



# Measuring the Relative Size of the 340B Program

*2018 Update*

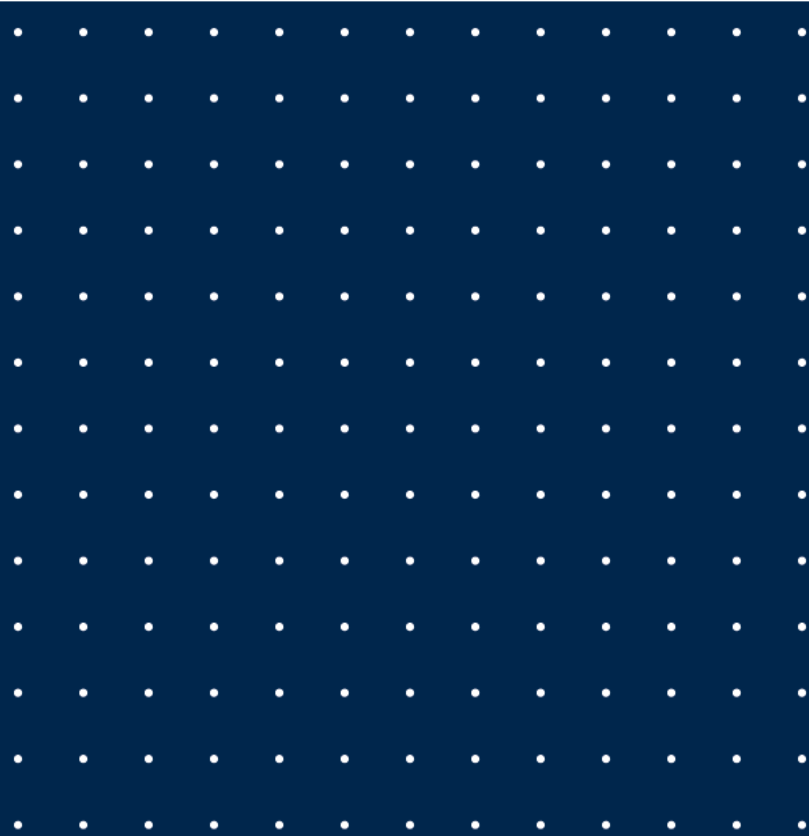
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INTELLIGENCE THAT WORKS



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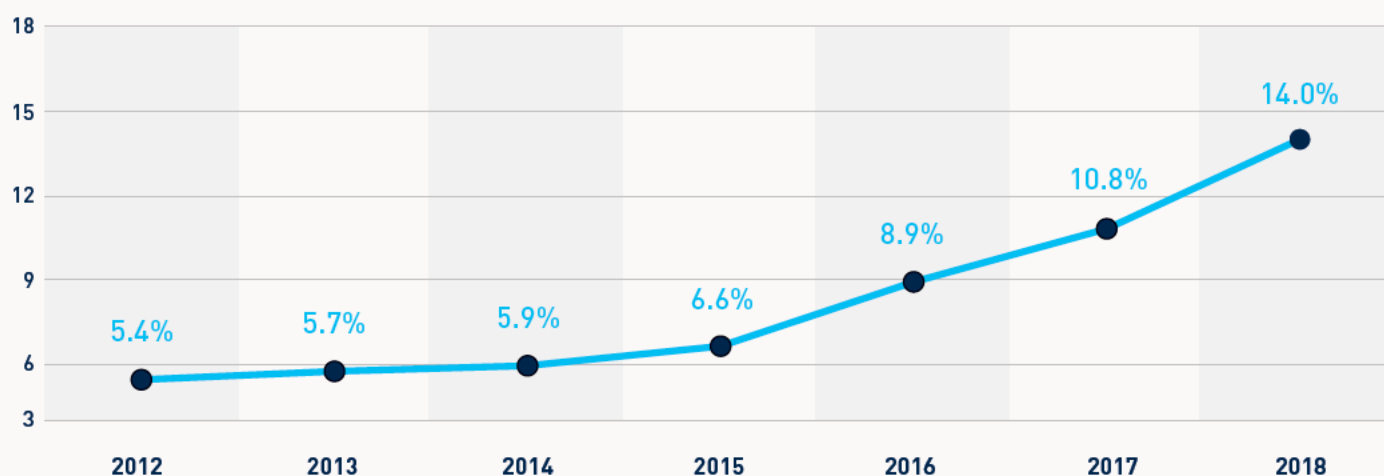
## Background

*In June 2015, BRG published an initial report on the size of the 340B program relative to its addressable market.<sup>2</sup> Since that study, the 340B program has experienced dramatic growth: total 340B purchases increased from \$9.0 billion in 2014 to \$24.3 billion in 2018.<sup>3</sup>*

