Case: 10-56529 10/26/2012 ID: 8377376 DktEntry: 66-1 Page: 1 of 23 (1 of 57)

No. 10-56529

UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

Palomar Medical Center,

Plaintiff-Appellant,

v.

Kathleen Sebelius,
Secretary of Health and Human Services,
Defendant-Appellee.

On Appeal From The United States District Court for the Southern District of California,
Case No. 3:09-cv-00605-BEN-NLS
The Honorable Judge Roger T. Benitez

PLAINTIFF-APPELLANT'S PETITION FOR REHEARING EN BANC

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Case: 10-56529 10/26/2012 ID: 8377376 DktEntry: 66-1 Page: 2 of 23 (2 of 57)

Table of Contents

Statemen	nt Under Fed. R. App. P. 35
Backgro	und
Argumei	nt5
I.	The Panel Erred in Upholding the Secretary's Interpretation of the Reopening Regulations, Based on the Needs of the RAC Program, When the Regulations Apply to All Contractors, Not Just RACs
II.	The Panel Erred By Permitting the Secretary to Divest Federal Courts of Jurisdiction to Review Whether She Has Violated the Law10
III.	The Secretary Has Unlawfully Subdelegated Unreviewable Authority to Private Entities
Conclusi	on17
Certifica	te of Service19

Case: 10-56529 10/26/2012 ID: 8377376 DktEntry: 66-1 Page: 3 of 23 (3 of 57)

Table of Authorities

Cases

Assiniboine and Sioux Tribes v. Bd. of Oil and Gas Conservation,
792 F.2d 782 (9th Cir. 1986)15
Califano v. Sanders, 430 U.S. 99 (1977)11
Coe v. Thurman, 922 F.2d 528 (9th Cir. 1990)14
Cole ex. rel. v. Barnhart, 288 F.3d 149 (5th Cir. 2002)
Escobar Ruiz v. I.N.S., 813 F.2d 283 (9th Cir. 1987)
Fayad v. Sebelius, 803 F. Supp. 2d 699 (E.D. Mich. 2011)
Harper v. Brown, 813 F.2d 737 (5th Cir. 1987)11
Matlock v. Sullivan, 908 F.2d 492 (9th Cir. 1990)11
Nat'l Ass'n of Regulatory Util. Comm'rs v. F.C.C.,
737 F.2d 1095 (D.C. Cir. 1984)16
Nat'l Park and Conserv. Ass'n v. Stanton, 54 F. Supp. 2d 7 (D.D.C. 1999) 15, 16
Nat'l Wildlife Fed'n v. Nat'l Marine Fisheries Serv., 524 F.3d 917
(9th Cir. 2008)9
Ocean Conservancy v. Evans, 260 F. Supp. 2d 1162 (M.D. Fla. 2003)15
R.H. Johnson & Co. v. SEC, 198 F.2d 690 (2d Cir. 1952)15
Service v. Dulles, 354 U.S. 363 (1957)10
Sierra Club v. Sigler, 695 F.2d 957 (5th Cir. 1983)16
Thomas Jefferson Univ. v. Shalala, 512 U.S. 504 (1994)9
U.S. Telecom Ass'n v. FCC, 359 F.3d 554 (D.C. Cir. 2004)
United Black Fund, Inc. v. Hampton, 352 F. Supp. 898 (D.D.C. 1972)15
United States ex rel. Accardi v. Shaugnessy, 347 U.S. 260 (1954)11
United States v. Ramos, 623 F.3d 672 (D.C. Cir. 2010)11
Varney v. Sec'y of Health and Human Servs., 859 F.2d 1396 (9th Cir. 1988)13
Administrative Cases
Canon Healthcare Hospice, LLC v. BlueCross BlueShield Ass'n/Palmetto Gov't
Benefits Adm'r, No. 2010-D34, 2010 WL 4214227 (PRRB June 4, 2010)4
Coosa Valley Med. Ctr. v. BlueCross BlueShield Ass'n/Cahaba Gov't Benefits
Adm'rs, No. 2011-D11, 2010 WL 5242167 (PRRB Nov. 22, 2010)

Case: 10-56529 10/26/2012 ID: 8377376 DktEntry: 66-1 Page: 4 of 23 (4 of 57)

Table of Authorities

Statutes	
5 U.S.C. § 706(2)(A)	11
42 U.S.C. § 405(g)	
42 U.S.C. § 1395ff(a)	
42 U.S.C. § 1395ff(a)(1)	
42 U.S.C. § 1395ff(b)(1)(a)	
42 U.S.C. § 1395ff(b)(1)(G)	
42 U.S.C. § 139500	
Medicare Prescription Drug, Improvement, and Modernization	
("MMA"), Pub. L. No. 108-173, § 306, 117 Stat. 2066, 2256	
Regulations	
42 C.F.R. § 405.926(<i>l</i>)	passim
42 C.F.R. § 405.980	
42 C.F.R. § 405.980(a)	
42 C.F.R. § 405.980(a)(5)	
42 C.F.R. § 405.980(b)	
42 C.F.R. § 405.986(a)	
42 C.F.R. § 405.1885(a)(6) (2008)	
Federal Registers	
70 Fed. Reg. 11,420, 11450-53 (Mar. 8, 2005)	
74 Fed. Reg. 65,296, 65,314 (Dec. 9, 2009)	
Other Authorities	
Social Security Handbook, 1986, § 2185	3

Case: 10-56529 10/26/2012 ID: 8377376 DktEntry: 66-1 Page: 5 of 23 (5 of 57)

Statement Under Fed. R. App. P. 35

This appeal involves a matter of exceptional importance and should be reheard en banc because the panel decision upheld an interpretation of Medicare "reopening" regulations that applies to numerous Medicare contractors, based on what the panel perceived as the needs of a single type of Medicare contractor, the Recovery Audit Contractor ("RAC"). This appeal also involves a matter of exceptional importance because the Secretary claims authority to divest federal courts of jurisdiction to review her unlawful acts. Finally, the Secretary has unlawfully subdelegated unreviewable authority to Medicare contractors to enforce the reopening regulations, a position that the Secretary did not reveal until after oral argument.

These regulations govern the reopening (auditing) of Medicare claims for health care services. The Secretary of Health and Human Services interprets the reopening regulations to preclude both administrative and judicial review of a contractor's compliance with the deadlines to reopen claims. Although the single claim underlying this case was reopened by a RAC, the Secretary did not argue that the RAC program was germane to her interpretation of the regulations. Those regulations apply across the board, not just to RACs. Yet, the panel repeatedly asserted that the congressionally mandated RAC program rendered the Secretary's interpretation reasonable. The panel's decision

eviscerates any finality for billions of Medicare claims, based on a false link between the RAC program and the reopening rules. The panel's decision also leaves open the important question of whether providers may appeal untimely reopenings by other, non-RAC contractors.

Background

Medicare regulations set the following deadlines for reopening claims:

Time frames and requirements for reopening initial determinations and redeterminations initiated by a contractor. A contractor may reopen and revise its initial determination or redetermination on its own motion—

- (1) Within 1 year from the date of the initial determination or redetermination for any reason.
- (2) Within 4 years from the date of the initial determination or redetermination for good cause as defined in § 405.986.
- (3) At any time if there exists reliable evidence as defined in § 405.902 that the initial determination was procured by fraud or similar fault as defined in § 405.902.
- (4) At anytime if the initial determination is unfavorable, in whole or in part, to the party thereto, but only for the purpose of correcting a clerical error on which that determination was based.
- 42 C.F.R. § 405.980(b) (2005). "Good cause" is defined as follows:
 - (1) There is new and material evidence that—
 - (i) Was not available or known at the time of the determination or decision; and
 - (ii) May result in a different conclusion; or

(2) The evidence that was considered in making the determination or decision clearly shows on its face that an obvious error was made at the time of the determination or decision.

42 C.F.R. § 405.986(a) (2005).

Medicare regulations also state, "The contractor's, QIC's, ALJ's, or MAC's decision on whether to reopen is final and not subject to appeal," 42 C.F.R. § 405.980(a)(5) (2005), and "A contractor's, QIC's, ALJ's, or MAC's determination or decision to reopen or not to reopen an initial determination, redetermination, reconsideration, hearing decision, or review decision" is not an initial determination that can be appealed, *id.* § 405.926(*l*) (2005).

Although this language may appear at first blush to support the Secretary's position, the Secretary also issued two rules with nearly identical language that have been interpreted only to forbid claimants from demanding a reopening or from halting a reopening before a claim is revised. First, in 1986, the Secretary issued a manual provision governing the reopening of Social Security claims: "The decision to reopen or not to reopen is *not* an initial determination and is *not* subject to appeal." *Social Security Handbook*, 1986, § 2185 (emphasis in original). This is the likely source of the Medicare regulations at issue here. Second, in 2008, the Secretary issued regulations

¹ A QIC is a Qualified Independent Contractor. An ALJ is an Administrative Law Judge. The MAC is the Medicare Appeals Council.

3

governing the reopening of Medicare cost reports: "A determination or decision to reopen or not to reopen a determination or decision is not a final determination or decision within the meaning of this subpart and is not subject to further administrative review or judicial review." 42 C.F.R. § 405.1885(a)(6) (2008).

These rules do not prevent a claimant from seeking to enforce the Social Security or cost report reopening deadlines once a claim has been revised. *See Cole ex. rel. v. Barnhart*, 288 F.3d 149, 150-51 (5th Cir. 2002) (Social Security claim); *Heins v. Shalala*, 22 F.3d 157, 161 (7th Cir. 1994) (Social Security claim); *Coosa Valley Med. Ctr. v. BlueCross BlueShield Ass'n/Cahaba Gov't Benefits Adm'rs*, No. 2011-D11, 2010 WL 5242167, at *7 (PRRB Nov. 22, 2010) (cost report); *Canon Healthcare Hospice, LLC v. BlueCross BlueShield Ass'n/Palmetto Gov't Benefits Adm'r*, No. 2010-D34, 2010 WL 4214227, *5 (PRRB June 4, 2010) (cost report).

