



**Statement for the Record Submitted by the
Association of American Medical Colleges (AAMC) to the
Energy and Commerce Subcommittee on Health
“Opportunities to Improve the 340B Drug Pricing Program”
Submitted July 11, 2018**

The Association of American Medical Colleges (AAMC) is pleased to submit this statement for the record for the House Energy and Commerce Health Subcommittee’s July 11 hearing, “Opportunities to Improve the 340B Drug Pricing Program.” The AAMC strongly supports the 340B Drug Pricing Program and is especially supportive of legislative efforts to improve the program and expand access to care, including the Stretching Entity Resources for Vulnerable (SERV) Communities Act (H.R. 6071) and the bill to rescind the Medicare cuts in the calendar year (CY) 2018 outpatient final rule (H.R. 4392).

The AAMC is a not-for-profit association representing all 151 accredited U.S. medical schools; nearly 400 major teaching hospitals and health systems; and more than 80 academic societies. Through these institutions and organizations, the AAMC services 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.

Many AAMC-member teaching hospitals are safety-net providers that rely on the savings from the 340B program to improve the health of their communities. At no cost to taxpayers, the 340B program has been successful in providing patients with access to health care services and relief from high drug prices. As the committee reviews the program, we believe that any potential changes should be measured against the goal of enhancing – not diminishing – the services made available by the 340B program.

Congress created the 340B program 25 years ago to support safety-net hospitals and other providers that serve low-income, vulnerable patients. The program allows participants, also known as covered entities, to purchase outpatient drugs at a discount from drug manufacturers to help “stretch scarce federal resources as far as possible, reaching more patients and providing more comprehensive services.”¹ In addition to providing low-income patients with free or discounted drugs, hospitals use their savings to address the needs of their local communities. Any proposal to reduce the scope of the program is counter to the intent of the program.

The 340B Program Provides Vital Support to Patients at No Cost to Taxpayers

Congress created the 340B program under the Public Health Service Act to help reduce the burden of high drug costs on safety-net hospitals. Under the rules of the program, pharmaceutical manufacturers that participate in Medicaid are required to sell outpatient drugs at discounted prices to eligible providers that care for a disproportionate share of uninsured and underinsured

¹ H.R. Rept. No. 102-384(II), at 12 (1992)

patients. There is no cost to taxpayers since the program allows safety-net hospitals and other eligible providers to leverage these discounts from pharmaceutical companies to provide patients and communities with access to care they otherwise would not receive.

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. In addition to providing low-income patients with free or substantially discounted prescription drugs, AAMC-member 340B 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.

The 340B Program Provides Enormous Benefits to Patients at Little Cost to Manufacturers

The 340B program is a relatively small program but is a lifeline for many safety-net hospitals and their patients. Without the savings from the program, hospitals may have to reduce access to these critical health care services.

According to the most recent data from the Health Resources and Services Administration (HRSA), which administers the program, 340B sales represent just 3.6 percent² of the total \$457 billion U.S. drug sales³. The net reduction to drug manufacturer revenue is even less - estimated to be approximately 1.9 percent.⁴ This is a negligible impact to drug manufacturers, whose worldwide estimated sales revenue increased to \$775 billion in 2015 with the largest 25 drug companies reporting annual profit margins between 15-20 percent.⁵

Drug manufacturers argue that the 340B program is responsible for the increase in drug prices. There is no question that drugs have become unaffordable for millions of Americans and the providers that care for them. However, it is illogical and misleading to suggest that the solution to rising drug costs is to shrink a program that represents a de minimis percentage of the total U.S. drug market and enables safety-net providers to care for vulnerable populations. We urge policymakers to address this national problem of unaffordable drug prices directly – not by

² Department of Health and Human Services Fiscal Year 2019, Health Resources and Services Administration, Justification of Estimates for Appropriations Committees

³ Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation. “Observations on Trends in Prescription Drug Spending.” <https://aspe.hhs.gov/system/files/pdf/187586/Drugspending.pdf>.

