *Ariz. State Dep't of Pub. Welfare v. HEW*, 449 F.2d 456, 478 (9th Cir. 1971). Federal courts considering the issue have also found – based on reasoning that this Court finds persuasive – that a political subdivision of a State also cannot constitute a "person" entitled to assert a due process violation under the Fifth Amendment. For example, in *City of Sault Ste. Marie v. Andrus*, 532 F. Supp. 157 (D.D.C. 1980), the court ruled that the plaintiff, a municipality, did not constitute a "person" within the meaning of the Fifth Amendment and therefore could not assert

a due process challenge. See id. at 167. The court explained:

> It is difficult to imagine how a municipality can be a "person" under the Fifth Amendment if its progenitor, the state, cannot be. . . . [A] state cannot confer a constitutional status upon a municipality which the state does not itself enjoy, since the municipality performs the same function as the state.

Id.

Similarly, in *Creek v. Village of Westhaven*, 1987 WL 5429 (N.D. Ill. Jan. 15, 1987), the court observed that "[t]he notion that a political body created by the state enjoys protection, by virtue of the due process clause, from enforcement of the laws of its own or some other sovereign is not supported by either the case law or the language of the clause." *Id.* at *7 (holding that municipality could not assert a due process violation); *see also El Paso County Water Imp. Dist. No. 1 v. International Boundary and Water Comm'n*, 701 F. Supp. 121, 123-24 (W.D. Tex. 1988) (holding that El Paso County Water Improvement District Number 1, a political subdivision of the State of Texas, could not assert a Fifth Amendment due process claim).

Plaintiffs' arguments as to why California counties should be considered "persons" under the Due Process clause of the Fifth Amendment are unconvincing. Plaintiffs offer no analysis of federal constitutional law. Instead, they cite to the directive in Federal Rule of Civil Procedure 17(b)

that the "capacity to sue or be sued shall be determined by the law of the state in which the district court is held . . . ." Plaintiffs then point to provisions in California state law that indicate that California counties, although they are political subdivisions of the state, are considered quasi-corporations with the power to sue and be sued under state law. *See* California Government Code §§ 23000 & 23004; *Pacific Gas & Elec. Co. v. County of Stanislaus*, 16 Cal. 4th 1143, 1150-59 (1997) (holding California county could bring action under state and federal antitrust laws). However, in this Court's view, neither the Federal Rules of Civil Procedure, nor California state law, inform the federal constitutional analysis of what entities qualify as a "person" for purposes of the Due Process clause of the Fifth Amendment. Although Congress can of course permit the states to determine whether their political subdivisions will constitute "persons" entitled to sue under federal statutes, and the California state legislature can confer to its own political subdivisions the power to sue under state statutes, neither the Federal Rules of Civil Procedure, nor the acts of the California state legislature, can confer the federal constitutional status to sue as a "person" under the Due Process clause of the Fifth Amendment. Taken to its logical end, Plaintiffs' argument that this constitutional determination depends on application of Federal Rule of Civil Procedure 17(b) would allow the States themselves to declare themselves "persons" under the Fifth Amendment's Due Process clause, a result flatly inconsistent with the Supreme Court's constitutional analysis. *See South Carolina*, 383 U.S. at 323-24.

The Court therefore finds that Plaintiffs, all California counties, do not constitute "persons" under the Due Process clause of the Fifth Amendment. The Court accordingly must dismiss their due process claims.

B. Because Equal Protection Limitations Apply To The Federal Government Only Through Operation Of The Due Process Clause Of The Fifth Amendment, Plaintiffs' Equal Protection Claims Also Fail.

Because Plaintiffs' equal protection claims are also predicated on the Due Process clause of the Fifth Amendment, they must be dismissed for the same reason. Constitutional limitations based on equal protection grounds apply to the federal government only through the Due Process clause of the Fifth Amendment. *See Bolling v. Sharpe*, 347 U.S. 497, 499-500 (1954); *Weinberger v. Wiesenfeld*, 420 U.S. 636, 638 n.2 (1975). As the Ninth Circuit recently observed in a case where equal protection claims were asserted against a federal agency:

> Although the Bureau of Reclamation, being a Federal agency, is not subject to the strictures of the Equal Protection Clause, [i]n *Bolling v. Sharpe*, 347 U.S. 497, 74 S.Ct. 693, 98 L.Ed. 884 (1954), the Supreme Court indicated that the Fifth Amendment's Due Process Clause, subjects the federal government to constitutional limitations that are the equivalent of those imposed on the states by the Equal Protection Clause of the

> Fourteenth Amendment. We therefore read [Plaintiff's] challenge as a Fifth Amendment claim.

Consejo de Desarrollo Economico de Mexicali, A.C. v. U.S., 482 F.3d 1157, 1170 n.4 (9th Cir. 2007) (internal quotation marks and citations omitted).

