UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

AMERICAN HOSPITAL ASSOCIATION, *et al.*,	)	
	)	
Plaintiffs,	)	
	)	Civil Action No. 14-cv-00851 (JEB)
v.	)	
	)	
ALEX M. AZAR, in his official capacity as Secretary of Health and Human Services,	)	
	)	
Defendant.	)	
_____	)	

DEFENDANTS' STATUS REPORT AND RESPONSE TO PLAINTIFFS' PROPOSED NON-DEADLINE REMEDIES

CHAD A. READLER
Acting Assistant Attorney General

JEAN LIN
Acting Deputy Director,
Federal Programs Branch

/s/ Nicholas Cartier
NICHOLAS CARTIER (D.C. Bar # 495850)
ADAM SIPLE (NY Bar # 4387296)
Trial Attorneys
U.S. Department of Justice
Civil Division, Federal Programs Branch
20 Massachusetts Avenue NW
Washington, DC 20530
Telephone: (202) 616-8351
Facsimile: (202) 616-8460
Counsel for Defendant Attorneys

Of Counsel:
ROBERT P. CHARROW
General Counsel
JANICE L. HOFFMAN
Associate General Counsel
SUSAN MAXSON LYONS
Deputy Associate General
Counsel for Litigation
KIRSTEN FRIEDEL RODDY
United States Department of Health and
Human Services

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases **Page(s)**

Statutes

Regulations

INTRODUCTION

Pursuant to this Court's March 22, 2018 Order, the Secretary of the Department of Health and Human Services ("HHS") provides this memorandum to detail the progress of his efforts to reduce the backlog and to provide a projection of when the backlog is expected to be eliminated. This memorandum also responds to AHA's proposed "non-deadline" remedies, and explains why those proposed remedies are either unhelpful, impossible to implement, or would actually worsen the backlog.

To begin, AHA's proposals cannot be justified based on the current record, which has changed considerably since the Court last determined that mandamus relief was appropriate in December of 2016. Indeed, the circumstances of the case have changed dramatically following the Court's last hearing in March of this year because Congress has since appropriated significant additional funding to the Office of Medicare Hearings and Appeals ("OMHA") that will allow OMHA to hire numerous new ALJs and staff and more than double its current adjudication capacity. Given this appropriation, HHS is now able to project that, with a continuation of current funding levels, the Secretary will be able to ***eliminate*** the backlog entirely in FY 2022.

In addition to the new funding from Congress, the Secretary's expanded settlement initiatives have borne fruit. *See* Part II.B. Furthermore, the steady declines in appeals of RAC determinations seen in FY 2017 have become even more pronounced in FY 2018: In the first three quarters of this year, only 661 RAC-related appeals have reached OMHA, amounting to 1.4% of appeals received by OMHA this year. *See* Part II.A. The data show that AHA's fundamental premise underlying this litigation — that the RACs are the drivers of the backlog and that further changes to the RAC program are needed to solve the problem —is no longer

valid. AHA's latest RAC-related proposals thus would not help to reduce the backlog but likely threaten the economic viability of an already significantly curtailed program that Congress requires to exist.

AHA's other non-deadline mandamus remedies similarly would not improve the backlog but can be expected to create new incentives to file additional appeals and discourage settlement. Moreover, throughout its brief, AHA mistakenly presumes that HHS is not acting in good faith, which has no basis in the record and conflicts with the presumption of regularity accorded to agency actions. *See, e.g.*, *CTIA–The Wireless Ass'n v. FCC*, 530 F.3d 984, 989 (D.C.Cir.2008) ("[W]e have long presumed that executive agency officials will discharge their duties in good faith."). In addition, AHA takes the position that the Court must order its proposed programmatic changes as long as they are possible to implement. *See* Plaintiffs' Response Regarding Non-Deadline Remedies at 1, ECF No. 82. That argument is based on a misreading of the D.C. Circuit's decision in *AHA II*, which held that "a court may not require an agency to render performance that is impossible," *Am. Hosp. Ass'n v. Price*, 867 F.3d 160, 167 (D.C. Cir. 2017) ("*AHA II*"), and vacated and remanded with instructions for this Court to determine whether it was possible for HHS to comply with the Court's prior mandamus order requiring the elimination of the backlog by December 31, 2020. *Id*. at 169. *AHA II* neither requires nor authorizes some wide-ranging "possibility" inquiry untethered to the predicate for mandamus relief.

In weighing the equities, the Court should follow the D.C. Circuit's guidance in *AHA I*, where it stated that "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" and instead order "the agency to submit status reports." *Am. Hospital Association v.*

Burwell, 812 F.3d 183, 193 (D.C. Cir 2016) ("*AHA I*"). Such is the case now. As noted, Congress's recent appropriation is projected, with the continuation of current funding levels, to allow the Secretary to eliminate the backlog in FY 2022. Coupled with the significant progress the Secretary has made to date (as explained below), mandamus relief is premature at this time. Instead, the Court could simply order the Secretary to submit status reports to apprise the Court of his progress. *Id.* at 193 (on remand, court could consider ordering status reports).

The Secretary will provide below a report of the progress HHS has made in eliminating the backlog and a response to AHA's proposals.

