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

BRIEF OF THE PLAINTIFF-APPELLANT PALOMAR MEDICAL CENTER IN REPLY TO THE APPELLEE'S SUPPLEMENTAL BRIEF

Ronald S. Connelly
Mary Susan Philp
Powers, Pyles, Sutter &
Verville, PC
1501 M Street, NW, 7th Floor
Washington, DC 20005
202-872-6762
ron.connelly@ppsv.com
Counsel for the Plaintiff-Appellant,
Palomar Medical Center

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Federal Cases

Administrative Cases

Statutes

Regulations

Federal Registers

Other Authorities

GLOSSARY

ALJ	Administrative Law Judge
CHA	California Hospital Association
CMS	Centers for Medicare & Medicaid Services
HHS	Department of Health and Human Services
MAC	Medicare Appeals Council
MMA	Medicare Prescription Drug, Improvement, and Modernization Act of 2003
PRRB	Provider Reimbursement Review Board
QIC	Qualified Independent Contractor
RAC	Recovery Audit Contractor
SSA	Social Security Administration

Introduction

The Secretary's supplemental brief demonstrates why private enforcement of the reopening regulations is necessary for those regulations to have any force at all. The Secretary now reveals that she interprets the reopening regulations to forbid even her from overturning a contractor's decision to reopen a claim in violation of the regulatory deadlines. Supplemental Brief for the Appellee ("Sec.'s Supp. Br.") at 4. Thus, absent this Court's intervention, there will be no enforcement of the regulations.

Further, the text of the regulations does permit enforcement of the deadlines and standards for reopening claims because 42 C.F.R. §§ 405.980(a)(5) and 405.926(*l*) only limit review prior to a claim being revised. Once a claim is revised, the timeliness of the reopening is subject to review. This has been the Secretary's consistent interpretation in Social Security Administration ("SSA") appeals, when the 2005 regulations at issue here were promulgated, and in appeals before the Provider Reimbursement Review Board ("PRRB").

The Secretary cannot violate the law and then shield her actions from federal court review simply by refusing to address what she has

done. This is the gist of the Secretary's argument for depriving federal courts of jurisdiction. The Secretary is mistaken because it is well established that a federal court has jurisdiction over an entire Medicare "action" once a provider exhausts its administrative remedies. *Shalala v. Ill. Council on Long Term Care, Inc.*, 529 U.S. 1, 23-24 (2000). Palomar has done so, and jurisdiction is established here.

Argument

I. The Regulations at 42 C.F.R. §§ 405.926(*l*) and 405.980(a)(5) Do Not Bar Administrative Review of a Contractor's Compliance with the Medicare Reopening Regulations, Including the Good Cause Standard for Reopening Set Forth at 42 C.F.R. §§ 405.980(b)(2) and 405.986

The Secretary reveals that she has abdicated any authority to correct her agents' specific reopening errors. The Secretary states, "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). Instead, she "enforces" the regulations solely through vague, undefined "contractor audits and evaluations." *Id.* at 5. In other words, according to the Secretary, when a contractor unlawfully reopens a claim, no remedy exists whatsoever. If the contractor violates the regulations often enough, it might get a slap on the wrist,

but none of its errors will be reversed. Those who are harmed by the contractor's errors will not be made whole. The Secretary presents no evidence that even "contractor audits and evaluations"—minimal checks on contractor abuse—have actually occurred, and, of course, even if they had, any future sanctions against a contractor would offer no relief to a provider that has had funds unlawfully recouped.

Although the Secretary will not enforce the reopening regulations, the Secretary does offer the cold comfort that a provider may notify the Department of Health and Human Services ("HHS") "outside the context of an individual claim adjudication" of a contractor's "repeated or flagrant noncompliance with the reopening requirements." Sec.'s Supp. Br. at 6 n.2. The Secretary claims to be unaware of any such problems, notwithstanding at least five federal lawsuits, including this one, challenging her contractors' repeated violations of the rules. *St. Francis Hosp. v. Sebelius*, No. 09-cv-01528 (E.D.N.Y. filed April 13, 2009); *Morton Plant Hosp. Ass'n, Inc. v. Sebelius*, 747 F. Supp. 2d 1349 (M.D. Fla. 2010); *Trustees of Mease Hosp., Inc. v. Sebelius*, No. 8:09-CV-1795-T-23MAP, 2010 WL 3222097 (M.D. Fla. July 26, 2010); *Hosp. Comm. for the Livermore-Pleasanton Areas v. Johnson*, No. C-09-

1786EMC, 2010 WL 1222764 (N.D. Cal. Mar. 24, 2010). In this appeal alone, organizations collectively representing several hundred thousand providers have filed amicus briefs challenging the Secretary's failure to oversee her contractors.

Throughout this litigation, the Secretary has placed considerable weight on her statement in the 2005 Federal Register preamble responding to a commenter who requested that CMS "create enforcement provisions for the good cause standard when contractors reopen claims":

> 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 contractors' performance. Thus, the necessary monitoring and enforcement mechanisms are already in place.

