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July 16, 2018

The Honorable Alex M. Azar II
Secretary
U.S. Department of Health and Human Services (HHS or the Department)
200 Independence Avenue, SW
Room 600E
Washington, DC 20201

Re: HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs. Policy Statement; Request for Information (RIN 0991-ZA49)

Dear Secretary Azar:

The Association of American Medical Colleges ("the AAMC" or "Association") welcomes this opportunity to comment on the "HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs Request for Information," 83 *Fed. Reg*. 22692 (May 16, 2018). The AAMC appreciates the administration's efforts to tackle high drug prices and develop ways to make prescription drugs more affordable. The nation's teaching hospitals struggle firsthand with this challenge, as they strive to ensure access to needed care, including prescription drugs, for their patients and communities to avoid excessive health care spending.

We agree that more must be done to stem the rising prices of existing prescription drugs and ensure that new drugs entering the market do not command prices that puts them out of reach of patients. Increasing transparency of manufacturer pricing policies is an important step to understanding skyrocketing prices. Meaningful competition among brand and generic drugs holds the promise of putting downward pressure on drug prices. By contrast, the 340B Drug Pricing Program (340B Program) is <u>not</u> a driver of high drug prices, and proposals to undermine this important program would be counterproductive in addressing access to affordable medications. Drug prices are set by the manufacturers, leaving consumers with limited options – to either pay these exorbitant prices or forgo treatment. We strongly urge HHS to work to implement drug pricing reforms that address the problem at its source, rather than reduce the scope of the 340B Program that provides needed services to underserved communities.

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 are all 151 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 more than 173,000 full-time faculty members, 89,000 medical students, 129,000 resident physicians, and more than 60,000 graduate students and postdoctoral researchers in the biomedical sciences.

As HHS evaluates its options for addressing high drug prices, the AAMC recommends that the Department:

- improve manufacturer transparency in drug pricing, including drug launch prices and systematic price increases, and increase competition among both brand and generic drugs;
- implement the final rule that outlines the calculation of the ceiling prices that drug manufacturers may charge for drugs purchased through the 340B Program and application of civil monetary penalties for violations;
- rescind the reductions to Part B reimbursement for drugs purchased under the 340B Program;
- lift restrictions on pharmacists informing consumers of cheaper drug alternatives;
- evaluate value-based purchasing proposals that meaningfully reduce prescription drug costs; and,
- **not** reduce payments for drugs strictly based on site of service in which they are administered.

HHS Should Focus on Drug Price Transparency and Improve Competition Among Drugs to Lower Prices

As drug prices continue to take a larger share of the health care dollar, the AAMC supports efforts to limit skyrocketing costs. Prescription drug prices continue to rise every year. Each year, there are more high-cost, brand-name drugs (including specialty drugs) entering the market. Even though more than 80 percent of prescriptions written are for generic drugs, the higher-cost drugs are negating any savings that could be achieved. New specialty medicines now represent $384 per person per year, or 43 percent of net spending.[1] With a pipeline of new, breakthrough therapies, there are expected to be 40 to 45 new innovative product launches per year through 2021.[2]

Drug manufacturers set the price of their drugs upon entry into the market. Subsequent price increases also contribute to the unsustainable rise in costs for prescription medicines. Prices for brand-named drugs rose in 2014 at an average rate of 13.5 percent.[3] Most cancer drugs launched between 2009 and 2014 were priced at more than $100,000 per patient for one year of treatment with more recent launch prices of more than $400,000 for a year of treatment.[4] These prices put needed medication out of reach for many Americans. Patients should not have to choose not to undergo needed treatment simply because it is too expensive. Oftentimes, not following prescribed drug regimens results in patients requiring high-cost treatment in hospitals. **HHS should increase transparency of drug prices and restrict excessive pricing and price increases to ensure patient access.**

