UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

AMERICAN HOSPITAL ASSOCIATION, *et al.*, Plaintiffs, v. SYLVIA M. BURWELL, in her official capacity as SECRETARY OF HEALTH AND HUMAN SERVICES,[2] Defendant.	Civil Action No. 14-cv-00851 (JEB)

DEFENDANT'S POINTS AND AUTHORITIES IN SUPPORT OF HER MOTION TO DISMISS FOR LACK OF JURISDICTION AND IN OPPOSITION TO PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

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[2] Pursuant to Fed. R. Civ. P. 25(d), Sylvia M. Burwell, the current Secretary of Health and Human Services, is automatically substituted as the named defendant for Kathleen Sebelius, the former Secretary of Health and Human Services.

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INTRODUCTION

Beginning in 2011, the number of Medicare claim denials appealed to the upper levels of the Health and Human Services ("HHS") administrative appeals process skyrocketed to unprecedented levels. From fiscal year 2011 through fiscal year 2013, appeals at the Administrative Law Judge ("ALJ") level of review grew 545%, from 59,600 appeals in 2011 to 384,151 appeals in 2013. At the next level of review, the Departmental Appeals Board ("DAB"), the number of appeals submitted to the Medicare Appeals Council ("Appeals Council") doubled between the beginning of fiscal year 2011 and the end of fiscal year 2013. This dramatic increase in appeals is attributable to a number of factors, including more Medicare beneficiaries, increased use of covered services, additional appeals from Medicaid State agencies, and Congress's recent expansion of the Recovery Audit Contractor ("RAC") Program to identify and correct improper Medicare payments. And this increase came without a corresponding increase in the number of adjudicators and other needed resources, which has caused substantial delays in the resolution of these appeals. While Plaintiffs challenge the resulting delays in this action, HHS is working diligently to ameliorate them through multiple efforts with limited resources, and Congress is actively monitoring many of those efforts. During the time the delays remain, HHS must address its competing programmatic responsibilities with the limited resources available to it.

Plaintiffs American Hospital Association ("AHA") and three individual hospitals seek a writ of mandamus that would compel HHS to resolve all Medicare payment appeals at the ALJ and DAB levels of the administrative process within 90 days. As a practical matter, HHS cannot feasibly meet such a deadline and still issue considered,

legally sufficient decisions. As a statutory matter, HHS is not required to do so. The Medicare statute contemplates that not all administrative claims at the ALJ and DAB level will be decided within 90 days. It specifically provides a remedy for claims that are not decided in that timeframe: appellants can "escalate" such claims to the next level of review. Plaintiffs therefore cannot establish either the "clear right to relief" or the "clear duty to act" by the agency that are required for the Court to exercise mandamus jurisdiction. Nor can Plaintiffs establish the third mandamus criterion—absence of an adequate remedy—given the Medicare statute's escalation provision for ALJ-level and DAB-level appeals that are not decided within 90 days. In fact, that statutory remedy is exclusive and independently precludes mandamus jurisdiction.

Even if there were a statutory requirement that HHS resolve the appeals at issue within 90 days—which there is not—Plaintiffs would not be entitled to mandamus relief. The D.C. Circuit has made clear that in circumstances such as these, where an agency facing competing priorities and limited resources operates in good faith, mandamus is not appropriate. *In re United Mine Workers of Am. Int'l Union*, 190 F.3d 545 (D.C. Cir. 1999); *In re Barr Labs., Inc.*, 930 F.2d 72 (D.C. Cir. 1991). Contrary to Plaintiffs' contention, this action does not involve the sort of delays that are so egregious as to warrant exercise of the Court's discretion to enter the extraordinary remedy of mandamus. Instead, the delays at issue in this case, while significant, are generally being experienced by providers and suppliers, including large organizations such as hospitals with significant financial resources, rather than elderly and disabled Medicare beneficiaries, and stem from circumstances largely beyond HHS's control.

For these reasons, expanded upon herein, the Court should dismiss this action for lack of subject matter jurisdiction and deny Plaintiffs' motion for summary judgment.

BACKGROUND

I. Medicare and the Administrative Appeals Process for Part A and Part B Claims

The Medicare statute, 42 U.S.C. § 1395, *et seq*., establishes a federal program of health insurance for the elderly and disabled. In general, Part A covers inpatient hospital stays and other institutional care, *see* 42 U.S.C. § 1395d; Part B covers physician and other medical services, *see* 42 U.S.C. § 1395k; Part C enables Medicare recipients to get the benefits of Parts A and B through private managed care plans, *see* 42 U.S.C. § 1395w-22; and Part D authorizes private insurers to offer federally subsidized insurance plans for prescription drugs to Medicare beneficiaries, *see* 42 U.S.C. § 1395w-102. The Secretary administers the Medicare program and has authority to promulgate implementing regulations, 42 U.S.C. §§ 1395hh(a)(1), which she has delegated to the Centers for Medicare & Medicaid Services ("CMS"). *See MacKenzie Med. Supply, Inc. v. Leavitt*, 506 F.3d 341, 343 (4th Cir. 2007).

For services covered under Medicare Parts A and B, health care providers and suppliers as well as beneficiaries submit claims for payment to Medicare Administrative Contractors (MACs), which are private companies with which CMS contracts to process claims and issue "initial determinations" on those claims. *See* 42 U.S.C. § 1395kk-1(a); 42 U.S.C. § 1395ff(a)(1)–(2); 42 C.F.R. §§ 405.904(a)(2), 405.920-928.

The Medicare statute establishes a four-level administrative appeals process for challenges to a MAC's initial determination. *See* 42 U.S.C. § 1395ff. At the first level of appeal, a party dissatisfied with the initial determination may seek a "redetermination" by

an individual at the MAC who was not involved in making the initial determination. 42 U.S.C. § 1395ff(a)(3); 42 C.F.R. §§ 405.904 (a)(2), 405.940-958. MACs generally are to issue redetermination decisions within 60 days of the timely filing of the redetermination request. *See* 42 U.S.C. § 1395ff(a)(3)(C)(ii); 42 C.F.R. § 405.950.

At the second level of administrative review, a party dissatisfied with the MAC's redetermination may seek "reconsideration" by a Qualified Independent Contractor ("QIC")—another independent organization under contract with CMS. 42 U.S.C. § 1395ff(b)–(c), (g); 42 C.F.R. §§ 405.902, 405.904(a)(2); 42 C.F.R. § 405.960-978. The QIC is required to conduct an "independent, on-the-record review of an initial determination, including the redetermination and all issues related to payment of the claim" and in doing so, "reviews the evidence and findings upon which the [previous determinations were] based, and any additional evidence the parties submit or that the QIC obtains on its own." 42 C.F.R. § 405.968(a). QICs generally issue reconsideration decisions within 60 days of the timely filing of the reconsideration request. *See* 42 U.S.C. § 1395ff(c)(3)(C)(i); 42 C.F.R. § 405.970. Where the QIC fails to render a decision on an appeal within the specified time period, however, the party requesting reconsideration may bypass QIC review and escalate the appeal to the third level of administrative review. 42 U.S.C. § 1395ff(c)(3)(C)(ii); 42 C.F.R. § 405.970.

At the third level of administrative review, a party dissatisfied with the QIC's reconsideration, or its failure to issue a reconsideration decision within 60 days, whose claim meets a statutory amount-in-controversy requirement may request a hearing before an ALJ. 42 U.S.C. § 1395ff(b), (d)(1); 42 C.F.R. §§ 405.904(a)(2), 405.1000-1054. HHS's Office of Medicare Hearings and Appeals ("OMHA"), a division within the Office

of the Secretary that is independent of CMS, administers the ALJ hearing program. *See* Griswold Decl. Ex. 1, July 10, 2014 Written Testimony at 3 ("Griswold Test."); *see also* Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, § 931 (2003); 76 Fed. Reg. 19995 (Apr. 11, 2011); 70 Fed. Reg. 36386 (June 23, 2005). The Medicare statute provides that ALJs "shall conduct and conclude a hearing on a decision of a [QIC] and render a decision on such hearing by not later than the end of the 90-day period beginning on the date a request for hearing has been timely filed." 42 U.S.C. §1395ff(d)(1)(A); *accord* 42 C.F.R. § 405.1016 (reiterating 90-day time frame unless extended). Where an ALJ fails to render a decision by the end of the specified time period, however, the party requesting the hearing may bypass ALJ review and escalate the appeal—without an ALJ hearing decision—to the fourth level of administrative review. 42 U.S.C. § 1395ff(d)(3)(A); 42 C.F.R. § 405.1104.

The Medicare Appeals Council within HHS's DAB is the fourth level of administrative review and conducts *de novo* review of ALJ decisions. 42 U.S.C. § 1395ff(d)(2); 42 C.F.R. §§ 405.904(a)(2), 405.1100, 405.1130. The Appeals Council is an adjudicatory division within the DAB, http://www.hhs.gov/dab/, that provides the final level of administrative review for individual Medicare claim and entitlement appeals within HHS. Tobias Decl. at ¶ 1. The Appeals Council decision is considered the final decision of the Secretary and is subject to judicial review. 42 C.F.R. § 405.1130. The Medicare statute directs the Appeals Council to make a decision or remand the case to the ALJ within 90 days of the date a request for review was timely filed. 42 U.S.C. § 1395ff(d)(2); *see also* 42 C.F.R. § 405.1100(c). For cases "escalated" from the ALJ level to this level, the Appeals Council is either to issue a final decision or dismissal order or to

remand the case to the ALJ within 180 days from receipt of the appellant's request for escalation. 42 C.F.R. § 405.1100(b). Where the Appeals Council fails to render a decision on an appeal within the specified time period, the appellant may bypass Appeals Council review and escalate the appeal to federal district court.[3] 42 U.S.C. § 1395ff(d)(3)(B); 42 C.F.R. § 405.1132.

II. The Recent Sharp Increase in Medicare Appeals and Resulting Backlog

As set forth above, OMHA is responsible for administering the ALJ-level of administrative appeals under Medicare Parts A and B. OMHA is also charged with administering appeals of entitlement decisions under Medicare Parts A and B, appeals of coverage determinations under Medicare Parts C and D, and appeals of the Social Security Administration's assessment of Income Related Monthly Adjustment Amount ("IRMAA") premium surcharges. *See* 79 Fed. Reg. 393-02 (Jan. 3, 2014).

