

Effects of an Out-of-Pocket Maximum in Medicare Part D

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Drug prices and out-of-pocket (OOP) spending among Americans, especially those with Medicare coverage, have received substantial policy attention. Despite drug coverage through Part D, OOP spending for Medicare beneficiaries in 2017 exceeded \$2000, or more than 10% of the average annual Social Security benefit,¹ for beneficiaries with the highest 5% of spending. Thirty percent of Medicare beneficiaries with a serious illness have reported problems paying for their prescription drugs.² In the calculation of marketplace subsidies, CMS has recommended that OOP spending be less than \$2000 to ensure beneficiary affordability.³ However, for the highest-cost beneficiaries, OOP expenditures for prescription drugs may exceed this affordability threshold year after year, in part because no OOP maximum exists for stand-alone prescription drug plans (PDPs) or Medicare Advantage prescription drug (MA-PD) plans.

The current standard Part D benefit requires beneficiaries to pay a percentage of a drug's negotiated price. Annual increases in drug list prices and the trend toward higher launch prices, especially for specialty drugs with no competitors, leads to an increasing financial burden of prescription drugs for Medicare beneficiaries.⁴ Under current law, the Part D benefit has 4 phases—deductible, initial coverage period, coverage gap, and catastrophic coverage—with the percentage paid by beneficiaries varying by benefit phase. Beneficiaries are responsible for all costs up to the initial deductible limit (\$480 in 2022) and 25% of gross drug costs between \$480 and the initial coverage limit (\$4430 in 2022); this is followed by a coverage gap “donut hole” in which beneficiaries pay 25% of drug costs (the donut hole was closed as of 2020, so only plan and manufacturer contributions change relative to the initial coverage limit). Finally, beneficiaries pay 5% of drug costs above the catastrophic coverage limit of \$7050 (2022 limit).

To ensure the accessibility and affordability of prescription drugs, a policy recommendation receiving considerable attention is an OOP maximum in Medicare Part D. Limits on OOP maximums have received bipartisan support in Congress and by independent organizations such as the Medicare Payment Advisory Commission⁵ and the National Academies of Science, Engineering, and Medicine.⁶

ABSTRACT

OBJECTIVES: Three different out-of-pocket (OOP) maximums in Medicare Part D have been proposed: \$2000 by the House of Representatives, \$3100 by the Senate Finance Committee, and the beginning of catastrophic coverage by the Medicare Payment Advisory Commission. However, little is known about how beneficiaries would be affected.

STUDY DESIGN: We estimated multivariate linear regression models to determine which beneficiary characteristics were associated with the greatest savings under each proposed OOP maximum and simulated a potential behavioral response by beneficiaries.

METHODS: Using Part D 2017 claims data for beneficiaries in stand-alone prescription drug plans (PDPs) and Medicare Advantage prescription drug (MA-PD) plans, we estimated the number of beneficiaries affected, their demographic characteristics, and their drug utilization patterns. We then simulated a potential behavioral response by beneficiaries.

RESULTS: Under the \$2000 OOP proposed threshold, only 7% of PDP and 4% of MA-PD plan beneficiaries would have spending high enough to reach the OOP maximum. Annual mean (SD) savings would be \$1301 (\$1849) for PDP beneficiaries and \$1363 (\$1888) for MA-PD plan beneficiaries, concentrated among beneficiaries taking specialty drugs. As the threshold increases, fewer beneficiaries would accrue savings, but savings would increase. For the highest proposed OOP maximum, mean (SD) savings would be \$2720 (\$3465) and \$2473 (\$2805) for PDP and MA-PD plan beneficiaries, respectively. In our simulations, we estimated that the number of beneficiaries affected by an OOP maximum could increase by 2% to 11%, depending on the magnitude of response, but changes in savings would be minimal.

CONCLUSIONS: As currently drafted, proposed OOP maximums would reduce OOP spending for a small population of Part D beneficiaries, with savings concentrated among beneficiaries with the very highest costs who are taking specialty medications.

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TAKEAWAY POINTS

- ▶ This study compares the impact on beneficiaries under 3 different out-of-pocket (OOP) maximum thresholds being proposed in Congress and by the Medicare Payment Advisory Commission.
- ▶ Under the most generous proposed OOP maximum, fewer than 7% of beneficiaries would be eligible for savings.
- ▶ This research can inform policy makers on how different approaches to reducing OOP spending for prescription drugs can affect both the number and the characteristics of beneficiaries affected.

However, these organizations have proposed different cap levels with little known about the characteristics of beneficiaries who would be affected.

The proposals differ along 3 dimensions: (1) the dollar amount of the OOP maximum; (2) the percentages paid by Medicare, the insurer, and drug manufacturers; and (3) which payers are included when determining OOP spending.⁶⁻⁹ By creating OOP maximums during the initial coverage limit, the 2 Congressional proposals would eliminate the coverage gap and thus the manufacturer coverage gap discount and instead require manufacturers to pay a percentage of drug costs above the OOP maximum. One objective in restructuring the Part D payment burden is to require insurers to pay more of the costs during the catastrophic coverage period, providing them with an incentive to negotiate lower drug prices for expensive drugs that will immediately push the beneficiary into the catastrophic phase.

In this study, we examine the impact of 3 proposed Part D OOP maximum thresholds on the number of beneficiaries in PDPs and MA-PD plans affected by each proposal and whether the different thresholds have policy implications for beneficiaries based on sociodemographic or prescription drug use characteristics. Our hypothesis is that the majority of savings from the OOP maximum thresholds will be accrued by beneficiaries who have chronic conditions treated by specialty drugs. Our focus is on those policies that specifically affect beneficiaries, so we do not assess the impact of redistributing payments across Medicare, insurance plans, and manufacturers, although we recognize that this could have an indirect effect on beneficiaries.

