

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

RENAL PHYSICIANS ASSOCIATION,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Civil Action No. 05-0067 (RBW)
	)	
DEPARTMENT OF HEALTH AND	)	
HUMAN SERVICES, <u>et al.</u> ,	)	
	)	
Defendants.	)	
	)	

**MEMORANDUM OPINION**

The Renal Physicians Association (“the plaintiff”) brings this action challenging the validity of the safe harbor provision published by the United States Department of Health and Human Services and the Center for Medicare and Medicaid Services (“the defendants”) as part of the Stark Law regulations governing physician referrals under the Medicare program. 42 C.F.R. § 411.351 (2004). The plaintiff claims that this regulatory provision, which sets forth two methodologies by which employers may safely compute the fair market value of hourly physician compensation, “violates the plain language of the Stark Law” and was promulgated “without proper notice or a meaningful opportunity for public comment and discussion.” Complaint (“Compl.”) ¶ 1. The plaintiff further alleges that although the compensation rates derived by these methodologies do not truly reflect the fair market value of physicians’ services, employers wishing to ensure compliance with the Stark Law routinely utilize the safe harbor provision when contracting with physicians. Id. ¶¶ 48-56. Consequently, the plaintiff asks the Court to

declare that the safe harbor provision is invalid and to enjoin its use by the defendants.

Id. ¶ 1. Currently before the Court is the defendants’ motion to dismiss the complaint for lack of standing.<sup>1</sup> For the reasons set forth below, the Court finds that the injury asserted by the plaintiff is not likely to be redressed by the requested relief. The Court therefore grants the defendants’ motion to dismiss.

## **I. Background**

Enacted to prevent abuse of the Medicare program, Section 1877 of the Social Security Act (“the Stark Law”) generally prohibits physician referrals of Medicare and Medicaid patients to health service providers, including dialysis facilities, with which the physician has an existing financial relationship. 42 U.S.C. § 1395nn (2000). One notable statutory exception to the Stark Law prohibition permits referrals if the physician and provider have a “bona fide employment relationship” or a “personal service arrangement” in which the physician is being compensated at the “fair market value” in a manner that does not take into account “the volume or value of any referrals.” 42 U.S.C. §§ 1395nn(e)(2), (3). In other words, if a physician is being paid by the provider for something other than patient referrals, and such payment is at the “fair market value” for the physician’s services, then the physician may refer Medicare patients to the provider. The Stark Law defines “fair market value” as “the value in arms length transactions, consistent with the general market value.” 42 U.S.C. § 1395nn(h)(3).

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<sup>1</sup> The following papers have been submitted in connection with this motion: (1) Memorandum of Points and Authorities in Support of Defendants’ Motion to Dismiss (“Def.’s Mem.”); (2) Memorandum of Points and Authorities in Opposition to Defendants’ Motion to Dismiss (“Pl.’s Opp.”); (3) Reply in Support of Defendants’ Motion to Dismiss (“Def.’s Reply”); and (4) Brief Amici Curiae of American Medical Association, Infectious Diseases Society of America, and American College of Physicians in Support of Plaintiff Renal Physicians Association.

In January 1998, the Center for Medicare and Medicaid Services (“CMS”) issued a Notice of Proposed Rulemaking (“NPRM”) setting forth draft regulations to implement the Stark Law. 63 Fed. Reg. 1,659 (January 9, 1998). For the purposes of the aforementioned statutory exception, the NPRM defined “fair market value” as follows:

Fair market value means the value in arm’s-length transactions, consistent with the general market value. “General market value” means . . . the compensation that would be included in a service agreement, as the result of bona fide bargaining between well-informed parties to the agreement. . . . Usually the fair market price is . . . the compensation that has been included in bona fide service agreements with comparable terms at the time of the agreement.

