

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
DALLAS DIVISION

Scooters Unlimited and DME, Inc., §
 Reliable Medical Supply, Inc., §
 Eastern Medical Equipment §
 Distributors, Inc., §
 JI Medical Inc., d/b/a Ramat Medical, §
 Preston Mobility Plus, Inc., §
 Jose M. Salas, Jr., and §
 Charles W. Bell §

Plaintiffs, §

v. §

Michael O. Leavitt, Secretary of the §
 Department of Health and Human §
 Services, in his official capacity, §

Case No. 3:08-cv-0980

and §

Kerry N. Weems, Acting §
 Administrator of the Centers for §
 Medicare and Medicaid Services, §
 in his official capacity, §

Defendants. §

PLAINTIFFS' APPLICATION FOR TEMPORARY
 RESTRAINING ORDER, REQUEST FOR EXPEDITED HEARING,
 AND BRIEF IN SUPPORT THEREOF

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**PLAINTIFFS' APPLICATION FOR TEMPORARY
RESTRAINING ORDER, REQUEST FOR EXPEDITED HEARING,
AND BRIEF IN SUPPORT THEREOF**

TO THE HONORABLE JUDGE OF THE COURT:

COME NOW PLAINTIFFS, Scooters Unlimited and DME, Inc., Reliable Medical Supply, Inc., Eastern Medical Equipment, Distributors, Inc., Preston Mobility Plus, Inc., Jose M. Salas, Jr., and Charles W. Bell, and pursuant to Federal Rule of Civil Procedure 65(b) make this Application for Temporary Restraining Order and in support thereof respectfully show as follows:

I. INTRODUCTION

1. Unless enjoined by this Court, the Defendants will on July 1, 2008, implement Section 302(b)(1) of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (Pub. L. 108-176) ("the MMA") which will prevent Plaintiffs from providing durable medical equipment ("DMEPOS") to Medicare beneficiaries. The loss of Medicare beneficiary business will be devastating to Plaintiffs and will cause irreparable harm to their businesses.

2. The Plaintiffs have filed suit alleging that Defendants' rulemaking and implementation of the MMA was done in violation of the MMA, the Regulatory Flexibility Act ("RFA") and The Administrative Procedures Act ("APA"), as well as in violation of Plaintiffs' Constitutional rights.

3. Plaintiffs Jose Salas, Jr. and Charles Bell are both individual Medicare beneficiaries. Scooters Unlimited and DME, Inc. ("Scooters Unlimited"); Reliable Medical

Supply, Inc. (“Reliable Medical”); Eastern Medical Equipment, Inc. (“Eastern Medical”); and Preston Mobility Plus, Inc. (“Preston Mobility”) are all engaged in providing DMEPOS such as power wheelchairs, oxygen, continuous positive airway pressure (“CPAP”) devices, hospital beds and the like to Medicare beneficiaries. These DMEPOS are critical for the health and care of Medicare beneficiaries, improve their quality of life and often are what allow them to live at home.

4. The Defendants are Michael O. Leavitt, Secretary of the Department of Health and Human Services, in his official capacity and Kerry N. Weems, Acting Administrator of the Centers for Medicare and Medicaid Services, in his official capacity.

II. ARGUMENT

5. The MMA directed Defendants to implement competitive bidding program (“CBP”) for nine categories of DMEPOS. Those items included:

- Oxygen Supplies and Equipment
- Standard Power Wheelchairs, Scooters, and Related Accessories
- Complex Rehabilitative Power Wheelchairs and Related Accessories
- Mail-Order Diabetic Supplies
- Enteral Nutrients, Equipment, and Supplies
- Continuous Positive Airway Pressure (“CPAP”) Devices, Respiratory Assist Devices (“RADs”), and Related Accessories
- Hospital Beds and Related Accessories
- Negative Pressure Wound Therapy (“NPWT”) Pumps and Related Accessories
- Walkers and Related Accessories
- Support Surfaces (Group 2 and 3 mattresses and overlays)

6. The CBP is to be implemented in rounds. Round 1 covered ten competitive bidding areas (“CBAs”) and included: Dallas-Ft. Worth-Arlington, Texas (“Dallas”); Kansas

City, Missouri/Kansas (“Kansas City”); and Miami-Ft. Lauderdale-Miami Beach, Florida (“Miami”).