70 Fed. Reg. 11,420, 11,453 (March 8, 2005). Palomar has pointed out that this passage shows that the Secretary intended two monitoring and enforcement mechanisms: 1) the regulations themselves, through private enforcement in administrative appeals; and 2) agency audits and evaluations. Br. of Plaintiff-Appellant at 38. But now, the Secretary claims that the agency will not enforce the regulations requiring good cause after one year, relying solely on contractor audits

and reviews. If this is true, the above passage does not respond to the commenter's request for "enforcement provisions for the good cause standard" because contractor audits and evaluations might change a contractor's behavior prospectively, or even result in a new contractor, but they do not "enforce" the regulations in any meaningful sense. A far more plausible interpretation of the above Federal Register passage is that the Secretary intended in 2005 to permit private enforcement, but the Secretary changed positions afterwards.

The Secretary's regulations do permit enforcement of the reopening deadlines and the good cause standard. The two regulations at issue here, 42 C.F.R. §§ 405.980(a)(5) and 405.926(*l*), simply prevent a claimant from stopping an audit midstream or from demanding a reopening. The regulations fit within a regulatory construct that ties all appeal rights to the revision of a claim. Sections 405.980(a)(5) and 405.926(*l*) speak solely to "reopening" and do not limit the scope of review once the claim has been revised. Thus, a claimant cannot initiate an appeal until the audit has concluded and the claim has been revised because initial determinations do not include "[a] contractor's, QIC's, ALJ's, or MAC's determination or decision *to reopen or not to*

reopen an initial determination."[1] *Id.* § 405.926(*l*) (emphasis added). Likewise, "[t]he contractor's, QIC's, ALJ's, or MAC's decision on whether *to reopen* is binding and not subject to appeal." 42 C.F.R. § 405.980(a)(5) (emphasis added). The regulations give the government an unfettered right to audit. Prior to a revision, the decision "to reopen" is not appealable.

Once there is a revision, however, the auditor's behavior is subject to review, including whether the audit was timely. The revised determination initiates the provider's appeal rights, 42 C.F.R. § 405.984, and an ALJ is permitted to decide "issues" pertinent to the revised determination above and beyond the revision itself. 42 C.F.R. § 405.1032.

This regulatory scheme has been in place for decades—no review until the audit is completed and the claim has been revised. Thus, the SSA could issue a nearly identical policy stating that the decision to reopen was not subject to review, U.S. Dep't of Health and Human Services, *Social Security Handbook, 1986* (Ninth Ed.) § 2185, and yet, following a revision, SSA claimants were nonetheless able to argue that

[1] A QIC is a Qualified Independent Contractor, an ALJ is an Administrative Law Judge, and the MAC is the Medicare Appeals Council.

their cases were improperly reopened. *See Cole v. Barnhart*, 288 F.3d 149, 150-51 (5th Cir. 2002); *Heins v. Shalala*, 22 F.3d 157, 161 (7th Cir. 1994). This is also why the Secretary could state in 2005 that the new regulations continued existing policy, 70 Fed. Reg. at 11,433, 11,450, even though the MAC in *UMDNJ* set aside an untimely reopening as invalid. *In the Case of UMDNJ–Univ. Hosp.* (MAC Mar. 14, 2005)[2]; *see also* Br. for the Appellee, at 23, 30 (conceding that the 2005 regulations continued prior policy). Likewise, the PRRB continues to enforce the cost report reopening regulations, *see, e.g., 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), even though a nearly identical regulation states that "[a] determination or decision to reopen or not to reopen" a cost report "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).

The Secretary's current interpretation is contrary to the text of the regulations and to long-established agency policy and would give contractors unprecedented and unfettered discretion to disregard

[2] *Available at* http://www.hhs.gov/dab/macdecision/umdnj.htm.

regulatory requirements. The Recovery Audit Contractor's ("RAC's") revision of Palomar's claim vested the ALJ with jurisdiction to review the RAC's compliance with the reopening regulations.

II. If the Regulations Bar Administrative Review of a Contractor's Decision to Reopen, Then Federal Courts Have Jurisdiction to Enforce the Agency's Compliance with the Good Cause Standard for Reopening

The Secretary renews her untenable argument that she may divest a federal court of jurisdiction over an issue simply by refusing to address it administratively. Sec.'s Supp. Br. at 10. As Palomar and amici have already shown, federal court jurisdiction over Medicare disputes is established under 42 U.S.C. §§ 405(g) and 1395ff(b)(1)(A) if a provider satisfies two requirements: 1) presentment, which is not waivable by the courts; and 2) exhaustion, which is waivable. *Weinberger v. Salfi*, 422 U.S. 749, 765-66 (1975); *see also Mathews v. Eldridge*, 424 U.S. 319, 328 (1976) (citing *Salfi*, 422 U.S. at 765); *Bowen v. City of New York*, 476 U.S. 467, 472 (1986). Palomar has met both requirements. Palomar presented its claim for payment and exhausted all administrative remedies. The Secretary issued a final decision, which Palomar appealed to federal court. It does not matter that the Secretary has refused to address the good cause issue because it is the

"action" that arises under Medicare, not specific issues. *Ill. Council on Long Term Care*, 529 U.S. at 23-24. Thus, jurisdiction is conferred under 42 U.S.C. §§ 405(g) and 1395ff(b)(1)(A).

