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 REPLY IN SUPPORT OF HER MOTION TO DISMISS FOR LACK OF JURISDICTION

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[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.

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INTRODUCTION

Plaintiffs' burden to establish jurisdiction under the Mandamus Act is high. The Court cannot exercise subject matter jurisdiction over this action unless Plaintiffs establish a clear right to relief, a clear duty that Defendant Secretary of Health and Human Services, Sylvia M. Burwell, has breached, and lack of an adequate remedy. Plaintiffs' Response in Opposition to Defendant's Motion to Dismiss and Reply in Further Support of Plaintiffs' Motion for Summary Judgment (ECF No. 14 Oct. 2, 2014) ("Opposition"), like their opening memorandum, falls far short of meeting their burden. The Opposition relies heavily on unjustified accusations that the Secretary is unconcerned about the current backlog in administrative appeals before the Office of Medicare Hearings and Appeals ("OMHA") and Departmental Appeals Board ("DAB") and has authority to increase funding for adjudication of those appeals that she is not exercising, as well as extensive criticism of the Recovery Audit ("RAC") Program. None of those assertions satisfies Plaintiffs' burden of establishing the necessary requirements for the Court to exercise mandamus jurisdiction.

Nor do Plaintiffs' arguments specific to the criteria for mandamus jurisdiction demonstrate that they have met their high burden. Plaintiffs, as well as the *Amicus Curiae* Brief by the Fund for Access to Inpatient Rehabilitation (ECF No. 18 Oct. 3, 2014) ("Amicus Brief"), emphasize the general rule that a statute's use of "shall" makes its direction mandatory. Their argument fails to account for the exception to the general rule that may apply where, as here, a statute's use of "shall" is followed by a specified remedy for when the statutory direction is not satisfied. When Administrative Law Judge- ("ALJ") and DAB-level appeals are not resolved within 90 days, the Medicare

statute specifies—in the *same* sub-section that provides the 90-day timeframe—the remedy: escalation to the next level of review. The statute therefore should be construed as directory rather than mandatory under canons of statutory construction. Indeed, the D.C. Circuit recently recognized that a statute's use of "shall" is directory and not mandatory when the statute prescribes the consequence if the directive is not followed. *See Halbig v. Burwell*, 758 F.3d 390, 399 (D.C. Cir. 2014), *rehearing en banc granted and judgment vacated*, No. 14-5018 (D.C. Cir. Sept. 4, 2014).[2] Plaintiffs therefore cannot establish a "clear" right to the relief they seek in the form of a writ of mandamus to compel the Secretary to resolve ALJ and DAB level appeals within 90 days or that the Secretary has a "clear" duty to ensure resolution of those appeals within 90 days.

Nor do Plaintiffs or Amicus establish that the statutory remedy of escalation is inadequate. The Medicare statute gives claimants the opportunity to present any written evidence in support of their appeal, and the paper hearing based on that evidence that is available for escalated appeals comports fully with due process. While, as Plaintiffs and Amicus emphasize, the rate of reversal of claims denials is higher at the ALJ level than at lower levels of administrative review, those statistics do not demonstrate that decisions at higher levels of review to which delayed appeals can be escalated (the DAB and federal court) are flawed or otherwise incorrect. And while there is also a backlog at the DAB, DAB review is the remedy that Congress provided for delays at the ALJ level, and presumably Congress deemed it adequate.[3] There is no basis for judicial intervention.

[2] In *Halbig*, it is uncontroversial that the statute is not mandatory. *See Halbig*, 758 F.3d at 399.

[3] 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);

The Secretary is fully cognizant of the scope of the problem of the Medicare claims denial appeals backlog. By no means does she dismiss the issue as not serious or not in need of urgent attention, as Plaintiffs repeatedly charge. To the contrary, she has worked with OMHA, the DAB, and Congress to try to reduce and ultimately eliminate the backlog. The Secretary emphasizes, however, that it is the province of the political branches to deal with tight budgetary constraints and how those constraints impact the vastly increased administrative appeals workload, rather than the Judiciary. HHS is diligently working on the problem and putting in place measures to alleviate it, under active congressional oversight. But without increased funding to augment OMHA's and DAB's resources, chiefly the number of trained adjudicators, the backlog is not likely to be completely eliminated. Contrary to Plaintiffs' and Amicus's assertions, the Secretary cannot secure the necessary additional funding through existing authorities. Only Congress has the power to appropriate the funds that would be necessary to put in place the additional OMHA and DAB staff required to adjudicate the claims that would eliminate the appeal delays. That the backlog of Medicare appeals is a problem for the political branches to solve is not a "misplaced policy argument" as Plaintiffs assert. Opp'n at 4. It is consistent with the fact that the matter falls outside of the "strictly confined" scope of jurisdiction under the Mandamus Act. *In re Cheney*, 406 F.3d 723, 729 (D.C. Cir. 2005) (en banc).

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42 C.F.R. §§ 405.904(a)(2), 405.1100, 405.1130. 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. 42 U.S.C. § 1395ff(d)(3)(B); 42 C.F.R. § 405.1132.

Because Plaintiffs have not met their burden of establishing grounds for the Court to exercise mandamus jurisdiction, the Court should dismiss this action pursuant to Rule 12(b)(1) of the Federal Rules of Civil Procedure.

