Biopharmaceuticals in Government Programs

SUMMER 2015

PhRMA
RESEARCH • PROGRESS • HOPE
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INTRODUCTION

This chart pack features key facts about prescription medicines in four major government programs—Medicare, Medicaid, the US Department of Veterans Affairs (VA), and the 340B program.

Medicare insures many of the nation’s retirees and disabled persons and covers medicines primarily through Part D and B. 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.
Sources of Prescription Drug Spending in the United States

Together, Medicare and Medicaid account for approximately one-third of outpatient drug spending.

US Prescription Drug Spending, 2013*

*Values may not sum to totals due to rounding.

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

Source: CMS¹
Federal Spending on Health Care

Over the next decade, total sales of brand medicines are projected to be 9% of federal spending in Medicare, Medicaid, VA, and TRICARE.

*Values may not sum to totals due to rounding.
**Excludes administration and distribution costs

Source: Avalere Health³

2. These figures do not include prescription drugs used during inpatient hospital stays or drugs provided through Medicaid managed care plans. The Medicaid figure does not include the state share of Medicaid drug spending but does contain a portion of physician-administered medical benefit drugs. The Medicare Part B estimate does not include payments for drugs that are part of bundled payment systems (eg, dialysis) or for medical benefit drugs provided to Medicare Advantage enrollees. The figure for Part D includes spending by Medicare Advantage plans that offer drug coverage and spending on the Retiree Drug Subsidy (RDS). Finally, the figures do not include the impact of any beneficiary premiums for Medicare Parts B and D, which would reduce the net impact to the federal government.

Medicare is the government program that insures many of the nation’s retirees and disabled persons. The following sections contain 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 Medicare Part D, which was implemented in 2006 to provide prescription drug coverage. Part D is administered by private plans using a competitive bidding system, which achieves savings and helps preserve 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, similar to the “medical benefit” provided under commercial insurance plans.
As Is Common With Commercial Insurance, Medicare Covers Medicines Under Two Benefits

Medicare’s retail pharmacy benefit is called Part D, and Medicare’s medical benefit is called Part B.

<table>
<thead>
<tr>
<th>MEDICARE</th>
<th>COMMERCIAL INSURERS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Part D</td>
<td>Retail Pharmacy Benefit</td>
</tr>
<tr>
<td>Includes most drugs, which are either picked up by patients at the pharmacy or delivered via mail order</td>
<td></td>
</tr>
<tr>
<td>Part B</td>
<td>Medical Benefit</td>
</tr>
<tr>
<td>Includes a minority of drugs that generally must be administered by a physician or other health care professional</td>
<td></td>
</tr>
</tbody>
</table>

Source: McDonald R^1
Sources of Outpatient Drug Coverage for Seniors and the Disabled

Medicare Part D plans covered about 35.7 million beneficiaries out of 52.3 million total Medicare enrollees in 2013, either through Medicare Advantage or stand-alone Prescription Drug Plans.

*Does not sum to 100% due to rounding. LIS is low-income subsidy. Total Part D and Medicare enrollment is based on 2012 intermediate estimates.

**Includes Veterans Affairs, Indian Health Service, Federal Employees Health Benefits Program, and TRICARE for Life

†Includes Retiree Drug Subsidy (RDS)

Source: Kaiser Family Foundation²
Part D Share of Medicare Expenditures

Medicare Part D drug spending, including brand and generic, made up 10.9% of Medicare spending in 2014.

*Not including outlays for mandatory administration. Medicare Advantage (Part C) expenditures are apportioned among Parts A, B, and D according to type of service. Does not sum to 100% due to rounding

Source: CBO³
Part D Standard Benefit in 2010

From 2006 to 2010, prior to implementation of the Affordable Care Act, Part D’s standard coverage included a deductible, an initial benefit, a “coverage gap,” and then catastrophic coverage for those with the highest drug spending. Beginning in 2011, beneficiaries receive a 50% discount on brand drugs while in the coverage gap.

*Indexed annually to program growth

*Source: CMS*
Phaseout of Coverage Gap in Part D Began in 2011

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 10 years (2012-2021).5

*Under the defined standard benefit in 2016 (for non-low-income enrollees), the coverage gap occurs between the initial coverage limit of $3,310 in total drug spending and an estimated $7,515 in total drug spending, where catastrophic coverage begins.7

Declining Brand Cost Sharing in the Coverage Gap*

Since 2010, 9.4M Medicare beneficiaries have saved over $15B on prescription drugs as a result of coverage gap discounts—an average savings of about $1,598 PER BENEFICIARY.6

Sources: PwC5; HHS6; CMS7
Leading Therapy Classes in Part D

Ninety-two percent of Part D enrollees filled at least one prescription in 2011; Part D enrollees filled an average of 4.3 prescriptions per month.8

*Number of prescriptions standardized to a 30-day supply

Sources: MedPAC8; PhRMA analysis of data from MedPAC9

<table>
<thead>
<tr>
<th>Top-10 Therapeutic Classes of Drugs Under Part D by Volume (2012)9</th>
</tr>
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<tbody>
<tr>
<td></td>
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<tr>
<td><strong>Volume of Part D Prescriptions, Millions</strong></td>
</tr>
<tr>
<td>----------------------------------------------------------------</td>
</tr>
<tr>
<td>1. Antihypertensives</td>
</tr>
<tr>
<td>2. Antihyperlipidemics</td>
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<tr>
<td>3. Beta Adrenergic Blockers</td>
</tr>
<tr>
<td>4. Diabetic Therapy</td>
</tr>
<tr>
<td>5. Antidepressants</td>
</tr>
<tr>
<td>6. Diuretics</td>
</tr>
<tr>
<td>7. Peptic Ulcer Therapy</td>
</tr>
<tr>
<td>8. Analgesics (Narcotic)</td>
</tr>
<tr>
<td>9. Calcium Channel Blockers</td>
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<tr>
<td>10. Thyroid Therapy</td>
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<tr>
<td><strong>Top 10 Total</strong></td>
</tr>
<tr>
<td><strong>Total, All Classes</strong></td>
</tr>
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*Number of prescriptions standardized to a 30-day supply
Part D Expanded Coverage and Improved Treatment Adherence for Seniors

As a result of Part D, 90% of Medicare beneficiaries have comprehensive drug coverage, and previously uninsured patients with heart failure are more likely to be adherent to their heart treatment regimens. Better adherence improves health and saves money on hospitalizations.

