American Hospital Association™
Advancing Health in America

Washington, D.C. Office
800 10th Street, N.W.
Two CityCenter, Suite 400
Washington, DC 20001-4956
(202) 638-1100

November 1, 2021

Michael Chernew, Ph.D.
Chairman
Medicare Payment Advisory Commission
425 I Street, N.W., Suite 701
Washington, D.C. 20001

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 Medicare Payment Advisory Commission's (MedPAC) discussions on the Medicare hospital wage index, the prices of pharmaceutical products, and the thoughtful design of possible improvements to alternative payment models (APMs). As the Commission continues its deliberations, we would like to share our thoughts, suggestions and concerns related to these issues.

Regarding the discussions during the October meeting on the hospital wage index, pharmaceutical products and APMs, we:

- Agree that the current wage index system is flawed, but have concerns about using non-hospital data to calculate the wage index.
- Present suggestions for recommendations to address the skyrocketing cost of drugs.
- Appreciate the Commission's work on APMs, particularly the discussion around ensuring there is a balance between incentivizing participation in models and securing cost savings and high-quality care for patients.

Our detailed comments on these issues follow.

WAGE INDEX

At the October meeting, the Commission discussed three main concerns about Medicare's hospital wage index policies. First, Commissioners and MedPAC staff discussed concerns over the source of the wage data and its circularity in setting wage indices. Second, they discussed labor market areas and the resulting wage index "cliffs." And third, they discussed the increasingly burdensome and complicated process for adjustments. **AHA has conducted extensive policy work on the wage index. As a result of that work, we and our members agree that it is greatly flawed in several respects.** As the Commission continues to discuss wage index redesign and/or modifications, we would like to take this opportunity to highlight the following information for your consideration.

First, our members — similar to MedPAC staff — have expressed concerns that current policies contain geographic boundaries that create "cliffs" where adjacent areas have very different indices. Any set of administrative market boundaries, especially boundaries set according to a national formula, will be imperfect. The wage index system should use labor markets that are defined broadly enough to encompass all hospitals competing for the same workers, yet narrowly enough to avoid encompassing hospitals with wage costs that greatly vary.

Second, our members also believe that the number of reclassifications and exceptions permitted under the current system is complex and confusing. Moreover, they are costly to hospitals. As more hospitals obtain reclassifications, the necessary budget neutrality adjustments increase, putting additional fiscal pressure on hospitals without reclassifications.

Third, our members agree that the current wage index policy is circular and self-perpetuating. The wage index is based on the hospital cost report, on which all hospitals are required to report their paid wages and salaries. There exists a problem from the use of only hospital data in setting the wage index, where hospitals have the ability to influence their own wage index values. Specifically, this could lead to a problem where hospitals with low wage indices may be unable to increase wages to become competitive in the labor market.

In its 2007 wage index recommendations, the Commission considered the use of Bureau of Labor Statistics (BLS) data rather than hospital-reported data collected on CMS' Medicare cost reports to correct for this problem. **AHA and our members have examined the BLS data closely and found that while they may be significantly less burdensome for hospitals, there are critical differences between the two data sets that should be carefully evaluated**. For example, BLS data excludes the cost of benefits. However, benefits are an important component of the wage index because the portion of total compensation attributable to benefits varies systematically. If benefits were excluded, the wage index would be understated in areas where benefits account for a greater portion of compensation and overstated in areas where they account for a lower portion. Therefore, any adjustments made to include benefit costs would have to be market-

specific. If benefits information is to be added, it would have to be collected on CMS' Medicare cost report in order to adjust the BLS data. This would negate the potential benefit of eliminating the collection of hospital-specific wage data.

Additionally, BLS data is derived from voluntary surveys and a sample of employers. Estimates using a sampling methodology like the BLS approach are going to be less reliable than using the entire universe of prospective payment system hospitals, as is done by CMS. Additionally, CMS' process allows for extensive public scrutiny of the data while the BLS approach does not. Unlike CMS' public process for review and correction of wage data at the hospital level, BLS has a strict confidentiality policy. This ensures that the sample composition, lists of reporting establishments, and names of respondents are kept confidential. Hospitals would thus be unable to verify the accuracy of the data.

