Insight

What the President's Budget Foreshadows for Future Drug Pricing Initiatives

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Introduction

President Trump released his 2020 Budget on March 11, and the health care section included many proposals for addressing drug prices. Most of the proposals have been included in the president's past budgets, the drug pricing blueprint that was released last May, or both, though there are a few new policy ideas. The proposed policies range from reforms to the Medicaid Drug Rebate Program and 340B Drug Discount Program and changes in reimbursement policies under Medicare Part B and Part D, to provisions intended to increase the supply of therapeutic alternatives and prohibit anti-competitive behaviors among drug manufacturers.

Medicaid Reforms

Medicaid Drug Rebate Program

The budget again calls for several reforms of the Medicaid Drug Rebate Program (MDRP), including eliminating the cap on mandatory drug rebates. The MDRP requires drug manufacturers, as a condition of having Medicaid cover their drugs, pay a rebate for all of their outpatient prescription drugs, including biologics, taken by Medicaid beneficiaries. The amount of the required rebate is set by law such that the net price of the drug is either equal to the best price available to anyone in the private market or equal to a certain percentage of the drug's average manufacturer price (AMP)—whichever gives Medicaid the lowest price. The percentage for this rebate varies by type of drug, with brand-name drugs requiring the greatest rebate. An additional rebate must also be paid if a drug's list price increases at a rate greater than inflation; this additional rebate is equal to the amount by which the price increase exceeds the rate of inflation, measured by the Consumer Price Index for All Urban Consumers (CPI-U).

Under current law, the maximum rebate amount that a drug manufacturer would have to provide to the Medicaid program (inclusive of the inflationary rebate) is limited to 100 percent of the drug's average manufacturer price. Lifting the cap would lead to some manufacturers having to pay—rather than be paid—for the use of their drugs in Medicaid. This idea is not just fundamentally bad in principle—in no free market would a company simply pay consumers to use their product—but history shows it is likely to be bad policy in practice. As explained here, this proposal could worsen, rather than mitigate, the problem it is intended to fix. The existence of a minimum mandatory rebate incentivizes companies to inflate the price of their product to offset the revenue lost from the rebate. Moreover, requiring that rebate to be at least as good as any discount offered to another payer disincentivizes the offering of discounts beyond the minimum rebate amount. Finally, penalties for price increases further incentivize higher launch prices. Any policy to increase the mandatory rebate amount will exacerbate the existing problems with this program.

The budget also calls for authorization to impose penalties on manufacturers that incorrectly classify their drugs

under the Medicaid drug rebate program. Two recent events drew attention to the need for this authority: congressional hearings regarding the price of EpiPen in 2016, and a subsequent investigation by the Department of Health and Human Services (HHS) Office of the Inspector General that found that the misclassification of products has resulted in more than $1.3 billion in lost Medicaid rebates between 2012 and 2016. Legislation to provide this authority has been introduced by Senator Grassley, Chairman of the Senate Finance Committee, and cosponsored by Ranking Member Wyden, making it more likely that this reform will become law.

The president's budget also supports a proposal, recommended by the Medicaid and CHIP Payment Advisory Commission (MACPAC), to eliminate a loophole that allows the price of an authorized generic to be included in the calculation of a brand-name drug's average manufacturer price for purposes of determining the required rebate. Doing so reduces the drug's AMP and thus reduces the amount of rebate that must be paid.

State Demonstrations

In a nod to calls for government negotiation of drug prices, the budget proposes allowing five states to test such a proposal combined with the authority to impose a state Medicaid formulary. Any price discount agreed to under the demo would not affect the "best price" for that drug, indicating the administration's belief that manufacturers may provide greater discounts to a single state if they won't have to provide that same level of discount to all beneficiaries.

340B Reforms

The 340B program is in desperate need of reform, primarily as a result of its dramatic growth over the past decade. The program's growth has been so extensive that it is noticeably distorting the health care market, resulting in higher prices and fewer choices for patients.

One criticism of the 340B program is that it does not include any requirement for participating hospitals to provide charity care, despite its mission to enable hospitals to do so. The Centers for Medicare and Medicaid Services (CMS) recently made changes to reduce reimbursement for 340B drugs under Medicare Part B, and the president's 2020 budget repeats its call to require hospitals to provide uncompensated care equal to at least 1 percent of patient care costs in order to receive any share of those savings; otherwise, savings will be returned to the Medicare trust fund.

The budget also includes a request to provide broad regulatory authority to define standards for participation in the 340B program and to require participating entities to report on how their savings from the program are used. Currently, eligibility for program participation is based solely on the type of facility a hospital is categorized as, regardless of the amount of indigent care it provides. Further, there is no binding regulatory definition of a "patient" for determining who may receive the discounted drugs provided under the program. There are also no requirements for how savings from the program should be used—including no requirement that the savings be passed on to the patients to whom the discounted drugs have been provided—or even for reporting the amount of such savings. These proposals would empower HHS and Congress with more information to provide better oversight of the program and ensure that the program's benefits are appropriately targeted to meet its mission.