As discussed above, however, the Plaintiffs here, as political subdivisions of a State, do not qualify as "persons" within the meaning of the Due Process clause of the Fifth Amendment, and therefore are unable to bring an equal protection challenge against the federal government.

Accordingly, the Court must dismiss Plaintiffs' equal protection claims as well.

III. To The Extent Plaintiffs' "Unlawful Delegation" Claim Sounds In Constitutional Law And Might Survive 42 U.S.C. § 1395w-4(i)(1)(D), It Is Not Adequately Pleaded.

Plaintiffs' eighth cause of action alleges that Medicare has unlawfully delegated its duty to reconfigure the localities used to calculate Part B Medicare payments to state medical associations. (Complaint ¶¶ 360-367.) However, neither the precise legal theory that Plaintiffs contend renders the delegation "unlawful", nor whether that legal theory is premised on constitutional principles, are clear from the Complaint, as currently pleaded. The eighth cause of action characterizes Medicare's allegedly unlawful delegation of authority as a violation of 5 U.S.C. § 706(2)(A) and (C), which are provisions of the APA. (Complaint ¶ 362.) 5 U.S.C.

§ 706(2)(A) and (C) authorize a Court to "hold unlawful and set aside agency action, findings, and conclusions found to be" either "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law" (subsection (A)) or "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right" (subsection (C)). Noticeably absent is any reliance by Plaintiffs on 5 U.S.C. § 706(2)(B), which authorize a Court to hold unlawful and set aside agency action that is "contrary to constitutional right, power, privilege, or immunity." Thus, as currently pleaded, Plaintiffs' eighth cause of action appears to assert solely a statutory basis for relief. However, some ambiguity in Plaintiffs' pleading of the eighth cause of action is created by paragraph 365 of the Complaint, which indirectly alludes to, but does not directly plead, a constitutional underpinning for the eighth cause of action. Paragraph 365 reads:

> Medicare delegated its authority to initiate locality changes to the state medical associations even though President George H. W. Bush deemed a similar delegation by Congress in 1990 to be unconstitutional. President Bush went so far as to direct Medicare not to enforce a provision of the 1990 Act because it vested significant authority to execute federal law to persons not appointed by the President, and attempted to confer lawmaking power on individual members of Congress. If Congress cannot constitutionally delegate authority to state medical associations to initiate

> locality changes, then Medicare certainly lacks the authority to do so.

For the reasons set forth above in Section I, to the extent Plaintiffs' eighth cause of action for "unlawful delegation" rests upon a statutory basis, the Court lacks subject matter jurisdiction to hear it because of the no-review provisions of 42 U.S.C. § 1395w-4(i)(1)(D). To the extent Plaintiffs intended to rely on a constitutional theory as a basis for their eighth cause of action, Plaintiffs have not adequately alleged the existence and contours of the alleged constitutional violation upon which their claim might be able to proceed. The Court will therefore dismiss Plaintiffs' eighth cause of action, but, unlike the other causes of action, finds it appropriate to grant Plaintiffs leave to amend the "unlawful delegation" claim to clarify its legal basis and constitutional underpinnings, if any.[6]

> Fn.6 Until the constitutional dimensions, if any, of Plaintiffs' "unlawful delegation" allegations are clearer, the Court will not attempt to resolve whether 42 U.S.C. § 1395w-4(i)(1)(D) would prevent judicial review of such a claim. The Court also finds it premature to attempt to determine whether the presentation and exhaustion requirements of 42 U.S.C. § 1395ff(b)(1)(A) have been met with respect to any constitutional claim for "unlawful delegation" that Plaintiffs may be able to plead.

Defendant's other challenges to the "unlawful delegation" claim raise factual disputes that fall outside the scope of a Rule 12 motion. Defendant contends that the Secretary has retained ultimate decisional authority and merely "considered"

private views, but Plaintiffs' Complaint contends that the Secretary went much farther than merely considering private views by "delegat[ing] its authority to initiate locality changes to state medical associations (Complaint ¶ 362) and "retain[ing] no authority, final or otherwise, over the action or inaction of those state medical associations with respect to the locality issue" (Complaint ¶ 363). For purposes of this Rule 12 motion, the Court must regard Plaintiffs' factual allegations as true, and cannot dismiss the unlawful delegation claim on the grounds advanced by Defendant.

