

United States Court of Appeals
FOR THE DISTRICT OF COLUMBIA CIRCUIT

Argued March 8, 2007

Decided June 12, 2007

No. 06-5133

RENAL PHYSICIANS ASSOCIATION,
APPELLANT

v.

U. S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, ET
AL.,
APPELLEES

Appeal from the United States District Court
for the District of Columbia
(No. 05cv00067)

Robert S. Plotkin argued the cause for appellant. With him on the briefs was *E. Duncan Getchell, Jr.*

Jeffrey T. Green was on the brief for *amici curiae* American Medical Association et al. in support of appellant.

Stephanie R. Marcus, Attorney, U.S. Department of Justice, argued the cause for appellees. With her on the brief were *Jeffrey S. Bucholtz*, Acting Assistant Attorney General, *Jeffrey A. Taylor*, U.S. Attorney, and *Thomas M. Bondy*, Attorney.

Before: GINSBURG, *Chief Judge*, and GARLAND and

BROWN, *Circuit Judges*.

Opinion for the Court filed by *Circuit Judge* BROWN.

BROWN, *Circuit Judge*: The issue in this case is standing to challenge a regulatory safe harbor where the direct cause of injury is the independent action of a third party. The same issue was before this court in *National Wrestling Coaches Ass'n v. Department of Education*, 366 F.3d 930 (D.C. Cir. 2004) (*National Wrestling*), though the factual context there was very different. Here, relying on *National Wrestling*, the district court dismissed the complaint for lack of standing. We affirm.

I

Congress first enacted the “Stark Law” as part of the Omnibus Budget Reconciliation Act of 1989. *See* Pub. L. 101-239, § 6204, 103 Stat. 2106, 2236-43 (1989). The law, which added section 1877 to the Social Security Act, limited the ability of a physician to refer Medicare patients to clinical laboratories with which the physician had a “financial relationship.” 42 U.S.C. § 1395nn(a)(1). In 1993, Congress extended the law to several other health services, *id.* § 1395nn(h)(6), and also included Medicaid patient referrals within the scope of the law, *id.* § 1396b(s). *See* Pub. L. 103-66, §§ 13562, 13624, 107 Stat. 312, 604, 636 (1993). Among other things, the law prohibits payment for services furnished pursuant to a prohibited referral, 42 U.S.C. §§ 1395nn(a)(1)(B), 1396b(s), imposing civil penalties in the case of a prohibited referral, *id.* § 1395nn(g). The Stark Law includes several exceptions, *id.* § 1395nn(b)-(e), and authorizes the Secretary of Health and Human Services to make additional exceptions by regulation, where the “financial relationship . . . does not pose a risk of program or patient abuse,” *id.* § 1395nn(b)(4).

One of the exceptions to the referral prohibition is for “[p]ersonal service arrangements.” *Id.* § 1395nn(e)(3). Essentially, this exception covers market-rate, pay-for-service arrangements. In other words, if the physician’s only financial interest in the clinic is receipt of agreed-upon compensation at or below “fair market value” for “reasonable and necessary” services, then the physician may make referrals to the clinic without violating the law. *Id.* § 1395nn(e)(3)(A). The Stark Law, however, limits the extent to which the physician’s compensation may be based on the volume or value of patient referrals. *Id.* at § 1395nn(e)(3)(B). The law defines “fair market value” as “the value in arm[']s length transactions, consistent with the *general market value*.” *Id.* § 1395nn(h)(3) (emphasis added). Obviously, this definition of “fair market value” is critical to determining the scope of the Stark Law exception, and the definition hinges on the term “general market value.”

