

MEASURING THE RELATIVE SIZE OF THE 340B PROGRAM



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I Background

The 340B program has expanded considerably since its inception in 1992 and is projected to grow further in coming years due to contract pharmacy arrangements, practice acquisitions, Medicaid expansion and other factors. This growth has led to increased focus on the program, its role in overall utilization of drugs, and its relative size. One frequently cited analysis estimates that the 340B program accounts for 2 percent of annual U.S. drug purchases,¹ but this statistic is misleading because it relies on methodological inconsistencies that prevent a true “apples-to-apples” comparison. For example:

- 340B drug purchases are made at a heavily discounted price. The “2 percent” calculation selectively reflects 340B program discounts while failing to account for the rebates and discounts that reduce net U.S. drug spending in other contexts. The calculation relies on an inconsistent methodology that minimizes the numerator and maximizes the denominator, resulting in an artificially low percentage.
- Current estimates of 340B drug sales exclude certain types of purchases, including direct sales to 340B covered entities, ADAP rebate sales, and sales made through certain specialty distributors. This further understates total 340B purchases and the “2 percent” calculation.
- By design, the 340B program is limited to a subset of the overall U.S. drug market, because 340B drugs are exclusively for outpatient use and are mutually exclusive of drugs subject to the Medicaid rebate (i.e. by law, outpatient drugs utilized by Medicaid members are supposed to be subject to either the discounted Medicaid price or the 340B price but not both). Including inpatient drugs and all Medicaid spending in the “2 percent” calculation inflates the denominator and skews the result.
- Branded drug utilization rates differ significantly between the overall U.S. market and the 340B program. About 90 percent of 340B sales are for branded medicines² while that same metric is approximately 72 percent for the overall U.S. market.³ Given the high concentration of brand utilization in the 340B program, comparisons that include overall generic utilization artificially decrease the relative size of the 340B program.

This whitepaper presents a methodology for determining the size of the 340B program relative to an appropriate benchmark and estimates the percentage of applicable US branded drug sales made at a 340B price from 2013 to 2019.

1 American Hospital Association, *Statement of the American Hospital Association before the Health Subcommittee of the Committee on Energy and Commerce of the U.S. House of Representatives*, “Examining the 340B Drug Pricing Program,” hearing, (March 24, 2015), accessed April 2, 2015, at: <http://www.aha.org/testimony>.

2 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):2012 2017. 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 forecast by IMS for 2013 is identical to the proportion at Walgreens in 2012. This implies that branded prescriptions accounted for 74 percent of all 2012 Walgreens prescriptions in dollar terms and that the average spend per branded prescription dispensed by Walgreens in 2012 was 13 times that of a generic. Using this ratio, an estimated 92 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 entitled “States’ Collection of Medicaid Rebates for Physician-Administered Drugs”.

3 IMS Health, “IMS Market Prognosis 2015-2019: North America – United States” (March 2015).

II Methodology

To better understand the relative size of the 340B program, and how it may change in the future, we use a methodology to compare 340B branded drug sales to total U.S. branded drug sales. This methodology addresses the inconsistencies noted above and provides better context for the size of the 340B program. The primary steps in our methodology are:

- Standardize drug pricing at wholesale acquisition cost (WAC) to properly align the highly discounted pricing in the 340B program with pricing in the broader U.S. market.
- Account for direct sales, ADAP rebate sales, and specialty distributor sales not included in Apexus' estimate of total 340B drug purchases.
- Exclude inpatient and Medicaid retail drug purchases from total U.S. drug sales to align the comparison market with the statutory definition of the 340B program.
- Exclude generic drug sales from both 340B program purchases and the total U.S. drug market.

By limiting the calculation to branded outpatient medicines 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.

To estimate branded 340B drug sales at a WAC price, we begin with Apexus' estimate of \$7.1 billion - \$7.5 billion in 2013 340B drug sales.^{4,5} Because Apexus does not account for direct 340B drug sales, 340B drug sales through certain specialty distributors, or ADAP rebate sales, we increased this number to \$8 billion to account for these omissions. This estimate is consistent with a recent MedPAC report that noted that 90 percent to 95 percent of all 340B purchases are made through Apexus.⁶ Using an estimate of \$8 billion in 2013 drug sales at a 340B price, we then account for the 40 percent discount⁷ from WAC that 340B drugs receive on average to determine total 340B drug sales at a WAC price. 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. Using this same methodology, we utilized 340B projections from prior research to estimate branded 340B sales at a WAC price from 2013 to 2019 (see Figure 1).

