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# Measuring the Relative Size of the 340B Program: 2012–2017

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## Background

The 340B Drug Discount Program has come under increased scrutiny in recent years from government agencies and others who note the negative impact the program may have on the broader market for pharmaceuticals.<sup>1</sup> This impact is in part due to the program's increasing size relative to the overall pharmaceutical market. Since 2010, the program has expanded at an average annual growth rate of 21 percent and has grown by 125 percent in the last three years alone.<sup>2</sup> In May 2017, the Health Resources and Services Administration (HRSA) reported that in 2016, 340B covered entities purchased more than \$16 billion in drugs at the 340B price.<sup>3</sup>

### 340B Purchases as Percentage of Outpatient Branded Drug Sales

|      |      |
|------|------|
| 2012 | 5.4% |
| 2013 | 5.7% |
| 2014 | 5.9% |
| 2015 | 6.6% |
| 2016 | 7.7% |
| 2017 | 7.8% |

This study evaluates the accuracy of an often-cited statistic that estimates 340B sales at only 2 percent of annual US drug sales.<sup>4</sup> This statistic compares the highly discounted 340B *net* sales amount to total US *gross* drug sales as reported by IMS Health (IMS). 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.

Because approximately 90 percent of utilization in the 340B program is on branded drugs<sup>5</sup> (versus 74 percent in the US market overall),<sup>6</sup> 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.

This whitepaper estimates the percentage of applicable US branded drug sales made at a 340B price from 2012 to 2017. This analysis relies in large part on the methodology we developed in 2015 but incorporates up-to-date data on 340B program sales as well as total US drug sales.<sup>7</sup>

1 US Government Accountability Office, *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).

2 Adam J. Fein, *Exclusive: The 340B Program Hits \$16.2 Billion in 2016; Now 5% of U.S. Drug Market* (May 2017), Drug Channels, accessed at: <http://www.drugchannels.net/2017/05/exclusive-340b-program-hits-162-billion.html>

3 Ibid.

4 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/advocacy-issues/testimony/2015/150324-statement-340b.pdf>

5 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). This study calculated the branded share of total prescriptions (18 percent) and 340B prescriptions (46 percent) dispensed by Walgreens' pharmacies in 2012. To convert these from quantity into dollar based breakdowns, this study assumes that the proportion of branded drug spend to all drug spend estimated by IMS 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 12 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*.

6 QuintilesIMS Institute, *Medicines Use and Spending in the U.S.: A Review of 2016 and Outlook to 2021* (May 2017).

7 Aaron Vandervelde, *Measuring the Relative Size of the 340B Program*, Berkeley Research Group white paper (June 2015), accessed at: [http://www.thinkbrg.com/media/publication/606\\_Vandervelde\\_340B\\_Whitepaper\\_20150526.pdf](http://www.thinkbrg.com/media/publication/606_Vandervelde_340B_Whitepaper_20150526.pdf)

## 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 addresses the inconsistencies noted above and provides, in our assessment, a better context for the size of the 340B program. The primary steps in our methodology are:

- Standardize drug pricing at WAC to 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 each year from 2012 to 2016.<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 increased the Apexus and HRSA estimates in each year to account for these omissions. This approach is consistent with a recent MedPAC report that noted that 90 percent to 95 percent of all 340B purchases are made through Apexus.<sup>9</sup> Using these annual estimates of 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 between 45 percent and 50 percent for the 2012–2016 period studied.<sup>10</sup> This estimate is derived from MACPAC's 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. Using this same methodology, we utilized 340B projections from prior research to estimate branded 340B sales at a WAC price in 2017 (see Table 1).

**TABLE 1: TOTAL BRANDED 340B PURCHASES AT WAC PRICE**

| 2012     | 2013     | 2014     | 2015     | 2016     | 2017     |
|----------|----------|----------|----------|----------|----------|
| \$12,848 | \$14,209 | \$16,996 | \$21,891 | \$28,068 | \$29,622 |

**Note(s):**

*Amounts in millions*

<sup>8</sup> Fein (2017).

<sup>9</sup> 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>

<sup>10</sup> MACPAC, *Medicaid Gross Spending and Rebates for Drugs by Delivery System* (November 2015), accessed at: <https://www.macpac.gov/publication/medicaid-gross-spending-and-rebates-for-drugs-by-delivery-system/>; MACPAC, *Medicaid Spending for Prescription Drugs* (January 2016), accessed at: <https://www.macpac.gov/wp-content/uploads/2016/01/Medicaid-Spending-for-Prescription-Drugs.pdf>

## Total US Branded Outpatient Drug Sales at WAC

To estimate total US outpatient branded drug sales at WAC, we rely on IMS estimates of total US non-generic sales for 2012 to 2016<sup>11</sup> and forecasts for 2017.<sup>12</sup> From this baseline, we removed 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). Table 2 shows our estimates of total US branded outpatient drug sales at WAC.