The Centers for Medicare and Medicaid Services (“CMS”)—formerly called the Health Care Financing Administration (“HCFA”)—is the division within the United States Department of Health and Human Services that oversees regulatory implementation of the Stark Law. In 1998, in a notice of proposed rulemaking, HCFA proposed a set of regulations to clarify and implement the various provisions of the law, including defining “general market value” as “the compensation that would be included in a service agreement, as the result of bona fide bargaining between well-informed parties to the agreement . . . at the time of the service agreement.” 63 Fed. Reg. 1659, 1721 (Jan. 9, 1998). Several comments on this proposed rule focused on how (i.e., with what sort of evidence) a party could establish it had met this standard. 66 Fed. Reg. 856, 944 (Jan. 4, 2001). HCFA responded in 2001 by stating its intent “to accept any method [of proof] that is commercially reasonable and provides us with evidence that the compensation is comparable to what is ordinarily paid for an item or service in

the location at issue, by parties in arm's-length transactions who are not in a position to refer to one another.” *Id.* At the same time, the HCFA issued a final rule defining “general market value” in accord with its proposed rule. *See* 66 Fed. Reg. at 856; 42 C.F.R. § 411.351 (2006).

The 2001 rulemaking did not address several subsections of the Stark Law, and HCFA stated it would address those subsections “shortly” in a “Phase II” rulemaking. 66 Fed. Reg. at 856. In addition, this Phase II rulemaking would address comments received in response to the 2001 rulemaking (i.e., “Phase I”). *Id.* Phase II was completed in 2004, when HCFA (by this time renamed “CMS”) issued an interim final rule, which it planned to finalize within three years. 69 Fed. Reg. 16,054, 16,126 (Mar. 26, 2004). To a large extent, the new rulemaking duplicated portions of the 1998 proposed rulemaking, addressing Stark Law subsections Phase I had not covered. *Id.* at 16,125. However, because a new law (effective December 8, 2003) required the agency to finalize its proposed rules within three years, *see* 42 U.S.C. § 1395hh(a)(3)(B), a question arose about the continuing viability of the 1998 proposal. Although the agency was unsure the new law prohibited the Secretary from finalizing rules proposed more than three years before December 8, 2003, it took the cautious approach of publishing the new rule as an interim final rule with a comment period. *See* 69 Fed. Reg. at 16,125.

In short, CMS restarted the rulemaking process from scratch but waived publication of a notice of proposed rulemaking, finding the customary notice and comment period “impracticable, unnecessary, or contrary to the public interest” because the public had been afforded two prior opportunities to comment and could also comment on the interim final rule. *See id.* at 16,125 (quoting 5 U.S.C. § 553(b)).

As part of this interim final rule, CMS created a safe harbor provision within the existing regulatory definition of “fair market value.” *Id.* at 16,092, 16,128. The agency emphasized the safe harbor was “entirely voluntary; [health service providers] may continue to establish fair market value through other methods.” *Id.* at 16,092. Thus, CMS added the safe harbor to give providers an easy way of proving fair market value, but providers remain free to ignore the safe harbor, and so long as they can show their personal service arrangements are nevertheless at fair-market rates, they are in full compliance with the law. The safe harbor offers two methods for showing that a physician’s hourly rate is at fair market value: (1) by reference to the hourly rate paid to emergency room physicians in the same market, and (2) by averaging the hourly compensation level for physicians in the same specialty, as determined in several national surveys. Specifically, the safe harbor provides as follows:

An 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 the following two methodologies:

(1) The hourly rate is 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.

(2) The hourly rate is determined by averaging the 50th percentile national compensation level for physicians with the same physician specialty (or, if the specialty is not identified in the survey, for general practice) in at least four of the following surveys and dividing by 2,000 hours. [The regulation then lists six salary surveys.]