METHODS

Medicare Part D Claims Data

This analysis used a 20%, nationally representative, random sample of 2017 Medicare Part D claims for beneficiaries in PDPs and MA-PD plans (excluding beneficiaries with employer group waiver plans, because those tend to be more generous than the standard Part D benefit structure). The data include information on prescription fills, cost sharing, and benefit phase for each beneficiary. The claims were supplemented with the Medicare beneficiary summary file to obtain demographic and socioeconomic characteristics. The sample ([eAppendix Figure](#) [eAppendix available at [ajmc.com](#)]) did not include people who died during the year ($n = 312,336$) because they

have different patterns of health care spending during the last months of life, but we included a sensitivity analysis to examine the impact on those beneficiaries. We then limited the sample to beneficiaries enrolled in the same plan all year (86%) to ensure that there were no sudden changes to plan design and thus OOP spending. Finally, we excluded beneficiaries who receive financial assistance through the low-income subsidy (LIS) program (income less than 140%

of the federal poverty line; 28.4% of beneficiaries) because these beneficiaries have on average less than \$100 in spending per year and would not be affected by the OOP maximum policies. These exclusions resulted in a sample of 4,893,965 beneficiaries.

OOP Threshold Simulation

Beneficiary OOP spending is the dollar amount paid by a beneficiary, equal to the sum of the deductible, co-payments, and coinsurance, and thus represents the actual financial burden borne by beneficiaries, not including premiums. Medicare calculates “true OOP spending,” known as “TrOOP,” which is the amount of drug payments that count toward designating movement through the benefit phases and hence toward the OOP maximum under these proposals. TrOOP includes beneficiary OOP and other payments made on behalf of the beneficiary, including payments through the manufacturer coverage gap discount, Medicare’s LIS, and some third-party payers (eg, payments from qualified state pharmaceutical assistance programs and charities are included, but employer contributions are not).

Using the 3 proposed thresholds, \$2000, \$3100, and \$4950, we simulated the number and percentage of beneficiaries affected under each threshold by assessing how many beneficiaries have TrOOP costs greater than each OOP maximum threshold. We excluded payments through the manufacturer coverage discount when calculating OOP spending, because all 3 proposals eliminate these payments from the calculation of beneficiary OOP liability. Estimated savings under each proposal were calculated by subtracting the OOP threshold from beneficiary actual OOP costs. These potential savings accrue to the beneficiary rather than to the other payers contributing to TrOOP.

Statistical Analysis

Among beneficiaries with spending sufficient to reach each of the OOP maximum thresholds, we estimated multivariate linear regression models to determine which beneficiary characteristics were associated with the greatest savings under each proposed OOP maximum, assuming no behavioral response (later we incorporate behavioral responses). Given the skewed distribution of spending, we used 2 outcome variables: savings simulated as dollar values and log transformed savings to account for the skewed distribution, which measures the percentage difference in savings received.

We examined the relationship between beneficiary characteristics, including demographics and prescription drug use, on changes in

OOP spending. Demographic characteristics included gender, race, and age. To assess prescription drug characteristics, we examined total annual prescription fills, and quintiles for the percentage of those fills for brand name drugs. We also examined whether or not individuals used a specialty drug. CMS defines specialty drugs as those with negotiated prices of \$670 or more per month. Negotiated prices are not publicly available data, so we identified drugs with gross costs of \$670 or more per month in the Part D claims data. Gross drug costs are higher than negotiated costs, so this definition is inclusive of all specialty drugs but may also include a few additional drugs not defined by CMS as specialty drugs. County fixed effects were included to account for geographic variation in utilization and prescribing patterns.

As a sensitivity analysis, we conducted these analyses on beneficiaries who died.

Simulating a Behavioral Response

Significant research findings have shown the inverse relationship between prescription drug costs and rates of nonadherence.¹⁰⁻¹² Lowering the OOP threshold would likely increase adherence and therefore increase drug use and spending. Much of the research has examined the impact of reducing co-payments on improving adherence for promoting chronic condition management, which requires long-term use. Chernew et al estimated the impact of a decline in co-pays in a large employer's value-based insurance program to increase adherence between 7% and 14% for the top 5 chronic conditions (elasticities of -0.1 to -0.4).¹³ Similar research for these populations found an increase in adherence rates between 1.5% and 6%.¹⁴⁻¹⁶ Focusing specifically on Part D, Fung et al found that insurers providing supplemental benefits in the coverage gap increased adherence by 4 to 8 percentage points for people taking diabetes, hypertension, and hyperlipidemia drugs.¹¹ For expensive specialty drugs, adherence concerns can be much higher because the cost of the drugs is so high. For example, among 28 specialty drugs, more than half had expected annual OOP costs of \$5444 in the catastrophic phase alone.¹⁷ As a result of these high prices, abandonment is also high. Estimates of abandonment vary substantially depending on the health status and age of the population, but estimates range from 10% to 31%, with the most common estimate being 13%.¹⁸⁻²²

All the previously mentioned studies were based on specific populations or diseases. A comprehensive determination of price elasticities of demand for Part D by Einav et al found that the average elasticity of demand was -0.24 among the 150 most common drugs in Medicare and -0.15 for the 100 most common therapeutic classes.²³ Although the elasticity estimates differ because they are studying different populations and drugs, both suggest relatively inelastic demand. The advantage of these estimates is that by aggregating elasticities across many drugs, these estimates have incorporated the cross-price elasticity between drugs, which is also what determines movement through the Part D benefit phases.

