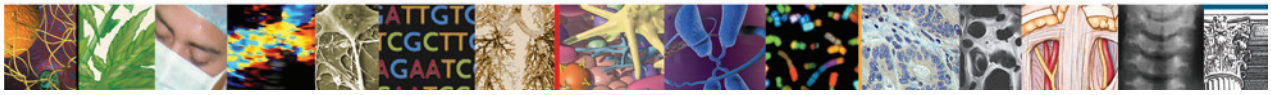

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Perspective

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Proposals to Redesign Medicare Part D — Easing the Burden of Rising Drug Prices

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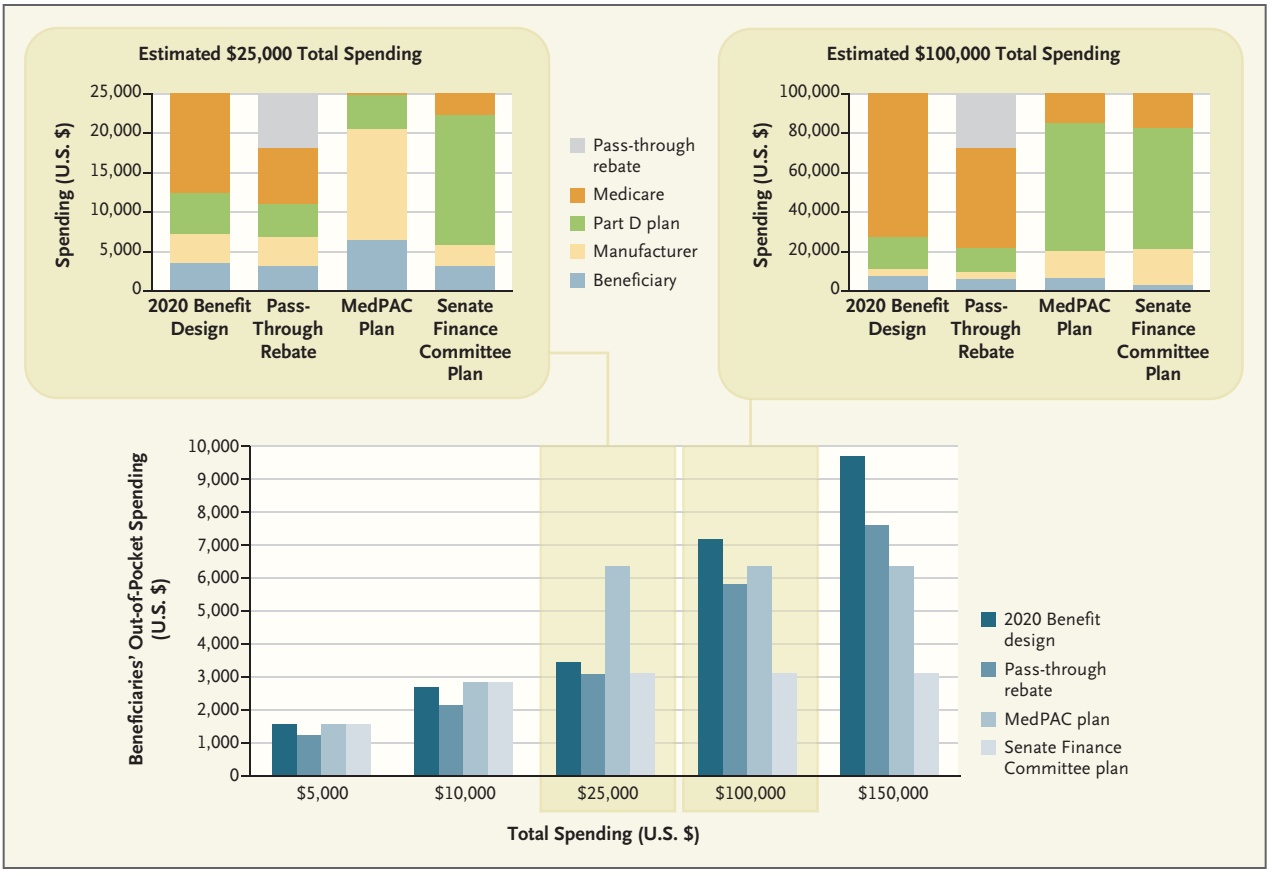
Amid concerns about high and rising drug prices, policymakers are considering options for modifying the Medicare Part D prescription-drug benefit to reduce spending by beneficiaries and taxpayers. Medicare beneficiaries without low-income subsidies currently face high and unlimited out-of-pocket spending under Part D. Options for supplemental insurance that may cover out-of-pocket expenses, which are available in Medicare Part B, are limited for Part D enrollees. List prices for specialty drugs averaged $4,455 per prescription in 2017, and prices continue to increase for new and existing drugs.[1] High prices create a substantial burden for patients that may reduce treatment uptake and adherence.

