FOR PUBLICATION

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

LOS ANGELES HAVEN HOSPICE, INC., a California corporation, *Plaintiff-Appellee,* v. KATHLEEN SEBELIUS, Secretary of United States Department of Health and Human Services Substituted for Michael O. Leavitt, *Defendant-Appellant.*	No. 09-56391 D.C. No. 2:08-cv-04469-GW-R OPINION

Appeal from the United States District Court
for the Central District of California
George H. Wu, District Judge, Presiding

Argued and Submitted
October 6, 2010—Pasadena, California

Filed March 15, 2011

Before: Cynthia Holcomb Hall*, Raymond C. Fisher, and Jay S. Bybee, Circuit Judges.

Opinion By Judge Hall

*Judge Hall fully participated in oral argument and the post-argument conference of the panel. Prior to her death, she circulated the opinion in which all judges concur.

COUNSEL

Nicholas Bagley and Benjamin M. Shultz, Department of Justice, Civil Division, Washington, D.C., for the defendant-appellant.

Brian M. Daucher, Sheppard, Mullin, Richter & Hampton, Costa Mesa, California, for the plaintiff-appellee.

OPINION

HALL, Circuit Judge:

The Secretary of Health and Human Services ("the Secretary") appeals a summary judgment in favor of Los Angeles Haven Hospice, Inc. ("Haven Hospice"), in this action challenging the so-called "hospice cap regulation," 42 C.F.R. § 418.309, pursuant to which Haven Hospice was ordered to repay more than $2.3 million it received in excess of the annual cap on reimbursement for hospice care it provided to Medicare beneficiaries in fiscal year 2006 ("FY 2006"). The district court declared the hospice cap regulation to be arbitrary, capricious, and contrary to law and, thus, invalid. It then set aside the FY 2006 repayment demand, ordered HHS to return the amounts Haven Hospice had already paid to satisfy that demand, and entered an injunction barring further enforcement of the unlawful regulation against Haven Hospice and all other certified hospice service providers nationwide.

The Secretary contends that Haven Hospice lacks standing to mount a facial challenge to the hospice cap regulation, and that the regulation is, in any event, a reasonable interpretation of the "hospice cap statute," 42 U.S.C. § 1395f(i)(2). The Secretary further contends that the district court exceeded its jurisdiction and abused its discretion by entering an overly broad injunction.

We conclude that Haven Hospice has Article III standing to challenge the hospice cap regulation, and that the district court had jurisdiction pursuant to 42 U.S.C. § 1395oo(f)(1) to determine the validity of the hospice cap regulation. We further conclude that the hospice cap regulation is facially invalid under the first prong of the test prescribed by the Supreme Court in *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984) ("*Chevron*"), and that the district court had the authority to enjoin further

enforcement of the regulation. However, because the injunction entered by the district court is more burdensome to the defendant than necessary to provide complete relief to the plaintiff before the court, we vacate the injunction to the extent it bars enforcement of the hospice cap regulation against hospice providers other than Haven Hospice.

I.

A.

Since 1982, Medicare Part A has included a hospice benefit for terminally-ill patients. *See* Tax Equity and Fiscal Responsibility Act of 1982 ("TEFRA"), Pub. L. No. 97-248, 96 Stat. 324, 356-63 (1982) (codified as amended at 42 U.S.C. § 1395c, et seq.). A Medicare beneficiary may elect hospice care if at least two physicians certify that he or she is terminally ill, with a life expectancy of six months or less. *See* 42 U.S.C. §§ 1395f(a)(7)(A), 1395x(dd)(3)(A).

Medicare generally pays certified hospice providers a fixed amount for each day they provide care to an eligible beneficiary. 42 U.S.C. § 1395f(i)(1); *see also* 42 C.F.R. § 418.302 (establishing rates). When the hospice benefit was established in 1982, beneficiaries were generally limited to six months of hospice care. *See* TEFRA, § 122, 96 Stat. at 356. However, under an amendment included in the Balanced Budget Act of 1997, Pub. L. No. 105-33, § 4443(a), 111 Stat. 251, 423 (1997), if a beneficiary lives longer than six months, coverage may be extended for an unlimited number of sixty-day periods. *See* 42 U.S.C. § 1395d(d)(1).

To ensure that payments for hospice care for qualified beneficiaries would not exceed the cost of care in a conventional setting, Congress established a retrospective "cap" on the aggregate amount that Medicare would reimburse hospice providers each year. H.R. Rep. No. 98-333, at 1 (1983), reprinted in 1983 U.S.C.C.A.N. 1043, 1043-44 (Jul. 28,

1983). To calculate the hospice cap for a provider for a particular fiscal year, a "cap amount" is multiplied by "the number of [M]edicare beneficiaries in the hospice program in that year." 42 U.S.C. § 1395f(i)(2)(A). The cap amount initially set by statute was $6,500 per beneficiary, subject to annual adjustment to reflect any increase or decrease in the Consumer Price Index for medical care expenditures. Pub. L. No. 98-90, 97 Stat. 606 (1983) (codified at 42 U.S.C. § 1395f(i)(2)(B)). Unsurprisingly, the cap amount per beneficiary has steadily increased since 1983: for FY 2005, it was $19,778; for FY 2006, it was $20,585; for FY 2009, it was $23,015; and for FY 2010, it was $23,875.[1]

When it enacted the hospice cap statute, Congress defined the term "number of Medicare beneficiaries" as follows:

> [T]he "number of [M]edicare beneficiaries" in a hospice program in an accounting year is equal to the number of individuals who have made an election [to enter hospice care] and have been provided hospice care by . . . the hospice program under this part in the accounting year, *such number reduced to reflect the proportion of hospice care that* ***each such individual*** *was provided in a previous or subsequent accounting year* or under a plan of care established by another hospice program.

42 U.S.C. § 1395f(i)(2)(C) (emphasis added).

In 1983, the Department of Health and Human Services ("HHS") promulgated and adopted the hospice cap regulation

[1]The Centers for Medicare and Medicaid Services ("CMS") publish an annual update to their claims processing manual to provide information about the aggregate cap amount for the fiscal year. *See, e.g.*, *Update to Hospice Payment Rates, Hospice Cap, Hospice Wage Index, and the Hospice Pricer for FY 2011* (July 23, 2010), *https://www.cms.gov/transmittals/downloads/R2004CP.pdf*.

challenged in this case, 42 C.F.R. § 418.309, and has used it ever since to calculate each provider's aggregate "cap" for each accounting year. Under the regulation, the cap period runs from November 1 to October 31 of the following year, 42 C.F.R. § 418.309(a), with the relevant "number of Medicare beneficiaries" who received hospice care from a single provider defined as follows:

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

42 C.F.R. § 418.309(b)(1). Thus, under the hospice cap regulation, terminally ill beneficiaries who entered hospice between September 28, 2005, and September 27, 2006, were counted in the cap calculation for FY 2006.