Finally, if the Commission continues to discuss wage index issues, we urge it to consider the issue in the broader context of the financial instability hospitals continue to face. This instability largely began with the public health emergency, but has expanded to include increasingly acute workforce, supply chain and security concerns, to name a few. Introducing additional instability in the form of wage index reform and discussions will add to and exacerbate these challenges. AHA would welcome the opportunity to engage in a discussion with Commission staff on these issues.

PART B DRUG PAYMENTS

America's hospitals rely on innovative drug therapies to save lives every day. However, high and rising drug prices are putting access and quality of care at risk by straining providers' ability to access the drug therapies they need to care for their patients. AHA is deeply committed to the availability of high-quality, efficient health care for all Americans. Hospitals, and the clinicians who work in them, know firsthand the lifesaving potential of drug therapies. Indeed, researchers in U.S. academic medical centers generate much of the evidence used to develop new drugs. However, an unaffordable drug is not a lifesaving drug. AHA appreciates the Commission's attention to this critical issue over the last several years and urges it to continue to take action to achieve sustainable drug pricing. Specifically, we continue to recommend:

- **Maintaining the average sales price (ASP) plus 6% payment methodology for Part B drugs;**
- **Establishing an ASP inflation cap for Medicare Part B drugs, and applying the cap to both high-cost and lower-cost drugs; and**
- **Further exploring a value-based approach using cost-effectiveness analysis and coverage with evidence development to prevent excessively high launch prices.**

At its October meeting, MedPAC once again discussed the high and increasing prices of Medicare Part B drugs and biologicals, reporting that spending on these products in 2019 was $39 billion, increasing nearly 10% per year since 2009. The Commission noted that higher prices are the largest driver of cost growth. Three issues were identified as

contributors to increases in Part B drug spending and Commissioners discussed policy options to address each of these issues. AHA discusses our views on these issues and policy options below.

Addressing Financial Incentives of ASP Plus 6%. Currently, Medicare pays for most separately payable Part B drugs in the outpatient setting at the rate of the 106% of ASP. In this discussion, as it has in the past, 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. In the past, the Commission has discussed a number of policy options to restructure the ASP add-on, including reducing the add-on from 6% to 3% and reducing payment to 103.5% of ASP plus a $5 fixed fee.

At its October meeting, three similar options to modify the ASP add-on were presented including:

- Reducing the percentage add-on, as recommended by MedPAC in 2017;
- Converting all or part of the percentage add-on to a fixed fee; and
- Placing a dollar cap on the percentage add-on payment.

AHA is concerned that these approaches shift the focus of responsibility for the rapid increase in drug prices from drug manufacturers to hospitals and patients. The fact is, drug manufacturers have full and sole control over the initial and subsequent prices for drugs. **While the Commission asserts that the current Part B drug payment policy may create a financial incentive to purchase more expensive drugs, it is important to note that there is no convincing evidence that hospitals and clinicians consider profitability over clinical effectiveness when deciding which drugs to use. In fact, in the October meeting, Commission staff noted that: "The literature is limited on the effect of the percent add-on on prescribing behavior."** Instead, hospitals purchase and physicians prescribe drugs based on clinical considerations, choosing drugs that are most effective in treating the individual patients for whom they care, while minimizing side effects and dangerous drug interactions.

In actuality, the ASP plus 6% statutory formula serves as a buffer to help address the gap between the manufacturer-reported ASP rate and the average purchase price across providers, which varies due to factors such as prompt-pay discounts, which wholesalers may not pass on to the final purchasers (hospitals and physicians), wholesaler markups and sales tax. Furthermore, because there is a two-quarter lag in the data used to set the ASP plus 6% payment rate, the percentage add-on provides protection for when price increases occur and the payment rate has not yet caught up.

