UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

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

DEFENDANT'S STATEMENT OF MATERIAL FACTS
AS TO WHICH THERE IS NO GENUINE DISPUTE

Pursuant to Rule 56 of the Federal Rules of Civil Procedure and Local Rule 7(h), Defendant Eric D. Hargan, in his official capacity as Acting Secretary of Health and Human Services ("HHS"), submits the following statement of material facts as to which there is no genuine dispute:

1. HHS's Office of Medicare Hearings and Appeals ("OMHA"), which administers the nationwide Medicare Administrative Law Judge ("ALJ") hearing program, is funded by a line-item appropriation that limits the number of appeals OMHA's ALJs can decide. *See* Continuing Appropriations Act, 2017, Pub. L. No. 114-223, div. C, 130 Stat. 857, 909 (2016).

2. Between fiscal year ("FY") 2010 and FY 2014, appeals to OMHA increased by 1,222%. Judge Nancy J. Griswold, Appellant Forum–Update from OMHA, at 8 (June 25, 2015), https://www.hhs.gov/sites/default/files/omha/OMHA%20Medicare%20Appellant%20Forum/presentations_june_25_2015.pdf.

3. Congress made trust fund appropriations of $71,147,000 to OMHA in 2010, $71,147,000 to OMHA in 2011, $72,147,000 to OMHA in 2012, $72,010,642 to OMHA in 2013, 82,381,000 to OMHA in 2014, 87,381,000 to OMHA in 2015 and 107,381,000 to OMHA in 2016. *See* OMHA, Department of Health and Human Services, *Fiscal Year 2017 Justification for*

Estimates to Appropriations Committee, at 13, https://www.hhs.gov/sites/default/files/fy2017-budget-justification-office-of-medicare-hearings-and-appeals_0.pdf.

4. At current funding levels, OMHA had the capacity to dispose of 76,000 appeals in FY 2017. Declaration of Nancy J. Griswold ("Griswold Decl.") ¶ 3

5. OMHA's estimated adjudication capacity for FY 2018 is up to 93,500 appeals. Griswold Decl. ¶ 4.

6. OMHA projects that it will receive 186,245 appeals in FY 2018. Griswold Decl. ¶ 4.

7. OMHA's current funding levels support 92 ALJ teams, consisting of one ALJ and four support staff. Griswold Decl. ¶ 5.

8. At OMHA's current disposition capacity, each ALJ team decides approximately 1,000 appeals per year. Griswold Decl. ¶ 8.

9. Each appealed claim must be individually reviewed and analyzed. Griswold Decl. ¶ 8.

10. That process requires: a review to confirm that the appeal meets statutory requirements for jurisdiction; record preparation; research of the issues the appeal presents; scheduling and conducting conferences and hearings; deciding any procedural issues or other matters the parties raise; reviewing and analyzing testimony as well as other evidence; and drafting and finalizing a decision. Griswold Decl. ¶ 8.

11. OMHA already has taken a number of steps to maximize the productivity of its ALJ teams. Griswold Decl. ¶ 7(a)-(e).

12. OMHA has established an on-the-record adjudication program. Griswold Decl. ¶ 7(a)

13. OMHA has established judicial training and other continuing training initiatives for adjudicators and staff on various issues that may be presented on appeals, reducing research time. Griswold Decl. ¶ 7(b).

14. OMHA has re-engineered its field office staffing structure to use more of its funding on direct case-support functions (a step which has allowed OMHA to increase ALJ support to include two legal assistants and two attorneys per ALJ). Griswold Decl. ¶ 7(c).

15. OMHA has utilized strategic case assignments to assign appellants with a large number of filings to a single ALJ, facilitating potential consolidated proceedings and more efficient adjudication. Griswold Decl. ¶ 7(d).

16. OMHA has introduced a number of electronic tools to reduce staff time spent on other tasks and redirect their efforts to processing more appeals. Griswold Decl. ¶ 7(e).

17. The average annual dispositions per ALJ more than doubled between FY 2009 and FY 2013. *See* Appellant Forum: February 12, 2014—Presentation, slide 15, *available at* https://www.hhs.gov/about/agencies/omha/about/special-initiatives/appellant-forums/index.html.

18. OMHA has established a process to streamline on-the-record decisions when appellants waive their right to an oral hearing. Griswold Decl. ¶¶ 6-7(a).

19. The process described in the preceding paragraph permits qualifying appeals to be resolved by OMHA senior attorneys with minimal ALJ involvement, freeing ALJs to devote more time to preparing for hearings. Griswold Decl. ¶ 7(a).

