340B PROGRAM SALES FORECAST: 2016 - 2021

BRG Healthcare

Prepared By:

Aaron Vandervelde
avandervelde@thinkbrg.com
202.480.2661

Eleanor Blalock
eblalock@thinkbrg.com
202.480.2772

Berkeley Research Group | 1800 M Street NW, Second floor | Washington, DC 20036

Executive Summary

In February 2016, Apexus made available data on total drug sales through the 340B program from 2005 through 2015. These data revealed that, based on total sales, the 340B program more than doubled in size between 2010 and 2015 and expanded by 66 percent between 2013 and 2015 alone. This rate of growth is unprecedented and reflects the cumulative effect of factors that we believe are likely to continue to drive growth for at least the next five years.

Accompanying this growth is additional scrutiny of the 340B program. The Government Accountability Office (GAO) published a study in June 2015 that concluded that the sizeable margins realized by covered entities on 340B purchased drugs were contributing to higher utilization rates of Part B drugs.[1] Since 2012, the Health Resources and Services Administration (HRSA) has conducted audits of covered entities to assess whether they comply with statutory prohibitions against diversion and duplicate discounts. The audit results reveal noncompliance rates that exceed 30 percent[2] and reflect challenges in covered entities' ability to comply with statutory requirements and HRSA's administration of the 340B program.

In light of the recent growth in 340B sales and existing challenges in administering the program, BRG professionals conducted a study to forecast growth in 340B sales over the next five years. This study builds on the methodology developed as part of our 2014 forecast of 340B program growth. Key findings from our current analysis include:

- The 340B program is forecasted to exceed $23 billion in total sales at the 340B price by 2021 and will exceed 2014 Medicare Part B drug reimbursement by 2021.
- Statutory 340B chargeback payments by manufacturers will exceed $16 billion by 2021—over five times the branded prescription drug fee mandated in the Affordable Care Act (ACA).[3]
- Incremental growth will largely be driven by expanded utilization at existing 340B covered entities through contract pharmacy programs and from practice acquisitions, physician practice affiliations, and patient referrals.
- By 2021, contract pharmacy utilization will exceed $6 billion and operate in a largely unregulated environment in which third-party administrators and contract pharmacies establish the operational backbone of 340B eligibility determination and purchasing.
- At current staffing levels, the average HRSA auditor by 2021 will be responsible for providing oversight of over 4,000 distinct covered entity and contract pharmacy locations, approximately 30 manufacturers, and over $1 billion in drug sales.

1 U.S. Government Accountability Office, *Medicare Part B Drugs: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals* (June 2015), accessed at: http://www.gao.gov/assets/680/670676.pdf

2 BRG analysis of results from HRSA audits of covered entities from 2012-2016, accessed at: http://www.hrsa.gov/opa/programintegrity/index.html

