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***Submitted via meetingcomments@medpac.gov***

April 26, 2024

Michael Chernew, Ph.D.
Chairman
Medicare Payment Advisory Commission
425 I Street, NW
Suite 701
Washington, DC 20001

Dear Chairman Chernew:

***Re: Public Comment on April 2024 meeting: 340B Drug Pricing Program; Telehealth; Physician Fee Schedule***

The Association of American Medical Colleges (AAMC or the Association) is pleased to submit comments on the topics discussed during the April public meeting of the Medicare Payment Advisory Commission (MedPAC or the Commission). Our comments focus specifically on the sessions related to the 340B Drug Pricing Program, telehealth in Medicare, and approaches for updating the Medicare physician fee schedule.

The AAMC is a nonprofit association dedicated to improving the health of people everywhere through medical education, health care, medical research, and community collaborations. Its members are all 158 U.S. medical schools accredited by the Liaison Committee on Medical Education; 13 accredited Canadian medical schools; approximately 400 academic health systems and teaching hospitals, including Department of Veterans Affairs medical centers; and more than 70 academic societies. Through these institutions and organizations, the AAMC leads and serves America's medical schools, academic health systems and teaching hospitals, and the millions of individuals across academic medicine, including more than 193,000 full-time faculty members, 96,000 medical students, 153,000 resident physicians, and 60,000 graduate students and postdoctoral researchers in the biomedical sciences. Following a 2022 merger, the Alliance of Academic Health Centers and the Alliance of Academic Health Centers International broadened participation in the AAMC by U.S. and international academic health centers.

We appreciate the Commission's discussion on issues important to Medicare beneficiaries and providers alike. As we discuss in further detail below:

- MedPAC should avoid issuing recommendations on the 340B Drug Pricing Program that would undercut the purpose of the program and undermine the ability of safety net providers to fulfill their missions and serve their diverse populations.
- MedPAC should recommend permanent and adequate payment for telehealth services and audio-only services, the removal of the in-person visit requirements for mental health services, and permanent payment to Federally Qualified Health Centers (FQHCs) and Rural Health Clinics (RHCs) for telehealth services.

- MedPAC should urge Congress to pass the Strengthening Medicare for Patients and Providers Act (HR 2474) which would tie future updates to the physician fee schedule to the full MEI. MedPAC should support approaches that would extend the QP bonus for participation in AAPMs and allow CMS to set lower thresholds for QP determinations in the future at a level that would incentivize participation in advanced alternative payment models.

**340B DRUG PRICING PROGRAM**

During the Friday morning session, MedPAC staff presented their findings on an analysis of the difference between Medicare Part B reimbursement for 340B drugs and the ceiling price for these drugs. While this session was framed as informational, the ensuing discussion touched on the possibility of future Medicare recommendations if the commissioners determine there is a need for Medicare policies to address the 340B program. **We strongly caution the Commission against pursuing Medicare recommendations that would diminish the benefit of the 340B program to safety net hospitals and their ability to expand access to care for the vulnerable patients they serve.**

We appreciate the robust discussion that commissioners engaged in during the session and concur with the points raised by many commissioners both stressing the importance of the 340B program to hospitals and expressing concern about how limiting the benefit of the 340B program would further threaten the viability of these under resourced hospitals and their ability to reach their underserved patients.

***Medicare Payment Cuts Would Undermine Congressional Intent for the 340B Program***

The 340B program is authorized through a statute separate from the Social Security Act—the Public Health Service Act—and administered not by the Centers for Medicare & Medicaid Services (CMS) but by the Health Resources and Services Administration (HRSA). Congress enacted the 340B program to allow covered entities "to stretch their scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."[1] 340B hospitals realize savings not by receiving higher reimbursement from any payer relative to non-340B hospitals but by purchasing drugs at discounted prices. Beyond funds allocated to program oversight, the 340B program does not cost the federal government or Medicare money because the benefit of the program is generated by the discounted prices manufacturers must provide as a condition of having their drugs covered by Medicaid and Medicare Part B.