Sources: PhRMA analysis of data from The Lewin Group and CMS10; Donahue JM, et al.11

*Impact of Part D on good refill adherence (≥80% of days covered); numbers are unadjusted descriptive statistics
Part D Implementation Improved Enrollees’ Access to Medicine and Reduced Out-of-Pocket Costs

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

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

Sources: Joyce GF, et al.12; Duggan MG, Scott Morton F13; Lichtenberg F, Sun SX14; Yin W, et al.15; Ketcham JD, Simon K16
Part D Reduced Costs and Improved Access to Medicines for Beneficiaries Previously Without Coverage and for Disabled Beneficiaries

Beneficiaries Who Gained Drug Coverage Under Part D\textsuperscript{17}

<table>
<thead>
<tr>
<th></th>
<th>2005 Before Part D</th>
<th>2007 After Part D</th>
<th>$31 in Monthly Savings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Average Out-of-Pocket Cost per Patient per Month*</td>
<td>$73</td>
<td>$42</td>
<td></td>
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</table>

Disabled Beneficiaries\textsuperscript{18} Under Age 65 Who Gained Drug Coverage Under Part D

<table>
<thead>
<tr>
<th></th>
<th>2005 Before Part D</th>
<th>2007 After Part D</th>
<th>$23 in Monthly Savings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Average Out-of-Pocket Cost per Patient per Month*</td>
<td>$50</td>
<td>$27</td>
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</table>

\*Cost figures are before coverage gap discounts as enacted in the Affordable Care Act.

Source: Amundsen Group\textsuperscript{19}
Part D Costs Less Than Initially Projected

Total Part D costs are 45% lower than the initial 10-year cost estimate.

**Congressional Budget Office Projections and Tallies of Total Part D Spending for 10-Year Period 2004-2013 ($ Billions)**

<table>
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<tbody>
<tr>
<td>Source</td>
<td>CBO20; IMS Institute for Healthcare Informatics21</td>
<td></td>
</tr>
</tbody>
</table>

“...The bids are coming in, and the pricing is coming in better than anticipated, and that is likely a reflection of the competition that's occurring in the private market.”

– Peter Orszag, Former CBO Director21
Average Beneficiary Premiums Are Far Below Original Estimates

According to the Centers for Medicare & Medicaid Services, “[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
Beneficiary Satisfaction With Part D

Several surveys show that about 90% or more of Part D enrollees are satisfied with their coverage and indicate that their coverage works well.\textsuperscript{23,24}

Sources: KRC Survey for Medicare Today\textsuperscript{23}; MedPAC\textsuperscript{24}
Seniors Rate Part D Highly on Many Measures

Beneficiaries report that their plans are affordable and work well.

“Seniors and people with disabilities are benefitting from steady prescription drug premiums and a competitive and transparent marketplace for Medicare drug plans.”

– Marilyn Tavenner, CMS Administrator, 2011-2015

**July 2014 Ratings**

- Plan Is Convenient to Use: 93%
- Understand How Plan Works: 92%
- Plan Has Good Customer Service: 90%
- Copays Are Affordable: 86%
- Monthly Premium Is Affordable: 85%
- Total Out-of-Pocket Costs Are Reasonable: 81%
- Plan Covers All Medicines: 78%

Sources: KRC Survey for Medicare Today25; CMS26
Satisfaction With Part D Is High Among the Most Vulnerable Beneficiaries

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

*Excludes nonrespondents
**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 Survey for Medicare Today
Competition in Part D Promotes Access and Helps Control Costs

Mechanisms to PROMOTE ACCESS

• Plans compete for enrollees based on benefits, quality, and price.
• Beneficiaries have a choice among plans to best meet their needs.
• Enrollees can switch plans each year during open enrollment.
• Premium and cost-sharing subsidies assist low-income beneficiaries.
• There are no limits on the number of prescriptions.
• Defined standard benefit and formulary rules set minimum plan requirements.

Mechanisms to CONTROL COSTS

• Plans are paid based on competitive bids submitted each year.
• Plans and manufacturers negotiate discounts for covered medicines.
• Plans attract enrollment through lower premiums and quality of coverage.
• Plans use tiered formularies, tiered copays, and other utilization management tools.
• Rebates and discounts are passed on to beneficiaries and the government.

Source: PhRMA analysis of data from MedPAC28
Beneficiaries Save Through Plan Competition and Manufacturer Negotiations

Large, powerful purchasers, who may represent as many as 63 million to 125 million covered lives, negotiate discounts and rebates on drugs in Part D. The Medicare Trustees report rebates are often as high as 20%-30% on brand medicines, helping to drive plan savings, which sponsors use to reduce costs for beneficiaries.

Sources: AIS; Medicare Trustees; GAO

PART D PLANS negotiate discounts with manufacturers.

These savings are used to help reduce premiums, deductibles, and cost sharing.

Sources: AIS; Medicare Trustees; GAO
Illustrative Pharmaceutical Lifecycle

New pharmaceutical medicines face competition after a relatively short period on the market. Over time, brand drugs lose patent protection and generic drugs are introduced, achieving significant cost savings for the Part D program. Savings free up program resources for the next generation of medical advances from innovators.

*For brand medicines with more than $100 million in annual sales in 2008 dollars, which account for 97% of sales of the brand medicines analyzed

Sources: PhRMA; Grabowski H, et al.; Tufts CSDD.
The US 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.

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

Source: Kleinrock M35
The US Prescription Drug Lifecycle Promotes Innovation and Affordability

Since 2006, the daily cost for the top-10 therapy areas in Medicare Part D has fallen by nearly half, and projections show that the daily cost of therapy will drop again by more than a third by 2017.

