IN THE UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

United States Court of Appeals
Fifth Circuit

FILED
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Lyle W. Cayce
Clerk

No. 10-10414

LION HEALTH SERVICES, INC., a Texas corporation, doing business as Lion Hospice,

Plaintiff–Appellee

v.

KATHLEEN SEBELIUS, Secretary, Health and Human Services,

Defendant–Appellant

Appeal from the United States District Court
for the Northern District of Texas

Before KING, DeMOSS, and PRADO, Circuit Judges.

EDWARD C. PRADO, Circuit Judge:

This appeal concerns the validity of 42 C.F.R. § 418.309(b)(1) (the "Regulation"), a regulation promulgated by the Secretary of the U.S. Department of Health and Human Services (the "Secretary"). The Regulation purports to implement 42 U.S.C. § 1395f(i)(2), which establishes a Medicare hospice-care provider's annual aggregate cap amount for reimbursement purposes. Lion Health Services, Inc. ("Lion") contends that § 1395f(i)(2) unambiguously requires the Secretary to calculate a provider's number of beneficiaries per year for annual-reimbursement-cap purposes by allocating patient stays that fell into multiple years proportionally into each year. The Regulation instead uses a

formula that allocates these multi-year patients into only one year. The district court granted summary judgment to Lion, finding that the Regulation was unlawful. The court set aside the Regulation and enjoined its past, present, and future use as to Lion. It also ordered the Secretary to refund Lion all monies repaid by Lion to the Medicare program pursuant to the previously calculated repayment obligations for fiscal years 2006 and 2007. We find that the district court correctly held that the Regulation was unlawful and correctly enjoined its use as to Lion. The district court abused its discretion, however, in ordering the Secretary to refund all payment obligations for the 2006 and 2007 fiscal years, because it should have remanded to the agency for a recalculation. We therefore affirm in part, and reverse and remand in part.

I. FACTUAL AND PROCEDURAL BACKGROUND

A. Medicare Hospice Program

In 1965, Congress established Medicare under Title XVIII of the Social Security Act, 42 U.S.C. § 1395 *et seq*. (the "Medicare Act"), and authorized the Secretary to issue regulations defining the reimbursable costs and to otherwise carry out the Medicare Act provisions. *See* 42 U.S.C. §§ 1395x(v)(1)(A) and 1395hh(a)(1). In 1982, Congress expanded the Medicare Act to include hospice care for terminally ill beneficiaries. *See* Tax Equity and Fiscal Responsibility Act of 1982, Pub. L. 97-248, § 122, 96 Stat. 356, 364. In order to initially classify a patient as "terminally ill," both the patient's "attending physician" and the hospice medical director must certify that the patient's life expectancy is six months or less. *See* 42 U.S.C. §§ 1395f(a)(7) and 1395x(dd)(3)(A). The hospice-care program provides for two initial ninety-day benefit periods followed by an unlimited number of sixty-day benefit periods. *See id*. § 1395d(a)(4). Either the patient's attending physician or the hospice medical director may re-certify the patient as terminally ill at the end of each period, provided the doctor still deems the patient to have less than six months to live. *See* 42 U.S.C. § 1395f(a)(7).

While the Medicare Act allows each individual *patient* to receive hospice care for as long as doctors re-certify the patient's terminally-ill diagnosis, the statute caps total reimbursement payments that hospice care *providers* may receive from Medicare in a fiscal year.[1] The relevant hospice-care statute provides:

> (A) The amount of payment made under this part for hospice care provided by (or under arrangements made by) a hospice program for an accounting year may not exceed the "cap amount" for the year (computed under subparagraph (B)) multiplied by the number of medicare beneficiaries in the hospice program in that year (determined under subparagraph (C)).
>
> . . . .
>
> (C) For purposes of subparagraph (A), the "number of medicare beneficiaries" in a hospice program in an accounting year is equal to the number of individuals who have made an election under subsection (d) of this section with respect to the hospice program and have been provided hospice care by (or under arrangements made by) the hospice program under this part in the accounting year, *such number reduced to reflect the proportion of hospice care that each such individual was provided in a previous or subsequent accounting year* or under a plan of care established by another hospice program.

Id. § 1395f(i)(2) (emphasis added). The statute requires an annual recalculation of the individual patient "cap amount" based on changes in the Consumer Price Index. *See id.* § 1395f(i)(2)(B).