In establishing the payment methodology for separately payable Part B drugs, the Social Security Act did not differentiate between 340B and non-340B hospitals—all Outpatient Prospective Payment System (OPPS) hospitals were to be paid at the same rate. Congress intentionally chose not to differentiate between 340B and non-340B hospitals in setting the payment rate for separately payable drugs. As the Supreme Court noted in its opinion invalidating CMS' Part B drug cuts: "when enacting this statute [the Part B reimbursement methodology for separately

[1] H.R. Rep. No. 102-384, pt. 2 (1992).

payable drugs] in 2003, Congress was well aware that 340B hospitals paid less for covered prescription drugs…In 2003, Congress nonetheless did not see fit to differentiate 340B hospitals from other hospitals when requiring that the reimbursement rates be uniform."[2] By making recommendations that would reduce Medicare reimbursement to 340B hospitals, this would fundamentally restructure the way Congress intended 340B hospitals to accrue savings. Commissioner Poulsen emphasized this point, cautioning that recommendations could "do a lot of damage, that the program was intentionally oriented to do what it's doing. It wasn't a mistake that there's a margin there…And to eviscerate that purpose without congressional participation was viewed, in my view, as being incorrect."[3] It is also worth noting that while MedPAC has been focused on the difference between Part B reimbursement and 340B ceiling price, the spread between Medicare reimbursement and acquisition cost is not a phenomenon unique to 340B hospitals, as even non-340B hospitals are able to negotiate significant discounts through entities such as group purchasing organizations.

***The 340B Program is a Lifeline for Safety-Net Providers***

The 340B program is critical to safety-net providers and the patients and communities they serve. 340B covered entities are a vital part of the nation's health care safety-net, ensuring access to cutting-edge technology, research, and health expertise for their patients. Over 90 percent of AAMC-member short-term non-federal hospitals are 340B eligible and provide highly specialized health care services that are often unavailable in other settings, including oncology services, transplant surgery, trauma care, pediatric specialty care, and treatment for rare and complex conditions. For example, although they account for just five percent of all short-term, non-federal hospitals nationwide, AAMC members comprise over 20 percent of all hospital beds, including 100 percent of all National Cancer Institute (NCI)-designated comprehensive cancer centers, 72 percent of all burn unit beds, 61 percent of all level-one trauma centers, and 63 percent of pediatric ICU beds.[4] AAMC member institutions share a common mission to care for the underserved and train the nation's future health care workforce, making life-saving health care services available to all patients, regardless of their ability to pay. This commitment to high-quality care, regardless of a patient's insurance coverage or socioeconomic status, can create significant financial challenges. Savings from the 340B program help our members to navigate these challenges, supporting their ability to maintain, improve, and expand access to care for their patients.

***Further 340B Cuts Would Devastate an Already Fragile Health Care Safety Net***

Given the historically low Medicare margins and financial challenges that health systems continue to face, reducing Medicare reimbursement or undermining the 340B program would be

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[2] *AHA vs. Becerra*, 596 U.S. ___ at 12-13 (2022).
[3] MedPAC April meeting transcript at 86.
[4] AAMC analysis of FY2022 American Hospital Association data, American College of Surgeons Level 1 Trauma Center designations, 2023, and the National Cancer Institute's Office of Cancer Centers, 2022. AAMC membership data, March 2024.

devastating to these health systems treating low-income patients.[5] In its March report, the Commission found low hospital all-payer operating margins in 2022 and record low Medicare margins of negative 12.7 percent.[6] The financial outlook for academic health systems is even more grim—AAMC member hospital overall Medicare margins were negative 17.5 percent and Medicare outpatient margins were an unsustainable negative 27.5 percent.[7] Part B payment reductions would directly reduce these Medicare outpatient margins even further and impede the ability of academic health systems to maintain the unique services they disproportionately provide, such as burn care, trauma care, and pediatric specialty care.

