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Executive Summary

This study is intended to explain:

1. the flow of financing under Medicare Part D and the role of those involved in getting medicines to beneficiaries;
2. how price discounts and rebates are generated along the supply chain;
3. how Part D plans may apply negotiated prices in designing their Part D benefit offerings and reducing overall beneficiary out-of-pocket costs; and
4. the need for CMS, as the sole repository of these data, to quantify the aggregate contribution of negotiated prices.

In the Medicare Modernization Act of 2003 (MMA), Congress chose to leverage market competition among private risk-bearing plans to create a cost-effective way of giving Medicare beneficiaries access to prescription drug benefits. The Part D pharmaceutical supply chain is, by Congressional design, similar to the supply chain underlying commercial prescription drug insurance plans. In the case of Part D, CMS plays the role of an employer or other large purchaser of health care in a commercial environment. By basing Part D on the private plan model, Congress chose to use the existing commercial pharmaceutical supply chain to determine the prices of and to physically deliver prescription drugs to Medicare beneficiaries who elect to participate in Part D.

Within this overarching statutory framework, the MMA allows Part D plans to negotiate independently with suppliers, and to decide how to leverage negotiated prices in order to reduce beneficiary out-of-pocket spending. Congress permitted Part D plans to make their own decisions about how to finance their plan benefit designs. Such decisions include how negotiated prices are passed along to beneficiaries, through cost-sharing for monthly premiums, annual deductibles, copayments or coinsurance costs, and prices at the pharmacy counter.

By law, only CMS can see the net prices manufacturers charge Part D plans. Congress chose to preserve the competitiveness of the marketplace by protecting the confidentiality of price negotiations between manufacturers and Part D plans. Yet, Congress did require plans to report data to CMS on price concessions. Because only CMS can see the total amount of these “price concessions” (discounts, rebates, etc.) agreed to by plans and manufacturers, simply looking at drug prices “at the pharmacy counter” will not show the degree to which manufacturers negotiated with Part D plans.

CMS analysis of aggregate discounts and trends over time could aid policymakers in evaluating how negotiated prices contribute to holding down beneficiary costs. CMS alone will have the necessary data, including mandatory reports from Part D plans on rebates and discounts received from manufacturers, to explain and quantify the impact of negotiated prices in reducing overall beneficiary costs and to understand how fully discounted Part D prices compare to those in other drug programs. With such analysis and reporting by CMS, policymakers, beneficiary advocates, and other interested parties will have an accurate assessment of the contribution of negotiated prices to holding down beneficiary out-of-pocket costs under Part D.
The Central Role of Private Plans in Negotiating Drug Prices and Determining Beneficiary Costs Under Medicare Part D

A. Background

Since Medicare was established in 1965, outpatient prescription drugs have become an indispensable part of health care practice and an essential feature of private health insurance. But Medicare did not evolve over the past 40 years to include coverage of these therapies. Thus it is not surprising that, in 1999, 38 percent of Medicare beneficiaries reported that they did not have any form of prescription drug coverage for some or all of the year. In addition, many beneficiaries who did have prescription drug coverage, whether through Medicare supplemental insurance (Medigap) policies, Medicare managed care plans, or employer-sponsored retiree drug coverage, were seeing that coverage erode. Before enactment of the Medicare prescription drug benefit, the Congressional Budget Office (CBO) estimated that Medicare beneficiaries would spend an average of about $2,400 on prescription drugs in 2003, and that about 64 percent of Medicare beneficiaries would spend over $1,000 on prescription drugs that year.

Private plans are the delivery vehicle for the Medicare drug benefit. The Medicare Modernization Act of 2003 (MMA) was signed into law in December 2003 to provide Medicare beneficiaries with the voluntary option of a prescription drug benefit under Medicare. Unlike Medicare Part A or Part B, which reimburse providers on a fee-for-service basis, the Centers for Medicare and Medicaid Services (CMS) is not the direct payer for prescription drugs under the Part D benefit. Instead, CMS contracts with private risk-bearing plans to deliver covered prescription drug benefits to Medicare beneficiaries. In selecting a private-payer model for the structure of the Medicare Part D benefit, Congress explicitly decided to utilize market competition among private risk-bearing plans to create a cost-effective way of providing Medicare beneficiaries with access to medically necessary prescription drug benefits.

Private plans use the commercial pharmaceutical supply chain to determine Medicare drug prices. By basing Part D on private plans, Congress also explicitly chose to use the existing commercial pharmaceutical supply chain to determine the prices of (and physically deliver) prescription drugs to Medicare beneficiaries who elect to participate in Part D. Thus, to understand how drug prices are determined under Part D, one must understand how the commercial pharmaceutical supply chain works.

B. Overview of the Pharmaceutical Supply Chain Under Part D

The Part D pharmaceutical supply chain is, by Congressional design, based on the supply chain underlying commercial prescription drug insurance plans. In the case of Part D, CMS plays the role that an employer or other large purchaser of health care would play in a commercial environment. Some of the financial flows between supply chain entities also are unique to Part D, such as the end-of-year reconciliation process for “risk corridor” payments between CMS and Part D plans, and payments of “low-income subsidies” from CMS to Part D plans, but by and large, the Medicare Part D and commercial supply chains look and work similarly.

