

**December 11, 2008**

**Elisabeth A. Shumaker**  
Clerk of Court

PUBLISH

**UNITED STATES COURT OF APPEALS**

**TENTH CIRCUIT**

PROTOCOLS, LLC, also known as  
Medical Settlement Protocols, LLC;  
SAGRILLO HAMMOND DINEEN &  
KASTETTER, LLC,

Plaintiffs - Appellants,

v.

No. 07-1175

MICHAEL O. LEAVITT, in his  
capacity as the Secretary of the  
Department of Health and Human  
Services; KERRY N. WEEMS,\* in his  
capacity as Acting Administrator of  
the Centers for Medicare and Medicaid  
Services,

Defendants - Appellees.

**APPEAL FROM THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF COLORADO  
(D.C. NO. 1:05-CV-1492-BNB)**

Jason B. Wesoky (Benjamin A. Kahn, with him on the briefs), Brownstein Hyatt  
Farber Schreck, P.C., Denver, Colorado, for Plaintiffs - Appellants.

Michael C. Johnson, Assistant United States Attorney (Troy A. Eid, United States  
Attorney, with him on the brief), Denver, Colorado, for Defendants - Appellees.

\*We substitute Kerry N. Weems for the original defendant, Mark B.  
McClellan, per Fed. R. App. P. 43(c)(2).

---

Before **TACHA**, **HARTZ**, Circuit Judges, and **DEGIUSTI**,\*\* District Judge.

---

**HARTZ**, Circuit Judge.

---

Plaintiff Protocols, LLC and the law firm Sagrillo Hammond Dineen and Kastetter, LLC (collectively, Protocols) provide consulting services for the settlement of workers' compensation claims. Protocols' claimed expertise is structuring settlements that comply with Medicare regulations—in particular, regulations designed to assure that Medicare is treated fairly in settlements of workers' compensation claims by persons eligible for Medicare benefits. Protocols brought this declaratory-judgment action against Defendants Michael O. Leavitt, the Secretary of the United States Department of Health and Human Services (HHS), and Dr. Mark B. McClellan, then the Administrator of the Centers for Medicare and Medicaid Services (CMS), which is an agency within HHS. The suit claims that a CMS memorandum issued in 2005 misinterprets the Medicare statute and regulations and exposes Protocols to unexpected liabilities arising out of settlements it has structured.

Defendants moved for summary judgment on several grounds. The district court granted the motion but on a ground not raised by Defendants—namely, that

---

\*\* Honorable Timothy D. DeGiusti, United States District Court Judge, Western District of Oklahoma, sitting by designation.

Protocols lacked constitutional standing because it had not suffered the requisite injury. Protocols appeals. We reverse because Protocols' potential liability presents a sufficient injury to confer standing under Article III of the United States Constitution. We remand to the district court for further proceedings, including consideration of Defendants' other arguments for summary judgment.

## **I. BACKGROUND**

### **A. The Regulatory Scheme**

To explain how Protocols may be exposed to liability arising out of its consulting services in workers' compensation cases, we begin by outlining some of the law governing the relationship between Medicare and workers' compensation medical benefits. The Medicare Secondary Payer statute, 42 U.S.C. § 1395y(b), provides that Medicare will ordinarily not pay medical expenses if workers' compensation insurance has paid "or can reasonably be expected to" pay for the expenses. *Id.* § 1395y(b)(2)(A)(ii). Medicare may, however, pay for an expense when the availability of workers' compensation insurance is unknown or prompt payment under such coverage is not expected. *See id.* § 1395y(b)(2)(B)(i) (permitting conditional Medicare payment when prompt insurance payment is not expected); 42 C.F.R. § 411.21 (defining *conditional payment* to include a Medicare payment made because of lack of knowledge of other coverage). If such a Medicare payment is made, CMS may seek reimbursement from the insurer or from one who receives payment from the insurer, if the insurer was responsible

for the expense. *See* 42 U.S.C. § 1395y(b)(2)(B)(ii); 42 C.F.R. § 411.22. If reimbursement is not made, CMS may sue the insurer or the recipient of a workers' compensation payment, *see* 42 U.S.C. § 1395y(b)(2)(B)(iii); 42 C.F.R. § 411.24, although CMS may waive its rights in the best interests of Medicare, *see* 42 U.S.C. § 1395y(b)(2)(B)(v); 42 C.F.R. § 411.28.

