

340B Update: Recent Trends and Outlook for the Future



Legal Made Me Do It



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- The speaker is a paid consultant for numerous pharmaceutical manufacturers, health plans and trade organizations.

Presentation Outline



- Intersecting trends in oncology and 340B
 - Shift in site of care
 - Reimbursement and pricing trends
 - Rise of contract specialty pharmacies
- Legislative and regulatory activity
 - HOPPS and MPFS changes
 - CMP final rule
 - Recent bills and potential regulatory action
- Outlook for 340B

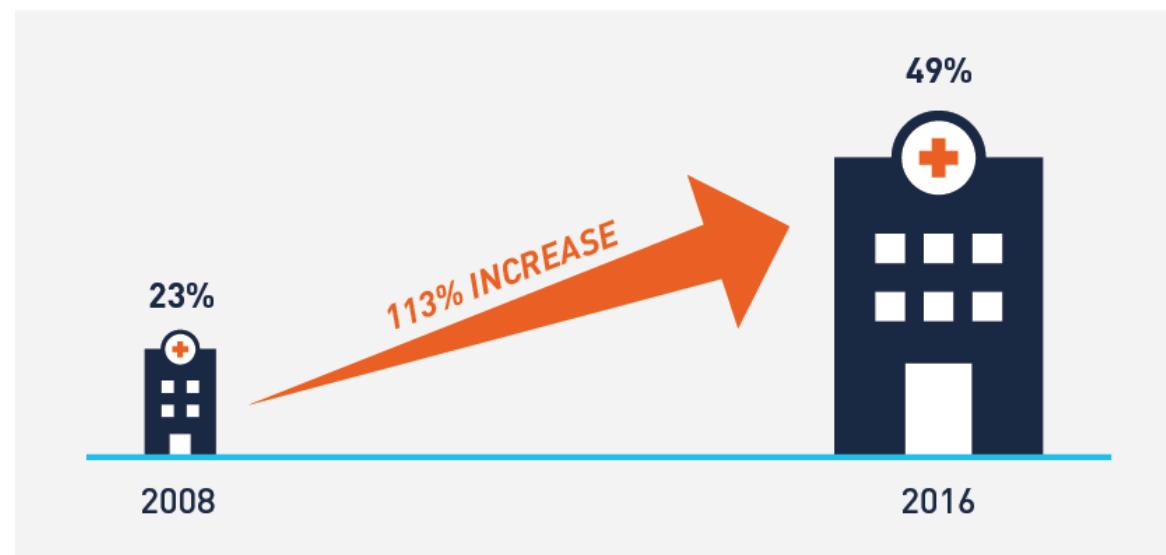


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INTERSECTING TRENDS IN ONCOLOGY AND 340B

Chemotherapy Claims: Shift in Site of Care

PERCENT OF TOTAL CHEMOTHERAPY DRUG ADMINISTRATION CLAIMS IN THE HOSPITAL OUTPATIENT SETTING

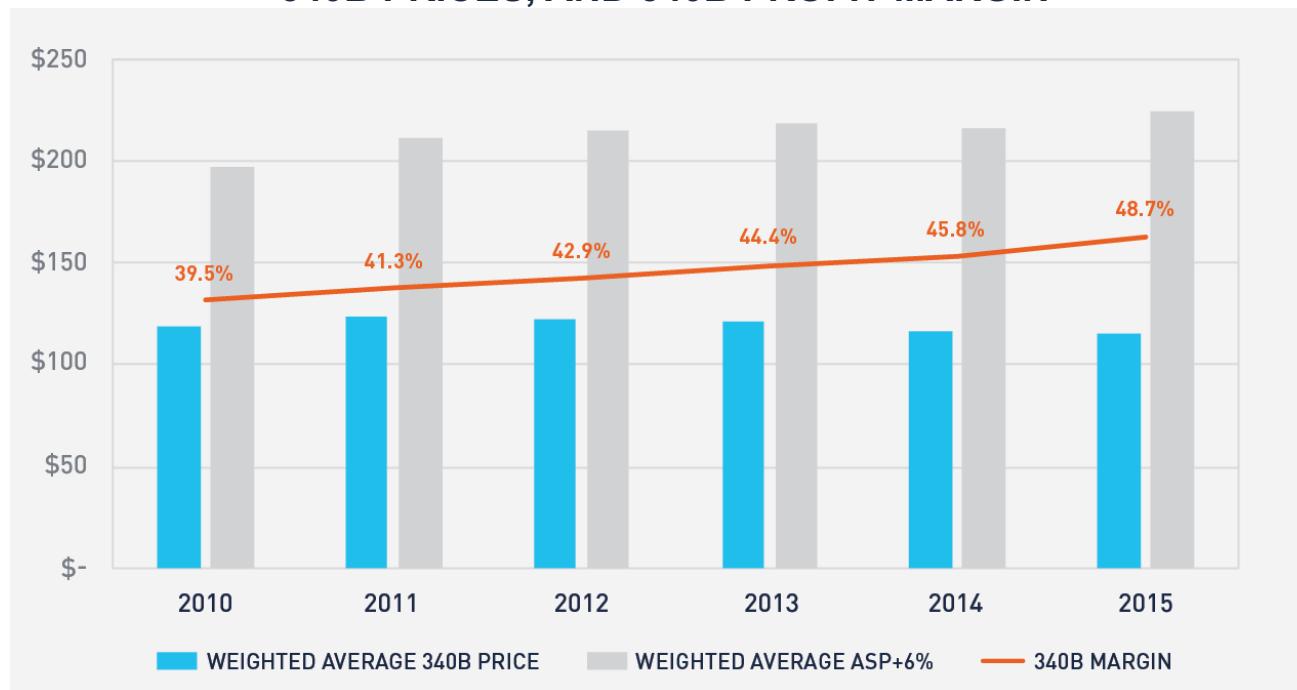


- Consolidation in the oncology marketplace has continued unabated between 2008 and 2016 as hospitals continue to expand oncology services through acquisition, joint ventures and referral arrangements