42 C.F.R. § 411.351.

Plaintiff Renal Physicians Association (“RPA”) brought this action in the district court, challenging the safe-harbor provision as violating the notice-and-comment requirements of the Administrative Procedure Act (“APA”) and as arbitrary and capricious agency action. RPA is “a national, nonprofit specialty society” whose “membership consists of nephrologists, advance practice nurses, and physician assistants specializing in the treatment of patients with kidney disease.” RPA’s complaint adds that “[m]any RPA members are medical directors of outpatient dialysis facilities.” The RPA alleges that a majority of nephrologists serve as medical directors of dialysis providers that own clinical laboratories. If these physicians refer patients to these in-house laboratories for services covered by Medicare or Medicaid, they violate the Stark Law, unless an exception applies. *See* 42 U.S.C. §§ 1395nn(a)(1)(A), 1395nn(h)(6)(A). Similarly, where a nephrologist has a financial relationship with a hospital-based dialysis facility, the physician may not refer patients to the hospital for hospital services covered by Medicare or Medicaid, unless an exception applies. *Id.* §§ 1395nn(a)(1)(A), 1395nn(h)(6)(K). As noted, health service providers that receive referrals in violation of the Stark Law face civil penalties, in addition to nonpayment for services furnished pursuant to the referral. *Id.* §§ 1395nn(a)(1)(B), 1395nn(g), 1396b(s).

The merits of RPA’s challenge to the safe harbor provision are not before us, because the district court dismissed the complaint for lack of standing. The complaint includes several paragraphs of allegations related to standing, though not the redressability aspect of standing. Specifically, RPA alleges:

[O]nly by complying with the safe harbor can a dialysis provider ensure that it will avoid investigation or

prosecution relating to compensation paid to medical directors. Thus, in an effort to obtain the protection of the safe harbor, dialysis providers are likely to limit compensation for medical director services to the amount “allowed” under the safe harbor.

. . . [If this occurs,] a significant number of nephrologists, including RPA members, will experience a substantial reduction in medical director compensation.

. . . .

. . . On the other hand, if nephrologists demand and are paid reasonable compensation, both parties run the risk that HHS will later allege, based upon the safe harbor, that the compensation paid is “excessive” and that the medical director arrangement violates the Stark Law.

. . . In fact, dialysis providers have already begun to insist upon strict compliance with the fair market value safe harbor. RPA members have advised RPA that in negotiating the renewal of a medical director agreement, certain dialysis providers have required reduction of medical director compensation to safe-harbored levels. In at least one instance, that position has resulted in an executed agreement which provides for significantly reduced compensation to an RPA member.

. . . .

. . . If interested parties had been accorded their statutory right to comment on the fair market value safe harbor, the RPA *would have demonstrated* that . . . based upon the use of the safe harbor, the compensation paid to nephrologists for the provision of medical director services

will *significantly and unfairly decrease*, causing RPA members *direct economic injury* and negatively affecting patient care.

....

... The Stark Law did not empower the Secretary to set “fair market value” compensation rates The Stark Law did not authorize the Secretary to reduce arbitrarily the compensation currently paid to physicians, in the free market, for personal services. The fair market value safe harbor *in effect does both*, and does so without benefit of any meaningful record.

. . . The fair market value safe harbor, now fully effective, poses the *threat of imminent economic harm* to RPA members and other medical directors of dialysis facilities who will not be compensated at fair market value. Although the safe-harbored compensation rates are well below the current market rate for medical director services furnished to dialysis providers, *dialysis providers are insisting upon compensating medical directors in accordance with the safe harbor* so as to avoid a governmental investigation or enforcement action.

(Emphases added.)

Despite these allegations regarding direct injury, the district court found RPA failed to meet the three-part test for standing set forth in *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-61 (1992), requiring (1) injury in fact, (2) causation, and (3) redressability. The district court focused on the third prong, concluding RPA could not show its alleged injury would be in any way ameliorated by the relief it was seeking. *Renal Physicians Ass’n v. Dep’t of Health & Human Servs.*, 422 F.

