

July 11, 2018

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

Dear Dr. Crosson:

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. We applaud both the Medicare Payment Advisory Commission (MedPAC or the Commission) and the Department of Health and Human Services (HHS) who have recently voiced significant concerns about rising pharmaceutical costs, as delineated in the June 2017 MedPAC report to Congress and the May 2018 HHS *Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs*.

The American Hospital Association (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. On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, and our 43,000 individual members, **the AHA appreciates the attention to this critical issue and urges the Commission to continue to take action to achieve sustainable drug pricing. Specifically, we recommend:**

- Mandating an average sales price (ASP) inflation cap for Medicare Part B and Part D drugs, and applying the cap to both high-cost and lower-cost drugs;
- Identifying approaches to preventing excessively high launch prices as a response to an ASP inflation cap;
- Maintaining the ASP plus 6 percent payment methodology for Part B drugs;
- Testing a new Part D payment model that reduces or eliminates reinsurance payments while making appropriate adjustments to the direct subsidy rate; and
- Improving annual public reports on Medicare Part B and Part D drug costs by making them more consumer and provider-friendly.



## CONTINUOUS RISE OF PHARMACEUTICAL COSTS

Spending on pharmaceuticals has increased dramatically over the past several years. The Office of the Assistant Secretary for Planning and Evaluation (ASPE) estimated that prescription drug spending made up nearly 17 percent of overall personal health care expenses in 2015—\$457 billion—compared to just 7 percent of personal health care spending in the 1990s.<sup>i</sup> This is not surprising, as hospitals frequently see patients show up in the emergency department or return for follow-up care sicker than when they left because they were unable to afford their medications. Indeed, in a 2017 Truven Health Analytics-NPR Health poll, nearly 67 percent of respondents cited cost as the main reason for not filling or picking up a prescription.<sup>ii</sup> Just as many patients face the challenge of high drug prices at the pharmacy, hospitals, as major drug purchasers, also face significant resource constraints and trade-offs as spending on drugs increases.

**The primary driver behind increased drug spending is higher prices, not increased utilization.** Within the health care field, “pharmaceuticals” was “the fastest growing category” in terms of pricing for every month of 2016 and for most months of 2017. A recent forecast suggests that drug prices will continue to increase by more than 7 percent from July 2018 through June 2019<sup>iii</sup> with similar annual growth projections through 2026.<sup>iv</sup> We see both higher launch prices for new drugs and increases in prices for existing drugs.

**Drug manufacturers have full control over the initial price for a drug and any subsequent price increases.** They are responsible for setting the price of a drug at \$89,000,<sup>v</sup> \$159,000,<sup>vi</sup> or even \$850,000<sup>vii</sup> for a course of treatment. They also solely decide whether to increase that price by 20 percent,<sup>viii</sup> 948.4 percent,<sup>ix</sup> or 1,468 percent.<sup>x</sup> With new immunotherapies coming to

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<sup>i</sup> Office of the Assistant Secretary for Planning and Evaluation, “Observations on Trends in Prescription Drug Pricing,” Mar. 8, 2016; accessed at: <https://aspe.hhs.gov/pdf-report/observations-trends-prescription-drug-spending>

<sup>ii</sup> Truven Health Analytics, “Health poll: Prescription Drugs,” June 2017; accessed at

[http://truvenhealth.com/Portals/0/Assets/TRU\\_18156\\_0617\\_NPR\\_Poll\\_Prescription\\_Drugs\\_FINAL.pdf](http://truvenhealth.com/Portals/0/Assets/TRU_18156_0617_NPR_Poll_Prescription_Drugs_FINAL.pdf)

<sup>iii</sup> Sanborn, B., “Vizient report warns of 7% drug price hike in 2018 – 2019,” Healthcare Finance, Jan. 31, 2018, <https://www.healthcarefinancenews.com/news/vizient-report-warns-7-drug-price-hike-2018-2019>

