Biopharmaceuticals in Medicare, Medicaid & Department of Veterans Affairs

Chart Pack
TABLE OF CONTENTS

Introduction ................................................................................. 1

Chapter 1  Medicare ................................................................. 7
            Part D ............................................................................. 8
            Part B ............................................................................. 36

Chapter 2  Medicaid ................................................................. 49

Chapter 3  Veterans Affairs ....................................................... 67
INTRODUCTION

This chart pack features key facts about prescription medicines in three major government programs. Medicare, Medicaid and the Veterans Affairs (VA) drug benefit each provide drug coverage through different methods of administration.

Medicare insures many of the nation’s retirees and disabled persons, and covers medicines primarily through Parts B and D. Payments for medicines in Medicare Part D are negotiated by competing private health plans. Payments for medicines under Part B, which are generally injected or infused by a physician, are based on the average of prices negotiated by doctors and other purchasers. In contrast, Medicaid and the VA use price controls in providing drug coverage to low-income people and veterans, respectively.

Information displayed here has been compiled from a variety of public and independent sources, and is intended to serve as a useful guide in conversations about the value of biopharmaceuticals in government programs.
Prescription Drug Spending in the U.S.

Public programs accounted for approximately one-third of outpatient drug spending in the U.S. in 2010.

*U.S. Prescription Drug Spending, 2010 ($ Billions)*

Values may not sum due to rounding.

**Includes employer-sponsored health insurance, including federal, state and local government employee health benefits, administered through private health plans.

Source: CMS
Federal Spending on Brand Medicines

Sales of brand medicines account for an estimated 8% of federal spending in Medicare and Medicaid.

*Estimated Federal Spending on Medicare & Medicaid, 2011-2019*

$9.9 Trillion

All Other (e.g., Hospitals, Physicians, Nursing Care, Generic Drugs, and Brand and Generic Distribution Costs), 92%

Brand Medicines,* 8%

Total $9.9 Trillion

*Spending is for brand drug ingredients, exclusive of distribution costs. Includes Medicare Part D spending, drug spending in Medicare Part B and federal share of Medicaid outpatient drug spending. Source: Avalere Health*
Notes and Sources


2. Drug spending estimate does not include spending for prescription drugs used during inpatient hospital stays. Due to limitations on how data are reported, Medicare Part B drug spending does not include payments for medical benefit drugs provided to Medicare Advantage enrollees. Medicaid drug spending contains a portion of physician-administered medical benefit drugs, but does not include drugs provided through Medicaid managed care plans. Spending estimates do not include the impact of any beneficiary premiums for Medicare Parts B and D, which would reduce net federal government spending.

MEDICINES IN
MEDICARE

Medicare is the government program that insures many of the nation’s retirees and disabled persons. The following sections provide information on prescription drug coverage under Parts D and B, which provide payment for the majority of medicines under the Medicare program.

Outpatient prescription medicines are generally covered by Part D, implemented in 2006 to provide prescription drug coverage. Part D is administered by plans using a competitive bidding system which both achieves savings and preserves the incentives for continued innovation in biopharmaceutical research and development.

Injected or infused vaccines and medicines that are administered or purchased by physicians are generally covered by Medicare Part B, which equates to the “medical benefit” provided under commercial insurance plans and primarily provides coverage for physician services.
Medicare Covers Medicines Under Two Benefits, as is Common With Commercial Insurance

Commercial insurers generally cover most drugs under a retail pharmacy benefit, and patients go to their local pharmacy to pick them up or have them delivered via mail order.

However, a minority of drugs are administered by a physician or other health care professional; these drugs generally are covered under a medical benefit by commercial insurers.

This structure exists under Medicare, as well, where the retail pharmacy benefit is called Part D, and the medical benefit is called Part B.

Source: R. McDonald
Part D Relies on Competition to Promote Access and Control Costs

Mechanisms to Promote Access

- Plans compete for enrollees.
- Beneficiary choice of plans.
- Enrollees can switch plans in any year.
- Subsidies assist low-income beneficiaries.
- No limits on number of prescriptions.
- Defined standard benefit and formulary rules set minimum plan requirements.

Mechanisms to Control Costs

- Plans paid based on competitive bidding.
- Negotiated discounts for covered medicines.
- Plans attract enrollment through lower bids and quality of coverage.
- Formularies, tiered co-pays, and utilization management tools.
- Rebates and discounts passed on to beneficiaries and the government.

Source: PhRMA analysis of MedPAC Data Book²
Part D Expanded Coverage for Seniors
In 2011, 90% of Medicare beneficiaries had comprehensive drug coverage.

Medicare Beneficiaries With Comprehensive Drug Coverage (in Millions)³

- 2005 Before Part D:
  - Comprehensive Drug Coverage: 24M, 59%
  - No Comprehensive Drug Coverage: 17M, 41%

- 2011 After Part D:
  - Comprehensive Drug Coverage: 42M, 90%
  - No Comprehensive Drug Coverage: 5M, 10%

Source: PhRMA analysis of data from The Lewin Group and CMS⁴
Sources of Drug Coverage for Seniors and the Disabled

Part D plans covered the majority (about 28 million) of Medicare beneficiaries in 2010.

Prescription Drug Coverage Among Medicare Beneficiaries, 2010

- No Drug Coverage: 4.7M, 10%
- Medicare Part D (Stand-Alone): 17.7M, 38%
- Medicare Advantage (Part D): 9.9M, 21%
- Employer/Union Retiree Coverage: 8.3M, 18%
- VA, Indian Health Service, Medigap, Other: 5.9M, 13%
- Source: Kaiser Family Foundation

1 • Medicare – Part D

Overview • 11
Part D Share of Medicare Expenditures

Medicare Part D drug spending, including brand and generic, will make up 10.6% of estimated Medicare spending in 2012.