Id. at 1,721. Phase I of the final rulemaking, issued in January 2001, adopted this definition with only slight modification.<sup>2</sup> 66 Fed. Reg. 856, 953-54 (January 4, 2001). In response to comments regarding the difficulty of determining whether a compensation arrangement reflects the fair market value, the Phase I preamble clarified that the CMS “intend[s] to accept any method [to determine the fair market value] that is commercially reasonable and provides [the agency] with evidence that the compensation is comparable to what is ordinarily paid . . . by parties in arm’s-length transactions who are not in a position to refer to one another.” Id. at 944. The preamble further stated that

[t]he amount of documentation that will be sufficient to confirm fair market value . . . will vary depending on the circumstances in any given case; that is, there is no rule of thumb that will suffice for all situations. The burden of establishing the ‘fairness’ of an agreement rests with the parties involved in the agreement. Depending on the circumstances, the parties may want to consider obtaining good faith, written assurances as to fair market value from the party paying or receiving the compensation, although such written assurances are not determinative.

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<sup>2</sup> The final definition added that the bargaining parties, in addition to being well-informed, must not otherwise be “in a position to generate business for the other party.” 66 Fed. Reg. 953; 42 C.F.R. § 411.351.

Id. The CMS continued to accept comments on Phase I rulemaking until April 2001, and the Phase I regulations became effective in January 2002. Id. at 856.

Phase II of the final rulemaking was designed to address all areas of the Stark Law not covered by Phase I, as well as “comments received in response to [the Phase I] rulemaking, as appropriate, and certain proposals for new exceptions to [the Stark Law] not included in the [NPRM], but suggested in public comments.” Id. The Phase II rulemaking was issued as an interim final rule on March 26, 2004, to take effect on July 26, 2004. 69 Fed. Reg. 16,054 (March 26, 2004). Included as part of Phase II was the safe harbor provision that is the focus of this litigation. Id. at 16,128. To begin with, the CMS reiterated in the Phase II preamble that it “will consider a range of methods of determining fair market value and that the appropriate method will depend on the nature of the transaction, its location, and other factors.” Id. at 16,107. The agency, responding to a comment recommending that it “establish[] a presumed appropriate fair market hourly rate” for medical directors at end-stage renal disease (ESRD) facilities, also stated:

With respect to the commenters’ suggestion that we fix a fair market value benchmark for medical directors, we are not in a position – nor would it be appropriate – to set a fixed, industry-wide fair market value for ESRD medical directors. However, we are creating a ‘safe harbor’ provision under the definition of ‘fair market value’ . . . for hourly payments to physicians for their personal services. The ‘safe harbor’ provision applies to payments for services provided personally by the physician. . . . The safe harbor is not limited to medical director services for ESRD facilities, but may be used for other hourly physician compensation paid by any [designated health services (“DHS”)] entity.

The safe harbor consists of two methodologies for calculating hourly rates that will be deemed to be ‘fair market value’ for purposes of [the Stark Law]. The first methodology requires that the hourly payment be less than or equal to the average hourly rate for emergency room physician

services in the relevant physician market, provided there are at least three hospitals providing emergency room services in the market. The second methodology requires averaging the fiftieth percentile salary for the physician's specialty of four national salary surveys and dividing the resulting figure by 2000 hours to establish an hourly rate. The 'safe harbor' provides a choice of six recognized, readily-available surveys. If the relevant specialty does not appear on the survey, the safe harbor looks to the salary for general practice.

Compliance with these safe harbor methodologies is entirely voluntary; DHS entities may continue to establish fair market value through other methods. DHS entities that choose to use either of the two 'safe harbor' methodologies will be assured that their compensation rates will be deemed fair market value for the purposes of [the Stark Law]. . . . DHS entities using other methodologies to determine fair market value will continue to bear the risk that their rates may not be considered fair market value.

Id. at 16,092 (emphasis added). Accordingly, the Phase II rules supplemented the regulatory definition of "fair market value," issued in Phase I and published as 42 C.F.R. § 411.351, by providing that "[a]n hourly payment for a physician's personal services . . . shall be considered to be fair market value if the hourly payment is established using either of . . . two methodologies." Id. at 16,128. The provision then described the methodologies already outlined in the preamble and named the six national salary surveys that could be used for the second methodology. Id.

