Measuring the Relative Size of the 340B Program

2020 Update

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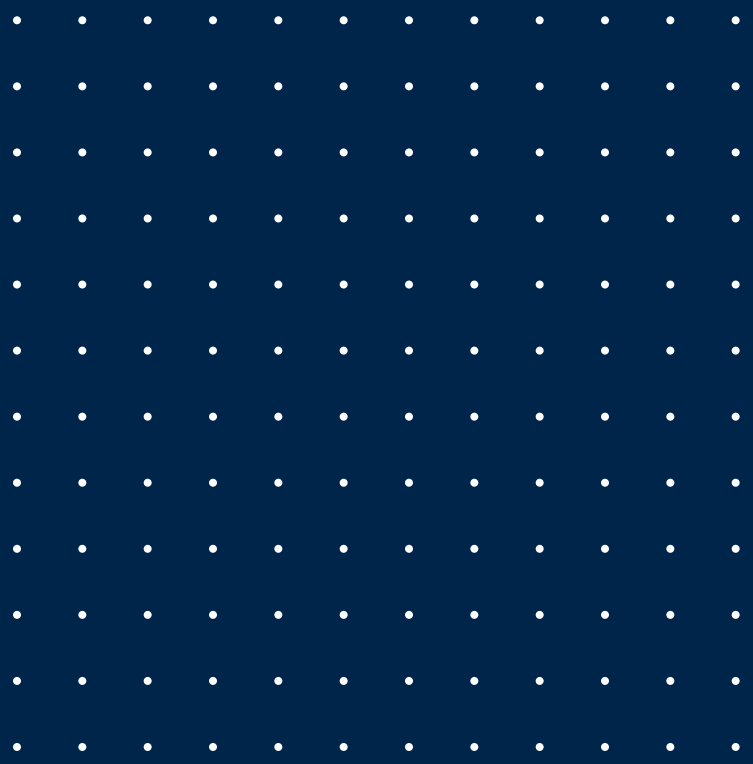

Background

The 340B Drug Pricing Program ("340B program") has experienced substantial growth over the past decade, driven by increased participation in the program, hospital and provider consolidation,[1] and expansion of contract pharmacy arrangements.

In 2020, total 340B program sales reached $38.8 billion when measured at the discounted 340B price. This figure represents enormous growth—more than three times the level of 340B sales compared to just five years prior.[2] However, $38.8 billion does not adequately represent the true size of the 340B program, as 340B prices were, on average, 59 percent lower than list prices in 2020,[3] and the discounted 340B price for some medicines is just a penny. Expressed in terms of the *undiscounted* list price, measured as the wholesale acquisition cost (WAC), 340B sales reached $93.6 billion in 2020.

This study seeks to place the size of the 340B program into perspective through a comparison to other federal prescription drug programs and to the overall market for brand outpatient pharmaceuticals in the United States.

1 See Sunita Desai and J. Michael McWilliams, "Consequences of the 340B Drug Pricing Program," New England Journal of Medicine 378:539-548 (2018). https://www.nejm.org/doi/full/10.1056/nejmsa1706475

2 340B Industry Roundtable, "340B Program at a Glance," Berkeley Research Group (BRG) (December 2021). https://media.thinkbrg.com/wp-content/uploads/2021/12/09062840/340B_Forecast-Report-Infographic_2021.pdf.

3 Estimate developed based on analysis of publicly available data on historical list prices, inflation, and commercial discounting.

Size of 340B Compared to Other Federal Programs

Medicare Parts B and D cover outpatient prescription drugs[5] and are administered by the Centers for Medicare & Medicaid Services (CMS).