Exhibit 1 provides a high-level schematic depiction of the flows of both dollars and physical product among the actors in the Medicare Part D pharmaceutical supply chain. Each arrow depicts payment flow, rebate flow, and product flow depending on the individual transaction. Immediately following the diagram, there is

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3 Ibid.
4 For more discussion of the commercial pharmaceutical supply chain, please see Follow the Pill: Understanding the U.S. Commercial Pharmaceutical Supply Chain, prepared for the Kaiser Family Foundation by The Health Strategies Consultancy LLC, March 2005.
a brief description of each of the major financial flows in the supply chain (denoted by numerals 1 through 6). The descriptions include a summary of the negotiations that take place between the entities involved in each step.

**Exhibit 1. The Pharmaceutical Supply Chain for Medicare Part D**

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**Description of Key Payment, Rebate, and Product Flows in the Pharmaceutical Supply Chain for Medicare Part D**

1. Drug manufacturers and Part D plans negotiate a unit price for the pharmaceutical products that the manufacturer wants to offer to the Medicare population. In addition to a drug’s unit price, often referred to as a drug’s “ingredient cost,” manufacturer-plan negotiations include other terms and conditions under which a drug will be made available to the plan’s members, including which level (“tier”) of cost-sharing will be applied and whether the drug will be subject to prior authorization, step therapy, or other utilization management procedures. The combination of these conditions – whether the drug is covered by the plan at all, the out-of-pocket cost (copayment or coinsurance) that a plan member must pay to consume a prescription of the drug, and whether there are restrictions placed on
plan members’ access to the drug – collectively comprise the drug’s position on the plan’s drug formulary.

There are generally two types of price discounts, both of which typically are calculated as percentage reductions in a drug’s “average wholesale price” (AWP): discounts (a flat percentage off of AWP, given up front) and rebates (a varying percentage off of AWP, typically determined after the end of a benefit year and tied to the actual volume of a drug that was sold through the plan’s pharmacy network). For most rebates, the formula by which the rebate will be calculated is set prospectively in the initial contract negotiation, but the actual calculation of the final rebate amounts is done after the benefit year has ended and final sales volume figures are available.

2. The physical supply chain for prescription drugs flows from drug manufacturers, drug wholesalers-distributors, and pharmacy providers. Pharmacy providers may be retail pharmacies, mail-order pharmacies, long-term care pharmacies, or specialty pharmacies (which specialize in the handling of high-cost, environmentally sensitive drugs that are usually administered through injection). Exceptions to the “traditional” system depicted in Exhibit 1 are common: some large retail pharmacy chains negotiate directly with drug manufacturers and serve as their own “wholesaler”; some PBMs operate their own mail-order pharmacies and therefore are actually involved in the physical distribution of drugs as well as negotiating with manufacturers over ingredient costs. In either of these two cases, rebates may be generated from the manufacturer to the pharmacy based on the volume of drugs sold through the pharmacy.

The relationship between manufacturers and drug wholesalers typically involves the wholesaler acting as a broker on behalf of multiple retail pharmacies, in terms of physically moving product, arranging financial terms under which the retail pharmacies will take possession of the manufacturer’s products, and, increasingly, providing the manufacturer with information about its product’s performance in the rest of the supply chain, for example, where, when, how much, and by whom is the manufacturer’s product is selling or not. Retail pharmacies that require the services of a wholesaler/distributor of course pay the wholesaler for those services, thereby generating a financial flow between them.

3. Part D plans (or their contracted PBMs) negotiate with pharmacies in order to include a sufficient number and geographic distribution of pharmacies in their “pharmacy networks.” Financially, the plan will reimburse the pharmacy at an agreed upon rate for the cost of the drug plus a dispensing fee for each prescription dispensed by the pharmacy. Pharmacies set their own rates for drug dispensing services, but often will give the plan a discount on their “usual and customary” rate. This is true especially in the case of retail pharmacies, because they have a pecuniary interest in being designated as a “preferred” or “network” pharmacy to as large a number of plan members as possible, in order to generate the maximum amount of foot-traffic to its pharmacy counter – and past the rest of the store’s retail product displays. Pharmacies also will often collect some or all of a plan member’s cost-sharing liability (copayment or coinsurance). Amounts collected directly from a plan member are deducted from the reimbursement amount that the plan would otherwise pay the pharmacy.

4. CMS is never involved in the physical supply chain, but the financial flows obviously are central to the government’s role in making Part D work. During the benefit year, Part D plans will receive funds from the federal government in three forms: direct (premium) subsidies, low-income subsidies (LIS), and reinsurance subsidies. After the end of the plan year, Part D plans may receive reconciliation and risk-corridor payments from the federal government, or they may have to pay the government, depending on the outcome of the final reconciliation and risk corridor calculations.

Direct premium subsidies are the core payment from CMS to the plan. The plan’s total premium is a “per member per month” amount equal to the plan’s final approved Part D bid. To calculate the direct
subsidy amount paid by CMS, the member/beneficiary’s share of the premium (paid under step 5) is subtracted from the total premium, and the remaining amount is the base direct subsidy amount. This base amount is then “risk-adjusted” for each member/beneficiary’s health status (as determined according to a CMS-specified risk-adjustment formula) and demographic characteristics (e.g., age and gender). Each individual risk-adjusted direct subsidy amount is summed across the plan’s total estimated enrollment, and CMS pays the plan that aggregate amount.