I. STATUS UPDATE ON THE EFFORTS TO ELIMINATE THE BACKLOG.

For years, HHS has explained that its ability to eliminate the backlog of appeals pending at OMHA is dependent on Congress appropriating additional funds to hire new ALJs. The agency's repeated requests have finally been answered. On March 23, 2018, Congress appropriated $182.3 million for OMHA to address the issue of the Medicare appeals backlog. *See* Consolidated Appropriations Act, 2018, Pub. L. No. 115-141, tit. II, 132 Stat. 348, 739 (2018). This represents a 70% increase over the amount appropriated for fiscal year 2017. *See* August 3, 2018 Declaration of Nancy J. Griswold ("Aug. 3, 2018 Griswold Decl.") ¶ 3, Ex. 1. With this additional appropriation, OMHA plans to increase ALJ staffing by approximately 80 ALJs and 600 new positions over the next 14 months. *Id*. When fully staffed, OMHA will have a total of approximately 170 ALJ teams onboard. This is projected to enable OMHA to resolve around nearly 188,000 appeals per year, more than doubling its FY 2017 disposition capacity level of approximately 85,000 appeals. *See* Long-term Projections FY 2018 Q3, Ex. 2; *see also* Medicare Appeals Dashboard, Ex. 3

OMHA's adjudication capacity in FY 2017 was not enough to keep pace with the almost 113,000 new receipts received by OMHA in that year, resulting in an additional 28,000 appeals

added to the backlog. *Id*. Thus, prior to the recent Congressional appropriation, and notwithstanding OMHA's success at maximizing its adjudication capacity at then-current funding levels, the backlog was expected to continue to grow. Now, in light of the new funding, OMHA will be able to process thousands ***more*** appeals each year than it receives. HHS projects that, at current funding levels, OMHA's adjudication capacity will increase over FY 2017 levels by 23% in FY 2018, 42% in FY 2019, 108% in FY 2020, and approximately 122% in FY 2021 and 2022. *See* Long-term Projections FY 2018 Q3.

Along with the Secretary's success at reducing the number of appeals entering the system, *see, e.g.*, Part II.A (addressing declines in RAC-related appeals), and the settlement of over 465,000 backlog-related appeals, *see* Part II.B, this increased adjudication capacity is projected, at a continuation of current funding levels, to eliminate the backlog entirely in FY 2022. Declaration of Norris W. Cochran ¶ 4, Ex. 4.

To be clear, even with the infusion of congressional appropriations, absent additional legislative action, compliance remains impossible with the Court's previous mandamus order requiring the elimination of the backlog by December 31, 2020, with fixed percentage reductions in the preceding years, and thus, the Court should not reissue it. *See AHA II*, 867 F.3d at 166, 170. The Secretary respectfully refers the Court to the Secretary's prior briefing demonstrating why it is impossible to do so. *See* Sec's Mem. in Supp. of Mot. for Summ. J. at 7-28, ECF No. 66-1; Sec's Reply Br. at 5-12, ECF No. 75. Among other reasons, the Secretary will not be able to settle the appeals in the backlog *en masse* given the thousands of appeals from providers with open Department of Justice investigations and other program-integrity concerns. Sec's Reply Br. at 9-10.

The writ of mandamus is an extraordinary form of relief that is inappropriate if the political branches are taking meaningful steps to resolve the problem and are doing so in good faith with all deliberate haste. *See AHA* I, 812 F.3d at 192-94; *see also In re Medicare Reimbursement Litig*., 414 F.3d 7, 10 (D.C. Cir. 2005) (even where the legal requirements for mandamus jurisdiction are satisfied, "a court may grant relief only when it finds compelling equitable grounds" for doing so) (citation and internal punctuation omitted); *CTIA–The Wireless Ass'n* , 530 F.3d at 989 (presuming that "executive agency officials will discharge their duties in good faith.").

II. SECRETARY'S RESPONSE TO AHA'S PROPOSED "NON-DEADLINE" MANDAMUS REMEDIES.

In accordance with the Court's order, the Secretary addresses each of AHA's proposed remedies and identifies whether it is "possible" or "helpful" for the agency to implement the proposal. Some of AHA's proposals would violate federal law (such as its proposals to incorporate a financial penalty into the RAC Statement of Work and to reduce the rate of interest applied to overpayment determinations). But even for the proposals that are "possible" to implement, they would not improve the backlog, and, if anything, would make the backlog worse. Therefore, the Court should not order these proposed mandamus remedies, even if such programmatic relief were a proper form of mandamus relief, which it is not. Under the Mandamus and Venue Act, 28 U.S.C. § 1361, a district court has "jurisdiction [over] any action in the nature of mandamus to compel an officer or employee of the United States or any agency thereof to perform a duty owed to the plaintiff." 28 U.S.C. § 1361. Thus, mandamus authorizes a court to issue an order to comply with a clear, non-discretionary duty and nothing more. *See AHA I*, 812 F.3d at 191 (while AHA "seeks to compel the Secretary to make decisions within the statutory time frames," AHA acknowledges that "the means the Secretary uses to ensure they are

reached in a timely fashion are discretionary"). Mandamus simply does not authorize this Court to order AHA's wish list of changes to the agency's operations, which are injunctive in nature and thus not available via a writ of mandamus. *See Wolcott v. Sebelius*, 635 F.3d 757, 766 (5th Cir. 2011) ("The plain language of § 1361 is clear that it only grants jurisdiction to consider a mandamus action; it does not grant jurisdiction to consider actions asking for other types of relief—such as injunctive relief."); *cf. In re Barr Labs., Inc.*, 930 F.2d 72, 74 (D.C. Cir. 1991) ("respect for the autonomy and comparative institutional advantage of the executive branch has traditionally made courts slow to assume command over an agency's choice of priorities"); *Norton v. Southern Utah Wilderness Alliance*, 542 U.S. 55, 66 (2004) (emphasizing the need to "protect agencies from undue judicial interference with their lawful discretion, and to avoid judicial entanglement in abstract policy disagreements which courts lack both expertise and information to resolve").

A. The Court Should Deny Plaintiffs' Request To Impose Further Limitations On The RACs Beyond Those Already Implemented By HHS.

AHA requests that this Court restructure the RAC program to impose steep financial penalties on RACs, as well as to prevent RACs from reviewing any hospital claims. Plaintiffs' Response Regarding Non-Deadline Remedies at 2-4. These proposals, which have no support in the record, would not have any impact on the backlog, but instead threaten the viability of the RAC program — a program that Congress mandates to exist.

