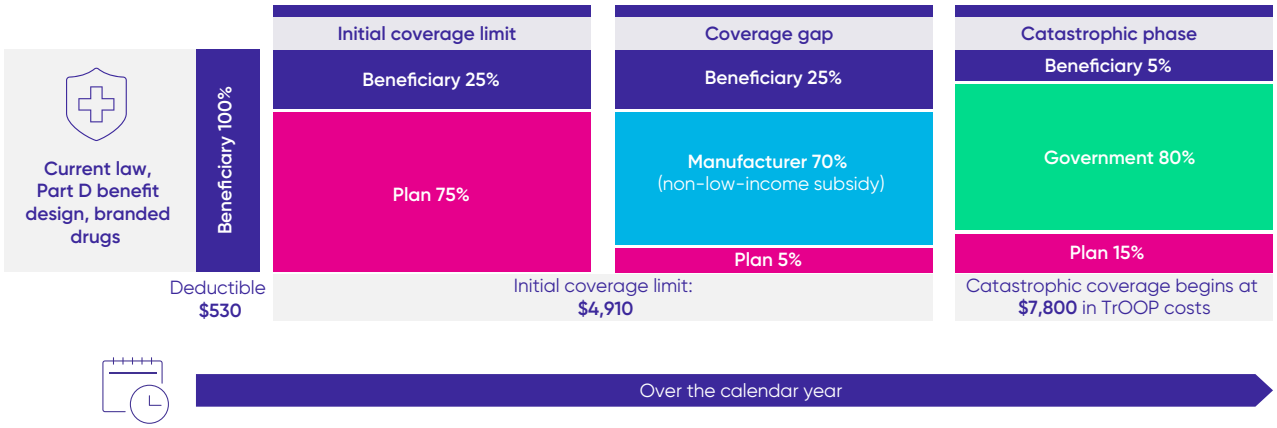
Build Back Better Act (BBBA) may not help build a future of innovation

As Congress looks at drug pricing reform, the details matter. On one hand, the Medicare prescription drug benefit program (Part D) is a successful demonstration of a public-private partnership with almost 50 million beneficiaries. And, on the other, beneficiaries are increasingly facing affordability challenges at the pharmacy, partly due to the structure of the Part D benefit.

The most recent proposal to update the Part D benefit design and enact drug pricing reforms is the Build Back Better Act (BBBA). BBBA represents a broad funding and programmatic package backed by President Biden. Among the BBBA's many healthcare policies are a series of initiatives aimed at addressing out-of-pocket expenses, price negotiations for Part D drugs, and the imposition of inflationary caps on price increases of certain Part D drugs.

It is no surprise that higher out-of-pocket (OOP) costs are associated with markedly higher rates of abandonment of new specialty drug prescriptions, reductions and delays in treatment initiation following a new diagnosis or disease progression, delays between refills or treatment interruptions, and earlier discontinuation of treatment.[1] As seen in (**Figure 1**), it is estimated that by 2024, beneficiaries would need to pay $7,800 in true out-of-pocket (TrOOP) costs before they enter catastrophic coverage. Even after reaching this phase, beneficiaries would still face a 5% coinsurance, which could be hundreds, if not thousands, of dollars a month for the rest of the year.[2]

Figure 1. Current baseline for Medicare Part D 2024



The BBBA proposes to address the gaps in the current Part D benefit design by setting an OOP spending cap for beneficiaries at $2,000 (starting in 2024).[3] As seen in (**Figure 2**), cost-sharing for nonsubsidized beneficiaries would drop from 25% to 23% during the initial coverage phase, and the manufacturer coverage discount program would be replaced by a 10% liability in the initial coverage phase and a 20% liability in the catastrophic phase. This liability would be phased in for low-income subsidy beneficiary claims. Government liability during the catastrophic phase would lessen and plan liability would increase.

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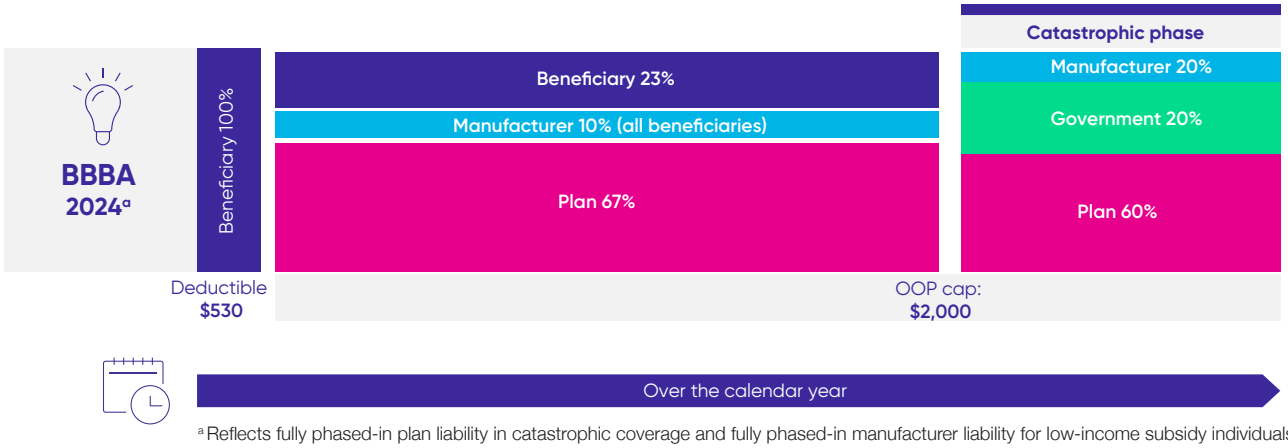
Figure 2. Proposed Part D benefit design for branded drugs under the BBBA



[a] Reflects fully phased-in plan liability in catastrophic coverage and fully phased-in manufacturer liability for low-income subsidy individuals.