The lack of competition among some drugs also contributes to high drug prices. Single source drugs – both brand and generic – afford manufacturers a monopoly in the marketplace. Patent-protected, single-source drugs now make up 63 percent of total drug spending, up from 29 percent of total spending in 2010, despite the fact that they comprise less than 10 percent of total prescriptions filled.[5] According to the Medicare Payment Advisory Commission (MedPAC), 8 of the top 10 drugs paid under the average sales price (ASP) system in Medicare in 2015 were biologics, many of which have limited to no competition.[6] AAMC agrees that more needs to be done to ensure that all Americans have access to

[1] https://www.iqvia.com/institute/reports/understanding-the-drivers-of-drug-expenditure-in-the-us
[2] Ibid.
[3] http://www.theimsinstitute.org/files/web/IMSH%20Institute/Reports/Medicines_Use_and_Spending_Shifts/Medicine-Spending-and-Growth_1995-2014.pdf
[4] https://www.cancer.gov/news-events/cancer-currents-blog/2018/presidents-cancer-panel-drug-prices
[5] https://www.bcbs.com/the-health-of-america/reports/rising-costs-patented-drugs-drive-growth-pharmaceutical-spending-us
[6] http://www.medpac.gov/docs/default-source/reports/jun17_ch2.pdf?sfvrsn=0

needed medication and not risk sacrificing treatment due to unaffordability of the medications. **HHS should monitor the price increases for drugs with limited or no competition and find ways to constrain these year-over-year increases that make these drugs unaffordable.** Efforts to increase competition should consider that new market entrants have a significantly lower price point than drugs currently on the market. Additionally, incentives offered to new products must include a requirement also limiting drug price increases.

340B Drug Pricing Program

The 340B Program Provides Vital Support and Access to Vulnerable Patients and Communities

Congress created the 340B Program in 1992 under the Public Health Service Act to support certain safety-net hospitals and other providers that serve low-income, vulnerable patients. The program allows these "covered entities" to purchase outpatient drugs at a discount from drug manufacturers to help "stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."[7]

Consistent with the intent of the program – to help stretch scarce resources as far as possible, reaching more eligible patients and providing more comprehensive services – 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. Since the savings come from drug manufacturer discounts, these services are provided at no cost to taxpayers.

In addition to providing low-income patients with free or substantially discounted prescription drugs, AAMC-member teaching hospitals use their savings to create and sustain critical programs that otherwise might not be financially possible, including:

- Improving access to specialized care previously unavailable in underserved areas;
- Establishing and improving neighborhood clinics;
- Creating multidisciplinary clinics to treat substance use and mental health disorders;
- Providing underfunded cancer patients with access to counseling from pharmacists at their bedside; and,
- Providing mobile clinics staffed by bilingual nurse practitioners, nurses, and social workers to vulnerable communities to provide free health care to children and their families.

Teaching hospitals share a commitment to advancing medical knowledge, therapies, and technologies to prevent disease, alleviate suffering and improve quality of life. The 340B Program allows safety-net hospitals to provide disadvantaged patients access to needed drugs, but also expand health care services to treat these patients and their communities. Any proposals to limit the Program will negatively impact the very individuals it was designed to serve. **The AAMC opposes any changes that will reduce the scope of the program and curb the benefits the 340B Program provides to patients and their communities.**

The 340B Program is Not Driving High Drug Costs

The RFI asks "how the growth of the 340B drug discount program affected list prices?" The 340B Drug Discount Program does not drive drug price increases. According to the most recent data from the Health Resources and Services Administration (HRSA), which administers the Program, 340B sales represent