Supp. 2d 75, 83-85 (D.D.C. 2006). Because the safe harbor was merely an available option for proving fair market value, the direct cause of the alleged injury was not the safe harbor but rather the actions the clinics decided to take independently. *Id.*

Moreover, concluded the court, invalidating the safe harbor would not relieve the RPA's alleged injury. At the time of the Phase I rulemaking, the agency clearly announced its intent "to accept any method [of proof] that is commercially reasonable and provides us with evidence that the compensation is comparable to what is ordinarily paid for an item or service in the location at issue, by parties in arm's-length transactions who are not in a position to refer to one another." 66 Fed. Reg. at 944. The safe harbor merely identified two "presumptively reasonable" methods of proof, without restricting parties from relying on other methods of proof. *Renal Physicians Ass'n*, 422 F. Supp. 2d at 84. And, in any event, once the agency had expressed its approval of those two methods, it could not "unring the bell." *Id.* at 85 (quoting *Maness v. Meyers*, 419 U.S. 449, 460 (1975)). Therefore, even if the safe harbor was invalidated, the two methods of proof would still be available to providers and they would still enjoy the implicit approval of the agency, absent a rulemaking expressly disapproving these methods. *Id.* at 84-85. The relief sought in RPA's complaint thus would not redress its alleged injury. *Id.* In reaching these conclusions, the district court relied on this court's decision in *National Wrestling*, a standing decision that likewise involved the independent action of a third party in response to a safe harbor and turned on the question of redressability. 366 F.3d at 933.

The district court granted the government's motion to dismiss, 422 F. Supp. 2d at 86, and RPA filed this appeal.

II

We review a dismissal for lack of standing de novo. *Nat'l Wrestling Coaches Ass'n*, 366 F.3d at 937. “As the Supreme Court explained in [*Lujan*], the burden of production a plaintiff must bear in order to show it has standing to invoke the jurisdiction of the district court varies with the procedural context of the case. At the pleading stage, ‘general factual allegations of injury resulting from the defendant’s conduct may suffice,’ and the court ‘presum[es] that general allegations embrace the specific facts that are necessary to support the claim.’” *Sierra Club v. EPA*, 292 F.3d 895, 898-99 (D.C. Cir. 2002) (quoting *Lujan*, 504 U.S. at 561).

The government emphasizes that the safe harbor is voluntary and that, even if the safe harbor were rescinded, the fair market value requirement would still remain. Therefore, the clinics might take the same action even without the safe harbor. Standing, however, surely cannot be so easily defeated solely on the basis that the challenged regulation creates a *voluntary* safe harbor. Voluntary or not, a safe harbor must achieve *some* useful purpose or an agency would not bother to create it, which suggests that every safe harbor has at least some substantive impact. The extent of this substantive impact turns on the scope of the risk associated with *not* using the safe harbor; the higher the risk, the more likely the safe harbor will attract regulated entities into its calm (litigation free) waters. If an agency uses a safe harbor to coerce parties toward a substantive result the agency prefers, and the safe harbor is voluntary in name only, then the agency is making substantive law.

Here, however, the alleged impact of the safe harbor on RPA members is indirect, the result of the actions of third parties. In *Lujan*, 504 U.S. 555, the Supreme Court emphasized the heightened showing required of a plaintiff alleging injury

from the government’s regulation of a third party:

When . . . a plaintiff’s asserted injury arises from the government’s allegedly unlawful regulation (or lack of regulation) of *someone else*, much more is needed. In that circumstance, causation and redressability ordinarily hinge on the response of the regulated (or regulable) third party to the government action or inaction—and perhaps on the response of others as well. . . . [I]t becomes the burden of the plaintiff to adduce facts showing that . . . choices [of the independent actors] have been or will be made in such manner as to produce causation and permit redressability of injury. Thus, when the plaintiff is not himself the object of the government action or inaction he challenges, standing is not precluded, but it is ordinarily *substantially more difficult to establish*.

504 U.S. at 562 (internal quotation marks and citations omitted; second emphasis added).

We grappled with these competing considerations in *National Wrestling*, a case involving a challenge to a 1979 “Policy Interpretation” of the Department of Education (“DOE”) addressing how colleges could comply with Title IX’s ban on sex discrimination in intercollegiate athletics. *Nat’l Wrestling Coaches Ass’n*, 366 F.3d at 933. The 1979 Policy Interpretation established what became known as the “Three-Part Test,” under which Title IX compliance can be demonstrated in any one of three ways: (1) strictly by the numbers (i.e., athletic opportunities for men and women in proportion to male and female enrollment at the college); (2) by showing that the college has been (and is) expanding programs that serve the underrepresented sex; or (3) by showing that the interest and abilities of the underrepresented sex are fully served by the existing program. *Id.* at 935. The first of the three

options—which was the easiest to objectively demonstrate—was in essence a safe harbor.