4

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² Hospitals that participate in the Medicare program submit annual cost reports, which the Secretary's contractors use to reconcile total program payments. Cost report determinations may be appealed to the Provider Reimbursement Review Board ("PRRB"). 42 U.S.C. § 139500.

Case: 10-56529 10/26/2012 ID: 8377376 DktEntry: 66-1 Page: 9 of 23 (9 of 57)

Argument

I. The Panel Erred in Upholding the Secretary's Interpretation of the Reopening Regulations, Based on the Needs of the RAC Program, When the Regulations Apply to All Contractors, Not Just RACs

The Secretary's interpretation runs afoul of the statutory command to reopen claims in compliance with regulations and is inconsistent with the Secretary's interpretation of virtually identical cost report regulations. In upholding the Secretary's interpretation of 42 C.F.R. § 405.980(a)(5) and § 405.926(*l*), the panel treated those regulation as though they are specific to RACs. They are not. The regulations at 42 C.F.R. § 405.980(a)(5) and § 405.926(*l*) apply equally to all Medicare audit contractors, not just RACs. These regulations govern a wide array of Medicare audit contractors and agency appellate bodies. *See* 42 C.F.R. § 405.980(a).

From the outset, the panel identified the RAC program as key to its analysis. The panel believed that this case is governed by "competing principles": "[o]n the one hand, Congress wanted an effective recovery audit program to reduce Medicare payments with resulting benefits for Medicare beneficiaries and taxpayers, under procedures set by the Secretary. On the other hand, the provider has a legitimate interest in finality of determinations on its revenue for medical services." Panel Opinion ("Op.") at 11013, ECF No. 5. The panel concluded that this legitimate interest in finality must give way "in

view of the goals of the RAC program and the Secretary's regulations stating that the decisions to reopen are 'final' and 'not appealable.'" *Id*.

The Medicare statute plainly states that the Secretary may reopen claims but must do so "under guidelines established by the Secretary in regulations." 42 U.S.C. § 1395ff(b)(1)(G). In response to Palomar's argument that the Secretary's regulations must be interpreted to comply with this statutory mandate, the panel stated that "Congress did not require 'good cause' for RAC reopenings, in either the MMA or § 1395ff." Op. at 11032, ECF No. 24.

The panel also relied on the RAC program in rejecting Palomar's contention that the regulations at 42 C.F.R. § 405.980(a)(5) and 42 § 405.926(*l*) do not prevent a claimant from seeking enforcement of the reopening deadlines once a contractor has revised the claim. According to the panel, such a system would be "inefficient" and "tilt the focus" to "the RAC's grounds for reopening." Op. at 11025, ECF No. 17. The panel believed that "the interest of Palomar in finality of its Medicare services receipts" was sacrificed by Congress because "the values that Congress stressed in setting up the RAC program" permit the Secretary to create a system in which a claimant has "no ability . . . to litigate good cause for reopening." *Id*.

³ The RAC demonstration project was established by Congress in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA"), Pub. L. No. 108-173, § 306, 117 Stat. 2066, 2256 (2003).

The panel found particular significance in the timing of the reopening regulations, which CMS promulgated the same month that the RAC demonstration program began: "Because CMS promulgated and began applying the 2005 reopening regulations when it began the RAC demonstration project, it had in mind the goals of the RAC program." Op. at 11028, ECF No. 20. Thus, "CMS made a policy choice not to subject RAC reopening decisions to administrative review." *Id.* Similarly, the panel distinguished the nearly identical cost report regulations, which do not prevent private enforcement of the deadlines, because "cost report determinations are subject to a separate appeals process from claim determinations and are not included in the RAC program." Op. at 11029, ECF No. 21.

The panel erred by treating the regulations at 42 C.F.R. § 405.980(a)(5) and § 405.926(*l*) as specific to RACs. These regulations govern a wide array of Medicare audit contractors and agency appellate bodies. *See* 42 C.F.R. § 405.980(a). There is no evidence that the Secretary "had in mind the goals of the RAC program," Op. at 11025, ECF No. 17, when the reopening regulations were promulgated, and the Secretary has never claimed that she "made a policy choice" to exempt RACs, in particular, from the reopening deadlines. The Secretary has not argued that her interpretation of the regulations was dictated by the special characteristics of the RAC program or that her interpretation

should be upheld on that basis. The Secretary did not even mention RACs when the 2005 regulations were promulgated. 70 Fed. Reg. 11,420, 11450-53 (Mar. 8, 2005). Not until 2009 did the Secretary clarify that the reopening rules apply to RACs, along with many other entities. 74 Fed. Reg. 65,296, 65,314 (Dec. 9, 2009). In addition to RACs, the reopening rules apply to Medicare Administrative Contractors ("MACs"), fiscal intermediaries, carriers, Zone Program Integrity Contractors ("ZPICs"), Program Safeguard Contractors, Qualified Independent Contractors, ALJs, and the Medicare Appeals Council. 74 Fed. Reg. at 63514.

The Secretary's interpretation of the regulations cannot be upheld, therefore, based upon the specific needs of the RAC program. Congress's silence about "good cause' for RAC reopenings" in the MMA and 42 U.S.C. § 1395ff, Op. at 11032, ECF No. 24, has absolutely no bearing on whether the generally applicable regulations at 42 C.F.R. § 405.980(a)(5) and 42 C.F.R. § 405.926(*l*) forbid review of non-RAC contractors, such as MACs or ZPICs. Furthermore, Congress's silence also cannot be read as exempting RACs from the deadlines because requiring RACs to play by the rules is no more "inefficient," Op. at 11025, ECF No. 17, than imposing deadlines on the many other audit contractors.

In creating the RAC program, Congress cannot be expected to cross-reference every requirement that is to apply. Congress's mandate that claims must be reopened "under guidelines established by the Secretary in regulations," 42 U.S.C. § 1395ff(b)(1)(G), applies to all contractors, and the Secretary cannot circumvent this requirement by issuing regulations purporting to permit contractors to flout the regulatory deadlines for reopening claims. A far more sensible interpretation of 42 C.F.R. § 405.980(a)(5) and 42 C.F.R. § 405.926(*l*), one that brings those regulations into compliance with 42 U.S.C. § 1395ff(b)(1)(G), is that the regulatory reopening deadlines may be enforced once the contractor has revised the claim.

Indeed, this is how the Secretary applied nearly identical language applicable to reopening Social Security claims and Medicare cost reports. The pertinent question is not whether cost reports are included in the RAC program, Op. at 11029, ECF No. 21, but whether the Secretary has proffered inconsistent interpretations. *See Thomas Jefferson Univ. v. Shalala*, 512 U.S. 504, 512 (1994); *Nat'l Wildlife Fed'n v. Nat'l Marine Fisheries Serv.*, 524 F.3d 917, 931 (9th Cir. 2008). The Secretary has been inconsistent, and her interpretation that the reopening regulations foreclose all enforcement of the reopening deadlines should be rejected. *Nat'l Wildlife Fed'n*, 524 F.3d at 929.

II. The Panel Erred by Permitting the Secretary to Divest Federal Courts of Jurisdiction to Review Whether She Has Violated the Law

The panel erred by holding that the Secretary may close the courthouse doors simply by defining an "initial determination" as not encompassing review of whether she has complied with her regulations. The panel states, correctly, that Congress has limited judicial review to a "final decision" of the Secretary. 42 U.S.C. § 405(g). The first step toward a "final decision" is the Secretary's "initial determination." *Id.* § 1395ff(a). The "initial determination" may be appealed through several levels of administrative review and then to federal court. *Id.* § 1395ff(b)(1)(a). Congress created a sweeping definition of "initial determination," which includes "whether an individual is entitled to benefits," "the amount of benefits available to the individual," and "[a]ny other initial determination with respect to a claim for benefits" *Id.* § 1395ff(a)(1).

The Secretary then issued regulations defining an "initial determination" as not including "[a] contractor's . . . determination or decision to reopen or not to reopen an initial determination" 42 C.F.R. § 405.926(*l*). The Secretary issued another regulation that states, "The contractor's . . . decision on whether to reopen is final and not subject to appeal." *Id.* § 405.980(a)(5). The panel has granted the Secretary vast new powers over the federal courts if these regulations can indeed remove compliance with the regulatory deadlines from the broad statutory definition of an "[a]ny other initial determination with

respect to a claim for benefits," 42 U.S.C. § 1395ff(a)(1), thus also removing the matter from the final determination subject to judicial review.

This Court should not permit the Secretary so easily to evade judicial review of her actions by altering the definition of "initial determination." It is a well-established principle of Due Process and administrative law that federal courts may review whether an agency has complied with its own regulations. Service v. Dulles, 354 U.S. 363, 388 (1957); United States ex rel. Accardi v. Shaugnessy, 347 U.S. 260, 267-68 (1954); United States v. Ramos, 623 F.3d 672, 683 (D.C. Cir. 2010). This principle is also enshrined in the Administrative Procedure Act, which authorizes federal courts to set aside agency actions "not in accordance with law." 5 U.S.C. § 706(2)(A). The Secretary has promulgated regulations setting deadlines and standards for reopening Medicare claims, and she and her contractors must abide by those regulations when reopening Medicare claims. 42 C.F.R. § 405.980.

The cases relied upon by the panel are not to the contrary. *Califano v. Sanders*, 430 U.S. 99 (1977), *Matlock v. Sullivan*, 908 F.2d 492 (9th Cir. 1990), and *Harper v. Brown*, 813 F.2d 737 (5th Cir. 1987), all concerned claimants who had failed to exhaust administrative remedies. In *Sanders*, the Appeals Council had denied a request to reopen a claim, and so there was no final decision subject to judicial review. 430 U.S. at 108. *Matlock* and *Harper* each

concerned a decision of the Medicare Appeals Council not to grant an extension of time to appeal. *Matlock*, 908 F.2d at 493; *Harper*, 813 F.2d at 738. Unlike here, the applicable regulations did not set binding standards for the agency to follow. The decisions were purely discretionary because there simply was no law to apply. Although the *Matlock* court did state that "the regulations prohibit judicial review of the Appeals Council's refusal to grant such an extension," 908 F.2d at 493, the court did not grapple with the very serious Due Process and separation of powers issues implicated by permitting the Secretary to foreclose judicial review of her *ultra vires* acts.