20. OMHA attorneys have resolved approximately 5,000 appeals under this program since it began in July 2015. Griswold Decl. ¶ 7(a).

21. OMHA has also made use of the Office of Personal Management's senior ALJ program, under which it may reemploy retired ALJs on a temporary and part-time basis. Griswold Decl. ¶ 6.

22. This program is subject to resource constraints and, in FY 2018, OMHA projects that this program will increase adjudication capacity by only 500 appeals. Griswold Decl. ¶ 6.

23. OMHA has undertaken all reasonable efforts to increase the number of dispositions of appeals within OMHA's existing statutory and budget constraints. Griswold Decl. ¶ 5.

24. In FY 2018, OMHA estimates that it will receive 186,245 new appeals, approximately double the 93,500 OMHA may be able to dispose of that year. Griswold Decl. ¶ 4.

25. HHS estimates that OMHA's new receipts will generally climb slightly over the next few years, reaching 223,412 in FY 2021. *See* Declaration of Michael Bagel ("Bagel Decl.") ¶ 8 and Exhibit 1.

26. OMHA's ability to reduce the flow of incoming appeals is limited, since appellants have a statutory right to appeal denied claims meeting amount-in-controversy requirements to an ALJ. 42 U.S.C. § 1395ff(b), (d)(1)

27. As of October 20, 2017, the number of pending appeals at OMHA was 531,926. Griswold Decl. ¶ 3.

28. HHS and its components have undertaken numerous efforts to reduce the influx of new appeals. Declaration of George G. Mills ("Mills Decl.") ¶¶ 11-13.

29. CMS has established the Targeted Probe and Educate Program, which allows providers to discuss claim errors with Medicare Administrative Contactors. Mills Decl. ¶ 11.

30. Providers subsequently have an opportunity under the above-described program to correct errors or improve their claims submissions, with the goal of ultimately decreasing the

numbers of denials and resulting appeals. Mills Decl. ¶ 11.

31. Last year, CMS launched a demonstration for durable medical equipment ("DME") suppliers that submit fee-for-service claims. Declaration of Michael Bagel ("Bagel Decl.") ¶ 10.

32. The program encompasses 37 states and territories covering the two largest DME Medicare Administrative Contractor jurisdictions, and gives providers the opportunity to discuss their claims by telephone with the DME Qualified Independent Contractor ("QIC") (the appeal level preceding ALJ review), submit additional documentation, as well as receive education on Medicare policies, the root causes of claim denials, and the documents the provider needs to submit and, under certain circumstances, obtain reopening of claims pending at OMHA that the QIC may now resolve in favor of the provider. Bagel Decl. ¶ 10.

33. HHS estimates that the above-described program will reduce the number of OMHA appeals by approximately 103,000 by the end of FY 2020 (in addition to other improvements it cannot yet quantify). Bagel Decl. ¶ 10(b).

34. CMS has further instituted a series of initiatives requiring providers and suppliers to obtain prior authorization from MACs for certain items or services in certain jurisdictions before billing for or providing a service or item. Mills Decl. ¶ 12.

35. HHS estimates that the initiatives described in the preceding paragraph will reduce the number of appeals that would otherwise have reached OMHA by nearly 323,000 by the end of FY 2021. Mills Decl. ¶ 12.

36. To improve accuracy rates at the lower levels of appeal, CMS has established an accuracy review team to verify (through monthly review of contractors' decisions) that contractors make accurate medical review determinations and are applying Medicare policies consistently. Mills Decl. ¶ 13.

37. CMS similarly uses validation contractors to assess the accuracy of RAC determinations. Mills Decl. ¶ 13.

38. The validation contractors described above establish accuracy ratings for each RAC that are set forth in an annual report to Congress. Mills Decl. ¶ 13.

39. Though the statute imposes no such requirement and HHS's regulations permit the MACs (Level I) and the QICs (Level II) to identify new issues, CMS has directed the MACs and the QICs to limit their reviews of each claim to the original basis for denial of the claim. Bagel Decl. ¶ 4(d).

40. The flow of incoming appeals to OMHA has been reduced to 113,000 appeals in the most recently completed fiscal year, Griswold Decl. ¶ 3, though HHS projects that annual incoming appeals will rise in upcoming years. Bagel Decl. ¶ 6 & Ex. 1.

41. From FY 2019 to FY 2021, HHS currently projects that it will receive new appeals more than double its maximum adjudication capacity each year. Bagel Decl. Ex. 1.