The plaintiffs in *National Wrestling* were “several membership organizations that represent the interests of collegiate men’s wrestling coaches, athletes, and alumni.” *Id.* at 933. The organizations claimed injury “from decisions by educational institutions to eliminate or reduce the size of men’s wrestling programs,” allegedly to comply with the first prong of the Three-Part Test. *Id.* at 935. The district court concluded the plaintiffs lacked standing, and we affirmed. *Id.* at 949.

We reasoned that the “direct causes of appellants’ asserted injuries—loss of collegiate-level wrestling opportunities for male student-athletes—are the independent decisions of educational institutions Appellants 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.” *Id.* at 936-37. In our discussion, *id.* at 933, 938-39, we relied on *Lujan* as well as several other Supreme Court decisions holding that standing to challenge a government policy cannot be founded merely on speculation as to what third parties will do in response to a favorable ruling. *See Allen v. Wright*, 468 U.S. 737, 758-59 (1984) (speculative whether change in tax exemption for private schools would lead to a change in school policies); *Simon v. E. Ky. Welfare Rights Org.*, 426 U.S. 26, 42-43 (1976) (speculative whether change in tax rules governing nonprofit hospitals would improve services for indigents); *cf. Warth v. Seldin*, 422 U.S. 490, 504 (1975) (plaintiffs claiming a local zoning ordinance excluded low income residents failed to show they would be able to buy or rent homes in the town if the court granted their requested remedy).

In *National Wrestling*, we also relied on our earlier holding

in *Freedom Republicans, Inc. v. Federal Election Commission*, 13 F.3d 412 (D.C. Cir. 1994). In *Freedom Republicans*, an independent, multiracial organization of Republicans sought to challenge the Federal Election Commission's funding of the Republican National Convention, arguing the party's delegate-selection processes discriminated against minority groups. *Id.* at 413-14. We found that, although the level of government funding was "substantial," the alleged injury was "not fairly traceable to any encouragement on the part of the government," and "we cannot begin to predict . . . what impact withdrawal [of government funding] might have on Party decisionmaking as to . . . delegate-allocation." *Id.* at 419.

The same deficiency that defeated standing in these cases doomed the plaintiffs in *National Wrestling*. Specifically, the plaintiffs had not "suggest[ed] that any particular school necessarily would forego elimination of a wrestling team or reinstate a previously disbanded program in the absence of [the Three-Part Test's safe harbor]." *Nat'l Wrestling Coaches Ass'n*, 366 F.3d at 939. Referencing a comment at oral argument that the plaintiff organizations would have "better odds" of retaining their wrestling programs if the court invalidated the Three-Part Test, we explained that "a quest for ill-defined 'better odds' is not close to what is required to satisfy the redressability prong of Article III." *Id.* We continued:

Even if appellants prevailed on the merits in their challenge to the Three-Part Test, Title IX and the 1975 Regulations 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 the statute and the 1975 Regulations. This is particularly so since Title IX itself permits evidence

of disproportion in the distribution of benefits between sexes to be considered in enforcement proceedings against recipients of federal funding. Moreover, other reasons unrelated to the challenged legal requirements[, such as a desire to do what is morally right,] may continue to motivate schools to take such actions.

Id. at 939-40 (citations omitted).

We identified two categories of cases where standing exists to challenge government action though the direct cause of injury is the action of a third party. First, standing exists where the challenged government action authorized conduct that would otherwise have been illegal. *Id.* at 940. In such cases, if the authorization is removed, the conduct will become illegal and therefore very likely cease. Hence, “[c]ausation and redressability . . . are satisfied in this category of cases, because the intervening choices of third parties are not truly independent of government policy. . . . [T]hey could only preclude redress if those third parties took the extraordinary measure of continuing their injurious conduct in violation of the law.” *Id.* at 940-41.

