IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

THE AMERICAN HOSPITAL ASSOCIATION, et al., Plaintiffs, v. SYLVIA M. BURWELL, in her official capacity as Secretary of Health and Human Services,[1] Defendant.	Civil Action No. 14-609 (RBW)

REPLY IN SUPPORT OF
DEFENDANT'S MOTION TO DISMISS

[1] Pursuant to Fed. R. Civ. P. 25(d), Sylvia M. Burwell is substituted for her predecessor as Secretary of Health and Human Services.

TABLE OF CONTENTS

INTRODUCTION 1

ARGUMENT 3

I. THE COURT LACKS JURISDICTION OVER PLAINTIFFS' CHALLENGE TO THE TWO-MIDNIGHTS RULE BECAUSE PLAINTIFFS HAVE FAILED TO EXHAUST THEIR ADMINISTRATIVE REMEDIES 3

A. The Court Lacks the Power to Deem the Exhaustion Requirement Waived Because Plaintiffs' Submission of Appeals Three Days Before Filing Suit Did Not Satisfy the Presentment Requirement 4

B. The Court Should Not Deem Exhaustion Waived 5

1. Plaintiffs have not demonstrated that exhaustion would be futile 6

2. Section 405(g) may not be waived here for futility alone 8

3. Waiver is unwarranted here 12

II. THE COURT LACKS JURISDICTION OVER PLAINTIFFS' CHALLENGE TO THE PHYSICIAN ORDER RULE 13

A. Most Plaintiffs Lack Standing to Challenge the Physician Order Rule 13

B. Plaintiffs Have Failed to Exhaust Their Administrative Remedies 14

1. The Court lacks the power to deem the exhaustion requirement waived because Plaintiffs have not satisfied the presentment requirement 14

2. The Court should not deem exhaustion waived 15

C. Plaintiffs' Challenge to the Physician Order Rule Is Not Ripe 16

III. THE COURT LACKS JURISDICTION OVER PLAINTIFFS' CHALLENGE TO THE ONE-YEAR FILING DEADLINE FOR REBILLING DENIED PART A CLAIMS UNDER PART B 17

A. Plaintiffs Lack Standing to Challenge the One-Year Time Limit 18

B. Plaintiffs Have Failed to Exhaust Their Administrative Remedies 22

C. The Court Lacks Jurisdiction to Review the Discretionary Decisions Whether To Reopen Part A Payment Determinations or To Extend the Statutory Deadline for Untimely Part B Claims 22

1. The Court lacks jurisdiction to review a refusal to reopen 23

2. The Court lacks jurisdiction to review a refusal to extend the one-year timely filing requirement..... 23

3. The Court lacks jurisdiction under 28 U.S.C. § 1331 24

CONCLUSION 25

INTRODUCTION

Plaintiffs urge the Court to skip straight to the merits of this case, casting Defendant's jurisdictional arguments as tactics designed to "shortchange hospitals" and "insulate [the challenged] policies from judicial review." Pls.' Opp'n 4. Their dismissiveness is unwarranted. In every case, the "first and fundamental" question is that of jurisdiction. Steel Co. v. Citizens for a Better Env't, 523 U.S. 83, 94 (1998). That question takes on special importance in "the context of a massive, complex health and safety program such as Medicare, embodied in hundreds of pages of statutes and thousands of pages of often interrelated regulations, any of which may become the subject of a legal challenge in any of several different courts." Shalala v. Ill. Council on Long Term Care, 529 U.S. 1, 13 (2000). Thus, to "assure[] the agency greater opportunity to apply, interpret, or revise policies, regulations, or statutes without possibly premature interference by different individual courts" — a significant threat in a program that processes more than a billion claims a year — Congress "demand[ed] the 'channeling' of virtually all legal attacks through the agency," even where channeling "comes at a price" of "occasional individual, delay-related hardship." Id.

This case is no different. Plaintiffs challenge three rules or regulations: (1) the two-midnights rule; (2) the physician order rule; and (3) the one-year statutory time limit for rebilling denied Part A claims under Part B. Each of these challenges is barred by Plaintiffs' failure to exhaust administrative remedies. Plaintiffs urge the Court to waive exhaustion as futile because, they say, these challenges raise "purely legal" issues and they do not expect to obtain relief from the administrative process. But the Medicare statute's exhaustion requirement is jurisdictional, not prudential, and it contains no exception for purely legal issues, even where agency adjudicators lack the power to grant the relief sought. And although the administrative scheme

does provide a route for providers to seek expedited judicial review of purely legal claims, 42 C.F.R. § 405.990, Plaintiffs have not followed that route here.

Regardless, the Court lacks the power to waive exhaustion as futile, because Plaintiffs have not satisfied the exhaustion requirement's nonwaivable "presentment" component. They cannot do so simply by sending a letter to the Secretary, as they claim, or by lodging administrative appeals just three days before filing a lawsuit, as they did here. Rather, Plaintiffs must give the Secretary an opportunity to actually render a decision on their claims; otherwise, presentment would be a pointless exercise.

In any event, Plaintiffs fail to demonstrate that exhaustion would be futile — that is, "clearly useless." In a related case brought by the lead Plaintiff here that also challenges the one-year statutory deadline for rebilling, Am. Hosp. Ass'n v. Burwell, No. 12-1770 (D.D.C.), the plaintiffs have acknowledged that their administrative appeals have met with some initial success, as several of their Medicare claims have, in fact, been paid — refuting the notion that exhaustion would be futile here. Moreover, Plaintiffs' appeals are not purely legal, but raise a number of fact-intensive issues, such as whether inpatient admission is "reasonable and necessary" for a particular patient; whether a physician's expectation about the length of a hospital stay is reasonable under the circumstances; and whether there is sufficient information in a medical record to determine that a physician intended to admit a patient. Thus, any initially denied claims that Plaintiffs appeal may not stand upon further administrative review, potentially mooting the need for judicial involvement — a practical reason to enforce the exhaustion requirement here.

Plaintiffs' challenge to the physician order rule is barred for an additional reason: it is unripe, in light of proposed changes to the rule's content and cited statutory basis. Plaintiffs' argument that the pending rulemaking cannot afford them relief, and thus cannot render their claim unripe, is belied by their own comments on the proposed rule, in which they ask the

Secretary to relieve them of the obligation to comply with the rule for all pending claims — the same relief they ask this Court to order.

Finally, Plaintiffs' challenge to the "application" of the one-year statutory time limit for rebilling denied Part A claims under Part B fails for an even more basic reason: lack of standing. No Plaintiff identifies any Part A claims denied by a Recovery Audit Contractor ("RAC"), or any rebilled claims to which the one-year time limit has actually been "applied." And Plaintiffs' contention that the Medicare statute's channeling requirement should not apply to this challenge because it would result in "no review at all" is meritless. Any unfavorable RAC determinations are administratively appealable, and the "no review at all" exception does not apply where review was available but not sought on time.

The Court should dismiss this case in its entirety for lack of jurisdiction.

