IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

THE AMERICAN HOSPITAL ASSOCIATION, *et al.*,

Plaintiffs,

v.

KATHLEEN SEBELIUS, in her official capacity as Secretary of Health and Human Services,

Defendant.

Civil Action No. 12-cv-01770-CKK

DEFENDANT'S REPLY IN SUPPORT OF HER MOTION TO DISMISS AND OPPOSITION TO HEALTHCARE ASSOCIATION OF NEW YORK'S AMICUS BRIEF

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PRELIMINARY STATEMENT

Congress has charged the Secretary with the administration of the massive Medicare program and, recognizing the billion-plus claims filed each year, has specifically authorized her to contract with outside entities (Medicare Administrative Contractors) to perform certain claims processing functions. The Secretary and her contractors have been busy indeed. Since Plaintiffs filed their Complaint and the Government moved to dismiss, Plaintiffs report, the contractors have in some cases processed and paid—paid!—the claims that Plaintiffs' Complaint projected would be denied. Compare Pls.' Opp. to Defs.' Mot. to Dismiss 15 n.6, ECF No. 32 ("Pls.' Opp.") ("Several amended bills in fact have been paid . . . by the Medicare contractors.") with, e.g., Am. Compl. ¶ 110, ECF No. 26 ("Compl.") ("[o]n information and belief, the CMS contractor will deny the claim"). The Secretary, meanwhile, is engaged in a rulemaking on the subject matter of this case. Opening Mem. 20–24, ECF No. 31-1 (citing Medicare Program: Part B Inpatient Billing in Hospitals, 78 Fed. Reg. 16,632, 16,636 (Mar. 18, 2013), Exhibit B to Opening Mem., ECF No. 31-4). The window for comments closed on May 17, 2013. Id. at 16,632.

The Court has a part to play in the administration of Medicare, too, but it is limited to the recurring judicial role: resolution of cases or controversies that the Congress has empowered the Court to resolve. This is not one of them.

There is not a fixed controversy here. Plaintiffs' dispute with the Secretary is evolving day by day, in part due to Plaintiffs' active pursuit of administrative remedies and in part due to the Secretary's pending rulemaking. For these two straightforward reasons, Defendant's opening memorandum explained, the Court should dismiss for failure to exhaust and for lack of ripeness. Opening Mem. at 17–20 (exhaustion); 20–24 (ripeness).

Plaintiffs' objections to these first two bases for dismissal are non-starters. Plaintiffs say that the Court should deem the exhaustion requirement of 42 U.S.C. § 405(g)-(h) waived because exhaustion would be futile, Pls.' Opp. 20–25, but as just mentioned attach to their opposition declarations stating that, just recently, the contractors have repeatedly granted (not denied) the requests Plaintiffs submitted only two days before (or in some cases, after) filing the Amended Complaint. See Decl. of Jill Robinson ¶ 17, ECF No. 32-2 ("On April 16, 2013, I requested Part B payment . . . [o]n June 20, 2013, th[e] claim was paid[.]"); Decl. of Lorelie Lauer ¶ 14, ECF No. 32-3 ("request has been designated for payment"); Decl. of Le Anne Trachok ¶ 11-12, ECF No. 32-5 ("on June 13, 2013, [Plaintiff] again submitted the request for Part B payment . . . [a]s of June 26, 2013, [the contractor] has designated these services for payment"). Plaintiffs' surprise at this result and expectation it will not last, Robinson Decl. ¶ 17; Lauer Decl. ¶ 17; Trachok Decl. ¶ 12, does not render futile their so-far successful efforts to obtain relief through the administrative process. Furthermore, even if pursuit of the administrative process would be futile, it would not warrant waiver here. Among other reasons, giving the agency an opportunity to make a decision would at a minimum generate an administrative record that the Court could use in weighing Plaintiffs' allegations that the unfavorable decisions they anticipate from their contractors would be "arbitrary and capricious." Compl. ¶¶ 153, 155, 166.

An amicus, the Healthcare Association of New York State ("HANYS"), also weighs in against requiring exhaustion. ECF No. 33-1 ("HANYS Brief"). But its discussion is focused exclusively on the operation of the administrative process for those hospitals that do file timely appeals. The Plaintiffs in this case did not do that. HANYS's submissions demonstrate only that administration of the Medicare payment appeals process is a gargantuan task even when hospitals play by the rules, and that many hospitals can and do obtain relief through the

administrative process by filing timely appeals. And while the amicus laments how long some of its members must wait to obtain a hearing, id. at 7–11, it offers no case law or other authority suggesting that the possibility of delay in obtaining relief through the administrative process can justify skipping that process altogether. Cf. Telecomm. Research & Action Center v. FCC, 750 F.2d 70 (D.C. Cir. 1984) (addressing standard for claim of unreasonable delay by agency). In fact, that very position has been rejected by the Supreme Court. See Heckler v. Ringer, 466 U.S. 602, 627 (1984). Wisely so, the rule that HANYS implicitly proposes would allow the flood of cases pending in the administrative process to wash into federal court, without even the benefit of an administrative decision to facilitate judicial review.

As for ripeness, Plaintiffs say the Secretary lacks the power to act retroactively, and so to moot this case in the pending rulemaking, Pls.' Opp. 25–26, but among other problems Plaintiffs get the law wrong. They rely on a 1988 Supreme Court case that has been abrogated in relevant part by a 2003 amendment to the Medicare statute in which Congress explicitly empowered the Secretary to act retroactively. Compare Bowen v. Georgetown Univ. Hosp., 488 U.S. 204, 213 (1988) ("The statutory provisions establishing the Secretary's general rulemaking power contain no express authorization of retroactive rulemaking."); with 42 U.S.C. § 1395hh(e)(1)(A)(ii) (allowing for retroactive application of rule upon Secretary's determination that "failure to apply the change retroactively would be contrary to the public interest").

Exhaustion and ripeness are not the only bases for dismissal. Even if this dispute matures into one of the three forms Plaintiffs now suggest it can take—either a dispute about the Secretary's claims processing policy in the abstract, Pls.' Opp. 30–32; a dispute about refusals to adjust (and reopen) Plaintiffs' adverse payment determinations, Pls.' Opp. 32–37; or a dispute about denials of Plaintiffs' "new" Part B payment claims, Pls.' Opp. 37–39—the Court still

would not have jurisdiction. As to the first frame, Congress has directed the Court to review "final decision[s] of the [Secretary] . . . made after a hearing," 42 U.S.C. § 405(g), not abstract policies. Id. § 405(h) (no federal question jurisdiction over cases "arising under" Medicare statute). As to the second and third frames, the discretionary procedural decisions refusing to revive their claims that Plaintiffs anticipate would simply not be "final decision[s]" reviewable under § 405(g), so framing Plaintiffs' claims that way does not re-open to Plaintiffs the avenue to judicial review that closed when they failed to file timely appeals. Repose is stubborn.

Plaintiffs are cognizant that the Court may conclude (as it should) that the bases for jurisdiction Plaintiffs offered in the Complaint are unavailing (indeed, they concede that the Court lacks mandamus jurisdiction by not arguing to the contrary), so in their Opposition Plaintiffs make a last-ditch request for leave to amend their Complaint to seek jurisdiction under an additional provision, 28 U.S.C. § 1331, as to the decisions they anticipate contractors will make denying their "new" Part B claims. Pls.' Opp. at 37 n.9. Section 405(h) of 42 U.S.C. by its terms prohibits federal question jurisdiction under 28 U.S.C. 1331 over actions "arising under" the Medicare statute, and Plaintiffs concede that this is such an action. Compl. ¶ 21. But Plaintiffs argue that, understood as a challenge to the rejection of their "new" Part B claims, this action is subject to the rule against interpreting § 405(h) to apply where its application would mean "no review at all" articulated in Shalala v. Illinois Council on Long Term Care, Inc., 529 U.S. 1 (2000). Pls.' Opp. 19. If the Court does not dismiss on other grounds, Plaintiffs' request for leave to amend should be denied as futile. Dismissal would not mean "no review at all." Plaintiffs could have obtained review of the adverse RAC payment determinations with which they ultimately take issue, but forfeited that right by not filing timely appeals. Illinois Council did not a mulligan make.

