

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

AFFINITY HEALTHCARE SERVICES,	:	
INC. d/b/a AFFINITY HOME HOSPICE	:	
SERVICES <i>et al.</i> ,	:	
	:	
Plaintiffs,	:	Civil Action No.: 10-0946 (RMU)
	:	
v.	:	Re Document No.: 8
	:	
KATHLEEN SEBELIUS,	:	
in her official capacity as Secretary of the	:	
U.S. Department of Health and	:	
Human Services,	:	
	:	
Defendant.	:	

MEMORANDUM OPINION

DENYING THE PLAINTIFFS' MOTION FOR A TEMPORARY RESTRAINING ORDER

I. INTRODUCTION

The plaintiffs are a group of fifteen hospice care providers participating in Medicare, a federal program administered by the Department of Health and Human Services ("HHS"). They commenced this action pursuant to the Administrative Procedure Act ("APA"), 5 U.S.C. §§ 553 *et seq.*, challenging HHS's demands for repayment of funds distributed to the plaintiffs purportedly in excess of the lawful cap on such distributions. The plaintiffs contend that the regulation pursuant to which HHS calculated the repayment amounts conflicts with the governing statute and must be set aside. The matter is now before the court on the plaintiffs' motion for a temporary restraining order seeking to enjoin HHS from collecting on the subject repayment demands or relying on the challenged regulation to demand further repayment from

the plaintiffs. Upon consideration of the parties' submissions, the court denies the plaintiffs' motion.

II. BACKGROUND

A. The Statutory and Regulatory Framework

Medicare provides health insurance to the elderly and disabled by entitling eligible beneficiaries to have payment made on their behalf for the care and services rendered by health care providers. *See* 42 U.S.C. §§ 1395 *et seq.* Among other services, the program covers hospice care for individuals who are “terminally ill,”¹ reimbursing hospices for services such as nursing care, physical or occupational therapy, home health aide services, medical supplies and counseling. *Id.* § 1395x(dd)(1). An individual remains entitled to hospice care benefits so long as he or she is certified as being “terminally ill.”² *See id.* § 1395d(d)(1) (establishing that reimbursement for hospice care may be provided “during two period of 90 days each and an unlimited number of subsequent period of 60 days each during the individual’s lifetime”).

The Medicare statute, however, places a cap on the total amount that Medicare may distribute to a hospice provider in a single fiscal year (November 1 through October 31). *See id.* § 1395f(i)(2)(A). Payments made to a hospice care provider in excess of the statutory cap are considered overpayments that must be refunded by the hospice care provider. *Id.*

¹ An individual is “terminally ill” if he or she has “a medical prognosis that the individual’s life expectancy is 6 months or less.” 42 U.S.C. § 1395x(dd)(3).

² An individual’s initial election of hospice care must be accompanied by a certification from the individual’s attending physician and the medical director of the hospice program that the individual is “terminally ill” as defined by the statute. *Id.* § 1395f(a)(7)(A)(i). At the expiration of this initial election period, the attending physician or medical director may recertify the individual’s eligibility for hospice care benefits for additional sixty or ninety day periods. *Id.* § 1395f(a)(7)(A)(ii).

More specifically, the statute provides that the total yearly payment to a hospice provider may not exceed the product of the annual “cap amount”³ and the “the number of [M]edicare beneficiaries in the hospice program in that year.” *Id.* For purposes of this calculation,

the “number of [M]edicare beneficiaries” in a hospice program in an accounting year is equal to the number of individuals who have made an election under subsection (d) of this section with respect to the hospice program and have been provided hospice care by (or under arrangements made by) the hospice program under this part in the accounting year, *such number reduced to reflect the proportion of hospice care that each such individual was provided in a previous or subsequent accounting year* or under a plan of care established by another hospice program.

Id. § 1395f(i)(2)(C) (emphasis added). Thus, the Medicare statute directs HHS to account for the fact that an individual may receive care in more than one fiscal year by requiring HHS to count that individual as a beneficiary in each year in which he or she receives hospice care benefits, with that number proportionally reduced to reflect care provided in previous or subsequent years.

Id.

To implement these statutory cap provisions, HHS promulgated a reimbursement regulation governing the calculation of the statutory cap amount. *See* 42 C.F.R. § 418.309. In pertinent part, the regulation provides that the “number of beneficiaries” portion of the statutory cap calculation includes

[t]hose Medicare beneficiaries who have not previously been included in the calculation of any hospice cap and who have filed an election to receive hospice care . . . from the hospice during the period beginning on September 28 (35 days before the beginning of the cap period) and ending on September 27 (35 days before the end of the cap period).

