



340B Covered Entity Acquisitions of Physician-based Oncology Practices

April 22, 2014

- The Physician-based Oncology Practice Acquisition study has three objectives:
 - Understand historical trends in physician-based oncology practice acquisitions by entities participating in the 340B program (“Covered Entities”)
 - Measure impact of such acquisitions on 340B chargebacks
 - Compare timing of such acquisitions with the registration date on the OPA database as a sub-entity of the covered entity (“Child Site”) for purposes of 340B participation
- BRG analyzed chargeback data for oncology-related products from six manufacturers and integrated third-party data from OPA, HCRIS and secondary research to address study objectives
 - Acquired practices were identified by correlating new registrations in the OPA database with significant increases in oncology-related 340B chargeback volume at the parent entity
 - Manufacturer data was standardized around registration date of the Child Site on the OPA database to allow for aggregation across Covered Entities
 - A subset of acquired practices were further analyzed to compare timing of acquisition relative to registration date on OPA database

- Acquisitions of physician-based oncology practices by 340B Covered Entities have increased significantly over the 2009 – 2012 time period and preliminary 2013 data indicate this trend continued
- Average oncology-related chargeback volume at Covered Entities that acquired a physician-based oncology practice (“Acquiring Covered Entities”) was comparable to those entities that did not acquire a physician-based oncology practice (“Non-Acquiring Covered Entities”) in 2009, but grew to be three times greater than Non-Acquiring Covered Entities by 2012
 - The vast majority of this growth is attributable to 340B purchases by the acquired physician-based oncology practice (“Acquired Site”)
- Over half of the Acquired Sites were located 10 or more miles from the Acquiring Covered Entity and 85% of the Acquired Sites were located in higher median income locations when compared to the Acquiring Covered Entity
- There does not appear to be any correlation between higher oncology-related chargeback volume and higher charity care costs at Acquiring Covered Entities
 - **28 of the 63 (~45%) Acquiring Covered Entities generated more oncology-related chargebacks than they reported in total charity care for the same fiscal year;** these chargeback data only represents the oncology-related products from the six participating manufacturers, so including the total 340B chargebacks for all products would increase this number

- Six manufacturers provided data for the study
 - There was a range in participants in terms of:
 - Size of oncology portfolio relative to overall portfolio
 - Number of marketed products
- 82 distinct NDCs included in dataset
 - There was a range in products in terms of:
 - Type of condition treated (e.g. cancer vs. common side-effects of cancer treatments)
 - Method of administration (oral, infused, injected, etc.)

Summary of Study Dataset

Year	340B sales (\$B) included in study	Chargebacks (\$B) related to 340B sales	WAC sales (\$B) included in study [1]
2009	\$ 1.04	\$ 0.52	\$ 1.56
2010	\$ 1.16	\$ 0.71	\$ 1.88
2011	\$ 1.21	\$ 0.89	\$ 2.10
2012	\$ 1.38	\$ 1.04	\$ 2.42

[1] Non-discounted price typically paid by wholesalers for drug sales included in this study.

- **340B Chargebacks** – Discount taken by a drug wholesaler representing the difference between the non-discounted price paid by the wholesaler (typically WAC) and the 340B price paid by a Covered Entity
- **Study-Eligible 340B Chargebacks** – All 340B chargebacks for oncology-related products manufactured by the six participating manufacturers and included in the study analyses
- **Acquiring Covered Entity** – Any 340B Covered Entity that acquired a physician-based oncology practice and had Study-Eligible 340B Chargebacks during the study time period (2009 – 2012)
- **Non-acquiring Covered Entity** – Any 340B Covered Entity that did not acquire a physician-based oncology practice but did have Study-Eligible 340B Chargebacks during the study time period
- **Acquired Site** – Any physician-based oncology practice acquired by an Acquiring Covered Entity, identified for purposes of this study on the grounds that it was registered as a 340B Child Site any time between July 1, 2009 and July 1, 2012 and resulted in a 10% or greater increase in Study-Eligible 340B Chargebacks

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HISTORICAL TRENDS 2009 - 2012