ARGUMENT

I. THE COURT LACKS JURISDICTION OVER PLAINTIFFS' CHALLENGE TO THE TWO-MIDNIGHTS RULE BECAUSE PLAINTIFFS HAVE NOT EXHAUSTED THEIR ADMINISTRATIVE REMEDIES

Defendant's opening brief explained that Plaintiffs' challenge to the two-midnights rule is barred by 42 U.S.C. § 405(g)-(h), which make exhaustion of administrative remedies a jurisdictional prerequisite to suit. Mem. in Supp. of Def.'s Mot. to Dism. ("Def.'s Br.") 15-19; see also Ryan v. Bentsen, 12 F.3d 245, 247 (D.C. Cir. 1993) ("The Secretary's 'final decision' is a prerequisite to subject matter jurisdiction in the district court and consists of two components, a presentment requirement and an exhaustion requirement."). Plaintiffs do not contend that they have exhausted their administrative remedies but, rather, argue that "exhaustion should be excused as futile." Pls.' Opp'n 28. It should not.

A. The Court Lacks the Power to Deem the Exhaustion Requirement Waived Because Plaintiffs' Submission of Appeals Three Days Before Filing Suit Did Not Satisfy the Presentment Requirement

Plaintiffs' argument that they satisfied the non-waivable "presentment" component of 42 U.S.C. § 405(g) by submitting appeals to Medicare contractors a mere three days before filing suit (or by sending a letter to the Secretary just four days earlier) is incorrect. See Compl. ¶ 85 (claims appealed by Banner Health on April 11, 2014); Pls.' Opp'n 30 (letter sent on April 7, 2014).[2] To satisfy the presentment requirement, Plaintiffs must at least provide Medicare contractors (or the Secretary) an opportunity to actually make a decision on their claims before filing suit. See Mathews v. Eldridge, 424 U.S. 319, 328 (1976) ("The nonwaivable element is the requirement that a claim for benefits shall have been presented to the Secretary. Absent such a claim there can be no 'decision' of any type. And some decision by the Secretary is clearly required by the statute."); see also Heckler v. Ringer, 466 U.S. 602, 621-22 (1984) ("Because Ringer has not given the Secretary an opportunity to rule on a concrete claim for reimbursement, he has not satisfied the nonwaivable exhaustion requirement of § 405(g)" (emphasis added)). The cases from this Circuit that Plaintiffs cite are not to the contrary. In each, unlike here, the agency was given and utilized the opportunity to make a decision, albeit not a "final decision," before suit was filed.[3]

---

[2] Although Plaintiffs state that "[e]ach of the four Plaintiff hospitals has appealed claims denied for failure to comply with the two-midnights rule," Pls.' Opp'n 29, neither the allegations in the complaint nor the declarations attached to their opposition support that assertion with respect to Wake Forest Baptist Medical Center. Moreover, because the appeals by Einstein Healthcare Network and Mount Sinai Hospital were submitted after the complaint was filed, they are not relevant to the jurisdictional analysis. See Carr Decl. (Einstein) ¶ 12 (July 15, 2014); id. ¶ 16 (Apr. 16, 2014); Farber Decl. (Mt. Sinai) ¶ 10 (July 29, 2014); Dataflux v. Atlas Global Grp., 541 U.S. 567, 570 (2004) ("It has long been the case that 'the jurisdiction of the court depends on the state of things at the time the action is brought.'") (citation omitted).

[3] In Mathews v. Eldridge, the Supreme Court held that the plaintiff's claim had been "denied by the state agency." 424 U.S. at 329. In Ryan v. Bentsen, 12 F.3d 245 (D.C. Cir. 1993), the plaintiff "requested reconsideration and was rebuffed." Id. at 247 n.3 (emphasis added). In Action Alliance of Senior Citizens v. Johnson, 607 F. Supp. 2d 33, 37-39 (D.D.C. 2009), the plaintiffs not

Timing aside, Plaintiffs' letter to the Secretary is insufficient to satisfy the presentment requirement for an independent reason: it is not tied to any concrete claim for reimbursement. Plaintiffs rely heavily on Action Alliance, see Pls.' Opp'n 30, but in that case, the plaintiff organizations "presented HHS with factually detailed letters regarding discrete claims on behalf of individuals. In that way, the Action Alliance letters were closer to the 'concrete claim for reimbursement' that the Supreme Court has held is required for proper presentment." Am. Orthotic & Prosthetic Ass'n, Inc. v. Sebelius, — F. Supp. 2d —, No. 13-697, 2014 WL 3817124, at *5 (D.D.C. Aug. 4, 2014) (quoting Ringer, 466 U.S. at 622). Here, by contrast, while Plaintiffs' letter contains critiques of the regulations at issue, it identifies no disputed claim for payment. "Because [it is] not tied to any concrete claims," that letter is "insufficient to establish presentment." Am. Orthotic, 2014 WL 3817124, at *5; see also Three Lower Counties Cmty. Health Servs. v. HHS, 517 F. Supp. 2d 431, 435 (D.D.C. 2007), aff'd, 317 F. App'x 1 (D.C. Cir. 2009) (rejecting plaintiff's claim that it "satisfied the applicable agency review procedures by submitting a letter" to the agency).

B. The Court Should Not Deem Exhaustion Waived

The only basis for waiver that Plaintiffs offer is their assertion that exhaustion would be futile. They do not argue that exhaustion would cause them irreparable harm (it would not), or

---

only "sen[t] a letter to the agency," as Plaintiffs say, Pls.' Opp'n 29, but also waited for, and received, a response. 607 F. Supp. 2d at 38 ("Plaintiffs received a response from Beatrice M. Disman, Chair of the SSA's Medicare Planning and Implementation Task Force ("Chair") denying their requests."). In Tataranowicz v. Sullivan, 959 F.2d 268 (D.C. Cir. 1992), all named plaintiffs had not only requested but "been denied [skilled nursing facility] benefits." Id. at 272. As for the Eighth Circuit case upon which Plaintiffs also rely, Linquist v. Bowen, 813 F.2d 844, 887 (8th Cir. 1987), the D.C. Circuit has since "respectfully disagree[d]" with the liberal interpretation of the presentment requirement in that case. Action Alliance of Senior Citizens v. Leavitt, 483 F.3d 852, 858 (D.C. Cir. 2007). Finally, Plaintiffs cite Justice Stevens's dissent in Heckler v. Lopez, 464 U.S. 879 (1983), Pls.' Opp'n at 29, but there Justice Stevens said "the non-waivable exhaustion requirement is simply the requirement that the Secretary have made some sort of decision on a claim for benefits." Id. at 882 (emphasis added).

that their claim is collateral to one for benefits (it is not), or press any other theory in support of waiver. Even if the Court had the power to deem exhaustion waived here, it should not exercise that power for three reasons: (1) Plaintiffs have not demonstrated that exhaustion would be futile; (2) section 405(g) may not be waived here for futility alone; and (3) waiver is unwarranted.

