

**UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF COLUMBIA**

|  |   |                                    |
|--|---|------------------------------------|
| AMERICAN HOSPITAL ASSOCIATION, <i>et al.</i> , | ) |                                    |
|  | ) |                                    |
| Plaintiffs,                                    | ) |                                    |
|  | ) | Civil Action No. 14-cv-00851 (JEB) |
| v.   | ) |                                    |
|  | ) |                                    |
| ERIC D. HARGAN, in his official capacity as    | ) |                                    |
| ACTING SECRETARY OF HEALTH                     | ) |                                    |
| AND HUMAN SERVICES,                            | ) |                                    |
|  | ) |                                    |
| Defendant.                                     | ) |                                    |

**DECLARATION OF MICHAEL R. BAGEL**

I, Michael R. Bagel, declare as follows:

1. I am a senior program analyst in the office of the Assistant Secretary for Financial Resources of the Department of Health and Human Services (HHS or Department) and the career leader of the intra-agency Medicare Appeals workgroup. I have held this position since August 13, 2012. Prior to joining the Department, I graduated cum laude from the William and Mary Law School and have previously worked for the Office of General Counsel at the Office of Management and Budget, the Office of Administrative Law Judges at the Department of Labor, and the Senate Finance Committee. Among my duties at HHS, I provide advice and guidance to HHS senior leadership in the areas of budget, performance, and program policy, and synchronize the implementation of these activities across the Department. I also lead the staff intra-agency Medicare appeals Departmental workgroup focused on administrative initiatives to reduce the backlog and improve the efficiency of the Medicare appeals process.

2. The statements made in this declaration are based on my personal knowledge, information contained in agency files, and information furnished to me in the course of my official duties.

Actions to Try to Reduce the Backlog

3. The Department, including current and former HHS senior leadership, has made the reduction of the OMHA backlog and improvements to the Medicare appeals process a Departmental priority. The Department is committed to trying to resolve the OMHA backlog despite the funding and resource constraints it faces.

4. As detailed below, over the last several years, the Department has taken numerous administrative actions to try to maximize OMHA adjudication capacity within the constraints of OMHA's limited resources, resolve the backlog of appeals at OMHA for appellants who do not wish to exercise the statutory remedy of escalation and has taken measures to try to decrease the number of new appeals that appellants file. Specifically, the Department has:

a. Promulgated new regulations and launched new administrative initiatives to expand the pool of adjudicators at the OMHA level of appeal within those limited resources. *See* Griswold Decl. ¶ 6; *see also* 82 Fed. Reg. 4974 (Jan. 17, 2017);

b. Offered appellants—including hospitals—options to settle pending appealed claims for fixed or negotiated amounts. *See* Griswold Decl. ¶¶ 10-14; McQueen Decl. ¶¶ 7-8.

c. Offered to use sampling and extrapolation to save appellants time and resources and resolve their appeals more quickly. *See* Griswold Decl. ¶ 16.

d. Directed Medicare Administrative Contractors conducting redeterminations (first level of appeal) and Qualified Independent Contractors (QICs)

conducting reconsiderations (the second level of appeal) to limit their reviews to the original basis for denial and to not identify any new issues – even though regulations permit them to do so – when reviewing post-pay claim denials, which reduces the number of new appeals received by OMHA.

e. Made changes to the Recovery Audit Contractor (RAC) program, including changes to the RAC Statement of Work, to reduce appeals of denials by RACs so much so that, by the end of fiscal year (FY) 2017, RAC appeals constituted only 14.2% of appeals pending at OMHA and only 12% of incoming appeals at OMHA. *See Mills Decl.* ¶¶ 4-10; *Griswold Dec.* ¶¶ 19-20;

f. Established a demonstration project to test whether voluntary discussion options for appellants at a lower level of the appeals process will reduce the number of new appeals to the OMHA level. *See infra* ¶ 10;

g. Established new policies and claim review processes to provide more guidance and opportunities to discuss claims for the same short-stay hospital inpatient claims that hospitals appealed in large numbers and were significant drivers of the exponential growth in appeals in 2013 and 2014; as a result of these efforts. *See Mills* ¶ 9(c);

h. The President's Budget, developed in close collaboration with the Department, requested resources for OMHA, as well as proposed new legislative authorities that would resolve appeals earlier in the process and provide needed flexibilities to address large volumes of appeals. *See infra* ¶¶ 11-12;

Review by New Administration

5. After the change in administration, the new leadership of the Department reviewed the OMHA backlog issue. Their review included not only an internal assessment but also listening sessions with external stakeholders to hear potential solutions from outside of the Department. The new leadership has developed two additional settlement initiatives that have the potential to substantially reduce the OMHA backlog. *See* McQueen Decl. ¶11; Griswold Decl. ¶ 15.

