

**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



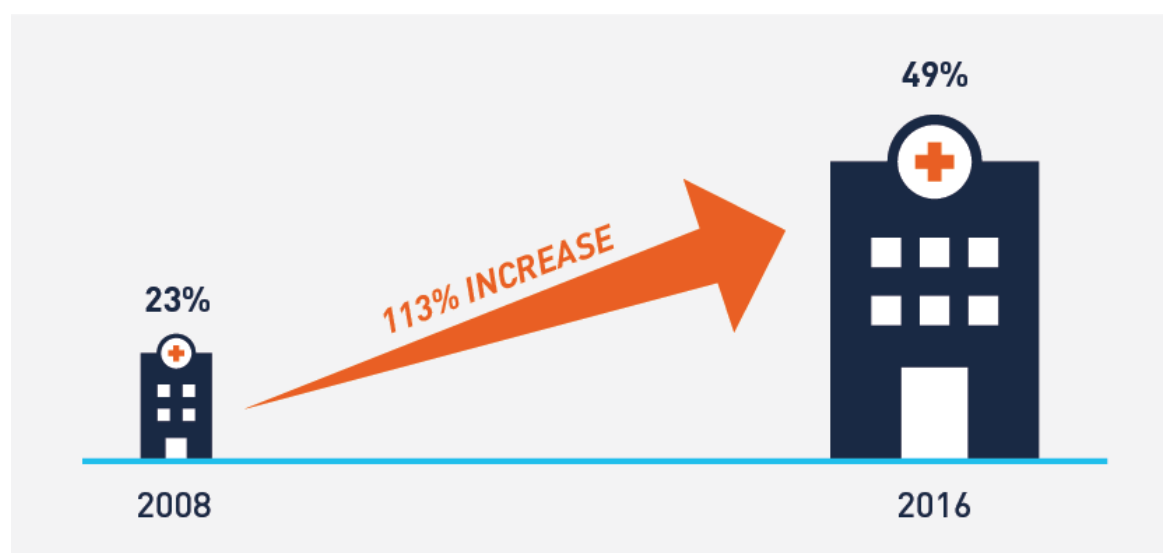
- Intersecting trends in oncology and 340B
  - Shift in site of care
  - Reimbursement and pricing trends
  - Rise contract specialty pharmacies
- Legislative and regulatory activity
  - HOPPS and MPFS changes
  - CMP final rule
  - Recent bills and potential regulatory action
- Outlook for 340B

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# **INTERSECTING TRENDS IN ONCOLOGY AND 340B**

# Chemotherapy Claims: Shift in Site of Care

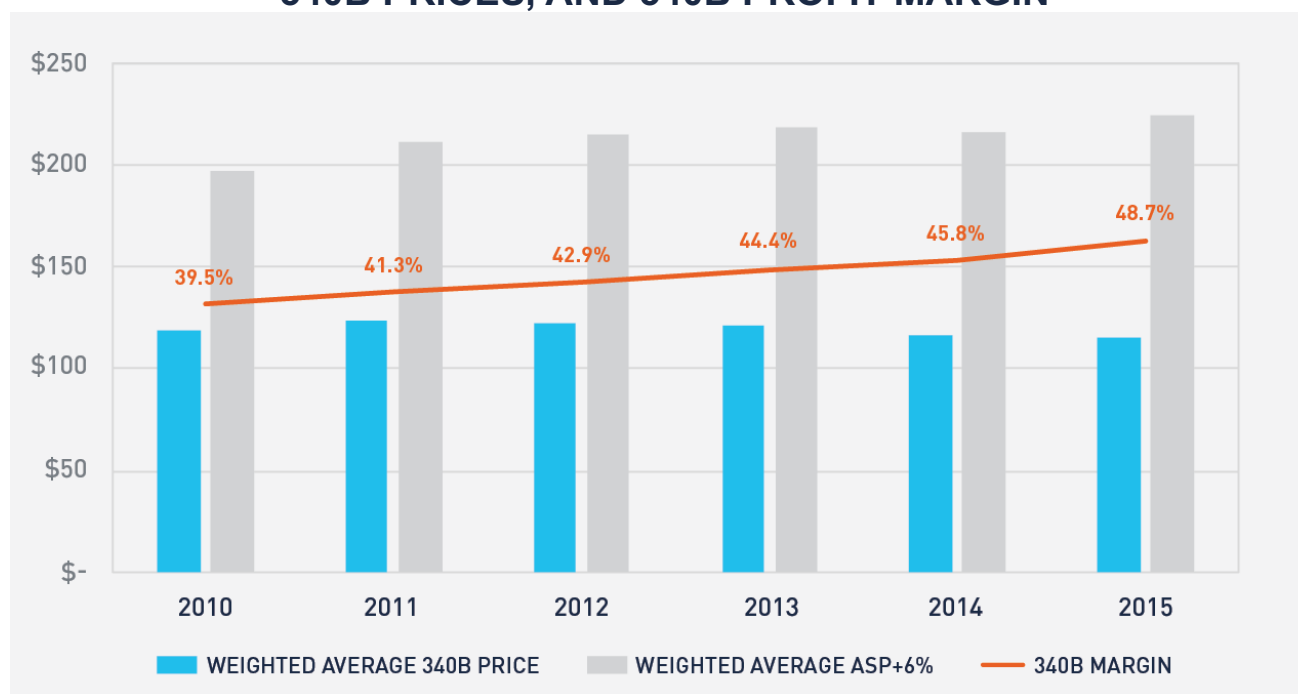
## PERCENT OF TOTAL CHEMOTHERAPY DRUG ADMINISTRATION CLAIMS IN THE HOSPITAL OUTPATIENT SETTING