*Not including outlays for Mandatory Administration. Medicare Advantage (Part C) expenditures are apportioned among Parts A, B and D according to type of service.

Source: CBO®
Leading Therapy Classes in Part D

92% of Part D enrollees filled at least one prescription in 2009; Part D enrollees filled an average of 4.1 prescriptions per month. Access to these drugs, which treat chronic conditions, help enrollees maintain health and avoid costly complications.

Top 10 Therapeutic Classes of Drugs Under Part D by Volume, 2010

<table>
<thead>
<tr>
<th></th>
<th>Volume of Part D Prescriptions, Millions</th>
<th>Percentage of Part D Prescriptions</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Antihypertensives</td>
<td>145.6</td>
</tr>
<tr>
<td>2</td>
<td>Antihyperlipidemics</td>
<td>136.2</td>
</tr>
<tr>
<td>3</td>
<td>Beta Adrenergic Blockers</td>
<td>88.9</td>
</tr>
<tr>
<td>4</td>
<td>Diabetic Therapy</td>
<td>88.2</td>
</tr>
<tr>
<td>5</td>
<td>Diuretics</td>
<td>77.4</td>
</tr>
<tr>
<td>6</td>
<td>Antidepressants</td>
<td>76.8</td>
</tr>
<tr>
<td>7</td>
<td>Peptic Ulcer Therapy</td>
<td>67.7</td>
</tr>
<tr>
<td>8</td>
<td>Analgesics (Narcotic)</td>
<td>67.2</td>
</tr>
<tr>
<td>9</td>
<td>Calcium Channel Blockers</td>
<td>60.3</td>
</tr>
<tr>
<td>10</td>
<td>Thyroid Therapy</td>
<td>49.5</td>
</tr>
<tr>
<td><strong>Top Ten Total</strong></td>
<td><strong>857.8</strong></td>
<td><strong>61.1%</strong></td>
</tr>
<tr>
<td><strong>Total, All Classes</strong></td>
<td><strong>1,406.0</strong></td>
<td><strong>100.0%</strong></td>
</tr>
</tbody>
</table>

*Number of prescriptions standardized to a 30-day supply.

Source: MedPAC
Part D Costs Less Than Initially Projected

Total Part D costs are 43% lower than the initial 10-year cost estimate.

"It's a competitive market. And we're seeing the effects of good competition among Part D plans..."

– CMS Administrator Dr. Donald Berwick

CBO has also reduced its ten-year forecast for Part D spending for the next decade by over $100 billion in both 2011 and 2012.¹²

Source: CBO¹³
Four out of Five Part D Prescriptions Are Generic
From 2006 to 2011, the generic share of prescriptions dispensed in Part D increased from 60% to 80%.

*Data includes chain and independent drug stores, mass merchants, foodstores, and long term care. Mail order data not available. 

Source: IMS Health*
The U.S. Prescription Drug Lifecycle Generates Savings for Part D

The prescription drug lifecycle is projected to save the Part D program $56 billion between 2006 and 2014.

Estimated Savings = $56B

- Drugs Expected to Lose Patent Protection 2011-2014*: $27.5B
- Drugs That Lost Patent Protection 2007-2010: $28.5B

*Estimated Cumulative Savings, 2006-2014

The Prescription Drug Lifecycle

- Innovator pharmaceutical companies invest in and develop novel medicines based on pioneering science.
- Over time, brand drugs lose patent protection and generic versions of these drugs are introduced which achieve significant cost savings for the Part D program.
- Savings free up program resources for the next generation of medical advances from innovators.

IMS estimate based on analysis of medicines with anticipated loss of patent protection, 2011-2014.

Source: M. Kleinrock15
Daily Cost of Therapy Falling Under Part D

Since 2006, the daily cost for the top 10 therapy areas in Medicare Part D has fallen by a third, and projections show that the daily cost of therapy will drop by another third by 2015.

*Ten therapeutic classes most commonly used by Part D enrollees in 2006, i.e.; lipid regulators, ace inhibitors, calcium channel blockers, beta blockers, proton pump inhibitors, thyroid hormone, angiotensin II, codeine and combination products, antidepressants, and seizure disorders.

Source: M.L. Aitken and E.R. Berndt\textsuperscript{16}
Drug Price Index Shows Little Growth Since Part D Inception

Analysis by an independent commission shows 1% price growth in Part D in four years for a market basket of medicines that includes the mix of brand and generic medicines that patients actually use.

Source: Adapted from MedPAC\textsuperscript{17}
Non-Drug Medical Spending Declined Significantly After Part D

Implementation of Part D was associated with a $1,200 decrease in annual non-drug medical spending among enrollees with prior limited or no drug coverage\textsuperscript{18} – an overall savings of $13.4 billion in 2007, the first full year of the Part D program.\textsuperscript{19}

\textbf{Average Annual Reduction in Non-Drug Medical Spending in 2006 and 2007, for Beneficiaries Gaining Drug Coverage Through Part D}

\begin{center}
\begin{tabular}{|c|c|}
\hline
Source & Reduction in Non-Drug Medical Spending  \\
\hline
Part A & -$816  \\
Part B & -$268  \\
Other Non-Drug\textsuperscript{*} & -$140  \\
\hline
\end{tabular}
\end{center}

\textsuperscript{*}Other non-drug figure is a PhRMA estimate of the balance of the total amount and consists of home health, durable medical equipment, hospice, and outpatient institutional services.