In general, OMHA met the 90-day time frame that Congress contemplated for most ALJ-level appeals from its establishment in June 2005 through fiscal year 2010. Griswold Decl. Ex. 1, Griswold Test. at 3. In fiscal year 2011, however, OMHA's workload began to expand dramatically in ways that had not been built into its workload models. *Id.* Between fiscal years 2011 and 2013, the upward trend in ALJ hearing requests "took an unexpectedly sharp turn," with the appeals administered by OMHA increasing by 545%. *Id.*

A combination of factors contributed to this expansion of OMHA's workload: more beneficiaries; increased utilization of Medicare-covered services—with CMS

[3] A party has 60 days from the date it receives the Appeals Council's notice that it is not able to issue a final decision in which to file an action in district court. 42 C.F.R. § 405.1132(b).

processing more than one billion claims annually; increased Medicaid State Agency appeals of Medicare coverage denials for beneficiaries enrolled in both Medicare and Medicaid; and the additional appeals from audits conducted under the RAC Program designed to identify and correct improper Medicare payments, which Congress instituted nationwide as of 2010.[4] *Id.*; *see also* 42 U.S.C. § 1395ddd(h). *See generally Palomar Med. Ctr. v. Sebelius*, 693 F.3d 1151, 1156–57 (9th Cir. 2012).

The magnitude of the increase to OMHA's workload far exceeds the ALJs' ability to keep up with the surge of incoming appeals. Griswold Test. at 4. While OMHA's ALJs have responded to the additional workload by increasing their productivity—the average number of dispositions per ALJ more than doubled between fiscal year 2009 and

[4] The RAC Program, which began as a demonstration project, has been very successful and has returned billions of improper payments to the Medicare Trust Fund, including $2.3 billion dollars in overpayments in 2012 alone. *See* CMS, *Recovery Auditing in Medicare and Medicaid for Fiscal Year 2012* at iv-v, 11, *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. In fiscal year 2012, only seven percent of all RAC determinations have been challenged and later overturned on appeal. *Id.* at 11. Plaintiff AHA has vigorously opposed the RAC Program and lobbied for its curtailment or elimination since its inception. *See, e.g.*, AHA President and CEO Rich Umbdenstock, *Reversing Medicare's downward spiral means reining in the RACs*, AHA Today (Aug. 29, 2014), http://www.aha.org/content/14/140829-rac-ahanews.pdf.[5] On December 24, 2013, OMHA's Chief ALJ, Nancy Griswold, wrote to appellants who had a significant number of pending Medicare appeals to apprise them of the nature of the backlog at the ALJ-level of review and OMHA's actions to address it, including deferring appeal assignments. Griswold Decl. Ex. 2, Mem. to OMHA Medicare Appellants from Chief ALJ Griswold of Dec. 24, 2013). On February 12, 2014, OMHA conducted a Medicare Appellant Forum during which Chief ALJ Griswold and other OMHA managers, and the Chair of the DAB, Judge Constance Tobias, provided updates on OMHA and DAB operations, information about OMHA and DAB initiatives designed to mitigate the backlog, and information on what appellants can do help the ALJ-level and DAB-level appeals process work more efficiently. *See* 79 Fed. Reg. 393, 393–95 (Jan. 30, 2014); *see also* http://www.hhs.gov/omha/omha_medicare_appellant_forum_presentations.pdf (presentations from OMHA forum).

fiscal 2013 (from 534 per year to 1260 per year)—the delays continue to persist. *Id.* The addition of seven new ALJs in late August 2014, as allowed by OMHA's funding level, brings OMHA's adjudication capacity to 72,000 appeals per year; yet as of July 1, 2014, OMHA had received over 509,000 appeals in fiscal year 2014 alone. *See id.* At its current receipt and adjudication capacity levels, every four to six weeks, OMHA is receiving enough appeals fill one year's worth of its adjudication capacity. *Id.* The present backlog—with the average adjudication time frame in fiscal year 2014 at 398 days (through July 2014)—is the result. *See* http://www.hhs.gov/omha/important_notice_regarding_adjudication_timeframes.html. Plaintiffs' assertion that this is "a problem that is of HHS's own making," Pls.' Mot. for Summ. J. ("MSJ") at 24, is wholly without basis.

OMHA has implemented measures to address the backlog at the ALJ level and is developing additional measures to alleviate the delay, contrary to Plaintiffs' assertion that there has been "no action by HHS," *id.* at 9.[5] OMHA has maximized its productivity by supporting each ALJ with a processing team comprised of attorneys and support staff so that the ALJs can focus on hearing and deciding appeals. *Id.* To maintain OMHA field

[5] On December 24, 2013, OMHA's Chief ALJ, Nancy Griswold, wrote to appellants who had a significant number of pending Medicare appeals to apprise them of the nature of the backlog at the ALJ-level of review and OMHA's actions to address it, including deferring appeal assignments. Griswold Decl. Ex. 2, Mem. to OMHA Medicare Appellants from Chief ALJ Griswold of Dec. 24, 2013). On February 12, 2014, OMHA conducted a Medicare Appellant Forum during which Chief ALJ Griswold and other OMHA managers, and the Chair of the DAB, Judge Constance Tobias, provided updates on OMHA and DAB operations, information about OMHA and DAB initiatives designed to mitigate the backlog, and information on what appellants can do help the ALJ-level and DAB-level appeals process work more efficiently. *See* 79 Fed. Reg. 393, 393–95 (Jan. 30, 2014); *see also* http://www.hhs.gov/omha/omha_medicare_appellant_forum_presentations.pdf (presentations from OMHA forum).

offices' ability to safely store the enormous number of files corresponding to pending appeals, in July 2013, OMHA began deferring its requests for case files from lower appeal levels and deferring assignment of appeals to ALJs until an ALJ's docket could accommodate them. *Id.*; *see also* Griswold Decl. Ex. 2, Mem. to OMHA Medicare Appellants from Chief ALJ Griswold of Dec. 24, 2013. In other words, OMHA initiated a "first in/first out" system whereby new requests are assigned to an ALJ on a rolling basis as the ALJ's docket is able to accommodate them. Griswold Test. at 4. These deferrals address the administrative issue of safe file storage and do not cause any additional delays in ALJ hearings and decisions.[6] *Id.*

In recognition of the vulnerability of many Medicare beneficiaries—OMHA considers them the most vulnerable of appellants—OMHA has continued to assign and give priority to appeals filed by beneficiaries. *Id.* In February 2014, OMHA began assigning a limited number of non-beneficiary appeals to ALJs whose dockets could accommodate additional appeals, and it has continued to conduct hearings and issue decisions on appeals that were already assigned. *Id.* OMHA is also developing an adjudicative business process manual to standardize its business practices (to be implemented at the end of fiscal year 2014 (September 30, 2014)), is in the process of converting its paper-based process to an electronic one, and has developed a Medicare Appeals Template System that allows staff to use standardized fillable forms for routine word processing. *Id.*

[6] Plaintiffs incorrectly assert that OMHA has "suspended the assignment of all new appeals to ALJs," MSJ at 7, and mischaracterize the first in/first out system as an "outright moratorium on agency action." MSJ at 20.

In addition, in 2013, a departmental interagency workgroup established by former HHS Secretary Kathleen Sebelius conducted a thorough review of the appeals process and developed a series of initiatives to reduce the current backlog. *Id.* OMHA is presently implementing several resulting pilot programs, including two new options for claim resolution. *Id.* The first option allows appellants to elect adjudication using statistical sampling and extrapolation, which facilitates resolution of a large number of claims based upon resolution of a statistically valid sample of claims. *Id.* The second option offers appellants alternative dispute resolution in the form of a settlement conference facilitated by OMHA attorneys trained in mediation techniques.[7] *Id.* OMHA recognizes, however, that its current initiatives are not sufficient to resolve the backlog. *Id.* It has expressed its commitment to working with Congress as well as HHS departmental leaders to bring the increased number of appeals and the ALJ appeal workload into balance. *Id.*

The DAB likewise has experienced a sharp increase in the appeals it has received for its Appeals Council Administrative Appeals Judges ("AAJs") to review. In fiscal year

[7] In addition to these OMHA initiatives, Chief ALJ Griswold outlined for Congress the steps that CMS has taken to reduce the number of appeals submitted to OMHA:

> a) beginning global settlement discussions involving similarly-situated claimants; b) under the new fee for service [RAC]contracts, requiring the new [RACs] to offer providers and suppliers a 30-day discussion period to allow an opportunity for resolution before the [RAC] refers a claim to the [MAC] for collection; c) under the new fee for service recovery audit contracts, allowing for payment only after [the QIC] has made a determination supporting the recovery auditor's determination of an overpayment; d) issuing a proposed rule requiring prior authorization for certain durable medical equipment frequently subject to overutilization; and e) using CMS's demonstration authority to require prior authorization for two particular Part B services.

Griswold Test.

2010, the DAB received approximately 2,000 Medicare appeals, but in fiscal year 2011, that number grew to approximately 3,000. Tobias Decl. ¶ 4. While that number remained steady through fiscal year 2012, in fiscal year 2013, the DAB received more than 4,000 appeals, which doubled its annual intake from 2010. *Id.* Current projections for fiscal year 2014 are between 4,000 and 5,000 appeals. *Id.* ¶ 3.

Like OMHA, the DAB has not received corresponding resources to handle this spike in appeals. While the DAB staff handling Medicare Appeals increased by four attorneys in 2012, no AAJs were added. *Id.* ¶ 5 And the DAB's Medicare appeals workload far exceeds the Appeals Council's ability to keep up with the volume of incoming appeals. *Id.* As a result of the lack of resources to address the current volume of appeals, the DAB is unlikely to meet the 90-day timeframe for issuing decisions in most appeals. *Id.*; *see also id.* Ex. 1, DAB Presentation at 9.

The DAB is focusing on two main efforts to combat the backlog. First, the DAB is giving priority to beneficiary appeals where practicable. *Id.* Ex. 1, DAB Presentation at 8–9. Second, the DAB is undertaking new process improvements for Medicare appeals, including the consolidation of appeals filed by a single appellant with identical issues of law and a new e-records system to minimize the use of paper files. *Id.* at 10–11. Both of these measures will allow the affected appeals be processed more quickly and help reduce the current backlog of appeals. *See id.* at 8–11.