For these reasons, discussed below and in Defendants' opening memorandum, Defendants respectfully request the Court dismiss Counts I–V of Plaintiffs' Complaint pursuant to Federal Rule 12(b)(1). Furthermore, Defendants also respectfully request that the Court dismiss Counts IV and V for failure to state a claim upon which relief can be granted, and that the Court dismiss Count VI for lack of subject matter jurisdiction, for reasons described in Defendants' opening memorandum and elaborated upon below.

ARGUMENT

I. The Court Should Dismiss Counts I, II, III, IV, and V of Plaintiffs' Complaint for Lack of Subject Matter Jurisdiction Pursuant to Federal Rule 12(b)(1)

A. Plaintiffs' Failure to Exhaust Bars This Case

Defendant's opening memorandum explained that Counts I–V of Plaintiffs' Complaint are barred by 42 U.S.C. § 405(g)-(h), which at a minimum make exhaustion of administrative remedies a jurisdictional prerequisite to suit. Opening Mem. 18, 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 argue that they have exhausted their administrative remedies but instead argue that, because in their view exhaustion "would be futile," "[t]his Court should excuse plaintiffs from meeting the exhaustion requirement." Pls.' Opp. 24. It should not.

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

The Court lacks the power to grant Plaintiffs' request for waiver because Plaintiffs' claim that they satisfied the non-waivable "presentment" component of 42 U.S.C. § 405(g) by submitting claims to their contractors (and sending a letter to the Secretary) a mere two days

before filing suit, see Compl. ¶ 67 (April 17, 2013), ¶ 109 (same), ¶ 77 (same); ¶ 90 (same), or even days after, id. ¶ 124 (Dignity Health was "in the process of submitting" claim when Complaint was filed), is incorrect. In order to satisfy the presentment requirement, Plaintiffs would have had to at a minimum provide the contractors (or the Secretary) an opportunity to make a decision on their claims before filing suit.[1] 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.[2]

[1] Plaintiffs do not describe the actual contents of their submissions to the contractors, so it is not possible to determine whether those submissions actually raise the claims that Plaintiffs wish to press here. That is another reason that Plaintiffs have failed to meet their burden to show that the Court has subject matter jurisdiction.

[2] In Mathews v. Eldridge, 424 U.S. at 329, the Supreme Court held that the plaintiff's claim had been "denied by the state agency." In Ryan v. Bentsen, 12 F.3d 245, 247 (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 only "sen[t] a letter to the agency," as Plaintiffs say, Pls.' Opp. at 19, 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, all named Plaintiffs had not only requested but "been denied [skilled nursing facility] benefits." 959 F.2d 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. at 19, but there Justice Stevens said "the non-waivable

2. The Court Should Not Deem Exhaustion Waived

In any event, even if the Court had the power to deem exhaustion waived here it should not exercise that power, for three reasons discussed below. In short: (1) Plaintiffs have not shown that exhaustion would be futile, (2) section 405(g) may not be waived here for futility alone, and (3) waiver is inappropriate.[3]

a. Waiver would not be futile

The only basis for waiver that Plaintiffs offer is their assertion that exhaustion would be futile, Pls.' Opp. 20–24. They do not allege that exhaustion would cause them irreparable harm (it would not), or that their claim is collateral to one for benefits (it is not), or press any other theory in support of waiver. Id.

In support of their assertion that exhaustion would be futile, Plaintiffs offer several declarations about recent developments in the administrative process. Pls.' Opp. 24. As a

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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).

[3] In arguing for waiver, Plaintiffs erroneously rely upon a number of cases discussing when courts in this Circuit will excuse the catch-all, prudential doctrine of exhaustion of administrative remedies that applies even in the absence of a statutory mandate. See, e.g., Pls.' Opp. at 22 (citing DL v. District of Columbia, 450 F. Supp. 2d 11, 17–18 (D.D.C. 2006); Pls.' Opp. at 23 (citing Randolph-Sheppard Vendors of America v. Weinberger, 795 F.2d 90, 106 (D.C. Cir. 1986)). These cases do not help Plaintiffs' case for reasons discussed above, and for the additional reason that they do not address the question at hand, i.e., whether to deem waived the "final decision" requirement of § 405(g). See Triad of Jeffersonville I, LLC v. Leavitt, 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)). Here, Congress has spoken directly to the Court's power vel non in 42 U.S.C. § 405(g)-(h), which by their terms require exhaustion without exception. The Supreme Court and the D.C. Circuit have held that the Court sometimes can review an initial decision rather than wait for the "final decision" mentioned in the statute, § 405(g), by treating the Secretary has having "waived" the latter requirement. E.g. Mathews v. Eldridge, 424 U.S. 319, 328 (1976). But both Courts 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; Tataranowciz, 959 F. 2d at 274–275 (discussing Supreme Court cases finding waiver under § 405(g)).

preliminary matter, Plaintiffs' reliance on these declarations is misplaced because the relevant date for evaluating the Court's subject matter jurisdiction vel non over the Complaint is the day it was filed, but Plaintiffs' declarations detail events that have happened since. See Grupo Dataflux v. Atlas Global Grp., 541 U.S. 567, 570 (2004) ("It has long been the case that 'the jurisdiction of the court depends upon the state of things at the time of the action brought.'" (quoting Mollan v. Torrance, 9 Wheat 537, 539 (1824)). That said, the declarations Plaintiffs attach to their Opposition in an attempt to demonstrate futility do the opposite.

According to Plaintiffs' declarations, since they filed claims with their contractors two days before filing the amended Complaint, numerous Plaintiffs have received decisions granting payment on their claims. See Decl. of Jill Robinson ¶ 17, ECF No. 32-2 ("On April 16, 2013, I requested Part B payment . . . [o]n June 20, 2013, th[e] claim was paid[.]"); Decl. of Lorelie Lauer ¶ 14, ECF No. 32-3 ("request has been designated for payment"); Decl. of Le Anne Trachok ¶ 11-12, ECF No. 32-5 ("on June 13, 2013, [Plaintiff] again submitted the request for Part B payment . . . [a]s of June 26, 2013, [the contractor] has designated these services for payment"). Indeed, the declarations describe three such decisions granting payment, but only one decision denying payment. (Accordingly, this case would be moot as to those Plaintiffs that have had their claims granted, if there were jurisdiction in the first place.) Plaintiffs claim these developments were unexpected and that they do not expect them to last. Robinson Decl. ¶ 17; Lauer Decl. ¶ 17; Trachok Decl. ¶ 12. Be that as it may, these developments underscore the wisdom of Congress's decision to require exhaustion of administrative remedies before suit may proceed in federal court under § 405(g).

b. 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 statutory or constitutional interpretation as to which the final decision requirement of § 405(g)

may be waived for futility alone. For the proposition that constructive waiver is appropriate even in such a circumstance, Plaintiffs point to Tataranowicz, which they say is the "leading case" on constructive waiver, Pls.' Opp. 20, but is more like the high water mark.[4] In that case, which the Government could not challenge because it prevailed on the merits, 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. 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 Tataranowicz, 959 F.2d 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. 21 ("[t]he Plaintiffs [in Tataranowicz] raised only a systemwide issue of law"). Indeed, the Court was very clear that the reason it did not require a showing that in addition to being futile declining review would cause irreparable harm was that the issue before it was so narrow. Tataranowicz, 959 F.2d at 275.