7. The bidding system implemented by Defendants was flawed, and Defendants failure to provide bidders with accurate reliable answers to questions resulted in over half of the bidding DMEPOS suppliers being “disqualified,” and only twenty-three percent (23%) of the participants were offered contracts. As a result seventy-seven percent (77%) of the current, accredited DMEPOS suppliers will be excluded from serving their existing Medicare beneficiary clients. (Appendix pp 422-426). Defendants did not provide any administrative procedure to assure that the disqualifications were proper.

8. On May 19, 2008 the Centers for Medicare and Medicaid Services (“CMS”) announced the “winners” of Round 1, and awarded exclusive contracts to those winners to provide DMEPOS in the bid categories. As of July 1, 2008, CMS will not reimburse non-contracted suppliers for goods and services provided to Medicare beneficiaries.

A. IRREPARABLE HARM TO PLAINTIFFS

9. Medicare beneficiaries make up a large segment of the DMEPOS consuming market and are critical to the economic viability of suppliers like the Plaintiffs.

a. Scooters Unlimited

- (i) Scooters Unlimited provides DMEPOS to Medicare beneficiaries in the Dallas, Texas area.
- (ii) Scooters Unlimited submitted a bid application to provide DMEPOS to Medicare beneficiaries in the Dallas CBA.

- (iii) Scooters Unlimited submitted all of the required financial data in connection with its bid.
- (iv) CMS determined that certain financial documents were missing from Scooters Unlimited's bid packet and that it was disqualified from contract consideration.
- (v) Approximately 95% of Scooters Unlimited's revenue is earned from servicing Medicare beneficiaries.
- (vi) Scooters Unlimited anticipates a loss of approximately 95% of its revenue if it cannot continue to service Medicare beneficiaries.
- (vii) The loss of Medicare revenue will likely result in the closing of Scooters Unlimited's business.

(Appendix pp 33-93)

b. Preston Mobility

- (i) Preston Mobility provides DMEPOS to Medicare beneficiaries in the Dallas, Texas area.
- (ii) Preston Mobility submitted a bid application to provide DMEPOS to Medicare beneficiaries in the Dallas CBA.
- (iii) Preston Mobility submitted all of the required financial data in connection with its bid.
- (iv) CMS determined that certain financial documents were missing from Preston Mobility's bid packet and that it was disqualified from contract consideration.
- (v) Approximately 65% of Preston Mobility's revenue is earned from servicing Medicare beneficiaries.
- (vi) Preston Mobility anticipates a loss of approximately 65% of its revenue if it cannot continue to service Medicare beneficiaries.
- (vii) The loss of Medicare revenue will likely result in the closing of Preston Mobility's business.

(Appendix pp 308-405)

- c. Reliable Medical
 - (i) Reliable Medical provides DMEPOS to Medicare beneficiaries in the Kansas City, Kansas area.
 - (ii) Reliable Medical submitted a bid application to provide DMEPOS to Medicare beneficiaries in the Kansas City CBA.
 - (iii) Reliable Medical submitted all of the required financial data in connection with its bid.
 - (iv) CMS determined that certain financial documents were missing from Reliable Medical's bid packet and that it was disqualified from contract consideration.
 - (v) Approximately 40% of Reliable Medical's revenue is earned from servicing Medicare beneficiaries.
 - (vi) Reliable Medical anticipates a loss of approximately 40% of its revenue if it cannot continue to service Medicare beneficiaries.
 - (vii) The loss of Medicare revenue will force Reliable Medical to release a significant portion of its staff.

(Appendix pp 94-151)

- d. Eastern Medical
 - (i) Eastern Medical provides DMEPOS to Medicare beneficiaries in the Miami, Florida area.
 - (ii) Eastern Medical submitted a bid application to provide DMEPOS to Medicare beneficiaries in the Miami CBA.
 - (iii) Eastern Medical submitted all of the required financial data in connection with its bid.
 - (iv) CMS determined that certain financial documents were missing from Eastern Medical's bid packet and that it was disqualified from contract consideration.

