

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

AMERICAN ASSOCIATION FOR	:		
HEMECARE <i>et al.</i> ,	:		
	:		
Plaintiffs,	:	Civil Action No.:	08-0992 (RMU)
	:		
v.	:	Document No.:	5
	:		
MICHAEL LEAVITT, in his official	:		
capacity as Secretary of the Department of	:		
Health and Human Services <i>et al.</i> ,	:		
	:		
Defendants.	:		

MEMORANDUM OPINION

DENYING THE PLAINTIFFS' MOTION FOR A PRELIMINARY INJUNCTION

I. INTRODUCTION

The court today considers, for the second time in as many weeks¹, whether to stay a Medicare competitive bidding program for medical supplies scheduled to commence on July 1, 2008. The plaintiffs, American Association for Homecare (an advocacy and counseling organization representing U.S. healthcare businesses supplying medical items and services to Medicare beneficiaries) and Ace Drug (one such member business), accuse the defendants, Michael Leavitt (Secretary of the United States Department of Health and Humans Services (“HHS”)) and Kerry Weems (Acting Administrator of HHS’s Centers for Medicare and Medicaid Services (“CMS”)) of failing to promulgate specific financial standards as provided for in the Medicare Prescription Drug Improvement and Modernization Act of 2003 (“MMA”), 42 U.S.C.

¹ On June 19, 2008, the court granted a motion to dismiss in the case of *Carolina Medical Sales, Inc. v. Leavitt*, mootng a pending preliminary injunction likewise seeking to delay the start date of the Medicare competitive bidding program. 2008 WL 2446319, at *1 (Jun. 19, 2008 D.D.C.).

§ 1395w-3(b)(2)(A)(ii), as well as failing to define (in a procedurally lawful manner) what type of business constitutes a “small supplier” of Medicare items and services, in violation of the MMA, the Administrative Procedure Act (“APA”), 5 U.S.C. § 706, and the Small Business Act, 15 U.S.C. § § 631 *et seq.* They seek a preliminary injunction to halt the initiation of the program which will exclude the plaintiffs from providing Medicare items and services to beneficiaries and receiving reimbursements absent an existing contract with CMS won through the competitive bidding process and until the next round of bidding. Because the court concludes that the plaintiffs are unable to demonstrate an irreparable injury, it denies the request for the extraordinary remedy of a preliminary injunction.

II. FACTUAL & PROCEDURAL BACKGROUND

Title XVIII of the Social Security Act, commonly known as Medicare, 42 U.S.C. §§ 1395 *et seq.*, establishes a national program of health insurance for the elderly and disabled. In 2003, Congress amended Medicare Part B (the supplementary medical insurance program covering healthcare services such as physical visits; outpatient diagnostic tests; and durable medical equipment, prosthetics, orthotics and supplies (“DMEPOS”)) to require the HHS Secretary to replace the current fee-schedule pricing system with a competitive bidding program by which businesses would compete for contracts to supply DMEPOS items and services to Medicare beneficiaries. 42 U.S.C. § 1395w-3. In addition to cost-saving, Congress articulated its concerns for ensuring the financial integrity of bidders and the continued participation of small suppliers. Thus, it mandated that, as a prerequisite to awarding a contract, the Secretary must find that “[t]he entity meets applicable financial standards specified by the Secretary, taking into account the needs of small providers.” *Id.* § 1395w-3(b)(2)(A)(ii). Congress further ordered the

Secretary to “take appropriate steps to ensure that small suppliers of items and services have an opportunity to be considered for participation in the program.” *Id.* § 1395w-3(b)(6)(D).

On May 1, 2006, CMS solicited comments for a proposed rule published in the Federal Register to implement a bidding program for certain DMEPOS items. 71 Fed. Reg. 25654. On April 10, 2007, CMS issued a final rule establishing bidding programs in ten metropolitan areas. 72 Fed. Reg. 17992. To participate in the bidding program, mail-order diabetes suppliers must meet certain accreditation and quality standards and submit a competitively priced bid to furnish an item or service. 42 C.F.R. § 414.412(a). After contracts are awarded to winning suppliers, Medicare beneficiaries can only obtain supplies from an entity that has entered into a contract with HHS. 42 U.S.C. § 1395w-3(b)(6)(A)(i)-(ii).