The Secretary's reliance on *SEC v. Chenery Corp.*, 332 U.S. 194 (1947), and its progeny is misplaced. Sec.'s Supp. Br. at 11-12. In *Chenery*, the Supreme Court held that "a reviewing court, in dealing with a determination or judgment which an administrative agency alone is authorized to make, must judge the propriety of such action solely by the grounds invoked by the agency." 332 U.S. at 196. The agency's decision must be "understandable" so that the court is not "compelled to guess at the theory underlying the agency's action." *Id.* at 196-97. *Chenery* concerns the thoroughness and clarity of agency reasoning and does not address the situation presented here, in which the agency professes to be powerless to decide an issue.

Chenery certainly does not stand for the proposition that an agency may deprive a court of jurisdiction by removing a matter from administrative review. To the contrary, whether the Secretary has complied with the statutory mandate to reopen "under guidelines established by the Secretary in regulations," 42 U.S.C. § 1395ff(b)(1)(G),

is not "a determination or judgment which an administrative agency alone is authorized to make," *Chenery*, 332 U.S. at 196. The Secretary's violation of the statute is an appropriate matter for judicial review, as is her failure to adhere to her own regulations. *See Service v. Dulles*, 354 U.S. 363, 388 (1957); *United States ex rel. Accardi v. Shaugnessy*, 347 U.S. 260, 267-68 (1954). If the Secretary "does not, or cannot, decide" the matter, "the court will consider the contention when it later reviews the action." *Ill. Council on Long Term Care*, 529 U.S. at 23-24.

Just last month, a federal district court in New York confirmed that it had jurisdiction over whether a RAC had good cause to reopen claims, notwithstanding the Secretary's failure to issue a decision on the issue.[3] *St. Francis Hosp. v. Sebelius*, No. 09-cv-01528 (E.D.N.Y. June 5, 2012) (order denying motion to dismiss for lack of jurisdiction). In *St. Francis*, the hospital accepted the Secretary's contention that the regulations bar administrative review, and, therefore, that issue was

[3] Thus, the Secretary is incorrect that no other court cases are pending in which a provider challenges a contractor's reopening. Sec.'s Supp. Br. at 6 n.2. The undersigned counsel for Palomar first became aware of the *St. Francis* proceeding on June 13, 2012, through media reports of the court's Memorandum and Order denying the Secretary's motion to dismiss. A copy of the Memorandum and Order in *St. Francis* is appended to this brief.

not before the court.[4] St. Francis filed suit in federal district court without exhausting administrative remedies, claiming that the Secretary had deprived it of due process and violated the statutory mandate to reopen only under guidelines issued in regulations. *Id.* at 4. The Secretary moved to dismiss, but the court denied the Secretary's motion. The court determined that St. Francis satisfied the non-waivable presentment requirement. *Id.* at 7. The court waived the exhaustion requirement, in part, because "the propriety of reopening a claim is not an issue that the agency is willing to review on appeal." *Id.* at 10. Thus, the *St. Francis* court will decide whether the RAC complied with the regulatory deadlines and the good cause standard when reopening the 225 claims at issue.

The Secretary's discussion of federal court jurisdiction muddles two distinct issues. Sec.'s Supp. Br. at 12-15. On the one hand, there is the question of whether federal courts have jurisdiction over the good cause issue if the Secretary's regulations do indeed bar administrative review. As explained above, and as most recently demonstrated by the

[4] Obviously, Palomar disagrees that the regulations bar administrative review. The court in *St. Francis* did not have the benefit of an alternative view of the regulations.

St. Francis decision, courts certainly do have jurisdiction in that situation. On the other hand, there is the question of what action this Court should take if it decides that the Secretary's regulations do *not* bar administrative review. Much of the Secretary's discussion of court jurisdiction, including her analysis of *Illinois Council*, *Anaheim Memorial Hospital v. Shalala*, 130 F.3d 845 (9th Cir. 1997), and *Loma Linda University Medical Center v. Leavitt*, 492 F.3d 1065 (9th Cir. 2007), actually focuses on this second question. Neither *Illinois Council*, nor *Anaheim*, nor *Loma Linda* supports the proposition that the Secretary may divest courts of jurisdiction by removing an issue from administrative review, and the Secretary's supplemental brief does not appear to argue otherwise.

Palomar has urged this Court to decide the good cause issue even if it determines that administrative review is available. Br. of Plaintiff-Appellant at 64-67; Reply Br. of Plaintiff-Appellant, at 31-34. There is no jurisdictional bar to the court doing so because Palomar has exhausted its administrative remedies and the entire action is before the Court. The Supreme Court has been clear that once a provider exhausts administrative remedies, jurisdiction is established even if the

Secretary "does not" decide a matter; jurisdiction is not dependent upon the Secretary's inability to decide a matter. *Ill. Council on Long Term Care*, 529 U.S. at 23-24.

Finally, a remand is at the Court's discretion. Although *Anaheim* appears to the contrary, 130 F.3d at 853, that case was decided prior to the Supreme Court's decision in *Illinois Council*. Other Ninth Circuit cases after *Illinois Council* show that a remand is discretionary under the present circumstances and that this Court may itself determine whether the RAC complied with the regulations. *See Benecke v. Barnhart*, 379 F.3d 587, 593 (9th Cir. 2004); *Harman v. Apfel*, 211 F.3d 1172, 1178 (9th Cir. 2000).