Study Results: Trends in Physician-based Oncology Practice Acquisitions



- Both the absolute number of Acquired Sites and the number of Acquired Sites per Acquiring Covered Entity have increased over time from 2009 to 2012
 - Top-line 2013 figures demonstrate a similar trend as 2012
- The study design only includes those Child Sites large enough to warrant a separate registration on the OPA database and therefore almost certainly underestimates the true volume of physician-based oncology practice acquisitions

Trend in Physician-based Oncology Practice OPA Registrations (2009 - 2012)

	Acquiring Covered Entities					Acquired Sites				
	2009	2010	2011	2012	2013 [1]	2009	2010	2011	2012	2013 [1]
New Child Sites in OPA Data	56	58	73	194	45	473	592	278	1,523	450
Oncology-related Child Sites	32	23	21	65	18	79	68	30	166	35
Acquired Within Date Range	25	21	21	38	0	52	53	29	119	0
≥ 10% Increase in 340B Purchases	18	19	11	15	0	39	51	17	37	0
Cumulative Total	18	37	48	63	63	39	90	107	144	144

[1] Represents registrations through April 1, 2013

Study Results: Characteristics of Acquiring Covered Entities

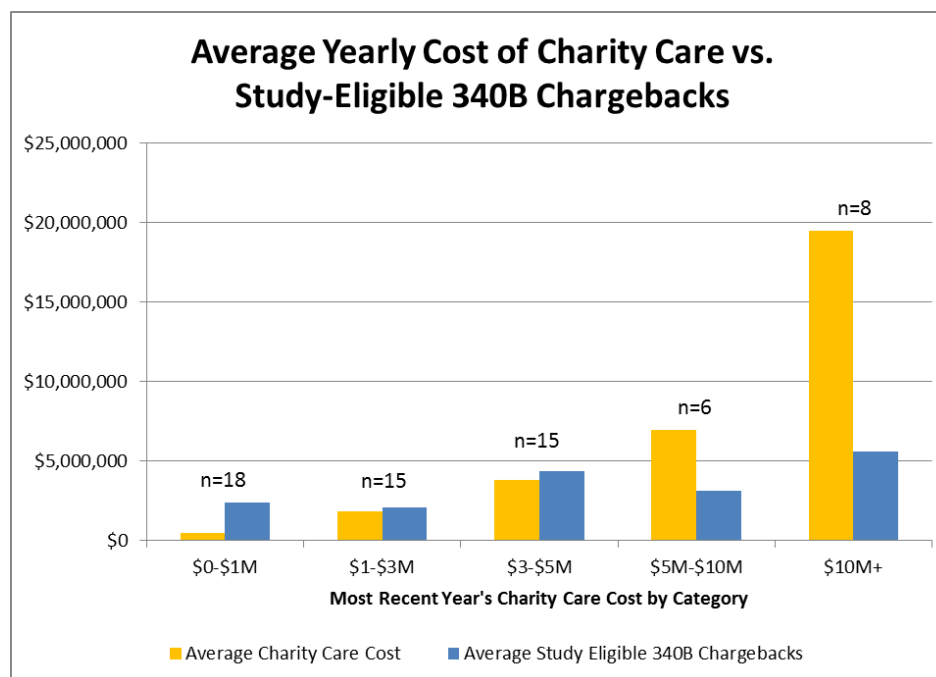


- Physician-based oncology practice acquisitions appear to be executed almost entirely by DSH-eligible Covered Entities
- While only half of the Acquiring Covered Entities are academic medical centers, these entities account for nearly two-thirds of the Study-Eligible 340B Chargebacks

Category	Total				% of Total			
	Covered Entities		Acquired Sites	Chargebacks	Covered Entities	Acquired Sites	Chargebacks	
<u>Registration Type</u>								
DSH	61		142	\$ 533,539,099	96.83%	98.61%	99.92%	
RRC	1		1	232,318	1.59%	0.69%	0.04%	
SCH	1		1	193,879	1.59%	0.69%	0.04%	
<u>Academic Medical Center</u>								
YES	31		84	\$ 347,650,673	49.2%	58.3%	65.1%	
NO	32		60	186,314,624	50.8%	41.7%	34.9%	
<u>DSH Percentage</u>								
	AMC	Non-AMC	AMC	Non-AMC				
Less than 11.75%	2	2	4	2	\$ 12,218,015	6.3%	4.2%	2.3%
11.75% - 15%	7	10	24	25	186,202,581	27.0%	34.0%	34.9%
15% - 20%	3	8	8	8	71,423,118	17.5%	11.1%	13.4%
20% - 25%	10	10	38	17	171,524,917	31.7%	38.2%	32.1%
Greater than 25%	9	2	10	8	92,596,666	17.5%	12.5%	17.3%