However, the 170 percent growth in 340B purchases over this five-year period does not tell the entire story. At the same time purchases at the 340B price have increased, the average discount off the list price of a drug purchased through the 340B program has also increased. Medicaid and CHIP Payment and Access Commission (MACPAC) reports annually on Medicaid rebates as a percentage of gross Medicaid spending on drugs. This is the best proxy for the discount off the list price of drugs in the 340B program, because the 340B price itself is based on the Medicaid rebate amount. The Medicaid rebate percentage increased from 46 percent to 60 percent between 2014<sup>4</sup> and 2018.<sup>5</sup> The combined effect of the growth in 340B discounts and the growth in drug purchases at the 340B price resulted in a 234 percent increase in gross purchases through the 340B program between 2014 and 2018, underscoring the relative growth of the program over this period.

In 2018, purchases through the 340B program accounted for 14 percent of the total branded outpatient drug purchases at list prices (see Figure 1). Healthcare providers enrolled in the 340B program (i.e., covered entities) now purchase one in every seven units of branded outpatient drugs at the 340B price. For perspective, when measured by total drug reimbursement (i.e., the amount paid to a pharmacy or provider by the health plan and patient), the 340B program is now the second-largest federal prescription drug program behind only Medicare Part D.

**FIGURE 1: 340B PURCHASES AS PERCENTAGE OF OUTPATIENT BRANDED DRUG SALES<sup>1</sup>**



<sup>1</sup> Previous estimates of the relative size of the 340B 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 and Eleanor Blalock, *Measuring the Relative Size of the 340B Program: 2017 Update*, BRG Healthcare (July 2018), available at: <https://www.thinkbrg.com/newsroom-publications-340b-size-2017-update.html>

<sup>2</sup> Aaron Vandervelde, *Measuring the Relative Size of the 340B Program*, BRG white paper (June 2015), available at: <https://www.thinkbrg.com/newsroom-publications-vandervelde-340b-growth.html>

<sup>3</sup> Adam Fein, "Exclusive: 340B Program Purchases Reach \$24.3 Billion – 7%+ of the Pharma Market – As Hospitals' Charity Care Flatlines," *Drug Channels* (May 2019), available at: <https://www.drugchannels.net/2019/05/exclusive-340b-program-purchases-reach.html>

<sup>4</sup> MACPAC, *Medicaid Drug Spending Trends* (February 2019), available at: <https://www.macpac.gov/wp-content/uploads/2019/02/Medicaid-Drug-Spending-Trends.pdf>

<sup>5</sup> MACPAC, *Medicaid Gross Spending and Rebates for Drugs by Delivery System, FY 2018* (December 2019), available at: <https://www.macpac.gov/wp-content/uploads/2019/11/EXHIBIT-28.-Medicaid-Gross-Spending-and-Rebates-for-Drugs-by-Delivery-System-FY-2018-millions.pdf>



Despite the significant role this program plays in the healthcare industry, little information on the 340B program is publicly available. There is no standard approach for reporting total purchases through the program, and 340B hospitals, which represent almost 90 percent of all purchases through the program,<sup>6</sup> have no reporting requirements on total 340B program income (i.e., the profit margin realized on 340B purchased drugs). As a result, it is unclear how patients or the federal government benefit directly from the program.

## Methodology

A recent estimate has mischaracterized the size of the 340B program as 1.3 percent of drug spending by applying an apples-to-oranges approach that compares the 340B discount amount to gross drug spending at the point of sale.<sup>7</sup> This approach is not appropriate for putting the size of the 340B program into context within the pharmaceutical industry overall.

To better understand the relative size of the 340B program, we use a methodology to compare undiscounted (or “gross”) 340B branded outpatient drug sales to total undiscounted US branded outpatient drug sales. This methodology provides better context for the size of the 340B program, which is limited to outpatient drugs and is dominated by branded drugs. The primary steps in our methodology are:

- Standardize drug pricing at the wholesale acquisition cost (WAC or list price) to align properly 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.

<sup>6</sup> Chris Hatwig, Apexus Update, 2016 340B Health Summer Conference (July 2016).

<sup>7</sup> 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), available at: [https://www.340bhealth.org/files/340B\\_Financial\\_Impact\\_7\\_17.pdf](https://www.340bhealth.org/files/340B_Financial_Impact_7_17.pdf)



## Total Branded 340B Sales at WAC

To estimate branded 340B drug sales at a WAC price, we begin with Apexus and the Health Resources and Services Administration's (HRSA) reporting of 340B drug sales in 2018.<sup>8</sup> 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.<sup>9</sup> Using this estimate of 2018 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 below 60 percent for the 2018 period studied.<sup>10</sup> This 60 percent figure represents an average across all drugs. For certain drugs, especially those subject to penny pricing,<sup>11</sup> the 340B discount off of WAC can be higher than 60 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.