III. This Action

On May 22, 2014, Plaintiffs filed this suit, alleging that the delays in ALJ hearings and decisions and in DAB decisions violate 42 U.S.C. § 1395ff(d)(1)(A). The Complaint seeks relief in the form of a writ of mandamus directing HHS to provide "the

hearing before an ALJ and ALJ decision required by law" for plaintiffs' appeals pending at the ALJ-level 90 days or more, directing HHS to provide "the resolution required by law" in appeals of Plaintiffs pending at the DAB for 90 days or more, and requiring HHS to "otherwise comply with its statutory obligations in administering the appeals process for all hospitals." Compl., Prayer for Relief.

ARGUMENT

I. Legal Standards for Rules 12(b)(1) and 56

"Federal courts are courts of limited jurisdiction." *Kokkonen v. Guardian Life Ins. Co.*, 511 U.S. 375, 377 (1994). "It is to be presumed that a cause lies outside this limited jurisdiction, and the burden of establishing the contrary rests upon the party asserting jurisdiction." *Id.* (internal citations omitted); *accord, e.g.*, *Gammill v. U.S. Dep't of Educ.*, 989 F. Supp. 2d 118, 120 (D.D.C. 2013). A federal court has an "affirmative obligation to ensure that it is acting within the scope of its jurisdictional authority," and on a rule 12(b)(1) motion gives "closer scrutiny" to the factual allegations of the complaint than on a rule 12(b)(6) motion for failure to state a claim upon which relief can be granted. *Turner v. Beers*, _ F. Supp. 2d _, No. 13-504, 2013 WL 6627983, at *1 (D.D.C. Dec. 17, 2013) (quoting *Grand Lodge of Fraternal Order of Police v. Ashcroft*, 185 F. Supp. 2d 9, 13 (D.D.C. 2001)), and 5A Charles A. Wright & Arthur R. Miller, *Federal Practice and Procedure* § 1350 (2d ed. 1987)). Further, in considering a motion to dismiss for lack of jurisdiction pursuant to Rule 12(b)(1), courts may consider materials outside the pleadings. *Id.* (citing *Jerome Stevens Pharms., Inc. v. FDA*, 402 F.3d 1249, 1253 (D.C. Cir. 2005)).

Under Rule 56, summary judgment should not be granted unless "the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a); *accord Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247–48 (1986).

II. Mandamus Jurisdiction is Rarely Available.

Plaintiffs assert subject matter jurisdiction solely pursuant to the Mandamus Act, 28 U.S.C. § 1361.[8] Compl. ¶ 17 (ECF No. 1, filed May 22, 2014). However, jurisdiction under the Mandamus Act is "strictly confined." *In re Cheney*, 406 F.3d 723, 729 (D.C. Cir. 2005) (en banc). Mandamus relief is considered "drastic," and it is available "only in 'extraordinary situations.'" *Id.*; *accord, e.g., Turner*, _ F. Supp. 2d _, 2013 WL 6627983, at *2. A writ of mandamus is "hardly ever granted; those invoking the court's mandamus jurisdiction must have a 'clear and indisputable' right to relief; and even if the plaintiff overcomes all these hurdles, whether mandamus relief should issue is discretionary." *In re Cheney*, 406 F.3d at 729; *accord, e.g., Turner*, _ F. Supp. 2d _, 2013 WL 6627983, at *2.

To establish mandamus jurisdiction, Plaintiffs must demonstrate each of the following criteria: that (1) they have "a clear right to relief," (2) the Secretary has a "clear duty to act," and (3) "there is no other adequate remedy available to [them]." *Power v. Barnhart*, 292 F.3d 781, 784 (D.C. Cir. 2002). Where, as here, plaintiffs have no "clear right to relief," there is no basis for the Court to exercise jurisdiction under 28 U.S.C. § 1361. *In re Cheney*, 406 F.3d at 729. Similarly, where, as here, an agency official owes no clear duty, mandamus jurisdiction is unavailable. *Id.* Mandamus jurisdiction also will not lie where, as in this case, an adequate remedy is available. *Action Alliance of Senior Citizens v. Leavitt*, 483 F.3d 852, 858 (D.C. Cir. 2007) (quoting *Fornaro v. James*, 416 F.3d 63, 69 (D.C. Cir. 2005)).

[8] Plaintiffs do not assert subject matter jurisdiction under any other provision; nor could they, because the Medicare statute precludes judicial review of Medicare claims as to which prescribed administrative remedies have not been exhausted. *See Shalala v. Ill. Council on Long Term Care, Inc.*, 529 U.S. 1, 12–13 (2000).

III. Mandamus Jurisdiction is Not Available in This Action.

Plaintiffs' petition for a writ of mandamus establishes none of the criteria for the Court to exercise subject matter jurisdiction under 28 U.S.C. § 1361. Because Plaintiffs fail to meet their burden of establishing jurisdiction, this action should be dismissed pursuant to Rule 12(b)(1).

A. The Current Delays in ALJ Appeals Do Not Constitute a Statutory Violation.

Plaintiffs' petition for mandamus rests upon the premise that the Medicare statute requires all administrative appeals at the ALJ-level of review to be heard and decided within 90 days of the filing of the request for hearing and requires the DAB to issue a decision in all administrative appeals at that level within 90 days of filing a request for review. Pls.' MSJ at 12-13. That premise is wrong. Contrary to Plaintiffs' contention, the Medicare statute does not establish absolute deadlines for ALJ hearings and decisions and DAB decisions. Instead, it specifically contemplates instances where appeals will not be resolved within 90 days and specifies the available remedy. Accordingly, Plaintiffs cannot establish either that they have a "clear right to relief" or that the Secretary has a "clear duty to act."

To be sure, section 1869(d)(1)(A) of the Medicare statute provides for ALJs to conduct hearings on Medicare claim appeals and render decisions on such hearings within 90 days of the filing of request for hearing, and section 1869(d)(2)(A) provides for the Appeals Council to conduct and conclude review of an ALJ decision or remand the matter to the ALJ for reconsideration within 90 days of the filing of a request for review. 42 U.S.C. § 1395ff(d)(1)(A), (d)(2)(A). However, section 1869(d)(3) of the Medicare statute itself specifies the consequences where the 90-day deadline is not met. 42 U.S.C.

§ 1395ff(d)(3). Section 1869(d)(3)(A), which Congress added to the Medicare statute in 2000, Pub. L. 106–554 (Dec. 21, 2000), provides that where an ALJ fails to meet the deadline, the claimant may escalate its claim to the next administrative appeal level, *viz.*, the Appeals Council. 42 U.S.C. § 1395ff(d)(3)(A). Section 1869(d)(3)(B) provides that where the Appeals Council fails to meet the deadline, the claimant may escalate its claim to the federal court and seek judicial review. 42 U.S.C. § 1395ff(d)(3)(B).

These statutory escalation provisions thus contemplate that not all ALJ appeals will be decided within 90 days and that not all Appeals Council reviews will be completed within 90 days. Accordingly, the Medicare statute does not establish an absolute deadline of 90 days for all ALJ decisions and hearings or for all Appeals Council decisions or remand orders. *See* 3 *Sutherland Statutes and Statutory Construction* § 57:8 (7th ed. 2013) ("the stated consequences of noncompliance may compel a directory construction [as opposed to mandatory construction of a statute]—for example, where a statute prescribes a remedial course that may be followed if the primary direction was not obeyed") (citing *Wysong v. Auto. Underwriters*, 204 Ind. 493 (1933); *Rainwater v. State ex rel. Strickland*, 237 Ala. 482 (1939)); *see also Ute Indian Tribe v. Hodel*, 673 F. Supp. 619, 621 (D.D.C. 1987) ("Traditionally the use of the word 'shall' indicates a mandatory nondiscretionary duty. A court, however, may always investigate beyond 'ritualistic incantation' of this standard rule.") (citations omitted). Even if the statute's plain language in its escalation provisions did not preclude Plaintiffs' contrary interpretation, it is reasonable to interpret 42 U.S.C. § 1395ff(d)(1)(A) not to compel resolution of all ALJ appeals within 90 days and resolution of all Appeals Council petitions within 90 days, given Congress's incorporation of the escalation provisions into the statute. In contrast,

Plaintiffs' interpretation of the 90-day provisions as mandatory ignores the remedy Congress specifically prescribed for cases where administrative appeal decisions were not rendered within the time Congress originally envisioned. Indeed, Congress obviously contemplated that the administrative appeal timeframes would not always be met and specified that the appellant could proceed to the next level of administrative (or judicial) review, not that mandamus would be available. Further, if the statute were interpreted to require resolution of any and all ALJ and Appeals Council appeals within 90 days, as Plaintiffs argue, HHS would be forced to conduct a massive number of hearings and issue decisions therein without nearly the ALJs, AAJs, staff, and other resources needed to carry out such a directive. *See* Griswold Decl. ¶ 3; Tobias Decl. ¶ 5.

B. Judicial Intervention is Unwarranted in Any Event.

Even if Plaintiffs could establish that the Medicare statute establishes an absolute 90-day deadline for ALJ hearings and decisions and an absolute 90-day deadline for Appeals Council decisions or remand orders, they still would not be entitled to mandamus relief. It is well-established in this Circuit that violation of a statutory deadline "does not, alone, justify judicial intervention." *In re Barr Labs.*, 930 F.2d at 75 (citing *In re Ctr. for Auto Safety*, 793 F.2d 1346, 1354 (D.C. Cir. 1986)); *accord*, *e.g.*, *In re United Mine Workers*, 190 F.3d at 551. Rather, a court applies the six principles the D.C. Circuit identified in *Telecommunications Research & Action Center v. FCC* ("*TRAC*"), 750 F.2d 70, 74–79 (D.C. Cir. 1984), in determining whether an agency's delay warrants a mandamus order:

> (1) the time agencies take to make decisions must be governed by a rule of reason; (2) where Congress has provided a timetable or other indication of the speed with which it expects the agency to proceed in the enabling statute, that statutory scheme may supply content for this rule of reason;

> (3) delays that might be reasonable in the sphere of economic regulation are less tolerable when human health and welfare are at stake; (4) the court should consider the effect of expediting delayed action on agency activities of a higher or competing priority; (5) the court should also take into account the nature and extent of the interests prejudiced by delay; and (6) the court need not find any impropriety lurking behind agency lassitude in order to hold that agency action is unreasonably delayed.