To conduct the simulation, we focus on beneficiaries with spending \$100 under the respective OOP maximum threshold and

higher. We apply the 2 Einav et al elasticity estimates for the most common drugs and therapeutic classes to beneficiary OOP spending to simulate additional expenditures that would have occurred if an OOP maximum policy had been in place. We do not analyze the impacts for beneficiaries with spending less than \$100 below the threshold, because although knowledge of the OOP maximum may incentivize a slight increase in their annual spending, it is unlikely to be enough for them to be affected by the policy. Our behavioral response is based on the assumption that the observed relationship between changes in co-payments with drug adherence and spending applies to changes in OOP spending for Medicare beneficiaries in response to an OOP maximum, and specifically for those with spending \$100 under the respective OOP maximum threshold and higher, regardless of their baseline adherence.

RESULTS

Sample Characteristics

Table 1 shows summary statistics for beneficiary OOP spending by demographic and prescription drug characteristics. Sixty percent of beneficiaries are in PDPs and 40% in MA-PD plans; the latter percentage is slightly higher than that in the overall Part D population, because the sample is restricted to non-LIS beneficiaries who did not die during the year, populations who are more likely to be enrolled in MA.

Mean (SD) annual OOP spending was higher for beneficiaries in PDPs, at \$620 (\$930), than for those with MA-PD plans, at \$415 (\$715), a trend exhibited across the demographic and prescription drug subgroups. The largest difference in OOP spending was associated with specialty drug use. Mean (SD) spending was \$1372 (\$1892) for PDP beneficiaries who took a specialty drug compared with \$512 (\$616) for those who did not. Similarly, for MA-PD plan beneficiaries, spending was \$952 (\$1542) for those who filled a specialty drug compared with \$344 (\$472) for those who did not.

OOP spending also increased as beneficiaries progressed through the benefit phases. Mean (SD) OOP spending was \$119 (\$98) for PDP beneficiaries and \$69 (\$72) for MA-PD plan beneficiaries who ended in the deductible phase compared with \$3848 (\$2329) for PDP beneficiaries and \$3349 (\$2512) for MA-PD plan beneficiaries who ended in the catastrophic coverage phase.

Beneficiaries Affected by OOP Maximum Policy

The **Figure** shows the distribution of annual TrOOP spending for non-LIS Medicare beneficiaries. OOP spending follows a right-skewed distribution with the majority of Medicare beneficiaries not reaching any of the OOP thresholds. **Table 2** shows the number of non-LIS beneficiaries affected by each policy and the simulated savings they would accrue based on 2017 spending levels (assuming no behavioral change). Under the \$2000 OOP maximum, only 7% of PDP beneficiaries and 4% of MA-PD plan beneficiaries would have savings. These beneficiaries would accrue mean (SD) annual savings of \$1301 (\$1849) for those with PDPs and \$1363 (\$1888) for those with MA-PD plans relative to current policy.

TABLE 1. Mean Annual Medicare Part D OOP Spending by Beneficiary Characteristics, 2017*

Characteristics	PDPs			MA-PD plans		
	No. of beneficiaries	%	Mean (SD) OOP spending in \$	No. of beneficiaries	%	Mean (SD) OOP spending in \$
All	2,741,766	100	620 (930)	2,152,199	100	415 (715)
Sex						
Male	1,163,969	42	637 (968)	951,229	44	416 (734)
Female	1,577,797	58	608 (901)	1,200,970	56	414 (700)
Age in years						
< 65	109,205	4	901 (1453)	161,485	8	598 (1094)
65-74	1,398,773	51	572 (916)	1,070,367	50	378 (678)
75-84	884,375	32	641 (899)	679,854	32	423 (680)
≥85	349,413	13	671 (826)	240,493	11	435 (624)
Race						
White	2,478,428	90	627 (929)	1,767,362	82	433 (723)
Black	134,708	5	552 (922)	193,405	9	367 (729)
Hispanic	11,080	0.4	531 (911)	52,971	2	209 (532)
Asian	24,264	1	482 (812)	47,897	2	287 (563)
Other	93,286	3	568 (988)	90,564	4	345 (661)
End-of-year benefit phase						
Deductible	464,029	17	119 (98)	254,453	12	69 (72)
Initial coverage limit	1,359,597	50	450 (352)	1,285,623	60	286 (299)
Coverage gap	287,988	11	1544 (681)	167,451	8	1223 (704)
Catastrophic coverage	94,958	3	3848 (2329)	43,614	2	3349 (2512)
Filled a specialty drug						
No	2,396,214	87	512 (616)	1,901,207	88	344 (472)
Yes	345,552	13	1372 (1892)	250,992	12	952 (1542)
Annual No. of prescription drug fills						
1-5	230,438	8	67 (181)	224,203	10	49 (165)
6-20	929,249	34	269 (439)	773,845	36	194 (356)
21-50	1,145,974	42	701 (859)	846,387	39	511 (714)
≥51	436,105	16	1447 (1394)	307,764	14	974 (1130)
% fills on brand name drugs						
0-20	1,264,168	46	350 (487)	1,079,349	50	237 (366)
21-40	862,008	31	785 (968)	639,325	30	548 (780)
41-60	418,880	15	997 (1309)	293,223	14	705 (1074)
61-80	123,190	4	1012 (1441)	82,998	4	726 (1147)
81-100	73,520	3	522 (1134)	57,304	3	343 (859)

MA-PD, Medicare Advantage prescription drug; OOP, out of pocket; PDP, stand-alone prescription drug plan.

