Estimated Impacts of Proposed Changes to Medicare Part D Rebates

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I. Executive Summary

Legislation is currently being considered by Congress that would change how drug manufacturer rebates are determined and paid under Medicare Part D for drugs used by full dual eligible beneficiaries. Currently, pharmacy benefit managers (PBMs) and drug manufacturers negotiate these rebates. On brand name drugs, the rebates average 15.9 percent of the average negotiated price, based on average wholesale price (AWP)[1] net of discounts. Plans can use these rebates to lower their Part D bid and thereby lower beneficiary premiums.

The proposed legislation would change this process by statutorily setting the rebates for branded drugs used by full dual eligibles at 22.1 percent. The rebates would flow from the manufacturers directly to CMS. The Pharmaceutical Care Management Association (PCMA) engaged The Lewin Group and Ingenix Consulting to analyze the impact of this proposed legislation.

While implementing the statutory rebate for full duals would increase manufacturer rebate dollars for that population, unintended consequences would result from plans no longer having access to rebate dollars they currently use to lower their *overall* Part D bids. Any resulting increase in bids would also increase Part D premiums and thereby raise costs for non-dual-eligible Part D beneficiaries.

Lewin and Ingenix Consulting modeled the impacts of the legislation using Ingenix's Medicare Part D Bid Tool. Ingenix prepared bids for a defined standard benefit plan based on two large sets of Part D plan data. The model incorporated current and proposed rebate levels and assumptions related to trends, rebate collection, manufacturer response to the rebate change, administrative fees, and profit margins. The resultant impacts were extrapolated to all Part D participants.

The Lewin-Ingenix model reveals that a 22.1 percent rebate of AMP (average manufacture's price) applied to brand drugs would:

- **Result in a $7.90 or 27.3 percent increase on members' basic monthly premiums.**
- **Increase beneficiary expenditures from 2010-2014 by $9 billion and $26.5 billion from 2010-2019.**
- **Decrease CMS expenditures from 2010-2014 by $10.3 billion and $30.1 billion from 2010-2019.**

[1] AWP is not defined in statute, thus price regulations tend to focus on AMP as described below.

II. Introduction

The Pharmaceutical Care Management Association (PCMA) commissioned The Lewin Group and Ingenix Consulting to study the impact of proposed legislation that would change how drug manufacturer rebates are determined and paid in Medicare Part D for drugs used by full dual eligible beneficiaries.

Currently, manufacturer rebates for all Part D beneficiaries are typically determined by competitive negotiations between pharmacy benefit managers (PBMs) and drug manufacturers. Part D plans may then leverage their contracted PBM's rebates to lower costs and/or provide enhanced coverage – both of which improve the competitiveness of the products offered to Medicare beneficiaries. Proposed legislation would set manufacturer rebates for branded drugs used by full dual eligible enrollees at a statutory level of 22.1 percent of the average manufacturer price (AMP). The legislation would also require rebates to flow directly from manufacturers to CMS.

To model the impact of these changes on CMS expenditures and Part D premiums, Ingenix Consulting prepared a 2009 Part D plan bid for a defined standard benefit plan using the CMS bid-pricing tool and 2007 Medicare Part D claims data sets encompassing a large national population. In addition, the Lewin Group conducted a survey of major PBMs operating in Part D to assess the current level of manufacturer rebates in the program.

III. Overview of Part D Rebate Dynamics

To fully understand the implications of the proposed statutory changes, it is useful to review the basic dynamics of how drug manufacturer rebates are currently determined and used in the commercial marketplace and Part D.

A. PBMs Negotiate Price Concessions from Drug Manufacturers in the Form of Rebates

In order to reduce the price of brand name drugs, most pharmacy benefit managers (PBMs) negotiate price concessions from pharmaceutical manufacturers in the form of rebates. Manufacturer rebates are most common (and are largest) for brand-name drugs with patent protection that face competition from potential substitute drugs used to treat the same medical condition.

