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, Defendant.	Civil Action No. 14-cv-00851 (JEB)

DEFENDANT'S REPLY MEMORANDUM IN SUPPORT OF HER MOTION FOR STAY

BENJAMIN C. MIZER
Principal Deputy Assistant Attorney General
CHANNING D. PHILLIPS
United States Attorney
JOEL McELVAIN
Assistant Director, Federal Programs Branch

CAROLINE LEWIS WOLVERTON
Senior Trial Counsel, Federal Programs Branch
D.C. Bar No. 496-433
U.S. Department of Justice
Civil Division
P.O. Box 883
Washington, D.C. 20001
Tel. (202) 514-0265
Fax (202) 616-8470
caroline.lewis-wolverton@usdoj.gov

Attorneys for Defendant

Of Counsel:
MARGARET M. DOTZEL
Acting General Counsel
JANICE L. HOFFMAN
Associate General Counsel
SUSAN MAXSON LYONS
Deputy Associate General
Counsel for Litigation
KIRSTEN FRIEDEL RODDY
Attorney
United States Department of
Health and Human Services

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INTRODUCTION

Plaintiffs' opposition brief focuses heavily on rhetoric rather than on any serious effort to counter the Secretary's factual showing in support of her motion for a stay. The Secretary has demonstrated that the political branches are making significant progress in addressing the current Medicare appeals delay and that, consequently, a limited stay of this action is appropriate to allow that progress to continue. The *amicus curiae* brief of Fund for Access to Inpatient Rehabilitation (hereinafter "Amicus") likewise presents no basis for discounting the work of the political branches, or any reason for the Court to undertake to decide whether to issue the extraordinary writ of mandamus before the impact of that progress can be more fully measured. Rather, the Secretary has demonstrated the sort of significant progress that the Court of Appeals suggested could warrant a stay of this action, with periodic status reports to the Court, through the end of the next fiscal cycle. *See Am. Hosp. Ass'n v. Burwell*, 812 F.3d 183, 193 (D.C. Cir. 2016) ("*AHA*") ("[I]f the district court determines on remand that Congress and the Secretary are making significant progress toward a solution, it might conclude that issuing the writ is premature. If so, it could consider such action as ordering the agency to submit status reports updating the court on the level of appropriations, the progress of the [Audit & Appeal Fairness, Integrity, and Reform in Medicare (AFIRM) legislation], and any other relevant information.").

The Secretary reiterates how seriously she and the Department of Health and Human Services (HHS) consider the backlog within the Office of Medicare Hearings and Appeals (OMHA). It is a matter of the highest priority. The insinuations of bad faith conveyed through the extensive rhetoric of Plaintiffs' opposition, and to a somewhat

lesser extent the Amicus brief, are completely unwarranted. There is absolutely no reason to doubt the Secretary's and HHS's firmness of purpose in acting to reduce and ultimately resolve the appeal delays. Indeed, both this Court and the Court of Appeals recognized that the Secretary has acted in good faith in addressing the backlog. *See id.* at 192.

The limited stay of this action that the Secretary requests would allow her and HHS to continue their good-faith actions to reduce the OMHA backlog with additional and enhanced administrative measures, many of which are newly implemented. Indeed, only this week, the Secretary further demonstrated her resolve to address the backlog by issuing a notice of proposed rulemaking that, if adopted, will codify in regulation many new administrative measures. The requested stay would allow the Secretary to continue in these administrative efforts and would allow Congress time to consider pending legislative proposals, including funding requests. Finally, periodic status reports at six-month intervals, as the Secretary proposes, would keep the Court as well as Plaintiffs and Amicus apprised of the political branches' progress toward resolving the backlog.

For these reasons, elaborated upon herein and in the Secretary's Motion for Stay and Memorandum of Points and Authorities in Support, ECF No. 30 (May 25, 2016) (the Secretary's "Opening Memorandum"), the balance of equities falls in favor of granting the requested stay.

ARGUMENT

I. A Limited Stay is Consistent with the Court of Appeals' Opinion and the Balance of Interests because HHS is Making Significant Progress Toward Resolution of the OMHA Backlog.

The Secretary has moved for a stay in light of the significant progress of the political branches toward resolving the current backlog of administrative appeals pending before OMHA. Plaintiffs' contentions notwithstanding, *see* Pls.' Mem. of Points and Authorities in Opp'n to Def.'s Mot. for Stay at 7, ECF No. 31 (June 13, 2016) (hereinafter "Pls.' Opp'n"), the Secretary's motion is fully consistent with the opinion of the Court of Appeals, which plainly contemplated that the political branches should be afforded the opportunity to respond to its opinion before the Court considers whether to take the extraordinary step of issuing a writ of mandamus. The Court of Appeals suggested that on remand this Court consider whether the political branches are making "significant progress" toward resolving the backlog and that, if they are, the Court could consider ordering the Secretary to submit status reports updating it on the progress. *AHA*, 812 F.3d at 193. The Secretary has demonstrated that the political branches are making such significant progress and that a stay is therefore warranted.