³ The statute defines the “cap amount” for a year as “\$6,500, increased or decreased . . . by the same percentage as the percentage increase or decrease, respectively, in the medical care expenditure category of the Consumer Price Index.” *Id.* § 1395f(i)(2)(B). According to the plaintiffs, the “cap amount” was \$20,585.39 for fiscal year 2006 and \$21,410.04 for fiscal year 2007. Pls.’ Mot. at 11.

Id. § 418.309(b) (emphasis added). The regulation does not provide for the proportional allocation of beneficiaries across years of service. *See id.*

B. The Plaintiffs' Claims

The plaintiffs are fifteen Medicare-certified hospice care providers to whom HHS issued cap repayment demands for fiscal years 2006 and 2007. *See generally* Compl. They challenge these repayment demands on the grounds that 42 C.F.R. § 418.309, the regulation pursuant to which the demands were calculated, conflicts with 42 U.S.C. § 1395f(i)(2), the statutory provision the regulation purports to implement. *See generally id.* The plaintiffs assert that whereas the Medicare statute requires HHS to allocate the cap amount across years of service by proportionally adjusting the “number of beneficiaries” in any given year to reflect hospice services provided to an individual in previous and subsequent years, the reimbursement regulation provides that an individual is counted as a beneficiary only in a single year, depending on when he or she first elects hospice benefits. *See id.* ¶¶ 49-53. The plaintiffs allege that as a result, “unused cap amounts in one fiscal year are ‘trapped’ in the prior year, regardless of whether the beneficiary continues to receive care in subsequent years. The failure to allocate the cap across years of care results in [] understated aggregate hospice cap allowances and, in turn, overstated repayment demands.” *Id.* ¶ 51.

On May 25, 2010, HHS’s Provider Review Reimbursement Board (“PRRB”) granted the plaintiffs’ request for expedited judicial review of their group challenge to the validity of 42 C.F.R. § 418.309. *Id.* ¶ 11. The plaintiffs subsequently filed a complaint in this court on June 8, 2010. *See generally* Compl. On June 21, 2010, the plaintiffs filed this motion for a temporary restraining order. *See generally* Pls.’ Mot. The plaintiffs seek an order enjoining HHS from continuing to collect from the plaintiffs on its hospice cap repayment demands for fiscal years

2006 and 2007 and from otherwise relying the challenged regulation in connection with the plaintiffs. *See generally id.* Upon receipt of the plaintiffs’ motion, the court set an expedited briefing schedule. *See* Minute Order (June 22, 2010). With this motion now ripe for adjudication, the court turns to the applicable legal standards and the parties’ arguments.

III. ANALYSIS

A. Legal Standard for Awarding Interim Injunctive Relief

This court may issue interim injunctive relief only when the movant demonstrates “[1] that he is likely to succeed on the merits, [2] that he is likely to suffer irreparable harm in the absence of preliminary relief, [3] that the balance of equities tips in his favor, and [4] that an injunction is in the public interest.”⁴ *Winter v. Natural Res. Def. Council, Inc.*, 129 S. Ct. 365, 374 (2008) (citing *Munaf v. Geren*, 128 S. Ct. 2207, 2218-19 (2008)). It is particularly important for the movant to demonstrate a 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 other critical factor in the injunctive relief analysis is irreparable injury. A movant must “demonstrate that irreparable injury is *likely* in the absence of an injunction.” *Winter*, 129 S. Ct. at 375 (citing *Los Angeles v. Lyons*, 461 U.S. 95, 103 (1983)). Indeed, if a party fails to make a sufficient showing of irreparable injury, the court may deny the motion for injunctive

⁴ The APA authorizes reviewing courts to stay agency action pending judicial review. 5 U.S.C. § 705. Motions to stay agency action pursuant to these provisions are reviewed under the same standards used to evaluate requests for interim injunctive relief. *See Cuomo v. U.S. Nuclear Regulatory Comm’n*, 772 F.2d 972, 974 (D.C. Cir. 1985).

relief without considering the other factors. *CityFed Fin. Corp. v. Office of Thrift Supervision*, 58 F.3d 738, 747 (D.C. Cir. 1995). Provided the plaintiff demonstrates a likelihood of success on the merits and of irreparable injury, the court “must balance the competing claims of injury and must consider the effect on each party of the granting or withholding of the requested relief.” *Amoco Prod. Co. v. Gambell*, 480 U.S. 531, 542 (1987). Finally, “courts of equity should pay particular regard for the public consequences in employing the extraordinary remedy of injunction.” *Weinberger v. Romero-Barcelo*, 456 U.S. 305, 312 (1982).

