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Passing a Portion of Negotiated Rebates Through to Seniors with Diabetes Can Improve Adherence and Generate Savings in Medicare

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Summary

Diabetes imposes a significant economic burden on Medicare, at a cost of more than \$100 billion annually.¹ Adherence to prescription medicines to treat diabetes is associated with better disease management and lower overall health care spending, yet high beneficiary out-of-pocket (OOP) costs are a common barrier to proper adherence. Passing through a share of negotiated manufacturer rebates to patients at the point of sale (POS) is a recently debated approach to lower patient OOP costs, but little attention has been paid to its potential to improve adherence and generate downstream savings. Our analysis is the first to consider the effects of passing through rebates at POS on Medicare Parts A and B spending as a result of improved adherence. We estimate that for each beneficiary using brand diabetes medicines in the Part D coverage gap or catastrophic phase, passing through a portion of rebates at the POS would reduce overall per beneficiary healthcare spending by \$1,352 and lower patient OOP spending by \$367 in one year. Over the next 10 years, we project that passing through rebates at the POS for diabetes medicines could reduce total medical spending by approximately \$20 billion. These findings highlight the capability of passing through rebates to not only improve access to recommended medicines, but also to improve health outcomes and reduce overall healthcare spending.

Cost and Management of Diabetes in Medicare

The economic and human cost burden of diabetes in Medicare is substantial. In 2017, an estimated one in five adults age 65 or older was diagnosed with diabetes, and incurred an additional \$13,240 in average annual healthcare expenditures.²

Medicines are essential for managing diabetes and helping to prevent, delay onset, or mitigate disease complications—including atherosclerotic cardiovascular disease, kidney disease, diabetic retinopathy, neuropathy, genitourinary disturbances, and many other conditions.³ Insulin is the primary therapy for individuals with type 1 diabetes, and because of the progressive nature many patients with type 2 diabetes eventually require insulin therapy. The insulins that are available today serve a variety of patient needs—including for example, long-acting insulins which provide a consistent level of insulin in the body throughout the day or short-acting and rapid-acting insulins which help patients manage glucose spikes occurring at meal times. In addition, antidiabetic oral agents help control blood glucose levels and reduce risk for complications. Extensive evidence links better medicine adherence to reduced diabetes complications, lower medical spending, and lower mortality.^{4,5,6,7,8,9,10,11,12} It is estimated that \$4 billion in Medicare spending on diabetes complications is driven by suboptimal adherence.¹³

Despite the known benefits of medicine adherence, only about half of Medicare beneficiaries taking medications have their diabetes under control.¹⁴ High cost-sharing is a commonly reported reason for poor adherence.¹⁵ As such, eliminating financial barriers to medications could encourage proper medicine use, as reflected in the literature on value-based insurance design,^{16,17} the general literature on adherence,¹⁸ and the literature specific to patients with diabetes.^{19,20}

Coverage and Cost of Diabetes Medications in Medicare

In Medicare, most medicine used to treat diabetes are covered under the Part D benefit, which consists of four coverage phases. The standard benefit includes a deductible, during which time beneficiaries pay 100% of the cost of their medicine, followed by an initial coverage phase where beneficiaries pay

25% of the cost and Part D plans are responsible for the remaining 75%. Many plans differ from the standard benefit design and, consequently, most beneficiaries are in plans with minimal or zero deductibles and pay a flat copayment during the initial coverage phase, rather than 25% coinsurance. Once a certain level of Part D drug spending is reached, beneficiaries move from the initial coverage phase into the coverage gap and are responsible for paying a larger portion of their medicines, although this share has decreased over time. Specifically, in 2015 beneficiaries paid 45% of the costs of brand medicines in the coverage gap, but this share will permanently decrease to 25% beginning in 2019. Once beneficiaries incur a certain level of out-of-pocket (OOP) spending in the coverage gap, they enter the final phase of coverage, the catastrophic phase, and beneficiaries are responsible for 5% of their drug costs until the end of the year.

