



Matthew Eyles
President and CEO

December 21, 2018

Seema Verma
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-5528-ANPRM
P.O. Box 8013
Baltimore, MD 21244-8013

Submitted electronically via www.regulations.gov

**RE: Medicare Program; International Pricing Index (IPI) Model for Medicare Part B Drugs—
AHIP Comments**

Dear Administrator Verma:

On behalf of America's Health Insurance Plans (AHIP), we appreciate the opportunity to offer comments on the Centers for Medicare and Medicaid Services (CMS) advanced notice of proposed rulemaking (ANPRM) soliciting comments on a new proposal to test changes to payment for certain Part B covered drugs and biologics.

AHIP is the national trade association whose members provide coverage for health care and related services to millions of Americans every day. Through these offerings, we improve and protect the health and financial security of consumers, families, businesses, communities and the nation. We are committed to market-based solutions and public-private partnerships that improve affordability, value, access, and well-being for consumers.

Drug prices are out of control, driven by high launch prices, as well as manufacturers hiking prices year over year for the vast majority of branded medications that patients need—sometimes multiple times per year. More than 23 cents of every health care dollar goes to pay for prescription drugs¹, and many families are having to make the difficult choice between paying their bills and paying for their medicines. This has created an urgent national problem that puts at risk the health and financial stability of hundreds of millions of Americans. We need solutions that ensure that every person can get the medications they need at the price they can afford.

We commend CMS for its continued commitment to reduce drug prices, and for advancing bold ideas to end drug makers' monopolistic practices that result in the price gouging of seniors and taxpayers. Spending for Medicare Part B drugs has dramatically increased, rising at an annual rate of 9.8 percent since 2011². Total spending for Part B covered drugs reached \$28 billion in 2016.³

¹ AHIP—Where Does Your Health Care Dollar Go? May 22, 2018. <https://www.ahip.org/health-care-dollar/>

² CMS—Spending and Enrollment Data from Centers for Medicare and Medicaid Services Office of Enterprise Data and Analytics.

³ CMS—Spending and Enrollment Data from Centers for Medicare and Medicaid Services Office of Enterprise Data and Analytics.

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While some portion of the growth in spending can be attributed to a growing Medicare population and utilization increases, the predominant factor is the high prices and price increases for Part B drugs and biologics used by Medicare beneficiaries.

As proposed in the ANPRM, CMS intends to test whether comprehensive reforms to Medicare Part B reimbursement for certain prescription drugs and biologics would lead to higher quality of care for Medicare beneficiaries and reduced expenditures to the Medicare program. The proposal would eventually expand to cover half the U.S. population (covered under Medicare) and would require mandatory participation by physicians and hospitals.

AHIP supports market-based approaches to curb prescription drug prices, and we support the following elements of the IPI Model:

- **Leverage private sector partners to negotiate lower drug prices.**
- **Limit application of the IPI Model to single source drugs, biologics and biosimilars, which represent a high percentage of Medicare Part B drug spending and utilization.**
- **Reform hospital and physician reimbursement for Medicare Part B covered drugs via the establishment of a “drug add-on” payment.**

Public policies that increase competition and enhance the ability of payers to negotiate lower prices for patients will result in lower costs for patients and taxpayers. By seeking to lower the costs for prescription drugs covered under Medicare Part B and addressing flawed incentives in the current payment system, the IPI Model holds promise in advancing the goals of improved access and affordability of drugs for millions of Medicare beneficiaries.

Our comments also offer these additional considerations as CMS solicits input and moves forward with reforms to Medicare Part B drug reimbursement.

- **Consider policies to prevent spillover and cost-shifting to the commercial market.**
- **Carefully consider how new policies could impact other federal programs to avoid unintended consequences.**
- **Consider adoption of clinically sensitive and relevant quality measures—such as those endorsed by the Core Quality Measurement Collaborative—as part of the evaluation and implementation of the IPI model.**

Health insurance providers are committed to working constructively with the public and private sector to lower drug prices and costs for everyone. Americans should not have to choose between innovation and affordability. With the right solutions and genuine collaboration, we can have both.

Leveraging private sector partners can strengthen negotiations and increase competition to reduce costs.

As an alternative to the current average sales price (ASP) reimbursement system for Medicare Part B covered drugs and biologics, CMS is considering contracting with a number of private sector partners to supply physicians, hospital outpatient departments, and others with prescription drugs and biologics covered under Medicare Part B.

