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Francis J. Crosson, M.D.
Chairman
Medicare Payment Advisory Commission

Via email

Dear Dr. Crosson:

The Medicare Payment Advisory Commission (MedPAC) will meet this week to discuss its June Report to Congress. On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, the American Hospital Association (AHA) asks that commissioners consider the following perspectives on payment policy governing Part B drugs, as well as inpatient rehabilitation facility (IRF) coding practices. These issues are of significant importance to our members, as well as Medicare beneficiaries, and we appreciate the Commission's efforts in these areas. We look forward to working together going forward to find solutions that will help improve the Medicare program for all stakeholders.

PART B DRUG PAYMENT POLICY ISSUES

At its March meeting, the Commission continued its discussion about Medicare Part B drug pricing. Currently, Medicare pays for most Part B drugs in the outpatient setting at the rate of the 106 percent of the average sales price (ASP). In discussions over the past two years, MedPAC has speculated that the ASP methodology may encourage the use of more costly drugs because the 6 percent add-on generates more revenue for more expensive drugs. Therefore, the Commission has reviewed a number of policy options to restructure the ASP add-on, including options that are purported to be budget neutral to overall Part B drug payments, such as 100 percent of ASP plus $24 and 102.5 percent of ASP plus $17.15. However, although most options discussed were designed to be budget neutral in aggregate, MedPAC's proposed policies are estimated to redistribute Part B drug payments, with the overall effect of shifting money away from hospitals and specialties that use higher-cost drugs to those physician specialties that use lower-cost drugs. In addition, at the March meeting, the Commission discussed an option of 103.5 percent of ASP plus $5, which would not be budget neutral.

Similar to the Medicare program, hospitals and their patients also bear the burden of escalating drug costs. Our members have expressed deep concerns over their ability to provide the highest quality care to patients due to the impact that high-drug costs, including unexpected price

increases, have on hospital budgets. **As such, the AHA supports finding ways to rein in skyrocketing drug prices. However, it is critical that the solutions MedPAC recommends do not unfairly penalize hospitals or physicians.** Hospital outpatient department (HOPD) Medicare margins, as reported by MedPAC, are already *negative* 12.4 percent. To make matters worse, the Commission reports that payment policy changes in 2015 and 2016 are expected to reduce Medicare margins even further. Negative Medicare margins are expected to continue in 2016, even for those providers that the Commission considers to be "relatively efficient." Imposing additional cuts in payments to Part B drugs would further reduce HOPD margins.

Further, 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, while minimizing side effects and dangerous drug interactions. In addition, hospitals treat the most severely ill patients and those with multiple co-morbidities, who often require treatment using the most costly drugs. Cutting payment for Part B drugs overall, or shifting payment from the most costly to the least costly drugs, penalizes HOPDs that treat complex and seriously ill patients.

Finally, Commission staff presented data at the March meeting that they claim suggest that, for a substantial portion of Part B drugs in their analysis, there is still adequate "headroom" between providers' acquisition costs and the Medicare payment rates, even taking the sequester into consideration. Specifically, they indicated that, for two-thirds of the 34 drugs included in their analysis, at least 75 percent of the volume had an invoice price less than 102 percent of ASP. However, the Commission's analysis is limited in that it evaluates just 34 of the thousands of drugs used by providers and suppliers in Part B.

The fact is that the ASP plus 6 percent 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 percent payment rate, the percentage add-on provides protection for when price increases occur and the payment rate has not yet caught up.

Also, the statutory add-on to ASP is 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 so the use of these drugs requires costly handling, storage and training. 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. Retaining an adequate add-on to ASP is critical to ensuring continued access to drug therapies for beneficiaries receiving care in hospitals and physician practices.

In addition to the ASP options described above, at the March meeting, Commission staff presented three new policy options that they said could create more incentives for price competition among drugs or that put downward pressure on ASP, including: (1) an ASP inflation cap; (2) consolidated billing codes for Part B drugs; and (3) restructuring the Competitive Acquisition Program (CAP) for Part B drugs. **We are encouraged by this new direction the Commission is heading in, which includes policy options that focus on the core of the problem – unrestrained pricing by drug companies. We are particularly interested in learning more about placing a cap on how much Medicare's ASP plus 6 percent payment for an individual drug can grow over time.**

MedPAC staff suggest that this ASP inflation cap could be operationalized through a manufacturer rebate to Medicare (or some other means) when the ASP for a drug increases faster than a specified inflation benchmark. Staff point out that such a cap would protect against the potential for a dramatic increase in the Medicare payment rate for a product and also could potentially generate savings for drugs with ASP growth above the inflation benchmark. While we share the concern voiced by several Commissioners that an inflation cap could incentivize drug manufacturers to protect their revenues by setting a very high launch price for new drugs, we believe that there are ways to address this as well, given Medicare's substantial potential negotiating power. **The AHA urges the Commission to continue to explore this policy option.**

The Commission also discussed consolidated billing codes for Part B drugs in which similar drugs would be placed into the same billing code and paid a rate that is based on the average ASP for drugs in the group. Commission staff speculate that this approach, which is essentially reference pricing, would promote price competition and generate savings for the program and beneficiaries. **However, the 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. 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 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.