Projected Impact on OMHA Backlog

6. Despite all of these actions and other initiatives which have reduced and will further reduce the number of pending appeals and new appeals coming to OMHA, the volume of appeals still will exceed OMHA's adjudication capacity for the next several years without additional funding and authorities from Congress. This volume is a result of annual incoming appeals that alone outpace OMHA's adjudication capacity in a given year, with or without the RAC program. Projected incoming appeals to OMHA are based on historical appeal receipt trend analysis which is adjusted by the continuing growth of the number of Medicare beneficiaries. This trend analysis is updated on a quarterly basis to reflect changes in appeal receipts.

For example, in FY 2017, while HHS achieved reductions in new appeals to OMHA, the approximately 113,000 appeals that were filed during the year still exceeded OMHA's FY 2017 adjudication capacity by approximately 37,000 appeals. In addition, while current out-year projections are down, they likewise suggest that a pattern of receipts exceeding capacity will

continue under current resource levels. *See* Exhibit 1, Backlog Projections as of September 2017; *see also* Griswold Decl. ¶ 3.

7. The liability to the Medicare Trust Funds in settling claims in the manner and proportion suggested by the Court's mandamus order would be significant. As of October 20, 2017, there were 531,296 appeals pending at OMHA with total billed amounts-in-controversy of approximately \$3,822,404,098. While the actual amounts paid may be lower because providers and suppliers generally bill Medicare at higher amounts than what Medicare fee schedules and agreements allow for payment, the impact of these payments on the Medicare Trust Funds would still be significant. The appealed claims pending at OMHA have already been rejected at three levels of review. Based on the FY 2017 ALJ reversal rate of 31%, it can reasonably be assumed at that least 69% of these claims lack merit or are procedurally flawed and should not be paid.

8. Based on my assessment of the record, including the declarations of Nancy J. Griswold, George G. Mills, and Sherri G. McQueen, and other information made available to me, I do not believe that the Department can meet the reduction targets required by the Court's December 5, 2016 order through regular OMHA adjudication process absent substantial new resources and authorities from Congress. Any court-ordered mandate to reduce to zero the number of appeals pending at OMHA more than 90 days is impossible to comply with given current resources because even if the Department could eliminate the current backlog, it still has far more appeals coming in than it has the capacity to adjudicate. *See* Exhibit 1, Backlog Projections as of September 2017.

Therefore, in order to eliminate the backlog entirely as the court's order required, the Department needs additional Congressional appropriations and authorities. The Department also needs more willing providers—which are not the subject of False Claims Act investigations or

litigation or other program integrity initiatives—to participate in administrative initiatives designed to produce efficient and reasonable resolutions (such as the SCF program). Without increased participation, the Department cannot eliminate the backlog of appeals at OMHA. In the meantime, HHS is committed to and continues to explore additional measures to reduce appeals reaching OMHA and to more effectively address appeals that are filed at OMHA.

9. The only way for the Department to theoretically meet such reduction targets without legislative action would be to settle for the full value or nearly the full value of each appeal without regard to the merits of the appeal or the program integrity issues presented by the appellant. Doing so would encourage appellants to flood the appeals system with every denied claim – regardless of merit – with the hope of obtaining full payment through a settlement with the Department under duress or perhaps a default judgment. This, of course, would make the backlog at OMHA even worse. It would also violate the Department’s responsibility to safeguard the Medicare Trust Funds.

#### Initiatives to Reduce Incoming Appeals

10. Qualified Independent Contractor (QIC) Discussion Demonstration: In January 2016, CMS launched a demonstration with Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) suppliers that submit Medicare fee-for-service claims in two DMEPOS MAC jurisdictions for diabetic testing supplies and oxygen equipment. In order to maintain a control group to measure the effects of the demonstration, CMS chose the two largest MAC jurisdictions, which cover 37 states and territories, to maximize the immediate impact from the demonstration. Under this demonstration, suppliers have the opportunity to discuss their claim by telephone with the QIC at the second "reconsideration" level of appeal (the level of appeal before it reaches OMHA), submit additional documentation to support their claim, and receive

feedback and education on CMS policies and requirements. HHS expects that, as a result of the discussions and educational outreach, new appeals for the DMEPOS items tested under the demonstration will decrease due to suppliers submitting accurate Medicare claims to the MAC at the outset, thus reducing the number of claims that are denied and then appealed to OMHA.

a. Under the demonstration, the QIC will also reopen certain QIC reconsideration decisions that are pending at OMHA that could be resolved favorably for the appellant using the information gained through the telephone discussion. Reopening these QIC decisions will reduce the number of appeals currently pending at OMHA.

