American Hospital Association™
Advancing Health in America

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February 16, 2023

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

Re: Comments on January 2023 Public Meeting Topics – Medicare Part B Drug Payments and Telehealth Services

Dear Dr. Chernew:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations; our clinician partners — including more than 270,000 affiliated physicians, 2 million nurses and other caregivers — and the 43,000 health care leaders who belong to our professional membership groups, the American Hospital Association (AHA) appreciates the opportunity to share our comments on two topics that were discussed during the January 2023 public meeting: Medicare Part B drug payments and telehealth services.

We appreciate your thoughtful discussions on these two topics. As you continue to examine these issues, we urge you to

- **Reject modifications to the current average sales price (ASP)-plus-6% methodology, and instead explore other initiatives such as extending inflation caps and rebates to generic Part B drugs; and**
- **Reconsider certain telehealth policy recommendations to ensure support the expansion of access to care via telemedicine.**

Our detailed comments on these issues follow.

MEDICARE PART B DRUG PAYMENTS

At its January 2023 meeting, MedPAC continued its discussion on the high and increasing prices of Medicare Part B drugs and biologicals. **The AHA appreciates the commission's continued attention to this critical issue over the last six years to achieve sustainable drug pricing.** Indeed, staff reported that 2021 spending on these

products was $42 billion, the result of a 9% average annual increase over the last decade. The commission noted that higher prices are the largest driver of health care cost growth and identified three issues as contributors to increases in Part B drug spending specifically: high prices of accelerated approval drugs with limited clinical evidence, lack of price competition among drugs with similar health effects, and financial incentives associated with add-on payments. As such, commissioners discussed policy options to address each of these issues.

Because MedPAC will discuss its updated recommendations at its March meeting and is expected to vote on them at its April meeting, we hope this correspondence will enable AHA to briefly reiterate our views on the commission's policy options. For additional context and details, we refer you to our letters from Nov. 1, 2021 and Sept. 26, 2022.

AHA continues to support:

- maintaining the ASP-plus-6% payment methodology for Part B drugs;
- exploring a payment model that expands the inflation rebate policy enacted under the Inflation Reduction Act by extending inflation caps and rebates to generic Part B drugs; and
- further exploring value-based approaches focused on first-in-class drugs approved under the FDA's accelerated approval pathway (AAP) in which Medicare could cap payment for such drugs with excessively high launch prices and uncertain clinical benefit.

Addressing Financial Incentives of ASP-plus-6%. Currently, Medicare pays for most separately payable Part B drugs at the rate of the 106% of ASP. MedPAC speculates that the ASP methodology may encourage the use of more costly drugs because the 6% add-on generates more revenue for more expensive drugs.

At its January 2023 meeting, MedPAC discussed an option to modify the ASP add-on; such a modification would yield an add-on that would be the lesser of: 6%; 3% plus $24; or $220 per drug per day. **However, such an approach shifts the responsibility for the rapid increase in drug prices away from drug manufacturers, and instead places the burden on hospitals and patients.**

Such a recommendation is premature given that the Inflation Reduction Act's impact on prices, reimbursement and access to Part B drugs is not fully understood at this time. Specifically, the Inflation Reduction Act requires that Medicare negotiate the price of a certain number of drugs annually and requires these selected drugs be made available to Medicare Part B providers and suppliers at no more than the negotiated rate of maximum fair prices (MFP); Medicare payment for the selected drugs are set at the reduced rate of MFP plus 6%. To the extent that providers depend on the add-on amount as noted above, this *double* reduction could be problematic.

Indeed, the ASP-plus-6% reimbursement serves as a buffer to help address the gap between the manufacturer-reported ASP rate and the average purchase price across providers. It also protects providers when price increases occur and the payment rate has not yet caught up due to a two-quarter lag in the data used to set the ASP-plus-6% payment rate. Finally, it is intended to help cover pharmacy overhead costs, such as those for drugs' storage and handling and the significant, additional pharmacy costs related to tackling drug shortages.

For all these reasons, AHA urges the commission not to modify the current ASP-plus-6% methodology.

Addressing High and Growing Prices for Part B Drugs with Therapeutic Alternatives. The commission also discussed using reference pricing as an approach for Medicare to address high prices and price growth of new and existing drugs with therapeutic alternatives. This policy would set a reference price – a standard payment rate – for a group of covered drugs that have similar health effects. MedPAC believes that this would promote price competition and generate savings for the program and beneficiaries.

