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Policy Proposal: Require Rebates on Drugs for Low-Income Medicare Beneficiaries

A series that examines policies to manage drug spending

What problem is this policy meant to address?

Of the 41 million Medicare Part D beneficiaries in 2016 (approximately 7.5 million of whom were also eligible for Medicaid),[1] 12 million received a low-income subsidy (LIS, also known as Extra Help). The LIS helps beneficiaries with limited incomes to pay their Part D premiums and any cost-sharing on drugs, including deductibles and co-payments. This assistance comes from subsidies the federal government pays to the Part D commercial drug plan in which the beneficiary enrolls.[2] The Medicare Payment Advisory Commission estimates that in 2014, nearly 70 percent of Medicare spending on the Part D benefit was for the 30 percent of enrollees receiving the LIS.[3]

Before 2006, low-income seniors and disabled individuals eligible for both Medicare and Medicaid received outpatient prescription drug benefits through Medicaid.[4] In 2006, when Medicare Part D was implemented, such "dually eligible" beneficiaries began receiving prescription drug coverage through Medicare Part D instead,[5] as required by the Medicare Modernization Act (MMA).[6] Today, state Medicaid programs do not directly pay the entire cost of prescription drugs used by dually eligible beneficiaries, but states continue to pay a large share of beneficiaries' Part D coverage through monthly payments intended to offset some Medicare spending for these individuals.[7] In 2016, states contributed approximately 9 percent of the revenue used to operate the Part D program.[8]

States receive mandatory rebates from drug manufacturers on prescription drugs provided through Medicaid in agreements established between manufacturers and the federal Department of Health and Human Services. The rebates are paid quarterly to states, and the savings are shared with the federal government.[9] Medicaid rebates apply to both brand and generic drugs and include an additional payment when a drug's price increases faster than inflation.[10]

However, Medicaid rebates are not available for dually eligible beneficiaries because they receive prescription drug benefits through Medicare Part D. Although private Part D plans are able to negotiate rebates and discounts directly with drug manufacturers, the savings are typically smaller than with mandatory Medicaid rebates.[11] Implementing mandatory rebates to the federal government for beneficiaries receiving the Medicare low-income subsidy, including dually eligible beneficiaries, could lower the cost of drugs for these beneficiaries and generate substantial federal savings.

How could this policy work?

Congress could update the MMA to create a mandatory rebate program for LIS beneficiaries in Medicare Part D that is similar to the Medicaid mandatory rebate program. Manufacturers could be required to pay a

rebate equal to 23.1 percent of a brand drug's average manufacturer price (AMP) (13 percent for generics) or the difference between AMP and the Medicaid Best Price,[12] plus an additional rebate for price increases that exceed the rate of inflation since the drug's introduction to market. The program would also include a requirement that manufacturers participate in the rebate program in order for their drugs to be covered under Medicaid and Medicare.

Private Part D plans already negotiate rebates on brand drugs, which reduce beneficiary premiums and some government costs.[13] Mandatory federal rebates would need to account for these price concessions. Manufacturers would be required to pay the difference between the total rebates secured by Part D plans for LIS beneficiaries and the mandatory rebate level. The rebate amounts could be calculated using data already reported by Part D plans, which are required to report the rebates and other discounts they received in the previous year to Medicare on a per-drug basis.[14] Medicare could use these reports to determine the difference between the rebates paid to the Part D plans and the mandatory rebate level for LIS beneficiaries, with the drug manufacturer required to pay this amount to the federal government. In cases in which negotiated Part D plan rebates exceed mandatory rebate levels, no additional payments would be required.

In 2014, the Congressional Budget Office (CBO) estimated that requiring mandatory rebates for LIS Part D beneficiaries would save the federal government $103 billion over 10 years.[15] While this estimate includes rebates of 23.1 percent for brand drugs, it does not include rebates for generic products. President Barack Obama's budget for fiscal year 2017 included a proposal to apply Medicaid-level rebates on brand and generic drugs to the Medicare LIS population[16] that was projected to generate $121 billion in savings to the federal government through 2026. No information is available on the assumptions used to inform these estimates.

What should policymakers consider?

This policy would generate federal savings. Medicaid rebates are typically larger than those negotiated by Part D plans.[17] The CBO wrote in 2014 that it expects Medicaid's average net price for drugs to remain at least 20 percent to 30 percent lower than Part D's average price after controlling for differences in health conditions.[18] Additional savings generated by mandatory rebates in Part D could be used to defray costs to fund and administer the program. In 2016, the federal government incurred more than $82 billion in expenses in the Part D program.[19] However, absent additional changes to the program, this policy would not directly reduce costs for Medicare LIS enrollees.