Finally, Palomar has exhausted administrative remedies. This is not a case where a claimant has sought judicial review to enforce the reopening deadlines at a point prior to the Medicare Appeals Council rendering a final decision. That final decision must vest a federal court with jurisdiction to decide whether the Secretary has complied with the law. Otherwise, the Secretary's regulation setting deadlines to reopen claims is an empty shell.

III. The Secretary Has Unlawfully Subdelegated Unreviewable Authority to Private Entities

The Secretary has unconstitutionally subdelegated to Medicare contractors unreviewable discretion to comply with the reopening regulations.

Congress empowered the Secretary to reopen claims and delegated to the

Secretary the authority to establish reopening regulations: "The Secretary may reopen or revise any initial determination or reconsidered determination described in this subsection under guidelines established by the Secretary in regulations." 42 U.S.C. § 1395ff(b)(1)(G). This statutory provision squarely places responsibility upon the Secretary to ensure that claims are reopened in compliance with the regulations, and the Secretary may not subdelegate this responsibility to Medicare contractors with no review by the agency.

Throughout this litigation, it was assumed that the Secretary retained authority to force a contractor to comply with the reopening deadlines, notwithstanding the Secretary's view that the deadlines are not a permissible subject for administrative appeal. When promulgating the reopening regulations, the Secretary plainly stated, "The regulations require that contractors abide by the good cause standard for reopening actions after one year from the date of the initial or revised determination." 70 Fed. Reg. 11,420, 11,453 (March 8, 2005). The Secretary asserted that her "enforcement mechanisms" included monitoring "a contractor's compliance with Federal . . . regulations." *Id.* At oral argument, the Secretary specifically conceded that RACs are bound by the reopening deadlines.

After oral argument, the Secretary revealed for the first time, in a supplemental brief, that she interprets the reopening regulations to forbid even

her from correcting her contractors' specific reopening errors: "neither a provider *nor the Centers for Medicare and Medicaid Services* may challenge a contractor's decision to reopen." Sec.'s Supp. Br. at 4 (emphasis added). In other words, the Secretary's position is that Medicare contractors have unfettered authority to police themselves, and only the contractor—not the federal agency entrusted with administering the Medicare program—may determine compliance with federal regulations.

Subdelegation to a private entity requires "affirmative evidence of authority to do so." *U.S. Telecom Ass'n v. FCC*, 359 F.3d 554, 566 (D.C. Cir. 2004). Although Congress did establish RACs and other audit contractors, Congress did not expressly authorize the Secretary to subdelegate authority to any contractor to determine whether claims are reopened "under guidelines established by the Secretary in regulations." 42 U.S.C. § 1395ff(b)(1)(G). Mere congressional silence on subdelegation does not create a statutory gap for

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⁴ Because the Secretary did not reveal the full scope of her position until the very end of this litigation, "extraordinary circumstances" exist for raising the subdelegation issue for the first time in this petition for rehearing. *See Varney v. Sec'y of Health and Human Servs.*, 859 F.2d 1396, 1397-98 (9th Cir. 1988) (citing *Escobar Ruiz v. I.N.S.*, 813 F.2d 283, 285- 286 (9th Cir. 1987)). Permitting no check on Medicare contractors would be a disservice to Palomar and to all health care providers who are subject to contractor audits. *See Escobar Ruiz*, 813 F.2d at 286. Failure to correct this important error on rehearing would "have profound implications for the conduct of numerous cases in the Ninth Circuit." *Coe v. Thurman*, 922 F.2d 528, 533 n.1 (9th Cir. 1990) (per curiam).

the agency to fill. *U.S. Telecom Ass'n*, 359 F.3d at 566. Therefore, the Secretary's subdelegation of enforcement of the reopening deadlines is wholly invalid.

Even when subdelegation is permissible as a general matter, a federal agency must retain final reviewing authority over matters subdelegated to a private entity. See Assiniboine and Sioux Tribes v. Bd. of Oil and Gas Conservation, 792 F.2d 782, 795 (9th Cir. 1986) (agency must engage in "meaningful independent review" of private action); R.H. Johnson & Co. v. SEC, 198 F.2d 690, 695 (2d Cir. 1952) (SEC did not unconstitutionally subdelegate because it retained power to approve or disapprove rules and to review disciplinary actions); Fayad v. Sebelius, 803 F. Supp. 2d 699, 705 (E.D. Mich. 2011) (subdelegation to Medicare Administrative Contractor to make initial determinations is permissible because Secretary retains sufficient final reviewing authority); Ocean Conservancy v. Evans, 260 F. Supp. 2d 1162, 1183 (M.D. Fla. 2003) (federal agency "retained sufficient final reviewing authority over the findings of the independent scientific panel"); Nat'l Park and Conserv. Ass'n v. Stanton, 54 F. Supp. 2d 7, 19 (D.D.C. 1999) (delegation by a federal agency to a private entity is lawful "so long as the federal agency or official retains final reviewing authority"); United Black Fund, Inc. v. Hampton, 352 F. Supp. 898, 904 (D.D.C. 1972) (no unlawful delegation of authority because

agency retained power to review policies to ensure they met federal requirements). Here, the Secretary has unlawfully abdicated all authority to review Medicare contractors' decisions to reopen claims. The Secretary's "audits and evaluations of contractors' performance," 70 Fed. Reg. at 11,453, are "vague or inadequate assertions of final reviewing authority" that will not "save an unlawful subdelegation." *U.S. Telecom Ass'n*, 359 F.3d at 568.

When an agency subdelegates power to outside parties, "lines of accountability may blur, undermining an important democratic check on government decision-making." *U.S. Telecom Ass'n*, 359 F.3d at 565; *see also Nat'l Ass'n of Regulatory Util. Comm'rs v. F.C.C.*, 737 F.2d 1095, 1143-1144, n. 41 (D.C. Cir. 1984). Subdelegation to a private party is particularly suspect when the private actor's objectivity may be questioned due to a conflict of interest. *See, e.g., Sierra Club v. Sigler*, 695 F.2d 957, 962 n. 3 (5th Cir. 1983); *Park and Conservation Ass'n v. Stanton*, 54 F. Supp. 2d 7, 18 (D.D.C. 1999). Therefore, while subdelegation of enforcement of the reopening deadlines is impermissible as to any contractor, subdelegation to a RAC is especially troublesome because the contingency fee payment creates an incentive to reopen claims, which is an inherent conflict of interest.

Case: 10-56529 10/26/2012 ID: 8377376 DktEntry: 66-1 Page: 21 of 23 (21 of 57)

Conclusion

For the foregoing reasons, this appeal should be reheard en banc.

Respectfully Submitted,

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October 26, 2012

Case: 10-56529 10/26/2012 ID: 8377376 DktEntry: 66-1 Page: 22 of 23 (22 of 57)

Form 11. Certificate of Compliance Pursuant to Circuit Rules 35-4 and 40-1

Form Must be Signed by Attorney or Unrepresented Litigant and Attached to the Back of Each Copy of the Petition or Answer

(signature block below)

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or		
In compliance with Fed. R. App. 32(c) and does not exceed 15 pages.		
	/s/ Ronald S. Connelly Signature of Attorney or Unrepresented Litigant	
(New Form 7/1/2000)		

Certificate of Service

I, Ronald S. Connelly, hereby certify that on October 26, 2012, I filed with this Court the foregoing Petition for Rehearing En Banc, by electronically filing it with the Clerk of the Court using the ECF system, which will send notification of such filing to the following:

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Dated: October 26, 2012

FOR PUBLICATION

UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

Palomar Medical Center,

Plaintiff-Appellant,

v.

Kathleen Sebelius, Secretary of Health and Human Services,

Defendant-Appellee.

No. 10-56529 D.C. No. 3:09-cv-00605-BEN-NLS OPINION

Appeal from the United States District Court for the Southern District of California Roger T. Benitez, District Judge, Presiding

Argued and Submitted March 7, 2012—Pasadena, California

Filed September 11, 2012

Before: Harry Pregerson, Ronald M. Gould, and Richard C. Tallman, Circuit Judges.

Opinion by Judge Gould

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OPINION

GOULD, Circuit Judge:

This case involves a Medicare provider at first paid in full for certain medical services but later determined, through operation of the congressionally mandated Recovery Audit Contractor ("RAC") program, to be liable to repay the government for these services found not to be medically reasonable and necessary. We must decide whether such a Medicare provider may in its appeal of the revised determination of overpayment challenge a lack of "good cause" for reopening the initial, erroneous determination.

Palomar Medical Center ("Palomar") is a Medicare service provider located in Escondido, California. The Secretary of Health and Human Services ("the Secretary") administers the Medicare program through the Centers for Medicare and Medicaid Services ("CMS"). This case concerns inpatient rehabilitation services that Palomar gave a Medicare patient after a hip surgery. There was no question that the patient needed rehabilitation services. But through several levels of administrative appeal, these services were found not reasonable and necessary and not covered by Medicare because they were done in the hospital rather than in a less intensive (and less expensive) setting.

CMS had reimbursed Palomar's claim for these services in full. Congress, however, had enacted the RAC program, aimed at recovering Medicare overpayments, and a RAC reopened Palomar's claim to determine whether there had

¹This case does not involve fraud or intentional wrongdoing by Palomar, just the provision of helpful services in a setting where they were more expensive than if they were delivered in another way. We must consider the significance of overpayments to Medicare providers for taxpayers, for providers who rely upon the approved revenues, and for the RAC program which was fashioned by Congress in an effort to control Medicare expenses.

been an overpayment. The audit did not fare well for Palomar, as the RAC determined that Palomar had been overpaid because the services provided were not medically reasonable and necessary. Palomar was held liable for the overpayment by the RAC, and this conclusion was confirmed at four levels of administrative appeal. Among these, an Administrative Law Judge ("ALJ") had decided that the overpayment would have to be accepted because there was not good cause to reopen the claim. But the Medicare Appeals Council ("MAC") then reversed that decision, concluding that the ALJ had no jurisdiction to review the RAC's decision to reopen.