Sources: J.M. McWilliams, et al.\textsuperscript{18}, C.C. Afendulis and M.E. Chernew\textsuperscript{19}
Reductions in Hospitalizations Following Part D Implementation

In the first year after introduction of Part D, the hospitalization rate declined about 4.1% – an estimated 77,000 hospitalizations avoided annually – for eight conditions sensitive to medication adherence.

Number of Avoided Ambulatory Care Sensitive Condition (ACSC) Hospitalizations by State

Avoided Hospitalizations

<table>
<thead>
<tr>
<th># of States</th>
</tr>
</thead>
<tbody>
<tr>
<td>13</td>
</tr>
<tr>
<td>10</td>
</tr>
<tr>
<td>17</td>
</tr>
<tr>
<td>5</td>
</tr>
<tr>
<td>3</td>
</tr>
<tr>
<td>3</td>
</tr>
</tbody>
</table>

"77,000 Hospitalizations Avoided Annually"¹

¹Estimated number of U.S. hospitalizations avoided annually was extrapolated from 23 states for which researchers had data.

Source: C.C. Afendulis, et al.²¹
Shrinking Costs of Part D

Estimated 2011 costs for Part D are less than half the initial CBO projections,\textsuperscript{22} when including savings in other health care services as a result of better drug coverage.\textsuperscript{23} 

\begin{center}
\begin{tabular}{|c|c|c|}
\hline
\textbf{March 2004} & \textbf{March 2012} & \textbf{March 2012 Baseline Less}\newline
\textbf{CBO Projection} & \textbf{CBO Estimate} & Non-Drug Savings for Those}\newline
\textbf{for 2011} & \textbf{for 2011} & Previously Without}\newline
\textbf{\hspace{1cm}} & \textbf{\hspace{1cm}} & \textbf{Comprehensive Rx Coverage}\textsuperscript{*} \\
$110.6B$ & $65.8B$ & $54.8B$ \\
\hline
\end{tabular}
\end{center}

\*CBO estimates assumed no savings in other health care services as a result of Part D coverage.

Source: PhRMA analysis of data from CBO, CMS, C.C. Afendulis and M.E. Chernew, J.M. McWilliams, \textit{et al.}, Bureau of Labor Statistics\textsuperscript{24}
Part D Improves Enrollees’ Access to Medicine and Saves Them Money

Peer-reviewed and academic literature confirms Medicare Part D substantially reduced out-of-pocket costs and increased access to medicine for seniors.*

“...Part D was associated with a 16% annual decrease in out-of-pocket spending and a 7% increase in the number of prescriptions.”
–American Journal of Managed Care25

“...an enrollee who moves from paying cash to buying through Medicare Part D pays 24% less for branded prescriptions...”
–National Bureau of Economic Research26

“We estimate that Medicare Part D reduced user cost among the elderly by 18.4%, [and] increased their use of prescription drugs by about 12.8%...”
–Health Affairs27

“[Our] estimates of the overall effect of Part D—an approximate 13.1% decrease in expenditures and an approximate 5.9% increase in prescription utilization—are remarkably similar to other predictors of these estimated based on economic theory.”
–Annals of Internal Medicine28

“Our results indicate that from 2005-2007, Part D reduced elderly OOP [out-of-pocket] costs per day’s supply of medication by 21.7% and increased elderly use of prescription drugs by 4.7%...”
–National Bureau of Economic Research29

*In comparing results across studies, magnitudes vary due to differences in data and methodology.

Sources: G.F. Joyce, et al.25; M.G. Duggan and F. M. Scott Morton26; F. Lichtenberg and S.X. Sun.27; W. Yin, et al.28; J.D. Ketcham and K. Simon29
Beneficiaries Save Through Plan Competition and Manufacturer Negotiations

Negotiated discounts and rebates on drugs, often as much as 20-30% on brand medicines, according to the Medicare Trustees, help drive plan savings which sponsors can use to reduce costs for beneficiaries.

Sources: CMS, MedPAC
Prices on the Plan Finder Website Do Not Reflect Payments to Manufacturers

Drug prices on Medicare Plan Finder exclude many manufacturer negotiated rebates, but do include Part D payments to pharmacies, such as dispensing fees.

- Net amounts paid by Part D plans can be substantially lower than the prices of medicines shown in Plan Finder as a result of negotiated rebates.

- Part D plan sponsors may use negotiated rebates to lower premiums, rather than to lower prices at the pharmacy counter:

  “Plan sponsors tend to use rebate revenues to offset plans’ benefit spending (reducing plan premiums) rather than lowering the price of prescriptions at the pharmacy counter.”

Sources: MedPAC32, Medicare.gov33
Improved Treatment Adherence for Patients With Serious Conditions

Previously uninsured patients with heart failure were more likely to be adherent to their heart treatment regimens after enrolling in the Medicare Part D program.

*Impact of Part D on Good Refill Adherence (>=80% of days covered). Numbers are unadjusted descriptive statistics.

Source: J. M. Donahue, et al.\textsuperscript{34}
Part D Reduced Costs and Improved Access to Medicines for Beneficiaries Previously Without Drug Coverage

Beneficiaries gaining drug coverage under Part D on average reduced their monthly out-of-pocket costs by $31 while filling more prescriptions.\(^{35}\)

### Impact on Medicare Recipients Gaining Drug Coverage Under Part D

<table>
<thead>
<tr>
<th></th>
<th>2005 Before Part D</th>
<th>2007 After Part D</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Average Out-of-Pocket Cost per Patient per Month</strong>(^{*})</td>
<td>$73</td>
<td>$42</td>
</tr>
<tr>
<td><strong>Average Number of Prescriptions per Patient per Month</strong>(^{**})</td>
<td>1.7</td>
<td>3.5</td>
</tr>
</tbody>
</table>

\(^{*}\)Cost figures are before coverage gap discounts as enacted in ACA.
\(^{**}\)30-day equivalent prescriptions.