As an extraordinary remedy, courts should grant such relief sparingly. *Mazurek v. Armstrong*, 520 U.S. 968, 972 (1997). The Supreme Court has 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 Because the Plaintiffs’ Have Failed to Demonstrate Irreparable Harm

To substantiate the plaintiffs’ claim that they will suffer irreparable harm absent immediate injunctive relief, the plaintiffs submit declarations from the administrators of four of the fifteen plaintiff hospices describing the hardships caused by the repayment demands at issue. *See generally* Decl. of Jenny Olivo Irizarry (“Irizarry Decl.”); Decl. of Sandra McKenzie (“McKenzie Decl.”); Decl. of Drew Martin (“Martin Decl.”); Decl. of Theresa Hidalgo

(“Hidalgo Decl.”).⁵ Each administrator states that his or her hospice received cap repayment demands seeking the repayment of hundreds of thousands of dollars paid by HHS for services rendered to eligible Medicare beneficiaries in 2006, 2007 and/or 2008. Irizarry Decl. ¶ 4; McKenzie Decl. ¶ 4; Martin Decl. ¶ 4; Hidalgo Decl. ¶ 4. Lacking the funds to repay these amounts, and unable to obtain commercial loans, the hospices ultimately entered into repayment plans with HHS, under which they are required to make monthly payments of principal and interest to HHS. Irizarry Decl. ¶¶ 5-6; McKenzie Decl. ¶¶ 5-6; Martin Decl. ¶¶ 5-6; Hidalgo Decl. ¶¶ 5-6. The strain of these monthly payments, which according to the plaintiffs account for between ten and forty percent of each hospice’s operating revenue, has forced them to lay off staff, drastically reduce expenditures and contemplate bankruptcy or closure. Irizarry Decl. ¶¶ 6-9; McKenzie Decl. ¶¶ 6-9; Martin Decl. ¶¶ 6-10; Hidalgo Decl. ¶¶ 6-9. The plaintiffs assert that the hardships detailed in these four declarations are representative of those facing all fifteen plaintiff hospices as a result of the payment demands. *See* Pls.’ Mot. at 5-6; Pls.’ Reply at 8-9; *see generally* Decl. of Brian Daucher.

HHS maintains that the plaintiffs have not made an adequate showing of irreparable harm. *See* Def.’s Opp’n at 12-19. It states that the plaintiffs have submitted no information whatsoever regarding the financial situation of eleven of the fifteen plaintiff hospices. *Id.* at 12-13. Moreover, HHS asserts that the four declarations submitted by the plaintiffs at best demonstrate hardship attributable to the existence of the statutory cap rather than the challenged regulation. *Id.* at 13. HHS argues that regardless of whether the court ultimately sets aside the challenged regulation, the plaintiffs will still be subject to the statutory cap provisions and will

⁵ Irizarry is the Executive Director of plaintiff Hospicio Toque de Amor, Irizarry Decl. ¶ 1; McKenzie is the President of plaintiff Affinity Home Hospice Services, McKenzie Decl. ¶ 1; Martin is the Director of Operations of plaintiff Local Hospice, Inc., Martin Decl. ¶ 1; Hidalgo is the Executive Director/Clinical Director of plaintiff Freedom Hospice, Hidalgo Decl. ¶ 1.

retain a significant hospice cap repayment liability. *Id.* Noting that the plaintiffs have offered no indication as to how much the cap repayment demands at issue would be reduced under a “permissible” calculation, HHS maintains that the plaintiffs have failed to show that the financial hardships they are suffering are due to the excessiveness of the repayment demands resulting from the challenged regulation. *Id.* at 13-14. Furthermore, HHS argues that the plaintiffs cannot rely on the repayment demands for fiscal year 2008 as they have not challenged the propriety of those demands in this action. *Id.* at 30-35.