1. Plaintiffs have not demonstrated that exhaustion would be futile

"In ordinary challenges to agency action, the exhaustion requirement 'may be waived only in the most exceptional circumstances.'" Am. Orthotic, 2014 WL 3817124, at *5 (quoting UDC Chairs Chapter v. Bd. of Trustees of Univ. of D.C., 56 F.3d 1469, 1475 (D.C. Cir. 1995)). A judicial finding of futility "require[s] the 'certainty of an adverse decision' or indications that pursuit of administrative remedies would be 'clearly useless.'" UDC Chairs, 56 F.3d at 1475 (citation omitted). "The mere 'probability of administrative denial of the relief requested does not excuse failure to pursue' administrative remedies." Id. (citation omitted).

Moreover, "in cases arising under the Medicare Act," such as this one, "the requirement for 'exceptional cases' and certainty [is] even more stringent because 'the bar of § 405(h) reaches beyond ordinary administrative law principles [such as] exhaustion of administrative remedies' and 'demands the channeling of virtually all legal attacks through the agency.'" Am. Orthotic, 2014 WL 3817124, at *5 (citation omitted); see also Tataranowicz, 959 F.2d at 274 (section 405(g)'s requirement of a "final decision" is "more than simply a codification of the judicially developed doctrine of exhaustion, and may not be dispensed with merely by a judicial conclusion of futility").[4] This is "consistent with Congress's intent to assure 'the agency greater opportunity

[4] For this reason, Plaintiffs' reliance on cases discussing the catch-all, prudential doctrine of exhaustion of administrative remedies that applies even in the absence of a statutory mandate is misplaced. See, e.g., Pls.' Opp'n at 32 (citing DL v. District of Columbia, 450 F. Supp. 2d 11, 17-18 (D.D.C. 2006)); id. at 33, 34 (citing Randolph-Sheppard Vendors of Am. v. Weinberger, 795 F.2d 90, 106 (D.C. Cir. 1986)). These cases do not address the question at hand: whether to deem waived the "final decision" requirement of § 405(g). See Triad of Jeffersonville I, LLC v. Leavitt,

to apply, interpret, or revise policies, regulations, or statutes without possibly premature interference by different individual courts.'" Am. Orthotic, 2014 WL 3817124, at *5 (citation omitted).

Here, although the American Hospital Association represents some 5,000 hospitals, Compl. ¶ 9, Plaintiffs fail to identify a single hospital that has exhausted the administrative remedies available at the agency level. (Of the five appeals that Plaintiffs lodged before the complaint was filed, one is pending at the first level of review, and four are pending at the second of four levels. Morgan Decl. (Banner) ¶¶ 11-13.) Instead, they assert that exhaustion would be futile because their appeals raise "purely legal" issues and they do not expect to receive relief from the administrative process. Pls.' Opp'n 31-34. But § 405(h) contains no exception for purely legal issues, "even if the agency cannot grant the relief sought." Three Lower Counties, 517 F. Supp. 2d at 435.[5] Regardless, as Defendant has explained, the central question in any such appeal — whether admission to the hospital for inpatient treatment is "reasonable and necessary" in a given case — may be heavily fact dependent, turning on the patient's "medical history and comorbidities, the severity of signs and symptoms, current medical needs, and the risk (probability) of an adverse event." 78 Fed. Reg. at 50,949-50; see Def.'s Br. 18. Indeed, Plaintiffs

---

563 F. Supp. 2d 1, 16 n.8 (D.D.C. 2008) (discussing distinction between traditional exhaustion cases and waiver of the "final decision" requirement of § 405(g)). In 42 U.S.C. § 405(g)-(h), Congress required exhaustion without exception. Although the Supreme Court and D.C. Circuit have held that courts may sometimes review an initial decision rather than wait for the "final decision" mentioned in the statute by treating the Secretary as having "waived" the latter requirement, e.g., Mathews v. Eldridge, 424 U.S. 319, 328 (1976), both have looked to their own past precedents applying § 405(g) in determining whether to recognize a constructive waiver, not the case law governing excuse of the prudential exhaustion requirement generally. See id. at 328; Tataranowicz, 959 F. 2d at 274-75.

[5] Notably, the administrative process provides a route for a provider to seek expedited judicial review of a "question of law" where "no material facts are in dispute" and the "Medicare Appeals Council does not have the authority to decide" the question, provided that the provider pursues an appeal to the ALJ level of review. 42 C.F.R. § 405.990; cf. Three Lower Counties, 517 F. Supp. 2d at 435 n.4. Plaintiffs have not taken advantage of that provision here.

themselves allege that "the question whether to admit a patient as an inpatient is fact-sensitive and a matter of judgment." Compl. ¶ 3.

Moreover, Plaintiffs' premature suggestion that exhaustion would be "clearly useless" is refuted by the history of litigation over the third of its challenges here — namely, to the "application" of the one-year statutory deadline for rebilling denied Part A claims under Part B. Compl. ¶¶ 102-09; see infra Part III at 17-25. That challenge is also the subject of an earlier lawsuit brought by the lead Plaintiff here. See Am. Hosp. Ass'n v. Burwell, No. 12-1770 (D.D.C.) (motion to dismiss for lack of jurisdiction pending). In that case, like this one, the central question in the appeals is a fact-intensive one: whether admission to the hospital for inpatient treatment is "reasonable and necessary" for a given patient.[6] And in that case, the plaintiffs have urged the court to waive exhaustion as futile for essentially the same reasons offered here. Yet they have acknowledged that their administrative appeals have met with some initial success, as several of their Medicare claims have, in fact, been paid. See Def.'s Reply to Pls.' Supp. Br. 3-5 [No. 12-1770, ECF No. 53]. This ongoing operation of the administrative process suggests that exhaustion is hardly futile here, and underscores the wisdom of Congress's decision to require exhaustion before suit may proceed in federal court, as required by 42 U.S.C. § 405(g).[7]

2. Section 405(g) may not be waived here for futility alone

Even if exhaustion were futile, this case does not present the sort of pure question of

[6] See, e.g., Compl. ¶ 56 ("RACs regularly have denied claims where they simply disagreed with the physician's judgment about the care the patient should have been expected to need to receive at the hospital. There is no reason to believe that will change now that physicians have to predict whether a beneficiary will need to be in the hospital for "two midnights," instead of 24 hours.").

[7] Indeed, in the earlier case, Judge Kollar-Kotelly requested supplemental briefing on the exhaustion issue, given the ongoing developments during the administrative process. Am. Hosp. Ass'n v. Burwell, No. 12-1770, ECF No. 50; see also Am. Orthotic, 2014 WL 3817124, at *6 ("Proving futility requires demonstration that defeat is certain, which the plaintiff cannot demonstrate if its members are succeeding in appeals before the agency.").

statutory or constitutional interpretation as to which the final decision requirement of § 405(g) may be waived for futility alone. For the contrary proposition, Plaintiffs point to Tataranowicz, which they say is the "leading case" on constructive waiver, Pls.' Opp'n 30, but is more like the high water mark.[8] In that case, the D.C. Circuit waived the "final decision" requirement of § 405(g) based on futility alone, dispatching from the usual requirements of futility plus a threat of irreparable harm and a constitutional claim collateral to a claim for benefits — requirements that Plaintiffs here do not even attempt to satisfy. Tataranowicz, 959 F.2d at 274. However, it did so only because it found that the case before it presented a pure question of statutory interpretation, such that neither the Court nor the agency would benefit from having the agency address the question in the first instance. See id. at 274-75 ("Here, the plaintiffs ask for a declaration that the Secretary's reading of § 101(b)(1)(C) was invalid and an injunction against his denying Medicare reimbursement for SNF patients who would be eligible once the allegedly erroneous interpretation is swept away. It is hard to see how any factual disputes might stand in the way of that relief, and the Secretary suggests none."); Pls.' Opp'n 31 ("[t]he Plaintiffs [in Tataranowicz] raised only a systemwide issue of law").