[7] H.R. Rept. No. 102-384(II), at 12 (1992)

just 3.6 percent of the total $457 billion U.S. drug sales.[8] The net reduction to drug manufacturer revenue is even less - estimated to be approximately 1.9 percent.[9] This is a negligible impact on drug manufacturers, whose worldwide estimated sales revenue increased to $775 billion in 2015 with the largest 25 drug companies reporting annual profit margins between 15 and 20 percent.[10] Such a small percentage of total drug sales cannot be driving skyrocketing drug prices. The responsibility for high drug costs rests with the high prices set by the manufacturers, not by the small sales associated with the 340B Program. **HHS should focus on the unsustainable prices of new therapies and identify ways to decrease skyrocketing costs. Shrinking the 340B Program will only harm patients who rely on the services provided by covered entities. It will not affect drug prices.**

Program Growth. The RFI questions whether the growth of the 340B Program is affecting list prices of drugs. Congress expanded the type of covered entities eligible to participate in the 340B Program as an acknowledgement of the success of the 340B Program. This deliberate expansion reflects Congress's desire to extend Program eligibility to other hospitals –mostly in rural communities – to reach more patients that may benefit from the Program. Additionally, HRSA changed registration requirements for existing child sites that resulted in what appeared to be growth in the Program. However, even with program expansion, total 340B drug spending has remained relatively constant – having only increased one percentage point compared to total drug sales between 2012 and 2015.

Program eligibility. The RFI asks whether "changing the definition of 'patient' or changing the requirements governing covered entities contracting with pharmacies or registering off-site outpatient facilities (*i.e.*, child sites) would refocus the program towards its intended purpose?" Simply put, no. As currently structured, the program is serving its intended purpose. At no cost to taxpayers, covered entities that participate in the program are leveraging discounts from pharmaceutical manufacturers to benefit vulnerable patients.

As previously noted, the 340B Program allows covered entities to use savings from pharmaceutical companies to expand outpatient services to low-income patients. HRSA allows covered entities to register qualifying off-campus outpatient facilities for participation in the program, including clinics that predominantly serve uninsured individuals. Many covered entities rely on the savings derived from the 340B discounts to continue operating facilities that otherwise would be financially unviable to maintain, such as free clinics. Limiting access for child sites to participate in the 340B Program will restrict the ability of safety-net hospitals to deliver needed care to these clinic patients. AAMC does not support limiting program eligibility for child sites.

Similarly, the AAMC would not support changes to the definition of "patient" under the 340B Program that are unnecessarily restrictive such that they would severely limit drugs eligible for 340B pricing and would undermine hospitals' efforts to expand care and services to underserved populations. Restricting patients' eligibility would negatively impact the patients the program is intended to help.

[8] Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation. "Observations on Trends in Prescription Drug Spending." March 8, 2016. https://aspe.hhs.gov/pdf-report/observations-trends-prescription-drug-spending
[9] Coukell, Allan and Dickson, Sean. "Reforming the 340B Drug Pricing Program: Tradeoffs Between Hospital and Manufacturer Revenues." JAMA Internal Medicine. Published online May 21, 2018.
[10] U.S. Government Accountability Office, "Drug Industry: Profits, Research and Development Spending, and Merger and Acquisition Deals." https://www.gao.gov/assets/690/688472.pdf

HHS Should Implement the 340B Program's Ceiling Price and Civil Monetary Penalty Final Rule to Increase Manufacturer Price Transparency

One way that HHS could improve manufacturer price transparency, and shine a light on drug prices, is to immediately implement the ceiling price and civil monetary penalty final rule.[11] This rule has gone through several public notice and comment periods with an initial implementation date of January 2017. The administration has delayed the final rule five times, pushing the implementation date back to July 2019. Delaying this final rule is inconsistent with HHS's stated objective of improving transparency and lowering drug prices.

