Insight

SOTU Preview: The Administration's Proposals for Lowering Drug Prices

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The Trump Administration has been aggressively looking for ways to lower prescription drug costs, and President Trump is expected to address these efforts in his State of the Union address to Congress. In preparation for tonight's speech, here's a round-up of some of the proposals that have been formalized thus far and some insight as to how these proposals might work together.

Drug Rebates

Two recent administration proposals on rebates—detailed below—are likely to have direct impacts on the cost of prescription drugs, particularly for Medicare Part D beneficiaries. For those individuals taking expensive medicines and bearing the highest costs, it is likely these proposals will achieve significant out-of-pocket (OOP) savings and overall cost reductions. Conversely, beneficiaries that take relatively few and inexpensive medicines, especially those who take only generic medications, will likely see minimal cost increases in the form of higher premiums. In the aggregate, it is expected that beneficiaries will see net cost reductions, but the increased costs and savings will not be evenly distributed. Other potential reforms to the Part D program, such as this one proposed by the American Action Forum, could reduce overall program costs.

Manufacturer Rebates at the Point of Sale

The most recent drug-pricing proposal from the administration concerns the rebates that manufacturers provide to insurers and pharmacy benefit managers (PBMs). At issue is the fact that these rebates, which average 30 percent in Medicare Part D, often do not directly benefit the patient taking the drug, even though the rebate was given for that patient. Rather, the value of these rebates is—typically—collectively provided to all beneficiaries through reduced plan premiums. In an effort to change this practice, the administration proposed last week to allow drug manufacturer rebates *only if* such rebates are fully passed along to the consumer at the point of sale.

Pharmacy Price Concessions

Similar to manufacturer rebates, pharmacy price concessions are another type of rebate often provided in the drug supply chain after the point of sale. These rebates (or fees) are typically provided to (or paid by) pharmacies based on certain contractual requirements, typically "pay-for-performance" measures such as generic dispensing rates and medication therapy management. Because these types of rebates are typically performance-based, their final amount is not determined until the end of the contract year; consequently, they do not impact the OOP cost of the drug when it is picked up at the pharmacy. The Centers for Medicare & Medicaid Services is considering requiring a portion of these rebates to be passed on to patients at the point of sale so that consumers can benefit directly from these rebates. Beneficiaries do benefit indirectly from these rebates under the current pricing structure in the form of reduced premiums, just as beneficiaries currently benefit indirectly from manufacturer rebates.

Price Setting

CMMI Demo: International Price Index for Part B Drugs

In October 2018, the administration proposed a bold plan to test a new payment model for drugs covered under Medicare Part B. This model would tie Medicare reimbursement rates for certain drugs to the average price of that drug in a set of other countries by establishing an International Pricing Index (IPI). The goal of this proposal is to reduce Medicare reimbursement for these drugs by 30 percent and more closely align the price Medicare pays with the price paid in other countries. While those goals are laudable, the solution that has been proposed here is not likely to achieve that objective, and in fact, could result in significant undesirable repercussions.

Adopting the non-market prices of other countries, and thus the punitive and restrictive policies used to obtain those prices, will likely also mean restricting American patients' access to new medicines. Currently, Americans have access to 96 percent of new medicines within three months, whereas patients in the other countries being considered for the IPI only have access to 48 percent of new medicines, on average, and only after waiting for more than a year. Worse yet, this demo may result in as many as three fewer new medicines being developed each year. Americans highly value their access to, and choice of, new treatment options. The reduced innovation that will occur as a consequence of the reduced revenues that will result from this model will have significant ramifications. Further, referencing the prices paid for drugs in countries that may not adequately reflect the value of medicines seems inconsistent with the administration's goal of adopting a value-based payment system. Finally, this model will undermine American trade policy, which may have repercussions far beyond the pharmaceutical industry.

Transparency

The lack of price transparency is often referred to as one of the fundamental challenges in addressing health care costs. It is difficult to know what the price should be—or what the implications of changing it are—when we don't know what the price is. The following provisions are aimed at injecting some price transparency into the market.

