
Measuring the Relative Size of the 340B Program: 2017 Update

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Background

In recent years, the 340B Drug Discount Program has come under increased scrutiny from government agencies and others who have noted the negative impact the program may have on the broader market for pharmaceuticals.² This impact is in part due to the program's increasing size relative to the overall pharmaceutical market. Since 2010, the 340B program has expanded at an average annual growth rate of just under 21 percent and has grown by 114 percent in the last three years alone.³ In May 2018, the Health Resources and Services Administration (HRSA) reported that in 2016, 340B covered entities purchased more than \$19 billion in drugs at the 340B price.⁴

This study evaluates the accuracy of an often-cited statistic that estimated 340B sales at only 1.3 percent of annual US drug sales in 2015.⁵ This statistic compares total 340B discounts in 2015 to total US net drug spend in 2015. A more accurate measure of the 340B program, and the measure used in this study, is to compare total *gross* 340B purchases to the total gross potential market for which 340B purchased drugs are eligible. By law, the 340B program is limited to a subset of the overall US pharmaceuticals market, because 340B purchased drugs are exclusively for outpatient use and for qualifying entities under the law. Because approximately 90 percent of utilization in the 340B program is on branded drugs⁶ (versus 77 percent in the US market overall⁷), we further limit this analysis to branded drugs. For purposes of this study, we define the 340B program's addressable market as total US branded drug sales at the manufacturer's wholesale acquisition cost (WAC) less drugs purchased for use in an inpatient setting.

340B Purchases as Percentage of Outpatient Branded Drug Sales¹

2012	5.4%
2013	5.7%
2014	5.9%
2015	6.6%
2016	8.9%
2017	10.1%

- 1 Since publication of our previous paper "Measuring the Relative Size of the 340B Program: 2012-2017" in the summer of 2017, the Medicaid and CHIP Payment and Access Commission (MACPAC) released 2016 data on Medicaid rebates as a percent of gross drug costs. Because it is the most recent data available to estimate the average 340B discount, we have utilized this updated data in our calculations for both 2016 and 2017. To the extent that the 2017 average Medicaid rebate percentage exceeds the 2016 percentage, our 2017 results could be understated.
- 2 US Government Accountability Office (GAO), *Medicare Part B Drugs: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals* (June 2015), accessed at: <http://www.gao.gov/assets/680/670676.pdf>; Rena M. Conti and Meredith B. Rosenthal, "Pharmaceutical Policy Reform—Balancing Affordability with Incentives for Innovation," *N Engl J Med* 374:8 (February 25, 2016); GAO, *Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement* (June 2018), accessed at: <https://www.gao.gov/assets/700/692697.pdf>
- 3 Adam J. Fein, "Exclusive: The 340B Program Hits \$16.2 Billion in 2016; Now 5% of U.S. Drug Market" Drug Channels (May 18, 2017), accessed at: <http://www.drugchannels.net/2017/05/exclusive-340b-program-hits-162-billion.html>; Adam J. Fein, "Exclusive: The 340B Program Reached \$19.3 Billion in 2017—As Hospitals' Charity Care Has Dropped" Drug Channels (May 7, 2018), accessed at: <https://www.drugchannels.net/2018/05/exclusive-340b-program-reached-193.html>
- 4 Fein (2018).
- 5 Allen Dobson, Kennan Murray, and Joan DaVanzo, *Assessing the Financial Impact of the 340B Drug Pricing Program on Drug Manufacturers, Dobson DaVanzo & Associates LLC* (July 2017), accessed at: https://www.340bhealth.org/files/340B_Financial_Impact_7_17.pdf
- 6 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," *Health Affairs* 33: 11 (2014). This study calculated the percentage of branded prescriptions dispensed by Walgreens' pharmacies in 2012 (18%), as well as the same percentage for 340B prescriptions (46%). 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, "States' Collection of Medicaid Rebates for Physician-Administered Drugs," accessed at: <https://oig.hhs.gov/oei/reports/oei-03-09-00410.pdf>
- 7 IQVIA Institute, *Medicines Use and Spending in the U.S.: A Review of 2017 and Outlook to 2022* (April 2018).