⁴ 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.

⁵ 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>

undermining a program that provides drug pricing relief and valuable health care services to patients.

The Closure of Oncology Practices and Physician Consolidation are Not Related to 340B

Critics have falsely asserted that the 340B program incentivizes physician-hospital consolidation in cancer care. However, the increase in hospital ownership of physician practices is a relatively recent phenomenon compared to the 25-year history of the 340B program and is explained by other factors, including a broader trend toward integrated health care systems.⁶

For many years, the most cited driver of consolidation was payment reform under the Medicare Modernization Act of 2003 (MMA), which significantly reduced physician reimbursements for cancer drugs beginning in 2005. According to a 2007 study, drug reimbursement accounted for 77 percent of oncology practice revenue.⁷ As recently as 2012, David Eagle, MD, past president of the Community Oncology Alliance (COA) noted “the key driver of consolidation in oncology is financial strain.”⁸

Other factors have also contributed to the dramatic increase in the number of oncology clinics that have either closed, struggled financially, merged, or been acquired since 2008. These include rising bad debt and tightened lending standards during the recession; the evolution of cancer care to integrate services like genetic testing, specialty pharmacies, and nutritional support, which made solo practice less economically viable; and the appeal of economies of scale for activities such as billing and general technology infrastructure, which provided strong incentives to consolidate.⁹

Legislative Proposals to Strengthen the 340B Program

The AAMC strongly supports two bills that the subcommittee is considering as part of this legislative hearing – H.R. 4392 and H.R. 6071. These bills strengthen the 340B program by rescinding the drastic Medicare cuts to 340B hospitals and improving program integrity by ensuring that drug manufacturers are held to the same level of oversight as other program participants.

Congress Must Rescind the \$1.6 Billion Cut to Safety-Net Hospitals

The AAMC supports **H.R. 4392**, bipartisan legislation introduced by Representatives David McKinley (R-W.Va.) and Mike Thompson (D-Calif.), which would rescind a flawed policy in the CY 2018 Medicare Outpatient Prospective Payment System (OPPS) final rule that

⁶ Alpert A, His H, and Jacobson M. “Evaluating the Role of Payment Policy in Driving Vertical Integration in the Oncology Market.” *Health Affairs*, Vol. 36, No. 4.

⁷ Akscin J, Barr TR, Towle EL. “Key practice indicators in office-based oncology practices: 2007 report on 2006 data.” *J Oncol Pract.* 2007; 3(4): 200-203. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2793811/>

⁸ Ullman K. “Oncologist Practice Consolidation Continues” *American Journal of Managed Care*, Dec. 2012. <http://www.ajmc.com/journals/evidence-based-oncology/2012/2012-2-vol18-n5/oncologist-practice-consolidation-continues>

⁹ Tetreault SA, Harwin WN, and Eagle D. “‘Economies of Scale’ Yield Multiple Benefits for a Private, Physician-run Oncology Practice.” *Practice and Policy, Oncology Journal*. Vol. 27, Issue 7.

dramatically reduces outpatient drug reimbursement rates for hospitals participating in the 340B program by nearly 30% annually. The legislation currently has nearly 200 bipartisan cosponsors.

The Centers for Medicare and Medicaid Services (CMS) finalized this proposal despite concerns from over half the members of both houses of Congress. Previously, Medicare paid for separately payable, non-pass through drugs under Part B at the average sales price (ASP) plus 6 percent. Under this final rule, Medicare now pays for drugs purchased under the 340B program at ASP minus 22.5 percent. According to CMS, this change will result in \$1.6 billion in payment cuts annually to safety-net hospitals. These reimbursement cuts further strain hospitals' ability to provide needed services to their patients and communities. A recent report from S&P Global Ratings concludes that the impact of these cuts will weaken the operating performance of safety-net hospitals at a time of already tightened margins.¹⁰

The OPPI final rule contravenes statutory intent by inappropriately leveraging Medicare to undermine the 340B program. CMS argues this policy will lower the cost of prescription drugs. 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.