Medicare Part B Reforms

Discouraging Anti-Competitive Behavior

A new and innovative proposal that had not previously been included in any administration proposals is aimed at penalizing drug manufacturers who engage in anti-competitive behaviors. This proposal would reduce Medicare Part B's payment for a drug when the primary patent for that drug expires *if* the manufacturer engages in pay-for-delay agreements or other schemes to keep competing drugs from entering the market. The payment would be reduced from average sales price (ASP) + 6 percent to ASP – 33 percent until a competitor drug is commercially available.

Eliminating Pass-Through Payments

The budget also newly proposes eliminating Medicare's "pass-through payments" for newly-approved drugs, biologics, and biosimilars that are made under the Outpatient Prospective Payment System. Since the 1990s, pass-through payments have been made for certain new drugs in order to encourage their use. Part B policy requires some drugs to be paid for as part of a larger bundled facility fee through the Outpatient Prospective Payment System when those drugs are used for treatment or diagnosis in conjunction with other services, rather than separately paying for the drug using the standard ASP+6 percent reimbursement formula.[1] When drugs are included in a bundled payment, providers are encouraged to use lower-cost drugs (when more than one option exists) because the bundled payment is based on the average cost of the available drugs for that procedure, which has the benefit of putting downward pressure on prices. Thus, when a new, innovative drug comes to market that would be included in that bundle but is significantly more expensive, providers will not be incentivized to use it. In some instances, however, CMS may actually want to encourage use of the new expensive medicine because of the increased value the drug is believed to offer. In these instances, CMS will provide a pass-through payment in addition to the bundled facility fee whenever a pass-through drug is used. These pass-through payments are paid for by estimating in advance the amount of pass-through payments that will be made in a year and moderately adjusting all payments for hospital outpatient department and ambulatory surgical center services such that net payments are not increased. Drugs may receive pass-through status for at least two years, but not more than three. During this time, CMS tracks their utilization and incorporates that data to increase appropriately the bundled facility fee once the drug loses its pass-through designation such that the payment rate will no longer financially disincentive the new product's use.

The recent regulatory change to Medicare Part B reimbursement for 340B drugs mentioned above has increased the importance of having pass-through status. Last year, CMS changed the reimbursement formula for Part B drugs acquired under the 340B program from ASP+6 percent to ASP-22.5 percent; pass-through drugs were excluded from this change, though. Eliminating pass-through payments would make the drugs eligible for this reduced reimbursement and—because beneficiaries' out-of-pocket (OOP) costs are based on the Medicare reimbursement rate—may therefore reduce patient OOP costs. As discussed earlier, however, eliminating these payments may prevent uptake of new, innovative technologies.

Moving Part B Drugs to Part D

Another repeat proposal is one to allow certain physician-administered drugs currently covered under Medicare Part B to instead be covered under Part D. The administration seems to have narrowed the scope of drugs they are considering for this proposal, since they originally floated the idea for only high-priced drugs with competing therapeutic alternatives. The proposal stipulates that this switch should not be done if it will limit beneficiaries' access to the drug or increase their cost-sharing. The intent is to employ the negotiating power of the Part D plans to drive greater discounts. The reimbursement rate for Part B drugs, however, already incorporates all discounts and rebates provided for such drugs in the private market, so it may be unlikely that the Part D plans could negotiate even greater discounts. Further, because cost-sharing under Part B is limited to 20 percent, but coinsurance for specialty drugs under most Part D plans is 25-33 percent, it is unlikely that such

a transition would reduce beneficiary cost-sharing.

Penalty for Price Increases

Another proposal again included in the president's budget is to impose an inflation penalty for drugs covered under Part B when the price increases faster than general inflation (measured by CPI). Various policymakers and Congressional advisors have floated this idea for several years now, and Congressman Sander Levin introduced legislation last year to implement this proposal. The concern here is the same as the concern with lifting the cap on rebates in the Medicaid program: Any penalty for price increases will simply encourage higher launch prices. And again, past analysis has shown that companies tend to incorporate the cost of any mandatory rebates into the price of the drug.

Reduced Reimbursement for New Drugs

The administration has also again proposed reducing the initial payment amount for new drugs covered under Medicare Part B. Due to a lag in price reporting, Medicare cannot benefit from any discounts or rebates provided in the private market, and this proposal seeks to (permanently) address this problem. Historically, the reimbursement rate for the initial six months of a drug's coverage has been the wholesale acquisition cost (WAC)+6 percent. Beginning this year, the administration reduced this amount through rulemaking to WAC+3 percent; the budget proposes making this change permanent through a change in legislation.

Medicare Part D Reforms

The president's budget clearly recognizes the importance and past success of the Medicare Part D program, yet it simultaneously acknowledges a need for structural reform of the benefit design to make the program, and Medicare broadly, more sustainable.

Benefit Structure Reform

There are three pieces to the benefit structure reform proposed in the budget. First, the proposal would provide beneficiaries with an OOP cap on drug spending; no such protection currently exists. Instead, beneficiaries who spend enough money to reach the catastrophic coverage phase (about $2,600 in 2019) are limited to paying 5 percent of the remainder of their drug costs for the year.