3 Sec. 9008 of the Patient Protection and Affordable Care Act.

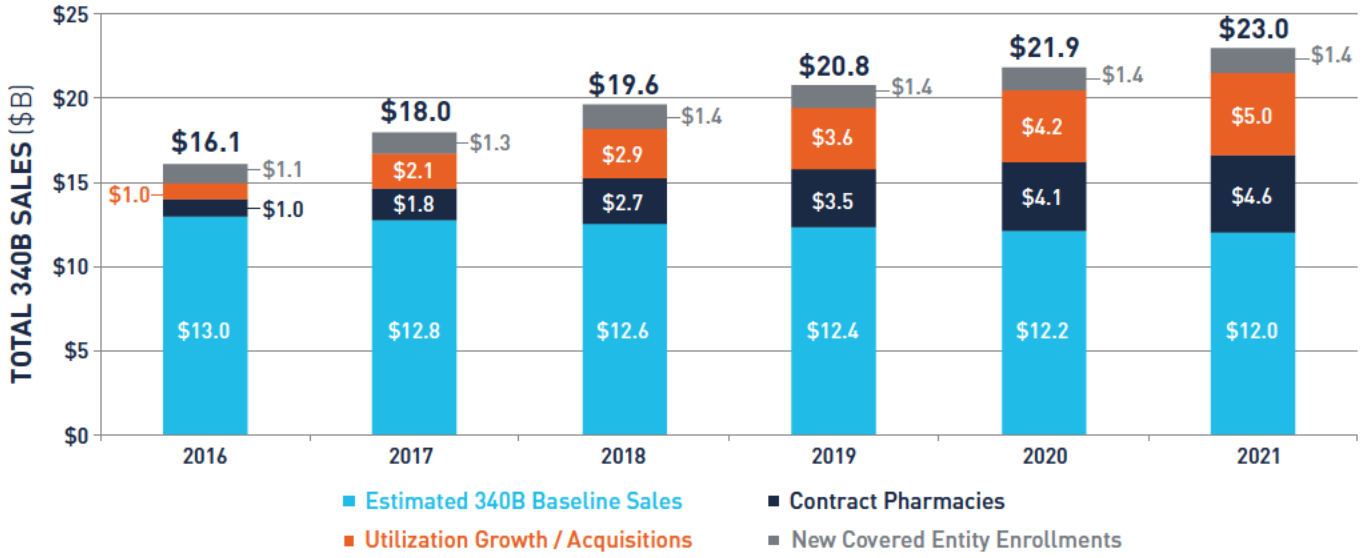
Study Findings

In November 2014, we published a six-year forecast of 340B sales that estimated total prescription drug sales at the 340B price would grow from $8 billion in 2013 to over $16 billion by 2019.[4] However, the program experienced unprecedented growth between 2013 and 2015, and we have revised our 2014 forecast to account for the underlying drivers of this growth.

Our 2016 forecast predicts annual program growth over the next six years ranging between $1.1 billion and $2.8 billion, with the majority of the growth occurring over the next three years (see Figure 1). We anticipate the 340B program will reach $20 billion in sales by 2019 and top $23 billion in sales at the 340B price by 2021.

The biggest change in our forecast relates to growth in sales attributable to hospital acquisitions of private practices, new physician-hospital affiliations, and expanded hospital referral networks. This growth driver now accounts for a similar volume of growth attributable to contract pharmacy expansion, whereas our 2014 forecast projected a much smaller effect.

FIGURE 1: ESTIMATED 340B PROGRAM SALES AT THE 340B PRICE 2016 - 2021[5]



Based on our current forecast, the 340B program will reach $23 billion in total drug sales at the 340B price by 2021, which exceeds the total of Medicare Part B drug reimbursement in 2014 ($22 billion). This comparison may understate the size of the 340B program because we are measuring 340B sales at the statutorily discounted 340B price rather than market prices. The size of the 340B program compared to Part B drug reimbursements is significant because the 340B program is currently administered by HRSA's Office of Pharmacy Affairs, which operates on an annual budget of approximately $10 million.[6] This pales in comparison to the $733 million in federal administrative budget for Medicare and Medicaid[7] and highlights the challenges HRSA faces in effectively regulating the 340B program.

4 Aaron Vandervelde, *Growth of the 340B Program: Past Trends, Future Projections*, BRG white paper (November 2014), accessed at: http://www.thinkbrg.com/newsroom-publications-vandervelde-growth-340B-program.html.

