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Assistant Secretary for Planning and Evaluation

ESTIMATES OF THE IMPACT ON BENEFICIARIES, CMS, AND DRUG MANUFACTURERS IN CY2020 OF ELIMINATING REBATES FOR REDUCED LIST PRICES AT POINT-OF-SALE FOR THE PART D PROGRAM

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At the request of the Office of the Assistant Secretary for Planning and Evaluation (ASPE), Wakely Consulting Group, LLC (Wakely) has estimated the financial impact to beneficiaries, CMS, and drug manufacturers should drugs in the market basket be reduced by the amount of current manufacturer rebates. Specifically, ASPE is interested in understanding the net effect of various cash flow components to different parties under the Part D program if drug costs are reduced at the point of sale by the amount of manufacturer rebates for contract year (CY) 2020.

Executive Summary

The purpose of this report is to provide a directional estimate of the impact of reductions to point-of-sale drug costs on different parties with liabilities in the Part D program. Our results are highly dependent on the assumptions made, so readers of this report should be familiar with the assumptions described below when evaluating this report.

Some of the key assumptions include:

- The benefit design is the Part D defined standard benefit for all Part D sponsors.
- The reduction in the cost of drugs at the point of sale is equal to the forgone manufacturer rebates.
- There are no changes to Part D sponsors' formularies in reaction to the change in treatment of rebates.
- Drug manufacturer discounts in the Defined Standard coverage gap for 2020 are assumed to be 70%.
- The distribution of Part D claims by annual spend per member is based on aggregated Wakely client experience, which may not necessarily be representative of a nationwide distribution.
- We have ignored any impact on changes to Part D risk corridor program payments.

Key findings of our analysis are as follows.

1) While beneficiary premiums are increased, average cost-sharing across all beneficiaries is reduced by a greater amount than premiums are increased.

2) We estimate that the average beneficiary would have a premium increase of about 8%, and average beneficiary cost sharing would be reduced by about 9.5%. Because average cost sharing amounts are higher than the premiums, we estimate that the net effect for beneficiaries is a 2% reduction in out-of-pocket expenses.

3) We found that approximately 30% of non-low income beneficiaries will see a net savings (i.e. cost sharing savings outweigh premium increases). Consequently, the other 70% of non-low income beneficiaries will on average experience a net increase in out of pocket expenses.

4) We estimate that the drug spend level threshold at which the non-low income beneficiary begins to experience a net savings will occur at an annual spend of $2,200 to $2,500.

This spend represents the allowed cost of drugs at the point of sale after the assumed shift of rebates to reduce costs at point of sale.

5) The impact to low income members is immaterial (although not 0).

6) Due primarily to increased direct subsidy payments, we estimate that CMS will see total payments increase by about 3%.

7) Although a smaller piece of the Part D spend, we estimate that Drug Manufacturers will experience a large decrease in their coverage gap discount obligation – about 30%.

Below we describe the results of our analysis and describe the method and assumptions used.

Background

ASPE engaged Wakely to evaluate the impact of requiring manufacturer rebates to be reflected at the point of sale in the Medicare Part D program through reduced drug costs. Currently, manufacturer rebates and other forms of direct and indirect remuneration (DIR) are typically paid after the point-of-sale transaction at the pharmacy. For example, manufacturer rebates are often paid in lump sum amounts on a quarterly basis by PBMs to Part D sponsors.

Under the Part D benefit structure, there are four "benefit phases" where the distribution of claim liability varies between the following four parties:

- Beneficiaries
- Part D sponsors
- CMS
- Drug Manufacturers

The determination of the point at which a beneficiary reaches each benefit phase depends on the accumulation of total Part D covered drug claims as well as total beneficiary out-of-pocket cost share expenses. Currently, the drug claim and cost-sharing accumulation excludes the DIR reductions that occur after the point of sale for purposes of determining the benefit phase and the allocation of liability between the four parties. Post point-of-sale payments ultimately reduce the cost of the drug, but do not factor into the determination of benefit phase, and are only shared between the Part D sponsor and CMS.

Summary of Results

Based on the models and assumptions described in this report, in particular that reduction in the cost of drugs at the point of sale is equal to the forgone manufacture rebates, we estimate that the net effect of removing manufacturer rebates and increasing cost reductions at point of sale is that beneficiaries will see average out-of-pocket expenditures decrease by about 2% nationwide, CMS will see its Part D payments increase by 3%, and Drug Manufacturers' coverage gap discount payments will decrease by 30%. The impact for the beneficiary and for CMS is the net result of different components of Part D cash flows. For beneficiaries, the decrease is driven by the net effect of increases in premiums, which affect most non-low income

beneficiaries, and decreases in cost sharing expenses, which affect beneficiaries to varying degrees depending on the level and type of claims incurred.