A. Neither Plaintiffs Nor Amicus Undercuts HHS's Demonstration of Significant Progress.

The Declaration of Ellen Murray, Assistant Secretary for Financial Resources and Chief Financial Officer of HHS, ECF No. 30-1 (May 25, 2016) ("Murray Declaration"), describes in detail HHS's administrative actions to address the backlog as well as the pending legislative proposals that, if enacted, would further reduce the backlog. Combined, these measures are projected to ultimately eliminate the backlog. Murray Decl. ¶ 18. The Declaration plainly demonstrates significant progress, and thus warrants

the Court's consideration of a stay along the lines described by the Court of Appeals. *See AHA*, 812 F.3d at 193 ("if the district court determines on remand that Congress and the Secretary are making significant progress toward a solution, it might conclude that issuing the writ is premature").

Plaintiffs' various attacks on HHS's efforts fail to undercut the Secretary's demonstration of significant progress. While Plaintiffs and Amicus are correct that the backlog has increased since the Court of Appeals' decision, they fail to account for the projected impact of the administrative actions that HHS has newly undertaken, or of increased funding and authorities such as the President's fiscal year (FY) 2017 Budget proposal that HHS seeks through legislation, which are designed to reduce the number of pending appeals and appeals that continue to come to OMHA. *See* Murray Decl. And while HHS anticipates that the backlog will increase in the short term because of the current number of incoming appeals, Plaintiffs again fail to account for the effects of the newly implemented administrative measures, which will ultimately reduce the backlog. *See id.*[1] Likewise, the current average processing time of appeals on which Plaintiffs

[1] Plaintiffs incorrectly assert that in 2013 the Secretary "suspend[ed]" assignment of appeals to ALJs. As OMHA Chief ALJ Nancy Griswold explained in her written testimony to the House Committee on Oversight & Government Reform Subcommittee on Energy Policy, Health Care & Entitlements, 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. Decl. of Nancy J. Griswold, Ex. 1, July 10, 2014 Written Test. at 4, ECF No. 12-1 (Sept. 11, 2014). Thus, instead of assigning appeals as requests were filed, only to have the appeals wait on ALJs' active dockets and the associated case files stored in the limited space available in OMHA field offices, OMHA began holding the assignment of appeals until an ALJ's active docket is ready for them. This allows OMHA ALJs and their support staff to focus on working through their assigned appeals and spend less time merely managing large volumes of appeals and associated case files. It also allows an appellant's request to be assigned to the next available ALJ, which helps get an appeal to hearing faster because, under the pre-2013 assignment practice, an appellant's appeal could be in the queue behind other appeals on

rely, Pls.' Opp'n at 4, necessarily pertains to appeals filed in the past and does not reflect the projected impact of these administrative actions and legislative proposals.

Plaintiffs' conclusory assertion that many of HHS's initiatives "show no signs of ever coming to fruition," *id.* at 7, is refuted by HHS's explanation that it has already taken each of the initiatives described in the declaration it submitted. Murray Decl. ¶¶ 19, 21. In addition to the changes to the Recovery Audit (RA) program and the administrative settlement project that are summarized in the Secretary's Opening Memorandum, Opening Mem. at 5, HHS is taking multiple additional administrative actions to reduce the backlog and has projected their impact on the backlog through fiscal year 2020: (i) prior authorization initiatives that encourage providers and suppliers to assess Medicare coverage criteria and meet documentation requirements, as well as correct errors and omissions, before providing services and supplies and submitting claims; (ii) QIC demonstration project for suppliers of certain durable medical equipment to discuss claims by telephone at the second level of administrative appeal, submit documentation, and receive feedback and education on Centers for Medicare & Medicaid Services (CMS) policies and requirements; (iii) OMHA settlement conference facilitations between CMS and appellants with a minimum number or value of claims; (iv) OMHA voluntary statistical sampling whereby appellants with a large number of pending appeals may choose to have their claims adjudicated by statistical sampling and extrapolation of their claims; (v) on-the-record adjudication by OMHA senior attorney advisors with ALJ review; and (vi) a senior ALJ program to reemploy retired ALJs to conduct hearings and issue decisions. Murray Decl. ¶ 19(c)-(h).

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an ALJ's sizable docket of complex cases, while other appeals filed later in time may have the good fortune of being behind less complex cases on another ALJ's docket.

Plaintiffs offer no reason to dispute the Secretary's conclusion that these actions will help to lessen the backlog, other than to dismiss demonstration projects as "limited experiments," Pls.' Opp'n at 9. And that characterization is entirely unwarranted. Demonstrations are "projects to test and measure the effect of potential program changes," and to "study the likely impact of new methods of service delivery, coverage of new types of service, and new payment approaches on beneficiaries, providers, health plans, states, and the Medicare Trust Funds." CMS.gov, Medicare Demonstration Projects & Evaluation Reports, *available at* https://www.cms.gov/Medicare/Demonstration-Projects/DemoProjectsEvalRpts/index.html. And demonstrations have the potential to become permanent programs if successful. The RA program, for example, started out as a demonstration. CMS, Recovery Audit Program , *available at* https://www.cms.gov/research-statistics-data-and-systems/monitoring-programs/medicare-ffs-compliance-programs/recovery-audit-program/. Regarding the Qualified Independent Contractor (QIC) demonstration, as HHS explained, CMS will determine the speed and extent of any expansion to additional types of services, items and supplies based on the agency's experience with the demonstration as it develops, Murray Decl. ¶ 19(d)(iii), which is precisely how HHS utilizes demonstrations to determine how best to implement significant initiatives on a larger scale.