However, we are concerned that reference pricing does not directly address manufacturer price inflation and, thus , shifts responsibility to providers and patients by placing hospitals and physician practices at risk for price differences between drugs that may or may not be "therapeutically similar" for individual patients.

We believe that the approach that holds the greatest promise for placing direct downward pressure on drug prices is instead to cap ASP inflation, an approach that Congress enacted in the Inflation Reduction Act. Under such a cap, Medicare would require manufacturers to pay rebates to the federal government when ASP growth exceeded an inflation benchmark. This Inflation Reduction Act provision is similar to rebate programs for Medicaid, which consistently achieve better pricing on drugs than Medicare. This approach is also similar to one previously recommended by MedPAC in its June 2017 report.

In addition, given that overall Medicare Part B drug spending is influenced by both price and volume, we support including generic drugs as part of an ASP inflation cap approach. Although high-cost, sole-source drugs are prominent in Medicare spending discussions, we have in recent years seen similar, significant price increases in generic drugs widely used in hospitals.[1]

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[1] For example, according to a 2019 hospital drug cost study commissioned by AHA and the Federation of American Hospitals, hospitals reported that, although large price increases occurred for both branded and generic drugs, annual price increases of 10% or 20% on widely used, older generic drugs can result in even greater financial burden, especially given the large quantities that hospitals must purchase. See also, "Trends in Hospital Inpatient Drug Costs: Issues and Challenges," from 2016.

The AHA encourages MedPAC to further explore a payment model that is parallel to the Inflation Reduction Act rebate proposal but would extend mandatory additional rebates to purchasers when a drug manufacturer increases the price of a generic Part B drug at a rate higher than inflation. We urge that such a model, if enacted, ensures both beneficiaries and providers benefit from the savings achieved from the rebate.

Addressing High Launch Prices of First-In-Class Drugs with Limited Clinical Evidence. The commission also discussed several policy options to address high launch prices of new Part B drugs approved under FDA's Accelerated Approval Program (AAP) with limited evidence about their clinical effectiveness and incomplete confirmatory post-approval trial data. To protect Medicare from paying a considerable amount for drugs with uncertain benefits, the commission discussed a possible "value-based" policy approach, which would focus on such drugs approved under its AAP. Under this policy, Medicare could cap payment for AAP drugs until confirmatory trials are completed.

The AHA believes that these approaches hold promise and we appreciate the commission's work here. In particular, we are hopeful that this could lead to better alignment between what Medicare and beneficiaries pay for drugs and these products' clinical value; spur price competition among drugs; and limit financial risks that beneficiaries, providers and the Medicare program face for products with limited evidence on clinical effectiveness.

TELEHEALTH SERVICES

We appreciate MedPAC's January 2023 update on telehealth use and beneficiary and clinician experiences during the pandemic. Expansion of virtual care has transformed care delivery, expanded access for millions of Americans and increased convenience in caring for patients. **Given some of the current health care challenges, such as major clinician shortages, telehealth holds tremendous potential to leverage geographically dispersed provider capacity to support patient demand. To help ensure access to such care, we recommend permanent extension of certain telehealth waivers, in line with what we have recently communicated to Congress, including:**

- telehealth reimbursement parity based on the place of service where the visit would have been performed in person;
- continued allowance of incident-to billing and direct supervision via telehealth;
- removal of the in-person visit requirement for the prescribing of controlled substances through rulemaking by the Drug Enforcement Agency (DEA);
- coverage and payment for audio-only telehealth services;
- the originating site to be any site at which the patient is located, including the patient's home;
- the ability to use telehealth services to meet the face-to-face recertification requirement for hospice care;

- the ability for federally qualified health centers (FQHCs) and rural health clinics (RHCs) to furnish telehealth services; and
- repeal of the six-month in-person requirement for mental health services furnished through telehealth, including the in-person requirements for FQHCs and RHCs.

However, several of the commission's 2021 policy options run contrary to what would be accomplished by these permanent extensions. They include reimbursing at only the physician fee schedule facility rate, requiring in person face-to-face visits prior to ordering durable medical equipment (DME) and lab services, and prohibiting incident-to billing for telehealth. **As discussed further below, we urge the commission to re-consider these recommendations. Also, in conducting additional research, we encourage the commission to consider the lessons learned from the COVID-19 pandemic and research additional provisions that have supported expansion of access to care via telemedicine during the state of emergency.**

Since the start of the COVID-19 pandemic, the telehealth landscape has changed significantly. For example, providers and patients have learned first-hand about application and benefits of technology in care delivery, and the use of virtual care modalities is now expected by many beneficiaries. Therefore, as outlined below, we think it would be illustrative to compare telehealth spending and use with aggregate Medicare spending and use; analyze longitudinal trends in outpatient/office E/M visits; and better target providers at risk for fraud, waste and abuse.