CONCLUSION

For the foregoing reasons, the Court **GRANTS** Defendant's Motion.[7] The Court **DISMISSES** Plaintiffs' statutory claims (the fifth, sixth, and seventh causes of action) for lack of subject matter jurisdiction under 42 U.S.C. § 1395w-4(i)(1)(D). The Court **DISMISSES** Plaintiffs' Fifth Amendment due process and equal protection claims (the first, second, third and fourth causes of action) for failure to state a claim because the named Plaintiffs, which are all political subdivisions of the State of California, do not qualify as "persons" within the meaning of the Fifth Amendment. Finally, the Court **DISMISSES WITH LEAVE TO AMEND** Plaintiffs' unlawful delegation claim (the eighth cause of action) because Plaintiffs have not adequately pleaded the claim in a manner that demonstrates it has a constitutional basis that might confer subject matter jurisdiction on this Court.

Fn. 7 The Court also DENIES AS MOOT Plaintiffs' Motion To Strike. (Docket No. 42.) The declaration of William Hardwick, which Plaintiffs seek to strike, related only to Defendants' assertion that certain of the Plaintiffs lacked standing because they do not operate facilities that are suppliers participating in Medicare Part B. Defendant withdrew this challenge at oral argument. The other materials that Plaintiffs seek to strike related to Rule 12 arguments that this Court need not reach given the disposition of Plaintiffs' claims described in this Order.

Plaintiffs shall filed their amended complaint, if any, **within twenty (20) days of entry of this Order**.

IT IS SO ORDERED.

Dated: March 11, 2008

s/ MARTIN J. JENKINS
UNITED STATES DISTRICT JUDGE

APPENDIX E: ORDER OF THE COURT OF APPEALS DENYING REHEARING AND REHEARING EN BANC (OCTOBER 9, 2014)

Case:13-16297 10/09/2014
ID:9271283 DktEntry:45

FILED
OCT 09 2014
MOLLY C. DWYER, CLERK
U.S. COURT OF APPEALS

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

COUNTY OF SANTA CRUZ; COUNTY OF SONOMA; COUNTY OF SAN DIEGO; COUNTY OF MARIN; COUNTY OF SANTA BARBARA; COUNTY OF SAN LUIS OBISPO; COUNTY OF MONTEREY; THEODORE M. MAZER, M.D.; WOLBERS AND POREE MEDICAL CORPORATION,

Plaintiffs–Appellants,

v.

SYLVIA M. BURWELL, Secretary, Department of Health and Human Services,

Defendant–Respondent.

No. 13-16297

D.C. No. 3:07-cv-02888-JSW
Northern District of California, San Francisco

ORDER

Before: O'SCANNLAIN, FERNANDEZ, and BEA, Circuit Judges.

The panel has voted to deny the petition for rehearing. Judges O'Scannlain and Bea voted to deny the petition for rehearing en banc, and Judge Fernandez so recommends.

The full court has been advised of the suggestion for rehearing en banc, and no active judge has requested a vote on whether to rehear the matter en banc. Fed. R. App. P. 35.

The petition for rehearing and the petition for rehearing en banc are therefore DENIED.

APPENDIX F: STATUTORY PROVISIONS INVOLVED (PORTIONS OF 42 U.S.C. § 1395W-4)

Pertinent Portions of
42 U.S.C. § 1395w-4
Payment for Physicians' Services*

*PETITIONERS' NOTE: The relevant subsections of 42 U.S.C. § 1395w-4 remained substantially unchanged during the litigation below from 2007 through early 2014. On April 1, 2014, legislation became effective that added 42 U.S.C. § 1395w-4(e)(6) and modified the payment locality structure for California to an MSA-based structure with the resulting changes to payment amounts to be phased in over a 6-year period beginning in 2017.

(a) Payment based on fee schedule

(1) In general

Effective for all physicians' services (as defined in subsection (j)(3) of this section) furnished under this part during a year (beginning with 1992) for which payment is otherwise made on the basis of a reasonable charge or on the basis of a fee schedule under section 1395m(b) of this title, payment under this part shall instead be based on the lesser of—

(A) the actual charge for the service, or

(B) subject to the succeeding provisions of this subsection, the amount determined under the fee schedule established under subsection (b) of this section for services furnished during that year (in this subsection referred to as the "fee schedule amount").

******

(b) Establishment of fee schedules

(1) In general

Before November 1 of the preceding year, for each year beginning with 1998, subject to subsection (p), the Secretary shall establish, by regulation, fee schedules that establish payment amounts for all physicians' services furnished in all fee schedule areas (as defined in subsection (j)(2) of this section) for the year. Except as provided in paragraph (2), each such payment amount for a service shall be equal to the product of—

(A) the relative value for the service (as determined in subsection (c)(2) of this section),

(B) the conversion factor (established under subsection (d) of this section) for the year, and

(C) the geographic adjustment factor (established under subsection (e)(2) of this section) for the service for the fee schedule area.

******

(c) Determination of relative values for physicians' services

(1) Division of physicians' services into components

In this section, with respect to a physicians' service:

(A) "Work component" defined

The term "work component" means the portion of the resources used in furnishing the service that reflects physician time and intensity in furnishing the service. Such portion shall—

(i) include activities before and after direct patient contact, and

(ii) be defined, with respect to surgical procedures, to reflect a global definition including pre-operative and post-operative

physicians' services.

