

CMS' International Pricing Index Model holds significant implications for U.S. Trade Policy

As shown by Administration officials' statements about the International Pricing (IPI) Model, as well as the construct of IPI in the Advance Notice of Proposed Rulemaking (ANPRM), the model will impact U.S. trade policy. It is important to ensure that Centers for Medicare & Medicaid Services (CMS) has consulted with relevant trade agencies and has considered more market-based alternatives to addressing the trade-related problem that officials have identified in discussing IPI.

1. The IPI Model will impact U.S. trade policy and is inconsistent with U.S. trade priorities. It is important for CMS to coordinate with relevant U.S. trade agencies and examine the likely impact on U.S. trade priorities before advancing the IPI model.

Executive Order 12866 requires each agency to avoid regulations that are “inconsistent, incompatible, or duplicative with its other regulations or those of other Federal agencies” and describes a coordinated process to ensure a unified regulatory agenda.ⁱ As a result, the CMS and the Office of Management and Budget (OMB) should ensure that the impact of the IPI model on U.S. trade policy, including potential conflict with U.S. trade priorities, has been assessed as part of this process, including through consultation with relevant trade agencies such as the United States Trade Representative (USTR), the Department of State, and the Department of Commerce.

a) The Administration has made clear that the IPI model is intended to impact the commercial behavior of manufacturers in foreign countries.

According to the Administration, the IPI Model has the goal of ending “foreign freeriding” in drug pricing, whereby “Americans pay more so other countries can pay less.”ⁱⁱ The President has stated that “[f]or decades, other countries have rigged the system” but that under the IPI proposal “foreign countries will be held accountable...”ⁱⁱⁱ In addition, HHS has stated in a question and answer document on the proposal that under IPI, “[t]he pharmaceutical industry would finally be pressured to fairly allocate the burden of funding innovation across wealthy countries” and “encourage manufacturers to cut down on foreign freeriding through higher prices abroad...”^{iv}

b) The IPI model conflicts with U.S. trade priorities.

CMS materials illustrate how the current Medicare Part B policy for reimbursing drugs is derived from a market-based “Average Sales Price.”^v The IPI model would replace this with a system in which reimbursement rates are obtained by referencing prices in foreign countries that rely on government price controls. As a result, the IPI model conflicts with U.S. trade objectives that seek to advance market-based principles abroad.

Recognizing and seeking to address this threat, the Bipartisan Congressional Trade Priorities and Accountability Act of 2015 (TPA) granted by Congress to the President identifies as a principle negotiating objective for trade agreements “to ensure that government regulatory reimbursement regimes are transparent, provide procedural fairness, are nondiscriminatory, and provide full market access for United States products.”^{vi} As noted in the TPA’s legislative history, ensuring full market access “includes setting the reimbursement amount based on competitive, market-derived pricing or an equivalent process, such as one that appropriately recognizes the value” of innovative products.^{vii}

- c) Concern over the conflict between the IPI model and U.S. trade priorities is reflected in stakeholder comments on the ANPRM.

“Adopting the failed and unfair practices of other countries will not solve the problem, it will simply import it while simultaneously undermining other efforts by the administration. For years, U.S. trade negotiators have been fighting the exact unfair trade practices the administration addresses in this proposal.”^{viii}

- American Action Forum, January 7, 2019

“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

2. CMS must consider alternatives to adoption of ex-U.S. government price controls to address its identified problem of “foreign freeriding,” and whether there are alternatives to new, direct regulation to solve a stated problem the new regulation is intended to solve.

Principle 3 of EO 12866 states: “Each agency shall identify and assess available alternatives to direct regulation...” In addition, OMB guidance sets a particularly high bar for regulatory adoption of price controls, stating in Circular A-4 that agencies must consider “market-oriented approaches rather than direct controls.”^x

OMB should ensure that HHS, in coordination with relevant trade agencies, has considered market-oriented trade-related alternatives to addressing the “foreign freeriding” problem that HHS identifies.