Some have argued that mandating minimum rebates on Part D drugs for LIS beneficiaries would create incentives for drug companies to raise prices or reduce voluntary rebates to Medicare Part D plans or outside Medicare Part D in order to compensate for revenue lost through increased rebates.[20] Similarly, manufacturers might launch new drugs at higher prices. The CBO also warns that some savings could erode over time because drug manufacturers may choose to raise prices for new brand drugs.[21]

These arguments assume that manufacturers do not already launch drugs at the highest, profit-maximizing price and that they currently offer larger-than-necessary rebates to some payers, including Part D plans. There is limited evidence on pharmaceutical cost shifting, though one study examining the effect of new mandatory rebates and the Best Price rule adopted by Medicaid in the 1990s found that the price of branded products facing generic competition increased an average of 4 percent and that brands protected by patents did not cost significantly more.[22] This analysis has limited applicability to the present day because of changes in drug pricing and reimbursement but suggests that additional rebates may not lead to higher prices for brand name drugs except in cases where generic alternatives are available. It is estimated that generic drugs account for 89.5 percent of dispensed prescriptions.[23]

However, given the complexity of pharmaceutical markets and the lack of empirical evidence on mandatory rebates in Medicare Part D, consideration should be given to other potential impacts if drug manufacturers were to respond to this policy by reducing voluntary rebates to Part D plans (or commercial payers). Rebates to Part D plans serve to lower overall Part D program costs, so this could result in higher premiums for enrollees as well as increased costs to the federal government to support the program. This may partially offset any savings from the mandatory rebates.

Policymakers should consider the potential savings to the federal government from rebates in the LIS subset of Medicare Part D beneficiaries in the context of the potential for some distortions in private-market drug prices.

Endnotes

1 Medicare Payment Advisory Commission, "Report to the Congress: Medicare Payment Policy" (2017), http://www.medpac.gov/docs/default-source/reports/mar17_entirereport224610adfa9c665e80adff00009edf9c.pdf?sfvrsn=0.

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6 Special Provisions Relating to Medicare Prescription Drug Benefit, 42 U.S.C. § 1396u–5(c).

7 Medicaid and CHIP Payment and Access Commission, "Medicaid Spending for Prescription Drugs" (2016), https://www.macpac.gov/wp-content/uploads/2016/01/Medicaid-Spending-for-Prescription-Drugs.pdf.

8 Centers for Medicare & Medicaid Services, "2017 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds" (2017), https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/Downloads/TR2017.pdf.

9 Payment for Covered Outpatient Drugs, 42 U.S.C. § 1396r-8(a)(1), § 1396r-8(b)(1); Medicaid.gov, "Medicaid Drug Rebate Program," last modified Feb. 15, 2017, https://www.medicaid.gov/medicaid/prescription-drugs/medicaid-drug-rebate-program/index.html.

10 The rebate amount for brand-name (innovator) drugs is either 23.1 percent of the average manufacturer price (AMP) or the difference between AMP and the Best Price, whichever is greater. There is an additional rebate, or inflation penalty, that increases the mandatory rebate when the drug's initial AMP grows faster than inflation. Generic (noninnovator) drugs are also subject to a 13 percent rebate and an inflation penalty. Best Price is the lowest manufacturer price paid for a drug by any purchaser, but it includes many significant exceptions, such as rebates to pharmacy benefit managers and Medicare Part D plans. Determination of Best Price, 42 CFR § 447.505; Payment for Covered Outpatient Drugs, 42 U.S.C. § 1396r-8(c), (c)(2), and (c)(3).

11 Department of Health and Human Services, "Medicaid Rebates for Brand-Name Drugs."

12 Best Price is the lowest manufacturer price paid for a drug by any purchaser, but it includes many significant exceptions, such as rebates to pharmacy benefit managers and Medicare Part D plans. Determination of Best Price, 42 CFR § 447.505.

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14 Centers for Medicare & Medicaid Services, "Final Medicare Part D DIR Reporting Requirements for 2016" (2017), https://www.healthlawpolicymatters.com/wp-content/uploads/sites/8/2017/06/Final-2016-DIR-Reporting-Reqs-Memo-06-23-2017.pdf.

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23 QuintilesIMS, "Medicines Use and Spending in the U.S." (2016), http://www.imshealth.com/en/thought-leadership/quintilesims-institute/reports/medicines-use-and-spending-in-the-us-review-of-2016-outlook-to-2021.

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