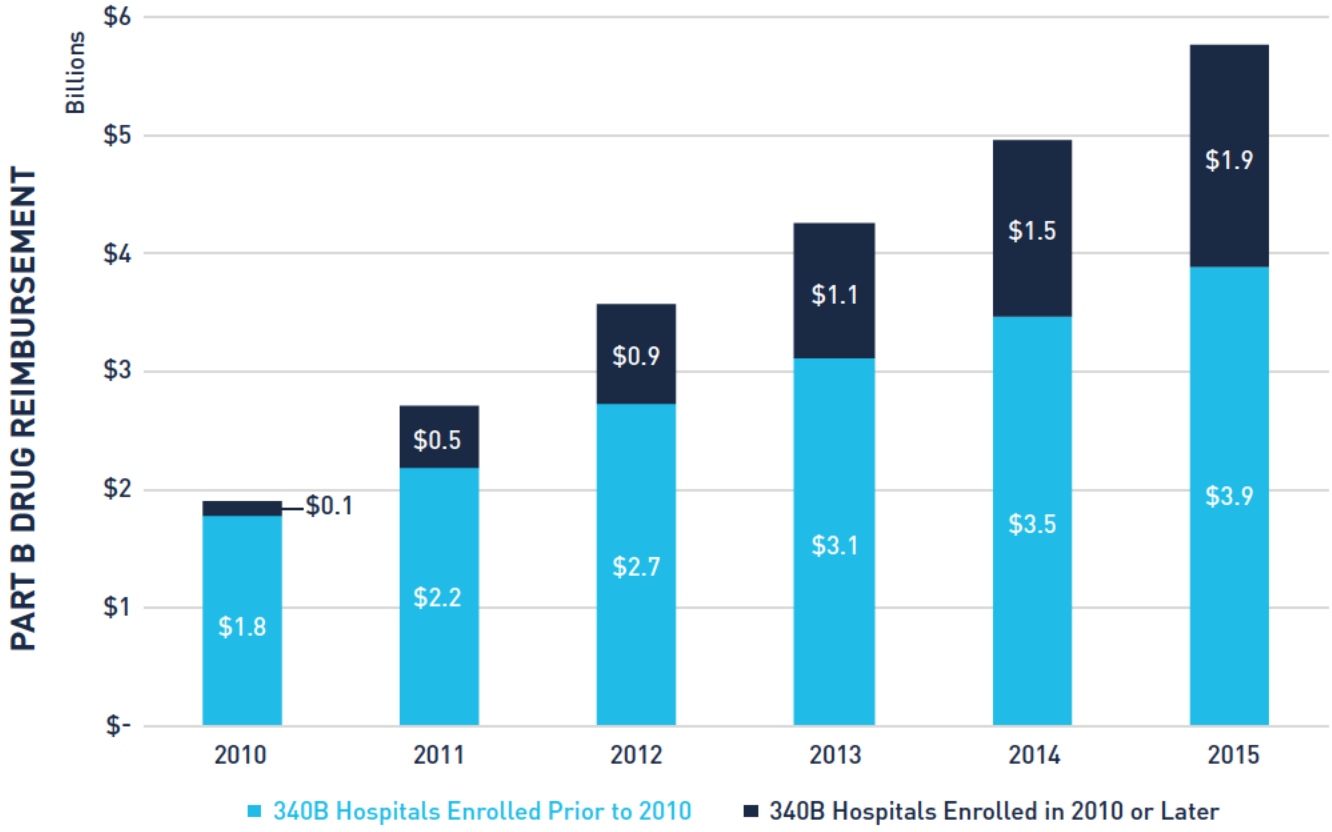
5 340B sales estimates include all 340B program sales, including direct sales and ADAP rebate sales not typically included in Apexus figures. Growth attributable to "New Enrollment" refers to newly enrolling critical access hospitals and hospitals with a DSH eligibility criterion. Baseline estimated 340B program sales are adjusted downward in future years to account for dis-enrolling entities.