[4] 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 but one element that Plaintiffs here do not even purport to satisfy. See, e.g., Triad of Jeffersonville I, LLC v. Leavitt, 563 F. Supp. 2d 1, 16 (D.D.C. 2008) (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, 247-48 (D.C. Cir. 1993), which case was decided more recently than Tataranowicz and applied a similarly stringent test for waiver. See Bentsen, 12 F.3d 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").

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. 21–22. The Complaint that Plaintiffs describe is not the one that they filed. As described below, the various counts of Plaintiffs' amended Complaint depend on numerous factual assertions, as well as assertions that certain anticipated actions would be arbitrary and capricious. The Court lacks the authority to order constructive waiver of the "final decision" requirement of § 405(g) in such a case; not even Tataranowicz went so far.

Questions of fact presented by Complaint: Unlike the Complaint Plaintiffs describe, theirs asks the Court to resolve allegations of fact. Plaintiffs allege that their failure to file timely appeals should be forgiven because, "[f]ollowing CMS's instructions[,]" they "reasonably conclude[ed] that appeals were too expensive and time-consuming." Compl. ¶ 53; see also Pls.' Opp. at 12–13 ("plaintiffs filed a Second Amended Complaint alleging, among other things . . . that CMS is estopped from [denying their claims] given that it induced plaintiffs not to seek Part B payment in the first place by telling them it was unavailable" (emphasis added)). That factual allegation is the sole basis for Counts IV and V of Plaintiffs' Complaint. Compl. ¶ 164 ("[i]f CMS had not issued longtime, explicit guidance telling hospitals not to seek Part B payment after a Part A denial, many hospitals would have appealed"); ¶ 169 ("Plaintiffs reasonably followed CMS's instructions and accordingly never sought payment") (emphasis added).

Indeed, in Count IV Plaintiffs allege that the CMS "deliberately misled Plaintiffs not to submit Part B claims." Compl. ¶ 169. That startling (and baseless) allegation does not present a legal question but a factual one. And the Secretary's contractors are empowered in certain circumstances to consider a related factual question in the administrative process. 42 C.F.R.

§ 424.44(b)(1) (allowing for extension of deadline if failure to file on time "was caused by error or misrepresentation of an . . . agent of HHS").

Record-review questions presented by Complaint: Plaintiffs' Complaint also calls on the Court to make record-intensive determinations about whether anticipated refusals to allow them to supplement their Part A claims or to waive the limitations period for their "new" Part B claims would be "arbitrary and capricious." Compl. ¶¶ 153, 155, 166. Although that is in a 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. Unlike the narrow question of statutory interpretation at issue in that case, the Court will best be positioned to review the question whether the agency's action was (or will be) "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. See id. at 112–13.

Even if some aspect of Plaintiffs' Complaint presented only a narrow question of statutory interpretation like the question at issue in Tataranowicz, this case would still not present "only" a question of law, as did the complaint in Tataranowicz. Rather, the other, less straightforward issues also presented by Plaintiffs' Complaint would nonetheless make exhaustion of administrative remedies worthwhile, and therefore waiver inappropriate.

c. Waiver is unwarranted

Finally, even assuming for the sake of argument that exhaustion would be futile and that Plaintiffs' Complaint presented the sort of interpretive question that can support waiver for futility alone under Tataranowicz, waiver would nonetheless be unwarranted. The Plaintiffs in Tataranowicz were Medicare beneficiaries who were being denied coverage to stay in a skilled nursing facility due to the Secretary's interpretation of a particular provision of the statute. Tataranowicz, 959 F.2d at 270. Here, by contrast, Plaintiffs are sophisticated hospitals and

hospital networks, as well as the American Hospital Association. They know well the administrative process and how to go about pursuing in that forum the payments they believe they are owed. Indeed, Plaintiffs are actively pursuing their administrative remedies even as they pursue this litigation, and developments day-by-day in that process could moot or otherwise affect the proceedings in this case.

On this point, amicus Healthcare Association of New York State offers background information that it says supports waiver. HANYS Br., ECF No. 33-1. The information HANYS offers does not do that; quite the opposite. HANYS's proffer does not speak to Plaintiffs' efforts to obtain adjustment (reopening) of their stale Part A claims or extension of the limitations period for their "new" Part B claims, but rather the process for filing a timely challenge to an adverse RAC payment determination. Plaintiffs did not do that, and do not purport to ask the Court to let them challenge those adverse determinations directly in this proceeding. See Opening Mem. 17–18. Rather, Plaintiffs' request that the Court deem exhaustion constructively waived is focused exclusively on their challenges to administrative decisions they anticipate from their contractors refusing to revive their claims (or the policy governing such claims processing decisions). Id.

Furthermore, the information amicus provides does not suggest that exhaustion would be (or would have been) futile, or cause irreparable harm, or speak to any other of the factors that courts have cited as weighing in favor of waiver. Instead, it focuses on the delay involved in obtaining administrative review. HANYS Br. 7–12. HANYS offers no authority suggesting that the threat of delay in the administrative process justifies excusing exhaustion; Ringer held to the contrary. See Heckler v. Ringer, 466 U.S. 602, 627 (1984) ("Congress must have felt that cases of individual hardship resulting from delays in 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."). That holding makes sense. The rule that HANYS implicitly suggests—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.

Moreover, the information HANYS provides is suspect. For example, HANYS argues that RAC determinations are frequently wrong, pointing to the appeal success rate of several of its members. HANYS Br. 12. If RAC determinations are reversed on appeal at a rate of more than 50%, the reasoning goes, then the RACs must make mistakes more often than not. This logic is flawed. Hospitals have access to 100% of the information about a claim, and can choose to appeal only those cases that they believe the RAC got wrong. Indeed, HANYS describes the thorough process its members go through in making the "decision . . . whether or not to appeal." Id. at 6 ("This review process is intensive and time consuming."). This self-selection may (and presumably does) lead to appeal only of those cases most likely to succeed and, so, potentially to a higher success rate on appeal. But that success rate tells us very little, if anything, about how often RACs actually make mistakes.

Last, HANYS also joins Plaintiffs in taking a critical view of the Recovery Audit Contractor program. E.g. HANYS Br. 6 ("it is vastly time consuming and resource sapping for a hospital to deal with the RAC experience"), id. at 7 ("RACs have forecefully pursued questionable denials"); Pls.' Opp. 29 ("The clawbacks the Secretary's contractors have inflicted on these plaintiffs have caused them significant hardship.") The wisdom of the RAC program is

not an issue in this case or Defendant's motion to dismiss. Defendant notes, however, that Congress enacted the RAC program after what it determined to have been a successful demonstration project. 42 U.S.C. § 1395ddd(h)(1), (3).

B. This Dispute is Not Ripe

1. The Secretary's Position is Tentative

Plaintiffs offer one argument that their still-evolving dispute with the Secretary is ripe for review. They say that "[t]he Secretary does not have the power to promulgate regulations that operate retroactively," Pls.' Opp. 25, so the Secretary cannot revive Plaintiffs' claims in the pending rulemaking. Plaintiffs are wrong. The Secretary does have the power to promulgate regulations that operate retroactively. As Defendant pointed out in her opening memorandum, Opening Mem. at 16 n.3, in 42 U.S.C. § 1395hh(e)(1)(A), added to the Medicare statute in 2003, Pub. L. 108-173, § 903(a)(1), Congress did authorize the Secretary to regulate retroactively. That provision says:

> A substantive change in regulations, manual instructions, interpretative rules, statements of policy, or guidelines of general applicability under this subchapter shall not be applied (by extrapolation or otherwise) retroactively to items and services furnished before the effective date of the change, unless the Secretary determines that
>
> > (i) such retroactive application is necessary to comply with statutory requirements; or
> >
> > (ii) failure to apply the change retroactively would be contrary to the public interest.