Plaintiffs make the conclusory assertion that their complaint asks the Court to decide only a simple legal question like the complaint in Tataranowicz. Pls.' Opp'n 31-32. But the complaint that Plaintiffs describe is not the one that they filed.

[8] Since Tataranowicz, courts in this Circuit have continued to evaluate constructive waiver under § 405(g) pursuant to a three-part test in which futility is just one prong. See, e.g., Triad of Jeffersonville, 563 F. Supp. 2d at 16 (three-part test for waiver: "(1) the issue raised is entirely collateral to a claim for payment; (2) plaintiffs show they would be irreparably injured were the exhaustion requirement enforced against them; and (3) exhaustion would be futile."); Hall v. Sebelius, 689 F. Supp. 2d 10, 18 (D.D.C. 2009) (same); Beattie v. Astrue, 845 F. Supp. 2d 184, 192 (D.D.C. 2012) (same). That approach is consistent with Ryan v. Bentsen, 12 F.3d 245 (D.C. Cir. 1993), which was decided more recently than Tataranowicz and applied a similarly stringent test for waiver. See id. at 247-48 (waiver if either "only issue . . . is one of the constitutionality of a provision of the Act" or "claimant's constitutional challenge is collateral to his claim of entitlement and he stands to suffer irreparable harm").

Questions of fact presented by the complaint. Plaintiffs strive to characterize the two-midnights rule as a redefinition of the term "inpatient." Pls.' Opp'n 32. That is mistaken. In fact, under longstanding Medicare policy, "a patient becomes an inpatient when formally admitted as such pursuant to a physician order." 78 Fed. Reg. at 50,941. The two-midnights rule addresses a separate question: whether, in a given case, inpatient treatment is "reasonable and necessary" and, thus, reimbursable under Medicare Part A. 42 U.S.C. § 1395y(a)(1)(A). As noted above, that question may be heavily fact dependent. The two-midnights rule creates a "presumption," but not a per se rule, that a hospital "stay surpassing 2 midnights . . . was appropriately provided as an inpatient service." 78 Fed. Reg. at 50,908; see Def.'s Br. 4-5.

Unlike the complaint Plaintiffs describe, theirs repeatedly emphasizes that the inpatient admission decision is a "fact-sensitive" one. See Compl. ¶ 2 ("CMS has recognized that the decision to admit a patient to the hospital is a fact-sensitive, 'complex medical judgment' that 'can be made only after the physician has considered a number of factors[.]'" (citation omitted)); id. ¶ 3 ("In short, the question whether to admit a patient as an inpatient is fact-sensitive and a matter of judgment."). Indeed, Plaintiffs illustrate this point with a lengthy example involving a hypothetical Medicare beneficiary. Compl. ¶ 31 ("[T]ake a 70-year-old Medicare beneficiary with high blood pressure and high cholesterol who comes the emergency room after experiencing dizziness and chest pain. A physician evaluates the patient and based on her medical history, the severity of her symptoms, the need for diagnostic tests, and the risk of an adverse event such as a heart attack, decides the patient should be admitted as an inpatient."). Plaintiffs' omission of comparable clinical details for their actual patients, cf. Morgan Decl. (Banner) ¶ 10; Carr Decl. (Einstein) ¶¶ 9, 13; Farber Decl. (Mount Sinai) ¶ 9, cannot mask that the inpatient admission decision is a "fact-sensitive" one. This Court is hardly in a position to evaluate whether inpatient admissions were "reasonable and necessary" without knowing any details about why those

patients were being treated in the first place.

Plaintiffs acknowledge that the two-midnights rule "sets forth only a presumption, not a per se rule," regarding when inpatient admission is appropriate, see Def.'s Br. 4-5, 18, yet assert that this "misses the point." Pls.' Opp'n 32-33. But it is Plaintiffs who miss the point. The presumption is just that — a presumption — and it is not outcome-determinative in any particular case.[9] Thus, the reimbursement decision ultimately turns on the underlying facts, including the reasonableness of the physician's expectation under the circumstances, not the presumption. Moreover, as a practical matter, Plaintiffs' pending appeals may well result in payment of their initially denied claims — a point that Plaintiffs do not dispute. See Pls.' Opp'n 32-33.

Record-review questions presented by complaint. Plaintiffs' complaint also indicates that the Secretary could cure any alleged defects in the two-midnights rule by offering a fuller explanation of why that rule is sensible, providing another practical reason to await a "final decision" of the Secretary. Although whether the rule is "arbitrary and capricious" is in some sense a "question of law," see Banner Health v. Sebelius, 797 F. Supp. 2d 97, 112 (D.D.C. 2011), it is quite different from the question of statutory interpretation at issue in Tataranowicz. 959 F.2d at 274. Indeed, Plaintiffs acknowledge that a further explanation of the basis for the rule could eliminate any alleged infirmities. See Compl. ¶ 50 ("[I]f CMS seeks to deviate from common meaning in this way, it is obliged to explain why that makes sense. It did not do so here."); id. ¶ 99 ("CMS made no attempt to explain why it adopted such a counterintuitive definition."); id. ¶ 100 ("At the very least, if [CMS] seeks to deviate from plain meaning and its historic interpretation, it must explain why it has chosen that course."). Thus, unlike the narrow question

[9] Hospital stays that do not span two midnights may still be reimbursed under Part A, depending on the circumstances — for example, when the physician's expectation that the patient would need a longer hospital stay was reasonable though ultimately incorrect, Fed. Reg. at 50,950, when the patient's condition improves, allowing earlier discharge, id. at 50,946, and in other "rare and unusual" circumstances, id.

of statutory interpretation at issue in Tataranowicz, the Court will best be positioned to review the question whether the agency's action was "arbitrary and capricious" only once it has before it some kind of an administrative record, which the Court will not have until Plaintiffs have exhausted their administrative remedies by obtaining a "final decision" from the Secretary. See Banner Health, 797 F. Supp. 2d at 112-13.

3. Waiver is unwarranted here

Even if exhaustion could be excused for futility alone, that step would be unwarranted here. The Plaintiffs in Tataranowicz were Medicare beneficiaries who were denied coverage to stay in a skilled nursing facility due to the Secretary's interpretation of a particular provision of the statute. 959 F.2d at 270. Here, by contrast, Plaintiffs are sophisticated hospitals and industry associations. They are well acquainted with the administrative process and how to properly pursue payments they believe they are owed. Indeed, some Plaintiffs are actively pursuing their administrative remedies even now, and day-to-day developments in that process could moot or otherwise affect the proceedings in this case.