ARGUMENT

I. The 90-Day Timeframe for ALJ and DAB Decisions is Directory Not Mandatory.

The Secretary's opening brief explains that because the Medicare statute's escalation provision anticipates that not all OMHA and DAB appeals will be decided within 90 days, the statute should be construed as directory, viz., that it directs the Department of Health and Human Services ("HHS") to resolve appeals within 90 days without mandating a 90-day deadline. Def.'s Points and Authorities in Supp. of Her Mot. to Dismiss for Lack of Jurisdiction and in Opp'n to Pls.' Mot. for Summ. J. ("Def.'s Opening Mem.") at 15–17. In arguing that the 90-day deadline is absolute, Plaintiffs emphasize the general rule that a statute's use of the word "shall" indicates that its provision is mandatory. Opp'n at 6–7. To be sure, "[t]raditionally the use of the word 'shall' indicates a mandatory nondiscretionary duty." *Ute Indian Tribe v. Hodel*, 673 F. Supp. 619, 621 (D.D.C. 1987) (*citing Planned Parenthood Fed'n of Am., Inc. v. Heckler*, 712 F.2d 650, 656 (D.C. Cir. 1983)). "A court, however, may always investigate beyond 'ritualistic incantation' of this standard rule." *Id.* (citing *FBI v. Abramson*, 456 U.S. 615, 625 n.7 (1982); *Planned Parenthood*, 712 F.2d at 657 n.32).

The D.C. Circuit recently found reason to depart from the standard rule that "shall means must" based on statutory provisions similar to those at issue here. *Halbig v. Burwell* involved an Affordable Care Act ("ACA") provision, 42 U.S.C. § 18031(b)(1), that "[e]ach State shall, not later than January 1, 2014, establish an American Health

Benefit Exchange . . . for the State" that meets certain requirements. *Halbig*, 758 F.3d 394. The ACA also incorporates a provision titled "Failure to establish Exchange or implement requirements," which specifies the consequences if a State does not establish an Exchange. 42 U.S.C. § 18041(c). Under that provision, if a State does not establish an Exchange consistent with federal requirements, then "the Secretary shall . . . establish and operate such Exchange within the State and the Secretary shall take such actions as are necessary to implement such other requirements." 42 U.S.C. § 18041(c)(1)(B)(ii)(II). The D.C. Circuit recognized, and the parties agreed, that in light of the statutory provision for instances where a State does not establish an Exchange, section 18031(b)(1)'s use of "shall" does not make its direction mandatory:

> Section 1311 [42 U.S.C. § 18031(b)(1)] provides that states "shall" establish Exchanges. But, as the parties agree, despite its seemingly mandatory language, section 1311 more cajoles than commands. A state is not literally required to establish an Exchange; the ACA merely encourages it to do so. And if a state elects not to (or is unable to), such that it "will not have any required Exchange operational by January 1, 2014," section 1321 [42 U.S.C. § 18041(c)(1)] directs the federal government, through the Secretary of Health and Human Services, to "establish and operate *such Exchange* within the State."

Halbig, 758 F.3d at 399 (emphasis in original).

Plaintiffs' Opposition fails to grapple with this exception to the "shall means must" general rule. The Secretary's opening memorandum cites the *Sutherland* treatise's recognition of that exception, Def.'s Opening Mem. at 16, yet Plaintiffs' Opposition does not address the exception at all. Again, *Sutherland* observes that "the stated consequences of noncompliance may compel a directory construction—for example, where a statute prescribes a remedial course that may be followed if the primary direction was not obeyed." 3 *Sutherland Statutes and Statutory Construction* § 57:8 (7th ed.

2013). The scenario described in the *Sutherland* treatise is precisely the scenario presented here, as well as in *Halbig*. The Medicare provision specifies escalation as the remedy for noncompliance with the direction that HHS decide ALJ and DAB level appeals within 90 days—in the same sub-section of the statute where the 90-day timeframe appears. 42 U.S.C. § 1395ff(d)(3). Because the statute specifies the consequences for failure to resolve ALJ- or DAB- level appeals within 90 days, it contemplates that HHS will not always meet the 90-day timeframe.[4] The timeframe therefore should be construed as directory rather than mandatory. *See* 3 *Sutherland Statutes and Statutory Construction* § 57:8; *accord Halbig*, 758 F.3d at 399.[5]

Plaintiffs' reliance on the *Sutherland* treatise's observation that "[c]ourts often find that where a deviation from the direction of a statute implies a consequence, the statute is mandatory" is unavailing to their position. Opp'n at 8 (quoting 3 *Sutherland Statutes and Statutory Construction* § 57:8). That reference is to statutory consequences in the nature of sanctions or penalties for noncompliance, not to alternative solutions such

[4] Plaintiffs acknowledge that "Congress anticipated that HHS might not always be able to comply with its deadlines, and created an alternative that might be invoked by Medicare appellants in some circumstances." Opp'n at 7–8. They offer no rationale for determining which are the "some circumstances" that would justify longer than 90 days under their theory that the 90-day timeframe is mandatory.

[5] Plaintiffs incorrectly assert that the interpretation advocated by the Secretary would undercut the Medicare statute's other usages of "shall." Opp'n at 7. The Secretary is speaking only in terms of 42 U.S.C. § 1395ff(d), which itself specifies appellants' remedy, should they wish to exercise it, when the 90-day timeframe is not met. The context of other usages determines whether they are mandatory or directory, as discussed above. *Ass'n of Civilian Technicians v. FLRA*, on which Plaintiffs rely, Opp'n at 6, did not involve a statute that specifies a remedy for failure to follow its directive. 22 F.3d 1150, 1153 (D.C. Cir. 1994). That case recognizes that it is only "generally" the case that a statute's use of "shall" is mandatory. *Id*. ("The word 'shall' *generally* indicates a command that admits of no discretion on the part of the person instructed to carry out the directive.") (emphasis supplied).

as the one Congress specified for administrative appeal delays. *See* 3 *Sutherland Statutes and Statutory Construction* § 57:8 ("The problem here is one of determining whether the legislature intended to impose sanctions to secure compliance, and if so, what sanctions were intended. . . The rule is essentially the same with respect to both criminal and noncriminal sanctions, and, in fact, cases dealing with nonpenal sanctions sometimes speak in terms of penalties."); *id.* n. 5–10 (citing cases). This case, in contrast, involves non-punitive consequences in the nature of a remedy, as does *Halbig*. The *Sutherland* treatise's recognition that a statute's provision of a remedy may compel a directory construction therefore is the relevant passage.