This whitepaper estimates the percentage of applicable US branded drug sales made at a 340B price in 2017. This analysis represents an update from a previous estimate published in July 2017.⁸ Although our methodology remains the same, this updated calculation relies on new data inputs (actual sales at the 340B price, actual total pharmaceutical sales, and typical discounts under the 340B program) that became available following the 2017 publication.

Methodology

To better understand the relative size of the 340B program, we use a methodology to compare 340B branded drug sales to total US branded drug sales. This methodology provides better context for the size of the 340B program. The primary steps in our methodology are:

- Standardize drug pricing at WAC to properly align the highly discounted pricing in the 340B program with pricing in the broader US market.
- Account for direct sales, ADAP rebate sales, and specialty distributor sales not included in Apexus' estimate of total 340B drug purchases.
- Exclude inpatient drug purchases from total US drug sales to align the addressable market with the statutory definition of the 340B program.
- Exclude generic drug sales from both 340B program purchases and the total US drug market.

By limiting the calculation to branded outpatient drugs and ensuring that both 340B sales and total sales are calculated using the same pricing methodology, we can calculate a more accurate percentage that properly puts the 340B program into perspective.

Total Branded 340B Sales at WAC

To estimate branded 340B drug sales at a WAC price, we begin with Apexus' and HRSA's reporting of 340B drug sales in 2017.⁹ Because Apexus does not account for direct 340B drug sales, 340B drug sales through certain specialty distributors, or ADAP rebate sales, we increase this number to account for these omissions. This approach is consistent with a recent MedPAC report that noted that 90 percent to 95 percent of 340B purchases are made through Apexus.¹⁰ Using this estimate of 2017 drug sales at the 340B price, we then account for the discount from WAC that 340B drugs receive on average to determine total 340B drug sales at a WAC price. We estimate the 340B discount from WAC to be just above 50 percent for the 2017 period studied.¹¹ This 50 percent figure represents an average across all drugs. For certain drugs, especially those subject to penny pricing, the 340B discount off of WAC can be higher than 50 percent. This estimate is derived from MACPAC's most recent reporting on average discounts received in the Medicaid program, which are generally consistent with discounts in the 340B program. Last, we exclude the approximately 10 percent of generic drug utilization in the 340B program to arrive at an estimate of branded 340B drug sales at a WAC price.

8 Aaron Vandervelde and Eleanor Blalock, *Measuring the Relative Size of the 340B Program: 2012-2017*, Berkeley Research Group white paper (July 2017), accessed at: http://340breform.org/wp-content/uploads/2017/02/July-2017-BRG-White-Paper_Percent-of-Sales.pdf

9 Fein (2018).

10 MedPAC, *Report to the Congress: Overview of the 340B Drug Pricing Program* (May 2015), accessed at: <http://www.medpac.gov/docs/default-source/reports/may-2015-report-to-the-congress-overview-of-the-340b-drug-pricing-program.pdf?sfvrsn=0>

11 MACPAC, *Medicaid Gross Spending and Rebates for Drugs by Delivery System, FY 2016* (December 2017), accessed at: <https://www.macpac.gov/wp-content/uploads/2015/11/EXHIBIT-28.-Medicaid-Gross-Spending-and-Rebates-for-Drugs-by-Delivery-System-FY-2016-millions.pdf>

FIGURE 1

	2017
Total Branded 340B Purchases at WAC Price	\$37,545
<i>Note: amount in millions.</i>	

Total US Branded Outpatient Drug Sales at WAC

To estimate total US outpatient branded drug sales at WAC, we rely on IQVIA estimates of total US non-generic sales for 2017.¹² From this baseline, we remove inpatient drug utilization using a ratio of inpatient to outpatient drug spend derived from hospital utilization data collected by the California Office of Statewide Health Planning and Development (OSHPD). Our prior analysis of the 2017 period relied on IQVIA projections, which differ slightly from the actual figures reported more recently. Figure 2 shows our estimates of total US branded outpatient drug sales at WAC.

