IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

THE AMERICAN HOSPITAL ASSOCIATION, *et al.*,	)	
Plaintiffs,	)	
v.	)	No. 1:18-cv-02084-RC
ALEX M. AZAR II, in his official capacity as Secretary of Health and Human Services, *et al.*,	)	
Defendants.	)	

DECLARATION OF ELIZABETH RICHTER

I, Elizabeth Richter, declare as follows:

1. I am the Deputy Center Director of the Center for Medicare within the Centers for Medicare & Medicaid Services ("CMS"). CMS is the federal agency within the United States Department of Health and Human Services ("HHS") responsible for administering the Medicare and Medicaid programs. The Center for Medicare is responsible for, among other things, developing the policies for, and managing the operations of, the fee-for-service portion of the Medicare program, including Medicare Part B payments. The statements made in this declaration are based on my personal knowledge, information contained in agency files, and information furnished to me by CMS staff and contractors in the course of my official duties.

2. I am familiar with the subject matter of the above-captioned lawsuit. More specifically, I am aware that the district court in this case has concluded that the defendants – the U.S. Department of Health and Human Services and its Secretary – acted in an *ultra vires* manner by reducing the payment rate for drugs purchased through the 340B Program in the 2018

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Outpatient Prospective Payment System ("OPPS") Final Rule. I further understand that the court instructed the parties to file "supplemental briefing on the appropriate remedy."

3. The Medicare OPPS typically processes more than 100 million outpatient hospital claims every calendar year. For the 2018 OPPS calendar year, the agency expects to process more than 110 million such claims.

4. These OPPS claims relate to items and services provided by approximately 3,900 facilities for outpatient items and services covered under the OPPS. These items and services are provided to millions of different Medicare beneficiaries, who, by statute, are required to pay cost-sharing for such items and services, which is usually 20% of the total Medicare payment rate.

5. To provide some additional context for this payment system, in the 2018 OPPS calendar year Final Rule CMS estimated that OPPS expenditures would exceed $55 billion in Medicare Part B payments by the federal government and almost $14 billion in Medicare beneficiary cost-sharing payments, for a total of more than $69 billion in Medicare payments for the more-than 100 million claims submitted.

6. Medicare OPPS claims are paid every year according to OPPS payment rates that are established in advance of the upcoming calendar year. Developing this payment system, which is done on an annual basis, is a complicated process that begins several months before the release of the proposed rule, which typically occurs around July of each year. The process culminates in a final rule, usually released on or around November 1 to allow for the 60-day period required under the Congressional Review Act before the new payment rates take effect on January 1. The complex and interconnected nature of the many calculations necessary to develop the OPPS payment rates are described in greater detail on the CMS website. This 40-page "claims

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accounting" document sets forth an accounting of the claims CMS used to calculate average costs for OPPS services, which were ultimately used to establish final payment rates for the 2018 OPPS. *See* https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/CMS-1678-FC-2018-OPPS-FR-Claims-Accounting.pdf

7. In the calendar year 2018 OPPS Rule, CMS provided that as a result of the policy change with respect to drugs acquired under the 340B program, the agency estimated a payment reduction of $1.6 billion in separately paid OPPS drug payments. As required by statute, this reduction was offset in a budget neutral manner, and, as a result, CMS adjusted payments for *all non-drug* OPPS services by an equal amount (that is, CMS raised rates for non-drug items and services by $1.6 billion). A potential remedy that would address reversing this policy would be to reprocess *all* claims for items and services furnished by all providers paid under the OPPS (including those that are not party to this case), but that potential remedy requires an arduous, disruptive and time-consuming process of recalculating all OPPS rates for 2018 (because of the budget neutral aspect of the policy change), as well as a significant update of the claims processing system that would then apply newly calculated OPPS payment rates to all previously submitted 2018 claims. We estimate that it would cost between $25 million and $30 million in additional administrative expenses.

8. Moreover, this potential remedy could have a significant impact on the cost-sharing obligations of Medicare beneficiaries. If CMS is required to undertake the process of recalculating and reapplying new 2018 OPPS payment rates, that retroactive change in payment amount could significantly alter a Medicare beneficiary's cost-sharing amount, which is generally 20% of the allowed Medicare payment rate. For example, if Medicare previously paid

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$3,300 for a drug in 2018, but as a result of a judicial decision it is determined that the Medicare-allowable payment amount should have been $5,300 for that drug, the cost-sharing amount borne by the Medicare beneficiary would increase by $400. Notably, this problem arises is in the context of a system that processes more than 100 million claims each calendar year. CMS is very concerned about the potential for confusion and anxiety among Medicare beneficiaries if CMS were to recalculate Medicare payments and change beneficiary financial obligations for calendar year 2018 because beneficiaries could be responsible for different cost-sharing amounts, which could be higher or lower than their original cost-sharing obligations, depending on the mix of items and services they received – i.e., if a beneficiary only received a 340B-acquired drug his cost-sharing would increase, and if he only received a non-drug OPPS service his cost sharing would decrease. The total amount of beneficiary cost-sharing impacted by reprocessing all such claims was estimated at $320 million in the 2018 OPPS final rule.

9. In addition, CMS utilizes Medicare contractors to process OPPS claims, and to reprocess all 2018 OPPS claims would take a substantial amount of time to effectuate. Based on the number of providers and claims involved for the 2018 OPPS calendar year, and the statutory requirement to continue to timely process real-time claims for the current period, among other things, we estimate this process would take at least a year. To date, CMS does not yet have all final-action claims submitted by providers for calendar year 2018, but based on claims received so far, we estimate if this potential remedy is mandated, that over 110 million claims would have to be reprocessed for 2018 OPPS claims, and that this would result in an additional administrative cost of paying Medicare contractors an additional $25-$30 million as referenced above. Moreover, based on current workload and agency estimates, for the vast majority of Medicare contractors (who process Medicare claims on behalf of CMS), it will take at least one

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year to complete all the adjustments for all the claims once new OPPS payment rates are calculated, developed, and loaded into Medicare claims-processing software. Medicare contractors have existing workloads to process claims, and they still are responsible for processing newly submitted claims for services furnished in 2019 in a timely manner. The timely processing of 2019 claims as they are submitted is important to ensure that providers receive payment from Medicare and can continue to provide services to beneficiaries, but it is also important because, by statute, the government would owe an additional amount of interest on such claims unless it continues to process them. Put simply, there is a limit to the number a claims a particular Medicare contractor can process in a day, and the year-long time estimate above is based on current workload and the additional claims that contractors might be able to process in addition to their normal workload.

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

Dated: January 31, 2019

Baltimore, Maryland

Elizabeth Richter