The hospice cap regulation provides a different methodology—one more in keeping with the statutory mandate—for counting "the number of Medicare beneficiaries" who elected to receive care from more than one hospice provider, as follows:

> In the case in which a beneficiary has elected to receive care from more than one hospice, each hospice includes in its number of Medicare beneficiaries only that *fraction* which represents the portion of a patient's total stay in all hospices that was spent in that hospice.

42 C.F.R. § 418.309(b)(2) (emphasis added). The regulation specifies that a hospice can obtain information to determine

the "fraction" of care it provided to a given beneficiary in a given year by contacting its fiscal intermediary.[2] *Id.*

When HHS first proposed rules to implement the hospice cap in 1983, the agency acknowledged the statutory directive to make a proportional allocation of the "number of Medicare patients" across years of service, as follows:

> The statute specifies that the number of Medicare patients used in the calculation is to be adjusted to reflect the portion of care provided in a previous or subsequent reporting year or in another hospice.

48 Fed. Reg. 38146, 38158 (Aug. 22, 1983). HHS nevertheless declared that:

> With respect to the adjustment necessary to account for situations in which a beneficiary's election overlaps two accounting periods, we are proposing to count each beneficiary only in the reporting year in which the preponderance of the hospice care would be expected to be furnished *rather than attempt to perform a proportional adjustment*.

Id. (emphasis added). In other words, HHS proposed that the regulation would *not* provide for the proportional allocation of individual beneficiaries, as Congress directed, but would instead count an individual only in a single year, the one in which he or she first elected the hospice benefit.

HHS appears to have decided to deviate from the statutory directive primarily as a matter of administrative convenience:

> Although section 1814(i)(2)(C) of the Act specifies

[2]Hospice care providers are reimbursed by "fiscal intermediaries," typically insurance companies, that contract with CMS to aid in administering the Medicare program. *See* 42 U.S.C. § 1395h.

> that the cap amount is to be adjusted "to reflect the proportion of the hospice care that each such individual was provided in a previous or subsequent accounting year . . . ," *such an adjustment would be difficult* in that the proportion of the hospice stay occurring in any given year would not be known until the patient dies or exhausted his or her hospice benefits. We believe the proposed *alternative* of counting the beneficiary in the reporting period where the beneficiary used most of the days of covered hospice care *will achieve the intent of the statute without being burdensome*.

48 Fed. Reg. at 38158 (emphasis added). However, HHS at least implicitly recognized that its method of limiting cap allocations to the initial year of service would prejudice hospices that provided some care in one fiscal year with the majority of care in the next fiscal year. In an attempt to ameliorate this prejudice, HHS established the "shift" embodied in 42 C.F.R. § 418.309(b)(1), under which the entire allowance for any patient admitted to hospice within the last 35 days of any accounting year would be moved into the next fiscal year. This shift assumed that the average length of stay in hospice care would be 70 days. *See* 48 Fed. Reg. 56008, 56020-22 (Dec. 16, 1983).

As we have noted, Medicare initially pays providers a predetermined amount for each day a beneficiary is in hospice. 42 U.S.C. § 1395f(i)(1). Sometime after the provider receives those payments, however, its fiscal intermediary calculates the hospice cap for the relevant accounting year. When it is determined that a provider exceeded its aggregate cap for an accounting year, the fiscal intermediary sends a letter demanding a refund of any overpayments. *See* 42 C.F.R. § 418.308(d).[3] If a hospice provider disagrees with the repay-

[3]In its calculation of the hospice "cap" and any associated overpayments, the fiscal intermediary is confined to "the mere application of the Secretary's regulations." *Bethesda Hosp. Ass'n v. Bowen*, 485 U.S. 399, 404 (1988).

ment demand, and the amount in controversy is at least $10,000, it may seek a hearing before the Provider Reimbursement Review Board ("PRRB"). 42 U.S.C. § 1395oo(a). The PRRB has the authority to affirm, modify, or reverse a final determination of the fiscal intermediary, 42 U.S.C. § 1395oo(d), and the Board's decision constitutes a final agency ruling, unless it is appealed to the Secretary, *id.*, § 1395oo(f)(1).

Where the provider's challenge to the action of the fiscal intermediary involves a strictly legal question, such as a claim that a regulation is inconsistent with the Medicare statute, the PRRB has no authority to decide that issue. *Bethesda Hosp. Ass'n*, 485 U.S. at 406 ("Neither the fiscal intermediary nor the Board has the authority to declare regulations invalid."). Rather, providers have the right to obtain direct, expedited judicial review "of any action of the fiscal intermediary *which involves a question of law or regulations* relevant to the matters in controversy whenever the Board determines . . . that it is without authority to decide the question, by a civil action . . . ." 42 U.S.C. § 1395oo(f)(1) (emphasis added). The PRRB's determination of its authority is a final agency decision, and is not subject to review by the Secretary. *Id.* In a civil action under § 1395oo(f)(1), the validity of the fiscal intermediary's action is subject to judicial review using the familiar standards of the Administrative Procedure Act ("APA")—i.e., whether the action was "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A).

B.

Since 2003, Haven Hospice has been a Medicare-certified hospice provider in Los Angeles, California. Through May 2009, Haven Hospice has served approximately 1,500 patients. In support of its motion for summary judgment, Haven Hospice presented evidence that the average length of stay for its Medicare patients for FY 2006 was 246 days.

Haven Hospice's historical average length of stay, from 2003 through the date of filing its summary judgment motion, was 205 days.

In April 2008, based on a report by HHS that its payments to Haven Hospice exceeded the hospice's cap allowance by $2,352,499, as calculated in accordance with the hospice cap regulation, the fiscal intermediary demanded that Haven Hospice repay that sum. Haven Hospice timely appealed the repayment demand to the PRRB, citing a then recent unpublished decision, *Sojourn Care, Inc. v. Leavitt*, Case No. 07-CV-375-GKJ-PJC (N.D. Okla. Feb. 19, 2008), in which the district court concluded that the hospice cap regulation is inconsistent with the hospice cap statute and declared it to be invalid.

In its administrative appeal, Haven Hospice did not dispute the accuracy of the overpayment demand as calculated using the hospice cap regulation, but asserted that the PRRB had jurisdiction of the matter because it was not asking the Board to determine the validity of the hospice cap regulation, only to order the intermediary to withdraw a demand made pursuant to a regulation that had been invalidated by the courts. In the alternative, Haven Hospice requested expedited judicial review if PRRB were to conclude that it was without jurisdiction to determine whether the demand was made pursuant to an invalid regulation.

Pursuant to 42 C.F.R. § 405.1842, the PRRB specifically found that it had jurisdiction over Haven Hospice's challenge to the fiscal intermediary's overpayment demand, and that the estimated amount in controversy exceeded $10,000, but determined that it was without authority to decide the legal question whether the hospice cap regulation is invalid. Accordingly, it granted Haven Hospice's request for expedited judicial review "for the hospice cap issue and the subject year." *See id.*, § 405.1842(f).