*Sample consists of people in PDPs available to fee-for-service beneficiaries and in MA-PD plans who had the same insurance plan over the course of the year. Sample sizes reflect the 20% Medicare claims file, so Ns should be multiplied by 5 to create a nationally representative sample size. CMS defines specialty drugs as those with negotiated prices of \$670 or more per month. Because negotiated prices are not publicly available data, we identified drugs using gross costs of \$670 or more per month across all payers in the Part D claims data. Gross drug costs are higher than negotiated costs, so this definition would be inclusive of all specialty drugs.

Source: 20% sample of Medicare Part D prescription drug claims, 2017.

The 2 alternate OOP thresholds of \$3100 and \$4950 would decrease the number of beneficiaries affected but increase the average savings, because the savings would be concentrated among the highest-cost beneficiaries. Under the \$3100 OOP maximum, 2% of PDP beneficiaries would have mean (SD) savings of \$1526 (\$2528), and 1% of MA-PD beneficiaries would have savings of \$1876 (\$2506). Finally, under the \$4950 threshold, only 0.6% of PDP beneficiaries and 0.4% of MA-PD plan beneficiaries would receive savings. The significant drop in the number of beneficiaries reaching the OOP maximum is due to the significantly higher threshold compounded by removing the contribution of the manufacturer coverage gap discount from the TrOOP calculation. The savings for this small population would be greater than the other options, at a mean (SD) of \$2720 (\$3465) for PDP beneficiaries and \$2473 (\$2805) for MA-PD plan beneficiaries.

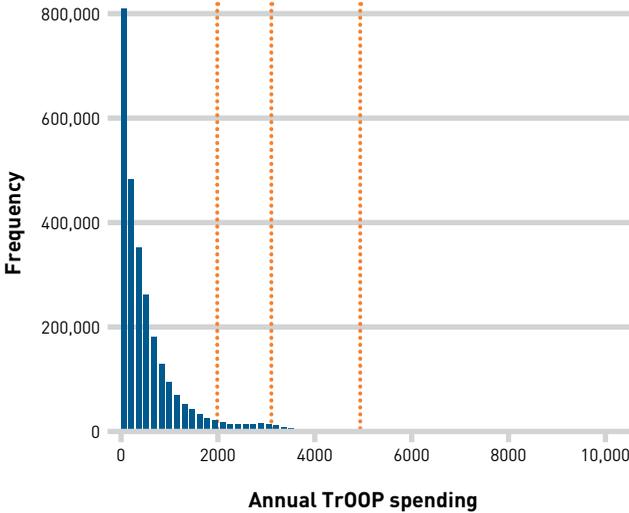
Conditional on being affected, MA-PD beneficiaries, relative to PDP beneficiaries, would have greater savings under the \$3100 OOP threshold (\$121 [SE, \$19]; 5% more), but less savings under the \$2000 OOP threshold (\$64 [SE, \$8]; 9% less) and the \$4950 OOP threshold (\$187 [SE, \$43]; 2% less). Most likely this is because MA-PD plans are more likely to offer supplemental benefits compared with PDPs,⁵ so MA beneficiaries tend to have lower deductibles and are less likely to reach catastrophic coverage.²⁴ Despite savings being higher for MA-PD beneficiaries, almost twice as many beneficiaries in PDPs are affected by these policies compared with MA-PD beneficiaries.

Table 3 shows the beneficiary characteristics most associated with accruing savings. Across all 3 OOP thresholds, the factor most associated with accruing savings is taking a specialty drug. Beneficiaries who fill a specialty drug would receive savings of \$1377 (SE, \$8; 156%), \$1713 (SE, \$14; 344%), and \$2153 (SE, \$61; 907%) more under the \$2000, \$3100, and \$4950 proposals, respectively, relative to beneficiaries who did not fill a specialty drug.

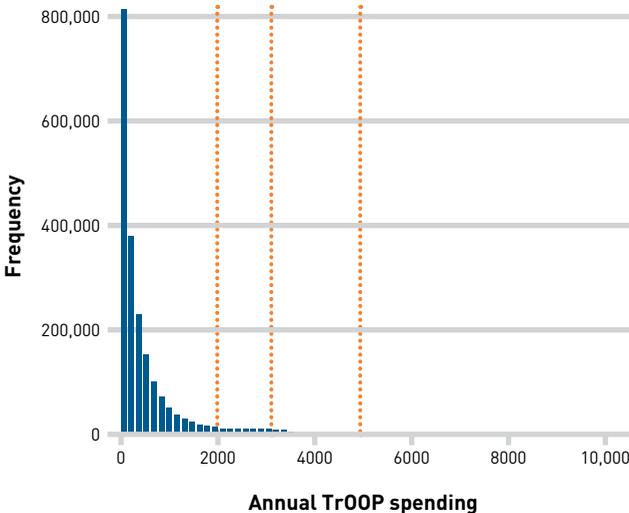
Beneficiaries with a higher percentage of brand name drugs would also be more likely to accrue savings. Beneficiaries with 80% to 100% of their fills on brand name drugs would have savings of \$337 (SE, \$33; 21%), \$372 (SE, \$67; 22%), and \$447 (SE, \$131; 9%) more under

FIGURE. Distribution of TrOOP Spending With Proposed OOP Maximum Thresholds Based on 2017 Spending Levels^a

A. Stand-alone prescription drug plans



B. Medicare Advantage prescription drug plans



OOP, out-of-pocket; TrOOP, true OOP.