5. In most cases, beneficiaries must pay a monthly premium to the plan in order to become a plan member and be covered by the plan. The exceptions are some Medicare Advantage Prescription Drug (MA-PD) plans being offered in 2006 with a zero premium for their drug coverage. On a national average basis, the MMA requires that beneficiary premiums must equal 25.5 percent of the national average standardized bid amount for all Part D plans.

6. Beneficiaries will make varying amounts of cost-sharing payments to the pharmacy to obtain their prescribed drugs. Cost-sharing amounts will vary according to the terms of a beneficiary’s particular plan. If the plan design includes a deductible and/or coverage gap, a beneficiary will pay the pharmacy 100 percent of the drug’s negotiated price (as defined in the MMA). At other points in the benefit, a beneficiary’s cost-sharing liability is defined by their plan formulary’s cost-sharing tier structure, which may include flat copayment amounts (e.g., $10 for a generic drug, $20 for a “preferred” brand drug, and $50 for a “non-preferred” brand drug) or coinsurance amounts based on a set percentage of the drug’s negotiated price. In all cases where a beneficiary cost-sharing amount is charged, the plan will deduct the specified cost-sharing amount from the reimbursement amount it pays to the pharmacy, under the presumption that the pharmacy will collect the balance from beneficiary.

C. “Negotiated Price” for Drugs Under Part D

The MMA allows individual Part D plan sponsors to negotiate with manufacturers, wholesalers, retail pharmacies, and LTC pharmacies, with the goal of ensuring that plans, and therefore, beneficiaries and the federal government, are getting access to “negotiated” drug prices that are below full retail prices. Under the MMA, a drug’s “negotiated price” is the price at which that drug is available to a Medicare beneficiary under the Part D plan in which they are enrolled. This negotiated price is typically the result of a private agreement between a Part D plan sponsor and manufacturers, wholesalers, and/or pharmacies, and is net of all or some – depending on what portion the plan decides to pass through to beneficiaries at the point of sale – rebates, discounts and other price concessions made at the product and aggregate levels. For Part D, a drug’s negotiated price could reflect the same prices that a health plan or PBM would get for the drug for its commercially insured members, or something different depending on the final terms of the agreement. Drug prices typically are based on average wholesale price or wholesale acquisition cost, and then discounted from there.

The federal government expects Medicare Part D plans to negotiate on behalf of their enrollees for significant price discounts from pharmaceutical manufacturers, retail pharmacies, and other entities in the pharmaceutical supply chain. Some or all of these discounts will be given to plan enrollees and the Medicare program in the form of lower premiums; lower copayment or coinsurance liabilities and deductibles than required under the standard Part D benefit defined in the MMA; broader formulary access than the minimums required under the MMA and Medicare regulations; and possibly lower out-of-pocket drug prices at the beneficiary’s retail or mail-order pharmacy (compared to typical full retail prices). In addition, plans may retain a portion of the manufacturers’ price concessions to help cover administrative risk protection and possible profit.

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1 Social Security Act §1860D-2(d)(1).
To enable the market mechanism to function, the law states that CMS may not release publicly the net negotiated prices that plans pay manufacturers. The prices that plan enrollees pay when they face partial or total cost liability – as happens in the coverage gap – are not the same as negotiated prices. Most likely, and logically, the publicly available prices are higher.

The reason for this is that Part D was designed as a drug insurance benefit to allow negotiated discounts to be reflected in lower costs to the beneficiary across a drug plan’s benefit design. In almost all commercial drug insurance products, price discounts typically are not passed through to the consumer solely in the form of lower prices at the retail point of sale. No matter how much price information is available to beneficiaries in a public forum like the Medicare website, that kind of drug price information by its very nature cannot reveal complete Part D drug pricing information, nor can it reveal why and how Part D plans made the benefit design decisions manifest in the plan choices beneficiaries have today. This reality increases the importance of any future reporting that CMS will do about the full extent to which all price discounts negotiated under Part D are translated into savings for Medicare beneficiaries and taxpayers. CMS is the only entity in a position to put all the pieces together and give a complete accounting of how much or how little drug price discounting was achieved by Part D plans.

D. What “Drug Price Transparency” Means Under Part D

Congress’ decision to use private plans to negotiate drug prices on behalf of the government and Medicare beneficiaries has significant implications for how transparent drug prices are under Part D. In the commercial pharmaceutical supply chain, all of the negotiated prices struck between pharmaceutical manufacturers, pharmacy benefit managers (PBMs), health plans, wholesale distributors and retail pharmacies have been protected by stringent non-disclosure agreements. No one entity in the pharmaceutical supply chain knows the contract terms among all parties. As CBO and the Federal Trade Commission and Department of Justice all recently concluded, the confidentiality of these price negotiations is an essential ingredient in maximizing the savings that may be obtained through a system of private party negotiations.  

Despite the preservation of confidentiality in the price negotiations in the pharmaceutical supply chain, CMS will have access to the information it needs to compare the results of Part D plans’ price concession negotiations with pharmaceutical manufacturers, pharmacies, and the other entities along the supply chain. The MMA requires Part D plans to report to CMS all pharmacy claims transactions, including drug ingredient costs and pharmacy dispensing fees, and beneficiary copayment amounts. The law also requires plans to report for each product all aggregate negotiated price concessions, including discounts, direct or indirect subsidies, and rebates. While this information is protected under strict confidentiality provisions, the availability of this information internally to the federal government will put increased attention on the Part D plan contracting process generally.

