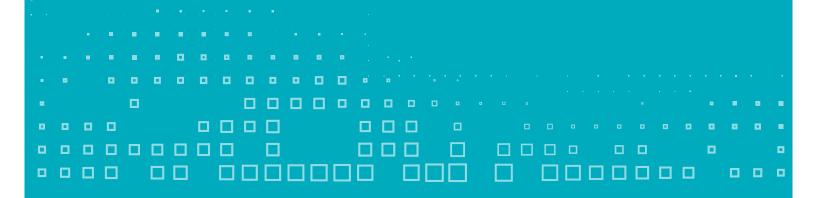
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The Benefits of Capping Medicare Part D Out-of-Pocket Costs Will Vary Substantially Depending on the Drugs That Beneficiaries Use

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Although delayed as a result of the COVID-19 public health emergency, there are persistent and ongoing efforts to reform the Medicare Part D benefit. Since its June 2016 Report to Congress, the Medicare Payment Advisory Commission (MedPAC) continues to recommend changes to the Part D benefit design, including eliminating the coverage gap and creating a maximum out-of-pocket (MOOP) cap on beneficiary costsharing that will be financed by a combination of plan, manufacturer, Medicare individual reinsurance payments and through greater flexibility for plans to manage formularies. A number of advocacy groups such as the American Action Forum have supported similar reforms, many of which have found their way into the Senate Finance Committee Prescription Drug Pricing Reduction Act of 2019 (PDPRA) and the House Lower Drug Costs Now Act of 2019. If the PDPRA is enacted, enrollees would be responsible for 25% of cost-sharing after the deductible, until they accrue \$3,100 in out-of-pocket spending, at which point enrollees enter the catastrophic phase and will have no additional cost-sharing. Payment for drugs in the catastrophic phase would be shared by Part D plans, manufacturers and Medicare individual reinsurance payments. Our analysis shows that if implemented, the PDPRA could bring down total out-of-pocket costs (excluding premiums) for Part D enrollees by 8%, or \$1.1 billion, on average across all Part D drugs, but with substantial variation across types of drugs. For example, total cost-sharing for antidiabetic drugs would decrease by 22%, or \$340.6 million; antineoplastic and adjunctive therapies by 42%, or \$240.5 million; and antiasthmatic and bronchodilator agents by 8%, or \$80.3 million, while leaving out-of-pocket costs for ophthalmic agents essentially unaffected.

A Manatt analysis¹ simulates the potential impacts of the PDPRA on how cost-sharing for enrollees and payments by Part D plans, manufacturers and Medicare would change if the PDPRA were to be fully implemented in CY 2020 relative to the current Part D standard benefit design for CY 2020. This analysis shows that compared with the CY 2020 baseline, the fully implemented PDPRA, including a MOOP cap of \$3,100, would decrease aggregate cost-sharing spending (excluding premiums) for enrollees by 8%, and would decrease aggregate low-income subsidy (LIS) cost-sharing subsidy payments by 50%, since Medicare is no longer subsidizing the coverage gap discount portion for LIS enrollees. The PDPRA would increase aggregate plan liability by 94% (prior to risk corridor payments and year-end reconciliations and changes in direct Medicare subsidies to plans), decrease aggregate Medicare individual reinsurance payments by 76% (prior to reconciliation of net rebates, chargebacks and other concessions), and increase aggregate manufacturer discount payments by 50%. Part D plan liabilities are estimated to increase but could be partially offset by an increase in Medicare direct subsidies and greater use of formulary management tools.

Because our approach uses Part D PDE data and the Medicare Master Beneficiary Summary File (MBSF) for 2018, along with the 2018 Part D Plan Characteristics File, as the basis for plan enrollment, formulary designs, drug prices and utilization, this study estimates the magnitude of changes in spending assuming no changes in enrollment, drug prices or utilization relative to 2018. We exclude enrollees in employer group waiver plans, Programs of All-Inclusive Care for the Elderly, demonstrations, medical savings accounts and special needs plans.

Part D CY 2020 Actual Standard Benefit Design and the PDPRA Proposed Standard Benefit Design: Comparisons of Aggregate **Spending**

If enacted, the PDPRA would simplify the benefit into three phases. Enrollees would start with a deductible, followed by an initial coverage period where enrollees are responsible for about 25% of cost-sharing. Enrollees would then exit the initial coverage period and enter the catastrophic phase once they have accrued \$3,100 in out-of-pocket spending.

In the catastrophic phase, Part D plans would be responsible for 60% of all spending, and manufacturers would be responsible for 20% of all brand and biosimilar spending. Medicare reinsurance payments in the catastrophic phase would cover 20% of brand and biosimilar spending, and 40% of all generic spending. The MOOP cap, which establishes the start of the catastrophic phase, would increase each year by the change in overall Part D spending growth. Sponsors would still be able to adjust this design as long as their design is actuarially equivalent. The PDPRA also includes a three-year transition to change the financial responsibility for each part of the benefit not paid through out-of-pocket costs.