As a result of CMS' reduction to Part B drug payments, the agency withheld $10.6 billion in drug payments from 340B hospitals over the nearly five years of cuts from 2018 to 2022. AAMC member hospitals were disproportionately impacted by these cuts—while representing 12 percent of the 340B hospitals that had Part B drug payments reduced, member hospitals received $5.17 billion, or nearly half, of the total cuts.[8] Although 340B hospitals have now been made whole for these years of payments, the reductions they experienced over these years hindered their operations, decreased their 340B savings, and frustrated their ability to continue the programs made possible by 340B savings. Repeating such a policy—or any policy that would target 340B hospitals—would result in similar harm to 340B hospitals and their patients. As commissioner Sarran noted, MedPAC should not "reflexively pull out a brick from a foundation of support for hospitals when the foundation is not as robust as we all might want it to be."[9]

340B hospitals have a demonstrated commitment to serving low-income, vulnerable populations—to qualify for the program, they must meet a minimum DSH adjustment percentage—representing their commitment to Medicaid and low-income Medicare patients. Destabilizing these hospitals would undermine not just 340B hospitals but their patients, many of whom are Medicare beneficiaries and individuals dually eligible for Medicaid. As commissioner Ryu noted during the session, the 340B program benefits Medicare beneficiaries by making possible hospital programs such as cancer treatments and rheumatologic treatments, and thus is ultimately an "access benefit to the beneficiaries."[10]

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[5] Kaufman Hall found in its Hospital Flash Report that year-to-date labor and labor-expenses were a staggering 20 percent higher than pre-pandemic levels, with no signs that this trend will abate. Kaufman Hall January 2024 National Hospital Flash Report. Jan. 30, 2024. https://www.kaufmanhall.com/sites/default/files/2024-01/KH_NHFR-2024-01-V2.pdf.
[6] MedPAC March 2024 Report to Congress at 64, 68.
[7] AAMC analysis of FY 2021 hospital cost reports from the Hospital Cost Reporting Information System (HCRIS) September 30, 2023, update obtained from CMS. Margins are as reported, after sequestration, and excludes outlier institutions, both high and low. General formula: (Revenues - Expenses) / Revenues. Patient Care Margin: both revenues and expenses are defined as those associated with service to patients. Operating Margin: revenues include all sources other than "Contributions, Donations, Bequests" and "Investment Income" and expenses include all hospital expenses. Total Margin: revenues include all sources of revenue and expenses include all hospital expenses.
[8] AAMC analysis of OPPS Remedy for 340B-Acquired Drug Payment Addendum AAA, CMS-1793-F and AAMC membership information, December 2023
[9] MedPAC April meeting transcript at 96.
[10] MedPAC April meeting transcript at 96.

***Should MedPAC Choose to Pursue Drug Pricing Recommendations, it Should Not be at the Expense of Hospitals Treating the Most Vulnerable Patients***

We share MedPAC's broader concerns about rising drug prices and its impact on Medicare beneficiaries. As providers, AAMC members experience firsthand the effect that runaway drug prices have on patients and providers alike. However, if MedPAC chooses to pursue drug pricing recommendations, it can look to other issues that do not single out one group of hospitals, and in this case, hospitals that have a demonstrated commitment to serving low-income patients. MedPAC has previously made wide-ranging recommendations on Part B and Part D drugs that would more broadly address rising drug prices without targeting one specific group of safety-net providers.

**TELEHEALTH**

In the June 2023 Commission Report to Congress, MedPAC responded to a mandate to study the expansion of telehealth. During the Thursday morning session, Commissioners reviewed and discussed updated information. We appreciate the robust conversation during the session and concur with the points raised by many Commissioners, including that telehealth and audio-only services expand access to care, adequate payment for these services is important, and the in-person visit requirement for mental health services unnecessarily impedes access to services when there are more clinically appropriate means of ensuring quality and preventing fraud.