As contemplated by CMS under the IPI model, three or more private sector partners operating nationwide would be responsible for the following key functions: negotiating drug prices with manufacturers; assuming the financial risk of buying and billing Medicare for drugs; and competing for business with hospitals and physicians. Private sector partners would compete for physicians' and hospitals' business based on fees and the ability to offer innovative delivery mechanisms. Partners would not be able to pay rebates or other volume-based incentive payments to physicians and hospitals under the IPI model.

As strong supporters of private market approaches, AHIP appreciates CMS' goal of facilitating competition and the use of market-driven and value-based tools. We recognize that CMS has carefully examined lessons learned from previous attempts to reform Part B reimbursement for drugs—such as the Competitive Acquisition Program—and has drawn on this experience to propose ways to improve on policy solutions.

We support this proposal, and we encourage CMS to consider additional steps to further enhance value and cost reductions:

- **Select private market partners with a demonstrated track record and capacity to fulfil their duties and responsibilities under the IPI model.** These responsibilities include negotiating with drug makers, establishing internal controls necessary for product integrity, and establishing a robust customer service and grievance process. By establishing high standards for vendor selection, CMS can help assure quality for patients, hospitals, and physicians.
- **Apply robust conflict-of-interest standards.** As success of the program is inextricably linked to the effectiveness of negotiations, we recommend CMS carefully consider those organizations that have success in these types of price negotiations. Such organizations could include pharmacy benefit managers, Part D plan sponsors, specialty pharmacies and drug wholesalers. At the same time, we do not believe that drug manufacturers and other organizations with a clear conflict of interest should be eligible to participate as vendors in the IPI program.
- **Consider steps to strengthen the ability of private sector vendors to negotiate meaningful cost reductions and discounts from manufacturers.** Such steps can include the use of effective pharmacy management tools, such as utilization management, step therapy and use of formularies.

Under the IPI Model, CMS would pay vendors for furnishing Part B drugs based on a target price—linked to the international pricing index. Yet, questions remain about whether vendors would be able to obtain discounts at or below the levels achieved in other developed, industrialized countries. To ensure successful implementation, we recommend CMS consider setting a price ceiling for drugs furnished through private sector partners. This would enable them to at least obtain prices comparable to those

included in the IPI—while enabling private sector entities to negotiate for additional discounts from manufacturers as they compete for hospital and physician business.

Included Drugs Should be Focused on Drugs that Face Limited or No Competition

CMS proposes to include in the IPI model drugs “incident to” a physician’s services and single source drugs, biologics, biosimilars, and multi-source drugs with a single manufacturer. According to CMS, these drug categories represent about 84 percent of Medicare Part B drug spending. In the first 2 years of the model, CMS would include those drugs that the agency could identify from reliable sources of international pricing data and expand the included drugs (in years 3-5) to cover more single source drugs as more pricing data becomes available. The proposal also seeks input as to whether to include multi-source, generic drugs in the IPI model.

AHIP supports limiting the Part B IPI Model to single source drugs, biologics, biosimilars and multi-source drugs from the same manufacturer, as contemplated under the ANPRM. Such an approach holds promise in achieving meaningful price reductions as drugs and biologics in these categories often face very limited competition and, as a result, feature some of the highest prices and price increases on a year-over-year basis.

Hospital and Physician Reimbursement Reform Will Result in Lower Taxpayer Costs

The IPI model would establish a “drug add-on” amount as a way to encourage appropriate drug utilization while addressing flaws in the current ASP methodology that create financial incentives for physicians and other clinicians to prescribe higher cost drugs and treatments.

Non-partisan policy experts—such as the Medicare Payment Advisory Commission (MedPAC)⁴—have long recognized problems with the current ASP-based reimbursement system, because it largely fails to adopt value-based incentives. Specifically, tying reimbursement to ASP + 6 percent creates misaligned financial incentives for providers to prescribe higher-cost treatments and drugs even when lower cost, but equally effective alternatives, are available with a drug class or category.

We commend CMS for recognizing problems with the current ASP methodology and proposing this alternative reimbursement policy. By developing an alternative payment model that is not directly tied to ASP, we believe this alternative approach holds promise in promoting a more value-based reimbursement structure.

In addition, we encourage CMS to take additional steps toward promoting appropriate drug utilization, such as the creation of physician bonus pools that would reward providers that prescribe lower-cost drugs and/or prescribe medicines consistent with evidence-based practice guidelines.