42. HHS has repeatedly asked Congress for increases to OMHA's budget. Bagel Decl. ¶ 11.

43. For the fiscal years 2015, 2016, and 2017, Congress declined to appropriate the additional OMHA funds that the Executive Branch had requested. Bagel Decl. ¶ 11.

44. Members of Congress from both parties have recognized that OMHA needs additional resources. *See, e.g., Wyden Statement at Finance Hearing on the Medicare Appeals Process* (Apr. 28, 2015) (stating that "with a 10-fold increase in the number of cases, it's clear that additional resources are needed")[1]; *Hatch Statement at Finance Hearing on Medicare Audit and*

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[1] https://www.finance.senate.gov/ranking-members-news/wyden-statementat-finance-hearing-on-the-medicare-appeals-process.

Appeals (Apr. 28, 2015) ("The Office of Medicare Hearings and Appeals has . . . taken steps to address its backlog, but there is only so much the agency can do with their current authorities and staffing.").[2]

45. In June 2015, the Senate Finance Committee unanimously reported out a bill, the Audit & Appeals Fairness, Integrity, and Reforms in Medicare Act of 2015 to address existing issues in the Medicare appeals process, but that legislation did not proceed further and no companion legislation was introduced in the House of Representatives. *See* S. 2368, 114th Cong. (2015); *see also* S. Rep. No. 114–177 (2015).

46. The President's latest budget proposals would introduce a number of reforms that would be reasonably expected to reduce the influx of pending appeals. Bagel Decl. ¶ 12.

47. Under the President's budget proposals, the minimum amount-in-controversy for adjudication by an Administrative Law Judge would be raised. Bagel Decl. ¶ 12(c).

48. Under the President's budget proposals, OMHA would be permitted to use Medicare magistrates for appealed claims below the Federal District Court amount-in-controversy threshold. Bagel Decl. ¶ 12(d).

49. Under the President's budget proposals, OMHA would be permitted to issue decisions without holding a hearing if there is no material fact in dispute. Bagel Decl. ¶ 12(e).

50. Under the President's budget proposals, appeals would be remanded to the first level of appeal when new documentary evidence is submitted into the administrative record at the second level of appeal or above. Bagel Decl. ¶ 12(b).

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[2] https://www.finance.senate.gov/chairmans-news/hatch-statement-atfinance-hearing-on-medicare-audit-and-appeals.

51. Under the President's budget proposals, the Department would be provided with $1.3 billion over 10 years in mandatory funding to implement system reforms and invest in addressing the backlog of pending appeals. Bagel Decl. ¶ 12(a).

52. HHS cannot dictate whether and how many claimants accept any settlement proposals that it makes.

53. Given the ongoing adjudication gap, to eliminate the backlog HHS would have to continually settle claims en masse as they reached OMHA.

54. Several providers responsible for a significant portion of the backlog have program integrity issues that have precluded or significantly constrained efforts to reach settlements with such appellants to further reduce or eliminate the OMHA backlog. Declaration of Sherri G. McQueen ("McQueen Decl.") ¶ 6.

55. These program integrity concerns include active False Claims Act investigations encompassing a wide range of alleged improper practices, past and ongoing civil and criminal investigations by federal and state authorities, evidence of past program abuse, revocation of billing privileges, and Medicare payment suspensions. McQueen Decl. ¶ 6.

56. In 2014, as part of the Hospital Appeals Settlement Program ("HASP"), CMS offered to resolve claims for the provision of medically necessary services in which contractors had denied the claim based on a determination that the underlying documentation supported payment at outpatient hospital rates, as opposed to the higher inpatient hospital rates sought by providers. McQueen Decl. ¶ 7a.

57. The above-described program allowed CMS to remove 323,492 appeals from the backlog. McQueen Decl. ¶ 7a.

58. In 2016, CMS announced that it would allow eligible providers who failed to avail

themselves of the original HASP settlement initiative another opportunity to settle their inpatient status claims appeals through HASP. McQueen Decl. ¶ 7b.

59. The above-described initiative allowed CMS to eliminate an additional 56,720 appeals from the backlog. McQueen Decl. ¶ 7b.

60. Providers representing 40,000-50,000 potentially eligible appeals did not participate in HASP and 7,000 of those appeals demonstrated program integrity concerns. McQueen Decl. ¶ 7(c).

61. CMS has entered into settlement agreements with State Medicaid Agencies (SMAs) from Connecticut, Massachusetts, and New York, which were three of the highest volume appellants at OMHA. McQueen Decl. ¶ 9.