Source: Amundsen Group\(^{36}\)
Part D Reduced Costs and Improved Access to Medicines for Disabled Beneficiaries

Disabled beneficiaries under age 65 who gained drug coverage under Part D on average reduced their monthly costs by $23 while filling more prescriptions.

### Impact on Disabled (<65) Medicare Beneficiaries

**Gaining Drug Coverage Under Part D**

<table>
<thead>
<tr>
<th></th>
<th>2005 Before Part D</th>
<th>2007 After Part D</th>
</tr>
</thead>
<tbody>
<tr>
<td>Average Out-of-Pocket Cost per Patient per Month*</td>
<td>$50</td>
<td>$27</td>
</tr>
<tr>
<td>Average Number of Prescriptions per Patient per Month**</td>
<td>1.3</td>
<td>3.7</td>
</tr>
</tbody>
</table>

*$23 in Monthly Savings

2.4 More Prescriptions per Month

*Cost figures are before coverage gap discounts as enacted in ACA.
**30-day equivalent prescriptions.

Source: Amundsen Group

---

Beneficiary Impact • 27
Average Beneficiary Premiums Far Below Original Estimates

According to CMS, “[t]hese very modest increases in premiums...are going to make medications more affordable to Medicare beneficiaries.”

*All original projection estimates are rounded to the nearest dollar.

Source: PhRMA analysis of data from CMS and HHS³⁹
Part D Standard Benefit

From 2006 to 2010, prior to implementation of the Affordable Care Act, Part D’s standard coverage included a deductible, an initial benefit, then a “coverage gap,” followed by catastrophic coverage for those with the highest drug spending. (Within some limitations, plans are permitted to offer alternative benefit designs.)

Structure of Defined Standard Benefit in Part D, 2006-2010*

*Under the defined standard benefit in 2010, there was a deductible of $310, and the coverage gap occurred between the initial coverage limit of $2,830 in total drug spending and $6,440, where catastrophic coverage began. Source: Kaiser Family Foundation40
Most Part D Enrollees Have a Reduced Deductible

In 2012, 66% of Part D beneficiaries were enrolled in plans (both stand-alone and Medicare Advantage prescription drug plans) offering a $0 or reduced deductible.

Percentage of Part D Enrollees in Plans by Deductible Type, 2012*

- $0 Deductible, 56%
- Reduced Deductible, 10%
- Standard Deductible,** 35%

*Total does not sum to 100% due to rounding.

**In 2012, the standard deductible was $320.
Under the defined standard benefit in 2012 (for non-low income enrollees), the coverage gap occurs between the initial coverage limit of $2,930.00 in total drug spending and an estimated $6,730.39 in total drug spending, where catastrophic coverage begins.

Beginning in 2011, beneficiaries receive a 50% discount on brand drugs while in the coverage gap, at a cost to brand manufacturers of $41 billion over ten years (2012 to 2021).\(^{42}\)

**Declining Brand Cost Sharing in the Coverage Gap**

- Biopharma companies provide a 50% discount on brands, immediately reducing the gap by two-thirds starting in 2011.
- The gap is further reduced starting in 2013.
- Starting in 2020, enrollees pay 25% in the gap, same as pre-gap cost sharing in a standard plan.

Across all coverage periods and plan years, Part D plans may employ formularies and utilization management tools to achieve lower costs.

Sources: PhRMA analysis of data from PwC\(^{42}\); HHS, MedPAC, and CMS\(^{43}\)

*Under the defined standard benefit in 2012 (for non-low income enrollees), the coverage gap occurs between the initial coverage limit of $2,930.00 in total drug spending and an estimated $6,730.39 in total drug spending, where catastrophic coverage begins.
Beneficiaries Have Choice of Plans

Part D beneficiaries have between 25 to 36 stand-alone Prescription Drug Plan (PDP) options in each state.

Number of Stand-Alone PDPs per State, 2012

Source: CMS
## Beneficiary Satisfaction With Part D

90% of Part D enrollees are satisfied with their Part D coverage.

### “Overall, how satisfied are you with your prescription drug coverage?”

<table>
<thead>
<tr>
<th>Month</th>
<th>Somewhat Satisfied</th>
<th>Very Satisfied</th>
</tr>
</thead>
<tbody>
<tr>
<td>March 2006</td>
<td>50%</td>
<td>47%</td>
</tr>
<tr>
<td>September 2006</td>
<td>29%</td>
<td>71%</td>
</tr>
<tr>
<td>September 2007</td>
<td>60%</td>
<td>40%</td>
</tr>
<tr>
<td>September 2008</td>
<td>63%</td>
<td>37%</td>
</tr>
<tr>
<td>October 2009</td>
<td>59%</td>
<td>41%</td>
</tr>
<tr>
<td>August 2010</td>
<td>53%</td>
<td>47%</td>
</tr>
<tr>
<td>October 2011</td>
<td>52%</td>
<td>48%</td>
</tr>
<tr>
<td>August 2012</td>
<td>59%</td>
<td>41%</td>
</tr>
<tr>
<td>August 2012</td>
<td>59%</td>
<td>41%</td>
</tr>
</tbody>
</table>

*Totals may not sum due to rounding.

Source: KRC Research
Seniors Rate Part D Highly on Many Measures

Beneficiaries report that their plans are affordable and work well.