1. Steady Declines In RAC-related Appeals.

The Government has previously detailed the Secretary's successful efforts to settle approximately 341,000 RAC-related appeals in the backlog, Sec's Reply Br. at 18, such that RAC appeals now represent only 12.6% of the appeals pending at OMHA (down from 58% in FY 2015). Aug. 3, 2018 Griswold Decl. ¶ 6. In addition, the Government explained that the

new controls and limitations placed on the RACs by the agency have resulted in steep declines in new RAC-related appeals reaching OMHA. *See* Sec's MSJ at 22-25; Sec's Reply Br. at 18-21; *see also* Declaration of George Mills. ¶¶ 4-9, ECF No. 66-5. These changes include a number of procedural adjustments to the RAC program, including restricting the number of topics RACs can review, limiting their authority to request additional documents, and limiting the lookback period for inpatient-status appeals (a type of claim that was one of the short-term drivers of the backlog). *See* Sec's Reply Br. at 20; Mills Decl. ¶ 9c. In addition, the new RAC contract and Statement of Work (SOW) includes requirements for RACs to maintain an accuracy rate of over 95% as determined by an independent contractor and an overturn rate of less than 10% at the first level of appeal. Sec's Reply Br. at 20. Failure to do so will result in CMS taking necessary corrective action against the RAC, including the option to terminate the contract. *See* Mills Decl. ¶ 7c. The RAC SOW also includes financial inducements for achieving results beyond these minimum requirements. *Id*. ¶ 7a-b.

In FY 2017, a year ***after*** the RACs became fully operational under the new SOW, RAC-related appeals amounted to only 12% of incoming appeals at OMHA. Sec's Reply Br. at 19-20. This is in stark contrast to FY 2013 and 2014, when appeals from RAC determinations were one of the drivers of the backlog and made up over 50% of new appeals reaching OMHA in these years. Aug. 3, 2018 Griswold Decl. ¶ 6. The most recent data from the first three quarters of this fiscal year show an even greater decline in RAC-related appeals from FY 2017. For the first three quarters of FY 2018, only 661 RAC-related appeals have reached OMHA, amounting to a mere 1.4% of total appeals received by OMHA this year. *Id.* ¶ 6. In short, the last six quarters of data spanning the past 18 months show a continual and steady decline in RAC-related appeals reaching OMHA:

- Q2, FY 2017: 4,325 RAC receipts
- Q3, FY 2017: 2,097 RAC receipts
- Q4, FY 2017: 1,360 RAC receipts
- Q1, FY 2018: 384 RAC receipts
- Q2, FY 2018: 127 RAC receipts
- Q3, FY 2018: 150 RAC receipts

Cochran Decl. ¶ 4. These numbers demonstrate that the agency's efforts to reshape the RAC program have succeeded in reducing RAC-related appeals. The former flood of RAC-related appeals has now turned into a tiny trickle. Therefore, imposing additional constraints on the RACs —beyond the measures already instituted by the Secretary — would have no impact on the backlog.

2. AHA's Proposal To Impose A Financial Penalty On The RACs.

In spite of the data showing that RACs are no longer part of the backlog problem, AHA persists in seeking to impose significant financial penalties on RACs and requests that this Court order the agency to restructure the RAC SOW to "impose a 25% financial penalty on RACs with a greater-than-40-percent overturn rate at the ALJ level in a given quarter." Plaintiffs' Response Regarding Non-Deadline Remedies at 2. As the Government has explained at length in prior briefing, this proposal is not possible to implement because it would amount to an illegal liquidated damages provision barred by federal contracting law. *See* ECF No. 41 at 27-28. AHA's attempt to get around this restriction — specifically, its proposal to dramatically reduce the current contingency fee in the RAC contract and then pay a higher contingency fee when

RACs maintain a greater than 40-percent-accuracy rate at the ALJ level (Br. at 4) — is still an illegal penalty in substance even if it is dressed up as a financial incentive.[1]

AHA is also wrong that the agency imposes penalties on RACs in the current RAC SOW. *See* Plaintiffs' Response Regarding Non-Deadline Remedies at 3-4. AHA's brief refers to a ***draft*** RAC SOW that went out to bid, but was never finalized. August 3, 2018 Declaration of George G. Mills ¶ 4 ("Mills August 3, 2018 Decl."), attached as Ex. 5. The current operative RAC SOW does not contain any penalty provision. *Id*. ¶ 3.

More fundamentally, there is no need to impose a financial penalty on the RACs since the ***existing*** RAC payment structure and incentives are having the desired effect. *See supra* (explaining requirements and incentives for accuracy in RAC SOW). The proof of this is undeniable: only 661 RAC-related appeals reached OMHA in the first three quarters of this year. Cochran Decl. ¶ 4. And AHA fails to explain why imposing a penalty on top of the existing RAC initiatives would have more than a marginal impact on the OMHA backlog, if at all. AHA's RAC-related proposal is a solution in search of a problem.[2]

---

[1] In addition, ALJ overturn rates are an imprecise measure of a RAC's accuracy. While the RACs are bound to follow CMS program guidance and local coverage decisions, ALJs are only required to give these policies substantial deference. *See* 42 C.F.R. § 405.1062; Mills August 3, 2018 Decl. ¶ 5. That is why the current SOW requires RACs to maintain an overturn rate of less than 10% at the first level of the administrative appeals process conducted by the Medicare Appeals Contractor (MAC). *See* Mills Decl. ¶ 7a, ECF No. 66-5. The MACs and the RACs are bound by the same rules in reviewing determinations.

[2] Contrary to AHA's unsupported claim, the RACs, even before the new SOW, did not identify overpayments in all, or even most, hospital claims. According to the most recent RAC Report to Congress (FY 2015), for complex reviews (where the RAC reviews the medical record and other documentation), the rate at which RACs found errors was only ***17.9%***. *See* Appendix H-1 of the FY 2015 RAC Report to Congress, https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Recovery-Audit-Program/Downloads/FY2015-Medicare-FFS-RAC-Appendices.pdf. Finding an overpayment when not warranted in the hopes of payment would not be a sustainable business model because RACs receive no contingency fee if they lose on appeal before an ALJ, or at any level of appeal

3. AHA's Proposal To Transfer All Hospital Claims From RACs to Another Medicare Contractor.

In addition to proposing a modification of the RAC SOW to impose legally impermissible and unnecessary financial penalties, AHA also requests that this Court order the agency to require that any new reviews of hospital claims that would have been performed by RACs instead be performed by another contractor, known as Quality Improvement Organizations (QIOs).[3] *See* Plaintiffs' Response Regarding Non-Deadline Remedies at 4-5. Again, there is no justification for making such a drastic change since the Department's changes to the RAC program have been so successful at reducing incoming appeals. *See, e.g.,* Cochran Decl. ¶ 4. (661 appeals from RAC determinations have reached OMHA in the first three quarters of FY 2018).