***MedPAC Should Recommend Permanent and Adequate Payment for Telehealth Services***

Congress extended the COVID-19 flexibility, until December 31, 2024, that allowed payment for telehealth services furnished by physicians and other health care providers to patients located in any geographic location and at any site, including the patient's home. This has allowed patients to remain in their home, reducing their exposure to COVID-19 and reducing the risk that they expose another patient or their physician. It also means that patients who find travel to an in-person appointment challenging can receive care, which may be particularly important to patients with chronic conditions or disabilities who need regular monitoring.

We urge MedPAC to support policies that permanently cover telehealth services as well as adequately reimburse the infrastructure and staffing costs for telehealth care. For example, providers must establish a video platform that is HIPAA compliant, accessible, user-friendly, and compatible with patient-owned devices, and that integrates with EHR scheduling and enables multiple concurrent participants (e.g., learners, patients' family members). They must establish workflows and staffing to ensure effective appointment scheduling, notifications, reminders for providers and staff, and learner supervision, as necessary. Protocols and infrastructure must be in place for managing patients' emergencies. Providers must ensure that both they and their patients have sufficient internet access and bandwidth, and in some instances must supply the appropriate devices (e.g., webcams, headsets, smartphones) for patients and clinicians. Providers must also offer effective technology training for providers and staff, including real-time technical support for providers and patients, with contingency plans in place for when failures occur, as well as private locations where others cannot hear or see the patient during the video visit. Providers also

need to employ nurses, medical assistants, and other staff to engage patients before, during, and after telehealth visits to coordinate care pre- and post-visit and ensure a seamless experience.

CMS previously recognized that the cost of furnishing telehealth services may not significantly differ from resource costs involved when those services are furnished in-person.[11] As a result, during the COVID-19 Public Health Emergency (PHE), CMS instructed the use of the CPT® telehealth modifier '95' and the Place of Service (POS) code of where the service would have taken place if the telehealth service had been provided in-person. This policy allowed telehealth services to be reimbursed at the non-facility rate, which is the same as the in-person rate, for office-based services provided via telehealth. In its rationale in an interim final COVID-19 rulemaking, CMS stated "we expect that physician offices will continue to employ nursing staff to engage with patients during telehealth visits or to coordinate pre- or post-visit care, regardless of whether or not the visit takes place in person, as it would have outside of the PHE for the COVID-19 pandemic, or through telehealth in the context of the PHE for the COVID-19 pandemic."[12]

***MedPAC Should Recommend Permanent Coverage for Audio-only Services***

Congress extended the COVID-19 flexibility, until December 31, 2024, that allowed separate payment for audio-only E/M services, CPT® codes 99441-99443.[13] Eliminating coverage for these important audio-only services will result in inequities in access to services for specific populations. Coverage of these audio-only services is particularly important for Medicare beneficiaries who may not have access to or may not feel comfortable with interactive audio/video technologies. Reports suggest that lack of video services or discomfort regarding the use of video may particularly affect certain populations, some of whom have high-risk and chronic conditions, including older adults, those with low socioeconomic status, those in rural communities, and certain races and ethnicities. In addition, patients in rural and other underserved areas and those with lower socio-economic status are more likely to have limited broadband access, making it more difficult to receive telehealth services by audio and video interactions. For these patients, their only option to receive services remotely may be through a phone. Not only is audio-only access a health disparities issue, covering audio-only visits is an important recognition of the value of provider effort. Many services can be provided in a clinically appropriate way via an audio-only interaction, and patients and practitioners should be able to choose this option when clinically appropriate.