Plan Is Convenient to Use: 94% (August 2012), 89% (March 2006)
Understand How Plan Works: 92% (August 2012), 88% (March 2006)
Plan Has Good Customer Service: 89% (August 2012), 85% (March 2006)
Co-pays Are Affordable: 86% (August 2012), 82% (March 2006)
Monthly Premium Is Affordable: 85% (August 2012), 82% (March 2006)
Total Out of Pocket Costs Are Reasonable: 83% (August 2012), 79% (March 2006)
Plan Covers All Medicines: 79% (August 2012), 72% (March 2006)

“You’re seeing intelligent behavior on the part of the beneficiary. They can make better choices for themselves.”

– CMS Administrator Dr. Donald Berwick

Sources: KRC Research⁴⁶; CMS Administrator Berwick⁴⁷
Satisfaction With Part D Is High Among the Most Vulnerable

Dual eligibles and beneficiaries with limited incomes exhibit the highest satisfaction rate with their drug coverage.

**Satisfaction of Selected Groups of Part D Enrollees, 2012**

- **All Seniors With Medicare Rx**
  - Satisfied: 90%
  - Not Satisfied: 9%

- **Dual Eligibles**
  - Satisfied: 95%
  - Not Satisfied: 5%

- **Limited Income**
  - Satisfied: 91%
  - Not Satisfied: 8%

- **Individuals With Disabilities**
  - Satisfied: 83%
  - Not Satisfied: 16%

*Excludes non-respondents
**Dual Eligibles are those enrolled in both Medicare and Medicaid. Duals not choosing a Part D plan are autoenrolled in a plan.
***Limited Income is defined as less than $15,000.

Source: KRC Research
Part B Generally Covers Injected and Infused Medicines, Representing Significant Medical Advances

**Breakthrough in Colorectal Cancer:**
“Progress in the management of colorectal cancer [with medicines] has been rapid during the past five years. The development of novel treatments ... has created a host of different management options from which to choose.”

– New England Journal of Medicine

**Avoiding Debilitating Disease:**
“[A]mong the most effective treatments available for rheumatoid arthritis” and “opening up a new era of targeted biologic therapies for rheumatoid arthritis.”

– New England Journal of Medicine
– Arthritis Foundation

**Preventing Blindness:**
“[T]he most significant advance in the treatment of macular degeneration in the history of the disease.”

– UPI

Sources: New England Journal of Medicine49-50; Arthritis Foundation51; UPI Health News52
In Part B, Beneficiaries Save Through Price Negotiations Between Manufacturers and Providers

Discounts and rebates negotiated by doctors, hospitals, health systems, and other purchasers are factored in the Medicare Part B payment (called “Average Sales Price” or “ASP”) rate and lead to lower costs to the Medicare program and beneficiaries.

Sources: 42 U.S.C. §1395w–3a (2003)53; MedPAC54
Prescription Drug Share of Part B Expenditures

Spending on prescription medicines accounted for 8.9% of Part B spending in 2010.

Part B Expenditures, 2010

- Physician Services and All Other Part B Spending, 91.1%
- Brand and Generic Drug Spending, 8.9%

Total $209.1 Billion

Source: PhRMA analysis of data from MedPAC and CBO
Total Drug Costs in Medicare Part B Have Been Stable

Since 2006, the annual total cost for drugs under Medicare’s Part B program have shown little increase.

Average Sales Price-Based Payments
Over Time ($ Billions)

(Data for 2011 are not included because the CMS ASP drug pricing file is only currently available through the third quarter of 2011. Source: The Moran Company)

1 • Medicare – Part B
Average Price Growth in Medicare Part B Less Than Medical Inflation

While medical inflation has increased since 2006, the trend of volume-weighted Average Sales Price (ASP) changes for Medicare Part B drugs has remained essentially flat.

Source: The Moran Company

*Weighted ASP* vs. *CPI-M*
Notes and Sources


3 Comprehensive drug coverage is defined as drug coverage through Medicare Part D (2011 only), employer-sponsored plans, Medicaid, Veterans Health Administration, Indian Health Services and state pharmaceutical assistance programs. In 2005, many Medicare beneficiaries had limited drug coverage through Medigap and Medicare Advantage plans (high deductibles, high copayments, annual benefit limits). Because these Medigap and Medicare Advantage plans did not offer comprehensive drug coverage, they are excluded in 2005.


5 Includes Veterans Affairs, retiree coverage without RDS, Indian Health Service, state pharmacy assistance programs, employer plans for active workers, Medigap, multiple sources and other sources.

6 Includes Retiree Drug Subsidy (RDS) and Federal Employees Health Benefits Plan (FEHBP) and TRICARE retiree coverage.


IMS Institute for Healthcare Informatics, National Prescription Audit™ (December 2011).


Short-term complications of diabetes; chronic obstructive pulmonary disorder; congestive heart failure (CHF); angina; uncontrolled diabetes; asthma; stroke; acute myocardial infarction (AMI).

22. The Congressional Budget Office (CBO) has not recognized the effects that Part D may have on reducing expenditures elsewhere in Medicare in official estimates. In general, CBO has not recognized preventive health products or services as producing budgetary savings. See, e.g., CBO letter to the Honorable Nathan Deal, 7 August 2009, www.cbo.gov/sites/default/files/cbofiles/ftpdocs/104xx/doc10492/08-07-prevention.pdf (accessed 1 September 2012).

23. The Congressional Budget Office’s estimates for Part D outlays have fallen significantly due to lower than projected spending per enrollee, lower than projected annual increases in drug spending, and savings in non-drug health care costs as a result of better drug coverage.


35 Patient Cost excludes premiums but includes all patient contributions to drug costs, such as co-payments, coinsurance, and any amounts applied to deductible.

36 Amundsen Group, Verispan Longitudinal Data, analysis for PhRMA (May 2008).

37 “Disabled beneficiaries” refers to individuals younger than 65 who qualify for Medicare based on a determination of disability. Analysis does not include Medicare-Medicaid dual eligible population, which had drug coverage in 2005 under Medicaid.

