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Trump's Importation Program May Have Small Reach for Now

Amid an ongoing outcry against rising drug costs, the Trump administration introduced two importation pathways to reduce what U.S. residents pay for drugs. Although industry insiders tell AIS Health the pathways likely will have no effect on drug costs over the next few years, they suggest partnering with states already working on reimportation schemes to build experience with such programs.

HHS Secretary Alex Azar on July 31 announced two pathways to help U.S. residents pay less for pharmaceuticals. Under the Safe Importation Action Plan, the first pathway would allow states, wholesalers and pharmacists to propose to HHS demonstration projects for importing certain drugs from Canada. Proposals would have to ensure no additional risk to health and safety and must result in "significant cost savings." However, this pathway would exclude biologics such as insulin, infused drugs and injectables, among other categories.

Under the second pathway, drug manufacturers could import non-U.S. countries' versions of their drugs into the United States; manufacturers would need to validate that the drug manufactured outside the United States is the same as the FDA-approved version and that the drug would be sold under a new National Drug Code, potentially making it less costly to U.S. residents.

Importation Is a Long Way Off

The Trump administration has been working to reduce drug prices at a time when the cost of insulin has nearly tripled between 2002 and 2013 and CAR T-cell treatments such as Novartis' Kymriah (tisagenlecleucel) cost $475,000 for a single use. But other Trump administration initiatives have fallen apart over the past month. A judge blocked an HHS rule requiring that manufacturers disclose drug prices in TV ads from taking effect, and the administration abandoned a proposal targeting drug rebates.

What do health plan executives need to worry about with these two pathways? Not much, at least not in the next couple of years. That's according to Jigar Thakkar, Pharm.D., a managing director at FTI Consulting, where he advises health care clients on pharmacy strategy.

"There are so many hurdles that this isn't something that's going to happen tomorrow or in the next year or two," says Thakkar. The hurdles include passage of legislation to allow biologics such as insulin to be imported and the ability of drugs imported from other countries to be tracked according to FDA-TRACK, the FDA's agency-wide performance system that monitors drugs during their journey from manufacturer to distributors to pharmacies.

Expect Resistance from Canada

Another significant hurdle is pushback from the Canadian Medical Association, the Canadian Pharmacists Association and other interest groups in Canada. Bloomberg News reported that the Canadian Medical Association and 14 other groups sent a letter to Canada Health Minister Ginette Petitpas Taylor protesting the Trump administration's moves.

"Hospital and community pharmacies in Canada are resourced to serve the Canadian public," wrote signatories to the letter. "They are not equipped to support the needs of a country 10 times its size without creating important access or quality issues."

The interest groups' representatives also wrote: "Encouraging Americans to look for cheap Canadian imports could also spur the growth of illegal online pharmacies misrepresenting themselves as licensed Canadian pharmacies — as it is, 600 new illegal pharmacy sites launch every month."

Canadian Supplies 'Would Be Exhausted'

Deb Devereaux, senior vice president of pharmacy at Gorman Health Group, isn't optimistic about the success of the first pathway where drugs would be imported to the United States from Canada. "The bottom line is the Canadian drug supply would be exhausted in 16 months with all the U.S. states trying to avail themselves of Canadian drugs."

Devereaux is confident Canadian lawmakers will pass legislation to prevent the import of drugs from Canada to the United States.

Bharat Rao, Ph.D., a principal at KPMG in the health care practice, applauds the Trump administration's efforts to reduce prescription costs for U.S. residents. Still, he describes the first pathway as "kicking it to the states" rather than causing systemic change that will reduce the cost of drugs in the United States.

Another hurdle to the first pathway is privacy laws such as HIPAA, he says, which U.S.-based health plans must adhere to. Health plan executives should be mindful of patient privacy, because there could be a data breach where notification is required. "It's unlikely that a Canadian [entity] is going to sign up for that," says Rao.

In terms of timing, he doesn't expect significant movement on either pathway until after the 2020 presidential election. Still, Rao doesn't rule out the political will of President Donald Trump, who could drive his administration to partner with a state such as Florida, which passed a law allowing it to import drugs from Canada. (Florida joins Colorado and Vermont, which have passed similar laws.)

Regarding the second pathway, where drug manufacturers could import their drugs from another country into the United States, Rao also sees the possibility of a short-term success. That is, if the Trump administration, to achieve a political win, provides financial incentives for pharmaceutical companies to encourage their participation.

U.S. Won't See Changes For Years

But Rao doesn't foresee fundamental changes to the way U.S. residents pay for drugs for at least five years. He points to two possible wild cards that could change his calculation: Either the Democratic or the Republican party takes over both houses of Congress and the White House, or Trump uses his political will to force a change.

Amid this uncertainty, what can health plan executives do? Rao suggests kicking off a small pilot project with a state like Florida that has already passed laws to allow importation from Canada. Before participating in a pilot project, he advises executives to study the appropriate regulations, assess the role of the FDA in the project and determine the liabilities if, for example, a breach of patient information occurs.

In addition, health plan executives typically negotiate three-year contracts with PBMs with the option to update specifics each year in response to market conditions, says Brian Anderson, a principal at Milliman where he advises clients on pharmacy benefits.

That's important to keep in mind, as any strategy moves related to the two new pathways would need to be integrated with those timeframes.

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by Aine Cryts