“To demonstrate irreparable injury, a plaintiff must show that it will suffer harm that is ‘more than simply irretrievable; it must also be serious in terms of its effect on the plaintiff.’” *Hi-Tech Pharmacal Co. v. U.S. Food & Drug Admin.*, 587 F. Supp. 2d 1, 11 (D.D.C. 2008) (quoting *Gulf Oil Corp. v. Dep’t of Energy*, 514 F. Supp. 1019, 1026 (D.D.C. 1981)); *accord Robinson-Reeder v. Am. Council on Educ.*, 626 F. Supp. 2d 11, 14 (D.D.C. 2009); *Sandoz, Inc. v. Food & Drug Admin.*, 439 F. Supp. 2d 26, 31-32 (D.D.C. 2006); *see also Wis. Gas Co. v. Fed. Energy Regulatory Comm’n*, 758 F.2d 669, 674 (D.C. Cir. 1985) (noting that to warrant emergency relief, the harm must be certain, great, actual and imminent). Purely economic harm is not considered sufficiently grave under this standard unless it will “cause extreme hardship to the business, or even threaten destruction of the business.” *Gulf Oil*, 514 F. Supp. at 1025 (observing that “some concept of magnitude of injury is implicit in the [standard for issuing a preliminary injunction]”).

In this case, the plaintiffs have offered substantial evidence that for four of the plaintiff hospices, the cap repayment demands issued by HHS are causing extreme hardship and threaten the survival of those entities. *See* Irizarry Decl. ¶¶ 7-9; McKenzie Decl. ¶¶ 7-9; Martin Decl. ¶¶ 7-10; Hidalgo Decl. ¶¶ 7-9. But even assuming that the concerns expressed in these declarations

are representative of the threat facing all the plaintiffs, there is no evidence of the extent to which these prospective injuries result from the application of the challenged regulation. At no point do the plaintiffs suggest that their success on the merits would relieve all, or even most, of their cap repayment obligations. *See generally* Compl.; Pls.’ Mot.; Pls.’ Reply. Indeed, the plaintiffs offer no indication whatsoever of the extent to which their repayment obligation for any fiscal year would be affected were they to succeed on the merits, beyond the bare allegation in the complaint that if HHS had properly applied the Medicare statute, their “cap liability for fiscal years 2006 and 2007 would have been materially reduced.” Compl. ¶ 56.

The significance of this oversight is borne out in other hospice cases in which the plaintiff hospices offered a calculation of the injury resulting from the challenged regulation. *See, e.g., Hospice of N.M., LLC v. Sebelius*, Civ. Action No. 09-145 (D.N.M.) (Docket Item No. 24-1); *IHG HealthCare, Inc. v. Sebelius*, Civ. Action No. 09-3233 (S.D. Tex.) (Docket Item No. 21); *Russell-Murray Hospice, Inc. v. Sebelius*, Civ. Action No. 09-2033 (D.D.C.) (Docket Item No. 13-9). In one such effort, the plaintiff hospice predicted that a proper cap calculation would have resulted in a reduction in cap liability of \$0 for 2004 and 2005, \$15,233.19 for 2006 and \$315,798.09 in 2007. *See IHG HealthCare, Inc. v. Sebelius*, Civ. Action No. 09-3233 (S.D. Tex.) (Docket Item No. 21). Given the potential for such vast, year-to-year variations, the court cannot assume, based on the evidence presented in this case, that the application of the challenged regulation, rather than a regulation that, from the plaintiffs’ perspective, complies with the Medicare statute, will result in any irreparable harm to the plaintiff hospices.

Naturally, any calculation offered by the plaintiffs will be hypothetical to some degree, as no alternative regulation exists to the challenged reimbursement regulation. This fact, however, does not relieve the plaintiffs of the obligation to demonstrate that they will be

