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)

DECLARATION OF GEORGE G. MILLS

I, George G. Mills, declare as follows:

1. I am the Deputy Director of the Center for Program Integrity (CPI) at the Centers for Medicare & Medicaid Services (CMS) within the Department of Health and Human Services (HHS or Department). I have held this position since June 2015. Prior to this position, from August 2013 to June 2015, I was the Deputy Director of the Office of Financial Management (OFM) within CMS, and from January 2009 to August 2013, I was the Director of the Provider Compliance Group within OFM. Among my duties in my current position, I oversee CMS's program integrity efforts to combat fraud, waste, and abuse in the Medicare and Medicaid programs, including the Recovery Audit Contractor (RAC) program.

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.

3. CPI has implemented several initiatives to reduce the number of appeals reaching the Administrative Law Judge (ALJ) level of appeal within the Office of Medicare Hearings and

Appeals (OMHA). These efforts are aimed at improving both the accuracy of the Medicare claims that providers submit and the accuracy of Medicare contractors' review of those claims in determining payment. This, in turn, reduces the number of appeals entering the Medicare administrative appeals process.

Changes to the RAC Program

4. The RAC program is a statutorily mandated audit program that uses independent contractors to review claims that have already been paid to determine whether there has been an improper overpayment or underpayment. Many times, this process requires the RACs to request records from providers to support their claims. If a RAC determines that a claim has been paid improperly, the provider may obtain review through the Medicare administrative appeal process. In FY 2016, RACs made 340,596 overpayment determinations, totaling $214 million returned to the Medicare Trust Funds, which is much lower than in previous years, in large part because of the changes to the RAC program that are detailed below.

5. The significant drop in RAC appeals at OMHA is the result of several changes undertaken by the Department. First, the Hospital Appeals Settlement Process (HASP) removed 380,212 appeals, and almost all (341,116) of those were appeals of RAC post-payment overpayment determinations.

6. Second, starting in 2014, CMS implemented multiple initiatives to reduce the number of RAC post-payment claim reviews, *see infra* ¶ 9, and included a number of new provisions in the new RAC Statement of Work (SOW), which took effect over a year ago on October 31, 2016, *see infra* ¶¶ 7-8. While CMS temporarily paused RAC reviews for three months in 2014, the RACs have been fully operational for almost a year under a new SOW, which took effect on October 31, 2016, without a corresponding spike in new RAC appeals.

This indicates that the changes to the RAC program are having the intended effect in reducing the number of appeals entering the administrative appeals process.

7. SOW Changes: CMS made several RAC SOW modifications to improve the accuracy of RAC reviews and decrease the number of RAC-identified claims that enter the Medicare appeals system. *See* https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Recovery-Audit-Program/Downloads/New_RAC-SOW-Regions-1-4-clean.pdf. Specifically, in the new RAC SOW, CMS included three additional financial incentives for RACs to make accurate claim determinations, which the Department estimates will reduce new appeals to OMHA:

a. CMS requires RACs to maintain an overturn rate of less than 10% at the first level of the four-level Medicare administrative appeal process (excluding claims where the provider submits new evidence to the appeal adjudicator or corrects the claims). Under the SOW, RACs will earn a 0.1% contingency fee increase for each percentage point below 10% that they maintain their overturn rates. For example, a RAC with a base contingency fee rate of 8% and a 9% appeal overturn rate would receive a 0.1% contingency fee increase, for a total contingency fee of 8.1%.

b. CMS requires the RACs to maintain an accuracy rate of at least 95%, as determined by an independent validation contractor, which reviews random, monthly samples of RAC improper payment decisions to determine the accuracy of those determinations. Under the SOW, RACs will earn a 0.2% contingency fee increase for each percentage point above 95% that they maintain their accuracy rates. For example, a RAC with a base contingency fee rate of 8% and a 96% accuracy score would receive a 0.2% contingency fee increase, for a total contingency fee of 8.2%.

c. Failure by a RAC to maintain an overturn rate of less than 10% at the first level of appeal or to maintain an accuracy rate of 95% as determined by the independent validation contractor will result in CMS taking necessary action, including, but not limited to, progressively reducing the additional documentation requests (ADRs) that the RAC can issue to providers, requiring the RAC to prepare a Corrective Action Plan, deciding to not exercise the next option period of the contract, or modifying or terminating the contract. For example, CMS has stopped certain RACs from doing reviews until sufficient corrective actions were completed by the RAC.

d. CMS withholds the RAC's contingency fee payment until after a reconsideration decision has been issued at the second level of appeal, or after the time frame to file an appeal at the second level of appeal has expired.

e. Before RACs refer a claim they have identified as improper for recoupment, they are required to first offer providers the opportunity for a 30-day discussion period to discuss the basis of the claim with the RAC and to submit additional information to substantiate payment of their claim.

8. These SOW changes build on the base structure of the RAC program, whereby RACs are paid on a contingency fee basis when their claim review results in an overpayment collection, or an underpayment returned to the provider. CMS does not compensate RACs for the costs of reviewing claims to identify those overpayments or underpayments. If a RAC determination is overturned on appeal, the RAC loses any payment that it may have previously earned from the collection that occurred because of the claim denial. This means that in the event that no overpayment is collected or the overpayment is returned, the RAC does not earn (or keep) any payment for the time spent reviewing the claim, nor does it receive any payment for

associated overhead costs for its operations and therefore loses money when it has a claim review overturned on appeal. Perhaps for these reasons, one of the incumbent RACs did not even submit a bid on any of the new contracts.