- 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

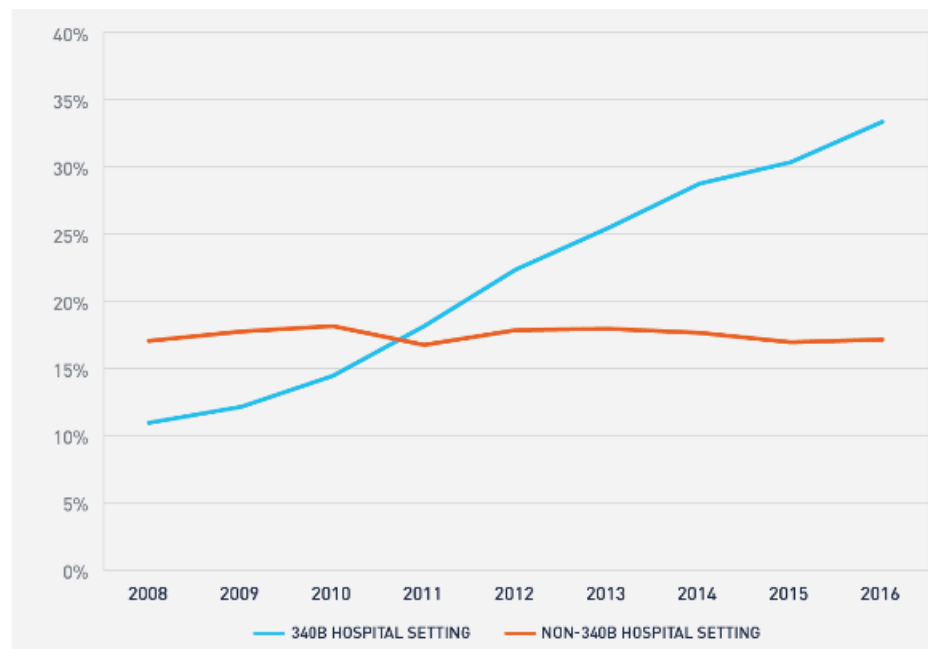


- Although ASP has increased at a steady pace, the CPI penalty and select commercial discounting have actually pushed 340B prices down