42 U.S.C. § 1395hh(e)(1)(A). In short. "[a] substantive change . . . shall not be applied . . . retroactively," "unless," id., i.e., "except on the condition that," Merriam–Webster's Collegiate Dictionary 1370, 1373 (11th ed.2003), "the Secretary determines that . . . failure to apply the change retroactively would be contrary to the public interest." 42 U.S.C. § 1395hh(e)(1)(A).

Plaintiffs' mistaken argument to the contrary is based on Bowen v. Georgetown Univ. Hosp., where the Supreme Court observed that "[t]he statutory provisions establishing the Secretary's general rulemaking power [42 U.S.C. § 1395hh] contain no express authorization of retroactive rulemaking," 488 U.S. at 213. In 1988 such a conclusion was possible, because Congress had not yet added § 1395hh(e)(1)(A) to the statute. But since Congress amended the statute in 2003, the Secretary has been empowered to act retroactively whenever she determines that failing to do so "would be contrary to the public interest."

The Secretary could exercise her power to act retroactively under 42 U.S.C. § 1395hh(e)(1)(A) in the pending rulemaking, and thereby moot this case.[5] Indeed, Plaintiffs themselves have asked her to do so. Compl. ¶ 67. That is one reason that the agency's current position is "tentative," and that this case is not ripe. Opening Mem. 20.

Furthermore, Plaintiffs are wrong to assume that any change the Secretary might make in the pending rulemaking that would affect their claims would be "retroactive." Plaintiffs assert, without explanation, that any change the Secretary might make would hurt their prospects for reviving their claims. Pls.' Opp. 25–26. But Plaintiffs have asked the Secretary to make changes to the claims processing rules that would help them by allowing their claims to proceed. Compl. ¶ 67. Any such change to Plaintiffs' benefit would not be "retroactive" in the problematic sense. See Arkema Inc. v. EPA, 618 F.3d 1, 7 (D.C. Cir. 2010) ("A rule operates retroactively if it takes away or impairs vested rights." (emphasis added)). Also, such a change would presumably alter the procedures for filing and processing Plaintiffs' Medicare claims, not the legal consequences

[5] For an example of a rulemaking in which the Secretary has exercised this power, see Medicare Program; Hospice Wage Index for Fiscal Year 2012, 76 Fed. Reg. 26,806, 26,814 (May 9, 2011) ("To the extent that these provisions could be considered a retroactive application of a substantive change to a regulation, section 1871(e)(1)(A) of the Act permits retroactive application of a substantive change to a regulation if the Secretary determines that . . . failure to apply the change retroactively would be contrary to the public interest.").

flowing from the services on which Plaintiffs' payment claims are based. See id. ("If a new rule is 'substantively inconsistent' with a prior agency practice and attaches new legal consequences to events completed before its enactment, it operates retroactively.") (internal quotation marks omitted)).

The Court need go no further, but the Opening Memorandum pointed out other reasons the agency's position is tentative that Plaintiffs simply ignore. Specifically, even if the Secretary's final rule does not moot this case, it would give the Secretary a chance, at least, to alter her position, Opening Mem. 21, could potentially simplify or clarify the issues at play, id., and would avoid the possibility of piecemeal review, id. Furthermore, the variation in theories offered in Plaintiffs' opposition to the Government's motion to dismiss about the nature of the agency action that Plaintiffs challenge, see infra Part I.C, adds an additional benefit to dismissing this case for lack of ripeness. Allowing this suit to ripen before proceeding further would at a minimum allow the nature of the agency action at issue to crystallize, and so save the Court from having to pontificate on its jurisdiction over multiple different sorts of agency decisions.

2. Abstaining Would Not Cause Plaintiffs Hardship

As for the counterweight of the ripeness inquiry under Abbott Labs v. Gardner, 387 U.S. 136, 149 (1967), declining review at this time would not cause Plaintiffs any hardship, let alone the sort of irreparable hardship that can counsel in favor of immediately reviewing an otherwise unripe case. See Opening Mem. 22–23. While Plaintiffs object to Defendant's characterization of the harm they have suffered—that they have "not been paid taxpayer money they believe is owed to them," Pls.' Opp. 28 (quoting Opening Mem. 22)—as "insulting and incorrect," id., Plaintiffs do not actually argue that declining review at this time would cause them any additional harm. Rather, they simply repeat the allegations of the Complaint that the adverse

RAC payment determinations they did not appeal caused them harm, albeit in pejorative terms. Id. at 29 ("The clawbacks the Secretary's contractors have inflicted on these plaintiffs have caused them significant hardship." (emphasis added)). That is not enough.

Plaintiffs must show not only that they have been harmed but also that declining review will cause some additional, substantial, irreparable harm that justifies immediate review of issues that are unfit for judicial resolution. Opening Mem. at 22–23 (citing Vill. of Bensenville v. FAA, 376 F.3d 1114, 1119-20 (D.C. Cir. 2004)). Plaintiffs neither argue in their opposition brief nor allege in their Complaint that declining review will do so here.

One additional note on hardship: Plaintiffs say in the introduction to their opposition brief that the Secretary's motion is part of a "long-running 'administrative shell game.'" Pls.' Opp. at 1 (quoting Alina Health Servs. v. Sebelius, 904 F. Supp. 2d 75, 78 n.2, 91 9 (D.D.C. 2012)). But cf. Comcast Corp. v. FCC, 526 F.3d 763, 769 n.2 (D.C. Cir. 2008) (Court "must presume an agency acts in good faith"). Plaintiffs do not later follow up on what they mean by this accusation. But Plaintiffs do also erroneously characterize the Secretary's opening memorandum, saying it implied that there would be a clear path to judicial review of Plaintiffs' procedural dispute with the Secretary if the Secretary were ultimately to refuse to do as Plaintiffs ask when she issues her final rule. See Pls.' Opp. 1, 17. But see Opening Mem. 4 ("even if Plaintiffs were finished pursuing their administrative remedies and their procedural dispute with the Secretary was ripe for review, the Court would lack jurisdiction to review it"); id. at 16–17, 22, 24. Together, Plaintiffs' statements might be read to imply that it would be improper for the Court to dismiss this case as unripe pending the completion of the Secretary's rulemaking in light of the fact that Defendant also maintains that the Court would lack jurisdiction to review

this case even if it were ripe. In an abundance of caution, Defendant replies: any such implication would be incorrect.

It is entirely proper for a court to dismiss a suit as unripe without first concluding that it would have jurisdiction over the case if it were ripe. See Toca Producers v. FERC, 411 F.3d 262, 266 n.* (D.C. Cir. 2005) (ripeness "may be resolved without first addressing whether the [plaintiffs] have Article III standing"). That makes sense; depending on the outcome of the Secretary's pending rulemaking, the Court might never have to decide whether it has jurisdiction over the different sorts of actions Plaintiffs purport to challenge. And Plaintiffs do not argue that their claim to jurisdiction would in any way be diminished if the Court were to address it at a later date.

