



Prescription Drug Rebates and Part D Drug Costs

Analysis of historical Medicare Part D drug prices and manufacturer rebates

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Table of Contents

EXECUTIVE SUMMARY	1
KEY FINDINGS	2
RESULTS	3
I. Types of drugs that offer manufacturer rebates	3
II. Level of rebates and price trends	5
METHODOLOGY AND ASSUMPTIONS	11
LIMITATIONS AND CONSIDERATIONS	13

EXECUTIVE SUMMARY

On November 28, 2017, CMS issued a Request for Information (RFI) regarding the “application of manufacturer rebates and pharmacy price concessions to drug prices at the point of sale” within a larger proposed rule titled “Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program.”¹ The RFI requested potential policy approaches for applying a minimum percentage of manufacturer rebates and 100% of pharmacy rebates at the point-of-sale (POS). President Donald J. Trump’s *Blueprint to Lower Drug Prices*² discusses the trends in list prices and the gap between list prices and net prices after rebates. The *Blueprint to Lower Drug Prices* also contains an RFI related to applying a portion of manufacturer rebates at the POS.

America’s Health Insurance Plans (AHIP) engaged Milliman to examine Part D drug prices and manufacturer rebates. This report was commissioned by AHIP to help inform their comments in response to President Trump’s *Blueprint to Lower Drug Prices*.

Drug manufacturer rebates are price concessions paid by drug manufacturers to health plans and pharmacy benefit managers (PBMs), which administer prescription drug benefits for health plans, after a member of a health plan utilizes a manufacturer’s drug. Manufacturer rebates are typically only provided for brand drugs, though manufacturers do not provide rebates for all brand drugs. The amount of rebate typically differs by drug and depends on arrangements with individual drug manufacturers. For Medicare Part D, health plans are required to estimate the value of manufacturer rebates and other price concessions and incorporate those amounts as cost savings that reduce beneficiary premiums and federal spending.

There are many other forms of direct and indirect remuneration (DIR) in Part D beyond manufacturer rebates, including post-POS pharmacy rebates, discount guarantees, incentive payments to/from pharmacies, and others³. Whereas manufacturer rebates typically only apply to brand drugs, other forms of DIR may apply to all drugs. Manufacturer rebates are the only form of DIR considered in this analysis, though others should be considered in a comprehensive analysis of Part D spending. For the remainder of this report, unless otherwise noted, any reference to “rebates” refers to manufacturer rebates and any reference to “gross cost” or “price” refers to the price reflected at the POS, prior to post-POS price concessions.

This report explores manufacturer rebates and prescription drug prices using publicly available Medicare Part D drug spending and utilization data combined with detailed rebate data from contributing health plans. For the most part, we do not opine on the drivers of drug prices and rebates, nor do we attempt to prove or disprove causal relationships between drug prices and rebates. Our goal is to provide stakeholders with better information about Part D drug spending and manufacturer rebates and about the types of drugs that have rebates.

This report relies on national 2013 to 2016 Part D cost and utilization data published by CMS and 2016 manufacturer rebate data provided by contributor health plans. We paired the detailed contributor rebate data with the national Part D spending and utilization data to estimate national manufacturer rebate levels by drug. Drug utilization patterns, rebate arrangements, formulary structure, and other factors can vary significantly

¹ “Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program.” Federal Register, Vol. 82, No. 227. November 28, 2017. Proposed Rules.

² American Patients First: The Trump Administration Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs. May 11, 2018. <https://www.whitehouse.gov/briefings-statements/president-donald-j-trumps-blueprint-lower-drug-prices/>

³ Medicare Part D DIR: Direct and indirect remuneration explained. January 2018. <http://www.milliman.com/uploadedFiles/insight/2018/Medicare-Part-D-DIR.pdf>

between Part D plans. We believe that the rebate information underlying this report provides a reasonable sample for performing market wide analysis. However, the sample is not necessarily a perfect representation of the entire Part D market.

This report focuses on overall drug price levels at the POS and rebates. We focused our analysis on approximately 1,300 drug and therapeutic class combinations, reflecting 97% of 2016 Part D gross drug spending.

KEY FINDINGS

Our key findings include:

- Manufacturer rebates are offered for a limited subset of drugs (81% of all Part D drugs analyzed do not offer rebates and 64% of brand drugs analyzed do not offer rebates), but that limited subset of drugs accounts for a significant portion of Part D spending (over half of all Part D spending and approximately three-quarters of brand spending).
 - Because manufacturer rebates are generally not offered for generic drugs, which comprise the majority of Part D utilization, utilization is concentrated in drugs without rebates. For CY2016, 89% of scripts had no rebates.
 - Out of 124 protected class⁴ brand drugs, 16 drugs (13%) received manufacturer rebates, compared to 36% of brand drugs overall.
- In 2016, manufacturer rebates totaled approximately 22% of total Part D brand drug gross spending. The average rebate for brand drugs with rebates was 30% of gross drug cost.
 - In general, non-specialty drugs have the highest manufacturer rebates when measured as a percentage of gross drug cost, followed by specialty⁵ drugs and protected class drugs, respectively.
 - For brand drugs with rebates, drugs in classes with brand competition had the highest average manufacturer rebate at 39% of gross cost, while protected class drugs had the lowest average rebate at 14% of gross cost.
- While brand drugs with manufacturer rebates appear to have higher historical price trends than brand drugs without rebates, among the drugs with rebates, drugs with higher rebates (as a percentage of gross drug cost) have similar historical price trends as drugs with lower rebates. Because we only had access to one year (2016) of detailed manufacturer rebate data, we did not analyze how changes in rebates affect price trends net of manufacturer rebates.
- On average, the highest cost drugs have the lowest manufacturer rebates (as a percentage of gross drug cost), for brand drugs with rebates.