Congress had said that Medicare claims could be reopened under guidelines set by the Secretary in regulations.² The Secretary had adopted regulations that are material here: one regulation says that a contractor's decision to reopen is "final" and "not subject to appeal";³ a second regulation says that such a decision is "not appealable";⁴ and a third regulation says that a reopening in the period of one to four years after an initial determination to pay a claim is to be upon "good cause" for reopening.⁵

²"The Secretary may reopen or revise any initial determination or reconsidered determination described in this subsection under guidelines established by the Secretary in regulations." 42 U.S.C. § 1395ff(b)(1)(G).

³"The contractor's, QIC's, ALJ's, or MAC's decision on whether to reopen is final and not subject to appeal." 42 C.F.R. § 405.980(a)(5) (2006). The regulations promulgated by the Secretary in 2005 are the regulations applicable to this case. The Secretary amended these regulations in 2009, after the date of her final decision on Palomar's administrative appeal, December 1, 2008.

^{4&}quot;Actions that are not initial determinations and are not appealable under this subpart include, but are not limited to . . . [a] contractor's, QIC's, ALJ's, or MAC's determination or decision to reopen or not to reopen an initial determination, redetermination, reconsideration, hearing decision, or review decision." 42 C.F.R. § 405.926(*l*).

^{5&}quot;A contractor may reopen its initial determination or redetermination on its own motion—

⁽¹⁾ Within 1 year from the date of the initial determination or redetermination for any reason.

A revised determination issued after a reopening is appealable. In this appeal, Palomar contends that a Medicare provider may challenge a revised determination based on lack of good cause for reopening, even though it could not challenge the reopening immediately thereafter. The district court granted summary judgment for the Secretary, holding that because the regulations bar appeals of reopenings, it makes no sense to permit challenges to the basis for reopening after a revised determination has issued.

That decision comes to us on appeal and poses the question whether the requirement of good cause for reopening should have been a limitation on the RAC's audit of Palomar that could be enforced by Palomar's appeal of the RAC's decision. It is not an easy question because of competing principles. On the one hand, Congress wanted an effective recovery audit program to reduce Medicare payments with resulting benefits for Medicare beneficiaries and taxpayers, under procedures set by the Secretary. On the other hand, the provider has a legitimate interest in finality of determinations on its revenue for medical services. However, in view of the goals of the RAC program and the Secretary's regulations stating that decisions to reopen are "final" and "not appealable," we hold that the issue of good cause for reopening cannot be raised after an audit's conclusion and the revision of a paid claim for medical services, and affirm the district court.

I. BACKGROUND

To place this appeal in context, we start with an explanation of Medicare and its system for payments and administra-

⁽²⁾ Within 4 years from the date of the initial determination or redetermination for good cause as defined in § 405.986."

⁴² C.F.R. § 405.980(b).

⁶See 42 C.F.R. § 405.984.

tive appeals, then discuss the RAC program, and end with a discussion of the nature of Palomar's claims.

A. The Medicare Program

Medicare is a federally funded health insurance program for aged and disabled persons. 42 U.S.C. §§ 1395 et seq. Medicare Part A gives insurance benefits for inpatient hospital and related services and makes reimbursement payments to those who provide such services. Id. §§ 1395d, 1395g. Through CMS, the Secretary contracts with fiscal intermediaries, generally private insurance companies, to perform coverage determination and payment functions. Id. §§ 1395h, 1395kk-1; Erringer v. Thompson, 371 F.3d 625, 627 (9th Cir. 2004).

Medicare coverage is limited to services that are medically "reasonable and necessary." 42 U.S.C. § 1395y(a)(1)(A). Medicare service providers, such as Palomar, submit claims for reimbursement for covered services, and their fiscal intermediaries make "initial determinations" of coverage and amount. Id. § 1395ff(a); 42 C.F.R. § 405.920. Initial determinations are appealable. See 42 C.F.R. § 405.904. In the administrative appeals process, a Medicare provider may: request a "redetermination" by its fiscal intermediary, id. § 405.940; appeal a redetermination to a Qualified Independent Contractor ("QIC") for a "reconsideration," id. § 405.960; appeal a reconsideration to, and request a hearing before, an ALJ, id. § 405.1000; and appeal an ALJ's decision to the MAC, id. § 405.1100. The MAC's decision is the final decision of the Secretary and may be appealed to a federal district court. 42 U.S.C. § 405(g); 42 C.F.R. § 405.1130.

In certain circumstances, an otherwise final determination or decision may be reopened. See 42 C.F.R. § 405.980. Early Medicare regulations on reopening generally incorporated Social Security regulations on reopening. Then, in 2000, Congress added to the Medicare statute a provision governing reopening and revision of determinations. This provision states, "The Secretary may reopen or revise any initial determination or reconsidered determination described in this subsection under guidelines established by the Secretary in regulations." 42 U.S.C. § 1395ff(b)(1)(G). In 2005, CMS promulgated an interim final rule that established regulations implementing the reopening provision and other statutory changes. 70 Fed. Reg. at 11,420.

The regulations define a reopening as "a remedial action taken to change a binding determination or decision that resulted in either an overpayment or underpayment, even though the binding determination or decision may have been correct at the time it was made based on the evidence of record." 42 C.F.R. § 405.980(a)(1). A provider may request a reopening, or the contractor, QIC, ALJ, or MAC may initiate a reopening on its own motion. *Id.* § 405.980(b)-(e); 70 Fed. Reg. at 11,450.

A contractor may reopen a determination on its own motion within one year for any reason or within four years for good cause. 42 C.F.R. § 405.980(b)(1)-(2). "Good cause" may be established if (1) there is "new and material evidence" that was "not available or known at the time of the determination" that "[m]ay result in a different conclusion," or (2) "[t]he evidence that was considered in making the determination or decision clearly shows on its face that an obvious error was made at the time of the determination or decision." *Id.* § 405.986(a).

Two of the 2005 reopening regulations are subject to conflicting interpretive arguments and to challenge on this appeal. First, 42 C.F.R. § 405.980(a)(5) states that "[t]he contractor's, QIC's, ALJ's, or MAC's decision on whether to

⁷CMS promulgated the final rule in 2009. 74 Fed. Reg. 65,296 (Dec. 9, 2009).

reopen is final and not subject to appeal." Second, 42 C.F.R. § 405.926(*l*) states that "[a] contractor's, QIC's, ALJ's, or MAC's determination or decision to reopen or not to reopen an initial determination, redetermination, reconsideration, hearing decision, or review decision" is not an initial determination and is "not appealable."

By contrast, a revised determination or decision that results from a reopening is appealable, but "[o]nly the portion of the initial determination . . . revised by the reopening may be subsequently appealed." 42 C.F.R. § 405.984(a), (f).

In the preamble to the interim final rule on reopenings, CMS responded to comments about enforcement of the good cause standard. 70 Fed. Reg. at 11,453. A commenter recommended that CMS "create enforcement provisions for the good cause standard when contractors reopen claims," because, according to the commenter, "contractors often ignore the guidelines set out in regulations and manuals and cite a request for medical records as good cause for a reopening, even though the medical records existed at the time the contractor initially reviewed the claim." *Id.* In response, CMS said:

The regulations require that contractors abide by the good cause standard for reopening actions after one year from the date of the initial or revised determination. CMS assesses a contractor's compliance with Federal laws, regulations and manual instructions during audits and evaluations of the contractors' performance. Thus, the necessary monitoring and enforcement mechanisms are already in place.

Id.9

⁸In the 2009 final rule, CMS replaced the term "final" with the term "binding." 74 Fed. Reg. at 65,308.

⁹In promulgating the final rule, CMS gave a similar response to a similar comment:

B. The Recovery Audit Contractor Program

More than one billion Medicare claims are processed each year. Ctrs. for Medicare & Medicaid Servs., The Medicare Recovery Audit Contractor (RAC) Program: An Evaluation of the 3-Year Demonstration 9 (2008) [hereinafter RAC Evaluation Report]. Thousands are paid improperly, most commonly because they are for services that were not medically necessary or were improperly coded. *See id.* at 6-7. CMS makes efforts to calculate, reduce, and prevent improper payments. Yet improper payments for Medicare constitute a high percentage, more than ten percent, of all payment errors in federal programs. *Id.*

To supplement CMS's efforts to protect the fiscal integrity of the Medicare program, Congress enacted the RAC program. Congress told the Secretary to conduct a demonstration project using RACs to "identify[] underpayments and overpayments and recoup[] overpayments under the medicare program." Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA"), Pub. L. No. 108-173, § 306(a), 117 Stat. 2066, 2256 (2003). Congress directed the Secretary to "examine the efficacy of [the use of RACs] with respect to duplicative payments, accuracy of coding, and other payment policies in which inaccurate payments arise." *Id.*

Contractors are required to follow Federal laws, regulations and manual instructions in their business operations. As noted in the interim final rule in response to a similar comment on the proposed rule ([70 Fed. Reg. at 11,453]), our regulations require that contractors abide by the good cause standard for reopening actions as set forth in § 405.980(b) and § 405.986. CMS conducts audits and evaluations of contractor performance in order to assess compliance with Medicare policies. Thus, the necessary monitoring and enforcement mechanisms are already in place and we do not believe it is necessary to add enforcement provisions to these regulations.

74 Fed. Reg. at 65,312.

§ 306(a)(3). The statute specified the scope and duration of the RAC demonstration project—at least two states having high per capita utilization of Medicare and not longer than three years—and certain qualifications for RACs, and also permitted payment to RACs on a contingent basis. *See id.* § 306(a)(1), (b), (d). Congress decided to rest on the Secretary's expertise and did not give the Secretary further direction on the means of implementing the RAC program.