***MedPAC Should Recommend Removal of the In-person Visit Requirements for Mental Health Services***

In previous rulemaking, CMS implemented provisions in the CAA, 2021 that removed geographic restrictions and permitted the home to be an originating site for telehealth services for the treatment of mental health disorders, if the practitioner furnishes an initial in-person visit 6

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[11] *Supra*, note 8
[12] *Id*, at 19233
[13] CMS, Medicare and Medicaid Programs; Policy and Regulatory Provisions in Response to the COVID-19 Public Health Emergency," 85 FR 19230 (Apr. 6, 2020)

months prior to the first telehealth visit. CMS also requires an additional in-person visit every 12 months thereafter. Congress then delayed the in-person visit requirements until December 31, 2024. The removal of Medicare's geographic and site of service limitations for services furnished via telehealth have significantly increased access to behavioral telehealth services. In April 2020, at the height of the COVID-19 PHE, telehealth visits for psychiatry and psychology surpassed 50% of the total services. According to data from faculty practices included in the AAMC-Vizient Clinical Practice Solutions Center (CPSC), the use of telehealth for mental health services remained consistent throughout 2020 and 2021.[14] And the use of telehealth services by behavioral health providers has remained high. In addition, there has also been a reduction in missed appointments for behavioral health services because telehealth expansion has made it easier for patients to access care. This is particularly important in mental health due to the significant shortage of providers.[15]

Continuation of care is crucial for mental health services, and this in-person visit requirement may result in a lapse of care and ultimately negative clinical outcomes for patients. Mental health services are the only type of service provided by telehealth that requires an in-person visit at a specific interval, which is arbitrary and discriminatory against this particular type of service. Furthermore, the in-person requirement will increase wait times for those in need of an in-person visit due to workforce shortages. It also creates an additional burden of travel to see the provider. This burden will disproportionally affect those in underserved communities or rural areas and anyone who does not have reliable transportation.

***MedPAC Should Recommend Permanent Payment to Federally Qualified Health Centers (FQHCs) and Rural Health Clinics (RHCs) for Telehealth Services***

During the PHE, the CARES Act established Medicare payment for telehealth services when RHCs and FQHCs serve as the distant site. RHCs and FQHCs have effectively furnished telehealth services and should continue to be permitted to do so. If FQHCs and RHCs are no longer able to furnish telehealth services to patients after December 31, 2024, this will limit access to care, which may negatively impact patient health.

## MEDICARE PHYSICIAN FEE SCHEDULE PAYMENT UPDATE

***Future Updates to the Physician Fee Schedule Rates Should be Based on the Full MEI***

The AAMC appreciates MedPAC's preliminary discussion on potential future approaches to update payment rates under the physician fee schedule (PFS) to address concerns that inflation and risking input costs continue to outpace PFS updates.

In fact, the Medicare Trustees 2023 report indicated that physician reimbursement has dropped over 20% over the last 20 years when accounting for inflation.[16] In addition to reductions in

[14] AAMC-Vizient Clinical Practice Solutions Center. The CPSC is a product of the AAMC and Vizient that collects billing data from member practice plans to provide benchmarks and help them improve performance.
[15] Data on Health Professional Shortage Areas by Discipline, HRSA. 6,136 Practitioners Needed (April 23, 2024)
[16] 2023 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds (Mar. 2023)

reimbursement, in recent years physicians have faced multiple challenges, including the COVID-19 pandemic and its aftermath, rising inflation, and workforce shortages.

The AAMC commends the commission for recognizing that a larger gap between MEI growth and updates could negatively affect beneficiary access to care in the future. In the 2023 Medicare Trustees Report, the trustees also expressed concern with the failure of Medicare payments to keep pace with the cost of running a practice and warned that they expect access to Medicare-participating physicians to become a significant issue in the long-term.[17] According to the AAMC's projections, by 2036, the country could experience a shortfall of between 13,500 and 86,000.[18] These shortages may be exacerbated if physicians continue to face these cuts in payment.