Prevent Spillover Effects in other Markets

AHIP encourages CMS to carefully consider the impact of the IPI model in other markets—including the potential for cost shifting to other segments of the Medicare program, the Medicaid program, and the commercial market. Both history and the experience of our members suggest that efforts to reduce

⁴ MedPAC—Medicare Part B drug and oncology payment policy issues. June 2016.
<http://www.medpac.gov/docs/default-source/reports/chapter-5-medicare-part-b-drug-and-oncology-payment-policy-issues-june-2016-report-.pdf?sfvrsn=0>

pharmaceutical prices in one segment of the market can result in higher costs through drug manufacturers setting higher launch prices for new drugs and pursuing even greater price increases on existing drugs.

As an example, the Medicaid Drug Rebate Program—which requires drug manufacturers to provide statutorily defined rebates to help offset federal and state costs for prescription drugs—has been successful in reducing program costs, saving the Medicaid program about \$15 billion annually.⁵ Yet, research by the Congressional Budget Office and other experts have also found that higher Medicaid rebates has likely led to increased prescription drug costs in private sector markets.⁶

To avoid unintended consequences and cost-shifting, we recommend CMS closely monitor prices for drugs included in the IPI model and consider additional policies or actions if drug prices in other markets rise above certain pricing thresholds (e.g. above CPI or inflation).

Analyze Potential Impacts to Other Federal Programs

In the ANPRM, CMS has acknowledged the potential overlap and interaction of the IPI model on other CMS Innovation demonstrations and federal programs, including the Oncology Care Model, the Medicare Shared Savings (ACO) Program, the Medicaid Drug Rebate Program and the 340B Drug Pricing Program.

As CMS examines how best to move forward with the IPI model, we encourage CMS to carefully consider potential impacts on other federal drug pricing programs in to avoid the potential for unintended consequences and maximize potential cost savings to beneficiaries and taxpayers.

In addition, we encourage CMS to carefully examine the impact on Medicare Advantage and MA-PD bidding. Specifically, we recommend that CMS ensure that any impacts of the IPI model are appropriately reflected in the benchmarks used to determine the payments to MA plans. Moreover, we recommend CMS to consult with stakeholders, including MA plans, in determining the geographic areas for the IPI Model—given that the size of the test areas selected by CMS under the IPI model would likely impact Medicare Advantage plan operations.

Quality Measures

Quality measurement will be integral to the IPI model to ensure that it preserves and ideally improves patient outcomes. We urge the Innovation Center to work with the Core Quality Measure Collaborative (CQMC), led by AHIP in partnership with CMS and the National Quality Forum (NQF), in selecting measures. The CQMC seeks to identify high-value and scientifically robust measures for implementation across public and private payers to reduce clinician burden and provide consumers with consistent information on which to base make healthcare choices.

The Innovation Center should look across the measures already collected in other CMS programs as well as work with CQMC to identify measures that:

⁵ HHS OIG Report—States' Collection of Offset and Supplemental Medicaid Rebates. December 2014. <https://oig.hhs.gov/oei/reports/oei-03-12-00520.pdf>

⁶ AAF Report—Cost Shifting Debt Reduction to America's Seniors. July 21, 2011.

https://www.americanactionforum.org/wp-content/uploads/sites/default/files/AAF_Part%20D%20Financial%20Impact%20%20.pdf

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1. Are scientifically sound (e.g., NQF-endorsed or otherwise proven to be evidence-based, reliable, and valid).
2. Provide a person-centered and holistic view of quality.
3. Provide meaningful and usable information to all stakeholders.
4. Promote parsimony, alignment, and efficiency of measurement (i.e., minimum number of measures and the least burdensome measures).
5. Emphasize measures that address cross-cutting domains of quality.
6. Promote the use of innovative measures (e.g., e-measures, measures intended to address disparities in care, or patient-reported outcome measures).
7. Include an appropriate mix of measure types while emphasizing outcome measures.

While we agree that utilization measures are important to the evaluation of the program and that minimal burden should be imposed, CMS should take care to augment them with more clinically sensitive and relevant measures. It may be difficult, for instance, to detect and directly attribute changes in performance on broad measures such as mortality or hospital admissions on the IPI. Thus, CMS should consider whether a select group of additional measures, such as medication adherence, are also warranted. By working with the CQMC and relying on measures already in use by CMS and/or private health plans, the burden on providers would be less so than de novo measures, yet still offer important information for clinical improvement as well as program evaluation.

Health insurance providers support lower drug prices for Americans. AHIP appreciates the opportunity to offer comments on the CMS Part B IPI model, and we look forward to continuing to work with CMS to achieve the shared goal of lower drug prices and more affordable access for seniors and taxpayers.

Sincerely,



Matthew Eyles
President and CEO