6 FY 2016 enacted budget. Department of Health and Human Services, *Fiscal Year 2017 Health Resources and Services Administration Justification of Estimates for Appropriations Committees*, accessed at: http://www.hrsa.gov/about/budget/budgetjustification2017.pdf

7 FY 2016 enacted budget for Federal Administration. Department of Health and Human Services, *Fiscal Year 2017 Centers for Medicare & Medicaid Services Justification of Estimates for Appropriations Committees*, accessed at: https://www.cms.gov/About-CMS/Agency-Information/PerformanceBudget/Downloads/FY2017-CJ-Final.pdf

The study findings also demonstrate the impact that the 340B program has on broader industry trends. 340B hospitals have grown from accounting for 13 percent of Medicare Part B drug reimbursement in 2010 to 25 percent by 2015.[8] Part of this growth is attributable to new hospital enrollments, but over half of the growth is due to expanded drug utilization at existing 340B hospitals (see Figure 2). The result is a shift in site of care to the higher-cost outpatient setting that is driven, at least in part, by the sizeable margins realized by hospitals on drugs purchased through the 340B program. Further, as a larger percentage of sales go through the highly discounted 340B channel, this may actually result in higher drug costs for the healthcare system. As a recent *New England Journal of Medicine* article explained, the 340B program is "so vast for drugs that are commonly infused or injected … that their prices are probably being driven up for all consumers."[9] These factors taken together result in higher healthcare costs.

FIGURE 2: PART B DRUG REIMBURSEMENT TO 340B ENROLLED HOSPITALS[10]



Although the current outlook for the 340B program is continued growth, other factors could result in slower rates of growth. HRSA may still release the Omnibus Guidance, which could limit the scope of the 340B program. Anticipated launches of biosimilars could further reduce 340B sales if prices for these drugs are substantially lower than the 340B price of the innovator product. Alternatively, reductions in provider reimbursements, such as those included in the Part B demonstration proposed by the Centers for Medicare and Medicaid Services, could result in a higher rate of utilization in the outpatient setting for separately payable drugs, which would likely increase 340B sales. This forecast assumes the current regulatory framework and market dynamics.

8 BRG analysis of Medicare Fee-for-Service (FFS) claims data for the hospital outpatient and physician office settings.

9 Rena M. Conti and Meredith B. Rosenthal, "Pharmaceutical Policy Reform—Balancing Affordability with Incentives for Innovation," *N Engl J Med* 374:8 (February 25, 2016).

10 BRG analysis of Medicare FFS claims data and the HRSA Office of Pharmacy Affairs (OPA) Covered Entity Database.

Methodological Approach

Given the complex nature of the 340B program, overall sales in the program can be affected by a wide range of factors including technology improvements, changes in regulations, provider consolidation, new product launches, and changes in payer reimbursement. However, there is strong evidence that at least three factors will likely continue to have a substantial impact on overall program growth for the next five years:

1. *New Entity Enrollment*: Hospitals and grantees continue to enroll in the 340B program and purchase drugs at the 340B price for the first time. Since the beginning of 2015, over 390 hospitals have enrolled in the program for the first time. This trend is expected to continue for the next two to three years.[11]

2. *Acquisitions and Utilization Growth*: Using hospital cost report and Medicare Fee-for-Service (FFS) claims data, we observed that several hospital metrics that are useful analogues for drug utilization have grown on average between 7 percent and 15 percent annually at hospitals continuously enrolled in the 340B program since 2010 (see Figure 4, Appendix 1). A number of factors have contributed to this growth, including private physician practice acquisitions, affiliation and referral networks, product launches, and other factors that influence site of care. We expect this trend to continue for the next five years.

3. *Contract Pharmacy Expansion*: In March 2010, HRSA issued guidance allowing covered entities to contract with an unlimited number of third-party pharmacies to dispense 340B drugs.[12] This has resulted in dramatic growth in contract pharmacy arrangements, and by 2016 over 68 percent of hospitals have at least one contract pharmacy, up from 13 percent in March 2010.[13] Although there is a natural limit to overall participation rates, our research indicates emerging growth trends in specialty pharmacies and covered entity ownership of contract pharmacies. Therefore, we expect contract pharmacies to continue to drive incremental 340B sales for at least the next five years.

