

September 26, 2022

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) continued discussions on the Medicare hospital wage index, the prices of pharmaceutical products and the Medicare Advantage (MA) program. 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 September meeting on the hospital wage index, high drug costs and MA, the AHA:

- agrees that the current wage index system is flawed, but continues to have concerns about using non-hospital data to calculate the wage index;
- presents recommendations to address the skyrocketing cost of drugs, such as a cap on ASP inflation; and
- strongly supports the Commission's work to monitor the accuracy and completeness of data on MA encounters.

Our detailed comments on these issues follow.

WAGE INDEX

At the September meeting, the Commission continued its discussions regarding Medicare's hospital wage index policies. First, MedPAC commissioners and staff discussed concerns with the current wage index system, including its circularity,



numerous and burdensome exceptions, and wage index “cliffs.” Second, staff discussed various elements of an alternative wage index that would “accurately measure the labor costs of doing business that differ solely because of geography.” These include the use of cross-industry, occupation-level wage data; an ability to account for county-level variation and smooth wage indices across adjacent counties; and a no exceptions process.

AHA has conducted extensive policy work on the wage index. As a result of that work, we share our members’ belief that it is greatly flawed in several respects. That said, we urge the Commission to consider the overall financial context hospitals face as its staff continue to discuss potential wage index redesign and/or modifications.

Hospitals’ financial instabilities largely began with the public health emergency, but have expanded to include increasingly acute workforce and supply chain concerns, to name a few. A recent study projected that total expenses for hospitals would increase by \$135 billion over 2021 levels.¹ Labor expenses account for most of this increase, projected to rise \$86 billion in 2022. Taken together, hospital margins are projected to remain depressed, down 37% relative to pre-COVID-19 pandemic levels.

These dramatic changes in expenses and shifts in workforce all speak to the current instability in the hospital field. Introducing additional changes in the form of wage index reform would add to, and exacerbate, this situation. The AHA urges the Commission to consider these ongoing financial and labor challenges in its discussion of any modification to the current wage index system.

AHA would welcome the opportunity to engage in a discussion with Commission staff on these financial challenges as they relate to the wage index.

We recognize that the current wage index system is flawed and our members – similar to MedPAC staff – have expressed many concerns about its design. For example, current policies include 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 instead 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. In addition, our members also believe that the number of reclassifications and exceptions permitted under the current system is complex and confusing.

Moreover, such reclassifications and exceptions are costly to hospitals. As more

¹ Kaufman Hall (September 15, 2022). “The Current State of Hospital Finances: Fall 2022 Update.” <https://www.aha.org/guidesreports/2022-09-15-current-state-hospital-finances-fall-2022-update>

hospitals obtain reclassifications, the necessary budget neutrality adjustments increase, putting additional fiscal pressure on hospitals without reclassifications.

However, we remain concerned over several specific methods proposed by MedPAC. For example, our members agree that the current wage index policy is circular and self-perpetuating. The wage index is based on the hospital cost report, the means by which all hospitals are required to report their paid wages and salaries. Using only hospital data in setting the wage index means that hospitals have the ability to influence their own wage index values. 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.

To correct for this problem, the Commission continues to consider the use of Bureau of Labor Statistics (BLS) data to calculate the wage index. **We remain concerned over the use of BLS data. The AHA and our members have examined these data closely and found that, while its collection and use may be significantly less burdensome for hospitals, there are critical differences between BLS data and the cost report data 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; it would similarly be overstated in areas where they account for a lower portion. Therefore, any adjustments made to include benefit costs would have to be market-specific.

Commission staff discussed adjusting the wage index for benefits' share of total compensation in a region, but did not provide enough details for the AHA to fully comment on this method. That said, if hospital-specific benefit information is to be added, it would have to be collected on CMS' Medicare cost report. Yet doing so would negate the potential regulatory relief brought about by eliminating the collection of hospital-specific wage data.

Additionally, BLS data are derived from voluntary surveys and a sample of employers. Estimates using a sampling methodology like the BLS approach will 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.

MEDICARE 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 life-saving 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 life-saving drug.** AHA appreciates the Commission's attention to this critical issue over the last several years and urges continued action to achieve sustainable drug pricing. Specifically, we continue to support:

- **maintaining the average sales price (ASP) plus 6% payment methodology for Part B drugs;**
- **exploring a payment model that expands the Inflation Reduction Act (IRA) inflation rebate policy by extending inflation caps and rebates to generic Part B 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 September meeting, MedPAC once again discussed the high and increasing prices of Medicare Part B drugs and biologicals, reporting that spending on these products in 2020 was \$41 billion, the result of a 9% annual increase on average over the last decade. **The Commission noted that higher prices are the largest driver of health care 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. They also noted that while the Inflation Reduction Act (IRA), enacted this past August, makes changes to Part B drug payment, it does not negate any of the policy options that the Commission is considering. The 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.