Of course, when a worker makes a workers' compensation claim, there may be doubt concerning whether the worker's medical expenses are compensable. The insurer may question whether the worker was injured, whether the injury arose in the course of employment, or whether the medical expense relates to the injury. Such questions may be litigated, but they are often settled. The settlement is likely to affect Medicare's responsibility to pay for the worker's medical expenses. So long as workers' compensation medical benefits are available, Medicare is relieved of responsibility. But if the settlement limits or eliminates the duty of the workers' compensation insurer to pay medical benefits, Medicare would be responsible for the payment.

As a result, the settling parties have an incentive to structure their settlement in a way that transfers liability from the insurer to Medicare, because such an arrangement can make both of them better off. This incentive can result in a settlement that is "unfair" to Medicare. For example, assume that a "fair" allocation of the settlement payment would be \$X to the worker for lost wages and \$Y set aside to pay for medical benefits. Further assume that the \$Y would

pay for medical services that would otherwise be payable by Medicare, so the worker gets no benefit from the \$Y. The worker and the insurer would be better off if the settlement is restructured so that no part of the settlement is allocated to medical benefits and the lost-wages allocation is correspondingly increased (even if not increased by the full \$Y, but by, say, \$Y-Z). The worker is better off by \$Y-Z (the increase in lost-wages benefits) and loses nothing by having Medicare, rather than the insurer, pay medical benefits. The insurer for its part saves \$Z (because it is replacing a payment of \$Y in medical benefits by an increase of \$Y-Z in its payment of lost-wages benefits). But Medicare now must incur \$Y of expenses that would have been paid by the insurer under a “fair” allocation of settlement proceeds.

To avoid this subsidization by Medicare, the regulations under the Medicare Secondary Payer statute permit CMS to refuse to recognize a workers’ compensation settlement. *See* 42 C.F.R. § 411.46(b)(2). Medicare then would not pay for treatment that should have been covered by workers’ compensation. And if Medicare had paid for such treatment before realizing that workers’ compensation should have paid for it, CMS could seek reimbursement from the workers’ compensation insurer or from someone who had received part of a workers’ compensation settlement. Protocols, which typically receives a fee from the settlement proceeds, might therefore have to relinquish its fee to CMS.

On the other hand, if CMS recognizes (approves) a workers' compensation settlement, the workers' compensation insurer—and the recipients of the settlement payment—bear no liability for medical expenses beyond what is provided in the settlement. One regulation, 42 C.F.R. § 411.47, describes an acceptable method for apportioning a settlement payment between lost-wage benefits and medical benefits. For purposes of this appeal, we need not describe the specifics of § 411.47. Suffice it to say that Protocols asserts that it has structured settlements involving future medical benefits (that is, payments for medical expenses that have not been incurred by the time of the settlement) by following § 411.47.

This suit arose after CMS clearly rejected such use of § 411.47, declaring that it applies only to medical expenses incurred before the workers' compensation settlement. In a memorandum issued on July 11, 2005 (the 2005 Memo), it said.

Q11. Compromising of Future Medical Expenses – Does CMS compromise or reduce future medical expenses related to a [workers' compensation] injury?

A11. No. Some submitters have argued that 42 C.F.R. § 411.47 justifies reduction to the amount [set aside for Medicare in a workers' compensation settlement]. The compromise language in this regulation only addresses conditional (past) Medicare payments. The CMS does not allow the compromise of future medical expenses related to a [workers' compensation] injury.

App. at 32 (Medicare Secondary Payer (MSP)—Workers' Compensation (WC) Additional Frequently Asked Questions memorandum) *available at*

<http://www.cms.hhs.gov/WorkersCompAgencyServices/Downloads/>

71105Memo.pdf (bold type omitted). The 2005 Memo also stated that there is no appeal from the CMS determination of the proper amount to be set aside for future medical expenses. *See id.* at 32–33.

## **B. Proceedings Below**

On August 5, 2005, a month after the issuance of the 2005 Memo, Protocols filed suit against Defendants in the United States District Court for the District of Colorado. The Complaint alleged that the 2005 Memo was contrary to the prior practice of CMS and sought a declaratory judgment that, among other things, the 2005 Memo is invalid because (1) it conflicts with the Medicare Secondary Payer statute and 42 C.F.R. § 411.47; (2) 42 C.F.R. § 411.47 provides a valid method for structuring settlements to account for future medical expenses; (3) the government bears the burden to prove noncompliance with 42 C.F.R. § 411.46 and, contrary to the 2005 Memo, there is a constitutional right to an appeal of an adverse decision; and (4) the 2005 Memo was promulgated without compliance with the rulemaking procedures established by the Administrative Procedure Act (APA). Protocols' complaint also seeks relief because CMS no longer reduces the amount to be recovered by Medicare out of a settlement by taking into account the costs (including legal fees) of procuring the settlement.