C.

In June 2008, Haven Hospice filed a civil action in the district court for the Central District of California, alleging "on information and belief that its cap liability for fiscal year 2006 would have been materially reduced" if Medicare had "followed the Congressional mandate to allocate cap room across years of service." In May 2009, the parties filed cross-motions for summary judgment. HHS argued that Haven Hospice lacked standing to challenge 42 C.F.R § 418.309(b) because the hospice offered no evidence showing that the current regulation caused it injury-in-fact in FY 2006, or that a new regulation applying its preferred methodology would redress any injury. HHS also defended the regulation on the ground that it provided a reasonable means of calculating the hospice cap and that it was, therefore, entitled to *Chevron* deference.

In July 2009, the district court granted Haven Hospice's summary judgment motion. The court first rejected the Secretary's standing arguments, ruling that "[t]he injury in fact in this context" was that "HHS is operating an invalid regulation, leading to accounting and payment inaccuracies." The court declined to address whether Haven Hospice suffered any pecuniary injury, noting that "the injury question here is not whether [Haven Hospice's] liability is greater under the operation of [the hospice cap regulation] than it would be under some other regulation." Turning to the merits, the district court concluded that the hospice cap regulation, 42 C.F.R § 418.309(b), was contrary to the hospice cap statute, 42 U.S.C. § 1395f(i)(2)(C). As the district court explained:

> Congress unquestionably required that the number of [M]edicare beneficiaries be reduced to reflect "the proportion" (not simply a proportion or *an* estimate, as Defendant would apparently have "reflect" mean in this context) of hospice care that "each such individual" (not individuals in the aggregate) "was provided in a previous or subsequent accounting year."

> The regulation in question runs counter to that directive. Congress has "directly spoken" to this "precise question," [and] "that is the end of the matter."

(Emphasis in original).

Haven Hospice submitted a proposed form of judgment that not only invalidated the 2006 overpayment demand and the hospice cap regulation, but also stated that "HHS is hereby enjoined prospectively from using the current [version of] 42 C.F.R. § 418.309(b)(1) to calculate hospice cap liability for *any* hospice." HHS objected, contending that federal courts have jurisdiction to review only those claims exhausted before the PRRB, and that the only claim presented to the PRRB challenged the fiscal intermediary's calculation of Haven Hospice's hospice cap for FY 2006. Thus, HHS argued, the district court had jurisdiction only to overturn the calculation, not to invalidate the regulation. After a hearing in August 2009, the district court entered the nationwide injunction proposed by Haven Hospice without amendment.

Less than two weeks later, the Secretary filed a notice of appeal and motion to stay the nationwide injunction pending appeal. The district court granted the Secretary's stay motion, reasoning that "[t]here is conflicting case law on whether injunctive relief (in a case where an agency's regulation is held to be improper or unconstitutional) should be broad (*e.g.*, nationwide) or more limited," and that the Secretary had "made the requisite showing of likelihood of success as to the issue of the nationwide scope of the injunctive relief." Specifically, the district court found that:

> [The nationwide injunction] would significantly disrupt the Medicare program because it would inhibit the agency from implementing the statutorily mandated hospice caps as to the approximate[ly] 3000 hospice providers during the period while a new regulation is being promulgated and would concomi-

> tantly create tremendous uncertainty for the government, Medicare contractors and hospice providers."

II.

We review de novo both the district court's determination that Haven Hospice has Article III standing, and its conclusion that the regulation implementing the hospice cap is contrary to law. *Wilderness Soc'y v. Rey*, 622 F.3d 1251, 1254 (9th Cir. 2010) (Article III standing); *Portland Adventist Med. Ctr. v. Thompson*, 399 F.3d 1091, 1095 (9th Cir. 2005) (summary judgment under APA standards).

We review the district court's entry of a nationwide injunction for an abuse of discretion, or an erroneous application of legal principles. *United States v. AMC Entm't, Inc.*, 549 F.3d 760, 768 (9th Cir. 2008). "[A] trial court abuses its discretion by fashioning an injunction which is overly broad." *Id.*

A.

Before turning to the merits, we must address the Secretary's contention that Haven Hospice lacks Article III standing to pursue the relief it seeks in this civil action—in particular, a declaratory judgment that the hospice cap regulation and the $2.3 million overpayment demand calculated under the regulation are invalid, and an injunction barring further enforcement of the regulation against both Haven Hospice and all other hospice providers nationwide. The Secretary concedes that if Haven Hospice has Article III standing, the district court had subject matter jurisdiction pursuant to 42 U.S.C. § 1395oo(f)(1), but only as to Haven Hospice's challenge to the overpayment demand for FY 2006, and not as to any other hospice provider or accounting year. We conclude that Haven Hospice has Article III standing and that the district court had jurisdiction pursuant to 42 U.S.C. § 1395oo(f)(1) to determine the validity of both the hospice

cap regulation and the FY 2006 overpayment demand, and to enjoin further enforcement of the regulation, at least as against Haven Hospice.[4]

[1] To invoke the jurisdiction of the federal courts, a plaintiff must demonstrate that it has Article III standing—i.e., that it has suffered an injury-in-fact that is both "concrete and particularized," and "actual or imminent, not conjectural or hypothetical"; that the injury is "fairly . . . traceable to the challenged action of the defendant"; and that it is "likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision" on the plaintiff's claims for relief. *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-61 (1992) (internal quotation marks omitted). The "gist of the question of standing" is, of course, whether the plaintiff has "alleged 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 of difficult [legal] questions[.]" *Baker v. Carr*, 369 U.S. 186, 204 (1962) (emphasis added). A plaintiff must demonstrate standing separately for each form of relief sought, *Friends of the Earth, Inc. v. Laidlaw Environmental Services (TOC), Inc.*, 528 U.S. 167, 184 (2000), but is not required to demonstrate that a favorable decision will relieve "his every injury," *Larson v. Valente*, 456 U.S. 228, 243 & n.15 (1982). Applying these standards, we conclude that Haven Hospice has made an adequate showing to support its claim of Article III standing to pursue declaratory and injunctive relief in this civil action.

[2] As the *Lujan* Court explained, a plaintiff is presumed to have constitutional standing to seek injunctive relief when it is the direct object of regulatory action challenged as unlawful:

[4]We will discuss in greater depth the scope of the district court's jurisdiction to enjoin further enforcement of the hospice cap regulation against Haven Hospice in section II.C.1, *post*.