That the Medicare statute gives claimants the choice of whether to escalate their appeals does not buttress Plaintiffs' interpretation, contrary to their argument, Opp'n at 8, 26. Escalation is a remedy, and it is logical that the claimant, as the party aggrieved by a delayed decision, would be the party who can elect to invoke the statutory remedy. *See, e.g.*, *Martini v. Federal Nat. Mortg. Ass'n*, 178 F.3d 1336, 1345 (D.C. Cir. 1999) (recognizing that Title VII's 180-day provision allows an aggrieved person to elect to pursue his or her own remedy) (quoting 42 U.S.C. § 2000e-5(f)(1)). That the statute provides that claimants may elect to waive the 90-day period, 42 U.S.C. §1395ff(d)(1)(B), as Plaintiffs emphasize, Opp'n at 8–9, does not alter the critical point that the statute specifies a remedy for when the 90-day period is exceeded.[6] Because

[6] As Plaintiffs recognize, at times the agency described the 90-day deadline as mandatory. *See* Opp'n at 10–11. Those descriptions do not alter the import of the statutory escalation clause, which makes the deadlines directory rather than mandatory. And that some of the cases cited in the Secretary's opening memorandum in support of her argument based on the factors enumerated in *Telecomms. Research & Action Ctr. v. FCC ("TRAC")*, 750 F.2d 70, 74–79 (D.C. Cir. 1984), did not involve statutory deadlines is also unavailing to Plaintiffs' position. *See* Opp'n at 11 (discussing *Action on Smoking & Health v. Dep't of*

Congress contemplated that the 90-day timetable would not always be met, it is not reasonable to conclude Congress intended the timetable to be mandatory. *Contrast In re People's Mojahedin Org. of Iran*, 680 F.3d 832, 837 (D.C. Cir. 2012) (addressing statutory deadline with no remedial provision[7]) (cited in Opp'n at 10).

Beshir v. Holder, on which Plaintiffs rely, Opp'n at 9, lends little support to their contention that the 90-day period is mandatory. In *Beshir*, the Court concluded that it lacked subject matter jurisdiction over a petition for review of the government's failure to decide an application for immigration status adjustment under, *inter alia*, the Mandamus Act. *Beshir v. Holder*, No. 10-652, 2014 WL 284886, at *1 (D.D.C. Jan. 27, 2014) (Bates, J.). The Court recognized that the status adjustment application was governed by 8 U.S.C. §§ 1159(b) and 1255(a), and that neither provision imposes a deadline on the government's decision on such applications. *Beshir*, 2014 WL 284886, at *6. In explaining its conclusion that it lacked jurisdiction, the Court contrasted a scenario where a statute imposes a mandatory deadline and quoted another decision's reference to 8 U.S.C. § 1447(b) as an example, characterizing that provision as requiring a 120-day deadline for decisions on naturalization applications. *Id.* at *8 (quoting *Orlov v. Howard*, 523 F.Supp.2d 30, 34 (D.D.C. 2007)). The Court's reference to 8 U.S.C. § 1447(b) that

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Labor, 100 F.3d 991 (D.C. Cir. 1996), *Liberty Fund, Inc. v. Chao*, 394 F. Supp. 2d 105, 120 (D.D.C. 2005), and a "previous case" referenced in *In re United Mine Workers of Am. Int'l Union*, 190 F.3d 545 (D.C. Cir. 1999)). The Secretary relies on those cases in support of her argument that the agency's competing priorities should weigh heavily against mandamus under the *TRAC* analysis, not in support of her statutory interpretation argument. *See* Def.'s Opening Mem. at 19–20, 25; *see also infra* at 14–23.

[7] The statute at issue in *In re People's Mojahedin Organization of Iran* contains no remedial provision. *See* 8 U.S.C. § 1189(a)(B)(iv)(I) ("Not later than 180 days after receiving a petition for revocation submitted under this subparagraph, the Secretary shall make a determination as to such revocation.").

Plaintiffs emphasize is *obiter dictum.* Whether 8 U.S.C. § 1447(b)'s 120-day provision—which, as Plaintiffs emphasize, includes an "escalation" clause whereby an applicant whose claim is not decided within 120 days may seek a hearing in federal district court—is in fact mandatory was not at issue in either *Beshir* or the *Orlov* decision that *Beshir* cites. Both *Beshir* and *Orlov* involved statutes that provided no timeframes at all, and in neither did the Court have occasion to confront the question of whether an escalation clause rendered a statutory provision directory rather than mandatory.

Contrary to Plaintiffs' suggestion, the Secretary does not dispute that Congress intended to direct HHS to resolve OMHA and DAB appeals within 90 days. Indeed, the agency has endeavored consistently to meet that timeframe, and it was able to do so until the recent dramatic increase in workload. *See* Decl. of Chief ALJ Nancy J. Griswold, Ex. 1, July 10, 2014 Written Testimony before the U.S. House Comm. on Oversight & Gov't Reform at 3 ("Griswold Test."") (ECF No. 12-1 Sept. 11, 2014); Decl. of DAB Chair Constance B. Tobias ¶ 4 (ECF No. 12-4 Sept. 11, 2014). But the 90-day timeframe should not be construed as mandatory because Congress obviously anticipated that it would not always be met by including the escalation clauses in the statute.

II. Even if the 90-Day Timeframe Were Mandatory, the Statutory Remedy of Escalation Precludes Mandamus Jurisdiction.

A. Congress's Specification of Escalation as the Remedy for Delay Makes It the Exclusive Remedy.

Plaintiffs' Opposition ignores the Supreme Court cases cited in the Secretary's opening memorandum establishing that where Congress creates a right and specifies a remedy that remedy is exclusive. Those cases are controlling here. Again, the Supreme Court has recognized that it is "well settled" 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) (discussed in Def.'s Opening Mem. at 26–27); *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"). Thus, even if the 90-day timeframes for OMHA and DAB decisions were mandatory, which they are not, *see supra* at 4–9, the Medicare statute's provision for escalation where those timeframes are not met is the exclusive remedy.[8] Mandamus, consequently, is unavailable.