b. HHS projects that by the end of FY 2020, the telephone discussion aspect of the demonstration will reduce the number of appeals that reach OMHA by more than 31,000 appeals and resolve nearly 72,000 appeals that are currently pending at OMHA. Thus, in total, HHS estimates that this action will reduce the number of appeals either pending at OMHA or that would otherwise reach OMHA by approximately 103,000 appeals by the end of FY 2020. In addition, the Department expects improvement in the quality of future claims submissions for durable medical equipment providers participating in the telephone discussions. While this improvement is reflected in the decreased number of new durable medical equipment receipts at OMHA, we cannot at this time estimate this specific impact.

c. In October 2016, CMS expanded the demonstration to include all DMEPOS claim types, still within the two MAC jurisdictions noted above, with exceptions to claims or suppliers that are already subject to another CMS initiative (e.g. prior authorization for power mobility devices (PMDs) or the settlement conference facilitation (SCF) process). CMS anticipates additional expansion of the scope of this

demonstration in the future to include additional types of services, items, and supplies and additional QIC jurisdictions. CMS is not in a position at this time, however, to determine how quickly or to what extent the demonstration should be expanded. These determinations will depend on CMS's empirical experience with the current demonstration as it develops.

### Legislative Challenges

11. For each of the past four President's Budgets, the Department has requested funding for OMHA that has exceeded what was appropriated by Congress. Additionally, the Department has requested several new legislative authorities which would improve the Medicare appeals process and allow the Department to increase adjudication capacity which Congress has yet to act upon.

### **OMHA BUDGET HISTORY**

| <b>OMHA BUDGET*</b>                      | <b>FY 2015</b> | <b>FY 2016</b> | <b>FY 2017</b> | <b>FY 2018</b> |
|--|----------------|----------------|----------------|----------------|
| President's Budget Program Level Request | \$100,000,000  | \$270,000,000  | \$250,000,000  | \$242,177,000  |
| Enacted Budget Program Level             | \$87,381,000   | \$107,381,000  | \$107,381,000  | TBD            |

\* Fiscal Years 2016 and 2017 President's Budget requests included access to funding from RAC recoveries and Statistical Sampling authorities that were not enacted. The FY 2018 President's Budget request includes access to proposed mandatory funding and new adjudicatory and administrative authorities.

12. On May 23, 2017, the Administration released the FY 2018 President's Budget. The President's Budget includes a series of legislative and budget proposals intended to improve the efficiency and effectiveness of the Medicare appeals process and address the



pending backlog of appeals. Specifically, the FY 2018 President's Budget proposes the following new legislative and budgetary actions:

a. Provide Additional Resources for Medicare Appeals: This proposal would provide the Department with \$1.3 billion over 10 years in mandatory funding to implement system reforms and invest in addressing the backlog of pending appeals. The Secretary would be authorized to transfer funding across all levels of the appeals system. HHS projects that the mandatory funding proposed in the FY 2018 President's Budget would increase Administrative Law Judge disposition capacity and advance other activities that address the pending backlog of appeals at OMHA.

b. Remand Appeals to the Redetermination Level with the Introduction of New Evidence: This legislative proposal would require adjudicators to remand an appeal to the first level of appeal when new documentary evidence is submitted into the administrative record at the second level of appeal or above. Exceptions could be made if evidence was provided to the lower level adjudicator but erroneously omitted from the record, or an adjudicator denies an appeal on a new and different basis than earlier determinations. This proposal would incentivize appellants to submit all evidence in support of their claims early in the appeals process so that claim disputes may be resolved at the earliest level of appeal possible and ensures the same record is reviewed and considered at subsequent levels of appeal for consistency throughout the appeals process.

c. Increase Minimum Amount-in-Controversy for Administrative Law Judge Adjudication: This legislative proposal would increase the minimum amount-in-controversy required for adjudication by an Administrative Law Judge to the Federal District Court amount-in-controversy requirement (\$1,560 in calendar year 2017 and

updated annually). This proposal would allow the amount at issue to better align with the amount spent to adjudicate the claim.

d. Establish Magistrate Adjudication: This legislative proposal would allow OMHA to use Medicare magistrates for appealed claims below the Federal District Court amount-in-controversy threshold, reserving Administrative Law Judges for higher amount-in-controversy appeals.

e. Expedite Procedures for Claims with no Material Fact in Dispute: This legislative proposal would allow OMHA to issue decisions without holding a hearing if there is no material fact in dispute. These cases include appeals, for example, in which Medicare does not cover a particular drug or the Administrative Law Judge cannot find in favor of an appellant due to binding limits on authority and therefore there is no benefit or reason to hold a hearing.