## Part B Oncology Drug Reimbursement: Shift in Site of Care

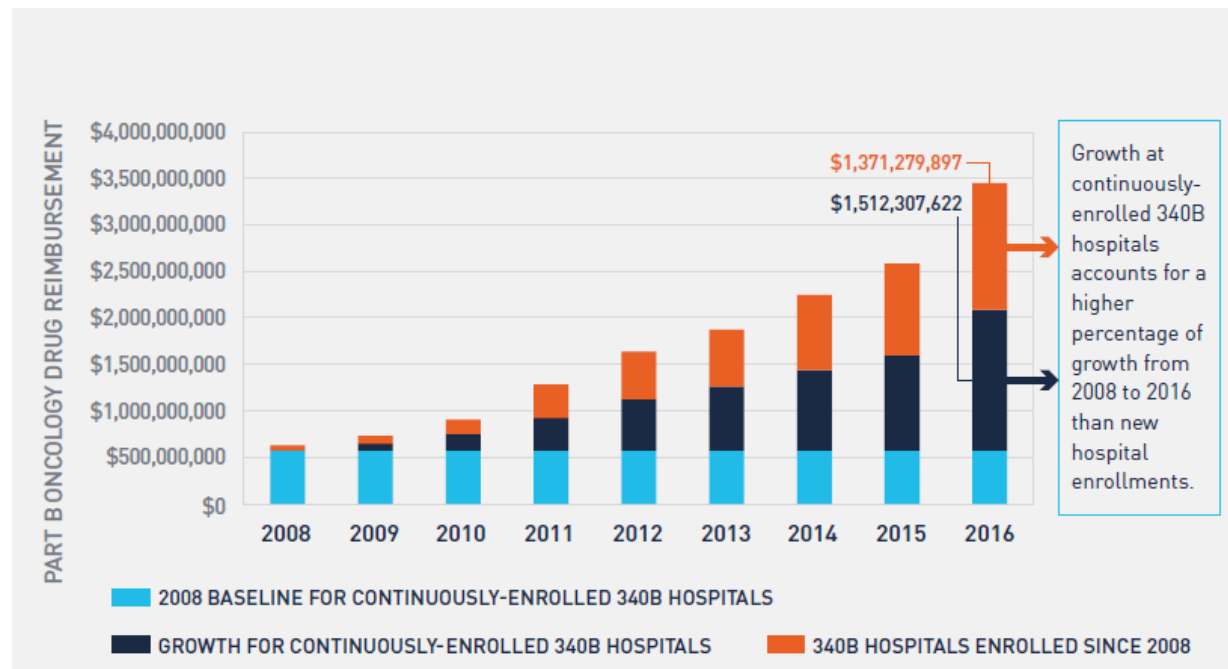


**PERCENTAGE OF PART B ONCOLOGY DRUG  
REIMBURSEMENT TO 340B AND NON-340B HOSPITALS**



- 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.

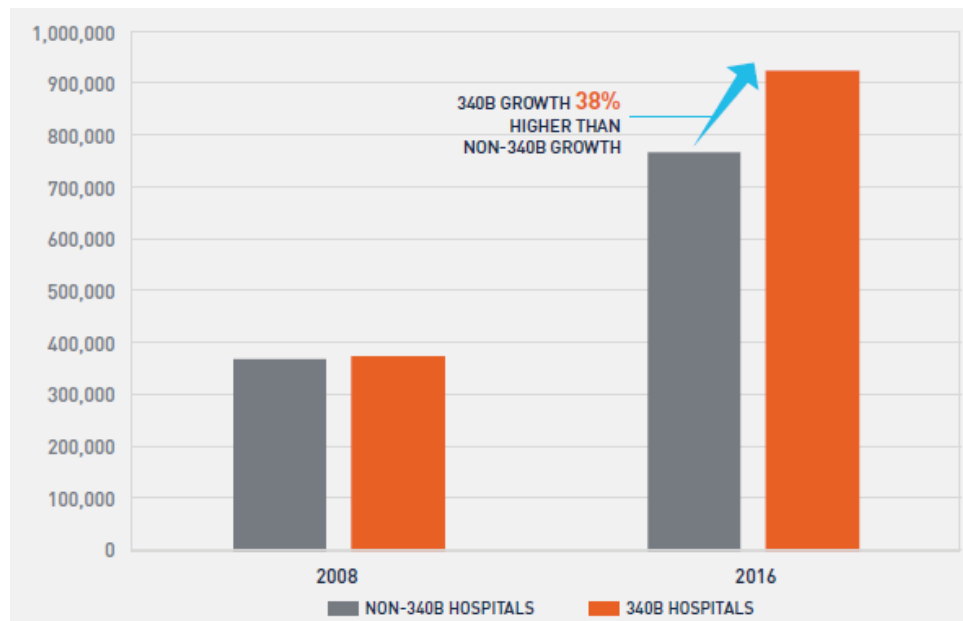
# Growth in Part B Oncology Drug Reimbursement at Continuously-Enrolled 340B Hospitals