All 340B Program Participants Should be Held to the Same Oversight Standards

In addition to rescinding the Medicare cuts in the OPPI final rule, the **SERV Communities Act (H.R. 6071)**, introduced by Rep. Doris Matsui (D-Calif.), would strengthen the 340B program by clarifying the intent of the program and enhancing program integrity.

The SERV Communities Act clarifies that the program is intended to provide safety-net providers with discounts on covered outpatient drugs so that they can use the savings to provide comprehensive services to the patients and communities they serve. It also codifies the definition of an eligible “patient” and prevents the Health and Human Services (HHS) Secretary from narrowing this definition, which would reduce the scope of the program, result in fewer services to vulnerable patients, and harm patient health.

During the June 19 Senate Health, Education, Labor, and Pensions (HELP) Committee hearing, Capt. Krista Pedley, PharmD, MS, Director, HRSA Office of Pharmacy Affairs, noted that covered entities are audited at a much higher rate than drug manufacturers.¹¹ H.R. 6071 would address this discrepancy by requiring parity in the percentage of audits for covered entities and manufacturers.

The SERV Communities Act also would address longstanding problems of drug manufacturers overcharging covered entities for 340B drugs by implementing the ceiling price and civil

¹⁰ S&P Global Market Intelligence, “Cuts To The 340B Drug Pricing Program May Render U.S. Hospitals Serving Vulnerable Patient Groups Vulnerable Themselves.” Published online May 29, 2018.

¹¹ U.S. Senate Committee on Health, Education, Labor and Pensions Hearing, Effective Administration of the 340B Drug Pricing Program. Statement of Capt. Krista Pedley, PharmD, MS.

monetary penalties final rule¹². The rule, which has gone through several notice and comment periods, was expected to go into effect in January 2017. However, the administration has delayed the rule five times, pushing back the implementation date until at least July 2019.

The HHS Office of Inspector General (OIG) has issued several reports finding high rates of 340B overcharges by manufacturers. Yet, providers have no significant remedies available to address this problem, such as auditing manufacturers or entering into litigation. They cannot even confirm whether or not they are being charged the correct price by manufacturers. In 2010, Congress mandated that providers be given access to 340B ceiling prices, but that information remains unavailable. The SERV Communities Act would address these problems and improve program integrity by holding drug manufacturers accountable for ensuring covered entities are able to verify the ceiling price for their 340B drugs.

Several Legislative Proposals Would Harm Patients and Worsen Health

The AAMC has significant concerns about several of the legislative proposals in the bills and discussion drafts that the subcommittee is reviewing; specifically, we have concerns about provisions related to creating a moratorium on hospital participation, imposing additional reporting requirements on covered entities, changing the definition of an eligible patient, and changes to the intent of the program.

A Moratorium Would Limit Access to Care

The 340B Protecting Access for the Underserved and Safety-Net Entities Act (PAUSE Act, H.R. 4710) would create a moratorium to prevent newly eligible DSH hospitals and new outpatient clinics associated with current 340B hospitals from enrolling in the 340B program. It would also prevent these hospitals from expanding services and prohibit other hospitals that provide a high level of care to underserved populations from leveraging the program to benefit their communities. Since many of the services that hospitals provide as a result of the discounts they receive through the 340B program are preventative, this would lead to higher health care costs and less access to services for those who need them the most. Because the 340B program is not funded by taxpayers, these changes would not save the government any money – they would simply limit discounts that pharmaceutical companies would be required to provide.