(B) "Practice expense component" defined

The term "practice expense component" means the portion of the resources used in furnishing the service that reflects the general categories of expenses (such as office rent and wages of personnel, but excluding malpractice expenses) comprising practice expenses.

(C) "Malpractice component" defined

The term "malpractice component" means the portion of the resources used in furnishing the service that reflects malpractice expenses in furnishing the service.

(2) Determination of relative values

(A) In general

(i) Combination of units for components

The Secretary shall develop a methodology for combining the work, practice expense, and malpractice relative value units, determined under subparagraph (C), for each service in a manner to produce a single relative value for that service. Such relative values are subject to adjustment under subparagraph (F)(i) and section 13515(b) of the Omnibus Budget Reconciliation Act of 1993.

(ii) Extrapolation

The Secretary may use extrapolation and other techniques to determine the number of relative value units for physicians' services for which specific data are not available and shall take into account recommendations of the Physician Payment Review Commission and the results of consultations with organizations representing physicians who provide such services.

(B) Periodic review and adjustments in relative

values

(i) Periodic review

The Secretary, not less often than every 5 years, shall review the relative values established under this paragraph for all physicians' services.

(ii) Adjustments

(I) In general

The Secretary shall, to the extent the Secretary determines to be necessary and subject to subclause (II), adjust the number of such units to take into account changes in medical practice, coding changes, new data on relative value components, or the addition of new procedures. The Secretary shall publish an explanation of the basis for such adjustments.

(II) Limitation on annual adjustments

Subject to clauses (iv) and (v), the adjustments under subclause (I) for a year may not cause the amount of expenditures under this part for the year to differ by more than $20,000,000 from the amount of expenditures under this part that would have been made if such adjustments had not been made.

(iii) Consultation

The Secretary, in making adjustments under clause (ii), shall consult with the Medicare Payment Advisory Commission and organizations representing physicians.

******

(d) Conversion factors

(1) Establishment

(A) In general

The conversion factor for each year shall be the conversion factor established under this subsection for the previous year (or, in the case of 1992, specified in subparagraph (B)) adjusted by the update (established under paragraph (3)) for the year involved (for years before 2001) and, for years beginning with 2001, multiplied by the update (established under paragraph (4)) for the year involved.

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(e) Geographic adjustment factors

(1) Establishment of geographic indices

(A) In general

Subject to subparagraphs (B), (C), (E), and (G), (H), and (I) the Secretary shall establish—

(i) an index which reflects the relative costs of the mix of goods and services comprising practice expenses (other than malpractice expenses) in the different fee schedule areas compared to the national average of such costs,

(ii) an index which reflects the relative costs of malpractice expenses in the different fee schedule areas compared to the national average of such costs, and

(iii) an index which reflects ¼ of the difference between the relative value of physicians' work effort in each of the different fee schedule areas and the national average of such work effort.

(B) Class-specific geographic cost-of-practice indices

The Secretary may establish more than one index under subparagraph (A)(i) in the case of classes of physicians' services, if, because of differences in the mix of goods and services comprising practice expenses for the different classes of services, the application of a single index under such clause to different classes of such services would be substantially inequitable.

(C) Periodic review and adjustments in geographic adjustment factors

The Secretary, not less often than every 3 years, shall, in consultation with appropriate representatives of physicians, review the indices established under subparagraph (A) and the geographic index values applied under this subsection for all fee schedule areas. Based on such review, the Secretary may revise such index and adjust such index values, except that, if more than 1 year has elasped since the date of the last previous adjustment, the adjustment to be applied in the first year of the next adjustment shall be ½ of the adjustment that otherwise would be made.

(D) Use of recent data

In establishing indices and index values under this paragraph, the Secretary shall use the most recent data available relating to practice expenses, malpractice expenses, and physician work effort in different fee schedule areas.

(E) Floor at 1.0 on work geographic index

After calculating the work geographic index in subparagraph (A)(iii), for purposes of payment for services furnished on or after January 1, 2004, and before January 1, 2013, the Secretary shall increase the work geographic index to 1.00

for any locality for which such work geographic index is less than 1.00.

[No subparagraph (F) enacted.]

