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CERTIFICATE OF SERVICE

I hereby certify that I electronically filed the foregoing document and that a true and correct copy was served on the parties listed below through the electronic case filing system if the Notice of Electronic Filing indicated that the parties received it or otherwise by mailing a copy by Certified Mail, Return Receipt Requested, to the parties this 2nd day of October, 2007.

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STANDARD OF REVIEW

Defendants move the Court to dismiss Plaintiffs' Complaint pursuant to Fed. R. Civ. P. 12(b)(1) and 12(b)(6). Defendants' 12(b)(1) motion is a facial attack challenging the Court's subject matter jurisdiction based on the sufficiency of the Plaintiffs' allegations. As such, the Court accepts all material allegations of the Plaintiffs' Complaint as true and construes those facts in the light most favorable to the non-moving party. *Scheuer v. Rhodes*, 416 U.S. 232, 236 (1974), *overruled on other grounds*, *Harlow v. Fitzgerald*, 457 U.S. 800 (1982). Similarly, in ruling on Defendants' 12(b)(6) motion, the Court must assume all facts as alleged in Plaintiffs' Complaint are true. *Davis v. Monroe Cty. Bd. of Educ.*, 526 U.S. 629, 633 (1999). Any inferences made or doubts resolved by the Court should be to the Plaintiffs' benefit. *Collins v. Morgan Stanley Dean Witter*, 224 F.3d 496, 498 (5th Cir. 2000). A motion to dismiss for failure to state a claim "is viewed with disfavor and is rarely granted." See *id.* at 498 (internal quotes and citations omitted).

ARGUMENT

I. THE COURT MAINTAINS SUBJECT MATTER JURISDICTION OVER THE COMPLAINT BECAUSE PLAINTIFFS FACE AN ACTUAL AND IMMEDIATE THREAT OF INJURY

The methodology of the competitive bidding scheme in Section 302 of the MMA (hereinafter, the "Act") presents a "real and immediate" threat of injury to the Plaintiffs. See *City of Los Angeles v. Lyons*, 461 U.S. 95, 103 (1983). Plaintiffs' injury is "fairly traceable" to the bidding criteria that will be used by Defendants, and can be redressed by enjoining the competitive bidding scheme. See *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-561 (1992). Despite the fact that small suppliers' interests are purportedly protected by the statute, the criteria

for the selection of bids under Section 302 is designed to prevent small suppliers from fairly competing for so-called “competitive” bids.

Plaintiffs’ injury is fairly traceable to the bidding methodology that specifically operates to exclude small suppliers like Plaintiffs because of: (1) the low-bid system in which the price of an item is the almost exclusive consideration used to determine the winning bid, (2) the fact that a supplier must bid on all items in any product category on which it wishes to place a bid, and (3) the requirement that all bidders must be able to cover the entire metropolitan statistical area. Furthermore, enjoining Defendants from implementing the statute will redress this injury.

A. DESPITE LIP SERVICE TO THE CONTRARY, SECTION 302 OF THE MMA IS DESIGNED TO EXCLUDE SMALLER SUPPLIERS, AND, IN TURN, INJURES THE SUPPLIERS AS WELL AS THE BENEFICIARIES WHO RELY ON THEM

Defendants argue that the Plaintiffs’ injury amounts to nothing more than conjecture. Defendants further assert that the Act provides protections for small suppliers, so “there is no basis for the Court to assume that Plaintiffs’ fearful predictions are warranted, much less that they will actually come to pass.” (Defendants’ Memorandum in Support of Defendants’ Motion to Dismiss, hereinafter “Defs. Memo,” p. 19). On the contrary, the “protections” of the Act and the success stories vaunted by Defendants are unimpressive upon closer inspection.

1. Defendants’ Assertions Regarding the Participation of Small Suppliers in the Demonstration Projects are Misleading

Defendants point out that “Congress found that... ‘three-quarters of the DMEPOS winners were *small businesses*’” (Defs. Memo, p. 4) (quoting H.R. Rep. No. 108-178 (II), at Title III § 302)(2003) (emphasis added). This is particularly relevant because it strongly suggests Congress meant the term “small supplier,” as used in Section 302 of the MMA, to refer to DMEPOS suppliers that were small businesses. At the same time, it seems reasonable to

interpret Congress's use of the term "small business" in the context of the Small Business Administration's definition of that term. See 72 Fed. Reg. 18058 (indicating "the SBA defines small business as generating less than \$6.5 million in annual receipts"). This is reinforced by the fact that CMS initially proposed to define the term "small supplier" based on the SBA definition:

In the May 1, 2006 proposed rule (71 Fed. Reg. 25682), we proposed using the SBA's small business definition when evaluating whether a DMEPOS supplier is a small supplier. We relied on the expertise of the SBA to determine what constitutes the appropriate definition of a small supplier.

72 Fed. Reg. 18056.

CMS ultimately decided to define "small supplier" differently from "small business," merely because the term "small business" would "encompass too many suppliers" premised upon their admission that "most DMEPOS suppliers are small." 72 Fed. Reg. 18056, 18058. Thus, it is important to point out that, notwithstanding Congress's apparent intent to protect small businesses, CMS has narrowed the relevant protections to small suppliers, a subset of businesses that are about 50% smaller than typical small businesses. Further, because of CMS's departure from the SBA definition of small business, the Congressional finding does not inform us of the percentage of winning bidders that were small suppliers. Consequently, the House of Representative's Report findings cannot support the conclusion that there was "successful participation of small suppliers" in the demonstration tests. (Defs. Memo, p. 10).