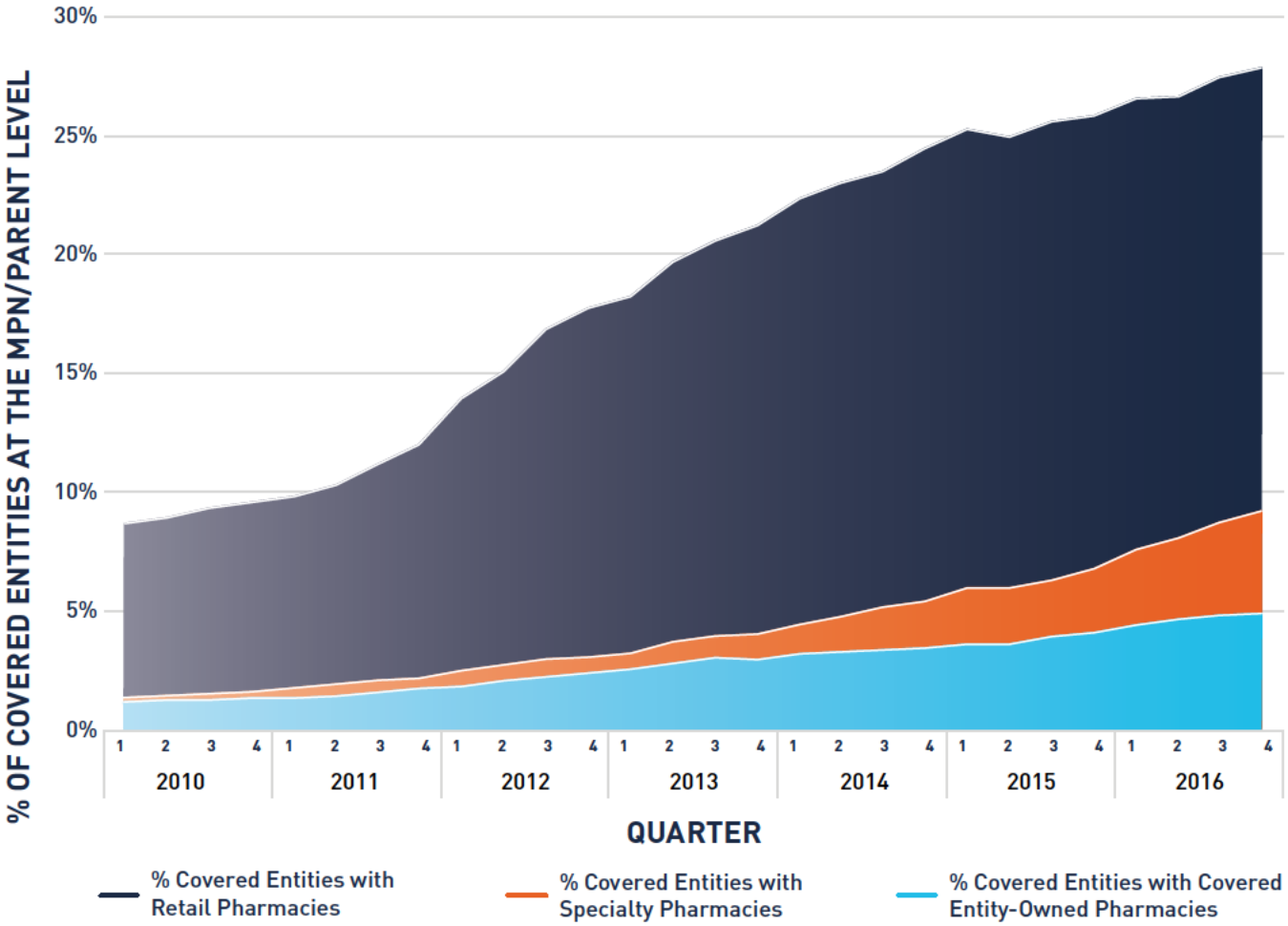
Although the methodology used for this forecast is based on our 2014 340B forecast, we have made two important refinements to the methodology. First, in 2014 we forecasted growth attributable to physician practice acquisitions but did not account for growth attributable to affiliations and referral networks. This factor had a significant impact on our 2014 forecast and 2015 340B sales. The 2016 340B forecast methodology uses the historical growth metrics detailed in Appendix 1 to more comprehensively account for growth at currently enrolled covered entities. Second, we estimate growth attributable to contract pharmacy expansion independently for retail, specialty, and covered-entity owned pharmacies. Not only do the enrollment rates for these three types differ substantially (see Figure 3), but differences exist in terms of capture rates, prescription volume, and average price of filled prescriptions. This approach allows us to reflect changes in the marketplace as greater emphasis is placed on specialty therapeutics.

