Client Update

The Latest on the Trump Administration's Drug Pricing Initiatives

Since President Trump's statement in the State of the Union that addressing drug prices would be one of his top 2018 priorities, the administration has signed one bill that includes a drug pricing provision and has made a variety of other proposals in the White House budget that are designed to lower prescription drug prices. Equally notably, the administration is not pursuing some of the most controversial proposals that President Trump and others have raised in the past that have been opposed by the pharmaceutical industry.

BIPARTISAN BUDGET ACT OF 2018

The "Bipartisan Budget Act," which was signed by President Trump on February 9, 2018, contains a provision that is intended to reduce prescription drug costs for some seniors. The Medicare Part D program covers outpatient prescription drugs. As originally designed in 2003, Part D included a "doughnut hole," a coverage gap between the initial threshold of drug costs that would be covered by Part D plans and a much higher catastrophic maximum after which Part D coverage would resume. The Affordable Care Act included a provision designed to gradually close the gap between 2013 and 2020. The recently enacted statute accelerated that process by one year. The statute also reallocates responsibility for payment of drug costs for patients in the coverage gap. Going forward, pharmaceutical manufacturers will be required to discount the cost of prescription drugs 70 percent (instead of 50 percent) and the Part D insurer will be responsible for paying five percent of the drug cost (instead of 25 percent). This provision is likely to cost the pharmaceutical industry billions of dollars. Moreover, some pharmaceutical companies may be incentivized to raise prices to recoup losses resulting from this provision.

WHITE HOUSE BUDGET

The White House budget, released on February 12, 2018, contains a number of proposed measures aimed at reducing drug pricing. Congress is free to accept or reject the President's proposals. The White House's proposals include the following:

Medicare Part D Formularies

Currently, each Medicare Part D plan is required to have a drug formulary (a list of drugs that the plan will cover) that includes at least two prescription drugs in each therapeutic class. The budget proposes that formularies need only have one drug in each therapeutic class. It would also allow formularies to use unspecified utilization management tools as a means of controlling prescription drug costs. The administration believes that allowing narrower formularies will lower prescription drug costs in at least some circumstances. If a formulary must have two prescription drugs in a therapeutic class and there are two only drugs on the market, then the plan has little bargaining power because the sellers know it is required to cover both drugs. If the plan is required to cover only one drug, then it can force both drug companies to bid against each other and can select the one that is cheaper. It also would impact physicians and patients because prescribing decisions would be dictated by whichever drug is included in the Part D program's formulary.

Medicare Rebates

The private insurers that operate Medicare Part D plans employ pharmacy benefit managers ("PBMs") who negotiate drug prices with pharmaceutical companies. Currently, if PBMs negotiate a rebate or discount with a drug company, that rebate is passed on to the insurer and it does not directly impact the patient's co-pay. The budget proposes that at least one third of any rebate or price discount should be passed on to reduce the patient's out-of-pocket expenditure at the "point of sale," *i.e.*, when the patient purchases a prescription drug at the pharmacy. This proposal is anticipated to have its greatest impact on pricing of drugs that are subject to substantial competition, which incentivizes their manufacturers to provide rebates.

Insurers that sponsor Part D plans are likely to be negatively impacted by this proposal. If Part D insurers receive the same rebates (or discounts) for prescription drugs but have to pass on part of those savings to patients, the insurers' net expenditures for prescription drugs will rise. That in turn is likely to result in higher premiums for Part D plans. Some of the premium increase will be offset by government subsidies.

Medicare Part D Catastrophic Insurance

Once Part D beneficiaries' prescription drug expenditures exceed the "doughnut hole," they fall into the "catastrophic" phase of Part D coverage. Currently, beneficiaries in this phase who are not eligible for low-income subsidies have a five percent cost sharing requirement. In 2015, there were approximately one million such people and they collectively paid $1.2 billion for out-of-pocket costs in this phase. The budget proposes altering cost allocations in this phase by increasing the share of prescription drug costs borne by the insurer that is sponsoring the Part D plan from 15 percent to 80 percent, decreasing Medicare's share from 80 percent to 20 percent and eliminating the beneficiaries' share (which was previously five percent). If this proposal were implemented, beneficiaries would have no cost sharing requirements once they entered

the "catastrophic" phase. The White House proposal would incentivize insurers that sponsor Part D plans to carefully monitor which drugs are prescribed because they would bear a significantly increased percentage of the costs of drugs used in the "catastrophic" phase.