In 2018, there were just under 35.9 million Part D enrollees in stand-alone prescription drug plans or Medicare Advantage prescription drug plans, excluding the enrollees noted above. Of those enrollees, 25.2 million (70%) were not eligible for LIS, and just under 10.7 million (30%) were LIS eligible.² Using 2018 PDE data, Manatt simulated payment under the current 2020 Medicare standard Part D benefit design, which we refer to as the baseline. We then simulated with 2018 PDE data the expected cost-sharing under the PDPRA standard benefit design as if it were fully implemented in CY 2020. Relative to the baseline and prior to adjusting for changes in Medicare direct subsidies and risk corridor payments,3 Manatt's Part D model estimates for the included enrollees are summarized in Figure 1 below.

Figure 1. Comparison of Aggregate Spending Under the CY 2020 Actual Standard Benefit Design and the PDPRA Proposed Standard Benefit Design

	CY 2020 Actual Standard Benefit Design (Baseline)	CY 2020 Proposed PDPRA Standard Benefit Design	Change in Aggregate Spending (%)	
Enrollee Cost-Sharing	\$13.6B	\$12.4B	-\$1.1B	(-8%)
LIS Cost-Sharing Subsidies	\$20.9B	\$10.4B	-\$10.5B	(-50%)
Plan Liability	\$40.9B	\$79.2B	\$38.4B	(94%)[1]
Medicare Individual Reinsurance ^[2]	\$38.8B	\$9.3B	-\$29.5B	(-76%)
Manufacturer Discount	\$5.3B	\$7.9B	\$2.6B	(50%)

Source: Manatt analysis of 2018 Medicare Part D PDE data, 2018 Plan Characteristics File and 2018 MBSF from the Centers for Medicare and Medicaid (CMS). Both Medicare PDE and MBSF data were obtained through a data use agreement with CMS.

Our model estimates that plan liabilities will increase due to a greater share of spending in the catastrophic phase and because enrollees take longer to reach the MOOP cap without the usual coverage gap discounts. Increased plan liabilities will be financed by a combination of greater use of formulary management tools to reduce costs, higher enrollee premiums and higher Medicare direct subsidies to plans. The federal government's overall subsidy (the sum of the Medicare direct subsidy to plans and the estimated federal reinsurance) represents 74.5% of standard coverage for all beneficiaries, although the makeup of the subsidy can change.

Manufacturer discount payments are estimated to increase, as manufacturers would be required to make these discount payments for brand-name drugs and biosimilars purchased by both non-LIS and LIS enrollees in the catastrophic phase. Currently, manufacturer discounts are limited to non-LIS enrollees in the coverage gap. Under the PDPRA, there will no longer be a cap on the maximum amount of manufacturer discount payments that can be paid for an individual enrollee. Overall enrollee out-of-pocket payments (excluding premiums) and LIS cost-sharing subsidies are expected to decrease due to the MOOP cap.

Part D CY 2020 Actual Standard Benefit Design and the PDPRA Proposed Standard Benefit Design: Comparisons of Enrollee Cost-Sharing by Ten Drug Groups Ranked by Total Drug Costs

Results in Figure 1 above show aggregate impacts; however, impacts will vary by drug groups. Figure 2 below compares the impacts of the PDPRA with the baseline on enrollee cost-sharing for each of the top ten drug groupings by total gross drug costs.4 Among the top ten drug groups by gross Part D drug costs, the drug groups with the largest percentage decrease in out-of-pocket payments include antineoplastic and adjunctive therapies (-42%), antidiabetics (-22%), and psychotherapeutic and neurological agents (-22%). Drug groups with the smallest percentage change in out-of-pocket payments include antipsychotics/antimanic agents (0%), ophthalmic agents (0%), and anticonvulsants (-6%) and antiasthmatic and bronchodilator agents (-8%). Some drug groups will experience increases such as antidepressants (+4%) (not pictured here).

^[1] A portion of the 94% increase in plan liabilities will be offset by increased Medicare direct subsidies.

^[2] Medicare individual reinsurance is calculated prior to the reconciliation of rebates and all other direct and indirect remuneration, which will reduce the reinsurance amount paid by Medicare to the plan.