Study Results: Comparison of Study-Eligible Chargebacks to Charity Care Costs

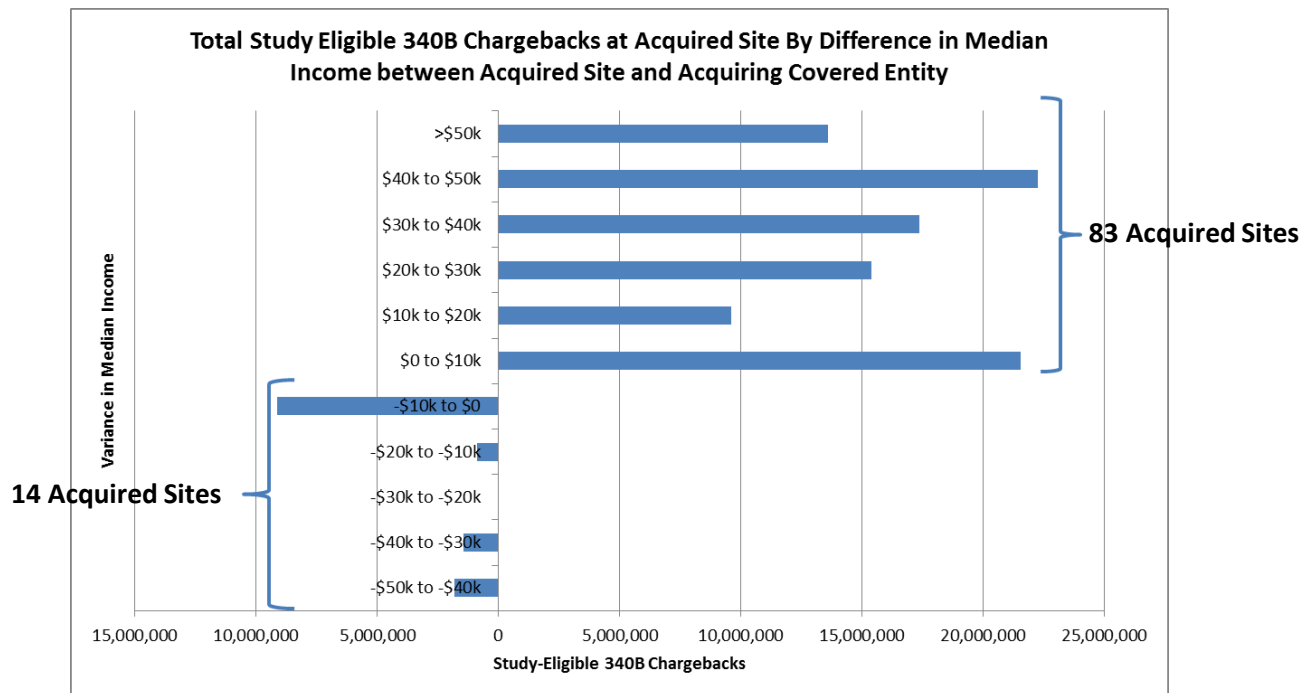
- For 28 of the 63 (~45%) Acquiring Covered Entities, the Study-Eligible 340B Chargebacks paid by manufacturers exceeded the charity care costs provided by those entities in accordance with their charity care policies as reported on the most recently filed cost reports
- The average yearly Study-Eligible 340B Chargebacks appear not to be correlated with the volume of charity care provided by the Acquiring Covered Entity



Note: Charity care costs calculated using the hospitals' operating cost-to-charge ratio