Second, standing has been found “where the record presented substantial evidence of a causal relationship between the government policy and the third-party conduct, leaving little doubt as to causation and the likelihood of redress.” *Id.* at 941. As examples we cited *Tozzi v. United States Department of Health & Human Services*, 271 F.3d 301 (D.C. Cir. 2001), and *Block v. Meese*, 793 F.2d 1303 (D.C. Cir. 1986). In *Tozzi*, we found a manufacturer had standing to challenge the government’s classification of dioxin as a carcinogen, because there was “little doubt” the government’s authoritative statement would affect demand for the manufacturer’s products. 271 F.3d at 309. Similarly, in *Block*, we found a film distributor had

standing to challenge the government's classification of certain films as "political propaganda," because the distributor submitted several declarations and affidavits detailing specific instances in which potential customers declined to take a film because of the classification. 793 F.2d at 1308.

In other words, to establish redressability at the pleading stage, we required more than a bald allegation; we required that the facts alleged be sufficient to demonstrate a substantial likelihood that the third party directly injuring the plaintiff would cease doing so as a result of the relief the plaintiff sought. *Nat'l Wrestling Coaches Ass'n*, 366 F.3d at 942-44. We did not find such allegations in *National Wrestling*, because a school's decision whether to keep a men's wrestling program might depend on factors having nothing to do with the Three-Part Test, not the least of which was the school's independent desire to shift more resources to women's sports. *Nat'l Wrestling Coaches Ass'n*, 366 F.3d at 939-40. The plaintiffs "offered nothing but 'unadorned speculation' to suggest that the schools covered by Title IX would change their decisions if appellants were to prevail in this case." *Id.* at 943. We continued:

There is nothing in *Tozzi* and *Block* indicating that the third parties whose conduct injured the plaintiffs would have had reason to continue their injurious conduct unaltered in the absence of the challenged government action. In this case, by contrast, the continued vitality of Title IX itself and the 1975 Regulations means that schools must continue to take gender equity into account when designing their athletic programs. And appellants have offered nothing to indicate that the schools will act any differently than they have in the past regarding decisions to comply with Title IX.

Id.

“In sum,” we concluded, “[t]he problem here is that appellants have failed completely to satisfy the redressability prong of Article III standing, for there is nothing to support appellants’ claim that a favorable ruling would alter the schools’ conduct.” *Id.* at 944.

III

Here, as in *National Wrestling*, an agency has created a voluntary safe-harbor provision; various regulated entities have independently chosen to take advantage of the safe harbor; and a party that is indirectly affected by the safe harbor has brought a law suit, challenging it. Under *National Wrestling*, RPA needs to show that the decision of clinics to reduce the hourly wage of medical directors is linked to the continuing existence of the safe-harbor provision such that invalidating the provision will be reasonably likely to cause the clinics to raise the hourly wage. Moreover, it is not enough simply to plead this causative link. *National Wrestling* makes clear that, even at the pleading stage, a party must make factual allegations showing that the relief it seeks will be likely to redress its injury.

RPA claims standing as the representative of its members, who allegedly suffered injury as a result of the safe harbor. *See Hunt v. Wash. State Apple Adver. Comm’n*, 432 U.S. 333, 343 (1977) (“an association has standing to bring suit on behalf of its members when: (a) its members would otherwise have standing to sue in their own right; (b) the interests it seeks to protect are germane to the organization’s purpose; and (c) neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit”). RPA has made detailed allegations regarding some elements of standing, but none regarding redressability. Although RPA alleges that its members were injured, and that the safe harbor was the cause, it does not allege facts showing that even a single hospital or

dialysis center would pay a medical director more if the court held the safe-harbor provision invalid.