While there is no question that a Part D OOP cap is a step in the right direction, a 20% manufacturer liability in the catastrophic phase would likely change the path of innovation. The incentives to develop drugs for rare or ultra-rare conditions will likely be affected because, unlike the current baseline, there is no cap to the manufacturer liability. Rare and ultra-rare disease drugs are inherently more expensive because they reach fewer beneficiaries. But these drugs address critical unmet needs and should be encouraged, not decimated, by legislation.

To highlight these impacts, Xcenda conducted an analysis of potential manufacturer contributions for various orphan-indicated products, which by definition have a patient population of less than 200,000 in the United States, compared to the current baseline.

As seen in (**Table 1**), manufacturer contributions for these orphan drugs would increase over 500% for all 3 examples. The example pulmonary hypertension product would see its contribution go up 1,423% above the current baseline and would face over $300 million more in manufacturer liability for that 1 product, per year. Rather than an almost $24 million cost under the current Medicare Part D plan, that pulmonary hypertension-treatment manufacturer would face over $360 million a year in the BBBA.

In addition to the changes in liability in Medicare Part D benefit design, manufacturers would face penalties if they raise prices faster than inflation. But, because the overall payer system operates on discounts and rebates—and higher prices are encouraged—manufacturers are likely to be trapped into inflation penalties on top of the increased liability due to the Part D benefit design changes.

Table 1. Total manufacturer costs for changes to Part D benefit design[a]

Manufacturer extrapolation to population level		
	Baseline 2024	BBBA
Primary biliary cholangitis	$5,214,614	$32,304,379
Difference from baseline		$27,089,766
Difference from baseline		519%
Oncology	$1,859,475	$12,590,086
Difference from baseline		$10,730,611
Difference from baseline		577%
Pulmonary hypertension	$23,820,385	$362,859,756
Difference from baseline		$339,039,371
Difference from baseline		1,423%

[a] Reflects fully phased-in plan liability in catastrophic coverage and fully phased-in manufacturer liability for low-income subsidy individuals.

To illustrate these dynamics, Xcenda modeled the inflation penalties for the market baskets previously discussed and found that, when combined with the impact of the Medicare Part D benefit design changes, the total increased liability for manufacturers could be staggering (**Table 2**). Manufacturer contributions for primary biliary cholangitis would increase 688% per year from the baseline, while the example products for oncology and pulmonary hypertension would **increase by over 1,000% per year.** Rather than the $1.8 million manufacturer liability in Part D, the oncology drug would have close to $23 million per year. And the pulmonary hypertension drug would now face a close to $400 million per year liability, up from $23.2 million.

These are often smaller companies that either specialize in the rare disease space or have only 1 or 2 products on the market and now must suddenly absorb these types of costs, in addition to any other changes that might result from other provisions of the legislation.

Finally, while the legislation also calls for Medicare negotiation of drug pricing, there is currently an exclusion for orphan drugs approved under Section 526 of the Federal Food, Drug, and Cosmetic Act. The BBBA would give the Secretary of Health and Human Services (HHS) the authority to negotiate on 50 brand name drugs that lack price competition as candidates for price negotiation (based on highest spend). For a drug to be considered for negotiation, it must be a small molecule or biologic treatment (including authorized generics) that has been outside the initial exclusivity period for at least 9 years for a small molecule or 13 years for a biologic. The negotiated price would not be extended to the private market, but the negotiated rate or "maximum fair price" would be available publicly.

Despite the exception for orphan drugs, rare disease manufacturers are watching this closely because, often, drugs may be approved for one indication but, through research and development, be discovered to have multiple therapeutic benefits.

Table 2. Total manufacturer liability for Part D benefit design change and inflation penalty in the BBBA[a]

Manufacturer extrapolation to population level	
	$ Impact Benefit design changes + inflation penalty in BBBA
Primary biliary cholangitis	$41,084,334
Difference from baseline	688%
Oncology	$22,569,158
Difference from baseline	1,114%
Pulmonary hypertension	$388,545,574
Difference from baseline	1,531%

[a] Reflects fully phased-in plan liability in catastrophic coverage and fully phased-in manufacturer liability for low-income subsidy individuals.

Innovation doesn't just happen; it needs time and investment and luck. Changing the manufacturer liability can be devastating when it comes to attracting the investors needed to gamble on pharmaceutical innovation. With a reduced return on investment, the money might be used in other sectors. This analysis shows that policy makers need to take a balanced approach to address patient OOP costs within the Medicare Part D design while balancing risks to research and development for orphan diseases.

References
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This work was done by Xcenda on behalf of the Rare Access Action Project.

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