> When the suit is one challenging the legality of government action or inaction, the nature and extent of facts that must be averred (at the summary judgment stage) or proved (at the trial stage) in order to establish standing depends considerably upon whether the plaintiff is himself an object of the action (or forgone action) at issue. *If he is, there is ordinarily little question that the action or inaction has caused him injury, and that a judgment preventing or requiring the action will redress it.*

504 U.S. at 561-62 (emphasis added); *see also Fund for Animals, Inc. v. Norton*, 322 F.3d 728, 733-34 (D.C. Cir. 2003) (a party's standing to seek judicial review of administrative action is typically "self-evident" when the party is the object of the action); *and cf. Summers v. Earth Island Inst.*, ___ U.S. ___, ___, 129 S.Ct. 1142, 1149 (2009) (where a regulation under challenge neither requires nor forbids any action on the part of the plaintiffs, "standing is not precluded, but is ordinarily 'substantially more difficult' to establish" (quoting *Lujan*, 504 U.S. at 562)).

[3] In this case, there is no question but that Haven Hospice was the object of the governmental action challenged in its complaint—an individualized demand for repayment of over $2.3 million for FY 2006, calculated pursuant to the allegedly invalid hospice cap regulation—and that a favorable judgment will relieve the alleged injury, at least in part. Regardless of the precise extent to which invalidation of the challenged regulation might ultimately affect its repayment obligation, the fact that the allegedly unlawful regulation was directly applied to Haven Hospice and exposed it to individual liability for the claimed overpayments, is sufficient to support its claim of Article III standing to pursue the declaratory and injunctive relief sought in the complaint. *See Lujan*, 504 U.S. at 561-62.

[4] The Secretary contends, however, that absent specific evidence that Haven Hospice's cap liability for FY 2006

would actually be *reduced* under a regulation drawn in conformity with the hospice cap statute, it cannot establish that it has suffered an injury-in-fact redressable by the relief sought in this litigation. We understand this argument to have at least three related, and interlocking facets, and will address each in turn.

First, to the extent the Secretary is suggesting that only economic or pecuniary injury to Haven Hospice would qualify as injury-in-fact in this case, she is mistaken. It is well established that less tangible forms of injury, such as the deprivation of an individual right conferred by statute, may be sufficiently particularized and concrete to demonstrate injury-in-fact. *Lujan*, 504 U.S. at 560 n.1 (violation of a legally protected interest must "affect the plaintiff in a personal and individual way"); *Warth v. Seldin*, 422 U.S. 490, 500 (1975) ("[t]he actual or threatened injury required by Article III may exist solely by virtue of 'statutes creating legal rights, the invasion of which creates standing' " (quoting *Linda R.S. v. Richard D.*, 410 U.S. 614, 617 n.3 (1973))); *see also Fernandez v. Brock*, 840 F.2d 622, 630-31 (9th Cir. 1988) (while a mere violation of a statutory duty may not qualify as a constitutional injury-in-fact, Article III may be satisfied by allegations that the statute imposes a statutory duty and creates correlative procedural rights in a particular plaintiff).

In the present context, Haven Hospice has a statutory right to reimbursement for hospice care provided to eligible Medicare beneficiaries up to the limits of the aggregate annual "cap," calculated in accordance with 42 U.S.C. § 1395f(i)(2). The Medicare statute also confers upon Haven Hospice (and other certified hospice providers) procedural rights to challenge the fiscal intermediary's cap calculation for any given accounting year (in which at least $10,000 is in dispute) in an administrative hearing before the PRRB, including judicial review of PRRB's decision and an initial judicial determination of any purely legal issue raised in the administrative appeal. 42 U.S.C. § 1395oo(f)(1). As the district court

observed, it is sufficient that Haven Hospice's "cap" for FY 2006, and the related repayment demand, were calculated using a method other than that specified by Congress. *See Russell-Murray Hospice, Inc. v. Sebelius*, 724 F.Supp.2d 43, 53 (D.D.C. 2010)*; Lion Health Servs., Inc. v. Sebelius*, 689 F.Supp.2d 849, 855 (N.D. Tex. 2010) ("The legal right asserted . . . [was] the right to have its cap and cap overpayments calculated according to the method specified by law, not the right to the return of a certain amount of money.").

The Secretary further contends, however, that Haven Hospice must prove that it suffered a "net" increase in its liability for overpayments from the operation of the hospice cap regulation in FY 2006, over and above the amount it would have been required to pay for the same period under the hospice cap statute or a hypothetical regulation drawn in conformity with the statute. The Secretary's argument on this point is not entirely clear. She seems to suggest that, as compared to a calculation utilizing the proportional allocation prescribed by the hospice cap statute, any given hospice's repayment liability under the hospice cap regulation—with its 35-day "shift" and its policy of giving a full cap allowance for each Medicare beneficiary only in the initial year of service, in which he or she is "likely to receive the bulk of her care"—will likely "even out" (be mathematically neutral) across accounting years, with no "net" effect on a hospice's liability. The Secretary further contends that operation of the hospice cap regulation in any given year is "equally likely" to *harm* a hospice provider (by decreasing its cap and increasing its repayment obligation) as to *help* it (by increasing its cap and reducing its repayment obligation), with the outcome in any given year "turn[ing] entirely on whether the number of partial beneficiaries shifted out of that year exceeds the number of partial beneficiaries shifted into that year." At the same time, however, the Secretary insists that the focus of our standing inquiry—and, indeed, our jurisdiction—be narrowly confined to FY 2006.

We reject this circular argument. Were we to accept the Secretary's logic *in toto*, no hospice provider could establish standing to challenge either a specific overpayment demand *or* the regulation under which all such demands have been calculated since 1983. Even if a hospice could prove that it would have been subject to a lesser demand in a given accounting year if HHS had employed the proportional allocation prescribed by the hospice cap statute, its standing would still be subject to challenge under the Secretary's theory that any benefit enjoyed in the year at issue was likely to have been offset by a higher demand in a prior year or would be offset in subsequent year.

Even narrowly focusing on the cap calculation for the accounting year challenged in the plaintiff's administrative appeal, FY 2006, we believe the Secretary asks too much when she contends that Haven Hospice must prove, with mathematical precision and certainty, that its overpayment liability under the current hospice cap regulation was actually greater in that year than it would have been under a regulation drawn in conformity with 42 U.S.C. § 1395f(i)(2). First, such an alternative calculation under a nonexistent regulation would necessarily be hypothetical and speculative in nature. *See Natural Res. Def. Council v. EPA*, 542 F.3d 1235, 1246 (9th Cir. 2008) (rejecting attack on environmental's group standing to require promulgation of pollution discharge regulations, and specifically dismissing claim that plaintiffs had to show that they would be better off under a new regulation, because "one cannot demonstrate the efficacy of regulations that have yet to be issued").

