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During the Medicare Payment Advisory Commission's (MedPAC) January 16 public session, MedPAC staff continued their drumbeat for reforming the Part D benefit following recommendations previously made in their June 2016 Report to Congress.^{1,2} Continuing themes include eliminating the coverage gap and creating a maximum out-of-pocket cap (MOOP) on beneficiary spending that will be financed by a combination of plan, manufacturer, and CMS payments and through greater flexibility for plans to manage formularies. More recently, a number of advocacy groups, such as the American Action Forum,³ have supported similar reforms, many of which have found their way into the proposed Senate Finance Committee Prescription Drug Pricing Act of 2019 (PDPRA).⁴

To help understand how these reforms may impact enrollees, Part D plans and manufacturers, Manatt has built a model that can analyze the impact of legislative changes to Part D. As a test case, Manatt ran its Part D model to simulate the potential impacts of the PDPRA.⁵ This study simulates how cost-sharing for enrollees, and payments by Part D plans, manufacturers and CMS compare under the PDPRA if it were to be fully implemented in CY 2020, relative to the current Part D standard benefit design for CY 2020, which we refer to as our baseline.⁶

Compared to this baseline, the fully implemented PDPRA with a MOOP cap of \$3,100 will slightly decrease aggregate enrollee out-of-pocket payments (excluding premiums) and significantly reduce Medicare reinsurance and low-income cost-sharing subsidies. Part D plan liabilities are estimated to increase but could be partially offset by an increase in CMS direct subsidies and greater use of formulary management tools. Manufacturer discount payments will increase sizably as well. Impacts of the PDPRA on individual drugs, drug classes, individual Part D plans and enrollee groups are likely to differ from these aggregate results.

Because our approach uses Part D Prescription Drug Event data and the Medicare Master Beneficiary Summary File for 2017, along with the 2017 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 2017. We exclude enrollees in employer group waiver plans, Programs for 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. CMS 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. Presumably, sponsors would still be able to continue 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 2017 there were just under 34.9 million Part D enrollees in stand-alone prescription drug plans or Medicare Advantage prescription drug plans, excluding the enrollees noted above. Of those enrollees, 24.0 million (69%) were not eligible for low-income subsidies (LIS) and just under 10.9 million (31%) were LIS eligible.⁷ Using 2017 PDE data we simulated payments under the current 2020 CMS standard Part D benefit design, which we refer to as the baseline. We then simulated, with 2017 PDE data, expected payments 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 CMS direct subsidies and risk corridor payments,⁸ Manatt’s Part D model estimates for the included enrollees that the PDPRA will:

- Decrease aggregate cost-sharing spending (excluding premiums) for enrollees by 7%
- Decrease aggregate LIS cost-sharing CMS subsidy payments by 49%
- Increase aggregate plan liability by 89%
- Decrease aggregate CMS reinsurance payments by 76%
- Increase aggregate manufacturer discount payments by 62%

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 | \$12.9B | \$12.0B | -\$0.9B (-7%) |
| LIS Cost-Sharing Subsidies | \$20.6B | \$10.5B | -\$10.1B (-49%) |
| Plan Liability | \$39.1B | \$73.8B | \$34.8B (89%) ^[1] |
| CMS Reinsurance | \$35.1B | \$8.5B | -\$26.6B (-76%) |
| Manufacturer Discount | \$4.4B | \$7.2B | \$2.8B (62%) |

Source: Manatt analysis of 2017 Medicare Part D Prescription Drug Event data (PDE), 2017 Plan Characteristics File, and 2017 Medicare Master Beneficiary Summary File (MBSF) from the Centers for Medicare & Medicaid Services. Both Medicare PDE and MBSF data were obtained through a data use agreement with the Centers for Medicare & Medicaid Services.

[1] A portion of the 89% increase in plan liabilities will potentially be offset by increased CMS direct subsidies.

Our model estimates that plan liability will increase due to a greater share of spending in the catastrophic phase. Increased plan liabilities could potentially be financed by a combination of greater use of formulary management tools to reduce costs, higher enrollee premiums and higher CMS direct subsidies to plans. The federal government's overall subsidy (the sum of the CMS direct subsidy to plans and estimated federal reinsurance) is intended to represent 74.5% of standard coverage for all beneficiaries, although the makeup of the subsidy can change.⁹

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, and because 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 CMS LIS cost-sharing subsidies are expected to decrease due to the maximum out-of-pocket cap that will apply to the first \$3,100 in out-of-pocket and low-income cost-sharing subsidies.

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 prescription drug event data for 2017, and Manatt's Part D model, which takes into account formulary and benefit designs for individual MA-PDP and PDP plans. Results are provided in this newsletter in the aggregate, but can be produced at a more granular level to isolate the potential impacts to different types of enrollees, drug classes and Part D 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 have occurred between 2017 and 2020, or in response to the implementation of the PDPRA.

¹ Medicare Payment Advisory Commission. “The Medicare Prescription Drug Program (Part D): Status Report and a Proposal for Restructuring.” January 16, 2020. http://medpac.gov/docs/default-source/default-document-library/part_d_public_jan_2020.pdf?sfvrsn=0.

² Medicare Payment Advisory Commission. “Chapter 6: Improving Medicare Part D” Report to Congress. June 2016.

³ Tara O’Neill Hayes, “Redesigning Medicare Part D to Realign Incentives.” American Action Forum, August 14, 2018. <https://www.americanactionforum.org/research/redesigning-medicare-part-d-realign-incentives-1/>.

⁴ Prescription Drug Pricing Reduction Act of 2019. September 25, 2019, last accessed 10/2/19 at <https://www.finance.senate.gov/imo/media/doc/PDPRA%20Statutory.pdf>.

⁵ Prescription Drug Pricing Reduction Act of 2019. September 25, 2019, last accessed 10/2/19 at <https://www.finance.senate.gov/imo/media/doc/PDPRA%20Statutory.pdf>.

⁶ We converted 2017 plan benefit designs in the 2017 Part D Prescription Drug Event 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*, 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. Cost-sharing for the coverage gap, 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.

⁷ Low-income subsidy status defined during the enrollee’s last month of Part D enrollment in 2017. For most enrollees this will be December.

⁸ Changes in plan payments may impact CMS direct subsidies and risk corridor payments.

⁹ Medicare Payment Advisory Commission. “Part D Payment System.” October 2019.

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