In support of standing, RPA supplemented the factual allegations in its complaint with a single affidavit of one of its members: Dr. Joseph Anzalone, a nephrologist, who was the medical director for the dialysis facility at Central Washington Hospital in Washington state. Affidavit of Joseph Anzalone, M.D. (June 9, 2005), Joint Appendix 83. In 2005, after the safe harbor was created, the facility where Dr. Anzalone performed services (and to which he made referrals) reduced his hourly wage, stating its “hands were tied” by a “new federal law.” *Id.* at 84-85. Rather than accept this reduction in his wage, Dr. Anzalone left his post as medical director of the facility, losing \$35,000 in income as a result. *Id.* Since that time, he has not been able to obtain a similar post at another facility, because he has not identified an opening for a medical director position in his area. *Id.* at 85.

Assuming, for purposes of argument, that Dr. Anzalone adequately asserts an injury, causation remains uncertain and redressability is not addressed at all. The affidavit does not even mention the safe-harbor provision in specific terms. Instead, it refers vaguely to a “new federal law,” which might be a reference to the Stark Law in general. Therefore, we really have no way of knowing why the dialysis facility at Central Washington Hospital reduced Dr. Anzalone’s hourly wage, and we cannot assume the safe-harbor provision was a critical factor. Nor do we have even an allegation that vacating the safe harbor would lead to an increase in Dr. Anzalone’s compensation.

Nor does the logic of Dr. Anzalone’s allegations regarding injury and causation make it “likely,” rather than “speculative,” that, if the safe harbor were invalidated or rescinded, the Central Washington Hospital dialysis facility would, in response, raise

the hourly wage it pays its medical director. *Ctr. for Law & Educ. v. Dep't of Educ.*, 396 F.3d 1152, 1157 (D.C. Cir. 2005) (quoting *Lujan*, 504 U.S. at 560-61) (internal quotation marks omitted). It is at least as plausible that, having established the market will easily bear the lower wage, the clinic will maintain the lower wage. See *E. Ky. Welfare Rights Org.*, 426 U.S. at 43 (holding, in a challenge to an IRS revenue ruling allowing favorable tax treatment to nonprofit hospitals that offered indigents only emergency room service, that the plaintiffs failed to establish redressability where, if such treatment were rescinded, it was “just as plausible that the hospitals to which [the plaintiffs] may apply for service would elect to forgo favorable tax treatment to avoid the undetermined financial drain of an increase in the level of uncompensated services” as it was that the “suit would result in the availability to [the plaintiffs] of such services”) (quoted in *Nat'l Wrestling Coaches Ass'n*, 366 F.3d at 938). If one effect of the safe harbor has been to lower wages for medical directors, a secondary effect has been to demonstrate to dialysis facilities that they can pay lower wages and still function effectively. Thus, it is “speculative,” rather than “likely,” that invalidating the safe harbor will somehow cause these facilities to pay more. The effect (if any) of the safe harbor cannot be simply undone.

There is a related point that the trial court found particularly persuasive, as do we. Even if a court invalidated the safe harbor, dialysis facilities would remain obligated under the Stark Law to pay no more than fair market value for medical director services, and CMS policy makes clear, in this regard, that a facility can offer any method of proof “that is commercially reasonable and provides [the agency] with evidence that the compensation is comparable to what is ordinarily paid . . . in the location at issue, by parties in arm's-length transactions who are not in a position to refer to one another.” 66 Fed. Reg. at 944. The effect of the safe-harbor provision has been to identify one