The RAC demonstration project began in March 2005 and ended in March 2008. RAC Evaluation Report 11, 14. CMS selected three states, California, New York, and Florida, and three RACs; each RAC had jurisdiction in a single state. *Id.*¹⁰

Under the demonstration project, RACs reviewed paid Medicare claims to identify and correct improper payments. They were bound by Medicare policies, regulations, local and national coverage determinations, and manual instructions. Id. at 11. During the demonstration, CMS gave each RAC Medicare claims data from 2001 through 2007. Id. at 12. CMS did not specify a procedure for analyzing the claims data. Rather, each RAC used its own methodology to identify claims that "clearly" contained errors resulting in improper payments and claims that "likely" contained such errors. Id. In cases of clear improper payments, such as duplicate claims, RACs performed "automated review," where they notified the provider of any underpayment or overpayment amount. Id. In cases of likely improper payments, RACs performed "complex review," where they requested medical records from the provider to further review the claim and then made a determination on the accuracy of payment. Id. RAC determinations constituted "initial determinations" that could be appealed to a fiscal intermediary, QIC, ALJ, MAC, and federal district court.

¹⁰In 2007, CMS added three additional states to the demonstration project, one to each RAC's jurisdiction. RAC Evaluation Report 11.

Through the demonstration project, RACs successfully corrected more than \$1 billion in improper Medicare payments: about \$980 million in overpayments collected from providers and about \$38 million in underpayments repaid to providers. *Id.* at 15. The net savings returned to the Medicare Trust Funds, after subtracting underpayments repaid, amounts overturned on appeal, and costs of operating the RAC demonstration, was nearly \$694 million.

In light of the demonstration project's success, Congress made the RAC program a permanent part of the Medicare Integrity Program and expanded its coverage to all states. 42 U.S.C. § 1395ddd(h)(1), (3).

C. The Facts Underlying Palomar's Claims and Appeal

In June 2005, Palomar provided inpatient rehabilitation facility ("IRF") services to John Doe, a 79-year-old man who had undergone a right total hip arthroplasty. On July 27, 2005, a fiscal intermediary paid Palomar's claim of \$7,992.92 for the IRF services provided to Doe.¹¹

Under the RAC demonstration project, the RAC for California, PRG-Schultz ("the RAC"), selected Palomar's claim for complex review. On April 27, 2007, CMS sent Palomar a letter notifying it that the RAC had selected one or more of its claims for review. On the same date, the RAC sent Palomar a letter requesting medical records and documentation to support the medical necessity of Doe's IRF stay. The letter said that the request was "due to a recent review and discovery of potential overpayment of your Medicare paid claim(s)." Palomar tendered the requested records and documentation, and on July 10, 2007, the RAC notified Palomar of its revised determination of overpayment because Doe's rehabilitation in

¹¹The amount in controversy here is not a large figure in itself, but the lawfulness of the procedures used to determine that this was an overpayment has implications for other claims.

an inpatient hospital facility was "not reasonable and necessary." See 42 U.S.C. § 1395y(a)(1)(A). The RAC told Palomar that it had to repay the overpayment amount.

Decisions at four levels of administrative review affirmed the RAC's initial determination of overpayment. A redetermination by a fiscal intermediary and a reconsideration by a QIC each held that the rehabilitation services were not medically necessary and excessive because they were given in a hospital instead of a less intensive setting such as a skilled nursing facility. The ALJ next agreed that Palomar's services were not medically reasonable and necessary, though it gave relief on the ground that there was not good cause for the reopening by the RAC.¹² The MAC then reversed the ALJ's decision, concluding that (1) neither the ALJ nor the MAC had jurisdiction to assess good cause for reopening because the RAC's decision to reopen was not subject to the administrative appeals process, ¹³ and (2) the services were not medically reasonable and necessary.

Palomar appealed the MAC's decision on the reviewability of the reopening to the district court, but did not challenge the MAC's decision that the IRF services were not reasonable and necessary. Palomar and the Secretary filed cross motions for summary judgment, and the district court referred the case to a magistrate judge.

¹²The QIC found that the RAC had good cause because "[a] high error rate and/or potential overutilization identified through data analysis" constituted good cause for reopening and Palomar's claim had been selected based on data analysis. But the ALJ disagreed and held that the RAC had "made no showing on [the] record of good cause for late reopening."

¹³Citing 42 U.S.C. §§ 405.926(*l*) and 405.980(a)(5), the MAC said that the decision to reopen was "final and not subject to appeal," and, citing 70 Fed. Reg. at 11,453, the MAC said that "CMS ha[d] expressly stated that the enforcement mechanism for good cause standards lies within its evaluation and monitoring of contractor performance, not the administrative appeals process."

The magistrate judge first gave the Secretary's interpretation of the reopening regulations "substantial deference" under Thomas Jefferson University v. Shalala, 512 U.S. 504 (1994), and gave the regulations themselves Chevron deference. See Chevron, U.S.A., Inc. v. Natural Res. Def. Council, Inc., 467 U.S. 837 (1984). Applying Thomas Jefferson, the magistrate judge concluded that the Secretary's interpretation was consistent with both the plain language of 42 C.F.R. §§ 405.926(l) and 405.980(a)(5) and CMS's statement in the interim final rule that it would enforce the good cause standard through its own internal procedures rather than through the administrative appeals process. See 512 U.S. at 512. The magistrate judge reasoned that 42 C.F.R. § 405.980(a)(5) "states on its face that a decision on whether to reopen is not appealable," and that there was "essentially no distinction" between "challenging the discretionary decision to reopen [and] challenging the legality of the reopening, because the fact of the reopening is not appealable." The magistrate judge thus accepted the Secretary's interpretation and concluded that Palomar could not challenge the reopening. It did not decide whether the RAC had good cause to reopen because, it stated, "that issue is not appealable." The magistrate judge recommended that the district court deny Palomar's motion for summary judgment and grant the Secretary's motion for summary judgment.

The district court adopted the magistrate judge's report and recommendation. The district court agreed that it owed deference to the Secretary's interpretation because it was consistent with the plain language of the regulations and the Secretary's intent at the time she promulgated the regulations; that the RAC's reopening of Palomar's claim was not subject to administrative appeal; and that Palomar was not deprived of due process. The district court also held that it did not have jurisdiction to review the merits of Palomar's challenge to the

reopening because the reopening was "not appealable." Palomar timely appealed.¹⁴

JURISDICTION AND STANDARDS OF REVIEW

We have jurisdiction under 42 U.S.C. §§ 405(g) and 1395ff(b)(1)(A) and 28 U.S.C. § 1291. We review a district court's grant of summary judgment de novo. Kaiser Found. Hosps. v. Sebelius, 649 F.3d 1153, 1157 (9th Cir. 2011). The Administrative Procedure Act ("APA") governs our review of the Secretary's actions. See id. Under the APA, we will hold unlawful and set aside an agency action that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A).

DISCUSSION

We consider Palomar's challenge to the Secretary's interpretation of the applicable regulations; Palomar's position that the regulations, if interpreted adversely to its position, violate the governing Medicare statute; and Palomar's argument that even if the agency cannot on administrative appeal assess good cause for reopening, a federal district court has jurisdiction to make that assessment.

¹⁴Before oral argument, the American Medical Association ("AMA") and California Medical Association ("CMA") filed an amicus brief with the parties' consent. See Fed. R. App. P. 29(a). The Federation of American Hospitals ("FAH"), American Hospital Association ("AHA"), and American Health Care Association ("AHCA") moved for leave to file an amicus brief, as did the California Hospital Association ("CHA"). See Fed. R. App. P. 29(b). We grant both motions for leave. After oral argument, at our invitation, AMA, joined by the state medical societies from the nine states in this circuit, and CHA each filed additional amicus briefs. All amici support Palomar's position. We appreciate the counsel and briefing given by all amici.

A. Palomar's Challenge to the Secretary's Interpretation of the Regulations

Palomar first challenges the Secretary's interpretation of 42 C.F.R. §§ 405.926(1) and 405.980(a)(5)under the APA, 5 U.S.C. § 551 *et seq*.

We give "substantial deference" to the Secretary's interpretation of Medicare regulations. *Thomas Jefferson*, 512 U.S. at 512; *Robert F. Kennedy Med. Ctr. v. Leavitt*, 526 F.3d 557, 561 (9th Cir. 2008). The Secretary's interpretation is controlling unless it is "plainly erroneous or inconsistent with the regulation." *Auer v. Robbins*, 519 U.S. 452, 461 (1997) (internal quotation marks and citation omitted). "In other words, we must defer to the Secretary's interpretation unless an alternative reading is compelled by the regulation[s'] plain language or by other indications of the Secretary's intent at the time of the regulation[s'] promulgation." *Thomas Jefferson*, 512 U.S. at 512 (internal quotation marks and citation omitted).

Palomar contends that the Secretary's interpretation of the regulations to bar provider challenges to RAC reopenings based on lack of good cause is not entitled to deference because it is inconsistent with the regulations' plain language and the Secretary's prior interpretation and application of similarly worded reopening provisions. We disagree.

The contested regulations provide by their express terms that "[t]he contractor's, QIC's, ALJ's, or MAC's decision on whether to reopen is final and not subject to appeal," 42 C.F.R. § 405.980(a)(5), and similarly that "[a] contractor's, QIC's, ALJ's, or MAC's determination or decision to reopen or not to reopen" is "not [an] initial determination[] and [is] not appealable," *id.* § 405.926(*l*). The reopening regulations elsewhere provide, on the other hand, that a revised determination or decision resulting from a reopening is appealable. *Id.* § 405.984.

[1] The Secretary interprets the language barring appeals of decisions "on whether to reopen" and decisions "to reopen or not to reopen" to mean that the regulations foreclose any challenge to a decision to reopen, even after a revised determination or decision has issued. So the Secretary reasons that Palomar could have appealed the issue of medical necessity the substance of whether it was compensated in an amount beyond what was covered under Medicare—but it cannot now gripe on appeal about whether its claim should have been reopened. Palomar argues that the cited regulatory language forecloses only challenges to the threshold decision to reopen or not to reopen. Under Palomar's interpretation, a provider may not appeal the denial of a request to reopen or the reopening of a claim that is not revised, but a reopened claim that is revised is fair game for appeal on both the portion of the determination or decision revised and the validity of the underlying reopening.