2. The Grandfathering Provisions of the Act do not Protect Plaintiffs from Imminent Injury

Defendants argue that Plaintiffs' injuries are not actual or imminent, in part because grandfather provisions would allow beneficiaries to elect to continue oxygen services from the Plaintiffs. (Defs. Memo, p. 10) (citing 42 U.S.C. § 1395w-3(a)(4); 42 C.F.R. § 414.408). Payment for oxygen services under the grandfather provisions would be made based on the single

payment amount, which is necessarily lower than the current payment rates (i.e., Medicare fee schedule). 42 C.F.R. § 414.408(j)(2)(iv). Thus, under the grandfather provisions, plaintiffs would be injured, because they would receive lower reimbursement rates. In addition, payments under the grandfather provisions will necessarily end, particularly for the rental of oxygen equipment, which is limited to a period of continuous use for 36 months. 42 C.F.R. §§ 414.408(j)(1)(ii) (limiting the payment of oxygen under the grandfather provisions to the “remainder of the rental period for that item”); 42 C.F.R. §414.226(a) (limiting the payment for rental of oxygen equipment to 36 months). The grandfather provisions, however, are only available to a grandfathered supplier’s current Medicare customers and would not allow a grandfathered supplier to service “new” Medicare customers.

3. The Defendants’ Reliance on the Demonstration Projects is Misplaced, Because the Projects Differ Significantly from the Act as it will be Implemented in the Ten CBAs

The demonstration programs are of limited utility in assessing the impact of competitive bidding as it will be applied in the ten CBAs, because the demonstrations differed from the program that is about to be implemented. Most significantly, payment under the demonstrations was based on an average of the adjusted bids. See SARA KARON, PH.D., ET AL, EVALUATION OF MEDICARE’S COMPETITIVE BIDDING DEMONSTRATION FOR DMEPOS: FIRST-YEAR ANNUAL EVALUATION REPORT A-4 (2001) (hereinafter “1st Evaluation Report”). The *1st Evaluation Report* further stated that the pricing methodology helped “ensure that [a supplier] receives at least as much as the projected allowed charges that would arise from its bid.” *1st Evaluation Report* at A-7.

Notwithstanding the *1st Evaluation Report’s* recommendations, CMS proposed to abandon the demonstration pricing method in favor of using a median price, despite “many

members [of the PAOC] [voicing] concerns on the proposal to base payment amounts on the median accepted bid for each HCPCS code, believing that *this would result in unreasonably low payment rates.*” PROGRAM ADVISORY AND OVERSIGHT COMMITTEE (PAOC) FOR QUALITY STANDARDS AND COMPETITIVE ACQUISITION OF CERTAIN DURABLE MEDICAL EQUIPMENT, PROSTHETICS, ORTHOTICS, AND SUPPLIES, MEETING 5 SUMMARY 10 (May 22, 2006)

4. While the Competitive Bidding System Presents Significant Barriers to the Participation of Small Suppliers, the Act does not Offer Workable “Protections”

The regulations provide essentially two “protections” for small suppliers: (1) opportunity to form networks; and (2) a target number for small supplier participation. See 42 C.F.R. §§ 414.418, 414.414(g). In order to form or join a network, a small supplier must certify that “it is unable independently to furnish all of the items in the product category for which the network is submitting a bid to beneficiaries throughout the entire geographic area of the CBA.” 42 C.F.R. § 414.418(b)(5). If a network is awarded a contract, however, each member of the network must furnish all of the items within the product categories for which the network is awarded a contract. 72 Fed. Reg. 18060. Membership in a network also precludes the small supplier from submitting a bid for the same product category in the same CBA. 42 C.F.R. § 414.418(b)(3). “Each network must form a single legal entity that acts as the bidder and submits the bid.” 42 C.F.R. § 414.418(b)(1). Seemingly contradicting the regulations, the Competitive Bidding Implementation Contractor (“CBIC”) requires each network to have a primary supplier (i.e., a designated network member) that submits the bid for the entire network. COMPETITIVE BIDDING IMPLEMENTATION CONTRACTOR, INSTRUCTIONS FOR COMPLETING BID FORMS FOR MEDICARE DMEPOS COMPETITIVE BIDDING PROGRAM 10 (2007) (hereinafter “*Bidding Instructions*”).

A network of small suppliers inherently raises antitrust concerns:

Comment: Many commenters expressed concern about potential violations of Federal antitrust laws that could arise under the proposed network provisions. For example, *they expressed concern that forming a network could violate the Federal antitrust laws because those laws do not permit suppliers to reach a mutual consensus on pricing. They also stated that the proposed rule would require suppliers to agree on proposed prices for all items within a competitive bidding product category....*

Many commenters believed that the option to form a network is not a realistic solution for ensuring that small suppliers participate in the competitive bidding program. They further believed the proposed rule is complex, and that suppliers would not have sufficient time to form a network and comply with all the requirements to meet the competitive bidding implementation timelines.

72 Fed. Reg. 18059 (emphasis added).

CMS fully acknowledged that networks raise antitrust concerns, but offered no protection or guidelines to address such concerns:

Response: We strongly agree that networks must not violate antitrust laws and that networks must take steps to ensure that they are not in violation of Federal antitrust laws. We emphasize that suppliers that pursue the network option must comply with all applicable Federal antitrust laws, and we will reject a network bid if we believe it has been prepared in violation of those laws. We will also refer any suspected cases of Federal antitrust violations to the Department of Justice for further review...

Once again, we stress that these rules are intended to assist us in evaluating network bids and to protect the Medicare program against anticompetitive behavior, and they should not be interpreted as superseding any Federal laws or regulations that protect against anticompetitive behavior.