- (v) Approximately 30% of Eastern Medical's revenue is earned from servicing Medicare beneficiaries.
- (vi) Eastern Medical anticipates a loss of approximately 20% of its revenue if it cannot continue to service Medicare beneficiaries.

(Appendix pp 153-307)

10. Each of the above Plaintiffs will suffer immediate and irreparable harm to their businesses and livelihood unless the Defendants are enjoined from proceeding with the implementation of the CBA.

11. The loss of such substantial portions of Plaintiffs' revenue constitutes an irreparable harm for which there is no adequate remedy at law. Losses of business interests or business opportunities constitute an irreparable injury. *See Lepelleter v. FDIC*, 164 F. 3d 37, 42 (D.C. Cir. 1999) (holding that "the denial of a business opportunity satisfies the injury requirement.")

12. It is a well established rule that a substantial loss of business may amount to irreparable injury if the amount of lost profits is difficult or impossible to calculate; especially where, as alleged by Plaintiffs, the loss of business may be so serious as to result in bankruptcy. *See Doran v. Salem Inn, Inc.*, 422 U.S. 922, 932 (1975). ("substantial loss of business and perhaps even bankruptcy" constitutes an irreparable injury); *Planned Parenthood v. Citizens for Community Action*, 558 F.2d 861, 866-67 (8th Cir. 1977); (incalculable loss of revenue); *New York Pathological and X-Ray Laboratories, Inc. v. Immigration and Naturalization Service*, 523 F.2d 79, 81-82 at n. 5 (2d Cir. 1975) (loss of 15% of business constitutes irreparable harm); and *Flying Cross Check, L.L.C. v. Central Hockey League, Inc.*, 153 F. Supp. 2d 1253, 1259 (D.

Kansas 2001) (“Loss of customers, loss of goodwill, and threats of business’ viability can constitute irreparable harm.”) If customers are likely to stop patronizing a supplier because it can no longer continue to provide goods or services available elsewhere, the impossibility of calculating the value of this loss of goodwill may amount to irreparable injury. *Fla. Businessmen for Free Enterprise v. City of Hollywood*, 648 F.2d 956, 958 (5th Cir. 1981).

13. In *Florida Businessmen* the Fifth Circuit held that plaintiff business owners would face irreparable injury as a result of an ordinance that proscribed the sale of certain items within a particular geographic area. 648 F.2d at 958. The Court reasoned that not only would the business owners lose profits from sales of the prohibited items within the geographic area, but they would also lose profits from sales of other items to competitors in nearby areas who could sell the prohibited items. *Id.* This rationale is clearly applicable to the irreparable injury imminently threatening the Plaintiff suppliers.

14. Just as in *Florida Businessmen*, Plaintiffs here will lose a majority of their revenues as a result of their inability to sell certain items to people in a particular geographic area. According to a May 19, 2008 CMS Press Release, 1,005 suppliers submitted bids within the various product categories for all 10 CBAs. However, CMS only awarded contracts to 325 suppliers. Consequently, the CBP threatens the existence of over 70 percent of the otherwise qualified and accredited suppliers in the DME industry. (Appendix pp 422-426)

B. PLAINTIFFS ARE SUBSTANTIALLY LIKELY TO PREVAIL ON THE MERITS.

15. The substantial likelihood of prevailing on the merits requirement is satisfied when “the movant has raised questions going to the merits so substantial as to make them fair ground for litigation and thus for more deliberate investigation.” *Finlan v. City of Dallas*, 888 F.Supp. 779, 791 (N.D.Tex. 1995). While Plaintiffs are able to show a substantial likelihood of success, the gravity of Defendants’ actions lower the necessary proof on this factor. As the level of persuasion in relation to the other three factors increases, the degree of persuasion necessary on the “substantial likelihood of success” factor may decrease. *See Productos Carnic, S.A. v. Central American Beef and Seafood Trading Company*, 621 F.2d 683, 686 (5th Cir. 1980) (“Where the other factors are strong, a showing of some likelihood of success on the merits will justify temporary injunctive relief.”). In considering a temporary restraining order in a Medicare proceeding, one court has held, “[h]aving established the first three prerequisites for temporary injunctive relief, the plaintiffs need only show that the issues presented are so serious to make them fair ground for litigation.” *Kansas Hospital Assn. v. Whiteman*, 835 F. Supp. 1548, 1553 (D. Ks. 1993).