The statutory add-on to ASP is also intended to cover pharmacy overhead costs, such as drug storage and handling costs. Many of the drugs used in hospitals require special handling. They may be hazardous for health care workers with repeated exposure and therefore the use of these drugs involves costly handling, storage and training, as required under the United States Pharmacopeial Convention's General Chapter <800> *Hazardous*

Drugs Handling in Healthcare Settings. Moreover, with many drugs in short supply, there are significant additional pharmacy costs for personnel time needed to source critical drugs, to rework clinical protocols and retrain clinical staff in the use of alternative products and to recalibrate automatic dispensing systems.

Finally, while some Commissioners stated their belief that market forces would lead drug manufacturers to reduce their prices in response to these policy options, we have observed manufacturers time and again exhibit unreasonable pricing even for older commonly used drugs, such as Rituxan[1].

For all these reasons, AHA urges the Commission not to reduce 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 standard payment rate — a reference price — 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. This approach is not new to MedPAC; in 2017, the Commission recommended a consolidated billing code policy — a type of reference pricing — for biosimilars and originator biologics that would pay for these products at the same average rate to spur price competition.

However, AHA is concerned that reference pricing does not directly address manufacturer price inflation and, instead, would put hospitals and physician practices at risk for price differences between drugs that may or may not be "therapeutically similar" for individual patients. That is, patients' medical conditions are not uniform: a drug that is effective on average may be ineffective, or even dangerous, for a particular patient. As several Commissioners noted, any such policy would have to include a well-thought out exceptions process if a patient had a medical need for a particular product with a price higher than the reference price.

In addition, this approach assumes that, by setting a benchmark price based on the average ASP for the drugs in the group, manufacturers would have an incentive to lower their price below their competitors' in order to make their product more attractive and garner market share. However, one also could foresee just the opposite happening. That is, a manufacturer with a product priced below the benchmark could reason that there would be no harm in increasing their price to the average rate so as to maximize their profit. This would have the impact of driving the average up and increasing overall spending for drugs in the group.

[1] Davio, Kelly. "For Price Hikes Without New Data, 3 Drugs with Approved Biosimilars are Key Offenders, Says ICER." 2019. https://www.centerforbiosimilars.com/view/for-price-hikes-without-new-data-3-drugs-with-approved-biosimilars-are-key-offenders-says-icer

Rather, an option that AHA believes holds promise to put downward pressure on drug prices is a cap on ASP inflation, whereby Medicare would require manufacturers to pay rebates to the federal government when ASP growth exceeded an inflation benchmark. This proposal is similar to rebate programs for Medicaid, which consistently achieve better pricing on drugs than Medicare. This approach, which would protect the program and beneficiaries from dramatic increases in the Medicare payment rate for drugs, was previously recommended by MedPAC in its June 2017 report to address rising Part B drug costs. While there is some concern that an inflation cap could incentivize drug manufacturers to protect their revenues by setting a very high launch price for new drugs, the Commission has promising proposals to address high launch prices, as discussed below.

Although high-cost drugs are prominent in Medicare spending discussions, we have seen similar significant price increases in low-cost generic drugs widely used in hospitals in recent years. Specifically, in a hospital drug cost study commissioned by AHA and the Federation of American Hospitals in 2019, 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, given the large quantities that a hospital must purchase.[2] Given that overall Medicare Part B drug spending is influenced by both price and volume, AHA also supports including low-cost drugs as part of an ASP inflation cap approach.

AHA encourages MedPAC to further evaluate a payment model that implements mandatory additional rebates to purchasers when a drug manufacturer increases the price of a Part B drug at a rate higher than inflation. If such a model were to be enacted, we would urge that it 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 options to address high launch prices of new Part B drugs with limited clinical evidence. MedPAC stated that because Medicare is required to cover Part B drugs for their FDA-labeled indications at 106% of ASP, the manufacturer effectively determines Medicare's payment rate for these products, regardless of whether the drug results in better outcomes than its alternatives. In particular, products approved under FDA's accelerated approval pathways are launching at high prices with limited evidence about their clinical effectiveness. One example is the newly approved Alzheimer's drug Aduhelm, which was approved under the FDA's accelerated pathway with unclear clinical benefit and with a manufacturer price set at $56,000 per year.