In 1983, the Secretary promulgated 42 C.F.R. § 418.309, a regulation purporting to implement 42 U.S.C. § 1395f(i)(2), the portion of the Medicare Act concerning the calculation of a hospice-care provider's annual aggregate cap amount. The annual aggregate cap amount restricts the maximum dollar amount that Medicare may reimburse a hospice care provider in any given fiscal year, calculated based on the number of individual patients treated in that fiscal

[1] A Medicare fiscal year ("FY") runs from November 1 to October 31 (e.g., November 1, 2005, to October 31, 2006, is considered FY06).

year multiplied by the individual patient cap amount. The Regulation provides in relevant part:

> For purposes of [the cap amount] calculation, the number of Medicare beneficiaries includes—
>
> > (1) 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, in accordance with § 418.24, 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).

Thus, the Regulation deals with patients whose hospice care stay extends into more than one fiscal year by using a single-year allocation method—allocating each individual patient cap amount to a single fiscal year based upon the date on which the patient elects for hospice care—rather than a proportional allocation method. A proportional method would allocate each individual patient cap amount to different fiscal years based on the exact proportion of care received by a patient in each relevant fiscal year. Under the Regulation's single-year approach, a patient who elects to receive hospice care on or before September 27, 2005, would be counted as receiving care only in FY05, even if the patient continues to receive hospice care in FY06. A patient who elects to receive hospice care on September 28, 2005, however, would be counted as receiving care only in FY06, even though she may have started receiving hospice care during FY05.

A hospice-care provider's Medicare bills are calculated and paid by a Medicare contractor called a "fiscal intermediary" shortly after the provider submits them. *See* 42 U.S.C. § 1395g(a); *see also* 42 C.F.R. §§ 413.64(b) and 418.302(d)–(e). Then, at the close of each fiscal year, the intermediary uses the Regulation to calculate a hospice care provider's aggregate cap amount for that

fiscal year. *See* 42 C.F.R. § 418.308(c). If a provider's total reimbursement payments received from the intermediary over the course of the fiscal year exceed its aggregate cap amount for that year, the intermediary demands that the provider refund the amount of the overpayments to Medicare. *See id.* § 418.308(d).

If a hospice-care provider is not satisfied with the intermediary's refund demand and the amount in controversy is at least $10,000, the provider may administratively challenge that demand before the Provider Reimbursement Review Board (the "PRRB"). *See* 42 U.S.C. § 1395oo(a). When the provider challenges the validity of a regulation itself, however, the PRRB lacks the authority to declare regulations invalid. *See Bethesda Hosp. Ass'n v. Bowen*, 485 U.S. 399, 406 (1988) ("Neither the fiscal intermediary nor the Board has the authority to declare regulations invalid."). In this situation, once the PRRB has determined "that it is without authority to decide the question" because the "action of the fiscal intermediary . . . involves a question of law or regulations," the provider may obtain "expedited judicial review." 42 U.S.C. § 1395oo(f)(1). Thus, the provider brings an action against the Secretary in federal district court, which the court tries pursuant to the standards of the Administrative Procedure Act, 5 U.S.C. § 701 *et seq.* (the "APA"). *See id.* § 1395oo(f)(1); 42 C.F.R. § 405.1842.

B. Lion's Lawsuit

Lion is a Medicare-certified hospice-care provider based in Hurst, Texas. It is one of dozens of hospice-care providers that over the past several years have filed lawsuits in district courts nationwide challenging the validity of the Secretary's single-year allocation method of calculation prescribed by 42 C.F.R. § 418.309(b)(1). On October 22, 2008, a fiscal intermediary notified Lion that calculations made pursuant to the Regulation indicated that Lion had exceeded its aggregate cap amount by $1,137,113 for FY06. In a similar letter dated July

8, 2009, the intermediary informed Lion that it had also exceeded its aggregate cap amount by $1,214,637 for FY07. Each letter demanded that Lion make refund payments to Medicare in the stated amounts, which Lion has been repaying on a monthly extended repayment schedule.