**TABLE 2: TOTAL OUTPATIENT BRANDED DRUG SALES**

| 2012      | 2013      | 2014      | 2015      | 2016      | 2017      |
|-----------|-----------|-----------|-----------|-----------|-----------|
| \$238,600 | \$247,962 | \$288,300 | \$329,296 | \$363,187 | \$379,317 |

**Note(s):**

Amounts in millions

## Results

Using the methodology noted above, we estimate that the 340B program accounted for almost 8 percent of total US branded outpatient drug sales in 2016 (see Table 3). This represents an increase of more than 40 percent from five years ago, when the 340B program accounted for over 5 percent of the addressable market.

**TABLE 3: 340B PURCHASES AS PERCENTAGE OF OUTPATIENT BRANDED SALES**

|   | 2012      | 2013      | 2014      | 2015      | 2016      | 2017      |
|---|-----------|-----------|-----------|-----------|-----------|-----------|
| <i>Total Branded 340B Purchases at WAC Price</i>            | \$12,848  | \$14,209  | \$16,996  | \$21,891  | \$28,068  | \$29,622  |
| <i>Total Outpatient Branded Drug Sales</i>                  | \$238,600 | \$247,962 | \$288,300 | \$329,296 | \$363,187 | \$379,317 |
| <i>340B Purchases as % of Outpatient Branded Drug Sales</i> | 5.4%      | 5.7%      | 5.9%      | 6.6%      | 7.7%      | 7.8%      |

**Note(s):**

Amounts in millions

This aggregated analysis does not necessarily reflect the 340B discount for any one product. In fact, because 87 percent of 340B drug purchases originate from hospitals,<sup>13</sup> certain drugs indicated for conditions commonly treated in a hospital outpatient setting have much higher percentages of total sales at a 340B price. To demonstrate this dynamic, we analyzed 2012–2015 Medicare Fee-for-Service outpatient claims data for three conditions commonly treated in the hospital outpatient setting: breast cancer, multiple myeloma, and rheumatoid arthritis. We limited our analysis to the top ten Part B drugs for patients with these conditions in any given year by reimbursement amount.<sup>14</sup> Table 4 below illustrates the degree to which hospital utilization for these drugs has shifted from non-340B to 340B hospitals. For certain products, nearly two-thirds of Part B hospital reimbursement went to 340B hospitals in 2015.

<sup>11</sup> QuintilesIMS Institute (2017).

<sup>12</sup> IMS, *Copy of Market Prognosis 2017-2021 USA-Tables.xls*, Microsoft Excel document (last modified April 21, 2017).

<sup>13</sup> Christopher Hatwig, "Apexus Update," presented at the 340B Coalition Summer Conference (July 11, 2016).

<sup>14</sup> See Appendix A for a list of the drugs examined for each condition and an explanation of how they were chosen.

**TABLE 4: PERCENTAGE OF PART B HOSPITAL REIMBURSEMENT FOR TOP TEN DRUGS USED TO TREAT CONDITION**

| Year | <i>Breast Cancer</i> |          | <i>Multiple Myeloma</i> |          | <i>Rheumatoid Arthritis</i> |          |
|------|----------------------|----------|-------------------------|----------|-----------------------------|----------|
|      | 340B                 | Non-340B | 340B                    | Non-340B | 340B                        | Non-340B |
| 2012 | 56.5%                | 43.5%    | 57.7%                   | 42.3%    | 50.4%                       | 49.6%    |
| 2013 | 59.7%                | 40.3%    | 61.3%                   | 38.7%    | 54.3%                       | 45.7%    |
| 2014 | 62.9%                | 37.1%    | 63.9%                   | 36.1%    | 57.1%                       | 42.9%    |
| 2015 | 64.9%                | 35.1%    | 65.8%                   | 34.2%    | 58.9%                       | 41.1%    |

**Note(s):**

*Analysis limited to the top 10 HCPCS Codes (by reimbursement amount) appearing on hospital outpatient and physician office Medicare claims coded with an ICD-9/ICD-10 diagnosis code associated with each condition listed in a given year.*

Over the same period, the share of Part B reimbursement to physician offices decreased markedly for the same therapeutic categories. This trend is highlighted in Table 5 below. The trend of an increasing share of drug utilization occurring in the hospital outpatient department was highlighted in a recent MedPAC report, which noted, “Between 2009 and 2014, Part B drug spending grew at an average annual rate of about 16.1 for HOPDs [Hospital Outpatient Departments] and 5.6 percent for physicians and suppliers.”<sup>15</sup>