^aThe red bars represent the 3 simulated OOP maximum thresholds: \$2000 (proposed by the House Lower Drug Costs Now Bill), \$3100 (proposed by the Senate Finance Committee Drug Pricing Bill), and \$4950 (proposed by the Trump administration's 2019 Presidential Budget). Sample consists of people in stand-alone prescription drug plans available to fee-for-service beneficiaries and in Medicare Advantage prescription drug plans who had the same insurance plan over the course of the year. TrOOP is the amount of drug payments that count toward designating movement through the benefit phases and includes beneficiary OOP and other payments made on behalf of the beneficiary, including payments through the manufacturer coverage gap discount, Medicare's low-income subsidy, and some third-party payers (eg, payments from qualified state pharmaceutical assistance programs and charities are included, but employer contributions are not). Source: Medicare Part D prescription drug claims, 2017.

TABLE 2. Beneficiaries Affected by Nationally Proposed OOP Maximum Thresholds^a

Thresholds	Fee-for-service	Medicare Advantage
n with Part D coverage	2,741,766	2,152,199
\$2000		
Eligible based on TrOOP, n	180,059	79,067
% of all Part D beneficiaries	6.6%	3.7%
Savings based on OOP, n	171,771	64,649
% of eligible	95%	81.8%
OOP savings in \$, mean (SD)	1301 (1849)	1363 (1888)
\$3100		
Eligible based on TrOOP, n	67,056	28,708
% of all Part D beneficiaries	2.4%	1.3%
Savings based on OOP, n	62,818	22,080
% of eligible	94%	77%
OOP savings in \$, mean (SD)	1526 (2528)	1876 (2506)
\$4950		
Eligible based on TrOOP, n	16,633	8880
% of all Part D beneficiaries	0.6%	0.4%
Savings based on OOP, n	16,049	7881
% of eligible	96%	89%
OOP savings in \$, mean (SD)	2720 (3465)	2473 (2805)

OOP, out-of-pocket; TrOOP, true OOP.

^aSample consists of all Medicare beneficiaries in stand-alone prescription drug plans available to fee-for-service beneficiaries or in Medicare Advantage drug plans who had the same insurance plan over the course of the year. Sample sizes reflect the 20% Medicare claims file, so Ns should be multiplied by 5 to create a nationally representative sample size. Percentage eligible is determined based on TrOOP, whereas savings are calculated for people whose OOP spending exceeded the threshold and as such would see savings from the thresholds. TrOOP is the amount of drug payments that count toward designating movement through the benefit phases and includes beneficiary OOP and other payments made on behalf of the beneficiary, including payments through the manufacturer coverage gap discount, Medicare's low-income subsidy, and some third-party payers (eg, payments from qualified state pharmaceutical assistance programs and charities are included, but employer contributions are not).

Source: Medicare Part D prescription drug claims, 2017.

the \$2000, \$3100, and \$4950 proposals, respectively, relative to beneficiaries who had 41% to 60% brand name fills.

There were also some differences among the types of beneficiaries affected under each OOP threshold. The largest differences occurred depending on how many drugs beneficiaries took. Under the \$2000 threshold, there were no significant differences in savings between beneficiaries with 0 to 20 vs 51 or more drug fills, but \$117 (SE, \$20; -7%) less savings for beneficiaries with 21 to 50 drug fills. In contrast, under the \$3100 threshold, the highest savings, \$199 (SE, \$36; 6%) more, accrued to the beneficiaries with 21 to 50 drug fills. Finally, under the \$4950 threshold, savings increased as beneficiaries filled more drugs; compared with beneficiaries with 6 to 20 drug fills, beneficiaries with 21 to 50 drug fills had additional savings of \$673 (SE, \$59; 27%) and beneficiaries with 51 or more drug fills had additional savings of \$1218 (SE, \$68; 40%).

TABLE 3. Beneficiary Characteristics Associated With Increased Savings Under Proposed OOP Maximums*

Characteristic	\$2000		\$3100		\$4950	
	Linear, \$	Log transformed	Linear, \$	Log transformed	Linear, \$	Log transformed
Plan type						
PDP	Reference					
MA-PD	-64*** [8]	-0.096*** [0.0056]	121*** [19]	0.049*** [0.012]	-187*** [43]	-0.014 [0.017]
Sex						
Male	Reference					
Female	-13* [7]	-0.059*** [0.0049]	52*** [16]	0.044*** [0.010]	-130*** [41]	-0.046*** [0.016]
Age in years						
< 65	364*** [17]	0.19*** [0.0088]	219*** [31]	0.27*** [0.015]	-118* [70]	-0.083*** [0.021]
65-74	Reference					
75-84	7 [8]	-0.025*** [0.0057]	82*** [18]	-0.00054 [0.012]	229*** [45]	0.14*** [0.019]
≥85	-48*** [9]	-0.061*** [0.0080]	-44* [23]	-0.074*** [0.018]	189*** [70]	0.11*** [0.034]
Race						
White	Reference					
Black	213*** [22]	0.060*** [0.013]	309*** [43]	0.19*** [0.024]	270*** [79]	0.10*** [0.030]
Hispanic	122** [58]	0.057 [0.035]	155 [110]	0.17*** [0.058]	228 [203]	0.087 [0.087]
Asian	-124*** [35]	0.0039 [0.025]	-385*** [71]	-0.30*** [0.056]	23 [160]	0.057 [0.078]
Other	-7 [21]	0.040*** [0.013]	-139*** [46]	-0.085*** [0.026]	-5 [133]	-0.10** [0.045]
Taking a specialty drug						
No	Reference					
Yes	1377*** [8]	0.95*** [0.0051]	1713*** [14]	1.49*** [0.011]	2153*** [61]	2.31*** [0.10]
No. of annual prescription drug fills						
0-5	34 [85]	0.24*** [0.049]	-372*** [96]	0.0047 [0.077]	-853*** [109]	-0.28*** [0.082]
6-20	Reference					
21-50	-117*** [20]	-0.068*** [0.013]	199*** [36]	-0.073*** [0.023]	673*** [59]	0.23*** [0.027]
> 50	-34* [20]	0.15*** [0.013]	-101*** [36]	-0.30*** [0.023]	1218*** [68]	0.34*** [0.028]
% of fills on brand name drugs						
0-20	-271*** [11]	-0.35*** [0.0094]	-284*** [25]	0.063*** [0.019]	-905*** [60]	-0.39*** [0.031]
21-40	-150*** [8]	-0.18*** [0.0056]	-123*** [19]	0.026** [0.012]	-430*** [49]	-0.13*** [0.018]
41-60	Reference					
61-80	108*** [14]	0.081*** [0.0080]	140*** [32]	0.051*** [0.018]	298*** [77]	0.075*** [0.025]
81-100	337*** [33]	0.19*** [0.015]	372*** [67]	0.20*** [0.030]	447*** [131]	0.080** [0.040]
Observations	236,420	236,409	84,898	85,895	23,930	23,927