11 BRG analysis of the HRSA OPA Covered Entity Database.

12 *Notice Regarding 340B Drug Pricing Program – Contract Pharmacy Services*, 75 Fed. Reg. 10272 (March 5, 2010), accessed at: https://www.gpo.gov/fdsys/pkg/FR-2010-03-05/pdf/2010-4755.pdf

13 BRG analysis of the HRSA OPA Covered Entity Database and Contract Pharmacy Database.

FIGURE 3: PERCENT OF COVERED ENTITIES WITH AT LEAST ONE CONTRACT PHARMACY BY TYPE OF PHARMACY[14]



Last, we developed an alternative 340B forecast based on historical 340B sales and covered entity and contract pharmacy enrollment trends. We then compared the forecasting results across the two methodologies for consistency. See Appendices 1 and 2 for additional information on the methodologies used in the 2016 340B forecast and the alternative 340B forecast.

Conclusions

The 340B program has experienced unprecedented growth over the last two years, and we are forecasting this trend to continue for at least the next three years. The underlying drivers of this recent growth are still in place, and the natural limits to shifts in site of care and expanded contract pharmacy programs have not been reached. We anticipate challenges for HRSA in its regulatory and enforcement duties for a program poised to grow to more than $20 billion in sales, with a $10 million HRSA budget and 22 part-time auditors. Further, as the program exceeds $16 billion in sales this year and heads towards $20 billion by 2018, it is unreasonable to think that there will not be ripple effects outside of the program. While continued shifts in site of care and increased drug reimbursements are likely outcomes, there may be additional unanticipated effects due to the size of the program.

14 BRG analysis of the HRSA OPA Covered Entity Database and Contract Pharmacy Database.

Appendix 1: 2016 340B Forecast Methodology

The 2016 340B forecast is adapted from the methodology we used in the 2014 340B forecast. The forecast starts with baseline sales representing the most recently available annual 340B sales data and then estimates incremental growth attributable to various factors. The baseline sales figure and each incremental growth estimate are combined to arrive at an aggregate forecast for 340B sales. Included below is a more detailed discussion regarding each component of the 2016 340B forecast.

2015 Baseline 340B Sales

Our methodology uses the 2015 Apexus 340B sales figures as a baseline. We then adjust baseline sales to account for sales made directly to covered entities by manufacturers that are not captured in the Apexus figure and to remove sales attributable to 340B entities that dis-enrolled in 2016. We have also assumed a 1.5 percent annual decrease in 340B sales attributable to ongoing dis-enrollments and have assumed no price appreciation in 340B prices due to the consumer price index (CPI) penalty and historical downward pressure on 340B prices attributable to manufacturer discounting. Because the baseline figure already includes utilization attributable to historical covered entity enrollments, acquisitions, and contract pharmacy expansion in 2014 and 2015, the figures reported in this study only reflect incremental utilization in 2016 and forward.