(G) Floor for practice expense, malpractice, and work geographic indices for services furnished in Alaska

For purposes of payment for services furnished in Alaska on or after January 1, 2004, and before January 1, 2006, after calculating the practice expense, malpractice, and work geographic indices in clauses (i), (ii), and (iii) of subparagraph (A) and in subparagraph (B), the Secretary shall increase any such index to 1.67 if such index would otherwise be less than 1.67. For purposes of payment for services furnished in the State described in the preceding sentence on or after January 1, 2009, after calculating the work geographic index in subparagraph (A)(iii), the Secretary shall increase the work geographic index to 1.5 if such index would otherwise be less than 1.54

(H) Practice expense geographic adjustment for 2010 and subsequent years

(i) For 2010

Subject to clause (iii), for services furnished during 2010, the employee wage and rent portions of the practice expense geographic index described in subparagraph (A)(i) shall reflect ½ of the difference between the relative costs of employee wages and rents in each of the different fee schedule areas and the national average of such employee wages and rents.

(ii) For 2011

Subject to clause (iii), for services furnished during 2011, the employee wage and rent

portions of the practice expense geographic index described in subparagraph (A)(i) shall reflect ½ of the difference between the relative costs of employee wages and rents in each of the different fee schedule areas and the national average of such employee wages and rents.

(iii) Hold harmless

The practice expense portion of the geographic adjustment factor applied in a fee schedule area for services furnished in 2010 or 2011 shall not, as a result of the application of clause (i) or (ii), be reduced below the practice expense portion of the geographic adjustment factor under subparagraph (A)(i) (as calculated prior to the application of such clause (i) or (ii), respectively) for such area for such year.

(iv) Analysis

The Secretary shall analyze current methods of establishing practice expense geographic adjustments under subparagraph (A)(i) and evaluate data that fairly and reliably establishes distinctions in the costs of operating a medical practice in the different fee schedule areas. Such analysis shall include an evaluation of the following:

(I) The feasibility of using actual data or reliable survey data developed by medical organizations on the costs of operating a medical practice, including office rents and non-physician staff wages, in different fee schedule areas.

(II) The office expense portion of the practice expense geographic adjustment described in subparagraph (A)(i), including

the extent to which types of office expenses are determined in local markets instead of national markets.

(III) The weights assigned to each of the categories within the practice expense geographic adjustment described in subparagraph (A)(i).

(v) Revision for 2012 and subsequent years

As a result of the analysis described in clause (iv), the Secretary shall, not later than January 1, 2012, make appropriate adjustments to the practice expense geographic adjustment described in subparagraph (A)(i) to ensure accurate geographic adjustments across fee schedule areas, including—

(I) basing the office rents component and its weight on office expenses that vary among fee schedule areas; and

(II) considering a representative range of professional and non-professional personnel employed in a medical office based on the use of the American Community Survey data or other reliable data for wage adjustments.

Such adjustments shall be made without regard to adjustments made pursuant to clauses (i) and (ii) and shall be made in a budget neutral manner.

(I) Floor for practice expense index for services furnished in frontier States

(i) In general

Subject to clause (ii), for purposes of payment for services furnished in a frontier State (as defined in section 1395ww(d)(3)(E)(iii)(II) of this title) on or after January 1, 2011, after

calculating the practice expense index in subparagraph (A)(i), the Secretary shall increase any such index to 1.00 if such index would otherwise be less that 1.00. The preceding sentence shall not be applied in a budget neutral manner.

(ii) Limitation

This subparagraph shall not apply to services furnished in a State that receives a non-labor related share adjustment under section 1395ww(d)(5)(H) of this title.

(2) Computation of geographic adjustment factor

For purposes of subsection (b)(1)(C) of this section, for all physicians' services for each fee schedule area the Secretary shall establish a geographic adjustment factor equal to the sum of the geographic cost-of-practice adjustment factor (specified in paragraph (3)), the geographic malpractice adjustment factor (specified in paragraph (4)), and the geographic physician work adjustment factor (specified in paragraph (5)) for the service and the area.

(3) Geographic cost-of-practice adjustment factor

For purposes of paragraph (2), the "geographic cost-of-practice adjustment factor", for a service for a fee schedule area, is the product of—

(A) the proportion of the total relative value for the service that reflects the relative value units for the practice expense component, and

(B) the geographic cost-of-practice index value for the area for the service, based on the index established under paragraph (1)(A)(i) or (1)(B) (as the case may be).

(4) Geographic malpractice adjustment factor

For purposes of paragraph (2), the "geographic malpractice adjustment factor", for a service for a

fee schedule area, is the product of—

(A) the proportion of the total relative value for the service that reflects the relative value units for the malpractice component, and

(B) the geographic malpractice index value for the area, based on the index established under paragraph (1)(A)(ii).

(5) Geographic physician work adjustment factor

For purposes of paragraph (2), the "geographic physician work adjustment factor", for a service for a fee schedule area, is the product of—

(A) the proportion of the total relative value for the service that reflects the relative value units for the work component, and

(B) the geographic physician work index value for the area, based on the index established under paragraph (1)(A)(iii).

