Q&A: A Model Act to Reduce Prescription Drug Costs Using International Pricing

How does this model act use international pricing to reduce prescription drug costs?
Drug prices in other countries are often many times lower than in the United States. This model legislation determines payment rates for certain prescription drugs based on international prices, and establishes the referenced rate as the upper payment limit for payers within a state.

Isn’t that price fixing?
No. Setting a payment rate in reference to international prices does not dictate what a manufacturer can charge for a drug – but it does limit how much payers in a state pay. A law enacted in Washington, DC that did attempt to use international reference pricing to set prices for costly drugs was struck down in a 2007 Federal Court of Appeals ruling for violating federal patent law. Unlike that law, this model act does not run afoul of patent law because it does not limit a manufacturer’s ability to set their own prices. Furthermore, because the model act focuses strictly on rates paid by selected purchasers within a state, it does not impact interstate commerce – an issue that led to the demise of Maryland’s 2017 anti-price-gouging law. A legal analysis of this model act, commissioned by the National Academy for State Health Policy (NASHP), provides additional details about how this act avoids legal pitfalls related to patent preemption and regulating commerce across state laws.

Which country/countries does this model use to determine international reference rates?

How do states access the pricing information they need?
This model act uses price data from the four most populous Canadian provinces (Ontario, Quebec, British Columbia, and Alberta) to compare drug prices between the United States and Canada. It then takes the lowest drug price as the referenced rate for payers in a state. If prices are not available for the provinces, the model act instead refers to the ceiling price set by Canada’s Patented Medicine Prices Review Board (PMPRB) for referenced rates, which are posted online.

How does Canada determine prices?
Canada’s PMPRB uses international reference pricing, among other factors, to establish maximum prices that set a ceiling for brand-name drug prices in Canada. As of January 2021, the basket of countries referenced by the PMPRB will include Australia, Belgium, France, Germany, Italy, Japan, the Netherlands, Norway, Spain, Sweden, and the United Kingdom. Provinces negotiate their own prices with manufacturers, which are under the ceiling price established by the PMPRB.

Because collecting and comparing prices across a basket of countries is time- and resource-intensive, states can instead rely on Canadian provincial prices that are determined in reference to other international prices.
How much will states save on their drug spending if they use this approach?

Prices in Canada can be dramatically lower than in the United States. While a number of states have passed laws to import drugs from Canada in order to capture those savings, this model act allows a state to “import” the drugs’ prices instead of the actual drugs. For example, the rheumatoid arthritis drug Xeljanz is $76.07 for a 5-mg tablet in the United States, while the lowest price for the drug across Canada’s four largest provinces is $16.96. The table below provides additional comparisons, with savings ranging from 60 to 85 percent off US prices, for an average savings of 75 percent for these examples.

<table>
<thead>
<tr>
<th>Drug*</th>
<th>US (NADAC)**</th>
<th>Quebec</th>
<th>Alberta</th>
<th>Ontario</th>
<th>British Columbia</th>
<th>Canadian PMPRB Maximum Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>Xeljanz [5 mg] (rheumatoid arthritis)</td>
<td>$76.07</td>
<td>$16.96</td>
<td>$17.49</td>
<td>$17.59</td>
<td>$18.47</td>
<td>$21.28</td>
</tr>
<tr>
<td>Eliquis [2.5 mg] (anticoagulant)</td>
<td>$7.53</td>
<td>$1.17</td>
<td>$1.19</td>
<td>$1.19</td>
<td>$1.29</td>
<td>$2.78</td>
</tr>
<tr>
<td>Epicusa [400/100 mg] (hepatitis C)</td>
<td>$869.05</td>
<td>$521.43</td>
<td>$521.43</td>
<td>$521.43</td>
<td>$531.86</td>
<td>$722.86</td>
</tr>
<tr>
<td>Zytiga [250 mg] (cancer)</td>
<td>$87.63</td>
<td>$20.68</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>$36.96</td>
</tr>
</tbody>
</table>

* Prices, effective as of June 2020, represent unit cost (i.e., per tablet, pill, etc.) in US dollars, converted at an exchange rate of $1 CAN = 73 cents USD.
+ Price not available online.

States considering this model act can work with NASHP to determine their savings by comparing Canadian referenced rates to current drug prices and utilization rates in their states. NASHP has a savings worksheet that it can provide, along with assistance, for states to use for this analysis.