72 Fed. Reg. 18059, 18060.

Thus, the only option available to a small supplier that cannot service an entire CBA is to engage in activity that contains a real and recognized risk of violating other federal law. This risk is in addition to the added burden and cost of seeking out potential network members, negotiating the required contract between members, and forming the network entity. *Bidding Instructions* at 1 (requiring the submission of “signed legal contracts between all network

members”); See 42 C.F.R. § 414.418(b)(1) (requiring “any agreement entered into for purposes of forming a network [to] be submitted to CMS”). In comparison, a large supplier would have no need to form a network, because it can service the entire CBA. Consequently, a large supplier does not incur the risks, burdens, and costs involved in forming a network that a small supplier that cannot service an entire CBA would in submitting a bid. The network provisions, therefore, act as an additional barrier to entry of small suppliers. The fact that Defendants do not so much as mention networks in their Memorandum is telling. Perhaps Defendants, too, understand how unworkable this “protection” is.

The other “protection” for small suppliers is the “target for small supplier participation.” 42 C.F.R. § 414.414(g). Under this regulation, CMS will multiply the number of “winning” suppliers in a product category by 30% (the “target number”). 42 C.F.R. § 414.414(g)(1)(i). CMS then identifies the number of small suppliers that won bids. 42 C.F.R. § 414.414(g)(1)(ii). If the number of small suppliers identified is less than the target number, then CMS will:

[Select] additional small suppliers whose composite bids are above the pivotal bid for the product category in ascending order based on the proximity of each small supplier’s composite bid to the pivotal bid, until the [target number] is reached or there are no more composite bids submitted by small suppliers for the product category.

42 C.F.R. § 414.414(g)(1)(iii).

In other words, if there are not enough small suppliers that bid at or below the pivotal bid, then CMS will invite small suppliers that bid above the pivotal bid. This process continues until the target number is reached or there are no more small supplier bidders in that product category. *Id.* Indeed, such suppliers are the intended beneficiaries of these provisions, because the small winning suppliers would be offered contracts without these provisions. The bids of the suppliers whose composite bids are above the pivotal bid will not be considered in calculating the single

payment amount. 42 C.F.R. § 414.414(g)(2). In effect, the small suppliers that bid above the pivotal bid will be offered contracts at a single payment amount that is lower, perhaps dramatically so, than the amounts at which they indicated they could furnish services. Furthermore, even if CMS to meet its “target,” the number of small suppliers would only total 30%, far less than the “75%” figure applauded by Defendants. (Defs. Memo p, 4).

B. PLAINTIFFS’ INJURY IS CLEARLY WITHIN THE ZONE OF INTERESTS PROTECTED BY THE ACT

The Plaintiffs can easily establish prudential standing because their injury is within the “zone of interests” protected by the Act. In order to establish prudential standing, Plaintiffs must show that “the interest sought to be protected by the complainant [is] arguably within the zone of interests to be protected or regulated by the statute or constitutional guarantee in question.” *National Athletic Trainers’ Ass’n, Inc. v. U.S. Dept. of Health and Human Services*, 455 F.3d 500, 503 (5th Cir. 2006) (citing *Clarke v. Sec. Indus. Ass’n*, 479 U.S. 388, 396 (1987)). The Fifth Circuit again cited *Clarke* explaining that:

[i]n cases where the plaintiff is not itself the subject of the contested regulatory action, the test denies a right of review if the plaintiff’s interests are so marginally related to or inconsistent with the purposes implicit in the statute that it cannot reasonably be assumed that Congress intended to permit the suit. The test is not meant to be especially demanding; in particular, there need be no indication of congressional purpose to benefit the would-be plaintiff.

National Athletic Trainers’, 455 F.3d at 503 (citing *Clarke*, 479 U.S. at 399-400).

Although relevant Fifth Circuit and Supreme Court authority states that an “indication of congressional purpose to benefit the would-be plaintiff” is not even necessary in order to satisfy the “zone of interests” test, in this case, there is indisputable evidence of just such a purpose. In order to find this language, the Court needs to look no further than Defendants’ Memorandum which cites § 1395w-3(6)(D). This provision requires that the Secretary “take appropriate steps

to insure that small suppliers are considered in the competitive bidding program.” Additionally, Defendants cite 42 C.F.R. § 414.414(g), which created “special rules for the participation in the competitive bidding program by small suppliers, including setting a target number for small suppliers...” (Defs. Memo, pp. 9-10). While Plaintiffs controvert the effectiveness of these provisions, they are nonetheless powerful indicators of intent that small providers and beneficiaries fall within the “zone of interests.”

If that is not enough, an analysis of similar cases shows that Plaintiffs have met their burden to establish prudential standing. Defendants state that “[a] supplier’s ability to provide DMEPOS to Medicare beneficiaries at a price of the supplier’s choosing is not within the “zone of interests protected by the law invoked.” (Defs. Memo, p. 13) (citing *Elk Grove Unified School Dist. v. Newdow*, 542 U.S. 1, 12 (2004)). Of course, Defendants cite *Elk Grove* only for the generic proposition regarding the zone of interests. *Elk Grove* has nothing to do with DMEPOS or Medicare, rather, the case involves a father (who did not have custody of his daughter) challenging his daughter’s school’s policy requiring that the children recite the Pledge of Allegiance. *Id.* at 1.

In *National Athletic Trainers’*, a far more factually similar case, the court held that in an amendment “standardizing the quality of therapy services provided to Medicare beneficiaries...the interests protected are the Medicare beneficiary’s interest in receiving and the physicians interest in providing quality care.” 455 F.3d at 503; see also *Am. Chiropractors Ass’n Inc. v. Leavitt*, 431 F.3d 812, 816 (D.C.Cir. 2005) (“[T]he interests of enrollees and the interests of chiropractors converge: the chiropractor provides the service, the enrollee receives it, and Medicare provides the reimbursement. This is more than enough to satisfy the less-than-demanding zone-of-interest test.”) In the case at bar, Plaintiffs, as both small suppliers of DME

items and as beneficiaries of Medicare who purchase DME, are well within the zone of interest of Section 302 of the MMA.

