CMS considers foreign drug prices to hold down Medicare Part B spending

An early-stage regulatory proposal put forth by the Trump administration would seek to set reimbursement prices for pharmaceutical products based on what a selection of foreign countries pay for those same drugs. While the preliminary impacts of the proposal—if enacted—on Medicare Part B would be small compared to overall pharmaceutical spend in the US, the impact on a handful of companies would be substantial, and the model could serve as a precursor to cost-controlling efforts in other government programs like Medicaid, according to an analysis by PwC’s Health Research Institute (HRI).

The International Pricing Index (IPI) proposal, released on Oct. 30, 2018, as an advance notice of proposed rulemaking, is part of a broader attempt by the Trump administration to rein in drug pricing, in part by inducing greater competition in the US. The proposal would base reimbursement of drugs in the Medicare Part B program on prices paid for the same drugs in 14 countries including Canada, Japan and 12 European countries.

CMS officials estimate using target prices based on foreign competition could reap substantial savings for Medicare Part B—and about 30 percent on a per-drug basis. Between 2020 and 2025, they expect to generate net savings of $17.9 billion for Part B, as well as $1.8 billion in reduced Medicaid spending due to impacts on the dual-eligible population.

According to an HRI analysis of data from HHS’ Office of the Assistant Secretary for Planning and Evaluation (ASPE), if the US adopted volume-weighted international pricing, five companies would be expected to lose revenue of $500 million per year or more—the difference between their international and domestic prices. Another six companies have between $100 million and $500 million in annual revenue at stake.

The proposed program would be phased in over five years, starting in 2020, and initially focus on single-source drugs encompassing a high percentage of drug utilization and spending (years one and two of the IPI pilot program). Starting in year three, the program would add other drugs and biologicals (see Figure 1).

Limiting drug price growth

Because prices under the IPI model would be tied to countries that have pricing regulators, which limit price increases, the IPI model could also limit pricing growth under Part B and reduce long-term spending.

Between 2012 and 2016, 27 percent of drugs covered by Medicare Part B saw greater than 10 percent annual average growth in the cost per dose, according to an HRI analysis of CMS data. Another 40 percent saw some form of increase. Those pricing increases helped drive Medicare Part B drug spending up from $18.1 billion in 2012 to $25.7 billion in 2016, according to an analysis of Medicare spending data by HRI.
Figure 1 – CMS’ International Pricing Index model would significantly differ from how Medicare Part B currently pays for drugs

<table>
<thead>
<tr>
<th>Policy element</th>
<th>Current practice</th>
<th>Proposed model</th>
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<tbody>
<tr>
<td>Reimbursement model</td>
<td>Average Sales Price (ASP), inclusive of any rebates and discounts</td>
<td>International Pricing Index model based on a market basket of 15 countries. CMS would calculate the average international price for each drug, and then set a target price. The aim is to achieve a 30 percent reduction compared to US-based ASP.</td>
</tr>
<tr>
<td>Payment coverage</td>
<td>All drugs under Part B, nationwide</td>
<td>Initial test to focus on Part B drugs, biologics and biosimilars encompassing a high percentage of drug utilization and spending and made by a single manufacturer. Starting in year three of the program, additional Part B drugs would be added. Drugs in short supply would be excluded from the program so as to not exacerbate the shortage.</td>
</tr>
<tr>
<td>Country from which pricing model is based</td>
<td>United States</td>
<td>Austria, Belgium, Canada, Czech Republic, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Japan, Netherlands, and the United Kingdom.</td>
</tr>
<tr>
<td>Phase-in period</td>
<td>None</td>
<td>Would be phased in over five years, starting at a blend of 80 percent of ASP and 20 percent of the IPI-based target price, and adjusting 20 percent each year until 100 percent of the IPI-based target price is achieved.</td>
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Source: PwC Health Research Institute analysis of CMS’ Medicare Part B IPI proposal

While pharmaceutical and biological products would ordinarily not be subject to US competition until the dates their patent protection or marketing exclusivities expired, the administration’s International Pricing Index approach would have these drugs essentially “compete” with prices paid by foreign governments, even if patent exclusivity remains in effect.

The effect of this policy change would be substantial, opening up 29 of the top 50 drugs under Medicare Part B to competition, according to an analysis of 2016 Medicare drug data and 2018 patent data by HRI (see Figure 2). Those drugs accounted for $14.4 billion in spending in 2016 and the vast majority are biological medicines. While biological medicines haven’t seen much competition in the US, they have in the EU, and the IPI model would take advantage of that competition to drive domestic prices lower. As of Dec. 31, 2018, just 16 biosimilar products had obtained FDA approval, of which just six were actively marketed, according to an HRI analysis. In comparison, the European Medicines Agency has authorized the use of 52 biosimilar medicines across Europe as of the end of 2018. Crucially, many of these products are actively marketed.

While the initial impact of the IPI model will affect just a small number of top-spending drugs—single-source drugs encompassing a high percentage of drug utilization—the impact on the Medicare Part B program would still be considerable.

