The International Pricing Index Model (IPI) Would Establish a New Domestic Price Control and Therefore Faces A Higher Regulatory Threshold in Order to Be Finalized

Current guidance documents for the Office of Management and Budget (OMB) under Executive Order (EO) 12866 reflect the fact that price controls have significant risk for negative effects, and therefore establishes a presumption against price controls and for market-based alternatives.[i]

As noted in the guidance: *"Government actions can be unintentionally harmful, and even useful regulations can impede market efficiency. For this reason, there is a presumption against certain types of regulatory action. In light of both economic theory and actual experience, a particularly demanding burden of proof is required to demonstrate the need for any of the following types of regulations: price controls in competitive markets."*[ii]

As a result, it is important to ensure CMS has met this higher standard in seeking to impose a new price control under IPI and address why more market-oriented, flexible approaches were not selected. The International Pricing Index (IPI) Model would replace the current market-based system for reimbursing drugs under Medicare Part B – which ensures that Medicare payment reflects discounts negotiated in the U.S. commercial market via an Average Sales Price (ASP) calculation – with International Reference Pricing (IRP), a government-dictated price control that is tied to practices and prices set by foreign governments that do not value medical innovation for patients.

1) **IPI meets well-accepted definitions of a "price control."**

The IPI proposes to reference prices set by governments in other countries (so-called "external reference pricing") to establish payment rates for drugs under Medicare Part B. This type of external or international reference pricing has long been recognized as a form of government price control by multiple government organizations and economists. For example:

- The U.S. Council for Economic Advisors recognized that "most OECD nations employ price controls in an attempt to constrain the cost of novel biopharmaceutical products, e.g. through cost-effectiveness or reference pricing policies."[iii]

- A World Health Organization (WHO) report describes ERP as a practice in which "the national regulated price is derived from or somehow related to those in a basket of reference countries." ERP is defined in this paper as "The practice of using the price(s) of a pharmaceutical product in one or several countries in order to derive a benchmark or reference price for the purposes of setting or negotiating the price of the product in a given country."[iv]

- The London School of Economics, in a paper about how countries implement reference pricing states that "ERP has been widely used across our sample as a cost-containment tool as well as a price control method."[v]

Because IPI employs international reference pricing as a price control, it is important for OMB to ensure that CMS meets the higher standards established in its guidance. According to guidance, CMS must consider: *"[m]arket-[o]riented [a]pproaches [r]ather than [d]irect [c]ontrols. Market-oriented approaches that use economic incentives should be explored."*[vi]

Given the presumption against price controls and the larger burden of proof necessary to implement a price control such as ERP, CMS must not only consider key market-based alternatives, but also show through regulatory analysis why those alternatives were not favorable to implementing a price control.

2) **Other stakeholders have expressed concerns that the IPI model replaces market competition with a government price control:**

"The proposal could block access to life-saving drugs for America's seniors, inhibit the research and development necessary to discover new treatments, and threaten our nation's free-market health care system — currently one of the best in the world"[vii]

- U.S. Chamber of Commerce, website

"[I]nstead of addressing the problems that foreign countries cause with respect to drug pricing and market access that the CEA discussed in its February report, the proposed rule veers wildly off course and essentially adopts foreign price controls. Reimbursing providers in Medicare Part B based on international prices would be devastating to biopharmaceutical innovation in the U.S. It would also pave the way to price controls in Medicare Part D and within the private sector."[viii]

- Citizens Against Government Waste, November 16, 2018, Comments on IPI ANPRM

"Instead of ensuring that foreign countries pay fairly for their innovative medicines, this proposal would actually import lower prices imposed by countries who ignore the true market value of medications."[ix]

- Trade Alliance to Promote Prosperity, November 28, 2018, Comments on IPI ANPRM

3) **OMB should ensure that CMS has assessed the health risks created by IPI's adoption of government price controls.**

Circular A-4 states: "*Since agencies often design health and safety regulation to reduce risks to life, evaluation of these benefits can be the key part of the analysis. A good analysis must present these benefits clearly and show their importance."*[x] According to guidance CMS must provide an analysis of how a regulation would reduce the risks to life, however, research shows that the use of European-style price controls presents a great risk to life expectancy and would reduce life expectancy both in the United States and abroad.[xi] The ANPRM contained no analysis of the health risks of IPI and the interaction between price controls and life expectancy. This is a critical issue that CMS must evaluate.

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[i] Circular A-4. September 17, 2003. https://www.transportation.gov/sites/dot.gov/files/docs/OMB%20Circular%20No.%20A-4.pdf

[ii] Id.

[iii] The Council of Economic Advisors, *Reforming Biopharmaceutical Pricing at Home and Abroad*, February 2018, available at https://www.whitehouse.gov/wp-content/uploads/2017/11/CEA-Rx-White-Paper-Final2.pdf

[iv] World Health Organization. WHO/HAI Project on Medicine Prices and Availability: Working Paper 1: External Reference Pricing. May 2011. https://haiweb.org/wp-content/uploads/2015/07/Working-Paper-1-External-Reference-Pricing.pdf

[v] Kanavos P, Fontrier A-M, Gill J, Kyriopoulos D. London School of Economics. The Implementation of External Reference Pricing within and Across Country Boarders. http://www.lse.ac.uk/business-and-consultancy/consulting/assets/documents/the-implementation-of-external-reference-pricing-within-and-across-country-borders.pdf. 2017. *In this quote, sample refers to the countries in the study.*

[vi] Circular A-4. September 17, 2003. https://www.transportation.gov/sites/dot.gov/files/docs/OMB%20Circular%20No.%20A-4.pdf

[vii] U.S. Chamber of Commerce. Stop Foreign Drug Pricing. https://www.uschamber.com/stop-foreign-drug-pricing (Accessed August 22, 2019).
[viii] Citizens Against Government Waste. CMS-5528-ANPRM Soliciting public comments on utilizing international price controls in Medicare Part B https://www.regulations.gov/document?D=CMS-2018-0132-0014
[ix] Trade Alliance to Promote Prosperity. Comments on International Pricing Index Model for Medicare Part B Drugs. https://www.regulations.gov/document?D=CMS-2018-0132-2651
[x] Circular A-4. September 17, 2003. https://www.transportation.gov/sites/dot.gov/files/docs/OMB%20Circular%20No.%20A-4.pdf
[xi] Lakdawalla, Darius N., Dana P. Goldman, Pierre-Carl Michaud, Neeraj Sood, Robert J. Lempert, Ze Cong, Han de Vries, and Italo A. Gutierrez, U.S. Pharmaceutical Policy in a Global Marketplace. Santa Monica, CA: RAND Corporation, 2009. https://www.rand.org/pubs/reprints/RP1380.html.