Plaintiffs also suggest that the Court should waive exhaustion because, due to a backlog of appeals, new requests for ALJ review may not be assigned for up to 28 months,[10] and state that "some 800,000" appeals are affected by this backlog. Pls.' Opp'n 34-35. But Plaintiffs say nothing to suggest that exhaustion would be useless or cause irreparable harm. And Plaintiffs offer no authority suggesting that the threat of delay in the administrative process justifies excusing exhaustion; indeed, in Ringer, the Supreme Court squarely held to the contrary. 466 U.S. at 627 ("Congress must have felt that cases of individual hardship resulting from delays in

[10] See HHS, Office of Medicare Hearings & Appeals, Requests Submitted After April 1, 2013 — Deferred Assignment & Filing Alert for Requests and Additional Documentation, available at http://www.hhs.gov/omha/important_notice_regarding_adjudication_timeframes.html#requests (last visited Sept. 3, 2014).

the administrative process had to be balanced against the potential for overly casual or premature judicial intervention in an administrative system that processes literally millions of claims each year. If the balance is to be struck anew, the decision must come from Congress and not from this Court."); see also Illinois Council, 529 U.S. at 13 (the benefits of § 405(h) "come[] at a price, namely, individual, delay-related hardship").

That holding makes sense. The rule that Plaintiffs implicitly suggest — excusing exhaustion when the administrative queue is sufficiently long — would be unworkable. Anytime the administrative review process became swamped with claims — and in Medicare, a program that processes more than a billion claims per year, it is not difficult for that to happen — its burden would be passed on to the federal courts. This Court should not open the floodgates.

II. THE COURT LACKS JURISDICTION OVER PLAINTIFFS' CHALLENGE TO THE PHYSICIAN ORDER RULE

Defendant's opening brief explained that Plaintiffs' challenge to the physician order rule should be dismissed for any of three independent reasons: lack of standing, failure to exhaust administrative remedies, or lack of ripeness. Def.'s Br. 19-29. Although Plaintiffs now submit declarations identifying a handful of claims that have been denied on the basis of this rule, they identify none for which they have exhausted their administrative remedies. And their argument that the pending rulemaking cannot afford them relief, and thus cannot render their claim unripe, is belied by their own comments on the proposed rule, in which they request the same relief they seek from this Court.

A. Most Plaintiffs Lack Standing to Challenge the Physician Order Rule

Defendant initially argued that all Plaintiffs lack standing to challenge the physician order rule, principally because their complaint identified no Medicare claim denied on the basis of that rule. Def.'s Br. 20-21. Plaintiffs acknowledge that deficiency in a footnote, Pls.' Opp'n 29 n.11,

and submit declarations identifying five claims by Banner Health that were initially denied "in March and April 2014" for failure to comply with the rule. Morgan Decl. (Banner) ¶ 16.[11] In light of these facts, Defendant no longer presses her standing argument with respect to Banner Health for purposes of her motion to dismiss, but reserves the right to renew it at a later stage.

B. Plaintiffs Have Failed to Exhaust Their Administrative Remedies

In any event, Plaintiffs have not exhausted their administrative remedies with respect to the physician order rule. Plaintiffs' complaint identified just one claim potentially implicating this regulation: a claim that Mount Sinai Hospital expected to be denied for failure to meet the "technical requirements" of the physician order rule, but that had not actually been denied. Def.'s Br. 22 (citing Compl. ¶ 86). Both Plaintiffs' opposition and Mount Sinai's declaration are conspicuously silent about the status of that claim. See Pls.' Opp'n 35; cf. Farber Decl. (Mount Sinai) ¶¶ 8-10. Is it still pending? Was it denied? Or was it paid, despite Plaintiffs' expectation to the contrary? The Court is left to wonder. Regardless, Plaintiffs do not assert that Mount Sinai has appealed any claims denied on the basis of the physician order rule, let alone that they have exhausted the administrative process by obtaining a "final decision" of the Secretary.

1. The Court lacks the power to deem the exhaustion requirement waived because Plaintiffs have not satisfied the presentment requirement

Plaintiffs now assert, for the first time, that a different hospital, Banner Health, has appealed a single claim that was initially denied on the basis of the physician order rule, and argue that that appeal satisfies § 405(g)'s presentment component. Pls.' Opp'n 35; Morgan Decl.

[11] Plaintiffs also identify a sixth claim that was initially denied in February 2014 for failure to comply with the two-midnights rule, and appealed on April 16, 2014, in which the Medicare contractor requested, in May 2014, that the hospital also provide a physician order. Carr Decl. (Einstein) ¶¶ 15-17. Because the contractor's request for a physician order was made after the complaint in this case was filed, this claim is not relevant to the standing analysis. Moreover, because the initial denial was appealed after the complaint was filed, this claim is not relevant to the exhaustion analysis. See Dataflux, 541 U.S. at 570 (jurisdiction "depends on the state of things at the time the action is brought").

(Banner) ¶¶ 16-17. That argument is meritless. According to Banner's declaration, that appeal was filed on July 17, 2014 — long after the complaint was filed in this case — and is thus irrelevant to the jurisdictional analysis. Dataflux, 541 U.S. at 570 ("It has long been the case that 'the jurisdiction of the court depends on the state of things at the time the action is brought.'") (citation omitted). And Plaintiffs' contention that their letter to the Secretary independently satisfies the presentment requirement fails for the reasons already discussed. See supra at 4-5.

2. The Court should not deem exhaustion waived

Regardless, the Court should not deem exhaustion waived with respect to the physician order requirement for the reasons already set forth in the context of the two-midnights rule. See supra Part I.B at 5-13. To avoid repetition, Defendant addresses those points only briefly here.

Plaintiffs again argue that exhaustion would be futile because their appeals raise "purely legal" issues and they do not expect to receive relief from the administrative process. Pls.' Opp'n 35-36. But, again, the complaint they describe is not the complaint they filed.

Questions of fact presented by the complaint. Plaintiffs acknowledge that preexisting regulations setting forth the Conditions of Participation in the Medicare program already required that each inpatient's record include a physician order of admission, Def.'s Br. 20-21, but say they fear being penalized for "one-off technical error[s]" in their recordkeeping, Pls.' Opp'n 37. On that score, they allege that the rule requires the order to "adhere to specific requirements regarding the practitioner who signs it" and to "contain fairly specific language related to the admission decision," such as a "recommendation to admit 'to inpatient,' 'as an inpatient,' 'for inpatient services,' or similar language." Compl. ¶ 59. But the question whether the physician order in a particular case contains sufficiently specific language is a factual one, not a purely legal one, and it is one that would benefit from record development and agency review.