TRAC, 750 F.2d at 80 (citations and internal quotes omitted); *accord United Mine Workers*, 190 F.3d at 549; *Barr Labs., Inc.*, 930 F.2d at 74–75. Application of those factors here—chiefly the reality of the competing priorities HHS must address with limited resources—compels the conclusion that mandamus relief is unwarranted.

The D.C. Circuit has applied the *TRAC* analysis to refuse to force federal agencies to meet statutory timetables where doing so would upend agency priorities. In so doing, the Circuit has cautioned that courts should "hesitate to require" an agency to expedite a particular action where "such a command would seriously disrupt" other agency activities "of higher or competing priority." *United Mine Workers*, 190 F.3d at 553 (quoting *Public Citizen Research Group v. Auchter*, 702 F.2d 1150, 1158 (D.C. Cir. 1983)); *see also Barr Labs*, 930 F.2d at 76 ("In short, we have no basis for reordering agency priorities.").

In *Barr Labs.*, the D.C. Circuit rejected a petition for mandamus to require the Food and Drug Administration ("FDA") to decide certain applications within the 180-day period required by the Food and Drug Act, 21 U.S.C. § 355. Although the Food and Drug Act required decision on applications within 180 days,[9] FDA decisions on the applications were delayed between 389 and 669 days by the agency's estimate, and even longer by the plaintiff's estimate, in violation of the statute. *Barr Labs.* at 74. The

[9] The Food and Drug Act provides that the FDA "shall approve or disapprove [such] application[s]" "[w]ithin one hundred and eighty days of the initial receipt," unless the applicant and the FDA agree to an additional period. 21 U.S.C. § 355(j)(4)(A).

Circuit began its analysis with the recognition that "[e]quitable relief, particularly mandamus, does not necessarily follow a finding of a violation: respect for the autonomy and comparative institutional advantage of the executive branch has traditionally made courts slow to assume command over an agency's choice of priorities." *Id.* at 74 (citing *In re Monroe Commc'ns Corp.*, 840 F.2d 942, 946 (D.C. Cir. 1988)). With respect to the first two *TRAC* principles, the D.C. Circuit assumed that the 180-day statutory period "supplies content for item one's 'rule of reason.'" *Barr Labs.*, 930 F.2d at 75. Regarding principles three, four and five, the Circuit found that any impact to human health caused by the delay was effectively nullified by the impact judicial intervention would have on competing agency priorities that also related to human health. *Id.* It recognized that "a judicial order putting [the appellant] at the head of the queue simply moves all others back one space and produces no net gain." *Id.* With regard to the sixth *TRAC* principle, there was no evidence that the agency had treated the appellant applicant differently from other applicants. *Id*. In refusing to mandate that the FDA decide the applications within 180 days, the Circuit emphasized that it "ha[d] no basis for reordering agency priorities," explaining:

> The agency is in a unique—and authoritative—position to view its projects as a whole, estimate the prospects for each, and allocate its resources in the optimal way. Such budget flexibility as Congress has allowed the agency is not for us to hijack.

Id. at 76.

Similarly in *United Mine Workers*, the D.C. Circuit refused to mandate that the Mine and Safety Health Administration ("MSHA") comply with a statutory 90-day timetable for initiating or deciding not to initiate a rulemaking. *United Mine Workers*, 190 F.3d at 546. The Circuit found that MSHA was "in clear violation" of the Mine

Safety and Health Act's requirement that the agency issue final regulations concerning diesel exhaust gases in coal mines, or decide to not issue such regulations, within 90 days of certification of the hearing record. *Id.* at 551. At the time of the Circuit's decision, the hearing record had been closed for eight years, but the agency had neither issued final regulations nor decided not to issue them. *Id.* at 550. Nevertheless, the Circuit refused to compel the agency to act. As in *Barr Labs.*, central to the *United Mine Workers* decision against mandamus was the Circuit's recognition that the agency faced other priorities. *Id.* at 552–53. The Circuit emphasized that ordering expedited treatment of one rulemaking "might well delay rulemaking for other contaminants that are at least as dangerous to the health of the nation's miners." *Id.* at 552 & n.6.[10] It declined to grant relief that would move diesel exhaust gases "to the top of the agency's regulatory agenda." *Id.* at 546.

Judge Bates of this Court also refused to issue mandamus relief to address delays of between two and four years in the Department of Labor's action on alien labor certification applications. *Liberty Fund, Inc. v. Chao*, 394 F. Supp. 2d 105, 120 (D.D.C. 2005). The Court emphasized the agency's competing priorities, which it found "weighed most heavily" in the *TRAC* analysis, as well the agency's good faith efforts to alleviate the delays. *Id.*

Like in *Barr Labs.*, *United Mine Workers*, and *Liberty Fund*, an order of mandamus is unwarranted in this case under the *TRAC* analysis. Under the first two principles of the *TRAC* analysis, the Medicare statute supplies a "rule of reason" to govern the timing of agency decisions and provides that ALJ appeals and Appeals Council appeals need not be resolved within 90 days of the applicable petition for review,

[10] Although the Circuit did not explicitly address the sixth *TRAC* factor, its opinion does not suggest that MSHA's delay was the result of any impropriety on the agency's part.

as set forth above.[11] 42 U.S.C. § 1395ff(d)(3)(A). With respect to the third, fourth and fifth *TRAC* principles (consideration of whether human health and welfare are at stake, competing agency priorities, and the nature and extent of interests prejudiced by delay), the Complaint seeks relief on behalf of Plaintiff hospitals and other hospitals with pending Medicare payment appeals. Compl., Prayer for Relief ¶ b. Plaintiffs emphasize that their claims implicate human health and welfare given that that is the nature of hospital services. MSJ at 21–24. It is important to recognize, however, that claims of other Medicare appellants also impact human health and welfare, particularly the claims of beneficiary appellants whom OMHA and the Appeals Council recognize as the most vulnerable group of appellants. *See* Griswold Test. at 4; DAB Presentation 8–9. In addition to beneficiaries, physicians and other non-hospital health care providers—whose services likewise impact human health and welfare—also have pending administrative appeals. *See* 42 C.F.R. § 405.906; *see also* DAB Presentation at 4 (noting ALJ decisions appealed by providers/suppliers). Indeed, nearly all of HHS's activities implicate human health and welfare. *See* *http://www.hhs.gov/about/* ("HHS is the U.S. government's principal agency for protecting the health of all Americans and providing essential human services, especially for those who are least able to help themselves."). The human health and welfare impact factor "alone can hardly be considered dispositive when . . . virtually the entire docket of the agency involves issues of this type." *Sierra Club v. Thomas*, 828 F.2d 783, 798 (D.C. Cir. 1987).

[11] Notably, the D.C. Circuit found statutory violations in both *Barr Labs.* and *United Mine Workers*. Here, by contrast, the Secretary is not in violation of the Medicare statute, as set forth above. *See supra* at 14–16. Further, those cases did not involve a statutorily prescribed remedy for administrative delay, in contrast to the Medicare statute's escalation provisions.

HHS, OMHA, and the DAB have a fixed amount of resources and must set priorities for how they will utilize those limited resources most effectively in light of the unprecedented number of administrative appeals they are facing. *See* Griswold Decl. ¶ 3; Tobias Decl. ¶ 5. OMHA and the DAB have made the policy determination that appeals filed by individual Medicare beneficiaries should have priority over other appeals, including hospitals' appeals. *See* Griswold Decl. Ex. 1, Griswold Test. at 4; *see also* Tobias Decl. Ex. 1, DAB Presentation. The mandamus relief Plaintiffs seek would force OMHA and the DAB to rearrange their priorities to put hospital appeals ahead of beneficiary appeals as well as appeals by other health care providers. Were the Court to grant Plaintiffs' petition, OMHA and DAB would be forced to move beneficiary and other appellants back in the line and give priority to hospital appeals, in contrast to OMHA's and the DAB's assignment of priorities, which was based on their expert knowledge of the various groups of persons and entities filing appeals and the groups' respective circumstances. And in the DAB's case, which provides adjudicatory functions for HHS beyond what its Appeals Council provides, see http://www.hhs.gov/dab, if it were directed to devote additional staff to deciding Medicare appeals, it would be unable to meet statutory and regulatory deadlines in other types of cases pending in its Appellate and Civil Remedies Divisions. Tobias Decl. ¶ 6.

As for OMHA, even if it were to shift all of its available resources to deciding hospital Medicare payment appeals, it still would be unable to issue legally sufficient decisions on the current the volume of appeals within 90 days because it would need to hire and train significant numbers of additional personnel to handle the appeals. As noted above, OMHA's current adjudication capacity is 72,000 appeals per year, but as of July 1,

2014, OMHA had received over 509,000 appeals in fiscal year 2014 alone. Griswold Decl., Ex. 1, Griswold Test. at 4. And OMHA does not have unlimited resources on which it can draw. OMHA is funded through its own appropriation. Department of Health & Human Services Appropriations Act, 2014, Pub. L. No. 113-76, Div. H, Title II, 128 Stat. 363, 380 (Jan. 17, 2014). The Department could look to authorities available to it to transfer funds from other HHS appropriations to OMHA, *see id.* at 128 Stat. 382, but the use of any such authorities would be subject to statutory limitations and would come at the expense of other Departmental programs and priorities. *See generally* 31 U.S.C. § 1532 ("An amount available under law may be withdrawn from one appropriation account and credited to another or to a working fund only when authorized by law.").

