



8th Annual Oncology Economics Summit

**Estimating the Impact of Recent Legislation on Future Growth
in the 340B Program**

La Jolla, CA
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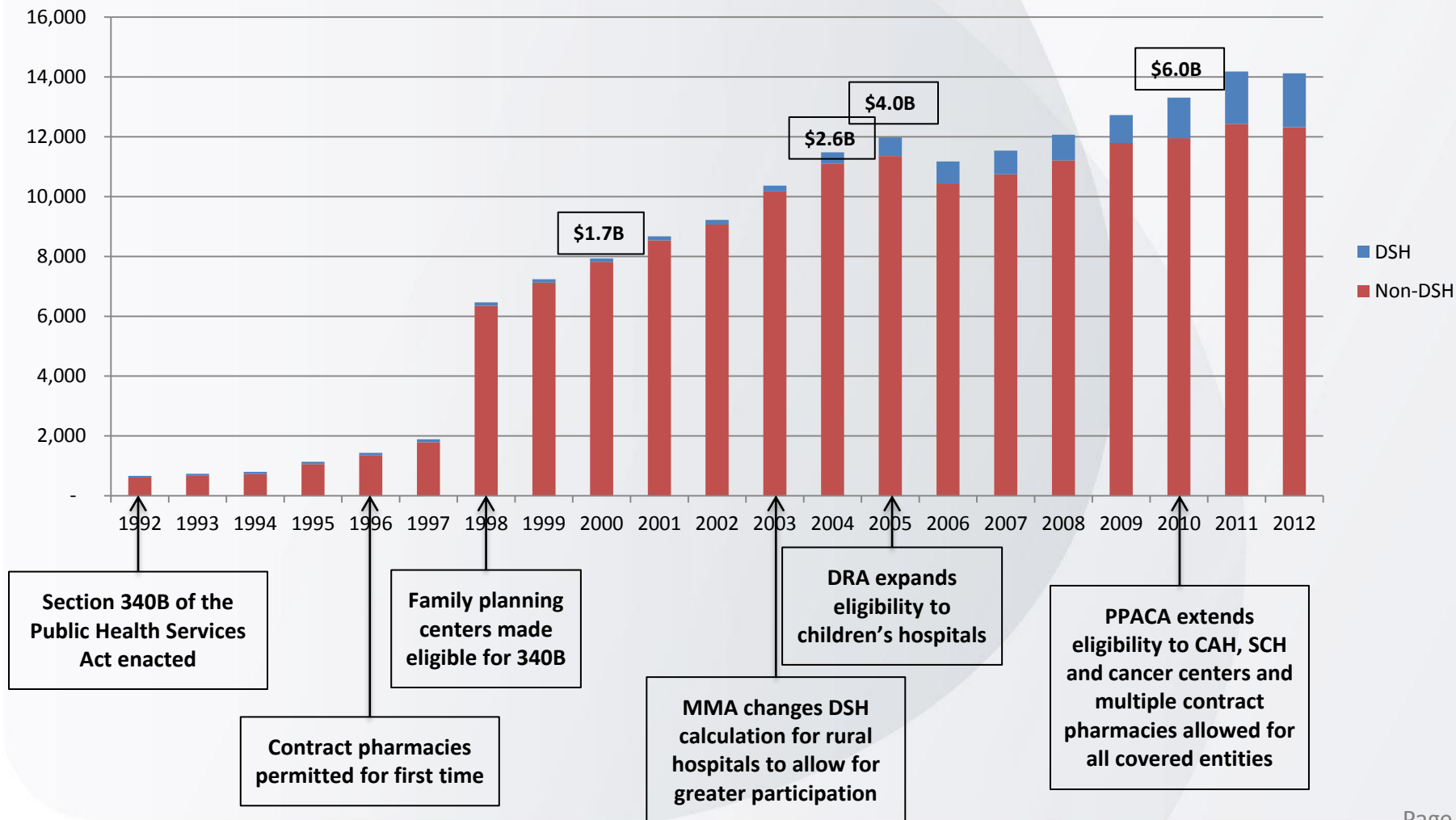
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Presentation Outline

- Timeline of 340B program and overview of growth to date
- Growth drivers over the next 5 years
 - Health Reform
 - Medicaid Expansion
 - Multiple Contract Pharmacy Networks
 - Organic Growth and Sub-Entity Expansion
- Assessment Framework
- Case Study