Plaintiffs offer a substantive criticism of only one aspect of one of the twenty-one administrative initiatives that HHS has undertaken. They dispute whether one of the three modifications to RA program contracts that the Secretary described in her Opening Memorandum—a provision that a RA contractor is to be paid only if a QIC upholds the

RA's decision on reconsideration or the time for appeal expires—will be effective, arguing that QICs merely "rubber stamp" RA contractors. Pls.' Opp'n 10. But Plaintiffs miss the mark even in that isolated critique of one aspect of the Secretary's initiatives.

First, the tables in the HHS Office of Inspector General report on which Plaintiffs rely do not remotely support their characterization of the QICs as a "rubber stamp." *See* Office of the Inspector General, HHS, *The First Level of the Medicare Appeals Process, 2008-2012:Volume, Outcomes, and Timeliness* at 26-28 tbls. A3-A11 (Oct. 2013), *available at* http://oig.hhs.gov/oei/reports/oei-01-12-00150.pdf. These tables represent outcomes at the *first* level of appeal (redetermination), not outcomes at the second, QIC level of appeal (reconsideration).[2] Second, one of HHS's administrative measures, Judicial Education Training for OMHA, ALJs and Adjudication Staff, "increases decisional consistency between adjudicators at all levels of appeal." Murray Decl. ¶ 21(c).[3] A low QIC overturn rate would not be surprising in light of increased decisional consistency between levels of appeal.

Amicus, likewise, is incorrect to assert that HHS's initiatives would not provide relief to inpatient rehabilitation facilities. Amicus Br. at 13. The objective of the Medicare Appeals Process Improvement and Backlog Reduction Plan is to reduce the delays faced by all appellants. *See* Murray Decl. ¶¶ 17-22. HHS's administrative actions are designed to alleviate the backlog by reducing the number of incoming appeals and reducing the time for OMHA adjudications. *See id.* Reduction of the backlog will work

[2] Even then, the report shows redeterminations fully or partially favorable to appellants at over 50% for many years depending on the type of claim. *See id.*

[3] Increased decisional consistency "may contribute to lower appeal rates by resolving issues at the lower levels of appeal and affecting appellants' business decisions whether to appeal to higher levels of appeal." Murray Decl. ¶ 21(c).

to reduce the wait time for all OMHA appellants, including inpatient rehabilitation facilities. *See id.* Further, many of the administrative actions on their face are designed to apply to all OMHA appellants without distinction, *e.g.*, based on provider type, and thus include inpatient rehabilitation facilities. *See id.* ¶ 19(b) (RA program contract modifications), ¶ 19(e) (OMHA settlement conference facilitations), ¶ 19(h) (senior ALJ program), ¶ 21(a) (expanding the Medical Appeals System). In fact, several inpatient rehabilitation facilities have expressed interest in the OMHA settlement conference facilitation described in paragraph 19(e) of Ms. Murray's declaration.[4] Amicus' assertion that rehabilitation hospitals are unlikely to request speedier on-the-record adjudication because it would eliminate the opportunity for treating physician testimony, Amicus Br. at 13, is not well-founded given that providers are required to provide a "full and early presentation of evidence" prior to ALJ review, which can include treating physician affidavits or declarations. *See, e.g.*, 42 U.S.C. § 1395ff(b)(3) (requiring provider to establish good cause to present evidence to ALJ that was not presented to QIC).

Moreover, that the impact of several administrative initiatives cannot at present be quantified, *see* Murray Decl. ¶ 21, does not mean that "HHS has no idea whether they will actually reduce the delays in processing Medicare claim appeals," as Plaintiffs assert. Pls.' Opp'n at 8-9. The Department designed the initiatives to reduce the backlog and increase adjudicative efficiency, and it believes that the initiatives are having the intended effect. Murray Decl. ¶ 21. Once these initiatives are fully implemented and their results can be measured, the Department will revisit their estimated impact and include

[4] While some inpatient rehabilitation facilities may not meet current eligibility criteria, OMHA and CMS continue to re-evaluate the criteria to determine if they can be modified to encompass additional providers.

projections on that score. HHS anticipates that, in the event the Court grants the Secretary's motion, it will be able to provide estimated impact data for many of the administrative initiatives described in paragraph 21 of Ms. Murray's declaration in status updates to the Court.