The plaintiffs’ complaint contests two parts of the final rule. First, the plaintiffs take issue with the Secretary’s failure to identify and disclose specific financial standards for assessing the eligibility of suppliers to submit bids and be awarded contracts. Compl. ¶¶ 63-78 (Count 1). Although the defendants received industry comments recommending advance specification of financial standards, the final rule provides only that each supplier must submit along with its bid certain financial documentation. 42 C.F.R. § 414.414(d); 72 Fed. Reg. 17992-01 at 18,088.

Second, the plaintiffs object to the manner in which the Secretary defined what type of businesses qualify as small suppliers. Compl. ¶¶ 79-96 (Count 2). In its proposed rule, CMS proposed using the Small Business Administration’s (“SBA”) definition of “small business” to evaluate whether a DMEPOS supplier qualifies as a “small supplier.” 72 Fed. Reg. at 18,056; 71 Fed. Reg. at 25,695. To be considered “small,” the SBA standard requires business engaged in renting home health equipment to earn no more than \$6.5 million in total annual receipts. 13

C.F.R. § 121.201 (NAICS code 532291); 72 Fed. Reg. at 18,056. CMS's final rule, however, classified a small supplier as an entity receiving less than \$3.5 million in annual receipts. 72 Fed. Reg. at 18,071. CMS also included, for the first time, in the final rule a provision allocating 30 % of contracts to small suppliers. *Id.* at 18,058. Neither of these changes were subjected to notice and comment.

On May 15, 2007, CMS issued a request for bids for the first round of the bidding program. *Pls.' Mot.*, Ex. 16. On May 25, 2007, CMS released a series of financial ratios that it would apply to the financial documents submitted with bids, but those ratios did not include specific figures or values. *Id.*, Ex. 18. The bidding window closed on September 25, 2007. *Id.*, Ex. 16. In May 2008, the government announced the winning bidders for each product category in the bidding program. *Id.*, Ex. 20. On July 1, 2008, sales under the program will commence, at which time the plaintiffs will be excluded from DMEPOS items and services to Medicare beneficiaries for which they have not been awarded a contract from CMS until the next round of bidding. 42 U.S.C. § 1395w-3(b)(3)(B).

On June 9, 2008, the plaintiffs simultaneously filed their complaint and motion for a preliminary injunction to enjoin the implementation of the bidding program on July 1, 2008. The defendants filed their opposition on June 25, 2008, and the court permitted the plaintiffs to file a reply no later than June 26, 2008. With briefing hot off the printers, the court now turns to the plaintiffs' motion.

III. ANALYSIS

A. Legal Standard for Injunctive Relief

This court may issue interim injunctive relief only when the movant demonstrates:

(1) a substantial likelihood of success on the merits, (2) that it would suffer irreparable injury if the injunction is not granted, (3) that an injunction would not substantially injure other interested parties, and (4) that the public interest would be furthered by the injunction.

Mova Pharm. Corp. v. Shalala, 140 F.3d 1060, 1066 (D.C. Cir. 1998) (quoting *CityFed Fin. Corp. v. Office of Thrift Supervision*, 58 F.3d 738, 746 (D.C. Cir. 1995)); see also *World Duty Free Americas, Inc. v. Summers*, 94 F. Supp. 2d 61, 64 (D.D.C. 2000). It is particularly important for the movant to demonstrate a substantial likelihood of success on the merits. Cf. *Benten v. Kessler*, 505 U.S. 1084, 1085 (1992) (per curiam). Indeed, absent a “substantial indication” of likely success on the merits, “there would be no justification for the court’s intrusion into the ordinary processes of administration and judicial review.” *Am. Bankers Ass’n v. Nat’l Credit Union Admin.*, 38 F. Supp. 2d 114, 140 (D.D.C. 1999) (internal quotation omitted).

The four factors should be balanced on a sliding scale, and a party can compensate for a lesser showing on one factor by making a very strong showing on another factor. *CSX Transp., Inc. v. Williams*, 406 F.3d 667 (D.C. Cir. 2005) (citing *CityFed Fin. Corp.*, 58 F.3d at 747). “An injunction may be justified, for example, where there is a particularly strong likelihood of success on the merits even if there is a relatively slight showing of irreparable injury.” *CityFed Fin. Corp.*, 58 F.3d at 747.