⁴ Under Part D, health plans must include all or substantially all drugs that make up the six protected classes on their formularies. The six protected classes are: immunosuppressant, (for prophylaxis of organ transplant rejection), antidepressant, antipsychotic, anticonvulsant, antiretroviral, and antineoplastic classes.

Source: Medicare Prescription Drug Benefit Manual. Chapter 6 – Part D Drugs and Formulary Requirements; Section 30.2.5. Rev. 18, 1/15/16.

⁵ Specialty defined as drugs whose average gross cost exceeds \$600 per month, consistent with the CMS specialty limit in 2016.

- Brand drugs with significant generic competition (three or more manufacturers) exhibited lower average price trends than other brand drugs between 2013 and 2016.

RESULTS

I. TYPES OF DRUGS WITH MANUFACTURER REBATES

In general, manufacturer rebates are only offered for brand drugs. Of the 706 brand drugs we analyzed (which account for over 95% of brand drug spend), approximately 36% had more than nominal manufacturer rebates (greater than 1% of the gross drug cost) and 27% had significant rebates (defined as the 25th percentile of rebates, or 12% of gross drug cost). Drugs with significant rebates only comprised approximately 10% of the total Part D utilization (scripts), but made up a higher proportion (48%) of the total Part D gross drug spending.

Table 1 shows the distribution of drugs with and without rebates, measured separately by raw drug count and by CY2016 script count.

Table 1: Percentage of CY2016 Part D Drugs with Rebates

	Drugs without Significant Rebates				Drugs with Significant Rebates	Total
	No Rebates		Some Rebates			
	Brand	Generic	Brand	Generic	Brand	
% of Scripts	2%	87%	1%	0%	10%	100%
% of Drug Count	34%	46%	5%	0%	15%	100%

We further classified brand drugs into categories that represent the level of brand and generic competition, as listed below, to examine how manufacturer rebates vary based on the availability of therapeutic equivalent alternatives.

- **Direct generic substitute: 1 or 2 manufacturers** – The brand drug has an interchangeable therapeutic equivalent generic drug produced by one or two manufacturers.
- **Direct generic substitute: 3+ manufacturers** – The brand drug has an interchangeable therapeutic equivalent generic drug produced by three or more manufacturers.
- **Direct brand competition:** The brand drug is in a therapeutic class that contains competing therapeutic equivalent brand drugs.
- **No direct brand competition or generic substitute:** The brand drug has no interchangeable therapeutic equivalent generic and is not in a therapeutic class that contains competing therapeutic equivalent brand drugs.
- **Protected class:** The drug belongs to a therapeutic class that is protected under Part D. Specifically, it falls under one of the following protected classes: antiretrovirals, immunosuppressants, antidepressants, antipsychotics, anticonvulsant agents, and antineoplastics⁶.

⁶ Medicare Prescription Drug Benefit Manual. Chapter 6 – Part D Drugs and Formulary Requirements; Section 30.2.5. Rev. 18, 1/15/16.

Our analysis revealed that drugs with direct brand competition had the highest proportion of drugs receiving rebates (64 out of 78 drugs) and the highest rebates as a percentage of gross drug cost for those drugs receiving rebates (39%). Among non-protected class drugs without direct brand competition, on average the percentage rebates increased as the availability of therapeutic equivalent generic drugs increased.

Brand drugs in protected classes had the lowest proportion of drugs with rebates and the lowest rebates as a percentage of gross drug cost for those drugs receiving rebates. Out of 124 protected class brand drugs, 16 drugs received rebates. Protected class brand drugs without rebates accounted for \$16.3B in gross drug spending compared to \$6.0B for protected class drugs with rebates. Of those that received rebates, the average rebate as a percentage of gross drug cost was 14%.

Chart I-A shows these results.