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

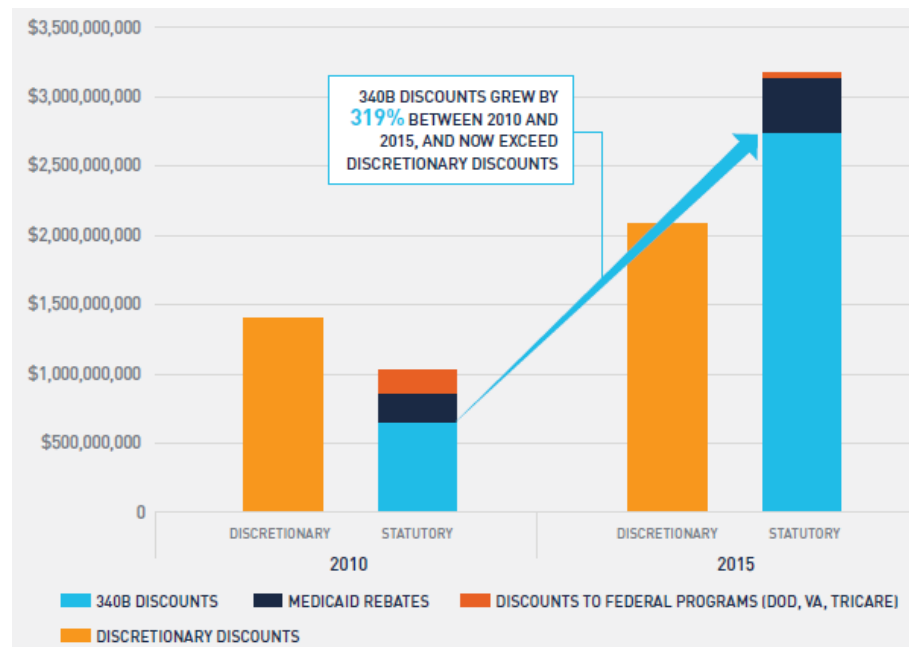


## Growth in Part B Oncology Drug Claims at 340B Hospitals vs. Non-340B Hospitals



- 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

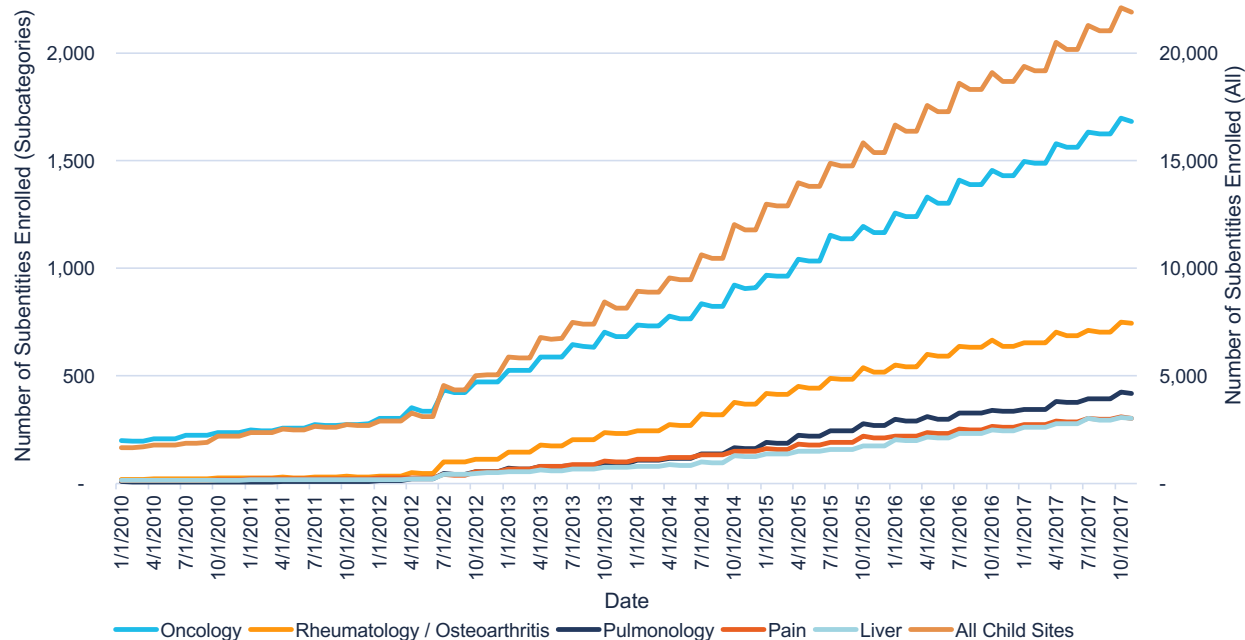


- Between 2010 and 2015, statutory discounts paid by manufacturers on oncology drugs have increased dramatically, driven in large part by expansion of 340B.

