COUNCIL FOR AFFORDABLE
HEALTH COVERAGE

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The Honorable Seema Verma
Administrator
U.S. Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Submitted electronically via regulations.gov

RE: CMS-5528-ANPRM; CAHC Comments on Advanced Notice of Proposed Rulemaking: Medicare Program; International Pricing Index Model for Medicare Part B Drugs

Dear Administrator Verma:

The Council for Affordable Health Coverage (CAHC) is pleased to respond to the Centers for Medicare & Medicaid Services' (CMS) Advanced Notice of Proposed Rulemaking (ANPRM) regarding an International Pricing Index (IPI) model for Medicare Part B Drugs. CAHC is a broad-based alliance with a singular focus: bringing down the cost of health care for all Americans. Our membership reflects a broad range of interests—organizations representing insurers, PBMs, patient groups, small and large employers, life science companies, consumers, and physician organizations.

The comments expressed in this letter reflect the views of the Council, and may not reflect those of our individual members.

CAHC's staff helped write the laws that created the ASP, CAP and Part D models. Evidence shows the underlying laws are working to hold down costs, but adjustments are necessary to improve incentives and to recognize advances in policy and markets.

While CAHC has offered strong support for many of the policy solutions outlined in the administration's "American Patients First" blueprint for improving prescription drug affordability released earlier this year and appreciates CMS's efforts to lower costs for Part B beneficiaries, we maintain deep concerns regarding an IPI model for these therapies. We support market-based solutions to lower total health costs, and the costs and prices of prescription drugs. We also seek to ensure patient access to care is maximized.

Reference Pricing

Many countries around the world have adopted price controls or utilization limits to lower costs. By tethering Medicare payments for physician administered treatments to a price index of what single payer countries have adopted for the same products, costs would be lowered, yes, but patient access to care could also be diminished, especially if reimbursement is less than acquisition cost. This is a difficult trade-off.

At CAHC, we believe this is tantamount to price controls, a policy that has historically threatened innovation and patient access to treatment.

CAHC agreed with the Trump administration when it criticized price controls as recently as this May, stating[1] in its "American Patients First" blueprint: *"Price controls … prevent drug companies from charging market rates for their products, while delaying the availability of new cures to patients living in countries implementing these policies."*

We urge CMS to heed its own words and resist the temptation to embrace foreign price controls by transferring other nations' drug policies directly onto American patients. Rather than surrender to anti-competitive ideas that the administration has rightfully decried all along, we encourage a solution that puts market forces to work for the consumer, similar to the Part D program.

ASP, CAP and Reforms

CMS does not set prices for Part B drugs, as Congress intended. The current law ties Medicare Part B's drug reimbursement to the Average Sales Price (ASP) – a market-based price that already reflects negotiations between private insurers and drug manufacturers and may include any number of price concessions (e.g., volume discounts, prompt pay discounts, cash discounts) agreed upon between private parties. Medicare benefits from these negotiations.

And while this is not a perfect system, your agency was proud to announce[2] earlier this year, it will lead to a net decrease in prices for 30 of the top 50 Part B drugs starting on January 1, 2019. As CMS explained in its findings: *"among the top drugs with a decrease, there are a number of competitive market factors at work"* – competitive market factors that risk elimination under the proposed IPI model. We need to build on these efforts to further lower costs for beneficiaries and we can achieve this without importing foreign price controls to American hospitals and doctors' offices.

Alternative Approaches to Lowering Costs

Reimbursement for drugs in part B is not the core problem; we argue the core problem is reimbursement and treatment silos that encourage actors to seek and obtain the greatest reimbursement available when treating patients with cancer, RA, HIV-AIDs and other diseases. This has always been the problem with fee-for-service, and it is a problem we believe the IPI model will exacerbate by shifting care into more expensive settings.

CAHC urges the administration to withdraw the International Pricing proposal and instead pursue a more narrowly tailored solution targeted to specific high-cost products where Medicare payment represents a disproportionate share of the market. We suggest:

- Requiring manufacturers to enter into a value-based payment arrangement as a condition of Medicare coverage whenever Medicare reimbursement for a covered Part B drug is more than 50 percent of all market sales. This will address the lack of leverage and price concessions where Medicare is a price taker.
- Reimbursement would be tied to specific metrics based on patient outcomes, medication adherence, or process improvements, or some combination of all three measures. Failure to hit specific metrics would

[1] https://www.hhs.gov/sites/default/files/AmericanPatientsFirst.pdf

[2] https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/2019ASPFiles.html

result in lower reimbursement. This could be achieved on a sliding scale, and be set at less than ASP+6 percent.

- A portion of the difference in reimbursement between baseline and the value-based program should be directed to provider bonus payments to encourage high quality care and better patient outcomes. Incentives for patient adherence could also be used to lower patient cost sharing or to provide a rebate on premiums. Taxpayers should also reap lower costs as a portion of the difference between baseline and the value-based program.
- To maximally allow price discounts, CMS should suspend Medicaid Best Price to allow price concessions and discounts below statutory thresholds without manufacturers incurring rebate liability.
- Manufacturers and providers should be allowed to help coordinate care without fear of violating the Stark and Anti-kickback rules. CMS should allow medication adherence, donations of software that tracks and reports patient progress, and risk adjusted patient outcomes measures.
- CMS should also adjust payment differences across sites of care to help reduce incentives for providers to treat patients in higher cost settings.

This would help avoid disruption to areas of the marketplace that, by CMS's own reporting, have been shown to work, while addressing areas HHS has expressed are a problem for taxpayers and beneficiaries. It would save consumers and taxpayers money and eliminate any incentive to use higher cost drugs due to the percentage add-on to ASP.

Conclusion

President Trump said[3] himself that "Competition is the key to lower drug prices" and we support his assessment.

In the new year, CAHC looks forward to working with the administration on efforts to lower list prices through increasing competition, removing government-imposed barriers to value-based contracting, and rejecting policies that stifle innovation and could ultimately harm the very consumers we all seek to serve.

We appreciate your consideration of our comments and your commitment to improving prescription drug affordability and access for all Americans.

Sincerely,

Joel White
President

[3] https://www.cnbc.com/2017/01/31/trump-tells-drugmakers-he-wants-them-to-manufacture-in-the-us.html