Chart I-A: Rebates as a Percentage of Gross Cost Limited to Brand Drugs with Rebates

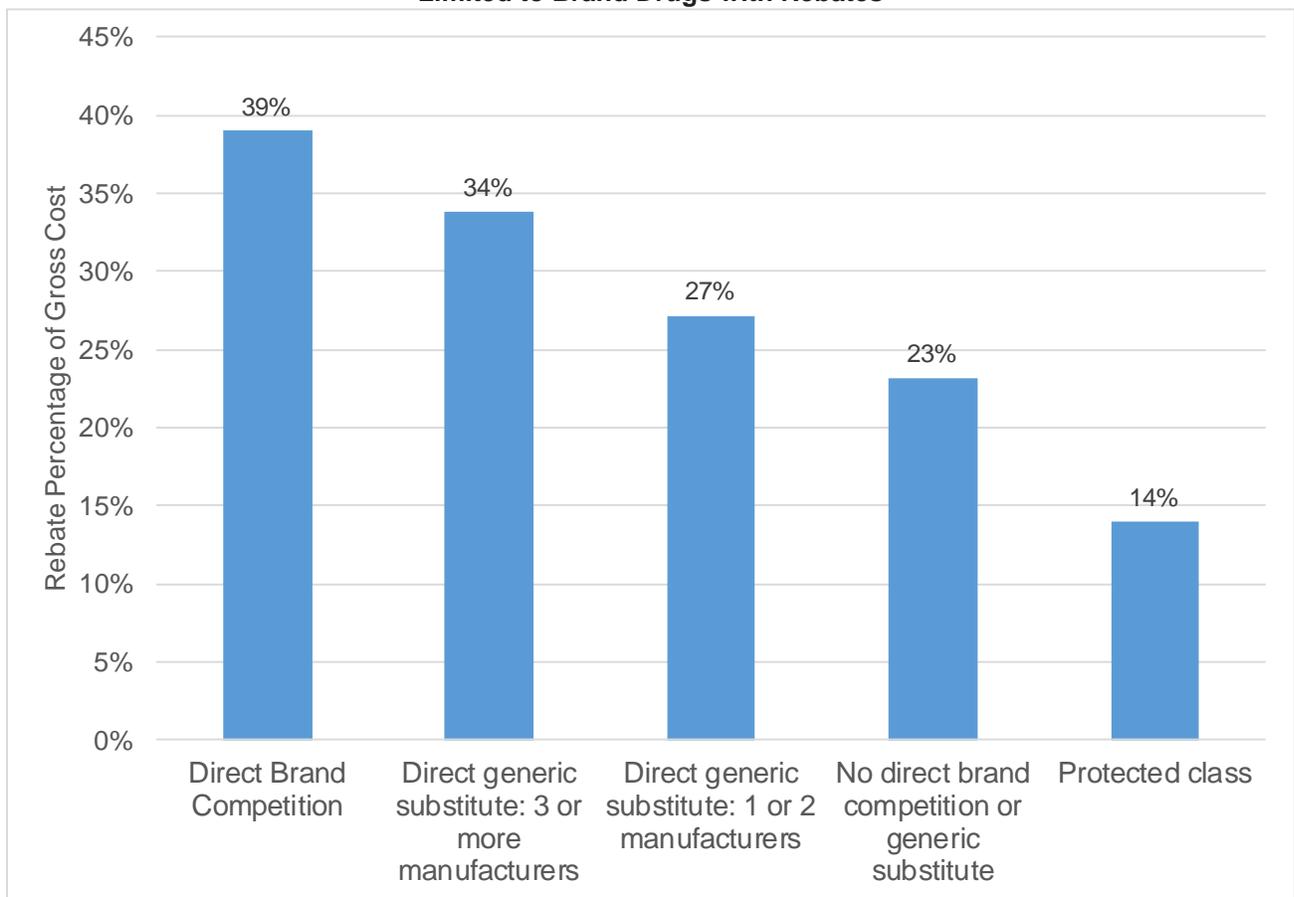


Chart I-A shows that among drugs receiving rebates, the drugs we identified as having direct brand competition have the highest average rebates as a percentage of gross drug cost, while drugs in protected classes have the lowest average rebates as a percentage of gross drug cost.

II. LEVEL OF REBATES AND PRICE TRENDS

In this section we examine prescription drug prices and manufacturer rebate levels. Our analysis focuses on gross cost trend, before the impact of manufacturer rebates and other forms of post-POS price concessions. Internal Milliman research suggests that total post-POS price concessions have increased as a percentage of gross drug costs over the duration of our study. Thus, net price trends could be lower than the gross cost trends shown below.

Two gross drug cost metrics are shown:

- **The average annual cost per beneficiary:** This reflects the average gross cost of a specific drug per beneficiary for one year. We did not make adjustments for beneficiaries who are enrolled in Part D for part of the year or for beneficiaries that only used a drug for part of the year, as that information was not available in the CMS data.
- **The average price per unit:** This reflects the average gross cost per dosage unit of a specific drug, paid at the point of sale. It reflects discounts applied at POS, but excludes post-POS price concessions (e.g., manufacturer rebates, pharmacy rebates, and Coverage Gap Discount Program amounts). Per the CMS Part D Drug Spending data, “Dosage units reflect how the drug is used (e.g., number of tablets, milligrams, etc.). Since drugs are available in multiple strengths and dosage forms, the average spending per dosage unit at the drug name level is weighted to account for variation in claims volume for specific drug brand name, generic name, strength, dosage form, routes of administration, and manufacturer levels.”⁷

To evaluate the differences in manufacturer rebates between drugs with different price characteristics, we use these metrics as follows:

- The average annual cost per beneficiary is used to stratify drugs by relative cost (e.g., quartiles), and
- The average price per unit is used to calculate annual drug price trends.

