VIEWPOINT

HEALTH POLICY

The States as Important Laboratories for Federal Prescription Drug Cost-Containment Efforts

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In public opinion polling, controlling pharmaceutical spending is often at the top of the list of health policy concerns.[1] States have been attempting to lower drug spending for years and have taken a number of different approaches. The Trump Administration proposed multiple reforms to address drug spending,[2] and Congress is holding hearings on how to lower drug spending. Given that states are often laboratories for federal action, this Viewpoint reviews the approaches the states have taken in 2 areas—drug importation and controlling drug costs that parallel policy thinking in the administration and in Congress.

Changes to Drug Importation

In July 2018, the US Food and Drug Administration (FDA) initiated a working group to consider authorizing short-term importation of very expensive, off-patent drugs that are sold by just one manufacturer. This is partially a response to congressional hearings involving a 2015 decision by Skhreli (former CEO of the company known as Turing Pharmaceuticals) to raise the price of pyrimethamine (Daraprim) by 5000%.[3] The idea was also recommended by outside experts.[4]

Importation has always been controversial. Two years ago, several former FDA commissioners issued a statement arguing against importation of all drugs.[5] The FDA's current proposed approach is to import only certain categories of drugs under certain circumstances. In a 2018 presentation, the FDA commissioner noted that any drug manufactured overseas for the US market is made in the same FDA-registered plant that makes the drug for markets in other countries, which is why importation can be safe.[6]

States are debating creation of state-administered importation of certain high-cost drugs. For example, Vermont enacted laws creating a program for state-administered wholesale importation of certain high-cost drugs from Canada in 2018. The idea is that state sponsorship can guarantee both safety and lower prices through contracting with legitimate, licensed Canadian and US suppliers and building on the same global supply system that provides most US drugs today. Six other states had introduced similar legislation as of January 2019 according to the National Conference of State Legislatures (NCSL). These state programs will need the approval of the federal government, and it appears that the Secretary of Health and Human Services (HHS) will be receptive toward state efforts as long as safety and savings are ensured.

Changes to Medicare Part B Payment Rates

In October 2018, HHS Secretary Azar announced a proposal to tie reimbursement of prescription drugs covered under Medicare Part B (drugs administered in physician offices and hospital outpatient settings) to an index of international prices. The payment rate would be based on prices in 16 countries and phased in over 5 years. The HHS estimated that international reference pricing could reduce Medicare spending by $16.3 billion from 2020 and 2025.[7]

States are debating a similar approach, by creating all-payor upper payment limits for certain high-cost drugs. The upper payment limit would be based on affordability, as defined by the cost at which state residents would have access to the drug and insurers would be able provide coverage for all who need the drug. Like the Medicare B proposal, state all-payor rating setting is not linked to manufacturer market prices. States have used the concept of upper payment limits for decades in Medicaid and other programs. This expanded concept of an upper payment limit would apply to all state-licensed distributors (wholesalers and pharmacies), purchasers (hospitals and nursing homes, for example) as well as all state-licensed health insurers, health plans, and health programs.

The main difference between the state and federal proposals is that instead of relying on international prices, the state all-payor approach would focus on the affordability of the drugs. The NCSL data show that 5 states had introduced upper payment limit legislation as of the end of January 2019.

Maryland has been a leader in addressing the costs of prescription drugs. In 2017, Maryland enacted legislation that would prevent "unconscionable" price increases for off-patent drugs that have fewer than 3 competitors. The US Supreme court declined to review the Maryland case, which leaves the Fourth Circuit Appeals Court ruling standing among states in the Fourth Circuit, Maryland, has also taken up the issue of the high price of branded drugs. Last year, the Maryland legislature debated the idea of a statewide upper payment limit for certain high-cost drugs and is taking up the idea again this year. Under the proposed legislation in Maryland and other states, a drug affordability board would be established and drug companies that set a list price of more than $30 000 or increased their list price by more than $3000 would be given the opportunity to appear before the board to justify their price or price increase. A state would not change a national manufacturer's list price, but instead will limit the amount that state, county, and local governments in Maryland will pay. This upper limit on costs will require that entities that supply and distribute drugs in Maryland negotiate with manufacturers to get drug costs down to the upper payment limit level. This is a process that happens regularly

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today in states to accommodate individual insurer's upper payment limits.

Louisiana and Washington State have taken different approaches to set an upper payment limit. The approach is commonly known as the "Netflix" model.[8] The state can purchase unlimited quantities of hepatitis C treatment each year at a set price. States have had difficulty affording hepatitis C drugs for Medicaid, for the uninsured, and for correctional facilities. Under this approach, the states will contract with one drug company or more to provide enough drugs to treat the population that the state and the drug company agreed to cover. Louisiana received multiple bids in response to its request for proposal, and the Louisiana Department of Health recently announced that it has chosen Asegua Therapeutics, a Gilead Sciences subsidiary, to supply a hepatitis C drug for the state.[9] The budget limit for the project in Louisiana is equal to the total dollar amount the state spent last year on hepatitis C treatments in Medicaid and in the corrections system.

Conclusions

There are similarities between the innovative state approaches to drug cost containment and those of the Trump administration and Congress. The administration should support state initiatives for state-administered wholesale importation and statewide upper payment limits for certain high-cost drugs and help these state programs to be enacted. These types of programs serve as demonstration projects for the federal government to determine what works and determine if there are unintended consequences. Importation and payment reforms are 2 examples for which the states can serve as laboratories for the federal government.

ARTICLE INFORMATION

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