Reimbursement Rates. Prior to the COVID-19 pandemic, CMS reimbursed providers administering telehealth at the physician fee schedule facility rate regardless of whether the provider was performing the visit from a facility or non-facility setting. Such reimbursement did not account for practice-related expenses, such as those for support staff who virtually room patients or for maintaining required software licenses. As such, this was a challenge for providers, who were performing the same level of work and quality of care as in-person visits but receiving inadequate reimbursement. During the COVID-19 public health emergency, CMS updated guidance to reimburse providers at the rate they would normally receive if the patient were seen in person, which provided much more adequate reimbursement and therefore facilitated patients' access to care.

Physician reimbursement should compensate for work expenses, malpractice expenses and practice expense related costs; these expenses generally are the same, regardless of whether the encounter were in person or virtual. For example, malpractice expenses, which cover professional liability insurance premiums, are the same regardless of the method that care is delivered.

In addition, for practice expense (which covers staffing, supplies and equipment), virtual encounters may reduce supply expenses (like exam gloves or paper for exam tables), but increase technology expenses (like software licenses and hardware). For providers

to continue delivering high-quality patient care through telehealth and other virtual services, they need appropriate reimbursement. Indeed, Section 1834 of the Social Security Act already requires that: "The Secretary shall pay to a physician or practitioner located at a distant site that furnishes a telehealth service to an eligible telehealth individual an amount equal to the amount that such physician or practitioner would have been paid under this title had such service been furnished without the use of a telecommunications system." **As such, we urge MedPAC to recommend providers be reimbursed at the same rate that they would have received if the visit were in person.**

DME and Lab Orders. Requiring in-person visits prior to ordering DME and lab services will serve as a barrier to accessing services for certain patients. It inserts additional visits that otherwise would not be clinically necessary. The ability to order lab services is an important aspect of care delivery.

For example, a patient may have symptoms of a urinary tract infection (which is commonly treated virtually) but require a urine sample to validate the diagnosis/presence of infection, determine type of bacteria, identify antibiotic resistance, and prescribe antibiotics as appropriate. This is consistent with the same standard of care that patients would receive in person. It should be left to clinical judgment, rather than an arbitrary general requirement, when an in-person assessment is required and when labs or DME are appropriate, regardless of if that is after a virtual or in person encounter. **Therefore, in the interest of supporting increased access and reducing potentially unnecessary in person visits, we urge MedPAC to recommend *not* adding an in-person visit requirement to order DME and lab services.**

Incident-to Billing for Telehealth. Prior to the COVID-19 pandemic, CMS required that physicians serving in supervisory capacities be physically present in the same office suite when auxiliary personnel performed visits under their supervision and be available if assistance was needed. During the state of emergency, this supervision could be completed virtually using real-time audio-video technology, which supported improved access for geographically dispersed patients. For example, physicians who were self-isolating or were relocated for "surge support" could fulfill supervisory functions without cancelling or rescheduling appointments. Flexibilities to cross leverage geographically dispersed providers are becoming more critical, especially as staffing shortages become more severe. This is also true for hospitals and health systems operating across multiple locations. **Therefore, we encourage MedPAC to recommend continued allowance of supervisory functions to be performed via virtual presence and the continued ability to bill for "incident-to" services provided via telehealth.**

Telehealth Spending and Use. Spurred in large part by waivers and legislative support, virtual care and telehealth services have increased dramatically over the course of the COVID-19 pandemic. A report from the Department of Health and Human Services

found that telehealth services in 2020 increased by over 51 million encounters, representing a 63-fold increase from the previous year.[2]

There is a growing body of evidence to suggest that for the vast majority of specialties telehealth services provided during the COVID-19 pandemic were not duplicative of in-person services. For example, a recent Epic study of over 35 million records found that for most telehealth visits across 33 specialties there was not a need for an in-person follow-up visit within 90 days of the telehealth visit.[3] In many cases, telehealth served as an effective substitute for in-person care and did not result in duplicative care.