9. Non-SOW RAC Initiatives:

a. Starting in January 2015, CMS began to limit the number of reviews RACs may initially conduct under an approved topic, and no additional RAC reviews may occur until CMS investigates the RAC reviews already conducted to ensure the RAC is complying with what the SOW requires, such as appeal overturn rates and accuracy scores, before providing approval for additional reviews. Fewer, more accurate reviews translate into fewer appeals of claim denials.

b. Starting in January 2016, CMS has imposed limits on the number of additional document requests (ADRs) that RACs can issue to providers. Sending an ADR letter is the first step in the RAC's medical review process. These limits have resulted in significantly fewer record requests. This in turn translates into a reduced number of RAC reviews, which decreases the potential identification of improper payments and results in fewer overpayment determinations to appeal.

c. Claim denials after RAC reviews focusing on whether medically necessary services should have been provided on an inpatient basis or on an outpatient basis ("patient status reviews") previously accounted for a substantial portion of RAC appeals. Starting in October 2015, CMS instituted a new process for reviewing patient status claims, which uses contractors under the Quality Improvement Organization program (QIOs) to review these claims instead of RACs. QIOs are paid on a flat-fee

basis, not on a contingency basis like the RACs, and are able to provide education to the providers related to the claim denial.

d. RACs are permitted to review an initial determination to pay a claim during the look back review period which is measured from the date the claim was paid. 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. Patient status reviews involve whether the services were properly provided on an inpatient basis. The purpose of reducing the look-back period for patient status reviews was to give providers the opportunity to timely rebill for the medically necessary services they provided, instead of having to file an appeal to receive payment for those services. Under the Medicare statute and applicable regulations, RACs are allowed to look back up to three years from the date a claim was paid.

10. Suspension of the RAC program will not eliminate the backlog. As detailed above, the Department has undertaken substantial and comprehensive measures to reduce the number of incoming RAC appeals while still implementing the RAC program as directed by Congress.

Non-RAC Initiatives

11. Targeted Probe and Educate Program: CMS recently expanded the Targeted Probe and Educate Program, which offers providers individualized educational opportunities both during and after the probe review cycle to discuss claim errors with the Medicare Administrative Contactors (MACs) that process their Medicare claims. Following the educational discussion, providers are given time to try to improve their claims submissions with the goal of reducing errors, preventing claim denials, and correcting billing behaviors, so as to

decrease the numbers of claim denials and resulting appeals. This program began as a pilot and, effective October 1, 2017, all complex medical review completed by the MACs, i.e., reviews of the medical record, will occur through the targeted probe and educate process. The Department anticipates that this program will decrease the number of appeals being filed by decreasing unnecessary denials as providers are educated throughout the review process.

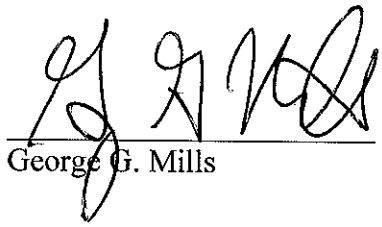
12. Prior Authorization Initiatives: Since September 2012, CMS has initiated a series of demonstration projects under which CMS requires that providers and suppliers obtain prior authorization from the MACs for certain items or services in certain jurisdictions before the provider or supplier furnishes the item or service and bills for it. The prior authorization process encourages providers and suppliers to assess Medicare coverage criteria and meet documentation requirements before they furnish the service or item and before submitting a claim. The process also gives providers and suppliers the opportunity to correct errors and omissions because the provider or supplier may resubmit a request for prior authorization an unlimited number of times. It also reduces the number of appeals entering the appeals process by allowing providers to address issues with their documentation before submitting the claim, thereby reducing the number of claim denials. Each of the prior authorization demonstrations tests the use of prior authorization in a particular claim type. CMS initially kept each demonstration small and then expanded some of them based on initial findings. The power mobility device demonstration was the first prior authorization demonstration; it began in September 2012 and now is in 19 states. The non-emergent scheduled ambulance transport demonstration began in December 2014 in three (3) states and is now in eight (8) states and Washington, D.C. The non-emergent hyperbaric oxygen demonstration began in March 2015 in three (3) states. CMS also finalized a prior authorization regulation for Durable Medical Equipment, Prosthetics, Orthotics, and

Supplies (DMEPOS). *See* 80 Fed. Reg. 81,674 (Dec. 30, 2015). CMS began prior authorizing the first two items under this regulation (both power wheelchairs) in four states in March 2017, and expanded it nationwide in July 2017. HHS estimates that these initiatives will reduce the number of appeals that would have otherwise reached OMHA by nearly 323,000 appeals by the end of FY 2021.

13. Accuracy Review Process: Since 2010, CMS has been using a comprehensive strategy to promote consistency and accuracy among all Medicare review contractors (including MACs, RACs, and others). To this end, CMS has established an Accuracy Review Team to verify that Medicare review contractors make accurate medical review determinations and apply Medicare policies consistently across the program. The Accuracy Review Team conducts monthly reviews of Medicare review contractors' decisions, looking at varying items and services, including those that are currently part of new medical review initiatives, as well as on an ad hoc basis in response to specific concerns. Additionally, CMS continues to use a validation contractor to assess the accuracy of RAC determinations. The validation contractor establishes an annual accuracy score for each RAC, which is identified in the annual Recovery Auditing in Medicare Report to Congress. CMS also began using an accuracy contractor to verify the complex medical review and prior authorization decisions made by the MACs and the Supplemental Medical Review Contractor. CMS uses the information gained through both of these activities to reexamine and clarify Medicare payment polices, furthering the effort to improve review consistency while addressing improper payment vulnerabilities. HHS expects that increasing consistency in review decisions and providing policy clarification where needed will result in a decrease in inappropriate denials, and therefore a decrease in appeals.

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 Baltimore, Maryland



George G. Mills