Overcharging by drug manufacturers for covered outpatient drugs in violation of the 340B Program requirements has long been problematic. The HHS Office of Inspector General (OIG) found systematic problems with the accuracy and reliability of ceiling price data. Additionally, OIG noted that HRSA lacked the oversight mechanisms to ensure that 340B covered entities pay at or below the 340B ceiling price.[12] OIG found in a subsequent report that 14 percent of the sampled purchases made by 340B covered entities exceeded the 340B ceiling price.[13] In 2010, Congress explicitly authorized HRSA in statute to outline the standards and methodology for calculating 340B ceiling prices, to make the ceiling prices available to covered entities, and to impose monetary penalties on drug manufacturers who knowingly and intentionally charge more than the ceiling price. As noted above, however, to date, HRSA has failed to complete any of these actions, with the administration recently postponing for the fifth time implementation of the associated final rule.

OIG noted in recent testimony that this lack of transparency leaves "340B providers unable to determine whether they are paying accurate amounts to drug manufacturers."[14] Implementing the final rule will be a major – and long overdue – step in promoting drug transparency by holding drug manufacturers accountable for ensuring covered entities are able to verify the ceiling price and that pricing for covered outpatient drugs does not exceed the 340B ceiling price and giving covered entities the means to verify the ceiling price. **AAMC strongly urges HHS to implement this final rule as part of their efforts to control drug prices.**

HHS Should Rescind Medicare Outpatient Payment Reductions for Drugs Purchased Under 340B Program

In the OPPS calendar year 2018 final rule, CMS finalized a proposal to reduce the outpatient reimbursement rate for hospitals participating in the 340B Program by nearly 30 percent despite concerns from more than half the members of both houses of Congress. Under the final rule, Medicare now pays for drugs purchased under the 340B Program at average sales price (ASP) minus 22.5 percent.

These payment reductions translate into cutbacks to safety-net hospitals' programs that benefit low-income patients. Decreasing reimbursement for Part B drugs will further strain hospitals' ability to provide needed services to their patients and communities. As evidenced by a recent report from the S&P

[11] https://s3.amazonaws.com/public-inspection.federalregister.gov/2016-31935.pdf
[12] Department of Health and Human Services (HHS) Office of Inspector General (OIG), Pharmaceutical Manufacturers Overcharged 340B-Covered Entities 3 (Mar. 10, 2003), https://oig.hhs.gov/oas/reports/region6/60100060.pdf.
[13] HHS OIG, Review of 340B Prices, 10 (July 2006), https://oig.hhs.gov/oei/reports/oei-05-02-00073.pdf.
[14] Testimony before the United States Senate Committee on Health, Education, Labor, and Pensions. May 15, 2018. https://www.oig.hhs.gov/testimony/docs/2018/maxwell-testimony05152018.pdf

Global Ratings, the impact of these cuts will weaken the operating performance of safety-net hospitals at a time of already tightened margins.[15]

While it is critical that policymakers take steps to make prescription drugs more accessible and affordable, reducing Medicare payment rates for prescription drugs in the 340B Program is not a solution to this problem. These cuts simply impede hospitals' ability to maintain programs to provide services to vulnerable populations – including Medicare beneficiaries – while doing nothing to bring down the cost of prescription drugs.

HRSA Currently Audits Covered Entities for Duplicate Discounts and to Ensure Compliance with Other Program Requirements

As the RFI notes, "manufacturers are not required to provide a discounted 340B price and a Medicaid drug rebate for the same drug." In an effort to ensure that 340B drugs are not receiving more than one discount, the RFI questions if there should be additional program integrity efforts to identify and prevent duplicate discounts.

The AAMC does not believe that additional reporting requirements for hospitals participating in the 340B Program are necessary. HRSA already has extensive reporting measures in place to maintain compliance among covered entities and has substantially enhanced its oversight of hospitals and other providers since 2011. To participate and remain in the program, covered entities must undertake an initial certification process to demonstrate that they serve a disproportionate share of underserved patients, recertify annually, and have mechanisms in place to prevent duplicate discounts and diversion to ineligible patients. HRSA also conducts random audits and posts the findings on its public website. Many hospitals go beyond these requirements and invest additional resources and staff to ensure continued compliance.