Defendants moved for summary judgment. With respect to Protocols' challenges to the 2005 Memo, they primarily argued that (1) Protocols lacked

standing, but on prudential, rather than constitutional, grounds; (2) the district court lacked jurisdiction because the 2005 Memo was not a “final agency action” under the APA, *see* 5 U.S.C. § 704; (3) the court also lacked jurisdiction because 42 U.S.C. § 405(g) is the exclusive waiver of sovereign immunity for claims under the Medicare Act and Protocols failed to exhaust its administrative remedies as required to proceed under § 405(g); (4) the 2005 Memo is consistent with 42 C.F.R. § 411.47; and (5) the 2005 Memo merely provides guidance, and is therefore not subject to the APA’s requirements for promulgation of regulations. (These grounds may have merit, but the district court did not address them; nor do we. *See Pac. Frontier v. Pleasant Grove City*, 414 F.3d 1221, 1238 (10th Cir. 2005) (“Where an issue has been raised, but not ruled on, proper judicial administration generally favors remand for the district court to examine the issue initially.”).)

In support of standing, Protocols argued that the 2005 Memo threatens the company with liability for settlements it has structured in the past. It submitted affidavits from its founder, Robert L. Sagrillo, and from a certified public accountant, Daniel Seff, indicating that Protocols had submitted proposed settlements structured in a manner that appears contrary to the 2005 Memo; that the manner in which CMS reviews settlements “is not published, is secretive, and is clearly violative of the applicable law,” App. at 334; that the settlements



arranged by Protocols exposed it to liability; and that this contingent liability caused present harm to the financial strength and fiscal planning of the company.

The district court granted summary judgment in favor of Defendants on the ground that Protocols lacked standing under Article III of the United States Constitution because its alleged injury was not “concrete and actual or imminent.” *Protocols, LLC v. Leavitt*, No. 05-cv-01492, 2007 WL 757644, at \*6 (D. Colo. Mar. 8, 2007) (*Protocols*). In particular, the court stated that Protocols had not presented evidence “that Medicare has actually reviewed a proposed set-aside in a way that is not published, is secretive and is clearly violative of the applicable law.” *Id.* (internal quotation marks omitted). As to Protocols’ claim that CMS was not giving proper credit for the costs of procuring a settlement, the court said that Protocols had failed to submit any evidence that it had suffered a concrete injury from the alleged illegality. *See id.* at \*7.

## **II. DISCUSSION**

### **A. Standard of Review**

On the issue of standing we review legal conclusions de novo. *See Wyoming ex rel. Crank v. United States*, 539 F.3d 1236, 1241 (10th Cir. 2008). We ordinarily review any underlying fact finding for clear error. *See Preminger v. Peake*, 536 F.3d 1000, 1005 n.3 (9th Cir. 2008); *Houston Chronicle Publ’g Co. v. City of League City*, 488 F.3d 613, 617 (5th Cir. 2007); *Gen. Instrument Corp.*

*v. Nu-Tek Elec. & Mfg., Inc.*, 197 F.3d 83, 86 (3d Cir. 1999). But because this appeal is from a summary judgment, there is no fact finding to review.

## **B. Standing**

Article III of the United States Constitution restricts the judicial authority to deciding “Cases” and “Controversies.” U.S. Const. art. III § 2. The case-or-controversy requirement “is satisfied only where a plaintiff has standing.” *Sprint Commc’ns Co. v. APCC Servs., Inc.*, 128 S. Ct. 2531, 2535 (2008). To satisfy the standing requirement, a plaintiff must have “such a personal stake in the outcome of the controversy as to assure that concrete adverseness which sharpens the presentation of issues upon which the court so largely depends for illumination.” *Massachusetts v. EPA*, 127 S. Ct. 1438, 1453 (2007) (internal quotation marks omitted). Accordingly, standing depends on the plaintiff’s showing (1) “an injury in fact that is both concrete and particularized as well as actual or imminent”; (2) a causal relationship between the injury and the challenged conduct; and (3) a likelihood that the injury would be redressed by a favorable decision. *Wyoming ex rel. Crank*, 539 F.3d at 1241. This showing “must be supported in the same way as any other matter on which the plaintiff bears the burden of proof, *i.e.*, with the manner and degree of evidence required at the successive stages of the litigation.” *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 561 (1992). In particular, to avoid a summary judgment, the plaintiff “must set forth by affidavit

or other evidence specific facts” supporting standing. *Id.* (internal quotation marks omitted). We address each element in turn.