Figure 1 is a simplified representation of the major flows of information and funds between CMS and a Part D plan sponsor. In order for a Part D plan to obtain the direct subsidy, reinsurance subsidy, and low-income subsidy payments from CMS, Part D plans are legally obligated to provide CMS with all patient-level paid claims transaction data on a monthly basis, and on a quarterly basis, plans must provide CMS with both aggregate and product-specific data on all rebates, discounts, and other “direct or indirect remunerations” the plan has received. These data will be used by CMS to calculate actual net incurred costs borne by the plan.

1 Congressional Budget Office, Issues in Designing a Prescription Drug Benefit for Medicare, October 2002
Congressional Budget Office and CMS Office of the Actuary Analyses of Private Part D Plans’ Ability to Achieve Drug Price Reductions  
During Congressional debate over the MMA, some policymakers were concerned that private plans would not be able to obtain price concessions from pharmaceutical manufacturers comparable to what they believed the federal government could obtain through direct price negotiations. In estimating the impact of the MMA on the federal budget, CBO decisively disagreed with this proposition, concluding that private plans acting on behalf of the government could obtain discounts at least equal to those that the government could obtain through direct negotiation. CBO concluded that Medicare could get the lowest drug prices possible by harnessing the negotiating power of competing private plans that have strong financial incentives to obtain maximum price discounts from pharmaceutical manufacturers and pharmacies.  

In its analysis, CBO also noted that Congress explicitly exempted Part D negotiated prices from the government’s calculation of a drug’s Medicaid “best price,” essentially creating the market conditions for Part D drug prices to be negotiated below Medicaid levels. CBO estimated that this provision will reduce spending in the Medicare Part D program by an additional 1.6 percent in the first few years of the benefit because manufacturers and pharmacies will be willing to provide better discounts and rebates knowing that they did not have to replicate it for other government programs.

In assuming that Part D plans could obtain discounts, CBO also assumed that those price concessions would, in part, be passed along to the beneficiary in the form of lower premium, deductible and cost-sharing amounts among Part D plans. Specifically in projecting the monthly premium for the Medicare Part D benefit, CBO began by estimating total drug spending. CBO ran two estimates; one assumed spending

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10 Centers for Medicare and Medicaid Services, Office of the Actuary, Memorandum from Richard S. Foster, Chief Actuary, to Mark B. McClellan, M.D., Ph.D., Administrator, dated February 11, 2005.
as if there was no drug benefit and the other estimated spending with the Medicare Part D implemented as
drafted in the MMA. Overall, CBO estimated a reduction of gross costs. The largest savings came from the
ability for plans to manage the benefit through formulary, tiered cost-sharing and pharmacy networks.
Plans are estimated to save 20 percent in 2006 versus an unmanaged benefit. CBO assumed that Part D
plans would leverage their negotiations with manufacturers and pharmacies as part of their cost
management strategy.

In sum, beneficiaries should have the benefit of lower drug prices in the form of reduced Part D premiums,
along with broad choice in benefit design and formularies, but those benefits come with the trade-off that it
is harder to determine and directly compare drug prices and plan costs. For monitoring and oversight
purposes, Congress directed Part D plans to make their drug price negotiations completely transparent to
CMS, which is charged with monitoring and tracking the drug price reductions achieved by Part D plans,
including the degree to which those savings are passed along to beneficiaries in one form or another.

CMS alone will have the necessary data, including mandatory reports from Part D plans on all direct and
indirect price discounts received from drug manufacturers, to be able to explain and quantify the role of
price concessions in reducing beneficiary costs. In its oversight role, Congress will have a strong interest
in understanding how fully discounted Medicare Part D drug prices compare with prices available to other
federal programs, including Medicaid, the Veterans Administration, Department of Defense, and possibly
other federally-funded drug purchasing programs. To this end, Congress may be interested in requiring
CMS to analyze, aggregate, and report on fully discounted Part D drug prices and how they contribute to
lowering beneficiary and program costs. Without such analysis and reporting, there will be little way for
policymakers, beneficiary advocates, and other interested parties to truly understand the value of
manufacturer price concessions under Part D.

**E. Evidence of Drug Cost Savings in the 2006 Part D Plan Marketplace**

It appears that the savings on prescription drug costs being generated by the private plan drug benefit
delivery mechanism are exceeding CBO’s and CMS’ initial expectations. In its cost estimate for the MMA,
CBO estimated that private risk-bearing Part D plans would reduce Medicare beneficiaries’ gross spending
on prescription drugs by 20 percent in 2006, through a combination of the plans’ ability to negotiate price
discounts or rebates from pharmaceutical manufacturers and to manage beneficiaries’ drug utilization.\(^\text{12}\)
CBO estimated that the resulting national average Part D premium would be $35 per month in 2006. The
Part D cost estimates prepared by the CMS Office of the Actuary for the Part D final regulations published
in January 2005 was $36.67,\(^\text{13}\) and the March 2005 Medicare Trustees’ Report estimated that the 2006
Part D monthly premium would be $37.37.\(^\text{14}\)

The actual 2006 national average Part D premium announced by CMS in August 2005 is $32.20, or about
14 percent below the CMS actuaries’ estimate in the Trustees’ Report released a few months prior. This
better-than-expected outcome – compared to a projection that already assumed significant savings off of
“full retail” drug prices – suggests that Part D plans negotiated deeper price discounts with pharmaceutical
manufacturers and other pharmaceutical supply chain entities than the federal government initially
assumed, and it also implies that at least some Part D plans elected to pass along negotiated price
discounts in the form of lower monthly premiums rather than lower out-of-pocket drug prices.