Additionally, we use the manufacturer rebate data from select contributor health plans to stratify drugs into rebate levels. Our analysis is limited to brand drugs, since manufacturer rebates are generally not offered for generic drugs.

Over the four-year period from 2013 to 2016, brand drugs with manufacturer rebates in 2016 had higher price trends than brand drugs without rebates. However, when measured using the average annual cost per beneficiary for brand drugs without rebates has grown faster than for drugs with rebates as shown in Chart II-A below. We note that the two measures differ for several reasons, including the price trends are based on a consistent mix of drugs and dosages, whereas the average cost per beneficiary is simply the gross drug costs divided by the unique beneficiaries utilizing each drug in each year.

⁷ Based on the “Part D Drug Spending Dashboard Methodology” dated May 14, 2018 and published by CMS as part of the “Medicare Part D Drug Spending Dashboard & Data.”

Chart II-A: Average Annual Gross Cost per Beneficiary for Brand Drugs with and without Rebates

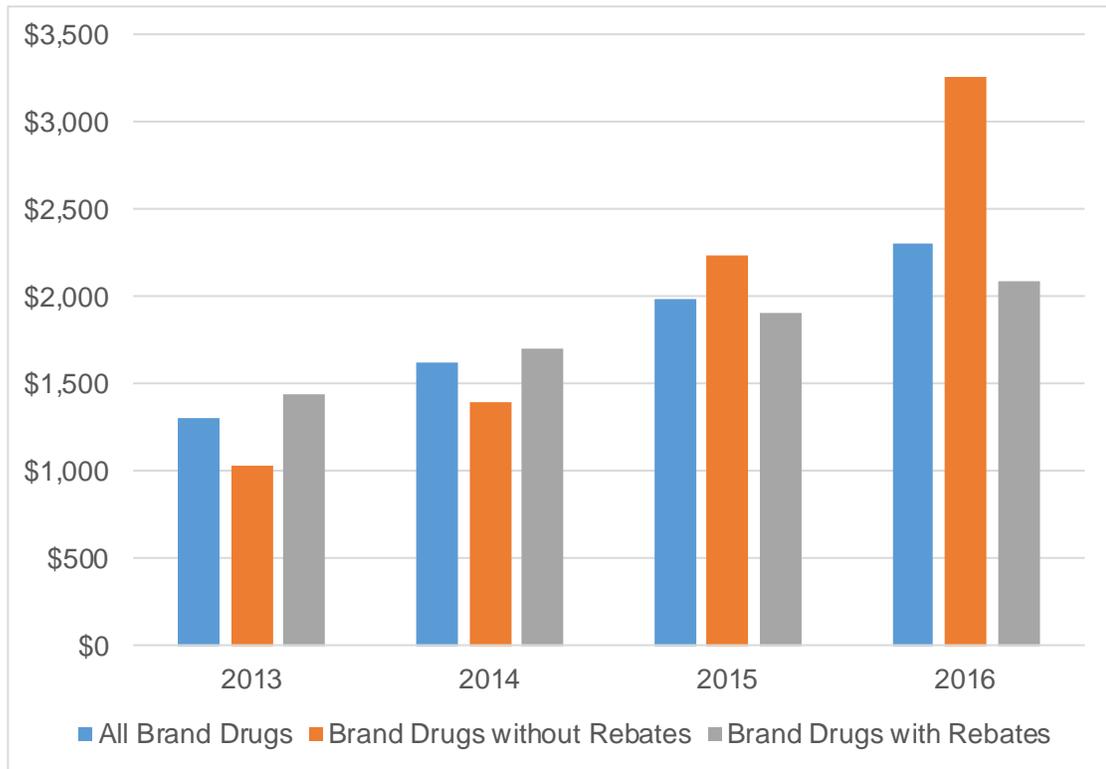


Chart II-A shows that average annual gross cost per beneficiary has increased more quickly for brand drugs without rebates than for brand drugs with rebates, particularly in 2015 and 2016.

We stratified drugs based on rebate level in order to explore differences in drug price trends between drugs with different rebate levels. The data show that higher cost drugs have lower average rebates as a percentage of gross cost. Chart II-B and II-C below show these results for brand drugs that offer rebates. In Chart II-B drugs are separated based on the 2016 percentage manufacturer rebate quartile.