relatively simple method of proof CMS finds persuasive, and there is no reason to think CMS will find this method of proof any less persuasive if the safe harbor is invalidated. *See Renal Physician Ass'n*, 422 F. Supp. 2d at 84-85. Indeed, the gravamen of RPA's complaint is that the safe harbor sets compensation rates *below* market, and there thus can be no doubt that a dialysis facility or hospital complies with the Stark Law if its compensation rates are set in accordance with the safe harbor methodologies. *See* 42 U.S.C. § 1395nn(e)(3)(A) (approving of compensation rates that “do[] *not exceed* fair market value” (emphasis added)). In short, the word is already out, and therefore it is too late to reverse course. Even if a court were to declare the safe harbor invalid, the same dialysis facilities that have opted to rely on the safe harbor will be likely to continue to rely on the safe-harbor method of proof, knowing with some assurance that the agency will be likely to accept this proof as indicative of fair market value. Indeed, the only way to prevent this result would be for a court not only to invalidate the safe harbor but also to repudiate the safe harbor as an acceptable method of proof, but RPA does not suggest any legal basis for such relief, nor does it seek such relief.

In sum, RPA has not satisfied the redressability prong of the standing requirement, because it has not alleged any facts showing that an order invalidating the safe harbor will likely cause dialysis facilities to increase the wages of RPA members. Specifically, RPA failed to allege facts showing that even a single hospital or dialysis center would pay a medical director more, or would forgo a planned pay cut, if the court held the safe-harbor provision invalid.

In reaching this conclusion, we do not read *National Wrestling* more broadly than is warranted by the facts of that case. We see *National Wrestling* as standing for two simple points, neither of which constitutes a shift in the law of standing,

but both of which doom RPA's claim of standing here. First, although less is required to survive a motion to dismiss than a motion for summary judgment, *National Wrestling* makes clear that a bald allegation of standing is not enough to survive even a motion to dismiss where neither the factual allegations nor their logic establish redressability. *See Nat'l Wrestling Coaches Ass'n*, 366 F.3d at 938, 941-43. Second, *National Wrestling* confirms that causation does not inevitably imply redressability. *See id.* at 937, 942-43. There might be some circumstances in which governmental action is a substantial contributing factor in bringing about a specific harm, but the undoing of the governmental action will not undo the harm, because the new status quo is held in place by other forces. That was the case in *National Wrestling*, where the independent desire of colleges to balance their athletic programs worked to hold in place changes that might have been influenced at the outset by the Department of Education's policies. *Id.* at 939-40. Likewise, that is the case here, where the independent choice of the dialysis facilities, seeking to keep costs down and avoid the risks of litigation, will hold in place the alleged effect of the safe harbor even if a court were to invalidate the safe harbor.

IV

RPA argues a lesser showing of redressability suffices here because it is alleging an injury to procedural rights. *See Lujan*, 504 U.S. at 572 n.7. This argument also fails, however.

The point of the lower standard for redressability in a procedural-injury case is that the injury in such a case is not associated only with the substantive decision the agency reached but also with the agency's failure to follow proper procedures in reaching that decision. Therefore, in a procedural-injury case, a plaintiff need not show that better procedures would have led to a different substantive result. *See Nat'l Parks Conservation*

Ass'n v. Manson, 414 F.3d 1, 5 (D.C. Cir. 2005); *Sugar Cane Growers Coop. v. Veneman*, 289 F.3d 89, 94-95 (D.C. Cir. 2002). Nevertheless, to have standing to bring a procedural-injury case, the procedure at issue must be one designed to protect a threatened interest of the plaintiff. *Lujan*, 504 U.S. at 573 n.8; *Nat'l Parks Conservation Ass'n*, 414 F.3d at 5; *Fla. Audubon Soc'y v. Bentsen*, 94 F.3d 658, 664 (D.C. Cir. 1996). Moreover, though the plaintiff in a procedural-injury case is relieved of having to show that proper procedures would have caused the agency to take a different substantive action, the plaintiff must still show that the agency action was the cause of some redressable injury to the plaintiff. *Ctr. for Law & Educ.*, 396 F.3d at 1157, 1160. Therefore, here, RPA must show the safe harbor inflicted on it or its members a redressable injury. For the reasons already stated, it has failed to do so.

V

We agree with the district court that RPA lacks standing to bring its case because it has not shown that a ruling in its favor will redress the injury it alleges. The dismissal for lack of subject matter jurisdiction is therefore

Affirmed.