For CMS, the increase is the net result of four aspects of its obligations – direct subsidy and low income premium subsidy payments to Part D sponsors (increases), federal reinsurance (decrease), and low income cost sharing subsidies (decrease). CMS could also be impacted by changes to risk corridor payments (either to or from CMS); however, we have ignored risk corridor impact in this report.

Table 1 shows our results.

Table 1: PMPM Impact of Replacing Rebates with Cost Reductions at POS by Party

Party	Part D Component	Current (Manufacturer Rebates after POS)	Rebates Replaced with Cost Reductions at POS	PMPM Difference	Percent Difference
Beneficiary	Cost Sharing	$60.55	$54.80	($5.75)	-9.5%
	Basic Premium	$47.02	$50.75	$3.73	7.9%
	Total	**$107.57**	**$105.55**	**($2.02)**	**-1.9%**
CMS	Direct Subsidy	$24.65	$60.52	$35.87	145.5%
	Low Income Premium Subsidy	$14.78	$15.95	$1.17	7.9%
	Federal Reinsurance	$155.71	$134.22	($21.49)	-13.8%
	Low Income Cost Sharing	$57.77	$50.60	($7.17)	-12.4%
	Total	**$252.90**	**$261.29**	**$8.39**	**3.3%**
Drug Manufacturers	**Coverage Gap Discount**	**$21.51**	**$15.08**	**($6.43)**	**-29.9%**

These results reflect an estimated nationwide average across the entire Medicare Part D program (non-low income and low income combined) for contract year 2020.

The results also reflect that rebates are allocated differently between Part D sponsors, Beneficiaries, CMS, and Drug Manufacturers when they are shifted to be cost reductions at the point of sale. While total drug costs (net of all price concessions) do not change, the net liability of all Part D cash flows increases for Part D sponsors and CMS, and decreases for Beneficiaries and Drug Manufacturers. When Part D sponsors expect increased claim liability, they will pass this increase on to beneficiaries and CMS in the form of increased premiums and direct subsidy payments. From the Beneficiary perspective, we estimate that the cost sharing reductions will more than offset premium increases. The reason the beneficiary does not have a zero net effect is that cost sharing decreases, whereas a portion of the total increased plan liability is paid for by CMS and is not passed on to beneficiaries' premiums.

We estimate that 30% of non-low income beneficiaries will have lower out-of-pocket expenses if rebates are shifted to point of sale. Also, we estimate that the annual drug spend at which beneficiaries begin to see cost sharing reductions exceed premium increases is between $2,200 to $2,500.

We tested our results under several alternative assumptions and found that the magnitude of the impact by party as shown in Table 1 can change, but the directional impact remains the

same. The results of these scenarios are discussed and shown in the "Scenario Testing" section.

Methodology and Assumptions

In this section, we describe the process used and assumptions made in estimating the impact of reduced cost at point of sale on beneficiaries, CMS, and Drug Manufacturers. In general, we projected Part D claims and the allocation of liability for those claims under two scenarios – current conditions and an assumption that manufacturer rebates after point of sale are no longer allowed, and that allowed costs for brand drugs are reduced uniformly by a factor to reflect cost reductions at the point of sale. That factor is calculated such that the allowed costs less any pharmacy rebates are identical in both scenarios.

Starting Base Data

The model we developed for this report aggregated estimated Part D claims and CMS payments related to all Medicare Advantage and Prescription Drug Plan (PDP) sponsors nationwide. Part D claims related to self-insured employer sponsored coverage are excluded.

We began by developing starting costs as of 2016 in order to calibrate to nationwide expenditure data. Our process to derive 2016 costs was as follows:

- We began with 2015 nationwide drug costs of $137.4B and total direct and indirect remuneration (DIR) of $23.6B as reported in the January 19, 2017 CMS news release "Medicare Part D – Direct and Indirect Remuneration (DIR)".

- We calculated an allowed drug cost PMPM (i.e. before cost-sharing) using Part D enrollment from the 2017 Trustees report.

- We trended this 2015 allowed drug cost PMPM to 2016 based on the observed change in gross drug costs from 2014 to 2015 from the January 19, 2017 CMS news release.

- We fit this estimated 2016 national allowed drug cost PMPM to detailed Wakely Part D claim data for calendar year 2016.

- In the Wakely data, we identified drugs as specialty, brand, and generic based on Wakely studies and external data sources.