irreparably harmed by the continued application of the challenged regulation.⁶ *Cf. Procter & Gamble Co. v. Ultreo, Inc.*, 574 F. Supp. 2d 339, 348-49 (S.D.N.Y. 2008) (holding that evidence of lost sales resulting from false advertising was insufficient to establish irreparable harm because the plaintiff failed to “distinguish between the lost sales it believes it would experience from lawful competition and truthful advertising from the lost sales it believes it would experience from the alleged false advertising”); *Fla. Wildlife Fed’n v. Goldschmidt*, 506 F. Supp. 350, 369-70 (S.D. Fla. 1981) (concluding that the plaintiffs failed to show irreparable harm as “there [was] no demonstrated proximate cause between the activities attacked and the harm feared”). And the hypothetical nature of any losses the plaintiffs may be suffering certainly does not justify the windfall to the plaintiffs that would result from a blanket injunction on the cap repayments demands at issue, as the court can plainly direct the refund of any amounts overpaid when resolving the merits of the litigation. *See Compassionate Care Hospice v. Sebelius*, 2010 WL 2326216, at *5 (W.D. Okla. June 7, 2010) (invalidating the reimbursement regulation and ordering HHS to calculate and refund any amounts overpaid by the plaintiff hospice); *accord Hospice of N.M., LLC v. Sebelius*, 691 F. Supp. 2d 1275, 1295 (D.N.M. 2010).

In sum, despite the plaintiffs’ allegations of hardship caused by their overall repayment obligations, they fail to demonstrate what they are required to demonstrate to obtain injunctive relief – namely, that the application of the challenged regulation in particular is causing them

⁶ This discussion should in no way suggest that the plaintiffs must offer such a calculation to satisfy the very different requirements of Article III standing. *See, e.g., Tri-County Hospice, Inc. v. Sebelius*, 2010 WL 784836, at *1-2 (E.D. Okla. Mar. 8, 2010) (concluding that the plaintiff hospice was not required to show the difference between the HHS calculation and a proposed calculation by the hospice to establish standing); *accord Lion Health Servs., Inc. v. Sebelius*, 689 F. Supp. 2d 849, 855 (N.D. Tex. 2010) (holding that to demonstrate injury-in-fact, “[the] plaintiff does not need to prove that its cap overpayments will certainly be less if calculated under lawful regulations”); *L.A. Haven Hospice, Inc. v. Leavitt*, 2009 WL 5868513, at *3-4 (C.D. Cal. Jul. 13, 2009) (holding that the plaintiff hospice had standing to challenge the reimbursement regulation without devising its own proposed regulation).

irreparable harm.⁷ Because this failure alone warrants denial of interim injunctive relief, the court denies the plaintiffs' motion.⁸ See *Chaplaincy of Full Gospel Churches v. England*, 454 F.3d 290, 297 (D.C. Cir. 2006) (observing that "[a] movant's failure to show any irreparable harm is . . . grounds for refusing to issue a preliminary injunction, even if the other three factors entering the calculus merit such relief"); *Fraternal Order of Police Library of Cong. Labor Comm. v. Library of Cong.*, 639 F. Supp. 2d 20, 25 (D.D.C. 2009) (holding that "[b]ecause [the] plaintiffs cannot establish that the Merger will cause irreparable harm . . . the Court need not address the remaining preliminary injunction factors, and . . . concludes that the motions for preliminary injunctions must be denied").

⁷ The plaintiffs rely on *National Mining Association v. U.S. Army Corp of Engineers*, 145 F.3d 1399 (D.C. Cir. 1998) in support of the alternative argument that they are not required to make a separate showing of irreparable injury because they are challenging the validity of a regulation. Pls.' Mot. at 9-10. Yet *National Mining Association* concerned the necessity of demonstrating irreparable harm to obtain a *permanent* injunction issued at the resolution of the merits, and expressly limited its holding to that species of injunction. See 145 F.3d at 1409 (holding that "once the court reached the conclusion that the rule was indeed illegal (i.e., not merely that the plaintiffs had a reasonable probability of success on the merits, as would be necessary for a preliminary injunction), there was no separate need to show irreparable injury, as that is merely one possible basis for showing the inadequacy of the legal remedy") (citations and quotation marks omitted).

⁸ The court notes that this matter appears ripe for expedited resolution. As the plaintiffs point out, numerous courts have already addressed the legal question at the heart of this dispute and have uniformly held that the challenged reimbursement regulation fails APA review. See Pls.' Mot. at 1-2; Pls.' Reply at 5-6; see generally Pls.' Notice of Status of Related Cases. The plaintiffs also rightly point out that numerous courts have already addressed the standing challenge alluded to in the defendant's opposition brief. See Pls.' Reply at 6-7. Accordingly, the court fully expects and intends to resolve the merits of this dispute without delay.

IV. CONCLUSION

For the foregoing reasons, the court denies the plaintiffs' motion for a temporary restraining order. An Order consistent with this Memorandum Opinion is separately and contemporaneously issued this 1st day of July, 2010.

RICARDO M. URBINA
United States District Judge