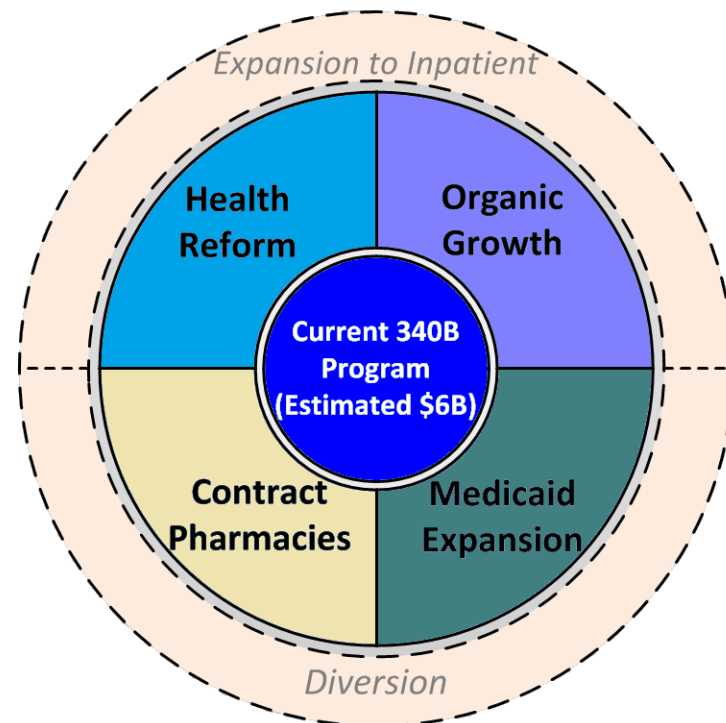
Overview of 340B Growth to Date

DSH v. Non-DSH 340B Enrollment

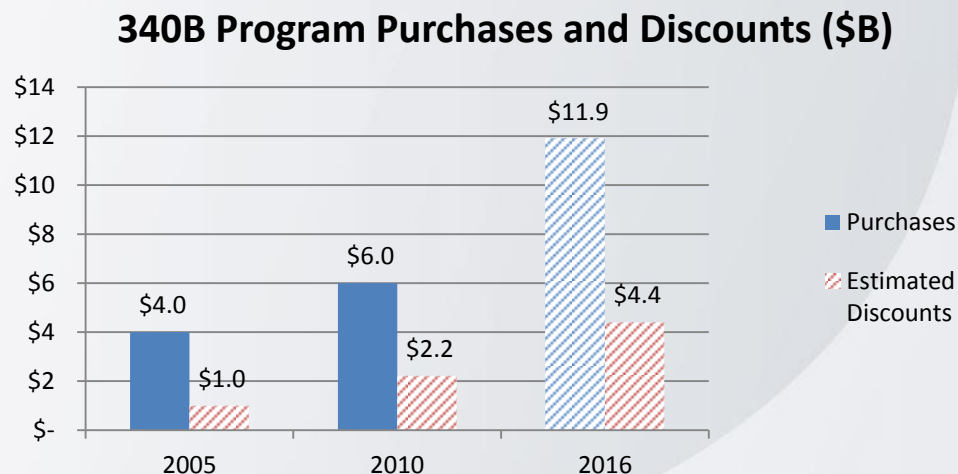


Growth in the 340B program will be driven by 4 primary factors over the next 5 years

1. Enrollment of entities made newly eligible through health reform
2. Enrollment of DSH and sole community hospitals that become newly eligible through Medicaid expansion in 2014
3. Expansion of multiple contract pharmacy networks (MCPNs)
4. Organic growth at entities already enrolled in the 340B program



- Our analysis estimates that drug purchases through the 340B program will double from \$6B in 2010 to \$12B by 2016
- Recent policy changes will drive much of this growth
 - Health reform expansion of eligible entities
 - Health reform expansion of Medicaid
 - Rule change allowing for multiple contract pharmacies
- The advent of multiple contract pharmacy networks (MCPNs) will drive over half of the growth in the 340B program



Source: BRG analysis of 2011 Office of Pharmacy Affairs data and 2009 and 2010 CMS data.