62. Each SMA agreed to resolve their pending appeals at OMHA or at the Medicare Appeals Council in exchange for partial payment at a negotiated percentage of the net allowable amount. McQueen Decl. ¶ 9.

63. The three SMAs also agreed to additional measures to resolve or reduce the number of new appeals entering the system through the summer of 2018. McQueen Decl. ¶ 9.

64. In total, these settlements will remove approximately 54,000 appeals from the backlog, and result in a reduction of approximately 9,000 new appeals being filed. McQueen Decl. ¶ 9.

65. CMS is currently engaged in settlement discussions with representatives of a significant number of Inpatient Rehabilitation Facilities (IRFs) which, if successful, could remove up to 15,000 IRF appeals from the backlog. McQueen Decl. ¶ 10.

66. OMHA staff trained in mediation techniques administer a settlement conference facilitation (“SCF”) program between CMS and individual appellants. Griswold Decl. ¶ 10.

67. As of May 2016, providers could be eligible for the SCF program if they had at least 20 claims, or $10,000, at issue in most Part B appeals pending before OMHA, or had at least 50 claims and $20,000 at issue in most Part A appeals pending before OMHA. Griswold Decl. ¶ 10.

68. The SCFs have thus far resulted in agreements to settle 15,500 appeals (in addition to the SMA settlements). Griswold Decl. ¶ 11.

69. Under OMHA's voluntary statistical sampling program which has been in place since 2014, appellants with 250 or more claims pending at OMHA may choose to have OMHA adjudicate their claims using statistical sampling and extrapolation. Griswold Decl. ¶ 16.

70. The program described in the preceding paragraph has resolved 532 appeals and over 14,000 appeals are currently in the process of being resolved. Griswold Decl. ¶ 16.

71. HHS has developed a settlement initiative for appellants with low appeal volumes (the "LVA"). McQueen Decl. ¶ 11(a).

72. HHS estimates that approximately 80% of appellants with appeals pending before OMHA, with approximately 166,000 corresponding appeals (or approximately 30% of the backlog), would be eligible for this initiative (i.e., the provider has fewer than 500 pending appeals, and the appeals are for no more than $9,000). McQueen Decl. ¶ 11(a).

73. LVA will be available to appellants with fewer than 500 eligible appeals (that is, 499 or fewer eligible appeals) pending at OMHA or the Council where program integrity concerns are not apparent. McQueen Decl. ¶ 11(a).

74. An eligible appeal has a billed amount of $9,000 or less and was filed with OMHA or the Council on or before November 3, 2017. McQueen Decl. ¶ 11(a).

75. Appellants eligible for the LVA may enter into an administrative agreement with

CMS to receive 62% of the net allowed amount of all of their eligible appeals in return for withdrawing all of their pending appeals. McQueen Decl. ¶ 11(a).

76. If all eligible providers were to resolve their eligible claims for LVA, CMS would pay out an estimated $131 million, but at a net savings of over $166 million. McQueen Decl. ¶ 11(a).

77. The LVA would be limited to appeals pending as of November 3, 2017 to prevent appellants from flooding the Medicare appeals process with new appeals that appellants would otherwise have not pursued in hopes of receiving a settlement. *See* McQueen Decl. ¶ 11(a).

78. In developing the LVA, CMS reviewed historic ALJ overturn rates in conjunction with costs of adjudication. McQueen Decl. ¶ 11(a).

79. The Department projects that the LVA will save the Trust Funds money because it will enable the Department to avoid adjudication costs, *i.e.*, the cost of collecting the claim, and to mitigate the Department's litigation risk. McQueen Decl. ¶ 11(a).

80. The Department set the appeal threshold, maximum billed amount, and payment percentage to maximize the projected cost avoidance of the initiative. McQueen Decl. ¶ 11(a).

81. The Department will be expanding the SCF option for most appellants not eligible for LVA based on their volume of pending appeals that do not have apparent program integrity concerns. McQueen Decl. ¶ 11(b).

82. The expanded SCF program will provide a vehicle for eligible providers and suppliers, with no apparent program integrity concerns, to explore means to remove their appeals from the backlog. Griswold Decl. ¶ 15.

83. With respect to the SCF program, OMHA reached out to 18 providers with a high number of appeals that CMS initially indicated did not present program integrity concerns, but

only four of those overtures has resulted in a settlement, and nearly half of the 18 did not respond to OMHA. Griswold Decl. ¶ 14.