According to an HRI analysis, the top 50 products reimbursed under the Part B program made up 83 percent of total spending, while the top 25 products made up 65 percent of all spending (see Figure 3). Reducing the prices paid for these drugs would therefore reap substantial savings for Medicare Part B. Just 476 drugs were paid for by Medicare Part B in 2016, compared to 2,828 by Part D, so even small changes have a disproportionately large impact on the program.
Critical reaction

Pharmaceutical companies and trade groups are critical of the administration’s proposed IPI model, arguing that it could stifle innovation. “By benchmarking US prices to prices in other countries, [HHS] will impede the development of and patient access to novel treatment options,” the Biotechnology Innovation Organization (BIO), a trade group representing biopharmaceutical companies, wrote in comments responding to the rule. BIO further argued that the proposal could negatively impact investment by smaller start-up companies that might develop drugs for an indication affecting a large population of Part B patients, like autoimmune diseases or some rare diseases.

The Pharmaceutical Research and Manufacturers of America (PhRMA), a pharmaceutical trade group, wrote in its comment letter that it was critical of the proposal’s potential to circumvent patents by leveraging foreign products’ pricing. “Because the US Constitution assigns sole responsibility for defining the scope of patent rights to the Congress, not the executive branch, importing prices derived from these foreign patent regimes raises constitutional separation of powers concerns,” the group wrote in comments.

PhRMA suggested, like BIO and most pharmaceutical companies commenting on the proposal, that HHS pursue market-based reforms to Part B instead of the IPI model.

Implications

Companies should assess their commercial launch strategies. The IPI proposal could alter the launch-timing dynamic for some companies, which might choose to heavily delay entry outside of the US, launch different versions of their products elsewhere or raise rates abroad. Biopharmaceutical companies generally seek to enter as many markets as possible, as quickly as possible, with the US often forming the first in a chain of countries. More than 66 percent of pharmaceutical companies launch first in the US compared to the EU.

Timing is another key concern with the model. While CMS has proposed that international pricing data be updated on a quarterly basis, it has not proposed the number of countries that would constitute a complete “basket” of countries. It remains unclear if a single market would constitute a “full” basket on which the US reimbursement allowance would be based. For new drugs entering the market, CMS has said it may apply a standard required discount. It is also unclear which measures might be used for volume weighing, price smoothing, and whether price would be based on the exact molecule or biosimilars and their respective indications.

The Trump administration says it expects the rule to raise prices abroad, which will likely put significant pressure on companies to either eat the difference in rates or act to further US policy goals in general. This could result in reputational harms, especially if the industry is accused of increasing prices or denying patients outside of the US access to the latest medications.

Figure 2 – Most of Medicare Part B’s spending is protected by patents
But the International Pricing Index model would open all Part B products to foreign competition

2016 spending on the top 50 drugs, by market pathway and patent status

<table>
<thead>
<tr>
<th>Orange Book-listed chemical drugs*</th>
<th>Purple Book-listed biological products</th>
</tr>
</thead>
<tbody>
<tr>
<td>Spending on drugs with expired patents</td>
<td>$5,161,960,157</td>
</tr>
<tr>
<td>Spending on drugs with active patents</td>
<td>$11,829,992,772</td>
</tr>
<tr>
<td>$1,887,762,379</td>
<td>$2,552,386,762</td>
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Note: Orange Book-listed drugs are typically chemically based, and are brought to market through the New Drug Application process. Purple Book-listed drugs are biologically-based drugs, and are brought to market through the Biologies License Application process. HRI’s Orange Book analysis includes one product, hyaluronic acid, approved as a medical device but now believed by FDA to be a drug.
Companies should assess the potential impacts of the proposal on their revenues. Medicare Part B is a small program, but for the companies involved in it, it brings in significant revenues. Companies should assess how much revenue may be at stake for their products, both now and in the future.

Companies may need to settle on a potential range of revenue rather than a specific number. CMS says it plans to multiply the average international price by “a factor” to achieve price reductions of “about” 30 percent, but has thus far declined to define either the methodology behind that factor or whether certain drugs may be treated differently. Some drug products may experience major reductions in price under the model, such as for drugs that are on patent in the US, but have generic or biosimilar competition in a foreign country. ASPE data show that compared to international products, top-spending Medicare Part B drugs were 1.8 times as expensive on average, while three drugs were more than four times as expensive.

Not all revenue losses will be immediate, as the program has a five-year phased-in implementation. However, more products are expected to be added to the program over time, and the model could spread to other public health programs as well. HHS says operation of the model is expected to begin in the spring of 2020 and run through spring of 2025, giving companies time to plan.

Companies should think about operational needs. Companies may need to build out new operational capabilities in order to support the data reporting HHS wants under its model since most companies don’t have unified global drug pricing data reporting systems.

This is also not as simple as it may initially seem. Many drugs are approved in other countries based on different indications, dose amounts, or even chemical or biological properties. The specifics about how to interpret and report this data will be challenging. Another key challenge: Maintaining confidentiality of contract terms so that competitors can’t reverse-engineer companies’ contracts to under-bid them in foreign markets.