340B HOSPITALS CONTINUE TO EXPAND: GROWTH AND DISTRIBUTION OF PHYSICIAN-ADMINISTERED DRUG REIMBURSEMENT ACROSS TEN THERAPEUTIC AREAS

AIR 340B
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The 340B program has undergone significant growth in recent years.[i] This has led to an increase in the share of brand outpatient prescription medicines sold at a 340B price compared to total sales.[ii] Several factors are driving this growth, including expanded 340B eligibility of hospitals and hospital offsite outpatient facilities, the acquisition of physician practices by participating hospitals, and guidance allowing the use of unlimited contract pharmacy arrangements.[iii] Studies have shown how the financial incentives involved in the 340B program have created market distortions that are influencing hospital business practices, negatively impacting community physician clinics, and leading to unintended consequences in billing patterns, particularly in the therapeutic area of oncology.[iv]

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BACKGROUND

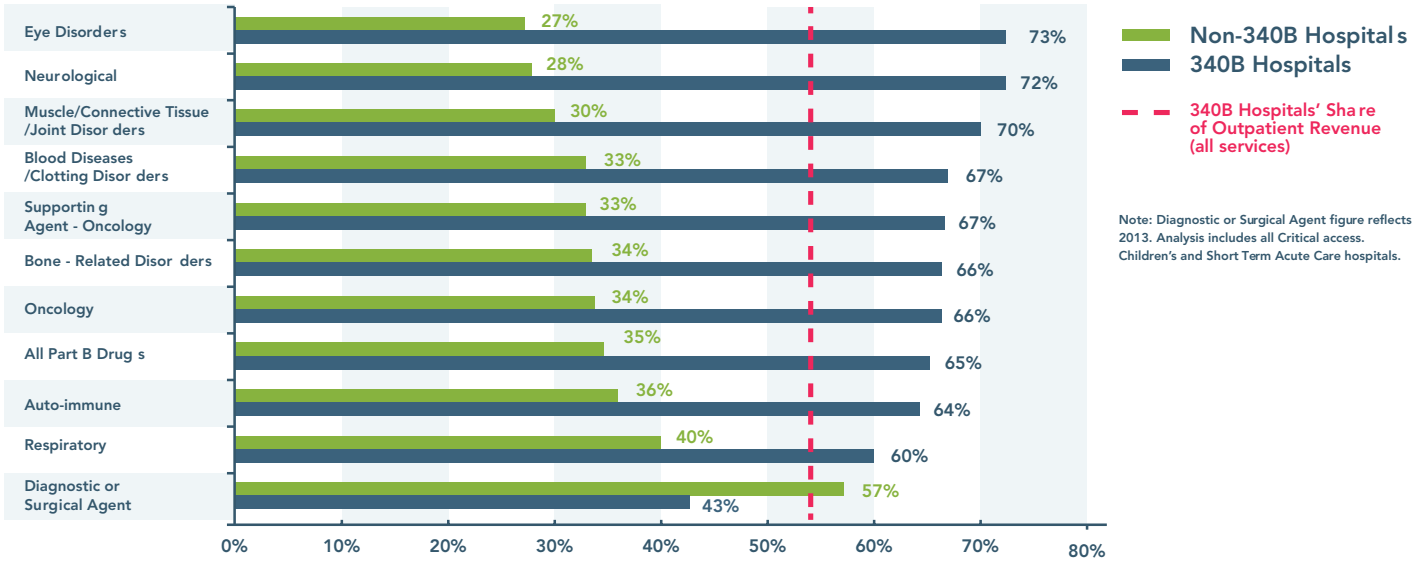
The 340B program requires manufacturers to sell steeply discounted medicines, averaging about 50 percent,[v] to qualifying hospitals and safety-net clinics. About 80 percent of the program's sales go to disproportionate share (DSH) hospitals.[vi] These hospitals have historically been reimbursed by private insurers and Medicare at the same rates that are paid for non-340B discounted medicines, and have been permitted to retain the resulting profit margin or spread.[vii] A change to Medicare rules on January 1, 2018, lowers Part B reimbursement for 340B-discounted medicines paid under the Medicare Hospital Outpatient Prospective Payment System.[viii] As discussed later in this paper, we do not expect this change to reverse the 340B program's growth.