Importantly, the CMS waived the normal notice-and-comment procedures for any rule that appeared for the first time in the Phase II rulemaking, including the safe harbor provision. Id. at 16,125-26. Rather than issue a proposed notice of rulemaking for these new provisions, the agency chose to publish Phase II as an interim final rule with a comment period. Id. The Phase II rules thus took effect on July 26, 2004, 120 days after their publication. Although the agency solicited comments on Phase II until June 24,

2004, there existed no prescribed mechanism that required the agency to respond to those comments before the Phase II provisions became effective in July 2004. Id. at 16,054.

The CMS justified its waiver of notice and comment for Phase II pursuant to Section 553(b) of the Administrative Procedures Act (“APA”), which states that an agency need not publish notice of proposed rulemaking “when the agency for good cause finds . . . that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest.” 5 U.S.C. § 553(b)(3)(B) (2000). Specifically, the CMS stated:

We believe it is impracticable and not in the public interest to offer what would essentially constitute a third opportunity to comment on much of the material in this rule and thereby delay finalizing useful exceptions and the many ‘bright-line’ rules necessary either to protect the Medicare program from fraud and abuse or permit nonabusive arrangements. We have already issued a proposed rule, major portions of which were finalized upon publication of the Phase I final rule with comment period and became effective on January 4, 2002. This interim final rule responds to public comments received on the January 1998 proposed rule as well as public comments received on Phase I. Phase I comments necessarily informed our rulemaking with respect to finalizing the remainder of the January 1998 proposed rule because those comments addressed definitions and other matters that apply throughout the regulatory scheme. To publish yet another proposed rule on this matter would prevent affected parties from using important new or expanded exceptions. Even if we were able to finalize a proposed rule in an expedited fashion, the inability to use the new or expanded exceptions could expose DHS entities to significant financial liability for otherwise nonabusive relationships. Moreover, the public will not be denied the opportunity to comment on this rule because we are publishing it as an interim final rule with comment period. . . . [W]e are obligated to consider comments on this interim final rule and publish a final rule addressing those comments within three years.

69 Fed. Reg. at 16,126 (emphasis added). As currently constituted, the regulatory definition of “fair market value” includes the safe harbor provision. 42 C.F.R. § 411.351.

On January 14, 2005, the plaintiff, a “national, non-profit specialty society,” brought this action on behalf of its members who “are medical directors of outpatient dialysis facilities and are directly affected by the regulation at issue.” Compl. ¶ 3. The complaint alleges that the safe harbor provision “violates the plain language of the Stark Law” and was issued “unexpectedly and without proper notice or a meaningful opportunity for public comment.” Id. ¶ 3. The plaintiff claims that the safe harbor methodologies articulated by the CMS are outdated and arbitrary, and that compensation figures derived by the methodologies do not truly reflect the fair market value of medical directors’ services. See id. ¶¶ 39, 48-51. Specifically, the plaintiff contends that the CMS

did not build a record of, or rely upon, relevant data in considering and establishing methods for calculating the fair market value of compensation paid to physicians for the rendition of personal services. It undertook no analysis to demonstrate why the “benchmark” was required, nor did it provide information about fair market value calculations it considered, rejected or adopted. Instead, [the] CMS used outdated national data on hourly physician compensation rates for the ordinary services of a given type of physician, and arbitrarily applied the non-comparable and unrelated data points as a means to extrapolate market compensation for all types of physicians, in all locations, under any kind of service agreement. [The] CMS entirely failed to consider the relevancy of the data to its intended purpose, and did not articulate a basis for choosing the particular methodologies.