# Growth in 340B Subentity Enrollments



## 340B Subentities Enrolled Over Time

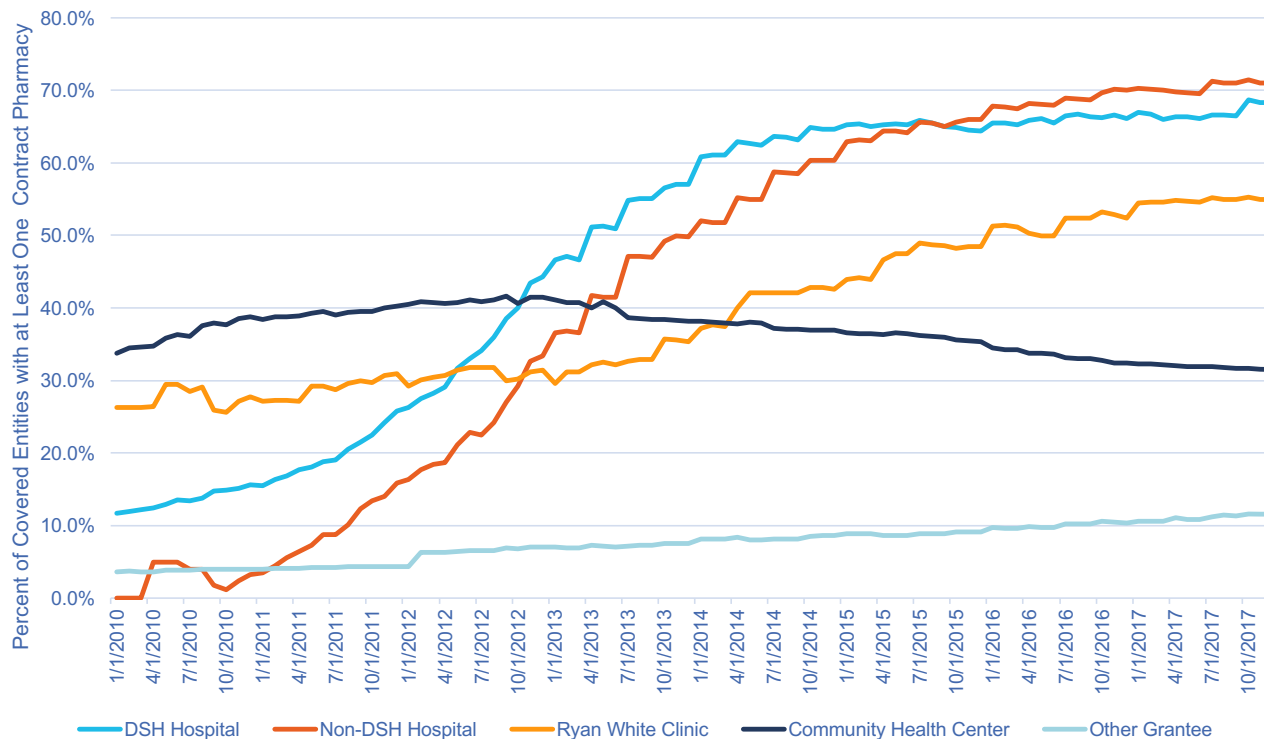


- 340B subentity enrollments have continued to increase in recent years as 340B hospitals acquire community practices or enroll additional locations within their health system.

# Hospitals and Ryan White Clinics Have Embraced Contract Pharmacy Arrangements



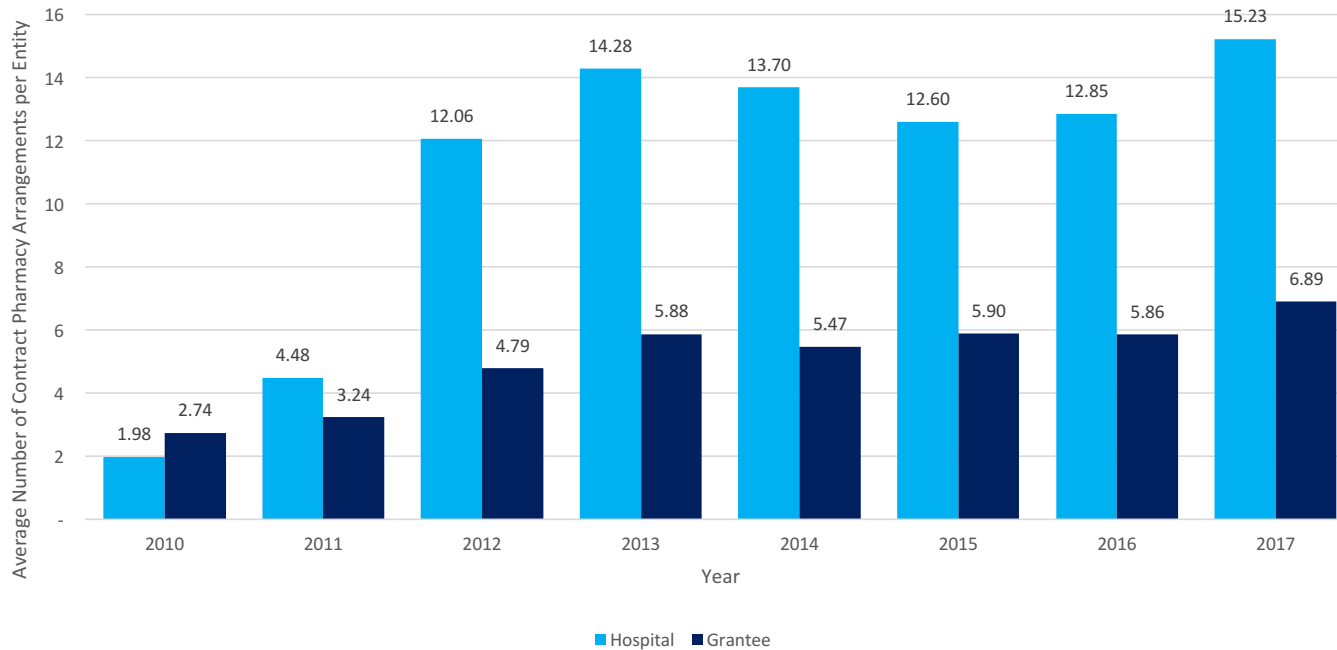
Percent of Covered Entities with at Least One Contract Pharmacy Over Time