C. The Court Lacks Jurisdiction over the Actions Plaintiffs Challenge, However Framed

In her opening memorandum the Defendant understood Plaintiffs to challenge two sorts of agency actions: (1) in Count I, anticipated contractor decisions refusing to allow Plaintiffs to amend their adverse Part A payment determinations (which are refusals to "reopen" for purposes of the administrative appeal process), and (2) in Counts II–V, anticipated refusals to waive the one-year filing period for Plaintiffs' "new" (resubmitted) Part B payment requests. See Opening Mem. 15. Plaintiffs disagree with the Secretary's reading of their Complaint. They say that they actually "are not challenging CMS's decision in any one particular case," but rather a "systemwide CMS policy of general applicability" of refusing to pay on their expired claims, Pls.' Opp. 30.[6] Pls.' Opp. 30. In the alternative, though, Plaintiffs say that the Secretary read the

[6] Defendant's opening memorandum supported Defendant's reading of Counts I–V of Plaintiffs' Complaint as challenging various discretionary claim processing decisions by citation to the relevant paragraphs therein. See Def's. Mem. 15 & n.2, 18. See also Compl. ¶ 153 ("CMS's refusal to let hospitals amend or supplement their original Part A claims . . . is arbitrary and capricious"); id. ¶ 158 ("CMS cannot both (i) arbitrarily decide that hospitals must file new

Complaint correctly; they are challenging contractor decisions refusing to allow Plaintiffs to amend their adverse Part A payment determinations (Plaintiffs incorrectly assume that insofar as this could be done via "adjustment" it would not entail "reopening"), Pls.' Opp. 32–37. Furthermore, if that framing does not support jurisdiction, Plaintiffs say that they are indeed challenging particular decisions denying their "new" (resubmitted) Part B payment requests. Pls.' Opp. 37–39.

Plaintiffs would understandably like the Court to conceptualize the "agency action" that they challenge however it must in order to conclude that it has jurisdiction over Plaintiffs' shifting procedural dispute with the Secretary. But while Plaintiffs can be flexible about the identity of the agency action that they challenge, the Secretary and the Court cannot be. The particular agency action, or actions, at issue in this lawsuit must be specified in order to determine whether the Court has jurisdiction to review that action, in order to compile the administrative record of that action, and ultimately in order to determine the scope of relief should the Court review the action and rule in the Plaintiffs' favor. Accordingly, as in her opening memorandum, the Secretary separates the various actions Plaintiffs claim to challenge in demonstrating that the Court lacks jurisdiction.

1. "Systemwide CMS Policy of General Applicability"

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claims . . . and (ii) apply a waivable time limit to those new claims"); id. ¶ 161 ("CMS's application of the one-year time limit also is arbitrary and capricious for a second reason."); id. ¶ 173 ("The Secretary must be equitably estopped from using the one-year time limit to bar Plaintiffs . . . claims[.]"); id. ¶ 178 ("Plaintiffs are entitled to equitable tolling of the Medicare Act's one-year time limit to file new claims[.]"). Plaintiffs do not provide any support—by citation to relevant Complaint allegations or otherwise—for their contrary reading of the Counts of the Complaint as collectively presenting a single challenge to "CMS policy of general applicability." Pls.' Opp. 30. In an abundance of caution, Defendant addresses Plaintiffs' argument § 405(g) empowers the Court to review their challenge to "CMS policy of general applicability" here even though it is not fairly presented by any Count of the Complaint.

Plaintiffs' preferred approach is to frame Counts I–V as a facial challenge to a "systemwide CMS policy of general applicability."[7] Pls.' Opp. 30. Specifically, Plaintiffs say that these counts challenge a policy promulgated in interim Ruling 1455-R, which Plaintiffs say "ruled that hospitals cannot rebill under Part B unless the RAC Part A denials that stripped away the original payments are newly issued or live on appeal." Id. at 17.

Plaintiffs are wrong to say that Ruling 1455-R created a "policy" that stands in the way of, or otherwise affects, Plaintiffs' attempts to breathe new life into their expired claims. Ruling 1455-R did not say that hospitals "cannot rebill," rather it announced a limited category of claims that hospitals can rebill. As to the claims at issue here, those for which the time to appeal had run when Ruling 1455-R was issued, the interim Ruling states repeatedly that it does not apply, as Plaintiffs recognize. See Opening Mem. 12; Medicare Program; Medicare Hosp. Ins. (Part A) & Medicare Supplementary Med. Ins., 78 Fed. Reg. 16,614, 16,616 (Mar. 18, 2013) (Def.'s Ex. A, ECF No. 31-3) ("This Ruling does not apply to Part A hospital inpatient claim denials for which the timeframe to appeal expired prior to the effective date of this Ruling[.]"); id. at 16,617 (same); Pls.' Opp. 14 ("The plaintiffs' requests for payment under Part B do not fall into either category" of claims to which Ruling 1455-R applies). The interim Ruling left the status quo in place as to Plaintiffs' expired claims.[8]

[7] That this action is unripe for review due to the pending rulemaking becomes all the more apparent when it is so framed. The first purpose of the ripeness doctrine is "to prevent the courts, through avoidance of premature adjudication from entangling themselves in abstract disagreements over administrative policies[.]" Abbott Labs v. Gardner, 387 U.S. at 149. Yet Plaintiffs' preferred framing of this action would have the Court do exactly that, weighing in on a "policy" that is by all accounts subject to change in a pending rulemaking. Perhaps for this reason, Plaintiffs' "policy" frame disappears when they discuss ripeness; there they present this case as a "challenge to the Secretary's refusal to pay [Plaintiffs'] previously presented requests for Part B payment." Pls.' Opp. 27.

[8] The status quo that makes Plaintiffs' efforts to revive their claims through the administrative process an uphill battle has as its source the ordinary timely-filing requirements that have long

Plaintiffs' error is of no moment because framing this action as a challenge to a "systemwide CMS policy of general applicability" does nothing to satisfy Plaintiffs' burden to demonstrate that the Court has jurisdiction under § 405(g), whatever the purported policy's source. The Medicare statute does not give the Court jurisdiction to review a "CMS policy of general applicability" in the abstract. It provides for review only of a particular "final decision of the [Secretary] . . . made after a hearing," § 405(g)-(h). See also Fund for Animals, Inc. v. U.S. Bureau of Land Mngmt, 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, such as Plaintiffs' here, 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 Shalala v. Illinois Council on Long Term Care, 529 U.S. 1, 14 (2000) ("Salfi and Ringer . . . foreclose distinctions based upon . . . the 'general legal' versus the 'fact-specific' nature of the challenge[.]").

Plaintiffs say that a "systemwide 'legal issue'" can be "appropriate for judicial cognizance" under § 405(g), and cite once again the D.C. Circuit's decision in Tataranowicz for that proposition. Pls.' Opp. at 30. But that case held nothing of the sort. While the D.C. Circuit

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been a feature of the Medicare claim processing regulations. First, the regulation providing that an adverse payment determination becomes binding if it is not appealed within 120 days prevents Plaintiffs from appealing (or amending) their adverse Part A payment determinations now, absent reopening. 42 U.S.C. § 1395ff(b)(1)(D)(i); 42 C.F.R. § 405.928 (appeal from adverse payment determination must be filed within 120 days). And second, the regulation providing that a new Part B claim must be filed within one calendar year of the date of service prevents Plaintiffs from filing new claims for Part B payment, unless a contractor grants an extension for cause. See 42 U.S.C. § 1395n(a)(1) (claim for payment under Part B must be filed within one year of date of service); 42 U.S.C. §1395(u)(b)(3)(B) (same) 42 C.F.R. § 424.44(b) (setting forth limited exceptions to time limit for filing new claim). Plaintiffs do not purport to challenge these regulations.

in Tataranowicz waived the requirement that a claim be exhausted all the way through the administrative review process in part because the claim presented only a pure question of statutory interpretation, 959 F.2d at 328, that question came attached to a claim that had actually been presented to a contractor and denied, id. at 272. The Court did not hold that the Medicare statute allows for judicial review of the Secretary's policy choices in the abstract.