Id. ¶ 39. Moreover, the plaintiff argues that because use of the nominally voluntary methodologies is the only way for an employer to ensure that it falls within the scope of the Stark Law exception, the de facto effect of the safe harbor provision has been “strict compliance with the fair market value safe harbor” by dialysis providers in contracting with physicians. Id. ¶¶ 52-56. This in turn, the plaintiff says, serves “to reduce significantly the compensation paid to highly skilled medical directors of dialysis

facilities, and to impair the quality of care provided to patients with end-stage renal disease.” Id. ¶ 1. Finally, the plaintiff asserts that had it and other “interested parties . . . been accorded their statutory right to comment on the fair market value safe harbor” as required by the APA, the unfair nature of the safe harbor methodologies would have been made clear and the agency, presumably, would not have adopted the provision at issue. Id. ¶ 59.

The plaintiff contends in its prayer for relief that “[a]lthough the safe-harbored compensation rates are well below the current market rate for medical director services furnished to dialysis providers, [such] providers are insisting upon compensating medical directors in accordance with the safe harbor so as to avoid a governmental investigation or enforcement action.” Id. ¶ 64. The plaintiff therefore requests, inter alia, that the Court declare the safe harbor provision to be invalid and “[e]njoin HHS and CMS from enforcing or applying or otherwise implementing [it].” Id. at 24.

On April 29, 2005, the defendants moved to dismiss this case, arguing that the plaintiff lacks Article III standing to challenge the validity of the safe harbor provision in two respects.<sup>3</sup> Def.’s Mem. at 11-15. First, the defendants contend that the asserted injury of the plaintiff’s member physicians is not fairly traceable to the promulgation of the safe harbor provision, as reliance on the safe harbor methodologies is voluntary and any allegedly below-market compensation is the result of independent third-party actions

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<sup>3</sup> The defendants also argue that the Court lacks subject-matter jurisdiction over the plaintiff’s claims because (1) the safe harbor provision is an exercise of the defendants’ enforcement discretion which is presumptively unreviewable, and (2) no meaningful standards exist against which the exercise of discretion may be judged. Def.’s Mem. at 15-18. Because the Court finds that the relief requested by the plaintiff is not likely to be redressed by a favorable decision, it need not visit this issue. Cf. Ctr. for Law and Educ. v. Dep’t of Educ., 396 F.3d 1152, 1156 (D.C. Cir. 2005) (stating that courts “need not identify every ground for holding that a claim is not justiciable”) (citation omitted).



rather than agency directive. Id. at 11-13. Second, the defendants claim that in any event the plaintiff's injury is not redressable by the desired relief, because rescission of the safe harbor provision would not alter the defendants' determination that compensation levels that fall within the safe harbor are fair market value, nor would it prevent the dialysis facilities, who are now on notice that the CMS will approve values that match those derived by the methodologies, from applying the safe harbor methodologies to determine physicians' compensation. Id. at 13-15; Def.'s Reply at 8-9.

The plaintiff argues in response that it has standing to assert its substantive claims regarding the merits of the safe harbor methodologies. Pl.'s Opp. at 10-19. It states that because the safe harbor provision is "binding as a practical matter" against employers wishing to avoid prosecution of the Stark Law, id. at 14 (quoting General Electric Co. v. EPA, 290 F.3d 377, 383 (D.C. Cir. 2002)), the allegedly resultant decline in physician compensation is fairly traceable to the defendants' actions, id. at 12-17. It also states that its asserted injury would readily be redressed by the invalidation of the safe harbor provision. Id. at 17-19. Finally, the plaintiff contends that the defendants' alleged procedural violation, the failure to provide for proper notice and comment, alone is sufficient to confer standing and survive a motion to dismiss. Id. at 6.

## **II. Standard of Review**

In considering a motion to dismiss for lack of standing, the Court "must accept as true all material allegations of the complaint, and must construe the complaint in favor of [the plaintiff]." Alliance for Democracy v. Fed. Election Comm'n, 362 F. Supp. 2d 138, 142 (D.D.C. 2005) (internal quotation marks and citations omitted); see also Nat'l Treasury Employees Union v. United States, 101 F.3d 1423, 1430 (D.C. Cir. 1996).