38 Amundsen Group, Verispan Longitudinal Data, analysis for PhRMA (May 2008).


41 Avalere Health analysis of 2012 MA and Part D landscape file and July 2012 enrollment data.

42 PhRMA analysis of data from PwC, “Implications of the US Supreme Court Ruling on Healthcare,” Health Research Institute (June 2012).


Ibid.

Centers for Medicare & Medicaid Services Administrator Dr. Donald Berwick as quoted in Matt DoBias, “Medicare Success Finds Fans on the Right,” POLITICO (4 August 2011).


Arthritis Foundation President and CEO Dr. John H. Kippel as quoted in J. Donn, “‘Smart’ Drug Proves Potent Against Rheumatoid Arthritis,” The Star-Ledger (17 June 2004).

Dr. David Brown, The Methodist Hospital, as quoted in “Good Result for Macular Degeneration Shots,” UPI Health News (5 October 2005).


ASP as defined for the Medicare Part B program is the manufacturer’s average price to all nonfederal purchasers in the United States, net of most discounts and rebates (other than rebates under the Medicaid drug rebate program).

CPI-M (Consumer Price Index for Medical Care) is the U.S. government’s measure of average price levels across all medical goods and services.

Medicaid provides health coverage for low-income and disabled individuals, and is jointly funded by state and federal governments. Under the Affordable Care Act, Medicaid eligibility is scheduled for expansion in 2014. Each state administers its own Medicaid program within broad federal guidelines. Some states administer pharmacy benefits directly, while beneficiaries in other states receive drug benefits from Medicaid managed care plans. Drugs sold to Medicaid beneficiaries are subject to statutory rebates. Policies meant to reduce the cost or use of medicines in Medicaid often result in barriers to access for patients, and have been shown to be associated with poor health outcomes for beneficiaries.
Brand Prescription Drugs Are About 4% of Total Medicaid Spending

**Medicaid Spending, 2010**

- Professional Services, 13.8%
- Hospital Care, 38.0%
- Other Health, Residential and Personal Care, 16.9%
- Nursing Facilities, 11.2%
- Administration Costs, 7.4%
- Home Health, 6.5%
- Generic Prescription Drugs, 1.5%
- Durable Medical Equipment, 1.2%
- Brand Prescription Drugs, 3.5%

**Total $401.4 Billion**

Source: PhRMA analysis of data from CMS, HHS Office of Inspector General, and The Lewin Group
Prescription Drugs Projected to Be Small Share of Medicaid Spending Through 2020

In 2010, Medicaid drug spending, including brands and generics, was $20.2 billion.

*Years 2011 and beyond are projections as of January 2012. Other services not shown separately include Durable and Non-Durable Medical Products, Home Health Care Expenditures, Other Health, Residential and Personal Expenditures, and others.

**Prescription drug spending includes brand and generic ingredients, pharmacy, and distribution costs.
Medicaid Price Controls

As a condition of a drug being covered by Medicaid, drug manufacturers pay a rebate to the states and CMS based on a statutory formula.

*Price Controls in Medicaid Are Manifested Through the Rebate Program*

- The **base rebate** for brand medicines is the greater of 23.1% of the average manufacturer price (AMP) OR the difference between AMP and a manufacturer’s “best price” (the best price to generally any non-governmental purchaser) for the drug.
- Brand manufacturers pay an **additional rebate** if their AMP increases more than inflation.
- Many states also require additional **state supplemental rebates** on brand medicines.
- Generic manufacturers also pay a statutory rebate of 13.0% of AMP.
- CBO has said that Medicaid price controls distort the market, resulting in higher prices elsewhere.⁶⁻⁷

*In FY2010, the cost to manufacturers of Medicaid rebates totaled $11.4 billion.*⁸

Sources: CBO⁶⁻⁷; CMS⁸
“Average Manufacturer Price” (AMP) Is Not the Average Price Received by Manufacturers

- AMP is defined in statute and is used to calculate Medicaid rebates.
- While originally intended only for use in the rebate calculation, over the years AMP has also become a metric for pharmacy reimbursement and has been redefined to reflect the price paid by retail community pharmacies.
- AMP excludes many manufacturer sales, discounts, and rebates. For example, it excludes prices paid by mail order pharmacies, physicians, clinics, or hospitals and rebates received by managed care organizations and pharmacy benefit managers.
- This definition results in AMPs that are higher than the average price manufacturers actually receive.
- Excluding many manufacturer rebates and discounts from the definition of AMP results in higher Medicaid rebates because AMP is the critical component of the formula.

Source: PhRMA, based on information from Medicaid.gov and CBO
Medicaid Rebates on Prescription Medicines Increase Substantially Under ACA

Independent analysts estimate the expansion of Medicaid prescription drug rebates in the Affordable Care Act could increase brand manufacturers’ costs by more than $40 billion over 10 years (2012-2021).10

Note: Graphic is illustrative only.

Sources: PwC Health Research Institute10, Medicaid.gov11
Medicaid Rebates Apply to More People Under ACA

Drug purchases by beneficiaries in Medicaid managed care organizations (MCOs) became eligible for statutory rebates in 2010. Beginning in 2014, Medicaid rebates could apply to medicines used by up to 26 million additional people.

*Point-in-time measurement.

Source: PhRMA analysis of data from CMS, CBO, and Kaiser Family Foundation13
Administration of Pharmacy Benefit in Medicaid Varies

In many states, Managed Care Organizations (MCOs) administer Medicaid pharmacy benefits, while in others, states administer benefits directly. In a few states, benefits are administered by either entity, depending on patient therapy.