Plaintiffs grudgingly acknowledge that the regulation does not establish a per se rule, but

argue that the point is irrelevant. Pls.' Opp'n 36. That is mistaken. Medicare contractors have "discretion to determine" that the requirement is "constructively satisfie[d]" if "the intent, decision, and recommendation of the physician . . . to admit the beneficiary can clearly be derived from the medical record" — even where "the order to admit is missing," "illegible," or "incomplete." 78 Fed. Reg. at 50,942. Thus, in a given case, application of the rule may be fact dependent, and technical noncompliance with the rule may be excused where the physician's intent is clear. As a practical matter, that means that any unfavorable initial determinations that Plaintiffs appeal may not stand upon further administrative review, allowing the agency to correct any errors of its contractors, and potentially mooting the need for judicial involvement.

Record-review questions presented by complaint. As with the two-midnights rule, Plaintiffs' complaint acknowledges that the Secretary could cure alleged deficiencies in the physician order rule by offering a further explanation of why that rule is sensible. See id. ¶ 121 ("CMS failed to provide any justification for creating the physician order rule now, despite sound reasons not to implement this new requirement."); id. ¶ 122 ("CMS's failure to provide any justification for this new requirement renders the physician order rule arbitrary and capricious and thus invalid under the APA."); id. ¶ 73 ("In any event, CMS has not provided any justification for creating such a requirement now."). This provides another practical reason that any judicial review should await a "final decision" of the Secretary.

C. Plaintiffs' Challenge to the Physician Order Rule Is Not Ripe

Plaintiffs contend that Defendant's ripeness argument is "inexplicable" because, they say, the pending rulemaking cannot possibly provide them with relief. Pls.' Opp'n 38-39. That is incorrect. To be sure, the proposed rule would take effect in January 2015 and does not state that it would apply retroactively. But Plaintiffs' suggestion that the final rule could not apply retroactively, and thus provide relief for pending claims, is disingenuous. Pls.' Opp'n 38. The

Medicare statute permits the Secretary to apply a regulatory change retroactively where "necessary to comply with statutory requirements" or where failure to do so "would be contrary to the public interest." 42 U.S.C. § 1395hh(e)(1)(A). And Plaintiffs have specifically asked the Secretary to invoke that power here. In their comments on the proposed rule, Plaintiffs "urge CMS to require its [contractors] to review and reverse all claims denials for services provided from Oct. 1, 2013 through Dec. 31, 2014 that are based on a failure to comply with the physician certification requirement." Letter from Linda E. Fishman to Marilyn B. Tavenner, at 13 (Aug. 27, 2014) (emphasis deleted) (Ex. A). Thus, Plaintiffs' own words make clear that "the ongoing agency rulemaking ha[s] the potential to obviate the plaintiffs' complaint," Pls.' Opp'n 39, which Plaintiffs themselves explain is the "fundamental" reason to defer review for lack of ripeness, id.[12]

At bottom, in the pending rulemaking, Plaintiffs have asked the Secretary to relieve them of the obligation to comply with the physician order rule for all pending claims — the same relief they ask this Court to order. Thus, if the Court does not decide this dispute now, it may never need to.

III. THE COURT LACKS JURISDICTION OVER PLAINTIFFS' CHALLENGE TO THE ONE-YEAR FILING DEADLINE FOR REBILLING DENIED PART A CLAIMS UNDER PART B

Defendant's opening brief explained that Plaintiffs' challenge to the "application" of the one-year statutory time limit to rebill denied Part A claims under Part B should be dismissed for any of three independent reasons: lack of standing, failure to exhaust, or because, under the unique

[12] Moreover, Plaintiffs entirely ignore another practical reason to defer review: if the proposed rule takes effect, the central legal question that Plaintiffs have put before the Court — whether the physician order rule is consistent with 42 U.S.C. § 1395f(a)(3) — will be moot, because the rule will no longer rely on that authority. Def.'s Br. 26. Plaintiffs also offer no response to the argument that deferring review would impose no hardship on them. The Court should therefore treat both points as conceded. See Johnson v. Williams, 699 F. Supp. 2d 159, 169-170 (D.D.C. 2010) (Walton, J.) ("'[W]hen a plaintiff files a response to a motion to dismiss but fails to address certain arguments made by the defendant, the court may treat those arguments as conceded, even when the result is dismissal of the entire case.'") (citation omitted).

review provisions of the Medicare statute, the Court lacks jurisdiction to review the discretionary claims processing decisions that Plaintiffs challenge. Def.'s Br. 29-36. Plaintiffs' opposition casts no doubt on any of these conclusions.

A. Plaintiffs Lack Standing to Challenge the One-Year Time Limit

The premise of this claim is that the Secretary has supposedly implemented a policy under which RACs may determine that inpatient admission was not "reasonable and necessary," and that payment under Part A was therefore inappropriate, after the one-year statutory deadline to rebill claims under Part B has elapsed. But Plaintiffs fail to meet their own premise. No Plaintiff alleges that it received an unfavorable RAC determination. No Plaintiff alleges that the one-year statutory deadline has actually been applied to it; indeed, for the claims identified in the complaint, that deadline has not even elapsed, see Compl. ¶¶ 84-85. Accordingly, Plaintiffs demonstrate no injury sufficient to support standing to challenge the "application" of the one-year statutory time limit to rebill denied Part A claims under Part B. Def.'s Br. 29-30.

In contrast to their other challenges in this case, Plaintiffs make no attempt to cure these defects in their declarations.[13] Indeed, Plaintiffs concede that they have not yet been harmed, and instead argue that they face a threat of future harm that is sufficient to establish a cognizable injury. Pls.' Opp'n 40-41. As they put it, they will soon face a "Hobson's choice: to relinquish an appeal they think meritorious or forgo the Part B reimbursement to which they [believe they] are entitled." Id. As an initial matter, that is an entirely different claim than the one raised in the complaint. There, Plaintiffs complain that it is arbitrary and capricious to apply the one-year time

[13] But they clearly know how. In the earlier challenge brought by the lead Plaintiff here to the same alleged policy, Am. Hosp. Ass'n v. Burwell, No. 12-1770 (D.D.C.) (motion to dismiss for lack of jurisdiction pending), the plaintiffs identified particular claims that had been denied by RACs and that they had attempted to rebill, and thus Defendant did not challenge their standing on this basis. Here, however, Plaintiffs have declined even to attempt to satisfy this basic jurisdictional requirement.

limit to rebilled claims where RACs issue an adverse determination after that deadline has elapsed. See, e.g., Compl. ¶ 105 ("CMS . . . knows full well that application of the one-year time limit means hospitals will almost never be paid, because contractors like the RACs almost never even begin reviewing claims until more than a year has elapsed."). Here, the "appeal" Plaintiffs say they may "relinquish" is not an appeal from an adverse RAC determination, but from an initial determination by a Medicare Administrative Contractor. Such determinations are generally issued within 30 days of a claim's submission, see Def.'s Br. 10, leaving Plaintiffs with ample time to rebill within the one-year time limit, if they so choose.