Under the Part D benefit, beneficiary OOP deductible and coinsurance payments are determined as a percentage of the gross, or undiscounted, price. Gross prices do not account for rebates negotiated by Part D plans. Rebates substantially reduce medicine costs for plans, with savings largely used to lower premiums. However, many patients with chronic disease do not benefit directly from these rebates and instead must pay cost sharing that is calculated based on the higher gross price. Passing along a share of these rebates at the POS would help improve affordability for millions of Medicare beneficiaries facing high OOP medicine costs.

Proposals to Pass Through Rebates to Patients at the Point of Sale

Over the past several years, manufacturer rebates for brand medicines have increased dramatically. For example, in 2017, rebates negotiated by commercial and Part D plans reduced the net price of brand medicines by an average of 34%.²¹ For brand diabetes medicines, wide availability of competing products within multiple therapeutic classes has enabled payers to negotiate additional savings, reducing the net prices of some products by more than 70%.^{22,23, 24, 25, 26}

To help alleviate patient cost burden, strategies to pass rebates on to patients at the POS have been proposed. For example, several health plans and pharmacy benefits managers—including Aetna, United Healthcare, and CVS Health—have announced plans to pass through a portion of rebates in the commercial market.^{27, 28}

Increased interest in passing through a portion of rebates at the POS is also reflected in a recent Request for Information (RFI) issued by the Centers for Medicare & Medicaid Services (CMS), which sought stakeholder input on a potential policy to require Medicare Part D plans to pass through a portion of rebates at the POS. In the RFI, CMS explained that at the time Part D was established, the agency believed that Part D plans would pass a portion of rebates through directly to beneficiaries at the POS. However, CMS has since observed that plans seldom use rebate savings to lower patient cost sharing in this manner.

Current debate around passing through rebates at POS in Medicare has focused on the potential impact on plan and government costs, as rebates currently feed into plan revenue and are typically used to maintain low premiums. However, as CMS noted in the RFI, “the higher cost sharing that results [from not reflecting manufacturer rebates in the gross price] can impede beneficiary access to necessary medications, which leads to poorer health outcomes and higher medical care costs for beneficiaries and Medicare.”²⁹ At present, there is no available evidence to understand the potential effects of

passing through rebates on improving adherence and subsequently reducing other healthcare spending as a result of better patient health outcomes.³⁰

Approach

This study attempts to fill a critical gap in the ongoing debate on passing through rebates at POS by highlighting the opportunity for plans to address suboptimal medicine adherence and reduce overall health costs.

Our analysis provides an illustrative example of the expected impact of passing 80% of rebates through to beneficiaries with diabetes at the POS in Medicare. We used 2015 administrative Medicare Research Identifiable Files³¹ to estimate Medicare A, B, and D costs and peer-reviewed literature to model the effect of lower cost sharing on adherence and spending. For consistency, we utilized the standard Part D benefit parameters in place in 2015 in our primary analysis. We focused the analysis on enrollees without the Low-Income Subsidy (LIS) using brand diabetes medicine in the coverage gap and catastrophic phases because beneficiary cost sharing in these phases is generally calculated as a percentage of the gross price.^a A detailed description of the methods, data, assumptions and study limitations is provided at the end of our report.

Findings

Impact of Passing Through a Portion of Rebates on OOP Cost per Fill

As described above, beneficiary OOP costs for brand diabetes medicines in Medicare Part D vary based on cost sharing requirements in each benefit phase. We estimated changes in OOP costs resulting from POS rebates by focusing on the coverage gap and catastrophic phase.

In 2015, beneficiary OOP costs in the coverage gap were 45% of gross price, or \$213 per fill, on average. Reducing the gross price by applying 80% of rebates at the POS would have decreased OOP costs in the coverage gap by \$90, to \$123 per fill (Table 1). Among patients who entered catastrophic coverage and faced 5% cost sharing, applying a share of rebates at the POS would have lowered average OOP costs from \$24 to \$14 per fill.