Chart II-B: Average 2016 Annual Gross Drug Cost, 2016 Rebates and 2013 to 2016 Price Trend By Percentage (of Gross Cost) Manufacturer Rebate Quartile Limited to Brand Drugs with Rebates

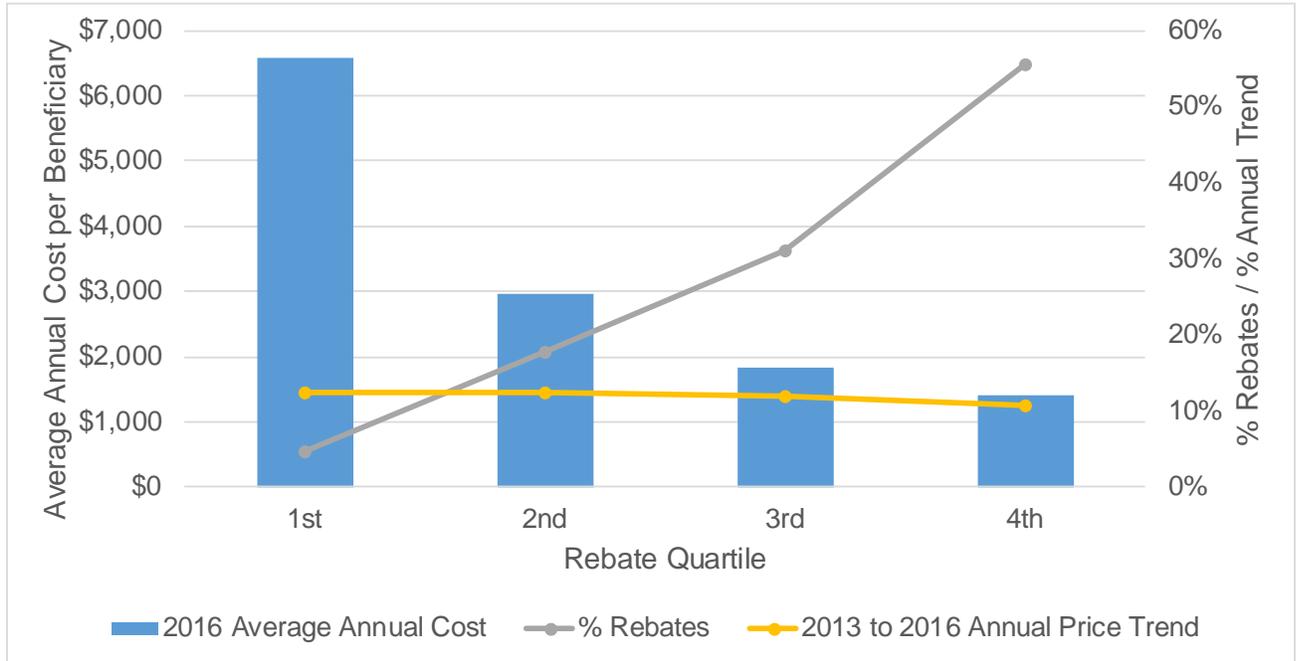


Chart II-B shows that among brand drugs with rebates, the average annual cost per beneficiary decreases (blue bars) as the average rebate (as a percentage of gross cost) increases (gray line). However, the average 2013 to 2016 price increases (yellow line) are similar for all four quartiles of rebate levels.

Chart II-C: Rebate Percentage by Price Trend Quartile Limited to Brand Drugs with Rebates

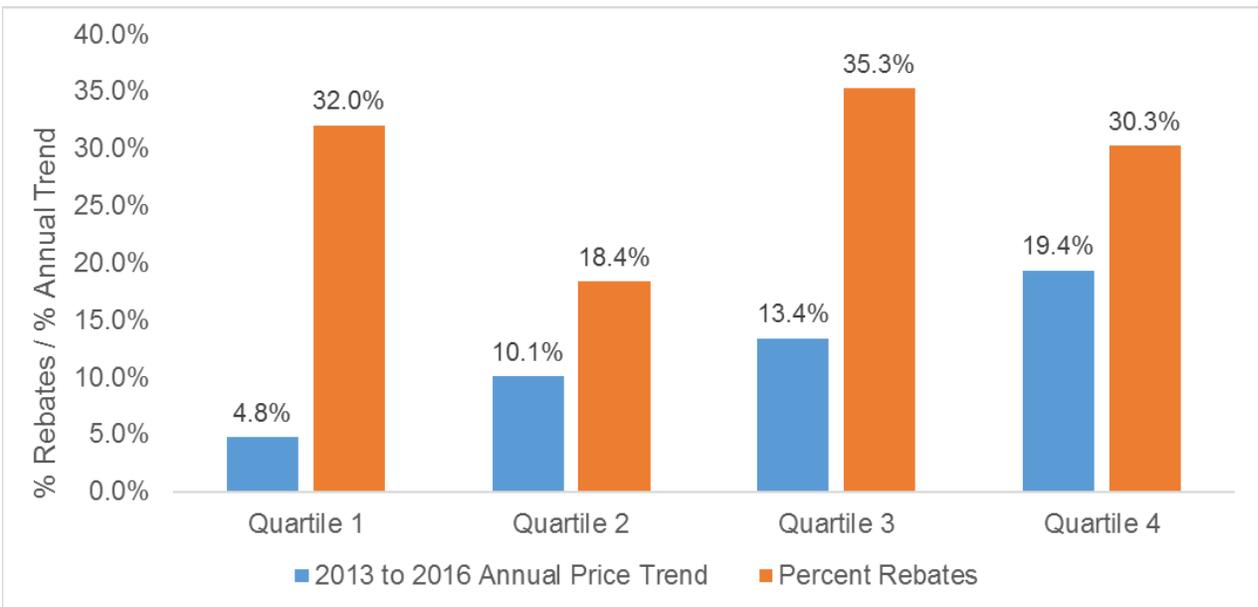


Chart II-C shows that among brand drugs with rebates, drugs with the lowest annual cost increases (quartile 1) have slightly higher average rebates (as a percentage of gross cost) than drugs with the highest annual cost increases (quartile 4).