Moreover, the other salient factor in the injunctive relief analysis is irreparable injury. A movant must “demonstrate at least ‘some injury’” to warrant the granting of an injunction. *Id.* at 747 (quoting *Population Inst. v. McPherson*, 797 F.2d 1062, 1078 (D.C. Cir. 1986)). Indeed, if a party makes no showing of irreparable injury, the court may deny the motion for injunctive relief without considering the other factors. *Id.*

Because interim injunctive relief is an extraordinary form of judicial relief, courts should grant such relief sparingly. *Mazurek v. Armstrong*, 520 U.S. 968, 972 (1997). As the Supreme Court has said, “[i]t frequently is observed that a preliminary injunction is an extraordinary and drastic remedy, one that should not be granted unless the movant, *by a clear showing*, carries the burden of persuasion.” *Id.* Therefore, although the trial court has the discretion to issue or deny a preliminary injunction, it is not a form of relief granted lightly. In addition, any injunction that the court issues must be carefully circumscribed and “tailored to remedy the harm shown.” *Nat’l Treasury Employees Union v. Yeutter*, 918 F.2d 968, 977 (D.C. Cir. 1990).

B. The Court Denies the Plaintiffs’ Motion for a Preliminary Injunction Because the Plaintiffs Do Not Demonstrate Irreparable Injury

The plaintiffs submit two different injuries. First, they assert a procedural injury due to the defendants’ allegedly unlawful implementation of the bidding program. Pls.’ Mot. at 36. Second, they declare that they have suffered economic injury through exclusion from the bidding program. *Id.* at 18. Tyler Wilson, President of plaintiff American Association for Homecare, avers generally and vaguely that his organization’s members will suffer “significant loss of clientele and revenue due to their inability to provide DMEPOS to Medicare beneficiaries.” *Id.* at 37, Ex. 1 ¶ 8. Robert Lichtenstein, President of plaintiff Ace Drug, estimates his business’s annual revenue loss for the first three years of Round 1 as \$75,000, *id.*, Ex. 27 ¶ 13.² Both plaintiffs anticipate sustaining possibly greater losses should the bidding program result in

² The court finds the plaintiffs’ representation of a “total cumulative loss . . . [of] at least \$225,000” a touch disingenuous. Pls.’ Mot. at 37, Ex. 27 ¶ 13. That loss is a multiple of the plaintiff Ace’s estimated annual losses for the next three years. This case will surely be resolved on the merits in less than three years. The court will likely dispatch it in less than one. Moreover, a motion for a preliminary injunction must allege actual, imminent injury. The court, therefore, disregards the figure of \$225,000 and assesses the irreparable injury factor based on the plaintiff’s estimate for the upcoming year only.

reduced Medicare reimbursement rates and the termination of referrals to non-contract suppliers, *id.*, Ex. 1 ¶¶ 9,10; Ex. 27 ¶¶ 14-15. Furthermore, the plaintiffs argue that in Round 2, when the small-supplier quota becomes effective, member businesses such as Ace with annual revenues between \$3.5 million and \$6.5 million – disqualifying them from small supplier status – will lose market share and business opportunities to small suppliers. *Id.* at 38-39. The defendants respond that economic injury alone, unless devastating, rarely suffices to demonstrate irreparable injury. Defs.’ Opp’n at 17. The plaintiffs reply that because their anticipated losses are not compensable by the future prospect of winning monetary damages, they need not establish financial ruin. Pls.’ Reply at 1.

That reasoning might carry the plaintiffs to victory in other jurisdictions, but this Circuit requires a movant seeking the extraordinary equitable relief of a preliminary injunction to show an injury that is certain, great, actual and imminent. *Wisconsin Gas Co. v. F.E.R.C.*, 758 F.2d 669, 674 (D.C. Cir. 1985). While this court has conceded that “there is some appeal to the proposition that any damage, however slight, which cannot be made whole at a later time, should justify injunctive relief,” nevertheless, “some concept of magnitude of injury is implicit in the [standard for issuing a preliminary injunction].” *Gulf Oil Corp. v. Dep’t of Energy*, 514 F. Supp. 1019, 1026 (D.D.C. 1981). Accordingly, a plaintiff seeking preliminary injunctive relief must show that it will suffer harm that is “more than simply irretrievable.” *Id.* at 1026. Harm

that is “merely economic” in character is not sufficiently grave under this standard.³ *See, e.g., Apotex, Inc. v. FDA*, 2006 WL 1030151, at *16-17 (D.D.C. Apr. 19, 2006) (refusing to recognize loss in market sales of \$9 million over 1 year out of total annual revenues of \$700 million as irreparable injury); *Sandoz, Inc. v. FDA*, 439 F. Supp. 2d 26, 32 (D.D.C. 2006) (refusing to recognize loss in market sales of \$11 million over the next six months as irreparable injury); *Bristol-Myers Squibb Co. v. Shalala*, 923 F. Supp. 212, 215 (D.D.C. 1996) (refusing to recognize loss of 0.7 percent of sales as irreparable injury). Only monetary losses that “cause extreme hardship to the business, or even threaten destruction of the business” will suffice. *Gulf Oil*, 514 F. Supp. at 1025; *Sandoz*, 439 F. Supp. 2d at 26.