Other Strategies to Address Drug Pricing

HHS Should Lift Restrictions on Pharmacists to Inform Patients of Cheaper Drugs

The AAMC supports HHS's proposal to lift restrictions on pharmacists to inform consumers about cheaper drug alternatives. Currently, some insurer contracts with pharmacies include a provision that prohibits the pharmacists from advising patients of cheaper alternatives to their prescribed drugs. This includes telling the patient that the prescription could be less costly if they elected not to use their insurance. Removing this restriction would immediately benefit patients that struggle to afford their medications.

HHS Should Evaluate Value-Based Arrangements that Measurably Decrease Drug Prices

Well-designed value-based initiatives have the capacity to drive better, cost-effective care. In some circumstances, prescription drugs play a large role in driving costs in value-based arrangements. While we support efforts to improve value-based care arrangements, so as HHS evaluates incorporating value-based designs with the goal of reducing prescription drug costs, we suggest beginning with smaller, voluntary models limited to treatments for which it is possible to identify drugs that have a measurable impact on drug pricing, including whether drug manufacturers should be held accountable for health outcomes. If the models reveal a significant reduction in drug prices, HHS should then consider taking lessons learned and propose an expansion as part of rulemaking.

[15] https://images.magnetmail.net/images/clients/AHA_MCHF/attach/2018/May/S_and_P_Report_05302018.pdf

Site Neutral Payments

The RFI also requests feedback on how the site of service should determine payment for prescription drugs and drug administration. It also questions whether beneficiary cost-sharing under Medicare plays a role in whether a drug is administered in the inpatient or the outpatient setting. Changing reimbursement rates to drive treatments to the outpatient setting has the potential to put patients at risk. Rapid advances in treatments for life-threatening illnesses and diseases have been made in recent years. More and more of these complex drug regimens are administered in the outpatient setting. The AAMC believes the decision as to whether a drug administration or procedure should be performed in the inpatient or outpatient setting rests with the treating physician in consultation with the patient and be based solely on the patient's clinical condition. **There are legitimate reasons that reimbursement should vary by site of service. CMS should not change this policy.**

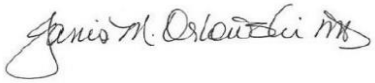
Some new targeted therapies – chimeric antigen receptor T-cell (CAR-T) therapy being one example – cannot be safely administered in the outpatient setting. While these new therapies hold great promise, they can require extensive hospital care – *e.g.*, longer hospitalizations with an increased number of intensive care unit (ICU) days – depending on the patient's response to the treatment. Patients receiving these treatments tend to be sicker and oftentimes must have exhausted all traditional treatments before being treated with these new therapies. Furthermore, when these therapies have been administered in the outpatient setting, patients are usually admitted to the hospital due to life-threatening side effects of the drugs.

Currently, Medicare recognizes that physician offices and hospital outpatient departments (HOPDs) are both essential care settings in the health care landscape and that they differ from each other in key ways that warrant different payment methods and rates. Unlike most physician offices, HOPDs are essential care settings providing comprehensive, coordinated care to a variety of patients, many having chronic or complex conditions. Oftentimes, HOPDs are the sole sources of care for low-income and otherwise underserved populations. Recently, HOPDs have seen an uptick in referrals of low-income and uninsured patients from community providers, particularly oncologists. These patients are often in advanced stages of disease that require management from a multifaceted team. HOPDs also provide wraparound services such as translators and other social services. Therefore, reimbursement for services cannot be solely classified by site of service. HHS must consider the critical role HOPDs play in the delivery of health care services and should not further decrease reimbursement for outpatient services provided in these settings.

Conclusion

Thank you for the opportunity to comment on the HHS Blueprint Request for Information. We would be happy to work with HHS on any of the issues discussed above or other topics that involve the academic medical community. If you have questions regarding our comments, please feel free to contact Mary Mullaney at 202.909.2084 or mmullaney@aamc.org.

Sincerely,



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