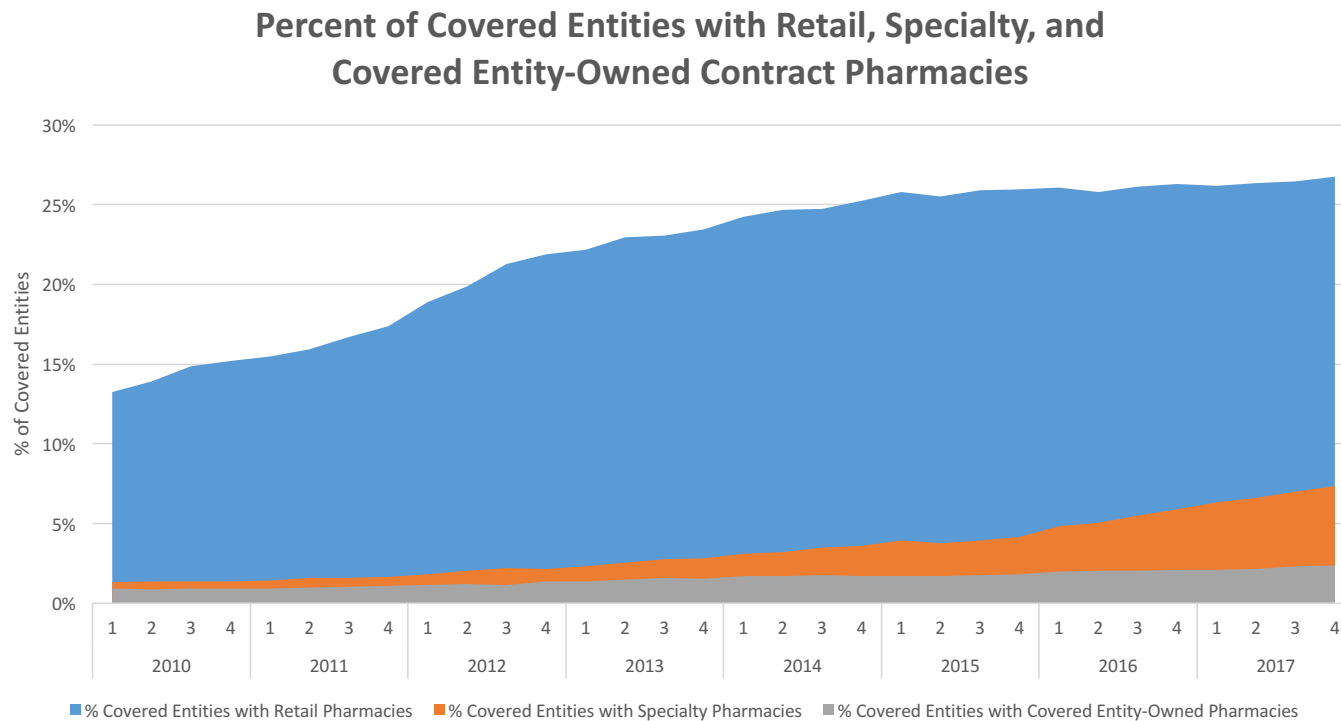
# The Overall Size of Contract Pharmacy Networks Continues to Grow