*The 10 therapeutic classes most commonly used by Part D enrollees in 2006 were: lipid regulators, angiotensin-converting-enzyme inhibitors, calcium channel blockers, beta blockers, proton pump inhibitors, thyroid hormone, angiotensin II, codeine and combination products, antidepressants, and seizure disorder medications.

Source: Kleinrock M36
Four out of Five Part D Prescriptions Are Generic

Before Part D, seniors used generic drugs at low rates, with about 54% generic utilization in 2005. Since Part D’s inception, generic utilization has steadily increased to 84% in 2013.

*Part D went into effect on January 1, 2006.

Sources: PhRMA analysis of data from IMS Health Vector One National Audit37; Medicare Trustees38
Beneficiaries Have Choice of Plans

Part D beneficiaries have 24 to 32 stand-alone Prescription Drug Plan (PDP) options in each state. Three-fourths of beneficiaries indicate that having a variety of plans to choose from is important to them.39

Number of Stand-Alone PDPs per State (2015)40

Sources: KRC Survey for Medicare Today39; Kaiser Family Foundation40
Medicare Plan Finder Is a Tool for Beneficiaries to Help Make Part D Plan Selections Each Year

The Medicare Plan Finder, available on Medicare.gov, allows beneficiaries to enter their individual drug lists and find out which plans cover their medicines and their expected out-of-pocket costs for the year. Beneficiary choice of plans is a key feature of Part D’s competitive structure.*

OPEN ENROLLMENT
The annual open enrollment period is from October 15 to December 7 each year.

STAR RATINGS
Plans are rated overall out of 5 stars, and Plan Finder provides information on how plans are performing on specific dimensions, such as customer service and patient safety.

*It is important to know what is and is not reflected in Plan Finder drug prices to ensure the information is not interpreted in a misleading way. For example, Plan Finder drug prices may not reflect all negotiated rebates, and therefore do not reflect actual payments to manufacturers. Source: Medicare.gov41
Better Use of Medicines Yields Significant Health Gains and Savings on Other Services

Due to a growing body of evidence, in 2012 the Congressional Budget Office (CBO) began recognizing reductions in other medical expenditures associated with increased use of prescription medicines in Medicare that were not taken into account when CBO originally estimated Part D's cost.

“Pharmaceuticals have the effect of improving or maintaining an individual’s health . . . adhering to a drug regimen for a chronic condition such as diabetes or high blood pressure may prevent complications . . . taking the medication may also avert hospital admissions and thus reduce the use of medical services.”

– CBO

Recent evidence suggests Medicare savings due to better use of medicines may be 3 to 6 times greater than estimated by the CBO for seniors with common chronic conditions:

- High cholesterol: more than 3 times greater
- Congestive heart failure: nearly 4 times greater
- Diabetes: more than 4 times greater
- Hypertension: nearly 6 times greater

Sources: CBO; Roebuck MC
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, resulting in an overall savings of $13.4 billion in 2007, the first full year of the Part D program.

*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: McWilliams JM, et al.; Afendulis CC, et al.
Shrinking Costs of Part D

Estimated 2014 costs for Part D are less than half the initial Congressional Budget Office (CBO) projections, and the savings are even larger after considering reductions in other medical expenditures as a result of increased use of medicines.\(^46\)

Estimated FY 2014 Part D Costs

- **March 2004 CBO Projection for 2014**: $153B
- **April 2014 CBO Estimate for 2014**: $70B
- **April 2014 Baseline Less Non-Drug Savings**: $63.3B

Sources: CBO\(^{46-48}\); Schneeweiss S, et al.\(^{49}\)
Improving Adherence Could Yield Additional Savings

Improving adherence to congestive heart failure (CHF) medicines could yield federal savings of $22.4 billion over 10 years.

Estimated 10-Year Savings to Medicare From Improved Adherence to CHF Medications, 2013-2022

- Savings to Medicare from gaining Part D coverage: $26.9 billion
- Additional savings to Medicare if adherence reaches recommended levels: $22.4 billion

Source: Dall TM, et al.

Additional savings to Medicare if adherence reaches recommended levels
Reductions in Hospital Admissions Following Part D Implementation

Researchers found that gaining Medicare Part D prescription drug coverage was tied to an 8% decrease in hospital admissions for seniors overall, with higher reductions for certain conditions.

The drop in admissions tied to Part D coverage was substantial for certain conditions including coronary atherosclerosis, congestive heart failure, chronic obstructive pulmonary disease, and dehydration.

Source: Kaestner R, et al.51
Improved Adherence for Parkinson’s Patients Linked With Reduced Health Care Utilization and Expenditures

A recent study found that for Part D enrollees with Parkinson’s disease, higher adherence to antiparkinson therapy and longer duration of use were associated with lower health care utilization and expenditures.

Compared to Parkinson’s patients in Part D with low adherence, those with HIGH ADHERENCE* had:

- Significantly lower rates of
  - Hospitalization
  - Emergency room visits
  - Skilled nursing facility episodes
  - Home health agency episodes
  - Physician visits

$2,242 lower total health care expenditures

*Over 19 months

Source: Wei YJ, et al.52
Coverage Gap Phaseout, to Date, Has Improved Medication Adherence for Diabetes

Research shows that the phaseout of the coverage gap is making medicines more affordable in the gap and has resulted in patients adhering better to prescribed therapies.

In 2010, ADHERENCE to diabetes medications DECREASED in the coverage gap for beneficiaries with partial or no gap coverage.

<table>
<thead>
<tr>
<th>Coverage Type</th>
<th>Adherence Decrease</th>
</tr>
</thead>
<tbody>
<tr>
<td>Partial coverage</td>
<td>-6.7%</td>
</tr>
<tr>
<td>No coverage</td>
<td>-7.4%</td>
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</tbody>
</table>

In 2011, when the 50% discount on brand medicines began, ADHERENCE to diabetes medications in the coverage gap IMPROVED for beneficiaries who previously had partial or no coverage.