Oncology Drug Reimbursement



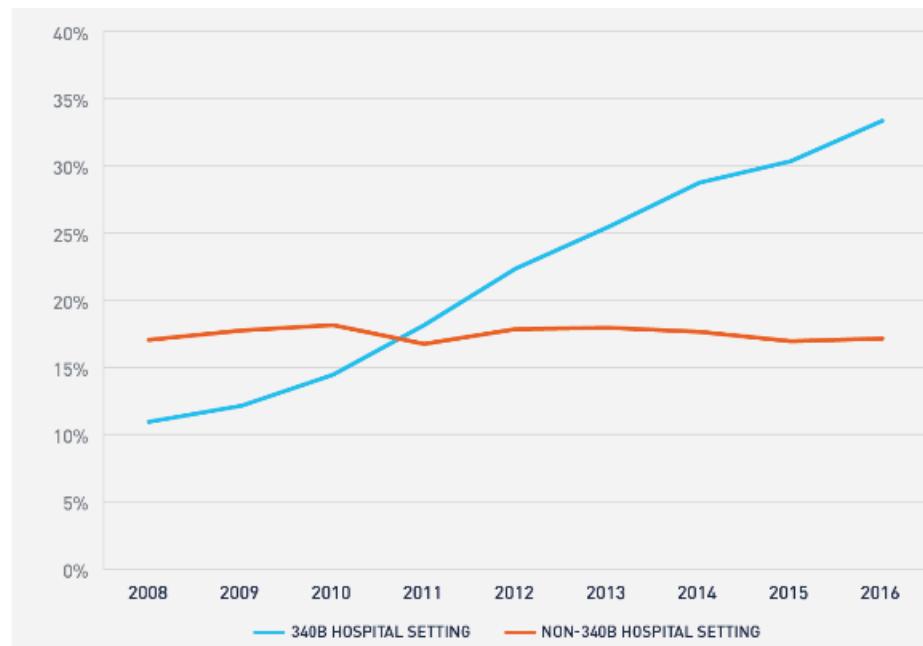
TRENDS IN ONCOLOGY DRUG REIMBURSEMENT, 340B PRICES, AND 340B PROFIT MARGIN



- Although ASP has increased at a steady pace, the CPI penalty and select commercial discounting have actually pushed 340B prices down

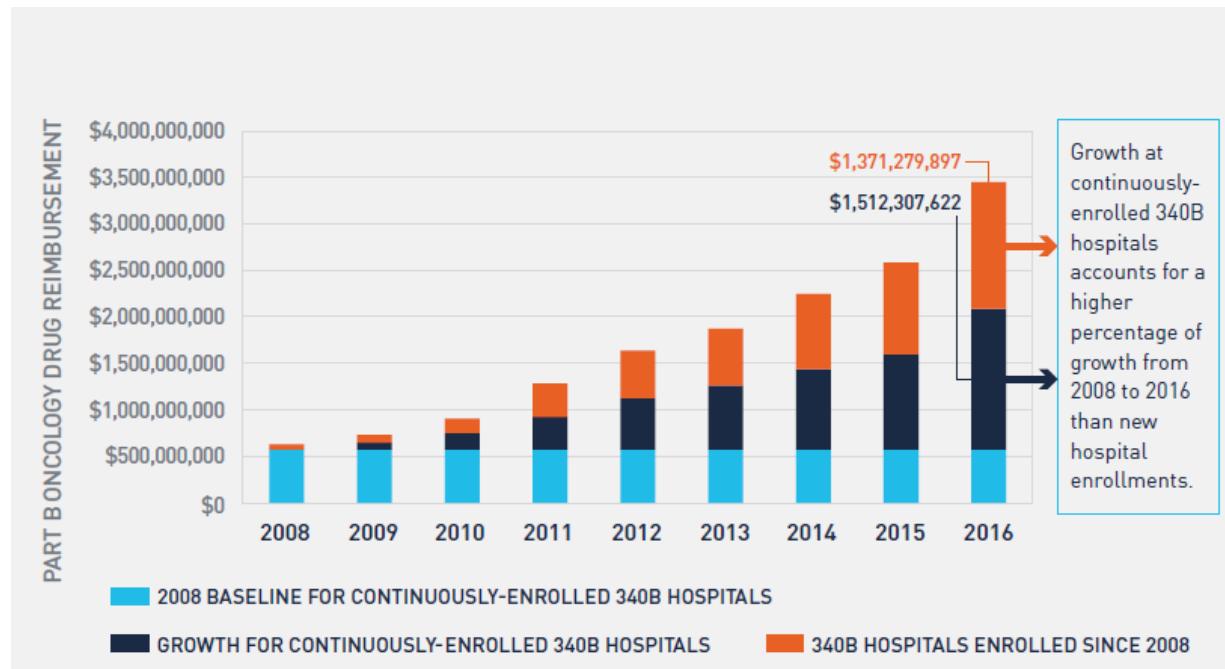
Part B Oncology Drug Reimbursement: Shift in Site of Care