FIGURE 2

	2017
Total Outpatient Branded Drug Sales at WAC Price	\$370,011
<i>Note: amount in millions.</i>	

Results

Using the methodology noted above, we estimate that the 340B program accounted for more than 10 percent of total US branded outpatient drug sales in 2017 (see Figure 3).

FIGURE 3

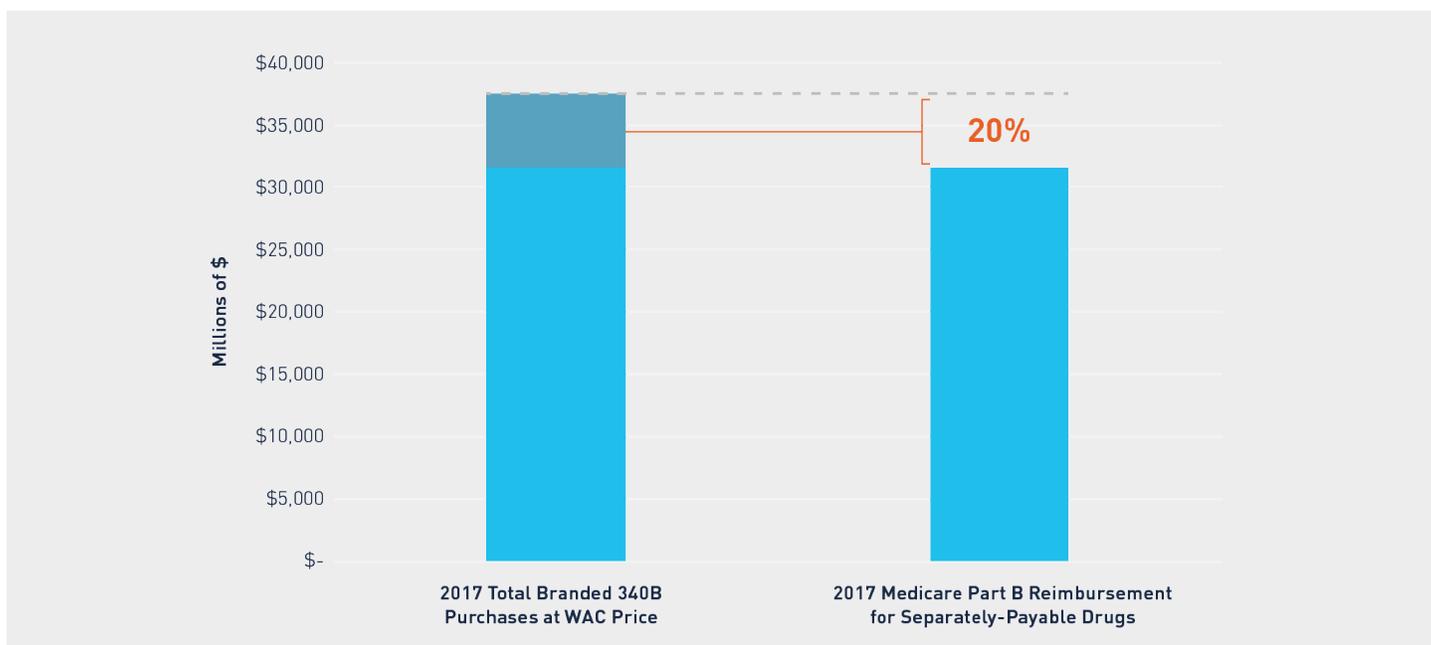
	2017
Total Branded 340B Purchases at WAC Price	\$37,545
Total Outpatient Branded Drug Sales at WAC Price	\$370,011
340B Purchases as % of Outpatient Branded Drug Sales	10.1%
<i>Note: amounts in millions.</i>	