<table>
<thead>
<tr>
<th>Coverage Type</th>
<th>Adherence Increase</th>
</tr>
</thead>
<tbody>
<tr>
<td>Partial coverage</td>
<td>6.5%</td>
</tr>
<tr>
<td>No coverage</td>
<td>3.0%</td>
</tr>
</tbody>
</table>

Note: Adherence measured as proportion of days covered

Source: Zeng F, et al.53
A recent study found that the introduction of Part D significantly reduced depressive symptoms among older adults, and that such gains in mental health grew stronger over time.

*Trends in Depressive Symptom Scores for Medicare-Eligible Individuals (65-70 years of age)*

Source: Ayyagari P, Shane D.54
Cardiovascular-Related Mortality Dropped Significantly Following Part D Implementation

Mortality rates dropped and years of life lost were reduced significantly in areas most impacted by the implementation of Part D. The estimates suggest that as many as 27,000 more beneficiaries were alive mid-2007 as a result of Part D implementation.

Source: Dunn A, Shapiro AH

15% Drop in Mortality Rates

33% Reduction in Years of Life Lost

19,000-27,000 More Beneficiaries Alive mid-2007

Source: Dunn A, Shapiro AH
Part B Generally Covers Injected and Infused Medicines Across Several Settings

Approximately 600 Part B drugs are administered in various locations.

**HOSPITAL OUTPATIENT DEPARTMENTS**
- Physician administered (infused/injected)
- Durable medical equipment (DME) drugs
- Some oral drugs

**PHYSICIAN OFFICES**
- Physician administered (injected/infused)
- Some oral drugs
- Some vaccines

**PATIENT’S RESIDENCE**
- Drugs requiring nebulizer or infusion pump (ie, DME drugs)
- Parenteral nutrition

**DIALYSIS CENTERS**
- Dialysis related (eg, erythropoietin for treatment of anemia)

Sources: MedPAC56, Medicare.gov57
Part B Medicines Represent Significant Medical Advances

**BREAKTHROUGHS IN CANCER**
Monoclonal antibodies are transforming the treatment of cancer and a broad range of other diseases. After many decades of research, there are nearly 20 monoclonal antibodies approved by the Food and Drug Administration to treat cancer. Antibody-based therapy has become an established strategy—and one of the most successful and important—for treating cancer in the past 15 years.58-60

**AVOIDING DEBILITATING DISEASE**
Biologic disease-modifying antirheumatic drugs (DMARDs) have transformed treatment for rheumatoid arthritis (RA) patients in the past 15 years. “Current therapy for RA is such that progression from symptom onset to significant disability is now no longer inevitable, and RA patients can anticipate comfortable and productive lives on medical therapy . . . Patients with RA can now expect to experience a quality of life that previously was unavailable to patients during the 20th Century.”61

**REMARKABLE ADVANCE AGAINST A CHALLENGING DISEASE**
A biologic medicine is providing an important breakthrough for patients with an unpredictable and life-threatening autoimmune disease. “This is a historic day for the millions of people with lupus and their families around the world who have waited more than 50 years for a treatment breakthrough for lupus.”62

– Sandra C Raymond, President and CEO of the National Lupus Foundation of America

Sources: Nature.com58; FDA59,60; Upchurch KS, Kay J61; Lupus Foundation of America62
Current Part B Drug Reimbursement Methodology Is Average Sales Price + 6%

AVERAGE SALES PRICES (ASP):

- Enacted in Section 303(c) of the Medicare Modernization Act
- Intended to reflect the weighted average of all manufacturer sales prices, net of rebates and discounts (except Medicaid and certain federal and other purchasers)
- Includes special rules for certain classes of drugs (e.g., durable medical equipment, infusion drugs, vaccines, biosimilars)

6% ADD-ON PAYMENT HELPS COVER:

- Geographic and provider purchasing variability
- Shipping fees
- Complex administration
- Ongoing patient monitoring and education
- Overhead for complex storing and handling requirements
- Bad debt and beneficiary copayment collection

Note: Due to federally mandated sequestration, ASP was reduced in 2013 by 1.6% and is currently ASP + 4.3%.

Sources: MMA63; Holtz-Eakin D, Zhong H64
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 into the Medicare Part B payment rate (called “Average Sales Price” or “ASP”) and can lead to lower costs to the Medicare program and beneficiaries.

Sources: 42 U.S.C. §1395w–3a (2003); MedPAC
Average Sales Price Is an Effective Pricing Mechanism for Part B

The Centers for Medicare & Medicaid Services’ (CMS’s) analysis of the ASP pricing mechanism found that for most higher volume drugs prices changed 2% or less, and prices for 17 of the top 50 drugs decreased.

“[T]here are a number of competitive market factors at work—multiple manufacturers, alternative therapies, new products, recent generic entrants, or market shifts to lower priced products.”

– CMS
Prescription Drug Share of Part B Expenditures

Program spending on prescription medicines accounted for about 8% of Part B spending in 2012.

Part B Expenditures, 2012

Physician Services and All Other Part B Spending 92%

Brand and Generic Drug Spending 8%

TOTAL $240.6 BILLION

Note: Part B drug spending includes Part B-covered drugs administered in a physician’s office or furnished by suppliers and Part B drugs provided in hospital outpatient departments. It does not include Part B-covered drugs provided to patients with end-stage renal disease in dialysis facilities.

Source: PhRMA analysis of data from MedPAC and CMS
Total Part B Drug Costs Have Been Relatively Stable

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

*2011-2012 are projections. Source: The Moran Company*69

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

*Source: The Moran Company*69
Average Price Growth in Medicare Part B Is Less Than Medical Inflation

While the Consumer Price Index for medical care (CPI-M) has increased since 2006, the volume-weighted Average Sales Price (ASP) for Medicare Part B drugs has remained essentially flat.