Gag Clauses

In September 2018, the president signed legislation prohibiting the use of "gag clauses" in pharmacy contracts. These types of contract provisions have previously been used to prohibit pharmacists from informing patients that they could pay less for their prescribed medication if they paid cash or used some other payment method

besides their health insurance. It might seem absurd for such a situation to exist, but it sometimes does, and now pharmacists will be allowed to share this information with patients. The trade-off for not using insurance to pay for a drug (or any other health care service) is that the OOP expense will not count toward the insurance plan's deductible and so the patient will have to spend more money before the deductible is reached. The use of gag clauses prevented patients from being able to make a well-informed decision whether to pay inside or outside of their insurance plan, and this prohibition is certainly a win for patients, if a small one.

Direct-to-Consumer Advertising

The administration last year proposed requiring drug manufacturers to include the price of a drug in any direct-to-consumer TV advertisement. The administration believes that such a requirement is another important step toward helping patients be more informed consumers. The usefulness of knowing a drug's list price may be limited, since almost no one pays list price, but some people do pay list price and no one pays more than list price, so at the very least it provides a ceiling. If implemented, this proposal probably won't significantly affect drug purchasing decisions, but it could increase public awareness about drug prices.

Greater Competition

This next set of items all relate to efforts to increase competition, particularly the competition that generics provide for brand-name drugs. History has shown that the best way to reduce the price of a drug is to increase its supply from multiple manufacturers.

FDA Action on Generics and Biosimilars

In fiscal year (FY) 2018, the Food and Drug Administration (FDA) approved a record number of generic drugs, beating the last record that had just been set in 2017. The month of October also saw a record number of generic drugs approved, indicating the trend may continue into FY2019. The FDA has also taken steps to advance generic drug development through issuing guidance on the appropriate use of Risk Evaluation and Mitigation Strategies (REMS) by brand-name manufacturers.

New Exceptions to Protected Classes

In Medicare Part D, there are six protected classes of drugs in which virtually all medicines must be included in a drug plan's formulary; in other words, patients may not be denied access to any of these medicines (with very few exceptions). The administration recently proposed allowing three new exceptions to the coverage rules for the six protected classes in an effort to increase competition for such drugs, which can be rather expensive. By providing the option for insurers to exclude a drug from its formulary, insurers will have more leverage to negotiate steeper discounts from drug manufacturers. Of course, patient advocates are concerned that such changes could result in patients losing access to the drugs they need; an appeals process will be required to help mitigate against such unintended consequences.

Preferential Coverage for Generics

The administration has taken and proposed several actions to encourage greater use of generic drugs. Beginning this year, the Part D rules were changed to allow plan sponsors to substitute a generic drug immediately in place of a brand-name drug as soon as it becomes available. For low-income subsidy (LIS) beneficiaries, biosimilars are also now treated as generics, which will reduce beneficiaries' cost-sharing liability for such drugs.

In the most recent rules for Affordable Care Act Exchange plans, the administration proposes allowing several new practices aimed at encouraging greater utilization of generic products over brand-name drugs. One proposal would allow insurers not to count the value of a manufacturer's coupon for a brand-name drug toward a beneficiary's OOP maximum when a generic equivalent is available. Another proposal related to use of a brand-name drug when a generic equivalent is available would allow insurers to exclude from a beneficiary's OOP maximum calculation the excess cost-sharing amount for the brand-name drug beyond what the cost-sharing amount would have been for the generic. Further, insurers would not be required to consider brand-name drugs an Essential Health Benefit (EHB), and thus the insurer could impose annual and lifetime benefit limits on such drugs. Moreover, premium tax credits could not be applied to the portion of the premium attributable to coverage of brand-name drugs excluded from the EHB. While these proposals are likely to produce system-wide savings through greater use of generic medicines, some individuals would certainly face significant cost increases.

Step-Therapy and Prior Authorization in Part B

Last year, the Centers for Medicare and Medicaid Services modified existing guidance to allow Medicare Advantage (MA) plans to impose step therapy requirements as a way to manage utilization of physician-administered drugs under the Part B benefit. Additionally, joint MA-Part D plans will have new authority to cross-manage Part B and Part D drugs by allowing drugs covered under one benefit to be the first step of a treatment plan before allowing use of a drug covered by the other benefit.

Conclusion

The administration has actively sought to reduce drug costs. While most of these actions thus far have come in the form of proposals, and typically raise more questions than provide answers, it is likely that *something* will happen. Given the increasing boldness of the proposals, it is also likely the eventual impact could be significant. The biggest question is: Who will be the ultimate winners and losers once final decisions are made?

Stay tuned to the president's State of the Union address for any new proposals.