[2] If the regulations had merely foreclosed an appeal of the decision to reopen, we might give more credence to Palomar's argument. But the regulations say that the reopening decision is not only "not appealable," it is also "final." The Secretary's interpretation of the words "final and not subject to appeal" and "not appealable" to mean that a contractor's decision to reopen may not be challenged at any time for any reason is not only reasonable and permissible; it is the most natural reading of the regulations. See 42 C.F.R. §§ 405.926(*l*), 405.980(a)(5). "Final" is defined as "not to be undone, altered, or revoked; conclusive." Oxford English Dictionary 920 (2d ed. 1989); see also American Heritage Dictionary (5th ed. 2011; online version 2012) ("[n]ot to be changed or reconsidered; unalterable"); Webster's Third New International Dictionary 851 (1993) ("not to be altered or undone"). The regulations expressly state that decisions on reopening are "final" and may not be appealed. If a decision to reopen could not be appealed immediately, but good cause for reopening could be litigated after a revised determination had issued, then the decision to reopen would not in a real sense be "final." We conclude that the regulations mean what they say: reopening decisions are final, and final means they cannot be challenged after an audit and revised determination.

Palomar's contrary position, if credited as a necessary interpretation of the regulations, would lead to a bizarre and inefficient system of recovery audits and appeals. All agree, including Palomar, that there could be no appeal of an initial decision to reopen a claim. But Palomar's interpretation that the "good cause" issue could then be brought in through the back door after a revised claim determination would mean that the government to state its best case would on every reopening have to make a record of the "good cause" for the reopening. That would be inefficient and tilt the focus from the reasonableness and necessity of providing medical services to the strength of the RAC's grounds for reopening.

We are not unsympathetic to the interest of Palomar in finality of its medical services receipts. But Congress created the RAC program and gave the Secretary discretion to set regulations that would govern reopening of Medicare claims. The Secretary in her 2005 regulations said that there would be no appeal of a reopening and that a decision to reopen was to be "final." In these circumstances, the values that Congress stressed in setting up the RAC program, as well as fairness to providers, seem to be accommodated well by a system in which: (1) there is no ability to appeal a reopening decision when made; (2) there is ability to appeal the merits of any revised determination of a claim after a reopening, but no ability at that time to litigate good cause for the reopening; and (3) the Secretary has discretion to enforce the "good cause" standard by means of her own choosing, including reviewing RAC performance by looking at determinations overturned on appeal, instructing RACs to "consistently document their 'good cause," and gaining independent, third-party reviews to ensure the accuracy of RAC claim determinations. RAC Evaluation Report 20-22, 27. Further, if good cause for reopening could be raised on appeal after a revised determinaFor the reasons stated, the plain language of the regulations supports the Secretary's interpretation. Palomar's contrary interpretation is by no means "compelled by the regulation[s'] plain language." *Thomas Jefferson*, 512 U.S. at 512 (internal quotation marks omitted).

Palomar urges us to consider the language of the regulations "in light of their prior interpretation and application" and argues that, so considered, the Secretary's current interpretation deserves no deference because it is inconsistent with her prior interpretation and application of reopening provisions in other contexts. *See Regents of Univ. of Cal. v. Shalala*, 82 F.3d 291, 294 (9th Cir. 1996) (internal quotation marks and citation omitted).

Palomar claims three examples of the Secretary's allegedly inconsistent prior interpretations. First, the Secretary permit-

¹⁵In addition to these practical considerations, the Secretary's 2009 "technical revisions" to the 2005 regulations at issue here support her interpretation. In 2009, CMS explained that it was "reserving the term 'final' to describe those actions or decisions for which judicial review may be immediately sought," and it revised 42 C.F.R. § 405.980(a)(5) to replace the term "final" with the term "binding." 74 Fed. Reg. at 65,307-08. CMS stated that "binding" means that "the parties are obligated to abide by the adjudicator's action or decision" and "[i]f . . . further recourse is unavailable to parties, then the adjudicator's decision . . . is final in the sense that no further review of the decision is available." Id. at 65,308 (emphasis added). Given that CMS intended this change in language to be "technical" and clarifying rather than substantive, the meaning of the pre-revision term "final" is the same as that of the post-revision term "binding." Because the regulations on their face preclude "further recourse" on a contractor's decision to reopen, such a decision is "final in the sense that no further review of the decision is available"—not after the reopening, not after the revised determination, not on appeal. See 74 Fed. Reg. at 65,308.

ted procedural challenges to Social Security Administration ("SSA") and pre-2005 Medicare reopenings, ¹⁶ despite a Social Security Handbook provision stating that "[t]he decision to reopen or not to reopen is *not* an initial determination and is not subject to appeal." See Soc. Sec. Admin., Social Security Handbook § 2185 (1986); see also, e.g., Cole ex rel. Cole v. Barnhart, 288 F.3d 149, 150-51 (5th Cir. 2002); Heins v. Shalala, 22 F.3d 157, 161 (7th Cir. 1994); In re UMDNJ-Univ. Hosp., 2005 WL 6290383 (M.A.C. Mar. 14, 2005). Second, the Secretary has permitted provider appeals challenging the lawfulness of Medicare cost report reopenings, despite a 2008 regulation stating, "A determination or decision to reopen or not to reopen a determination or decision is not a final determination or decision within the meaning of this subpart and is not subject to further administrative review or judicial review." 42 C.F.R. § 405.1885(a)(6); see, e.g., Canon Healthcare Hospice, LLC v. BlueCross BlueShield Ass'n/Palmetto Gov't Benefits Adm'r, No. 2010-D34, 2010 WL 5570979, at *1, *5-6 (H.C.F.A. Aug. 2, 2010); see also Harrison House of Georgetown v. BlueCross BlueShield Ass'n/Empire Medicare Servs., No. 2009-D14, 2009 WL 2423098, at *2, *5-6, *9 (H.C.F.A. Mar. 17, 2009). Third, in Palomar's separate appeal of a different RAC reopening, In re Palomar Medical Center (Palomar I) (M.A.C. Jan. 11, 2008), the MAC vacated the ALJ's decision that the RAC did not establish fraud or good cause for reopening and remanded the case to the ALJ to give the parties an opportunity to present evidence on the basis for reopening, as the ALJ had raised that issue in the first instance.

Palomar contends that because the Secretary has permitted procedural challenges to SSA reopenings, pre-2005 Medicare

¹⁶The Secretary's interpretation and application of SSA reopening provisions are relevant here because the Secretary previously administered both Social Security and Medicare, and because before the 2005 Medicare reopening regulations took effect, SSA reopening regulations generally governed the reopening of Medicare claims.

claim reopenings, post-2008 Medicare cost report reopenings, and impliedly, the RAC reopening in *Palomar I*, her interpretation of 42 C.F.R. §§ 405.926(*l*) and 405.980(a)(5) to bar such challenges is not entitled to deference and is invalid. We are not persuaded for several reasons.

First, Palomar overlooks that the Secretary promulgated the 2005 regulations at about the same time that the RAC program started. Congress set the RAC demonstration project in December 2003. RAC Evaluation Report 54. CMS announced the demonstration in January 2005, and the demonstration began on March 28, 2005. Id. On March 8, 2005, CMS promulgated the 2005 reopening regulations, including 42 C.F.R. $\S\S 405.926(l)$ and 405.980(a)(5), and they became effective on May 1, 2005. Id. Because CMS promulgated and began applying the 2005 reopening regulations when it began the RAC demonstration project, it had in mind the goals of the RAC program. Congress had authorized the RAC program to improve the accuracy of Medicare payments and recoup overpayments. CMS made a policy choice not to subject RAC reopening decisions to administrative review, thereby placing the focus of an appeal of a revised determination on the merits of the revision, in furtherance of congressional aims, rather than on the RAC's basis for reopening.

Moreover, in the preamble to the 2005 regulations, CMS made clear its aim to enforce the time limits and standards for reopening through internal procedures rather than through administrative appeals. In response to a commenter's complaint that contractors request medical records to justify reopening decisions even though the records existed when the initial determinations were made, CMS said that it monitored and enforced contractors' compliance with the good cause standard through "audits and evaluations of the contractors' performance," and it declined to "create enforcement provisions for the good cause standard," in addition to the internal mechanisms already in place. 70 Fed. Reg. at 11,453. These statements by CMS reinforce the plain language of the regula-

tions, and make clear that providers may not challenge reopening decisions based on lack of good cause or the other regulatory requirements for reopening.

Finally, the issue we face is the Secretary's interpretation of two newly promulgated regulations on the reopening of Medicare claim determinations, not her interpretation of other regulations governing SSA reopenings or Medicare cost report reopenings. Congress did not intend to forever bind CMS to SSA policies. Before Congress authorized the reopening and revision of Medicare claim determinations, no independent set of regulations governed Medicare reopenings; instead, SSA regulations generally governed. Then, in 2000, Congress authorized Medicare reopenings, and in 2003, Congress mandated the RAC demonstration project. The Secretary then promulgated independent Medicare reopening regulations and included in them two regulations that nowhere exist in SSA regulations. See 20 C.F.R. §§ 404.987, 404.988 (containing no analogue of 42 C.F.R. § 405.980(a)(5)). Compare 42 C.F.R. § 405.926 (listing among "[a]ctions that are not initial determinations and are not appealable" a Medicare contractor's decision "to reopen or not to reopen") (emphasis 20 C.F.R. § 404.903 (listing "[a]dministrative actions that are not initial determinations . . . [and] are not subject to the administrative review process" an SSA denial of a request to reopen but not an affirmative decision to reopen). The challenged regulations are similarly distinct from the Medicare cost report reopening regulations cited by Palomar, as cost report determinations are subject to a separate appeals process from claim determinations and are not included in the RAC program.