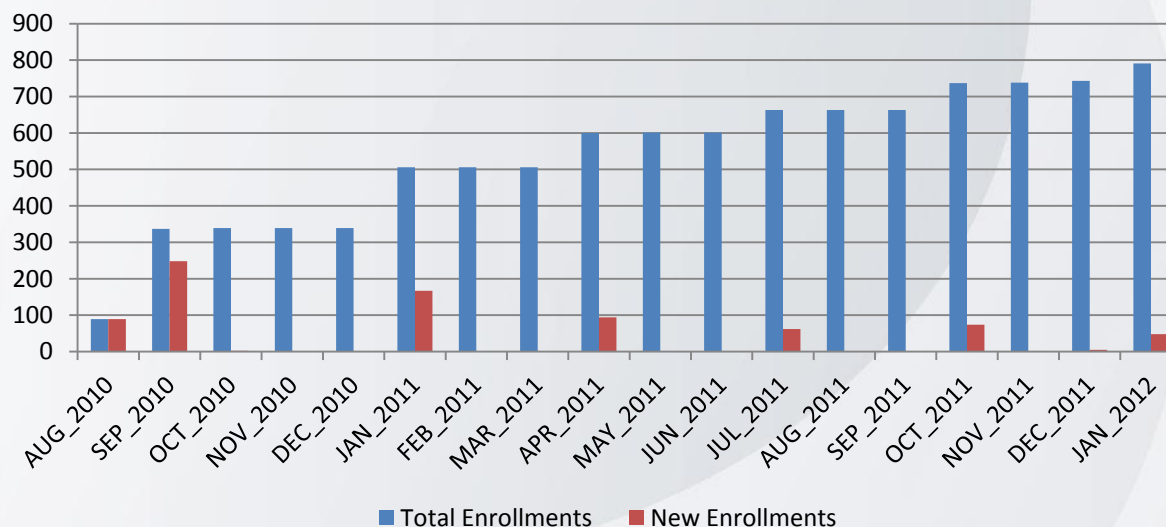
Growth Drivers

HEALTH REFORM

Growth Drivers: Health Reform

- PPACA expanded eligibility to include:
 - Critical Access Hospitals – typically 35 beds or less
 - Sole Community Hospitals – DSH threshold of 8%
 - Children's Hospitals & Cancer Centers – DSH threshold of 11.75%
- As of 1/31/2012, 791 of the estimated 1,400 newly eligible entities have already enrolled in the 340B program, representing an enrollment rate in the first 18 months of ~55%

340B Enrollments by Newly Eligible Entities



Newly Eligible Entities Through Health Reform

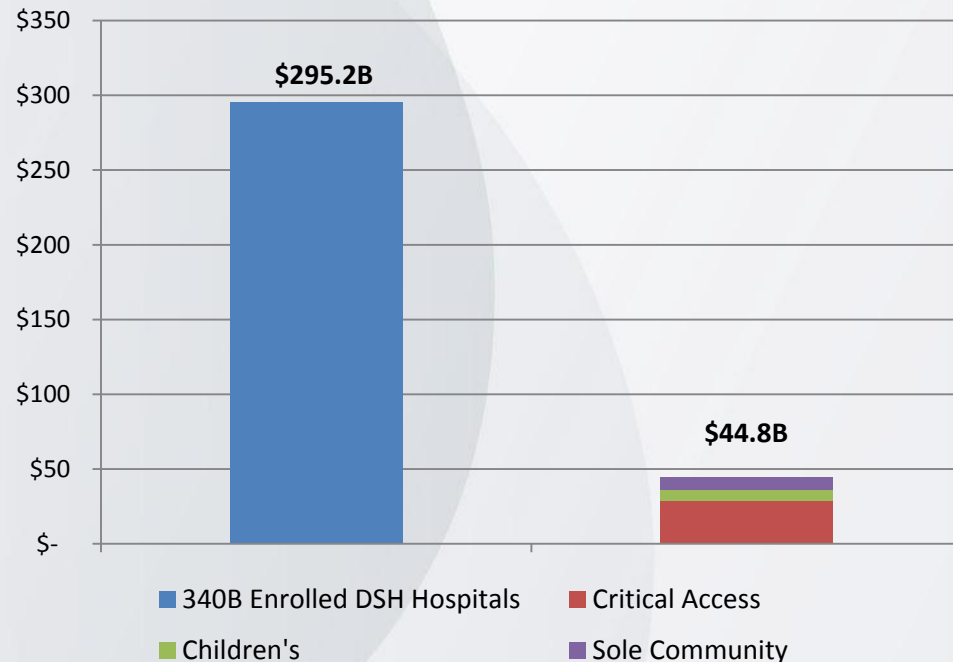
Overview of Methodology

- Identify all newly eligible entities resulting from PPACA legislation
- Calculate the outpatient revenue at the newly eligible entities accounting for likelihood that some entities will not enroll
- Estimate the percentage growth attributable to newly eligible entities by comparing total outpatient revenue with the currently enrolled DSH entities

Key Findings

- Entities attaining eligibility as a result of health reform represent additional purchases in 2016 of over \$500M

Comparison of 2009 Outpatient Revenue



Source: BRG analysis of 2009 and 2010 CMS data.

Growth Drivers

MEDICAID EXPANSION

340B DSH Eligibility Overview

- The 340B program includes a variety of eligibility categories including non-profit & government hospitals with a DSH adjustment percentage greater than 11.75% or sole community hospitals with a DSH percentage greater than 8%.
- The DSH adjustment percentage formula is based on the DSH Patient Percentage (DPP) which is calculated as follows:

$$\text{DPP} = \frac{\text{Patient Days of Medicare Part A \& SSI Enrollment}}{\text{Patient Days of Medicare Part A Entitlement}} + \frac{\text{Patient Days of Medicaid Eligibility \& Not Medicare Part A}}{\text{Total Hospital Patient Days}}$$

- A DPP score of 27.32% or higher translates to a DSH adjustment percentage of 11.75% or higher and a score of 22.77% translates to 8% or higher.
- Therefore, non-profit or government hospitals with a DPP greater than 27.32% and sole community hospitals with a DPP greater than 22.77% are eligible for the 340B program through the DSH eligibility category.