II. THE COURT MAINTAINS SUBJECT MATTER JURISDICTION OVER THE COMPLAINT BECAUSE PLAINTIFFS' CLAIMS ARE RIPE FOR REVIEW.

Under applicable United States Supreme Court and Fifth Circuit jurisprudence, the law establishes that Plaintiffs' claims are presently ripe for adjudication. While Defendants cite to convenient ripeness doctrine quotations from inapposite cases, they fail to adequately address the pertinent facts of the present matter.

The general rule is that in determining whether a controversy is ripe for adjudication, the court must consider “(1) the fitness of the issues for judicial decision, and (2) the hardship to the parties of withholding court consideration.” *Abbott Labs. v. Gardner*, 387 U.S. 136, 149 (1967), *overruled on other grounds*, *Califano v. Sanders*, 430 U.S. 99 (1977); *Texas v. United States*, -- F.3d --, 2007 WL 2340781 (5th Cir. 2007). “Whether particular facts are sufficiently immediate to establish an actual controversy is a question that must be addressed on a case-by-case basis.” *Orix Credit Alliance v. Wolfe*, 212 F.3d 891, 896 (5th Cir. 2000). A challenge to administrative regulations is fit for judicial review if “(1) the questions presented are ‘purely legal one[s],’ (2) the challenged regulations constitute ‘final agency action,’ and (3) further factual development would not ‘significantly advance [the court’s] ability to deal with the legal issues presented.’” *Nat’l Park Hospitality Ass’n v. Dep’t of Interior*, 538 U.S. 803, 812 (2003) (internal citations omitted); *Abbott Labs.*, 387 U.S. at 149-54. Courts also consider “whether resolution of the issues will foster effective administration” of the regulation. *Merchs. Fast Motor Lines, Inc. v. ICC*, 5 F.3d 911, 920 (5th Cir. 1993); *Abbott Labs.*, 387 U.S. at 154. Further, where litigation based on application of the regulation is certain to immediately arise between the parties to a suit,

a controversy concerning the enforceability of the subject act is ripe. *Exxon Corp. v. Busbee*, 644 F.2d 1030, 1031-32 (5th Cir. 1981).

A. THE ISSUES IN THIS CASE ARE FIT FOR JUDICIAL DECISION

The constitutionality of a regulation is purely a question of law. *See McCarthy ex rel. Travis v. Hawkins*, 381 F.3d 407 (5th Cir. 2004). In the present matter, Plaintiffs claims are asserted to challenge the constitutional validity of the Act. As such, the claims involved raise questions of law that are proper for adjudication.

A final agency action includes a rule or regulation “of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy.” *Abbott Labs.*, 387 U.S. at 149. A regulation formulated and instituted through formal procedure is a final agency action. *Texas*, 2007 WL 2340781. The Act is both generally applicable to all Medicare beneficiaries and particularly applicable to those DME providers that provide medical care and equipment to those beneficiaries. There can be no argument that the Act does not prescribe law or policy: the providers must submit to the bidding process if they want to provide care and equipment to Medicare beneficiaries in the CBAs, and Medicare beneficiaries are forced to obtain their medical care and equipment from those providers that carry the favor of the federal government in the bidding process or else face paying for these needs without the aid of Medicare benefits that they are dependent upon.

Additional fact finding is not necessary or helpful in answering the purely legal question of the Section 302 of the MMA’s validity. See *Id.* There are no additional facts that can be unearthed over time that will change the validity of the Act as CMS plans to implement it. Certainly the validity of the Act will not be affected when the Plaintiff DME providers are pushed out of business as the Wal-Marts of the DME industry gobble up bid awards in the CBAs.

Likewise, the Act will not become more or less constitutional when Medicare beneficiaries are forced to accept care and equipment from a source other than their chosen medical needs provider.

Resolution of the claims brought by Plaintiffs will provide the Secretary significant guidance in effective administration of the Act with regard to small DME providers and to Medicare beneficiaries with special medical needs. Similar to *Abbott*, where the Court found claims ripe for adjudication that involved yet-to-be-enforced FDA regulations, if the government prevails, the adjudication of these claims now will settle the matters in issue as to future claims, and if the Plaintiffs prevail, the Department “can more quickly revise its regulation.” *Abbott Labs.*, 387 U.S. at 154.

Furthermore, litigation between Plaintiffs and Defendants based on the Act is certain to follow application of the regulation. Provider Plaintiffs who are unable to meet the Act’s requirements to submit a competitive and compliant bid will be forced to turn to the Court to protect their rights and remedy the harm suffered when their bids are rejected by the Secretary. Medicare beneficiary Plaintiffs who are forced to seek their medical care and equipment from providers forced upon them by the Department will also have to turn to litigation to protect their right to choose to the provider, to remedy the harm suffered, and to receive the Medicare benefits upon which they have become dependent.

B. IMMINENT HARM TO THE PLAINTIFFS WILL RESULT IF THE COURT WITHOLDS CONSIDERATION

Plaintiffs will suffer imminent harm and hardship absent the Court’s consideration of the Plaintiffs’ claims. The Supreme Court has found hardship resulting from legal harms such as the harmful creation of legal rights and the harm of being forced to modify one’s behavior in order to

avoid future adverse consequences. *Texas*, 2007 WL 2340781. In *Texas*, ripeness was found where the State challenged newly enacted, but yet-to-be-enforced Interior Department gaming regulations. Similar to the Plaintiff in *Texas*, the DME provider Plaintiffs have two unseemly alternatives. They can incur significant expense by participating in an invalid process by preparing bids that they will not likely win because they cannot meet the Act's impractical criteria and, only after rejection and loss of livelihood, seek to invalidate the Act. The Plaintiffs' alternative is to decline to participate and face significant loss of business when the Medicare beneficiary customers are forced to seek out other providers whose bids have received approval from the Department. Provider Plaintiffs who cannot sell to Medicare beneficiaries will immediately see a loss of the majority of their revenues. (See, *e.g.*, Compl. ¶ 47). Thus, "withholding court considerations" will clearly result in "hardship to the parties." *Abbott Labs.*, 387 U.S. at 149.