The second proposal is to exclude manufacturers' coverage gap rebates from the calculation of the "true out-of-pocket" (TrOOP) threshold, which determines when a beneficiary reaches the catastrophic coverage phase. Drug manufacturers are now required to provide a 70 percent rebate for brand-name drugs while a beneficiary is in the coverage gap phase of the benefit, and insurers pay 5 percent. A beneficiary reaches the catastrophic threshold after paying a certain amount OOP, and the rebates are included in the calculation of a beneficiary's OOP spending for purposes of determining when the catastrophic threshold is reached. This enables the beneficiary to reach the catastrophic phase much more quickly. Because the government currently finances a large majority of the costs in the catastrophic phase, this provision (and others) have led to significant cost increases for the federal government. Excluding the rebates from TrOOP means a much greater amount of spending must occur before a beneficiary leaves the coverage gap. If this change is in effect by 2020, the amount of total drug spending that would occur before a beneficiary reaches catastrophic coverage is projected to more than double, increasing from $11,297, on average, to $24,520.

This increase breaks down as follows for the different stakeholders. Since 70 percent of the costs in the coverage gap are now financed by the drug manufacturers, they will bear the brunt of this change. Brand-name drug manufacturer costs would nearly quadruple, increasing from $3,488 to $13,152. Beneficiaries will also be worse off from this change, since they pay 25 percent of costs in the coverage gap compared with only 5 percent in catastrophic coverage. A beneficiary reaching catastrophic coverage would see their OOP costs in the coverage gap nearly triple, increasing from $1,772 to $5,260. If the OOP cap is imposed, however, they will pay nothing once (that is, if) they reach catastrophic coverage. Insurer costs in the coverage gap would barely increase, from $1,827 to $1,898.

Third is a proposal to increase insurer liability in the catastrophic phase to 80 percent while reducing the government's reinsurance rate to 20 percent. Insurers currently pay only 15 percent of catastrophic costs, while the government provides reinsurance equal to 80 percent. Many are concerned that the government's exposure for high-cost drugs is too high and that the plans' liability is not enough to incentivize stronger spending controls; reversing the share of liability should certainly change that.

While the first and third of these proposals are sound policy with promising benefits, implementing them in combination with the proposal to exclude manufacturer rebates from TrOOP will likely not have the desired result given the changes made by the Bipartisan Budget Act of 2018 (BBA). Because the BBA reduced plan liability in the coverage gap to only 5 percent, excluding manufacturer rebates from the TrOOP calculation—and thus keeping beneficiaries in the coverage gap longer—may actually lead to reduced plan liability, even when accounting for an increase in their liability in the catastrophic phase to 80 percent, as explained here. To account for this potential outcome, the American Action Forum has instead proposed a Part D benefit design restructuring that similarly imposes a cap on beneficiary OOP spending and significantly increases insurer liability in the catastrophic phase (while reducing the government's reinsurance percentage) but moves the mandatory manufacturer rebates to the catastrophic phase. This combination of reforms is more likely to alter incentives in a way that will reduce overall program costs while protecting beneficiaries from significant cost increases.

Reduced Cost-Sharing for LIS Beneficiaries

The president's budget also once again proposes eliminating cost-sharing for generic and biosimilar drugs for low-income subsidy (LIS) beneficiaries. Currently, LIS beneficiaries have nominal co-pay amounts for generics and slightly higher co-pay amounts for brand-name drugs; the difference is small, though, and seemingly does not provide enough incentive to convince them to take the cheaper alternatives. This incentive failure is demonstrated by the fact that LIS beneficiaries have historically had lower rates of generic drug use relative to non-LIS beneficiaries, partially accounting for the higher average spending rates for LIS beneficiaries.[2] This reform is intended to change that discrepancy by creating a greater financial incentive for generic utilization, without adversely impacting beneficiaries who may need to take the brand-name medicine.

Increase Competition

Finally, the administration is continuing its support to increase supply and prevent any stifling of competition. This year's budget again includes a proposal to prevent abuse of the market exclusivity rights that are granted to first-to-file generic applicants. Some applicants have previously blocked other generic entrants by "parking" their application at the FDA without completing the application process and putting their product on the market. This proposal would prohibit that practice. Similarly, first-to-file generic applicants may prevent other generics from coming to market through a delayed approval process. The budget proposes stripping first-to-file generic applicants of their 180-day exclusivity rights if their application is found to be deficient; this would only be

waived if a change in approval requirements that was made after the application was filed is the only reason the application was not approved.

Conclusion

The president's budget indicates a continued support for efforts to reduce drug prices and costs. Most of the proposals in this year's budget have been proposed before, and some seem to be gaining traction and may become law this year. Some proposals will have severe negative consequences, while others are new and creative ways to address some of the complex challenges in the drug pricing space.

[1] http://www.medpac.gov/docs/default-source/payment-basics/medpac_payment_basics_17_partb_final.pdf?sfvrsn=0

[2] http://www.medpac.gov/docs/default-source/reports/mar19_medpac_ch14_sec.pdf?sfvrsn=0 (pages 394, 411)