MA-PD, Medicare Advantage prescription drug; OOP, out of pocket; PDP, stand-alone prescription drug plan.

*P < .10; **P < .05; ***P < .01.

*The 3 simulated OOP maximum thresholds are \$2000 (proposed by the House Lower Drug Costs Now Bill), \$3100 (proposed by the Senate Finance Committee Drug Pricing Bill), and \$4950 (proposed by the Trump administration’s 2019 Presidential Budget). Sample sizes reflect the 20% Medicare claims file, so Ns should be multiplied by 5 to create a nationally representative sample size. The left set of results for each OOP maximum represents the dollar savings that beneficiaries would accrue. The right set of results when exponentiated for each OOP maximum represents the percentage difference in savings. Sample consists of all Medicare beneficiaries in PDPs available to fee-for-service beneficiaries or in MA-PD plans who had the same insurance plan over the course of the year. Sample sizes reflect the 20% Medicare claims file, so Ns should be multiplied by 5 to create a nationally representative sample size. Regressions include fixed effects for county of residence. We report means from a regression followed by standard errors in parentheses.

Source: 20% sample of Medicare Part D prescription drug claims, 2017.

There were also some differences by age and race. Across all 3 proposals, disabled Medicare beneficiaries (younger than 65 years) benefited the most of any age group—mean savings were \$364 (SE, \$17; 21%) under the \$2000 threshold and \$219 (SE, \$31; 31%), under the \$3100 threshold, with no significant differences under the \$4950 OOP threshold. Relative to White beneficiaries, Black beneficiaries also received higher mean savings under the OOP maximum, \$213

(SE, \$22; 6%), \$309 (SE, \$43; 22%), and \$270 (SE, \$79; 10%), under the \$2000, \$3100, and \$4950 OOP thresholds, respectively.

Taken together, these results show that the socioeconomic and clinical impact of an OOP maximum in Part D is similar among the 3 proposals. The key finding is that beneficiaries filling specialty drugs or more brand name drugs would receive the most benefit. In addition, beneficiaries in PDPs would receive more benefit than

TABLE 4. Simulating a Medicare Beneficiary Response to an OOP Maximum*

	\$2000		\$3100		\$4950	
	Therapeutic class	Common drugs	Therapeutic class	Common drugs	Therapeutic class	Common drugs
Fee for service						
Simulated n (% total Medicare) eligible	184,133 (6.7)	186,512 (6.8)	71,647 (2.6)	74,302 (2.7)	17,072 (0.6)	17,223 (0.6)
Relative to original policy, n (%)	4074 (2.3)	6453 (3.6)	4591 (6.8)	7246 (10.8)	439 (2.6)	590 (3.5)
Simulated OOP savings in \$, mean (SD)	1320 (1866)	1332 (1876)	1493 (2511)	1479 (2503)	2768 (3500)	2813 (3526)
Relative to original policy, \$	19	31	-33	-47	48	93
Medicare Advantage						
Simulated n (% total Medicare) eligible	80,910 (3.8)	82,005 (3.8)	30,657 (1.4)	31,855 (1.5)	9104 (0.4)	9193 (0.4)
Relative to original policy, n (%)	1843 (2.3)	2938 (3.7)	1949 (6.8)	3147 (11.0)	224 (2.5)	313 (3.5)
Simulated OOP savings in \$, mean (SD)	1380 (1905)	1389 (1915)	1830 (2506)	1804 (2506)	2534 (2841)	2580 (2864)
Relative to original policy, \$	17	26	-46	-72	-186	107

OOP, out-of-pocket.

*The 3 simulated OOP maximum thresholds are \$2000 [proposed by the House Lower Drug Costs Now Bill], \$3100 [proposed by the Senate Finance Committee Drug Pricing Bill], and \$4950 [proposed by the Trump administration's 2019 Presidential Budget]. Sample sizes reflect the 20% Medicare claims file, so Ns should be multiplied by 5 to create a nationally representative sample size. The left set of results for each OOP maximum represents the dollar savings that beneficiaries would accrue. The right set of results when exponentiated for each OOP maximum represents the percentage difference in savings. Sample consists of all Medicare beneficiaries in stand-alone prescription drug plans available to fee-for-service beneficiaries or in Medicare Advantage prescription drug plans who had the same insurance plan over the course of the year. Sample sizes reflect the 20% Medicare claims file, so Ns should be multiplied by 5 to create a nationally representative sample size. Regressions include fixed effects for county of residence. We report means from a regression followed by standard errors in parentheses. Source: 20% sample of Medicare Part D prescription drug claims, 2017.

MA beneficiaries, after controlling for their demographic and prescription drug characteristics.

