IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

THE AMERICAN HOSPITAL)	
ASSOCIATION, et al.,)	
)	
Plaintiffs,)	
V.)	No. 1:18-cv-02112-JDB
THE DEPARTMENT OF HEALTH)	
AND HUMAN SERVICES, et al.,)	
)	
Defendants.)	
)	

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

March 14, 2019, HRSA completed its preparations and provided covered entities access to the OPAIS pricing system starting at 9:00 AM on April 1, 2019.

- 5. Upon opening of the OPAIS pricing system, HRSA sent an email to all covered entities and drug manufacturers announcing that the pricing system is available for authorized covered entity use. The email included a link to OPAIS pricing system "frequently asked questions," as well as a link to a recorded tutorial to assist covered entities accessing the pricing system.
- 6. As of 9:00 AM on April 2, 2019, over 275 authorized users successfully accessed the system.

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

Date: 4/2/2019

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