B. Plaintiffs Fail to Meet Their Burden of Showing that the Statutory Remedy is Inadequate.

Again, it is Plaintiffs' burden to establish each of the criteria for mandamus jurisdiction. *See Power v. Barnhar*t, 292 F.3d 781, 784 (D.C. Cir. 2002). In addition to failing to identify a clear duty on the part of the Secretary or that they have a clear right to relief, Plaintiffs do not show that the statutory remedy of escalation is inadequate. They offer no response to the Secretary's point that Congress presumably deemed the escalation provisions adequate when it specified them as the remedies for delay. And Plaintiffs fail to show that the choice the statute gives claimants between an ALJ hearing after the current wait time and escalated review without ALJ hearing is inadequate on due process grounds or other grounds.

[8] Plaintiffs' assertion that "[i]f escalation were the exclusive remedy for delays, it would be automatic, or at least at the election of HHS, not Medicare appellants," is unsupported by any authority, Opp'n at 25–26, nor does it make sense given that invocation of a remedy is typically the prerogative of the aggrieved party. *See supra* at 7.

Plaintiffs and Amicus contend that the remedy of escalation is inadequate because the lack of a guaranteed in-person ALJ hearing on an escalated appeal deprives them of the opportunity to fully present their claims. However, due process is "flexible," and a hearing based on written evidence can satisfy due process where, as here, it provides adequate notice and opportunity to explain one's case.[9] *See Califano v. Yamasaki*, 442 U.S. 682, 695–96 (1979); *Mathews v. Eldridge*, 424 U.S. 319, 334, 344–45 (1976) (discussed in Def.'s Opening Mem. at 28–32). Plaintiffs and Amicus fail to show that the paper hearing based on written evidence that is guaranteed on an escalated appeal will not provide the opportunity for full presentation of the basis for appeal, at least in most cases.[10] Notably, neither Plaintiffs nor Amicus offers any concrete example of an instance where a hospital has escalated an appeal and the paper hearing the hospital received did not afford it opportunity for full presentation of its appeal. Indeed, neither Plaintiffs nor Amicus asserts that they or other hospitals have elected to escalate their appeals to the DAB or federal court and had the appeals dismissed or otherwise decided

[9] As set forth in the Secretary's opening memorandum, Medicare regulations give claimants the opportunity to develop a written record at the Medicare Administrative Contractors ("MAC") and Qualified Independent Contractor ("QIC") levels of administrative review. *See* 42 C.F.R. § 405.968(a) (the QIC "reviews the evidence and findings upon which the [previous determination] was based, and any additional evidence the parties submit or that the QIC obtains on its own"). The DAB can conduct a hearing on an escalated claim, 42 C.F.R. § 405.1108(d)(2), but has stated that it will not unless there is an extraordinary question of law, policy, or fact. Ex. 2 to Pls.' Mot. for Summ. J. (OMHA Medicare Appellant Forum Presentation at 117) (ECF No. 8-2 July 11, 2014).

[10] It is of course possible that some issues presented on administrative appeal might benefit from in-person hearing, as reflected in the Federal Register excerpt quoted by Plaintiffs. For those instances, claimants may have an in-person ALJ hearing after the current wait time. *See* 67 Fed. Reg. 69,312, 69,329 (Nov. 15, 2002) (advising appellants to "carefully consider the type of review that is best to resolve their case before deciding to escalate an appeal" and noting that "when a case is escalated from the ALJ level to the MAC, an appellant will lose the right to present his or her case during an oral hearing").

adversely to them. Nor do they offer evidence that Medicare appeals typically present issues of witness credibility and veracity—rather than written documentation on a patient's condition and treatment— such that only an in-person hearing would allow adequate presentation of the claimant's evidence.[11]

Plaintiffs do not explain why they cannot adequately support the validity of their claims though written evidence. Plaintiffs emphasize that at an ALJ hearing they can present oral testimony of clinicians and testimony on clinical factors underlying what they describe as complex hospital claims and can explain written materials in the record. Opp'n at 26. Amicus similarly emphasizes that treating physicians can testify at the ALJ hearing and explain the basis for a claim. Amicus Br. at 18. But neither offers any explanation as to why that information cannot be conveyed adequately in written form, including through declarations, as part of a paper hearing. They point out that at a live hearing they can respond to questions posed by the ALJ, but on an escalated appeal, appellants can always request an oral argument before the DAB, *see* 42 C.F.R. § 405.1124, the DAB can present any questions to the claimant in writing, *see* 42 C.F.R. § 405.1108(d)(2) (authorizing the DAB to conduct any additional proceedings necessary

[11] Providers' obligation to be honest in submitting claims for payment does not suggest that witness credibility is a significant factor in most reimbursement claim appeals, contrary to Plaintiffs' assertion, Opp'n at 26. The Medicare system is dependent on providers' honesty and accuracy because, given the enormous volume of claims in general, most are paid without review of medical records supporting the services billed. *See, e.g.*, CMS, *Recovery Auditing in Medicare for Fiscal Year 2013* at 1–2 ("2013 RAC Report") ("Claims submitted to Medicare are screened by thousands of system edits prior to payment; however, due to the large volume of claims submitted, most are generally paid without requesting and reviewing the medical records to support the services billed. As a result, claims may be paid inappropriately, resulting in improper payments."), *available at* http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Recovery-Audit-Program/Downloads/FY-2013-Report-To-Congress.pdf.

to issue a decision of an escalated appeal), and a federal court may hear oral argument where it would be helpful. Thus, there is no basis for a conclusion that the paper hearing afforded on an escalated appeal would not provide adequate opportunity for claimants to present their appeal consistent with due process requirements.