PERCENTAGE OF PART B ONCOLOGY DRUG REIMBURSEMENT TO 340B AND NON-340B HOSPITALS



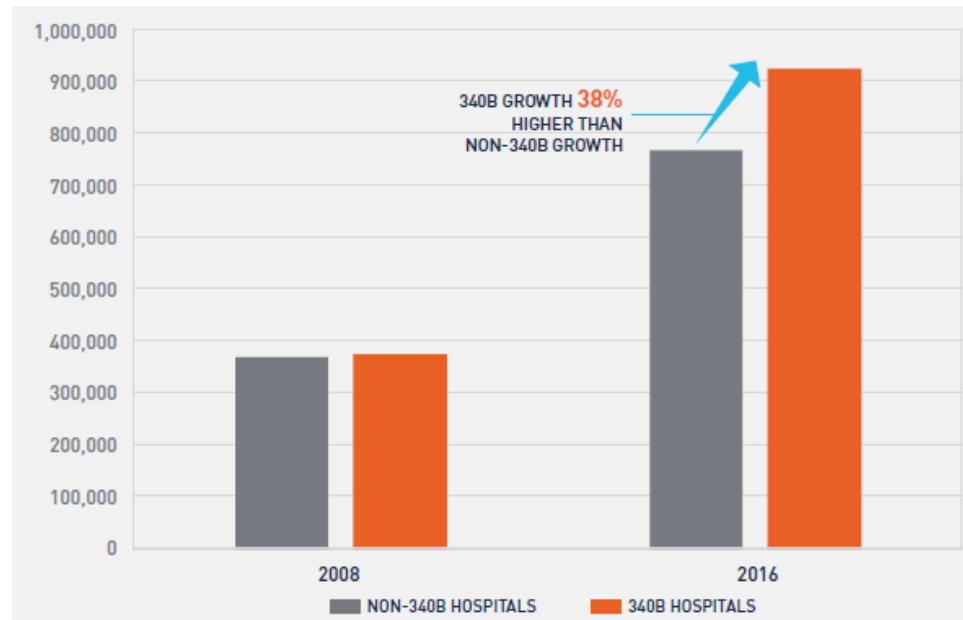
- New 340B hospital enrollment and expansion of existing 340B oncology programs have tripled 340B hospitals' share of Part B oncology drug reimbursement, while the share of reimbursement to non-340B hospitals remained nearly constant.

Growth in Part B Oncology Drug Reimbursement at Continuously-Enrolled 340B Hospitals



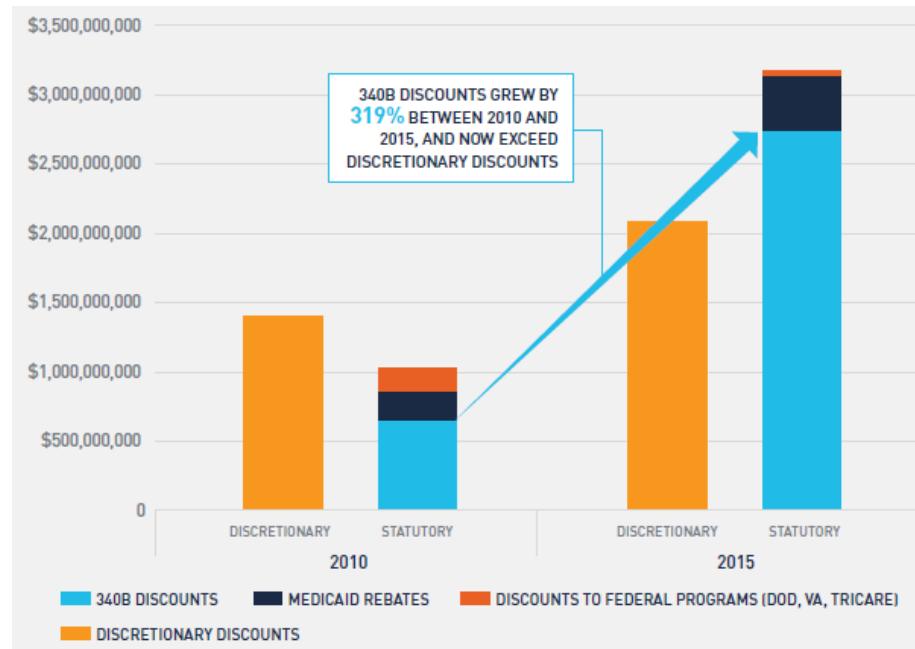
- Between 2008 and 2016, growth at continuously-enrolled 340B hospitals exceed utilization at newly-enrolled 340B hospitals combined.

Growth in Part B Oncology Drug Claims at 340B Hospitals vs. Non-340B Hospitals



- Between 2008 and 2016, oncology claims at continuously-enrolled 340B hospitals grew 38% faster than claims at hospitals that were not enrolled in the 340B program during this period reflecting the huge financial incentives in 340B.