## 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 2018.<sup>12</sup> 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). Figure 3 shows our estimates of total US branded outpatient drug sales at WAC.

## Results

- Using the methodology noted above, we estimate that the 340B program accounted for 14 percent of total US branded outpatient drug sales in 2018 (see Figure 4).
- This figure is more than ten times the estimate that the 340B program represents only 1.3 percent of the US drug market (in 2015).<sup>13</sup> 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.<sup>14</sup> In 2018, the 340B program as calculated in this paper is the second largest federal prescription drug program, trailing only Medicare Part D (approximately \$168 billion).<sup>15</sup> The 340B program as calculated exceeds the Medicare Part B reimbursement for drugs (approximately \$33 billion) by nearly 90 percent.<sup>16</sup> It also exceeded both Medicaid (approximately \$61 billion)<sup>17</sup> by 4 percent and was more than six times larger than Tricare/Department of Defense reimbursement for drugs (approximately \$9.7 billion).<sup>18</sup>
- In FY 2018, OPA's budget was only \$10 million<sup>19</sup> compared to the \$728 million federal administration budget for the Centers for Medicare & Medicaid Services, the agency overseeing Medicare and Medicaid.<sup>20</sup>

FIGURE 2

Total Branded 340B Purchases at WAC Price	2018
	\$56,786

Note: amount in millions

FIGURE 3

Total Outpatient Branded Drug Sales at WAC Price	2018
	\$405,820

Note: amount in millions

FIGURE 4

	2018
Total Branded 340B Purchases at WAC Price	\$56,786
	÷
Total Outpatient Branded Drug Sales at WAC Price	\$405,820
340B Purchases as % of Outpatient Branded Drug Sales	14.0%

Note: amount in millions

8 Fein (2019).

9 MedPAC, *Report to the Congress: Overview of the 340B Drug Pricing Program* (May 2015), available 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>

10 MACPAC, *Medicaid Gross Spending and Rebates for Drugs by Delivery System, FY 2018* (September 2019), available at: <https://www.macpac.gov/wp-content/uploads/2019/11/EXHIBIT-28-Medicaid-Gross-Spending-and-Rebates-for-Drugs-by-Delivery-System-FY-2018-millions.pdf>

11 "340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation," 83 Fed. Reg. 3, Final Rule (January 5, 2017), p. 1215 (discussion of penny pricing), available at: <https://www.govinfo.gov/content/pkg/FR-2017-01-05/pdf/2016-31935.pdf>

12 IQVIA Institute, *Medicine Use and Spending in the U.S.: A Review of 2018 and Outlook to 2023* (May 2019), available at: <https://www.iqvia.com/insights/the-iqvia-institute/reports/medicine-use-and-spending-in-the-us-a-review-of-2018-and-outlook-to-2023>

13 Dobson, Murray, and DaVanzo (2017).

14 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](https://energycommerce.house.gov/wp-content/uploads/2018/01/20180110Review_of_the_340B_Drug_Pricing_Program.pdf)

15 For the purposes of this comparison, the 340B program size calculation included both branded and generic products, to remain consistent with the Medicare Part B, Medicare Part D, Medicaid, and VA/DOD calculations. Centers for Medicare & Medicaid Services (CMS), *Medicare Part B Drug Spending Dashboard* (Calendar Year 2018 Total Spending), available at: <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/MedicarePartB>

16 CMS, *Medicare Part D Drug Spending Dashboard* (Calendar Year 2018 Total Spending), available at: <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/MedicarePartD>