PBMs normally negotiate a rebate agreement for a particular drug based on a number of factors, including the drug's formulary placement, the presence or absence of administrative restrictions on the drug such as prior authorization, required cost sharing for the drug, the size of the population the PBM serves, and the amount of market share the drug achieves against its competitors. The rebate amount depends on the extent to which these factors encourage the use of the drug relative to its competitors.

B. How Manufacturer Rebates May Be Used to Lower Costs

It is common for PBM clients—including plan sponsors such as health insurance companies, self-insured employers, unions, and plans covering federal employees and Medicare Part D beneficiaries—to receive either part or all of the manufacturer rebates based on the terms of the contract they negotiate with their PBM. In Medicare Part D, manufacturer rebates received by prescription drug plans (PDPs) may be used by the PDP to lower their members' monthly premiums and/or copayments. Most Medicare Part D plans "redeploy" rebates to reduce member premiums.

C. Part D Requirements Influence the Use of Manufacturer Rebates

In Medicare Part D, manufacturer rebates are defined in statute as "direct or indirect remuneration" (DIR). As DIR, all manufacturer rebates must be reported to the Centers for Medicare and Medicaid Services (CMS). Any rebates retained by the PBM and not passed on to the plan must be reclassified as an administrative cost. Because PDPs must compete to attract and retain enrollees and because CMS requires all rebates to reduce claim costs, PDPs have strong incentives to require their PBMs to negotiate large rebates to improve competitiveness.

D. How Manufacturer Rebates Can Lower Part D Bids and Premiums

To win approval to offer a Medicare prescription drug plan, potential plan sponsors must submit a bid submission to CMS that includes a description of the benefit package, a list of drugs on the formulary, a list of network pharmacies, and a bid amount. The bid amount is the plan sponsor's per-member, per-month (PMPM) estimated cost of providing drug coverage based on estimated utilization, drug costs, and administrative fees. Manufacturer rebates can help plans to lower their bids.

Bid amounts are used by CMS to determine payments to plan sponsors. The beneficiary pays part of the bid amount through premium payments. CMS pays the remaining part of the bid amount through direct subsidy payments. By helping plans to lower their bids, manufacturer rebates help to lower Part D premiums.

IV. Current Manufacturer Rebate Levels and Proposed Legislative Changes

In Medicare Part D, PBMs have negotiated manufacturer rebates on brand name drugs averaging 15.9 percent of the average negotiated price[2], net of discounts, according to a Lewin survey of major PBMs operating in Part D. Plans can then use these rebates to lower their Part D bid and thereby lower beneficiary premiums.

A legislative proposal under consideration would change how manufacturer rebates are determined and collected for full dual eligible beneficiaries in Part D. Rather than manufacturer rebates for this population being negotiated, collected, and allocated by individual plans

[2] AWP is not defined in statute, thus price regulations tend to focus on AMP as described below. We estimate that the 15.9 percent discount off the average negotiated price equates to a 12.8 percent discount off of AWP and a 16.2 percent discount off of AMP.

(and/or their PBMs) based on competitive forces, as is the case now, the legislation would have CMS impose a flat statutory manufacturer rebate of 22.1 percent of average manufacturer price (AMP).[3] These rebate dollars would flow directly from manufacturers to CMS.

Implementing a statutory rebate of 22.1 percent of AMP for full duals would increase manufacturer rebate dollars for this population. However, plans would no longer have access to these funds to reduce their Part D bids. The plans currently use their existing rebates on dual eligibles' prescriptions to lower *overall* Part D premiums. Thus, the proposed legislation – even though it focuses on rebates for dual eligibles – will impact the premiums charged to non-dual eligible Part D participants in the absence of additional policy changes. The following section presents the outcomes of our modeling of the legislation's impacts on non-dual eligible Part D participants and on CMS expenditures.

V. Key Findings from Modeling Efforts

A. Summary Results

As described earlier, the impacts of the legislation have been modeled using the Part D bid pricing tool and applying the historical prescription drug claims of a large Medicare population. Our findings are summarized in Tables 1-3, which show the estimated financial impact on average monthly premiums (Table 1) and the 5 and 10 year total dollar change in member premiums (Table 2) and CMS expenditures (Table 3). The additional dual eligible rebates create large-scale CMS savings but will also create large increases in costs for non-dual Part D participants (unless additional changes are made to the bid process and/or to federal subsidy levels).