(6) Use of MSAs as fee schedule areas in California

(A) In general

Subject to the succeeding provisions of this paragraph and notwithstanding the previous provisions of this subsection, for services furnished on or after January 1, 2017, the fee schedule areas used for payment under this section applicable to California shall be the following:

(i) Each Metropolitan Statistical Area (each in this paragraph referred to as an "MSA"), as defined by the Director of the Office of Management and Budget as of December 31 of the previous year, shall be a fee schedule area.

(ii) All areas not included in an MSA shall be treated as a single rest-of-State fee schedule area.

(B) Transition for MSAs previously in rest-of-State payment locality or in locality 3

(i) In general

For services furnished in California during a year beginning with 2017 and ending with 2021 in an MSA in a transition area (as defined in subparagraph (D)), subject to subparagraph (C), the geographic index values to be applied under this subsection for such year shall be equal to the sum of the following:

(I) Current law component

The old weighting factor (described in clause (ii)) for such year multiplied by the geographic index values under this subsection for the fee schedule area that included such MSA that would have applied in such area (as estimated by the Secretary) if this paragraph did not apply.

(II) MSA-based component

The MSA-based weighting factor (described in clause (iii)) for such year multiplied by the geographic index values computed for the fee schedule area under subparagraph (A) for the year (determined without regard to this subparagraph).

(ii) Old weighting factor

The old weighting factor described in this clause—

(I) for 2017, is $^{5}/_{6}$; and

(II) for each succeeding year, is the old weighting factor described in this clause for the previous year minus $^{1}/_{6}$.

(iii) MSA-based weighting factor

The MSA-based weighting factor described in this clause for a year is 1 minus the old weighting factor under clause (ii) for that year.

(C) Hold harmless

For services furnished in a transition area in California during a year beginning with 2017, the geographic index values to be applied under this subsection for such year shall not be less than the corresponding geographic index values that would have applied in such transition area (as estimated by the Secretary) if this paragraph did not apply.

(D) Transition area defined

In this paragraph, the term "transition area" means each of the following fee schedule areas for 2013:

(i) The rest-of-State payment locality.

(ii) Payment locality 3.

(E) References to fee schedule areas

Effective for services furnished on or after January 1, 2017, for California, any reference in this section to a fee schedule area shall be deemed a reference to a fee schedule area established in accordance with this paragraph.

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(i) Miscellaneous provisions

(1) Restriction on administrative and judicial review

There shall be no administrative or judicial review

under section 1395ff of this title or otherwise of—

(A) the determination of the adjusted historical payment basis (as defined in subsection (a)(2)(D)(i) of this section),

(B) the determination of relative values and relative value units under subsection (c) of this section, including adjustments under subsections (c)(2)(F), (c)(2)(H), and (c)(2)(I) of this section and section 13515(b) of the Omnibus Budget Reconciliation Act of 1993,

(C) the determination of conversion factors under subsection (d) of this section, including without limitation a prospective redetermination of the sustainable growth rates for any or all previous fiscal years,

(D) the establishment of geographic adjustment factors under subsection (e) of this section, and

(E) the establishment of the system for the coding of physicians' services under this section.

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(j) Definitions

In this section: …

(2) Fee schedule area

The term "fee schedule area" means a locality used under section 1395u(b) of this title for purposes of computing payment amounts for physicians' services.

APPENDIX G: STATUTORY PROVISIONS INVOLVED (PORTIONS OF 135 CONG. REC. H5984-05)

On September 27, 1989, the House of Representatives proposed adding the following provision to the 1989 OBRA as 42 U.S.C. § 1395w-4(j)(2):

"(2) RESTRICTION ON ADMINISTRATIVE AND JUDICIAL REVIEW.-There shall be no administrative or judicial review under section 1869 or otherwise of-

"(A) the percentage adjustments for evaluation and management services under subsection (a)(1)(B)(i);

"(B) the relative values established for physicians' services under this section, including the relative value of components of services;

"(C) the national standard conversion factors established under this section;

"(D) the geographic indices and adjustment factors established under this section; and

"(E) the selection of fee schedule areas under subsection (c)(3)(B)."

Source: 135 Cong. Rec. H5984-05, at H6023 (9/27/1989)

APPENDIX H: STATUTORY PROVISIONS INVOLVED (PORTIONS OF 135 CONG. REC. S13911-04)

On October 24, 1989, the Senate renumbered the House proposal as 42 U.S.C. § 1395w-4(i) and modified subdivision (E) as follows:

"(i) MISCELLANEOUS PROVISIONS.-

"(1) RESTRICTION ON ADMINISTRATIVE AND JUDICIAL REVIEW.-There shall be no administrative or judicial review under section 1869 or otherwise of-

"(A) the determination of the adjusted prevailing charge (as defined in subsection (a)(2)(D)(i)),

"(B) the determination of relative value units under subsection (c),

"(C) the determination of conversion factors under subsection (d),

"(D) the establishment of values in the geographic practice cost index, the values in the geographic overhead index and the values in the geographic malpractice index under subsection (e), and

"(E) the establishment of the system for the coding of physicians' services under this section."