As an initial matter, Plaintiffs' proposal is in tension with Congress's adoption of the RAC program, which occurred well after the QIO program was already in place. *See* 42 U.S.C. § 1320c-3; Pub. L. No. 97-248, 96 Stat 324 (1982) (creation of the QIOs, previously called Peer Review Organizations). If Congress had intended QIOs to conduct all hospital post-pay reviews, it would not have specified that RACs are to identify overpayment and underpayments and recoup overpayments "with respect to ***all services*** for which payment is made under [Medicare]" and be paid on a contingency-fee basis on the amounts the RAC recovered. *See* 42 U.S.C.

---

for that matter. That creates a strong incentive not to be overturned. Furthermore, RACs must now comply with the accuracy requirements of the new SOW or face the possible termination of their contracts. *See* Mills Decl. ¶¶ 7-8, ECF No. 66-5.

[3] The Secretary previously transferred a certain type of hospital claim (known as an inpatient-status claim) from RACs to the Medicare Administrative Contractors (MAC) and then to the QIOs to allow providers time to comply with the newly clarified inpatient stay rule and to provide education to providers on claims submitted after that rule. Mills Decl. ¶ 9c, ECF No. 66-5; Iwugo Decl. ¶ 4

§ 1395ddd(h)(1) (emphasis added). And AHA's proposal is also in tension with the contingent-fee payment structure that Congress established in the RAC program for post-payment review, where RAC payments are based on the overpayments collected as a result of a RAC's review, while QIOs are paid on a per-claim basis out of the Medicare Trust Funds. *See* Declaration of Jeneen Iwugo ¶ 8, Ex. 6.

Moreover, HHS anticipates that transferring post-payment review of all hospital claims to QIOs would involve extensive capacity building and training and could take at least a year. *See* Iwugo Decl. ¶¶ 6-7; Mills Aug. 3, 2018 Decl. ¶ 7. In the interim, fewer reviews of hospital claims necessarily would mean fewer program integrity checks to find payment errors, abuse, and fraud, which would undermine the Department's ability to maintain the financial integrity of the Medicare Trust Funds. Indeed, AHA fails to show that transferring hospital claim review to another contractor would speed up the elimination of the existing backlog aside from reducing the number of claims that are reviewed for accuracy.

On the other hand, withdrawing the entire universe of hospital claims from the RAC's purview could very well deter companies from bidding on RAC contracts and threaten the continued existence of the RAC program. Mills Decl. ¶ 10. Starting with the new RAC SOW, CMS requires the RACs to review different types of claims, which ensures the RACs are focusing on areas susceptible to high error rates and are not targeting only one provider or claim type. *Id.* ¶ 9. As a result, in order to remain financially viable, RACs need to be able to review high-dollar claims to compensate for their review of low-dollar claims, and most of the high-dollar claims are from hospitals. *Id.* ¶ 10. The economic viability of being a RAC would be threatened if all hospital claims were transferred to QIOs. This is not an idle concern. After the new RAC SOW and other restrictions were put in place, one existing RAC did not bid on the

new contract. *Id*. ¶ 9. And as AHA points out, the RAC trade-industry association has complained that "[t]he significant scale back of the RAC program over the past few years has caused [RACs] to lose the ground we had previously gained." Plaintiffs' Response Regarding Non-Deadline Remedies at 3. In addition to the six quarters of data showing a steep and steady decline in RAC-related appeals, Cochran Decl. ¶ 4, the complaints from the RAC trade association are a testament to the meaningful nature of the agency's restructuring of the RAC program.

Essentially acknowledging the reality that the RACs are no longer a problem, AHA suggests that if the Court does not order its RAC-related proposals, the agency may be "tempted in the future once again to use questionable tactics targeting high-dollar hospital claims to increase RAC receipts." *See* Plaintiffs' Response Regarding Non-Deadline Remedies at 3. The agency's good faith commitment to resolving the backlog should be presumed. The agency has settled hundreds of thousands of RAC-related appeals in the backlog and instituted a number of changes to the RAC program that have been remarkably successful. *See supra*. Moreover, by design, the agency's RAC-related changes impose new controls over the RACs. *Id.* These controls will prevent a return to the state of affairs when RACs were significant contributors to the backlog. In contrast, AHA's RAC-related proposals have no support in the present record and should be denied.

B. AHA's Proposal For This Court To Dictate The Terms Upon Which HHS Makes Settlement Offers And For HHS To Report On The Details Of Confidential Settlement Communications Should Be Rejected.

AHA has proposed a mandamus order in which the Department would be compelled to make a settlement offer to every provider who participates in the Settlement Conference Facilitation (SCF) program "based on the claimant's historical success rate at the ALJ level or the historical success rate at the ALJ level for claims of a similar kind." *Id*. Plaintiffs' Response

Regarding Non-Deadline Remedies at 6. AHA's argues that its proposal is needed because, "[a]s it stands, HHS does not promise that it will make a settlement offer or that the settlement offer will bear any relation at all to the strengths and weaknesses of its position." *Id*. at 7. AHA is mistaken, and its proposed mandamus remedy would likely lead to an increase, not a reduction, in the backlog.