13. In the 114<sup>th</sup> Congress, the Audit & Appeals Fairness, Integrity, and Reforms in Medicare Act of 2015 (AFIRM Act) was favorably reported out of the Senate Finance Committee on June 3, 2015 and was introduced in the Senate on December 8, 2015. However, no further action was taken on the bill, and no companion legislation was introduced in the House of Representatives. While Senate Finance Committee Chairman Orin Hatch (R-UT) has called the backlog of Medicare appeals “unacceptably high,” the AFIRM Act has yet to be reintroduced in the 115<sup>th</sup> Congress, and there have not yet been any Congressional hearings in the 115<sup>th</sup> Congress related to reducing the Medicare appeals backlog. The Department, however, continues to evaluate additional potential legislative changes for submission to Congress and is committed to working with Congress to achieve enactment of a comprehensive and common-sense reform package to improve the Medicare appeals process and address the pending backlog.

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge and belief.

Executed on November 3, 2017 in Washington, D.C.

  
Michael R. Bagel

**Exhibit 1: MEDICARE APPEALS BACKLOG STATUS UPDATE**  
 Projections with Impact of Taking Administrative Actions and Legislative/Budget-Dependent Actions  
 Data as of 6/30/2017 (through Quarter 3 of FY 2017)

|  | FY 2017          | FY 2018         | FY 2019          | FY 2020          | FY 2021          |
|--|------------------|-----------------|------------------|------------------|------------------|
| Beginning Workload Balance   |                  |                 |                  |                  |                  |
| New Receipts   | 673,143          | 579,277         | 637,935          | 751,260          | 845,179          |
| Disposition by Administrative Law Judge Hearing  | 167,899          | 186,245         | 227,888          | 209,719          | 223,412          |
|  | (76,000)         | (88,000)        | (88,000)         | (88,000)         | (88,000)         |
| CMS Hospital Settlement  | (77,311)         | (3,000)         | -                | -                | -                |
| Settlement Conference Facilitations for non-State Medicaid Agencies  | (5,000)          | (5,000)         | (5,000)          | (5,000)          | (5,000)          |
| Settlement Conference Facilitation for State Medicaid Agencies   | (56,726)         | (11,262)        | -                | -                | -                |
| On-the-Record Adjudication   | (3,000)          | -               | -                | -                | -                |
| Senior Administrative Law Judge program  | (500)            | (500)           | (500)            | (500)            | (500)            |
| Statistical Sampling with Appellant Consent  | (4,000)          | (2,500)         | (2,500)          | (2,500)          | (2,500)          |
| QIC Demonstration - Resolution of Appeals Pending at OMHA  | (16,088)         | (17,325)        | (18,563)         | (19,800)         | -                |
| Appeals Consolidated into one Action   | (23,140)         | -               | -                | -                | -                |
| Prior Authorization (non-add - item results in lower 'New receipts')                                       | (51,815)         | (54,630)        | (28,630)         | (93,885)         | (93,885)         |
| QIC Demonstration - Appeals Resolved before Reaching OMHA (non-add - item results in lower 'New receipts') | (6,325)          | (7,350)         | (8,375)          | (9,400)          | 0                |
| <b>Administrative Actions Impact Total</b>   | <b>(185,765)</b> | <b>(39,587)</b> | <b>(26,563)</b>  | <b>(27,800)</b>  | <b>(8,000)</b>   |
| <b>Cumulative Pending - With Current Actions Taken</b>   | <b>579,277</b>   | <b>637,935</b>  | <b>751,260</b>   | <b>845,179</b>   | <b>972,591</b>   |
| Legislation: Magistrates; Procedural Issues and Revised Amount-in-Controversy                              |                  | (12,500)        | (75,000)         | (75,000)         | (75,000)         |
| Additional ALJ Adjudication Teams (Budget Dependent)   |                  | (17,667)        | (106,000)        | (106,000)        | (106,000)        |
| On-the-Record Adjudication (Additional Capacity - Budget Dependent)  |                  | (1,250)         | (7,500)          | (7,500)          | (7,500)          |
| <b>Legislative/Budget Dependent Actions Impact Total</b>   | <b>-</b>         | <b>(31,417)</b> | <b>(188,500)</b> | <b>(188,500)</b> | <b>(188,500)</b> |
| <b>Cumulative Pending - Legislative/Budget Dependent Actions Taken</b>                                     | <b>579,277</b>   | <b>606,518</b>  | <b>531,343</b>   | <b>436,762</b>   | <b>375,674</b>   |