Perhaps tipping their hand to their true grievance, Plaintiffs assert that HHS could "rein in" RAC audits. MSJ at 25. However, HHS cannot simply "rein in" the RAC audits, which are a critical tool for fighting improper Medicare payments. Congress created the RAC program to recoup what has turned out to be billions of dollars of Medicare overpayments. *See, e.g.*, CMS, *Recovery Auditing in Medicare and Medicaid for Fiscal Year 2012* at iv-v, 11, *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. Because of the enormous volume of Medicare claims, MACs cannot audit or otherwise closely scrutinize each individual claim before payment lest the payment system grind to a halt. Recognizing that a system so dependent on prompt payment and presumed honesty and accuracy of providers of services may lead to improper payments, Congress established the RAC

Program. *See* 42 U.S.C. § 1395ddd. In Fiscal Year 2012 alone, the RACs recouped $2.3 billion dollars in overpayments by the Medicare program.[12] *Id.*

Lastly, regarding the sixth *TRAC* factor, Plaintiffs do not allege any impropriety by the Secretary or suggest that ALJs, AAJs, or other HHS personnel have "just been twiddling their thumbs." *Barr Labs.*, 930 F.2d at 75 (internal quotations marks omitted). To the contrary, the Secretary has been actively addressing the current delays and implementing measures to reduce the backlog, as OMHA Chief ALJ Griswold recently reported to Congress. *See supra* at 8–10. Judge Bates recognized in *Liberty Fund, Inc.* that the Department of Labor's good faith efforts to reduce its backlog of alien labor certification applications—which included implementing automated systems, providing additional funding, and adding personnel dedicated to processing applications—weighed against mandamus. *Liberty Fund, Inc.*, 394 F. Supp. 2d at 120. HHS's similar measures to alleviate the delays in its administrative appeals before OMHA and the DAB—including moving to electronic processes, adding ALJs, and supporting ALJs with processing teams so as to maximize productivity, as well as offering adjudication using statistical sampling and extrapolation and alternative dispute resolution, *see supra* at 10—should likewise counsel against mandamus relief. *See id.* ("the good faith of the agency in addressing the delay weighs against mandamus") (citing *In re Am. Fed'n of Gov't Employees*, 837 F.2d 503, 507 (D.C. Cir. 1988)); *see also Barr Labs.* at 76 ("the absence

[12] The RAC program is also used to identify underpayments to providers so that providers can be paid correctly and CMS can implement actions that will prevent future improper payments. In 2012, RAC identified and repaid $109.4 million in underpayments. *See* CMS, *Recovery Auditing in Medicare and Medicaid for Fiscal Year 2012* at iv-v, *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.

of bad faith, as here, is relevant to the appropriateness of mandamus") (citing *In re Monroe Commc'ns Corp.*, 840 F.2d at 946–47).

For these reasons, even if the current administrative appeal delays constituted a statutory violation, which they do not, *see supra* at 14–16, the Court should exercise its discretion to refuse to enter an order that would force the agency to reorder its priorities and to put Plaintiffs' appeals ahead of other agency priorities, including appeals filed by beneficiaries. Indeed, in *United Mine Workers* the agency missed a 60-day statutory deadline by eight years. Nonetheless, the D.C. Circuit declined to exercise mandamus jurisdiction, primarily because the agency had matters of higher priority to address. *Id*. at 553. *Barr Labs.* involved agency delays expected to range from more than double to nearly quadruple the statutory timetable. *Barr Labs.*, 930 F.2d at 74. Again, the Circuit declined to exercise its equitable powers to enforce the statutory deadline. *Id.* at 76; *see also, e.g., The Mashpee Wampanoag Tribal Council v. Norton*, 336 F.3d 1094, 1100–01 (D.C. Cir. 2003) (recognizing "importance of 'competing priorities' in assessing the reasonableness of an administrative delay," and concluding that district court erred "by disregarding the importance of there being 'competing priorities' for limited resources"); *Action on Smoking & Health v. Dep't of Labor*, 100 F.3d 991, 994 (D.C. Cir. 1996) (agency delay in issuing final rule was justified where more expedited action "would have threatened other items on its·regulatory agenda"); *Barr Labs.*, 930 F.2d at75 ("sluggish pace" of agency action was "effectively irrelevant" in light of the adverse effect of mandamus relief "on competing agency priorities"); *Monroe Commc'ns*, 840 F.2d at 946 ("agency's setting of priorities is not a proper subject of judicial inquiry").

Likewise here, the Court should exercise its discretion to decline to enter an order of mandamus that would force the Secretary to reorder the agency priorities that she has set.

C. The Medicare Statute's Remedies for Delayed ALJ-Level and DAB-Level Appeals Precludes Mandamus Jurisdiction.

As explained above, Plaintiffs lack a clear right to have OMHA and the Appeals Council decide their appeals within 90 days, and the Secretary has no clear duty to ensure that such decisions are issued within 90 days. For those reasons alone, the Court lacks mandamus jurisdiction. *See Power*, 292 F.3d at 784 (party seeking mandamus must establish all three criteria for relief). Even if Plaintiffs could establish those criteria for mandamus jurisdiction, they still would not establish the third criterion—the lack of an adequate remedy. And not only is the Medicare statute's remedy for appeal delays adequate, it is exclusive.

1. The Statutory Remedies Are Exclusive.

It is a "well settled" rule that "where a statute creates a right and provides a special remedy, that remedy is exclusive." *United States v. Babcock*, 250 U.S. 328, 331 (1919) (citations omitted); *accord Switchmen's Union of N. Am. v. Nat'l Mediation Bd.*, 320 U.S. 297, 301 (1943) (declining judicial review of National Mediation Board decision where "Congress for reasons of its own decided upon the method for the protection of the 'right' which it created," and recognizing that "[a]ll constitutional questions aside, it is for Congress to determine how the rights which it creates shall be enforced").

The Medicare statute creates the right to ALJ hearing and Appeals Council review, 42 U.S.C. § 1395ff but also specifies the "[c]onsequences of failure to meet deadline[s]" at the last three levels of administrative review. 42 U.S.C. §§ 1395ff(d)(3);

1395ff(c)(3)(C)(ii). Again, with respect to ALJ-level appeals, the consequence is that "the party requesting the hearing may request a review by the [ALJ], notwithstanding any requirements for a hearing for purposes of the party's right to such a review." 42 U.S.C. § 1395ff(d)(3)(A). With respect to Appeals Council-level appeals, the consequence is that "the party requesting the hearing may seek judicial review, notwithstanding any requirements for a hearing for purposes of the party's right to such a review." 42 U.S.C. § 1395ff(d)(3)(B). Congress obviously contemplated that there would be cases in which the target timeframes for completing review at these steps of the administrative appeal process would not be met and established the mechanism for dealing with such cases. Escalation to the Appeals Council is therefore the exclusive remedy for ALJ-level appeal delays, and escalation to judicial review is therefore the exclusive remedy for DAB-level appeal delays. *See, e.g.*, *Babcock*, 250 U.S. at 331. The availability of those remedies precludes Plaintiffs' petition for mandamus relief. *See, e.g., id.*

2. Plaintiffs Cannot Show that the Statutory Remedies Are Inadequate.

Plaintiffs' allegation that the Medicare statute's remedies for delayed appeals are not adequate is without merit. First, Congress presumably deemed the escalation provisions adequate when it specified them as the remedies for delay. Second, there is no basis for Plaintiffs' suggestion of a Fifth Amendment due process violation. Plaintiffs contend that the statutory remedies are not constitutionally adequate because they do not allow for hearing and associated fact development. MSJ at 14-18. The Medicare statute effectively gives Plaintiffs and other appellants a choice between an ALJ hearing after the current wait time and escalated review without ALJ hearing. Plaintiffs' contention that this choice is constitutionally inadequate rests on the premise that the Medicare statute

gives them a right to an ALJ hearing and decision within a fixed amount of time. That premise is unfounded for the reasons set forth above. *See supra* at 14–16.

Plaintiffs' assertion that they must forego a hearing if they escalate their claim to the Appeals Council level or to district court is also incorrect. It is well-established that due process is "flexible and calls for such procedural protections as the particular situation demands." *Mathews v. Eldridge*, 424 U.S. 319, 334 (1976). A hearing based on written evidence may be sufficient to satisfy due process where it provides adequate notice and a genuine opportunity to explain one's case. *See Califano v. Yamasaki*, 442 U.S. 682, 695–96 (1979); *Mathews*, 424 U.S. at 344. This is especially true where, as in Medicare payment appeals, the determination typically does not involve questions of credibility and veracity. *See Mathews*, 424 U.S. at 344. Here, Medicare appellants receive an opportunity to present their case with written evidence and argument before they reach the ALJ level. As previously discussed, the QIC performs an "independent, on-the-record review of an initial determination, including the redetermination and all issues related to payment of the claim" and in doing so, "reviews the evidence and findings upon which the [previous determinations] was based, *and any additional evidence the parties submit or that the QIC obtains on its own*." 42 C.F.R. § 405.968(a) (emphasis supplied); *see also id.* § 405.966 (detailing evidence to be submitted when a party files a reconsideration request, including "evidence and allegations of fact or law related to the issue in dispute" and an "expla[nation] why it disagrees with the initial determination, including the redetermination"). For cases escalated from the ALJ-level to the Appeals Council, the Appeals Council can "[c]onduct any additional proceedings, including a hearing, that the MAC determines are necessary to issue a decision." 42

C.F.R. § 405.1108(d)(2); *see also id.* § 405.1112(b) (requiring the request for Appeals Council review to "explain why he or she disagrees with" the decision being appealed). As set forth below, due process does not require more.

Even if the Medicare statute set an absolute 90-day requirement for OMHA and DAB appeals, which it does not, *see supra* at 14–16, Plaintiffs could not establish that the statute's escalation remedies fall short of due process requirements on the ground that they do not provide for an in-person hearing and associated fact development. Because due process is "flexible," determination of what process is due depends on "three distinct factors":

> First, the private interest that will be affected by the official action; second, the risk of an erroneous deprivation of such interest through the procedures used, and the probable value, if any, of additional or substitute procedural safeguards; and finally, the Government's interest, including the function involved and the fiscal and administrative burdens that the additional or substitute procedural requirement would entail.

Mathews, 424 U.S. at 335 (citing *Goldberg v. Kelly*, 397 U.S., 254, 263-271 (1970)). Plaintiffs cannot show that application of the *Mathews* factors indicates that the option of an ALJ hearing or Appeals Council review after the current wait times or escalated review without an in-person hearing fails to satisfy due process requirements.

First, the private interests at issue are the hospitals' interests in contested Medicare payments. Plaintiffs assert that protecting their interests via escalation may be cost-prohibitive in some appeals because of the relatively small amount of money at stake. MSJ at 18. But in such cases Plaintiffs cannot reasonably assert significant harm from delayed administrative review of claims of relatively low value. Moreover, regulations allow for aggregation of appeals that may be of small value individually so long as they meet basic criteria establishing relatedness and collectively meet the amount

in controversy requirement. 42 C.F.R § 405.1006(e). Regardless, in 2013, there were only two escalation requests to federal court from the Appeals Council, Tobias Decl. Ex. 1, DAB Presentation at 17, and the DAB is not aware of an instance where a case escalated from OMHA to the Council has been appealed to federal district court without action by the Council, Tobias Decl. ¶ 7. Plaintiffs also have no basis for suggesting that after escalation the Appeals Council or district court is likely to remand the appeal to the prior level for additional fact development. MSJ at 16–18.