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\(^{12}\) Centers for Medicare and Medicaid Services, Department of Health and Human Services, “Medicare Program; Medicare Prescription Drug Benefit; Final Rule,” Federal Register 70, January 28, 2005: 4466.

\(^{13}\) Ibid.

An exclusive Avalere Health analysis of publicly available data on the benefit designs of the nearly 3,000 Medicare Part D plans that are being offered in 2006 shows wide variation in benefit designs.\textsuperscript{15}

**Monthly Premiums**  One of the most important prices beneficiaries will consider when selecting a Part D plan is the plan’s monthly premium. The wide variety of premiums across Part D plans indicates that different plan sponsors made very different decisions about how to pass along drug price concessions in the form of high, average, or below average monthly premiums.

As shown in Figure 2, a significant number of Part D plans will charge monthly premiums at or below the national average benchmark premium of $32.20\textsuperscript{16}. It is possible that these plans were able to (and chose to) offer low monthly premiums at least partly by passing along (in the form of low monthly premiums) all or most of the drug price concessions that they negotiated with drug manufacturers and the other entities in the pharmaceutical supply chain that affect drug prices. It may be reasonably inferred that these plans made a business judgment that the monthly premium will be the most critical price point beneficiaries will consider when choosing a Part D plan. Some plans may have a more restricted formulary that allowed a lower monthly premium. On the other end of the distribution, some plans decided to price themselves with higher monthly premiums, either because they offer less restricted formularies, a low or zero deductible, lower co-payments per prescription, and/or lower 100 percent out-of-pocket drug prices for enrollees who are in the coverage gap.

![Figure 2. Variation in 2006 Medicare Part D Plan Premiums](image)

Source: Avalere Health analysis of Medicare Part D plan data.

\textsuperscript{15} This analysis was performed by Avalere Health using Medicare Part D plan data available from CMS in October 2005. For more information about Avalere’s Part D plan data analysis capabilities, see www.avalerehealth.net.

\textsuperscript{16} In recent public presentations about the Part D plan marketplace, Avalere Health has reported that the average 2006 Part D monthly premium across all PDPs is $37.38. This figure is not directly comparable to the $32.20 national benchmark premium figure, the calculation of which includes both PDPs and MA-PD plans and includes only the premiums for the standard Part D benefit plans offered by those entities.
Annual Deductible  Most Part D plans decided to reduce or eliminate the $250 deductible found in the standard Part D benefit design. As shown in Figure 3, about two-thirds of the approximately 1,400 PDP plan designs have a zero deductible or one that is less than $250.

As with the plan’s decision about what monthly premium to charge, the standard $250 deductible could be eliminated or reduced based on each plan’s judgment of what aspects of a drug insurance product would most appeal to Medicare beneficiaries. All else being equal, such as the list of specific brand and generic drugs on a plan’s formulary and the cost management policies applied, a plan that chose to offer a below-average premium and a zero deductible may have to charge beneficiaries higher prices for those prescriptions purchased during the plan’s coverage gap, compared to a plan design in which the plan passed along more of drug manufacturers’ negotiated discounts in the form of lower out-of-pocket drug prices paid by a plan enrollee during the coverage gap.

Copayment Amounts and Coinsurance Percentages  Another aspect of the drug price discounts negotiated between pharmaceutical manufacturers and Part D plans is manifested in the ability of plans to offer drug products at a variety of different beneficiary cost-sharing amounts. If a Medicare beneficiary has no drug insurance, they will pay 100 percent of the full retail price of a drug; if they are enrolled in a Part D plan, they will pay a smaller percentage (often in the form of a flat copayment) of a price for the drug that reflects some level of manufacturer price discounts.

Figure 4 displays the variety of cost-sharing amounts in the 2006 benefit designs of all of the “national” PDPs (i.e., those PDPs serving all or nearly all of the 34 PDP regions designated by CMS). As shown in Figure 4, cost-sharing arrangements are typically copayments of less than $50 or coinsurance less than 30 percent (of the negotiated price), which is more advantageous for beneficiaries than if they did not have insurance and had to pay 100 percent of a non-negotiated price.
Figure 4. Cost-Sharing Across Drug Formulary Tiers of National PDPs in 2006

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<th>Formulary Cost-Sharing Tier</th>
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<th>Aetna</th>
<th>WellCare</th>
<th>CIGNA</th>
<th>SilverScript</th>
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<td>$69</td>
</tr>
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<table>
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<tr>
<th>Formulary Cost-Sharing Tier</th>
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<th>Coventry</th>
<th>United</th>
<th>Medco</th>
<th>Humana</th>
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<td>30%</td>
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</tbody>
</table>

Notes: For plans that have regional variation in cost-sharing requirements, data shown are for California (Region 32), which has most Medicare lives. Humana is included as a “national” PDP as its plans are offered in 31 out of 34 regions.

Source: Avalere Health analysis of Medicare Part D plan data.
Coverage of Drugs in the Part D Benefit’s “Coverage Gap” Part D plan sponsors also had the option of offering to cover some or all of an enrollee’s drug costs beyond the standard Part D benefit’s “initial coverage limit” of $2,250 in total drug spending. As with all the other forms of benefit enhancements, this would have required the plan to expend some of the savings it had obtained (or expected to obtain) from pharmaceutical manufacturer price concessions. As shown in Figure 5, few PDPs—only 15 percent—chose to extend the initial coverage limit beyond $2,250, and most of those plans offer only coverage of generic drugs in the coverage gap.