Lion timely filed administrative appeals with the PRRB and sought expedited judicial review on the question of whether the Regulation is invalid because it conflicts with Congress's unambiguous intent as provided in its authorizing statute, 42 U.S.C. § 1395f(i)(2)(C). The PRRB granted the requests for expedited judicial review for both FY06 and FY07. On August 18, 2009, Lion timely filed its Complaint in the U.S. District Court for the Northern District of Texas, challenging the validity of the Regulation and requesting various forms of relief. On October 26, 2009, Lion filed a motion for summary judgment, claiming that Congress expressly required that its annual aggregate cap amounts be determined using a proportional method of calculation and that the single-year allocation method was therefore in direct conflict with Congress's mandate. Lion attached to its motion for summary judgment a "hypothetical spreadsheet" showing that a "proportional allocation" would have resulted in Lion owing $217,862.43 less in refunds for FY06 and $441,877.33 less in refunds for FY07. On February 22, 2010, the district court granted Lion's motion for summary judgment. In its order, the district court: (1) declared the Regulation to be unlawful and set aside; (2) enjoined the Secretary from enforcing against Lion any overpayment determinations calculated using the Regulation; (3) enjoined the Secretary from using the Regulation to calculate Lion's annual aggregate cap amount for any past, present, or future accounting year; and (4) ordered the Secretary to refund to Lion all monies paid by Lion to the Medicare program pursuant to previously calculated repayment obligations for FY06 and FY07. The Secretary timely appealed.

II. DISCUSSION

The Secretary raises several issues on appeal. First, while acknowledging that Lion has standing in this case because it offered evidence to show a financial injury from the Regulation's application, she claims that the district court improperly found that the Regulation's alleged invalidity itself creates an injury for Article III standing purposes. Second, the Secretary argues that the Regulation provides a reasonable interpretation of an ambiguous authorizing statute, 42 U.S.C. § 1395f(i)(2), by using a method that *reflects* proportionality. Finally, the Secretary contends that the district court granted Lion improper relief. She maintains that even if the Regulation is invalid, the district court lacked jurisdiction to award Lion relief for fiscal years that have not yet been administratively exhausted. She further argues that the district court abused its discretion by ordering the Secretary to return all money collected in satisfaction of her overpayments to Lion, rather than remanding to the agency for a redetermination of monies owed using Lion's suggested proportional method.

A. Standing

As a first matter, the Secretary challenges the district court's method for determining standing in this case. This Court reviews determinations of standing de novo. *See United States v. $500,000.00 in U.S. Currency*, 591 F.3d 402, 404 (5th Cir. 2009). In its opinion, the district court stated that Lion suffered an injury "because the amount of its overpayments were calculated according to an unlawful regulation." *Lion Health Servs., Inc. v. Sebelius*, 689 F. Supp. 2d 849, 855 (N.D. Tex. 2010). The Secretary contends that the application of an allegedly unlawful regulation does not itself constitute an injury in fact for Article III standing purposes, but that a plaintiff must demonstrate that striking down the regulation would reduce its overpayment amount.

Lion undisputedly established standing by demonstrating that it has suffered an actual and concrete financial injury due to the Secretary's use of the Regulation, and that setting aside the Regulation and using a proportional method will redress its injury. *See Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560–61 (1992) (noting the requirements for Article III standing). Because Lion has established standing through a showing of financial harm, we need not decide whether a hypothetical plaintiff who alleges that the Regulation is invalid but cannot show financial harm would have standing.

B. Validity of the Regulation

This Court reviews a grant of summary judgment de novo, using the same standard as the district court. *Apache Corp. v. W & T Offshore, Inc.*, 626 F.3d 789, 793 (5th Cir. 2010). Summary judgment is appropriate when "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." FED. R. CIV. P. 56(a). Here, it is undisputed that the questions at issue are purely legal determinations and that there are no issues of fact in dispute.

The Secretary argues that the district court should have deferred to the Regulation as a "permissible construction" of the enacting statute, 42 U.S.C. § 1395f(i)(2), when Congress did not unambiguously express its intent. She notes that the statute requires that the number of Medicare beneficiaries be reduced "to *reflect* the proportion of hospice care that each such individual was provided in a previous or subsequent accounting year." *Id.* (emphasis added). Because the statute only requires that the reduction *reflect* the portion of care that a patient receives in the current accounting year, she argues, a strictly proportional calculation is not required. The Secretary contends that an empirical study conducted by the Department of Health and Human Services ("HHS") shows that in the aggregate, the Regulation's single-year allocation

method reasonably approximates the number that a strictly proportional method would produce.

Lion argues that Congress has spoken to the precise question at issue, and that the statute unambiguously requires a proportional calculation. It notes that the text refers to "*the proportion* of hospice care that *each such individual* was provided," and not an aggregate approximation. *Id.* § 1395f(i)(2) (emphasis added). Lion also directs us to commentary that HHS issued when it proposed the Regulation:

> Although section 1814(i)(2)(C) of the Act specifies that the cap amount is to be adjusted "to reflect the proportion of 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 died or exhausted his or her hospice benefits. We believe that 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. 38146, 38,158 (Aug. 22, 1983). This comment, Lion asserts, indicates that HHS acknowledged that it was not following the letter of the statute in enacting the Regulation but instead was striving for administrative convenience.