As we understand Protocols’ standing argument, it asserts that over the years it has arranged for workers’ compensation settlements that were acceptable to CMS at the time but that CMS now would refuse to recognize under the 2005 Memo. Liability of Protocols could therefore result as follows: When CMS refuses to recognize a settlement, the settlement does not relieve the workers’ compensation insurer of the obligation to pay postsettlement medical expenses that would otherwise be covered by workers’ compensation. If Medicare pays for such an expense, it would then be entitled to reimbursement (and could sue to collect) from anyone who received part of the settlement paid by the insurer. Because Protocols received consulting fees out of the settlement payment, it could be liable to repay that sum. Protocols will not know whether it has a liability, however, until Medicare pays a postsettlement medical expense and then decides to seek reimbursement from Protocols. According to affidavits submitted by Protocols, this potential (contingent) liability hanging over it hampers its business in several ways: (1) the company’s value is decreased because of contingent liabilities; (2) the uncertainty of the liability harms Protocols’ ability to plan how much revenue it may use for capital and operating costs; and (3) the company has postponed discussions with potential investors while awaiting the outcome of this lawsuit, because potential investors want to know about contingent liabilities.

In our view, Protocols has established the three elements of constitutional standing. The contingent liability it identifies presents an injury in fact, it is caused by the refusal of CMS to recognize the validity of settlements structured by Protocols, and a ruling favorable to Protocols would eliminate Protocols' potential liability and the consequences of that potential liability.

To begin with, courts—including the Supreme Court, both explicitly and implicitly—have recognized that contingent liability may present an injury in fact. To be sure, an injury in fact must be “actual or imminent,” *Wyoming ex rel. Crank*, 539 F.3d at 1241, and a contingent liability, by definition, may not arise for a considerable time, if ever. The consequences of a contingent liability, however, may well be actual or imminent. The explicit recognition of this proposition is in *Clinton v. City of New York*, 524 U.S. 417 (1998), which considered the constitutionality of line-item vetoes. Congress had passed a bill whose provisions included relief to New York State from liability for as much as \$2.6 billion in health-care-related taxes owed to the federal government. *Id.* at 422. But President Clinton exercised a line-item veto to eliminate that relief when he signed the bill. *See id.* at 422–23. The City,<sup>\*\*\*</sup> which would be assessed by the State for part of the State's tax liability if the line-item veto were upheld, challenged the constitutionality of the veto. The President raised several

---

<sup>\*\*\*</sup>The City had coplaintiffs in its challenge to the line-item veto, but for convenience we will refer to all plaintiffs collectively as the City.

arguments against the City's standing. One argument was that the City's injury was speculative because it still had the right to try to secure a waiver of its tax liability from the Department of Health and Human Services. *See id.* at 430. The Court rejected this argument. The possibility of a waiver did not extinguish the City's injury, it said, because the City "suffered an immediate, concrete injury the moment that the President used the Line Item Veto . . . and deprived [it] of the benefits of the [vetoed] law." *See id.* (internal quotation marks omitted). The Court analogized the line-item veto to a "judgment of an appellate court setting aside a verdict for the defendant and remanding for a new trial of a multibillion dollar damages claim" when the outcome of the second trial is in doubt. *Id.* at 430–31. It concluded that an injury in fact existed because the "revival of a substantial contingent liability immediately and directly affects the borrowing power, financial strength, and fiscal planning of the potential obligor." *Id.* at 431. These immediate and direct effects were certainly actual and imminent.

A second Supreme Court decision offers substantial support for the proposition that a contingent liability can confer standing, although the Court did not explicitly speak in terms of standing. In *Aetna Life Insurance Co. v. Haworth*, 300 U.S. 227 (1937), the insurer brought a declaratory-judgment action to determine the validity of disability-insurance policies for which the insured had ceased to pay premiums. *See id.* at 237–38. The insured had claimed that he had been excused from paying premiums, and was entitled to benefits, because he was

suffering from a disability that had begun before the unpaid premiums were due. *See id.* at 238. The insured, however, had not brought suit against the insurer. *See id.* at 239. The insurer then filed suit because of its concern about having to maintain reserves exceeding \$20,000 to cover the potential liability and about the possible loss of evidence over time. *See id.* Although the Declaratory Judgment Act at the time permitted actions “[i]n cases of actual controversy,” *id.* at 236 n.1 (quoting 1934 version of the Act), the district court ruled that Aetna’s complaint “did not set forth a controversy in the constitutional sense and hence did not come within the legitimate scope of the statute,” *id.* at 236 (internal quotation marks omitted). Aetna petitioned for a writ of certiorari, and the Supreme Court reversed. The Court agreed with the district court that the Declaratory Judgment Act’s use of the phrase “cases of actual controversy” manifestly has regard to the constitutional provision and is operative only in respect to controversies which are such in the constitutional sense.” *Id.* at 239–40. But it disagreed with the lower court’s view that Aetna had not presented a controversy. The Court’s discussion invoked concepts now commonplace in standing analysis, stating for example that a “controversy” must not be “hypothetical or abstract,” but “must be definite and concrete, touching the legal relations of parties having adverse legal interests.” *Id.* at 240–41. And “[i]t must be a real and substantial controversy admitting of specific relief through a decree of conclusive character.” *Id.* at 241; *see Surefoot LC v. Sure Foot Corp.*,