Study Results: Characteristics of Acquired Sites

- Acquiring Covered Entities appear to be selecting physician-based oncology practices located in higher median-income communities
 - Only 14 of the 144 Acquired Sites (9.7%) were located in a zip code with a lower median income than the Acquiring Covered Entity and represent 8.5% of the Study-Eligible 340B Chargeback volume at Acquired Sites
 - Half of all Acquired Sites were located 10 or more miles from the Acquiring Covered Entity and 89% of these Acquired Sites were located in a higher median-income community than the Acquiring Covered Entity



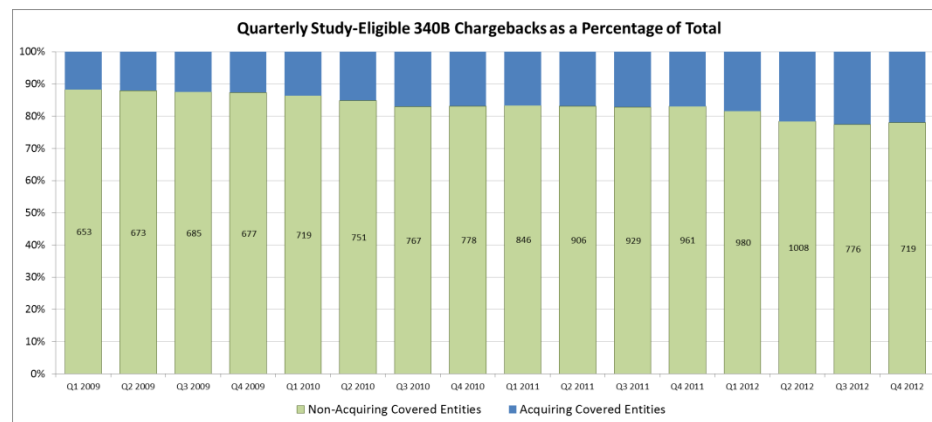
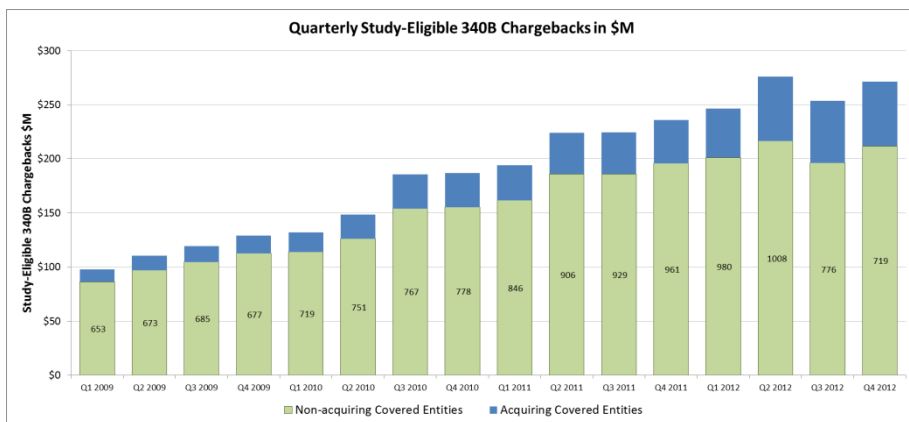
Note: 47 Acquired Sites are excluded from this analysis because they have the same median income as the Acquiring Covered Entity.

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IMPACT OF PRACTICE ACQUISITIONS

