



Site-of-Care Shift for Physician-Administered Drug Therapies: Update

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INTELLIGENCE THAT WORKS

Introduction

In October 2017, BRG professionals published a white paper evaluating the breakdown in site of care for top drugs used to treat several conditions (breast cancer, rheumatoid arthritis, and multiple myeloma). The paper analyzed data on physician-administered medicines covered by Medicare Part B and found that as of 2015, nearly one-third of Medicare Part B drug reimbursement for breast cancer and multiple myeloma treatments, and nearly 19 percent for rheumatoid arthritis treatments, occurred in the 340B hospital setting. For all three conditions, historical trends indicated a significant shift in site of care since 2008.

This paper updates the prior analysis to reflect Medicare claims data through 2017 and provide a broader view of all Part B drugs. This paper also compares the total size of the 340B Drug Discount Program to the total size of Part B drug sales, both measured at wholesale acquisition cost (WAC), and provides an updated analysis of the impact of the Centers for Medicare and Medicaid Services' (CMS) cut in reimbursement for most 340B-purchased Part B drugs.

Background on 340B Program and Shift in Site of Care

The 340B Drug Discount Program allows certain qualifying clinics and hospitals access to discounted prices for outpatient drugs covered by Medicaid (these drugs include both retail and physician-administered drugs). Many 340B hospitals also access the discount for their off-campus hospital outpatient departments (HOPDs) under US Health Resources and Services Administration (HRSA) guidance and CMS cost-reporting rules. These HOPDs may include previously independent physician offices that have since been acquired by a hospital. Such purchases of independent physician offices by hospitals, in addition to less formal arrangements such as referral networks, have contributed to the documented shift in site of care from the physician office setting to the hospital outpatient department setting.

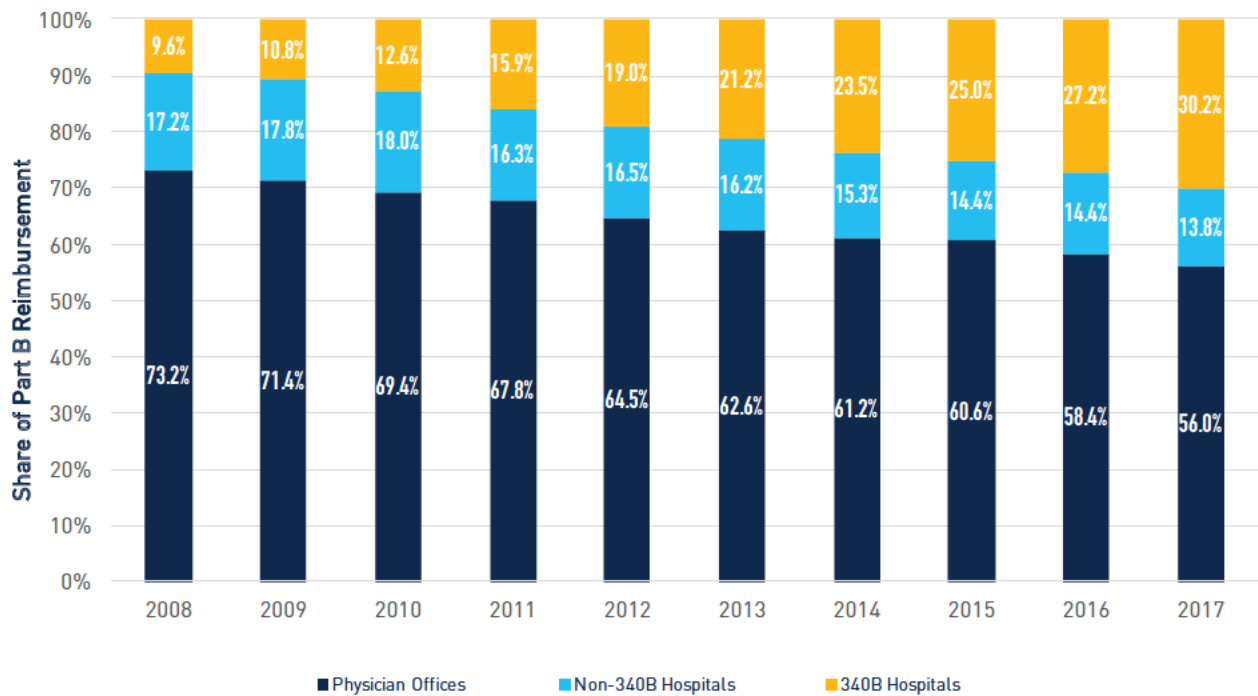
Shift in Site of Care for Common Drug Therapies