Won’t this hurt state efforts to import drugs from Canada?

The federal government is currently scheduled to issue a final rule enabling importation from Canada by December 2020. The draft rule had several significant barriers that must be addressed in the final rule to make importation feasible. As states await the final rule, applying international referenced rates is another cost savings strategy, allowing states to import more affordable drug payment rates from Canada as an alternative to importing actual drugs. Furthermore, federal law prohibits the importation of several major classes of drugs, such as controlled substances, biological products, infused and parenteral drugs, intravenously injected drugs, and drugs inhaled during surgery. International referenced rates can help reduce costs for drugs that are ineligible for importation – including well-known examples, such as Humira, a medication for rheumatoid arthritis.

Is rate setting already in use?

Yes – determining maximum payment levels or payment rates for health care and other public goods is a state practice that has existed for decades. States regulate insurers and other public goods and services in markets with little or no market competition and set payment rates for
health services through their public purchasing. This model act extends that precedent to prescription drugs by using international prices as reference points to set fair payment rates.

Will international prices be used for setting payment rates for all drugs within a state?
No. In order to limit the administrative activity necessary to implement this model while also maximizing its impact, the model act limits international referenced rates to the most costly 250 drugs sold within a state based on net price multiplied by utilization.

How would it work?
The state’s superintendent of insurance, in consultation with the board of pharmacy and the state’s employee health insurance plan, would generate a list of the state’s 250 costliest drugs which would be subject to international referenced rates. The costliest drugs would be determined by looking at net price multiplied by utilization for the state employee health insurance plan.
The superintendent of insurance would determine the equivalent Canadian prices for the 250 drugs in the top four most populous Canadian provinces and the PMPRB’s ceiling price. The lowest drug price, which in some cases may be the current US wholesale acquisition price or list price, would be published as the legal upper payment limit for those drugs for participating purchasers within a state.

What about self-funded plans?
States cannot compel self-funded plans regulated under ERISA to participate, however, this model act creates an opt-in option for self-funded plans. Many plans may elect to participate in order to benefit from savings captured by paying lower rates.

How are savings passed on to consumers?
The model act directs participating plans to utilize savings to reduce costs for their members. Participating plans must submit a report to the superintendent of insurance indicating how much they saved by participating and how they passed those savings on to consumers. Self-insured plans that elect to opt-in to the program must also accept these terms as conditions for their voluntary participation.

What about Medicaid?
Because Medicaid is a federal/state partnership subject to unique and complex policies, the model act excludes Medicaid programs. Medicaid programs are already able to access deeply discounted prices for prescription drugs under the Medicaid Drug Rebate Program.

Won’t pharmacies end up getting penalized if list prices for drugs are higher than payment rates?
The model act protects pharmacies from getting squeezed between payers and manufacturers by prohibiting pharmacies from purchasing drugs at a rate higher than the international referenced rate. Pharmacies are still free to charge reasonable dispensing fees.

What about rebates?
Setting an international reference rate does not limit rebates or other price concessions negotiated between payers and drug manufacturers. Rebates and other price concessions would certainly
continue for drugs that are not subject to international reference rates. For high-priced drugs affected by this model act, the rebate mechanism should no longer be necessary – however it is not prohibited.

**How is this model act enforced?**

Payers are subject to a fine of $1,000 for each individual transactions in which payment for a referenced drug exceeds the referenced rate.

**What happens if a manufacturer refuses to sell a drug that is subject to an international reference rate in the state?**

Any manufacturer that withdraws a drug from sale in a state in response to this model act must notify the state 180 days before doing so. The superintendent of insurance may assess a penalty on a manufacturer for withdrawing the drug from the state and use the funds – and the advance warning – to ensure continued access to the drug for the state’s consumers.

**The examples in this table compare Canadian prices to prices listed in the Centers for Medicare & Medicaid Services’ (CMS) National Average Drug Acquisition Cost (NADAC) database. CMS determines the NADAC prices for outpatient drugs by averaging invoice prices reported to CMS from retail community pharmacies. Canadian prices listed in the provincial formularies represent the prices that public programs will reimburse pharmacies for a certain drug, excluding dispensing fees and in some cases a mark-up for wholesalers. Although NADAC and Canadian formulary prices are not exact equivalents, NADAC pricing is an adequate proxy for estimating potential savings from referenced rates, and may indeed even underestimate savings.**

*August 2020*