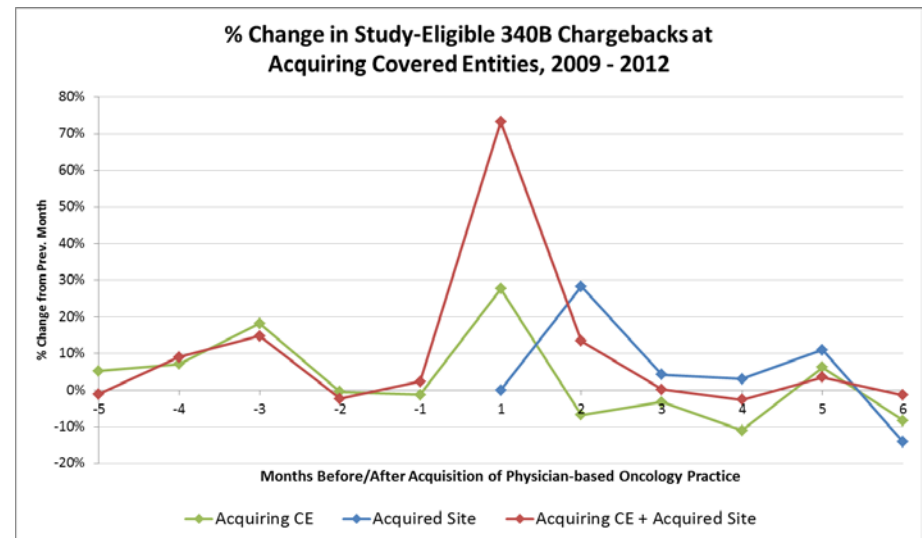
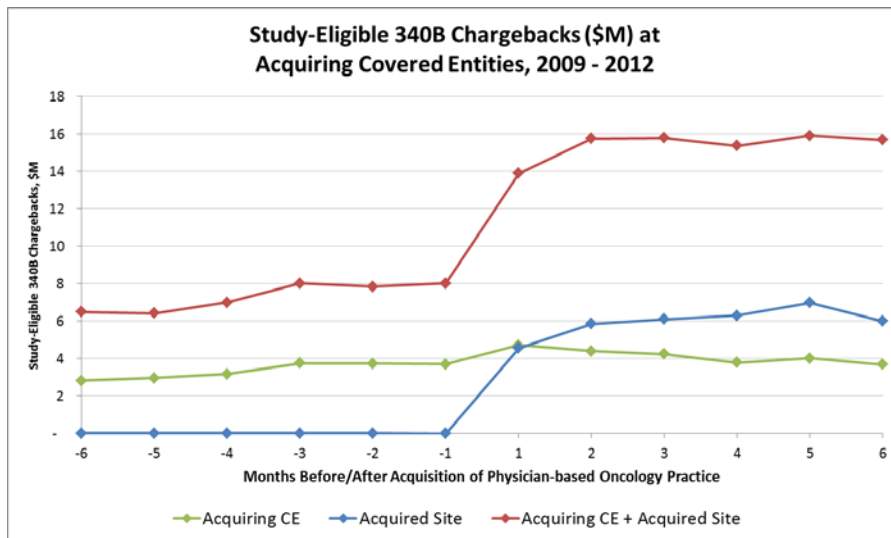
Study Results: Total Study-Eligible 340B Chargebacks

- Total Study-Eligible 340B Chargebacks increased by over 250% during the study period (2009-2012) due to a combination of physician-based oncology practice acquisitions, new Covered Entity enrollments and unit price increases
- Acquiring Covered Entities and their Acquired Sites accounted for an increasing percentage of these chargebacks over time (12% in 2009 vs. ~25% in 2012)
 - This result is particularly notable because the number of Non-Acquiring Covered Entities grew over time due to new registrations in the 340B program