We analyzed Medicare Part B drug claims across the period from 2008 to 2017 using 340B program enrollment data from the HRSA Office of Pharmacy Affairs (OPA) to identify claims occurring at a 340B-enrolled hospital. We then calculated the share of reimbursement for those claims (payments from Medicare and beneficiaries) occurring in the 340B hospital setting, the non-340B hospital setting, and the physician office setting. Across all Part B drugs, more than 30 percent of reimbursement occurred in the 340B hospital setting in 2017, as compared to less than 10 percent in 2008.¹

¹ Metrics developed using: Medicare Outpatient Research Identifiable Files (RIF) for 2008 to 2017; Medicare Carrier Limited Data Sets (LDS) for 2008 to 2017; HRSA OPA 340B Covered Entity Database.

FIGURE 1

Site of Care for All Drug Therapies Reimbursed in Medicare Part B (2008-2017)

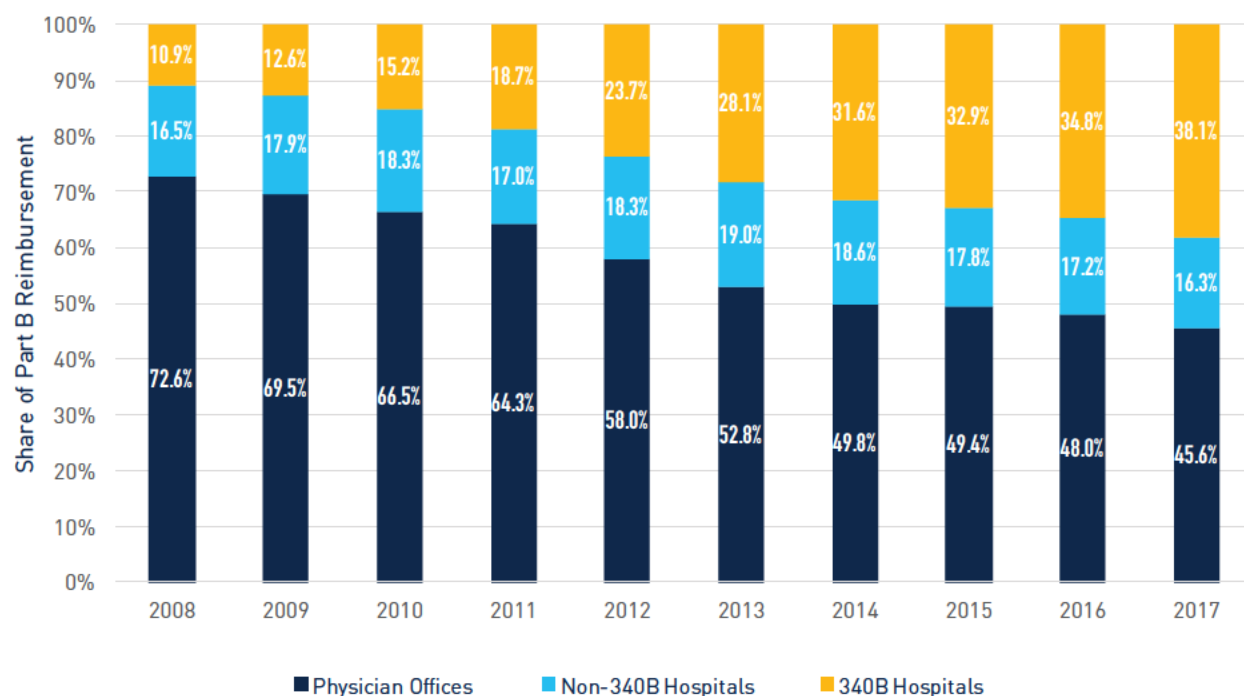


In a similar manner, we broke down reimbursement for the top ten drugs, as measured by Part B drug reimbursement, indicated for treatment of breast cancer, rheumatoid arthritis, and multiple myeloma.²

² Metrics developed using: Medicare Outpatient RIF for 2008 to 2017; Medicare Carrier (LDS for 2008 to 2017; HRSA OPA 340B Covered Entity Database.