Regardless, this supposed "Hobson's choice" is not a cognizable injury. At bottom, it is nothing more than an assertion of harm from the need to file a claim, whether under Part A or Part B, within a year of the date of service, assuming Medicare payment is sought. But to support standing, an injury must be not only "concrete and particularized, and . . . actual or imminent," but also an "invasion of a legally protected interest." Lujan v. Defenders of Wildlife, 504 U.S. 555, 560 (1992) (citations and internal quotation marks omitted); see Salt Inst. v. Leavitt, 440 F.3d 156, 158-59 (4th Cir. 2006) (distinguishing between the two inquiries). Here, Plaintiffs do not have a freestanding entitlement to reimbursement that is being cut off by the application of the one-year time limit. On the contrary, to the extent they have a legally protected interest, its source is the Medicare statute, which conditions any entitlement to payment on the submission of a claim within "1 calendar year after the date of service." Def.'s Br. 6-7 (citing 42 U.S.C. §§ 1395f(a)(1), 1395n(a)(1)). It grants no legal rights beyond that, and thus cannot give rise to a cognizable injury. See Salt Inst., 440 F.3d at 159 (where "statute upon which appellants rely does not grant the rights that appellants claim were invaded, appellants cannot establish an injury in fact").

Even if this injury were cognizable, it is not sufficiently certain to support standing. "An allegation of future injury may suffice if the threatened injury is 'certainly impending,'" or, in

some circumstances, where "there is a 'substantial risk' that the harm will occur." Susan B. Anthony List v. Driehaus, 134 S. Ct. 2334, 2341 (2014) (citation omitted). Plaintiffs cannot meet that standard, however it is formulated. They identify no particular Medicare claim that they believe is likely to be denied by a RAC. Nor could they, for no particular claim would fit the bill. More than one billion Medicare claims are filed each year. See Def.'s Br. 10. But in fiscal year 2012 — the most recent year for which statistics are available — only 518,154 of those were Part A claims in which RACs issued overpayment determinations.[14] That is a tiny fraction: just five hundredths of one percent. Plaintiffs' suggestion that, surely, some claim, someday, will eventually fall into this category is pure speculation.

Moreover, Plaintiffs cannot establish that their alleged injuries are either caused by the so-called "policy" they challenge, or would be redressed by setting it aside. See Lujan, 504 U.S. at 560. On the contrary, if they are injured, it is not by any policy that the Secretary adopted, but rather by the preexisting statutory and regulatory requirements governing the timely submission of claims. The "policy" at issue, Plaintiffs contend, is the Secretary's decision "to apply the [statutory] one-year time limit in situations where (i) a [RAC] has clawed back a Part A payment on the basis that treatment should have been provided on an outpatient basis and (ii) the hospital has sought to rebill for Part B payment." Compl. ¶ 104. Under this approach, the argument goes, because many "RAC Part A denials are issued more than a year after the date the service was provided," "hospitals could almost never rebill under Part B after a Part A denial" because "[t]heir Part B claims would be untimely." Id. ¶ 51.

But nothing in the final rule affected Plaintiffs' ability to rebill untimely claims. That rule

[14] CMS, Recovery Auditing in Medicare and Medicaid for Fiscal Year 2012, at 34 (App'x E), available at http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Recovery-Audit-Program/Downloads/Report-To-Congress-Recovery-Auditing-in-Medicare-and-Medicaid-for-Fiscal-Year-2012_013114.pdf.

did not say that hospitals "cannot rebill"; rather, it announced a limited category of claims that hospitals could rebill. It had no effect on Plaintiffs' (hypothetical) expired claims, as to which it left the status quo in place. A comparison of prior law with the final rule makes this clear:

- Prior law. "[U]nder Medicare's longstanding policy," where a Part A claim was denied because inpatient treatment was not reasonable and necessary, a provider could rebill "for only a limited list of ancillary medical and other services," provided that it did so "within the usual timely filing requirements," 78 Fed. Reg. 16,633-34 — that is, within "1 calendar year after the date of service," 42 U.S.C. § 1395n(a)(1).

- Final rule. The final rule permits more generous rebilling under Part B of improper Part A claims (generally, "payment of all hospital services that were furnished and would have been reasonable and necessary if the beneficiary had been treated as a hospital outpatient") provided that "the statutorily required timeframe for submitting claims is not expired," 78 Fed. Reg. at 50,909 — that is, within "1 calendar year after the date of service," 42 U.S.C. § 1395n(a)(1). The final rule also provides that Part B claims will not be denied as untimely if not rebilled within a year of service, so long as the original Part A claim was itself timely and was denied either:
  - while an interim ruling, Ruling 1455-R, was in effect (3/18/2013 to 10/1/2013); or
  - before the interim ruling took effect, if an appeal was pending or there was still time to appeal;
  - or after the interim ruling expired, if the patient was admitted before that date. 78 Fed. Reg. 50,924.

Thus, the final rule set forth a limited category of claims that hospitals could rebill despite the ordinary one-year time limit on Part B claims. But as to Plaintiffs' (hypothetical) Part A claims that were denied but not timely appealed, the final rule had no effect. Under both the final rule and prior law, Plaintiffs could rebill denied Part A claims under Part B only within the one-year time frame set forth in the Medicare statute itself. 42 U.S.C. § 1395n(a)(1).

By the same token, setting aside the final rule could not remedy Plaintiffs' alleged injuries. If the rule were invalidated, Plaintiffs would be no more able to rebill any expired claims than they are today. Rather, prior law would again govern, meaning that Plaintiffs could rebill only "within the usual timely filing requirements," 78 Fed. Reg. 16,633-34 — that is, within "1 calendar year after the date of service," 42 U.S.C. § 1395n(a)(1).

B. Plaintiffs Have Failed to Exhaust Their Administrative Remedies

Regardless, Plaintiffs have failed even to begin, let alone to exhaust, their administrative remedies with respect to any unfavorable RAC determination, as Defendant has explained. Def.'s Br. 31. Plaintiffs' assertion that their letter to the Secretary satisfies the presentment requirement should be rejected for reasons already discussed, see supra at 4-5, as should Plaintiffs' argument that exhaustion should be excused as futile, see supra at 5-13.

C. The Court Lacks Jurisdiction to Review the Discretionary Decisions Whether To Reopen Part A Payment Determinations or To Extend the Statutory Deadline for Untimely Part B Claims

In her opening brief, Defendant understood Plaintiffs to argue that the Secretary has the discretion to reopen denied Part A claims, Compl. ¶ 107, or to extend the deadline for untimely Part B claims, id. ¶ 108, and that her "refusal" to do so was arbitrary and capricious, id. ¶¶ 107-08. See Def.'s Br. 31-32. Plaintiffs disagree with that reading of their complaint, and assert that they are not challenging "claims processing decisions" in individual cases, but rather a systemwide "rule of general applicability." Pls.' Opp'n 42. Yet they continue to argue, in the alternative, that the Court does have jurisdiction over these individual claims processing decisions. Id. at 42-44. Plaintiffs would understandably like the Court to conceptualize the "agency action" at issue however it must in order to find jurisdiction. But Defendant and the Court cannot be so flexible. Under the Medicare statute's unique channeling provisions, the precise agency action at issue governs the scope of the Court's review.