However, because “[s]tanding is one of the essential prerequisites to jurisdiction under Article III,” Crow Creek Sioux Tribe v. Brownlee, 331 F.3d 912, 915 (D.C. Cir. 2003) (citation omitted), the plaintiff bears the burden of establishing proper standing “at the outset of its case,” Sierra Club v. Env’tl. Prot. Agency, 292 F.3d 895, 901 (D.C. Cir. 2002). In so doing, the plaintiff must allege facts sufficient to satisfy the “irreducible constitutional minimum” of Article III standing. Lujan v. Defenders of Wildlife, 504 U.S. 555, 560 (1992). That is, the plaintiff must demonstrate (1) that it has suffered an injury in fact, the cause of which is (2) fairly traceable to the defendants’ challenged conduct and (3) likely to be redressed by a judicial decision granting the plaintiff the relief it seeks.<sup>4</sup> See, e.g., Ctr. for Law and Educ. v. Dep’t of Educ., 396 F.3d 1152, 1157 (D.C. Cir. 2005) (quoting Lujan, 504 U.S. at 560-61). Moreover, when causation and redressability “hinge upon the independent choices of [a] regulated third party, it becomes the burden of the plaintiff to adduce facts showing that these choices have been or will be made in such manner as to produce causation and permit redressability of injury.” Nat’l Wrestling Coaches Ass’n v. Dep’t of Educ., 366 F.3d 930, 938 (D.C. Cir. 2004) (quoting Lujan, 504 U.S. at 562) (internal quotation marks omitted). No Article III

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<sup>4</sup> When the plaintiff is an association bringing suit on behalf of individual members, it must additionally show that “(1) at least one of its members would have standing to sue in his own right, (2) the interests the association seeks to protect are germane to its purpose, and (3) neither the claim asserted nor the relief requested requires that an individual member of the association participate in the lawsuit.” Nat’l Wrestling Coaches Ass’n v. Dep’t of Educ., 366 F.3d 930, 937 (D.C. Cir. 2004) (citing Hunt v. Wash. State Apple Adver. Comm’n, 432 U.S. 333, 343 (1977)). The plaintiff here purports to meet the Hunt “associational standing” test, Pl.’s Opp. at 4 n.1, and provides an affidavit of a member physician who alleges that his medical director compensation was reduced as a result of the safe harbor provision, id., Ex. 1, Affidavit of Joseph Anzalone, M.D. However, even assuming that the plaintiff satisfies the Hunt test, it must still demonstrate that it, or its members, have Article III standing. See Nat’l Wrestling Coaches Ass’n, 366 F.3d at 937 (stating that a plaintiff-association “must establish that at least one of [its] members has suffered a cognizable injury that is fairly traceable to [the challenged agency provision] and likely to be redressed by a judicial decision declaring [the provision] to be unlawful and enjoining its use”). Because the Court concludes that the redressability requirement cannot be met in this case, it is immaterial whether the plaintiff possesses “associational standing” to bring suit on behalf of its members.

standing thus exists “where it is purely speculative that a requested change in government policy will alter the behavior of regulated third parties that are the direct cause of the plaintiff’s injuries.” Nat’l Wrestling Coaches Ass’n, 366 F.3d at 938 (citing Simon v. E. Ky. Welfare Rights Org., 426 U.S. 26 (1976)). Rather, a plaintiff’s injury is redressable when “the relief sought, assuming that the court chooses to grant it, will likely alleviate the particularized injury” that is being alleged. Florida Audubon Soc’y v. Bentsen, 94 F.3d 658, 663-64 (D.C. Cir. 1996) (citation omitted).

