

## Analysis: Trump International Price Index Model Is Not Reference Pricing As Commonly Understood; Maintains U.S. Pricing Premium

On October 25, President Trump unveiled a new proposal that he argued "[takes] aim at the global freeloading that forces American consumers to subsidize lower prices in foreign countries through higher prices in our country." Public Citizen and others have previously debunked this argument.

Prescription drug prices in the United States are higher than those paid in other countries because of the combination of expansive monopoly protections provided in the United States and only very limited measures to counteract that monopoly power through negotiations, price controls or other mechanisms. Moreover, U.S. prices are set by prescription drug corporations to maximize profits, not because of R&D spending.<sup>III</sup>

A key component of the Trump-proposed Medicare Part B demonstration project is to align Medicare payments for certain drugs and biologics more closely with international prices. Typically, international reference pricing systems utilized in other countries set reimbursement rates at an average of what reference countries pay for a particular drug or sometimes the lowest price achieved in reference countries.

Instead, the Trump plan sets a savings goal for the demonstration of reducing Medicare spending on the included drugs by 30% over time and develops a calculation to determine a multiplier to be applied to average international prices that will achieve that savings goal.

Mexico applies a multiplier of 1.72 to the average price of the six countries where the medicine has the highest sales, which reportedly "corresponds to what is normally considered the combined average wholesale and retail margins in Mexico."

Toumi, Mondher, MD, PhD, MSc; Rémuzat, Cécile, PharmD, MSc; Vataire, Anne-Lise, MSc; Urbinati, Duccio, PharmD, MSc. European Commission. (2013, December). External reference pricing of medicinal products: simulation-based considerations for cross-country coordination, Final Report. Retrieved October 31, 2018 from https://ec.europa.eu/health/sites/health/files/healthcare/docs/erp\_reimbursement\_medicinal\_products\_en.pdf

<sup>&</sup>lt;sup>1</sup> "One of the main methods is the calculation of the average price of reference countries (Austria, Belgium, Cyprus, Denmark, Iceland, Ireland, Portugal, Switzerland, and the Netherlands). Another method applied is to use the lowest price among all the reference countries (Bulgaria, Hungary, Italy, Romania, Slovenia (for original drugs and biosimilars), and Spain). Some countries such as Greece, Norway, Slovakia and Czech Republic -the latter only to calculate the maximum price- use the average of the 3 or 4 lowest prices of all countries in the basket. France, with only 4 countries in its basket, applies prices that are similar to those in the reference countries. Malta uses 2 [external reference pricing] systems, one for the private market and one for the public sector medicines. These 2 systems are characterized by different rules; for instance, the average wholesale price of the basket is used for the public sector and an algorithm is used for the private sector for price calculation."

No matter what countries are included as reference countries in the basket, the multiplier applied to average international prices will be adjusted to meet the 30% savings goal.

The administration puts forth the following calculation in the International Price Index Model<sup>y</sup>:

- 1) CMS calculates the average international price<sup>2</sup> for each drug included in the model.
- 2) CMS calculates the International Price Index (IPI) ratio of Medicare spending on the selected drugs at current volumes under the current Average Sales Price (ASP) reimbursement system vs. how much Medicare would be spending on the selected drugs at current volumes if it were paying the average international price for each drug.

3) CMS establishes a Target Price for each drug by "multiplying the IPI by a factor that achieves the model goal of more closely aligning Medicare payment with international prices, which would be about a 30% reduction in Medicare spending for included Part B drugs over time, and then multiplying that revised index (IPI adjusted for spending reduction) by the international price for each included drug" (emphasis added).<sup>3</sup>

IPI  $\mathbf{x} \alpha$  = Target Price multiplier

Where  $\alpha$  is a number that is necessary to result in a 30% overall reduction in Medicare spending for included Part B drugs at the given volumes, so  $\alpha$  = 0.7.

The Administration states in its IPI policy brief $^{vi,4}$  that IPI = 180%, or 1.8.

1.8 x 0.7 = Target Price multiplier 1.26

The 1.26 Target Price multiplier is consistent with the policy brief statement that "[t]he target price is 126% of the average price other countries pay for the drug."

Office of the Assistant Secretary for Planning and Evaluation. U.S. Department of Health and Human Services. (2018, October 25). Comparison of U.S. and International Prices for Top Spending Medicare Part B Drugs. Retrieved October 30, 2018 from:

https://aspe.hhs.gov/system/files/pdf/259996/ComparisonUSInternationalPricesTopSpendingPartBDrugs.pdf

<sup>&</sup>lt;sup>2</sup> Currently the model proposes including pricing data from the following countries: Austria, Belgium, Canada, Czech Republic, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Japan, Netherlands, and the United Kingdom.
<sup>3</sup> CMS would calibrate the Target Price multiplier for the rare instances when ASP is lower than the resulting Target

<sup>&</sup>lt;sup>4</sup> It is worth noting that the 180% figure included in the policy brief seems to be lifted from the HHS analysis "Comparison of U.S. and International Prices for Top Medicare Part B Drugs by Total Expenditures", which did not take into account volume of drugs purchased by Part B in arriving at that figure. With volume taken into consideration, 2016 Medicare Part B spending was ~190% of what it would have been if paid at the international average price.

4) Finally, the Target Price multiplier is applied to the international average price of each drug to determine the Target Price for each drug.

Target Price multiplier  $\mathbf{x}$  ASP<sub>(drug a)</sub> = Target Price<sub>(drug a)</sub>

5) Over the five year period of the Model, the Target Price is phased in and reimbursement is based on a combination of the ASP and the Target Price of a particular drug.