^a We make the simplifying assumption that medications filled in the deductible phase or before the initial coverage limit will not be affected by passing through a portion of rebates at POS. Few prescriptions for diabetes medicines are filled in the deductible and most diabetes prescriptions filled in the initial coverage limit have flat dollar copayment, which are independent of the medicine's gross price.

Table 1 Beneficiary out-of-pocket cost per fill with and without passing through a portion of rebates at POS

Benefit Phase	Without POS Rebate Pass Through	With POS Rebate Pass Through	Savings
Coverage Gap	\$ 213	\$ 123	\$ 90
Catastrophic	\$ 24	\$ 14	\$ 10

Note: Based on a gross price per fill of \$474 with a 53% rebate (\$223 net price).

Impact of Passing through a Portion of Rebates on Adherence and Medicare Spending

Total spending per Medicare beneficiary with diabetes—including medical services and prescription medicines—averaged \$22,467 in 2015, of which beneficiaries paid \$3,775 OOP.

Consistent with economic theory, a large literature demonstrates that patients decrease utilization of healthcare when faced with higher OOP costs. In the case of prescription medicines, studies have shown that a 10% increase in OOP costs is associated with a 1-3% decrease in the number of medicines filled.^{32, 33, 34} Based on this literature and as described later, we estimate that the cost sharing reductions resulting from passing through 80% of rebates at the POS would increase the number of diabetes medicines filled by 12.7%.

Although the resulting improvement in adherence would increase spending for diabetes medicines, research has consistently shown that higher adherence is associated with a decline in spending on avoided healthcare resource use, such as hospitalizations and emergency visits, for diabetes-related complications.^{35,36} For example, one study reported that improved adherence to diabetes medicines could avert nearly 700,000 emergency department visits and 341,000 hospitalizations for annual savings of \$4.7 billion.³⁷ Additional research has shown that medical savings generated from better adherence can offset the increased cost of medicines for Medicare beneficiaries with diabetes.³⁸

Using estimates derived from Roebuck (2014) on the association between adherence and medical spending³⁹, we calculate that adherence improvements resulting from passing through a portion of rebates at POS could decrease total healthcare spending by 6% or \$1,352 per year for each beneficiary using brand diabetes medication in the coverage gap or catastrophic phase (Table 2). These savings include a reduction in beneficiary OOP spending in the amount of \$367 per year—or about 10%—and a reduction of nearly \$1,000 in spending by Medicare and other third parties.

Table 2 Total annual per capita spending with and without passing through a portion of rebates at POS

	Total Spending	Paid by Patient (OOP)	Paid by Medicare and Third Parties
Without POS Rebate Pass Through	\$ 22,467	\$ 3,775	\$ 18,693
With POS Rebate Pass Through	\$ 21,116	\$ 3,407	\$ 17,708
Difference	\$ 1,352	\$ 367	\$ 985
% Reduction	6.0%	9.7%	5.3%

Note: Annual average per beneficiary using brand diabetes medication in the coverage gap or catastrophic phase and who did not receive the Low-Income Subsidy.

To illustrate the potential magnitude of the overall savings to Medicare resulting from passing through a portion of rebates at POS we estimated the change in spending over ten years. To be consistent with current law, we assumed that the coverage gap would close fully by 2019.⁴⁰ We also accounted for forecasted growth in Medicare costs and the Medicare population. Our projections indicate that passing through a portion of rebates at POS is expected to reduce total aggregate spending among Medicare beneficiaries using brand diabetes in the coverage gap by \$20 billion (6.0%) over ten years (Table 3).

Table 3 Estimated Medicare spending with and without passing through a portion of rebates at POS 2018-2027

	2018-2027 (Billions)		
	Total Spending	Paid by Patient (OOP)	Paid by Medicare and Third Parties
Without POS Rebate Pass Through	\$331.7	\$55.7	\$276.0
With POS Rebate Pass Through	\$311.7	\$50.3	\$261.4
Difference	\$20.0	\$5.4	\$14.5
% Reduction	6.0%	9.7%	5.3%

Putting Results in Context

This analysis is the first to consider the potential magnitude of the effects of passing through rebates on Medicare Parts A and B spending because of better adherence. We find that passing through 80% of rebates at the POS could generate 10-year medical savings of \$20 billion among Medicare beneficiaries for just one therapeutic area. These results suggest that the adherence improvements resulting from passing through a portion of rebates could generate substantial savings across the entire Medicare program, and that omitting these program-wide spillover effects provides an incomplete picture.

