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Francis J. Crosson, M.D.  
Chairman  
Medicare Payment Advisory Commission  
425 I Street, N.W. Suite 701  
Washington, DC 20001

Dear Dr. Crosson:

At its January meeting, the Medicare Payment Advisory Commission (MedPAC or the Commission) discussed items that will be covered in its June report to Congress. On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, and our 43,000 individual members, the American Hospital Association (AHA) asks that commissioners consider the following issues as they continue their discussions, each of which would have a significant impact on hospitals, health systems, other providers and the Medicare beneficiaries we serve.

### **MEDICARE ACCESS AND CHIP REAUTHORIZATION ACT OF 2015 (MACRA)**

The AHA appreciates the Commission's interest in identifying ways to improve the implementation of MACRA. The new Merit-based Incentive Payment System (MIPS) and Advanced Alternative Payment Model (APM) tracks established under the law are major public policy changes that will impact the health care field significantly. As such, the law merits ongoing evaluation to ensure it achieves its goals, and to address any unintended consequences.

At the January meeting, commissioners discussed several policy considerations, including redesigning the MIPS, balancing between the MIPS and APMs, redesigning the 5 percent APM incentive payment and risk-sharing designs. **The AHA strongly urges the Commission to draw upon data and experience from the field before proposing policy changes to MACRA.** The first performance period for the MIPS and APMs began on Jan. 1, 2017 – less than two months ago. As a result, clinicians and hospitals with whom they partner are at the very beginning of putting the MACRA's policy requirements into action. Furthermore, the Centers for Medicare & Medicaid Services (CMS) has appropriately deemed the first year of the MIPS as a "transition year" to enable clinicians to gain experience under the programs before increasing requirements. As a result, the significant policy changes discussed by the Commission at its January 2017 meeting do not yet have the benefit of data and experience.



**Rather than assigning clinicians to groups or regions, we believe the Commission should focus on policy approaches that expand the options for clinicians to voluntarily collaborate with others on quality and cost. Specifically, we strongly support the implementation of a MIPS participation option that allows for hospital-based physicians to use their hospital's CMS quality and resource use measure performance in the MIPS.** We believe such an option would not only help address the “small numbers” problem that the Commission raises, but also would help physicians and hospitals to align quality improvement goals and processes across the care continuum.

**For example, the AHA is concerned by the Commission's proposal to aggregate MIPS quality and cost performance results at the local market level.** As we understand it, the Commission is considering a policy that would assign clinicians in particular areas the cost and quality score of that geographic region to address the concern that performance scores for many clinicians are based on a small number of observations. The AHA has always supported the notion of clinicians coming together voluntarily to participate in the MIPS as a group practice, as it provides a way to share resources and improvement strategies. But simply assigning clinicians an aggregate score based on the performance of all others in their community is arbitrary, especially since there is considerable variation in market composition and the ability of clinicians to collaborate on improving performance.

**The AHA also is concerned by the Commission's proposal to replace most clinician-reported measures with outcomes measures calculated by CMS.** We appreciate that MedPAC recognizes the significant resources required to collect and submit quality data. However, most measures calculated by CMS would be based on Medicare claims data. While claims data have a role in quality measurement, they cannot and do not fully reflect the details of a patient's history, course of care and clinical risk factors. Such information is crucial to performing the risk adjustment that most outcome measures require to fairly compare provider performance. As a result, many claims-derived outcome measures do not accurately reflect provider performance. Basing clinician performance on unreliable data would be highly problematic.

**In addition, we strongly disagree with the principle that clinicians participating in advanced APMs should only receive the 5 percent MACRA APM incentive if they are successful at achieving the goals of the APM.** This principle misses the key purpose of the APM incentive payment, which is to *encourage participation* in advanced APMs, not *reward or penalize performance*. APM performance should be rewarded or penalized solely by the design of the model. Under the Commission's principle, the incentive essentially would create a double reward for successful APM participants and a double penalty for those participants that fall short of meeting the APM's goals. Entities bearing financial risk in an advanced APM already face the threat of repayment of any losses, and it is not clear why the Commission believes additional performance incentives are needed.