Despite AHA's claims to the contrary, CMS already provides good-faith, evidence-based settlement offers to all providers who participates in the SCF. *See* August 3, 2018 Declaration of Sherri G. McQueen ("McQueen August 3, 2018 Decl.") ¶ 5, Ex. 7. This offer is based on "the provider's historical overturn rate on appeal at the Administrative Law Judge level," as well as "the type of item or service at issue, "the governing policy regarding the item or service at issue," "the cost to the Department for adjudicating the appeals at issue," and "a sample of provider's claims." *Id.*

In addition, CMS now offers an express SCF option in which it automatically makes a settlement offer to all eligible providers "based on preliminary data available to CMS, e.g., ALJ overturn rates, cost of adjudication, and type of claim or service." McQueen Aug. 3, 2018 Decl. ¶ 6. The provider need not participate in an individual SCF negotiation to receive this offer, but can choose to take the SCF Express offer or proceed to the full SCF process. *Id*.

As this makes clear, the SCF process already operates largely along the lines of Plaintiff's mandamus proposal. The key difference is that the provider's past success rate or the success rate for similar claims at the ALJ level are not the sole criteria upon which CMS bases its settlement offers. Instead, SCF is a mediation program designed to take into account the individualized information from providers to arrive at a more tailored settlement offer. Requiring CMS to mechanically apply AHA's chosen settlement formula would not improve the

current process. Indeed, given the low average success rate of providers at the ALJ level — 30.7% in FY 2017 and 26.6% in FY 2018 (as of April 16, 2018) [4] — this formula would worsen the prospects of settlement for some providers.

Beyond proposing to dictate how CMS makes settlement offers, AHA demands that the Department file a report with the court in cases where settlement is not reached "(1) detailing the settlement offer made to the provider or supplier, including the evidence supporting the settlement offer, (2) the provider's or supplier's last, best, and final counteroffer, if any, and (3) HHS's reasons for not accepting the provider's or supplier's final counteroffer." Plaintiffs' Response Regarding Non-Deadline Remedies at 6. There is no justification for this intrusion into the confidential settlement communications between CMS and providers that participate in the SCF, or into CMS's reasons for not accepting a counteroffer, which would reveal litigation assessment and strategy. If implemented, this proposal would discourage providers from entering into settlement talks lest their confidential settlement offers become public knowledge. While AHA allows that these reports can be submitted "under seal, if necessary," *see* Plaintiffs' Response Regarding Non-Deadline Remedies at 6, many providers would still be wary of having the details of their private settlement offers subject to review by an Article III court. Moreover, the work that would be required to provide this type of information to the Court on a quarterly basis would divert scarce resources away from the very settlements at issue, which could ***reduce*** the number of appeals settled. It would also impose a significant strain on the Court if the Court were to function as the superintendent of all unsuccessful settlements, which is decidedly not the Court's role, whether or not in the context of mandamus.

[4] https://www.hhs.gov/about/agencies/omha/about/current-workload/decision-statistics/index.html.

AHA apparently believes that the Department does not have a real interest in settling appeals in the backlog and must be told how to settle claims and then be policed by the Court. That suggestion is untenable in light of HHS's demonstrated commitment to resolving appeals in the backlog. As the Secretary has explained, CMS's Hospital Appeals Settlement process (HASP) settled over 380,000 inpatient status appeals. McQueen Decl. ¶ 7, ECF No. 66-6. In addition, the agency has implemented a new settlement initiative for low-volume appellants (LVA), defined both in terms of the number of appeals the provider has in the backlog (fewer than 500) and the value of the individual appeals ($9,000 or less). *Id*. ¶ 11a. As of June 30, 2018, CMS has settled 13,315 appeals as part of the LVA initiative. McQueen Aug. 3, 2018 Decl. ¶ 3. And CMS expects to eventually settle over 25,000 appeals through LVA. *Id*.

As of July 31, 2018, the SCF program has removed a total of more than 72,000 appeals pending at OMHA. Aug. 3, 2018 Griswold Decl. ¶ 4. In addition, the Department recently expanded SCF to make it available for most appellants not eligible for LVA. Specifically, SCF is now available for appeals with claims worth up to $1 million, an increase from the previous cap of $100,000.[5] And, as noted, the SCF program now includes an express SCF option, through which an eligible provider can receive a settlement offer without undertaking a full negotiation. McQueen Aug. 3, 2018 Decl. ¶ 6. OMHA previously estimated that LVA and SCF provide potential settlement relief to approximately 92% of the remaining appeals in the backlog without program integrity concerns. Griswold Decl. ¶ 4, ECF No. 75-1.

In short, far from justifying Plaintiffs' intrusive settlement proposals, the record here shows that the Department's settlement initiatives have been many, have expanded over time and

[5] https://www.hhs.gov/about/agencies/omha/about/special-initiatives/settlement-conference-facilitation/index.html

have had demonstrable success: in particular, the settlement of over 465,000 appeals in the backlog. *See supra* (HASP settlement of 380,000 appeals, SCF settlements of 72,000 appeals, and LVA settlement of over 13,300 appeals). Given that record, there is no basis for AHA's intrusive, counterproductive mandamus proposal. Moreover, the Secretary respectfully submits that the Court lacks the authority to require the proposed measures. A court cannot compel an agency to settle. *See Cantu v. United States*, 565 F. App'x 7, 9 (D.C. Cir. 2014) ("It is well established that a court cannot order a party to settle[.]"), *see Gevas v. Ghosh*, 566 F.3d 717, 719 (7th Cir.2009) ("A judge may not coerce a party into settling."); *In re NLO, Inc.*, 5 F.3d 154, 157 (6th Cir.1993); *Kothe v. Smith*, 771 F.2d 667, 669 (2d Cir.1985) (citing *MacLeod v. D.C. Transit Sys., Inc., 283 F.2d 194*, 195 n. 1 (D.C.Cir.1960)). This is particularly true where the party is an Executive Branch agency. *See United States v. LaCroix*, 166 F.3d 921, 923 (7th Cir.1999). Nor can the Court prescribe specific programmatic changes as part of ordering mandamus. *See AHA I*, 812 F.3d at 191 (while AHA "seeks to compel the agency to make decisions within the statutory time frames," AHA acknowledges that "the means the Secretary uses to ensure they are reached in a timely fashion are discretionary"); *Southern Utah*, 542 U.S. at 67 (emphasizing the need to "protect agencies from undue judicial interference with their lawful discretion, and to avoid judicial entanglement in abstract policy disagreements which courts lack both expertise and information to resolve").