Plaintiffs and Amicus rely heavily on statistics showing a significant reversal rate at the ALJ-level relative to lower levels of administrative review. But a higher rate of reversal at the ALJ level relative to lower levels does not indicate that review at the upper levels of review—the DAB and federal court—is inadequate. Plaintiffs and Amicus provide no basis for their suggestion that claim denials escalated to the DAB or federal court would be reversed at a lower rate than if they are not escalated. Additionally, it can be expected that hospitals will elect to pursue ALJ-level review only for claims on which they are more likely to prevail, as previously explained. *See* Def.'s Opening Mem. at 30–31. Plaintiffs and Amicus rely only on speculation that escalated claims could "flood" the federal courts. As of the signing of Chief Judge Tobias' declaration, only seven coverage appeals had been escalated to federal court. Tobias Decl. ¶ 3. And while, as Plaintiffs and Amicus emphasize, there is also a backlog at the DAB, escalation is the remedy that Congress selected for claimants whose appeals are pending longer than 90 days. Presumably, Congress considered the remedy adequate, and the current delays do not warrant judicial intervention for the reasons set forth previously and immediately below. *See* Def.'s Opening Mem. at 20–25; *infra* at 14–23. Lastly, Plaintiffs' assertion that the availability of aggregation of smaller value claims does not alleviate the problem of cost-prohibitive appeals at both the DAB level and in federal court is unsupported by the conclusory assertions in the declarations on which they rely. *See* Decl. of I. Holleman

¶ 13 (ECF No. 8-11); Decl. of J. Geppi ¶ 15 (ECF No. 8-12); Decl. of J. Wallace ¶ 16 (ECF No. 8-14) (cited in Opp'n at 29). Aggregated appeals may be appealed to the DAB and federal court in aggregated form. 42 U.S.C. § 1395ff(b)(1)(E)(ii); 42 C.F.R § 405.1006(e).

III. Plaintiffs Establish No Basis for Judicial Intervention under the *TRAC* Analysis.

Plaintiffs also fail to show that even if the Medicare statute mandated a 90-day deadline for ALJ and DAB decisions—which it does not—judicial intervention would be warranted under the analysis set forth in *Telecommunications Research & Action Center v. FCC*, 750 F.2d 70 (D.C. Cir. 1984) ("*TRAC*"). Plaintiffs emphasize that the D.C. Circuit has described the first two principles of the analysis (need for a rule of reason to govern the time agencies take to make decisions and that a statutory timetable may supply content for the rule of reason) as the most important. Opp'n at 13 (citing *People's Mojahedin*, 680 F.3d at 837). There is no dispute that the Medicare statute directs HHS to resolve ALJ- and DAB- level appeals within 90 days and that that timetable supplies the applicable rule of reason. The reality of HHS's competing priorities that it must address with fixed resources makes the fourth principle—that "the court should consider the effect of expediting delayed action on agency activities of a higher or competing priority"—more significant to this action.[12] *TRAC*, 750 F.2d at 80. The D.C. Circuit has

[12] Plaintiffs incorrectly assert that the Secretary ignores the fifth *TRAC* principle. Opp'n at 12. To the contrary, she considers it in conjunction with the third and fourth factors, like the D.C. Circuit in *Barr Labs*. *See* Def.'s Opening Mem. at 21; *In re Barr Labs.*, Inc., 930 F.2d 72, 75 (D.C. Cir. 1991) (finding that, because any impact to human health due to agency delay was effectively nullified by the impact judicial intervention would have on competing agency priorities that also related to human health, the third *TRAC* factor overlapped with the fifth and that both were largely irrelevant in light of the importance of the fourth factor—the agency's competing priorities); *see also In re United*

emphasized agencies' competing priorities in refusing to issue mandamus relief, even where the agency had violated a statutorily mandated deadline by a substantial amount of time, as described in the Secretary's opening memorandum. *See* Def.'s Opening Mem. at 18–20 (discussing *In re United Mine Workers of Am. Int'l Union*, 190 F.3d 545 (D.C. Cir. 1999), and *In re Barr Labs., Inc*., 930 F.2d 72 (D.C. Cir. 1991)).[13] Courts should not second-guess the Executive Branch's judgment in determining the priorities for allocation of limited funds. *See, e.g.*, *Barr Labs*, 970 F.2d at 76 ("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 [the court] to hijack.").

A. HHS's Competing Priorities Weigh Against Mandamus Jurisdiction.

As previously explained, OMHA and DAB have prioritized beneficiary appeals relative to provider appeals such as those of the Plaintiff hospitals and the hospitals represented by Amicus. *See* Def.'s Op. Mem. at 9, 11. Plaintiffs clarify that they do not seek to be moved in front of beneficiary appellants, Opp'n at 14, even though their Complaint seeks relief only on behalf of hospitals, Compl., Prayer for Relief ¶ b (ECF No. 1 May 22, 2014). Nevertheless, the priority afforded beneficiary appeals is a factor in the current wait time for provider appeals. As Plaintiffs recognize, Medicare

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Mine Workers of Am. Int'l Union, 190 F.3d 545, 552 n.6 (D.C. Cir. 1999) (finding third and fifth factors to overlap as in *Barr Labs.*).