FIGURE 2

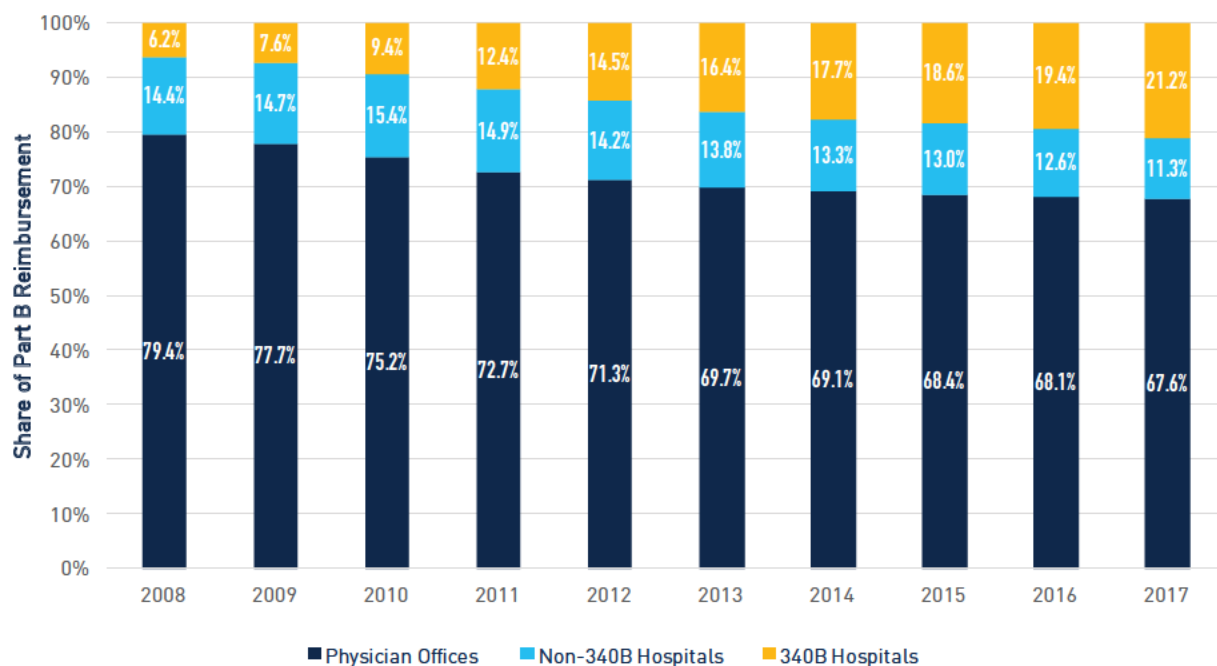
Site of Care for Breast Cancer Drug Therapies Reimbursed in Medicare Part B (2008-2017)



Note: Analysis includes top ten drugs reimbursed under Part B and used for breast cancer treatments.