Plaintiffs' preferred approach — to frame this claim as a systemwide "rule of general applicability" — does nothing to satisfy their burden to demonstrate that the Court has jurisdiction under § 405(g). The Medicare statute does not give the Court jurisdiction to review a policy of "general applicability," or even a substantive rule, in the abstract. It provides for review of only a particular "final decision of the [Secretary] . . . made after a hearing." 42 U.S.C. § 405(g)-(h); see

also Fund for Animals, Inc. v. BLM, 460 F.3d 13, 18 (D.C. Cir. 2006) ("The federal courts are not authorized to review agency policy choices in the abstract."). For that reason, courts have long rejected attempts to avoid the strictures of § 405(h) by framing an action as a general legal challenge. See Weinberger v. Salfi, 422 U.S. 749, 762 (1975) ("[Section 405(h)]'s reach is not limited to decisions of the Secretary on issues of law or fact. Rather, it extends to any 'action' seeking 'to recovery on any (Social Security) claim[.]'"); see also Ill. Council, 529 U.S. at 14 ("Salfi and Ringer . . . foreclose distinctions based upon . . . the 'general legal' versus the 'fact-specific' nature of the challenge[.]").

1. The Court lacks jurisdiction to review a refusal to reopen

Plaintiffs' first alternative argument — that, where a claim would be untimely when rebilled under Part B, the Secretary has the discretion to instead reopen and adjust the denied Part A claim, and her "refusal" to do so is arbitrary and capricious, Compl. ¶ 107 — gets them no further. Plaintiffs do not dispute that the Court lacks jurisdiction to review a refusal to reopen, see Def.'s Br. 33-35, or that a claim cannot be "adjusted" or "revised" without first being reopened, see id. at 32 n.12, and thus concede both points. See Johnson, 699 F. Supp. 2d at 159. Instead, they seem to backtrack, arguing that reopening the denied Part A claim is not necessary after all, because the Part B claim should be treated as "new" and "separate." Pls.' Opp'n 43. But Plaintiffs do not explain how that solves the (hypothetical) timeliness problem, which was presumably the reason Plaintiffs proposed reopening in the first place.

2. The Court lacks jurisdiction to review a refusal to extend the one-year timely filing requirement

Plaintiffs' second alternative argument — that the Secretary has the discretion to extend the deadline for untimely Part B claims, and her "refusal" to do so was arbitrary and capricious, Compl. ¶ 108 — also fails. Defendant's opening brief established that the reasoning of Palomar

Medical Centrer v. Sebelius, 693 F.3d 1151 (9th Cir. 2012), compels the conclusion that the Court lacks jurisdiction to review the claims processing decision whether to extend the one-year statutory filing period. Def.'s Br. 35-36. Although Plaintiffs halfheartedly attempt to distinguish Palomar, arguing that it "applies only to reopenings," Pls.' Opp'n 43, its reasoning is not so limited, and the Court should follow it here. See Def.'s Br. 33-36.

3. The Court lacks jurisdiction under 28 U.S.C. § 1331

Finally, Plaintiffs make a last-ditch request for leave to amend their complaint to invoke the general federal question statute, 28 U.S.C. § 1331, as an alternative basis for jurisdiction. Pls.' Opp'n 44-45. If the Court does not dismiss Count II on other grounds, it should deny Plaintiffs' request as futile.

As Defendant has explained, § 405(g) provides for judicial review of certain claims arising under the Medicare statute, specifically, those challenging the "final decision of the [Secretary] . . . made after a hearing." 42 U.S.C. § 405(g). Section 405(h) separately forbids the Court from exercising general federal question jurisdiction over claims "arising under" the Medicare statute. 42 U.S.C. § 405(h) ("No action against the United States, the [Secretary] or any officer or employee thereof shall be brought under section 1331 or 1346 of Title 28 to recover on any claim arising under this subchapter."). See Def.'s Br. 15-16, 32.

Plaintiffs' attempt to invoke the exception to this rule recognized in Illinois Council is misplaced. In that case, the Supreme Court considered whether a particular claim was one "arising under" the Medicare statute such that the § 405(h) bar would apply. 529 U.S. at 10. It concluded that jurisdiction was precluded by that provision, id. at 25, but explained that the § 405(h) bar would be interpreted not to apply where its application would mean "no review at all," id. at 19. Here, Plaintiffs claim that the "no review at all" exception applies, notwithstanding their admission that this case, in which Plaintiffs ultimately seek payment of their Medicare

claims, arises under the Medicare statute. Compl. ¶ 20. Their rationale for this dubious assertion is that, if Defendant is correct that neither a decision denying a request for reopening nor a decision refusing to extend the one-year time-limit can become a "final decision of the [Secretary] . . . made after a hearing," because neither is an "initial determination" that can be administratively appealed, then applying § 405(h) would mean "no review at all." Pls.' Opp'n 45.

But here, Plaintiffs assuredly do have the opportunity to seek judicial review. As Defendant has explained, any provider who disagrees with a RAC determination on a claim for payment under Part A has the right to appeal that determination administratively, and ultimately to district court. Def.'s Br. 8, 10-11. Thus, application of § 405(h) in a case like this would simply require that, in order to obtain judicial review, a claimant follow the procedures — including timing limitations on seeking administrative and judicial review — that Congress and the Secretary have set forth. See 42 U.S.C. § 1395ff(b)(1)(D)(i); 42 C.F.R. § 405.928(b)(2). The "no review at all" exception cannot be invoked where a claimant is simply out of time in pursuing a claim for which administrative review was available but not sought.

To be sure, a contractor's decision whether to reopen a claim or to extend the one-year statutory time limit would not be subject to judicial review, but even Plaintiffs do not argue that Illinois Council mandates that such discretionary claim processing decisions be reviewable. Such a broad reading of the limited exception articulated in that case could not be reconciled with the Supreme Court's decision in Your Home Visiting Nurse Services, Inc. v. Shalala, 525 U.S. 449 (1998), which held that decisions whether to reopen hospital cost report determinations are immune from judicial review altogether. See id. at 456.

CONCLUSION

For the foregoing reasons, in addition to those set forth in Defendant's opening brief, the Court should grant Defendant's motion to dismiss and dismiss this case in its entirety.

Dated: September 4, 2014

Respectfully submitted,

STUART F. DELERY
Assistant Attorney General

SHEILA M. LIEBER
Deputy Director

/s/ *Eric Beckenhauer*
ERIC B. BECKENHAUER
Trial Attorney
U.S. Department of Justice
Civil Division, Federal Programs Branch
20 Massachusetts Ave. NW
Washington, DC 20530
Tel: (202) 514-3338
Fax: (202) 616-8470
E-mail: Eric.Beckenhauer@usdoj.gov

Counsel for Defendant

CERTIFICATE OF SERVICE

I hereby certify that on September 4, 2014, I filed the foregoing document with the Clerk of Court via the CM/ECF system, causing it to be served electronically on Plaintiffs' counsel of record.

/s/ *Eric Beckenhauer*
ERIC B. BECKENHAUER