Neither party disputes that the Supreme Court's two-step *Chevron* test governs this Court's review of the question of whether the Regulation conflicts with its enacting statute. *See Chevron, U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837 (1984). Under this test, we first ask "whether Congress has directly spoken to the precise question at issue." *Id.* at 842. If so, we "must give effect to the unambiguously expressed intent of Congress." *Id.* at 843. Only if we find that the statute is "silent or ambiguous with respect to the specific issue"

do we then ask whether the regulation is "based on a permissible construction of the statute." *Id.*

We find that Congress has "spoken directly to the precise question at issue" with the text of § 1395f(i)(2)(C), and that only a proportional calculation method based on each individual patient is permitted by the statute. The text of the statute explicitly refers to "*the proportion* of hospice care that *each such individual* was provided," which cannot be accomplished through a single-year allocation that only seeks proportionality on the aggregate level across several years. That the statute unambiguously requires a proportional calculation is further borne out by HHS's comments in proposing the Regulation, where it acknowledged that the single-year allocation method was an "alternative" to the proportional requirement in the statute's text.

The Secretary contends that the statute's use of the word "reflect" creates ambiguity and allows flexibility in its calculation so long as a multi-year aggregate approximates what a proportional calculation achieves. In particular, she cites a Seventh Circuit opinion where the court found that one stock index "reflected" a broader portfolio when the two had a 92% correlation. *See Bd. of Trade of City of Chi. v. SEC*, 187 F.3d 713, 719 (7th Cir. 1999). In that case, the Seventh Circuit looked at a statute that required that one index "shall reflect, the market for all publicly traded equity or debt securities or a substantial segment thereof." *Id.* (quoting 7 U.S.C. § 2(a)(ii) (internal quotation marks omitted)). That court then noted that "[t]he index must 'reflect' a substantial segment; § 2a(ii)(III) does not require that the index *be* a substantial segment." *Id.*

The Seventh Circuit's analysis using the word "reflect," however, is inapposite to the case before us. The statute at issue speaks directly in terms of the proportion of care that *each such individual* was provided. *See* 42 U.S.C. § 1395f(i)(2)(C). A regulation that assigns an individual patient's care to a single

year cannot possibly "reflect" the portion of a fiscal year that the individual spent at the hospice. Allocating 100% of an individual patient's cap amount to FY06 does not "reflect" the proportion of care that patient received when the actual proportion of care received by that patient was 10% in FY06 and 90% in FY07. Because the statute requires the Secretary to calculate the proportion of care in a fiscal year on an individual level, only a proportional calculation method meets this requirement.

Therefore, we agree with the district court that the statute unambiguously requires the Secretary to use a strict proportional method of calculation, and the Regulation therefore contradicts Congress's expressed intent.

C. Remedies

The Secretary avers that the district court granted several remedies in error. First, she claims that the district court lacked jurisdiction to order relief that applies to any years other than FY06 and FY07, arguing that it did not have the authority to prospectively enjoin her from using the invalid Regulation. Second, she claims that the district court should have remanded Lion's FY06 and FY07 claims to the agency rather than ordering her to reimburse Lion the entirety of the refunds already collected from those fiscal years.

1. Jurisdiction to Issue Prospective Relief

This Court reviews questions of the district court's jurisdiction de novo. *See Texas v. United States*, 497 F.3d 491, 495 (5th Cir. 2007).

While the Secretary agrees that Lion timely exhausted its administrative remedies as to its repayment demands for FY06 and FY07, she claims that the district court lacked subject-matter jurisdiction to set aside the Regulation and enjoin her from using it to calculate Lion's cap for future years. She notes that decisions by both this Court and the Supreme Court make apparent that there is no general federal question jurisdiction under 28 U.S.C. § 1331 for Medicare Part A reimbursement cases. *See Shalala v. Ill. Council on Long Term Care,*

Inc., 529 U.S. 1, 10–20 (2000); *Dr. John T. MacDonald Found., Inc. v. Califano*, 571 F.2d 328, 331 (5th Cir. 1978) (en banc). Therefore, she claims, Lion can only seek review of the action of the fiscal intermediary's actions as contrary to law under 42 U.S.C. § 1395oo(f)(1), and only after exhausting those claims administratively. Finally, the Secretary argues that even if the district court has the power to set aside "agency action" pursuant to the APA, the Regulation itself is not such an "agency action," and the district court may only regard the refund demands as such.