Lastly, AHA requests that the Court order HHS to file settlement reports detailing the confidential settlement information between the Department and inpatient rehabilitation facilities (IRFs). Plaintiffs' Response Regarding Non-Deadline Remedies at 6. Again, these intrusive reports are unnecessary and predicated on AHA's unfounded belief that HHS will act in bad faith in these settlement negotiations. CMS is actively negotiating with IRF representatives and last

met with them on May 23, 2018 and August 2, 2018. McQueen Aug. 3, 2018 Decl. ¶ 4. The negotiations were fruitful, and CMS expects that additional settlement meetings will be scheduled in the upcoming months. If settlement talks are successful, nearly 12,000 IRF appeals could be removed from the backlog. *Id*. In the interim, there is no reason to divulge the settlement communications of non-parties participating in an active settlement negotiation. AHA's intrusive settlement-related mandamus remedies would not be helpful and should be rejected. *See CTIA–The Wireless Ass'n* , 530 F.3d at 989 (presuming that "executive agency officials will discharge their duties in good faith").

C. AHA's Proposal To Reduce The Rate of Interest On Overpayments Would Be Unlawful And Make The Backlog Worse.

By statute, when HHS determines that a provider has been paid money to which it is not entitled, within 30 days of this overpayment determination, "interest shall accrue on the balance . . . at a rate determined in accordance with the regulations of the Secretary of the Treasury applicable to charges for late payment." 42 U.S.C. § 1395g(d). Under current regulations, this amount is 10.25%. *See* https://www.hhs.gov/about/agencies/asfr/finance/financial-policy-library/interest-rates/index.html; 56 Fed. Reg. 31,332 (July 10, 1991). AHA proposes that this rate be reduced on overpayments to the London Interbank Offered Rate (LIBOR), which, as of June 1, 2018, was 2.7%.[6] Plaintiffs' Response Regarding Non-Deadline Remedies at 8. It is not possible to implement AHA's proposal because the Medicare statute requires that the same rate of interest be applied to overpayments and underpayment determinations, 42 U.S.C. § 1395ddd

[6] http://www.global-rates.com/interest-rates/libor/american-dollar/usd-libor-interest-rate-12-months.aspx

(f)(2)(B). Furthermore, HHS's regulations impose the aforementioned 10.25% rate.[7] Thus, there are statutory and regulatory limitations on the ability to reduce the current rate of interest on overpayments to the LIBOR rate. Furthermore, doing so would not reduce the number of pending appeals at OMHA.

AHA claims that the current 10.25% rate "creates an incentive for HHS to offer low-ball settlements or resist potential backlog-reduction efforts." Plaintiffs' Response Regarding Non-Deadline Remedies at 9. That is not the case and ignores the fact the Medicare statute requires that the ***same*** rate of interest be applied to overpayments as to underpayments, i.e., amounts the Secretary is found to owe providers upon the conclusion of an appeal.[8] *See* U.S.C. § 1395ddd (f)(2)(B) (when the Secretary loses on appeal, the "Secretary shall provide for repayment of the recouped amount plus interest ***at the same rate*** as would apply" to the amount determined to be owed by a provider "where such appeal is against the provider of services or supplier") (emphasis added). Given this statutory framework, providers who successfully appeal an overpayment determination are entitled to be repaid back any monies recouped by the Department at the current 10.25% rate of interest. *Id*. Conversely, providers who unsuccessfully appeal an overpayment determination must pay back any existing overpayment balance at this same rate of interest. *Id*. This creates a level, two-way street, in which the Secretary has appropriate incentives to settle meritorious claims to avoid paying large amounts of interest in the event he loses on appeal. At the same time, the current interest rate encourages providers not to file appeals for weak claims.

[7] 45 C.F.R. 405.378(d)(1); 56 Fed. Reg. 31,332 (July 10, 1991); https://www.hhs.gov/about/agencies/asfr/finance/financial-policy-library/interest-rates/index.html.

[8] It also ignores the fact that many appeals pending at OMHA are pre-payment appeals where interest is not at issue. *See* Murray Suppl. Decl. ¶ 28.

AHA's proposal, which is designed to encourage providers to retain overpayments while an appeal is pending, would make it less costly for providers to file frivolous appeals and would create new and powerful incentives among the provider community not to settle. Thus, it would become harder, not easier, to reduce the backlog. *See, e.g.*, Sec's Reply Br. at 13 (discussing holdouts from the agency's HASP settlement). Nor could the flaws in AHA's proposal be solved by applying the same lower interest rate to both overpayments and underpayments. This would create its own set of new and counterproductive incentives. Providers who prevail on appeal would be paid substantially less in interest under AHA's proposal than under the current 10.25% interest rate. And lowering the interest rate on overpayments would, as noted, make it less costly for a provider to gamble on a weak appeal. Punishing meritorious appeals while at the same time creating new incentives for providers to file weak appeals are, again, exactly the wrong incentives to create in order to promote settlement or decrease the backlog.

AHA repeats its prior arguments that the agency's demonstration authority permits it to implement AHA's proposal. Plaintiffs' Response Regarding Non-Deadline Remedies at 10. The Government has responded to these arguments at length before and respectfully refers the Court to its prior briefing.[9] In short, neither of the demonstration authorities AHA cites would authorize AHA's proposed mandamus remedy. 42 U.S.C. § 1395b-1(a)(1)(A) authorizes HHS to test "methods of payment or reimbursement" which "would have the effect of increasing efficiency and economy of health services." CMS has interpreted this authority to involve demonstrations that test a different way of paying for Medicare services. Supp. Murray Decl.