- We assumed that the beginning costs reflected the same distribution of low-income and non-low-income members as found in the 2017 Medicare Trustees report. It showed that 28.5% of all beneficiaries were low income. The distribution by specific low-income category was developed from three sources:

    - Enrollment projections in the 2017 Medicare Trustees report – used to develop the percentage of low-income members that are partial duals
    - 2015 Medicare Limited Data Set (LDS) data – used to develop an estimated percentage of members with an institutional status
    - Wakely internal data – used to develop the percentage of low-income members that are above or below the federal poverty limit

Projection to 2020

Numerous assumptions were needed in order to project Part D payments and claim amounts to 2020. The following projection assumptions were used:

- Total enrollment was based on projections in the 2017 Medicare Trustees report. Our analysis includes individual and employer group waiver program (EGWP) enrollees, but excludes retiree drug subsidy beneficiaries. The distribution of non-low income and low-income members was assumed to vary based on the enrollment projections to 2020 in the 2017 Medicare Trustees report. This includes amounts used to determine the distribution of enrollment by low-income category from the 2017 Medicare Trustees report.

- Total drug costs (before cost-sharing) were trended based on several components. First, we estimated an annualized impact of patent expirations based on Wakely analysis of 2017-2018 anticipated expirations by brand, generic, and specialty; and applied three-year adjustment factors to the claims. Second, we trended brand, generic, and specialty drugs at annual rates based on Wakely drug trend studies that excluded the impact of brand patent expirations. We separated costs for high-cost Hepatitis C drugs from other specialty drugs, and applied a flat 1.0 trend factor to these drugs. Induced utilization adjustments were not made in the projections. Overall, the annual allowed drug trend was about 12%.

- The Part D Defined Standard benefit design was used for the analysis. While many Medicare Advantage Organizations (MAOs) offer enhanced benefits, we used the simplifying assumption of a defined standard benefit to assess the impact on beneficiary basic premiums and cost sharing. Pricing for 2020 reflects the changes to beneficiary cost sharing and drug manufacturer discounts as specified in the Affordable Care Act and the January 2018 Bipartisan Budget Act. Values for the Part D deductible, initial coverage limit, and attachment point for the maximum out-of-pocket threshold are based on the parameters in the April 2, 2018 Final Announcement, adjusted for annual trends of 2-4%. The national average bid amount (NABA) and base beneficiary premium (BBP) were projected assuming that any change in the national average bid caused by shifted DIR would directly translate as change to the NABA.

- The 2020 low-income premium subsidy amount was calculated as 24% of the estimated Part D basic premium amount. This assumption is based on data in the publicly available 2015 minimum loss ratio filings. Note that the 24% factor considers both the relationship of the LIPSA to the national average BBP as well as the percentage of Part D beneficiaries nationwide who are low income.

Other Assumptions for 2020

Our cost model also required other assumptions in addition to claim costs. These included the following:

- We modeled results assuming that plans' 2020 pricing would change as a result of the shift from post point-of-sale rebates to point-of-sale cost. This is reasonable as long as

legislation is in place in time for plans sponsors to incorporate re-negotiated contracts into CY2020 bid pricing. Plan sponsors would need to be aware of changes in the treatment of DIR by early 2019 in order for our directional analysis to hold.

- An RxHCC risk score of 1.0 was used for the analysis. We believe an assumption of 1.0 is an accurate representation of nationwide Part D plan sponsors because publicly available data from 2014 and 2015 showed a nationwide average very close to 1.00 in both years.

- Non-benefit expenses were assumed to be equal to 10.5% of required revenue, prior to the shift towards point-of-sale price concessions. This is based on publicly available minimum loss ratio filings.

- Profit margin was set equal to 5.3% of required revenue on a pre-sequestration basis, prior to the shift towards point-of-sale price concessions. This is based on a nationwide post-sequestration average of about 3.2% profit, as reported in minimum loss ratio filings.

- Profit and non-benefit expense PMPM amounts were held constant between the current and drug cost reduction at POS scenarios.

- We assumed that 90% of all forms of DIR represent manufacturer rebates and so would no longer be paid after point of sale basis and that Part D sponsors and PBMs would re-negotiate contracts such that the discounted ingredient cost for brand drugs at point of sale would be reduced by this same amount.

- The reductions to ingredient costs were assumed to apply only to brand drugs since the majority of DIR is manufacturer rebates, which are typically only received for brand drugs.

- No changes to MAO formularies was assumed.

- The impact of the Part D risk corridor program has been ignored.

- Other than changing the drug cost at point of sale, we have not incorporated any other proposed regulatory changes, (e.g. those proposed in the President's FY2019 budget impacting pharmacy pricing and beneficiary cost sharing.)

- The 2020 National Average Bid and Average Basic Part D Beneficiary Premium reflect changes in brand drug costs in reaction to the change in rebate treatment, but no other changes in formulary or benefit design or member behavior.

Scenario Testing

As noted above, the results discussed in this report are highly dependent on our assumptions. There are many variables that cause uncertainty in results, particularly when attempting to model the entire Part D program nationwide.

