PATIENTS FOR AFFORDABLE DRUGS

Comments of Patients For Affordable Drugs on the Advance Notice Of Proposed Rulemaking International Pricing Index Model for Medicare Part B Drugs December 10, 2018

Patients For Affordable Drugs (P4AD) is pleased to offer comments in support of the International Pricing Index Model for Medicare Part B Drugs. Patients For Affordable Drugs is the only national patient organization focused exclusively on policies to lower prices of prescription drugs. P4AD is bipartisan and does not accept funding from any organizations that profit from the development or distribution of prescription drugs. We represent a community of more than 125,000 patients and allies who have signed on to support reforms to lower drug prices.

Background

The US pays prices for drugs that are too high relative to the rest of the world. Why? Because Medicare does not negotiate directly with drug companies while the other countries do. According to HHS, patients in the US are paying 180 percent of the price paid by 16 other wealthy nations for drugs covered by Medicare Part B. It is generally accepted that patients and consumers in the US are paying about 2-3 times what people in other nations pay for drugs covered by Part D.

We strongly support direct Medicare negotiations. But we are pleased that HHS proposes a step forward with international reference pricing because — if implemented — it will in fact lower prices on Part B drugs for patients in the US and produce measurable savings for Medicare beneficiaries.

Payments to Physicians

The current structure of reimbursement in Medicare Part B drugs is broken. Reimbursing physicians based on the average sales price plus 6 percent incentivizes drug companies to price drugs higher and doctors to prescribe higher priced drugs if all other factors are equal.

P4AD agrees with the Administration's proposal to create a fixed payment for physicians. We support a payment calculated to generally keep physicians whole in comparison to the current

PATIENTS FOR AFFORDABLE DRUGS

ASP+6 model. We do not have the expertise to suggest how to calculate payment for the greatest positive impact in terms of encouraging participation and protecting physician practices.

The International Pricing Index

P4AD supports the 14 proposed countries for inclusion in the index. It would be helpful, however, for CMS to offer greater detail on how these prices will be determined given the confidential nature of many national pricing agreements. It will help the model gain acceptance if the mechanisms are more clearly spelled out. It will also help to protect from gaming of the system by players abroad in which, for example, one price is reached but a different price is disclosed.

Speed Up the Reduction In Prices and Fully Implement Over Three Years

We see no reason to wait five years to fully implement the index pricing to reach 126 percent of prices in reference countries. We believe full implementation could be achieved in three years. Three years should be adequate for the players to adjust to the new system. Most importantly, we want Medicare beneficiaries to feel the benefits of LOWER PRICES more quickly to encourage adoption of the IPIM across the entire Medicare program.

Include a Mechanism to Automatically Extend to 100% of Medicare If Successful

The final rule should include an explicit mechanism or trigger to extend the demonstration to 100 percent of the Medicare Part B program if the program proves successful at the three-year mark. Full implementation should take place over two additional years, which should be easily achievable given the experience gained in the demonstration and the structures and vendors that will be in place. We believe the program will be successful and that beneficiaries will be clamoring to be included. Elected officials will want to extend this positive program to all Medicare beneficiaries.

The Vendors

The structure built for this initiative must ensure there are multiple vendors who compete based on quality service. It is not clear from the ANPRM how the government will engage vendors and compensate them to create a business model that is both viable and responsive to customers. We are not clear on how much of a charge the vendor will take for the service and how that charge will be set. Nor are we clear on how many vendors will be optimal to render the model profitable and sustainable. We hope the final rule will clarify these points.

PATIENTS FOR AFFORDABLE DRUGS

Ensuring Drug Company Participation

We believe the incentive for drug companies to participate in Part B under the IPIM should be explicit: The drug company must accept the Part B demo reference price in order to participate in Medicare and Medicaid. Period. This incentive would apply when the program is expanded to the full Medicare program, and it would eliminate the potential challenge of a pharmaceutical company refusing to sell drugs to vendors at the new reference price.

Furthermore, in order to participate in Medicare and Medicaid, the drug company should be required to fully disclose reference prices and any other price concessions in the reference countries. This will disincentivize drug companies from setting a higher U.S. reference price while giving countries additional discounts or kickbacks.

Prevent Cost Shifting to the Private Sector & Extend Benefits of IPIM

The IPIM price must be publicly disclosed. Then, private sector negotiations can be conducted in light of that knowledge and contribute to downward pressure on prices across the U.S. health care system. We believe in an open and informed market, private sector payors should be able to capture at least the same level of savings achieved by Medicare.

Keep Protected Classes

Access to the protected classes should be maintained. We are aware there are other proposals in other segments of Medicare to alter management of protected classes. We strongly encourage CMS not to include changes to protected class treatment in this program to ensure broad patient and political support.