Percentage of Recipients Receiving Drug Benefits Through an MCO by State, 2010

*States in which certain classes of drugs are not included in the MCO drug benefit.

Source: Avalere
States Limit Access to Prescription Medicines in Medicaid

Nearly all states use Preferred Drug Lists (PDLs),* and 16 states limit the number of prescriptions that beneficiaries can fill each month.

*Even though every state is guaranteed sizable statutory discounts on all medicines, states may also define a list of Medicaid covered medicines (i.e., Preferred Drug Lists) with CMS approval. Patients seeking access to medicines not on the PDL must obtain prior authorization.

Source: Kaiser Commission on Medicaid and the Uninsured

PDL and Monthly Limit on Number of Prescriptions

★

PDL

PDL and Monthly Limit on Number of Prescriptions

Source: Kaiser Commission on Medicaid and the Uninsured
Restrictive State Medicaid Preferred Drug Lists May Reduce Adherence and Lead to Poor Outcomes

In Alabama, 51% of patients discontinued statin therapy after Preferred Drug List (PDL) restrictions were imposed, compared to 39% in the previous period.\textsuperscript{18}

\begin{figure}
\centering
\includegraphics[width=\textwidth]{therapy_discontinuation_rates}
\caption{Therapy Discontinuation Rates Before and After PDL Implementation in Alabama\textsuperscript{*}}
\end{figure}

\begin{itemize}
\item Access restrictions may deter patients, especially vulnerable low-income patients, from adhering to important therapies, which could ultimately drive up long term medical costs.\textsuperscript{18}
\item In comparison, another state (North Carolina), which did not institute a PDL, experienced no significant change in therapy discontinuation during the same period.
\end{itemize}

\textsuperscript{*}In comparison, another state (North Carolina), which did not institute a PDL, experienced no significant change in therapy discontinuation during the same period.

\textsuperscript{18}Source: D. Ridley and K. Axelsen
Use of Prior Authorization to Contain Costs May Not Be Clinically Appropriate

In Maine’s Medicaid program, treatment disruptions increased by 29% after implementation of a prior authorization (PA) policy among patients initiating schizophrenia therapy with atypical antipsychotics.19

“Our results indicate that PA and step therapy requirements for new users of [atypical antipsychotics] may result in problematic disruptions in therapy among patients with schizophrenia.”19

— Stephen Soumerai, et al.

Treatment Disruption Rates Before and After Implementation of Prior-Authorization Policy in Maine**

<table>
<thead>
<tr>
<th></th>
<th>% of Medicaid Patients Who Experienced AA Treatment Discontinuities*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-PA</td>
<td>53%</td>
</tr>
<tr>
<td>PA</td>
<td>68%</td>
</tr>
</tbody>
</table>

Source: S. Soumerai, et al.19

*Discontinuity in treatment refers to a gap in therapy, a change of medicine, or augmentation with another antipsychotic medicine.

**151 of 222 patients experienced discontinuities after PA implementation, a rate of 68%. The discontinuity rate after PA implementation was 29% higher than the pre-PA rate, implying a pre-PA discontinuity rate of 53%. Comparison state (New Hampshire), which did not institute a PA policy, did not experience a significant change in treatment disruptions during the same period.
Greater Adherence to Medicines in Medicaid Can Reduce Spending on Other Health Care Services

Among Medicaid beneficiaries with congestive heart failure, total health care costs for adherent patients* were 23% lower than those of non-adherent patients.

*Defined as patients with a “medication possession ratio” (i.e., total days supply of medication divided by number of days between first fill and the last day patient had no medication available) of 80% or higher.

Source: Esposito, et al.20
Increasing Prescription Drug Cost-Sharing for Medicaid Patients May Lead to Higher Total Medicaid Costs

For patients with very low incomes, even small increases in cost-sharing can reduce access to needed care, which can lead to poor outcomes and increased program costs.

*Increased Drug Copayments in Georgia’s Medicaid Program Led To:*\(^{21}\)

- Reduced use of prescribed medicines among cancer patients...
- ...and a subsequent increase in emergency room visits...
- ...resulting in higher total Medicaid costs.

Source: S. Subramanian\(^{22}\)
Notes and Sources

1. Professional Services includes Physician and Clinics, Dental and Other Professional.

2. Other Health, Residential and Personal Care includes school health, worksite, residential mental/substance abuse, some ambulance, Medicaid home/community waivers.

3. Administration Costs includes Federal and State Administration and Net Cost of Private Insurance.

4. PhRMA analysis based on data from Centers for Medicare & Medicaid Services, Office of the Actuary, National Health Statistics Group, National Health Expenditures Data, Table 4 (January 2012); U.S. Department of Health and Human Services, Office of Inspector General, Higher Rebates for Brand-Name Drugs Result in Lower Costs for Medicaid Compared to Medicare Part D (August 2011); The Lewin Group, Potential Federal and State-by-State Savings if Medicaid Pharmacy Programs were Optimally Managed (February 2011).


6. Congressional Budget Office letter to Senate Finance Committee Chairman Chuck Grassley (R-IA), 21 June 2005.


10. The $40B cost of increased Medicaid rebates that PwC reports does not include the cost of paying those larger rebates for individuals who will newly receive Medicaid coverage under the ACA. PwC Health Research Institute, Implications of the US Supreme Court Ruling on Healthcare (June 2012).
In states where the drug benefit was partially carved out, the entire drug benefit was considered carved out for the purpose of estimating the number of lives covered by Medicaid rebates. States with carved-out drug benefits and MCO enrollment as a percentage of total Medicaid enrollment were assumed to be constant through 2014 in the absence of the ACA.