[5] More importantly, however, we disagree with the Secretary's premise that a hospice provider may be found to have standing to mount a facial challenge to the hospice cap regulation only if it suffered a "net" increase in its overpayment liability within the accounting year at issue in its administrative appeal. We have previously rejected a similar objection to the Article III standing of parties challenging an administrative

decision. In *Aluminum Company of America v. Bonneville Power Admin.*, 903 F.2d 585 (9th Cir. 1989) ("*Alcoa*"), the defendant agency argued that the plaintiffs, California electric utility companies, lacked standing to challenge a portion of a ratemaking decision that allegedly established excessive rates (due to costs that should not have been included in the so-called "nonfirm" rate schedules), because the utilities probably enjoyed a "net" benefit from the ability voluntarily to purchase surplus energy from the BPA at below-market rates. *Id.* at 590. We rejected the agency's standing argument, saying "[t]here is harm in paying rates that may be excessive, no matter what the California utilities may have saved." *Id*. As to redressability, we further observed that "if the utilities are correct, the relief sought would cure their injury: they will receive a refund of overpayments with interest." *Id.* As relevant here, *Alcoa* implies that, so long as Haven Hospice can point to some concrete harm logically produced by 42 C.F.R. § 418.309(b), it has standing to challenge the hospice cap regulation even though in a prior, current, or subsequent fiscal year it may also have enjoyed some offsetting benefits from the operation of the current regulation.

[6] In this case, although it did not present detailed patient flow data or other evidence definitively showing that application of the methodology prescribed by the hospice cap statute would have *netted* a lower repayment demand than that calculated by the fiscal intermediary under the hospice cap regulation, Haven Hospice points to several factors that support its claim of redressable injury-in-fact.[5] In particular, for hospices

[5]We need not, and do not, decide whether the PRRB's findings (without objection by HHS) that there was more than $10,000 in dispute in this case was sufficient, alone or together with other evidence before the district court, to support Haven Hospice's claim to Article III standing. We note, however, that the "amount in controversy" requirement in 42 U.S.C. § 1395oo(a)(2) appears to be a jurisdictional provision, similar to the $75,000 amount in controversy required to establish diversity jurisdiction under 28 U.S.C. § 1332. *See Beacon Healthcare Servs., Inc. v. Leavitt*, 629 F.3d 981, 983-84 (9th Cir. 2010).

with an average length of stay longer than the 70-day period on which the hospice cap regulation was based, there is a mismatch of allowances given by HHS in the initial year toward that year's "cap," and revenue paid by HHS in later years—to date, uniformly under a higher, inflation-adjusted per-patient annual cap amount—resulting in overstated repayment demands in later years. As Haven Hospice puts it, by counting a whole beneficiary only in the initial year of service even where the patient received the bulk of the care in a subsequent year, a significant portion of the "cap room" that would be available for that beneficiary under the hospice cap statute becomes "trapped" in the earlier year.

A few simplified examples illustrate the problem. If a hypothetical "average" Haven Hospice patient elected hospice care the day before the 35-day "shift" period for FY 2006 began—i.e., on September 28, 2005—and then continued in hospice for 246 days, that beneficiary would have been allocated entirely to FY 2005 under the hospice cap regulation, and Haven Hospice would have been credited with a total of $19,778, the "cap amount" for that beneficiary, in the FY 2005 accounting year. By contrast, under the proportional allocation methodology required by the hospice cap statute, approximately 15 percent of the care the beneficiary received in FY 2005 would have been included in the cap for that year (0.15 x $19,778 = $2,967), but approximately 85 percent (0.85 x $20,585 = $17,497) of the care the patient actually received in FY 2006 would have been included in the cap for that year at the higher $20,585 rate per-patient cap amount, for a total of $20,464.[6] A similarly beneficial effect of propor-

[6]For simplicity's sake, we use the number of days of hospice care provided to determine the proportional allocation across accounting years that the hospice cap statute calls for. If specific reimbursement data were available, we could as easily allocate the beneficiary across years of service to reflect the proportion of the total reimbursements collected by Haven Hospice in each year for care it provided to the beneficiary. As Haven Hospice notes, this is one of the many uncertainties in trying to demonstrate how a valid hospice cap regulation might actually work. *See Natural Res. Def. Council*, 542 F.3d at 1246.

tional allocation could be predicted for any "average" patient who elected hospice care in 2005 between 36 and 123 days before the start of FY 2006, for whom up to half of the beneficiary's "cap room" would be trapped in FY 2005 at the lower cap amount for that year, while Haven Hospice received between 50 to 85 percent of the reimbursement payments but no cap room at all for those patients in FY 2006. At the other end of the accounting year, only those patients who elected hospice care between September 28 and October 31, 2006, were shifted entirely out of FY 2006 by operation of the hospice cap regulation and counted using the higher cap amount for FY 2007, but Haven Hospice lost cap credit in FY 2006 only for that portion of their care provided during the 35-day shift period.

Of course, if the regulation is invalidated as to FY 2006, Haven Hospice also stands to lose the marginal benefit of the 35-day shift for those patients who elected hospice care between September 27 and October 31, 2005. But having that fraction of its FY 2005 patients counted using the higher FY 2006 cap amount for that period would yield only a small loss compared to the benefit Haven Hospice—with an average length of stay that is well above the norm and more than three times higher than the 70-day national average that existed when the regulation was promulgated in 1983—is likely to garner from releasing substantial amounts of cap room "trapped" in FY 2005.

Indeed, the existence of this marginal benefit from operation of the current regulation only serves to bolster Haven Hospice's case for Article III standing. Clearly, HHS itself understood that hospices would be prejudiced or injured by its adoption of a regulation allocating cap room only to the initial year of service, rather than proportionally across years of service as required by the hospice cap statute, and it attempted to counteract this prejudice by adopting the 35-day shift in 42 C.F.R. § 418.309(b)(1). But while that "shift" might have been sufficient to ameliorate the resulting prejudice in 1983,

when the average length of stay in hospice was only 70 days, it is plainly insufficient for providers with significantly higher average lengths of stay in recent years.

As Haven Hospice explains, the assumptions implicit in the "shift" adopted by HHS are twofold: (a) to be fair to hospices, HHS would have to shift admissions forward into the next year in proportion to the actual average length of stay;[7] and (b) if the average length of stay assumption is wrong, hospices would be prejudiced by the misallocation of cap allowances. In other words, by definition, the effectiveness of the shift in ameliorating the prejudice depends upon the accuracy of the length of stay assumption. For a hospice with a length of stay longer than assumed, such as Haven Hospice, cap room will be trapped in prior years because the shift will be insufficient to even roughly match cap allowances and revenue. This problem is then exacerbated by the fact that the per beneficiary "cap amount" increases each year by inflation; one unit allocated to 2005 is simply not as valuable as a unit allocated to 2006.

[7] In these circumstances, we are satisfied that Haven Hospice has established a substantial likelihood that application of the hospice cap regulation resulted in an unlawful increase in its FY 2006 cap liability, at least in part, and that invalidation of the regulation would redress that portion of its injury. Thus, we conclude that Haven Hospice has established that it has Article III standing to pursue the declaratory and injunctive relief prayed for in the complaint, and that the district court had subject matter jurisdiction pursuant to 42 U.S.C. § 1395oo(f)(1) to determine the validity of the hospice cap regulation.