340B DSH Eligibility Overview - continued

- The DPP formula includes a ‘Medicaid Fraction’ which measures the number of Medicaid eligible patient days as a percentage of total hospital patient days.
- A shift toward Medicaid eligible patient days result in a higher DPP – all else remaining equal – as demonstrated in the example below.

	Baseline	10% Increase in Medicaid Patient Days
Patient Days of Medicare Part A & SSI Enrollment	50	50
Patient Days of Medicare Part A Entitlement	500	500
SSI Fraction	10.0%	10.0%
Patient Days of Medicaid Eligibility & Not Medicare Part A	500	550
Total Hospital Patient Days	3000	3000
Medicaid Fraction	16.7%	18.3%
DSH Patient Percentage	26.7%	28.3%

- As Medicaid eligibility increases, the number of non-profit and government hospitals that become 340B eligible through the DSH adjustment percentage will also increase.

Newly Eligible DSH & SCH Hospitals Due to Medicaid Expansion

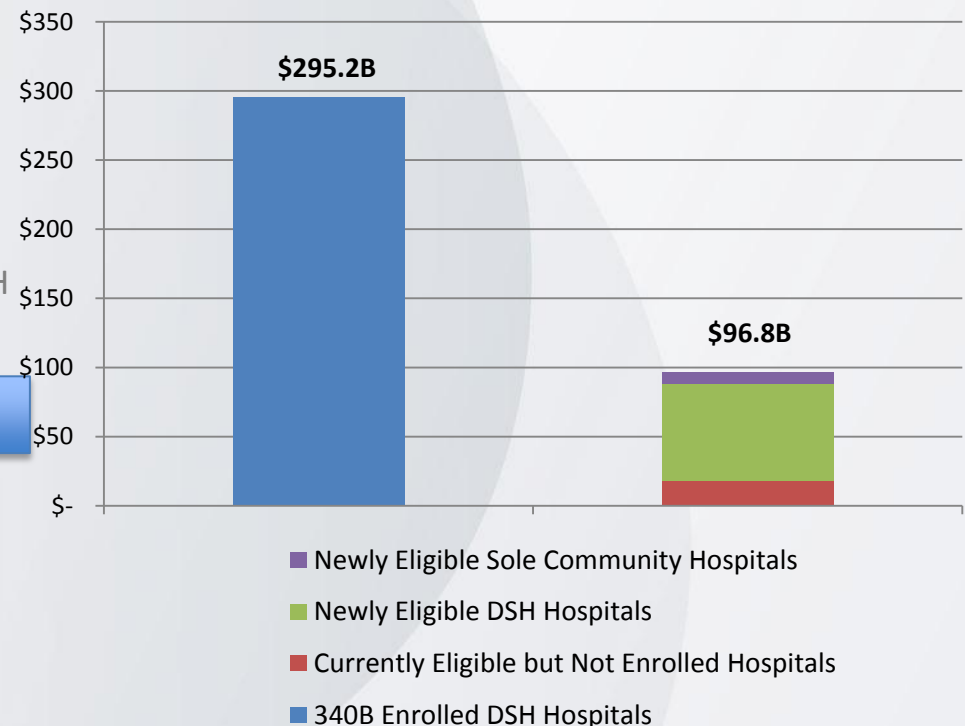
Overview of Methodology

- Calculate growth in Medicaid inpatient days needed to reach DSH eligibility for non-enrolled DSH and SCH hospitals
- Compare growth needed for eligibility with expected growth in Medicaid enrollees in 2014
- Estimate the percentage growth attributable to newly eligible entities by comparing total outpatient revenue with the currently enrolled DSH entities

Key Findings

- Total of 342 hospitals may become newly eligible as a result of Medicaid expansion in 2014
- These hospitals represent an estimated \$1.2B increase in 340B drug purchases

Comparison of 2009 Outpatient Revenue



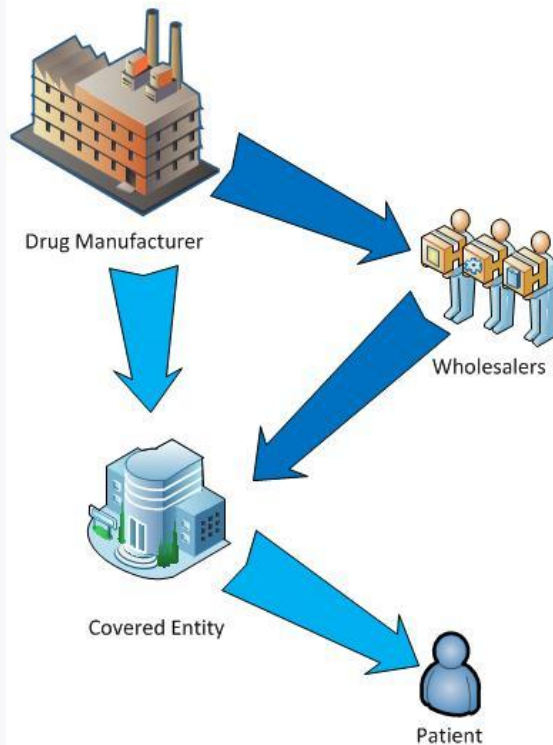
Source: BRG analysis of 2009 and 2010 CMS data.