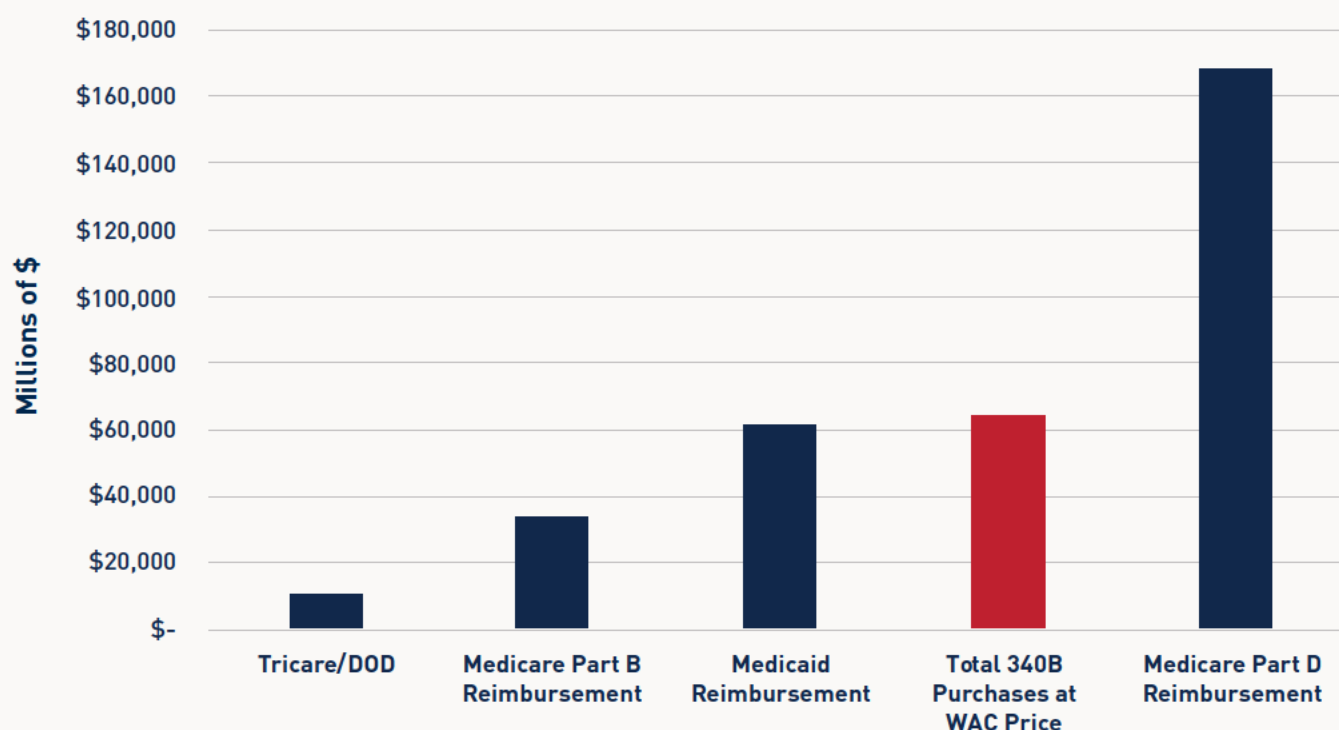
17 MACPAC (September 2019).

18 Military Health System, *Evaluation of the TRICARE Program: Fiscal Year 2019 Report to Congress* (MHS Outpatient Drug Spending, FYs 2006–2018), accessed at: [file:///C:/Users/aslotkoff/Downloads/TRICARE\\_2019\\_04\\_09\\_19\\_v5\\_2.pdf](file:///C:/Users/aslotkoff/Downloads/TRICARE_2019_04_09_19_v5_2.pdf)

19 Department of Health and Human Services, *Fiscal Year 2019 Health Resources and Services Administration Justification of Estimates for Appropriations Committees* (FY 2018 annualized continuing resolution), accessed at: <https://www.hrsa.gov/sites/default/files/hrsa/about/budget/budget-justification-fy2019.pdf>

20 Ibid.

**Figure 5: Size of 340B Program Compared to Medicare Part B, Part D, Tricare/DOD, and Medicaid Drug Reimbursement<sup>23</sup>**



## Conclusion

The 340B program has grown significantly over the past decade and has accelerated in recent years. In 2018, 340B purchases represented **14 percent of the overall branded outpatient drug market**. This is likely to increase in future years absent changes to the regulatory system or market dynamics that have fueled recent growth. Viewed in absolute dollar terms, reimbursement for 340B purchased drugs exceeded Medicare Part B, Medicaid, and VA/Tricare/DOD drug reimbursement in 2018, making it the second largest federal prescription drug program behind Medicare Part D. Despite the large and growing size of the 340B program, it is administered by the relatively small HRSA OPA, whose annual budget (at \$10 million) reportedly does not provide adequate resources to properly regulate the covered entities participating in the program.<sup>21</sup> At the same time, there is limited evidence to suggest that increased revenue derived from hospital participation in the program has translated to improvements in care for the vulnerable and uninsured the program is intended to serve. In fact, hospital charity care rates have continued to decline during this period of accelerated growth in the size of the 340B program.<sup>22</sup> Without greater transparency and oversight of this program, we can expect these trends to continue in the absence of an effort to advance meaningful reforms.

<sup>21</sup> Committee on Energy and Commerce (2018).

<sup>22</sup> Sunita Desai and J. Michael McWilliams, "Consequences of the 340B Drug Pricing Program," *N Engl J Med* (2018), available at: <https://www.nejm.org/doi/full/10.1056/NEJMsa1706475>

<sup>23</sup> Total 340B sales at the WAC price include sales of both branded and generic drugs

## About the Author

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Aaron Vandervelde has over fifteen years of experience providing strategy, health policy, and litigation consulting services to clients in the healthcare industry. He specializes in financial and economic analysis of health policy and provides litigation consulting services related to issues arising from contracts and transactions between healthcare entities and with the federal government. Specifically, he focuses on deriving strategic insight through the integration and analysis of large, complex data sets including claims data, risk adjustment data, internal and external sales data, and publicly available health data.



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