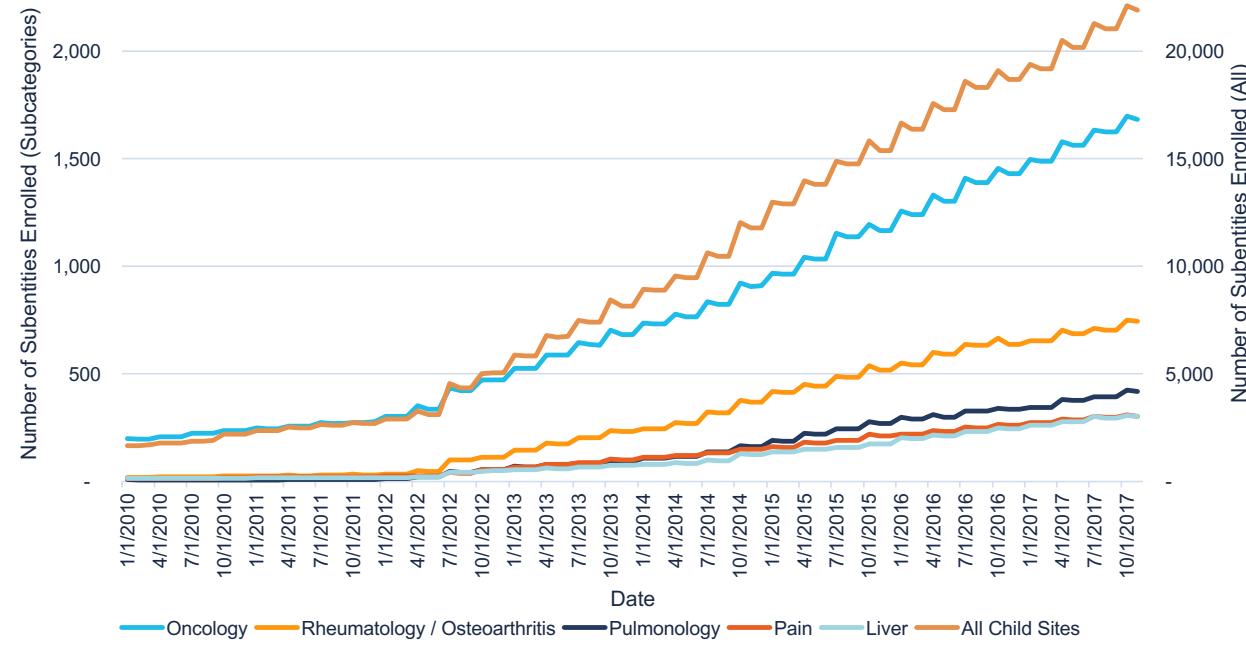
Change in Statutory and Discretionary Price Concessions on Oncology Drugs



- Between 2010 and 2015, statutory discounts paid by manufacturers on oncology drugs have increased dramatically, driven in large part by expansion of 340B.

