International Reference Pricing: How it Works and Considerations

Introduction

The administration's potential International Pricing Index (IPI) Model for Medicare Part B Drugs would use "reference pricing" in an attempt to lower U.S. prescription drug costs. In simple terms, this means that Medicare would calculate a ceiling for U.S. drug prices by looking to the prices paid in other countries with lower drug spending. While there are several legislative proposals that use international reference prices to address high drug costs in various ways, the administration's IPI model is the most prominent effort to actually enforce reference pricing as policy and serves as a helpful example for understanding the concept as a whole.

At the start, it is important to consider that other countries' drug costs are kept down by government interventions that the U.S. has not enacted—suggesting that any use of reference pricing must be just one aspect of more systemic change in order to have long-lasting impacts. This brief explains the administration's potential IPI model before providing an overview of how drug pricing works in other countries. It closes with an analysis of questions and possible unintended consequences raised by the model that must be addressed with broader reforms.

THE ADMINISTRATION'S IPI PROPOSAL

It is estimated that Medicare Part B pays 1.8 times that which other countries do on the same drugs.[1] Seeking to address this problem, on October 25, 2018, the Centers for Medicare and Medicaid Services (CMS) published an advanced notice of proposed rulemaking (ANPRM) seeking public input on an International Pricing Index (IPI) Model for Medicare Part B Drugs, with the stated goal of reducing Medicare Part B spending by 30 percent. A proposed rule is expected in 2019 with the potential model to start in spring 2020 and last for five years.[2] Regardless of the final proposal, the ANPRM itself is an example of how international reference prices could be introduced into the U.S. system.

Currently, Medicare Part B reimburses through a buy and bill model, where the physician or hospital will purchase and store the drug until it is administered to the patient. The physician or hospital is then reimbursed based on Average Sales Price (ASP) plus a six percent add-on payment.[3]

The potential model[4] would test changes to this system by requiring physicians and hospitals in selected geographic regions to participate. Physicians and hospitals mandated to participate in the model would receive their Part B drugs from private vendors[5] that may include group purchasing organizations (GPOs), wholesalers, distributors, specialty pharmacies, individual or groups of physicians and hospitals, manufacturers, Part D sponsors, and/or other entities. CMS stated it will select at least three vendors to encourage competition.[6]

Those vendors would be reimbursed using IPI-determined rates, shifting away from ASP. CMS is proposing to calculate an average international price for each Part B drug and establish a "target price" for each Part B drug. CMS would then phase in the target price as reimbursement rates to vendors. The "target price" will be 126 percent[7] of the average international price (the "reference price") which will be based on data from Austria, Belgium, Canada, Czech Republic, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Japan, Netherlands, and the United Kingdom.[8]

For prescription drugs without prices established yet in other countries, the proposal suggests that a "standard factor" could be calculated in some manner to create a

temporary price.[9] Once other countries begin selling the prescription drug, the standard factor price would presumably be replaced by the target price generated from other countries once actual price information would be available. Details in this section of the ANPRM are light, and the administration specifically requests feedback on how to calculate prices for new drugs.[10]

Under the potential IPI model, physicians and hospitals would still receive an add-on payment above/beyond the reimbursement for the drug; however, the add-on payment will be converted to a flat rate paid per encounter or per month for an administered drug. CMS believes this add-on payment structure removes incentives for providers to prescribe high cost drugs. This alternative add-on payment structure would be budget neutral. Physicians and hospitals would still be responsible for collecting cost-sharing from the patient as well.[11]

DRUG PRICING POLICY IN OTHER COUNTRIES

Adopting international reference pricing would implicitly import not only prices, but the cost savings that have resulted from different regulatory schemes abroad. And while some of the countries listed in the ANPRM use international price referencing, these countries also have complex systems in place—such as government-run negotiation processes or comparative-effectiveness research standards that influence pricing—that create a backstop to price spikes. America does not yet have any such protections, which could introduce significant issues in implementing an IPI model that will be discussed more below. To better understand this disconnect, however, it is first helpful to understand the basics of other countries' approaches to drug pricing.

England

The National Health Service (NHS) is the primary purchaser of pharmaceutical products in England. The Department of Health, which oversees the NHS, negotiates with pharmaceutical manufacturers for a voluntary agreement called the Pharmaceutical Price Regulation Scheme (PPRS) to regulate costs and spending on branded drugs. The PPRS is renegotiated every five years.[12] In the most recent PPRS for 2019 to 2023, the agreement allows for 2 percent growth each year.[13] The Association of the British Pharmaceutical Industry reports that the PPRS has helped the NHS's spending growth on drugs remain stable at 1.1 percent, where the wider NHS spending has risen by 3.3 percent.[14]

In addition, while not a direct part of the negotiation process, the National Institute for Health and Care Excellence (NICE) evaluates the clinical and cost-effectiveness of new drugs before approving drugs to go to market.[15] NICE assesses and evaluates new drugs based on quality-adjusted life years (QALYs), which measure gains in life expectancy and quality of life.[16] When NICE approves a drug, it must come to market within 90 days of approval. Pharmaceutical companies may give discounts on higher priced brand-name drugs in order to receive NICE's approval.