<sup>iv</sup> Johnson, C., “U.S. spending on drugs will grow faster than on other health-care services over the next decade,” Washington Post, Feb. 14, 2018. [https://www.washingtonpost.com/news/wonk/wp/2018/02/14/u-s-spending-on-drugs-will-grow-faster-than-other-health-care-services-over-the-next-decade/?utm\\_term=.e32a933d6a48](https://www.washingtonpost.com/news/wonk/wp/2018/02/14/u-s-spending-on-drugs-will-grow-faster-than-other-health-care-services-over-the-next-decade/?utm_term=.e32a933d6a48)

<sup>v</sup> Tribble, S.J., “Duchenne Drug Delayed After Outrage Over Price,” National Public Radio, Feb. 14, 2017

<https://www.npr.org/sections/health-shots/2017/02/14/515046376/duchenne-drug-delayed-after-outrage-over-price>

<sup>vi</sup> Szabo, L., “As Drug Costs Soar, People Delay Or Skip Cancer Treatments,” National Public Radio, Mar. 15, 2017, <https://www.npr.org/sections/health-shots/2017/03/15/520110742/as-drug-costs-soar-people-delay-or-skip-cancer-treatments>

<sup>vii</sup> Fox, M. “Luxturna gene therapy for blindness to cost \$850,000,” NBC News, Jan. 3, 2018.

<https://www.nbcnews.com/health/health-news/luxturna-gene-therapy-blindness-cost-850-000-n834261>

<sup>viii</sup> Herman, B. “Drug prices are still going through the roof,” Axios, Mar. 21, 2018. <https://www.axios.com/drug-prices-exploding-2017-1521564090-aa025591-9e50-491d-b3e2-c981e85adb60.html>

<sup>ix</sup> Tirrell, M. “Martin Shkreli's legacy: Putting a 'fine point' on the drug pricing debate,” CNBC, Mar. 9, 2018 <https://www.cnn.com/2018/03/09/martin-shkreli-legacy-shaping-the-drug-pricing-debate.html>

<sup>x</sup> Herman, B. “Drug prices are still going through the roof,” Axios, Mar. 21, 2018. <https://www.axios.com/drug-prices-exploding-2017-1521564090-aa025591-9e50-491d-b3e2-c981e85adb60.html>

market at launch prices of \$373, 000<sup>xi</sup> and \$475,000,<sup>xii</sup> solutions for tackling pharmaceutical costs are essential to ensure access to lifesaving treatments for those who need them.

As noted above, hospitals are heavily impacted by these growing costs. In 2016, the AHA and the Federation of American Hospitals worked with the NORC at the University of Chicago to document hospital and health system experience with inpatient drug spending. Results showed that, **while retail spending on prescription drugs increased by 10.6 percent between 2013 and 2015, hospital spending on drugs in the inpatient space rose 38.7 percent per admission during the same period.**<sup>xiii,xiv</sup> **Moreover, more than 90 percent of surveyed hospitals reported that inpatient drug price increases had a moderate or severe effect on their ability to manage costs.**<sup>xv</sup> As specialty pharmaceuticals make up a growing portion of drug spending,<sup>xvi</sup> the impact of pharmaceutical prices on inpatient costs is not likely to wane.

## AHA RECOMMENDATIONS

The 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. The full set of recommendations are outlined in **Attachment A**. Given the widespread and ongoing need for access to pharmaceuticals among Medicare beneficiaries, we highlight several proposals below that would have a significant impact on hospitals and health systems, and the Medicare beneficiaries we serve.

## MEDICARE PART B

Medicare pays for most separately payable Part B drugs in the outpatient setting at the rate of 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. Importantly, MedPAC noted that “about half of the growth in Part B drug spending from 2009 to 2013 was accounted for by price growth” in its June 2017 report to Congress.<sup>xvii</sup> One of the policy options to address rising Part B drug costs put forward by the Commission is a cap on ASP inflation, whereby Medicare would require manufacturers to pay rebates to the federal government when ASP growth exceeded an

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<sup>xi</sup> Caffrey, M. “With Approval of CAR T-Cell Therapy Comes the Next Challenge: Payer Coverage,” American Journal of Managed Care, Feb. 21 2018. <https://www.ajmc.com/journals/evidence-based-oncology/2018/february-2018/with-approval-of-car-tcell-therapy-comes-the-next-challenge-payer-coverage>

<sup>xii</sup> Ibid.