*Weighted ASP vs CPI-M*

Source: The Moran Company
Notes and Sources


5. PwC Health Research Institute. Implications of the US Supreme Court ruling on healthcare. Published June 2012.


Notes and Sources


17. Patient cost excludes premiums but includes all patient contributions to drug costs, such as copayments, coinsurance, and any amounts applied to the deductible.

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


Notes and Sources


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MEDICATIONS IN MEDICAID

Medicaid provides health coverage for low-income and disabled individuals and is jointly funded by states and the federal government. Under the Affordable Care Act, states have the option to expand Medicaid to all low-income adults. Each state administers its own Medicaid program within broad federal guidelines. Some states administer pharmacy benefits directly, while beneficiaries in other states receive pharmacy benefits from Medicaid managed care plans. Federal law requires manufacturers to pay rebates on many medicines sold to Medicaid beneficiaries, and often states negotiate for additional discounts. Policies meant to reduce utilization 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 Account for Approximately 3% of Total Medicaid Spending

Note: Professional services include physician and clinic, dental, and other professional services. Administration costs include federal and state administration and net cost of private insurance. Other health, residential, and personal care includes school health, work site, residential mental/substance abuse, some ambulance, and Medicaid home/community waivers.

Source: PhRMA analysis of data from CMS, HHS OIG, and The Lewin Group
Prescription Drugs Are Projected to Be a Small Share of Medicaid Spending Through 2023

In 2013, Medicaid drug spending, including brands and generics, was $21.2 billion, while total Medicaid spending was $449.4 billion.²

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*Years 2013 and beyond are projections. Other services not shown separately include durable and nondurable 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.

Sources: Hartman M, et al.²; CMS³
Medicaid Price Controls

As a condition of a drug being covered by Medicaid, drug manufacturers pay a rebate to the states and the Centers for Medicare & Medicaid Services 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 for the drug.*

- **AN ADDITIONAL REBATE**
  is paid by brand manufacturers if their AMP increases more than inflation.

- **ADDITIONAL STATE SUPPLEMENTAL REBATES**
  are also often required on brand medicines.

- **GENERIC MANUFACTURERS**
  also pay a statutory rebate of **13.0%** of AMP.

- **ACCORDING TO THE CONGRESSIONAL BUDGET OFFICE**
  Medicaid price controls distort the market, resulting in higher prices elsewhere.⁴,⁵

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In FY 2013, manufacturers paid Medicaid rebates totaling **$18.6 billion.**⁶

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*Certain brand medicines are subject to a different rebate percentage.

Sources: CBO⁴,⁵, The Menges Group analysis of CMS data⁶
“Average Manufacturer Price” Is Not the Average Price Received by Manufacturers

• Average Manufacturer Price (AMP) is defined in statute and is used to calculate Medicaid rebates.

• While originally intended only for use in the rebate calculation, over time 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 analysis of data from Medicaid.gov and CBO

2 • Medicaid
Medicaid Rebates on Prescription Medicines Are Increasing Substantially Under the Affordable Care Act

Independent analysts estimate that the Affordable Care Act (ACA) will increase the Medicaid prescription drug rebates brand manufacturers pay by $48 billion over 10 years (2016-2025).\(^8\)

Note: The graphic is illustrative only.

Source: PwC Health Research Institute\(^8\)
Initial Medicaid Costs for Medicines Greatly Overstate Costs Net of Rebates

On average, about 60% of the initial cost of brand medicines is returned to states through rebates.

How rebates dramatically lower costs for states:

<table>
<thead>
<tr>
<th>Initial cost of a brand medicine</th>
<th>$100.00</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manufacturer rebates returned to Medicaid*</td>
<td>$59.00</td>
</tr>
<tr>
<td>Cost to Medicaid of brand medicine net of manufacturer rebates</td>
<td>$41.00</td>
</tr>
</tbody>
</table>

Rebates from manufacturers repay Medicaid for about half of their initial ingredient costs for medicines. In addition to the rebate amount required by law, states and Managed Care Organizations (MCOs) often negotiate for additional rebates. Manufacturers may pay these rebates to obtain favorable placement for their medicines on preferred drug lists or managed care formularies.

*Includes statutory rebates and supplemental rebates negotiated by states and Medicaid MCOs or their pharmacy benefits managers.

Source: The Menges Group®
Medicaid Rebates Apply to More People Under ACA

Drug purchases by beneficiaries in Medicaid Managed Care Organizations became eligible for statutory rebates in 2010. Beginning in 2014, the Medicaid expansion allowed states to expand Medicaid to more adults, further increasing the number of people whose prescriptions are eligible for rebates.

*Point-in-time measurement

Source: PhRMA analysis of data from CBO, CMS, and Kaiser Family Foundation

Rebates Could Apply to as Many as 28 Million More People
Control Over Pharmacy Benefit in Medicaid Varies

In many states, Managed Care Organizations (MCOs) cover and set Medicaid pharmacy benefits for some or all beneficiaries, while in others, state government administers benefits directly or determines the drug list that plans must use. In some cases, benefits can be administered by either entity, depending on type of therapy.

Among Non-Dual Enrollees With Medicaid and Children’s Health Insurance Program (CHIP) Prescription Drug Coverage, Percentage Receiving Drug Benefits Through an MCO by State, 2015
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 (ie, PDLs) with Centers for Medicare & Medicaid Services approval. Patients seeking access to medicines not on the PDL must obtain prior authorization. In some cases, exceptions to script limits are made for individuals with certain conditions or other special circumstances.

Source: Kaiser Commission on Medicaid and the Uninsured and Georgia Department of Community Health
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.

"Access restrictions may deter patients, especially vulnerable low-income patients, from adhering to important therapies, which could ultimately drive up long term medical costs."

– David Ridley and Kirsten Axelsen

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

Source: Ridley D, Axelsen K15
Patients Facing Access Restrictions Incur Greater Medical Spending

Non-elderly Medicaid patients facing formulary restrictions* for antipsychotic medications were 7% to 13% more likely to be hospitalized and had higher medical costs than patients in states without formulary restrictions.