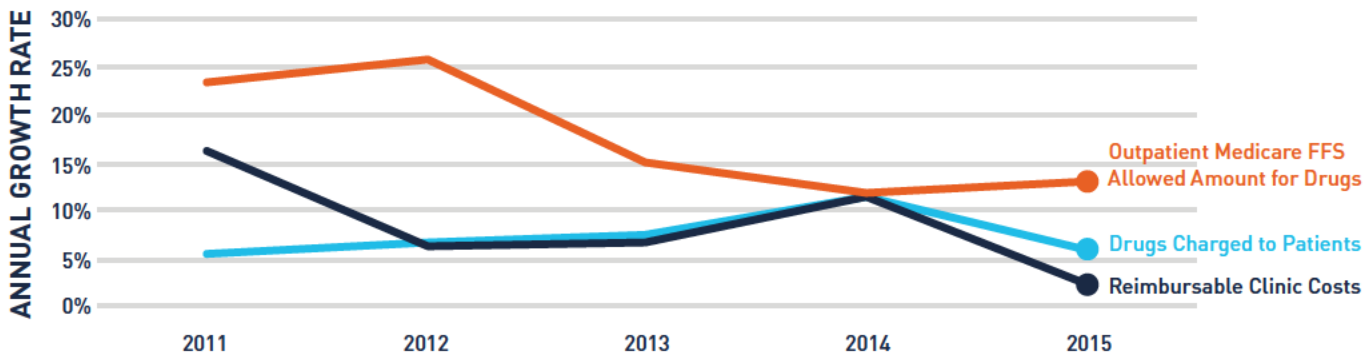
New Entity Enrollment

Historically, new entity enrollment has contributed significantly to growth in the 340B program. However, our analysis of the number of hospitals that are currently eligible but not enrolled as well as hospitals that are likely to become eligible due to Medicaid expansion reveals that new enrollments likely will not drive substantial growth in 2017 and beyond. Our methodology estimates new hospital enrollments based on analysis of 2016 registrations on the OPA database, the impact of Medicaid expansion on hospital eligibility, and currently eligible hospital enrollments. Using hospital cost report data, we compare outpatient revenue at hospitals forecast to enroll in the 340B program with outpatient revenue at currently enrolled hospitals to forecast incremental 340B sales attributable to the newly enrolled hospitals.

Acquisitions and Utilization Growth

340B covered entities can expand utilization of 340B drugs in many ways, including physician practice acquisitions or affiliations, conversion of existing non-eligible practice locations to 340B eligible locations, referral network expansion, and physician employment. As a result, a variety of metrics can reflect expansion of a hospital's 340B program. Our methodology utilizes three metrics: the volume of costs reported as 'Drugs Charged to Patients' on hospital cost reports, the volume of costs reported as 'Reimbursable Clinics' on hospital cost reports, and total Part B drug reimbursement to 340B hospitals. We calculate the compound annual growth rate for each of these metrics for hospitals continuously enrolled in the 340B program from 2010 to 2015 (see Figure 4).

FIGURE 4: 340B PROGRAM GROWTH METRICS: ANNUAL GROWTH RATE AT CONTINUOUSLY ENROLLED 340B HOSPITALS[15]



15 BRG analysis of Hospital Annual Cost Reports and Medicare FFS claims data.

We then apply the average growth rate across the three metrics to the portion of 2015 340B sales attributable to 340B hospitals (excluding contract pharmacy utilization) to forecast incremental 340B sales attributable to acquisitions and utilization growth through 2021. We assume that the historical average growth rate will decrease over time as this rate approaches a natural limit to utilization growth in the outpatient setting. Table 1 depicts the annual growth rate that we applied for each year through 2021.

TABLE 1

Annual Growth Rate	2016	2017	2018	2019	2020	2021
	11%	10%	7%	5%	5%	5%

Contract Pharmacy Expansion

Our forecast for growth attributable to contract pharmacy expansion is based on the 2014 340B forecast. Similar to the 2014 forecast, we estimate total 340B prescription volume based on actual discharges and outpatient visits at 340B enrolled hospitals and grantees and assume capture rates representing the percentage of 340B eligible prescriptions filled at contract pharmacies. This 340B prescription volume is then multiplied by an average 340B purchase price to estimate total 340B sales in the contract pharmacy channel. Growth in this channel is based on historical growth in contract pharmacy registrations. However, the 2016 340B forecast differentiates between entities with retail, specialty, and covered-entity owned contract pharmacies in their networks and uses custom growth rates, average 340B sales prices, and capture rates for each pharmacy type. Table 2 lists the assumptions relevant to each type of pharmacy.