Figure 5. Percentage of PDPs in 2006 Offering Coverage in “Coverage Gap” (Beyond $2,250 Initial Coverage Limit)

Source: Avalere Health analysis of Medicare Part D plan data.

F. Conclusion

Drug prices under the Part D benefit are varied and complex because Congress chose to employ competitive markets in establishing the new drug benefit. This decision has enabled private market structures, from managed care to pharmaceutical distributors to deliver the benefit. Drug prices in this system are not the result of unilateral decisions made by a drug’s manufacturer, a health plan or PBM, or any other entity in the pharmaceutical supply chain.

It is important for Medicare policymakers and other stakeholders to appreciate the trade-offs that Part D plan sponsors made amongst these different elements of plan benefit design when they were creating their Part D plan offerings. Understanding drug price variance due to plan design and the supply chain is necessary to make sense of the prices contained in the Medicare plan comparison website and paid by Medicare beneficiaries at the pharmacy counter.

Recognizing the interplay between drug price negotiations and Part D plans’ benefit design choices will help Medicare policymakers and stakeholders understand the impact of those interactions. It is also useful for beneficiaries to comprehend why prices vary, and that the decisions that Congress made were intended to provide for a more competitive and cost-effective solution to delivery of a pharmaceutical benefit under Medicare.
CMS will have data, thanks to mandatory reports from Part D plans on all direct and indirect price discounts received from drug manufacturers, to be able to explain and quantify the role of price concessions in reducing beneficiary costs. In its oversight role, Congress will have a strong interest in understanding how fully discounted Medicare Part D drug prices compare with prices available to other federally funded drug purchasing programs such as DoD TRICARE, the Department of Veteran Affairs, and Medicaid. Through objective analysis and reporting, policymakers, beneficiary advocates, and other interested parties can come to understand the value of manufacturer price concessions under Part D.
Appendix

A. Part D Plan Bidding Process: Role of Drug Manufacturer Price Concessions on Part D Plan Benefit Designs

Medicare Part D plan sponsors had to make a series of difficult decisions in constructing benefit offerings that would attract an actuarially sustainable mix of beneficiaries to the plan. Throughout the benefit design and bid construction process, each plan had to balance the effects of each element of the plan design on total cost and impact on beneficiary access to prescription drugs.

When determining a benefit design, plans also factored in the level of price concessions that they expected to obtain from (or had agreed upon with) the manufacturers of the exact drug products that the plan wished to have on its formulary. Together with the premium charged to beneficiaries and the cost-sharing structure of the plan design, each plan’s ability or inability to negotiate price concessions from pharmaceutical manufacturers affected the plan’s benefit design. If price negotiations were competitive for certain classes of drugs, and plans were able to negotiate steep price discounts from manufacturers, plans would have been much better positioned to offer an enhanced benefit.

The ability of plans to reduce projected drug costs through aggressive negotiations with pharmaceutical manufacturers (as well as other pharmaceutical supply chain entities such as retail pharmacies) was the critical success factor in a plan being able to offer a richer or poorer Part D benefit design. Negotiating deeper discounts from manufacturers would give those Part D plan sponsors more flexibility to create plans that pass on those savings to beneficiaries in a variety of ways that makes the plans more attractive to prospective enrollees by influencing the plan’s premium, formulary access, and out-of-pocket cost sharing requirements.

On June 6, 2005, all Part D plan sponsors that wanted to offer a Part D plan in 2006 had to submit a standardized actuarial bid for each plan offering they proposed. These bid submissions were essentially the plans’ best estimates of the projected costs to administer the basic Part D benefit, taking into account variables such as government subsidies, premiums paid by beneficiaries, unit costs (net of all price concessions negotiated between the plan and pharmaceutical manufacturers) of all drugs expected to be consumed by the plan’s enrollees during the benefit year, estimated utilization of all drugs, enrollment projections, and administrative costs (including profits). Bids were required to accurately reflect the costs of providing the benefit in each region of the country.

After bids were submitted, CMS reviewed the estimates provided by plans, evaluating the feasibility of administration costs, the use of cost controls, plan management, actuarial certification and reasonableness of revenue requirements. In addition, plans that offered supplemental benefits were also reviewed to ensure that they met revenue feasibility. If CMS determined that a plan bid met these cost and revenue criteria, as well as all other conditions of participation, CMS awarded a contract to that plan.