As to the second *Mathews* factor, risk of erroneous deprivation in an escalated claim that is resolved on a paper record is mitigated by the previous administrative review that the hospitals have had before they are eligible for ALJ-level review and DAB-level review. *See supra* at 3–4 (discussing MAC redeterminations and QIC reconsiderations); *see also* 42 C.F.R. §§ 405.940-978 (detailing processes for redeterminations and reconsiderations). Plaintiffs unfairly criticize the quality of lower-level administrative review. They incorrectly assert that the ALJ is the "first independent adjudicator in the appeals process." MSJ at 15. To the contrary, the QIC (the adjudicator at the previous level of review), which is a separate entity with no relation to the MAC that rendered the initial decision on a claim, is required to conduct an independent determination of the claim. *See* 42 U.S.C. § 1395ff(c); 42 C.F.R. § 405.968(a). Plaintiffs' assertion that hospitals are most likely to succeed in their appeals at the ALJ level, MSJ at 15, does not undercut the quality of lower-level review. As sophisticated businesses, it is to be expected that hospitals will choose to pursue claims on which they are more likely to succeed to the upper levels of administrative review, and that they will elect not to pursue claims on which they are unlikely to prevail beyond the lower levels

of review. Regarding the third *Mathews* factor, the Secretary's interests are in maintaining OMHA's and the Appeals Council's ability to give appropriate consideration to each administrative appeal so they may render legally sufficient decisions, and in prioritizing beneficiary appeals at the ALJ and DAB levels in the face of the unprecedented number of Medicare payment appeals before it and HHS's resource constraints.

Absent an absolute statutory deadline, administrative delay in holding a hearing and reaching a decision should not amount to a due process violation where the agency is operating in good faith and the delay is attributable to circumstances largely outside the agency's control. *See Givens v. United States R.R. Retirement Bd.*, 720 F.2d 196, 201 (D.C. Cir. 1983) (citing *Frock v. United States R.R. Retirement Bd.*, 685 F.2d 1041, 1047 n.13 (7th Cir. 1982)); *accord, e.g.*, *Silverman v. Barry*, 845 F.2d 1072, 1084 (D.C. Cir. 1988); *Wright v. Califano*, 587 F.2d 345, 356 (7th Cir. 1978). Plaintiffs do not allege bad faith, nor is there any evidence that the Secretary, OMHA, or Appeals Council are acting other than in good faith to address constraints largely beyond their control. The Court should not "ignore the practical constraints" that HHS faces. *Silverman*, 845 F.2d at 1084 (citing *Wright*, 587 F.2d at 356). Plaintiffs' assertion that HHS should shift resources from other programs to address their appeals is inappropriate, as previously discussed. *See supra* at 22. Under these circumstances, the current delays in ALJ hearings cannot be characterized as so unreasonable as to violate due process. *See Givens*, 720 F.2d at 201. *Contrast In re People's Mojahedin Org. of Iran*, 680 F.3d 832 (D.C. Cir. 2012) (Secretary of State's delay in issuing ruling on petition to revoke foreign terrorist organization designation was unreasonable where it had been pending nearly nine years, including two

years since Circuit remanded matter to Secretary) (cited in MSJ at 19–20); *In re Am. Rivers and Idaho Rivers United*, 372 F.3d 413 (D.C. Cir. 2004) (over six-year delay in responding to petition to formally consult under Endangered Species Act with National Marine Fisheries Service of the National Oceanic and Atmospheric Administration was unreasonable where statute contemplated consultation within 90 days in usual cases) (cited in MSJ at 21).

The Seventh Circuit's observation in *Wright v. Califano* is instructive:

> [I]n the name of due process as a flexible standard, we are not justified in sanctioning the imposition of unrealistic and arbitrary time limitations on an agency which for good faith and unarbitrary reasons has amply demonstrated its present inability to comply.

Wright, 587 F.2d at 356. A similar conclusion is warranted here.

In sum, the Medicare statute provides an adequate exclusive remedy for Medicare claimants that do not receive an ALJ hearing and decision within 90 days or an Appeals Council decision within 90 days.[13] Plaintiffs therefore cannot establish the third criterion for mandamus jurisdiction.

[13] In addition, Plaintiffs may be in a position to avail themselves of one of the three alternative options for claim resolution offered by OMHA and CMS. *See supra* at 10 and n.9 (discussing adjudication using statistical sampling and extrapolation, alternative dispute resolution, and global settlement discussions involving similarly-situated claimants).

CONCLUSION

For the foregoing reasons, the Court should dismiss the Complaint for lack of jurisdiction and deny Plaintiffs' Motion for Summary Judgment.

Respectfully submitted this 11th day of September, 2014.

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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

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-cv-00851 (JEB)

DEFENDANT'S RESPONSE TO PLAINTIFFS' STATEMENT OF UNDISPUTED MATERIAL FACTS IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

In accordance with Local Rule 7(h)(1), Defendant hereby responds to Plaintiffs' Statement of Undisputed Material Facts in Support of Plaintiffs' Motion for Summary Judgment, ECF No. 8.

Plaintiffs' Statement 1:

The Medicare program was enacted in 1965 under Title XVIII of the Social Security Act to provide health insurance primarily to individuals sixty-five years of age and older. *See* Social Security Amendments of 1965, Pub. L. No. 89-97, 79 Stat. 286 (1965) (codified as amended at 42 U.S.C. §§ 1395-1396v).

Defendant's Response to Plaintiffs' Statement 1:

Undisputed but immaterial.

[1] Pursuant to Fed. R. Civ. P. 25(d), Sylvia M. Burwell, the current Secretary of Health and Human Services is automatically substituted as the named defendant for Kathleen Sebelius, the former Secretary of Health and Human Services.

Plaintiffs' Statement 2:

The program's main objective is to ensure that its beneficiaries have access to health care services. *Id*.

Defendant's Response to Plaintiffs' Statement 2:

Undisputed.

Plaintiffs' Statement 3:

The Plaintiff hospitals qualify as "providers of services" under Title XVIII, also known as the Medicare Act. See 42 U.S.C. § 1395x(u).

Defendant's Response to Plaintiffs' Statement 3:

Undisputed.

Plaintiffs' Statement 4:

When hospitals furnish services to a Medicare beneficiary, they thereafter submit a claim for reimbursement to a Medicare Administrative Contractor ("MAC") that conducts the initial review of the claim. 42 U.S.C. § 1395ff(a)(2)(A).

Defendant's Response to Plaintiffs' Statement 4:

Undisputed.

Plaintiffs' Statement 5:

MACs are government contractors responsible for processing Medicare claims and making payments to hospitals, doctors, and others that furnish medical care to Medicare beneficiaries. 42 U.S.C. § 1395kk-1(a)(3).

Defendant's Response to Plaintiffs' Statement 5:

Undisputed.

Plaintiffs' Statement 6:

MACs review a hospital's claim for reimbursement and either pay the claim or deny it. *See id*. § 1395kk-1(a)(4).

Defendant's Response to Plaintiffs' Statement 6:

Disputed to the extent the statement suggests that MACs review a hospital's claim for reimbursement and either pay the claim in full or deny the claim in full; MACs may pay the claim in part and issue a partial denial determination. *See* 42 C.F.R. § 405.921(b)(2)(i).

Plaintiffs' Statement 7:

Some claims initially paid by MACs are then subjected to an additional level of oversight. In a process known as "post-payment review," third-party contractors, including Medicare Recovery Audit Contractors ("RACs"), audit MAC payment decisions. *See* 42 U.S.C. § 1395ddd(h)(1).

Defendant's Response to Plaintiffs' Statement 7:

Undisputed.

Plaintiffs' Statement 8:

RACs are paid based on the amount of Medicare reimbursement they recover for alleged overpayments. *Id*. § 1395ddd(h)(1).

Defendant's Response to Plaintiffs' Statement 8:

Disputed to the extent the statement suggests that RACs are paid based on "alleged" overpayments; a RAC is paid on a contingent basis only from Medicare overpayments that are recovered, and it is also paid when it identifies and effectuates reimbursement for underpayments." *See* 42 U.S.C. § 1395ddd(h)(1).

Plaintiffs' Statement 9:

RACs can audit hospital claims paid by MACs dating back three years. *See* Statement of Work for the Medicare Fee-for-Service Recovery Audit Program, at 9, *available at* https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/recovery-audit-program/downloads/090111RACFinSOW.pdf (last visited Jul. 11, 2014).

Defendant's Response to Plaintiffs' Statement 9:

Undisputed.

Plaintiffs' Statement 10:

When a hospital's claim for reimbursement under Medicare is denied (by a MAC, RAC, or otherwise), the hospital has a right to file an administrative appeal under the Medicare Act. 42 U.S.C. § 1395ff(b)(1)(A).

Defendant's Response to Plaintiffs' Statement 10:

Disputed with respect to claims for reimbursement that do not satisfy the minimum amount in controversy. *See* 42 U.S.C. § 1395ff(b)(1)(E). Otherwise undisputed.

Plaintiffs' Statement 11:

Appeals of both pre- and post-payment claim denials are subject to an administrative process set forth by statute. *Id.* § 1395ff.

Defendant's Response to Plaintiffs' Statement 11:

Undisputed that an administrative review process is available for appeals of claim denials, including post-payment claim denials; otherwise disputed. *See* 42 U.S.C. § 1395ff.

Plaintiffs' Statement 12:

When a hospital's claim for reimbursement under Medicare is denied by a MAC, or in post-payment review by a RAC or other contractor, the first step in the administrative appeals process is for the hospital to present the denied claim to the MAC again for redetermination. *Id.* § 1395ff(a)(3)(A).

Defendant's Response to Plaintiffs' Statement 12:

Undisputed.

Plaintiffs' Statement 13:

The MAC must render a redetermination decision within sixty days. *Id.* § 1395ff(a)(3)(C)(ii).