Applying a portion of rebates at the POS is an attractive approach to lower patient OOP burden, particularly as an increasing number of prescriptions for brand medicines are subject to cost sharing linked to gross price. Patients with deductibles and coinsurance would immediately and directly benefit from lower OOP costs at the POS. Patients paying flat copays for their medicines would also indirectly benefit from passed through rebates, since their progression through the phases of the Part D benefit would now be based on the net prices of their medicines, which would allow many more beneficiaries to avoid reaching the coverage gap.

POS rebates offer the potential to improve affordability in the commercial market as well; recent data show that over half of patient OOP spending in the commercial market is based on gross prices.⁴¹ If the recent trends of rising rebates continue into future years, particularly for many therapeutic categories associated with chronic illnesses, cost sharing may continue to grow more rapidly than plan costs for many patients in the absence of policy change to shift more negotiated rebates to the POS.

Some have argued that passing through rebates at POS could increase costs for the Medicare Part D program, resulting in higher premiums for beneficiaries. However, much of the debate around rebate pass through has ignored likely behavioral changes—such as efforts by Part D plans to reduce the generosity of their formularies and benefit designs to avoid premium increases—that could reduce Part D costs. An analysis by CMS actuaries—which did not attempt to account for anticipated plan behavioral or formulary or benefit design changes—estimated that passing through 66% of the rebate at the POS could increase government spending by \$55 billion and raise Part D premiums by 7% over 10 years.⁴² In contrast, a separate analysis by independent actuaries, which took these likely behavioral changes into account, concluded that pass through of 50% of rebates at the POS could reduce government costs by as much as \$73 billion, with no increase in beneficiary premiums.⁴³

Our analysis highlights the importance of improved adherence as one key consequence of passing through rebates at the POS that should not go overlooked, but there is no single study that captures all potential intended and unintended consequences of passing rebates through to patients. We addressed uncertainty in many of our study assumptions using sensitivity analysis, and found that results did not differ directionally from the main findings (see Appendix).

This study focuses on the impact for just one therapeutic area. Diabetes is a condition for which there is evidence of significant underuse of clinically indicated medicines, and thus substantial opportunity to avoid costly disease complications by improving adherence for a large number of Medicare beneficiaries. Nevertheless, this study brings attention to the opportunity of passing through rebates at the POS to impact total Medicare expenditures, in addition to improving affordability and the health of beneficiaries.

Methods, Data and Assumptions

This analysis was designed to offer a stylized example of the impact of passing through rebates at the POS on Medicare spending.

We focused on use and costs of brand diabetes medicines, including both oral and insulin medicines. All calculations were conducted separately for beneficiaries who used oral diabetes medicines only, insulin only, and both oral and insulin medicines. We also calculated changes in cost sharing and the effects of changes in cost sharing separately for each Part D benefit phase. The final results represent average estimations weighted by use of diabetes oral or insulin medications in each phase.

Data

This analysis used a combination of information from several data sources. We used data from the 2015 administrative Medicare Research Identifiable Files⁴⁴ to measure medicines use and spending. The claims analysis was restricted to Part D enrollees in stand-alone PDPs who used brand diabetes medicines, did not receive the Low-Income Subsidy and had at least one month of fee-for-service Parts A, B, and D coverage in 2015. Using these data, we measured the following data elements by benefit phase: 1) mean total and OOP costs of brand diabetes medicines, 2) annual mean total and OOP spending in Parts A and B, 3) the number of diabetes medicines filled, 4) and the number of beneficiaries with diabetes medicines.

Findings from the peer-reviewed literature were used to quantify the association between medicines OOP costs, adherence, and Parts A and B spending.