*Restrictions examined: prior authorization, step therapy, and quantity limits

Source: Seabury SA, et al.16

**Medicaid Total Annual Medical Expenditures, Per Patient (2008)**

- **Schizophrenia**
  - Without Formulary Restrictions: $10,952
  - With Formulary Restrictions: $13,299

- **Bipolar Disorder**
  - Without Formulary Restrictions: $12,344
  - With Formulary Restrictions: $13,735

*Restrictions examined: prior authorization, step therapy, and quantity limits

Source: Seabury SA, et al.16
Increased Use of Medicines Reduces Other Medicaid Costs

Similar to the Congressional Budget Office’s findings in Medicare, increased use of medicines among Medicaid patients decreases other Medicaid costs.\textsuperscript{17} This pattern is seen across Medicaid populations.

\textit{Percent Impact of a 1\% Increase in Prescription Drug Utilization on Medicaid Costs}\textsuperscript{18}

\begin{table}
\begin{tabular}{|c|c|c|}
\hline
\textbf{Inpatient Costs} & \textbf{Outpatient Costs} \\
\hline
-0.31\% & -0.05\% \\
-0.24\% & -0.18\% \\
-0.14\% & -0.13\% \\
\hline
\end{tabular}
\end{table}

Note: All results are statistically significant (p<0.01)

Sources: CBO\textsuperscript{17}, Roebuck MC, et al.\textsuperscript{18}
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.

*Outcomes were measured during 6-month periods before and after a copay increase in Georgia. Impact estimates are adjusted to reflect changes in a similar state with no change in copays over the same period. “Rx days” is the number of prescriptions multiplied by the number of days supply over a 6-month period.

Source: Subramanian S19
Notes and Sources

1. Pharmaceutical Research and Manufacturers of America analysis based on data from Centers for Medicare & Medicaid Services, National health expenditures, 2013; US 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; and The Lewin Group, Potential federal and state-by-state savings if Medicaid pharmacy programs were optimally managed, February 2011.


6. The Menges Group analysis based on Centers for Medicare & Medicaid Services data. Financial management report, FY2012-2013. Medicaid.gov Web site. http://medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Data-and-Systems/MBES/CMS-64-Quarterly-Expense-Report.html. Accessed January 2015. In 13 states, the rebate amounts reported on the CMS-64 reports for FFY 2014 did not fall within a range believed to be credible given the statutory Medicaid rebate parameters. In these states, FFY 2014 rebate amounts have been estimated by The Menges Group such that all states’ rebates fall within a range of 40%-62% of initial (prerebate) Medicaid payments to pharmacies.


8. The 2012 PwC estimate of $40 billion cost grew to $48 billion to reflect growth in Medicaid spending as estimated by the Centers for Medicare & Medicaid Services. The increased Medicaid rebates that PwC reports do not include the cost of paying those larger rebates for individuals who will newly receive Medicaid coverage under the Affordable Care Act. PwC Health Research Institute. Implications of the US Supreme Court ruling on healthcare. August 2012.


11. Denotes a partial carve-out state—a state in which certain classes of drugs are not included in the drug benefit provided by Managed Care Organizations (MCOs) but are provided directly by the state. Drugs commonly excluded from MCO contracts as partial carve-outs include mental health, hemophilia, substance abuse, and HIV/AIDS products.

12. Denotes states that use Managed Care Organizations (MCOs) to cover some or all beneficiaries (including drug benefits), but require MCOs to adhere to a state-generated drug list. In these states, MCOs have minimal control over drugs’ formulary placement and utilization management; accordingly, these lives are counted here as fee-for-service. Louisiana currently allows MCOs to set their own formularies but plans to adopt a unified formulary approach by September 2015.


Notes and Sources


The US Department of Veterans Affairs (VA) serves a special population—veterans with service-related disabilities and, in some cases, their families. The VA administers a smaller drug benefit and serves a smaller population than Medicare and Medicaid. 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 Four” government agencies: the VA, US Department of Defense, US Public Health Service, and US Coast Guard.

- Pharmaceutical companies are required to sell medicines at the lower of two controlled prices:

  1. **FEDERAL CEILING PRICE (FCP)**
     FCP requires 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, the VA requires further discounts below the FCP.
VA Formulary Covers Fewer Drugs Than Part D

For 2015, the VA formulary included a lower share of the top 200 Part D drugs relative to stand-alone Prescription Drug Plans (PDPs) and Medicare Advantage Prescription Drug (MA-PD) Plans.

Average Coverage of Top 200 Medicare Part D Drugs by VA National Formulary, PDPs and MA-PDs, 2015

- VA National Formulary: 81.5% (163 drugs)
- PDP: 95.5% (191 drugs)
- MA-PD Plans: 97% (194 drugs)

Note: Avalere Health analysis of VA National Formulary data (March 2015) and DataFrame®, a proprietary database of Medicare Part D plan features. 2015 plan data were released in October 2014. PDP and MA-PD Plan coverage data are enrollment-weighted using February 2015 enrollment data.

Source: Avalere Health²
Veterans Prefer More Drug Coverage Than VA Offers

VA enrollees obtain many prescriptions outside the VA system.

Sources: VA3-7

![Enrollees Planning to Use VA System Primarily for Prescriptions](chart)

![Prescriptions Obtained Outside VA System](chart)

Sources: VA3-7
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.

Of Prescriptions Written for Veterans by Community Physicians...

- 58% Available on the VA Formulary
- 42% Not Available on the VA Formulary
- 35% Were Converted to the VA Formulary
- 65% Could Not Be Converted to the VA Formulary

Total Number of Prescriptions Written

Of Prescriptions Not Initially Available on the VA Formulary

*VA pharmacists worked with community physicians to convert prescriptions to the VA formulary. Results are through week 20 of the pilot program.

Source: Dr. Jonathan Perlin, Deputy Under Secretary of Health, VA
Many VA Enrollees Supplement Their VA Drug Coverage With Part D or Private Insurance

Nearly 7.9 million veterans were enrolled in the VA health care system in 2011; nearly 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, 2011*

Source: VA10
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.