[9] *See* Sec's Reply at 22-23; Sec.'s Mot. for Summ. J. at 12-19, 21-23; Sec's Reply at 7-8; *see also* Nov. 7, 2016 Murray Decl." ¶¶ 27-36.

¶ 35, ECF No. 41-1. Reducing the rate of interest that accrues on overpayments does not demonstrate a different way of paying for Medicare services. *Id*. Plaintiffs' proposal is also not appropriate for a demonstration project under 42 U.S.C. § 1315a, which permits "test[ing] innovative payment and service delivery models to reduce program expenditures. . . while preserving or enhancing the quality of care furnished to individuals." AHA's proposed mandamus remedy would encourage more frivolous appeals and discourage settlement, and would lower the amounts HHS collects when it prevails on appeal. AHA's proposals would thus increase program expenditures. HHS also reiterates its position that this Court does not have the authority to order the agency to exercise its discretion to implement a demonstration project. *See* Sec's Reply in Supp. of Mot. for Summ. J. and Opp. to Pls.' Cross-Mot. at 22-23.

In sum, in addition to being contrary to the Medicare statute and the Department's regulations, AHA's interest proposal is entirely unnecessary given the current posture of the case and would create new incentives that would make it harder to resolve the backlog.

D. AHA's "Rebilling" Proposal Would Not Reduce the Backlog, But Would Make It Worse.

By statute, a claim for reimbursement of Medicare services must be submitted within one year of the services being provided.[10] As AHA notes, "[i]n some instances, a claim is denied because a RAC or other reviewer concludes that a provider should have used a billing code different than the one submitted." *See* Plaintiffs' Response Regarding Non-Deadline Remedies at 10. AHA contends that "a provider whose argument for a different code is rejected on appeal can frequently 'rebill' the claim under the reviewer-preferred code and receive some repayment" before the one-year statutory time limit has expired. *Id*. at 10-11. According to AHA, "[w]ith

[10] *See* 42 U.S.C. §§ 1395f(a)(1), 1395n(a)(1), 1395u(b)(3)(B)(ii).

the backlog, however, providers have been deprived of the ability to rebill following an adverse ALJ decision because the provider's claim will always be adjudicated one year after the services were rendered." *Id.* at 11. To supposedly ameliorate this situation, AHA requests that this Court order HHS to make settlement offers to all providers and suppliers with appeals in the backlog, in which they would have the right "to rebill denied claims in return for dismissing any pending appeal related to that claim." *Id*. at 10.

AHA's proposal would make the backlog worse and is not authorized under current law. As an initial matter, the prospect that a provider may be unable to rebill after an adverse ALJ decision is not a creation of the OMHA backlog. Congress permits RACs to review all claims submitted by a provider within the past four years. 42 U.S.C. § 1395ddd(h)(4)(B). Therefore, Congress was aware that claims could be denied by RACs well after the one-year statutory time for a provider to rebill had expired. In addition, the time to ALJ decision — assuming all decisions are issued in a timely manner and no extensions are granted— can be nearly 600 days. *See* Nov. 7, 2016 Murray Decl. at ¶ 43 (citing statutory and regulatory provisions). Clearly, the situation described by AHA is not a new issue. In fact, in a separate litigation, AHA sought unsuccessfully to compel the Secretary to issue a regulation to allow for rebilling after the one-year deadline set by statute. There, it claimed the change was needed "because of the time it takes RACs to review paid claims," not because of the backlog.[11] *American Hosp. Ass'n v. Burwell*, Civ. No. 12-1770 (D.D.C.), 2d Am. Compl. ¶ 65, ECF No. 26 (April 19, 2013).

[11] The Court in that case rejected AHA's challenge and dismissed the lawsuit, observing that Congress had set the review periods for the RACs, and had also vested the discretion to specify exceptions to the one-year time period for filing claims solely with the agency. *See Mem. Op., Am. Hosp. Ass'n v. Burwell*, Civ. No. 12-1770 (D.D.C., Sept. 17, 2014), ECF No. 55.

Further, AHA's "settlement" proposal is both unhelpful and would not improve the backlog. A provider who withdraws an appeal in exchange for the right to rebill might still receive an adverse determination following rebilling. At that point, the provider could presumably appeal again, producing no net reduction in the backlog. In addition, the most likely result of AHA's proposal is that providers will appeal ***every*** coding denial, knowing that the agency will be forced to offer the "settlement" of rebilling if they appeal. AHA acknowledges as much. It states that it considered requesting that the Court order HHS to allow providers with appeals in the backlog to have up to six months to rebill, "[b]ut Plaintiffs understand that allowing rebilling after ALJ appeals are concluded could ultimately *add* to the backlog by creating an incentive for providers to appeal every coding denial, knowing that they can rebill after an appeal." Plaintiffs' Response Regarding Non-Deadline Remedies at 11 (emphasis in original). But that incentive remains whether this particular form of mandamus relief is styled as a "settlement offer" or not. AHA also acknowledges that it does not even know how many appeals in the backlog would be eligible for its settlement proposal. *Id*. In fact, in its brief, AHA categorizes this proposal as one that would "ameliorate" the backlog's effect on providers, not one that would remove pending appeals or prevent new appeals from being filed. *See* Plaintiffs' Response Regarding Non-Deadline Remedies at 6 (section heading).

Furthermore, through the existing SCF process, appellants have the opportunity to submit a position paper detailing the claims that could have been payable if the provider had billed with a different code, which CMS will evaluate in formulating its offer. *See* McQueen Aug. 3, 2018 Decl. ¶ 5. The existing SCF process is a far better vehicle for reducing the backlog than AHA's proposal because SCF results in a single settlement agreement resolving all of the provider's pending appeals. AHA's proposal, in contrast, would allow providers to cherry pick as few as

one appeal for an individual settlement, diverting resources away from other, more effective existing settlement initiatives.