Growth Drivers

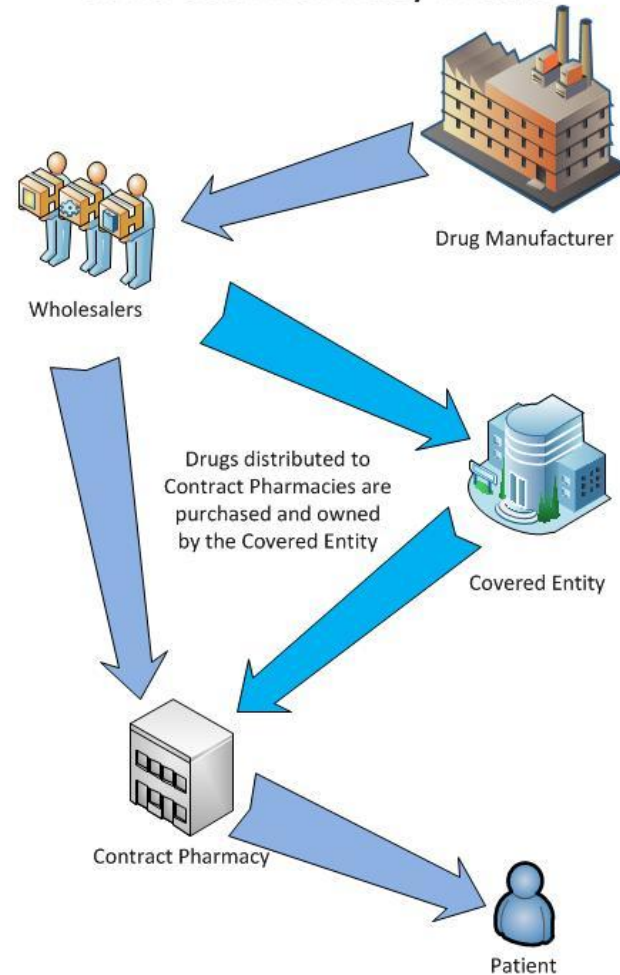
MULTIPLE CONTRACT PHARMACY NETWORKS

How Contract Pharmacies Work – Product Distribution

340B Product Distribution Traditional Model

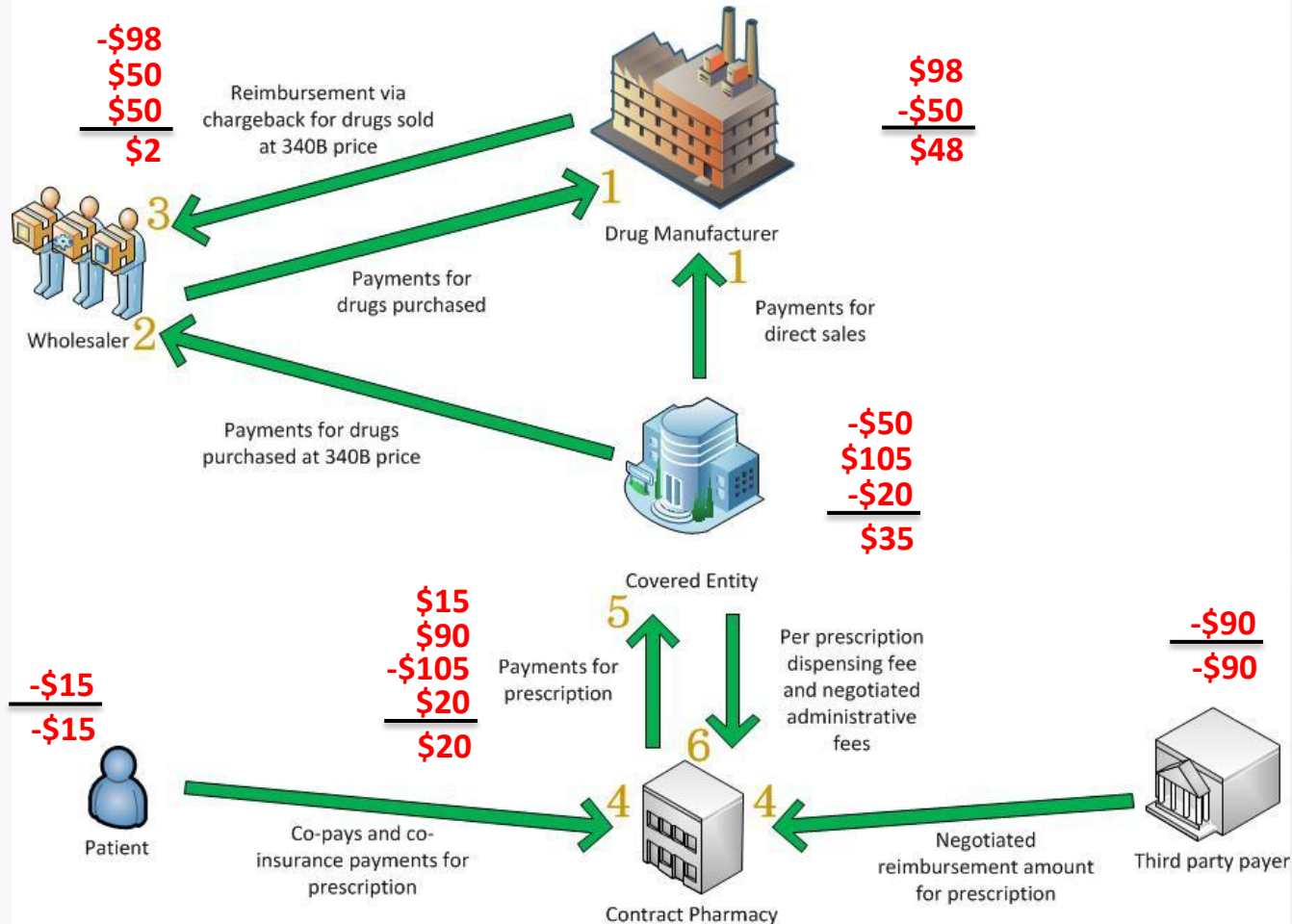


340B Product Distribution Contract Pharmacy Model



How Contract Pharmacies Work – Capital Distribution

340B Capital Distribution

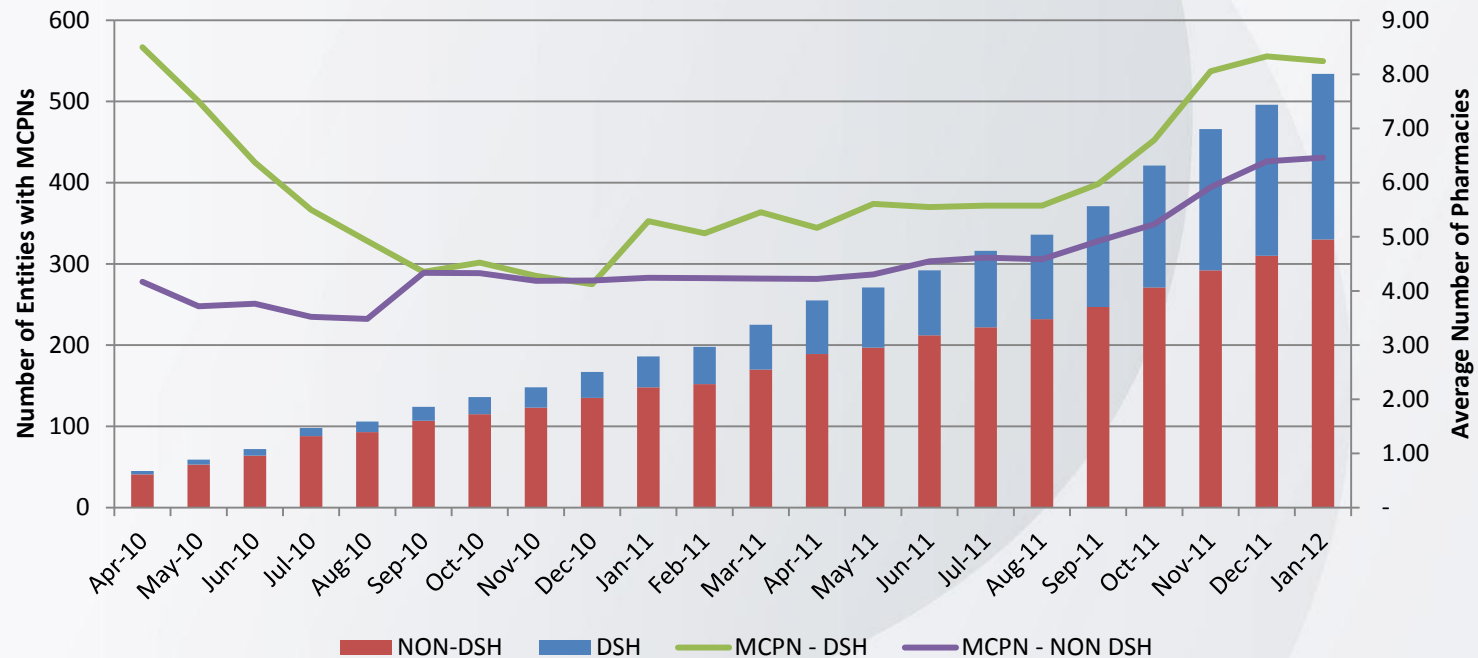


- Contract pharmacy services firms contract with Covered Entities to develop networks of contract pharmacies that fill prescriptions at 340B prices
- These firms pre-process the prescriptions on behalf of a Covered Entity and determine whether the prescription will be profitable to both the pharmacy and the Covered Entity
 - If yes, dispense from 340B inventory and remit payment to Covered Entity
 - If no, dispense from pharmacy's own inventory and retain payment
- Contract pharmacy services firms handle inventory management and ensure that 340B inventory is available for all eligible prescriptions