[7]In this regard, it is noteworthy that HHS specifically adopted the 35-day shift based on the assumption that the average length of stay in hospice would be 70 days, after that estimate was revised upward from an initial assumption of only 44 days, for which a 22-day shift period had been proposed. *Compare* 48 Fed. Reg. at 38158; *with* 48 Fed. Reg. at 56020-22.

B.

[8] We turn now to the merits of Haven Hospice's claim that the hospice cap regulation, 42 C.F.R. § 418.309(b)(1), impermissibly conflicts with the hospice cap statute, 42 U.S.C. § 1395f(i)(2)(C), and is, thus, facially invalid.[8] The parties agree that *Chevron* analysis is appropriate in reviewing Haven Hospice's claim that the hospice cap regulation is facially invalid. The *Chevron* inquiry proceeds in two steps. First, we must ask "whether Congress has spoken to the precise question at issue." 467 U.S. at 843. In answering this first question, no deference to the agency is due. *See Medtronic, Inc. v. Lohr*, 518 U.S. 470, 512 (1996) ("[W]here the language of the statute is clear, resort to the agency interpretation is improper."). If the agency interpretation conflicts with Congress's clearly expressed intent, "that is the end of the matter," and the inquiry ends. *Chevron*, 467 U.S. at 843. Only if the statute is ambiguous or silent do we proceed to the second step, which requires us to defer to the agency's interpretation so long as it is reasonable. *Id.*

[9] As Judge Wu noted, the hospice cap *statute* plainly states that in determining the "number of Medicare beneficiaries" served in a given accounting year, the fiscal intermediary and HHS are required to count every individual who received care in that year, with "such number reduced to

[8]This is an issue of first impression in the United States Courts of Appeals. The issue has been previously considered in numerous published decisions from the federal district courts, all of which to date have rejected the Secretary's position, and several of which are currently pending on appeal. *See, e.g., Russell-Murray Hospice, Inc. v. Sebelius*, 724 F.Supp.2d 43, 57-59 (D.D.C. 2010), appeal docketed, No. 10-5115 (D.C. Cir., Apr. 19, 2010); *IHG Healthcare v. Sebelius*, 717 F.Supp.2d 696, 707-09 (S.D. Tex. 2010), appeal docketed, No. 10-20531 (5th Cir., Aug. 11, 2010); *Hospice of New Mexico v. Sebelius*, 691 F.Supp.2d 1275, 1288-93 (D.N.M. 2010), appeals docketed, Nos. 10-2136, 10-2168 (10th Cir., June 16 & July 28, 2010); *Lion Health Servs., Inc. v. Sebelius*, 689 F.Supp.2d 849, 856-57 (N.D. Tex. 2010), appeal docketed, No. 10-10414 (5th Cir., Apr. 24, 2010).

reflect the proportion of hospice care that each such individual was provided in a previous or subsequent accounting year." 42 U.S.C. § 1395f(i)(2)(C). Under the hospice cap *regulation*, however, an individual patient is counted as a beneficiary only in a single year, depending on when she elects hospice care, regardless of how much care the patient actually received that year, or whether she actually received the bulk of her care in subsequent years. *See* 42 C.F.R. § 418.309(b)(1). The regulation is at odds with the plain language of the statute in that it omits the individualized, proportional allocation calculation expressly called for in the statute, and substitutes an "alternative" that HHS considers more convenient and less burdensome. Indeed, when HHS first proposed the challenged regulation in 1983, it acknowledged as much. *See* 48 Fed.Reg. at 38158.

The Secretary contends, however, that Congress's mandate was ambiguous, and that the hospice cap regulation is a "reasonable" interpretation of the statutory language. In particular, the Secretary suggests that the words "reflect" and "proportion" in 42 U.S.C. § 1395f(i)(2)(C) are, by their nature terms of ambiguity and imprecision, allowing HHS to use a methodology that estimates the "number of Medicare beneficiaries" to be counted toward an annual cap. We disagree.

When read in the context of the surrounding statutory language, these terms are not ambiguous or imprecise. *See NLRB v. Federbush Co.*, 121 F.2d 954, 957 (2d Cir. 1941) ("Words are not pebbles in alien juxtaposition; they have only a communal existence; and not only does the meaning of each interpenetrate the other, but all in their aggregate take their meaning from the setting in which they are used."). The term "reflect" as used in § 1395f(i)(2)(C) conveys Congress's intent that the number of beneficiaries should be reduced to make apparent that a portion of hospice care for each individual was provided in a different fiscal year, or by another hospice program. Moreover, by using the phrase "each such individual," Congress indicated its intent that the reduction is

to be carried out on an individualized basis for each hospice patient, *not* estimated by allocating "whole" patients to a fiscal year based on the date they elected to receive hospice care. The statute also specifically requires that the proportional reduction of the number of beneficiaries be carried out to reflect the amount of hospice care "provided in a previous or subsequent year." That is, each hospice patient's benefit cap allowance must be allocated across years of service, *not* lumped into a single year in which some care was provided without regard to the length of the beneficiary's overall stay.

[10] In sum, we conclude that Congress's language and intent when it drafted § 1395f(i)(2)(C) were clear and unambiguous, and the district court did not err in finding that the hospice cap regulation, 42 C.F.R. § 418.309(b)(1), is inconsistent with the statute. By choosing to count beneficiaries only in the year in which HHS "anticipated" that the majority of hospice care would be furnished, it ignored Congress's clear statutory mandate. Thus, the regulation under which the Secretary adopted that methodology was contrary to law, and was properly declared invalid at step one of the *Chevron* inquiry.

C.

Having concluded that the hospice cap regulation is invalid, we must address the Secretary's further contention that the district court acted in excess of its jurisdiction by entering the injunction in this case or, at a minimum, abused its discretion by barring enforcement of the hospice cap regulation against all certified Medicare hospice providers nationwide. We conclude that the district court had jurisdiction to enjoin further enforcement of the invalid regulation as against Haven Hospice, but abused its discretion by entering a nationwide injunction.

1.