Direct Generic Competition and Protected Classes

Consistent with Section I, we summarized the level of rebates for brand drugs with direct generic competition, with direct brand competition, without direct competition, and within protected classes.

Chart II-D summarizes the 2016 average cost per beneficiary (blue bar), 2016 rebate levels (gray line), and 2013 to 2016 price trends (yellow line) for brand drugs by competition category. The results are limited to brand drugs with rebates.

Chart II-D: 2016 Rebates and Average 2013 to 2016 Price Trend by Drug Competition Category Limited to Brand Drugs with Rebates

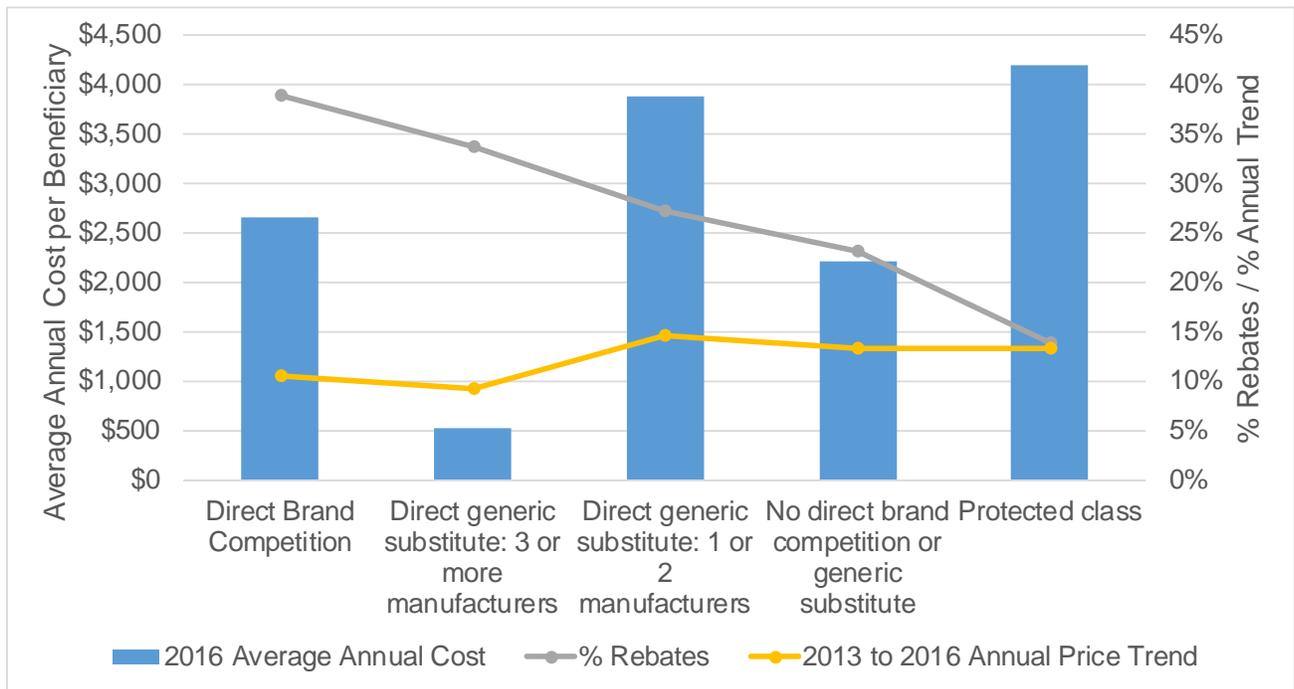


Chart II-D shows that brand drugs with significant generic competition (three or more manufacturers) exhibited lower price trends than other drugs between 2013 and 2016. However, the price trends by drug competition category (yellow line) do not exhibit a similar pattern as the rebate levels by drug competition category (gray line).

We further split out the results between specialty and non-specialty drugs. Chart II-E below summarizes the results for non-specialty, specialty, and protected class drugs. Overall, the average annual cost per beneficiary is the highest for specialty drugs, followed by protected class drugs and non-specialty/non-protected class drugs, respectively. Non-specialty/non-protected class drugs have the lowest average annual cost per beneficiary and offer the highest rebates as a percentage of gross cost. Specialty drugs have the next highest average rebates as a percentage of gross cost and protected class drugs have the lowest average rebates as a percentage of gross cost.