After the Part D plan contracts were established, CMS calculated and released the national average bid amount. This amount represents the national average monthly cost of offering the Medicare Part D basic benefit. The national average bid amount serves as a “benchmark” to determine beneficiary premiums seen at the individual plan level. If a plan had an individual bid above the benchmark amount, the beneficiary will pay the difference in the form of additional premium. If a plan bid below benchmark, the beneficiary pays a reduced or zero premium.
B. Part D Plan Bidding Process: Medicare’s Rules for Plan Benefit Designs and Their Implications for Beneficiary Costs

Beneficiary costs are driven by each individual plans’ Part D benefit design. Congress defined the standard Part D benefit design in statute, to provide a clear definition of its structure for federal budget estimating purposes and to allow CMS and beneficiaries to compare plans’ proposed cost structures on a uniform basis. In addition to a monthly premium beneficiaries could face costs in the form of a deductible, copayment and/or coinsurance amounts. For 2006, the standard benefit design includes the following elements:

- A $250 deductible;
- 25 percent beneficiary coinsurance for total drug expenditures between $251 to $2,250; this is equal to $750 in beneficiary “true out-of-pocket” (TrOOP) spending;
- A “coverage gap” during which the beneficiary is responsible for paying 100 percent of drug costs out-of-pocket until he or she has reached $3,600 in TrOOP spending; during this coverage gap, the beneficiary must be given access to the negotiated price at the point of sale; and
- Catastrophic coverage after the beneficiary has a total of $3,600 in TrOOP spending (equal to $5,100 in total drug spending), after which the beneficiary’s liability is limited to a 5 percent coinsurance payment for each prescription.

The MMA gave plan sponsors three general options for the types of Part D coverage they could offer to beneficiaries. The flexibility to offer more than one plan and to alter the plan design allowed plan sponsors to offer multiple plans with multiple benefit structures. Plans were allowed to offer the standard plan design outlined in the MMA, the actuarial equivalent of the standard plan design (known as basic alternative coverage), or enhanced alternative coverage. Figures B-1, B-2, and B-3 outline the key components of each benefit design option specified in the MMA:

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17On April 5, 2006, CMS released updated Medicare Part D benefit parameters for 2007 that Part D plans must use in designing their 2007 plan offerings. The Part D deductible will increase to $265; the initial coverage limit will increase to $2,400; the out-of-pocket threshold will increase to $3,850; and the catastrophic coverage limit will increase to $5,451.25. The CMS announcement is available at http://www.cms.hhs.gov/MedicareAdvtgSpecRateStats/downloads/2007_Part_D_Parameter_Update.pdf.
Figure B-2. Medicare Part D Basic Alternative Coverage

- Plan provides:
  - Access to covered Part D drugs, subject to plan formulary
  - Access to negotiated prices in all phases of benefit
  - Option for reduced annual deductible
  - Option for reduced cost-sharing above the annual “true out-of-pocket” (TrOOP) threshold
- Subject to actuarial equivalency tests:
  - Annual deductible amount and cost-sharing above the annual “true out-of-pocket” (TrOOP) threshold must be less than or equal to amounts offered under defined standard coverage
- Benefit package must have actuarial value equal to defined standard coverage

Figure B-3. Medicare Part D Enhanced Alternative Coverage

- Plan adds supplemental benefits to standard Part D coverage:
  - Expanded formulary (i.e., access to drugs not statutorily covered by Part D); and/or
  - Increased actuarial value of benefits
- Three options for increasing actuarial value of benefits:
  - Reduce annual deductible
  - Reduce cost-sharing under initial coverage limit or above annual TrOOP threshold
  - Increase in initial coverage limit
- Plan must charge beneficiary 100% of any added premium (MA-PDs may elect to buy down part or all of added premiums)
- PDP sponsor may offer enhanced alternative plans only if also offering standard coverage option

The variety of benefit design choices available in the Part D plan marketplace means that beneficiaries must weigh many variables when choosing a Part D plan:

- What is the monthly premium?
- How broad or narrow is the formulary?
- What are the cost-sharing amounts an enrollee will have to pay during the initial coverage period? Are those amounts based on flat copayments or percentages of a drug’s negotiated price (coinsurance)? How many “tiers” of cost-sharing does the plan have, and how many (and which) drugs are on each tier?
• Does the plan offer any coverage of drug spending in the standard benefit’s “coverage gap”?

• What are the drug prices an enrollee will encounter when incurring drug costs to satisfy a deductible or in the “coverage gap”?

Across each of these variables, a plan sponsor had to decide how to create each plan’s own balance of cost and access. Along each step of the way, and ever-mindful of the impact of each plan design choice on the ability of the total plan offering to attract Medicare enrollees, the plan sponsor would be deciding whether to pass along all, some, or potentially none of the price concessions it negotiated with pharmaceutical manufacturers and other entities along the pharmaceutical supply chain. This is the result intended by Congress, as shown in the MMA’s definition of negotiated prices under Part D:

For purposes of this part, negotiated prices shall take into account negotiated price concessions, such as discounts, direct or indirect subsidies, rebates, and direct or indirect remunerations, for covered part D drugs, and include any dispensing fees for such drugs. 18

By using the phrase “take into account,” Congress was deliberately vague in mandating how much of the savings garnered from negotiations with manufacturers and pharmacies plans are required to be passed along to beneficiaries. The clear implication of this wording is that plans are not required to provide Medicare beneficiaries with all of the savings negotiated from pharmaceutical manufacturers or other entities in the pharmaceutical supply chain.

Congress anticipated that, for competitive reasons, plans would pass along some or perhaps even most of these negotiated savings to beneficiaries in the form of lower costs at the retail or mail-order pharmacy, lower monthly premiums, or reduced cost-sharing per prescription. Plans also have incentives to retain portions of negotiated discounts in order to cover administrative costs and to realize a competitive profit margin.

Therefore, one result of the Part D plan design process created by the MMA is that it is impossible for any observer outside of the plan to see the full measure of all negotiated drug price concessions simply by looking at the drug prices that an enrollee would pay at the pharmacy counter.