- a) Stakeholders have identified trade policy as an alternative solution in comments on the IPI ANPRM.

“The Trump Administration has the power to alter this dynamic by working to change the policy behavior of foreign countries through trade negotiations and deals. Just as U.S. trade negotiators are currently responding to intellectual property (IP) theft and the unfair trading practices of some of our trading partners through talks and potential deals, it can do the same on the cost-distorting issue of drug price controls.”^{xi}

- Small Business & Entrepreneurship Council, December 31, 2018, Comments on IPI ANPRM

“As the administration has articulated, innovative manufacturers in the United States continue to face efforts by other governments to force U.S. taxpayers to shoulder higher costs in areas such as health care by protecting their own domestic manufacturers and devaluing innovative American products. Such unfair foreign practices have allowed those countries to avoid contributing fairly to the research and development (R&D) needed to create new innovative products, forcing U.S. taxpayers and patients to pay more. Yet the way to combat these practices is not to replicate them by implementing price controls. Instead, aggressively advancing intellectual property protection through strong provisions in ongoing trade negotiations such as the recent United States-Mexico-Canada Agreement (USMCA) is one approach to ensure overseas nations assume a share of the cost burdens and risks associated with pharmaceutical research and development.”^{xii}

- National Association of Manufacturers, December 31, 2018, Comments on IPI ANPRM

“While many factors explain this, including some countries’ unfair foreign trade practices, including weak IP enforcement, a key reason is that U.S. exporters have been unable to earn a market price for pharmaceuticals sold abroad...But the response to this challenge should not be importing the very drug price controls other countries are using, but rather for the United States to reject this practice and then prevail on peer countries to do likewise.”^{xiii}

- Information Technology & Innovation Foundation, December 31, 2018, Comments on IPI ANPRM

ⁱ Exec. Order No. 12866. 58 FR 51735 (1993).

ⁱⁱ Trump speech to HHS <https://www.npr.org/sections/health-shots/2018/10/25/660641997/trump-aims-to-lower-some-u-s-drug-spending-by-factoring-in-what-other-countries->

ⁱⁱⁱ Id.

^{iv} Best D, Answering Your Questions about the IPI Drug Pricing Model. <https://www.hhs.gov/blog/2018/10/30/answering-your-questions-about-the-ipi-drug-pricing-model.html>. October 30, 2018.

^v Center for Medicare & Medicaid Services. 2019 ASP Drug Pricing Files. <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/2019ASPFiles.html>. (Accessed August 21, 2019)

^{vi} 19 USC 4201

^{vii} The Bipartisan Congressional Trade Priorities and Accountability Act 2015. S. Rept. 114-42.

^{viii} O’Neill Hays T. American Action Forum. Comments To CMS On Proposed International Pricing Index for Medicare Part B Drugs. <https://www.americanactionforum.org/comments-for-record/comments-to-cms-on-proposed-international-pricing-index-for-medicare-part-b-drugs/#ixzz5xA1zufEw>

^{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 Exec. Order No. 12866. 58 FR 51735 (1993)

^{xi} Small Business & Entrepreneurship Council. Re: The Center for Medicare and Medicaid Services (CMS) Proposed Rule – Medicare Programs: International Pricing Index Model for Medicare Part B Drugs (CMS – 5528-ANPRM). <https://www.regulations.gov/document?D=CMS-2018-0132-1159>

^{xii} National Association of Manufacturers. Re: International Pricing Index Model for Medicare Part B Drugs (CMS-5528-ANPRM). <https://www.regulations.gov/document?D=CMS-2018-0132-1603>

^{xiii} Information Technology & Innovation Foundation. RE: Medicare Programs: International Pricing Index Model for Medicare Part B Drugs (CMS-5528-ANPRM). <https://www.regulations.gov/document?D=CMS-2018-0132-1060>