Chart II-E: 2016 Rebates and Average 2013 to 2016 Price Trend by Drug Type Limited to Brand Drugs with Rebates

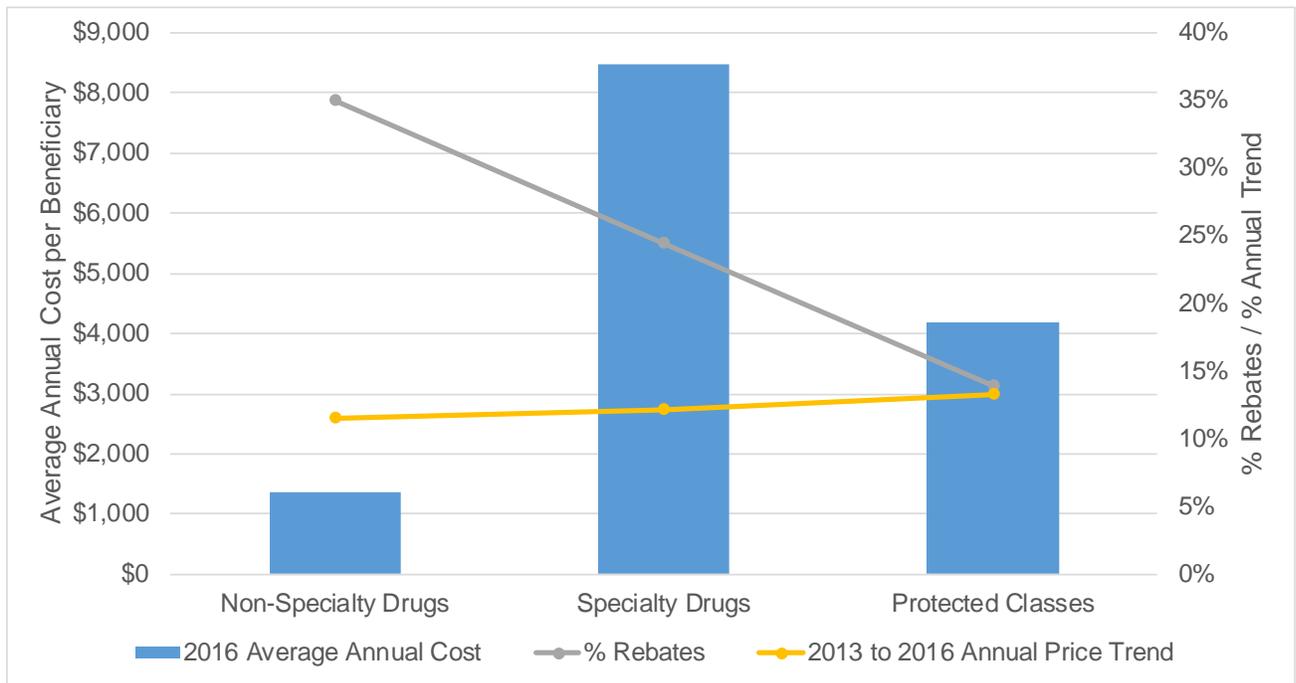


Chart II-E also shows that the price trend is relatively consistent by drug category whereas level of rebate (as a percentage of gross cost) varies.

METHODOLOGY AND ASSUMPTIONS

In general, the drug costs shown in this report are gross costs before the application of rebates. Gross drug cost includes the ingredient cost (including the impact of negotiated price discounts), dispensing fees, sales tax, and vaccine administration fees (if applicable). Gross cost does not reflect manufacturer rebates, pharmacy rebates, Coverage Gap Discount Program amounts, and other post-POS price concessions. For brand drugs, the ingredient cost is the largest component of the gross costs. The rebates shown in this report are an estimate of 2016 manufacturer rebates.

For this report, we relied primarily on the following data sources:

- **Part D drug-level expenditure information published by CMS.** We utilized the data set underlying the “Medicare Part D Drug Spending Dashboard” published by CMS⁸, which contains cost, utilization, manufacturer, and drug use information for approximately 2,800 drugs for CY 2012 through CY 2016.
- **Detailed CY 2016 Part D direct and indirect remuneration (DIR) reports.** Detailed DIR report for five large and medium size Part D health plans. Due to the proprietary nature of manufacturer rebate data, we do not disclose the health plans that contributed rebate data. However, we have verified that the contributors include a range of organization sizes, collectively cover the majority of Part D regions, have rebates in line with the national average from the Medicare Trustees Report, include both stand-alone prescription drug plans (PDPs) and Medicare Advantage Part D plans (MA-PDs), and use multiple pharmacy benefit managers (PBMs). We believe they reflect a representative sample of the Part D market.
- **Summarized Part D prescription drug event (PDE) claims data.** The five contributor health plans also provided detailed or summarized PDE data. PDE data was summarized by National Drug Code (NDC) and attached to rebate data to determine average rebates as a percentage of gross drug cost.

The 2018 Medicare Trustees Report⁹. Specifically, we used the overall annual Part D rebate information published in the Trustees Report.

The information presented in this report is based on combining these data into a multi-year Part D experience database by drug, containing estimated national 2016 manufacturer rebates. We combined these data using the following steps:

- 1) **Calculate drug-level rebates as a percentage of gross cost.** The detailed CY 2016 Part D DIR reports contain NDC-level manufacturer rebate data. We matched this rebate data with health plan-specific CY 2016 utilization and gross cost information by NDC. We calculated rebates as a percentage of gross cost for each health plan and NDC. The experience for all contributors is weighted equally except for the largest contributor, to which we applied double the weight. Additionally, we accounted for differences in utilization between carriers at the NDC level by weighting the average rebate calculation by each carrier’s average utilization rate for each specific NDC. This ensured that we did not artificially deflate our rebate assumptions if a carrier had low utilization and low rebates for an NDC due to its exclusion from the formulary or non-preferred formulary placement. Finally, the NDC-level rebate assumptions were rolled up to the drug name level in order to be combined with the publicly available CMS Part D expenditure data.