<sup>xiii</sup> National Health Expenditure Data for 2013 – 2015.

<sup>xiv</sup> “Trends in Hospital Inpatient Drug Costs: Issues and Challenges,” American Hospital Association and the Federation of American Hospitals, October 11, 2016. <http://www.aha.org/content/16/aha-fah-rx-report.pdf>

<sup>xv</sup> Ibid.

<sup>xvi</sup> Sanborn, B., “Vizient report warns of 7% drug price hike in 2018 – 2019,” Healthcare Finance, Jan. 31, 2018, <https://www.healthcarefinancenews.com/news/vizient-report-warns-7-drug-price-hike-2018-2019>

<sup>xvii</sup> MedPAC. Chapter 2: Medicare Part B drug payment policy issues, *Report to Congress: Medicare and the Health Care Delivery System*, June 2017, p. 33.

inflation benchmark. This proposal is similar to rebate programs for Medicaid, which consistently achieves better pricing on drugs than Medicare.

**The AHA continues to believe that an ASP inflation cap holds promise to put downward pressure on drug prices. In order to support effective policy recommendations, the AHA suggests the Commission consider and address the following in their future discussions on capping ASP inflation:**

Application of ASP inflation cap to lower-cost drugs. 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 2016, 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 result in even greater financial burden, given the large quantities that a hospital must purchase. **Given that overall Medicare Part B drug spending is influenced by both price and volume, the AHA strongly recommends that MedPAC consider including low-cost drugs as part of an ASP inflation cap approach.**

Downstream effects of ASP inflation cap. While this policy proposal would help to protect the Medicare program and its beneficiaries from dramatic increases in prices, 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. Historical growth in ASP plus 6 percent payment rates are driven solely by manufacturer pricing decisions, and there is currently no national ceiling for a drug's initial price. As noted earlier, new innovative therapies are coming to market with prices in the hundreds of thousands of dollars. **Given the possibility of even higher launch prices in the future, we urge the Commission to consider approaches to limiting excessively high launch prices as a response to ASP inflation caps.**

Maintaining the ASP plus 6 percent payment methodology. In prior discussions, MedPAC has speculated 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. As a result, the Commission has considered reducing the payment rate to providers by basing the ASP add-on amount on the inflation-adjusted ASP. However, this approach would unfairly penalize providers for the rapid increase in manufacturer drug prices, which are clearly outside of provider control, and reduce resources for providers to sustain critical functions in storing and handling necessary pharmaceuticals.

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 observed manufacturers time and again exhibit unreasonable pricing even for older commonly used drugs. As noted above, some pharmaceutical companies have increased their prices by nearly—or more than—1,000 percent. A more striking example involves Marathon Pharmaceutical's recent 6,000 percent price

increase for deflazacort, which some have indicated is possible abuse of the orphan drug program.<sup>xviii</sup> **Because drug pricing and exorbitant price increases remain outside of provider control, the AHA urges the Commission against reducing the current ASP plus 6 percent methodology.**

## **MEDICARE PART D**

In prior MedPAC meetings, Commissioners also have discussed numerous potential changes to Part D in order to rein in Medicare spending on pharmaceutical drugs. **We recommend that MedPAC consider the following proposals related to the Part D program:**

