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

COUNSEL

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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.[1] 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

[1]This 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]

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[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]"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]"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.[6] 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).

[6]*See* 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.[7]

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

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

reopen is final and not subject to appeal."[8] 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]

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

[9]In 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.
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> 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.

[10]In 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

[11]The 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.

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[12]The 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."

[13]Citing 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]

II. 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).

III. 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.

[14]Before 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(l) 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 determina-

tion, this would result in inefficiency in any case where "good cause" was later rejected, because all of the evidence and proceedings on the merits of medical necessity would be wasted.[15]

For 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-

[15]In 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

[16]The 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. §§ 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 added), *with* 20 C.F.R. § 404.903 (listing among "[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

[17]Our 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]

[18]Palomar 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"[19]—not in the sense that judicial review may be

[19]In 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(*l*). 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 *Califano 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.

[20]Our 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

[21]*Sanders* 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.