Alignment of Incentives is Translating to Substantial Growth in Creation of Multiple Contract Pharmacy Networks

- Although non-DSH hospitals were the primary participants in the multiple contract pharmacy demonstration project, DSH hospitals are driving current growth in enrollment of MCPNs
 - DSH hospitals typically create much larger networks and have more outpatient discharges

340B Entities With Multiple Contract Pharmacy Networks



Source: BRG analysis of 2011 Office of Pharmacy Affairs data.

Revenue Impact on Pharmaceutical Manufacturers

- Creation of MCPNs by Covered Entities likely results in both incremental sales volume and conversion of sales from a retail price to a 340B price
 - There is evidence that some entities are purchasing products for the first time once an MCP network is established

- Because 340B prices are typically substantially lower than retail prices, pharmaceutical manufacturers will experience a decrease in net revenue on converted units

	<u>Pre-Contract Pharmacy</u>			<u>Post-Contract Pharmacy</u>		
	340B Program	Non-340B Program	Total	340B Program	Non-340B Program	Total
Units Sold	1,000	19,000	20,000	7,000	13,000	20,000
Net Sales Price	\$ 15.00	\$ 30.00	\$ 29.25	\$ 15.00	\$ 30.00	\$ 24.75
Net Revenue	\$ 15,000	\$ 570,000	<u>\$ 585,000</u>	\$ 105,000	\$ 390,000	<u>\$ 495,000</u>

BRG Estimates that MCP Networks Will Drive Over \$3B in 340B Purchases by 2016

Overview of Methodology

- Calculate outpatient discharges at 340B entities
- Multiply total discharges by average scripts per discharge expected to be filled at contract pharmacies
- Calculate incremental 340B sales attributable to newly formed contract pharmacy arrangements accounting for likelihood of covered entity to establish contract pharmacy arrangements

Key Findings

- Multiple contract pharmacy network arrangements at all covered entities increased by 73% from July of 2010 to July of 2011
- The growth in contract pharmacy arrangements represent an estimated increase of \$3.2B in 340B sales at DSH hospitals alone

Statistics for Hospitals with MCP Networks

	2010	2011	2016 (Projected)
Total MCP Network Purchase Volume (est.)	\$75,000,000	\$436,000,000	\$3,200,000,000
Hospitals	16	163	2,214
Contract Pharmacies	77	1,021	13,868

Source: BRG analysis of 2011 Office of Pharmacy Affairs data and 2009 and 2010 CMS data.

Growth Drivers

ORGANIC GROWTH

Organic Growth – Oncology Site Expansion

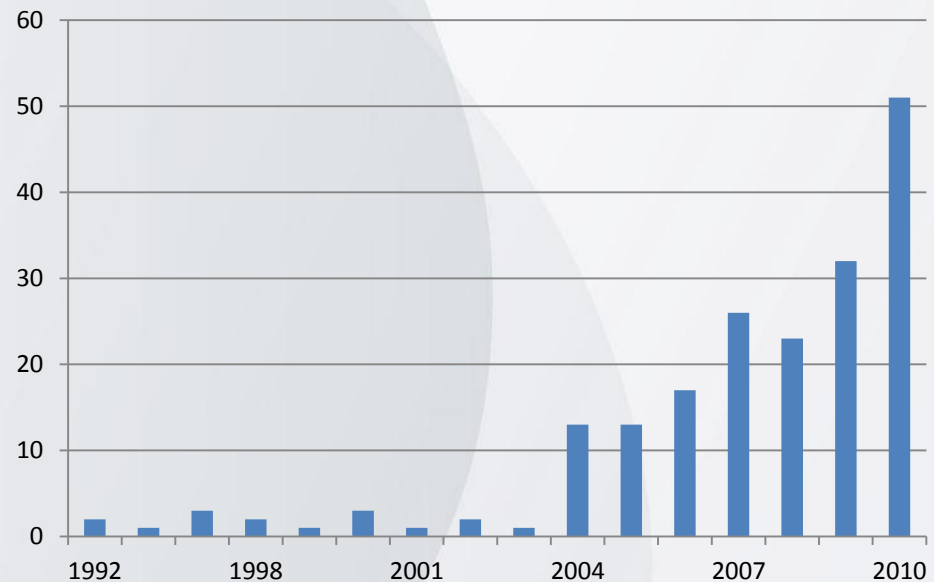
Sources of Organic Growth

- Increase in overall outpatient visits or prescriptions per visit
- Shift from inpatient to outpatient utilization
- Hospital acquisitions of satellite sites that are registered as sub-entities with OPA
- Expansion of patients through off-site arrangements such as prison populations

Key Findings

- New oncology sites have been registered at a CAGR of 30% since 2005.