To address this concern, the Commission discussed a possible policy to set payment based on cost-effectiveness analysis and applying coverage with evidence development in order to increase the value of Medicare spending. This “value-based approach” would focus on first-in-class Part B drugs that the FDA approved based only on surrogate or

[2] See also, “Trends in Hospital Inpatient Drug Costs: Issues and Challenges.” 2016. www.aha.org/system/files/2018-01/aha-fah-rx-report.pdf

intermediate clinical endpoints[3] under its accelerated approval pathway. Under this approach, Medicare could set a value-based price based on an assessment of the new product's comparative clinical effectiveness and cost effectiveness compared to the standard of care. Under this approach, Medicare would also apply "coverage with evidence development" to generate clinical evidence on a new drug's risk and safety profile and impact on patients' functional status and quality of life.

This approach holds promise and we appreciate the Commission's work on it. In particular, we are hopeful that this approach could lead to better alignment between what Medicare and beneficiaries pay for drugs and the clinical value of those products, spur price competition among drugs, and limit the financial risk that beneficiaries, providers and the Medicare program face for products with limited evidence on clinical effectiveness. We look forward to future Commission discussions on this approach.

Other AHA Recommendations. Given the widespread and ongoing need for access to pharmaceuticals among Medicare beneficiaries, AHA has worked with its members to document the challenges hospitals and health systems face with drug prices and to develop policy solutions that protect access to critical therapies while encouraging and supporting much-needed innovation. Our full set of recommendations are outlined on AHA's webpage.

ALTERNATIVE PAYMENT MODELS

Over the past several meetings, MedPAC has continued to explore the future of Medicare APMs. The Commission has frequently discussed possible approaches to refining the portfolio of models to best serve patients while executing the mission of the Centers for Medicare and Medicaid Innovation (CMMI) to reduce costs while maintaining or improving quality. In this meeting, Commissioners took a deeper dive into how CMMI could harmonize its suite of models. **AHA strongly supports the Commission's work in this domain and thanks the commissioners for their thoughtfulness on how best to design a more streamlined and coordinated portfolio of APMs.**

Specifically, AHA supports exploration of a multi-track model that could meet providers wherever they are along the path to value. Such a model could be designed to decrease the complexity and regulatory burden currently inherent in models, thereby maximizing the ability of a variety of providers to enter and succeed in APMs. **There is particular value in discussing how a multi-track model could provide a glide path to risk for all potential participants to ensure there is a balance between incentivizing**

[3] A surrogate endpoint is a clinical trial endpoint used as a substitute for a direct measure of how a patient feels, functions or survives. A surrogate endpoint does not measure the clinical benefit of primary interest in and of itself, but rather is expected to predict that clinical benefit. One example of this is cholesterol levels and the risk of having a heart attack. Likewise, an intermediate clinical endpoint is a measure of a therapeutic effect that is considered reasonably likely to predict the clinical benefit of a drug, such as an effect on irreversible morbidity and mortality. An example of an intermediate clinical endpoint is the relapse rate in multiple sclerosis. A product was approved based on a large therapeutic effect on relapse rate through approximately 13 months of treatment, but where there was uncertainty about the durability of the observed effect.

participation in models and securing cost savings and high-quality care for patients. This would be particularly useful for rural and urban hospitals and health systems serving a high number of Medicaid and uninsured patients. Hospitals and health systems are committed to providing more accountable, coordinated care that advances health equity and are redesigning delivery systems to increase value and better serve patients. Making changes to do so takes significant time and resources. Recommendations should create an environment in which hospitals and health systems can build upon this preexisting work, while still keeping their doors open for patient needs.

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, 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