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Association of  
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March 9, 2020

William N. Parham, III  
Director, Paperwork Reduction Staff  
Office of Management and Budget  
Office of Information and Regulatory Affairs  
Attention: CMS Desk Officer  
Washington, DC

**Re: Agency Information Collection Activities: Submission for OMB Review; Document Identifier CMS-10709**

Dear Mr. Parham:

The Association of American Medical Colleges (AAMC or the Association) welcomes the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS's or the Agency's) notice 85 *Fed. Reg.* 7306 (February 7, 2020) to collect acquisition cost data for specified outpatient drugs acquired under the 340B Drug Pricing Program (340B Program). The AAMC has significant concerns with CMS undertaking this survey and ask that the Office of Management and Budget (OMB) not provide a document identifier for this survey.

The AAMC is a not-for-profit association dedicated to transforming health care through innovative medical education, cutting-edge patient care, and groundbreaking medical research. Its members comprise all 154 accredited U.S. and 17 accredited Canadian medical schools; nearly 400 major teaching hospitals and health systems, including 51 Department of Veterans Affairs medical centers; and more than 80 academic societies. Through these institutions and organizations, the AAMC serves the leaders of America's medical schools and teaching hospitals and their 173,000 faculty members, 89,000 medical students, 129,000 resident physicians, and more than 60,000 graduate students and postdoctoral researchers in the biomedical sciences.

We have concerns about this data collection effort that is aimed at only a subset of hospitals, those that are committed to serving their communities and rely on the 340B Program to do so. The data collection effort appears to contravene the intent of Congress when it created the 340B Program in 1992 and, due to its success, later expanded to include more entities. As the District Court concluded in its opinion in *American Hospital Association et al. v. Azar* (Case number 1:18-cv-2084, December 27, 2018), CMS did not have statutory authority to implement a nearly 30 percent decrease in Medicare reimbursement for drugs acquired under the 340B Program for calendar year (CY) 2018 (later extended when CMS again imposed the decreased payment for CY 2019). In the CY 2020 Outpatient Prospective Payment System (OPPS) final rule CMS for the third time imposes draconian cuts in payments to 340B hospitals.

In this notice and the previous notice<sup>1</sup> announcing CMS's intent to collect this data, the Agency justifies its request for data by saying that "[w]e want to ensure that the Medicare program pays for specified covered outpatient drugs purchased under the 340B Program at amounts that approximate what hospitals actually pay to acquire the drugs." (85 FR 7307). Congress did not design the 340B Program to pay hospitals at acquisition costs. Rather, the program allows eligible hospitals to purchase covered drugs at a discounted rate below the reimbursement rate – whether the payer be Medicare or in the case of non-Medicare beneficiaries, a commercial insurer – and use the difference to generate funds that will be used to reach vulnerable patients by making more services available to them. Consistent with the intent of the program safety-net hospitals invest their 340B savings in a wide variety of programs to meet the needs of their local communities and help vulnerable patients at no cost to taxpayers.

CMS also seems to have prejudged the results of the data survey as it stated in the OPPI CY 2020 final rule that "[w]e thus anticipate that the survey data collected for CY 2018 and 2019 will confirm that the ASP minus 22.5 percent is a conservative measure that overcompensates 340B hospitals." (84 FR 61322). Should CMS try to set payment rates based on the data collected as a result of this notice, it will need to engage in new rulemaking. The Agency will have to make the data available as part of the proposed rule to provide stakeholders with the opportunity to analyze it and respond to any proposed change in the payment rate.

The AAMC disagrees that the data collected in this survey could be used to "craft an appropriate remedy in the event of an unfavorable decision [to CMS] on appeal." (84 FR 61322). As CMS is aware, the AAMC and other litigants have proposed an appropriate remedy that would return money to all hospitals in full. In the end, the Court will determine the remedy that is to be applied.

Additionally, we believe that CMS has grossly underestimated the expenditure of time and resources hospitals will incur in order to collect and submit the data. For example, hospitals would be expected to report the 340B acquisition cost data for more than 400 HCPCS codes and 1,100 national drug codes, easily adding up to tens of thousands of units of data a hospital would need to account for. To comply with this and other requirements, hospitals will likely be forced to redirect financial resources that would otherwise be used to care for low-income patients.

Thank you for the opportunity to present our views. If you have questions regarding our comments, please feel free to contact Mary Mullaney at 202.909.2084 or [mmullaney@aamc.org](mailto:mmullaney@aamc.org).

Sincerely,



Janis M. Orlowski, M.D., M.A.C.P.  
Chief Health Care Officer

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<sup>1</sup> 84 FR 51591