

# EXHIBIT 1

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

THE AMERICAN HOSPITAL	)	
ASSOCIATION, <i>et al.</i> ,	)	
	)	
Plaintiffs,	)	
v.	)	No. 1:18-cv-02112-JDB
THE DEPARTMENT OF HEALTH	)	
AND HUMAN SERVICES, <i>et al.</i> ,	)	
	)	
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, Healthcare Systems Bureau, Health Resources and Services Administration (“HRSA”), U.S. Department of Health and Human Services (“Department”).

2. I currently lead the Office of Pharmacy Affairs (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. Section 340B(d)(1)(B)(iii) of the PHSA provides for covered entity “access through the Internet website of the Department of Health and Human Services to the applicable ceiling prices for covered outpatient drugs.”

5. Section 340B(d)(1)(B)(iii) of the PHSA imposes the additional requirement that ceiling price posting occur in a way that “limits such access to covered entities and adequately assures security and protection of privileged pricing data from unauthorized re-disclosure.”

6. In addition, prior to HRSA posting 340B ceiling prices on the website, Section 340B(d)(1)(B)(iii) of the PHSA requires the Department to verify that the ceiling price conforms to the statutory formula, which includes comparing the ceiling price calculated by the Secretary with quarterly pricing data that is reported by drug manufacturers.

7. In part to satisfy these statutory requirements, HRSA has developed the Office of Pharmacy Affairs Information System (OPAIS), a new, integrated information system that focuses on security, user accessibility, and data accuracy.

8. In the process of developing the OPAIS, HRSA made security updates and enhancements to the existing 340B database that has been used for covered entity and manufacturer registrations. These updates have strengthened the integrity and accuracy of 340B stakeholder information. It was also critical to enhance the security of the registration system, as it will be used to verify user identity for those seeking to access the OPAIS.

9. After several years of development and a significant financial investment in developing a functional and secure system, the OPAIS infrastructure has been completed. OPAIS consists of two components: registration and pricing. HRSA released the registration component of OPAIS in September 2017, but has not released the pricing component of OPAIS.

10. The Department recently finalized the requirements for the pricing methodology manufacturers must use in calculating the 340B ceiling price in a final rule (82 FR 1210, January 5, 2017) to be effective January 1, 2019. This final rule clarifies the methodology manufacturers are required to use to calculate the 340B ceiling price on a quarterly basis and sets forth the requirement that manufacturers charge \$0.01 (penny pricing) for each unit of a drug when the ceiling price calculation equals zero. The Department determined that the OPAIS pricing component should not be made available to covered entities until the pricing methodology in the final rule was in effect to alleviate any confusion among regulated entities.

11. As the pricing methodology in the final rule will take effect on January 1, 2019, the Department is working to expeditiously implement the pricing component of OPAIS. Since the delay of the 340B ceiling price final rule in March 2017, HRSA has continued to make improvements to the OPAIS pricing component, improving the functionality, user interface, and security of the system. The Department currently expects that covered entities will have access to ceiling prices via the OPAIS pricing component on April 1, 2019. More than 15,000 covered entities will have access to the pricing data.

12. HRSA has announced on its website (<https://www.hrsa.gov/opa/>) and in an email sent to all covered entities and drug manufacturers participating in the 340B Program that the OPAIS pricing component will be open for the submission of manufacturer pricing data in the first quarter of 2019 and that HRSA expects to publish 340B ceiling prices on April 1, 2019.

13. The OPAIS pricing component will list approximately 50,000 ceiling prices from over 600 different drug manufacturers. The OPAIS pricing component will incorporate multiple data points (e.g., average manufacturer price (AMP), unit rebate amount (URA), drug package

size, and case package size) for each of the 50,000 ceiling prices, requiring the analysis of hundreds of thousands of data points obtained from multiple sources each quarter.

14. Prior to publication of the 50,000 340B ceiling prices every quarter, the Department must verify each ceiling price, which requires the collection and comparison of data from several different sources: AMP and URA pricing data obtained from the Centers for Medicare & Medicaid Services (CMS), AMP, URA, package size, and case package size data obtained from manufacturers, and drug package size data obtained from a third party vendor.

15. HRSA uses this data to compute 340B ceiling prices according to the formula set forth in the 340B statute.

16. As part of the new OPAIS pricing system, a manufacturer will submit corresponding data electronically to HRSA. Manufacturer data will be compared to the data that HRSA obtains from CMS.