Both Plaintiffs and Amicus cite to a Government Accountability Office (GAO) Report that was issued after the Secretary filed her motion. Pls.' Opp'n at 5 (citing GAO, *Medicare Fee-for-Service: Opportunities Remain to Improve Appeals Process* (May 2016), *available at* http://www.gao.gov/assets/680/677034.pdf ("GAO Report")); *see also* Amicus Br. at 5. The report further demonstrates the seriousness with which the Secretary has addressed the backlog and the progress of the political branches. The GAO recommended that the Secretary take four additional actions to reduce the number of Medicare appeals and strengthen oversight of the appeals process, and the Secretary concurred with each.[5] *Id.* at 42-43; *id.* at 78-80 (App. V, HHS comments on draft of GAO Report at 2-4).

As Plaintiffs and Amicus emphasize, the administrative efforts to reduce the OMHA backlog that are presently underway are not projected to eliminate the appeal

[5] The Secretary observed that the GAO's recommendation in its draft of the report, that HHS implement a more efficient way of adjudicating certain repetitive claims, is already included in the President's Budget for FY 2017. GAO Report at 80 (App. V, HHS comments on draft of GAO Report at 4). Additionally, as Plaintiffs and Amicus emphasize, the GAO was concerned that, without more reliable and consistent data to monitor the appeals system, HHS "will continue to lack the ability to identify issues and policies contributing to the appeals backlog, as well as measure the funds tied up in the appeals process." GAO Report at 41. It recommended that HHS modify the various Medicare appeals data systems to address those concerns. *Id.* at 42. HHS generally concurred with the recommendation and expressed that it will work toward changes to systems or establishing new systems that will address the recommendations. *Id.* at 42, 78-80. HHS is currently exploring the systems requirements necessary to implement the recommendations and the costs and timelines for making the systems changes.

delays by themselves. HHS, of course, remains open to additional administrative measures, including some that Plaintiffs describe, if those measures are projected to reduce the backlog in a manner consistent with the agency's statutorily-assigned mission. *See infra* at 20-22. In fact, on June 28, 2016, HHS displayed for public inspection a Notice of Proposed Rulemaking (NPRM) that introduces even more administrative measures designed to reduce the backlog. *Medicare Program: Changes to the Medicare Claims and Entitlement, Medicare Advantage Organization Determination, and Medicare Prescription Drug Coverage Determination Appeals Procedures* (2016), *available at* https://federalregister.gov/a/2016-15192.[6] The Secretary proposed to codify in regulation additional efforts to expand the pool of available OMHA adjudicators, increase consistency among the levels of appeal, and improve efficiency by streamlining the appeals process so that less time is spent by adjudicators and parties on repetitive issues and procedural matters. *See id.* at 14. The NPRM further demonstrates HHS's continuing commitment to addressing the appeals workload challenges, and is one part of the Department's comprehensive effort to address the appeals workload through every available administrative means under its current statutory and budgetary authorities.

And if the current administrative measures are coupled with the legislative proposals pending before Congress, HHS projects that the OMHA appeals backlog will be eliminated by fiscal year 2021. Murray Decl. ¶ 18. Plaintiffs' and Amicus cursory dismissal of the prospect for legislative action is unwarranted, as explained in section II below.

[6] The proposed rule is scheduled to be published in the Federal Register on July 5, 2016. A pre-publication copy of the proposed rule is attached hereto as Exhibit A.

B. Neither Plaintiffs nor Amicus Undercuts HHS's Demonstration of Meaningful Reforms to the RA Program.

Plaintiffs and Amicus are simply incorrect to deny that the Secretary has made meaningful reforms to the statutorily-required RA program. *See* Pls.' Opp'n at 13; Amicus Br. at 11-13. HHS described in detail the ways in which the reforms are projected to reduce the appeals backlog. *See* Murray Decl. ¶ 19(b).

None of Amicus' criticisms of HHS's reforms of the RA program has merit. The first two reforms—which add a discussion period before a claim may be referred for recoupment, and impose a limit on the number of reviews under an approved topic—are newly implemented initiatives expected to improve the accuracy of RA reviews and decrease the number of RA-related appeals, but they are too recent for their impacts to be fully assessed. *See id*. Amicus incorrectly asserts that these provisions were in place prior to the RA contract modifications; the provisions result from the contract modifications. *Id.* The web link and statement of work that Amicus cites do not show otherwise, but instead reflect that these initiatives arose from the recent contract modifications. *See* CMS, *Recent Updates* (last modified June 2, 2016), *available at* https://www.cms.gov/research-statistics-data-andsystems/monitoring-programs/medicare-ffs-compliance-programs/recovery-auditprogram/recent_updates.html; CMS, *Statement of Work for the Recovery Audit Program at 25–26, available at* https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/recovery-audit-program/downloads/090111racfinsow.pdf. And, again contrary to Amicus' contention, the third modification—a provision deferring payment until after the QIC decision—strengthens the financial incentive to RA contractors to issue accurate

determinations, as compared to simply requiring the contractor to refund its fee if a denial is reversed, because of the time-value of money.

Amicus is also incorrect in asserting that the 2014 rate of RA appeals was 20% only because the RA program was "placed on hold" that year. Amicus Br. at 12. HHS's 2014 Report to Congress for RA contractors makes clear that the program hold was due to contract closeouts, was brief, and was only part of the reason for the decrease of RA-related appeals. *See* CMS, *Recovery Auditing in Medicare for Fiscal Year 2014, FY 2014 Report to Congress as Required by Section 1893(h) of the Social Security Act* at 4, 13 (Oct. 15, 2015), *available at* https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Recovery-Audit-Program/Downloads/RAC-RTC-FY2014.pdf. Prohibition on inpatient status reviews also led to a decrease in reviews and, as a consequence, appeals. *See id.* at 13.