Source: 135 Cong. Rec. S13911-04, at S13928-13929 (10/24/1989)

APPENDIX I: STATUTORY PROVISIONS INVOLVED (42 C.F.R. § 414.4)

42 C.F.R. § 414.4

Fee schedule areas.

(a) General. CMS establishes physician fee schedule areas that generally conform to the geographic localities in existence before January 1, 1992.

(b) Changes. CMS announces proposed changes to fee schedule areas in the Federal Register and provides an opportunity for public comment. After considering public comments, CMS publishes the final changes in the Federal Register.

Credits

[58 FR 63686, Dec. 2, 1993; 59 FR 63463, Dec. 8, 1994]

APPENDIX J: COMPONENTS OF THE PHYSICIAN FEE SCHEDULE FORMULA

1. The Geographic Practice Cost Indexes or "GPCIs"

Under § 1395w-4(e)(1)(A)(i), the **practice expense GPCI ("practice expense GPCI" or "$GPCI_{pe}$")** must reflect "the relative costs of the mix of goods and services comprising practice expenses (other than malpractice expenses) in the different fee schedule areas compared to the national average of such costs."

Under § 1395w-4(e)(1)(A)(ii) the **malpractice GPCI ("malpractice GPCI" or "$GPCI_{mp}$")** must reflect "the relative costs of malpractice expenses in the different fee schedule areas compared to the national average of such costs."

Under § 1395w-4(e)(1)(A)(iii) the **work GPCI ("work GPCI" or "$GPCI_{w}$")** must reflect "¼ of the difference of the between the relative value of physicians' work effort in each of the different fee schedule areas and the national average of such work effort."

Under 42 U.S.C. § 1395w-4(e)(1)(C), the Secretary must review these GPCIs at least every three years. The first review and revision of the GPCIs was implemented in 1995. The Second GPCI Update was prepared by Health Economics Research, Inc., in December 1996 and was implemented in 1998-2000. The Third GPCI Update was prepared by KPMG in March 2000 and was implemented in 2001-2004. The Fourth GPCI

Update was prepared by Bearing Point in March 2004 and was implemented in 2005-2007. The Fifth GPCI Update was prepared by Acumen in November 2007 and was implemented in 2008-2010. The Sixth GPCI Update was prepared by Acumen, LLC, in July 2010 and was implemented in 2011-2013. The Seventh GPCI Update was prepared by Acumen, LLC, in June 2014.

2. The Relative Value Units or "RVUs"

Under § 1395w-4(c), physicians' services are divided into three **RVU** components, a "work component" (**"work RVU"** or **"RVU_w"**), a "practice expense component" (**"practice expense RVU"** or **"RVU_{pe}"**), and a "malpractice component" (**"malpractice RVU"** or "RVU_{mp}").

The **work RVU** is defined under § 1395w-4(c)(1)(A) as "the portion of the resources used in furnishing the service that reflects physician time and intensity in furnishing the service." It includes physicians' activities before and after direct patient contact, and, for surgical procedures, includes pre-operative and post-operative physicians' services.

The **practice expense RVU** is defined under § 1395w-4(c)(1)(B) as "the portion of the resources used in furnishing the service that reflects the general category of expenses (such as office rent and wages of personnel, but excluding malpractice expenses) comprising practice expenses."

The **malpractice RVU** is defined under § 1395w-4(c)(1)(C) as "the portion of the resources

used in furnishing the service that reflects malpractice expenses in furnishing the service."

Under § 1395w-4(c)(2)(A)(I), the Secretary is required to develop a methodology for the work, practice expense, and malpractice RVUs for each service to produce a single RVU for that service.

Under § 1395w-4(c)(2)(B), the Secretary is required to review the RVUs not less than every 5 years, and to make adjustments "to take into account changes in medical practice, coding changes, new data on relative value components, or the addition of new procedures." Under § 1395w-4(c)(2)(B)(ii)(II), such adjustments for a year may not cause Medicare payments to physicians "to differ by more than $20,000,000 from the amount of expenditures under [Part B] that would have been made if such adjustments had not been made."

CMS publishes a table of the RVUs for over 10,000 medical services every year in the Federal Register. 75 FR 73630-73815 (11/29/2010).

3. The Geographic Adjustment Factor or "GAF" Used to Calculate Payments

Under § 1395w-4(e)(2), the **geographic adjustment factor ("GAF")** used to calculate payments for all physicians' services for each fee schedule area is equal to the sum of the **practice expense GAF**, the **malpractice GAF**, and the **work GAF** for the specific service and the specific locality.