III. MMA § 306(c) Does Not Bar Enforcement of the Reopening Regulations

The Secretary does not dispute amicus California Hospital Association's ("CHA's") argument that § 306(c) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA"), Pub. L. No. 108-173, 117 Stat 2066, 2256 (2003), does not bar enforcement of the good cause regulations. At oral argument, the Court questioned both parties about whether subsection (c) requires the Secretary to waive the reopening deadlines and the good cause standard. The

Secretary responded that the reopening regulations and the good cause standard do apply to RACs. Now, the Secretary offers no response to CHA's position, implying that the Secretary agrees that § 306(c) has no bearing on this case.

MMA § 306(a) established the RAC demonstration project. Subsection (c) states, "The Secretary shall waive such provisions of title XVIII of the Social Security Act [i.e., the Medicare statute] as may be necessary to provide for payment for services under the project in accordance with subsection (a)." Amicus CHA correctly notes that subsection (c) limits any waiver to provisions "necessary to provide for payment" to RACs, and paying the RACs does not require waiver of the reopening deadlines. Second Amicus Curiae Br. of CHA at 15.

The Secretary has not formally interpreted MMA § 306(c) or waived any provision of title XVIII of the Social Security Act in implementing the RAC demonstration program.[5] Presumably, this is because the Secretary concluded that no waiver was required to pay the RACs.

In fact, the reopening deadlines and the good cause standard could have no impact on paying RACs under the demonstration project

[5] There is no legislative history of MMA § 306(c).

because the Secretary permitted RACs to keep their contingency fees, even if a RAC's denial of payment was overturned on appeal. 75 Fed. Reg. 69,037, 69,039 (Nov. 10, 2010). If the ALJ's decision in this case had stood, the RAC would still have received its payment, and if the Court reverses the Secretary's final decision, the RAC will not be obligated to refund its payment to the Medicare program. The reopening regulations affect only the deadlines and standards to be used by RACs for reopening claims, not the Secretary's ability to pay RACs under the demonstration program. Section 306(c) does not affect this case, and the Secretary does not argue otherwise.

Conclusion

For the foregoing reasons, and for the reasons set forth in the Brief of the Plaintiff-Appellant and the Reply Brief of the Plaintiff-Appellant, this Court should hold that the timeliness of the reopening is both administratively and judicially reviewable and that there was no "good cause" to reopen in this case. Accordingly, the decision of the district court should be reversed.

Respectfully submitted,
Palomar Medical Center
By its counsel,

/s/Ronald S. Connelly
Ronald S. Connelly
D.C. Bar No. 488298
Mary Susan Philp
D.C. Bar No. 295287
POWERS PYLES SUTTER & VERVILLE, PC
1501 M Street, NW, 7th Floor
Washington, DC 20005
tel. (202) 466-6550
fax (202) 785-1756
ron.connelly@ppsv.com

Attorneys for Plaintiff-Appellant,
Palomar Medical Center

Dated: July 13, 2012

Certificate of Compliance

1. The Court did not establish a word or page limit for this Reply to the Secretary's Supplemental Brief. This brief contains 2,999 words, excluding the parts of the brief exempted under Fed. R. App. P. 32(a)(7)(B)(iii).

2. This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because this brief has been prepared in a proportionally spaced typeface using Microsoft Word version 2007 in 14 point Century Schoolbook font.

/s/Ronald S. Connelly
Ronald S. Connelly
Attorney for Palomar Medical Center

Dated: July 13, 2012

Certificate of Service

I, Ronald S. Connelly, hereby certify that on July 13, 2012, a copy of the foregoing Brief of the Plaintiff-Appellant Palomar Medical Center in Reply to the Appellee's Supplemental Brief was served upon all counsel of record by electronically filing it with the Clerk of the Court for the United States Court of Appeals for the Ninth Circuit by using the Appellate ECM/ECF system, which automatically provides electronic notification to the following:

Christine N. Kohl
U.S. Department of Justice,
Civil Division, Appellate Staff
950 Pennsylvania Avenue NW
Washington, DC 20530
(202) 514-4027

Anthony J. Steinmeyer
U.S. Department of Justice,
Civil Division, Appellate Staff
950 Pennsylvania Avenue NW
Washington, DC 20530
(202) 514-3388

/s/ Ronald S. Connelly
Ronald S. Connelly
Attorney for Plaintiff
Palomar Medical Center

Dated: July 13, 2012.

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK
----------X
ST. FRANCIS HOSPITAL,

Plaintiff,

- against -

KATHLEEN SEBELIUS, in her capacity as Secretary, United States Department of Health and Human Services,

Defendant.
----------X

MEMORANDUM & ORDER
09 CV 1528 (DRH)(AKT)

APPEARANCES:

Duane Morris
Attorneys for Plaintiff
111 S. Calvert Street, Suite 2000
Baltimore, Maryland 21202
By: Ray M. Shepard
Susan V. Kayser

United States Attorney's Office
Attorneys for Defendant
610 Federal Plaza, Fifth Floor
Central Islip, New York 11722
By: Robert B. Kambic

HURLEY, District Judge:

Plaintiff brings this action for judicial review of certain administrative determinations issued by defendant in her capacity as Secretary of Health and Human Services, which resulted in the recoupment of approximately $1.2 million in Medicare reimbursements from plaintiff. Presently before the Court is defendant's motion to dismiss the complaint pursuant to Fed. R.