Modeling the Effect of Passing through Rebates at the POS on Patient OOP Cost Per Fill

To model the effect of passing through rebates at the POS, we assumed that rebates would only be passed through to beneficiaries filling medicines in the coverage gap and catastrophic phase because cost sharing is calculated as a function of gross price in these phases. The majority of brand diabetes medicines filled in the initial coverage phase face fixed copayments and only a small share of these medicines is filled in the deductible. Based on 2015 Part D claims files, 62% of Part D enrollees filled brand diabetes medicines fills while in the coverage gap and 12% reached the catastrophic phase.

We estimated gross price (excluding rebates) for diabetes medicines by calculating mean total cost per fill weighted by the number of medicines fills among beneficiaries using brand diabetes medicines. Using this approach, gross price for brand diabetes medicines was \$474 in 2015.

Since actual rebate amounts are confidential and may differ within each category (e.g., within the insulin class, average rebates may be greater for rapid-acting insulins than long-acting insulins) and from product to product, we assumed average rebate amounts of 70% for insulins and 45% for oral diabetes medicines based on publicly available information.⁴⁵ Applying the assumed average rebates for insulins and oral diabetes medicines to actual 2015 utilization, we derive a weighted average rebate of 53%, or \$251. Accounting for rebates, the net price was \$223 per fill.

OOP costs were calculated by applying the cost sharing rate required under the 2015 Part D standard benefit design to the medicine price. In 2015, the cost sharing rate was 25% before the initial coverage limit, 45% in the coverage gap, and 5% in the catastrophic phase. The cost sharing rate in the coverage gap reduces to 25% beginning in 2019.

Before passing through rebates at the POS, OOP costs are calculated based on gross price. To calculate prices in the scenario after passing through rebates at the POS, we assumed that 80% of the rebate would be passed through to beneficiaries. As such, to calculate OOP costs after passing through rebates at the POS, we calculated OOP cost by subtracting 80% of the rebate from the gross price before applying the cost sharing rate.

Modeling the Effect of Passing through Rebates at the POS on Parts A and B Spending

The effect of passing through a portion of rebates at the POS on improved adherence and reduced medical spending was estimated using results derived from peer-reviewed literature. Based on existing research, the analyses assumed that a 10% change in OOP cost is associated with a 3% change in medication fills.^{46, 47, 48} Applying this assumption to the change in OOP cost resulting from passing through rebates at the POS we found that the number of medicine fills increased by 12.7%. In sensitivity analysis, patients were assumed to be somewhat less responsive to changes in cost sharing, but varying this assumption did not substantially change the main results.

The association between increased adherence and reduced spending on Medicare A and B services was derived from Roebuck (2014), which reports that a 1% increase in diabetes medicine utilization among seniors is associated with a 0.83% reduction in medical spending.^{49 b}

In sensitivity analyses we found that the results varied somewhat with the size of the assumed utilization effect, but all analyses consistently demonstrated overall net savings. For example, reducing adjusting the estimated effect of medicines use on medical spending from 0.83% to 0.5% decreases the total savings by about 40%.

Projecting Ten-year Cost Impact

We used the results from our primary analysis to project the ten-year impact of POS rebates on spending for all Medicare (non-LIS) Part D enrollees who can be expected to reach the coverage gap and fill brand diabetes medicines. We estimate that 910,000 non-LIS Part D enrollees filled one or more brand diabetes medicines in the coverage gap in 2015. We applied projected Medicare cost and population growth estimates from CBO to estimate savings resulting from POS rebates from 2018 to 2027⁵⁰. For this projection, cost sharing in the coverage gap was assumed to be 25%.

Study Limitations

This analysis aimed to illustrate the potential magnitude of the impact of POS rebates on medical spending due to better adherence. Results from this analysis should be viewed in light of several limitations.