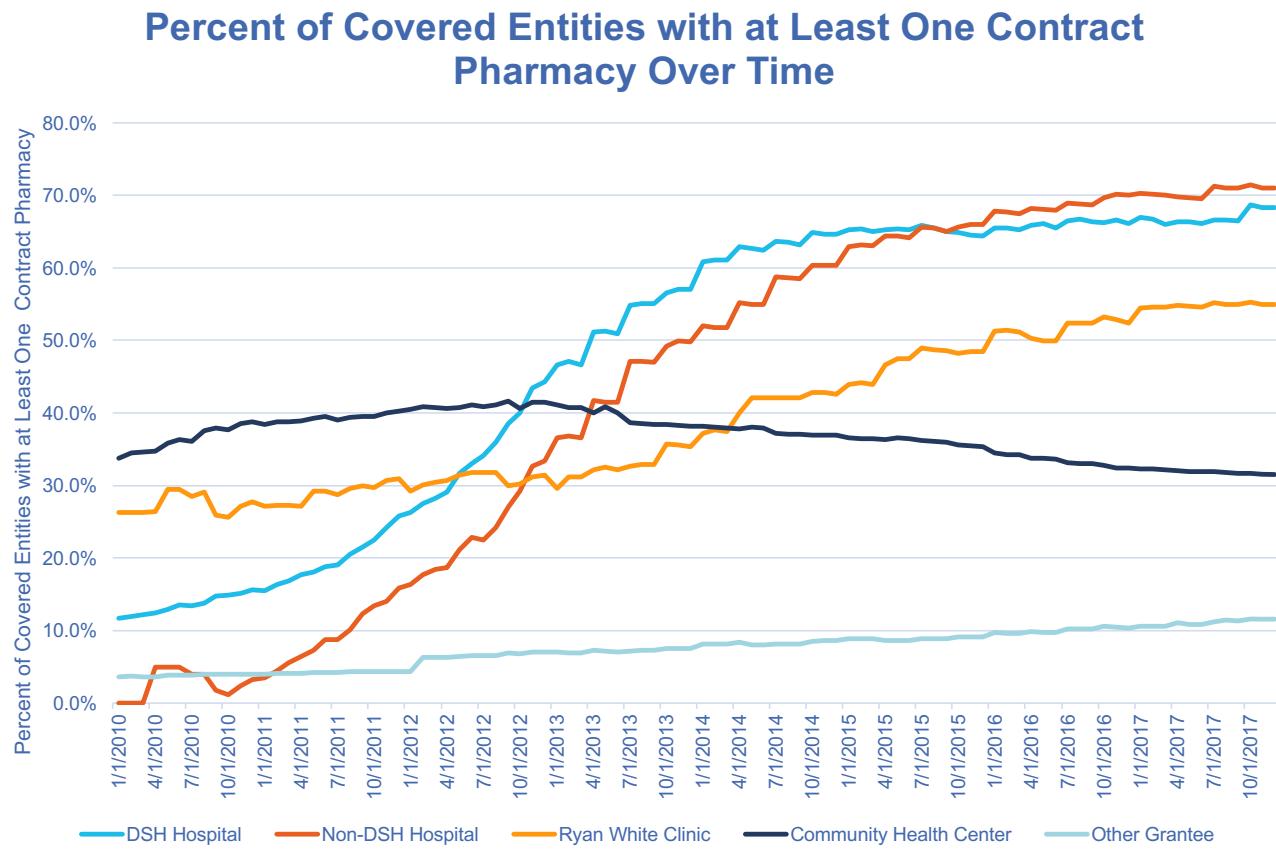
Growth in 340B Subentity Enrollments

340B Subentities Enrolled Over Time

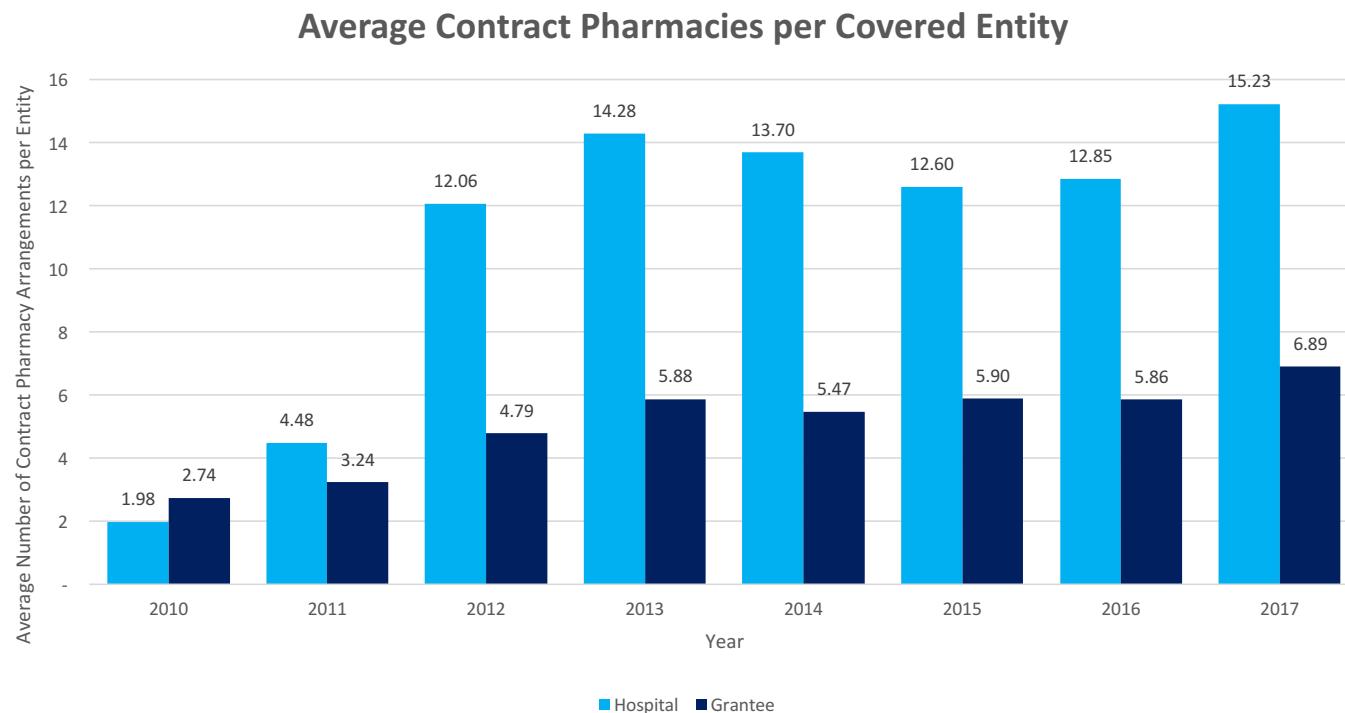


- 340B subentity enrollments have continued to increase in recent years as 340B hospitals acquire community practices or enroll additional locations within their health system.