However, in the very next section of the law, Congress also was unambiguously clear that it intended for all Part D plan sponsors to disclose to the government how the plan chose to distribute its aggregate negotiated price concessions to construct the plan’s coverage design:

A PDP sponsor offering a prescription drug plan or an MA organization offering an MA-PD plan shall disclose to the Secretary (in a manner specified by the Secretary) the aggregate negotiated price concessions described in paragraph (1)(B) made available to the sponsor or organization by a manufacturer which are passed through in the form of lower subsidies, lower monthly beneficiary prescription drug premiums, and lower prices through pharmacies and other dispensers. 19

This information is subject to audit by the government, but protected from public disclosure to the same extent as federal Medicaid drug rebate information.

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19 Social Security Act §1860D-2(d)(2).
C. Medicare’s Monitoring of Part D Drug Prices

Under the final regulations for Part D promulgated in January 2005, CMS will obtain a large amount of information about how Part D plan sponsors’ decide to distribute the price concessions they negotiated with pharmaceutical manufacturers and other players in the pharmaceutical supply chain. While most of this data will not be released to the public, CMS has stated it will be used by the agency to reconcile the plans’ actual financial performance to the plans’ costs structures underlying their approved bids, and to adjust any prospective payments that were made during the course of the benefit year.

Six months after the end of each benefit year, CMS will reconcile these estimated payments with data submitted by the plan on final price concessions received (e.g., back-end rebates paid by a manufacturer after the end of the benefit year) to determine any differences between the Medicare payments made to a plan based on its cost estimates and actual settled-out benefit and administrative costs. The reconciliation process provides the government an opportunity to “make plans whole” if it finds that the plan was underpaid during the year, or to recoup overpayments if applicable.

On the most detailed transaction level, Figure C-1 displays the claims-level data elements that CMS will collect from Part D plans for every prescription dispensed to a plan enrollee. CMS eventually will be privy to a phenomenal degree of individual drug price transparency. While this drug pricing information will, according to CMS, be used solely for plan contract compliance purposes, the information’s very existence – and potential for use in government analyses and even public release – has profound longer-term implications for drug pricing practices among Part D plans, pharmaceutical manufacturers, and the other entities that constitute the pharmaceutical supply chain. This new source of detailed drug pricing information, and its uses for purposes other than Part D program compliance activities, will be closely scrutinized by all stakeholders over the next several years.

**Figure C-1. Prescription Drug Event (PDE) Data That Part D Plans Must Submit to CMS for Every Prescription Dispensed**

- Beneficiary Identification
  - Beneficiary identification (HIC) number, name, date of birth, gender
- Prescription Identification
  - Prescription ID number, Drug’s NDC, quantity dispensed, fill number, date of service
- Drug Cost Information Detail
  - Ingredient cost, dispensing fee, sales tax, total gross cost
- Payment Information Detail
  - Beneficiary amount paid, low-income cost-sharing subsidy amount, secondary or other payer amount, supplemental insurance amount
Glossary of Selected Medicare Part D Terms

Actuarial Equivalence
Term used to describe when two different health insurance plan benefit designs have an equal economic value under a given identical set of actuarial assumptions.

Coinsurance
A cost-sharing requirement in which the insured person pays some of the costs of covered services. For example, under the standard Part D benefit, in 2006, beneficiaries will pay 25 percent of total drug costs between $250 and $2,250.

Co-payment
Flat fees or payments that a patient pays for a medical service (i.e., physician visit or prescription).

Coverage Gap
The portion of the Part D benefit structure in which beneficiaries pay 100 percent of their Part D drug expenditures. In 2006, there will be a $2,850 coverage gap in the standard benefit between the initial coverage limit ($2,250) and the catastrophic threshold ($5,100). This gap corresponds to $3,600 in out-of-pocket spending for the beneficiary. (Also referred to as the “doughnut hole”)

Formulary
The entire list of Part D drugs covered by a PDP sponsor’s or MA organization’s drug plan. Includes both a therapeutic classification system and other elements, such as tiered cost-sharing and “generic drug substitution” programs.

Medicare Advantage (MA) Program
MA offers Medicare beneficiaries the option of enrolling in a managed care plan to receive their Medicare benefits. Private participating plans must cover all Medicare benefits under Parts A and B. The MMA makes significant changes to the payment system in order to encourage Medicare participation by managed care plans.

Medicare Advantage Prescription Drug Plan (MA-PD)
Medicare Advantage plans that choose to offer the Part D prescription drug benefit. In 2006, all MA plans must offer at least the basic Medicare Part D benefit in addition to its MA plan.

Prescription Drug Plan (PDP)
Prescription drug coverage that is offered to beneficiaries enrolled in FFS Medicare by a plan sponsor under a contract with CMS.

Risk Adjustment
A process by which premium dollars are allocated to plans based on the health of their enrollee population. It is intended to minimize any financial incentives health plans may have to select healthier than average enrollees.

Risk Corridor
A financial arrangement between a payer of health care services (such as Medicare) and a provider (such as a managed care organization) that shares the risk for providing healthcare services. Risk corridors protect the provider from excessive care costs for individual beneficiaries by instituting certain protections, and they protect the payer by limiting the profits that the provider may earn.

True Out-of-Pocket Costs (TrOOP)
The portion of cost-sharing incurred by the individuals in a health plan. Under Medicare Part D, TrOOP will be counted to determine when a beneficiary reaches the coverage gap and when a beneficiary qualifies for catastrophic coverage.