84. As of October 27, 2017, only seven providers (out of an estimated 466 eligible) have chosen to participate in the voluntary statistical sampling initiative. Griswold Decl. ¶ 17.

85. The Recovery Audit Contractor ("RAC") program is statutorily required. 42 U.S.C. § 1395ddd(h).

86. In FY 2015, OMHA received 31,624 new RAC-related appeals, representing 14.1 percent of the new appeals OMHA received that year. Griswold Decl. ¶ 19.

87. This means that in FY 2015 OMHA received over 192,000 non-RAC related appeals, while its adjudicators were able to issue 78,881 dispositions, *see* ECF No. 41-1 at 48.

88. In FY 2016, OMHA received 15,761 RAC-related appeals, representing 9.5 percent of new appeals OMHA received that year. Griswold Decl. ¶ 19.

89. This means that in FY 2016 OMHA received over 150,000 non-RAC related appeals while its adjudicators were able to issue only 87,123 dispositions, ECF No. 41-1 at 48.

90. In FY 2017, OMHA received a total of approximately 113,000 new appeals and OMHA only had the capacity to dispose of approximately 76,000 appeals through ALJ adjudications Griswold Decl. ¶ 3.

91. RACs have now been operational under a new Statement of Work since October 31, 2016. Mills Decl. ¶ 6.

92. From October 1, 2016 to September 30, 2017, OMHA received 13,782 RAC-related appeals, 12.2 percent of total new appeals OMHA received during that period. Griswold Decl. ¶ 19.

93. The Hospital Appeals Settlement Program (discussed further below) removed

380,212 appeals, and almost all (341,116) of those were appeals of RAC overpayment determinations. Mills Decl. ¶ 5.

94. As of September 30, 2017, the total RAC-related appeals pending at OMHA numbered 82,329, compared to 437,524 just two years ago. Griswold Decl. ¶ 19.

95. The new RAC SOW requires RACs to maintain an accuracy rate of at least 95%, as determined by an independent contractor reviewing random monthly samples of improper payment decisions and provides a 0.2% contingency fee increase for each percentage point above 95%. Mills Decl. ¶ 7(b).

96. The new RAC SOW requires RACs to maintain an overturn rate of less than 10% at the first level of appeal, providing a 0.1% contingency fee increase for each percentage point below 10%. Mills Decl. ¶ 7(a).

97. RACs receive no contingency fee payment until after the second level of appeal is completed. Mills Decl. ¶ 7(d).

98. RACs are paid on a contingent basis and, if a RAC determination is overturned at any level of appeal, the RAC loses any payment that it may have previously earned from the denial. Mills Decl. ¶ 8.

99. Before a RAC may refer a claim for recoupment, it now must give the provider 30 days to discuss the basis of the claim with the RAC and submit additional information to substantiate payment. Mills Decl. ¶ 7(e).

100. CMS also now restricts the number of reviews RACs may initially conduct under a topic CMS has approved for review. Mills Decl. ¶ 9(a).

101. CMS has imposed limits on how many additional document requests that a RAC can issue to a provider. Mills Decl. ¶ 9(b).

102. CMS has removed the RACs' authority to conduct patient status reviews—previously accounting for a substantial portion of RAC appeals—which are now assigned to contractors under the Quality Improvement Organization ("QIO") program. Mills Decl. ¶ 9(c).

103. Contractors under the QIO program are paid on a flat-fee basis, not on a contingency basis. Mills Decl. ¶ 9(c).

104. In May 2015, CMS reduced the look-back review period for patient status reviews from three years to six months in cases where the provider submits its claim within three months of the date of service. Mills Decl. ¶ 9(d).

105. In FY 2015, the amount of money returned to the Medicare Trust Funds by the RAC program was $141 million, down 91% from the $1.6 billion returned in fiscal year 2014. *See* Centers for Medicare & Medicaid Services, HHS, Recovery Auditing in Medicare Fee-For-Service for Fiscal Year 2015, at v, https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Recovery-Audit Program/Downloads/FY2015-Medicare-FFS-RAC-Report-to-Congress.pdf.

106. There is no evidence that Congress disapproves of the way the Secretary has implemented the RAC program.

107. Based on historic overturn rates, only about 31% of the appeals pending at OMHA are likely to be successful, in whole or in part, on appeal. Bagel Decl. ¶ 7.

108. HHS cannot eliminate the backlog through reforms to the RAC program. Griswold Decl. ¶ 21.

Dated: November 3, 2017

Respectfully submitted,

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