[11] Both in its briefs on appeal and during oral argument, the Secretary has mounted an elaborate argument that the dis-

trict court exceeded its jurisdiction under 42 U.S.C. § 1395oo(f)(1) by issuing the injunction in this case, *both* as to Haven Hospice and as to all other certified hospice providers. The Secretary contends that the court's statutory jurisdiction was limited to a determination whether the "action of the fiscal intermediary" that was challenged before the PRRB—i.e., its calculation of Haven Hospice's FY 2006 cap and the related overpayment demand—was erroneous and must be set aside, and that the only proper disposition is a remand to the PRRB for a recalculation of the amount Haven Hospice received in excess of its hospice cap for FY 2006, not an injunction against further enforcement of the hospice cap regulation. In support of this argument, the Secretary relies on the Supreme Court's decision in *Shalala v. Illinois Council on Long Term Care*, 529 U.S. 1 (2000), and our decision in *Pacific Coast Medical Enterprises v. Harris*, 633 F.2d 123 (9th Cir. 1980), contending that the only claim Haven Hospice "channeled through" the special administrative review procedures set forth in the Medicare statute was the narrow claim that the hospice cap regulation was invalid *as applied* to calculate its aggregate "cap" and overpayment liability for FY 2006. *See Shalala*, 529 U.S. at 13; *Pacific Coast*, 633 F.2d at 137-38. We disagree.

[12] Contrary to the Secretary's contention, we believe it is clear from the record that Haven Hospice's claim that the hospice cap regulation is invalid is a *facial* challenge.[9] As

[9]In its briefs on appeal, the Secretary seemed to suggest that Haven Hospice did not, and could not, bring a facial challenge to the validity of the hospice cap regulation. At oral argument, however, counsel for the Secretary acknowledged that Haven Hospice's complaint "could be read" as bringing a facial challenge. Thus, the Secretary's ultimate argument is that "as a jurisdictional necessity," Haven Hospice could not have brought a facial attack, but only an as-applied challenge to the action of the fiscal intermediary for a particular accounting year, here the overpayment demand for FY 2006. To the extent the Secretary is suggesting that a facial challenge to a Medicare regulation is never appropriate, except immediately upon adoption and before it is ever applied to any provider, she cites no authority to support such a contention.

such, and because the Secretary is apparently unwilling to give any assurance that she will voluntarily refrain from enforcing the invalid regulation against Haven Hospice and other hospice providers in the Ninth Circuit for accounting years subsequent to FY 2006,[10] the district court had both the authority and discretion to enjoin future application of the invalid regulation, at least as against Haven Hospice. *See* 42 U.S.C. § 1395oo(f)(1) (civil action for judicial review of an action of the fiscal intermediary involving a question of law or regulations shall be tried pursuant to applicable provisions under Chapter 7 of Title 5, 5 U.S.C. §§ 701 *et seq*., notwithstanding any other provision in 42 U.S.C. § 405); 5 U.S.C. § 702 (waiving sovereign immunity to suit by individuals suffering a legal wrong because of agency action, and "seeking relief other than money damages," and prescribing proper form for injunctive relief that is not otherwise prohibited); *id*., § 703 (the form of proceeding under the APA is "any applicable form of legal action, including actions for declaratory judgments or writs of prohibitory or mandatory injunction . . . in a court of competent jurisdiction"); *see also Russell-Murray Hospice*, 724 F.Supp.2d at 60; *Hospice of New Mexico*, 691 F.Supp.2d at 1295; *Lion Health Services*, 689 F.Supp.2d at 858.

[13] Nothing in the cases cited by the Secretary requires a different conclusion. Haven Hospice fully complied with the requirements of *Illinois Council* by proceeding through the special administrative review procedures set forth in the Med-

[10]At oral argument, counsel for the Secretary contended that but for the injunction prohibiting use of the hospice cap regulation to compute Haven Hospice's cap and any repayment demand for accounting years after FY 2006, she "would not be risking contempt" sanctions if she continued to enforce the regulation against Haven Hospice or other providers in the Ninth Circuit. Counsel conceded only that the Secretary would probably refrain from doing so, but only "as a practical matter" to avoid imposition of fee awards under the Equal Access to Justice Act should the providers find it necessary to bring a future civil action to set aside repayment demands for subsequent accounting years.

icare statute—specifically 42 U.S.C. § 1395oo(f)(1), which was not at issue in *Illinois Council*—to challenge the fiscal intermediary's calculation of its hospice cap and determination of its overpayment liability for FY 2006.[11] In this case, Haven Hospice did not dispute that the overpayment demand was correctly calculated by the fiscal intermediary pursuant to the hospice cap regulation, but it gave the PRRB an opportunity to correct the errors allegedly caused by application of a regulation that at least one court had declared to be invalid. Haven Hospice also gave the PRRB the opportunity to determine its authority to consider a challenge to the hospice cap regulation, as required by § 1395oo(f)(1). Once the PRRB determined that the fiscal intermediary's action involved "a question of law or regulations relevant to the matters in controversy," and that it was "without authority to decide the question," Haven Hospice exhausted all available administrative avenues of redress and was free to bring a civil action seeking a judicial determination of the validity of the hospice

[11]*Illinois Council* involved claims of an association of nursing homes that the regulations governing imposition of sanctions for deficiencies in care provided by its members were unconstitutionally vague, violative of statutory provisions that require enforcement consistency, inconsistent with the Due Process Clause, and promulgated without complying with APA requirements. 529 U.S. at 7. The plaintiff association did not comply with the "special Medicare review" procedures established by statute for administrative and judicial review of decisions of the Secretary regarding sanctions, *see* 42 U.S.C. §§ 1395i-3(h)(2)(B)(ii), 1395cc(b)(2)(A), 1395cc(h)(1), which incorporate the general provisions for review of decisions of the Commissioner of Social Security, *see* 42 U.S.C. §§ 405(b), (g), (h). *Illinois Council*, 529 U.S. at 7. Instead, it alleged that the district court had general federal question jurisdiction pursuant to 28 U.S.C. § 1331. *Id.* The Supreme Court held that federal question jurisdiction was foreclosed in that case by 42 U.S.C. § 1395ii, which incorporates 42 U.S.C. § 405(h) and makes it applicable to the Medicare Act "to the same extent" as it applies to the Social Security Act, except perhaps where requiring a Medicare provider to "channel" its claims through the "special Medicare review procedures" would result in no judicial review at all. 529 U.S. at 8-9, 19-24. In this case, the Secretary has conceded that, assuming Haven Hospice has Article III standing, the district court had subject matter jurisdiction pursuant to 42 U.S.C. § 1395oo(f)(1).

cap regulation in the only forum authorized to decide that question of law. *Id.*; *see also Bethesda Hosp. Ass'n*, 485 U.S. at 406.

Because Haven Hospice's claim is that the hospice cap regulation is inconsistent with the hospice cap statute and, thus, facially invalid, this case is also distinguishable from *Pacific Coast*. In that case, the plaintiff provider challenged the fiscal intermediary's action denying its claim for increased reimbursement in a hearing before the PRRB pursuant to 42 U.S.C. § 1395oo(a). 633 F.2d at 126-27. The PRRB ruled in the plaintiff's favor, but the Secretary reversed the decision of the Board based upon his application of certain Medicare regulations to a particular type of transaction—a two-step acquisition of a hospital by purchase of 100% of the stock of the corporation that owned the hospital, followed by liquidation of the corporation—and found that the transaction did not qualify as a "purchase of an ongoing provider." *Id.* at 127-28, 129. The plaintiff sought judicial review of the Secretary's decision pursuant to an earlier version of 42 U.S.C. § 1395oo(f), the relevant portion of which is retained in the first and second sentences of § 1395oo(f)(1).[12] 633 F.2d at 128, 130-31.