2. Refusal to Reopen Binding Part A Claim Determinations

In the alternative, Plaintiffs ask the Court to treat their claims as challenging refusals to let them amend their Part A claims. Pls.' Opp. 37. Defendant's opening memorandum read Count I of Plaintiffs' Complaint to do that, and explained that the Court lacks subject matter jurisdiction over such a challenge. Opening Mem. 24–27. Specifically, Defendant noted that when Plaintiffs did not appeal their adverse RAC payment determinations, those determinations became binding, and therefore can be altered only if a contractor exercises its discretion to "reopen" the determination. Id. at 15 n.2. Such a reopening determination is not subject to judicial review. Id. at 24–27 (citing Your Home Visiting Nurse Servs., Inc. v. Shalala, 525 U.S. 449, 456 (1999); Palomar Med. Ctr. v. Sebelius, 693 F.3d 1151, 1165–67 (9th Cir. 2012)).

Plaintiffs concede that a refusal to reopen is not subject to judicial review by not disputing the point. See Buggs v. Powell, 293 F. Supp. 2d 135, 141 (D.D.C. 2003) ("[W]hen a plaintiff files an opposition to a dispositive motion and addresses only certain arguments raised by the defendant, a court may treat those arguments that the plaintiff failed to address as conceded.") (citing Fed. Deposit Ins. Corp. v. Bender, 127 F.3d 58, 67–68 (D.C.Cir. 1997)); see also United States v. Real Prop. Indentified as: Parcel 07139-005R, 287 F. Supp. 2d 45, 61 (D.D.C. 2003) (discussing cases). Instead, they argue that the change they seek would count as an "adjustment" and therefore not a "reopening" for purposes of the regulations governing the

appeals process, in particular 42 C.F.R. § 405.926, and would therefore be susceptible to judicial review. Pls.' Opp. 35. Plaintiffs misunderstand the rules.

"Adjustment billing," a term used in the CMS Medicare Claims Processing Manual ("MCPM"), Pub. No. 100-4,[9] refers to a mechanism by which one of the millions of Medicare payment claims processed each day can (sometimes) be manually altered by the submitter. Interim Ruling 1455-R considered the possibility of using adjustment billing to convert into Part B claims the still-live Part A claims to which it applies, but rejected it because such a change is too "fundamental" to be effected by the adjustment mechanism. Ruling 1455-R, 78 Fed. Reg. at 16,640 ("[A]n adjustment claim supplements information on a claim that was previously submitted without changing the fundamental nature of the original claim. In these Part B claim situations, however, the fundamental nature of the originally filed claim is changed completely (from a Part A claim to a Part B claim)").

Even assuming that the change Plaintiffs seek could be made through adjustment billing, such adjustment would nonetheless entail reopening. Absent a change in the regulations, the stale payment claims at issue in Counts I–V of Plaintiffs' Complaint could be altered only if reopening were granted, because the time for Plaintiffs to appeal their adverse Part A payment determinations (or file new claims) has "long since expired," Pls.' Compl. ¶ 72, making those payment determinations "binding." See 42 U.S.C. § 1395ff((a)(3)(C)(i) (appeal available "only if notice is filed . . . not later than" 120 days of initial determination); id. § 1395ff(b)(1)(D)(i) (no reconsideration and judicial review under § 1395ff(b)(1)(A) unless appeal is timely filed). Reopening is the only method by which the regulations permit a payment determination that has become binding to be altered in the administrative process. Id. (permitting reopening "under

[9] Available at http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs-Items/CMS018912.html?DLPage=1&DLSort=0&DLSortDir=ascending.

guidelines established by the Secretary"); 42 C.F.R. § 405.928(b)(2) (un-appealed determination is binding unless reopened).

The conclusion that Plaintiffs' requests that their contractors "adjust" their Part A claims into Part B claims necessarily involve reopening for purposes of the regulations governing administrative appeals, including 42 C.F.R. § 405.926, is further compelled by the definition of "reopening" set forth in the Secretary's regulations, which provides that "[a] reopening is a remedial action taken to change a binding determination or decision that resulted in either an overpayment or underpayment[.]" 42 C.F.R. § 405.980(a)(1). Despite Plaintiffs' preferred label, reopening is exactly what they seek—a change to now-binding adverse RAC payment determinations that they say resulted in underpayments by the Secretary.

These provisions leave no room for doubt about whether the rules of procedure governing reopening apply to Plaintiffs' requests that their stale Part A claims be "adjusted." But if there were any doubt, the Secretary's interpretation of her own regulations is "controlling unless plainly erroneous or inconsistent with the regulation." See Auer v. Robbins, 519 U.S. 452, 461 (1997).[10] "This broad deference is all the more warranted when, as here, the regulation concerns

[10] Plaintiffs argue that the Secretary's interpretation of her own regulations is not entitled to deference because it is not the product of notice and comment rulemaking, but rather is offered in a legal brief. Pls.' Opp. at 36. Plaintiffs confuse the deference owed to an agency's interpretation of a statute it is entrusted to administer, that is, Chevron deference, with the deference owed an agency's interpretation of its own regulation, that is, Auer or Seminole Rock deference. Compare Chevron USA, Inc. v. Natural Res. Def. Council, Inc., 467 U.S. 837 (1984), with Bowles v. Seminole Rock & Sand Co., 325 U.S. 410 (1945); and Auer v. Robbins, 519 U.S. 452 (1997). The latter form of deference is especially strong, and is owed even to interpretations offered for the first time in legal briefs; indeed, Auer was such a case. See Auer, 519 U.S. at 462; see also Polm Family Found., Inc. v. United States, 644 F.3d 406, 409 (D.C. Cir. 2011) ("An agency's interpretation of its regulation is controlling unless the interpretation is 'plainly erroneous or inconsistent with the regulation' Auer, 519 U.S. at 461. This is so even if the interpretation appears for the first time in a legal brief."). Furthermore, Plaintiffs are wrong to say that Ruling 1455-R undercuts the interpretation offered in the Government's opening memorandum, Opening Mem. at 15 n.2. Ruling 1455-R reflects the interpretation offered here. That Ruling does not permit adjustment of an expired Part A claim without reopening, it

a complex and highly technical regulatory program." Thomas Jefferson Univ. v. Shalala, 512 U.S. 504, 512 (1994) (internal quotation marks omitted) (deferring to Secretary's interpretation of Medicare regulations).

Plaintiffs' belief that a correction to a stale Part A claim that was the subject of an un-appealed adverse payment determination can be billed as an "adjustment" without reopening is premised upon two fundamental misreadings of the Medicare Claims Processing Manual. First, Plaintiffs assert that "[w]here a hospital seeks only to 'correct or supplement' incorrect 'information' on the original bill, it may submit an adjustment bill," but "[b]y contrast, where the hospital seeks to add items and services omitted from a previously processed bill, it cannot submit an adjustment bill; instead, it must seek reopening." Pls.' Opp. 33 (internal citations omitted). There is in the cited passages of the Medicare Claims Processing Manual such a distinction—between efforts to "correct" an existing bill and those to "add items and services" to a bill—but the Manual does not say that the former (a mere correction) is an "adjustment" and the latter (an addition) a "reopening." It says that an adjustment that adds can only be filed prior to "the expiration of the time limitation for filing of the initial claim[.]" MCPM Ch. 1 ¶ 70.5. An adjustment that merely "corrects or supplements" a previously filed claim, on the other hand, "is subject to the rules governing administrative finality, rather than the time limitation for filing (see Chapter 29 on Reopenings)." Id.; see also MCPM Ch. 3, § 50(B) (same). In other words, an adjustment bill that corrects rather than adds can be filed even as to a claim for which the one-year filing deadline has passed, but only pursuant to the procedures permitting reopening (which is occasionally referred to as "administrative finality" in the Medicare Claims Processing

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provides a limited extension of the time limit for filing certain Part B claims, and states that adjustment is not the appropriate billing mechanism for processing the amendment that Plaintiffs seek. Ruling 1455-R, 78 Fed. Reg. 16,634, 16,640 (Mar. 18, 2013).