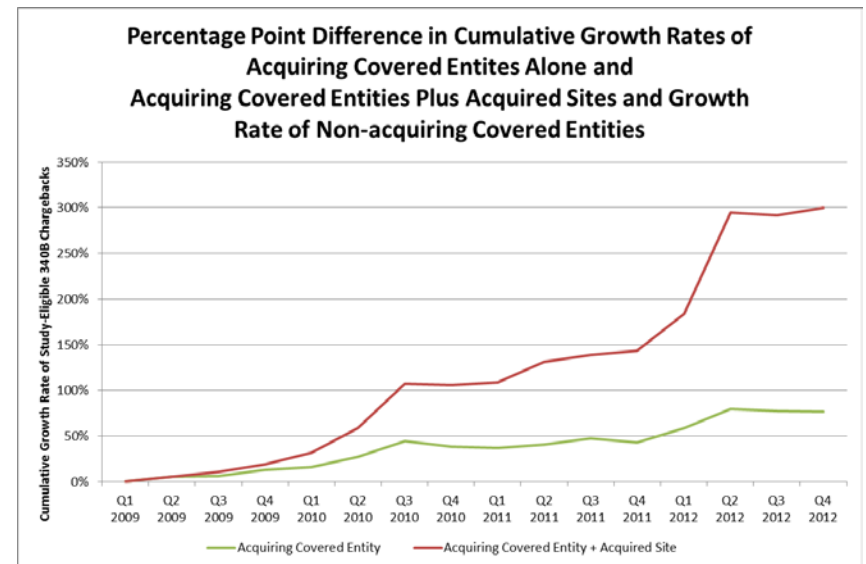
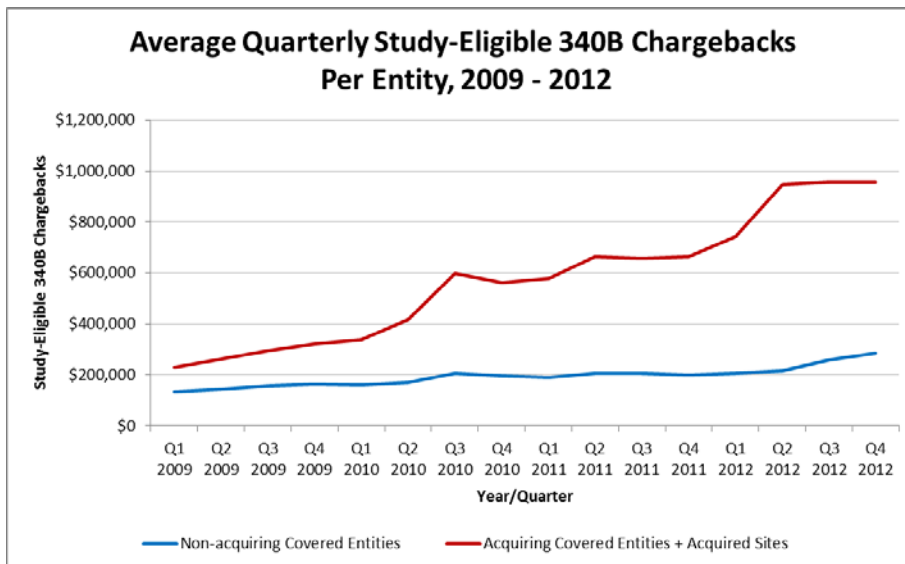
Study Results: Change in Study-Eligible 340B Chargebacks Following Site Acquisition

- Following registration of an Acquired Site as a Child Site on the OPA database, the increase in Study-Eligible 340B Chargebacks was almost always immediate
- Within two months of OPA registration, the total chargeback volume at the Acquired Site represented ~40% of total Study Eligible 340B Chargebacks for the Acquiring Covered Entity, on average
- These acquisitions represent an immediate and sizeable increase in revenue and product margins to the Acquiring Covered Entity due to the increased utilization and lower drug expense