Defendant's Response to Plaintiffs' Statement 13:

This statement constitutes a legal conclusion, not a statement of fact and thus violates Local Rule 7(h)(1).

Plaintiffs' Statement 14:

This first step of the process is overseen by the Centers for Medicare & Medicaid Services ("CMS") within the Department of Health and Human Services ("HHS").

Defendant's Response to Plaintiffs' Statement 14:

This statement constitutes a legal conclusion, not a statement of fact and thus violates Local Rule 7(h)(1).

Plaintiffs' Statement 15:

If unsatisfied with the MAC's redetermination, a hospital can appeal the MAC's decision to a Qualified Independent Contractor ("QIC") for reconsideration. *Id*. § 1395ff(c).

Defendant's Response to Plaintiffs' Statement 15:

Undisputed.

Plaintiffs' Statement 16:

QICs must render a decision within sixty days. *Id*. § 1395ff(c)(3)(C)(i).

Defendant's Response to Plaintiffs' Statement 16:

This statement constitutes a legal conclusion, not a statement of fact and thus violates Local Rule 7(h)(1).

Plaintiffs' Statement 17:

This second step of the process is overseen by CMS.

Defendant's Response to Plaintiffs' Statement 17:

This statement constitutes a legal conclusion, not a statement of fact and thus violates Local Rule 7(h)(1).

Plaintiffs' Statement 18:

A hospital may next request a hearing before an ALJ. *Id.* §§ 1395ff(b)(1)(E), 1395ff(d)(1)(A).

Defendant's Response to Plaintiffs' Statement 18:

Undisputed except to clarify that the hospital must satisfy the minimum amount in controversy. *See* 42 U.S.C. §1395ff(b)(1)(E);42 CFR § 405.1002(a)(2)

Plaintiffs' Statement 19:

The ALJ is required both to hold a hearing and render a decision within ninety days. 42 U.S.C. § 1395ff(d)(1)(A); 42 C.F.R. § 405.1016(a).

Defendant's Response to Plaintiffs' Statement 19:

This statement constitutes a legal conclusion, not a statement of fact and thus violates Local Rule 7(h)(1).

Plaintiffs' Statement 20:

This third step of the process is overseen by HHS's Office of Medicare Hearings and Appeals ("OMHA").

Defendant's Response to Plaintiffs' Statement 20:

This statement constitutes a legal conclusion, not a statement of fact and thus violates Local Rule 7(h)(1).

Plaintiffs' Statement 21:

ALJs are independent adjudicators. *See* Medicare Modernization Act of 2003, Pub. L. No. 108-173, § 931(b)(2), 117 Stat. 2066, 2398 (2003) ("The Secretary shall assure the independence of administrative law judges . . . . In order to assure such independence, the Secretary shall place such judges in an administrative office that is organizationally and functionally separate from [CMS].").

Defendant's Response to Plaintiffs' Statement 21:

This statement constitutes a legal conclusion, not a statement of fact and thus violates Local Rule 7(h)(1).

Plaintiffs' Statement 22:

Next, a hospital can appeal its claim to the Departmental Appeals Board ("DAB") within HHS. 42 U.S.C. § 1395ff(d)(2); 42 C.F.R. § 405.1108(a).

Defendant's Response to Plaintiffs' Statement 22:

Undisputed.

Plaintiffs' Statement 23:

The DAB conducts a de novo review of the ALJ decision and either renders its own decision or remands to the ALJ for further proceedings. *Id.*

Defendant's Response to Plaintiffs' Statement 23:

This statement constitutes a legal conclusion, not a statement of fact and thus violates Local Rule 7(h)(1).

Plaintiffs' Statement 24:

In either event, the DAB must act within ninety days. *Id*.

Defendant's Response to Plaintiffs' Statement 24:

This statement constitutes a legal conclusion, not a statement of fact and thus violates Local Rule 7(h)(1).

Plaintiffs' Statement 25:

The Medicare Act also provides for a process by which the QIC, ALJ, and DAB levels of review may be bypassed, known in the regulations as "escalation."

Defendant's Response to Plaintiffs' Statement 23:

Undisputed.

Plaintiffs' Statement 26:

Specifically, if the QIC is unable to complete its review within sixty days, it must notify all parties that it cannot complete the reconsideration within the statutory timeframe and offer the hospital the opportunity to "escalate" the appeal to an ALJ. 42 U.S.C. § 1395ff(c)(3)(C)(ii); 42 C.F.R. § 405.970.

Defendant's Response to Plaintiffs' Statement 26:

Undisputed.

Plaintiffs' Statement 27:

The QIC will continue the reconsideration process unless and until the hospital files a written escalation request. 42 C.F.R. § 405.970(c)(2).

Defendant's Response to Plaintiffs' Statement 27:

Undisputed.

Plaintiffs' Statement 28:

Similarly, if an ALJ has not held a hearing and rendered a decision within ninety days, a hospital may bypass the ALJ level by escalating its claim to the DAB. 42 U.S.C. § 1395ff(d)(3)(A).

Defendant's Response to Plaintiffs' Statement 28:

Undisputed.

Plaintiffs' Statement 29:

In such situations, the QIC's decision becomes the decision subject to DAB review. 42 C.F.R. § 405.1104; 42 C.F.R. § 405.1108(d).

Defendant's Response to Plaintiffs' Statement 29:

Undisputed.

Plaintiffs' Statement 30:

If a hospital escalates from the ALJ level after having previously escalated from the QIC level, only the record from the MAC is available for consideration by the DAB.

Defendant's Response to Plaintiffs' Statement 30:

Disputed insofar as the statement does not take into account that evidence may be entered into the record at the QIC and ALJ levels, which may be considered by the DAB, or the DAB's discretion to conduct a hearing or to consider other evidence or written statements filed by parties requesting review. *See* 42 C.F.R. §§ 405.966, 405.1018, 405. 1120, 405.1122(b), 405.1124.

Plaintiffs' Statement 31:

The DAB may conduct additional proceedings, including a hearing, but is not required to do so. 42 C.F.R. § 405.1108.

Defendant's Response to Plaintiffs' Statement 31:

Undisputed.

Plaintiffs' Statement 32:

Judge Constance B. Tobias, Chair of the DAB, has stated that, in escalation situations, the DAB will "NOT hold a hearing or conduct oral argument unless there is an extraordinary question of law/policy/fact." Ex. 2 (OMHA "Medicare Appellant Forum" Presentation dated Feb. 12, 2014) ("OMHA Forum Presentation") at 117.

Defendant's Response to Plaintiffs' Statement 32:

Undisputed.

Plaintiffs' Statement 33:

The DAB has 180 days in which to act on an escalation request, rather than the ninety days it has to act on direct appeals. 42 C.F.R. § 405.1100(c)-(d).

Defendant's Response to Plaintiffs' Statement 33:

This statement constitutes a legal conclusion, not a statement of fact and thus violates Local Rule 7(h)(1).

Plaintiffs' Statement 34:

If the DAB has not rendered a decision within ninety days on its review of an ALJ's decision, a hospital may bypass the DAB and seek judicial review in federal court. 42 U.S.C. § 1395ff(d)(3)(B); 42 C.F.R. § 405.1132.

Defendant's Response to Plaintiffs' Statement 34:

Undisputed except to recognize that an appellant must complete the steps described in 42 C.F.R. § 405.1132 and meet the minimum amount in controversy before seeking judicial review. *See* 42 C.F.R. §§ 405.1132., 405.1136(a)

Plaintiffs' Statement 35

A hospital may file an action in federal district court if the DAB notifies it that no decision will be issued and if the claim meets an amount-in-controversy requirement (currently $1,430). 42 C.F.R. § 405.1132(b); 42 C.F.R. § 405.1006(c); Notice of Adjustment to the Amount in Controversy Threshold Amounts for Calendar Year 2014, 78 Fed. Reg. 59702-03 (Sept. 27, 2013).

Defendant's Response to Plaintiffs' Statement 35:

Undisputed.

Plaintiffs' Statement 36.

In cases of an initial escalation past the ALJ level, a hospital may escalate the appeal to federal court if the DAB fails to render a decision within 180 days. 42 C.F.R. § 405.1132; 42 C.F.R. § 405.1100(d).

Defendant's Response to Plaintiffs' Statement 36:

Undisputed.

Plaintiffs' Statement 37:

In the event of "double escalation" past both the ALJ and the DAB levels, the only agency decision available to the federal court for review is the QIC's decision, made without a hearing.

Defendant's Response to Plaintiffs' Statement 37:

Disputed to the extent the statement suggests that such "double escalations" have occurred to date; otherwise undisputed. *See* Tobias Decl. ¶ 7.

Plaintiffs' Statement 38:

In the event of a "triple escalation" past the QIC, the ALJ, and the DAB, only the MAC record is available for review.

Defendant's Response to Plaintiffs' Statement 38:

Disputed to the extent the statement suggests that such "triple escalations" have occurred to date and does not take into account that evidence may be entered into the record at the QIC and ALJ levels, which may be considered by the DAB, or the DAB's discretion to conduct a hearing or to consider other evidence or written statements filed by parties

requesting review. *See* 42 C.F.R. §§ 405.966, 405.1018, 405. 1120, 405.1122(b), 405.1124; Tobias Decl. ¶ 7.

Plaintiffs' Statement 39.

The statutory time periods governing the appeals process provide for all levels of administrative review to be completed within a total of about one year. *See* 42 U.S.C. § 1395ff.

Defendant's Response to Plaintiffs' Statement 39:

This statement constitutes a legal conclusion, not a statement of fact and thus violates Local Rule 7(h)(1).

Plaintiffs' Statement 40:

Increases in the rates of appeal have caused a significant backlog at the ALJ level of the appeals process. *See* Ex. 4 (OMHA Important Notice Regarding Adjudication Timeframes) ("Important Notice").

Defendant's Response to Plaintiffs' Statement 40:

Undisputed.

Plaintiffs' Statement 41:

These increases are due in part to providers challenging RACs' claim denials. See Ex. 2 (OMHA Forum Presentation) at 17.

Defendant's Response to Plaintiffs' Statement 41:

Undisputed.

Plaintiffs' Statement 42:

In just two years (2012 and 2013), the backlog of ALJ-level appeals quintupled, growing from 92,000 to 460,000 pending claims. Ex. 3 (Mem. from Nancy J. Griswold to OMHA Medicare Appellants dated Dec. 24, 2013) ("Griswold Memorandum").