Finally, AHA's proposed order is not authorized under current law. While HHS can make exceptions, via formal rulemaking, to the one-year time limit to submit a claim, it has already determined in notice-and-comment rulemaking not to do so in this situation, *see* 42 C.F.R. § 424.44(b)(1)-(5); *see also* 78 Fed. Reg. 50,496, 50,922-23, 26 (Aug. 19, 2013), which has been upheld by the courts. *See American Hosp. Ass'n v. Burwell*, Civ. No. 12-1770 (D.D.C.), Mem. Op., ECF No. 75. AHA's request is also an improper form of mandamus relief because as already discussed above, a court cannot compel an agency to settle, nor can it prescribe the means by which an agency complies with a statutory timeframe. *AHA I*, 812 F.3d at 191.

AHA's "rebilling" order would violate the law and likely make the backlog worse. The Court should reject this proposed mandamus remedy.

E. The Court Should Reject AHA's Proposal To Toll The Time To File Section 340B Hospital Appeals.

In a separate lawsuit, AHA has brought a challenge to a recent rulemaking by HHS that adjusts Medicare Outpatient Prospective Payment System ("OPPS") payments to hospitals under the Section 340B Drug Discount Program. *See Am. Hosp. Ass'n v. Azar*, Slip Op. 18-5004 at 11. (D.C. Cir. July 17, 2018). AHA contends that the OPPS reimbursement change was illegal. Following the district court's dismissal of its suit, AHA appealed to the D.C. Circuit, and in the interim, requested that the Secretary agree to toll the time for Section 340B hospitals to file administrative appeals. The Secretary refused because OPPS payment adjustments are not administratively reviewable. AHA now requests that this Court order this tolling as part of its

proposed mandamus relief in this case while the hospitals await a resolution of the appeal. *See* Plaintiffs' Response Regarding Non-Deadline Remedies at 12-13.

Shortly after Plaintiffs filed their brief, the D.C. Circuit affirmed the district court's dismissal of AHA's suit on jurisdictional grounds. *See Am. Hosp. Ass'n v. Azar*, Slip Op. 18-5004 at 11. (D.C. Cir. July 17, 2018). As we stated in the briefs we filed in the separate AHA litigation challenging the reimbursement change to 340B hospitals, Congress has expressly precluded administrative and judicial review of OPPS adjustments meaning that any such appeals should be summarily dismissed. *See Amgen, Inc. v. Smith*, 357 F.3d 103, 112 (D.C. Cir. 2004) (applying 42 U.S.C. § 1395l(t)(12) to preclude review of equitable adjustments made to the OPPS under section 1395l(t)(2)(E)).

F. The Court Should Reject AHA's Proposal That Would Require HHS To Seek Leave Before Making Any Changes To Its Programs That Impact The Backlog.

AHA asks this Court to order HHS to "maintain its current efforts to combat the backlog, including all of the measures outlined in its motion for summary judgment. Dkt. No. 66-1. HHS may reduce or alter its existing programs to fight the backlog upon application to the Court and for good cause shown." Plaintiffs' Response Regarding Non-Deadline Remedies at 13. AHA argues that this mandamus remedy is necessary to "ensure that HHS remains committed to its current efforts by requiring leave of court to alter the programs set forth in HHS's motion for summary judgment." *Id*. at 14.

The Court should reject this proposal. The Secretary's good faith should be presumed, and there is no reason for entering a mandamus order that will not make it any more likely that HHS will be able to reduce the backlog. Moreover, HHS is continually looking for new ways to reduce the backlog. AHA's proposal to require the Department to receive leave of court based on a showing of "good cause" (Br. at 13) before it can act would make it harder to implement

future changes and amount to an unprecedented and intrusive expansion of mandamus. Mandamus does not authorize a court to stand in the shoes of the Secretary of Health and Human Services and make predictive judgments about which policy measures will help reduce the backlog in light of the agency's other priorities. This proposed mandamus remedy is improper and unhelpful and should be rejected.

G. The Government Is Prepared To File Status Reports.

Finally, AHA requests that this Court order HHS to submit status reports every 90 days regarding the status of the backlog, "including the information required by other portions of this order." Plaintiffs' Response Regarding Non-Deadline Remedies at 14.

The D.C. Circuit stated in *AHA I* that "if the district court determines on remand that Congress and the Secretary are making significant process toward a solution, it might conclude that issuing the writ is premature" and simply order status reports. *AHA I*, 812 F.3d at 193. The Secretary submits that Congress's recent appropriation, along with the Secretary's other efforts, constitute more than "significant progress" toward a solution to the backlog problem. Indeed, the Secretary is now able to project, at current funding levels, that the backlog could be ***eliminated*** in FY 2022. In light of this development, the Court could enter judgment in favor of the Secretary or order status reports to ensure that the new funding is having the desired effect. These reports could include updates about the Secretary's progress at eliminating the backlog as well as the number of appeals settled within the past reporting period.

CONCLUSION

For the reasons set forth above, the Court should deny Plaintiffs' motion for summary judgment (ECF No. 72), deny Plaintiffs' non-deadline mandamus remedies (ECF No. 82), and either grant the Secretary's motion for summary judgment (ECF No. 66) and dismiss the case or require no more than periodic status reports.

Dated August 3, 2018

Respectfully submitted,

CHAD A. READLER
Acting Assistant Attorney General

JEAN LIN
Acting Deputy Director
Federal Programs Branch

/s/ Nicholas Cartier
NICHOLAS CARTIER (D.C. Bar # 495850)
ADAM SIPLE (NY Bar # 4387296)
Trial Attorneys
U.S. Department of Justice
Civil Division, Federal Programs Branch
20 Massachusetts Avenue NW
Washington, DC 20530
Telephone: (202) 616-8351
Facsimile: (202) 616-8460
Counsel for Defendant

Of Counsel:
ROBERT P. CHARROW
General Counsel
JANICE L. HOFFMAN
Associate General Counsel
SUSAN MAXSON LYONS
Deputy Associate General
Counsel for Litigation
KIRSTEN FRIEDEL RODDY
HHS Department Attorneys