Consolidate Part B and Part D Prescription Drug Coverage

Medicare Part B currently covers drugs that are administered by physicians in outpatient clinics, whereas Part D covers prescription drugs that beneficiaries receive at pharmacies. Part B covers many high-cost specialty drugs that treat conditions such as cancer, blood diseases and ophthalmology. The budget proposes giving the Department of Health and Human Services ("HHS") the authority to shift coverage of some drugs currently covered in Part B into Part D. It assumes that patients would fill prescriptions for such drugs and the drugs would be administered by physicians, but it does not explain how this would work. This proposal may hurt the pharmaceutical industry because in some cases, there is greater price competition for drugs that are covered under Part D.

Medicaid Formularies

Currently, each state Medicaid program is generally required to provide coverage for any drug in the Medicaid Drug Rebate Program. Medicaid programs are not allowed to establish drug formularies that are used by many private insurers and Medicare Part D sponsors. The administration proposes creating an experimental project involving five unspecified states. These states would be permitted to establish drug formularies and negotiate the price of covered drugs with pharmaceutical companies. These states would also be required to have an appeals process so that beneficiaries with a medical need could access drugs that are not on the formulary. The administration's budget does not provide details regarding how broad or narrow the experimental Medicaid formularies would be. However, the budget contemplates that this proposal would save only $85 million over 10 years, which suggests that this initiative is unlikely to have a significant impact.

Accelerating Generic Entry

The first generic manufacturer to file an Abbreviated New Drug Application ("ANDA") for a reference-listed drug may be awarded a 180-day period of marketing exclusivity. In some instances, a first filer with a deficient application that is not immediately approved by the FDA may nevertheless block subsequent generic applicants from entering the market during the marketing exclusivity period. Generics can enter the market after the 180-day period has expired. The administration proposes that in this circumstance, the FDA should be able to tentatively approve an ANDA from a subsequent generic drug manufacturer. At that point, the 180-day exclusivity clock would begin for the first filer. This proposal may harm innovator pharmaceutical manufacturers in some circumstances by shortening the time during which the innovator has the only product on the market. Once the first ANDA is approved, the innovator typically loses its pricing power and a large portion of its market share. Once two generics reach

the marketplace, the innovator's pricing power and market share diminish even more precipitously.

WHAT IS NOT IN THE WHITE HOUSE BUDGET?

The CREATES Act

Some have alleged that innovator pharmaceutical companies delay generic competition by declining to sell generic drug companies the drugs that these companies need to conduct bioequivalence studies necessary to file an ANDA (although there are circumstances in which innovators may face legal impediments to selling their product to a generic drug company, particularly when the drugs at issue are subject to restricted distribution systems). A bipartisan group of senators co-authored the "CREATES" Act to address this issue. This bill would provide that, under certain circumstances, a generic drug company could sue an innovator drug company if the innovator does not sell the drug to the generic drug company in sufficient quantities for bioequivalence testing. If successful, the generic drug company could recover "a monetary amount sufficient to deter the license holder from failing to provide other eligible product developers with sufficient quantities of a covered product" and attorney fees. The CREATES Act is not included in the White House budget.

HHS Negotiation of Prescription Drug Prices

Since the inception of the Part D program, HHS has not been allowed to engage in direct negotiations with pharmaceutical manufacturers regarding drug costs. Instead, each Part D plan separately negotiates with pharmaceutical manufacturers. At various times during the campaign and in office, President Trump has suggested that HHS should be able to take advantage of its enormous purchasing power to negotiate discounts for the Part D program. This proposal has been strongly opposed by the pharmaceutical industry, which originally conditioned its support for the Part D program on the understanding that HHS would not negotiate Part D drug prices. The White House budget does not propose HHS negotiation of prescription drug prices.

Importation of Less Expensive Foreign Drugs

With certain exceptions, the FDA currently prohibits consumers from purchasing prescription drugs outside the United States and then importing them to the United States. A bipartisan group of senators has proposed lifting that ban, as did President Trump during the presidential campaign. Many have raised concerns about safety and quality issues posed by unregulated drug imports. In fact, over many years HHS has repeatedly refused to certify the legality of drug importation. Furthermore, President Trump's economic advisors recently expressed concern about the very phenomenon that motivates proposals for drug importation, suggesting that foreign governments impose price controls on drugs manufactured by United States pharmaceutical companies. This practice allows foreign governments to free ride on drugs developed in the United States while leaving American consumers and taxpayers to bear most of

the cost. The White House budget does not propose authorizing prescription drug reimportation.

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