17. HRSA plans to collect these data from manufacturers beginning in the first quarter of 2019. As part of this data collection, HRSA will ask each manufacturer to identify an Authorizing Official (AO) and Primary Contact (PC) for the new system. HRSA will issue credentials to these individuals for logging into the new system and for uploading quarterly price files. Each AO and PC will be required to obtain an authenticated and authorized 340B information system account and will need to confirm his/her identity through a two-step authentication process. There will be strict segregation of each manufacturer's data with mechanisms to protect privileged pricing data from unauthorized access and re-disclosure.

18. HRSA will need to compile the data from CMS and the manufacturers. Once collected, HRSA will compare pricing data for all 50,000 340B prices to validate the 340B pricing. The validation process is complex and requires pricing data expertise. In addition, the

validation process must be completed and tested prior to releasing the ceiling price data to covered entities for the first time on April 1, 2019, to ensure the system is fully operational and secure.

19. CMS will send HRSA its pricing data in early February 2019. Manufacturers will upload their pricing data into OPAIS by the end of February 2019. HRSA will analyze and validate the data with the goal of completing the OPAIS pricing component release by April 1, 2019.

20. As part of this process, prior to April 1, 2019 and on a continuing basis, HRSA will identify differences between HRSA and manufacturer-calculated ceiling prices and will manually reconcile any discrepancies with the manufacturer prior to publication in OPAIS each quarter. HRSA will raise discrepancies with the manufacturers and the manufacturers will have the ability to upload replacement data, if appropriate, and to assist HRSA in the reconciliation of the discrepancy. HRSA estimates that approximately 10 percent of all 340B ceiling prices (approximately 5,000 340B ceiling prices) will need to be manually reconciled each quarter prior to posting.

21. The OPAIS pricing component that will be used for 340B ceiling prices is a complex, secure system that requires the analysis of hundreds of thousands of data points from multiple sources that must be verified and manually reconciled every quarter by HRSA. While HRSA is working diligently to provide covered entities access to ceiling price information on April 1, 2019, as with any new and complex system, there is a chance that system complications or other unanticipated events could prevent HRSA from meeting the April 1 deadline.

22. One of these potential complications that could prevent HRSA from meeting the April 1 deadline is the number of ceiling prices that must be manually reconciled when there are

discrepancies in the calculated ceiling price. As previously stated, HRSA has estimated that approximately 10 percent of the 50,000 ceiling prices will need to be manually reconciled, which can be a labor intensive and time consuming process. HRSA is reasonably confident in this estimate. However, to the extent that this estimate is too low, HRSA may not be able to manually reconcile all of the ceiling prices prior to April 1. In this situation, HRSA may determine that it is better to wait to publish ceiling price information until all ceiling prices can be reconciled, rather than to publish inaccurate or incomplete information.

23. Another potential complication is the receipt of data from outside sources. The pricing system is dependent upon receipt of data from hundreds of different sources. HRSA does not directly control the sources of the data. If there are significant disruptions that are beyond the control of HRSA in the flow of data into the pricing system, HRSA may determine that it is better to wait to publish ceiling price information, rather than to publish inaccurate or incomplete information. For instance, manufacturers will be required for the first time to enter data in the pricing system in the first quarter of 2019. HRSA will be undertaking a significant education effort to familiarize manufacturers with the new system. However, given that this is the first time manufacturers will be entering data there logically may be mistakes and delays caused by human error.

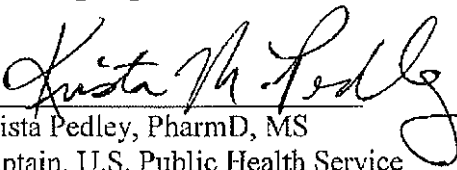
24. Another potential complication is unforeseen technical issues. The system is designed to be segmented to ensure that the sensitive data remains secure. Testing and verifying that security is a time sensitive process that ensures the over 270,000 lines of code are functional and meet national security standards. For example, users will log in securely and only have access to certain data contained within the system according to specific rules of behavior. The system architecture is structured to keep the different groups of users on different firewalled

segments of the environment, as well as logical firewalls between the user groups. HRSA has performed extensive testing to make certain that the system is reliable and secure. HRSA is confident the system is ready to receive pricing data from manufacturers and others. However, prior to covered entity access to ceiling prices, there may be unforeseen technical issues that do not reveal themselves until drug manufacturers begin reporting data. Depending upon the nature of an unforeseen technical issue, it may not be possible to post ceiling prices by April 1.

25. While HRSA does not expect there to be significant complications in the release of the pricing system, it would not be possible to guarantee that such issues will not arise to delay the April 1 date, especially in the context of the sensitive and confidential nature of the system's pricing information. HRSA's role is to ensure that the pricing data released is secure and accurate and does not want to jeopardize that information by prematurely releasing the system if issues arise.

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

Date: 12/3/2018

  
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