

What to Do – *And Not to Do* – on **R_x** Reform

THE PROBLEM

While overall drug prices have been falling for 2 years, the prices of some drugs, including some of the most expensive ones, have continued to rise. Higher prices for physician-administered drugs and specialty medicines contribute to rising health insurance premiums and to higher taxpayer spending on Medicare. Government policies have led to this situation.

THE PROPOSAL

Congress should reform Medicare prescription drug programs and remove barriers to competition by closing loopholes in federal law. These proposals will provide relief from high costs for patients and taxpayers, help taxpayers by reducing handouts to industry, and “do no harm” to America’s leadership role in innovation and access to new cures.

Reform Medicare Prescription Drug Programs: End Flawed Incentives Contributing to Higher Costs

Medicare pays for prescription drugs through two programs: Medicare Part D and Medicare Part B. Both need reform.

Medicare Part **D**

The Medicare Part D program allows seniors to choose the prescription drug coverage that best meets their needs.

- **It’s generally working really well, because it relies on private, market competition** among drug plans that compete against each other based on quality and price. These private plans negotiate discounts, rebates and other price concessions with drugmakers, without government interference. This private competition has resulted in a program that costs far less than projected by government estimators, something virtually unheard of in federal health care entitlement programs. One study found that for every \$100 spent on Part D, Medicare saves \$95 on hospital and doctor spending, while delivering better outcomes.
- **Reform should build on this success, by removing an unintended incentive in the program for drug makers to drive up costs on expensive drugs.** One area of the program has seen big cost growth: expenditures on costly, “specialty drugs.” Under Medicare Part D, taxpayers pay most of the costs of expensive specialty drugs. Private drug plans bear a very small percentage of the costs of these medicines and manufacturers bear none at all. Drugmakers have little incentive to offer discounts and rebates for these medicines, and prescription drug plans have little motivation to seek them. Congress should restructure the Part D program to require drug manufacturers and prescription drug plans to bear more of the costs of these expensive drugs. It should also protect seniors against high drug expenditures by capping the amount a senior has to pay in a calendar year for their medicines. No longer would seniors with cancer and other diseases that require expensive treatments face onerous bills for their medicines.
- **Benefits:** These changes would lower drug spending among seniors, reduce costs to taxpayers, and strengthen the already highly-functional Part D benefit structure.

Medicare Part B

Medicare Part B covers drugs that are administered by physicians (e.g., chemotherapy drugs), as opposed to those drugs that seniors typically get at their pharmacies. Unlike Part D, the government sets the prices Medicare pays for drugs under Part B. Unlike with other administered prices in Medicare, the government attempts to base reimbursement rates for Part B drugs on a product's average sales price, net of rebates, discounts and other price concessions. Flaws in this approach have contributed to an explosion in Part B spending, as opposed to the market-based Part D program, where spending growth has remained moderate. This higher spending affects beneficiaries, since they are responsible for 20 percent of the cost of a Part B drug. And since premiums must finance 25 percent of the Part B program, that higher spending also leads to higher premiums for seniors, and higher costs to taxpayers.

- **Proposed Change:** Congress can moderate these costs by removing government incentives that encourage higher prices. Congress should cap so-called "add-on payments" for Medicare Part B drugs, end the policy of paying more to hospital outpatient departments to administer such drugs than it pays in other clinical settings, and explore moving coverage of Part B drugs to Part D.
- **Benefits:** These changes would help taxpayers by moderating Part B drug spending, and give seniors relief from rising Part B premiums and pay less for Part B drugs.

Reduce drug prices by removing barriers to choice and competition

Federal law encourages innovation by granting manufacturers a limited period of market exclusivity, during which their product has no competitors. It encourages competition by limiting this period of exclusivity, encouraging the introduction of generic competitors. As a result, 90 percent of prescriptions filled by Americans in 2017 were for generics. Generics are very affordable, with 93 percent costing \$20 or less. These lower prices saved consumers nearly \$1.8 trillion in drug spending between 2008 and 2017. Some manufacturers have exploited legal loopholes to impede generic competition.

- **Proposed Change:** Congress should close these loopholes by:
 - Outlawing payments from manufacturers to generic companies in order to keep the generic company from introducing its product into the marketplace.
 - Outlawing tactics used by manufacturers to prevent generic companies from obtaining samples of their products, samples that are needed to develop and test their generic alternatives.
 - Ending the abuse of "citizen petitions," when drug manufacturers use them merely to delay the introduction of lower-priced generic alternatives.
- **Benefits:** These changes will make lower cost prescription drugs available more quickly to Americans who need them, help moderate prescription drug spending growth, and strengthen and improve a legal arrangement that both encourages innovation and makes affordable generic products available throughout the marketplace.

Congress Also Should Reject Flawed Policies in RX Drugs Legislation

In addition to pursuing positive reforms, policymaker must also reject flawed policies – price controls – that will undermine America’s standing as the world’s innovator in new medicines.

Some in Congress support legislation that would impose government price controls on prescription drugs. H.R. 3, for example, would invest the HHS Secretary with the authority to “negotiate” drug prices with manufacturers, based on the prices foreign governments have set for those products. While price controls will reduce unit prices for some products, they also would reduce access to new cures and curb innovation.

This isn’t speculative. In Europe, government uses various means to control the price of drugs. These systems, in place for decades, have had two major adverse consequences.

- First, Europeans have access to fewer new treatments than do Americans. Of new active substances introduced between 2011 and 2018, 89% are available to Americans, compared with 62% in Germany and 60% in the United Kingdom. One-half or more of these new therapies are unavailable to Australian, Canadian, French, and Japanese patients. Price controls reduce patient access to breakthrough drugs.
- Second, price controls reduce investment in the development of new treatments. Price controls have been common in Europe since the 1980s. As a result, pharmaceutical research and investment has shifted dramatically from Europe to the U.S. In 1986, European firms led the U.S. in spending on pharmaceutical research and development by 24%. After the imposition of price control regimes, they fell behind. By 2015, they lagged the U.S. by 40%. Because of its relatively free market system, the U.S. is now a center for pharmaceutical research and development, something that both serves patients and bolsters our economy.

If we follow the example of Europe and impose government price controls, Americans will have access to fewer cutting-edge medicines, fewer new cures and shorter lives because:

- Price controls will reduce – through government fiat - the available money pharmaceutical companies can devote a substantial share of their margins to research and development. That in turn will reduce the amount companies have to invest in innovation and make innovation less attractive to investors. Price controls will disproportionately impact new biotech companies. These start-ups rely on investors willing to back high-risk propositions that will, if successful, produce high rewards. Price controls reduce these rewards, making such high-risk investments unattractive.
- Less capital means less research. Less research means fewer new cures. The President’s Council of Economic Advisers (CEA) estimates that if the price controls in H.R. 3 were to become law, as many as 100 fewer drugs would enter the United States market over the next decade. That’s a one-third reduction over the 300 new drugs that the president’s economist believe would be introduced if H.R. 3 were not enacted.
- Fewer cures means shorter lives. CEA estimates that by limiting access to lifesaving drugs, H.R. 3 would reduce Americans’ average life expectancy by about four months.

Congress should reject these flawed ideas and instead pursue positive reforms, as outlined above, that address existing government policies that drive up costs and reduce competition.