Germany

Germany enacted the Pharmaceutical Market Restructuring Act (ANMOG) to manage prescription drug costs. Under this law, prescription drugs that enter the market must prove that they are clinically superior to the products that are currently on the market. If a drug is not deemed clinically superior to its predecessors, insurance companies cover the cost up to an equivalent drug on the market through a process referred to as internal reference pricing, and the patient may pay the difference for the new drug if they desire it over the equivalent drug. If internal reference pricing is not possible, the new clinically non-superior drug is negotiated under a process similar to a drug deemed clinically superior.[17]

The drugs that are deemed clinically superior to the predecessors are priced using negotiations. Negotiations begin after one calendar year of a clincically superior drug being sold on the market and if negotiations fail after six months, external reference pricing is used as an international benchmark, and a three-person binding arbitration committee defines the reimbursement level.[18] All negotiation or arbitration set prices take affect after the first year. During the first year on the market, manufacturers may set prices unilaterally.[19]

Canada

Canada's Patented Medicine Prices Review Board (PMPRB), established in 1987, is responsible for regulating brand-name prescription drug prices if a patented drug's price is found to be excessive.[20] In the Canadian process, a brand-name drug is evaluated based on the price sold in relevant markets, in similar therapeutic classes in relevant international markets, in the same therapeutic class, changes in the Consumer Price Index, and other factors set out by regulation.[21] If a brand-name drug's price is deemed to be excessive, the PMPRB will hold public hearings and require price reductions.

As part of this process, Canadian officials create an international reference price to be the maximum average potential price for a newly patented drug. This number is updated annually and is the average price of the brand-name drug in France, Germany, Italy, Sweden, Switzerland, the United Kingdom, and the

United States. If a drug is sold in less than five countries at the time it is first sold in Canada, officals calculate the drug's median international price and reevaluate this price after three years.[22] Individual provinces purchase prescription drugs from manufacturers and may use the reference price when setting drug prices for each province's public drug plan.[23] In 2010, provinces created the pan-Canadian Pharmaceutical Alliance to negotiate prices below the reference price and use bulk purchasing.[24]

ASSESSING THE USE OF INTERNATIONAL REFERENCE PRICING IN THE U.S.

When evaluating the potential use of IPI domestically, it is helpful to keep in mind the examples above—borrowing prices from other countries to influence a relatively small part of U.S. drug spending will not solve the broader issue of the lack of effective domestic drug pricing policies writ large. In addition to this broader issue, the administration's potential IPI model has important outstanding questions that could help inform implementation of international reference pricing not only in the Part B program but in a variety of other policy settings as well.

To start, the administration does not provide clarity on how prices would be set for new drugs not yet sold internationally. The proposal does not suggest a detailed approach of how a model payment for new drugs would be calculated, and is silent on how many countries have set a price for a prescription drug in order for the target price to kick in and what the transition process to a target price would be. The number of prescription drugs that could be affected by the transition from this temporary price and the eventual target price is significant: In 2017, 88 new drugs were approved in the United States compared to 51 new drugs in the European Union.[25] Policies to address the prices of new drugs must be an important part of any reform efforts.

The administration's potential model also has implementation hurdles to overcome that illuminate the need for any proposal incorporating international reference prices to address how the model would influence the current drug supply chain. For example, the model works to lower the price by having the government setting the price of prescription drugs to vendors at 126 percent of the average reference price. Vendors then negotiate with pharmaceutical companies to purchase the products below 126 percent, and keep the spread—their incentive for participating in the system. We do not know, however, if it is possible for vendors to be able to get under 126 percent from pharmaceutical companies and make a profit. Because of that, requirements to ensure drugs enter the market are needed.

Finally, due to the United States market share compared to other countries, any IPI model must consider the possibility of unintended international consequences. For example, a company could consider strategically launching their prescription drugs in certain countries that will have the highest price, keeping the price in the United States as high as possible. This would have two negative consequences, keeping the price in the United States higher than expected and not launching the prescription drug in countries with small market shares in a timely manner. As with considering the lack of clarity on how new drugs would be treated under the model, this issue also points to the need for robust policies to ensure the U.S. system adopts broader reforms past reference pricing that would discourage such gaming.

CONCLUSION

Before finalizing a model, the administration will collect comments that will further shape the IPI model. In order to fully judge the impact this model, we must wait for more details of the plan to emerge but the issues the ANPRM raise in regard to international price referencing generally will remain instructive for other future policy proposals as well. Regardless of the eventual details, however, the fact remains that the IPI model is designed to garner the lower prices of countries that have put more policies into place to achieve affordable drugs—officials in the U.S. must work toward enacting similarly comprehensive policies for patients to truly see significant savings.

ENDNOTES

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3 But note: "While the statutory payment rate remains ASP + 6 percent, the sequestration provisions of the Budget Control Act of 2011 mandate a 2 percent reduction across Medicare expenditures. Because the sequester does not affect the patient copay component of reimbursement, the 2 percent cut means that the effective payment rate for Part B is now ASP + 4.3 percent." Werble, C. (2017, August 10). *Medicare Part B*. https://www.healthaffairs.org/do/10.1377/hpb20171008.000171/full/

4 The model is based on the Competitive Acquisition Program (CAP), which was in place from 2006 to 2008. In the IPI model, CMS proposes to have vendors purchase the drugs and bill Medicare, removing physicians and hospitals from performing these tasks. Vendors would also be responsible for negotiating with manufacturers for drug acquisition prices, taking title to the drugs, and competing for physician and hospital business.

5 CMS anticipates the selected geographic regions would include 50 percent of Part B spending on drugs. Center for Medicare and Medicaid Services (CMS), HHS. (2018, October 25). *Medicare Program; International Pricing Index Model for Medicare Part B Drugs*. Retrieved from https://www.cms.gov/sites/drupal/files/2018-10/10-25-2018%20CMS-5528-ANPRM.PDF

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