16. The Defendants’ failures in the rulemaking and implementation of the MMA have been well publicized. (Appendix pp 1-19)

i. The Secretary Failed to Specify Financial Standards as Required by Section 302 of the MMA, in Violation of the APA

17. Through the MMA, Congress explicitly mandated that “[t]he Secretary may not award a contract to any entity” unless “the Secretary finds,” among other things, that “[t]he entity meets applicable financial standards specified by the Secretary, taking into account the needs of small providers.” 42 U.S.C. § 1395w-3(b)(2)(A)(ii). The purpose of determining financial standards was to assist HHS in “assessing the expected quality of suppliers, estimating the total potential capacity of selected suppliers, and ensuring that selected suppliers are able to continue to serve market demand for the duration of their contracts.” 72 Fed. Reg. 17,992, 18,037 (April 2007) (“Final Rule”) Proper financial standards would serve as a means of comparing potential performance among suppliers. The lack of properly promulgated standards simply became a trap resulting in disqualification of large numbers of suppliers.

18. The definition of a “standard” is “a *definite level* or degree of quality that is proper and adequate for a specific purpose,” and something that is “set up and established by authority *as a rule* for the measure of quantity, weight, extent, value or quality.” *Webster’s Third New International Dictionary* 2223 (1993). In business, a “standard” is a written definition, limit, or rule, approved and monitored for compliance by an authoritative agency or professional or recognized body as a minimum acceptable benchmark. *BusinessDictionary.com*. Thus, a “financial standard” is a definitive level of financial degree and/or quality that is used as a benchmark for comparing two entities.

19. The Defendants recognized this definition of financial standards when implementing two other Medicare statutes. Specifically, in 42 U.S.C. § 1396w-26(a)(1)(2)(D), CMS and HHS required unlicensed Medicare Part C providers to demonstrate a net worth of at least \$1.5 million (or \$1 million if other criteria are satisfied), 42 C.F.R. § 422.283(a); an ability to maintain a current ratio of 1:1, *Id.* § 22.375(b)(2), (d)(3); and a \$100,000 deposit for insolvency assurance. *Id.* § 422.388. Similarly, the Defendants established standards for unlicensed Medicare Part D providers, as required by 42 U.S.C. § 1395w-112(d)(1), including: (1) net worth of \$1.5 million, (2) “cash” net worth of \$750,000, and (3) maintenance of a 1:1 current ratio. Under both statutes Defendants provided guidance and transparency regarding the method of provider evaluation in the form of thresholds and numerical ratios.

20. The MMA distinguishes between financial standards and simple financial data. For example, in one section of the MMA the statute provides that the PAOC (which is established to aid the Secretary in its implementation of the CBP) “shall provide advice to the Secretary with respect to...[t]he establishment of financial standards for purposes of subsection (b)(2)(A)(ii),” 42 U.S.C. § 1395w-3(c)(3)(A)(ii). In a separate section, the statute provides that the PAOC shall provide advice on the “establishment of requirements for collection of data for the efficient management of the program,” § 1395w-3(c)(3)(A)(iii).

21. Notwithstanding Defendants’ previous utilization of proper financial standards in the Medicare program or the statutory mandate to specify financial standards before a supplier can be awarded a contract, Defendants failed to specify financial standards in the DMEPOS CBP

Final Rule. Even more troubling is that CMS ignored industry comments in the Final Rule regarding the need for specification of financial standards as well as the opportunity for notice and comment. 72 Fed. Reg. 18,037-8. Instead, CMS referred suppliers to the *financial documentation* requirements necessary for bid submission as specified in the request for bids (RFBs). 42 C.F.R. § 414.414(d) (“Financial standards. Each supplier must submit along with its bid the applicable financial documentation specified in the requests for bids.”). Unlike financial standards, the RFB instructions for Round 1 provided only a list of financial documents to be provided under the heading, “Financial Information.”