Medicare Part D primarily covers medicines that patients receive from a retail or mail-order pharmacy and administer themselves. CMS reports total reimbursement for medicines under Part D was $199 billion in 2020. This includes the amount paid by patients out of pocket and discounts paid in the coverage gap by pharmaceutical manufacturers, but it generally does not reflect rebates or other price concessions negotiated by Part D plans and pharmacy benefit managers (PBMs).[6] The average rebate for medicines covered under Part D was 27 percent across all brand and generic medicines in 2020, accounting for both pharmaceutical rebates as well as pharmacy price concessions and weighted by sales.[7] Discounts paid in the coverage gap by pharmaceutical manufacturers represented an estimated $17.6 billion for 2020.[8] Applying these discounts to total reimbursement for medicines, net Part D spending totaled $127.4 billion in 2020.

FIGURE 1: TOTAL OUTPATIENT NET MEDICINE SPENDING ($B) BY GOVERNMENT PROGRAM, 2020[4]

	TOTAL NET SPENDING
Part D	$127.40
340B	$38.80
Part B	$38.50
Medicaid	$32.60
TRICARE/DoD	$8.00

Medicare Part B primarily covers medicines that are administered by a healthcare provider in a physician office or hospital outpatient department.[9] CMS reports total Part B reimbursement for medicines, typically based on average sales price (ASP) data, in the Medicare Part B Spending by Drug database. In 2020, net Part B drug spending totaled $38.5 billion, inclusive of amounts paid by patients out of pocket and by supplemental insurers on patients' behalf.[10]

Medicaid, which is administered jointly by CMS and state governments, reimburses for prescription drugs both directly to pharmacies and indirectly through managed care organizations (MCOs). The Medicaid and CHIP Payment and Access Commission (MACPAC) reports total Medicaid reimbursement for medicines in the annual publication *MACStats: Medicaid and CHIP Data Book*. In 2020, total Medicaid reimbursement for medicines, including amounts borne by federal and state governments and patients out of pocket, totaled $71.8 billion.[11] In 2020, rebates on medicines covered by the Medicaid program totaled $39.2 billion.[12] Accounting for these discounts, net Medicaid spending on medicines totaled $32.6 billion in 2020.

4 While the other federal programs evaluated are payers, 340B is fundamentally a drug purchasing program. To compare the magnitude of the various programs, the most appropriate unit of measure is the price paid by covered entities (in the case of 340B) or the government payer and its beneficiaries (in the case of Parts B and D, Medicaid, and TRICARE), net of all discounts offered by manufacturers or pharmacies.

5 Medicare reimburses providers indirectly, through managed care plans, for Part D.

6 CMS, *Medicare Part D Spending by Drug* (latest data available, 2020). https://data.cms.gov/summary-statistics-on-use-and-payments/medicare-medicaid-spending-by-drug/medicare-part-d-spending-by-drug.

7 Medicare Trustees, *2022 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds* (June 2, 2022). https://www.cms.gov/files/document/2022-medicare-trustees-report.pdf

8 Andrew Brownlee and Jordan Watson, *The Pharmaceutical Supply Chain, 2013-2020*, BRG (January 2022). https://ecommunications.thinkbrg.com/44/2328/uploads/brg-pharmaceutical-supply-chain-2022.pdf?intlaContactId=lXKabwLWBtOm%2fz%2fpgW%2btPQ%3d%3d&intExternalSystemId=1

9 MedPAC, *Part B Drugs Payment Systems* (revised November 2021). https://www.medpac.gov/wp-content/uploads/2021/11/medpac_payment_basics_21_partb_final_sec.pdf

10 CMS, *Medicare Part B Spending by Drug* (latest data available, 2020). https://data.cms.gov/summary-statistics-on-use-and-payments/medicare-medicaid-spending-by-drug/medicare-part-b-spending-by-drug.

11 MACPAC, *MACStats: Medicaid and CHIP Data Book*, Exhibit 28 (December 2021). https://www.macpac.gov/wp-content/uploads/2021/12/MACStats-Medicaid-and-CHIP-Data-Book-December-2021.pdf.

12 Ibid.

Even at the discounted 340B price, the 340B program is larger than all other federal drug programs considered, except for Medicare Part D.

