America's Health Insurance Plans

601 Pennsylvania Avenue, NW
South Building
Suite Five Hundred
Washington, DC 20004

202.778.3200
www.ahip.org

May 9, 2016

Andy Slavitt
Acting Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1670-P
P.O. Box 8016
Baltimore, MD 21244-8016

On behalf of America's Health Insurance Plans (AHIP), we appreciate this opportunity to offer comments in response to the Centers for Medicare & Medicaid Services' (CMS') Part B Drug Payment Model Proposed Rule (CMS-1670-P).

At its core, the proposed rule seeks to address the significant impact that spending for high cost drugs and biologicals has on the Medicare Part B program and the beneficiaries it serves. Importantly, by recognizing that pharmaceutical costs are rising at unsustainable rates in Medicare Part B (and across the healthcare system) and proposing solutions, CMS is shining a light on a fundamental concern about the affordability of prescription drugs for beneficiaries and taxpayers. Further, we appreciate that CMS' proposed approach includes market-driven, value-based tools used today by health plans and other private sector entities.

We also strongly urge CMS to assess carefully the potential unintended impacts of its proposal, including the potential for cost shifting to other segments of the Medicare program as well as to Medicaid and the commercial market. Both history and the experience of our members suggest that efforts to reduce pharmaceutical prices in one market segment can result in higher costs through manufacturers setting higher launch prices for new drugs and pursuing greater price increases on existing drugs. We also encourage CMS to promote parity across the entire Medicare program and ensure that the tools made available in the fee-for-service (FFS) program are also made available to health plans that provide Medicare's benefits to millions of beneficiaries through Medicare Advantage (MA) plans and Medicare prescription drug (Part D) plans.

The Problem

As noted in the rule's preamble, Part B payments for drugs have increased at an average annual rate of 8.6% since 2007, and total spending for drugs in the Part B program doubled from 2007 to 2015 – growing from $11 billion to $22 billion. While some portion of the growth in spending can be attributed to the growing Medicare population, a more significant factor is that Medicare Part B covers, with few limitations, some of the most expensive drugs and biologics on the market today. Some of these drugs have been on the market for years (or decades) and their

prices only continue to rise, resulting in higher costs for consumers and taxpayers than what would be seen in a truly competitive market.

For example, in 2014, Medicare Part B spent $1.5 billion for Rituxan, which was first approved by the Food and Drug Administration (FDA) in 1997. The price of Rituxan increased nearly 20% from 2010-2014. Medicare Part B spending for Remicade spending in 2014 was $1.2 billion, and its price increased nearly 21% over 5 years. This drug has been on the market for 18 years.[1] Given these trends, and with high cost specialty drugs projected to comprise an increasing share of overall drug spending in the future, we believe CMS' focus on this issue is even more critical.

Impact on Medicare Advantage, Part D

We believe the Agency's proposed approach may have significant downstream effects on the Part D and Medicare Advantage programs, which are described in more detail below. Potential impacts on other Medicare programs, beyond Part B, should figure prominently in the agency's consideration of which policies will most effectively address the core issue at hand – the increasing prices that manufacturers are charging for medications across the healthcare system.

Part B to Part D Cost Shift. The proposed model could create unintended consequences that shift coverage of drugs and costs to the Part D program. For example, certain drugs furnished by a physician and not usually self-administered are covered under Medicare Part B as incident to a physician service. However, a drug is not covered under Part B if it is dispensed at a pharmacy and carried by the beneficiary to the physician (a practice commonly known as "brown-bagging") or shipped directly from the pharmacy to the physician's office ("white-bagging").

Phase I of the proposal would likely increase the incidence of brown-bagging and white-bagging by changing incentives for physicians to provide higher-cost drugs incident to physician services. How often and when these practices may occur would likely differ upon a range of factors, such as the specific drug that is prescribed, the size of the provider practice, whether the practice it is rural or urban, and payer mix. CMS should carefully assess the potential scope of these shifts and their effects, including the impact on patient safety, quality of care, and the affordability of the Part D program for beneficiaries and taxpayers.

Use of Phase II Tools and Techniques in Medicare Advantage & Part D. Medicare Advantage and stand-alone Part D prescription drug plans' (PDPs) innovations serve as the model for the proposed approaches in Phase II of the model. We support these value-based tools, including prospective payment arrangements that have proved effective in improving quality while reducing costs. However, while the model addresses a variety of value-based options to be used in Part B, we have significant concerns that the proposal is silent on the extent to which Medicare Advantage and PDPs can apply similar approaches.

[1] Data on drug spending for Rituxan and Remicade obtained from the Medicare Drug Spending Dashboard.

For example, Medicare Advantage and PDPs are prevented from using several strategies described in Phase II, including more cost-sharing flexibility (soon to be tested in a limited Medicare Advantage Value-Based Insurance Design Model by CMMI in seven states), and other barriers limit value-based arrangements between plans and pharmaceutical manufacturers (e.g., the CMS bidding tool does not permit reporting of multiyear rebates that may be negotiated as part of these arrangements). AHIP has long advocated for removal of these barriers. The need for similar tools in Part D is critical given the impact high cost specialty drugs are having in the program. For example, Humira, which was first approved in 2002, is the top selling drug in the world and accounted for $1.2 billion in Medicare Part D spending in 2014; its price increased 66% from 2010 to 2014.[2] It is therefore crucial for CMS to permit plans to use the clinically-based tools that are working effectively in the commercial marketplace to improve outcomes, reduce costs, and ensure beneficiary parity throughout the Medicare program, particularly as enrollment in these programs continues to grow.

Other Part D and Medicare Advantage Implications. There are a number of other operational implications of the proposed model identified below.

- Medicare Advantage and Part D bidding: Medicare Advantage and Part D plans are in the midst of preparing bids for 2017, which must be submitted in early June 2016. The planned implementation of the model as early as 2017 could significantly affect cost projections for both Part B drugs (Medicare Advantage) and Part D (Medicare Advantage plans providing prescription drug coverage and PDPs) given the cost-shifting concerns described above.

- Potential long-term effects on Medicare Advantage: Any long-term savings accruing to the Part B program are likely to flow through to Medicare Advantage county rates under the new benchmark calculations established by the Affordable Care Act. These rate reductions will be problematic to the extent Medicare Advantage plans are not provided the same flexibility to use tools established in the model. Also, Phase I may significantly change Medicare Advantage negotiations with network providers for Part B drugs and raise concerns if cost-shifting from Part B to Medicare Advantage were to take place.

- Medicare Advantage payments to out-of-network providers: The proposed approach to vary reimbursement under Phase I based on the Primary Care Service Areas in which the provider practices is likely to raise operational concerns for Medicare Advantage plans. For example, Medicare Advantage plans would need information from CMS to determine whether out-of-network providers are included in the control or demonstration groups to ensure they are paid at FFS rates according to federal law.

[2] EvaluatePharma,"EP Vantage 2016 Preview," December 2015; Data on Humira obtained from the Medicare Drug Spending Dashboard.

Thank you for the opportunity to comment on this proposed rule. We look forward to continuing to work with you to address the impact that high cost drugs are having on the Medicare program and the entire U.S. healthcare system.

Sincerely,

Matthew Eyles
Executive Vice President
Policy and Regulatory Affairs