[13] The cases finding unreasonable delay on which Plaintiffs rely did not involve the competing priorities for limited agency resources that underlie the delay at issue here as well as in *In re Barr Labs* and *United Mine Workers*. *See Ganem v. Heckler*, 746 F.2d 844, 854 (D.C. Cir. 1984)*; Pub. Citizen Health Grp. v. Auchter*, 702 F.2d 1150, 1157 (D.C. Cir. 1983); *MCI Telecomms. Corp. v. FCC*, 627 F.2d 322, 327 (D.C. Cir. 1980); *Sandoz, Inc. v. Leavitt*, 427 F. Supp. 2d 29, 40 (D.D.C. 2006) (all cited in Opp'n at 13).

beneficiaries have filed suit challenging delays that they have faced in their Medicare appeals. However, with the priority that OMHA affords to beneficiary appellants, the delays in beneficiary appeals are far less than in provider appeals. As of October 1, 2014, the average processing time for beneficiary appeals filed and decided in fiscal year 2014 was 109 days, Decl. of Nancy J. Griswold ¶ 12, *Lessler v. Burwell*, No. 3:14-CV-1230 (D. Conn. Oct. 9, 2014) (copy attached hereto as Ex. 1),[14] compared to an average of 415 days for all appeals decided in fiscal year 2014, *see* OMHA, Adjudication Timeframes, http://www.hhs.gov/omha/important_notice_regarding_adjudication_timeframes.html. Further, OMHA has redirected senior attorneys' efforts to assisting in adjudicating beneficiary appeals, and advised any beneficiary who believes that his/her claim has not been given priority to contact OMHA directly by e-mail or OMHA's toll-free telephone number. Griswold Test. at 5.

Plaintiffs criticize the Secretary's opening memorandum for not specifying other agency priorities that compete with resolution of pending OMHA and DAB reimbursement claim appeals. Opp'n at 13. All of HHS's many programs, however, impact human health and welfare, as the agency's mission is to promote health and provide essential human services. *See* About HHS, 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."). HHS encompasses, for example, the Centers of Disease Control, the National Institutes for Health, and the Food and Drug Administration. *See* HHS, Operating Divisions, http://www.hhs.gov/about/foa/opdivs/index.html. It is not

[14] Information specific to individual plaintiffs in the *Lessler* case has been redacted from the declaration.

reasonable for the Secretary to rank each HHS program and the priority she has assigned it relative to the OMHA and DAB appeals processes. However, the following are examples of HHS activities that compete with the administrative appeal programs for the limited discretionary funds available to the Secretary.[15] In fiscal year 2014, HHS transferred $109 million to CMS to help ensure continued operations of the health insurance Marketplace (healthcare.gov) operations, including providing assistance to consumers and health insurance issuers. Letter from former Secretary Kathleen Sebelius to Hon. Jack Kingston, Committee on Appropriations of Feb. 21, 2014 (Ex. 1 to Decl. of Lester D. Cash, attached hereto as Ex. 2). Also in fiscal year 2014, HHS transferred approximately $44 million to the Administration for Children and Families' Refugee and Entrance Assistance appropriation to meet its responsibility to house and care for the dramatic increase in the number of unaccompanied alien children arriving in the United States. *Id.*[16] For HHS to move resources from any one of these or other of its programs necessarily would be to shift the budgetary priorities that the Secretary in her discretion has established. The D.C. Circuit has cautioned against the sort of intrusion into an agency's decisionmaking as to budget and resource allocation that Plaintiffs and Amicus advocate. *See Barr Labs*, 970 F.2d at 76.

Plaintiffs are off base in asserting that HHS ignores the harm that the hospital Plaintiffs allege and disregards the effect on them of the current delays. Opp'n at 15.

[15] The limited nature of the Secretary's authority to transfer funds between discretionary appropriations is discussed in detail herein. *See infra* at 18–22.

[16] *See also* Letter from former Secretary Kathleen Sebelius to Hon. Jack Kingston, Committee on Appropriations of May 23, 2014 (Ex. 2. to Cash Decl.) (reporting HHS's transfers of funding to address the department's cybersecurity needs and to support the Ryan White HIV/AIDS Program).

The Secretary is fully cognizant that the delays impact hospitals and is actively addressing the backlog with the limited resources, as discussed previously and immediately below. *See* Def.'s Opening Mem. at 6–11; *infra* at 18–23. Because all of HHS's numerous programs impact health and welfare to varying degrees, Plaintiffs' and Amicus's alleged harm does not justify a mandamus order that would require the agency to shift to the Medicare appeals process resources needed in other important programs. *See Sierra Club v. Thomas*, 828 F.2d 783, 798 (D.C. Cir. 1987) (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.").

B. The Secretary's Resources for Resolving OMHA and DAB Appeals Are Limited.

Plaintiffs and Amicus are incorrect in asserting that the Secretary can use discretionary funding transfer authority to get OMHA and DAB the additional funds that they would need to eliminate their backlogs and meet the 90-day timetable for newly filed appeals. That HHS is a large department with a large budget does not mean that the Secretary can simply shift money to OMHA and DAB. The Secretary may not transfer funds from one appropriation to another except as authorized by Congress. *See* 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.").[17]

[17] *See also* 2 Gov't Accountability Office, *Principles of Federal Appropriations Law* 6-162 (3d ed. 2006) ("Federal Appropriations Law") ("As a general proposition, an agency may not augment its appropriations from outside sources without specific statutory authority. When Congress makes an appropriation, it also is establishing an authorized program level. In other words, it is telling the agency that it cannot operate beyond the level that it can finance under its appropriation. To permit an agency to operate beyond this level with funds derived from some other source without specific congressional sanction would amount to a usurpation of the congressional prerogative.").

Transfer of funds without authority would violate statutory restrictions on the use of appropriations, would constitute an unauthorized augmentation of the receiving appropriation, and could result in an Anti-Deficiency Act violation. *See* 31 U.S.C. § 1301(a) (providing that appropriations may only be used for the purposes for which they were appropriated); 31 U.S.C. § 1341(a)(1)(A) ("An officer or employee of the United States Government . . . may not . . . make or authorize an expenditure or obligation exceeding an amount available in an appropriation or fund for the expenditure or obligation.").