Medicare beneficiaries with special medical needs will be forced to either (1) seek their medically prescribed care and equipment from sources other than the provider of their choosing or else (2) continue to exercise their right to choose the provider of their medical care and equipment at the expense of losing their Medicare benefits. In contrast, other Medicare beneficiaries whose generic needs are met by providers large enough and able meet the impractical criteria of the Act will be able to continue to receive their care and equipment from their chosen provider *and* continue to receive Medicare benefits.

Plaintiffs' claims are ripe for review. Plaintiffs' claims are not speculative and hypothetical but are, unfortunately, based on the imminent harm that will certainly flow from the Act. While Defendants argue against ripeness by utilizing convenient quotes from cases factually incongruent to the matter presently before the Court, Defendants fail to establish that

the Plaintiffs' claims are not ripe for adjudication. The law clearly requires application of the ripeness doctrine to each unique factual situation. It is apparent the Plaintiffs face imminent harm from the implementation of the Act, and when the ripeness doctrine is properly applied to the present matter, Plaintiffs' claims are ripe for consideration.

III. THE COURT MAINTAINS SUBJECT MATTER JURISDICTION OVER THE COMPLAINT BECAUSE THE "NO REVIEW" PROVISION INVOKED BY DEFENDANTS DOES NOT BAR PLAINTIFFS' CLAIMS

Defendants assert that the Court lacks subject matter jurisdiction over Plaintiffs' claims because "Congress explicitly barred judicial review of the key aspects involved in establishing and implementing the program." (Defs. Memo, p.16). Defendants' Memorandum appears to interpret 42 U.S.C. § 1395w-3(b)(10) so broadly as to preclude any challenge, whether administrative or judicial, to Section 302 of the MMA.

However, there is a "strong presumption that Congress intends judicial review of administrative action." *Bowen v. Michigan Academy of Family Physicians*, 476 U.S. 667, 670 (1986). Defendants' attempt to thwart judicial review by invoking this "no review" provision fails because the provision does not apply to Plaintiffs' claims. And furthermore, even if Congress intended this provision to operate as a bar to Plaintiffs' constitutional claims, such preclusion is not constitutionally permissible.

A. THE "NO REVIEW" PROVISION DOES NOT APPLY TO THE INSTANT CASE BECAUSE A PROPER CONSTRUCTION OF THE PROVISION SHOWS THAT IT DOES NOT PRECLUDE PLAINTIFFS' CHALLENGE TO THE METHODOLOGY OF COMPETITIVE BIDDING

If this "no review" provision is interpreted so broadly as to preclude constitutional claims, or at least those constitutional claims that Defendants deem "insubstantial" or not "serious" (Defs. Memo, p. 18), as suggested by Defendants, then such a construction would raise serious

constitutional concerns, which are discussed below. See *Johnson v. Robinson*, 415 U.S. 361, 366-367 (1974). However, in such a situation, “it is the cardinal principal that [the Supreme] Court will first ascertain whether a construction of the statute is fairly possible by which the [constitutional] question[s] may be avoided.” *Id.* (quoting *United States v. Thirty-seven Photographs*, 402 U.S. 363, 369 (1971)). In this case, a proper construction of this no review provision avoids the constitutional issue by illustrating the fact that this statute does not preclude the judicial review sought by Plaintiffs.

This strong presumption of review in *Michigan Academy* cannot be overcome absent “clear and convincing evidence” that Congress intended to preclude the suit. *Abbott*, 387 U.S. at 141 (quoting *Rusk v. Cort*, 369 U.S. 367, 380 (1962)). Perhaps in an attempt to offer such evidence, Defendants cite several cases including *Amgen, Inc. v. Smith*, 357 F.3d 103, 112 (D.C. Cir. 2004), *American Society of Cataract and Refractive Surgeons v. Thompson*, 279 F.3d 447, 453 (7th Cir. 2002), and *Painter v. Shalala*, 97 F.3d 1351, 1356-57 (10th Cir. 1996) as examples of instances where courts have “upheld ‘no review’ provisions as overcoming the presumption in *Michigan Academy* with respect to similar Medicare Part B programs.” (Defs. Memo, p. 18). However, a careful analysis of these cases demonstrates that while the “no review” provisions upheld in these cases are, in many respects, similar to 42 U.S.C. § 1395w-3(b)(10), the claims precluded by these provisions were quite distinct from the claims in this case.

Amgen, *American Society*, and *Painter* were all challenges to individual determinations made by agency administrators. In *Amgen*, the plaintiffs challenged equitable adjustments to payments made to hospitals. 357 F.3d at 112. In *American Society of Cataract and Refractive Surgeons*, the plaintiffs challenged the Administrator’s calculations of relative value units. 279 F.3d at 453. In *Painter*, the plaintiffs’ suit regarded the manner in which the conversion rate was

calculated. 97 F.3d at 1356-57. In all three cases, the courts upheld the “no review” statutes and prevented the plaintiffs from challenging the decisions of the agency administrators. The court in *Amgen* noted that Congress’s use of the preclusion statute is unsurprising, because “piecemeal review of individual payment determinations could frustrate the efficient operation of the complex prospective payment system.” 357 F.3d at 112 (citing *Block v. Community Nutrition Inst.*, 467 U.S. 340, 348 (1984)).