Although, as Plaintiffs emphasize, appeals from RA contractor decisions still constitute a sizeable portion of the OMHA backlog, they are incorrect in suggesting that an order of mandamus requiring the Secretary to gut the RA program would solve the problem. As an initial matter, eliminating the RA program today would have absolutely no effect on the existing backlog or the pending appeals of RA decisions. Regardless, the backlog is attributable to multiple factors, and the percentage of pending RA-related appeals is dropping significantly as a result of HHS's changes to the RA program; as of April 25, 2016, RA-related appeals represented just 31% of pending appeals. Murray Decl. ¶¶ 9-16. Notably, apart from claiming that the Secretary overstates the impact of the increase in the number of new beneficiaries, Plaintiffs avoid discussing the impact of the other backlog contributors that HHS describes, which include a trend of providers

appealing every denied claim as a matter of course, a significant increase in appeals filed by Medicaid state agencies, and other program integrity efforts to identify inappropriate Medicare payments. *Id.* ¶¶ 11-13.

Plaintiffs' assertion that the RA program is the "primary culprit in creating and sustaining" the existing backlog is unsupported. *See* Pls.' Opp'n at 5.[7] In support of this claim, Plaintiffs compare beneficiary-filed appeals to appeals of RA-denials and assert that, because the number of RA appeals greatly exceeds the number of beneficiary appeals, the RA program is the major contributor to the backlog. *Id*. The comparison is grossly misleading because it ignores provider-filed appeals not related to a RA denial. In fact, for 2014, nearly half of the appeals filed with OMHA in 2014 were not related to RA denials (184,527 out of 404,377 appeals). *See* GAO Report at 61.[8] Plaintiffs' claim further overlooks three of the four additional contributing factors described by HHS. *See* Murray Decl. ¶¶ 11-13 (describing increase in OMHA's traditional workload, trend of providers appealing every denied claim, and increase in Medicaid state agency appeals). Plaintiffs' suggestion that eliminating the RA program (a course of action that, in any event, is statutorily foreclosed) would resolve the backlog is further undermined by their reliance on statistics on RA-related appeals from two years ago and before many of the administrative measures that HHS has undertaken, Pls.' Opp'n at 5. HHS, in contrast, presents statistics concerning RA-related appeals that are much more recent (as of April 25, 2016). Murray Decl. ¶ 15. And Plaintiffs' bald assertion that non-RA Medicare

[7] HHS prioritizes beneficiary appeals, and the average wait time for an ALJ decision on a beneficiary appeal was 68.4 days as of April 30, 2016. Murray Decl. ¶ 14.

[8] Notably, many of the RA-related appeals were removed from the backlog as part of the CMS hospital settlements. *See* Murray ¶ 19(a).

contractors exhibit "pathologies" is without any support in the declaration of HHS's Assistant Secretary for Financial Resources and Chief Financial Officer that they cite. Pls.' Opp'n at 5 (citing Murray Decl. ¶ 16).

Plaintiffs and Amicus criticize the Secretary's reliance on HHS statistics showing a decrease in incoming RA-related appeals, maintaining that the decline is only a temporary consequence of a suspension in 2014 of initiation of RA claim review to enable RA contractors to complete outstanding claim reviews by the end of their contracts. *Id.*; Amicus Br. at 12-13. The Department's long-term projections estimate, however, that with the modifications included in the new RA contracts the level of RA-related appeals will continue to represent a minority of new appeals reaching OMHA. Murray Decl. ¶ 19(b). As stated previously, the program hold due to the contract closeout was brief and only part of the reason for the decrease in RA-related appeals in 2014. *See supra* at 12. While the appeals may increase when the new contracts are awarded, HHS expects that this should be offset by the RA program changes. *See* Murray Decl. ¶ 19(b).

II. Plaintiffs and Amicus Demonstrate No Basis for Dismissing the Prospect of Legislative Action that Would Enhance HHS's Ability to Reduce the OMHA Backlog.

Plaintiffs assert that "[t]here is virtually no chance that the legislative proposals will become law," Pls.' Opp'n at 8, and Amicus echoes that the additional funding and authorities that HHS has requested of Congress are "highly unlikely," Amicus Br. at 6. The available evidence, however, does not support the conclusion that Congress is ignoring pending legislative proposals to combat the OMHA backlog.

First, the GAO report—which itself was prepared pursuant to a congressional request, *see* GAO Report at 1-5—reflects Congress's continued engagement with the problem of the backlog. The report was issued only in May 2016, and there is no basis for concluding that Congress will not consider this report in determining whether the pending legislative proposals should be enacted.