### **III. Analysis**

The plaintiff alleges that dialysis facilities, seeking to ensure compliance with the Stark Law, are likely to apply the purportedly flawed safe harbor methodologies provided in 42 C.F.R. § 411.351 when contracting with medical directors, resulting in an hourly compensation rate that is below market value. Compl. ¶¶ 52-56; Pl.’s Repl. at 12-17. Even assuming that the plaintiff’s member physicians have been injured in fact in a manner that is fairly traceable to the defendants’ promulgation of the safe harbor provision,<sup>5</sup> it is “purely speculative” that this injury would be redressed if the Court were to grant the plaintiff the full extent of the relief that it requests. Nat’l Wrestling Coaches Ass’n, 366 F.3d at 938. Accordingly, the Court concludes that the plaintiff lacks Article

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<sup>5</sup> The Court is sympathetic to the plaintiff’s argument that its injury is fairly traceable to the defendants’ conduct because “the incentive to seek refuge in the safe harbor is so powerful that the [provision] is a de facto regulation.” Pl.’s Opp. at 14. Indeed, the District of Columbia Circuit has observed that “if the language of the [agency] document is such that parties can rely on it as a norm or safe harbor by which to shape their actions, it can be binding as a practical matter.” General Electric Co., 329 F.3d at 383 (internal quotation marks and citation omitted). Moreover, while the defendants here do make it clear that “[c]ompliance with [the] safe harbor methodologies is entirely voluntary,” and expressly allow health care providers to “continue to establish fair market value through other methods,” 69 Fed. Reg. at 16,092, such statements do not appear in the text of the regulation itself, 42 C.F.R. § 411.351, but are published as part of the Phase II Preamble in the Federal Register. Nevertheless, in light of its conclusion that the plaintiff has not demonstrated that the asserted injury is redressable by judicial relief, the Court need not consider whether the plaintiff’s injury is fairly traceable for the purposes of Article III standing.

III standing to bring this action.<sup>6</sup> See U.S. Ecology, Inc. v. U.S. Dep’t of Interior, 231 F.3d 20, 24 (D.C. Cir. 2000) (observing that “a deficiency on any one of the three prongs suffices to defeat standing.”).

The District of Columbia Circuit has stated that “[w]hen a plaintiff’s asserted injury arises from the Government’s regulation of a third party that is not before the court, it becomes substantially more difficult to establish standing.” Nat’l Wrestling Coaches Ass’n, 366 F.3d at 938 (quoting Lujan, 504 U.S. at 562) (internal quotation marks omitted); see also Fulani v. Brady, 935 F.2d 1324, 1329 (D.C. Cir. 1991) (stating that no redressability exists when an injury “depends not only on [the defendant’s challenged conduct] but on independent intervening or additional causal factors”) (citing Warth v. Seldin, 422 U.S. 490 (1975)). Here, the plaintiff does not, and cannot, dispute that the ultimate injury arises not from the safe harbor provision itself, but from regulated third parties who “insist on limiting medical director compensation to the safe-harbored levels.” Compl. ¶ 52.

In National Wrestling Coaches Ass’n (“NWCA”), several organizations “represent[ing] the interests of collegiate men’s wrestling coaches, athletes, and alumni” brought suit alleging that “the Three-Part Test,” which is part of a Title IX enforcement policy promulgated by the Department of Education, had unlawfully resulted in “the

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<sup>6</sup> In its opposition to the defendants’ motion to dismiss, the plaintiff cites National Wrestling Coaches Ass’n for the proposition that “[w]here traceability under Lujan can be established, redressability ‘inexorably follows.’” Pl.’s Opp. at 17 (quoting Nat’l Wrestling Coaches Ass’n, 366 F.3d at 942). If this were true, the Court would need only inquire whether the plaintiff had suffered a cognizable injury that is fairly traceable to the promulgation of the safe harbor provision in order to determine the existence of Article III standing. The plaintiff, however, grievously misreads National Wrestling Coaches Ass’n, which noted simply that “appellants’ submissions [in that case] fail to demonstrate that causation is so clear that redressability inexorably follows.” 366 F.3d at 942. Indeed, it should be obvious that redressability does not “inexorably follow” from causation in the ordinary course. That all the king’s horses and all the king’s men knew that Humpty Dumpty’s injuries were fairly traceable to the wall from which he fell in no way means that they could have put him back together again.

elimination of men’s varsity wrestling programs at certain universities,” id. at 933, and asking that the Court invalidate the Test and enjoin its use, id. at 936. The NWCA Court held that the plaintiffs lacked standing “because they have not demonstrated that their alleged injuries will be redressed by the requested relief.” Id. The Court went on to say that