TRICARE, which is administered by the Department of Defense (DoD), reimburses for prescription drugs for active-duty members of the military and their dependents. The Military Health System reports TRICARE net outpatient medicine spending (including beneficiary copayments) in congressional reports. In 2020, this spending totaled $8 billion.[13]

The 340B program, which is administered by the Health Resources & Services Administration (HRSA) Office of Pharmacy Affairs (OPA), provides certain healthcare providers (referred to as "covered entities") access to deeply discounted outpatient medicines for qualifying patients. HRSA and its third-party vendor, Apexus, report partial 340B sales at the discounted 340B price. Adjustments were made to include direct sales, AIDS Drug Assistance Program (ADAP) rebate sales, and specialty distributor sales not included in the HRSA-reported figure.[14] With these adjustments, net 340B medicine spending totaled $38.8 billion in 2020.

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Despite the size of the 340B program, HRSA OPA had a budget of only $10 million in fiscal year 2020,[15] compared to the $733 million budgeted for federal administration at CMS.[16] Additionally, the data reported by HRSA OPA on the 340B program is significantly more limited than what is reported for other programs. HRSA OPA released just one figure on 2020 program utilization, which was provided only in response to a Freedom of Information Act request.[17] This disclosure included the total amount of indirect 340B sales as reported by Apexus, a figure that excludes an unknown share of sales at the 340B price, conservatively estimated here at 2 percent.

In comparison, CMS provides detailed reports on utilization and spending by drug in both Medicare Parts B and D and high-level figures on Part D rebates paid by manufacturers and pharmacies.[18] Similarly, Medicaid reports data on gross spending by drug,[19] as well as aggregated manufacturer rebate amounts.[20] TRICARE reports annual drug spending by dispensing pharmacy type, as well as certain offsets including manufacturer payments under the Retail Refund Program.[21]

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13 Military Health System, *Evaluation of the TRICARE Program: Fiscal Year 2021 Report to Congress* (February 26, 2021). https://www.health.mil/Military-Health-Topics/Access-Cost-Quality-and-Safety/Health-Care-Program-Evaluation/Annual-Evaluation-of-the-TRICARE-Program.

14 The data reported by Apexus were assumed to include 98 percent of total 340B drug sales at the 340B price. This is a conservative estimate given historical MedPAC reporting that Apexus data accounts for 90 to 95 percent of total 340B sales. See MedPAC, *Report to the Congress: Overview of the 340B Drug Pricing Program* (May 2015). https://www.medpac.gov/document/http-www-medpac-gov-docs-default-source-reports-may-2015-report-to-the-congress-overview-of-the-340b-drug-pricing-program-pdf/

15 Department of Health and Human Services, *Fiscal Year 2021 Health Resources and Services Administration Justification of Estimates for Appropriations Committees* (FY 2020 enacted). https://www.hrsa.gov/sites/default/files/hrsa/about/budget/budget-justification-fy2021.pdf.

16 Department of Health and Human Services, *Fiscal Year 2021 Centers for Medicare and Medicaid Services Justification of Estimates for Appropriations Committees* (FY 2020 enacted). https://www.cms.gov/About-CMS/Agency-Information/PerformanceBudget/FY2021-CJ-Final.pdf.

17 Adam J. Fein, "Exclusive: The 340B Program Soared to $38 Billion in 2020—Up 27% vs 2019," Drug Channels (June 16, 2021). https://www.drugchannels.net/2021/06/exclusive-340b-program-soared-to-38.html.

18 Medicare Trustees (2022).

19 CMS, State Drug Utilization Data, Medicaid.gov (last updated February 7, 2022). https://www.medicaid.gov/medicaid/prescription-drugs/state-drug-utilization-data/index.html.