The data presented here from the Berkeley Research Group (BRG) add to the existing body of research on 340B trends by analyzing fresh data across several therapeutic categories and highlights additional areas where the 340B program has created market distortions in the physician-administered medicine space.[ix] Looking at the latest data available, BRG used a combination of Medicare Part B claims and Office of Pharmacy Affairs data to examine the distribution of Medicare Part B reimbursement for physician-administered medicines to 340B and non-340B hospital outpatient departments from 2008 through 2016.[x] These data were then benchmarked against hospital outpatient revenues as reported by hospitals in Medicare cost reports. The analysis focused on 10 of the top therapeutic categories based on total Medicare Part B reimbursement.[xi]

DISTRIBUTION OF REIMBURSEMENT IN 2016

According to 2016 data, 340B hospitals are generally using more medicines (in dollar terms) relative to their size than non-340B hospitals (See: red line in Figure 1). Specifically, 340B hospitals accounted for 65 percent of total Part B drug reimbursement, even though these hospitals only represented just over half (54%) of total Medicare hospital outpatient revenue.[xii] The percentage of Medicare Part B drug reimbursement to 340B hospitals varies markedly when broken out by therapeutic category. In 9 of the 10 therapeutic categories, 340B hospitals accounted for between 60 and 72 percent of Medicare Part B hospital outpatient reimbursement. This data, combined with the Government Accountability Office's (GAO) findings that per beneficiary Medicare Part B spending was substantially higher at 340B DSH hospitals, provides more evidence to suggest that Medicare patients treated in 340B hospitals have disproportionately high outpatient drug spend as compared to patients treated at non-340B hospitals. For patients who are directly responsible for their 20% coinsurance, this will result in higher out-of-pocket costs.

Figure 1: Medicare Part B Reimbursement 340B vs. Non-340B Hospitals, 2016



Trends in Reimbursement

The share of total hospital Medicare Part B drug reimbursement substantially shifted to 340B hospitals from 2008 to 2016. As illustrated in Figure 2, all 10 therapeutic categories examined saw large increases in the share of Part B drug reimbursement at 340B hospitals. Auto-immune and respiratory medicines had the largest increases, at 120.4 percent and 106.3 percent, respectively. Meanwhile, non-340B hospitals saw large decreases in their share of Part B drug reimbursement in each of the 10 therapeutic areas.

Past analysis suggests that one key factor driving this shift to 340B hospitals is the shift from community-based care to care at 340B hospitals. While hospital consolidation is occurring at all hospitals, a recent study in the New England Journal of Medicine found 340B hospitals are driving more consolidation than other hospitals. [xiii] Past BRG research also showed a shift from community-based physicians to 340B hospitals.[xiv] This consolidation to hospital-based practices leads to higher costs for commercial patients. [xv]

Figure 2: Percent Change in Share of Part B Hospital Reimbursement 2008-2016

Top 10 Part B Therapeutic Categories	340B	Non-340B
Auto-immune	120.4%	- 49.5%
Respiratory	106.3%	- 43.5%
Bone-Related Diseases	98.5%	- 49.5%
Supporting Agent-Oncology	98.4%	- 49.6%
Muscle/Connective Tissue/Joint Disorders	68.9%	- 48.8%
Oncology	68.3%	- 44.1%
Diagnostic or Surgical Agent	40.2%	- 17.6%
Blood Diseases/Clotting Disorders	38.1%	- 36.0%
Neurological	34.4%	- 40.1%
Eye Disorders	13.4%	- 24.0%

Notes: [1] Analysis of Critical Access, Children's, and Short Term Acute Care Hospitals. [2] Diagnostic Surgical Agent reflects 2013

Changes in Reimbursement Policy

In an effort to address concerns economists and the GAO have raised that the 340B program leads to hospitals administering more and higher cost medicines in Part B, the Administration in 2018 changed Medicare reimbursement for Part B hospital outpatient medicines purchased through the 340B program. [xvi] The Medicare reimbursement rate for such medicines changed from Average Sales Price plus 6 percent to Average Sales Price less 22.5 percent (before sequestration). The change reduces both Medicare spend and the related patient coinsurance obligation under Part B (which is 20 percent of the total reimbursable amount). This change impacts only 340B revenue derived from Part B hospital outpatient drug reimbursement, and it does not apply to all hospital settings. Overall, BRG has estimated that this policy change will result in only a 13 percent reduction in the total hospital margin on 340B purchased medicines.[xvii]

Conclusion

Growth in the 340B program has been well documented, and these new data provide additional information regarding the large role that 340B hospitals play in the market for medicines reimbursed through Part B. This new analysis demonstrates that growth in the share of Medicare Part B reimbursement attributable to 340B hospitals has been high across all 10 therapeutic areas, and disproportionately affects certain therapeutic areas to an even greater degree.

