

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF COLUMBIA

THE AMERICAN HOSPITAL )  
ASSOCIATION, *et al.*, )  
 )  
Plaintiffs, )  
v. )  
THE DEPARTMENT OF HEALTH )  
AND HUMAN SERVICES, *et al.*, )  
 )  
Defendants. )  
\_\_\_\_\_ )

No. 1:18-cv-02112-JDB

**DECLARATION OF KRISTA PEDLEY**

I, Krista Pedley, PharmD, MS, Captain, U.S. Public Health Service, hereby declare and certify as follows:

1. I am the Director of the Office of Pharmacy Affairs (OPA), Healthcare Systems Bureau, Health Resources and Services Administration (“HRSA”), U.S. Department of Health and Human Services (“Department”).

2. I currently lead OPA, which is the Departmental component responsible for overseeing the 340B Drug Pricing Program (“340B Program”).

3. The 340B Program, which is codified in section 340B of the Public Health Service Act (PHSA), 42 U.S.C. § 256b (“Section 340B”), was established by section 602 of the Veterans Health Care Act of 1992 (Pub. L. 102-585). Section 340B implements a drug pricing program by which manufacturers who participate in Medicaid are required to sell covered outpatient drugs to particular entities listed in the statute (“covered entities”) at a price that does not exceed the amount determined under a statutory formula (“ceiling price”).

4. Since the last update, concerning the implementation of the pricing component of HRSA’s Office of Pharmacy Affairs Information System (OPAIS) provided to the Court on

December 3, 2018, HRSA has continued to work to provide covered entities access to the OPAIS pricing system.

5. HRSA received drug pricing data from the Centers for Medicare & Medicaid Services (CMS) on February 11, 2019. This data, which will be compared to pricing data received from drug manufacturers, has been loaded into the OPAIS pricing system.

6. On February 15, 2019, HRSA opened the OPAIS pricing system for the submission of pricing data by drug manufacturers. Drug manufacturers have until March 4, 2019, to enter pricing information.

7. Since December of last year, HRSA has performed targeted outreach to drug manufacturers via email and phone to ensure that drug manufacturers have created user accounts to enable the drug manufacturers to enter drug pricing data into the OPAIS.

8. As of February 28, 2019, approximately 81 percent of applicable drug manufacturers (as measured by the total number of active labeler codes in the OPAIS) registered with the OPAIS pricing system.

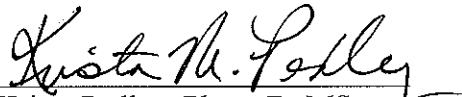
9. The pricing data received from CMS indicates that approximately 39,000 separate national drug codes (NDCs) are subject to 340B pricing. As of February 28, 2019, HRSA received manufacturer pricing data for approximately 45 percent of these 39,000 NDCs. HRSA is sending daily reminder emails to manufacturers to upload NDC pricing.

10. OPA conducted several stakeholder education efforts to introduce the OPAIS system and to respond to stakeholder inquiries regarding OPAIS operations.

11. Consistent with HRSA's last update to the Court, the Department still expects that covered entities will have access to ceiling prices via the OPAIS pricing system on April 1, 2019, assuming that it timely receives manufacturer pricing data from the drug manufacturers.

I declare under penalty of perjury that the foregoing is true and correct.

Date: 2/28/19



Krista Pedley, PharmD, MS  
Captain, U.S. Public Health Service  
Director, Office of Pharmacy Affairs  
Healthcare Systems Bureau  
Health Resources and Services Administration  
U.S. Department of Health and Human Service