During the April 11 session, MedPAC staff presented three approaches to update payment rates. We have significant concerns with the first approach that would annually increase only the practice expense portion of fee schedule rates by the hospital market basket minus productivity. As MedPAC staff stated, this approach would result in varying financial effects across different services and specialties. In particular, specialties and services where practice expense represent a large portion of total payments would receive larger updates compared to services where practice expense is a smaller share of the services. We are especially concerned that this approach would exacerbate revenue differences between clinicians who specialize in primary care, behavioral health and other specialties, and beneficiaries would have even more difficulty accessing those clinicians in the future.

The AAMC directionally supports the second approach that would increase PFS rates annually based on the MEI since the effects on payment rates would be evenly distributed across services and specialties. However, we believe that increasing PFS rates by MEI minus 1 percentage will not fully offset the impact of inflation and risking input costs. Instead, we recommend that MedPAC urge Congress to pass the Strengthening Medicare for Patients and Providers Act (HR 2474) which would tie future updates to the full MEI.

***The Advance APM Bonus for Qualified Participants (QPs) Should be Extended and the Statute Should be Amended to Allow CMS to Set Lower Thresholds for QP Determinations in the Future***

In addition to the payment updates, we appreciate the Commissioners thoughtful discussion regarding whether to extend the AAPM participation bonus for a few years, how large a bonus might be appropriate, whether to freeze the payment and patient thresholds used to qualify for the bonus and thoughts on restructuring the bonus. The sunsetting of the payment bonus for qualifying participants (QPs) in Advanced APMs (AAPMs), and the increase in the thresholds to be classified as QPs will discourage physicians from engagement in alternative payment models. Beginning in CY 2026, clinicians in AAPMs have the opportunity for a 0.75% update to the CF while those not in AAPMs would receive a .25% update. While there will be a higher update to the conversion factor beginning in the 2026 payment year for QPs in an AAPM as compared to non-QPs, we do not believe that this higher update would be sufficient to incentivize participation. In the 2023 physician fee schedule rule, CMS projected that it might not be until

[17] *Id*.
[18] AAMC, The Complexities of Physician Supply and Demand: Projections From 2021 to 2036 (March 2024)

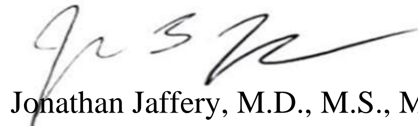
after the CY 2038 payment year when the QP conversion factor will equate to the anticipated maximum positive payment adjustment under MIPS.[19]

We encourage MedPAC to support the approach in the Value in Health Care Act of 2023[20] that would extend the QP bonus for participation in AAPMs and allow CMS to set alternative thresholds for QP determinations in the future at a level that would incentivize participation in advanced alternative payment models. We further encourage MedPAC to explore alternatives to how bonus payments are currently structured, with payments calculated on providers' entire population of Medicare fee for service beneficiaries. Given the limitations that many specialists have to engage in advanced alternative payment models with thresholds determined based on their entire populations, the current system disincentivizes participation for many providers. Instead of thresholds, a system of bonus payments based only on a provider's beneficiaries actually in advanced alternative payment models would encourage more participation by specialists, be administratively easier for providers to manage, and may result in savings to the Medicare program. These policies, if passed by Congress, would incentivize broad physician engagement with alternative payment models and strengthen value-based care delivery in the Medicare program.

**CONCLUSION**

Thank you for considering our comments in any future work the Commission undertakes on these issues. We would be happy to work with MedPAC on any of the issues discussed or other topics that involve the academic medicine community. If you have questions regarding our comments, please feel free to contact Shahid Zaman (szaman@aamc.org), Gayle Lee (galee@aamc.org), or Ki Stewart (kstewart@aamc.org).

Sincerely,



Jonathan Jaffery, M.D., M.S., M.M.M., F.A.C.P.
Chief Health Care Officer

cc: Paul Masi, M.P.P, MedPAC Executive Director
David Skorton, M.D., AAMC President and Chief Executive Officer

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[19] 87 FR 46333
[20] H.R. 5013, introduced in the 118th Congress 1st session (July 2023).