Figure 2. Comparison of Enrollee Cost-Sharing Amounts Under the CY 2020 Actual Standard Benefit Design and the PDPRA Proposed Standard Benefit Design for Top Ten Drug Groups (Ranked by Total **Gross Drug Costs**)

Drug Group (Highest to Lowest Total Gross Drug Cost)	CY 2018 Total Gross Drug Costs	CY 2020 Actual Standard Benefit Design (Baseline) Cost-Sharing	CY 2020 Proposed PDPRA Standard Benefit Design Cost-Sharing	Change in Aggregate Cost-Sharing (%)	
Antineoplastics and adjunctive therapies	\$10,170.2M	\$574.0M	\$333.6M	-\$240.5M	(-42%)
Antidiabetics	\$18,212.6M	\$1,530.8M	\$1,190.2M	-\$340.6M	(-22%)
Psychotherapeutic and neurological agents (miscellaneous)	\$6,178.2M	\$361.9M	\$283.9M	-\$78.0M	(-22%)
Antivirals	\$7,338.6M	\$285.8M	\$228.3M	-\$57.5M	(-20%)
Anticoagulants	\$6,771.2M	\$881.1M	\$724.7M	-\$156.4M	(-18%)
Analgesics, anti- inflammatories	\$4,584.2M	\$233.3M	\$207.5M	-\$25.8M	(-11%)
Antiasthmatic and bronchodilator agents	\$8,757.2M	\$1,008.2M	\$927.9M	-\$80.3M	(-8%)
Anticonvulsants	\$4,597.4M	\$422.4M	\$397.4M	-\$25.0M	(-6%)
Antipsychotics/antimanic agents	\$4,621.2M	\$138.5M	\$138.1M	-\$0.4M	(0%)
Ophthalmic agents	\$3,191.9M	\$600.6M	\$603.3M	\$2.7M	(0%)

Source: Manatt analysis of 2018 Medicare Part D PDE data, 2018 Plan Characteristics File and 2018 Medicare MBSF from CMS. Both Medicare PDE and MBSF data were obtained through a data use agreement with CMS. Drug groups defined by two-digit Generic Product Identifiers from the Medispan® database.

Figure 3 provides a visual depiction of the varying impact of the PDPRA on total enrollee cost-sharing amounts for the same top ten drug groups. Not only do antidiabetics and antineoplastic and adjunctive therapies have the largest percentage reduction in cost-sharing amounts, they also have the largest overall decrease in total cost-sharing dollar amounts. Although antiasthmatic and bronchodilator agents show a relatively small percentage decrease in cost-sharing, these agents have a significant overall decrease in total cost-sharing dollar amounts.

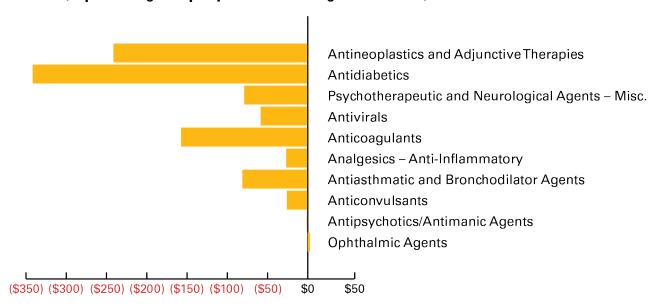


Figure 3. Estimated Change in Out-of-Pocket Costs in PDPRA Relative to 2020 Part D Baseline, in Millions (Top Ten Drug Groups by Total Gross Drug Costs in 2018)

Estimated Change in OOP Spend Under PDPRA Relative to Part D 2020 Baseline, in Millions

Several reasons may explain the substantial variation in changes in enrollee out-of-pocket costs among drug groups as a result of the proposed PDPRA. These may include the distribution of enrollees by indication, as well as by utilization of drug groups or by LIS status, across Part D benefit phases, by Part D plan type (Medicare Advantage Part D Plan (MA-PDP) or stand-alone Part D Plan (PDP)), and/or whether a drug is in a protected class.

This analysis was performed by simulating cost-sharing under the Part D standard benefit parameters for CY 2020 and under the PDPRA assuming full implementation in 2020. These simulations were performed using the full 100% sample of Part D PDE data for 2018, and Manatt's Part D model, which considers formulary and benefit designs for individual MA-PDP and PDP plans.

This analysis does not address changes in enrollee behavior that could result from changes in the Part D benefit and does not capture changes in price, enrollment, plan offerings and/or utilization that may occur between 2018 and 2020, or in response to the implementation of the PDPRA.

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1 We convert 2018 plan benefit designs in the 2018 Part D Prescription Drug Event (PDE) data to match the 2020 Part D Standard Benefit Design as published in the Announcement of Calendar Year (CY) 2020 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter, dated April 1, 2019, and displayed in this table. Cost-sharing for the deductible and initial coverage periods was calculated for each drug based on the plan's tier placement and copayment/coinsurance for that tier. Costsharing for the coverage gap, for the catastrophic phase and after the MOOP cap was calculated based on the drug's brand/generic status and proposed parameters under the Part D standard benefit design for CY 2020 and PDPRA once fully implemented.

- ² LIS status defined during the enrollee's last month of Part D enrollment in 2018. For most enrollees, this will be December.
- ³ Changes in plan payments may impact Medicare direct subsidies and risk corridor payments.
- ⁴ Drug groups defined by two-digit Generic Product Identifiers from the Medispan® database.

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