In order to better understand the potential for different results based on alternative assumptions, we tested several scenarios.

The scenarios all reflected that 90% of DIR would be reported as reductions to drugs costs at point of sale. Other details are as follows:

1. We assumed that the drug manufacturer discount in the coverage gap was returned to 50%, which reflects the original rule under the ACA, prior to the 70% discount implemented in the Bipartisan Budget Act of 2018. In general, the change in expenditures for members and CMS were slightly more favorable compared with our baseline result (i.e. more net savings for members and less of a net cost increase for CMS). However, drug manufacturers saw less of a cost reduction under the 50% discount scenario than the baseline (70%) discount scenario when shifting cost reductions to point of sale.

2. We ran an alternative scenario where forgone rebates are re-negotiated on a one-to-one basis as reduced ingredient costs at point of sale for both brand and generic drugs (even though most DIR is rebates, which apply to brand drugs). This scenario produced the biggest net savings for beneficiaries' and the biggest net incremental cost for CMS. Drug Manufacturers saw somewhat lower savings than in the baseline.

3. We tested a scenario where the assumed portion of drug costs in the catastrophic benefit phase was assumed to increase significantly by assuming a large trend on specialty drugs. This scenario produced results nearly the same as our baseline analysis.

4. We tested a scenario where claim adjustments were made to bring the estimated national average bid and federal reinsurance closer in line with recent national average amounts released by CMS. We observed that the projected national average bid and federal reinsurance amounts developed in our baseline analysis are significantly higher than the recently released national average bid and federal reinsurance amounts. This is likely due to the fact that our analysis relies on an underlying Part D claims distribution table from our proprietary data based largely on MA-PD plan data as well as the assumptions and adjustments discussed above, rather than a dataset comprised of all Part D plans, which was not available.

   The directional impacts of the results in this scenario were the same as our baseline scenario, although the PMPM magnitude of the impact to CMS and Drug Manufacturers decreased fairly significantly. However, on a "percentage change" basis, the impact to CMS is roughly the same while the impact to beneficiaries and Drug Manufacturers is more favorable in this scenario compared to the baseline.

The results of these scenarios are summarized in the table below.

Table 2: Differences if Manufacturer Rebates Replaced with Drug Cost Reductions at POS

Scenario		Description	Beneficiary	CMS	Drug Manufacturers
Baseline	PMPM Difference	Baseline	-$2.02	$8.39	-$6.43
1		50% Manufacturer Discount in Gap	-$2.51	$7.81	-$5.36

2		Discounts go to brand and generic	-$3.75	$9.49	-$5.81
3		Federal reinsurance increases	-$2.21	$8.39	-$6.24
4		Adjust claims to better align with recent NAB & Federal reinsurance	-$1.60	$4.79	-$3.23
Baseline	Percent Difference	Baseline	-1.9%	3.3%	-29.9%
1		50% Manufacturer Discount in Gap	-2.3%	3.0%	-30.9%
2		Discounts go to brand and generic	-3.5%	3.8%	-27.0%
3		Federal reinsurance increases	-1.9%	2.9%	-28.6%
4		Adjust claims to better align with recent NAB & Federal reinsurance	-2.7%	3.4%	-31.3%

Comparison to CBO Estimate

It is important to note that our model may not reconcile to the estimates shown in Tables 10 and 11 in the November 28, 2017 Federal Register (Vol. 82, No. 227). We believe there are different assumptions and different regulatory provisions being modeled in the CMS estimates; therefore, our results are not appropriate to directly compare.

Disclosures

Tim Courtney, Julia Lambert, and Drew McStanley are financially independent and free from conflict concerning all matters related to performing the actuarial services underlying this analysis. In addition, Wakely is organizationally and financially independent from ASPE.

The assumptions and resulting estimates included in this report are inherently uncertain. Users of the results should be qualified to use and understand the results their inherent uncertainty. Actual results may vary, potentially materially, from our estimates. Wakely does not warrant or guarantee that projected results in this report will be realized.

It is the responsibility of the organization receiving this output to review the assumptions carefully and notify Wakely of any potential concerns.

We have relied on others for data and assumptions used in this report. We have reviewed the data for reasonableness, but have not performed any independent audit or otherwise verified the accuracy of the data/information. If the underlying information is incomplete or inaccurate, our estimates may be impacted, potentially significantly.

Our work on this report conforms to the following Actuarial Standards of Practice (ASOP) issued by the Actuarial Standards Board:

- ASOP #5, “Incurred Health and Disability Claims”
- ASOP #23, “Data Quality”
- ASOP #41, “Actuarial Communications”

This information has been prepared for the sole use of the ASPE. Distribution to parties should be made in its entirety and should be evaluated only by qualified users. The parties receiving this report should retain their own actuarial experts in interpreting results.

Sincerely,

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