FIGURE 3

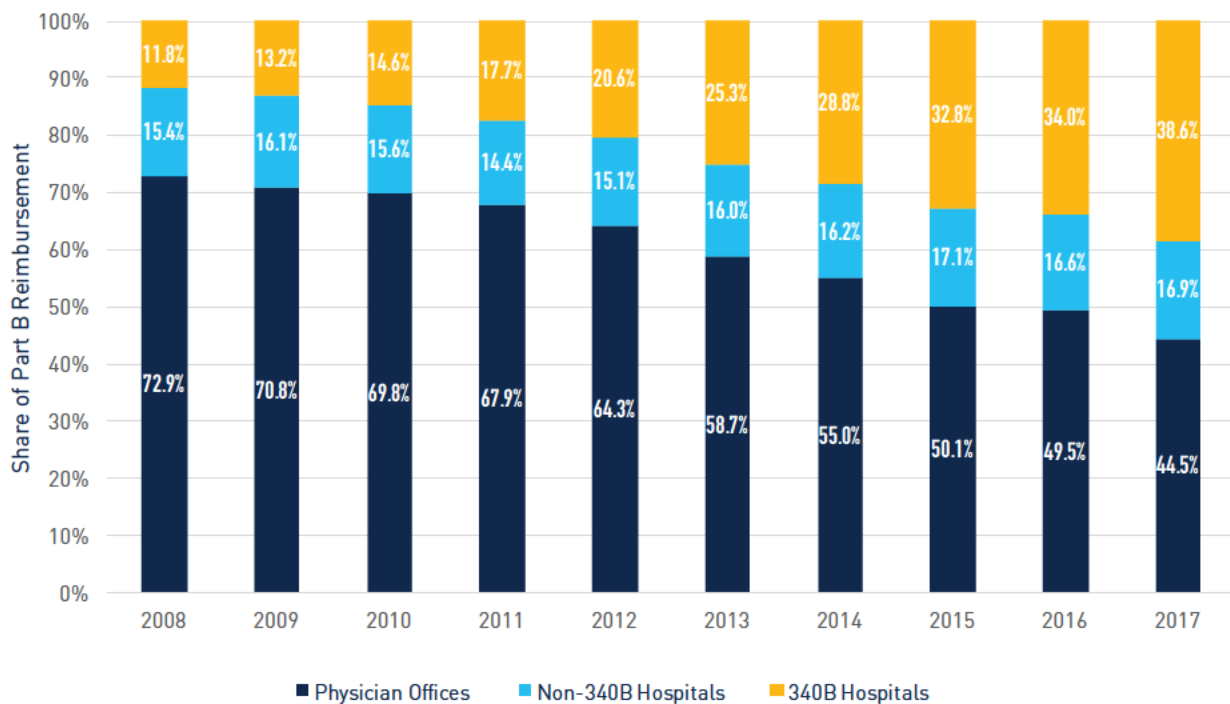
Site of Care for Rheumatoid Arthritis Drug Therapies Reimbursed in Medicare Part B (2008-2017)



Note: Analysis includes top ten drugs reimbursed under Part B and used for rheumatoid arthritis treatments.

FIGURE 4

Site of Care for Multiple Myeloma Drug Therapies Reimbursed in Medicare Part B (2008-2017)



Note: Analysis includes top ten drugs reimbursed under Part B and used for multiple myeloma treatments.

The shift in site-of-care trend continued into 2016 and 2017 for treatments related to all three conditions. The 340B HOPD setting share of the total of Part B reimbursement increased to more than 38 percent for both breast cancer and multiple myeloma treatments, and now exceeds 21 percent for rheumatoid arthritis treatments.