At its October meeting, MedPAC discussed an option to modify the ASP add-on in which the add-on would be the lesser of: 6%; 3% plus \$21; or \$175 per drug per day. **However, such an approach simply shifts the responsibility for the rapid increase in drug prices to hospitals and patients, and away from drug manufacturers.** The fact is that drug manufacturers have *full and sole control* over pricing decisions of their products. **While the Commission asserts that the current Part B drug payment policy may create a financial incentive to prescribe 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 its June report, the Commission notes, “The size of the effect is difficult to quantify because many factors affect prescribing. Identifying what portion of utilization patterns reflects the effect of the 6 percent add-on versus other factors is challenging.” Rather, drugs are purchased by hospitals and prescribed by physicians based on clinical considerations; the chosen drugs are determined to be the most effective in treating the individual patients for whom hospitals and clinicians 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 those for drugs’ storage and handling. 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 have previously 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, put forth unreasonable pricing – even for older, commonly used drugs, such as Rituxan,² a type of antibody therapy to treat cancer.

Furthermore, for the Commission to recommend a policy that will reduce Part B payment for drugs and biologicals before the impact of the IRA’s impact on prices, reimbursement and access to Part B drugs is fully understood is premature. That is, among other provisions, the IRA 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), with Medicare payment for the selected drugs set at the reduced rate of MFP plus 6%. To the extent that providers depend on the add-on amount to help cover pharmacy overhead costs, such as drug storage and

² 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>

handling costs, or to supplement Medicare underpayment for other services, this *double* reduction could be problematic.

While we recognize MedPAC has raised concerns regarding 340B, we continue to respectfully disagree and note that some of the proposals here would further exacerbate the health care system's ability to care for some of our most vulnerable communities. For the over 2,000 hospitals around the country that participate in the 340B drug pricing program, the impact could be particularly severe and problematic. 340B hospitals, by law, are afforded the ability to purchase certain outpatient drugs at discounted prices because they treat high numbers of low-income patients or care for specific populations, such as patients living in rural areas, cancer patients or children.

The difference between the discounted price for a given drug and the drug's reimbursement allows 340B hospitals to generate savings that are then used to invest in critical programs and services to benefit the patients and communities they serve, just as Congress intended when it created the program 30 years ago. The specter of lower reimbursement for drugs subject to negotiation under the IRA is already a major concern for 340B hospitals as it will reduce their 340B savings for those drugs.

MedPAC's proposals to reduce the add-on payment will only exacerbate this problem, further reducing 340B hospitals' savings. Ultimately, it will jeopardize the ability of 340B hospitals to furnish programs and services that are either partially, or wholly, subsidized by 340B savings, and are relied upon by patients around the country.

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 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, again, 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. 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, there was some concern about using reference pricing outside of drugs that are originator biologics and their biosimilar counterparts, with one commissioner noting “I think it's much easier to think about this for drugs that are reference and biosimilars. That's easy to say, bundle those two things together. The other therapeutic alternatives piece is more complicated in figuring out how we define what gets to be counted as a substitute I think makes that part a bit trickier.”

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, manufacturers with products 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 up the average and increasing overall spending for drugs in the group.

This is not a concern held solely by AHA; one Commissioner asked, “Do we see any evidence that the entities that manufacture and sell generics or biosimilars might raise their price kind of in response, so over time, you sort of see some elevation in the reference against which you're setting the [price],” a scenario the MedPAC chairman acknowledged having seen in the past.

The approach that AHA believes holds the greatest promise for placing direct downward pressure on drug prices is a cap on ASP inflation, an approach that Congress enacted in the IRA, whereby Medicare would require manufacturers to pay rebates to the federal government when ASP growth exceeded an inflation benchmark. Part B drugs subject to the IRA inflation rebates include any single source drug or biological (including most biosimilars) that are paid under Part B, with certain exceptions. Exceptions include: drugs with low average Medicare Part B total allowed charges (i.e. less than \$100 in 2023); vaccines; and certain qualifying biosimilar biological products. This IRA provision is similar to rebate programs for Medicaid, which consistently achieves better pricing on drugs than Medicare.

This approach is similar to one previously recommended by MedPAC in its June 2017 report. While there are some concerns that an inflation cap policy 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.

In addition, given that overall Medicare Part B drug spending is influenced by both price and volume, AHA also supports 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. For example, according to 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, especially given the large quantities that a hospital must purchase.³

AHA encourages MedPAC to further explore a payment model that is parallel to the IRA inflation 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. 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 uncertain clinical benefit. 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 (AAP) are launching at high prices with limited evidence about their clinical effectiveness.

Although the FDA requires manufacturers to complete confirmatory post-approval trials, some trials are never completed or take many years to complete. One example is the newly approved Alzheimer's drug Aduhelm, which was approved under the FDA's accelerated pathway, yet has unclear clinical benefit and a manufacturer price of \$56,000 per year.

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 first-in-class Part B drugs that the FDA approved based only on surrogate or intermediate clinical endpoints⁴ under its AAP. Under this policy, Medicare could cap payment for AAP drugs until confirmatory trials are completed.

³ See also, "Trends in Hospital Inpatient Drug Costs: Issues and Challenges." 2016. www.aha.org/system/files/2018-01/aha-fah-rx-report.pdf

⁴ 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.