The 2014 HHS Appropriations Act authorizes the Secretary to make certain funds transfers, as Plaintiffs and Amicus emphasize. However, that Act (i) limits the Secretary's transfer authority between appropriations to one percent (1%) of any discretionary Department fund for a particular fiscal year and (ii) limits the amount that a receiving appropriation may be increased to 3 percent (3%). 2014 HHS Appropriations Act, Pub. L. No. 113-76 § 206, 128 Stat. 363, 380, 382 ("Not to exceed 1 percent of any discretionary funds (pursuant to the Balanced Budget and Emergency Deficit Control Act of 1985) which are appropriated for the current fiscal year for HHS in this Act may be transferred between appropriations, but no such appropriation shall be increased by more than 3 percent by any such transfer."). Because OMHA is funded through a specific appropriation, *id.* at 380, the Secretary's ability to use her discretionary authority to transfer funds to it is limited 3 percent of the OMHA appropriation.[18] *See id.* And even

[18] A reprogramming of funds, such as Plaintiffs reference, Opp'n at 18, differs from a transfer of funds in that a reprogramming is generally a non-statutory arrangement wherein an agency utilizes funds in one appropriation account for purposes other than those contemplated at the time of appropriation. 1 *Federal Appropriations Law* at 2030 (3d. ed. 2004). In other words, a reprogramming is a shift of funds within a single

if the Secretary were to use her transfer authority to boost OMHA's funding by the full 3 percent of its appropriation to the detriment of other HHS programs, the amount would not be near enough to fund the number of additional adjudicators and training that would still be necessary to handle the dramatic increase in ALJ-level appeals. Three percent of OMHA's $83,381,000 appropriations in fiscal year 2014 would be less than $2.5 million. As of July 1, 2014, OMHA had received 509,000 appeals and at the current funding level OMHA can adjudicate approximately 72,000 appeals per year, *see* Griswold Test. at 4.[19]

Plaintiffs' and Amicus's assertion that the Secretary can rely on authority under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA"), Pub. L. No. 108-173, § 931 (2003), to transfer the funding that OMHA and DAB would need to eliminate the backlog in appeals is also incorrect. Section 931 of the MMA provides an authorization of appropriations; it is not itself an appropriation, which involves independent action by Congress. *Id.* § 931(c) ("to ensure timely action on appeals before [ALJs] and the [DAB] . . . there are authorized to be appropriated . . . to

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appropriation. But Plaintiffs are not demanding (and cannot demand) a reprogramming of funds within OMHA itself.

[19] The DAB is authorized under Title III of the PHS Act, and is funded annually through the General Departmental Management ("GDM") Appropriation in the Labor, HHS, and Education bill. *See* 2014 HHS Appropriations Act, Pub. L. No. 113-76 § 206, 128 Stat. 363. DAB's work on Medicare appeals is funded solely out of the GDM account. Even if the DAB received 3% of its $10,450,000 appropriation for fiscal year 2014, that only amounts to an additional $313,500. *See* Department of Health and Human Services Fiscal Year 2015 Justification of Estimates for Appropriations Committees, at 45, *available at* http://www.hhs.gov/budget/fy2015/fy-2015-hhs-congressional-budget-justification.pdf ("FY 2015 HHS Budget"). In fiscal year 2013 (with the same appropriation as fiscal year 2014), DAB decided 2,592 appeals, the largest number of decided cases in the history of the Medicare Appeals Council. *See* Departmental Appeals Board Update at 5 (Feb. 12, 2014) (Tobias Decl., Ex. 1) (ECF No. 12-5). But by the end of fiscal year 2013, the number of pending appeals was still 4,888, and the backlog of cases is projected to increase to over 14,000 by the end of fiscal year 2015. *See* FY 2015 HHS Budget at 45.

the Secretary such sums as are necessary for fiscal year 2005 and each subsequent fiscal year to—(1) increase the number of [ALJs] (and their staffs) . . . ; (2) improve education and training opportunities for [ALJs] (and their staffs); and (3) increase the staff of the [DAB]"). An authorization of appropriation is in effect a directive to Congress itself, which a future Congress is free to follow or to disregard. 1 *Federal Appropriations Law* at 2-40 (3d ed. 2004) ("The mere authorization of an appropriation does not authorize expenditures on the faith thereof or the making of contracts obligating the money authorized to be appropriated.") (citing 16 Comp. Gen. 1007, 1008 (1937)). Section 931(c) merely authorizes Congress to appropriate funds, but Congress is free to appropriate more, less, or the same amount, or to not appropriate funds at all.

Plaintiffs are also wrong in asserting that the Secretary has not asked Congress to appropriate additional funds to address the appeal delays, Opp'n at 19. The President's Budget requested more money for OMHA than Congress appropriated in each year between the beginning of the backlog in 2011 and 2013. *See Department of Health and Human Services Fiscal Year 2015 Justification of Estimates for Appropriations Committees*, at 180, http://www.hhs.gov/budget/fy2015/fy-2015-hhs-congressional-budget-justification.pdf. Fiscal year 2014 was the first time since fiscal year 2010 that the Congress appropriated the amount for OMHA requested in the President's Budget. *See* S. Rep. No. 113-71, at 149 (2013) (recommending appropriation of full amount of requested OMHA funding). While Congress has expressed concern about the appeal delays, during the recent hearing conducted by the Committee on Oversight & Government Reform, Subcommittee on Energy, Policy, Health Care, and Entitlements, the subcommittee's Chairman, James Lankford, indicated that Congress was not inclined

to approve funding for a large number of ALJs such as would be needed to eliminate the backlog and restore the 90-day appeal resolution period. *See Medicare Mismanagement Part II: Exploring Medicare Appeals Reform: Hearing Before the H. Oversight and Government Reform Subcomm. on Energy Policy, Health Care, and Entitlements*, 113th Cong., at 56:40–57:00 (July 10, 2014) (statement of Subcomm. Chairman Lankford), *available at* http://oversight.house.gov/hearing/medicare-mismanagement-part-ii-exploring-medicare-appeals-reform/. At that same hearing, Representative Jackie Speier recognized that the current appeals backlog is "a problem that Congress created" by directing CMS to implement the RAC program but not providing "additional funds to address the influx of claims and appeals that have resulted." *Id.* at 6:14–9:48; *accord* Def.'s Opening Mem. at 7–8, 11. Absent additional funding to hire and train more ALJs and DAB adjudicators and support staff, HHS cannot fully eliminate the backlog and keep pace with the deluge of reimbursement appeals to OMHA and the DAB.[20]