**TABLE 5: PERCENTAGE OF PART B REIMBURSEMENT AMOUNT FOR TOP TEN DRUGS USED TO TREAT CONDITION**

| Year | <i>Breast Cancer</i> |                    |                   |
|------|----------------------|--------------------|-------------------|
|      | 340B Hospitals       | Non-340B Hospitals | Physician Offices |
| 2012 | 23.7%                | 18.3%              | 58.0%             |
| 2013 | 28.1%                | 19.0%              | 52.8%             |
| 2014 | 31.6%                | 18.6%              | 49.8%             |
| 2015 | 32.9%                | 17.8%              | 49.4%             |

  

| Year | <i>Multiple Myeloma</i> |                    |                   |
|------|-------------------------|--------------------|-------------------|
|      | 340B Hospitals          | Non-340B Hospitals | Physician Offices |
| 2012 | 20.6%                   | 15.1%              | 64.3%             |
| 2013 | 25.3%                   | 16.0%              | 58.7%             |
| 2014 | 28.8%                   | 16.2%              | 55.0%             |
| 2015 | 32.8%                   | 17.1%              | 50.1%             |

  

| Year | <i>Rheumatoid Arthritis</i> |                    |                   |
|------|-----------------------------|--------------------|-------------------|
|      | 340B Hospitals              | Non-340B Hospitals | Physician Offices |
| 2012 | 14.5%                       | 14.2%              | 71.3%             |
| 2013 | 16.4%                       | 13.8%              | 69.7%             |
| 2014 | 17.7%                       | 13.3%              | 69.1%             |
| 2015 | 18.6%                       | 13.0%              | 68.4%             |

**Note(s):**

*Analysis limited to the top 10 HCPCS Codes (by reimbursement amount) appearing on hospital outpatient and physician office Medicare claims coded with an ICD-9/ICD-10 diagnosis code associated with each condition listed in a given year.*

<sup>15</sup> MedPAC, *June 2016 A Data Book: Health Care Spending and the Medicare Program* (June 2016), accessed at: <http://www.medpac.gov/docs/default-source/data-book/june-2016-data-book-health-care-spending-and-the-medicare-program.pdf?sfvrsn=0>

## Conclusion

The 340B program has grown significantly over the past decade and has accelerated in recent years. Despite this growth and the resulting increase in scrutiny of the program,<sup>16</sup> the statistic that 340B sales represent only 2 percent of US drug sales continues to be referenced widely. As discussed in this paper, this statistic does not put the 340B program into proper perspective. Viewed as a percentage of brand, outpatient drug sales, 340B purchases represented **almost 8 percent of the overall market in 2016**, nearly four times the 2-percent figure that is often referenced. For some therapeutic areas, the impact of the program is much greater.

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<sup>16</sup> Aaron Vandervelde and Eleanor Blalock, *340B Program Sales Forecast: 2016–2021*, Berkeley Research Group white paper (December 2016), accessed at: [http://www.thinkbrg.com/assets/htmldocuments/Vandervelde\\_Blalock\\_340B\\_Dec2016\\_WEB.pdf](http://www.thinkbrg.com/assets/htmldocuments/Vandervelde_Blalock_340B_Dec2016_WEB.pdf)

## Appendix A

The drugs below are included within the condition-specific drug baskets referenced in Table 4:

### BREAST CANCER

| HCPCS Code   | Description   | Brand Name(s)  |
|--------------|---|----------------|
| J9264        | INJECTION, PACLITAXEL PROTEIN-BOUND PARTICLES, 1 MG | Abraxane       |
| J2469        | INJECTION, PALONOSETRON HCL, 25 MCG                 | Aloxi          |
| J9035        | INJECTION, BEVACIZUMAB, 10 MG                       | Avastin        |
| J9070        | CYCLOPHOSPHAMIDE, 100 MG                            | Cytosan        |
| J9395        | INJECTION, FULVESTANT, 25 MG                        | Faslodex       |
| J9179        | INJECTION, ERIBULIN MESYLATE, 0.1 MG                | Halaven        |
| J9355        | INJECTION, TRASTUZUMAB, 10 MG                       | Herceptin      |
| J9207        | INJECTION, IXABEPILONE, 1 MG                        | Ixempra        |
| J9354        | INJECTION, ADO-TRASTUZUMAB EMTANSINE, 1 MG          | Kadcyla        |
| J2505        | INJECTION, PEGFILGRASTIM, 6 MG                      | Neulasta       |
| J9306        | INJECTION, PERTUZUMAB, 1 MG                         | Perjeta        |
| J3487/ Q2051 | INJECTION, ZOLEDRONIC ACID, 1 MG                    | Reclast/Zometa |
| J9171        | INJECTION, DOCETAXEL, 1 MG                          | Taxotere       |
| J0897        | INJECTION, DENOSUMAB, 1 MG                          | Xgeva/Prolia   |