[t]he direct causes of [the] appellants’ asserted injuries – loss of collegiate-level wrestling opportunities for male student-athletes – are the independent decisions of educational institutions that choose to eliminate or reduce the size of men’s wrestling teams. [The a]ppellants offer nothing but speculation to substantiate their claim that a favorable decision from this court will redress their injuries by altering these schools’ independent decisions. . . . Even if [the] appellants prevailed in the merits of their challenge to the Three-Part Test, Title IX . . . would still be in place. Federally funded schools would still be required to provide athletic opportunities in a manner that equally accommodated both genders. . . . Schools would remain free to eliminate or cap men’s wrestling teams and may in some circumstances feel compelled to do so to comply with [Title IX].

Id. at 936-37, 939-40 (emphasis added).

Similarly, in the absence of the safe harbor provision, the Stark Law would remain in force, and employers would still be required to compensate physicians at the fair market value in order to qualify for the Stark Law exception. See generally 42 U.S.C. §§ 1395nn. The Stark Law concerns not the methodology used to compute a physicians’ level of hourly compensation but the compensation itself, and the safe harbor provision is simply a means for parties to ensure that their bargained-for compensation falls within the statutory definition of “fair market value.” See 42 U.S.C. § 1395nn(h)(3) (defining fair market value as “the value in arms length transactions, consistent with the general market value”); 42 C.F.R. § 411.351 (same). The Phase I rulemaking, which the plaintiff does not challenge, states in its preamble that the CMS “intend[s] to accept any

method [to determine fair market value] that is commercially reasonable and provides [the agency] with evidence that the compensation is comparable to what is ordinarily paid . . . by parties in arm's length transactions who are not in a position to refer to one another.”<sup>7</sup> 66 Fed. Reg. at 944. The plaintiff does not claim that the defendants lack the authority to determine fair market value under the Stark Law, nor does it allege that the statute prescribes a particular method by which such a determination must be made. Instead, the plaintiff seeks solely to invalidate the regulatory provision that identifies two methodologies as presumptively reasonable to calculate physicians' compensation levels. But while the safe harbor provision may have alerted employers that a given rate of compensation would be deemed by the agency to fall within the ambit of the Stark Law exception, the provision itself is not responsible for the statutory requirement that employers compensate physicians at a fair market value. Thus, the plaintiff has inadequate support for its claim that “the harm [alleged] from application of the safe harbor would surely be redressed if the Court invalidated its use.” Pl.'s Opp. at 17.

The safe harbor provision has put employers on notice that the CMS considers compensation rates matching those derived by the articulated methodologies to be within the fair market value for the purposes of the Stark Law exception. This notice, and employers' knowledge that use of the methodologies represents a regulatory safe harbor, will persist whether or not the Court grants the plaintiff's requested relief, until such time as the CMS itself repudiates the safe-harbored rates and establishes a higher benchmark value. In any event, even if the safe harbor provision is rescinded from 42 C.F.R. §

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<sup>7</sup> The Phase II preamble reiterated that the CMS “will consider a range of methods of determining fair market value.” 69 Fed. Reg. at 16,107.

411.351, dialysis facilities would remain free to set compensation rates at safe-harbored levels, with or without the use of the challenged methodologies, and the CMS would remain free to determine that such rates “are comparable to what is ordinarily paid . . . by parties in arm’s length transactions who are not in a position to refer to one another.” 66 Fed. Reg. at 944. Rescission of the safe harbor provision would neither require dialysis facilities to compensate physicians at a greater level nor prevent the agency from approving compensation levels commensurate with those derived by the safe-harbor methodologies. As the District of Columbia Circuit observed in U.S. Ecology, Inc., “whether [the plaintiff’s] claims of economic injury can be redressed by a favorable decision [here] depends on the unfettered choices made by independent actors not before the courts and whose exercise of broad discretion the courts cannot presume either to control or to predict.” 231 F.3d at 24 (quoting ASARCO, Inc. v. Kadish, 490 U.S. 605, 615 (1989)) (internal quotation marks omitted).