This figure is more than five times the 2015 estimate that the 340B program represented only 1.3 percent of the US drug market. Further, the overall size of the 340B program raises concerns about the reported lack of resources in HRSA's Office of Pharmacy Affairs (OPA) which is responsible for administering the 340B program.¹³ In 2017, the size of the 340B program as calculated in this paper exceeded Medicare Part B reimbursement for drugs (approximately \$32 billion) by nearly 20 percent.¹⁴

¹² IQVIA Institute (2018).

¹³ Committee on Energy and Commerce, *Review of the 340B Drug Pricing Program* (January 2018), available at: https://energycommerce.house.gov/wp-content/uploads/2018/01/20180110Review_of_the_340B_Drug_Pricing_Program.pdf

¹⁴ 2017 Medicare Outpatient Standard Analytic File (SAF), 2017 Medicare Carrier Limited Data Set (LDS).

FIGURE 4: SIZE OF 340B PROGRAM COMPARED TO MEDICARE PART B DRUG REIMBURSEMENT

In FY 2017, OPA's budget was only \$10 million¹⁵ compared to the \$731 million federal administration budget for CMS, the agency overseeing Medicare.¹⁶

Conclusion

The 340B program has grown significantly over the past decade and accelerated in recent years. This growth and the resulting increase in scrutiny of the program is of great interest to lawmakers.¹⁷ Unfortunately, statistics that show that 340B sales represented less than two percent of US drug sales in 2015 continue to be referenced.¹⁸ As discussed in this whitepaper, this statistic underestimated the size of the 340B program. Viewed as a percentage of brand, outpatient drug sales, 340B purchases represented **more than 10 percent of the overall branded, outpatient drug market in 2017**. Viewed in absolute dollar terms, 340B brand, outpatient drug sales exceeded Medicare Part B reimbursement for drugs in 2017. Despite the large and growing size of the 340B program, it is administered by the relatively small HRSA Office of Pharmacy Affairs, whose annual budget (at \$10 million) reportedly does not provide adequate resources to properly regulate the covered entities participating in the program.¹⁹

15 Department of Health and Human Services, *Fiscal Year 2018 Health Resources and Services Administration Justification of Estimates for Appropriations Committees*, accessed at: <https://www.hrsa.gov/sites/default/files/hrsa/about/budget/budget-justification-2018.pdf> (FY 2017 annualized continuing resolution).

16 Department of Health and Human Services, *Fiscal Year 2018 Centers for Medicare & Medicaid Services Justification of Estimates for Appropriations Committees*, accessed at: <https://www.cms.gov/About-CMS/Agency-Information/PerformanceBudget/Downloads/FY2018-CJ-Final.pdf> (FY 2017 annualized continuing resolution).

17 In 2018 alone, three hearings on the 340B program were held in the Senate HELP Committee and one hearing on the program was held in the Energy and Commerce Committee.

18 Allen Dobson, Kennan Murray, and Joan DaVanzo, *Assessing the Financial Impact of the 340B Drug Pricing Program on Drug Manufacturers*, Dobson DaVanzo (July 2017), accessed at: https://www.340bhealth.org/files/340B_Financial_Impact_7_17.pdf; Susanna Luthi, "Senate Lays Groundwork for 340B Reporting Legislation" *Modern Healthcare* (March 15, 2018), accessed at: <http://www.modernhealthcare.com/article/20180315/NEWS/180319937>

19 Committee on Energy and Commerce, *Review of the 340B Drug Pricing Program* (January 2018), available at: https://energycommerce.house.gov/wp-content/uploads/2018/01/20180110Review_of_the_340B_Drug_Pricing_Program.pdf