Lion claims that once the Regulation's validity was properly before the district court pursuant to § 1395oo(f)(1), its review over the question was governed by the APA, notwithstanding restrictions in the Medicare Act. *See* 5 U.S.C. § 706 (providing that "the reviewing court shall decide all relevant questions of law" and shall "hold unlawful and set aside agency action" that was "arbitrary, capricious, . . . or otherwise not in accordance with law" or "in excess of statutory . . . authority"). It asserts that the promulgation of the Regulation is itself "agency action" that the district court can set aside pursuant to a prospective injunction.

The Secretary correctly notes that there is no general federal question jurisdiction under 28 U.S.C. § 1331 in Medicare reimbursement cases. *See Dr. John T. MacDonald Found.*, 571 F.2d at 331. The district court may only hear a claim and grant relief pursuant to the specific jurisdictional provisions of the Medicare Act. *See* 42 U.S.C. § 1395oo(f)(1); *Califano v. Sanders*, 430 U.S. 99, 105 (1977) (holding that the APA provides no independent grant of subject matter jurisdiction to review agency actions). The Medicare Act states that district courts have jurisdiction to review "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." 42 U.S.C. § 1395oo(f)(1). Each of these prerequisites to judicial

review was met for FY06 and FY07—Lion was dissatisfied with the fiscal intermediary's calculations made pursuant to the Regulation and properly obtained the PRRB's determination that it was without authority to resolve the question of the Regulation's validity.

Once the question of the Regulation's validity was before the district court, the APA provided the district court with the authority to hold the Regulation unlawful and set it aside. *See* 5 U.S.C. § 706. Because the question of the Regulation's validity was properly before the district court pursuant to 42 U.S.C. § 1395oo(f)(1), no statute precludes judicial review under the APA. *See* 5 U.S.C. § 701(a). The Secretary, however, cites a number of cases for the proposition that a district court never has authority to provide prospective relief for non-administratively exhausted years, even if it finds the underlying regulation to be invalid. *See Lujan v. Nat'l Wildlife Fed'n*, 497 U.S. 871, 891 (1990); *Hosp. Ass'n of R.I. v. Sec'y of Health & Human Servs.*, 820 F.2d 533, 539–40 (1st Cir. 1987); *Riley Hosp. & Benevolent Ass'n v. Bowen*, 804 F.2d 302, 305 (5th Cir. 1986); *Charter Med. Corp. v. Bowen*, 788 F.2d 728, 732–35 (11th Cir. 1986); *Abington Mem'l Hosp. v. Heckler*, 750 F.2d 242, 244 (3d Cir. 1984); *Pac. Coast Med. Enters. v. Harris*, 633 F.2d 123, 137–39 (9th Cir. 1980).

We find that none of these cases compel the conclusion that the Regulation itself cannot be the "agency action" challenged, or that the district court may not set aside such an invalid regulation. In fact, the APA has defined "agency action" to include "the whole or part of an agency rule." *See Nat'l Wildlife Fed'n*, 497 U.S. at 882 ("The meaning of 'agency action' for purposes of § 702 is set forth in 5 U.S.C. § 551(13) . . . which defines the term as 'the whole or a part of an agency rule, order, license, sanction, relief, or the equivalent or denial thereof, or failure to act.'" (internal citations omitted)). In *National Wildlife Federation*, the Supreme Court noted that a challenge to a specific order or regulation is quite different than a "generic challenge" to a "program," and therefore that the

program of operations did not qualify as "agency action" within the meaning of the APA. *Id.* at 890 & n.2. Here, however, Lion challenged the facial validity of a specific regulation promulgated by the Secretary and enforced against Lion, not simply a general and amorphous "program" of operations performed by an agency.

Further, this Court's decision in *Riley* does not preclude the district court's injunction. In *Riley*, we affirmed the district court's finding that it was without jurisdiction to compel the Secretary to pay interest for years in which the plaintiff has not exhausted its claims before the PRRB. 804 F.2d at 305. This relief would have required the district court to order the agency to compute interest for years in which the plaintiff had not yet exhausted its claims. This is distinct from the relief ordered by the district court here, which merely forbade the Secretary from continuing to apply an invalid regulation. The other cases cited by the Secretary also involve situations where the plaintiffs asked the district court to affirmatively order reimbursement or interest payments for unexhausted years. *See Hosp. Ass'n of R.I.,* 820 F.2d at 539–40; *Charter Med. Corp.*, 788 F.2d at 732; *Abington Mem'l Hosp.*, 850 F.2d at 243–44; *Pac. Coast Med. Enters.*, 633 F.2d at 138–39. In this case, the district court, acting pursuant to the APA, merely enjoined enforcement of an invalid regulation rather than making premature refund determinations for unexhausted years.