Neither the Secretary's prior conduct of SSA reopenings nor her subsequent conduct of cost report reopenings make her interpretation of 42 C.F.R. §§ 405.926(*l*) and 405.980(a)(5) "plainly erroneous or inconsistent with the regulation[s]." *Auer*, 519 U.S. 461 (internal quotation marks and citation omitted). The Secretary has consistently held that

these regulations bar administrative review of RACs' compliance with the time limits and standards for reopening. *See*, *e.g.*, *In re Motta*, 2011 WL 7177038, at 2-3 (M.A.C. Dec. 1, 2011); *In re St. Joseph's Hosp.*, 2011 WL 6025979, at 8-10 (M.A.C. Mar. 9, 2011); *In re Reg'l Med. Ctr.*, 2010 WL 2895740, at 4-5 (M.A.C. Mar. 9, 2010); *In re Providence St. Joseph Med. Ctr.*, 2008 WL 6113483, at 4-8 (M.A.C. July 23, 2008). *Palomar I* does not undermine the Secretary's position because there, in contrast to above-cited cases, the issue of administrative reviewability was not raised or decided.

[3] We hold that the Secretary's interpretation of her reopening regulations is "controlling" and is not arbitrary and capricious under the APA. *See Auer*, 519 U.S. at 561.¹⁷

B. Palomar's Contention That If the Secretary's Regulatory Interpretation Is Followed, the Regulations Violate the Medicare Statute

Palomar next contends that if the reopening regulations foreclose review of the reopening deadlines and standards, the regulations are invalid under the APA.

In reviewing an agency's construction of a statute that it is charged with administering, we ask, first, "whether Congress has directly spoken to the precise question at issue." *Chevron*, 467 U.S. at 842; *Resident Councils of Wash. v. Leavitt*, 500 F.3d 1025, 1030 (9th Cir. 2007). "If the intent of Congress is

¹⁷Our holding is in accord with the decisions of the other federal courts that have considered this issue. *See Morton Plant Hosp. Ass'n v. Sebelius*, 747 F. Supp. 2d 1349 (M.D. Fla. 2010); *Trs. of Mease Hosp., Inc. v. Sebelius*, No. 8:09-CV-1795-T-23MAP, 2010 WL 3222097 (M.D. Fla. July 26, 2010); *Hosp. Comms. for the Livermore-Pleasanton Areas v. Johnson*, No. C-09-1786 EMC, 2010 WL 1222764 (N.D. Cal. Mar. 24, 2010). These district court cases have not been appealed, and no court of appeals has decided the issue presented here. *See also St. Francis Hosp. v. Sebelius*, ___ F. Supp. 2d ___, No. 09 CV 1528(DRH)(AKT), 2012 WL 200841, at *4 (E.D.N.Y. June 5, 2012).

clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress." *Chevron*, 467 U.S. at 842-43. But "if the statute is silent or ambiguous with respect to the specific issue," we "do[] not simply impose [our] own construction on the statute," but rather, ask, second, "whether the agency's answer is based on a permissible construction of the statute." *Id.* at 843. If the agency's construction is reasonable, we defer to it. *See Resident Councils*, 500 F.3d at 1030.

"If Congress has explicitly left a gap for the agency to fill, there is an express delegation of authority to the agency to elucidate a specific provision of the statute by regulation. Such legislative regulations are given controlling weight unless they are arbitrary, capricious, or manifestly contrary to the statute." *Chevron*, 467 U.S. at 843-44.

[4] The Medicare statute states: "The Secretary may reopen or revise any initial determination or reconsidered determination described in this subsection under guidelines established by the Secretary in regulations." 42 U.S.C. § 1395ff(b)(1)(G). The statute does not address appeal rights to enforce the reopening regulations and so, under *Chevron* step one, is silent on the precise question at issue. *See Chevron*, 467 U.S. at 842. We apply *Chevron* step two.¹⁸

¹⁸Palomar argues that employing traditional tools of statutory construction at Chevron step one makes clear Congress's intent that there be administrative review of Medicare reopenings. But we reject that argument because Congress's intent is not clear. First, though § 1395ff(b)(1)(G) is located in a section called "Appeal rights" and must be read in context, "a subchapter heading cannot substitute for the operative text of the statute." See Fla. Dep't of Revenue v. Piccadilly Cafeterias, Inc., 544 U.S. 33, 47 (2008). The text of the statute says nothing about appeals of reopening decisions. Second, that in § 1395ff Congress twice limited administrative review of certain determinations, but not of reopenings, does not make clear Congress's intent to provide appeal rights to challenge reopenings. Palomar omits that § 1395ff includes administrative review for, among other things, initial determinations, redeterminations, and reconsiderations, but not for reopenings. See 42 U.S.C. § 1395ff(a)(3)(A), (b)(1)(A), (c)(1); Barnhart v. Sigmon Coal Co., 534 U.S. 438, 452 (2002).

- [5] Because Congress in § 1395ff(b)(1)(G) "explicitly left a gap for the agency to fill," it gave the Secretary "an express delegation of authority" to "elucidate" the reopening and revision of initial determinations "by regulation." 467 U.S. at 844. We give the Secretary's reopening regulations "controlling weight unless they are arbitrary, capricious, or manifestly contrary to the statute." *Id*.
- [6] Palomar contends that the reopening regulations as interpreted by the Secretary are arbitrary, capricious, and manifestly contrary to the Medicare statute because they allow her to reopen claim determinations in violation of the "guidelines [she] established . . . in regulations." See 42 U.S.C. § 1395ff(b)(1)(G). The Secretary's responsive position is that claim determinations are reopened and revised under the guidelines she established in the reopening regulations, but that those guidelines are enforced internally rather than through provider appeals. There is nothing arbitrary or capricious about this position, and it reasonably avoids the inefficiencies that we noted above.
- [7] In basing its argument on § 1395ff, Palomar ignores Congress's statutory directive to establish the RAC program. Concerned about the millions of dollars of Medicare Trust Funds being lost to improper payments, Congress directed the Secretary to use RACs to identify and correct past overpayments and underpayments. Congress did not require "good cause" for RAC reopenings, in either the MMA or § 1395ff. Nor did Congress specify how any reopening conditions "established by the Secretary in regulations" should be enforced. See 42 U.S.C. § 1395ff(b)(1)(G). The Secretary in her discretion has chosen to require good cause for reopenings and to enforce that standard internally. This enforcement scheme sensibly balances providers' interests in fairness and finality against Congress's and the public's interests in paying Medicare claims accurately and preserving funds for future Medicare beneficiaries. It certainly is not contrary to the Medicare statute. For these reasons, the district court correctly gave the

challenged regulations *Chevron* deference and rejected Palomar's contention that they are invalid under the APA.

C. Palomar's Contention That Even If the Regulations Bar Administrative Review of Good Cause for Reopening, That Issue May Be Considered by a Federal District Court

Palomar contends that even if the regulations bar administrative review of the RAC's compliance with the good cause standard for reopening, federal courts have jurisdiction to review the issue.

- [8] The Medicare statute limits judicial review of the Secretary's decisions to "final decision[s] . . . made after a hearing." 42 U.S.C. §§ 405(g)-(h), 1395ff(b)(1)(A). The statute "does not define 'final decision' and 'its meaning is left to the Secretary to flesh out by regulation.' "See Matlock v. Sullivan, 908 F.2d 492, 493 (9th Cir. 1990) (quoting Weinberger v. Salfi, 422 U.S. 749, 766 (1975)). Under the Medicare regulations, the MAC's decision in this case is a "final decision" of the Secretary and is subject to our review. See 42 U.S.C. § 405(g); 42 C.F.R. § 405.1130; 70 Fed. Reg. at 11,421.
- [9] But in asking us to determine if the RAC had good cause for reopening, Palomar asks us to review not the Secretary's final decision, but the RAC's decision to reopen its claim. The decision to reopen a paid Medicare claim, however, is discretionary and does not constitute a "final decision" for purposes of § 405(g). See Davis v. Schweiker, 665 F.2d 934, 935 (9th Cir. 1982); see also Your Home Visiting Nurse Servs., Inc. v. Shalala, 525 U.S. 449, 457-58 (1999); Udd v. Massanari, 245 F.3d 1096, 1098-99 (9th Cir. 2001). First, the 2005 regulations provide that a decision to reopen is "final" —not in the sense that judicial review may be

¹⁹In the current regulations, "final" has been changed to "binding." *See* 74 Fed. Reg. at 65,308.

sought but, as CMS explained, "in the sense that no further review of the decision is available," 74 Fed. Reg. at 65,307-08 —and "not subject to appeal." 42 C.F.R. § 405.980(a)(5); see also id. § 405.926(1). By barring any further review of reopening decisions, the regulations in effect foreclose not only administrative review, but also judicial review. See Matlock, 908 F.2d at 493 (stating that SSA regulations listing actions that are not initial determinations "prohibit judicial review" of such an action); Harper v. Bowen, 813 F.2d 737, 743 (5th Cir. 1987) (discussing Fifth Circuit's adoption of rationale in *Cali*fano v. Sanders, 430 U.S. 99 (1977), "that where the regulations prohibit it, there is no judicial review"). Second, the decision to reopen a paid Medicare claim may lawfully be made, and here was made, without a hearing. See Cappadora v. Celebrezze, 356 F.2d 1, 4 (2d Cir. 1966) ("[T]he reasonable reading of § 405(g) is that it was intended to apply to a final decision rendered after a hearing thus made mandatory [by statute], not to a decision which could lawfully have been made without any hearing at all "); cf. Evans v. Chater, 110 F.3d 1480, 1482 & n.1 (1997). As the Supreme Court noted in Califano v. Sanders, "the opportunity to reopen final decisions and any hearing convened to determine the propriety of such action are afforded by the Secretary's regulations and not by the Social Security Act." 430 U.S. at 108. In Sanders the Court held that federal courts lacked jurisdiction to review a refusal to reopen and Palomar's challenge in this case is to a reopening. It is equally true here that the standards governing reopenings "are afforded by the Secretary's regulations and not by the [Medicare] Act" and no hearing on a reopening decision is required by statute. See id.