Test modifications to Part D reinsurance program. Under the Part D prescription drug program, the federal government covers 80 percent of the costs for enrollees who cross the out-of-pocket threshold. Insurers and beneficiaries share the responsibility for the remaining 20 percent, at 15 and 5 percent, respectively. These reinsurance payments are substantial: in 2013, the federal government's portion totaled nearly \$20 billion for approximately 2 million Medicare beneficiaries.<sup>xix</sup> This program shields Part D plan sponsors from high costs and may create disincentives for these insurers to aggressively negotiate drug prices with manufacturers and manage enrollees' care. **Thus, we support a proposal for CMS to design a pilot project to test a new Part D payment model that either reduces or eliminates reinsurance payments while making appropriate adjustments to the direct subsidy rate.** CMS could test whether shifting more of the financial risk to insurers leads to appropriate reductions in program spending due to stronger negotiations with drug manufacturers or improved care management. Importantly, this proposal is consistent with the Commission's recent recommendations to improve the Part D program.

Require mandatory, inflation-based rebates for Medicare Part D drugs. Similar to the Part B drug inflation cap proposal described above, inflation-based rebates could be also applied to the Part D program. This approach could be especially useful for Part D given the results of a 2012 HHS Office of Inspector General analysis, which found that Medicaid achieved rebates worth 47 percent of the program's expenditures compared to Medicare Part D plan sponsors achieving rebates worth only 15 percent of their expenditures. Moreover, Medicaid programs also were able to negotiate net unit costs of less than half of the amount paid by Part D sponsors for 110 of the 200 drugs evaluated by OIG. Part D sponsors were only successful in negotiating lower net unit prices for five of the drugs.<sup>xx</sup> Accordingly, an inflation-based rebate policy would protect the program and beneficiaries from dramatic increases in the Medicare payment rate for Part D drugs and potentially generate savings for drugs with price growth above the inflation

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<sup>xviii</sup> Letter from Senator Bernie Sanders, Ranking Member, Subcommittee on Primary Health and Retirement Security, Senate Health, Education, Labor, and Pensions Committee, and Ranking Member Elijah Cummings, House Committee on Oversight and Government Reform, to Jeffery Aronin, Chairman and Chief Executive Officer of Marathon Pharmaceuticals, LLC, February 13, 2017. <https://www.sanders.senate.gov/download/february-2017-letter-to-marathon?id=06256FA4-D5AA-4E3F-AD40-589E7D664E84&download=1&inline=file>

<sup>xix</sup> MedPAC, "Chapter 6: Sharing risk in Medicare Part D," June 2015.

<sup>xx</sup> HHS Office of Inspector General, "Medicaid Rebates for Brand-name Drugs Exceeded Part D Rebates by a Substantial Margin," April 2015.

benchmark. **We suggest the Commissioners consider a policy proposal to require inflation-based rebates, while taking into account the broader contextual factors outlined earlier.**

Issue consumer and provider-facing annual reports on drug pricing. In recent years, the Centers for Medicare & Medicaid Services (CMS) has begun publicly reporting the costs associated with drugs covered by Medicare Part B or Part D, including average spending per dose and per beneficiary and year-over-year changes in spending.<sup>xxi</sup> This is an important first step; however, we believe CMS could take steps to make the data easier to use for patients and providers. **The AHA recommends that MedPAC consider a policy proposal for CMS to issue consumer and provider-friendly reports on an annual basis.** Furthermore, making drug cost information available in a machine-readable format will facilitate analysis of financial impact. Such information will help providers and consumers make informed decisions about preferred drugs, and will help hold drug manufacturers accountable for their initial launch prices and price changes over time.

The Medicare program and its beneficiaries cannot continue to bear the increased cost of pharmaceutical drugs. We appreciate your consideration of these issues during your future discussions on Medicare Part B and Part D drug spending. If you have any questions, please feel free to contact me or have a member of your staff contact Erika Rogan, senior associate director of policy, at (202) 626-2963 or [erogan@aha.org](mailto:erogan@aha.org).

Sincerely,

/s/

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

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

*Attachment*

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<sup>xxi</sup> [https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Dashboard/Medicare-Drug-Spending/Drug\\_Spending\\_Dashboard.html](https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Dashboard/Medicare-Drug-Spending/Drug_Spending_Dashboard.html)