### MULTIPLE MYELOMA

| HCPCS Code          | Description  | Brand Name(s)  |
|---------------------|--|----------------|
| J2469               | INJECTION, PALONOSETRON HCL, 25 MCG  | Aloxi          |
| J0881               | INJECTION, DARBEPOETIN ALFA, 1 MICROGRAM (NON-ESRD USE)                                | Aranesp        |
| J9070               | CYCLOPHOSPHAMIDE, 100 MG   | Cytosan        |
| J0885               | INJECTION, EPOETIN ALFA, (FOR NON-ESRD USE), 1000 UNITS                                | Epogen/Procrit |
| J1569               | INJECTION, IMMUNE GLOBULIN, (GAMMAGARD LIQUID), NON-LYOPHILIZED, (E.G. LIQUID), 500 MG | Gammagard      |
| J9047               | INJECTION, CARFILZOMIB, 1 MG   | Kyprolis       |
| J2562               | INJECTION, PLERIXAFOR, 1 MG  | Mozobil        |
| J2505               | INJECTION, PEGFILGRASTIM, 6 MG   | Neulasta       |
| J1441/J1442         | INJECTION, FILGRASTIM (G-CSF), EXCLUDES BIOSIMILARS, 1 MICROGRAM                       | Neupogen       |
| J3487/ J3489/ Q2051 | INJECTION, ZOLEDRONIC ACID, 1 MG   | Reclast/Zometa |
| J9033               | INJECTION, BENDAMUSTINE HCL, 1 MG  | Treanda        |
| J9041               | INJECTION, BORTEZOMIB, 0.1 MG  | Velcade        |

**RHEUMATOID ARTHRITIS**

| HCPCS Code   | Description   | Brand Name(s)       |
|--------------|---|---------------------|
| J3262        | INJECTION, TOCILIZUMAB, 1 MG  | Actemra             |
| J0881        | INJECTION, DARBEPOETIN ALFA, 1 MICROGRAM (NON-ESRD USE)                                   | Aranesp             |
| J0717/ J0718 | INJECTION, CERTOLIZUMAB PEGOL, 1  | Cimzia              |
| J0885        | INJECTION, EPOETIN ALFA, (FOR NON-ESRD USE), 1000 UNITS                                   | Epogen/Procrit      |
| J1561        | INJECTION, IMMUNE GLOBULIN, (GAMUNEX-C/GAMMAKED), NON-LYOPHILIZED (E.G. LIQUID), 500 MG   | Gamunex-C /Gammaked |
| J1568        | INJECTION, IMMUNE GLOBULIN, (OCTAGAM), INTRAVENOUS, NON-LYOPHILIZED (E.G. LIQUID), 500 MG | Octagam             |
| J0129        | INJECTION, ABATACEPT, 10 MG   | Orencia             |
| J1459        | INJECTION, IMMUNE GLOBULIN (PRIVIGEN), INTRAVENOUS, NON-LYOPHILIZED (E.G. LIQUID), 500 MG | Privigen            |
| J3488/Q2051  | INJECTION, ZOLEDRONIC ACID, 1 MG  | Reclast/Zometa      |
| J1745        | INJECTION INFLIXIMAB, 10 MG   | Remicade            |
| J9310        | INJECTION, RITUXIMAB, 100 MG  | Rituxan             |
| J1602        | INJECTION, GOLIMUMAB, 1 MG, FOR INTRAVENOUS USE   | Simponi             |
| J0897        | INJECTION, DENOSUMAB, 1 MG  | Xgeva/Prolia        |

Each of these was determined to be among the top ten drugs by reimbursement amount in any given year (between 2012 and 2015) based on a ranking of drugs for patients with these conditions. The data sets used for this determination and the calculations presented in tables 4 and 5 are:

- 2012–2015 **Medicare Outpatient Standard Analytic File** (SAF), which contains 100 percent of Medicare fee-for-service claims submitted by institutional outpatient providers
- 2012–2015 **Medicare Carrier Limited Data Set** (LDS), which contains a 5 percent sample<sup>17</sup> of fee-for-service claims submitted primarily by non-institutional providers.

<sup>17</sup> Per-drug reimbursement totals found within the Carrier LDS file were multiplied by 20 to compare them with reimbursement amounts from the 100-percent Medicare Outpatient SAF.