22. The financial documentation requirements did not satisfy the MMA’s mandate to establish financial standards because the requirements did not designate benchmark levels or objective standards by which CMS could distinguish between suppliers. Even CMS’s one-page announcement dated May 25, 2007, entitled “CMS Announces Financial Measures for the Medicare DMEPOS Competitive Bidding Program” did not fulfill the Defendants’ obligations under the MMA. The announcement merely listed several financial ratios that the CBIC would ostensibly use “to determine whether the supplier will be able to participate in the program and maintain viability for the duration of the contract period”:

- Current ratio = current assets/current liabilities
- Collection period = (accounts receivable/sales) x 360
- Accounts payable to sales = accounts payable/net sales
- Quick ratio = (cash + accounts receivable)/current liabilities
- Current liabilities to net worth = current liabilities/net worth
- Return on sales = net sales/inventory
- Sales to Inventory
- Working capital = current assets – current liabilities

- Quality of earnings = cash flow from operations/(net income + depreciation)
- Operating cash flow to sales = cash flow from operations/(revenue-adjustment to revenue).

Id. The CMS release is ineffective because it was not promulgated as a regulation with notice and comment. A laundry list of ratios is not equivalent to specifying financial standards to be used in evaluating bidders and thus is in violation of the MMA mandate.

23. Incidentally, in its response to a comment in the Final Rule regarding defining set ratios for financial standards, the HHS declared that it would “use *appropriate* financial ratios to evaluate suppliers. If suppliers do not meet certain ratios, they could be disqualified from the competition.” *Id.* CMS never publicized the “appropriate” ratios or any other method of evaluation it used to assess suppliers. Consequently, all bids were subject to theoretical and clandestine guidelines that were unpublished and could never be questioned. In this way, the bidding process lacked transparency and guidance, leaving suppliers no way of knowing how or why certain aspects of their business affected their chance of being awarded a contract.

24. There can be no doubt that financial standards are subject to notice-and-comment under the MMA. No entity can furnish DME items or services in a CBA without a contract, and an entity’s “eligibility...to furnish...services” depends on meeting the financial standards specified by the Secretary. 42 U.S.C. § 1395w-3(b)(2)(A)(ii). Thus, the Secretary’s failure to specify financial standards as mandated by the MMA is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law. 5 U.S.C. § 706(2)(A). Further, the

Secretary's failure to promulgate financial standards as a regulation with required notice and opportunity for comment is "without observance of procedure required by law." § 706(2)(D).

ii. Defendants' Abandonment of the Statutory Definition of Small Supplier is in Violation of the SB Act, the MMA and the APA

25. Congress, through the MMA, mandated that "[i]n developing procedures relating to the awarding of contracts . . . the Secretary shall take appropriate steps to ensure that small suppliers of items and services have an opportunity to be considered for participation in the program." 42 U.S.C. § 1395-3(d)(6)(D).

26. The SB Act requires federal agencies to either use the SBA standard or adhere to the strict procedural and substantive limitations of 15 U.S.C. § 632(a)(2)(C) prior to departing from the SBA standard. Originally, Defendants correctly proposed to apply the SBA standard for DMEPOS suppliers. "In the May 1, 2006 proposed rule (71 Fed. Reg. 25,682) 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 small supplier." 72 Fed. Reg. 18,056. Clearly Defendants recognized their obligation to apply the SBA's definition of small business. The SBA classified DMEPOS suppliers in the class of home health equipment rental or pharmacies and defined a small business as one with \$6.5 million in annual receipts. Astonishingly, Defendants abandoned the SBA's definition and, without following the mandated rulemaking procedures, unilaterally adopted a final rule defining small business as one with gross revenue of \$3.5 million or less in annual receipts, including Medicare and non-Medicare revenue. 72 Fed. Reg. 18,071.