Civ. P. 12(b)(1) for lack of subject matter jurisdiction. For the reasons stated below, defendant's motion is denied.

BACKGROUND

Plaintiff, a hospital located in Roslyn, New York, regularly obtains reimbursement under Part A[1] of the Medicare program from the U.S. Department of Health and Human Services ("HHS") for services rendered to Medicare beneficiaries. (Compl. ¶ 8.) Under Agency regulations, the reimbursement process starts with an "initial determination" by a private "fiscal intermediary" regarding the coverage and payment of a particular claim. (Compl. ¶¶ 14-17 (citing 42 U.S.C. § 1395h; 42 C.F.R. §§ 405.704(b), 405.924(b)).) In this case, the fiscal intermediary, Empire Medical Services ("Empire"),[2] determined from 2002 to 2004 that a number of reimbursement claims at issue in this action were covered and payable to plaintiff under Medicare Part A.

As part of an experimental demonstration project authorized by the Medicare Prescription Drug, Improvement and Modernization Act of 2003, HHS engaged the services of recovery audit contractors ("RACs") to identify underpayments and overpayments made to Medicare service providers. (Compl. ¶ 37.) The RACs were offered a percentage of each overpayment that it identified and which was later recovered by the Agency. Under this project, Connolly Consulting, an RAC, informed plaintiff that it had identified a total of 225 reimbursement claims previously paid to plaintiff that were subject to overpayment. (Compl. ¶ 54.) The RAC then forwarded these purportedly overpaid claims to Empire, the original fiscal intermediary, for reconsideration. (*Id.* ¶ 55.)

[1] Part A of the Medicare program covers reimbursements for inpatient hospital services. (Compl. ¶ 11.)
[2] Empire Medical Services has since been renamed "National Government Services." (Compl. ¶ 18.)

This referral triggered a multi-step review process, beginning with Empire's decision whether or not to reopen a claim for further consideration.[3] Empire chose to reopen all 225 claims identified by the RAC, and later issued "revised reimbursements," resulting in a substantial recoupment to HHS for overpayments to plaintiff. (Compl. ¶ 55.) Plaintiff then entered a four-layer appeal process. The first appeal is made to the fiscal intermediary (Empire), the second to a "Qualified Independent Contractor," the third to an Administrative Law Judge for a hearing and decision, and the fourth to the Medicare Appeals Council ("MAC"). 42 C.F.R. §§ 405.904(b), 405.984; 42 U.S.C. §§ 405g, 1395ff.

Plaintiff took advantage of this administrative appeals process to an extent. Through those efforts, 104 of the original 225 overpayment claims at issue were overturned in plaintiff's favor, 18 went as far as the MAC, 15 are pending before an Administrative Law Judge, and the remaining claims were abandoned by plaintiff at various stages in the appeals process. In the present action, plaintiff does not challenge the Agency's determinations on the merits of the reimbursement claims. Rather, plaintiff alleges that there is no mechanism within the administrative appeals process to challenge the propriety of Empire reopening these claims in the first instance.

Under agency regulations, a reimbursement claim may be reopened either within one year of the initial determination without cause, or within four years of the initial determination with cause.[4] (Compl. ¶ 25 (citing 42 C.F.R. § 405.980(b)).) Plaintiff claims that none of the claims were reopened within a year of the initial determination, and that in some cases they were reopened more than four years after the fact. (*Id.* ¶ 56.) And, in no event, plaintiff alleges, was

[3] HHS is empowered with the authority under 42 U.S.C. § 1395ff(b) to reopen an initial determination. Through Agency regulations, HHS delegated this power to the fiscal intermediary who initially processed the claim at issue. See 42 C.F.R. 405.980.

[4] A claim may also be reopened under the same regulation at any time where there exists reliable evidence of fraud or where a clerical error has occurred. Neither is at issue in this case. (Compl. ¶ 67.)

good cause ever shown. (*Id.* ¶¶ 57-60.) According to plaintiff, in order to show such cause, Empire and the RAC must cite "new and material evidence," or establish that "reopening was necessary to correct an obvious facial error made at the time of the initial determination to pay the claims." (*Id.* ¶ 59, 68 (citing 42 C.F.R. 405.986).) No new evidence was available at the time of reopening that was not previously available at the time of the initial determination. (*Id.* ¶ 69.)

However, under 42 C.F.R. § 405.926(*l*), "[a] contractor's . . . decision to reopen or not to reopen an initial determination" is not appealable. Therefore, plaintiff was unable to challenge the untimely reopening of a Medicare reimbursement claim at the administrative level, resulting in a substantial monetary loss through recoupment, and allegedly depriving plaintiff of its due process rights.