Source: Safran DG, et al.11

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**Beneficiaries Reporting Non-Adherence to Rx Therapy**

- **Cost-Related Non-Adherence**:
  - VA, 2003: 22.5%
  - Part D, 2006: 11.8%

- **Didn't Fill Rx 1+ Times**:
  - VA, 2003: 14.5%
  - Part D, 2006: 7.0%

- **Taking Smaller Doses of Rx**:
  - VA, 2003: 16.9%
  - Part D, 2006: 4.8%

Source: Safran DG, et al.11
Notes and Sources


8. The transitional pharmacy benefit was a temporary program to help veterans who were unable to schedule an initial primary care appointment with a VA doctor within a 30-day 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.


The 340B program was created in 1992 to help vulnerable or uninsured patients served by safety net facilities. The program requires pharmaceutical manufacturers to provide steep discounts to certain types of clinics and hospitals as a condition of their drugs being covered by Medicaid.

Many clinics qualify for 340B based on receiving certain federal grants. These grants typically require 340B clinics to use revenue from the program to improve services to the vulnerable patients they serve. Hospitals and their satellite clinics qualify based on a range of criteria that are not tied to obligations to reinvest resources into care for uninsured or vulnerable patients.

Hospital participation in the program has increased over time; now about 45% of all Medicare acute care hospitals participate in 340B. The program bears little resemblance to what Congress envisioned in 1992. Its reach has expanded in part through both hospital purchases of community-based physician practices and through prescriptions filled at retail pharmacies, also known as contract pharmacies. The program is projected to nearly double in size, from more than $8 billion in 2014 to more than $16 billion in 2019.
340B: Past and Present

1992

340B was envisioned as a small program to address unintended consequences of the 1990 Medicaid drug rebate statute by reinstating deep discounts that pharmaceutical manufacturers had voluntarily provided to certain clinics and true safety net hospitals.

Early 2000s-Present

Insufficient guidance, historically weak oversight, and other factors led to dramatic program growth, driven by the participation of large hospitals in the 340B program.

“[340B] has expanded beyond its bounds.”

– Kathleen Sebelius, Former HHS Secretary, 2014

**Hospitals Participating in 340B**

<table>
<thead>
<tr>
<th>Year</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>1992</td>
<td>51</td>
</tr>
<tr>
<td>2002</td>
<td>151</td>
</tr>
<tr>
<td>2015</td>
<td>2,228</td>
</tr>
</tbody>
</table>

Sources: US Senate hearing on President’s fiscal year 2015 health care proposals\(^1\); BRG analysis of HRSA OPA 340B Database\(^2\)
How 340B Discounts Work

1. Manufacturer provides 340B hospital with discounted drug
2. 340B hospital provides medicines to patients, including those with commercial insurance
3. Insurer reimburses at full negotiated rate; hospital keeps difference as profit

Source: AIR 340B³
How Entities Qualify to Participate in 340B

340B DESIGNATION
Unlike government programs designed to provide insurance coverage, patients do not enroll in 340B. Instead, the 340B designation applies to the hospital or clinic, which may claim steep discounts on outpatient drugs dispensed to all patients regardless of whether the patients are insured or uninsured.
A hospital’s satellite or child sites do not have to meet the 340B criteria to obtain discounts, even if all their patients are fully insured.

340B ELIGIBILITY
The key metric determining whether a nonprofit hospital is eligible for 340B is the Disproportionate Share Hospital (DSH) percentage.
DSH is a calculation based on inpatient admission of low-income Medicare and Medicaid beneficiaries.
Congress believed DSH eligibility would target safety net facilities, however, research has since shown that the DSH percentage does not correlate with the amount of uncompensated or charity care a hospital provides or the number of uninsured persons it cares for.4

GRANTEES
Clinics, rural facilities, and other entities qualify largely based on the receipt of a federal grant from the Health Resources and Services Administration (HRSA) to support care for vulnerable populations.

Sources: MedPAC4,5; HRSA6
Disproportionate Share Hospitals Are Driving Current Volume and Future Program Growth

Disproportionate Share Hospitals (DSHs) drive 81% of 340B sales volume but only make up 9% of 340B entities.

Sources: Apexus⁷; Avalere Health analysis of HRSA OPA 340B Database⁸
No Meaningful Standards to Ensure Disproportionate Share Hospitals Are Providing Care to Low-Income Patients

Nonpublic hospitals must meet criteria that show they 1) have been formally delegated governmental powers by a state or local government, or 2) have a contract to provide care to low-income or uninsured patients. However, the US Government Accountability Office (GAO) noted that there are no meaningful standards for the second criterion.

Rep. Larry Bucshon, MD (IN-08):
“I am assuming you think additional steps are needed for the program’s eligibility criteria for hospitals to be consistent with the program’s mission to support entities that care for uninsured and vulnerable patients?”

Debra A. Draper, GAO:
“Yes. We believe the guidance needs to be clear as to who participates.”

Source: US House hearing on examining the 340B drug pricing program
Current Hospital Eligibility Criteria Do Not Match Program Goals

- Most 340B hospitals qualify to dispense 340B outpatient drugs based on the share of inpatient days used by low-income Medicare and Medicaid beneficiaries.
- Counterintuitively, as a hospital treats fewer uninsured patients, it generally becomes more likely to qualify for 340B. In particular, the expansion of Medicaid eligibility, which has decreased uncompensated care, has also led to more hospitals qualifying for 340B.

In 2014, 45% of all Medicare Acute Care Hospitals PARTICIPATED IN 340B.

“In 2007 the Commission noted that DSH payments were not well targeted at hospitals with high uncompensated care costs.”
– Medicare Payment Advisory Commission, 2014

Sources: MedPAC10,11
Most 340B Hospitals Provide Little to Below Average Levels of Charity Care

Sixty-nine percent of 340B hospitals report charity care levels below the national average (3.3%); 24% report levels below 1% of total costs.