Defendants' reasoning is fundamentally flawed. "We believe that \$6.5 million is not representative of small suppliers that provide DMEPOS items to Medicare beneficiaries, as it would encompass too many suppliers." 72 Fed. Reg. 18,058. Defendants' decision was made without Congressional authorization in the MMA, without complying with the mandatory procedure of obtaining SBA's approval, and without publishing the revised standard for notice and comment. The affected small DMEPOS suppliers never had the opportunity to address and remedy Defendants' undisclosed concerns or the abrupt deviation of the accepted definition. Defendants' adoption of its own arbitrary size definition is in direct violation of the SB Act and the MMA.

27. Even if Defendants were free to adopt size definitions in disregard of the SBA standards, their decision to adopt a \$3.5 million standard is arbitrary and capricious in violation of the APA. It is also in blatant violation of the notice and comment requirements of the MMA and APA because the redefinition is not a logical outgrowth of the proposed rule adopting the SBA definition.

iii. All Federal Agencies Must Apply SBA's Published Standards or Lawfully Obtain Approval to Apply a Different Standard

28. Congress has established a national policy "to implement and coordinate *all* Federal department, agency, and instrumentality policies, programs, and activities in order to foster the economic interests of small businesses" and afford them an opportunity to compete. 15 U.S.C. § 631a(a). The SBA's size standards are used for government contracting and aid

programs administered by the SBA, *see* 13 C.F.R. pt. 121, and indeed extend to all other federal programs where a business's "small" status is relevant, *see Id.* §§ 121.901-121.904.

29. Congress has recognized that an agency's program might occasionally present a compelling need to modify SBA's generally-applicable size standard for the relevant industry. When an agency wants to use a non-SBA definition, Congress has mandated that the agency base its alternative standard on specified statutory factors, propose that standard for notice-and-comment, and then request the SBA Administrator's approval of the alternative standard. 15 U.S.C. § 632(a)(2)(C)(i); *accord* 13 C.F.R. § 121.903. An agency may only depart from these procedural and substantive restrictions if it is "specifically authorized" by statute to define the size of small business concerns. 15 U.S.C. § 632(a)(2)(C). Congress specifically sought to limit the common practices of agencies to promulgate their own small business size standards after merely consulting with the SBA Chief Counsel for Advocacy. Congress instead "require[d] *any* agency size standard to be approved by the SBA Administrator . . . and to *comply with SBA policies* regarding the establishment of size standards." 138 Cong. Rec. S11,770,S11,7775.

30. The MMA did not authorize Defendants to avoid compliance with the SB Act's rules governing size standards, nor does the MMA grant the Secretary specific independent authority to define size standards for determining which entities would receive "small supplier" protection. "An agency rule is arbitrary and capricious if the agency has relied on factors Congress has not intended it to consider . . . offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a

different view or product of the agency expertise.” *Texas Oil & Gas Assn. v. E.R.A.*, 161 F3d 923, 933 (5th Cir. 1998). In this instance, Defendants simply ignored Congress’s intent.

31. The SBA also recognizes that its size standards govern all agency definitions where an entity’s “small” status is significant, even if the agency does not explicitly state that it is defining small *businesses*. In *Implementation of Sections of the Cable Television Consumer Prot. & Competition Act of 1992: Rate Regulation*, 9 F.C.C.R. 5327 (1994), the SBA affirmatively (and successfully) argued that the Federal Communications Commission must use notice-and-comment rulemaking to adopt a non-SBA definition of “small [cable] operator.” Congress specifically instructed Defendants to protect small businesses’ right to participate in the CBP. Congress did not authorize a departure from the SB Act in the MMA, and thus Defendants were not free to re-define “small supplier” without adhering to the procedural and substantive safeguards of the SB Act.