Second, the Court of Appeals plainly intended its ruling to pressure Congress to act, which necessarily means that the Court contemplated that Congress would be afforded some time to respond to that ruling. *See AHA*, 819 F.3d at 193-94 (citing *In re Aiken County*, 725 F.3d 255, 258-59 (D.C. Cir. 2013), in which the Court of Appeals had first afforded Congress the opportunity to act before issuing mandamus); *see also* Oral Arg. at 47:47-49:47, *AHA*, 819 F.3d 183 (No. 15-5015) (Tatel, J., suggesting that an order short of granting mandamus would put pressure on Congress to give the Secretary the resources necessary to issue OMHA decisions within the statutorily contemplated time frame), *available at* https://www.cadc.uscourts.gov/recordings/recordings.nsf/DocsByRDate?OpenView&count=100&SKey=201511. Neither Plaintiffs nor Amicus provides any basis for concluding that Congress will ignore the D.C. Circuit if given sufficient time to act.

Third, with respect to the President's proposed FY 2017 Budget, Congress continues to work on appropriations legislation for the coming fiscal year. Until an appropriations bill receives a vote in either the House or Senate and is conferenced between the two chambers, it is premature to speculate on the level of FY 2017 funding. Plaintiffs' assertion that the amount requested in the President's Budget would be insufficient to meaningfully reduce the backlog misleadingly relies on the comparison of

estimated incoming appeals to a single legislative proposal—additional funding from RA collections estimated to increase the number of appeals adjudicated per year by 101,000. Pls.' Opp'n at 11. The President's Budget includes *eight* additional legislative proposals, each of which is expected to increase the number of appeals adjudicated. *See* Murray Decl. ¶ 22(a), (c)-(i). For example, HHS estimates that the budget proposals to use Medicare magistrates and to increase the amount-in-controversy for an ALJ hearing, proposals also included in the AFIRM Act, would divert 294,000 appeals from the ALJ hearing queue by the end of FY 2020. *Id.* ¶ 22(a). Additionally, the funding increases requested in the President's Budget together with HHS's administrative measures would result in OMHA's disposition capacity outpacing incoming receipts by approximately 60,000 appeals beginning in FY 2017 and continuing to outpace receipts by approximately 200,000 appeals in FY 2020. *See id*., Ex. 1. And the additional resources that would become available if the AFIRM legislation is enacted would increase OMHA's disposition capacity even further. *See id*. ¶ 22.

Plaintiffs inaccurately assert that the Secretary has "only half-heartedly pursued" additional funding. Pls.' Opp'n at 13 n.4. The FY 2016 President's Budget included a robust increase in budget authority designated for increased adjudication capacity at OMHA (an appropriations level that Congress did not fund), as does the FY 2017 President's Budget. HHS, *FY 2016 Budget in Brief* at 139; HHS, *FY 2017 Budget in Brief* at 158, both *available at* http://www.hhs.gov/about/budget#brief.

Plaintiffs are also incorrect in suggesting that the Secretary could have but has not reprogrammed 2016 funds. Pls.' Opp'n at 13 n.4. As the Secretary explained previously in this action with respect to FY 2014, *see* Def.'s Reply in Supp. of Mot. to Dismiss at

18-21, ECF No. 19 (Oct. 17, 2014), appropriations legislation for HHS authorizes the Secretary to make certain funds transfers but (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%). Consolidated Appropriations Act, 2016, Pub. L. No. 114-113, Div. H, § 205, 129 Stat. 2242, 2619.

Because OMHA is funded through a specific appropriation, *id.* at 2618, the Secretary's ability to use her discretionary authority to transfer funds to it is limited 3 percent of the OMHA appropriation.[9] *See id.* And even 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 $107,381,000 appropriation in FY 2016 would be less than $3.25 million. And 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.").[10] Transfer of funds without authority would violate statutory restrictions on

[9] A reprogramming of funds, such as Plaintiffs reference, 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 appropriation. But Plaintiffs are not demanding (and cannot demand) a reprogramming of funds within OMHA itself.

[10] *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

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. § 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 AFIRM bill was favorably reported by the Senate Finance Committee in June 2015, *see* S. Rep. No. 114-177 (2015), and remains pending before the full Senate. The bill has bipartisan support, unlike other more controversial bills. *See* Press Release, Senate Finance Committee, *Hatch, Wyden Applaud Introduction of Bipartisan Bill to Overhaul Medicare Audit & Appeals Process* (Dec. 9, 2015), *available at* http://www.finance.senate.gov/chairmans-news/hatch-wyden-applaud-introduction-of-bipartisan-bill-to-overhaul-medicare-audit-and-appeals-process.[11] It is also possible that the House of Representatives may take up a bill similar to the Senate's once the Senate passes the bill. *See id.* In short, Plaintiff's cursory dismissal of Congress's active legislative efforts is disrespectful of a coordinate branch of government and is contrary to the Court of Appeal's remand instructions, which plainly contemplate that Congress should be afforded an opportunity to respond.

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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.").

[11] The AFIRM Act thus stands in stark contrast to Plaintiffs' reference to the Affordable Care Act. *See* Pls.' Opp'n at 10. Whatever the likelihood of congressional action may be in the politically-charged atmosphere concerning that statute, here, the AFIRM Act enjoys bipartisan support, and it is widely understood in Congress that further legislative action would be appropriate to address the backlog in OMHA appeals.