Additional Reporting Requirements Would Increase Burden on Hospitals Without Helping Patients

The AAMC supports HRSA's program integrity efforts to ensure the 340B program continues to allow safety-net hospitals to strengthen care for patients and their communities. However, several of the legislative proposals, including the **PAUSE Act** and a discussion draft, **To Require Certain 340B Covered Entities to Report Charity Care Expenditures**, include additional reporting requirements for covered entities that seek to limit the scope of the program and impose excessive administrative burdens on participants and HRSA. These changes would

¹² 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 82 Fed. Reg. 1,210 (Jan. 5, 2017)

weaken the 340B program by reducing access to health care services without saving the government money.

The AAMC does not believe that additional reporting requirements for hospitals 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.

Some legislative proposals call for increased hospital reporting within the program. Any changes to program integrity and oversight of the 340B program must consider the extensive information that hospitals already publicly report. Hospitals are among the most highly regulated and transparent organizations in the country. They complete extensive Medicare cost reports each year, which include information related to levels of uncompensated care they provide. Non-profit hospitals also report information annually to the Internal Revenue Service on Schedule H regarding the community benefits they provide and every three years must complete a community health needs assessment and an implementation strategy. Moreover, efforts to link charity care to the 340B program do not take into account the magnitude of comprehensive services DSH hospitals provide for underinsured and uninsured patients, including bad debt and underpayment by public programs. This change would shift the focus of the program and reduce the amount of services hospitals are able to provide to low-income patients and communities.

As noted above, in stark contrast to existing requirements for hospitals in the 340B program and beyond, there is little transparency or accountability among the pharmaceutical manufacturers that participate in the 340B program. Any proposal to increase reporting for hospitals should also include provisions to improve transparency for manufacturers, including the implementation of the ceiling price and civil monetary penalties final rule.

Changes to the Definition of “Patient” Will Significantly Reduce the Scope of the Program

The AAMC is very concerned about the discussion draft, **Defining the Term “Patient” for Purposes of the 340B Drug Discount Program**, which would change drastically the definition of an eligible patient. This proposal is unnecessarily restrictive and would severely limit drugs eligible for 340B pricing – including limitations on discharge prescriptions and infusion services – which would undermine the original intent of the 340B program and efforts by covered entities to expand care and services to underserved populations.

Many hospitals employ discharge prescription programs to maximize the likelihood that patients will comply with medication therapy regimens after they leave the hospital. By ensuring that patients have necessary medications in hand when leaving the hospital, these programs reduce the hurdles that patients – especially low-income and high-risk patients – face in the transition from hospital to home recovery. In addition to improving patient convenience, this practice seeks

to improve patient education on adherence to the prescribed therapy and avoid deterioration of the patient's condition to the point of crisis, which would require readmission to the hospital. Excluding discharge prescriptions and orders from the program would effectively penalize hospitals that issue discharge prescriptions for their patients' benefit, substantially reducing the savings available to them to reinvest in expanding access to care.

Teaching hospitals routinely treat patients referred by community physicians, including oncologists. Often, these are complex patients with advanced disease requiring high-cost, intensive treatment and many are uninsured or underinsured. These proposed changes would limit the ability of covered entities to utilize savings from the 340B program to expand access to needed medications and services for these referred patients.

The discussion draft would also exclude infusion orders that are not written as a result of services provided by an eligible provider of the covered entity or one of its registered sites. Infusion services involve administration of medication intravenously under the careful attention of supervising physicians and other skilled health professionals. Hospitals are legally responsible for the clinical care these individuals receive. For all intents and purposes, the individual would be considered a "patient" of the covered entity. Yet, if the order originated from outside of the covered entity or one of its child sites, it appears the individual would not be considered a "patient" under 340B. Infusions are highly complex services that require careful attention and skilled clinical care. Administration of infusion drugs should not be treated in the same manner as dispensing of a drug and should not be excluded from 340B pricing as the discussion draft proposes.

Contract Pharmacies Expand Resources to Low-Income Patients

The Government Accountability Office's (GAO) recent report on contract pharmacies highlights that these arrangements play an important role in helping uninsured and low-income patients access needed care, including prescription drugs. The report includes a series of recommendations to increase HRSA oversight of contract pharmacy arrangements, including additional reporting, registration, and auditing of 340B covered entities that have these arrangements.