Furthermore, Medicare spending in Part D's catastrophic-coverage phase — in which Medicare pays 80% of expenditures — nearly quadrupled between 2010 and 2018 and is projected to reach nearly $90 billion per year by 2028.[2] This growth, driven by high prices and price increases for brand-name specialty drugs, has led to concerns that plans have insufficient incentives to manage drug spending for enrollees who qualify for catastrophic coverage, since they pay only 15% of expenditures during that phase.[1] Recognizing these challenges, Congress and the Trump administration are considering various redesigns to the Part D benefit.

The Medicare Part D standard benefit design for 2020 has a $435 deductible; 25% coinsurance for brand-name drugs in the initial-coverage phase and the coverage gap; a 70% manufacturer discount on brand-name drugs in the coverage gap, the value of which counts as out-of-pocket spending; and 5% coinsurance in the catastrophic-coverage phase. Beneficiaries transition between phases after reaching prespecified spending thresholds that increase each year (see the Supplementary Appendix, available at NEJM.org). They also pay premiums averaging approximately $30 per month.

Three redesigns are being considered — the Department of Health and Human Services (recently withdrawn) rebates rule,[3] the Medicare Payment Advisory Commission (MedPAC) proposed redesign[4] (included in the administration's proposed budget and drug-pricing blueprint), and a recent bipartisan proposal from the Senate Finance Committee.[5] All these redesigns shift spending for relevant stakeholders and benefit



Spending on Brand-Name Drugs under Proposed Redesigns of the Medicare Part D Benefit.

The lower graph shows estimated 2020 beneficiary out-of-pocket spending on brand-name and biosimilar drugs under current and proposed Part D designs at various levels of drug spending. The insets show estimated spending by payer under these designs for beneficiaries with $25,000 and $100,000 in drug spending. The $25,000 spending level approximates average spending among nonsubsidized beneficiaries classified as high spenders by the Medicare Payment Advisory Commission (MedPAC) in 2016 ($29,797), and the $100,000 level represents beneficiaries with particularly high expenditures. Total spending observed from pass-through rebates assumes point-of-sale price reductions of 27.7%.[2] For the other proposals, postsale rebates of 27.7% would reduce spending for Part D plans and Medicare but are not shown because of the lack of transparency regarding the way rebates are divided among stakeholders. Stakeholder liability by benefit phase is detailed in the Supplementary Appendix.

phases in different ways. For beneficiaries with annual spending on brand-name drugs by all payers of $10,000 or less (more than 90% of beneficiaries in 2017[1]), the proposals would have similar effects on out-of-pocket spending (see figure). For the growing number of beneficiaries with very high expenditures, however, their implications would vary considerably.

The pass-through rebates proposal[3] uses the current standard benefit design but bans manufacturer rebates typically retained by plans. Rebates would be allowed only when plans share them with patients when they fill their prescriptions. Average Part D rebates are expected to be 27.7% in 2020,[2] but there is considerable variation among drugs. Some of the most expensive drugs lack competition and have small rebates, meaning savings may not accrue to beneficiaries with the highest spending. In addition, rebates under the administration's proposal may be smaller than current rebates. Although this proposal would reduce out-of-pocket spending for beneficiaries taking drugs with large rebates relative to the 2020 design, the lack of an out-of-pocket cap would continue to expose beneficiaries to unlimited out-of-pocket spending.

The MedPAC proposal modifies the standard benefit by excluding the value of the 70% manufacturer discount on brand-name drugs purchased in the coverage gap from out-of-pocket spending and adds a cap on out-of-pocket spending at the current catastrophic-coverage threshold ($6,350).[4] Under this proposal, it would take longer for beneficia-

ries taking brand-name drugs to reach the catastrophic-coverage threshold, but once they did, they would be responsible for no additional spending. Because manufacturer discounts would no longer count toward out-of-pocket spending limits, beneficiaries with annual total spending on brand-name drugs of $25,000, for example, would have increased spending relative to the 2020 design, but those with higher expenditures would have decreased spending. Medicare's share of spending in the catastrophic-coverage phase would also decrease from 80% to 20% and plans' share would increase from 15% to 80%, which would encourage plans to expand price-negotiation and utilization-management efforts.

Under the Senate Finance Committee proposal, beneficiaries would pay a deductible and 25% coinsurance up to an out-of-pocket cap of $3,100. Manufacturers would provide a 20% discount on brand-name drugs filled after the out-of-pocket cap is reached (instead of a 70% discount in the coverage gap). This design substantially reduces out-of-pocket spending for beneficiaries with high drug spending as compared with the current benefit and other redesign proposals. It also reduces Medicare's share of spending in the catastrophic-coverage phase from 80% to 20% and increases plans' share from 15% to 60%.

As proposals shift spending from one stakeholder to another, plans may raise premiums to offset their increased responsibility in the catastrophic-coverage phase and lower cost sharing by beneficiaries. Under the rebates proposal, one estimate suggests that premiums could rise by an average of approximately 15% per month. Estimates for the MedPAC and Senate Finance Committee plans vary and suggest that there could be either decreases or increases in monthly premiums. For all proposals, responses by stakeholders, including changes to drug prices by manufacturers, will influence premiums. Although it is uncertain how Part D plan operators will respond, they will probably aim to keep premium increases small to ensure that they remain competitive and that healthy people enroll in the benefit.