Lastly, contrary to the suggestion of Amicus, Amicus Br. at 8, the Statutory Pay-As-You-Go Act of 2010, Pub. L. No. 111-139, 124 Stat. 8 (2010) (codified at 2 U.S.C. §§ 931-39), does not require an offset for all legislation that increases mandatory expenditures. It requires both the House of Representatives and the Senate to provide the budgetary effects of any PAYGO Act, which is "a bill or joint resolution that affects direct spending or revenue relative to the baseline," and defines a "budgetary effect" as the amount that PAYGO legislation changes outlays from direct spending or revenues relative to the baseline. *Id.* § 3 (codified at 2 U.S.C. § 932). The Act further requires, *inter alia*, the Congressional Budget Office to make PAYGO estimates and the Office of Management and Budget to keep PAYGO scorecards for both 5 and 10-year periods. *Id.* § 4 (codified at 2 U.S.C. § 639). But the Act does not require that for every PAYGO Act that involves expenditure of funds there be enactment of an equal savings. *See* Pub. L. No. 111-139.

III. Plaintiffs and Amicus Have Not Demonstrated that the Court Should Issue an Order of Mandamus Now.

The Court of Appeals recognized that any order of mandamus must be based on a showing of "compelling equitable grounds." *AHA*, 812 F.3d at 192. Plaintiffs and Amicus have not made such a showing.[12] Although they have alleged hardship to some hospitals as a result of the Medicare appeal delays, they have not demonstrated that the Judiciary should infringe upon the authority and discretion of the Executive Branch while it is in the midst of making significant progress toward reducing the OMHA backlog and disregard legislative proposals pending before Congress. Again, the Court of Appeals

[12] Nor have they even moved for an order that the writ issue. The only matter pending before the Court is the Secretary's motion for a limited stay.

recognized that the backlog ideally should be resolved by the political branches, *id.* at 192-93, and the political branches are making significant progress in that regard. And, as referenced in the Secretary's Opening Memorandum, there is no basis to expect that an order of mandamus now would succeed in expediting Plaintiffs' appeals any more than the actions that HHS is taking.

Plaintiffs simplistically suggest that this Court should just order the Secretary to decide all appeals in 90 days. Such an order could serve no useful purpose. The magnitude of the backlog and the limits on available resources make it impossible that the agency could comply with such an order while continuing to maintain the quality and integrity of OMHA decisions that are required by statute. *See* 42 U.S.C. § 1395ff(d)(4) (ALJs must issue reasoned written decision setting forth, *inter alia*, specific reasons for determination, including, to the extent appropriate, a summary of the clinical or scientific evidence used in making the determination); 42 C.F.R. § 405.1046(b) (same).[13]

Issuing a writ of mandamus before the administrative efforts now underway and any proposed legislative actions have had a chance to take effect would be premature. Again, the Secretary has not dismissed the idea of additional administrative measures, including those described by Plaintiffs, Pls.' Opp'n at 13-14. It is plain, however, that most of the proposals that Plaintiffs have put forth would not meaningfully add to the Secretary's current efforts to resolve the backlog.

Plaintiffs' proposal that a physician review and approve all RA denials after "complex review," i.e., review of the medical record, is cost-prohibitive, given the high

[13] OMHA certainly could not issue decisions that comply with these requirements on all pending claims within the 180 days that Plaintiffs' proposed order contemplates, ECF No. 31-1, June 13, 2016.

volume of complex review denials—537,144 in FY 2014. *See* CMS, *Recovery Auditing in Medicare for Fiscal Year 2014, FY 2014 Report to Congress as Required by Section 1893(h) of the Social Security Act* at 38, *available at* https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Recovery-Audit-Program/Downloads/RAC-RTC-FY2014.pdf. The new Statement of Work for RA contracts, however, does provide for medical expertise in complex review by requiring that medical necessity determinations be made by registered nurses (RNs) or therapists. *E.g.*, Statement of Work for the Part A/B Medicare Fee-for-Service Recovery Audit Program – Region 1, May 16, 2016 Amendment ("SOW"), at 22-23, copies by region *available at* https://www.fbo.gov/index?s=opportunity&mode=form&id=05f9dd6dd1ff87c0f4184b20ca037836&tab=core&_cview=1.[14]

In addition, the financial penalty that Plaintiffs propose HHS impose on RA contractors when a claim denial is overturned is unnecessarily punitive. Instead, the new Statement of Work for RA contracts provides a financial incentive for RAs to exceed CMS appeal overturn targets at the first level of appeal; for every percentage point below a 10% appeal overturn rate, the contractor earns a 0.1% contingency fee increase. *Id.* at 39 (Task 3). CMS also requires RA contractors to maintain an accuracy rate of at least 95% in making their determinations, and for each percentage point above 95% the contractor earns a 0.2% contingency fee increase. *Id.* at 40 (Task 4). And CMS takes

[14] The CMS Program Integrity Manual similarly allows other contractors to use nurses (licensed practical nurses (LPNs) as well as RNs), physicians, and other clinicians for complex medical review. Medicare Program Integrity Manual § 3.3.1.1. (Rev. 634, Jan. 22, 2016), *available at* https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/pim83c03.pdf.

action against contractors who exceed the 10% appeal overturn rate or do not achieve the 95% accuracy rate, including not exercising the next option period of the contract. *Id.* at 39-40 (Tasks 3-4).