There are complex dynamics in the bid process. By diverting dual rebates from the plans to CMS, bids increase, causing the national average bid, basic member premium and direct subsidy to increase. While member premiums will increase, duals would not see an increase in out-of-pocket expenses because of a corresponding increase in the low income premium subsidy (LIPS). However, non-dual eligible members would bear the full burden of their own increased premium cost **– a premium increase of 27.3 percent is projected for non-duals under the current draft legislation provisions.**

[3] AMP is defined in the GAO report "Medicaid Drug Price Comparisons: Average Manufacturer Price to Published Prices" in the following manner: "The average manufacturer price (AMP) is the average price paid by wholesalers for drugs distributed to the retail class of trade, net of customary prompt pay discounts." The Congressional Budget Office has estimated that, on average, AMP prices represent 79 percent of AWP (or a 21 percent discount off of AWP).

Table 1. Estimated Impacts of Higher Rebates for Dual Eligibles' Medications
Impact on Average Member Premium

Rebate Scenario for Full Dual Eligibles	Impact on Member's Basic Monthly Premium (PMPM)	Impact on Member's Basic Monthly Premium (Percent)
22.1% Rebate off of AMP, applied to Brand Drugs	$7.90	27.3%

Table 2. Estimated Impacts of Higher Rebates for Dual Eligibles' Medications
Impact on Total Beneficiary Expenditures

Rebate Scenario for Full Dual Eligibles	Change in Beneficiary Expenditures, 2010-2014 (in Billions)	Change in Beneficiary Expenditures, 2010-2019 (in Billions)
22.1% Rebate off of AMP, applied to Brand Drugs	$9.0	$26.5

Table 3. Estimated Impacts of Higher Rebates for Dual Eligibles' Medications
Impact on Total CMS Expenditures

Rebate Scenario for Full Dual Eligibles	Change in CMS Expenditures, 2010-2014 (in Billions)	Change in CMS Expenditures, 2010-2019 (in Billions)
22.1% Rebate off of AMP, applied to Brand Drugs	-$10.3	-$30.1

B. Key Assumptions Used to Derive Estimates

To create the estimated impact of the proposed legislative changes shown in Tables 1-3, Part D bids were prepared for a defined standard benefit using data from an Ingenix Consulting internal data base of Part D plans, normalized for LIS mix and cost based on AWP. The modeling was done on one large data set, then modeled and validated on a second large data set.

Rebate Levels: The mandated rebates of AMP minus 22.1 percent were modeled. A baseline average rebate level of 15.9 percent of average negotiated price (based on the results of Lewin's PBM survey) was applied. Scenarios were modeled for member type -- full duals, all duals, all members -- and therapeutic drug class (6 protected classes, all drugs). Only brand rebates were considered in this analysis. Thus, no rebates were assumed to occur on generic drugs.

Trend Forecast: To estimate impacts from 2010 - 2019, CMS liability trends were derived from the Medicare Trustees report.

Rebate Collection: These estimates assume that CMS will obtain, directly from the drug manufacturers, all rebates from Part D medications prescribed to dual eligible members.

Manufacturer Response to Rebate Change: The degree to which drug manufacturers will be able to offset any additional, legislatively-mandated rebates is unknown, although it is likely that they will strive to avoid absorbing a pure revenue loss through pricing mechanisms that change their net price. The estimates in Tables 1-3 assume that manufacturers will offset 50 percent of lost dual eligibles' rebates within the Part D program (through agreeing to smaller rebates for non-dual eligibles' medications than currently exist).

Administrative Fees and Profit Margins: The Medicare Part D Bid Tool used to price the various scenarios assumed a $10.00 per member per month administrative fee and 5 percent profit margin.

Extrapolation to All Part D Participants: The PMPM impacts derived from the sample population used in the modeling effort were translated into nationwide dollar figures by drawing upon Part D population estimates from the 2009 Medicare Trustees Report (excluding those participants enrolled in the Retiree Drug Subsidy program).