C. Plaintiffs' Criticisms of the Secretary's Measures to Alleviate the Backlog are Unwarranted.

Defendants' opening memorandum describes the measures that HHS is taking to alleviate the backlog in the upper levels of administrative review and acknowledges that those alone will not eliminate the delays. *See* Def.'s Opening Mem. at 8–11. Plaintiffs' criticisms of HHS's individual initiatives—some of which are designed to mitigate the effects of the backlog while others are aimed at reducing it—are short-sighted and fail to acknowledge the cumulative impact. They merely serve to demonstrate why Congress has entrusted the agency—not Plaintiffs or the Courts—to make hard choices on how

[20] Even with such funding, it would take time to train additional ALJs and DAB Appeals Council members.

limited resources can best be used. As previously referenced, additional funding is needed to clear the backlog.

As Plaintiffs' note, the OMHA statistical sampling pilot program requires a minimum number of appealed claims to make the sampling process more advantageous than individual adjudications, and some hospitals do not have the requisite number of appeals to participate. However, for hospitals that do have the requisite number of claims, electing the statistical sampling option will resolve hundreds of appeals through the examination of a sample and thereby dramatically reduce both the number of those hospitals' appeals pending and the wait time for all appeals. Similarly, although the OMHA settlement conference facilitation pilot program is currently limited to Part B claim appeals, settlement of those appeals will reduce the total number of appeals awaiting adjudication. Plaintiffs' assertion that CMS's settlement offer with respect to inpatient status denials shows that HHS "can find funds" to alleviate the backlog, Opp'n at 21, reflects Plaintiffs' misunderstanding of appropriations law. Medicare payments are disbursed from Trust Funds under appropriations separate from the appropriations for the administration of OMHA and DAB appeals. *See, e.g.*, Consolidated Appropriations Act, 2014, Pub. L. No. 113-76, 128 Stat. 5, 374 (Jan. 17, 2014). HHS's development and implementation of these extraordinary measures demonstrates that the agency is making considerable efforts to reduce the size of the backlog.[21]

[21] Later this month, OMHA will conduct a second Medicare appellant forum to discuss OMHA and CMS initiatives designed to mitigate the backlog at the ALJ-level. DAB will also participate in the forum to provide information about the Medicare Appeals Council operations. *See* OMHA, Medicare Appellant Forum, http://www.hhs.gov/omha/omha_medicare_appellant_forum.html.

IV. Plaintiffs' and Amicus's Extensive Criticisms of the RAC Program are Misplaced.

Both Plaintiffs and Amicus argue at length that the RAC program is the root cause of the administrative appeals backlog and that CMS should "rein in" the RACs. This confirms that Plaintiffs' and Amicus' real objective in pursuing this action is to weaken the RAC program. Opp'n at 22-25; *see generally* Amicus Br. This action is not the proper forum for the airing of those grievances, which Plaintiffs and Amicus have already brought to Congress's attention. Plaintiffs' and Amicus's criticisms about the RAC program do not bear on whether Plaintiffs have a clear right to relief regarding the length of time that ALJ- and DAB-level appeals are pending, whether the Secretary has a clear duty to ensure that the appeals are decided within 90 days, or whether there is an adequate remedy available for when the 90-day period is exceeded.

Nonetheless, is important to recognize that Congress instituted the RAC program as a powerful weapon to combat Medicare fraud and that it has been highly successful in recouping Medicare payments. *See* Def.'s Opening Mem. at 7 n.4, 23-24 & n.12. In fiscal year 2013 alone, the Recovery Auditors identified and corrected $3.75 billion in improper payments. *See* 2013 RAC Report at iv, 11; *see also* Def.'s Opening Mem. at 7 n.4 (citing RACs' reported recovery of $2.3 billion in overpayments in fiscal year 2012). In addition to correcting improper payments, CMS uses results of RAC audits to identify and address vulnerabilities in the Medicare system. 2013 RAC Report at v.

And CMS is taking measures to improve the RAC program. For example, CMS has made changes in the program such as modifying the RAC contracts to require, *inter alia*, that RACs wait 30 days to allow for a discussion with the provider before the RAC refers one of its claims for adjustment, implementing additional documentation request

limits, and waiting until the QIC level of appeal is exhausted before the RACs receive their contingency fee. *See* http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Recovery-Audit-Program/Downloads/RAC-Program-Improvements.pdf. Plaintiffs' argument that the Secretary should be taking additional or other measures to rein in the RACs, is a matter for the political branches and is not an argument this Court need or should address in order to determine whether it has mandamus jurisdiction over this action.

* * *

Plaintiffs fail to meet their burden of establishing any of the three criteria for mandamus jurisdiction: a clear right to relief, a clear duty by the Secretary, and lack of an adequate remedy. Further, there is no reason for the Court with respect to retain jurisdiction over this action. *See In re Barr Labs.*, 930 F.2d at 76 (declining to retain jurisdiction where the courts lacked power to issue order that would remedy delays). While HHS continues to implement measures to mitigate the ALJ and DAB level appeal delays and to work with stakeholders to develop additional measures, it cannot resolve the problem of the backlog with its current resource limitations and the priorities that compete for them.

CONCLUSION

For the foregoing reasons and those set forth in the Secretary's Opening Memorandum, the Court should dismiss the Complaint for lack of jurisdiction.

Respectfully submitted this 17th day of October, 2014.

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