Plaintiffs have also proposed that interest on a claim not be assessed until an ALJ decision, but this proposal squarely conflicts with the Medicare statute. *See* 42 U.S.C. § 1395ddd(f)(2)(B) ("Insofar as the determination on such appeal is against the provider of services or supplier, interest on the overpayment shall accrue on and after the date of the original notice of overpayment."). Plaintiffs' proposal of permitting hospitals to delay repayment of denied claims until after an ALJ decision also is in conflict with statutory requirements. *See* 31 U.S.C. § 3711 (requiring Federal agencies to collect a claim for money arising out of the activities of the agency); 42 U.S.C. § 1395ddd(f)(2)(A) (authorizing suspension of recoupment of an overpayment only through the reconsideration level of appeal). And in any event, delaying repayment—after three previous determinations that the claim is not valid—would do nothing to resolve the backlog; indeed, such a measure would likely create an incentive for providers to appeal at even greater rates, thereby worsening the backlog.[15]

[15] Plaintiffs also suggest that the agency could alleviate the backlog by promulgating regulations requiring RA contractors to consider only the evidence available to the treating physician at the time of treatment. *See* Pls.' Opp'n at 13. While HHS has not ruled out promulgating such a regulation, it is unlikely that it would have any effect on the backlog because CMS already has in place a longstanding policy requiring exactly that limitation of evidence that RA contractors consider. *See* CMS, *Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Fiscal Year 2014 Rates; Quality Reporting Requirements for Specific Providers; Hospital Conditions of Participation; Payment Policies Related to Patient Status*, 78 Fed. Reg. 50,496, 50,950-51(Aug. 19, 2013); CMS, Frequently Asked Questions at 1, *available at* https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medical-Review/Downloads/QAsforWebsitePosting_110413-v2-CLEAN.pdf.

Amicus' criticism of HHS's rejection of its proposal of a global settlement for inpatient rehabilitation facilities at 80% of the total value of their claims is also misplaced. *See* Amicus Br. at 9-11. The proposal concerned various types of claims with multiple denial reasons, unlike the homogenous claims of the hospitals with which CMS entered global settlements at 68% of the total value of the claims. *See* Murray Decl. ¶ 19(a). Global settlement on the terms that the inpatient rehabilitation facilities demanded was consequently unworkable given the Department's statutory responsibility to ensure that payments from the Medicare Trust Funds are made only for valid claims for reimbursement. *See id*. ¶ 7.[16]

* * *

The balance of the equities falls in favor of entering a limited stay through the close of the next appropriations cycle, September 30, 2017, *see* 2 U.S.C. § 631, with the Secretary to provide status reports every six months. The interest in allowing the political branches to continue to make significant progress in addressing the OMHA appeals backlog is strong, as the both this Court and the Court of Appeals have recognized. A writ of mandamus while that progress is underway would be premature, and there is no showing of compelling equitable circumstances that would justify premature entry of the extraordinary and drastic remedy of mandamus.

[16] Notably, Amicus' claimed 80.2% reversal rate includes all appeals of inpatient rehabilitation facilities, not just appeals at the ALJ level. *See* Decl. of Yurong Zhang ¶ 8, ECF No. 32-2 (June 20, 2016). And the reference is based on a survey to which just 21.5% of the facilities responded; Amicus presents no evidence that the 21.5% sample is representative of inpatient rehabilitation facilities nationwide. *See id*. ¶ 7. Further, the overall reversal rate of Part A denials on appeal has been trending downward. *See* GAO Report at 69.

CONCLUSION

For the foregoing reasons and those set forth in the Secretary's Opening Memorandum, the Court should grant the Secretary's motion for a stay, and order this action stayed until September 30, 2017, during which time the Secretary shall submit status reports every six months.

Respectfully submitted,

BENJAMIN C. MIZER
Principal Deputy Assistant Attorney General
CHANNING D. PHILLIPS
United States Attorney
JOEL McELVAIN
Assistant Director, Federal Programs Branch

/s/ Caroline Lewis Wolverton

CAROLINE LEWIS WOLVERTON
Senior Trial Counsel, Federal Programs Branch
D.C. Bar No. 496-433
U.S. Department of Justice
Civil Division
P.O. Box 883
Washington, D.C. 20001
Tel. (202) 514-0265
Fax (202) 616-8470
caroline.lewis-wolverton@usdoj.gov

Attorneys for Defendant

Of Counsel:
MARGARET M. DOTZEL
Acting General Counsel
JANICE L. HOFFMAN
Associate General Counsel
SUSAN MAXSON LYONS
Deputy Associate General Counsel for Litigation
KIRSTEN FRIEDEL RODDY
Attorney
United States Department of Health and Human Services