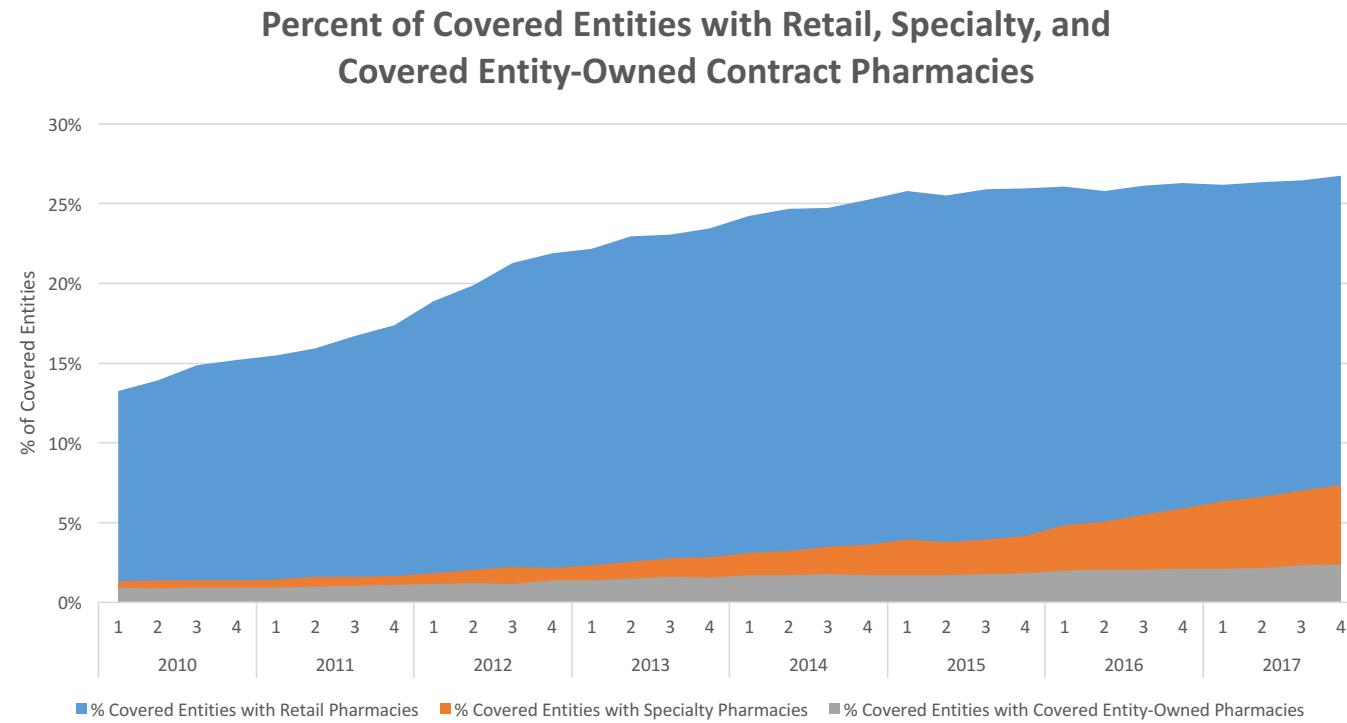
Hospitals and Ryan White Clinics Have Embraced Contract Pharmacy Arrangements



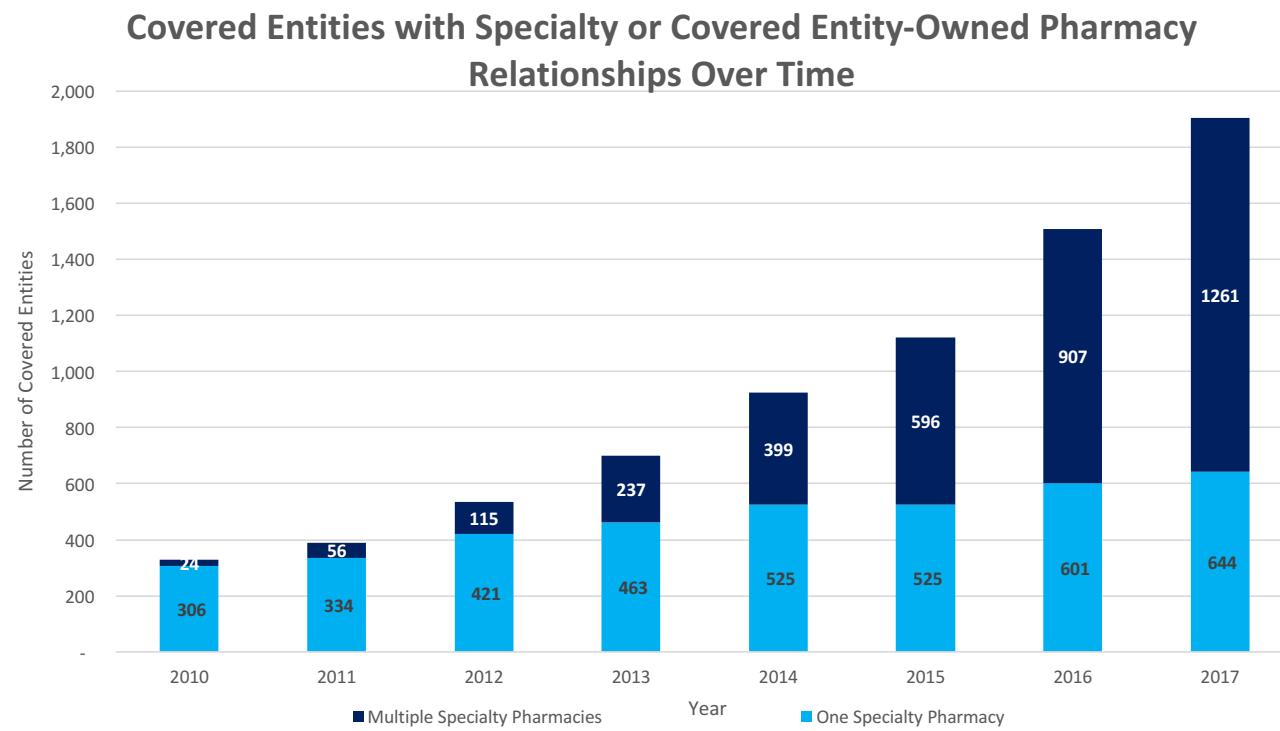
The Overall Size of Contract Pharmacy Networks Continues to Grow



