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

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| AMERICAN HOSPITAL ASSOCIATION, *et al.*,<br><br>Plaintiffs,<br><br>v.<br><br>ALEX M. AZAR II, in his official capacity as ACTING SECRETARY OF HEALTH AND HUMAN SERVICES,<br><br>Defendant. | Civil Action No. 14-cv-00851 (JEB) |

**DECLARATION OF JENEEN IWUGO**

1. I am the Deputy Director, Quality Improvement and Innovation Group, of the Center for Clinical Standards and Quality (CCSQ) 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 December 2012 to June 2015, I was the Director for the Beneficiary and Healthcare Improvement and Safety Division within CMS. Among my duties in my current position, I oversee the Quality Improvement Organization (QIO) 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. The mission of the QIO program is to improve the effectiveness, efficiency, economy, and quality of services delivered to Medicare beneficiaries and to ensure that those services are reasonable and necessary. CMS has identified the core functions of the QIO program as improving care for Medicare beneficiaries, protecting beneficiaries by expeditiously

addressing individual complaints, reviews, or appeals from provider notices of discharge or termination of services or violations of the Emergency Medical Treatment and Labor Act (EMTALA), and protecting the integrity of the Medicare Trust Funds by ensuring that Medicare pays only for services and goods that are reasonable and necessary and that are provided in the most appropriate setting. The quality improvement strategies of the Medicare QIO program are predominantly implemented by QIO contractors who work directly with health care providers and practitioners in their geographic service areas. In 2014, CMS separated QIO functions into two separate sets of contractors: (1) Beneficiary and Family Centered Care (BFCC)-QIOs, which primarily perform case review; and (2) Quality Innovation Network (QIN)-QIOs, which support healthcare delivery professionals and systems in performing quality improvement work.

3. There are currently two BFCC-QIO contractors which are under a 5-year contract until 2019: Livanta LLC and KePRO. They are responsible for performing statutorily mandated case review activities and interventions. BFCC-QIOs help Medicare beneficiaries exercise their right to high-quality health care. They manage all beneficiary complaints and quality of care reviews to ensure consistency in the review process while taking into consideration local factors important to beneficiaries and their families. They also handle cases in which beneficiaries want to appeal a health care provider's decision to discharge them from the hospital or discontinue a service, and Emergency Medical Treatment and Labor Act (EMTALA) reviews.

4. On September 12, 2016, CMS transferred responsibility for reviewing inpatient-status claims (also known as "two-midnight reviews") to the BFCC-QIO contractors, who perform peer review of quality of care cases and claim reviews, instead of the Recovery Audit Contractors (RACs) or Medicare Administrative Contractors (MACs). In response to instructions from CMS, BFCC-QIOs review far fewer of these claims than the RACs did. For

example, they may only review 175 providers in each of 5 geographic regions and may review as few as 10 claims per provider. While RACs are directed to reduce program integrity risk to the Medicare Trust Funds by seeking out and correcting improper payments, QIOs are funded to perform reviews to ensure the quality of Medicare services meets appropriate standards and to ensure beneficiary protection. To this end, QIOs provide education to all providers with inpatient-status claims denied as a result of QIO review, including individualized, claim-by-claim denial rationales and clinical details. This provider-specific education is interactive, allowing the provider an opportunity to review the BFCC-QIO claim decisions, ask questions, and receive meaningful feedback from the QIO conducive to behavioral change and increased provider compliance. The QIO can subsequently refer a provider to the RAC after the provider fails to make improvements in billing practices despite repeated educational efforts from the QIOs.

5. The total number of inpatient-status claim reviews performed by the BFCC-QIOs from September 12, 2016 through June 12, 2018 is 66,183, with approximately 19,000 reviews performed in 2017. To date, CMS has recouped approximately $32 million in overpayments resulting from QIO two-midnight reviews.

6. Shifting all hospital claim reviews – not just inpatient-status claim reviews – to the QIOs would not be feasible as a practical matter. QIOs do not perform as many reviews as the RACs, and most of the reviews QIOs perform focus on beneficiary appeals, not post-payment review of submitted claims. During the last four years (48 months) of the QIO contract, the BFCC-QIOs have performed approximately 840,000 total reviews. Of these, approximately 560,000 reviews were expedited beneficiary appeals of discharges or service terminations by hospitals, skilled nursing facilities, and other providers. The BFCC-QIOs also reviewed over

150,000 Diagnostic Related Groups (DRG) cases from hospitals, in which the hospitals are seeking an increased Medicare payment. BFCC-QIO DRG reviews are designed to validate if the diagnosis code billed matches the care a patient received to ensure the correct code has been billed. BFCC-QIO DRG reviews examine how a patient presented to a hospital for care, how they were diagnosed and treated by the hospital provider and then how the claim was coded by the hospital for Medicare payment, using various Medicare payment rules and guidelines. As discussed above, the BFCC-QIOs have also performed 66,183 inpatient-status reviews as of June 12, 2018. Because the QIOs perform fewer reviews overall, and far fewer post-payment reviews than the RACs, we believe a transition of all hospital claim reviews to QIOs would decrease the agency's ability to correct the improper payments of hospital claims and would create an increased risk to the integrity of the Medicare Trust Funds.

7. Based on our experience with transferring the inpatient-status reviews to the QIOs, during which we suspended review to make sure that the QIO reviewers were trained and reviewing claims consistently, we anticipate that transferring post-pay review of all hospital claims to the QIOs would also involve extensive capacity building and training, and could take at least a year.

8. Unlike the RACs (which are paid on a contingency basis), the BFCC QIOs are paid from the Medicare Trust Funds. They are paid on a cost-plus basis for the reviews. Adding all hospital claim reviews to the BFCC QIO contracts would substantially increase payment for these reviews from the Trust Funds.

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

Executed on August 3, 2018 in Baltimore, Maryland.

Jeneen Iwugo