First, we assumed rebates would be passed onto beneficiaries in the coverage gap or catastrophic phase only. We applied the effect of increased adherence over the full course of the year due to the lack of data on time spent in each benefit phase. To offset any potential overestimation of medical savings we conservatively applied the estimated savings to the number of patients in coverage gap only (rather than both the coverage gap and catastrophic phase).

^b Roebuck (2014) built on Congressional Budget Office methodology which assumes that a one percent increase in medicine fills prompts a 0.2% reduction in medical spending in Medicare.^b The CBO assumption applies to all medicines used by the general Medicare population and likely underestimates this association among beneficiaries with chronic conditions.

Our estimates of beneficiary savings from POS rebates are also conservative because they only capture direct reductions in OOP costs at the time medicines are filled. We do not account for indirect benefits likely to accrue from beneficiaries progressing through the Part D benefit phases more slowly (with POS rebates, progression through the phases of the Part D benefit would be based on net, rather than gross spending; as a result, many more beneficiaries would not reach the coverage gap, and would incur lower annual OOP costs).

Secondly, the analysis assumed no change in patient utilization and adherence for other non-diabetes medicines. It is expected that diabetes patient may fill fewer other medicines due to overall improvement in health. This renders the baseline analysis outcomes conservative.

Thirdly, the study used 2015 Medicare claims data, when patients paid 45% cost sharing in the coverage gap. The cost share percentage is reducing overtime. We tested a lower 25% cost share in sensitivity analysis and found the results to change only slightly.

Fourthly, the patient response to changes in OOP costs and the impact of adherence on medical spending were applied in the model as fixed values. In reality, these associations may not be linear and may vary by patient and external factors. Additionally, we did not account for beneficiaries who aren't currently on therapy due to cost concerns reacting to changes in OOP costs by initiating therapy for the first time. Only 73% of Medicare beneficiaries with diabetes were taking medicines for their diabetes.⁵¹ We expect the benefits to beneficiaries who newly initiate therapy to be even greater.

Moreover, stakeholders' behavior may change after rebate (e.g. health plans may change benefit designs or formulary changes), introducing further unpredictability in analysis outcomes.

Last, this study did not consider any potential growth in the prevalence of diabetes in the US. It also did not consider potential change in the severity of Medicare patients' diabetes over time. For our ten-year projections, the study population would age 10 years in the analysis time frame and their health conditions might deteriorate, leading to more medical resource use and consequently higher savings.⁵²

Appendix: Sensitivity Analysis

The following inputs were varied in sensitivity analysis to verify the robustness of model forecasts under real-life uncertainties and study the influence of inputs on outcomes: % rebate passed through, rebate size, cost share in the initial coverage phase and coverage gap, price elasticity of demand, and offset effect (impact of adherence on medical expense).

Figure 1 and Figure 2 show the magnitude of deviation from base case when inputs were varied to upper and lower bounds. Rebate size (+/- 20%), % rebate pass through (+/- 10 percentage points), offset effect (+/- 20%), and price elasticity (+/- 20%) all influenced model outcomes but none had material impact on the conclusion of the analysis. The most influential factor in determining annual savings in OOP cost and Medicare expense is rebate size and offset effect, respectively.

In addition, we tested other scenarios and found the model conclusion to be robust (results not shown). For example, passing through 50% of the rebate rather than 80% reduced annual patient OOP and third-party savings by less than 40%. Reducing cost sharing in coverage gap to 25% (base case is 45%) to reflect closing of the coverage gap reduces average annual patient OOP cost savings by 20% and increases third party payer savings by 7% (projected ten-year savings are based on 25%, based on current law). To account for plan behavior to potentially increase cost sharing in the initial coverage

phase to offset lost revenue from rebates, we found that increasing cost sharing in the initial coverage phase to 35% and 40% had a negligible impact on results.