However, the Plaintiffs do not seek to frustrate the efficiency of the system by challenging individual determinations such as the CBAs selected by the Administrator or the awarding of bids. Rather, Plaintiffs seek to challenge the methodology of the competitive bidding scheme. In the context of “no review” provisions, the Supreme Court recognizes a difference between attempts to preclude review of decisions made by an administrative agency regarding the “interpretation or application of a particular provision of the statute to a particular set of facts” and attempts to preclude review of a decision regarding a statutory class. *Johnson*, 415 U.S. at 367. In *Michigan Academy*, the Court drew another important distinction between challenges to amount determinations and “challenges mounted against the method by which... amounts are to be determined.” 476 U.S. at 675. The Court further states in *Shalala v. Illinois Council on Long Term Care, Inc.*, that the “no review” provision adjudicated in that case would *not* apply to certain categories of cases, like “‘methodology’ challenges,” where application of the provision would completely foreclose any opportunity for review. 529 U.S. 1, 17 (2000) (citing *Michigan Academy*, 467 U.S. at 680).

Plaintiffs’ Complaint asserts a challenge to the methodology of the competitive bidding scheme, including (1) the low-bid system in which the price of an item is the almost exclusive consideration used to determine the winning bid, (2) the fact that suppliers must bid on all items

in any product category on which they wish to place a bid, and (3) the requirement that all bidders must be able to cover the entire metropolitan statistical area.¹

As Defendants point out, the *Michigan Academy* presumption can be overcome only by “specific language or specific legislative history that is a reliable indicator of Congressional intent.” *Block*, 467 U.S. at 349. However, Defendants offer no evidence of legislative history, and the “specific language” of the statute also offers little support for Defendants’ position.

The areas covered by the “no review” provision are: (A) the establishment of payment amounts, (B) the awarding of contracts, (C) the designation of competitive acquisition areas, (D) the phased-in implementation of competitive bidding, (E) the selection of items and services for competitive acquisition, and (F) the bidding structure and the number of contractors selected. 42 U.S.C. § 1395w-3(b)(10)(A)-(F). This statute offers no “specific language” barring a suit that challenges the methodology of the competitive bidding scheme in Section 302 of the MMA.

Of these six, subsection (F), which regards “the bidding structure,” is the only provision that could conceivably be understood as relating to the methodology of competitive bidding. However, Plaintiffs are not able to locate any authority that sheds light on this rather vague

¹ Plaintiffs’ Complaint offers many challenges to the bidding methodology: including, but not limited to: “making the system even more onerous for small DME providers, each bidder is required to bid all products in any category on which it wishes to place a bid.” (Compl. ¶ 27). “The two-pronged strategy to award bids to the lowest bidders that can cover the entire metropolitan statistical area created a naked preference for large durable medical equipment suppliers, as smaller suppliers lack the economies of scale to lower prices and the physical size to cover the whole of vast geographical regions.” (Compl. ¶ 28). “The competitive acquisition scheme has created a low-bid system in which the price of a product is the almost exclusive consideration used to determine which businesses may participate in Medicare.” (Compl. ¶ 29). “[S]mall suppliers are left with the almost unworkable option of forming networks of small suppliers to artificially create the economies of scale and geographical presence already enjoyed by larger competitors.” (Compl. ¶ 30). “[T]he threat of competitive bidding is particularly onerous for CHS as a result of the fact that the MMA requires that a company be able cover the entire metropolitan area in order to submit a bid. (Compl. ¶ 47). “The legislation discriminates against some, the Medicare beneficiaries and small DME providers, including all of the Plaintiffs, and favors others, the non-Medicare patients and larger DME suppliers.” (Compl. ¶ 50). “The relation between the classifications adopted—favoring large DME providers over smaller providers—and the objectives sought by the MMA are not rationally related.” (Compl. ¶ 54). “The low bid regime created by the MMA relegates Medicare beneficiaries to purchasing the cheapest products...” (Compl. ¶ 55).

phrase. On its face, the phrase “bidding structure” appears to mean the procedure by which DME providers make bids. If Defendants maintain that “bidding structure” should be read to preclude challenges to the bidding methodology, this interpretation is not tenable given the context.

One helpful canon of construction, *noscitur a sociis* (it is known by its companions), *cf. Washington Sate Dept. of Social and Health Services v. Guardianship Estate of Keffeler*, 537 U.S. 371, 384-85 (2003), is “often wisely applied where a word is capable of many meanings in order to avoid giving unintended breadth to the Acts of Congress. *Jarecki v. G.D. Searle & Co.*, 367 U.S. 30, 307 (1961). The canon is very instructive in this case. Excluding subsection (F) for a moment, the remaining five areas of preclusion listed in the provision are all directed at barring challenges to individual administrative determinations made in the implementation of the competitive bidding scheme. None of these areas include a bar on the methodology of the bidding program as established by Congress or CMS. Accordingly, it is proper to read “bidding structure” as limited to determinations made in the course of administering the Act, not the substantive methodology by which bids are selected.² Such an interpretation is sensible and would allow the Court to avoid any constitutional questions regarding the preclusion of judicial review. In any event, the vague language about “bidding structure” is a very far cry from “plain and unambiguous language” directed at precluding challenges to the bidding methodology. *Painter*, 97 F.3d at 1356.

Additionally, applying 42 U.S.C. § 1395w-3(b)(10) as suggested by Defendants would improperly bar any and all review for Plaintiffs’ claims, as well as any other challenge to any part of the Act. A statutory provision that bars review does not apply if application of that provision

² As further evidence of this interpretation, the “bidding structure” language is paired with the phrase “the number of contractors selected.” 42 U.S.C. § 1395w-3(b)(10)(A)-(F). The “number of contractors selected” clearly regards

“would not simply channel review through the agency, but would mean no review at all.” *Illinois Council*, 529 U.S. at 19; see also *National Athletic Trainers’ Ass’n, Inc. v. U.S. Dept. of Health and Human Services*, 455 F.3d 500 (5th Cir. 2006) (holding that the relevant question in determining the applicability of a statute precluding judicial review is whether that provision would result in “no review at all.”). As Defendants point out, this statute bars both administrative and judicial review. If the bar on challenges to the “bidding structure” includes challenges to the methodology used in any aspect of the Act, then subsections (A)-(E) would be redundant, as it is difficult to conceive of any challenge to the Act that would not be precluded by 42 U.S.C. § 1395w-3(b)(10)(F), including the challenges precluded by subsections (A)-(E).³ In this case, therefore, even if the “no review” statute is read to bar methodology challenges, it could not be applied in the instant case as it would result in “no review at all” for Plaintiffs’ claims, or any other challenges the Act, for that matter.