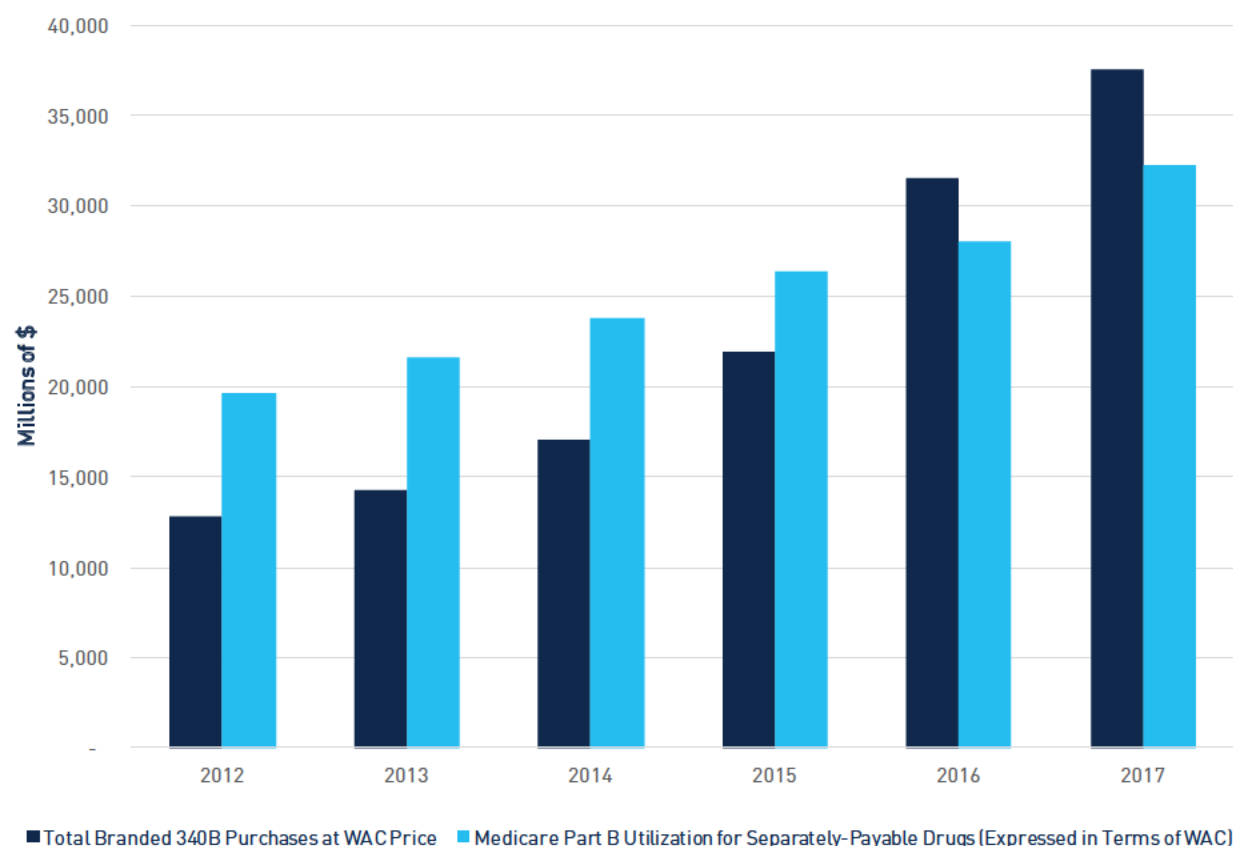
The shift in site of care into the 340B hospital setting has contributed to the rapid growth in the size of the 340B program, particularly over the last few years. In July 2018, BRG professionals published an estimate that total branded 340B purchases at the WAC price accounted for 10.1 percent of the addressable market in 2017.³ Below, we compare the size of the 340B program (defined in the same manner) to total Part B drug utilization (expressed in terms of WAC) over time. Beginning in 2016, the 340B program sales exceeded the size of total Part B drug utilization.⁴

3 Aaron Vandervelde and Eleanor Blalock, *Measuring the Relative Size of the 340B Program: 2017 Update*, BRG white paper (July 2018), available at: <https://www.thinkbrg.com/newsroom-publications-340b-size-2017-update.html>

4 Part B drug spending metrics for 2012-2016 developed based on the Medicare Part B Drug Spending Dashboard; Part B drug spending metric for 2017 developed using: Medicare Outpatient RIF for 2017 and Medicare Carrier LDS for 2017; 340B metric developed based on BRG analysis of Apexus/HRSA reporting of 340B drug sales.

FIGURE 5

Size of 340B Program Compared to Medicare Part B Drug Utilization



Analysis of Potential Impact of Regulatory Response

In 2018, CMS reduced Medicare Part B reimbursement for drugs purchased by hospitals at the 340B price from the Average Sales Price (ASP) plus 6 percent to ASP minus 22.5 percent, acknowledging that hospital participation in the 340B program appears to be correlated with “drug spending increases.”⁵ The payment reduction was subsequently litigated, and in December 2018, the District Court for the District of Columbia held that the 340B drug payment cuts were outside the authority of the Secretary of Health and Human Services.⁶ Specific implications for affected hospitals’ 2018 340B drug reimbursement are unclear at this time as the court further considers the hospitals’ remedies. While the recent court ruling does not apply to CMS’ 2019 340B drug reimbursement cut, the 2019 cut will likely be litigated in the future.

