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November 27, 2019

Ms. Seema Verma
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Attention: Document Identifier CMS-10709/OMB Control Number _____

Dear Administrator Verma:

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 to collect acquisition cost data for specified outpatient drugs acquired under the 340B Drug Pricing Program (340B Program).

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% 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. 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.

In the notice CMS writes 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." (84 Fed Reg 51591). Congress did not design the 340B Program to pay hospitals at acquisition costs. Congress designed the program so that eligible hospitals could purchase covered drugs at a discounted rate below the Medicare reimbursement rate and use the difference to reach more eligible patients and provide more comprehensive services. 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 says in the OPPS 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." (p. 61322). Should CMS try to set payment rates based on the data collected as a result of this notice, it would have to engage in new rulemaking and make the data

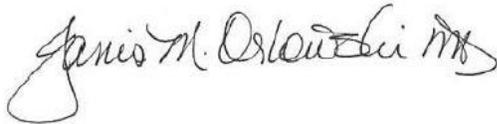
available at the time a change is proposed to provide stakeholders with the opportunity to analyze it and respond to any proposed change in the payment rate.

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.” (p. 61322). As CMS is aware, the AAMC and other litigants have proposed an appropriate remedy that would return money to all hospitals in full.

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. Therefore, we ask that CMS not move forward with the data collection.

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.

Sincerely,

A handwritten signature in black ink, appearing to read "Janis M. Orlowski M.D.", with a stylized flourish at the end.

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

cc: Ivy Baer