Defendant's Response to Plaintiffs' Statement 42:

Undisputed.

Plaintiffs' Statement 43:

The workload of OMHA's sixty-five ALJs increased by almost 300 % percent from fiscal year 2012 to fiscal year 2013. *See* Ex. 2 (OMHA Forum Presentation) at 16.

Defendant's Response to Plaintiffs' Statement 43:

Undisputed.

Plaintiffs' Statement 44:

In fiscal year 2013, of the 384,151 appeals that were filed, only 79,303 were decided. *See* Ex. 2 (OMHA Forum Presentation) at 12 (reflecting decision figures); see Ex. 4 (Important Notice) (reflecting adjusted appeals receipts figures).

Defendant's Response to Plaintiffs' Statement 44:

Undisputed that OMHA decided 79,303 appeals in fiscal year 2013; otherwise disputed. *See* Plaintiffs' Ex. 2 (OMHA Forum Presentation at 14); Plaintiffs' Ex. 4 (OMHA Adjudication Timeframes).

Plaintiffs' Statement 45:

As of December 2013, it was taking an average of sixteen months before an ALJ heard a case – approximately thirteen months longer than the ninety-day statutory deadline for an ALJ decision. See Ex. 2 (OMHA Forum Presentation) at 11; Ex. 3 (Griswold Memorandum).

Defendant's Response to Plaintiffs' Statement 45:

Undisputed that as of December 2013, it was taking an average of sixteen months before an ALJ heard a case; otherwise this statement constitutes a legal conclusion, not a statement of fact and thus violates Local Rule 7(h)(1).

Plaintiffs' Statement 46:

As of June 2014, the average processing time for appeals was 463.9 days. Ex. 4 (Important Notice).

Defendant's Response to Plaintiffs' Statement 46:

Disputed; as of June 2014, for appeals decided in fiscal year 2014, the average number of days from the date of the ALJ hearing request until the date of the ALJ's issuance of a decision was 387.2 days. Plaintiffs' Ex. 4 (OMHA Adjudication Timeframes).

Plaintiffs' Statement 47:

On December 24, 2013, HHS announced through OMHA's Chief ALJ, Nancy Griswold, that HHS had suspended the assignment of all new appeals to ALJs (other than those by Medicare beneficiaries) as of July 15, 2013. Ex. 3 (Griswold Memorandum).

Defendant's Response to Plaintiffs' Statement 47:

Undisputed.

Plaintiffs' Statement 48:

The moratorium is expected to last for a minimum of two years. [Ex. 3, Griswold Memorandum].

Defendant's Response to Plaintiffs' Statement 48:

Disputed insofar as Plaintiffs characterize the suspension as a "moratorium." *See* Plaintiffs' Ex. 3 (Griswold Memorandum). Undisputed that OMHA, as of December 24, 2013, did not expect general assignments of non-beneficiary appeals to resume for at least 24 months; otherwise disputed. *See* Plaintiffs' Ex. 3. OMHA is now assigning a limited number of non-beneficiary appeals received between April and June 2013. *See* Plaintiffs' Ex. 4; *see also* http://www.hhs.gov/omha/important_notice_regarding_adjudication_timeframes.html#adjudication. .

Plaintiffs' Statement 49:

Additional post-assignment hearing wait times are expected to exceed six months when the suspension is eventually lifted. *Id*. [Ex. 3, Griswold Memorandum]

Defendant's Response to Plaintiffs' Statement 49:

Undisputed that OMHA expects that post-assignment hearing wait times will continue to exceed six months; otherwise disputed. *See* Plaintiffs' Ex. 3.

Plaintiffs' Statement 50:

As recently as February 14, 2014, Judge Griswold stated that the wait times for a hearing before an ALJ are "unacceptable." Ex. 6 (Michelle M. Stein, ALJs Lay Out Path Forward For Stakeholders As Appeals Backlog Continues, Inside Health Policy, Feb. 20, 2014).

Defendant's Response to Plaintiffs' Statement 50:

Undisputed.

Plaintiffs' Statement 51:

OMHA has received from 10,000 to 16,000 ALJ appeals per week in fiscal year 2014. Ex. 7 (Statement of N. Griswold before the U.S. House Committee on Oversight and Government Reform, Subcommittee on Energy Policy, Health Care & Entitlements on July 10, 2014) ("Griswold Statement") at 4.

Defendant's Response to Plaintiffs' Statement

Undisputed.

Plaintiffs' Statement 52:

OMHA has stated that it projects a twenty to twenty-four week delay in docketing new appeals. Ex. 4 (Important Notice).

Defendant's Response to Plaintiffs' Statement 52:

Undisputed.

Plaintiffs' Statement 53:

As of July 1, 2014, 800,000 appeals were pending at the ALJ level. Ex. 7 (Griswold Statement) at 4.

Defendant's Response to Plaintiffs' Statement 53:

Undisputed that OMHA had over 800,000 appeals pending on July 1, 2014; otherwise disputed. Plaintiffs' Ex. 7 at 4.

Plaintiffs' Statement 54:

Plaintiff Baxter currently has appeals pending at the ALJ level that have been pending longer than ninety days.

Defendant's Response to Plaintiffs' Statement 54:

Undisputed.

Plaintiffs' Statement 55:

Plaintiff Baxter currently has appeals pending at the ALJ level that are subject to the moratorium imposed as of July 15, 2013.

Defendant's Response to Plaintiffs' Statement 55:

Disputed insofar as Plaintiffs characterize the suspension in ALJ assignments as a "moratorium." *See* Plaintiffs' Ex. 3

Plaintiffs' Statement 56

Plaintiff Covenant currently has appeals pending at the ALJ level that have been pending longer than ninety days.

Defendant's Response to Plaintiffs' Statement56:

Undisputed.

Plaintiffs' Statement 57:

Plaintiff Covenant currently has appeals pending at the ALJ level that are subject to the moratorium imposed as of July 15, 2013.

Defendant's Response to Plaintiffs' Statement 57:

Disputed insofar as Plaintiffs characterize the suspension in ALJ assignments as a "moratorium." *See* Plaintiffs' Ex. 3.

Plaintiffs' Statement 58:

Plaintiff Rutland currently has appeals pending at the ALJ level that have been pending longer than ninety days.

Defendant's Response to Plaintiffs' Statement 58:

Undisputed.

Plaintiffs' Statement 59:

Plaintiff Rutland currently has appeals pending at the ALJ level that are subject to the moratorium imposed as of July 15, 2013.

Defendant's Response to Plaintiffs' Statement 59:

Disputed insofar as Plaintiffs characterize the deferral in ALJ assignments as a "moratorium." *See* Plaintiffs' Ex. 3.

Plaintiffs' Statement 60:

HHS's suspension in assignment of appeals to ALJs does not alter the requirement that a hospital appeal an unfavorable QIC decision within sixty days. *See* 42 U.S.C. § 1395ff(b)(1)(D)(ii); 42 C.F.R. § 405.1014(b)(1).

Defendant's Response to Plaintiffs' Statement 60:

This statement constitutes a legal conclusion, not a statement of fact, and is immaterial, and thus violates Local Rule 7(h)(1).

Plaintiffs' Statement 61:

At the end of fiscal year 2013, the DAB had 5,108 pending appeals, 112% more than it had at the end of fiscal year 2012. Ex. 2 (OMHA Forum Presentation) at 106.

Defendant's Response to Plaintiffs' Statement 61:

Disputed; since February, with the additional processing of FY 2013 appeals, the size of the DAB case backlog at the end of FY 2013 was 5,108 cases. Tobias Decl. ¶ 3.

Plaintiffs' Statement 62:

There are four Appeals Officers responsible for DAB review of Medicare entitlement, managed care, prescription drug claims, and fee-for-service payment denials.

Defendant's Response to Plaintiffs' Statement 62:

Disputed. In addition to the DAB's four Administrative Appeals Judges (AAJs), members of the Board also act as AAJs to issue decisions. In addition, the DAB has

designated two senior attorney advisers Appeals Officers to assist with cases appropriate for disposition on procedural grounds. Tobias Decl. ¶ 2.

Plaintiffs' Statement 63:

HHS projects that 7,000 DAB appeals will be received in fiscal year 2014. *Id*. [Ex. 2 (OMHA Forum Presentation)] at 107.

Defendant's Response to Plaintiffs' Statement 63:

Disputed. Current projections for fiscal year 2014 are between 4,000 and 5,000 appeals. Tobias Dec. ¶ 3.

Plaintiffs' Statement 64:

That number is expected to rise to over 8,000 for fiscal year 2015. *Id*. [Ex. 2 (OMHA Forum Presentation)]

Defendant's Response to Plaintiffs' Statement 64:

Undisputed except to clarify that that number was expected to rise to over 8,000 in fiscal year in 2015 during the first quarter of fiscal year 2014 but was not expected to rise to that level following the third quarter of fiscal year 2014. *See* Tobias Decl. ¶ 3.

Plaintiffs' Statement 65:

As with the ALJs, the DAB is seeing an increased caseload due to the behavior of the RACs and other Medicare contractors. *Id*. [Ex. 2 (OMHA Forum Presentation)] at 108.

Defendant's Response to Plaintiffs' Statement 65:

Undisputed that the DAB is seeing an increased caseload primarily due to additional appeals from audits conducted under the recently expanded RAC Program, *see* Tobias Decl.; otherwise disputed, including Plaintiffs' suggestion that RACs behave other than in furtherance of their Congressional mandate to identify and correct improper Medicare payments, s*ee* 42 U.S.C. 1395ddd(h), *see generally Palomar Med. Ctr. v. Sebelius*, 693 F.3d 1151, 1156–57 (9th Cir. 2012), or that other Medicare contractors behave other than in furtherance of their Congressional mandate to apply Medicare rules and requirements to claims, *see* 42 U.S.C. § 1395ff(a)-(c).

Plaintiffs' Statement 66:

HHS has stated that the DAB is "unlikely to meet the ninety-day deadline for issuing decisions in most appeals." [Ex. 2, OMHA Forum Presentation] at 110 .

Defendant's Response to Plaintiffs' Statement 66:

Undisputed**.**

Respectfully submitted this 11th day of September, 2014.

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