32. In passing the MMA, Congress intended that the Secretary comply with the requirements of the SB Act. While CMS feigned compliance by sending a letter to the SBA with a proposed alternative definition, (Appendix pp. 406-421) that action does not exonerate CMS from the notice-and-comment requirements of the SB Act. “In the absence of the application of some exemption, notice-and-comment rulemaking under Section 4 of the APA, 5 U.S.C. § 553 necessarily requires interested parties be given a fair chance to comment.” *Global Van Lines, Inc. v. ICC*, 714 Fed. 1290, 1298 (5th Cir. 1983). (Internal quotes omitted)

33. Defendants failed to provide the required comment opportunity.

iv. Even If the Defendants Were Free to Re-define Small Supplier Without Regard to the Rules of the SB Act, Their Definition is Arbitrary and Capricious

34. Even if the Defendants were free to re-define the size standard for small suppliers without regard to the rules of the SB Act, their choice of a \$3.5 million-or-less-in-total-annual-revenues standard is arbitrary and capricious in violation of the APA. *See* 5 U.S.C. § 706(2)(A). Small business suppliers were denied reasoned analysis in the Final Rule as to why they were excluded. The Defendants’ sole “explanation” for why they decided to define “small supplier” differently from “small business” under the SBA was that the SBA’s definition of “small business” “would encompass too many suppliers”¹ given that most DMEPOS suppliers are small businesses under the SBA. 72 Fed. Reg. at 18,058. The Defendants’ failure to “articulate [a] rational connection between [their] factual judgment and [their] ultimate policy choice,” created an arbitrary and capricious rule. *Crowley’s Yacht Yard, Inc. v. Pena*, 863 F. Supp. 18, 21 (D.D.C. 1994) (internal quotation marks omitted).

35. More importantly, the Final Rule does not explain why it is appropriate to deny a small supplier falling in the \$3.5 to \$6.5 million range the protections intended by Congress. [E]ven under the “arbitrary, capricious” standard, agency action will not be upheld where inadequacy of explanation frustrates review.” *Nat’l Nutritional Foods Ass’n v. Weinberger*, 512 F.2d 688, 701 (2d Cir. 1975). “The grounds upon which the agency acted must be clearly disclosed in the record.” (internal citations omitted) The agency must make plain its course of inquiry, its analysis and its reasoning. However, if the agency failed to

¹ Emphasis added.

provide a reasoned explanation for its action or if limitations in the administrative record makes it impossible to conclude the action was the product of reasoned decision making, the reviewing court should ordinarily remand the case to the agency for further explanation.” *Aztec General Agency v. FDIC*, 111 F.3d 898, 894 (5th Cir. 1997). (Internal citations omitted). Defendants’ lack of reasoned analysis produced a rule that is thus arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law. *See* 5 U.S.C. § 706(2)(A).

v. The Defendants’ Failures to Publish and the Proposed Size Standard Also Violated the Notice-and-Comment Provisions of the MMA and APA

36. Section 902 of the MMA, which is modeled after the notice-and-comment provision of the APA, 5 U.S.C. § 553, requires that when HHS publishes a final rule that includes a provision that is not a “logical outgrowth” of the proposed rule, it must treat that provision as a proposed rule subject to public comment and publication before being adopted as a final rule:

If the Secretary publishes a final regulation that includes a provision that is not a logical outgrowth of a previously published notice of proposed rulemaking or interim final rule, such provision shall be treated as a proposed regulation and shall not take effect until there is the further opportunity for public comment and a publication of the provision again as a final regulation.

42 U.S.C. § 1394hh(a)(4). Even if notice-and-comment were not independently required by the SB Act, the Defendants’ abandonment of the SBA’s definition of a small supplier and adoption of a definition allowing no more than \$3.5 million in total annual revenues to qualify as a small supplier was *not* a logical outgrowth of the Proposed Rule. The

Defendants' re-definition of the size standard was subject to notice-and-comment rulemaking pursuant to the MMA and APA before being adopted in final form.