Plaintiff brings four causes of action to remedy its alleged deprivation: (1) that defendant violated the Medicare statute and regulations governing the timing of reopening decisions, (2) that defendant denied plaintiff's Fifth Amendment right to due process (3) that regulation 42 C.F.R. § 405.926(*l*) is inconsistent with the mandates of 42 U.S.C. § 1395ff(b)(1)(A), in that it does not provide an administrative review mechanism to challenge the act of reopening a particular Medicare claim, and (4) that defendant's regulation shielding decisions to reopen a claim from administrative review is arbitrary, capricious, and an abuse of the Agency's discretion, and should therefore be invalidated pursuant to 5 U.S.C. § 706(2) of the Administrative Procedures Act.

Defendant brings this motion to dismiss, arguing that the Court lacks subject matter jurisdiction to hear this claim.

DISCUSSION

I. STANDARD OF REVIEW

A case may properly be dismissed for lack of subject matter jurisdiction pursuant to Rule 12(b)(1) "when the district court lacks the statutory or constitutional power to adjudicate it." *Makarova v. United States*, 201 F.3d 110, 113 (2d Cir. 2000). "In contrast to the standard for a motion to dismiss for failure to state a claim under Rule 12(b)(6), a 'plaintiff asserting subject matter jurisdiction has the burden of proving by a preponderance of the evidence that it exists.'" *MacPherson v. State St. Bank & Trust Co.*, 452 F. Supp. 2d 133, 136 (E.D.N.Y. 2006) (quoting *Makarova*, 201 F.3d at 113); *see also Tomaino v. United States*, 2010 U.S. Dist. LEXIS 24980, 2010 WL 1005896, at *1 (E.D.N.Y. Mar. 16, 2010). "On a Rule 12(b)(1) motion, the court may consider matters outside the pleadings, including affidavits, documents, and testimony if necessary." *Tsanganea v. City Univ. of N.Y.*, 2008 U.S. Dist. LEXIS 66236, 2008 WL 4054426, at *3 (S.D.N.Y. Aug. 28, 2008) (citing *Kamen v. Am. Tel. & Tel. Co.*, 791 F.2d 1006, 1011 (2d Cir. 1986)).

II. JURISDICTION UNDER THE MEDICARE ACT

The Complaint cites 42 U.S.C. §§ 405(g) and 1395ff(b)(1)(A) of the Medicare Act as the basis for federal subject matter jurisdiction over this case. (Compl. ¶ 4.) Section 1395ff(b)(1)(A) incorporates the judicial review provisions of section 405(g) of the Social Security Act, which empowers federal district courts to review administrative decisions only where there has been a "final decision . . . made after a hearing." 42 U.S.C. § 405(g); *see also Pavano v. Shalala*, 95

F.3d 147, 150 (2d Cir. 1996)("[A] federal court may review a Medicare determination . . . only where a claimant has obtained a final agency decision.").

Defendant argues that this Court cannot presently take up this matter because plaintiff has failed to meet this threshold requirement of obtaining a final administrative decision following a hearing. (D's Br. at 8-10.) As noted above, of the remaining claims that have not otherwise been overturned in plaintiff's favor, or abandoned by plaintiff, 15 are, as of the time of the filing of the pleading, "pending disposition at the ALJ level," (compl. ¶¶ 61-62), and 18 were dismissed by the MAC following a determination that plaintiff did not timely request a hearing before an ALJ, (compl. Ex. E). Notably, plaintiff raised the issue of the propriety of reopening the claims before the MAC, which denied review as it was "a substantive issue that had not been presented to the ALJ at a hearing." (Compl. Ex. E.) Defendant further contends that the MAC's review of the ALJ's refusal to allow an untimely hearing does not amount to a "final decision" following a hearing as it is defined in the statute. (D's Br. at 9 (citing *inter alia Dietsch v. Schweiker*, 700 F.2d 865, 867 (2d Cir. 1983)).) Moreover, defendant urges, even if the administrative determinations were reviewable here, the Court's review would be limited to issues raised and decided below, which does not include the question of reopening the claims in the first place. (D's Br. at 10.)

Plaintiff does not object to defendant's assertion that it has not obtained a "final decision," but nevertheless argues that this Court should exercise jurisdiction under the Medicare Act by waiving the administrative exhaustion requirement. (P's Opp. at 3.)

"The 'final decision' requirement has two elements, one which is waivable and one which is non-waivable. The waivable element is the requirement that the administrative remedies prescribed by the Secretary be exhausted. The non-waivable element is the requirement

that a claim for benefits shall have been presented to the Secretary." *Long Island Ambulance, Inc. v. Thompson*, 220 F. Supp. 2d 150, 160 (E.D.N.Y. 2002)(citing and quoting *Mathews v. Eldridge*, 424 U.S. 319, 327 (1976), and *Abbey v. Sullivan*, 978 F.2d 37, 43 (2d Cir. 1992))(internal quotes omitted). Here, there is no dispute that plaintiff satisfied the non-waivable jurisdictional element by initiating the administrative appeals process regarding the overpayment determinations.[5] *See Heckler v. Lopez*, 464 U.S. 879, 882 (1983)(holding that all a claimant must do to satisfy the presentment requirement is to "specifically present[] the claim that his benefits should not be terminated").