Newly Registered Oncology Sites



Source: BRG analysis of 2011 HRSA data.

Growth Drivers

PRODUCT ASSESSMENTS: FRAMEWORK AND CASE STUDY

Conduct Product Assessment

- Develop product profiles
- Trend 340B sales by product and customer
- Isolate sales for Covered Entities with MCPNs
- Isolate sales to Covered Entities with oncology clinics
- Identify comparable hospitals to Medicaid Expansion hospitals and measure sales volume

Identify Alternative Strategies

- Pricing strategy
- 340B supplemental discounting strategy
- Pharmacy discounting strategy
- Promotional & sales strategy

Model Strategy Outcomes

- Impact on sales volume and product margins
- Impact on other government prices (AMP, ASP, NFAMP, etc.)
- Impact on double discounts with Part D

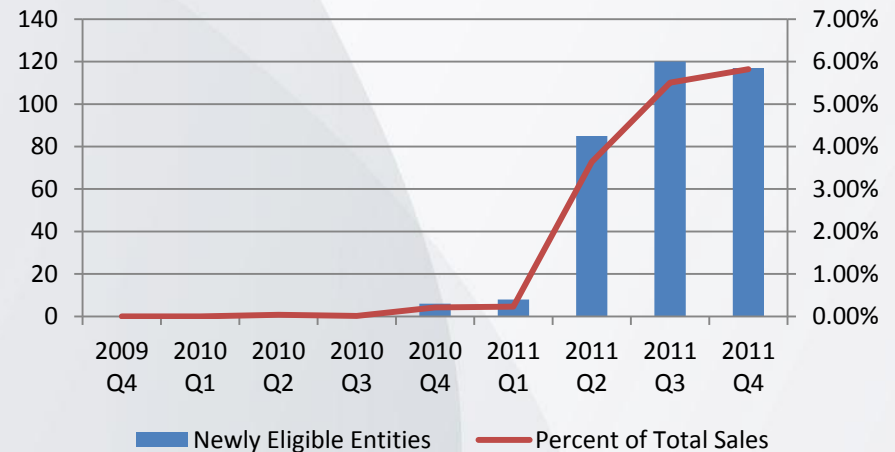
Implement Strategy

- Use model outcomes to identify optimal strategy

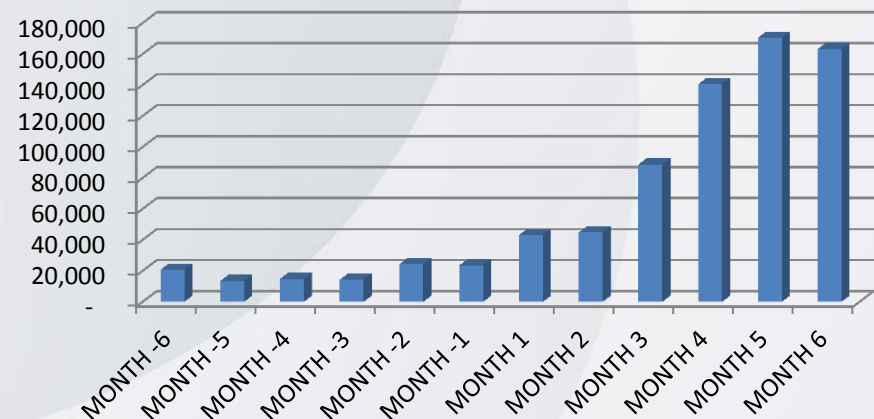
Case Study – Impact of Health Reform & MCPNs

- We analyzed 340B sales data from January 2010 through November 2011 for 6 brand pharmaceutical drugs representing over \$1B in total sales
- Analysis shows that newly eligible entities account for almost 6% of sales as of November 2011
- Analysis reveals 8-fold growth in total 340B drug purchases following the creation of an MCPN
 - Growth was evident in drugs typically dispensed in the retail setting but was not evident in drugs typically distributed in the home health setting
 - Growth was a function of expanded volume for Covered Entities with prior sales history as well as new sales volume at Covered Entities not previously purchasing drugs through the 340B program

Sales at Newly Eligible Entities



**Total 340B Unit Purchases Before & After MCP Network
(volume scaled)**



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About the Author

Aaron Vandervelde is a Principal with Berkeley Research Group's Health Analytics practice in Washington, DC. He has over 10 years of experience providing strategy, health policy, and litigation consulting services to clients in the health care industry. He specializes in financial and economic analysis of health policy and provides litigation consulting services related to issues arising from contracts and transactions between health care entities. Specifically, he focuses on deriving strategic insight through the integration and analysis of large, complex data sets including claims data, internal and external sales data and publicly available health data.

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