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# Washington may become the second state to distribute its own generic drugs



By Ed Silverman<sup>2 3</sup> March 17, 2021



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Abill moving through the Washington legislature may make the state only the second in the U.S. with hopes of distributing its own line of generic drugs, an idea hatched last year in California as a way to combat the rising cost of prescription medicines that are straining government budgets.

The <u>legislation</u><sup>5</sup> would authorize the state Health Care Authority to form partnerships with other state agencies or nonprofits to distribute generics and

insulin. However, any drug must be made or distributed by a pharmaceutical company that is registered with the Food and Drug Administration.

To save money, the bill would also require health insurance programs purchased through the state to buy the medicines available through those partnerships. However, estimated savings have not yet been calculated, according to state Sen. Kevin Van De Wege, a Democrat who introduced the bill. Earlier this month, the state senate passed the bill, which will be heard a house health committee on Thursday.

"The goal of this bill is to find ways for the state to enter into a competitive bidding process in a partnership with a nongovernmental entity," Van De Wege wrote us. "The long term goal is savings by any means necessary, eliminating costly middle steps and giving our constituents access to more affordable prescription drugs."

"We know that direct production, distribution, or purchasing is very likely to lead to savings, but it will likely vary according to each drug. Direct manufacturing is likely not feasible to do on our own, but it becomes more feasible if states or nonprofits join together to manufacture, and that's what this bill will allow."

Toward that end, the legislation would make it possible for Washington officials to work with California, which last fall adopted a groundbreaking  $\underline{law}^7$  to pursue many of the same steps outlined by Van De Wege. California, for instance, is exploring partnerships, rather than pursuing any type of manufacturing, because the state is not yet authorized to make medicines itself.

"This bill will allow us to work with California when they get their program up and running. That's why our bill doesn't direct our state to produce drugs but instead directs the state to enter into partnerships to do so," he explained. "This bill was formed because of an express interest in joining with states like California to produce, distribute, or purchase drugs."

This is only the latest effort at the state level to constrain prescription drug spending as frustration mounts over a lack of action by the federal government.

A <u>poll</u><sup>9</sup> released in late 2019 found that a growing share of U.S. adults did not have enough money to pay for medicines during the previous year. That fall, 23% reported lacking funds to pay for a prescription, up from 19% at the beginning of 2019. In all, about 58 million adults experienced "medication insecurity," according to the poll from Gallup and West Health, a group of nonprofit and nonpartisan organizations focused on lowering healthcare costs for seniors.

Over the past few years, legislators around the U.S. have explored a variety of methods to cope.

These have included the possibility of importing medicines from Canada; establishing regulatory boards to oversee price increases; capping the cost of insulin; creating a Netflix-style subscription model; tying prices paid by state residents to what Canadians are charged 10 for prescription drugs; taxing 11 drug makers for raising prices without providing clinical evidence to justify the increases, and passing so-called transparency laws requiring drug makers to disclose certain costs.

So far, none of these approaches have gained national momentum, given the patchwork politics across the country. The pharmaceutical industry, meanwhile, has regularly opposed state initiatives and, in some cases, the trade group for brand-name manufacturers has filed lawsuits to thwart certain efforts.

A spokesperson for the Association for Accessible Medicines, the trade group for generic drug makers, explained that the organization is neutral about the Washington state bill as long as it "does not limit the ability for direct and fair competition between manufacturers." The trade group, by the way, did not oppose the California law, either.

As noted previously, a state has the ability to claim sovereign immunity if a brand-name drug maker filed a lawsuit claiming patent infringement, a defense generic manufacturers do not have. This assumes a state holds what is called an abbreviated new drug application, which could allow it to enter the market with a new generic months or even years before an established generic maker could do so.

The state is not required to hold such an application to develop generics, which might have dissuaded existing generic makers from entering the market. Moreover, lawmakers defined "eligible prescription drug" as one not protected by patents, which would prevent the state from gaining an unfair advantage, explained Brett Michelin, senior director for state government affairs at the generic trade group.

To what extent the California law will attract similar moves by still other states is unclear. So far, lawmakers in other states have not introduced similar legislation, but have shown interest, according to Trish Riley, who heads the National Academy for State Health Policy, a group of state policy makers that has proposed different forms of model legislation to control prescription drug spending.

However, Riley added that NASHP has looked at the possibility that states could form partnerships with Civica Rx, a nonprofit that contracts with pharmaceutical manufacturers to ensure sufficient supplies to hospitals across the U.S. The nonprofit was formed three years ago by a group of large hospital systems and philanthropic organizations in response to ongoing shortages.

The goal is to entice companies that make injectable and infused medicines with a minimum amount of sales to warrant ramping up investment in production. As of January, Civica Rx was able to supply 41 different generic

medicines to more than 50 health systems, representing more than 1,350 hospitals in the U.S. The nonprofit is also working with health insurers.

Civica Rx played a behind-the-scenes role in the California law by consulting with legislators as they crafted the bill. An official at the nonprofit indicated, at the time, that there was a willingness to work with California officials as the developed its plans for distributing generics. But a spokesman for Van De Wege told us that talks have not been held with Civica Rx.

#### **About the Author**



#### Ed Silverman<sup>2</sup>

Pharmalot Columnist, Senior Writer

Ed covers the pharmaceutical industry.

ed.silverman@statnews.com <sup>13</sup>
@Pharmalot <sup>3</sup>

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