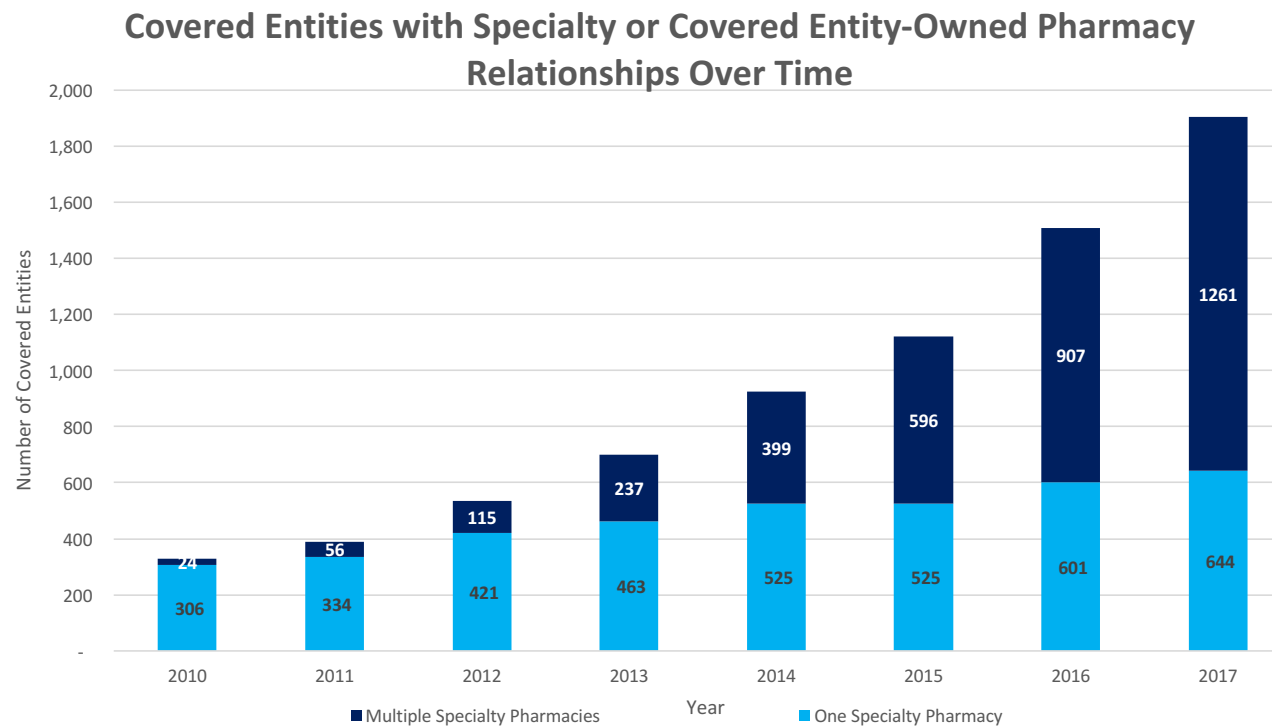
Average Contract Pharmacies per Covered Entity



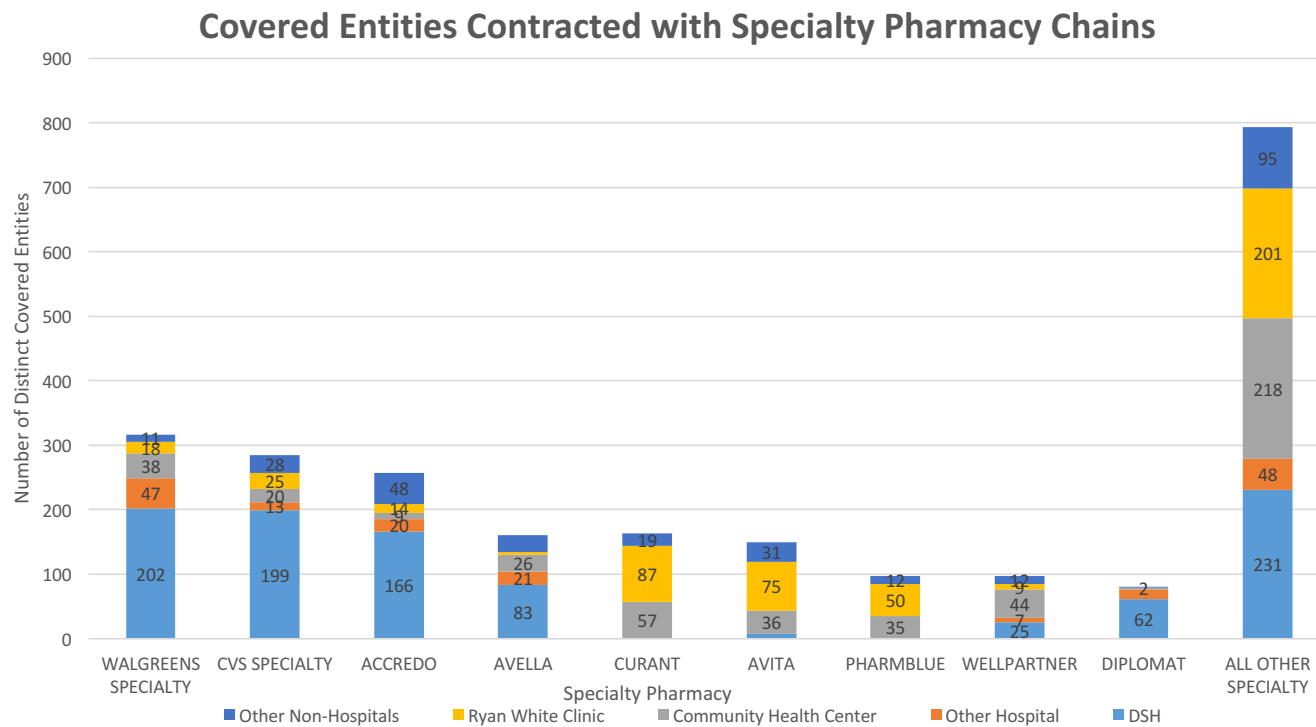
## Although Traditional Retail Pharmacies Are Still Most Prevalent, Recent Growth is Concentrated in Specialty Pharmacies