In addition, we share the concern voiced by several of the Commissioners about the feasibility and complexity of implementing a restructured CAP for Part B drugs. Commissioners were skeptical that this approach could generate much interest from drug vendors given the past failure of the 2006-2008 CAP. They also questioned whether CAP vendors would be able to guarantee they could supply the right amount of the right drug at the right time, particularly for specialties where drug therapy is central and essential, such as oncology. Further, the AHA is concerned that a CAP-like program would not be feasible for Part B drugs in HOPDs given the large volumes and variety of drugs that are purchased and

administered in hospitals and health systems. **While it may be worth further exploration of this option as a voluntary program for free-standing physician practices, we agree that there are better options to which the Commission should give priority and dedicate its time and resources.**

Finally, the AHA believes that there are other policies that the Commission and other policy makers should consider to help address rapidly rising drug prices. The AHA has been working with a number of stakeholders to raise awareness of and develop policy solutions to combat the problems caused by drug price increases. For instance, we are a steering committee member of the Campaign for Sustainable Rx Pricing (CSRxP), a multi-stakeholder coalition that works to raise consumer and other stakeholder awareness of the rising cost of drugs. The CSRxP is developing a set of policy solutions that seek to minimize the negative impact of high drug costs on patient access to care, health care premiums and taxes while still enabling drug companies to innovate and develop new therapies. The AHA is exploring policy positions drawn from the work of the CSRxP and from conversations with our members and health care field thought leaders. Among the general approaches we are exploring are:

- strengthening Medicare's negotiating power;
- reducing the backlog of generic applications;
- increasing transparency through the collection of information on drug pricing, comparative effectiveness, and investment in research and development;
- increasing competition by shortening the exclusivity period for biologics and prohibiting anti-competitive practices such as "ever-greening" and "pay for delay;" and
- strengthening requirements around direct-to-consumer drug advertising.

We encourage the Commission to evaluate such policy options in future meetings and we look forward to working together to find ways to ensure that rapid increases in drug prices do not harm the Medicare program, its providers, suppliers or beneficiaries.

IRF CODING PRACTICES

In its March 2016 report, MedPAC made a recommendation that the Secretary of the Department of Health and Human Services (HHS) conduct focused medical record reviews of IRFs that have unusual patterns of case mix and coding. As it noted, coding of Medicare IRF cases is complex, and accurate coding on claims is critically important. Indeed, the AHA invests substantial resources to help our members achieve this goal, such as our collaboration with the National Center for Health Statistics and the Centers for Medicare & Medicaid Services (CMS) to maintain the integrity of the classification system. In addition, the AHA serves as the national clearinghouse for issues related to the use of ICD-9-CM, ICD-10-CM, and ICD-10-PCS codes, publishes the nationally respected *AHA Coding Clinic*® guide on hospital coding, and advocates on national coding classification and data issues, including helping to develop IRF-specific coding guidance. **Given both our coding resources and IRF-member stakeholders, we stand ready to provide our substantial expertise for any IRF coding reviews that occur.**

MedPAC's recommendation includes a call for CMS to review IRF medical records in combination with the associated patient assessment data, an assessment of inter-rater reliability across IRFs, and related research. The Commission also suggests that these audits focus on providers with atypical patterns of coding or case mix, and facilities with wide discrepancies between patients' severity of illness at hospital discharge versus IRF admission. This multi-faceted recommendation calls for research of the IRF field, as a whole, and a complex form of coding audits of a particular subset of providers and cases. **The AHA stresses the importance of a balanced and transparent approach when interpreting and implementing this recommendation.** We are committed to working with CMS on its selection of the types of IRF claims to receive coding audits, and the unique protocols that would be required to jointly assess a patient's medical records and the corresponding patient assessment – a highly atypical and complex form of audit.

We also want to stress that the IRF-specific training and experience of auditors engaged in carrying out this recommendation will be paramount to the accuracy of audit findings, given the clinical expertise needed to assess two, potentially lengthy medical documents – the patient assessment and medical record – to determine coding accuracy. The patient assessment alone includes a complex review of 18 physical and cognitive elements using unique scales, and the medical record and claim that help assign patients to a payment category rely upon "etiologic diagnoses" solely used for IRFs. **Collectively, these highly unique audit variables demand the use of auditors with demonstrated expertise in IRF coding and payment policy.** Prior IRF audits by recovery audit contractors (RAC) lacking this expertise have gone poorly and required several CMS interventions – a scenario that can and should be prevented going forward. In addition, we will encourage CMS to identify and share both best practices for IRF coding and any common coding errors that are identified through this research and these audits.

Finally, the AHA agrees with the report's numerous references that the relatively high IRF Medicare margins are due to differences in facility size and resulting economies of scale, different degrees of focus on controlling costs, and different rates of cost growth. We note that, while the quintile of IRFs with the highest margins includes many freestanding and for-profit IRFs, it is actually fairly heterogeneous: hospital-based IRFs account for more than one-third of the quintile and non-profit IRFs account for more than one-fourth of the quintile, as shown in the chart on page 258 of the March report. Therefore, we suggest that any examination of IRF inter-rater reliability, which MedPAC has speculated also may contribute to higher Medicare margins for IRFs, recognize this heterogeneity.

We appreciate your consideration of these issues. Safeguarding adequate payment for hospital services will ensure Medicare beneficiaries continue to have access to high-quality, innovative and effective care in their communities. 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.

Sincerely,

/s/

Ashley Thompson
Senior Vice President
Public Policy Analysis and Development

Cc: Mark Miller, Ph.D.
MedPAC Commissioners