FIGURE 1

<i>Total Branded 340B Sales at WAC</i>	2013	2014	2015	2016	2017	2018	2019
	\$ 12,000	\$ 13,264	\$ 15,164	\$ 18,540	\$ 20,938	\$ 22,885	\$ 25,168

Note: Amounts in millions

To estimate total U.S. outpatient branded drug sales at WAC, we rely on IMS Health (IMS) forecasts of total U.S. non-generic sales between 2013 and 2019.⁸ From this forecast we removed inpatient drug utilization using a ratio of inpatient to outpatient

4 Ariel Winter and Daniel Zabinski, *The 340B Drug Pricing Program*, MedPAC (November 6, 2014), accessed at: <http://www.medpac.gov/documents/november-2014-meeting-presentation-the-340b-drug-pricing-program.pdf?sfvrsn=0>

5 Kara Stencel, "The 340B Drug Discount Program," *Health Affairs* (November 17, 2014), accessed at: http://www.healthaffairs.org/healthpolicybriefs/brief.php?brief_id=130

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

7 Aaron Vandervelde, *Growth of the 340B Program: Past Trends, Future Projections*, Berkeley Research Group white paper (November 2014), accessed at: http://www.thinkbrg.com/media/publication/524_Vandervelde_340B_GrowthDrivers_WhitePaper_20141202_FINAL.pdf

8 IMS Health 2015. Per guidance from IMS, these forecasts were adjusted upward by 8 percent to bring them to WAC level.

drug spend derived from 2013 hospital utilization data collected by the California Office of Statewide Health Planning and Development (OSHPD). According to HRSA's March 2010 guidance on contract pharmacy arrangements, Medicaid utilization is supposed to be excluded from 340B contract pharmacy purchases. We therefore excluded retail brand Medicaid purchases from the IMS sales total using CMS National Healthcare Expenditure (NHE) annual Medicaid drug spending projections (adjusted so that only brand medicines were excluded using IMS market share estimates). We did not exclude Medicaid physician-administered drug utilization from the IMS total drug sales number. We believe this is a conservative approach given that 340B contract pharmacy utilization (i.e. retail prescriptions) is supposed to exclude Medicaid utilization. Covered entities may carve in the drugs they dispense or administer in house, including physician-administered drugs for Medicaid patients in the outpatient setting, by submitting their Medicaid provider number to HRSA's exclusion list. Thus, our methodology did not exclude physician-administered drugs. Figure 2 shows our estimates of total U.S. branded outpatient drug sales at WAC.

FIGURE 2

<i>Total U.S. Branded Outpatient Drug Sales at WAC</i>	2013	2014	2015	2016	2017	2018	2019
	\$ 231,829	\$ 263,428	\$ 283,680	\$ 295,920	\$ 305,745	\$ 308,566	\$ 315,202

Note: Amounts in millions

III Results

Using the methodology noted above, we estimate that the 340B program accounted for over 5 percent of total U.S. branded outpatient drug sales in 2013 (see Figure 3). We also predict that the 340B program will more than double between 2013 and 2019—outpacing growth in overall outpatient pharmaceutical sales. This trend will lead to 340B purchases increasing to 8 percent of outpatient brand drug sales by 2019.

FIGURE 3

	2013	2014	2015	2016	2017	2018	2019
<i>Total Branded 340B Sales at WAC</i>	\$ 12,000	\$ 13,264	\$ 15,164	\$ 18,540	\$ 20,938	\$ 22,885	\$ 25,168
<i>Total U.S. Branded Outpatient Drug Sales at WAC</i>	\$ 231,829	\$ 263,428	\$ 283,680	\$ 295,920	\$ 305,745	\$ 308,566	\$ 315,202
<i>340B Purchases as % of Non-Medicaid Outpatient Branded Drug Sales</i>	5.2%	5.0%	5.3%	6.3%	6.8%	7.4%	8.0%

IV Conclusion

The 340B program has grown rapidly over the last decade and is forecast to continue this growth for at least the next five years. As a result, the program is becoming an increasingly large part of branded outpatient drug spend. However, properly putting the program into perspective is difficult due to challenges of incomplete data, large discounts allowed by the program, and the fact that certain segments of U.S. drug sales are mutually exclusive with the program by regulation. Accounting for these challenges, we estimate the 340B program represented over 5 percent of total U.S. branded outpatient drug sales in 2013 and predict this percentage will increase to 8 percent by 2019. These results show that the 340B program is already more than twice as large of a share of branded outpatient drug spend as the “2 percent” figure suggests and by 2019 will grow to be four times as large as that widely used number.

About the Author

Aaron Vandervelde

Aaron Vandervelde has over 12 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.

Mr. Vandervelde's practice is focused primarily on clients across the healthcare continuum, including Fortune 500 health insurers, pharmaceutical manufacturers and biotech companies, PBMs, and others. He has advised clients in a variety of federal investigations, contract disputes, litigation, and strategic health policy analyses.

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