Distribution of 340B Hospitals by Level of Charity Care as a Percent of Patient Costs Provided*

- Above Average Charity Care: 16%
- Slightly Above Average Charity Care: 15%
- Minimal Charity Care: 24%
- Below Average Charity Care: 45%

69% of 340B hospitals have CHARITY CARE RATES below the 3.3% national average for all hospitals

*The national average charity care rate for all hospitals is 3.3% of total costs. Hospitals are defined as providing 0%-1% of total costs as minimal, 1%-3.3% as below average, 3.3%-5% as slightly above average, and 5%-10% as above average.

Source: AIR 340B12
Combination of Vague Rules Defining a Patient and Lack of Enforcement Leads to Program Abuse

- The lack of an appropriate patient definition means hospitals can profit from 340B discounts for patients whose prescriptions should not qualify for 340B.
- Without a clear definition of a 340B patient, it is difficult for audits of 340B hospitals to identify instances where discounts are diverted to prescriptions that are ineligible for 340B because the patient does not meet the patient definition.

“HRSA’s current guidance on the definition of a 340B patient is sometimes not specific enough to define the situations under which an individual is considered a patient of a covered entity for the purposes of 340B.”

– US Government Accountability Office

“[There is] a lack of clarity on how HRSA’s patient definition should be applied in contract pharmacy arrangements.”

– Office of Inspector General

Sources: GAO¹³; OIG¹⁴
Hospitals and Grantees Have Different Requirements for Use of 340B

Grantees eligible for 340B on the basis of a federal grant use revenue from 340B and other sources to help vulnerable patients. Unlike grantees, hospitals face no such requirements.


**Hospitals eligible for 340B include Children's Hospitals, Critical Access Hospitals, Disproportionate Share Hospitals, Free-Standing Cancer Hospitals, Rural Referral Centers, and Sole Community Hospitals.

Source: HRSA15
340B Can Increase Revenue for Hospitals Purchasing Physician Practices While Raising Health Care Costs

Higher rates are paid for care provided at hospital outpatient sites compared to care provided in physician offices.\textsuperscript{16,17} The availability of 340B discounts allows 340B hospitals to generate more revenue than independent physician offices for administering the same medicine.

340B hospitals are more likely than other hospitals to purchase independent physician offices that administer medicines.\textsuperscript{18} This may be partially due to 340B hospitals’ ability to gain additional revenue through 340B discounts by reclassifying the physician practice as a hospital outpatient site. In addition, research has shown that these sites are often located in relatively higher income areas,\textsuperscript{19} raising questions about who is truly benefitting from hospital consolidation.

**340B Participation Among Hospitals**

<table>
<thead>
<tr>
<th>Percentage of Hospitals Participating in 340B</th>
</tr>
</thead>
<tbody>
<tr>
<td>All Hospitals: 45%</td>
</tr>
<tr>
<td>Hospitals with a Potential Practice Acquisition: 61%</td>
</tr>
</tbody>
</table>

Sources: IMS Institute for Healthcare Informatics\textsuperscript{16}; BRG\textsuperscript{17}; Avalere Health\textsuperscript{18}; Conti RM, Bach PB\textsuperscript{19}
Retail Pharmacies Extend the Reach of the 340B Program, But Do Not Always Help Patients

Here's How It Works When 340B Discounts Are Extended to Retail Pharmacies Through Contract Pharmacy Arrangements

Uninsured patient gets sick

Uninsured patient gets treated at a 340B hospital

Patient goes to 340B contract pharmacy and fills prescription at full retail price ($100)

Drug qualifies for $50 340B discount, which is split between the hospital and pharmacy

The hospital and pharmacy profit while the patient may see no direct benefit from the 340B discount.

Source: AIR 340B

20
In 1996, the Health Resources and Services Administration (HRSA) stated that it would allow 340B entities without their own pharmacy to access 340B discounts through a contract with a single retail pharmacy. This “contract pharmacy” program was dramatically expanded in 2010 to allow any entity to have an unlimited number of contract pharmacies. Although the original intent of the contract pharmacy program was to help small clinics without their own in-house pharmacy, large hospitals are now more likely than small clinics to have large networks of contract pharmacies.

*Large as measured by top 20% of hospitals, based on total outpatient revenue

Sources: OIG\textsuperscript{21}, Catalyst\textsuperscript{22}
Uninsured Rate Is Dropping, Yet Participation in 340B Retail Pharmacy Program Is Growing

The number of contract pharmacy arrangements has increased dramatically as the percentage of individuals without drug coverage has fallen. Pharmacies can generate higher returns by dispensing 340B prescriptions than other prescriptions.23 In 2014, 44% of all contract pharmacies were Walgreens.24

*Each relationship between a 340B entity and a contract pharmacy is counted separately for this analysis. Some pharmacies have relationships with more than one 340B entity, and those pharmacies are counted more than once in this analysis.

Sources: Talyst23; BRG24; Avalere Health25,26
Without Significant Reforms 340B Will Continue to Grow As Uninsured Rate Declines

- Simply enforcing current rules will not be sufficient to tailor the program to match Congress’ original intent. Instead, 340B policies and structure require fundamental reform.
- Unless there are changes to hospital eligibility, the patient definition, and contract pharmacy rules, 340B will continue to grow at a time when fewer people lack prescription drug coverage and hospital uncompensated care is declining.27

*Trends in 340B Drug Purchases and Percentage of Total Population Without Prescription Drug Coverage*

Sources: DeLeire T, et al.27; Vandervelde A28; Avalere Health analysis of data from CBO Medical Expenditure Panel Survey, Census, and Medicare Trustees29
Notes and Sources


Notes and Sources


29. 2014 data based on Avalere Health analysis for the Pharmaceutical Research and Manufacturers of America of the Congressional Budget Office Medical expenditure panel survey. Projections are based on Avalere Health analysis for the Pharmaceutical Research and Manufacturers of America of CBO, US Census, and Medicare Trustees report data.