PhRMA analysis based on the following data sources: Centers for Medicare & Medicaid Services (CMS), 2009 Medicaid Managed Care Enrollment Report (data as of 30 June 2009); CMS, 2010 Medicaid Managed Care Enrollment Report (data as of 1 July 2010); CMS, “Dual Eligible Enrollment as of June 30, 2009”, table; CMS, “Dual Eligible Enrollment as of July 1, 2010”, table; Kaiser Family Foundation, “Comprehensive Medicaid Managed Care Organization Acute Care Benefit Carve-Outs, October 2010” at www.statehealthfacts.org/comparemaptable.jsp?ind=9878&cat=4; Congressional Budget Office (CBO), March 2009 Baseline: Medicaid (June 2009); CBO, March 2011 Baseline: Medicaid (March 2011); CBO, March 2012 Baseline: Medicaid (March 2012); CBO, Updated Estimates for the Insurance Coverage Provisions of the Affordable Care Act (March 2012); CBO, Estimates for the Insurance Coverage Provisions of the Affordable Care Act Updated for the Recent Supreme Court Decision (July 2012).

Vermont Medicaid managed care is through the state’s publicly sponsored MCO. Texas requires MCO formularies to adhere to the state’s prescription drug list.

Avalere analysis of Centers for Medicare & Medicaid Services, 2010 Medicaid Managed Care Enrollment Report (data as of 1 July 2010).

Numbers indicate the monthly prescription limit for brands and generics, unless otherwise specified. Most states exempt children and institutionalized beneficiaries from these limits. Prescription limit data as of 2010 in most cases.


21 Outcomes were measured during six-month periods before and after copay increase in Georgia. Impact estimates are adjusted to reflect changes in a similar state with no change in co-pays over same period. “Rx days” is the number of prescriptions multiplied by the number of days supply over a six-month period.

The U.S. Department of Veterans Affairs (VA) serves a special population – veterans with service-related disabilities and, in some cases, their families. The VA administers the smallest of the three public drug benefit programs featured here. The VA uses price controls for prescription medicines, and also uses a more restrictive drug formulary than Medicare Part D plans. Many veterans use other coverage for their medicines rather than rely exclusively on VA coverage.
VA Price Controls

To participate in Medicaid and Medicare Part B, drug manufacturers are subject to statutory price controls for medicines sold to the “Big 4” government agencies: VA, Department of Defense, Public Health Service and Coast Guard.

- Pharmaceutical companies are required to sell medicines at the lower of two controlled prices:¹
  1. **Federal Ceiling Price (FCP).** A minimum 24% discount off the “non-Federal Average Manufacturer Price” (non-FAMP). A statutory formula requires additional discounts if necessary to prevent the FCP from rising faster than the rate of inflation.
  2. **Federal Supply Schedule (FSS) price.** Manufacturers must disclose to the VA the prices they make available to their commercial customers. On a drug-by-drug basis, the parties identify a customer who purchases the drug at the lowest price on terms substantially similar to the VA. The FSS price must be no greater than the price paid by this “tracking” customer.

- In the mid-1990s, the VA also instituted a national formulary that included closed and preferred classes of medicines. In some instances, for placement of medicines on formulary, VA requires further discounts below the FCP.

VA Formulary Covers Fewer Brand Drugs Than Part D

For 2011, the VA formulary included far fewer brand name drugs than Part D.

Percentage of Brand Name Drugs Most Commonly Used by Seniors Included in Formularies

Source: The Lewin Group
Veterans Prefer More Drug Coverage Than VA Offers

VA enrollees obtain many prescriptions outside the VA system.

**Enrollees Planning to Use VA System Primarily for Rx**

- 2005: 17.3%
- 2008: 11.0%
- 2010: 8.2%

**Prescriptions Obtained Outside VA System**

- 2005: 17.0%
- 2008: 26.0%
- 2010: 28.6%

Sources: Department of Veterans Affairs
VA Formulary Excludes Medicines Commonly Prescribed by Community Physicians

In a 2003 VA pilot program allowing veterans to use non-VA physicians, 42% of prescriptions written by community physicians were not available on the VA formulary.

Source: Dr. Jonathan Perlin, Department of Veterans Affairs

*VA pharmacists worked with community physicians to convert prescriptions to the VA formulary. Results are through week 20 of the pilot program.
Many VA Enrollees Supplement Their VA Drug Coverage With Part D or Private Insurance

7.8 million veterans enrolled in the VA health care system in 2010; almost 1.5 million were also enrolled in Medicare Part D, and 2 million had private drug insurance.

Percentage of VA Enrollees Reporting Other Sources of Drug Coverage, 2010

Source: Department of Veterans Affairs®
Treatment Adherence Improved for Veterans After Enrolling in Part D

Beneficiaries whose primary drug coverage was through the VA in 2003 and through Part D in 2006 reported lower rates of non-adherence to therapy after enrolling in Part D.

*Beneficiaries Reporting Non-Adherence to Rx Therapy*

Source: D.G. Safran, et al.\(^9\)
Notes and Sources


2. The analysis began with the top 300 drugs with the highest script volumes for the 65 and older population. 17 of the top 300 are not covered by the Part D program due to statutory and regulatory requirements, and three influenza vaccines are covered by Part B. The analysis was conducted using the remaining 280 Part D covered drugs.


6. The transitional pharmacy benefit (TPB) was a temporary program to help veterans who were unable to get their initial primary care appointment with a VA doctor within a 30 day time period. Under the program, VA would fill prescriptions from private physicians until a VA physician examined the veteran and determined an appropriate course of treatment. The VA reported that 8,298 veterans had prescriptions filled through the program.