[10] Congress gave the Secretary discretion to set guidelines governing the reopening and revision of claim determinations and to structure the means of enforcing such guidelines so as to achieve efficiency and accuracy in the administration of the Medicare program. See 42 U.S.C. § 1395ff(b)(1)(G). The Secretary made a permissible choice to place RAC reopening decisions beyond review. Because

the RAC's decision to reopen Palomar's claim is not a "final decision of the [Secretary] made after a hearing," the district court and this court lack jurisdiction to review it. *See id.* § 405(g); *Sanders*, 430 U.S. at 108; *Matlock*, 908 F.2d at 493; *see also Loma Linda Univ. Med. Ctr. v. Leavitt*, 492 F.3d 1065, 1074-75 (9th Cir. 2007).²⁰

Palomar argues that in light of our jurisdiction to review the MAC's decision, the APA entitles it to judicial review of the Secretary's adverse action, and that "action" encompasses the reopening of Palomar's claim. See 5 U.S.C. § 702; Shalala v. Ill. Council on Long Term Care, Inc., 529 U.S. 1, 23 (2000). But the APA is not an independent grant of subject-matter jurisdiction. Your Home, 525 U.S. at 457-58; Sanders, 430 U.S. at 107. And pursuant to 42 U.S.C. §§ 405(g) and 1395ff(b)(1)(A), our jurisdiction is generally limited by the scope of the agency's "final decision." See Loma Linda, 492 F.3d at 1074. Here, as discussed above, there has been no final decision on the RAC's good cause for reopening, and so that issue is beyond our power to review.

²⁰Our rationale differs from the Secretary's argument relying on our decisions in Loma Linda University Medical Center v. Leavitt, 492 F.3d at 1074-75, and Anaheim Memorial Hospital v. Shalala, 130 F.3d 845, 853 (9th Cir. 1997). The Secretary argues that because her final decision, the decision of the MAC, did not address the RAC's good cause for reopening, federal courts lack jurisdiction to review that issue. In Loma Linda and Anaheim, because there had been no final agency decision on certain claims, we held that there was no federal court jurisdiction to review those claims and remanded to the Secretary for a final decision thereon. Loma Linda and Anaheim are not controlling, however, because the reason there was no "final decision" in those cases differs from that here. There the agency had jurisdiction to decide, but did not address, the issues not previously decided. Here, by contrast, CMS did not have jurisdiction to decide the RAC's good cause for reopening, and remanding to the Secretary for a final decision on that issue would serve no purpose. But because, for the reasons stated, there has been no "final decision" on good cause for purposes of § 405(g), our conclusion here is the same as in Loma Linda and Anaheim: we do not have jurisdiction to review that issue.

[11] Shalala v. Illinois Council on Long Term Care, Inc. is not to the contrary. There the Supreme Court stated that the fact that an agency may not provide a hearing for a "particular contention" is "beside the point" because after the "action" has been channeled through the agency, "a court reviewing an agency determination under § 405(g) has adequate authority to resolve any statutory or constitutional contention that the agency does not, or cannot, decide." 529 U.S. at 23. This means that federal courts may review certain contentions that the agency does not decide; it does not mean that federal courts may review any and every contention. For example, the district court considered and rejected Palomar's due process claim,21 and we have considered and rejected Palomar's claim that the reopening regulations are contrary to the Medicare statute, see supra Part IV, though the agency did not decide either of these claims. But for the reasons stated, the district court correctly held that § 405(g) "does not afford subject-matter jurisdiction" over the RAC's reopening decision. See Sanders, 430 U.S. at 109.

IV. CONCLUSION

As stated above, this is not an easy case and Palomar has a legitimate interest in finality which it advances. But as we see it, Congress set the stage here by establishing the RAC program aimed at recouping excessive Medicare payments. It said expressly that reopenings were to be permitted under guidelines set by the Secretary in regulations. The Secretary

²¹Sanders recognizes an exception to § 405(g)'s "final decision" requirement for challenges based on constitutional grounds, but Palomar does not make a due process argument on appeal, so that exception does not apply. See 430 U.S. at 109. In St. Francis Hospital v. Sebelius, the district court's rationale for denying the Secretary's motion to dismiss was largely based on the plaintiff's "plausible" due process claim. See 2012 WL 2000841, at *10, 12. Because Palomar does not raise a due process claim, and because the procedural posture in St. Francis is different from that here, Palomar's argument for federal court jurisdiction based on that case is not persuasive.

by her regulations made explicit that there would be no appeal of a reopening decision, and that such a decision was "final." In these circumstances we agree with the district court that the question of good cause to reopen could not then be litigated after a claim determination was revised upon audit by a RAC.

AFFIRMED.

United States Court of Appeals for the Ninth Circuit

Office of the Clerk

95 Seventh Street San Francisco, CA 94103

Information Regarding Judgment and Post-Judgment Proceedings

Judgment

• This Court has filed and entered the attached judgment in your case. Fed. R. App. P. 36. Please note the filed date on the attached decision because all of the dates described below run from that date, not from the date you receive this notice.

Mandate (Fed. R. App. P. 41; 9th Cir. R. 41-1 & -2)

• The mandate will issue 7 days after the expiration of the time for filing a petition for rehearing or 7 days from the denial of a petition for rehearing, unless the Court directs otherwise. To file a motion to stay the mandate, file it electronically via the appellate ECF system or, if you are a pro se litigant or an attorney with an exemption from using appellate ECF, file one original motion on paper.

Petition for Panel Rehearing (Fed. R. App. P. 40; 9th Cir. R. 40-1) Petition for Rehearing En Banc (Fed. R. App. P. 35; 9th Cir. R. 35-1 to -3)

(1) A. Purpose (Panel Rehearing):

- A party should seek panel rehearing only if one or more of the following grounds exist:
 - ► A material point of fact or law was overlooked in the decision;
 - A change in the law occurred after the case was submitted which appears to have been overlooked by the panel; or
 - An apparent conflict with another decision of the Court was not addressed in the opinion.
- Do not file a petition for panel rehearing merely to reargue the case.

B. Purpose (Rehearing En Banc)

• A party should seek en banc rehearing only if one or more of the following grounds exist:

- Consideration by the full Court is necessary to secure or maintain uniformity of the Court's decisions; or
- ► The proceeding involves a question of exceptional importance; or
- The opinion directly conflicts with an existing opinion by another court of appeals or the Supreme Court and substantially affects a rule of national application in which there is an overriding need for national uniformity.

(2) Deadlines for Filing:

- A petition for rehearing may be filed within 14 days after entry of judgment. Fed. R. App. P. 40(a)(1).
- If the United States or an agency or officer thereof is a party in a civil case, the time for filing a petition for rehearing is 45 days after entry of judgment. Fed. R. App. P. 40(a)(1).
- If the mandate has issued, the petition for rehearing should be accompanied by a motion to recall the mandate.
- See Advisory Note to 9th Cir. R. 40-1 (petitions must be received on the due date).
- An order to publish a previously unpublished memorandum disposition extends the time to file a petition for rehearing to 14 days after the date of the order of publication or, in all civil cases in which the United States or an agency or officer thereof is a party, 45 days after the date of the order of publication. 9th Cir. R. 40-2.

(3) Statement of Counsel

• A petition should contain an introduction stating that, in counsel's judgment, one or more of the situations described in the "purpose" section above exist. The points to be raised must be stated clearly.

(4) Form & Number of Copies (9th Cir. R. 40-1; Fed. R. App. P. 32(c)(2))

- The petition shall not exceed 15 pages unless it complies with the alternative length limitations of 4,200 words or 390 lines of text.
- The petition must be accompanied by a copy of the panel's decision being challenged.
- An answer, when ordered by the Court, shall comply with the same length limitations as the petition.
- If a pro se litigant elects to file a form brief pursuant to Circuit Rule 28-1, a petition for panel rehearing or for rehearing en banc need not comply with Fed. R. App. P. 32.

- The petition or answer must be accompanied by a Certificate of Compliance found at Form 11, available on our website at www.ca9.uscourts.gov under *Forms*.
- You may file a petition electronically via the appellate ECF system. No paper copies are required unless the Court orders otherwise. If you are a pro se litigant or an attorney exempted from using the appellate ECF system, file one original petition on paper. No additional paper copies are required unless the Court orders otherwise.

Bill of Costs (Fed. R. App. P. 39, 9th Cir. R. 39-1)

- The Bill of Costs must be filed within 14 days after entry of judgment.
- See Form 10 for additional information, available on our website at www.ca9.uscourts.gov under *Forms*.

Attorneys Fees

- Ninth Circuit Rule 39-1 describes the content and due dates for attorneys fees applications.
- All relevant forms are available on our website at www.ca9.uscourts.gov under *Forms* or by telephoning (415) 355-7806.

Petition for a Writ of Certiorari

• Please refer to the Rules of the United States Supreme Court at www.supremecourt.gov

Counsel Listing in Published Opinions

- Please check counsel listing on the attached decision.
- If there are any errors in a published <u>opinion</u>, please send a letter in writing within 10 days to:
 - West Publishing Company; 610 Opperman Drive; PO Box 64526;
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 - ▶ and electronically file a copy of the letter via the appellate ECF system by using "File Correspondence to Court," or if you are an attorney exempted from using the appellate ECF system, mail the Court one copy of the letter.

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Form 10. Bill of Costs			(Re	v. 12-1-09)

United States Court of Appeals for the Ninth Circuit

BILL OF COSTS

Note:	service, within late bill of costs	o file a bill of costs, it MUST be submitted on this form and filed, with the clerk, with proof of in 14 days of the date of entry of judgment, and in accordance with 9th Circuit Rule 39-1. A sts must be accompanied by a motion showing good cause. Please refer to FRAP 39, 28 0, and 9th Circuit Rule 39-1 when preparing your bill of costs.								
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