B. THE PRECLUSION STATUTE SHOULD NOT BE APPLIED AS SUGGESTED BY DEFENDANTS BECAUSE IT WOULD FORECLOSE PLAINTIFFS’ CONSTITUTIONAL CLAIMS

Defendants state that “[w]hile a preclusion statute should not be applied where it will have the effect of foreclosing serious constitutional claims”... “where a constitutional claim is clearly insubstantial, Congress’s preclusion of review prevails.” (Defs. Memo, p. 18). Of course, the nebulous language about “serious constitutional claims” is not present in the cases cited by Defendants. See *Johnson*, 415 U.S. at 366. While Defendants may not view Plaintiffs’ constitutional claims as “serious” or “substantial,” the actual case law makes it abundantly clear

questions of individual determinations made while administering the Act.

³ In keeping with another canon of interpretation, the Court should avoid reading subsection (F) so broadly as to swallow the other subsections of this provisions, because the Court should not interpret a statute in a way that makes

that the courts do not take some constitutional rights more seriously than others.⁴ Plaintiffs need only establish that they have pled legitimate constitutional claims, which they do below. See *Painter*, 97 F.3d at 1357. Given the legitimacy of Plaintiffs' constitutional claims, Plaintiffs' claims cannot be precluded under the "no review" provision. See *Johnson*, 415 U.S. at 366-67; see also *Illinois Council*, 529 U.S. at 17 (citing *Michigan Academy*, 476 U.S. at 762).

IV. PLAINTIFFS' COMPLAINT PROPERLY STATES A CLAIM FOR VIOLATIONS OF PLAINTIFFS' EQUAL PROTECTION AND DUE PROCESS RIGHTS

The facts asserted in Plaintiffs' Complaint support the essential elements of Plaintiffs' Due Process and Equal Protection claims because Plaintiffs' Complaint established that the Act violated Plaintiffs' Equal Protection and Due Process Rights.

A. PLAINTIFFS' EQUAL PROTECTION CLAIMS STATE A CLAIM UPON WHICH RELIEF MAY BE GRANTED

The Equal Protection Clause of the Fourteenth Amendment "is essentially a direction that all persons similarly situated should be treated alike." *City of Cleburne, Tex. v. Cleburne Living Center*, 473 U.S. 432, 439 (1985); see also *Plyler v. Doe*, 457 U.S. 202, 216 (1982). Individuals or entities are "similarly situated" if they are similarly situated in all "relevant respects." *Apache Bend Apartments, Ltd. v. United States*, 987 F.2d 1174, 1180 (5th Cir.1993)(en banc).

1. The Requirements to Submit Bids Under Section 302 of the MMA Improperly Discriminate Between Small Suppliers and Large Suppliers

With regard to Section 302 of the MMA, small suppliers and beneficiaries who depend

part of the statute redundant. See, e.g., *TRW Inc. v. Andrews*, 534 U.S. 19, 31 (2001).

⁴ One authority cited by Defendants explains that "[i]t would be passing odd to suppose that the Office of Workers' Compensation Programs could turn down the claim of an injured federal worker on racial or religious grounds, and the worker have no judicial remedy whatever, or even an administrative remedy. This is not a race or religion case, but are we to pick and choose among constitutional rights?" *Czerkies v. U.S. Dept. of Labor*, 73 F.3d 1435, 1442 (7th Cir. 1996).

on them are discriminated against despite being similarly situated in all relevant respects to larger suppliers: first, the fact that a supplier must bid on all products in any category on which it wishes to place a bid, and second, the requirement that all bidders must be able to cover the entire metropolitan statistical area.

Defendants cite Plaintiffs' Complaint in arguing that small suppliers and large suppliers are not "similarly situated," because, for example, larger suppliers have "necessarily lower" per-unit expenses. (Defs. Memo, p. 20). With regard to the way the Act seems to unduly reward low bidders at the cost of other considerations, Plaintiffs view this as unwise, but Defendants are probably correct that this competitive advantage for large suppliers, alone, does not give rise to an Equal Protection claim. After all, while an undue focus on low bids is sure to have many negative consequences for Medicare providers and beneficiaries, it is rationally related to one of the stated purposes of Section 302 of the MMA: to reduce "waste," and as a result, reduce the cost of a program that Defendants deem "too expensive." (Defs. Memo, p. 3)(citing H.R. Rep. No.108-178 (II), at Title III, § 302 (2003).

However, as stated in Plaintiffs' Complaint, the Act also discriminates against small suppliers with respect to qualities that are not relevant to the purposes of the Act. (See Compl. ¶ 54). In particular, the requirements in suppliers submitting a bid must be able to cover the entire metropolitan area (42 C.F.R. § 414.422(e)(1)) and bid on all items in a product area (42 C.F.R. § 414.412(d)) create barriers for small suppliers. Defendants also note that small suppliers are not similarly situated to large suppliers based on Plaintiffs' pleading that small suppliers are "clearly excluded from covering an entire metropolitan area." (Defs. Memo, p. 20, n. 16). Of course, the distinction between providers that can and cannot cover an entire CBA is a

creation of CMS, and is the very distinction Plaintiffs challenge in their Equal Protection claim. Distinctions between providers that can or cannot (1) serve an entire CBA, or (2) bid on items in any product category, are not relevant to the purposes of the Act, and accordingly, an ability or inability to satisfy these requirements is not a difference in a “relevant respect.”