An audio interview with Dr. Dusetzina is available at NEJM.org

Ultimately, the complex design of Part D makes restructuring challenging. Proposals that limit out-of-pocket spending for beneficiaries needing expensive drugs by shifting spending from beneficiaries to plans will require trade-offs in the form of premium increases or reduced generosity in other parts of the benefit. Such trade-offs should be carefully weighed, given the potential for adverse selection if rising premiums cause people with relatively low drug expenditures to drop coverage. The purpose of insurance, however, is to safeguard against catastrophic financial loss — something Part D is failing to do for beneficiaries who need expensive drugs.

None of these proposals address drug prices directly — they merely shift costs between stakeholders. Moreover, capping out-of-pocket spending could reduce price sensitivity for patients and thus lessen public scrutiny of drug companies' pricing strategies. Each proposal carries risks and uncertainties. For example, the rebates proposal relies on assumptions of voluntary list-price reductions, which are unlikely to occur. The MedPAC and Senate Finance Committee proposals encourage greater price negotiation and utilization management by plans, but the path to achieve these aims is unclear.

How, then, do we ensure a sustainable benefit with acceptable premiums and sufficient protection from catastrophic costs? First, we believe solutions should target people with the highest out-of-pocket spending by introducing an out-of-pocket spending cap. Ideally, plans could include monthly and annual spending limits in order to distribute out-of-pocket costs over the benefit year and retain price sensitivity among beneficiaries, rather than having some beneficiaries be responsible for drug costs early in the year only. Caps could also be tied to enrollees' income to ensure that costs are manageable. Second, Medicare could do more to directly address drug prices — both high prices at launch and price increases over time — in Part D. Such efforts could include direct negotiation of prices for expensive drugs, use of inflation-based rebates (another feature of the Senate Finance Committee's package of drug-price reforms), and reimbursement of drugs based on the relative value that they provide. These types of policies, combined with changes to the Part D benefit, are needed to ensure that the program is sustainable in the long run. They also require trade-offs, but informed trade-offs will serve beneficiaries better than the status quo, which makes even highly effective drugs unaffordable. We believe it is time for Congress to redesign Part D to meet its intended goal of making prescription drugs accessible to beneficiaries while ensuring the benefit's long-term sustainability.

Disclosure forms provided by the authors are available at NEJM.org.

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Medicare Drug-Price Negotiation — Why Now . . . and How

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Drug spending, price, and affordability problems in the United States stem directly from insufficient competition. In prescription-drug markets in which competition is weak, Medicare's purchasing rules tilt the bargaining process in favor of the pharmaceutical industry at the expense of consumers and taxpayers. That's because the rules in Medicare Part D pit fragmented private plans making purchases on behalf of beneficiaries against monopolistic sellers of drugs delivered through pharmacies. Meanwhile, Medicare Part B is required to passively accept industry prices for clinician-administered drugs. Consequently, Part B drug spending has been growing by 9% per year since 2009, roughly double the rate of Medicare spending as a whole.[1] In these specific markets, a carefully designed Medicare negotiation approach could be particularly effective.

Pharmacy benefit managers and insurers offering private Medicare Part D plans can obtain lower prices on drugs for which generic substitutes are available and on some classes of drugs in which there are brand-name substitutes. But fragmented insurers have little recourse regarding drugs that lack effective competition. Part D spending has also grown faster than average Medicare spending, at a clip of 7.3% per year since its inception.[2] The Congressional Budget Office (CBO) recently reported that in 2015, the net price (after accounting for rebates) for brand-name specialty drugs paid for by Part D was $3,590 per standardized prescription (about 30 days' worth) as compared with the average net price of brand-name nonspecialty drugs of $210.[3] The result is that 63% of the spending growth in Medicare Part D between 2010 and 2015 was attributable to new specialty drugs.

Specialty drugs are high-cost, are often aimed at smaller patient populations, require careful clinical supervision, and are delivered through specialty pharmacies. These drugs are frequently biologic products and typically have few, if any, competitors.

Today, much pharmaceutical research and development targets specialty drugs that will become de facto monopolies and remain so for a long time, distorting the balance between encouraging innovation and protecting consumers' interests. As a result, launch prices and subsequent price inflation are higher than credible measures of fair market value. We believe that a targeted bargaining strategy using tried and tested arbitration techniques could help Medicare better balance innovation and affordability. Allowing the government to negotiate on behalf of Medicare, and possibly for other drug buyers that have weak bargaining power, could lower excessively high prices, even as the parts of the market where competition works reasonably well are left alone.

It would be essential both to target the right drugs and to establish reference prices to guide negotiation. The former requires identifying drugs that lack competition and for which the payoffs of negotiation are likely to be significant. We recommend that at least one of two criteria be met