Plaintiff Homecare offers no figures for any estimated loss, and the court will not rely on pure speculation – much less speculation that is vague and general – to grant a stay. *Wisconsin Gas Co.*, 758 F.2d at 674. Plaintiff Ace estimates its loss this upcoming year at \$75,000. Pls.’ Mot., Ex. 27 ¶ 13. This is something less than catastrophic or even crippling considering that Ace earned \$3.7 million in revenue last year. Pls.’ Mot., Ex. 27 ¶ 5. The plaintiffs also both anticipate further losses based on lost referrals and competitive price reductions, but they have submitted no evidence as to the magnitude or likelihood of those speculative losses, which, therefore, the court simply will not consider. *Wisconsin Gas Co.*, 758 F.2d at 674; *see*

³ The plaintiff cites one case in this jurisdiction to support the proposition that unrecoverable financial losses of any magnitude will constitute an irreparable injury – *Hoffman-Laroche, Inc. v. Califano*, 453 F. Supp. 900, 903 (D.D.C. 1978). Pls. Reply at 1-3. This case, however, has not been widely followed. *See infra* at 7-8; *but see Bracco Diagnostics, Inc. v. Shalala*, 963 F. Supp. 20, 29 (D.D.C. 1997) (J. Friedman). And while the plaintiffs argue that *Sandoz* and *Mylan Laboratories* are “inconsistent with higher precedent,” Pls.’ Reply at 2 n.1, they fail to identify any such precedent on point, citing only a D.C. Circuit case involving standing not irreparable injury, *Lepelletier v. FDIC*, 164 F.3d 37, 42 (D.C. Cir. 1999), and a Supreme Court case recognizing irreparable injury for a movant facing “substantial loss of business and perhaps even bankruptcy,” *Doran v. Salem Inn, Inc.*, 422 US. 922, 932 (1975).

Chaplaincy of Full Gospel Churches v. England, 454 F.3d 290, 298 (D.C. Cir. 2006) (refusing to recognize irreparable injury based on speculation that Navy's illegal conduct would perpetuate certain chaplains in their positions to the potential detriment of plaintiff chaplains seeking promotion).

The plaintiffs' claim of procedural injury summarily fails. For the purposes of a preliminary injunction, courts will not base a finding of "irreparable injury" on a procedural violation standing alone. *See Amoco Prod. Co. v. Vill. of Gambell*, 480 U.S. 531, 545 (1987) (holding that there could be no presumption of irreparable harm based on a statutory violation); *Fund For Animals v. Norton*, 281 F. Supp. 2d 209, 222 (D.D.C. 2003) (recognizing that a procedural violation "standing alone" is insufficient to constitute irreparable harm); *Fund For Animals v. Clark*, 27 F. Supp. 2d 8, 14 (D.D.C. 1998) (recognizing that irreparable injury cannot stand on procedural violation alone without showing another actual injury "not compensable in money damages"). Moreover, as the defendants aptly observe, any putative procedural violation has (1) already occurred and (2) will be remedied by a decision on the merits. Defs.' Opp'n at 18. The plaintiffs cannot bootstrap themselves into irreparable injury on the basis of a procedural violation.

The court leaves the analysis here, as it may after concluding that the movant has failed to demonstrate any irreparable injury. *CityFed Fin. Corp.*, 58 F.3d at 747. Turning to the merits of the case would be premature, as a motion to dismiss or any other dispositive motions have yet to be filed. Moreover, as recently as June 27, 2008 the defendants filed a supplemental notice of two recent cases that issued yesterday on this very topic. Defs.' Notice of Supp. Authority (Jun. 27, 2008). Congruent with the court's denial of the plaintiffs' motion and the expected commencement of the program on July 1, no impending deadline renders the matter so exigent as

to discourage further briefing on the merits.

IV. CONCLUSION

For the foregoing reasons, the court denies the plaintiffs' motion for a preliminary injunction. An order consistent with this Memorandum Opinion is separately and contemporaneously issued this 30th day of June, 2008.

RICARDO M. URBINA
United States District Judge