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February 2018 | Issue Brief

Summary of Recent and Proposed Changes to Medicare Prescription Drug Coverage and Reimbursement

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On February 9, 2018 the President signed into law the Bipartisan Budget Act of 2018 (BBA of 2018), which included some provisions related to Medicare Part D prescription drug coverage. Just days later, on February 12, the Office of Management and Budget (OMB) released the President's fiscal year (FY) 2019 budget, which also included several proposals related to Medicare Part D drug coverage and Part B drug reimbursement. This brief summarizes these recent and proposed changes. Budget estimates for provisions in the BBA of 2018 reflect the 10-year (2018-2027) effects as estimated by the Congressional Budget Office. Budget estimates for proposals in the President's FY2019 budget reflect the 10-year (2019-2028) effects as estimated by OMB.[1]

Summary of Changes in the BBA of 2018

- **Part D coverage gap and manufacturer discount:** Closes the Part D coverage gap in 2019 instead of 2020 by accelerating a reduction in beneficiary coinsurance from 30 percent to 25 percent in 2019; also increases the discount provided by manufacturers of brand-name drugs in the coverage gap from 50 percent to 70 percent, beginning in 2019. In 2019 and later years, Part D plans will cover the remaining 5 percent of costs in the coverage gap, which is a reduction in their share of costs (down from 25 percent). The manufacturer discount will continue to count towards a beneficiary's "true out-of-pocket spending" (TrOOP), the spending amount that triggers the start of catastrophic coverage. *Estimated budget impact: not estimated separately by CBO; included in biosimilars provision below*
- **Biosimilars:** Beginning in 2019, biosimilars will be treated the same as other brand-name drugs in the Part D coverage gap, with manufacturer discounts of 70 percent; previously biosimilars were not included in the coverage gap discount program. *Estimated budget impact: -$10.05 billion*
- **Income-related Medicare premiums:** Increases Medicare Part B and Part D premiums for beneficiaries with incomes of $500,000 (for individuals) and $750,000 (for married couples) or more, to 85 percent of program costs, up from 80 percent, beginning in 2019. *Estimated budget impact: -$1.63 billion*

Summary of Proposed Changes in the President's FY2019 Budget

Part D

- **Share rebates with Part D enrollees:** Would require Part D plans to pass on at least one-third of total rebates and price concessions to enrollees at the point of sale. The Administration solicited comments on potential policy approaches related to this idea in a November 2017 proposed rule for the Medicare Advantage and Part D programs. *Estimated budget impact: +$42.16 billion*

- **Add an out-of-pocket limit to Part D and change reinsurance:** Would establish an out-of-pocket limit in the Part D benefit by phasing down beneficiary coinsurance in the catastrophic coverage phase of the benefit from the current 5 percent level to 0 percent (no cost sharing) over four years, beginning in 2019.[2] Also would increase plans' share of costs in the catastrophic coverage phase of the benefit from 15 percent to 80 percent, and decrease Medicare's reinsurance from 80 percent to 20 percent. The Medicare Payment Advisory Commission (MedPAC) recommended similar changes to Part D reinsurance in 2016. *Estimated budget impact: +$7.36 billion*
- **Change TrOOP calculation:** Would exclude manufacturer discounts from the calculation of beneficiaries' "true out-of-pocket spending." MedPAC also recommended this change, in combination with the proposed changes to catastrophic coverage above. *Estimated budget impact: -$47.02 billion*
- **Change Part D formulary standards:** Would loosen Part D plan formulary standards by requiring plans to cover a minimum of one drug per drug category or class, down from the current two-drug requirement. Would expand plans' ability to use utilization management tools for specialty drugs and drugs in the six protected classes (anticonvulsants, antidepressants, antineoplastics, antipsychotics, antiretrovirals, and immunosuppressants for the treatment of transplant rejection). *Estimated budget impact: -$5.52 billion*
- **Eliminate cost sharing for generics for low-income enrollees:** Would eliminate cost sharing on generic drugs for Part D enrollees receiving the low-income subsidy (LIS), including biosimilars and preferred multisource drugs, beginning in 2019. MedPAC recommended a similar change in 2016. *Estimated budget impact: -$0.21 billion*
- **Retroactive Part D coverage for low-income enrollees:** Would permanently authorize CMS to contract with a single Part D plan to provide Part D coverage to low-income beneficiaries while their LIS eligibility is processed, beginning in 2020; this is currently a demonstration program scheduled to run through 2019. *Estimated budget impact: -$0.30 billion*

Part B Drug Reimbursement

- **Average sales price data reporting:** Would require manufacturers of Part B drugs to report average sales price (ASP) data and would authorize the Secretary of Health and Human Services (HHS) to apply civil monetary penalties if manufacturers do not meet reporting requirements, beginning in 2019. *Estimated budget impact: no budget impact*
- **Establish a limit on Part B reimbursement growth rate:** Would establish an inflation limit for reimbursement of Part B drugs paid based on ASP, with the growth in the ASP portion of Medicare's reimbursement to physicians for these drugs (currently ASP plus 6 percent) limited to growth in the Consumer Price Index for all Urban Consumers (CPI-U), beginning in 2019. Currently there is no limit on updates to the ASP plus 6 percent reimbursement if the ASP increases. Under the budget proposal, reimbursement to physicians for Part B drugs paid based on ASP would be the lesser of actual ASP plus 6 percent or the inflation-adjusted ASP plus 6 percent. *Estimated budget impact: not available*
- **Coverage of certain Part B drugs under Part D:** Would authorize the HHS Secretary to consolidate coverage of certain drugs under Part D that are currently covered under Part B, beginning in 2019, subject to a determination that there are savings to be gained from the consolidation (shifting from the ASP plus 6 percent reimbursement under Part B to negotiated pricing under Part D). *Estimated budget impact: not available*

- **Reduce wholesale-acquisition-cost based reimbursement rate:** Would reduce wholesale acquisition cost (WAC) based payments for new Part B drugs where ASP data are not available, from 106 percent to 103 percent of WAC, beginning in 2019. *Estimated budget impact: not available*

- **Redistribution of savings from 340B payment reductions:** Would make changes to the 340B discount program, building on recent changes to Medicare's payment rate for certain Medicare Part B drugs purchased by hospitals through the 340B program, which is decreasing from ASP plus 6 percent to ASP minus 22.5 percent, beginning in 2018. Under the budget proposal, savings generated by this reimbursement change for 340B drugs would be redistributed to certain hospitals that provide a minimum level of charity care or would be returned to the Medicare trust funds, beginning in 2019. Hospitals would be eligible for an allocation of the savings from the 340B drug payment reduction if the value of uncompensated care they provide equals at least one percent of their total patient care costs. *Estimated budget impact: not available*

Endnotes

[1] The Administration's budget did not specify whether the budget estimates took into account changes in the BBA of 2018 that would affect the costs or savings associated with proposals in the FY2019 budget.

[2] In 2015, 1 million Part D enrollees who did not receive low-income subsidies had spending in the catastrophic coverage phase of the Part D benefit. While those who reach the catastrophic coverage phase of the benefit would see savings from the elimination of coinsurance above the catastrophic threshold, the Administration's proposed changes to the TrOOP calculation (described above) would likely mean that fewer enrollees would reach the catastrophic coverage phase in future years since they would be required to spend more out of pocket to pass through the coverage gap and enter the catastrophic phase of the benefit.