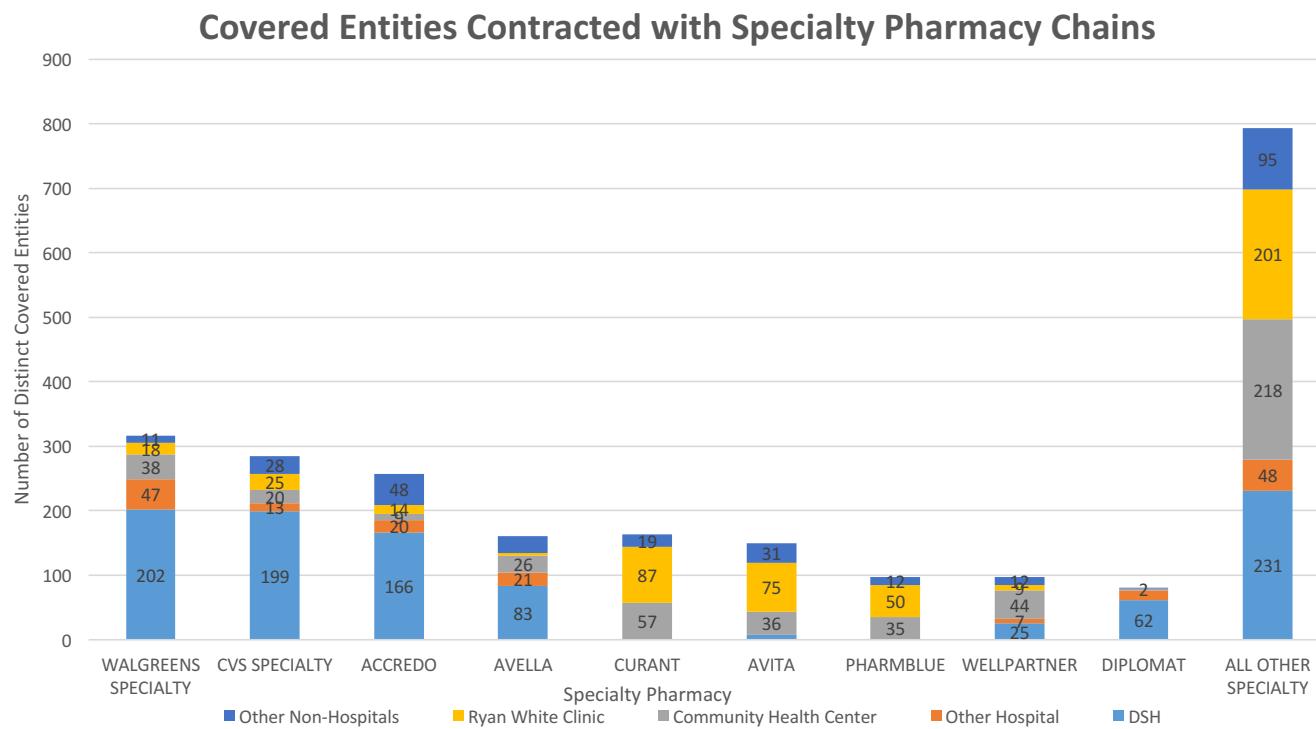
Although Traditional Retail Pharmacies Are Still Most Prevalent, Recent Growth is Concentrated in Specialty Pharmacies



An Increasingly Larger Percentage of Covered Entities Are Contracting with Multiple Specialty Pharmacies



Hospitals Tend to Contract with Large Specialty Pharmacies with National Coverage





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LEGISLATIVE AND REGULATORY ACTIVITY

Legislative Activity



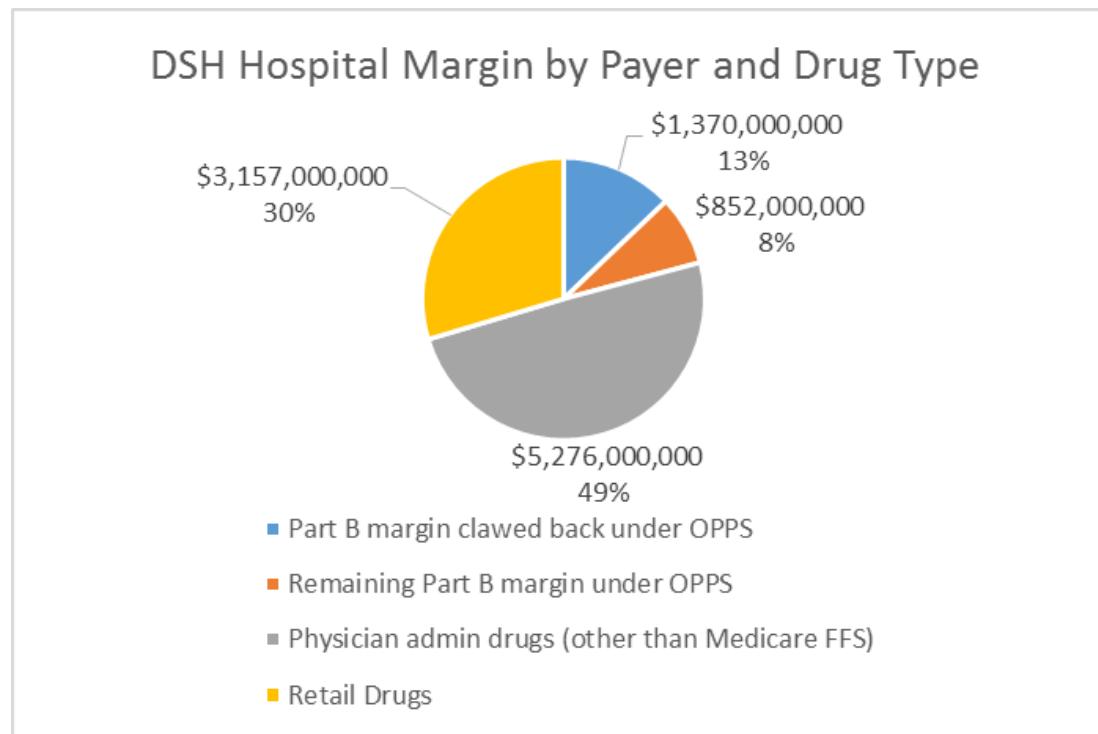
- 340B PAUSE Act
 - Introduced in late Dec. 2017 by Republican Rep. Larry Bucshon with bi-partisan support
 - Places a 2 year moratorium on new DSH hospital enrollments and child site registrations
 - Creates reporting requirements for DSH, cancer and children's 340B hospitals
- 340B HELP Act
 - Introduced in mid January 2018 by Republican Sen. Bill Cassidy
 - Places a 2 year moratorium on new DSH hospital enrollments and child site registrations
 - Grants regulatory authority to HHS for child site registration requirements
 - Creates reporting requirements similar to PAUSE Act and requires claims modifiers for claims to public and private payers