20 MACPAC (2021).

21 Military Health System (2021).

340B as Percentage of Market

Medicines purchased through the 340B program are limited to outpatient drugs and are composed primarily of branded pharmaceuticals. This means that a like-to-like comparison of the 340B program to overall pharmaceutical sales in the US should exclude inpatient drugs and generics. Additionally, a valid comparison must rely on a common unit of measure. To develop this comparison, we performed the following steps:

1. Adjust 2020 340B sales from the discounted 340B price to the undiscounted list price (WAC).

FIGURE 2

	2020
Total 340B Purchases at WAC Price	$93,647

Note: amount in millions

2. Adjust 2020 340B sales at the list price to exclude approximately 10 percent of sales for generic drugs.[22]

FIGURE 3

	2020
Total Branded 340B Purchases at WAC Price	$84,282

Note: amount in millions

3. Adjust IQVIA estimates of total US non-generic sales for 2020[23] to exclude inpatient hospital sales, based on a ratio of inpatient to outpatient drug spend derived from hospital data collected by the California Department of Health Care Access and Information (HCAI).[24]

FIGURE 4

	2020
Total Outpatient Branded Drug Sales at WAC Price	$485,916

Note: amount in millions

Using this methodology, we estimate that 340B sales accounted for 17 percent of total US branded outpatient drug sales in 2020 (see Figure 5), more than twice what they represented in 2015 (see Figure 6).[25]

FIGURE 5

	2020
Total Branded 340B Purchases at WAC Price	$84,282
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Total Outpatient Branded Drug Sales at WAC Price	$485,916
340B Purchases as % of Outpatient Branded Drug Sales	17.3%

Note: amount in millions

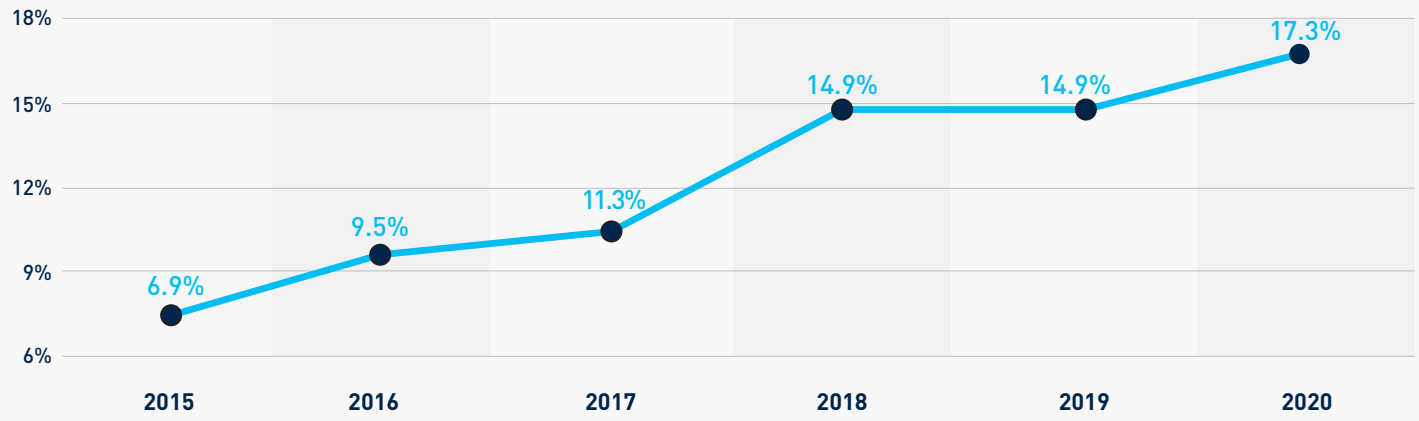
22 See Bobby L. Clark, John Hou, Chia-Hung Chou, Elbert S. Huang, and Rena Conti, "The 340B Discount Program: Outpatient Prescription Dispensing Patterns Through Contract Pharmacies in 2012," *Health Affairs* 33: 11 (2014). https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2014.0833 This study calculated the percentage of branded prescriptions dispensed by Walgreens' pharmacies in 2012 (18 percent), as well as the same percentage for 340B prescriptions (46 percent). To convert these quantity breakdowns into dollar-based breakdowns, this study assumes that the proportion of branded drug spend to all drug spend estimated by IQVIA for 2012 is identical to the proportion at Walgreens in 2012. This implies that branded prescriptions accounted for 72 percent of all 2012 Walgreens prescriptions in dollar terms and that the average spend per branded prescription dispensed by Walgreens in 2012 was nearly twelve times that of a generic. Using this ratio, an estimated 91 percent of 2012 Walgreens' 340B prescriptions were branded, in dollar terms. This study assumes that the 340B branded/generic spending breakdown is similar for physician-administered drugs that would not be dispensed through retail pharmacies such as Walgreens. This assumption is supported by a June 2011 HHS OIG study, which found that brand drugs account for more than 90 percent of spending on physician administered drugs in Medicaid; see *States' Collection of Medicaid Rebates for Physician Administered Drugs* (June 2011). https://oig.hhs.gov/oei/reports/oei-03-09-00410.pdf.