As to the waivable element, which requires exhaustion of administrative remedies prior to judicial review, the parties also do not dispute that plaintiff has failed to obtain a final Agency decision regarding the propriety of reopening its claims. In determining whether the exhaustion requirement should be waived, courts consider the following factors: (1) whether requiring the plaintiff to administratively exhaust its claim would be "futile"; (2) whether the judicial claim is "collateral" to the administrative claim for benefits; and (3) whether the plaintiff would suffer irreparable harm if required to exhaust administrative remedies. *Pavano*, 95 F.3d at 150 (citing *Abbey*, 978 F.2d at 44); *see also Bowen v. City of New York*, 476 U.S. 467, 483 (1986); *Eldridge*, 424 U.S. at 330-32. However, "exhaustion is the rule, waiver the exception," and "[g]iving the agency first crack at correcting its own errors also conserves judicial resources." *Abbey*, 978 F.2d at 44-45. "[N]o one element is critical to the resolution of the [exhaustion] issue; rather, a more general approach, balancing the competing considerations to arrive at a just result, is in order." *Pavano*, 95 F.3d at 151 (citing *New York v. Sullivan*, 906 F.2d 910, 918 (2d Cir. 1990)).

[5] Indeed, defendant's memorandum of law does not address the non-waivable element at all, focusing solely on the waivable exhaustion requirement. (D's Br. at 10-14.)

a. Futility

Plaintiff contends that awaiting a final decision from HHS would prove futile because "the issue presented is one the Secretary lacks either jurisdiction or the desire to consider in the course of the administrative process." (P's Opp. at 5.) Plaintiff's arguments recognize that the policy of requiring administrative exhaustion prior to judicial review "prevent[s] premature interference with agency processes . . . so that it may have an opportunity to correct its own areas." (*Id*. (quoting *Abbey*, 978 F.2d at 44).) However, plaintiff argues, such policy considerations are "chimerical when the challenge is to regulations promulgated and consistently enforced by the agency, and which the agency has either no power, or no inclination, to correct." (*Id.* (quoting *Abbey*, 978 F.2d at 45).)

The particular issue here, *viz.*, the propriety of the reopening of plaintiff's reimbursement claims, is indeed not administratively reviewable. Under Medicare regulations, 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," are not considered "initial determinations" and are not administratively appealable. 42 C.F.R. § 405.926(*l*). Likewise, a separate regulation provides that "[t]he contractor's, QIC's, ALJ's, or MAC's decision on whether to reopen is binding and not subject to appeal." 42 C.F.R. §§405.980(a)(5). Pursuant to these regulations, the MAC has, on at least three occasions in

other cases,[6] ruled that an ALJ and the MAC is without jurisdiction to review a contractor's decision to reopen a claim.[7] One of those decisions states in relevant part as follows:

> The Appellant is expressly asking that the ALJ and [MAC] 'review a contractor's decision to reopen an initial determination.' The regulation at 42 C.F.R. § 405.926(*l*) forbids this. The appellant's position contradicts the specific language of the regulation and the intent expressed in the preamble to the final rule that reopenings 'continue to be discretionary actions on the part of contractors . . . not subject to appeal.
>
> . . . This lack of jurisdiction extends to whether or not the contractor met good cause standards for reopening set forth in 42 C.F.R. §§ 405.980(b)(2). The [Centers for Medicare and Medicaid Services ("CMS")] has expressly stated that the enforcement mechanism for good cause standards lies within CMS's evaluation and monitoring of contractor performance, not the administrative appeals process. An appellant's due process rights are preserved by the ability to appeal the merits of revised determination.

In re Providence St. Joseph Medical Ctr., Order of the Medicare Appeals Council (July 23, 2008)(attached to the Complaint as Exhibit A-3).

Defendant counters that administrative exhaustion would not be futile, but rather would "fully advance the policies underlying the exhaustion requirement." (D's Br. at 11.) In particular, requiring plaintiff to exhaust "may, as in this case, enable the agency to resolve the case on non-constitutional grounds." (*Id.* at 12 (quoting *Abbey*, 978 F.2d at 45)); *see Shalala v. Illinois Council on Long Term Care, Inc.*, 529 U.S. 1, 24 (2000)("Proceeding through the agency . . . provides the agency the opportunity to reconsider its policies, interpretations, and regulations in light of those challenges."). As defendant notes, plaintiff has 15 claims pending before an

[6] Plaintiff attaches copies of three such decisions by the MAC to its Complaint. Generally, MAC decisions are not published.

[7] Plaintiff further suggests that when it presented this same issue to the MAC in its own administrative appeal, "the Council refused to consider the issue." (P's Opp. at 6.) This assertion is somewhat misleading, as the MAC declined to take up the issue in that instance not because of the jurisdictional issues addressed above, but because plaintiff had failed to raise the issue timely before an ALJ. (Compl. Ex. E at 3.)

ALJ, wherein it could ultimately prevail. Defendant further argues that exhaustion would allow the agency to compile a complete record of the proceedings to aid judicial review.