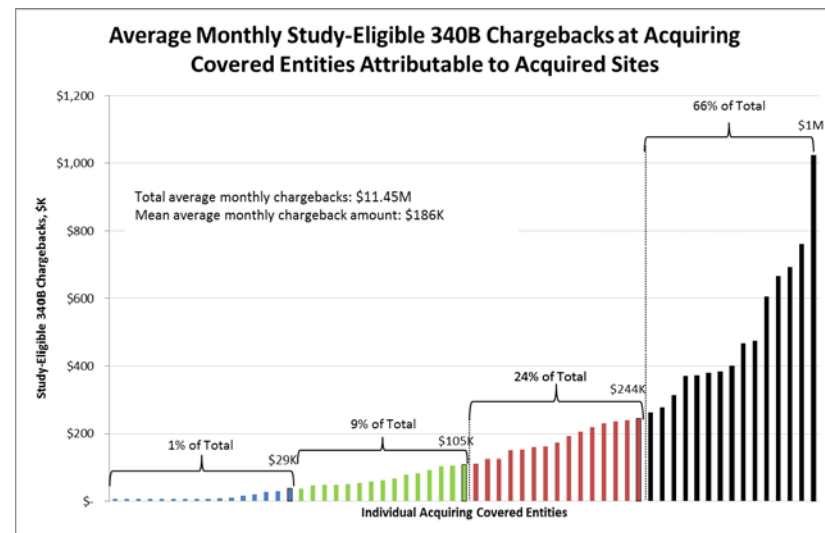
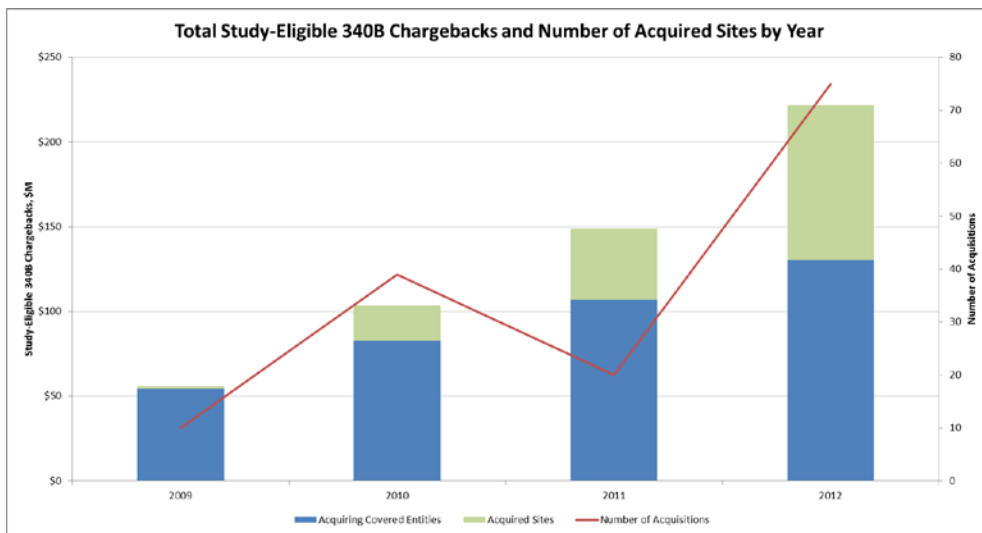
Study Results: Change in Study-Eligible 340B Chargebacks Following Site Acquisition (continued)

- Although average Study-Eligible 340B Chargeback volume per Covered Entity was comparable in 2009, by 2012 Acquiring Covered Entities had over three times as many Study-Eligible 340B Chargebacks as Non-acquiring Covered Entities
 - In 2012, 75% of the disparity in average Study-Eligible 340B Chargebacks per entity was attributable to the Acquired Sites
- CAGR of Study-Eligible 340B Chargebacks differed widely when accounting for the effect of Acquired Sites
 - Acquiring Covered Entities plus Acquired Sites: 58.2%
 - Acquiring Covered Entities Alone: 34.3%
 - Non-acquiring Covered Entities: 24.0%



Study Results: Total Study-Eligible 340B Chargebacks at Acquired Sites

- Total Study-Eligible 340B Chargebacks at Acquired Sites are growing rapidly and represented over \$90M in Study-Eligible 340B Chargebacks in 2012 alone
 - The Acquired Sites accounted for over 40% of total Study-Eligible 340B Chargebacks for Acquiring Covered Entities in 2012
- There is high concentration in overall Study-Eligible 340B Chargebacks attributable to Acquired Sites in the top quartile of Acquiring Covered Entities
 - 66% of the total Study-Eligible 340B Chargebacks associated with an Acquired Site were concentrated in 16 of the 63 (~25%) Acquiring Covered Entities



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TIMING BETWEEN ACQUISITION & OPA REGISTRATION

Comparison of Timing of OPA Registration of Acquired Site and Announcement of Acquisition



- In the instances where BRG was able to find information on the acquisition date, the lag time between the public announcement of the acquisition and the registration of the Acquired Site as a Child Site on the OPA database was generally short
 - 23 out of the 32 acquisitions studied appeared in the OPA database within six months of the first identified public announcement

Year of Acquisition	No. Entities	Same Month	1 – 3 Months	4 – 6 Months	7 – 12 Months	12+ Months
2009	3	1	-	-	2	-
2010	5	1	2	1	1	-
2011	4	2	1	1	-	-
2012	17	2	4	5	5	1
2013	3	1	1	1	-	-
Total	32	7	8	8	8	1

Contact Information



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About the Author

Aaron Vandervelde is a Director 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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