Figure 1 Sensitivity analysis outcomes on annual savings in OOP cost/patient

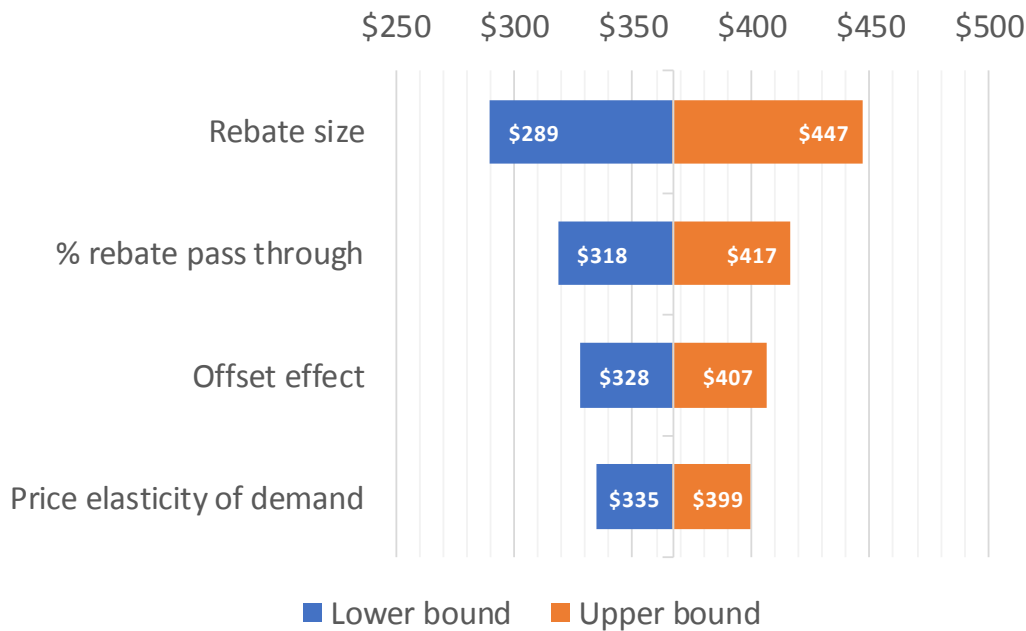
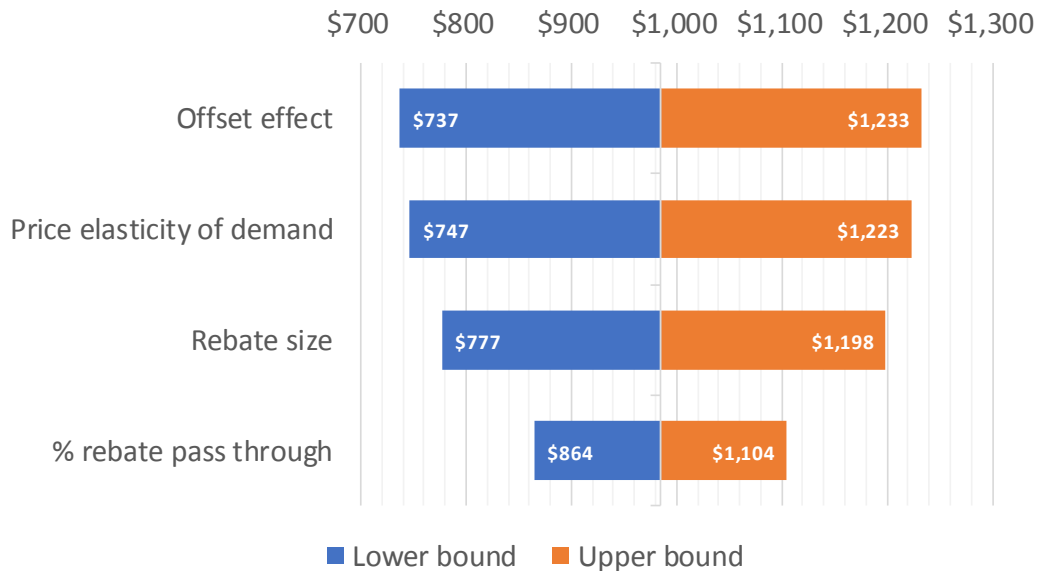


Figure 2 Sensitivity analysis outcomes on annual Medicare cost/patient



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