Regulatory Activity



- HOPPS Final Rule
 - Implemented on Jan. 1 2018
 - Reduces HOPPS Part B drug reimbursement from ASP +6% to ASP -22.5% (does not apply to drugs with pass-through status)
 - Litigation by three hospital associations is proceeding
- Medicare Physician Fee Schedule
 - Further reduces reimbursement to recently acquired community practices from 50% to 40% of the HOPPS rates
 - HOPPS reimbursement cut does not apply to recently acquired sites
 - Creates conflicting incentives pertaining to acquisitions of community oncology practices
- 340B CMP Final Rule
 - Delayed until July 1, 2018
 - Addresses “knowing and intentional overcharges” and penny pricing rule
 - Also states that manufacturers are responsible for actions of wholesalers
 - But...340B is wholesalers’ highest margin business, they own third party administrators and support reclassifications

Significant Hospital 340B Margin Remains After HOPPS Rule



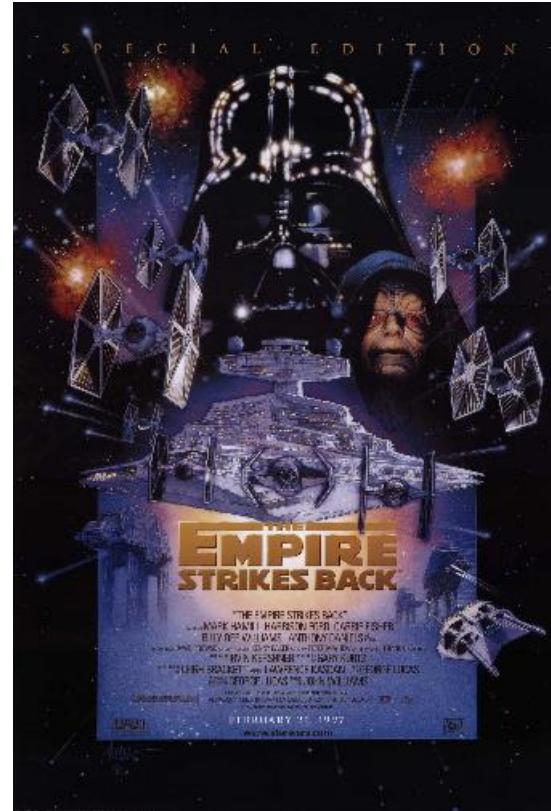
Note: The \$5.3B of spread from physician administered drugs (other than Medicare FFS) includes MA, commercial and Medicaid MCO sales.



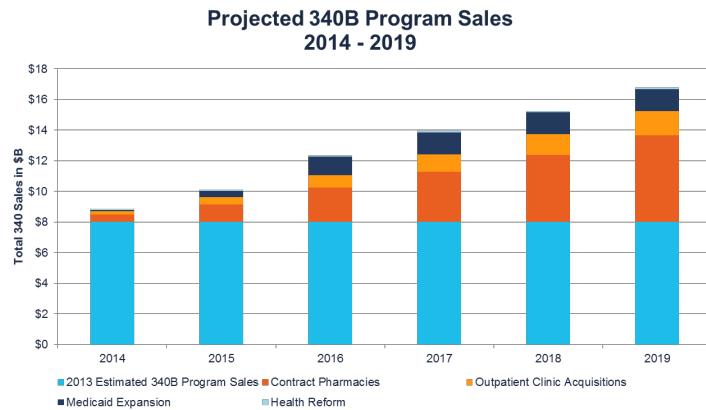
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OUTLOOK FOR 340B

The Empire Strikes Back?

- Unlikely that any meaningful legislation passes
- HOPPS rule could be reversed through litigation
- Regulatory action may not materialize
- AIDS Health Foundation and 340B Health are going on the offensive
 - www.let340B.com



How Big Can It Get?



- BRG's 2014 forecast for 340B growth met with widespread skepticism
- Within 2 years, forecasted sales were 25% less than actual sales
- Primary driver of difference attributable to increased shift in site of care

- BRG's 2016 forecast for 340B growth met with widespread skepticism
- 2016 actual sales were within 1% of actuals
- We now believe 2017 actuals will exceed \$19B in sales