⁸ Centers for Medicare and Medicaid Services; Medicare Part D Drug Spending Dashboard & Data; Accessed 6/21/2018; URL: <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/MedicarePartD.html>

⁹ The Boards of Trustees, Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds. 2018 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds. 6/5/2018.

- 2) **Combine the CY 2016 drug-level rebates with the 2013 to 2016 Part D expenditure database published by CMS.** The drug level manufacturer rebates as a percentage of gross cost developed in step (1) were combined with the CY 2013 to CY 2016 drug-level Medicare Part D expenditures published by CMS.
- 3) **Scale the drug-level rebates to match the overall CY 2016 rebate levels from the 2018 Medicare Trustees Report.** We applied a uniform scalar to our rebate assumptions in order to target 16.9% rebates as a percentage of total gross drug spending. This benchmark was based on the 2016 overall rebate percentage of 19.9%, as reported in the 2018 Medicare Trustees Report. This includes both manufacturer and other forms of DIR. We assumed that pharmacy rebates and other DIR were 15% of the total in order to arrive at our final assumption of manufacturer rebates equaling 16.9% of gross drug spending.
- 4) **Classify brand drugs for reporting.** We classified each brand drug based on its level of competition: drugs without generic equivalents, drugs with generic equivalents produced by 1-2 manufacturers, and drugs with generic equivalents produced by three or more manufacturers. For brand drugs with no generic equivalent, we identified 13 drug classes with significant brand drug competition within the class and categorized these separately. That is, we separated brand drugs with no generic equivalent into two classes: drugs with significant direct brand competition and drugs without significant direct brand competition. We also identified drugs within the six protected classes: immunosuppressant (for prophylaxis of organ transplant rejection), antidepressant, antipsychotic, anticonvulsant, antiretroviral, and antineoplastic classes¹⁰. Additional break-outs were created based on each drug's 2016 average annual cost per beneficiary (gross cost divided by unique beneficiaries taking the drug) and the drug's 2013 to 2016 annual gross cost per unit trends as reported by CMS.

We summarized the final data set by various drug characteristics and levels of detail to create the information presented in this report. Table 2 shows the total volume of 2016 gross costs included in our analysis.

Table 2: Summary of 2016 Part D Experience used in Analysis

	Gross Costs
All drugs	\$141,403 M
Drugs included in analysis	\$137,056 M
Brand drugs	\$105,656 M
Brand drugs with rebates	\$78,335 M

When calculating gross cost trends per dosage unit (price trend), we used a consistent drug-level weighting for each pair of years. We relied on CMS's weighted average spending per dosage unit to account for "variation in claims volume for specific brand name, generic name, strength, dosage form, routes of administration, and manufacturer levels."

Throughout the report, we relied on the metrics (e.g. rebates measured as a percentage of allowed, gross cost per dosage unit) and drug classifications discussed above. We chose the metrics and drug classifications used in this report based on the availability of data and our assessment of the value of each metric. Other metrics and classifications may also be useful and could potentially highlight other patterns or relationships.

¹⁰ Medicare Prescription Drug Benefit Manual. Chapter 6 – Part D Drugs and Formulary Requirements; Section 30.2.5. Rev. 18, 1/15/16.

LIMITATIONS AND CONSIDERATIONS

Any opinions expressed in this report are solely those of the authors.

Any reader of this report must possess a certain level of expertise in areas relevant to this analysis to appreciate the significance of the approaches and assumptions and the impact of these approaches and assumptions on the results. This report was prepared at the request of America's Health Insurance Plans and should only be considered in its entirety. Milliman does not intend to benefit and assumes no duty or liability to other parties who receive this report. Milliman recommends that any recipient of this report be aided by its own actuary or other qualified professional when reviewing the report. This report is intended solely for educational purposes and presents information of a general nature. It is not intended to guide or determine any specific individual situation and persons should consult qualified professionals before taking specific actions. Neither the authors, nor Milliman, shall have any responsibility or liability to any person or entity with respect to damages alleged to have been caused directly or indirectly by the content of this report. Milliman does not provide legal advice and recommends that AHIP and any reader of this report consult with legal advisors regarding legal matters.

As documented in the report, this analysis has relied extensively on historical prescription drug and rebate data, and publicly available data sources. The data were reviewed for reasonableness, but no independent audits were performed. Should errors or omissions be discovered in the source data, the results of our analysis may need to be modified. Future results will differ from the historical estimates in this report.

Guidelines issued by the American Academy of Actuaries require actuaries to include their professional qualifications in all actuarial communications. We are members of the American Academy of Actuaries and meet the qualification standards for performing the analyses in this report.