23 IQVIA Institute, *The Use of Medicines in the U.S. 2022* (April 2022). https://www.iqvia.com/insights/the-iqvia-institute/reports/the-use-of-medicines-in-the-us-2022. Estimate of percent of sales to nonfederal hospital based on IQVIA Institute, *The Use of Medicines in the U.S. A Review of 2017 and Outlook to 2022* (April 2018). https://www.iqvia.com/insights/the-iqvia-institute/reports/medicine-use-and-spending-in-the-us-review-of-2017-outlook-to-2022.

24 California Health and Human Services Agency, "Hospital Annual Financial Disclosure Report – Complete Data Set: 2019-2020 Fiscal Year Hospital Annual Financial Data," HCAI (November 2021). https://data.chhs.ca.gov/dataset/hospital-annual-financial-disclosure-report-complete-data-set.

25 Previous estimates of the relative size of the340B program incorporated the most recently available data at the time of publication. Figures in this report may vary slightly from prior estimates due to changes in the underlying data sources. See Aaron Vandervelde, *Measuring the Relative Size of the 340B Program: 2018 Update*, BRG Healthcare (June 2020). https://www.thinkbrg.com/insights/publications/measuring-the-relative-size-of-the-340b-program-2018-update/

FIGURE 6: 340B PURCHASES AS PERCENTAGE OF OUTPATIENT BRANDED DRUG SALES



Conclusion

The 340B program is now the second largest pharmaceutical program under the purview of a federal agency. As the 340B program has grown, it has come to represent an increasingly large share of branded outpatient drug sales. Nevertheless, comprehensive data on the program remains sparse and program guidance remains vague.

This growth in 340B has had unintended consequences and may contribute to shifts in the site of care, which can increase costs to both payers and patients.[26] Additionally, with no available data on how covered entities use the margin earned from 340B drugs (the difference between reimbursement and the discounted 340B price), the overall benefit of the program to patients is unclear.

Without additional transparency into a program that represents nearly one in five branded outpatient drugs purchased in the United States today, it is impossible to understand the full impact of this program on the overall healthcare system and on patients.

26 Aaron Vandervelde, Henry Miller, and JoAnna Younts, *Impact on Medicare Payments of Shift in Site of Care for Chemotherapy Administration*, BRG white paper (June 2014), accessed at: https://www.thinkbrg.com/insights/publications/impact-on-medicare-payments-of-shift-in-site-of-care-for-chemotherapy-administration/

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Eleanor Blalock is a member of the Health Analytics practice. She currently concentrates on healthcare-related strategy and litigation consulting with a focus on data analysis.

She specializes in leveraging large datasets to gain insight into the opportunities and risks facing healthcare entities. She works with clients across the healthcare industry, including pharmaceutical manufacturers, industry groups, hospitals, pharmacy benefit managers, and insurers.

Ms. Blalock has significant experience assisting clients with aspects of the 340B drug discount program. She has published extensively on issues related to 340B and on pharmaceutical pricing issues generally.