Here, Lion challenged the validity of a specific regulation, the promulgation and enforcement of which qualifies as "agency action." Further, the question of the regulation's validity was properly before the district court pursuant to 42 U.S.C. § 1395oo(f)(1). Therefore, the district court had the authority under § 706 of the APA to enjoin the Secretary from using the Regulation to calculate Lion's aggregate cap amount for any past, present, and future year.

2. Failure to Remand

Where an injunction is not based upon an error of law, this Court reviews the injunction for an abuse of discretion. *See Overstreet v. El Paso Disposal, L.P.*, 625 F.3d 844, 850 (5th Cir. 2010).

The Secretary urges that the district court should not have ordered her to refund to Lion all monies paid by Lion to the Medicare program pursuant to the previously calculated repayment obligations for FY06 and FY07. She claims that the only appropriate remedy is remand to the agency so that the PRRB can recalculate Lion's potential liability for refund payments using the proportional method urged by Lion. Specifically, the Secretary points us to this Court's decision in *Presbyterian Hospital of Dallas v. Harris*, where we stated the following:

> Where an error of law has been corrected by a reviewing court, and the only issues remaining in the case are questions which have not yet been considered by the administrative agency but are nevertheless within the agency's authority, the appropriate action is a remand to the agency so that it may exercise its authority.

638 F.2d 1381, 1389 (5th Cir. Unit A Mar. 1981). The Secretary states that the PRRB must perform additional fact-finding and data collection in order for it to recalculate Lion's FY06 and FY07 refund liability.

Lion claims that to the extent such a remand would permit the Secretary to retain Lion funds collected pursuant to an invalid regulation, such a remedy should be rejected. It also claims that the Supreme Court's decision in *Bowen v. Massachusetts* stands for the proposition that the APA allows the district court to order refund of all monies that Lion has paid because such relief does not constitute money damages. *See* 487 U.S. 879, 893 (1988). Because the district court properly set aside the Regulation, Lion argues, the injunction to order a full refund of monies collected pursuant to it was proper in order to effectuate full relief. Lion also notes that nothing in the district court's

judgment precludes further action by the Secretary, the PRRB, or the fiscal intermediary with respect to issuing a new regulation which implements a strict proportionality method of calculation, recalculating Lion's repayment liability amounts for FY06 and FY07, or issuing new repayment demands once such calculations are performed.

As a general principle, "injunctive relief should be no more burdensome to the defendant than necessary to provide complete relief to the plaintiffs." *Califano v. Yamasaki*, 442 U.S. 682, 702 (1979). Additionally, "a court of appeals should remand a case to an agency for decision of a matter that statutes place primarily in agency hands." *I.N.S. v. Orlando Ventura*, 537 U.S. 12, 16 (2002). Therefore, even if the APA provides authority for the district court to order the Secretary to refund all monies paid by Lion for FY06 and FY07, we must consider whether there are "questions which have not yet been considered by the administrative agency but are nevertheless within the agency's authority." *Presbyterian Hosp.,* 638 F.2d at 1389.

Under the principle articulated in *Yamasaki*, the relief ordered by the district court is broader and more burdensome than necessary to afford Lion full relief. *See* 442 U.S. at 702. Even using Lion's proportional calculation method, it still owes a substantial amount of refund to the Secretary for FY06 and FY07. Additionally, the determination of the amount of refund owed to Lion is a matter properly within the agency's authority. Therefore, the district court's decision to order a full refund rather than remanding for recalculation of the refund amount was an abuse of discretion.

III. CONCLUSION

We join a unanimous group of district courts around the country in finding that 42 C.F.R. § 418.309(b) is invalid, because it directly contradicts Congress's unambiguously expressed intent. Further, we find that the district court had subject-matter jurisdiction to declare the Regulation invalid, set it aside, and

enjoin the Secretary from enforcing it against Lion in the future. The district court did abuse its discretion, however, in failing to remand to the agency to recalculate Lion's refund amount in proper accordance with 42 U.S.C. § 1395f(i)(2). We therefore direct the district court to remand this case to the Secretary for proceedings consistent with this opinion.

AFFIRMED IN PART and REVERSED IN PART with DIRECTIONS TO REMAND.