In our 2017 report, we noted that the ASP payment cut would result in only a 13 percent reduction in Disproportionate Share Hospital (DSH) hospital margin earned on 340B purchased drugs, as it does not affect reimbursement for patients covered under Medicare Advantage, commercial insurance, or Medicaid, nor does it eliminate all hospital margin opportunity under Medicare Part B for heavily discounted drugs.

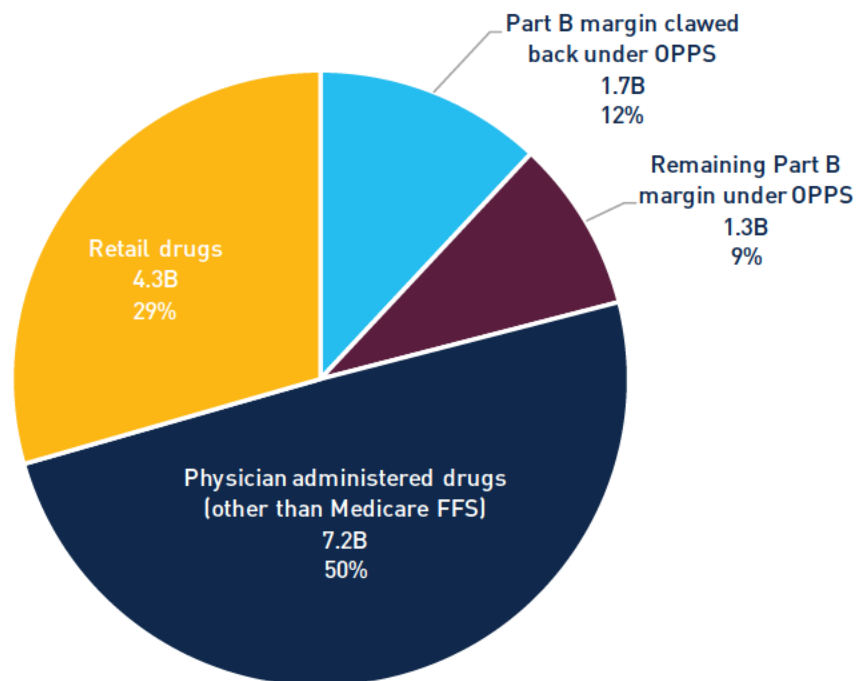
In this report, we have updated this calculation to reflect the latest data on total 340B sales and typical discounts off of the WAC. Our updated findings are that the reimbursement cut results in a 12 percent (\$1.7 billion) reduction in DSH hospital 340B margin.

5 “Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs,” 42 CFR Parts 414, 416, and 419, Federal Register 82:239 (December 14, 2017), available at: <https://www.govinfo.gov/content/pkg/FR-2017-12-14/pdf/R1-2017-23932.pdf>

6 *Am. Hosp. Ass’n v. Azar*, No. 18-2084, “Memorandum Opinion Denying Defendants’ Motion to Dismiss; Granting Plaintiffs’ Motion for a Permanent Injunction; Denying as Moot Plaintiffs’ Motion for a Preliminary Injunction” (DDC Dec. 27, 2018), available at: https://ecf.dcd.uscourts.gov/cgi-bin/show_public_doc?2018cv2084-25

FIGURE 6

2017 DSH Hospital Margins for Medicines Purchased through the 340B Program



Total DSH Hospital Margins = \$14.5 B

Source: BRG analysis of Apexus disclosures of 2017 total sales at the 340B price; analysis of the typical 340B discount off of Wholesale Acquisition Cost (WAC), and analysis of typical payer reimbursement as a percentage of WAC.

Conclusion

Our latest analysis indicates that the shift in site of care to the 340B HOPD setting continued into 2016 and 2017. The trend has impacted Part B drug therapies broadly, with a greater impact on drugs that treat certain conditions (breast cancer and multiple myeloma, for example). One driver of this shift is the financial incentive created by the 340B program, in which hospitals have historically been able to retain the difference between standard drug reimbursement and the discounted 340B acquisition cost. It is unclear at this time whether CMS' reimbursement cut for 340B-purchased drugs will be reversed or continue in some form into the future. Either way, significant margin opportunity remains for 340B hospitals on drugs, and as a result we expect the consolidation trend to continue in the future.

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