Providers entering new payment models must invest significant resources in the development of infrastructure, such as care management and data analytics, and the redesign of care processes. It takes time to understand how to effectively and efficiently manage a population or episode of care, and providers enter APMs with varying experience at this and, thus, different learning

curves. An incentive based on participation, not performance, helps stabilize providers shifting into new payment models while they learn how to operate in the new APM environment. **For that reason, we continue to urge CMS to expand its definition of financial risk to include the investment risk borne by providers who participate in APMs, and to develop a method to capture and quantify such risk.**

**Finally, the AHA is concerned by several proposals intended to "balance" the relative incentives to participate in MIPS and APMs.** The proposals appear to be aimed at making the MIPS an even less attractive option than the APMs. Our members have significant concerns that the MIPS is *already* a much less attractive option than APMs. Specifically, they believe it may disrupt the sustainability of some clinicians' practices, which could ultimately impact access to care for Medicare beneficiaries. These concerns focus not only on the burden of reporting under the MIPS, which commissioners have acknowledged, but also the financial incentive structure. It is important to note that because of the budget-neutral payment structure, some clinicians will receive the maximum MIPS penalty each year. Though these penalties may not seem significant in the abstract, in reality it would be very difficult for a small primary care practice, for example, to operate with a potential 9 percent cut in payment rates each year. The Commission's proposals to, for example, limit the upside potential under the MIPS and eliminate the exceptional performance bonus could serve to punish providers who are devoting significant resources to transitioning into the more value-based approach encompassed by the MIPS. It could be especially biased against small practices that have many fewer options to participate in advanced APM models.

## **DRUG PRICING**

The high and rising cost of pharmaceutical drugs is putting a significant financial strain on the U.S. health care system. As such, in January, commissioners discussed the impact of the cost of prescription drugs on the Medicare Parts D and B programs. **The AHA strongly supports an increased focus on drug pricing, and has developed a wide-ranging set of policy proposals to improve access to more affordable drug therapies (see Attachment A).** Fully addressing high drug prices will require action beyond the purview of the Medicare program. However, there are a number of ways in which the federal government could reduce costs for Medicare beneficiaries receiving coverage through Medicare Parts D and B.

### **Medicare Part D**

In January, MedPAC staff discussed many potential changes to Part D, including the reinsurance threshold, which the AHA agrees could be a component of a set of solutions. **In addition to these options, we recommend that MedPAC consider the following specific policy proposals within the Part D program, each of which is described in more detail in Attachment A:**

- Disallow co-pay assistance cards within the Part D program;

- Use the Center for Medicare and Medicaid Innovation's authority to develop and test Medicare-negotiated value-based payment arrangements that could be used by Part D sponsors;
- Require mandatory, inflation-based rebates for Medicare Part D drugs;
- Vary patient cost-sharing for certain drugs based on value; and
- Issue consumer and provider-facing annual reports on drug pricing.

## **Medicare Part B**

The Commission also continued its discussion related to Medicare Part B drug payment issues at the January meeting. Currently, Medicare pays for most separately payable Part B drugs in the outpatient setting at the rate of average sales price (ASP) plus 6 percent. In discussions over the past several years, the Commission has examined ways to address the rapid growth in Part B drug spending, speculating that the ASP methodology may encourage the use of costlier drugs because the 6 percent add-on payment generates more revenue for more expensive drugs.

**The AHA is concerned that many of the solutions MedPAC is considering unfairly penalize hospitals for price increases that are outside of their control.** 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. 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. In addition, hospitals treat the most severely ill patients and those with multiple co-morbidities, who often require treatment using the costliest drugs. Cutting payment for Part B drugs overall, or shifting payment from the costliest to the least costly drugs, penalizes hospitals that treat complex and seriously ill patients. More specifically, the AHA is concerned with the following proposals:

1. Reducing payments for drugs and biologicals paid at the wholesale acquisition cost (WAC). Currently, new single-source drugs and the first biosimilar to a reference biological are paid at WAC plus 6 percent for up to three quarters until ASP-based data become available. The Commission reports that, based on its analysis of the top 50 highest expenditure Part B drugs, small discounts (between 0.7 and 2.7 percent) from the WAC are "sometimes" available. Based on this analysis, the Commission discussed reducing the payment rate for WAC-priced drugs to ASP plus 3 percent.

**The AHA does not support this approach because it would unfairly shift the burden for the high list prices imposed by drug manufacturers onto hospitals and physicians.**

Further, as several commissioners noted, with the 2 percent sequester still in effect, payment for drugs and biologicals would effectively be reduced to a level below what was actually proposed by the Commission. Such a significant reduction in payment could negatively impact the ability of providers to afford new single-source drugs and would not account for the growing pharmacy overhead costs that the add-on percentage was intended to cover.

2. Implementation of an ASP inflation cap and rebate. Currently, growth in ASP plus 6 percent payment rates are driven solely by manufacturer pricing decisions. Therefore, the Commission staff described a potential policy in which Medicare would require manufacturers to pay rebates to the federal government when ASP growth exceeded an inflation benchmark. **The AHA continues to believe that an ASP inflation cap holds promise to put downward pressure on drug prices. However, we have several concerns about the proposal and the Commission's discussion.** First, we remain concerned that an inflation cap could incentivize drug manufacturers to protect their revenues by setting a very high launch price for new drugs, and urge the Commission to address this in future discussions.