The discussion draft, **To Require the Secretary of Health and Human Services to Implement the Government Accountability Office Report on 340B Contract Pharmacy Arrangements**, would implement all of the GAO's recommendations, including those that HRSA has characterized as impractical. The AAMC shares HRSA's concern, as expressed in the report, that many of the recommendations are overly burdensome for both the agency and covered entities, including the recommendation for all covered entities to register contract pharmacies for each site of the entity for which a contract exists. Additionally, HRSA already reviews contract pharmacy arrangements for child sites as part of its standard auditing protocol.

Additional Concerns:

The discussion draft, **Protect Safety-Net 340B Hospital Act**, would increase the Medicare DSH adjustment percentage from 11.75 percent to 18 percent for program participation¹³. The current eligibility threshold already ensures that covered entities are safety-net hospitals. 340B DSH hospitals treat significantly more Medicaid and low-income Medicare patients, provide more uncompensated care, and are more likely to provide specialized health care services that are critical for low-income patients compared to non-340B DSH hospitals. While 340B DSH hospitals represent just 34 percent of short term general hospitals, they bear 70 percent of charity care costs, 57 percent of bad debt costs, and 61 percent of Medicaid shortfalls.¹⁴ They also treat more low-income patients than non-340B hospitals.¹⁵ Increasing the Medicare DSH threshold for program eligibility would reduce the number of hospitals in the program and threaten access for patients.

The **User Fees Under the 340B Drug Discount Program** (H.R. 6240), would impose user fees on 340B hospitals. These hospitals already invest resources and staff to ensure rigorous compliance with the program's extensive requirements for participation. Any funding for program administration and oversight should come through the appropriations process, not from user fees paid by covered entities. In fact, the draft report to accompany the fiscal year (FY) 2019 Labor, Health and Human Services, Education appropriations bill currently under consideration by the House Appropriations Committee provides a \$5 million increase for HRSA's Office of Pharmacy Affairs to implement recommendations from the Energy and Commerce Committee's 340B report. Specifically, the draft spending bill directs HRSA to use the additional funding to conduct additional audits of covered entities, finalize guidance to clarify parameters of the 340B program, and complete the rulemaking process for areas where HRSA has regulatory authority.

The discussion draft, **To Require Certain Covered Entities Under the 340B Drug Discount Program to Establish Certain Fee Amounts Charged to Certain Low-Income Patients for 340B Drugs**, is counter to the intent of the program. The 340B program provides hospitals and other covered entities the ability to identify the needs of their community and to provide low-income patients and communities with access to the broad array of health care services that address these needs. While we appreciate the interest in ensuring that low-income patients have access to affordable drugs, many safety-net hospitals already have programs in place to ensure this access. We are concerned that by reducing the scope of the 340B program, the discussion draft likely would be counterproductive in making medications more affordable.

The discussion draft, **Granting HRSA Regulatory Authority**, would give HRSA additional regulatory authority. However, the AAMC is concerned that HRSA is not currently using its existing regulatory authority to improve transparency around drug manufacturers that participate in the program. By once again delaying implementation of the ceiling price final rule, the administration is neglecting to provide sufficient oversight over drug manufacturers.

¹³ Note that a DSH adjustment percentage of 11.75% equates to low-income DSH patient percentage of 27.3%

¹⁴ AAMC analysis of 2015 Medicare cost report data

¹⁵ Tomai, Lisa. Analysis of 340B Disproportionate Share Hospital Services to Low-Income Patients. L&M Policy Research, March 2018.

Conclusion

The AAMC appreciates the opportunity to submit this statement in support of the 340B Drug Pricing Program and looks forward to working with the committee to strengthen the program so that it continues to provide vital support to safety-net hospitals and other health care providers as they work to improve the health of their communities.