2. The Bidding Methodology of Section 302 of the MMA Creates Barriers for Small Suppliers that are not Rationally Related to the Act’s Purposes

Plaintiffs agree with Defendants that the applicable standard of review is the rational basis test. However, Defendants fail to establish a rational basis for the Act’s bidding methodology. In particular, the criteria that a supplier, in order to submit a bid, must (1) be able to cover the entire CBA, and (2) bid on items in any product category on which it wishes to place a bid, are not rationally related to the purposes of the Act.

Under the rational basis test, the Act fails because the Act’s bidding methodology are completely bankrupt of any legitimate purpose. For example, in *Cleburne*, the Court notably used the rational basis analysis to invalidate a law that in effect discriminated against the mentally retarded. The Court in *Cleburne* ruled that the law was invalid after determining that none of the stated purposes for the legislation explained the governmental actions. 473 U.S. at 448-56. In its analysis, the Court rejected the stated purposes of preventing harassment from a neighboring junior high school and complaints from the adjacent neighborhood community. *Id.* at 449. Thus, the Court applied the rational basis test and rejected the government’s proffered purposes as implausible and then ruled that the only remaining explanation for the classification was prejudice.

Cleburne advances the idea that the government cannot simply use a clever strategy to mask favoritism of one group over another, and that courts will use a searching rational basis

test to determine if the government is employing such a strategy. In this case, the requirements that bidders must be able to (1) cover the entire CBA, and (2) bid on items in any product category, bear no relationship to any legitimate goals of the Act. These requirements do not serve any purpose other than to exclude small suppliers from the competitive bidding process. Defendants' Memorandum is completely silent as to why these provisions are in place, and what legitimate state interest they are rationally related to. While Defendant may be able to come up with some creative post hoc legitimate purpose for these requirements, none are apparent. What is apparent, however, is that these requirements are antithetical to aspirations that small suppliers should be protected by the act as embodied in 42 U.S.C. § 1395w-3(b)(2)(A)(ii), and § 414.414(g).

B. THE ACT VIOLATES PLAINTIFFS' DUE PROCESS RIGHTS

Plaintiff Suppliers have a protectable property interest.⁵ A provider's "expectation of continued participation in the Medicare program is a property interest protected by the Due Process Clause of the Fifth Amendment." *Ram v. Heckler*, 792 F.2d 444, 447 (4th Cir. 1986) (citing *Bowens v. North Carolina Dept. of Human Resources*, 710 F.2d 1015, 1018 (4th Cir. 1983)). The Ninth Circuit held that health providers operating under the Medicare program have a protectable liberty interest, as opposed to a property interest, at stake. *Erickson v. United States ex rel. Dept of Health and Human Services.*, 67 F.3d 858, 862 (9th Cir. 1995).

The property interest in the Plaintiff Beneficiaries is even stronger.⁶ It has long been held that recipients of government entitlements have a property interest under the Due Process Clause.

⁵ "Oxyonly, Inc. d/b/a Procair Inc., M.S.B., Inc. d/b/a C & B Medical, Inc., and Cardiorespiratory Home Systems have a property interest in providing their goods and services to Medicare beneficiaries." (Compl. ¶ 61).

⁶ "Gregory Hewitt, Jose M. Salas, Jr., and Charles W. Bell have been denied the specialized care they require because of the operation of the competitive acquisition scheme, and have been denied their substantive due process

Goldberg v. Kelly, 397 U.S. 254, 261-262 (1970); see also *Mathews v. Eldridge*, 424 U.S. 319 (1976). Moreover, at least one district court within the Fifth Circuit has encouraged other Medicare beneficiaries to assert their claim (a procedural Due Process claim) under the Due Process Clause rather than the beneficiaries' providers. *Sudderth v. Shalala*, 1999 WL 1095329, at *5, n. 1 (E.D. La. 1999) (“[I]t seems to this Court that the individual or individuals having a right to oppose such an exclusion would be the *patients* who are the beneficiaries of the Medicare programs...”). In this case, the beneficiary Plaintiffs have a property right in their benefits, and accordingly, Plaintiffs' Complaint states a claim based on Due Process.

Finally, Plaintiffs' Complaint establishes that the alleged taking goes far beyond merely “frustrating business expectations.” (See Defs. Memo, p. 24)(citing *Air Pegasus of D.C., Inc. v. U.S.*, 424 F.3d 1206, 1216 (Fed.Cir. 2005). The Complaint states that “[f]or individuals such as Gregory Hewitt, Jose M. Salas, Jr. and C.W. Bell, the regulations imposed under the [Act] imminently threaten their ability to receive adequate durable medical equipment and individualized service and care so as to remain self-sufficient. Oxyonly, M.S.B., CHS will suffer imminent and irreparable harm to their businesses.” (Compl. ¶ 63). The Provider Plaintiffs, in some cases, will lose over half of their revenue. (See Compl. ¶ 47). Accordingly, Plaintiffs' injuries are much more than mere “frustration.”

CONCLUSION

The Plaintiffs have established the Court's basis for subject matter jurisdiction and have shown that the Complaint states a claim based upon both Equal Protection and Due Process. Accordingly, Plaintiffs request that the Court deny Defendants' Motion to Dismiss.

rights. These Plaintiffs will suffer imminent harm and irreparable injury.” (Compl. ¶ 60.).

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that I electronically filed the foregoing document and that a true and correct copy was served on the parties listed below through the electronic case filing system if the Notice of Electronic Filing indicated that the parties received it or otherwise by mailing a copy by Certified Mail, Return Receipt Requested, to the parties this 2nd day of October, 2007.

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