

State Wholesale Importation Program Explained



Rationale

Because the federal government has not been able to agree on an approach to constrain prescription drug prices, states need to address the problem. Study after study show how U.S. consumers pay the highest prices in the world for life-saving and life-enhancing drug treatments. The prices we pay may fund the research and development that benefits the entire world but those same prices make treatment options unavailable here at home if patients cannot afford their medicines or public programs cannot finance expensive treatments for everyone in need.

We don't need to scour the world to find substantially better prices and we don't need to engage in risky drug purchasing strategies to obtain lower-cost prescription drugs. We need only look across the border to Canada.

A 2013 Canadian Price Board study found that we pay about twice as much for brand name drugs.* Below is a table with recent, point-in-time price comparisons for a selection of brand prescription medications. Per-unit prices were found in the formulary provided by the Government of Saskatchewan and compared with wholesale acquisition cost (WAC) prices in CMS' National Average Drug Acquisition Cost (NADAC) database. In instances where NADAC data was not available Drugs.com provided U.S. data.

* 2013 Annual Report." Ottawa, Ontario. September 15, 2013. Accessed online at: http://www.pmprb-cepmb.gc.ca/CMFiles/Publications/Annual%20Reports/2013/2013-Annual-Report_2013-09-15_EN.pdf

Table 1. Unit Price Comparison of High-Cost Patented Non-Biologic Drugs

Product	United States ^{1, 2}	Canada (in USD) ³
Advair-Diskus (100 mg capsule) GSK	\$9.52	\$3.96
Eliquis (5 mg tablet) Bristol-Myers Squibb	\$6.21	\$1.60
Harvoni (90/400 mg tablet) Gilead Sciences	\$1,090.35	\$797.62
Lyrica (25 mg capsule) Pfizer	\$6.04	\$0.63
Strattera (100 mg tablet) Eli Lilly	\$14.81	\$3.96
Tecfidera (120 mg capsule) Biogen	\$119.24	\$11.92
Tracleer (125 mg tablet) Actelion Pharmaceuticals Ltd	\$173.09	\$47.18
Triumeq (300 mg tablet) ViiV Healthcare	\$83.36	\$31.51
Xarelto (15 mg tablet) Janssen, Inc	\$12.44	\$2.11

^{1.} Centers for Medicare and Medicaid Services. Medicaid.gov. National Average Drug Acquisition Cost. Accessed online May 22, 2017 at https://www.medicaid.gov/medicaid/prescription-drugs/pharmacy-pricing/index.html

The Idea

A U.S. state could implement a wholesale drug importation program to purchase drugs from Canada that are approved for sale on the Canadian market. These drugs are on the market in full compliance with Canadian law and regulation.

A state-administered wholesale drug importation program could be large or small:

- Available to all state residents or just people covered under state payer programs (such as state employees and prisons);
- Include all state-licensed payers, distributors, and dispensers, or just a subgroup; and
- Include many drugs or just a small number of products.

What the Wholesale Importation Program IS NOT

The state-administered wholesale importation program is not a program of personal importation. A personal importation program – even if state-administered – cannot assure the safety, potency, or purity of products shipped from Canada to individual patients. Such a program also cannot assure that consumers will save money.

All current public policy discussions surrounding the dangers of importation apply to only personal importation. In contrast, a state-administered wholesale Canadian drug importation program can assure product safety, potency, and purity, as well as consumer cost savings.

^{2.} Drugs.com. Accessed online at https://www.drugs.com/

^{3.} Government of Saskatchewan. Saskatchewan Online Formulary Database. Accessed online May 22, 2017 at http://formulary.drugplan.ehealthsask.ca/

What the Wholesale Importation Program IS

A state would administer a wholesale importation program by contracting with a fully licensed, regulated Canadian suppler that is required to provide only drugs that are fully regulated and compliant with Canadian law. The state may decide to license the Canadian supplier under its own laws, as well. While the state is the responsible party, it would contract with a state-licensed wholesaler, operating under the terms of the state program, to handle the imported product and manage distribution to state-licensed retail pharmacies. Shipments from Canada would be tested on a sample basis for purity and potency by a state agency or contractor. Products would be labeled properly for the U.S. market and distributed out to retail pharmacies and any other settings included in the program. Just as in the regular commercial market, retail pharmacies and other dispensing settings order and pay for products. The state government is not providing free products. Rather, it is simply taking responsibility for importing product from Canada that is then distributed and purchased through commercial channels.

Imported drug product cannot be shipped or dispensed out of state. Even if there are state-licensed dispensing entities outside the state, those entities cannot receive imported product. This prohibition ensures that the state levers to control safety and cost savings are effective, while providing additional assurances of minimal risk to the federal government, which needs to approve the program.

To ensure that consumers see the savings, all entities choosing to participate must limit their profit/margin/markup on imported drugs. Wholesalers and distributors will charge for administrative services with limits set by the state to be paid by product purchasers. Pharmacies and other dispensers will bill payers at the acquisition cost (the Canadian price without mark-up). That price can be made publicly available via a state website. Pharmacies and other dispensers will charge the Canadian price without mark-up for uninsured people or people in their deductible period. Health plans and other payers will pay dispensers for the product at the Canadian price without mark-up, and the product reimbursement will be separate from professional fees (as it is today). Health plans will design their pharmacy benefits so that enrollee cost sharing is based on the Canadian price without mark-up. Health plans will also demonstrate to the state how they apply savings on drugs to premium calculations.

In addition to administering the program, the state will establish a routine audit function to ensure that the program is cost-effective, safe, and that consumers are benefitting financially from the program.

The state administrative functions can be financed by a fee. A fee on each dispensed prescription to be paid by the insurers/payers is one option.

How States Implement the Program

Federal approval is needed in order for any entity other than the original manufacturer to bring drugs into the U.S. Federal approval is available for wholesale importation programs that meet certain operational requirements, such as testing imported products. Federal approval is also contingent on the assurance that the program puts consumers at no greater health risk than they are under the U.S. system and the assurance that the program generates significant consumer savings. The model outlined above can meet these federal standards.

Contact Us

States interested in this model legislation will have access to a legislator's guide and additional background materials as they become available. If you have questions about the model act or are interested in technical assistance please contact Jane Horvath (ihorvath@nashp.org).