C. BALANCE OF HARM FAVORS GRANTING A TEMPORARY RESTRAINING ORDER

37. By granting Plaintiffs' request for a temporary restraining order, the court will not impose any undue hardship on Defendants. As the Southern District of California recently held regarding the CBP, "[t]he Secretary [Defendant Leavitt] cannot identify hardships that even remotely rival those identified by Plaintiffs. *Sharp Healthcare v. Leavitt*, No. 08-CV-0170, 2008 WL 962628, at *6 (S.D. Cal. Apr. 8, 2008)." The court in *Sharp* explained that "[g]iven that roughly five years have passed since Congress authorized the [competitive bidding] project, it is doubtful that a short delay will have a significant impact in the ultimate long term goal of reducing Medicare costs." *Id.* The effect of the temporary restraining order is to continue the status quo. In other words, the Defendants, the Plaintiffs' DMEPOS industry and Medicare would continue to do business the way they have for many years.

38. Further, Defendants have the ability to minimize any perceived harm by adjusting the fee schedule for DMEPOS in the affected CBAs. Medicare currently pays for DMEPOS pursuant to a fee schedule. *See* 42 U.S.C. § 1395m(a). If the requested temporary restraining order is granted, Defendants may simply incorporate the single payment amounts determined in the CBP into the existing fee schedules for the affected CBAs, thus assuring the anticipated cost savings.

D. THE REQUESTED TEMPORARY RESTRAINING ORDER WILL PROMOTE THE PUBLIC INTEREST

39. An analysis of public interest favors granting Plaintiffs' request for a temporary restraining order. Delaying the implementation of a program that has been instituted in violation of statutory requirements advances the long-term success of the CBP, the interests of Medicare beneficiaries, the interests of DMEPOS suppliers, and promotes the public interest to require government agencies to comply with federal law. Granting the temporary restraining order would assure the public that the changes to the Medicare program were done properly and received due consideration.

40. At least two courts have found the granting of a temporary restraining order in a Medicare/Medicaid reimbursement case to be in the public interest, notwithstanding the defendants' position that budgetary savings were in the public interest. "If the proposed copay increase is unlawful as the plaintiffs contend, then the effect of a temporary restraining order would be to enforce the federal law and regulations governing the Medicaid program would clearly be in the public interest. While achieving budgetary savings is also a public interest of state and federal taxpayers, that interest must give way if it is in conflict with federal substantive law. *Kansas Hospital Assn. v. Whiteman* 835 F. Supp. at 1553 (citing *AMISUB (PSL), Inc. v. State of Colo. Dept. of Social Services*, 879 F.2d 789, 800-01 (10th Cir. 1989).

E. TEMPORARY RESTRAINING ORDER BOND

41. Plaintiffs are willing to post a bond in the amount the Court deems appropriate. However, due to the important public interest involved, Plaintiffs request that the court find no bond be required.

III. CONCLUSION

42. The granting of the requested temporary restraining order is proper because of the important public interest in assuring that the implementation of the MMA was done properly before sweeping changes are made in the Medicare program. The balance of harm is decidedly in favor of the Plaintiffs who are at risk of the loss of their businesses versus a minimal impact, if any, on Defendants. Plaintiffs have sustained the burden of showing imminent, irreparable harm if the temporary restraining order is not granted. Finally, Plaintiffs have established the substantial merits of their claims compelling the court's deliberate investigation of Defendants' conduct and Plaintiffs' substantial likelihood of success on the merits.

43. Plaintiffs respectfully request an expedited hearing on their Application for a Temporary Injunction no later than July 1, 2008.

44. Accordingly, Plaintiffs request the court grant their request for a temporary restraining order restraining the Defendants from implementing the MMA on July 1, 2008 as announced.

Respectfully submitted,
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By: /s/ Matthew H. Hand
Matthew H. Hand

ATTORNEYS FOR PLAINTIFFS

CERTIFICATE OF CONFERENCE

The undersigned has conferred with Scott Risner, Esq., United States Department of Justice, concerning the foregoing Application for Temporary Restraining Order, and copies have been served on him via e-mail as requested.

 /s/ Matthew H. Hand
Matthew H. Hand

CERTIFICATE OF SERVICE

This is to certify that on the 20th day of June, 2008, a true and correct copy of the foregoing document was served upon Defendants by ECF as follows:

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