However, the narrow issue before the Court pertains to the lack of process available to challenge reopening decisions through an administrative appeal. HHS regulations, in addition to the MAC opinions furnished by plaintiff, demonstrate that the propriety of reopening a claim is not an issue that the agency is willing to review on appeal. The Court recognizes that MAC opinions do not serve as precedent for other decisions by the MAC, and that it is therefore possible for the Council to rule differently. Nevertheless, their determinations are based on straightforward language contained within agency regulations which reflect an established policy not to subject the reopening decisions of its contractors to review. As the Supreme Court held in *Eldridge*, and as is true here, "[i]t is unrealistic to expect that the Secretary would consider substantial changes in the current administrative review system at the behest of a single [claimant] raising a constitutional challenge in an adjudicatory context." 424 U.S. at 330. Likewise, the Second Circuit has recognized futility in cases where the claim asserted on judicial review would not benefit "from further factual development or from the agency's experience and expertise" or where waiving exhaustion would not "prevent premature interference with agency processes." *See New York v. Heckler*, 742 F.2d 729, 737 (2d Cir. 1984); *see also Ellis v. Blum*, 643 F.2d 68, 78 (2d Cir. 1981)("[I]t would be foolish to expect the Secretary in an adjudicatory administrative proceeding to take steps to remedy what plaintiff alleges to be a full-blown policy."). Furthermore, much of plaintiff's claims here hinge on questions of constitutional due process, and the constitutionality of a statute or regulation is generally considered "a matter [ ] beyond [the Secretary's] jurisdiction to determine." *Weinberger v. Salfi*, 422 U.S. 749, 765 (1975); *see also Califano v. Sanders*, 430 U.S. 99, 109 (1977)("Constitutional questions

obviously are unsuited to resolution in administrative hearing procedures and, therefore, access to the courts is essential to the decision of such questions.").

Accordingly, holding plaintiff to the administrative exhaustion requirement in this instance would prove futile.

b. Collateral Issues

Plaintiff's present case is also collateral to its demand for benefits. Plaintiff here is challenging the "validity of agency regulations," rather than "the application of regulations." *See Pavano*, 95 F.3d at 150. Whereas, the Agency's "mere deviation from the applicable regulations . . . [is] fully correctable upon subsequent administrative review," *City of New York*, 476 U.S. at 484-85, the validity of the regulations and procedures themselves is a different matter. In essence, the merits of the redetermination below are not at issue, but rather the purported lack of appellate remedies available to address a decision to reopen a claim. The two are not inextricably intertwined in this case. Clearly this is not the case where the plaintiff is "challenging the application of concededly valid regulations." *Abbey*, 978 F.2d at 45. On the contrary, plaintiff here is arguing that the Secretary closely follows such regulations.

Defendant, however, argues that the issue presented here cannot be considered collateral because it is "outcome determinative." (D's Reply at 7.) In other words, defendant urges, if plaintiff prevails on the claims before this Court, the overpayment determinations below will necessarily be reversed. In support, defendant distinguishes this case from *Eldridge* where the judicial determination did not have an automatic effect on the benefits claim itself, but on the timing of the claimants hearing. (D's Reply at 7.) Although such a distinction may exist in the present circumstances, defendant provides no authority for the broader proposition that issues

must not be "outcome determinative" to be considered collateral. Moreover, it is not entirely clear why success here would necessarily lead to a reversal below. One of the alternative forms of relief requested by plaintiff in its complaint is a directive remanding the matter to HHS "with instructions directing the Secretary to comply with its own regulations for reopenings, subject to the further review of this Court through the normal administrative appeals process." (Compl. at 18-19.) Success on the merits is by no means assured in that scenario, particularly where the agency is to determine whether good cause existed for reopening the claims.

c. Irreparable Harm

Finally, plaintiff has alleged a sufficient irreparable harm to pass muster under the final element of waiver. The alleged facts make a plausible claim that plaintiff has suffered a deprivation of its Fifth Amendment due process rights. Generally, in this Circuit, a constitutional deprivation constitutes per se irreparable harm. *See Covino v. Patrissi*, 967 F.2d 73, 77 (2d Cir. 1992)(discussing irreparable harm in the context of preliminary injunctions); *Mitchell v. Cuomo*, 748 F.2d 804, 806 (2d Cir. 1984)(same).

Accordingly, as a judicial waiver of the administrative exhaustion requirement is appropriate in this case, the Court has subject matter jurisdiction over this case pursuant to 42 U.S.C. §§ 405(g) and 1395ff(b)(1)(A).

III. SECTION 1331 AND MANDAMUS JURISDICTION

As it has been determined *supra* that subject matter jurisdiction exists under the Medicare Act, the Court need not determine whether jurisdiction also exists under the two other bases

identified by the parties: federal question jurisdiction under 28 U.S.C. § 1331, and mandamus jurisdiction under 28 U.S.C. § 1361.

CONCLUSION

For the above-stated reasons, the Court has subject matter jurisdiction to hear this case, and defendant's motion to dismiss pursuant to Fed. R. Civ. P. 12(b)(1) is therefore denied. This action is respectfully referred to the Honorable A. Kathleen Tomlinson for discovery and pretrial supervision.

SO ORDERED.

Dated: Central Islip, New York
June 5, 2012

/s
Denis R. Hurley
Unites States District Judge