Among the subgroup of beneficiaries who died during the year, results would be similar except that the age distribution of beneficiaries is different (fewer beneficiaries younger than 65 years, more 85 years and older), which would change savings by age group ([eAppendix Table](#)).

Simulating a Behavioral Response

Table 4 incorporates 2 potential behavioral responses assuming that beneficiaries would increase their drug spending in response to an OOP maximum. Under the more conservative estimate, elasticity of 0.15, an additional 4074 PDP beneficiaries and 1843 MA-PD beneficiaries would be eligible for the \$2000 threshold, an additional 4591 PDP beneficiaries and 1949 MA-PD beneficiaries would be eligible for the \$3100 threshold, and an additional 439 PDP and 224 MA-PD beneficiaries would be eligible for the \$4950 threshold. In percentage terms, this would be equivalent to an additional 2.3%, 6.8%, and 2.6% of non-LIS beneficiaries eligible under the \$2000, \$3100, and \$4950 thresholds, respectively.

Using the alternate assumption of elasticity of 0.24, an additional 3474, 3853, and 240 beneficiaries would be eligible for the \$2000, \$3100, and \$4950 thresholds, respectively. In percentage terms, this would be an additional 3.6%, 10.9%, and 3.5% non-LIS beneficiaries under the \$2000, \$3100, and \$4950 thresholds, respectively.

Savings would be similar relative to current spending levels (**Table 4**). A behavioral response allows lower-spending beneficiaries to become newly eligible for the OOP maximum, so aggregate savings do not change substantially because more people are saving

money close to the threshold (individual beneficiaries always have larger savings). Using an elasticity of 0.15, mean savings would be \$1320 for PDP beneficiaries and \$1380 for MA-PD beneficiaries under the \$2000 threshold, \$1493 for PDP beneficiaries and \$1830 for MA-PD beneficiaries under the \$3100 threshold, and \$2768 for PDP beneficiaries and \$2534 for MA-PD beneficiaries under the \$4950 threshold.

DISCUSSION

Policy makers are interested in lowering beneficiary OOP spending in Medicare Part D; however, the current proposals affect only a small percentage of beneficiaries. The \$2000 OOP maximum affects the largest portion of the Medicare population—which is still only 7% of the non-LIS Part D population—because many beneficiaries have supplemental coverage that already limits their OOP spending. For the beneficiaries who exceed the threshold, however, the savings—\$1302 for beneficiaries in PDPs and \$1363 for beneficiaries in MA-PD plans—would be half a month's average Social Security benefit, a large impact for some beneficiaries. Assuming a limited behavioral response, the percentage of beneficiaries affected by the lowest threshold of \$2000 increases by 2.3%, with savings of \$1320 per year for beneficiaries in PDPs and \$1380 for beneficiaries in MA-PD plans.

Across all 3 OOP maximum thresholds, beneficiaries in PDPs are more likely to be eligible than beneficiaries in MA-PD plans. This is likely because MA-PD plans are more likely than PDPs to be enhanced plans with more generous benefits than the standard benefit structure.⁷ This means that beneficiaries in MA-PD plans

are paying lower OOP costs under current policy than beneficiaries in PDPs, so they stand to benefit less from the proposed policies.

The possibility also exists of additional price increases, especially for specialty drugs, because beneficiaries who are concerned about cost sharing will no longer face the impact, but we did not model this behavior. Many policy proposals, when coupled with an OOP maximum, could reduce OOP expenditures for Medicare beneficiaries while maintaining some beneficiary “skin in the game.” This includes shifting from a percentage-based coinsurance system to a fixed co-payment for each drug fill, which is currently being conducted as a model test for insulin by the CMS Innovation Center.²⁵ Other policy proposals include requiring plans to share rebates with beneficiaries and allowing the government to negotiate for lower list prices.²⁶

Limitations

A significant limitation of this study is the lack of data on patient assistance programs (PAPs). For high-cost drugs in particular, PAPs often reimburse OOP costs, making it possible that co-payments reported in claims data are reimbursed by PAPs.²⁷ There are no data associating these programs with specific beneficiaries and therefore no way to discern how frequently this is occurring and the amount of OOP burden erased. PAPs are not officially part of Medicare and vary substantially depending on the drug; thus, identifying how OOP spending is structured in the formal Medicare program remains important.

In addition, our definition of specialty drugs relies upon gross costs, not negotiated prices, which tend to be lower. As a result, the data are likely to include drugs that are not actually specialty drugs. Also, we did not account for plan characteristics, which, particularly in the coverage gap, can affect beneficiary OOP spending.

Finally, under all these OOP maximum proposals, other entities would need to compensate for the reduction in beneficiary liability. These changes are not calculated in this paper.^{5,28,29}

CONCLUSIONS

We assessed 3 proposals to implement an OOP maximum in Medicare Part D. We found that each of these proposals would affect a small minority of Part D beneficiaries, but the average savings for those affected would be significant. ■

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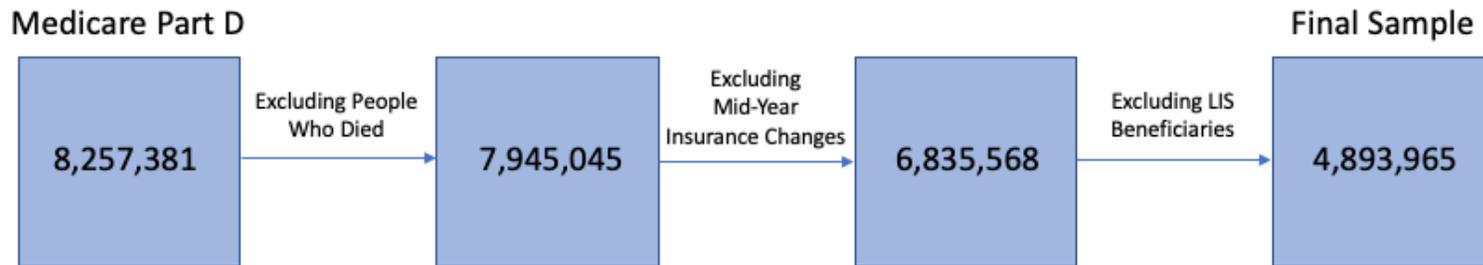
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eAppendix

eAppendix Figure. Flow Chart Detailing Sample Creation



Source: 20% Sample of Medicare Part D Prescription Drug Claims, 2017.