[12]As originally enacted in 1972, 42 U.S.C. § 1395oo(f) provided that:

> A decision of the Board shall be final unless the Secretary, on his own motion, and within 60 days after the provider of services is notified of the Board's decision, reverses or modifies (adversely to such provider) the Board's decision. In any case where such a reversal or modification occurs the provider of services may obtain a review of such decision by a civil action commenced within 60 days of the date he is notified of the Secretary's reversal or modification.

See Pacific Coast, 633 F.2d at 130, n.25(quoting 42 U.S.C. § 1395oo(f) (1980)). It was not until the statute was amended in 1980 that direct judicial review was authorized for "any action of the fiscal intermediary which involves a question of law or regulations relevant to the matters in controversy," as to which the PRRB determines it is without authority to decide the question. *See* Pub. L. No. 96-499, § 955, 94 Stat. 2599 (Dec. 5, 1980).

[14] In this case, by contrast, Haven Hospice sought judicial review pursuant to the *third* sentence of § 1395oo(f)(1), which did not and would not have applied to the decision of the Secretary in *Pacific Coast*. On its face, that provision specifically authorizes the district courts to decide pure questions of law, such as the claim that the hospice cap regulation is inconsistent with the enabling statute, at least where, as here, the plaintiff has complied with the presentment requirements in § 1395oo(f)(1) before bringing a civil action, and notwithstanding the fact that the legal question is raised in connection with the plaintiff's appeal of a repayment demand for a specific accounting year. *Id.*; *see also Bethesda Hosp. Ass'n*, 485 U.S. at 406. As there is no statutory or case law bar to declaratory or injunctive relief in such an action, we conclude that the district court had the authority and acted within its discretion to enjoin further application of the hospice cap regulation against Haven Hospice.

2.

Finally, we turn to the Secretary's contention that the district court abused its discretion by entering a nationwide injunction. We agree that it did.

[15] Our Supreme Court has cautioned that "injunctive relief should be no more burdensome to the defendant than necessary to provide complete relief to the plaintiffs" before the court. *Califano v. Yamasaki*, 442 U.S. 682, 702 (1979). This rule applies with special force where there is no class certification. *See Easyriders Freedom F.I.G.H.T. v. Hannigan*, 92 F.3d 1486, 1501 (9th Cir. 1996) ("[I]njunctive relief generally should be limited to apply only to named plaintiffs where there is no class certification."); *Meinhold v. U.S. Dep't of Defense*, 34 F.3d 1469, 1480 (9th Cir. 1994) (district court erred in enjoining the defendant from improperly applying a regulation to all military personnel (citing *Califano*, 442 U.S. at 702)); *cf. Bresgal v. Brock*, 843 F.2d 1163, 1170-71 (9th Cir. 1987) (there is no bar against nationwide relief in the dis-

trict courts or courts of appeal, even if the case was not certified as a class action, if such broad relief is necessary to give prevailing parties the relief to which they are entitled).

[16] The Supreme Court has also suggested that nationwide injunctive relief may be inappropriate where a regulatory challenge involves important or difficult questions of law, which might benefit from development in different factual contexts and in multiple decisions by the various courts of appeals. *Califano*, 442 U.S. at 702 (noting that nationwide injunctions "have a detrimental effect by foreclosing adjudication by a number of different courts and judges"); *United States v. Mendoza*, 464 U.S. 154, 160 (1984) (allowing only one final adjudication deprives the Supreme Court of the benefit it receives from permitting multiple courts of appeals to explore a difficult question before it grants certiorari); *see also Virginia Soc'y for Human Life, Inc. v. Federal Election Comm'n*, 263 F.3d 379, 393 (4th Cir. 2001) (nationwide injunction was an abuse of discretion where it was broader than necessary to afford relief to the plaintiff, and would " 'thwart the development of important questions of law by freezing the first final decision rendered on a particular legal issue' " (quoting *Mendoza*, 464 U.S. at 160)).

As we have noted, the district court initially agreed with Haven Hospice that a nationwide injunction would be appropriate in this case because of the facial invalidity of the hospice cap regulation. Ultimately, however, the district court decided to stay that portion of the injunction granting nationwide relief while this appeal is pending. The district court itself raised serious questions whether it should have entered such a sweeping injunction in the first place. The district court noted that a nationwide injunction would not be in the public interest because it would significantly disrupt the administration of the Medicare program by inhibiting HHS from enforcing the statutorily mandated hospice cap as to over 3,000 hospice providers, and would create great uncertainty for the government, Medicare contractors, and the hospice providers.

The district court also observed that the same challenge to the hospice cap regulation had been decided by other district courts, and that there was thus "some prospect of the issue reaching other circuit courts" in the near future.

[17] For reasons the district court acknowledged, the national injunction was too broad. An order declaring the hospice cap regulation invalid, enjoining further enforcement against Haven Hospice, and requiring the Secretary to recalculate its liability in conformity with the hospice cap statute, would have afforded the plaintiff complete relief. Indeed, Haven Hospice conceded as much during oral argument. As we have already noted, moreover, several other courts of appeals are currently reviewing decisions of other district courts that have found the hospice cap regulation to be facially invalid and enjoined enforcement against the individual hospice care providers who have sued to set aside repayment demands—in one case where the evidence suggested that a demand of over $1 million was more than twice the amount the hospice care provider would be obliged to repay under a proper application of the hospice cap statute. *Hospice of New Mexico*, 691 F.Supp.2d at 1288 & n.2. The Secretary's concerns about the potential for disruption in the process for enforcing the hospice cap statute, and the great uncertainty and confusion that would likely flow from a nationwide injunction, are also legitimate and well-founded.

[18] In these circumstances, we conclude that the nationwide injunction must be vacated, and we remand the matter to the district court for entry of an injunction that is no broader, and no more burdensome to the defendant, than necessary to provide complete relief to Haven Hospice.

III.

For all the foregoing reasons, we AFFIRM the judgment of the district court insofar as it concluded that Haven Hospice has Article III standing to mount a facial challenge to the hos-

pice cap regulation, and declared the hospice cap regulation to be arbitrary, capricious, and contrary to law and, thus, invalid. We also AFFIRM the injunction insofar as it barred future enforcement of the hospice cap regulation against Haven Hospice, but VACATE that portion of the injunction barring enforcement of the regulation against hospice providers other than Haven Hospice, and REMAND for further proceedings consistent with this decision.

AFFIRMED IN PART; VACATED IN PART AND REMANDED.

Haven Hospice shall recover its costs on appeal.