Manual). (For the same reason, Plaintiffs' assertion that adjustment bills do not "implicate timely claim-filing requirements," Pls.' Opp. at 34, is incorrect.)

Finally, Plaintiffs point to a line in § 10.4.1 of Chapter 34 of the Manual that says that "Part A providers that are able to submit an adjusted or corrected claim to correct an error or omission may continue to do so and are not required to request a reopening." Contrary to Plaintiffs' suggestion, this provision does not say that any Part A provider (let alone Plaintiffs) may "adjust" a bill indefinitely, even after having its claim decided, without reopening. Instead, it simply states that those who may seek adjustment without seeking reopening, e.g., those with claims for which the one-year initial claim filing period (or 120-day payment determination appeal period) has not yet run, may continue to do so. Because Plaintiffs' un-appealed adverse Part A payment determinations are now binding, they may not change them without reopening, 42 C.F.R. § 405.928(b)(2), and this line says nothing to the contrary.

3. Refusal to Extend Time Limit for "New" Part B Claims

Last, framing Counts I–V as challenging refusals to extend the timely filing requirement for Plaintiffs' "new" Part B claims, Pls.' Opp. at 37–39, does not cure the jurisdictional defect in Plaintiffs' Complaint. Plaintiffs appear to concede that such a decision is not a "final decision" of the Secretary reviewable under 42 U.S.. § 405(g); they do not dispute Defendant's position on that point, Opening Mem. at 27–28. See Buggs, 293 F. Supp. 2d at 141. Instead, Plaintiffs ask the Court to grant them leave to amend their Complaint to assert jurisdiction under 28 U.S.C. § 1331 as to this version of their claims. Pls.' Opp. 37 n.9.

General federal question jurisdiction pursuant to 28 U.S.C. § 1331 over claims "arising under" the Medicare statute is barred by 42 U.S.C. § 405(h) (incorporated by 42 U.S.C. § 1395ii), as Plaintiffs acknowledge. Pls.' Opp. at 37. In Shalala v. Illinois Council on Long

Term Care, Inc., 529 U.S. 1 (2000), the Supreme Court recognized an exception of sorts to this rule, however. Confronted with an ambiguity as to whether a particular claim was one "arising under" the Medicare statute for purposes of § 405(h), id. at 10, the Supreme Court held that this provision would be interpreted not to apply where a contrary result would mean "no review at all." The D.C. Circuit discussed this exception—without purporting to alter or expand it—in American Chiropractic Association v. Leavitt, 431 F.3d 812, 816 (D.C. Cir. 2005), the case upon which Plaintiffs principally rely. (Despite discussing this exception to § 405(h) in the course of their analyses, both cases found jurisdiction precluded by that provision. Illinois Council, 529 U.S. at 25 ("The bar of § 405(h) applies."); American Chiropractic Ass'n, 431 F.3d at 26–28. The only § 405(h) cases Plaintiffs cite actually finding jurisdiction are Second Circuit cases involving constitutional claims. Pls.' Opp. 38 (citing Furlong v. Shalala, 238 F.3d 227 (2d Cir. 2001); Binder & Binder PC v. Barnhart, 399 F.3d 128 (2d Cir. 2005)).

Plaintiffs say that the interpretive rule discussed in Illinois Council applies here, notwithstanding their admission that this case, in which Plaintiffs ultimately seek payment of their Medicare claims, arises under the Medicare statute. Compl. ¶ 21. Plaintiffs' rationale for this dubious assertion is that "if plaintiffs' attempt[s] to obtain payment under Part B do not adjust a previous bill, then they constitute a new bill—i.e., a new claim for payment under Part B, distinct from the original claim for payment under Part A." Pls.' Opp. 38. So understood, Plaintiffs say, the Secretary's position would mean no "administrative or judicial review" of the rejection of this "new" Part B claim. Id. This tortured logic ignores the fact that Plaintiffs had, but forfeited, the opportunity to obtain judicial review. The "no review at all" exception is not one that can be invoked where Plaintiffs are simply out of time in pursuing a claim for which administrative review was available but was not sought.

Plaintiffs admit that what they call "new" Part B claims in fact seek to bill for precisely the same services at issue in the adverse payment determinations that they never appealed. E.g. Compl. ¶ 100. And Plaintiffs admit that they could have obtained judicial review of those adverse payment determinations if they had filed appeals on time. Compl. ¶ 50. So this is not a situation in which application of § 405(h) would mean "no review at all." Rather, application of § 405(h) in cases 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 of claims—that Congress and the Secretary have set forth for doing so. See 42 U.S.C. § 1395ff(b)(1)(D)(i); 42 C.F.R. § 405.928(b)(2).

To be sure, a contractor's decision whether to extend the limitations period for Plaintiffs' "new" Part B claims would not be subject to judicial review, but even Plaintiffs do not argue that Illinois Council mandates that such a discretionary claim processing decision be subject to judicial review. Such a broad reading of the limited exception articulated in that case would contradict Your Home Visiting Nurse Servs., 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 (no judicial review of decision refusing to reopen binding hospital notices of program reimbursement).

II. Counts IV and V Fail to State a Claim

Plaintiffs' attempt to avoid the conclusion that Counts IV and V of their Complaint fail to state a claim in light of Sebelius v. Auburn Regional Medical Center, 133 S.Ct. 817 (2012), rests upon an irrelevant distinction and a misreading of the Secretary's regulations. As for the irrelevant distinction, Plaintiffs say that Defendant's reliance on Auburn Regional "fails" because in that case the Supreme Court addressed the Court's power to invoke "equitable tolling" but "says nothing about estoppel." Pls. Opp. 39. This argument can save only Count V

of Plaintiffs' Complaint, because Count IV does seek equitable tolling, rather than equitable estoppel. But it saves neither Count, because the Supreme Court's reasoning was not as limited as Plaintiffs make it out to be.

The salient fact in Auburn Regional was that a judicially-created extension would "undermine the regime established by the Secretary" pursuant to Congress's authorization, 133 S.Ct. at 826, not that the particular judicial exception the plaintiffs there happened to invoke was equitable tolling. The Court held that a court "lacks authority to undermine the regime established by the Secretary," id., not that a court lacks authority to do so by applying equitable tolling but may accomplish the same end by invoking one of the many other pliable equitable doctrines, such as estoppel, the discovery rule, or fraudulent concealment.

Plaintiffs also say that this case is different from Auburn Regional because there the Secretary had provided a "hard cap" limiting extensions of the time limit to no more than three years, a fact noted by the Supreme Court in holding that judicial extension could undermine the Secretary's rules. Pls.' Opp. 40. Plaintiffs say that such a hard cap "is conspicuously absent here," id. at 42, and also argue that judicial exception would not undermine the regime Congress authorized the Secretary to setup because the bases for waiver listed in 42 C.F.R. § 424.44(b) are, in Plaintiffs' view, "non-exhaustive." Plaintiffs again misread the law.

The Secretary has indeed provided an outer-bound to the provision governing extension of the limitation period. Specifically, where a claimant seeks an extension upon the ground that its failure to file timely was due to an "error or misrepresentation" of the agency "[n]o extension of time will be granted . . . when the request for that exception is made . . . more than 4 years after the date of service." 42 C.F.R. § 424.44(b)(5). Plaintiffs are also wrong to say that 42 C.F.R. § 424.44(b) is not an exhaustive list of bases for extending the limitations period. Pls.'

Opp. at 40. Section 424.44(a) makes clear that it is; it provides that a claim "must be filed no later than" one year after the date of service "[e]xcept as provided in paragraphs (b) and (e) of this section." (Section 424.44(e) is not relevant here, it governs submission of payments by newly-enrolled Medicare Part B suppliers.)