The plaintiff argues that without the safe harbor provision, “[t]he parties could negotiate contracts at arms length, just as they had previously, without the strictures of preconceived and erroneous methodologies.” Pl.’s Opp. at 17. This, however, is plainly untrue. By approving of the safe harbor methodologies, the defendants have informed employers that certain rate calculations yield fair market value, and the Court cannot “unring the bell [now that] the information has been released” simply by invalidating the challenged provision. Maness v. Meyers, 419 U.S. 449, 460 (1975) (internal quotation marks omitted).

Alternatively, the plaintiff contends that the alleged violation of its procedural rights under the APA is sufficient to confer Article III standing without the usual

showing of redressability as to the underlying substantive injury. Pl.’s Opp. at 6-9. Thus, the plaintiff posits that “the mere denial of notice and comment to a party interested in the ultimate agency rule establishes, by itself, a separate and remediable injury to that interested party which confers standing on that party.” Id. at 9. In support of its position, the plaintiff cites Lujan, which states that “[t]he person who has been accorded a procedural right to his concrete interests can assert that right without meeting all the normal standards for redressability and immediacy.” Id. (quoting Lujan, 504 U.S. at 573 n.7). The defendant claims in response that the plaintiff’s argument is “flatly contradicted” by the District of Columbia Circuit’s interpretation of Lujan in later cases. Def.’s Reply at 4. The Court agrees with the defendant.

Acknowledging the “special nature” of procedural injuries, Florida Audubon Soc’y, 94 F.3d at 674, the District of Columbia Circuit has stated that “the primary focus of a standing inquiry” in a procedural rights case is not redressability, but “whether a plaintiff who has suffered personal and particularized injury has sued a defendant who has caused that injury,” id. at 664 (discussing Lujan). Nevertheless, because redressability is one of the “‘irreducible’ elements of [constitutional] standing,” it cannot be dispensed with by virtue of “the particular nature of a case.” Id. (quoting Lujan, 504 U.S. at 560); see also Ctr. for Law and Educ., 396 F.3d at 1157 (holding that in procedural rights cases, “the courts relax – while not wholly eliminating – the issues of imminence and redressability”) (emphasis added) (citations omitted). Therefore, even assuming arguendo that the plaintiff has demonstrated that its members have suffered a “personal and particularized injury” resulting from the defendants’ alleged failure to comply with APA procedures, Florida Audubon Soc’y, 94 F.3d at 664, it must still



demonstrate that it is “likely, not speculative, that the [C]ourt can redress the injury,” Ctr. for Law and Educ., 396 F.3d at 1157 (citing Lujan, 504 U.S. at 560-61). As discussed above, the plaintiff has not done so here.

#### **IV. Conclusion**

The Court has no authority in this case to compel dialysis facilities to compensate physicians at a higher rate, nor can it direct the defendants to limit their definition of “fair market value” to exclude values derived by the safe-harbor methodologies. Neither is the judicial relief requested by the plaintiff likely to accomplish either of these goals.

Instead, the plaintiff’s appropriate avenue of remedy is to petition the defendants, or Congress itself, regarding the assertedly severe methodological flaws that now exist in the safe harbor provision. The CMS has stated that a final rule addressing the Phase II comments must be released by July 2007, 69 Fed. Reg. at 16,126 (the agency is “obligated to consider comments on [the] interim final rule and publish a final rule addressing those comments within three years”), and it is through this rule – or similar rulemaking – that the plaintiff’s concerns are likely to be redressed. Accordingly, and for the foregoing reasons, the Court grants the defendants’ motion to dismiss.

**SO ORDERED** this 7th day of March, 2006.<sup>8</sup>

REGGIE B. WALTON  
United States District Judge

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<sup>8</sup> An Order consistent with the Court’s ruling accompanies this Memorandum Opinion.