531 F.3d 1236, 1240 (10th Cir. 2008) (Declaratory Judgment Act’s “‘actual controversy’” language imposes “a requirement the Supreme Court has repeatedly equated to the Constitution’s case-or-controversy requirement”). Aetna’s complaint presented a controversy because the parties “had taken adverse positions with respect to their existing obligations,” *Aetna Life*, 300 U.S. at 242, and a declaratory judgment could “definitely and finally adjudicate[.]” the rights of the parties, *id.* at 243. By holding that Aetna’s contingent liability presented a “controversy” under Article III, the Court necessarily held that standing can be predicated on such liability. *See Sprint*, 128 S. Ct. at 2535 (Article III can be satisfied only if plaintiff has standing).

Several circuit-court opinions further support the proposition that a contingent liability can present a sufficient injury for Article III standing. *See Lac Du Flambeau Band of Lake Superior Chippewa Indians v. Norton*, 422 F.3d 490, 498 (7th Cir. 2005) (“[T]he present impact of a future though uncertain harm may establish injury in fact for standing purposes.”); *Walters v. Edgar*, 163 F.3d 430, 434 (7th Cir. 1998) (“A probabilistic harm, if nontrivial, can support standing.”); *see also Jones v. Gale*, 470 F.3d 1261, 1267 (8th Cir. 2006) (feedlot owner had standing to challenge constitutionality of law that would prevent him from entering into certain contracts with out-of-state corporations; even though he had not entered into such a contract, the law negatively affected his “ability to earn income, borrow, and plan for [his] financial future”).

In light of this precedent, we conclude that Protocols has suffered an actual injury. It admits that it has arranged settlements that are contrary to what CMS has declared to be required. As a result, CMS may sometime in the future demand that Protocols reimburse Medicare for Protocols' portion of settlement proceeds. And according to affidavits submitted by Protocols, this potential liability has a present impact on its business—that is, the contingent liability has created an actual and imminent injury.

The other elements of standing—causation and redressability—follow readily from the above. Protocols' contingent liability is caused by CMS's interpretation of the Medicare Secondary Payer statute and the regulations under that law. And a favorable decision by the court in this case would resolve that Protocols' past practice conforms to Medicare law, so Protocols would no longer be facing possible (contingent) liability.

The district court ruled that Protocols had not shown an actual injury because it had not shown that the 2005 Memo was inconsistent with CMS's prior evaluation of workers' compensation settlements. On appeal, Defendants have endorsed that ruling. This view regarding Protocols' injury is understandable because Protocols repeatedly speaks of its injury as being the result of the change effected by the memo. But it is CMS's present position, regardless of whether that position was different before 2005, that has created Protocols' contingent liability. If the rule stated in the 2005 Memo had been favorable to Protocols'



prior practice, Protocols would not have cared whether the memo was inconsistent with prior CMS practice and would not have filed suit. What injures Protocols is that CMS's current view, even if consistent with CMS's prior view, is contrary to Protocols' prior practice, thereby exposing Protocols to liability. And Protocols has made the factual showing necessary to establish that injury. Protocols' chief executive undoubtedly would know how Protocols constructed settlements in the past, and Defendants do not dispute that CMS's present view of the law is contrary to Protocols' understanding and contrary to the manner in which Protocols has constructed settlements.

Likewise, we believe that the district court missed the mark in stating its ground for ruling that Protocols lacks standing. The court said that Protocols had not supported its chief executive's assertion that CMS is reviewing settlement set-asides "in a way that is 'not published, is secretive, and is clearly violative of the applicable law.'" *Protocols*, 2007 WL 757644, at \*6. The issue relevant to standing, however, is only whether CMS is taking a position contrary to Protocols' past practice. Whether CMS has done so in a secretive manner does not affect whether Protocols has been injured.

### **III. CONCLUSION**

For the purposes of summary judgment Protocols has established Article III standing. We therefore REVERSE the judgment below and REMAND to the

district court for further proceedings, including a decision on Defendants' other arguments for summary judgment.