Several policy approaches were discussed for setting a cap:

- CMS could cap payment based on an assessment of both the comparative clinical effectiveness and the new product's cost compared to the standard of care. CMS would also have the discretion to apply coverage with evidence development, as appropriate.
- The cap could be set at some increment of the payment rate for the standard of care. A cap at 100% of the standard of care is a type of reference pricing.
- CMS could pay 106% of the new drug's ASP for three years and thereafter, if confirmatory trials have not been completed, cap payment based on the standard of care.

As an alternative to a cap, the Commission discussed establishing rebates based on a percentage of the new drug's price. This is similar to the June 2021 MACPAC recommendation increasing Medicaid rebates for accelerated approval drugs.

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. We have furthermore sought 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](#).

MEDICARE ADVANTAGE

Improving Encounter Data. The AHA strongly supports the Commission's work to monitor the accuracy and completeness of Medicare Advantage (MA) encounter data. The Commission's analysis, as well as efforts to improve the quality and completeness of the data, are more critical than ever, especially as MA enrollment continues to grow rapidly, providing coverage to nearly half of all Medicare enrollees.

As described in [AHA's detailed comments](#) to the Centers for Medicare & Medicaid Services (CMS) in response to their August 2022 Request for Information on the MA program, we believe more rigorous data collection and reporting is needed to improve the transparency and oversight of the MA program. In addition to more specific data collection on Medicare Advantage Organization (MAO) denials, appeals, grievances and delays in care, we believe more consistent and accurate encounter data is essential

to understanding how MAO payment corresponds with service use. It would also enable policymakers to better understand quality and access in the MA program, which is particularly important in the wake of [a recent government report](#) highlighting that certain MAOs are inappropriately denying and delaying medically necessary covered services with alarming frequency.

Further, as noted in the Commission staff presentation, there are clear incentives for MAOs to submit certain encounter data, which are used to identify diagnoses for the purpose of calculating MA plan risk scores – and therefore increasing MAO capitation payments. But there is less incentive for MAOs to submit other types of encounter data, such as records for care provided in certain post-acute care settings, which are not used for risk adjustment. This is a major source of data incompleteness and discrepancy. It is imperative that MAOs are held accountable for ensuring that the encounter data they are using and submitting to CMS is accurate and complete, and that this responsibility, for which MAOs are being paid, is not passed on or delegated to other stakeholders.

In addition to improving public transparency, we believe there are a number of other important goals that could be advanced by the availability of accurate and complete encounter data, including enabling more rigorous oversight of the MA program. There is often insufficient data available to conduct meaningful program oversight, which allows certain plans to engage in abusive practices without the threat of being held accountable. For example, the AHA maintains serious concerns about certain MAOs routinely removing diagnoses and service codes from provider claims for the purpose of reimbursement, but then submitting those same diagnosis codes to CMS in order to increase their risk scores.

The AHA has strongly urged CMS to prohibit MAOs from submitting codes for risk adjustment purposes in cases where they failed to reimburse the provider for the care associated with those diagnosis codes. Accurate and complete MA data would improve the ability of federal regulators to identify these types of circumstances and inform the development of policy solutions to rectify inappropriate MAO business and data reporting practices. It would also enable greater oversight in specific areas where there is a history of inappropriate denials, such as post-acute care. For example, more complete encounter data would allow policymakers to identify problematic patterns in utilization (or lack thereof), which may suggest the use of overly restrictive plan policies or inadequate provider networks.

Accordingly, the AHA believes greater oversight and enforcement is needed with respect to reviewing the data submitted by plans for completeness and accuracy; ensuring that submitted encounter data accurately reflects utilization and payment for health care services; and achieving greater transparency in the MA program.

Standardization of Benefit Design. The AHA supports MedPAC's exploration of benefit design and enrollee cost-sharing standardizations. Once a Medicare beneficiary

opts to enroll in the MA program, they face an unprecedented assortment of MAOs from which to choose. A total of 3,834 MAOs are available nationwide; the average beneficiary has 39 MAO options in their service area. These plans can vary significantly in terms of cost sharing, covered services, provider networks and quality ratings. They also vary significantly from Traditional Medicare in ways that may not be easily understood to a beneficiary when evaluating their Medicare enrollment options.

For example, MAOs routinely use prior authorization and utilization management techniques that are not widely used in Traditional Medicare. As noted during MedPAC's preliminary discussion on this topic, there are benefits to offering consumers a broad range of coverage choices to meet their needs, but having too many options, with wide variation in features, can create challenges for consumers. This is particularly true for those with lower health literacy when asked to navigate, compare and truly understand their coverage options. In addition to the confusion around choosing an appropriate plan, high variation can also lead to patient uncertainty about their benefits, which can result in patients receiving unexpected bills or even avoiding care all together.

We appreciate the Commission's discussion on this topic given the significant potential benefit to consumers of more streamlined MA offerings and support further exploration of such an approach. Additional research on this topic should look at both the potential benefits as well as any potential costs, such as curtailing innovation and limiting the development of personalized health coverage options that support specific consumer needs. The AHA looks forward to engaging with MedPAC as you continue to discuss the merits of standardization in Medicare Advantage.

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