California's Governor Gavin Newsom signed legislation last week that allows the state to partner with drug manufacturers to make or distribute generic prescription drugs—the first such law in the United States.

The law, SB 852, builds on a plan described last January in Governor Newsom's proposed 2020-2021 annual budget to increase manufacturing of generic drugs through a state-sponsored prescription drug label called Cal Rx. It requires the California Health and Human Services Agency (CHHSA) to enter into partnerships with drug makers and, through such partnerships, produce or distribute generic prescription drugs to increase access to more affordable drugs.

The cost of prescription drugs is an increasing concern for US consumers. Tracking polls conducted in 2015 through 2020 by the Kaiser Family Foundation found that about 6 in 10 US residents reported taking at least 1 prescription drug. In addition, 79% said the cost is unreasonable, and approximately 3 in 10 reported not taking their medicine as prescribed because of its cost.

According to California's Office of Statewide Health Planning and Development, the wholesale cost of prescription drugs, which is the list price for wholesalers without discounts or rebates, increased by a median of 25% from January 2018 through June 2020.

There are other potential benefits of partnering with drug makers besides lowering costs, including the potential to address shortages of essential drugs, especially in crises like the coronavirus disease 2019 (COVID-19) pandemic. In a statement in the Senate floor analyses, the bill's author, State Senator Richard Pan, noted that in areas particularly hard hit by COVID-19, there were some reports of hospitals running low on medications, such as the muscle relaxers required for intubation of patients.

Creating a structure for California to have its own drug manufacturing capability also "will help prepare the state for the next pandemic," said Pan, who noted that the COVID-19 crisis highlighted "glaring gaps" in supplies of essential, lifesaving drugs, medical equipment, and supplies.

A fiscal analysis estimates that under the new law, the state would pay an estimated $1 million to $2 million in startup funding in addition to ongoing staff costs. The law specifies that any state-developed generic medications "shall be made available to providers, patients, and purchasers at a transparent price and without rebates, other than federally required rebates."

The law directs the CHHSA to prioritize the selection of generics that are likely to have the greatest effect on reducing the cost of these drugs to patients and public and private purchasers, as well as on improving public health, increasing competition, and addressing shortages in the prescription drug market. The measure also calls for prioritizing drugs for chronic and high-cost conditions, and perhaps those that can be delivered through the mail as well.

In addition, the law specifically calls for the production of at least 1 form of insulin, "provided that a viable pathway for manufacturing a more affordable form of insulin exists." According to a 2019 report from the Health Care Cost Institute, average prices for insulin doubled from 2012 to 2016.

For the next step, the CHHSA will provide a report to the California legislature on or before July 1, 2022, with a list of drugs for development and an analysis of how the CHHSA's activities in this area "may impact competition, access to targeted drugs, the costs of those drugs, and the costs of generic prescription drugs to public and private purchasers."

The CHHSA will also submit a report to the legislature the following July with an assessment of the feasibility of the agency directly manufacturing its own generics and selling them at a fair price.
“Our bill will help inject competition back into the generic drug marketplace—taking pricing power away from big pharmaceutical companies and returning it to consumers,” Governor Newsom said in a statement. “California is using our market power and our moral power to demand fairer prices for prescription drugs.”