As noted by economists in the Journal of the American Medical Association, the current structure of the 340B program raises concerns that the program may be increasing costs for patients.[xviii] While the data above does not report on reimbursement trends outside of Medicare Part B, we believe that 340B hospitals may play an outsized role in the physician-administered medicine space in other markets. An analysis by Milliman of commercial reimbursement of 340B medicines, which replicated a 2015 study by the Government Accountability Office that looked at Medicare Part B reimbursement, found 340B DSH hospitals have higher per-patient outpatient pharmacy costs for their commercially-insured patient than their non-340B counterparts.[xix]

Additionally, the structure of the program and the disproportionately large role 340B plays in some therapeutic categories poses questions about how the program's financial incentives may create distortions in specific markets. Specifically, the data in this report, combined with recent analysis from BRG on shift in site of care, raise concerns about how these incentives drive care to costlier settings, resulting in higher costs to patients. The previous analysis from BRG found that from 2008 to 2015, there was a significant shift in site of care from the less costly physician office setting to more expensive 340B hospital outpatient settings for physician administered drugs to treat breast cancer, rheumatoid arthritis and multiple myeloma. All of three of these classes fall into the 10 therapeutic areas which this report highlights as increasing at 340B hospitals. [xx] This shift in site of care and other distortions in the program potentially undermine the sustainability of 340B as the utilization-based incentives for 340B providers may not be in the best interests of patients because of the increased costs to them. This has raised the attention of policy and lawmakers and resulted in calls for program reform.

Sources:

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[ii] A Vandervelde and E Blalock, "Measuring the Relative Size of the 340B Program: 2012-2017," Berkeley Research Group, July 2017.

[iii] S Desai and JM McWilliams, "Consequences of the 340B Drug Pricing Program, February 8, 2018 N Engl J Med 2018; 378:539-548 DOI: 10.1056/NEJMsa1706475; GAO, Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals, June 2015. Available at http://www.gao. gov/products/GAO-15-442; MedPAC, Report to the Congress, Overview of the 340B Drug Pricing Program, May 2015. Available at http://www.medpac.gov/ documents/reports/may-2015-report-to-the-congress-overview-of-the-340b-drug-pricing-program.pdf?sfvrsn=0 ; A Vandervele and E Blalock, "340B Program Sales Forecast," Berkeley Research Group, December 2016. Available at: http://340breform.org/userfiles/December%202016%20BRG%20Growth%20Study.pdf

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[v] Congressional Budget Office, "Prices for Brand-Name Drugs Under Selected Federal Program," June 2005.

[vi] Chris Hatwig, Apexus Update, 2016 340B Health Summer Conference, July 2016.

[vii] Safety net clinics typically have a sliding fee scale and are required to reinvest any revenue from 340B into services for their target populations.

[viii] 80 Fed Reg 59216, (Dec. 14, 2017).

[ix] R. Conti, P. Bach, Cost Consequences of the 340B Drug Discount Program, JAMA : the Journal of the American Medical Association, 2013;309(19):1995-1996. doi:10.1001/jama.2013.4156. ; Government Accountability Office, Medicare Part B Drugs: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals, GAO-15-442, June 2015.; S. Desai and J.M. McWilliams, "Consequences of the 340B Drug Pricing Program," N Engl J Med 2018; A Vandervelde and E Blalock, "Site of Care Shift for Physician-Administered Drug Therapies," Berkeley Research Group, October 2017.AIR340B, 340B Hospitals vs. Non-340B Hospitals: Growth and Distribution of Physician Administered Drug Reimbursement Across Ten Therapeutic Areas, February 2016.

[x] These data do not include grantees, contract pharmacies, or Part B reimbursement to physician offices.

[xi] IVIG was excluded as a category as these drugs are not typically purchased at 340B prices. Full methodology available upon request.

[xii] The analysis did not examine the underlying health conditions of the patients served, however, the June 2015 GAO report examining Part B drug spending at 340B DSH hospitals as compared to non-340B hospitals found that the differences in reimbursement were not explained by hospital characteristics or patients' health status.

[xiii] S. Desai and J.M. McWilliams, "Consequences of the 340B Drug Pricing Program," N Engl J Med 2018.

[xiv] A. Vandervelde and E. Blalock, "Site of Care Shift for Physician-Administered Drug Therapies," BRG, Oct. 2017.

[xv] MedPAC, Report to Congress: Medicare Payment Policy (March 2017), accessed at http://www.medpac.gov/docs/default-source/reports/mar17_entirereport224610adfa9c665e80adff00009edf9c.pdf?sfvrsn=0 (see Page 70)

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[xviii] R Conti and P Bach, "Cost Consequences of the 340B Drug Discount Program," Journal of the American Medical Association, May 2013.

[xix] M Hunter, J Gomberg, C Kim, "Commercial payers spend more on hospital outpatient drugs at 340B participating hospitals, Milliman, March 2018.

[xx] A Vandervelde and E Blalock, "Site of Care Shift for Physician-Administered Drug Therapies," Berkeley Research Group, October 2017