The Secretary has, pursuant to Congress's authorization, 42 U.S.C. § 1395n(a)(1), provided for extension of the one-year limitations period for filing Medicare Part B claims only in limited circumstances. 42 C.F.R. § 424.44(b). For the Court to extend those circumstances beyond what the statute and the Secretary have provided would undermine the regime that Congress and the Secretary have established; it cannot do so. Auburn Reg'l, 133 S.Ct. at 826.

III. The Court Lacks Jurisdiction over Count VI, which is also Unripe

In Count VI of the Complaint Plaintiffs look forward not backward; they challenge certain aspects of Ruling 1455-R insofar as it limits the products and services for which a hospital may obtain Part B payment after a RAC denies Part A payment going forward. Pls.' Opp. 40–43. Defendant's opening memorandum offered three bases for dismissal of this Count: failure to exhaust, lack of standing, and ripeness. Plaintiffs' objection to each basis for dismissal fails.

Exhaustion: Plaintiffs say that in this case the "final decision," requirement of § 405(g) can be waived, id. at 41, and that they satisfied the "presentment" requirement by attempting to "rebill[] for inherently outpatient services." Id. This argument fails for three reasons. First, Plaintiffs attempt to satisfy the "presentment" requirement by reliance on declarations submitted with their opposition to the Government's motion to dismiss, id. at 42, which they cite for the proposition that they "have requested Part B payment for services that CMS has called 'inherently outpatient' services" and so are likely to be denied under Ruling 1455-R. Pls. Opp. at 14. But the cited declarations do not say Plaintiffs had submitted such bills as of April 19,

2013, the relevant date for assessing the Court's jurisdiction. See Grupo Dataflux v. Atlas Global Grp., 541 U.S. 567, 570 (2004). In fact the only date specified is June 24, 2013, well after the Complaint was filed. See Decl. of Jill Robinson ¶ 20, ECF No. 32-2; see also Decl. of Le Anne Trachok ¶ 17, ECF No. 32-5 (no date given). Second, the declarations Plaintiffs now offer do not allege that there has been any adverse decision at any level on the bills. But see supra, Part I.A.1. Third, Plaintiffs ask that the exhaustion requirement be deemed waived, Pls.' Opp. at 42, but Plaintiffs fail to meet any (much less all) of the criteria for waiver of exhaustion and such waiver would be inappropriate for the reasons given, supra, Part I.A.2. See also Le Anne Trachok Decl. ¶ 17 (request for payment was granted).

Standing: As to standing, Plaintiffs also rely on newly-submitted declarations alleging that certain Plaintiffs actually have submitted claims that, they believe, will be denied (in part) pursuant to Ruling 1455-R. Again, the only date specified in those declarations is June 24, 2013, which is after the relevant date for assessing Plaintiffs' standing. See Davis v. FEC, 554 U.S. 724, 734 (2008) (standing inquiry is "focused on whether the party invoking jurisdiction had the requisite stake in the outcome when the suit was filed").

Furthermore, Plaintiffs say that the Complaint itself alleges that particular hospital Plaintiffs have actually submitted or plan to submit payment claims that will be denied pursuant to the limitation attacked in Count VI, and point to 11 different paragraphs for support. Pls.' Opp. at 42. But none of the paragraphs cited by Plaintiffs makes such an allegation. Indeed, the few paragraphs Plaintiffs cite that actually discuss specific claims by Plaintiffs have to do with Plaintiffs' stale claims (addressed in Counts I–V), not new claims that Plaintiffs expect to be denied on the basis of interim Ruling 1455-R's limitation on inpatient re-billing. See Compl. ¶¶ 79, 92, 103, 116, 126. And those that discuss the limitation on inpatient re-billing in interim

Ruling 1455-R offer no suggestion, conclusory or otherwise, that any Plaintiff has submitted a claim that may be denied pursuant to the limitation. See Compl. ¶ 61, 147.

Ripeness: Plaintiffs' only objection to dismissal of Count VI on ripeness grounds is the same objection they offered to dismissal of Counts I–V for lack of ripeness: that the Secretary cannot act retroactively and that she would have to do so to change the policy that applies to Plaintiffs' claims. Pls.' Opp. 43. This objection fails for the reason discussed above. Supra at I.B. (Even if their claim were ripe, Plaintiffs' failure to exhaust would still be fatal to their claim to jurisdiction as discussed above.)

CONCLUSION

Repose is not just stubborn but blind. Neither Congress nor the Secretary has, in setting forth the comprehensive rules of procedure that govern Medicare payment claims and appeals, provided for an exception to the timely-filing requirements based on alleged or even probable merit. See 42 U.S.C. § 1395ff(b)(1)(D)(i); 42 C.F.R. § 405.928(b)(2). Expiration of the time limits puts to rest both losing claims and winning claims alike. To a disappointed claimant who comes to believe, rightly or wrongly, that it had a case after the deadline has passed—including Plaintiffs here—this result may seem inequitable. But it reflects the balance between the claimant's interest in its claim and the system's interest in efficiency and finality struck by Congress and the Secretary. See 42 U.S.C. § 1395ff(b)(1)(D)(i) (appeal from adverse payment determination must be filed within 120 days); id. § 1395f(a)(1) (claim for payment under Part A must be filed within one year of date of service); id. § 1395n(a)(1) (claim for payment under Part B must be filed within one year of date of service); id. § 1395u(b)(3)(B) (same); 42 C.F.R. § 405.928 (appeal from adverse payment determination must be filed within 120 days); 42 C.F.R. § 424.44(b) (setting forth limited exceptions to time limit for filing new claim). In a system that processes more than a billion claims a year—and one in which both providers such

as Plaintiffs and beneficiaries depend on reasonably timely review and payment of claims—requiring the Secretary to re-review stale claims while attempting to process current ones comes at a price that both Congress and the Secretary have found to be too high.

Plaintiffs would like to alter the balance, and believe that the Secretary's prospective change in payment policy reflected in interim Ruling 1455-R (for the time being) may provide a basis for them to do so. They have pled their case, simultaneously, to the contractors, the Secretary, and the Court. The "simultaneous" aspect of their efforts underlies the first two bases on which Defendant respectfully requests dismissal of Counts I–V of Plaintiffs' Complaint, failure to exhaust and lack of ripeness.

The third basis for dismissal flows from what has already happened in this dispute rather than what might still come to pass. Plaintiffs concede that they did not make use of the avenue that Congress set up for them to pursue the relief they ultimately seek here, viz., payment on their denied Part A claims. E.g. Compl. ¶ 27 (time for Missouri Baptist Sullivan to appeal has "long since expired"). Time closed the congressionally-created route, so Plaintiffs have had to be creative. But, as Defendant has explained, Congress has not empowered the Court to review either the Secretary's Medicare claim-processing policy in the abstract or the discretionary claim processing decisions that Plaintiffs anticipate will result from their revival efforts. So even if the Court looks past exhaustion and ripeness, Counts I–V of Plaintiffs' Complaint should be dismissed for lack of subject matter jurisdiction.

A separate defect would warrant dismissal of Counts IV and V of Plaintiffs' Complaint for failure to state a claim on the merits even if the Court refused to dismiss pursuant to Federal Rule 12(b)(1), namely, the Court lacks the power to do what Plaintiffs request there. And last,

the Court should dismiss Count VI for lack of subject matter jurisdiction pursuant to Federal Rule 12(b)(1) for reasons explained in the Defendant's opening memorandum and above.

Accordingly, Defendant respectfully repeats her request that the Court dismiss Plaintiffs' Complaint in its entirety.

Dated: July 23, 2013

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on this 23rd day of July 2013, I caused the foregoing document to be served on Plaintiff's counsel of record electronically by means of the Court's CM/ECF system.

/s/ Matthew J.B. Lawrence
MATTHEW J.B. LAWRENCE