Year	Percentage of ASP and Target Price
Year 1	80 percent ASP and 20 percent Target Price
Year 2	60 percent ASP and 40 percent Target Price
Year 3	40 percent ASP and 60 percent Target Price
Year 4	20 percent ASP and 80 percent Target Price
Year 5	100 percent Target Price

The driving force behind setting reimbursement under the Trump administration proposal is the model goal of reducing spending on the products included in the demonstration by 30% -- not the prices being paid in the reference countries.

As noted above, according to the administration, U.S. prices for the included drugs at the volumes purchased by Part B are 180% of what they would be at the average price for these products in the reference countries, resulting in an IPI of 1.8 and a Target Price multiplier of 1.26.

But if other countries were included as reference countries, it would not impact the overall savings realized under the model because the target price multiplier is derived by "multiplying the IPI by a factor that achieves the model goal of more closely aligning Medicare payment with international prices, which would be about a 30% reduction in Medicare spending for included Part B drugs over time."

For example, if countries were included in the model that pay substantially lower prices than the currently proposed countries, perhaps an IPI would be 3.0 instead of 1.8. The Target Price multiplier would then equal 2.1 (resulting from multiplying 3.0 by 0.7), rather than the 1.26 multiplier resulting from the currently proposed reference countries.

In other words, the Target Price multiplier changes based on the composition of the countries to meet the 30% reduction model goal regardless of what countries are referenced.

However, the composition of countries included as reference countries in the model would matter insofar as they impact the average that those counties pay for one drug included in the model relative to another drug included in the model (but not to the extent they pay lower or higher prices than other countries included in the model overall).

For example, imagine a scenario in which there are only two drugs implicated by the model – Drug A and Drug B. Part B purchases the same volume of each of these drugs and the ASP for each of these drugs is \$180. In the selected reference countries, the international average price for Drug A and Drug B are both \$100. This results in an IPI is 1.8, which in turn results in a Target Price multiplier of 1.26. The Target Price for Drug A would be \$126, and the Target Price for Drug B would be \$126. Medicare Part B spending would be 30% less than it was once the Target Prices are fully phased in.

Now imagine another scenario in which a different set of reference countries is used. In these countries, the average international price for Drug A is \$75 and the average international price for Drug B is \$125. The ASP in the U.S. for these drugs is still \$180 for each drug. In this scenario, the IPI would also be 1.8, which in turn would result in a Target Price multiplier of 1.26. But the Target Price for Drug A would be \$94.50 and the Target Price for Drug B would be \$157.50. Medicare Part B spending would still be 30% less than it was once the Target Prices are fully phased in, but the extent to which prices are impacted for Drug A and Drug B would be much different.

Finally, President Trump's rhetoric about the proposal, even when Target Prices are fully phased in, the model would maintain a U.S. pricing premium for drugs with international average prices at least 30% below prices paid under the U.S. ASP system.

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<sup>&</sup>lt;sup>1</sup> Associated Press. (2018, October 25). Trump Says New Proposal Will Lower Some US Drug Prices. *The New York Times*. Retrieved October 31, 2018 from: <a href="https://www.nytimes.com/aponline/2018/10/25/us/politics/ap-us-trump-prescription-drug-prices-.html">https://www.nytimes.com/aponline/2018/10/25/us/politics/ap-us-trump-prescription-drug-prices-.html</a>

<sup>&</sup>lt;sup>ii</sup> Public Citizen. (2017, June). Exporting Monopoly Rules Does Not Lower U.S. Prescription Drug Prices. Retrieved October 31, 2018 from: <a href="https://www.citizen.org/system/files/case">https://www.citizen.org/system/files/case</a> documents/trump-drug-pricing-eo-trade-and-monopolies-memo.pdf

iii Office of the Assistant Secretary for Planning and Evaluation (ASPE). (Dec. 7, 2016). Prescription Drugs: Innovation, Spending, & Patient Access. U.S. Department of Health & Human Services. Retrieved October 31, 2018 from: <a href="https://delauro.house.gov/sites/delauro.house.gov/files/Prescription-Drugs-Innovation-Spending-and-Patient-Access-12-07-16.pdf">https://delauro.house.gov/sites/delauro.house.gov/files/Prescription-Drugs-Innovation-Spending-and-Patient-Access-12-07-16.pdf</a>

<sup>&</sup>lt;sup>iv</sup> Centers for Medicare & Medicaid Services. (2018, October 25). ANPRM International Pricing Index Model for Medicare Part B Drugs. Retrieved October 31, 2018 from: <a href="https://www.cms.gov/newsroom/fact-sheets/anprm-international-pricing-index-model-medicare-part-b-drugs">https://www.cms.gov/newsroom/fact-sheets/anprm-international-pricing-index-model-medicare-part-b-drugs</a>

<sup>&</sup>lt;sup>v</sup> Center for Medicare & Medicaid Services. (2018, October 25). Medicare Program; International Pricing Index Model for Medicare Part B Drugs, Advance notice of proposed rulemaking with comment. Retrieved October 30, 2018. https://www.cms.gov/sites/drupal/files/2018-10/10-25-2018%20CMS-5528-ANPRM.PDF

vi HHS Press Office. (2018, October 25). What You Need to Know about President Trump Cutting Down on Foreign Freeloading. Retrieved October 30, 2018 from: <a href="https://www.hhs.gov/about/news/2018/10/25/ipi-policy-brief.html">https://www.hhs.gov/about/news/2018/10/25/ipi-policy-brief.html</a> vii HHS Press Office. (2018, October 25). What You Need to Know about President Trump Cutting Down on Foreign Freeloading. Retrieved October 30, 2018 from: <a href="https://www.hhs.gov/about/news/2018/10/25/ipi-policy-brief.html">https://www.hhs.gov/about/news/2018/10/25/ipi-policy-brief.html</a>