In addition, we oppose reducing the payment rate to providers by basing the ASP add-on amount on the inflation-adjusted ASP. This again unfairly penalizes providers for the rapid increase in manufacturer drug prices, which are clearly outside of their control. We also are concerned about the suggestion to eliminate the rebate altogether and, instead, simply reduce the rate Medicare pays providers for Part B drugs by inflation-adjusting the entire reimbursement rate. While some believe that market forces would lead drug manufacturers to reduce their prices in response to these cuts, we have seen manufacturers time and again exhibit unreasonable pricing even for older commonly used drugs. The most recent example involves Marathon Pharmaceutical's 6,000 percent price increase for deflazacort, which potentially included not only price gouging, but also abuse of the orphan drug laws.<sup>1</sup>

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 last year, hospitals reported that, although large price increases occurred for both branded and generic drugs, annual price increases of 10 or 20 percent on widely used older generic drugs can have an even greater effect, given the large quantities that a hospital must purchase. As such, we do not support excluding low-cost drugs from the cap.

3. Using consolidated billing codes. The Commission discussed consolidated billing codes for Part B drugs in which drugs and biologics with "similar health effects" would be placed into the same billing code and paid at the same rate. **However, consolidated billing does not directly address manufacturer price inflation; instead it puts hospitals at risk for large price differences between drugs that may or may not be "therapeutically similar" for individual patients.** Patients' medical conditions are not uniform; a drug that is effective on average may be ineffective, or even dangerous, for a particular patient. In addition, this approach wagers that by setting a benchmark price based on the average ASP for the other drugs in the group, manufacturers would have an incentive to lower their price below their

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<sup>1</sup> "An old drug gets a new price to fight a rare disease: \$89,000 a year," Washington Post, Feb. 10, 2017. Last accessed on Feb. 16 at: [https://www.washingtonpost.com/news/wonk/wp/2017/02/10/an-old-drug-gets-a-new-price-to-fight-a-rare-disease-89000-a-year/?hpid=hp\\_regional-hp-cards\\_rhp-card-business%3Ahomepage%2Fcard&utm\\_term=.69adad5aea68](https://www.washingtonpost.com/news/wonk/wp/2017/02/10/an-old-drug-gets-a-new-price-to-fight-a-rare-disease-89000-a-year/?hpid=hp_regional-hp-cards_rhp-card-business%3Ahomepage%2Fcard&utm_term=.69adad5aea68).

competitors' in order to make their product more attractive and garner market share. However, one also could foresee the opposite happening – 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 price up and increasing overall spending for drugs in the group.

4. Creation of a Voluntary Drug Value Program (DVP). The Commission discussed the development of a voluntary DVP, which would be a market-based alternative to the ASP payment system, intended to create more incentives for provider efficiency and obtain lower prices from manufacturers. **While additional details are needed for full evaluation, we are not convinced that hospitals and health systems would benefit from a DVP; as a result, we would not expect many to enroll.** First, most hospitals already have access to reduced drug prices through their membership in group purchasing organizations (GPOs). Second, many of the additional tools described by Commission staff that DVP vendors could use to encourage savings, such as step-therapy and formularies, are already widely used within hospitals and health systems.

Third, unless a hospital could see a timely and direct link between their activities and shared savings, it is unlikely that the prospect of some unknown future shared savings would be enough to overcome the other less appealing aspects of a DVP. Finally, we share the skepticism expressed by many commissioners about the likelihood that these new DVP vendors could effectively negotiate lower prices and achieve substantive savings under Part B. While it may be worth further exploration as a voluntary program for free-standing physician practices who do not have the same access to GPO pricing that hospitals and health systems do, we believe that there are better options for the Commission to consider.

5. Reductions in ASP add-on rate. Commission staff continue to recommend reductions in the current ASP add-on of 6 percent in order to reduce overall Part B drug expenditures and give providers an incentive to enroll in the voluntary DVP discussed above. **We continue to object to this approach and reiterate the objections raised in our April 2016 [letter](#) to MedPAC.**

We appreciate your consideration of these issues. If you have any questions, please feel free to contact me or Priya Bathija, senior associate director of policy, at (202) 626-2678 or [pbathija@aha.org](mailto:pbathija@aha.org).

Sincerely,

/s/

Thomas P. Nickels  
Executive Vice President

Cc: Mark Miller, Ph.D.  
MedPAC Commissioners