We encourage continued evaluation of the comparison in use and spending of telehealth to aggregate volume (in-person and telehealth). Data presented at the January 2023 meeting only showed trends in telehealth use and spending for 2020 and 2021, not aggregate Medicare use and spending or comparisons to in person use and spending. Indeed, a report from ASPE showed that in 2020, overall visits decreased 11.4% across specialties when accounting for both in-person and telehealth visits, despite the significant increase telehealth growth.[4]

Distribution of E/M Office/Outpatient Visit Codes. At the January 2023 meeting, staff presented data demonstrating that the distribution of severity levels of office/outpatient E/M visits was similar for in-person and telehealth visits; however in focus groups, clinicians indicated that telehealth visits take less time.

CMS' current definition of telehealth services are those that are analogous to an in person visit. In its CY2023 Physician Fee Schedule, CMS states its belief "that the statute requires that telehealth services be so analogous to in-person care such that the telehealth service is essentially a substitute for a face-to-face encounter." As such, it is not surprising that the distribution of appointment lengths for telehealth visits compared to in-person visits are similar for established E/M codes.

However, we encourage a longitudinal breakout of the comparison of in person versus telehealth E/M visit levels over time. The data presented were a snapshot from only 2021 and did not show the trends by month or quarter for that calendar year. Yet, we know, for example, that there was a surge in COVID-19 cases in early 2021, which may have impacted trends in appointment lengths earlier in the year for both in person and virtual visits.

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[2] https://www.cms.gov/newsroom/press-releases/new-hhs-study-shows-63-fold-increase-medicare-telehealth-utilization-during-pandemic
[3] Telehealth Visits Unlikely to Require In-Person Follow-Up Within 90 Days (epicresearch.org)
[4] https://aspe.hhs.gov/sites/default/files/documents/a1d5d810fe3433e18b192be42dbf2351/medicare-telehealth-report.pdf

Additionally, **we encourage MedPAC to look at other data points in addition to visit length to see if telehealth impacted the number of appointments that providers were able to complete.** Outside of the billable encounter, telehealth may save time from a process mapping perspective for things like walking to a patient exam room, washing hands before and after going to a patient room, etc. This may impact the number of appointments providers are able to schedule in their templates. Also, there is emerging evidence to suggest that telehealth visits had lower no-show rates for certain specialties. The bottom line is that appointment duration may not be the only indicator of time savings (since there may be reduction in time required between appointments) or efficiency.

Telehealth and Program Integrity. Staff at the January 2023 meeting indicated that policymakers have been reticent to cover telehealth services, since "little is known about the effect of telehealth on quality of care and patient outcomes," and concerns exist regarding susceptibility to overuse and fraud. However, other programs, like the Military Health System and Veteran's Health Administration have been expanding telehealth for over two decades.

Indeed, Section 718 of the 2017 National Defense Authorization Act *mandated* enhancement and expansion of telehealth across the Military Health System due to its potential to increase access, improve quality and reduce costs. Historical data from these programs and other early adopters, combined with emerging data from the COVID-19 pandemic, demonstrate the benefits of increasing access and convenience for geographically dispersed patient populations, and ability to maximize limited provider capacity.

Staff at the January 2023 meeting also highlighted a recent OIG report on program integrity risks. This report found that 0.2% of all telehealth providers were "potentially high-risk". We recognize and appreciate the importance of identifying risks and establishing reasonable guardrails to prevent fraud, waste and abuse. However, the fact remains that overwhelming majority of providers (the 99.8%) administer telehealth services in a compliant manner. **These providers should not be subject to blanket and general regulatory burdens – such policies should be targeted and specific.**

Additionally, we encourage analysis on program integrity risks compared to the aggregate program and other programs like Medicare Advantage. For example, it would be useful to understand the number of high-risk providers in the general Medicare program to uncover any differences, if they exist. A report from 2020 indicated that the rate of improper payment was around 6.27% (equating to approximately $25.75 billion) for the general Medicare program.[5] Furthermore, it would be useful to see if this has

[5] https://www.cms.gov/newsroom/fact-sheets/2020-estimated-improper-payment-rates-centers-medicare-medicaid-services-cms-programs

changed over time as providers became more educated and experienced with telehealth coding.

We thank you for your consideration of our comments. Please contact me if you have questions or feel free to have a member of your team contact Shannon Wu, AHA's senior associate director of policy, at swu@aha.org or 202-626-2963.

Sincerely,

/s/

Ashley B. Thompson
Senior Vice President
Public Policy Analysis and Development

Cc: James E. Mathews, Ph.D.
MedPAC Commissioners