## 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



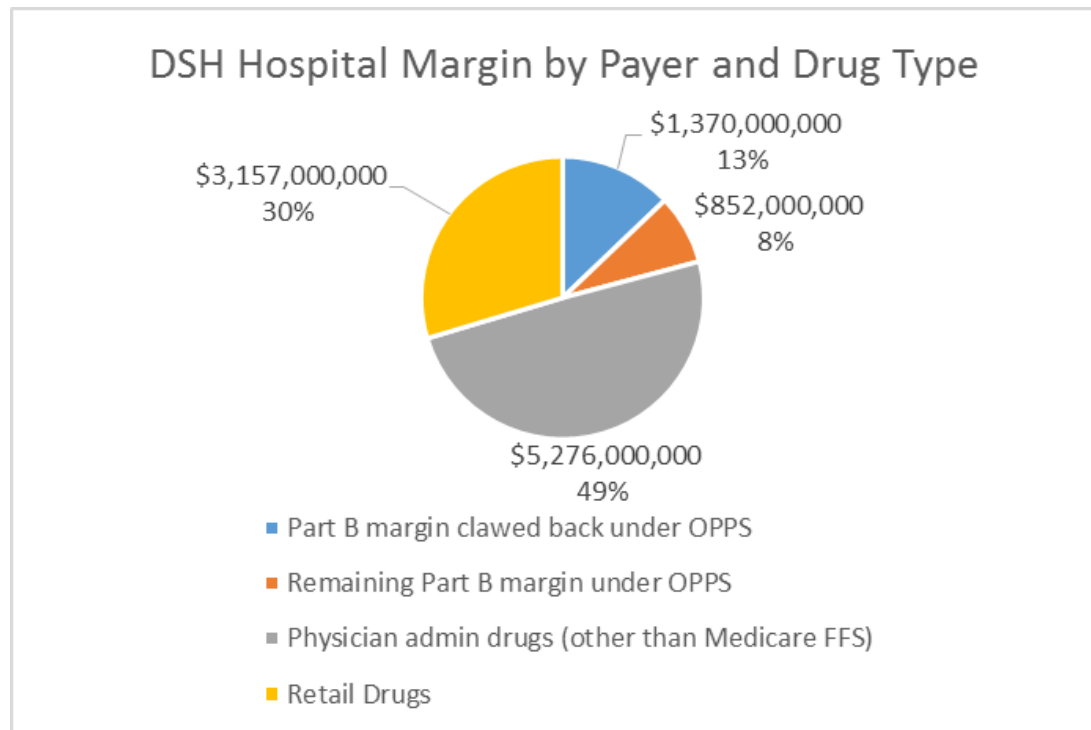
- 340B PAUSE Act
  - Introduced in late Dec. 2017 by Republican Rep. Larry Bucshon with bi-partisan support
  - Places a 2 year moratorium on new DSH hospital enrollments and child site registrations
  - Creates reporting requirements for DSH, cancer and children's 340B hospitals
- 340B HELP Act
  - 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?

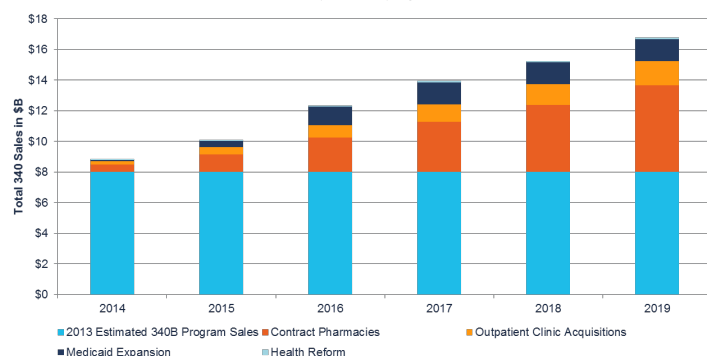
- Unlikely that any meaningful legislation passes
- HOPPS rule could be reversed through litigation
- Regulatory action may not materialize
- AIDS Health Foundation and 340B Health are going on the offensive
  - [www.let340B.com](http://www.let340B.com)



# How Big Can It Get?



Projected 340B Program Sales  
2014 - 2019



- 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