Under § 1395w-4(e)(3), the **practice expense GAF** for a service in a particular area is the product

of: (A) the **practice expense RVU** for the service; and (B) the **practice expense GPCI** for the area for the locality.

Under § 1395w-4(e)(4), the **malpractice GAF** for a service in a particular area is the product of: (A) the **malpractice RVU** for the service; and (B) the **malpractice GPCI** for the locality.

Under § 1395w-4(e)(5), the **work GAF** for a service in a particular area is the product of: (A) the **work RVU** for the service; and (B) the **work GPCI** for the locality.

4. The Conversion Factor or "CF"

The **conversion factor ("CF")** is calculated under a complex formula set forth in 42 U.S.C. § 1395w-4(d) and represents the effect on costs of annual variations in the economy, utilization of physicians' services in prior years, and estimates for changes in utilization of physicians' services in the applicable year involved.

The conversion factor is used in the physician fee schedule payment formula to convert the local cost of providing a particular service relative to the national average into a dollar amount. For example, the conversion factor in 2011 was $33.9764. 76 Fed. Reg. 73036, 73035 (11/28/2011).

5. The Physician Fee Schedule Formula

The physician fee schedule payment formula is used to calculate payments to suppliers for providing specific services to Medicare beneficiaries

in specific geographic locations ("localities" or "fee schedule areas" or "FSAs"). "Fee schedule area" is defined by statute in 42 U.S.C. § 1395w-4(j)(2) as "a locality used under section 1395u(b) of this title for purposes of computing payment amounts for physicians' services."

The GPCIs and RVUs described above are the statutorily created methods for measuring costs of providing medical services in localities relative to the national average of providing those services.

Under 42 U.S.C. § 1395w-4, subject to exceptions for certain services (radiology, anesthesia, electrocardiograms, and imaging), suppliers of medical services under Medicare Part B are paid for performance of specific services using the following formula: payment for a specific service equals the sum of the products of each the three GPCIs for the specific locality and each of the three RVUs for the specific service times the conversion factor for the year.

CMS has stated the formula (see CY 2007 Proposed Rule, 8/22/2006, 71 FR 48985) as follows: Payment = $[(RVU_w \times GPCI_w) + (RVU_{pe} \times GPCIpe) + (RVU_{mp} \times GPCI_{mp})] \times CF$.

6. The "Locality GAF"

The term "Geographic Adjustment Factor" or "GAF" is defined in two distinct ways. One is defined by statute (see § 3, above) and is rarely, if ever, actually used and is referred to here as the "payment GAF." The other is not defined by

statute, and is referred to here as the "locality GAF."

Locality GAFs" are not statutorily defined, but are values used by CMS to illustrate the differences in costs between different localities by ranking the overall cost of providing medical care in a particular locality against a nationwide average of "1." The Locality GAFs are "a weighted composite of each area's work, PE, and malpractice GPCIs using the national GPCI cost share weights." CY 2011 Final Rule, 75 Fed. Reg. 73601 (11/29/2010). The "national GPCI cost share weights" are the relative percentage values assigned to each of the three GPCIs. These cost share weights were the same for each year from 2001 through 2010: (a) the cost share weight for the GAF_w = 0.52466; the cost share weight for the GAF_{pe} = 0.43669; and (c) the cost share weight for the GAF_{mp} = 0.03865. Thus, the formula for calculating a Locality GAF is: $[(0.52466 \times GPCI_w) + (0.43669 \times GPCI_{pe}) + (0.03865 \times GPCI_{mp})]$. *Id.* at p. 73817. Beginning in 2011, the cost share weights were reanalyzed and modified pursuant to the ACA.

For example, the 2010 Locality GAF for San Francisco (a single-county locality) was 1.201. San Francisco's GPCIs are: (a) $GPCI_w$ = 1.059; (b) $GPCI_{pe}$ = 1.441; and (c) $GPCI_{mp}$ = 0.414. Employing the formula for the Locality GAF: $[(1.059 \times 0.52466) + (1.441 \times 0.43669) + (0.414 \times 0.03865)] = 1.20886$ (which rounds to 1.201).

Locality GAFs are published annually in the Federal Register; payment GAFs are not. *See, e.g.*,

CY 2008 Final Rule, 11/27/2007, 72 Fed. Reg. 66545-66546 (11/27/2007).

7. Significance of County-Level Data

The calculations of GPCIs, RVUs, and GAFs are made first at the county level. They are then aggregated to the locality level. CY 2004 Proposed Rule, 68 Fed. Reg. 49042-49044 (8/15/2003); CY 2005 Proposed Rule, 69 Fed. Reg. 47503-47504 (8/5/2004). Thus, payment GAFs can be calculated for single-county localities or for multi-county localities made up of any combination of counties.