Notes: “LIS” is an abbreviation for low-income subsidy beneficiaries. The sample also excludes beneficiaries in Employer Group Waiver Plans, EGWPs, because these plans tend to be more generous and do not follow the standard defined benefit.

eAppendix Table 1. Savings Accrued Under Proposed OOP Maximums for Beneficiaries that Died

	House Bill: \$2,000		Senate Finance Bill: \$3,100		Presidential Budget: \$4,950	
	Linear, \$	Log Transformed	Linear, \$	Log Transformed	Linear, \$	Log Transformed
Plan Type						
Standalone Prescription Drug Plan	<i>Reference</i>					
Medicare Advantage Drug Plan	-47 (36)	-0.055** (0.028)	64 (57)	0.036 (0.052)	15 (119)	0.012 (0.088)
Sex						
Men	<i>Reference</i>					
Women	-89*** (32)	-0.076*** (0.024)	-65 (52)	-0.042 (0.044)	74 (131)	-0.018 (0.087)
Age						
Under 65	91 (83)	-0.022 (0.058)	85 (119)	0.020 (0.092)	86 (282)	0.10 (0.17)
65-74	<i>Reference</i>					
75-84	-79* (41)	-0.095*** (0.028)	-5 (61)	-0.046 (0.051)	-185 (136)	-0.074 (0.090)
85+	-191*** (43)	-0.19*** (0.033)	-108 (70)	-0.096 (0.062)	-221 (178)	-0.077 (0.12)
Race						
White	<i>Reference</i>					
Black	15 (72)	0.063 (0.052)	-84 (96)	0.0081 (0.091)	-533*** (176)	-0.20 (0.15)
Hispanic	99 (182)	0.056 (0.21)	-236 (262)	-0.047 (0.25)	-548 (348)	-0.033 (0.34)
Asian	21 (217)	-0.045 (0.12)	469 (355)	0.17 (0.26)	626 (570)	0.15 (0.38)
Other	-71 (98)	0.014 (0.074)	-133 (140)	-0.029 (0.13)	-498 (338)	-0.17 (0.24)
Taking a Specialty Drug						

No	<i>Reference</i>					
Yes	1323*** (34)	1.07*** (0.031)	1451*** (65)	1.49*** (0.077)	2566*** (555)	3.3*** (0.30)
# Annual Prescription Drug Fills						
0-5	-516*** (83)	-0.21*** (0.065)	-582*** (136)	-0.67*** (0.14)	-1132 (802)	0.29 (0.41)
6-20	<i>Reference</i>					
21-50	306*** (48)	-0.025 (0.035)	596*** (63)	0.61*** (0.065)	476** (191)	0.56*** (0.15)
0-5	129** (58)	-0.12*** (0.042)	478*** (94)	0.37*** (0.082)	964*** (246)	0.76*** (0.17)
% Fills on Brand Name Drugs						
0-20	-506*** (48)	-0.29*** (0.040)	-776*** (74)	-0.58*** (0.075)	-1080*** (203)	-0.78*** (0.16)
21-40	-250*** (42)	-0.15*** (0.028)	-400*** (67)	-0.22*** (0.051)	-590*** (152)	-0.37*** (0.091)
41-60	<i>Reference</i>					
61-80	63 (77)	-0.015 (0.050)	132 (119)	0.20** (0.088)	170 (220)	0.052 (0.15)
81-100	101 (172)	-0.14 (0.11)	419 (285)	0.40** (0.16)	1027 (813)	0.16 (0.49)
Time of Death						
Continuous Variable Based on Month of Death	58*** (7)	0.028*** (0.0053)	95*** (10)	0.059*** (0.0095)	128*** (25)	0.12*** (0.022)
Observations	8,419		4,209		1,121	

Source: 20% Sample of Medicare Part D Prescription Drug Claims, 2017.

Notes: The 3 simulated OOP maximum thresholds are \$2,000 (proposed by the House “HR 3 - Lower Drug Costs Now” Bill), \$3,100 (proposed by the Senate Finance Committee Drug Pricing Bill), and \$4,950 (Proposed by the Trump Administration’s 2019 Presidential Budget). Sample sizes reflect the 20% Medicare claims file, so Ns should be multiplied by 5 to create a nationally

representative sample size. The left set of results for each OOP maximum represents the dollar savings that beneficiaries would accrue. The right set of results when exponentiated for each OOP maximum represents the percent difference in savings. Sample consists of all Medicare beneficiaries in standalone prescription drug plans available to fee-for-service beneficiaries or a Medicare Advantage drug plan who had the same insurance plan over the course of the year. Sample sizes reflect the 20% Medicare claims file, so Ns should be multiplied by 5 to create a nationally representative sample size. Regressions include fixed effects for county of residence. Standard errors are reported in parentheses. Statistical significance * $p < 0.10$, ** $p < 0.05$, *** $p < 0.01$.