TABLE 2

	Entities with Retail Pharmacies Only	Entities with Specialty Pharmacies	Entities with Covered-Entity Owned Pharmacies
Number of prescriptions (including refills) per patient encounter[16]	2.0	2.0	2.0
Total 2015 patient encounters[17]	115,124,800	53,999,013	43,308,853
2015 share of hospitals and CHCs[18]	36.3%	17.0%	13.6%
Expected annual growth rate in share of Hospitals and CHCs[19]	1.9%	4.2%	3.3%
Capture rate as a percent of all prescriptions	3.1%	3.4%	8.6%
Estimated 340B price per captured prescription[20]	$155	$279	$286

16 BRG analysis of 2012 CDC data.

17 BRG analysis of Hospital Annual Cost Reports and Medicare FFS claims data; community health center discharge data based on 2014 data sourced from NACHC.

18 BRG analysis of the HRSA OPA Covered Entity Database and Contract Pharmacy Database.

19 BRG analysis of the HRSA OPA Covered Entity Database and Contract Pharmacy Database.

20 BRG analysis of IMS spending and prescription data. IMS Institute for Healthcare Informatics, *Medicines Use and Spending in the U.S.: A Review of 2015 and Outlook to 2020* (April 2016).

Appendix 2: 2016 Alternative 340B Forecast

In forecasting growth of the 340B program over the next five years, we also developed an alternative 340B forecast using a different methodological approach than presented in the body of this paper. The rationale for doing so was to do a "reasonableness" check on the results of the 2016 340B forecast and the assumptions contained therein.

The alternative forecast relied on historical data disclosed by Apexus on sales through the 340B program.[21] As previously discussed, these sales data were adjusted upward to reflect direct sales not included in the amounts reported by Apexus. As a first step, 340B sales in each year from 2010 to 2015 were apportioned among hospitals and grantees based on available disclosures from Apexus and analysis of the HRSA OPA database.

2010 340B sales to hospitals were then apportioned between hospitals that had enrolled in the 340B program before 2010 and those enrolling in 2010 using outpatient revenue from Medicare cost reports as a proxy for the size of the facility's 340B program. The 2010 starting sales amounts for the two hospital cohorts (pre-2010 enrollees and 2010-or-later enrollees) were then grown based on annual changes in the following metrics for both groups: Medicare Part B drug reimbursement, Medicare Part B drug claims, and outpatient revenue as reported in the hospital cost reports. Growth in the pre-2010 enrollee group reflects utilization growth and the effect of care shifting into the hospital setting. Growth in the 2010-or-later group reflects these factors along with new hospitals entering the 340B program. To estimate the impact of contract pharmacy, 340B sales calculated as described were subtracted from total hospital 340B sales as reported by Apexus in each year.[22]

Through this process, we developed estimates of 340B utilization associated with grantees, hospitals enrolled before 2010, hospitals enrolling since 2010, and contract pharmacy volume in each year from 2010 to 2015. Based on historical trends in these four segments, we developed estimated growth rates and applied these rates going forward into future years.

In the early years of the forecast (2016 to 2018), the alternative 340B forecast predicts a slightly smaller 340B program in aggregate. By 2021, however, the two forecasts differ by less than $500 million. This likely reflects the fact that the alternative 340B forecast relies on historical trends across the entire period from 2010 to 2015. Growth was more modest in the earlier years during this period than in 2014 and 2015, when it accelerated sharply. Because the 2016 340B forecast builds off of 2015 sales, it is likely to predict higher sales in the initial forecasted years.

The 2016 340B forecast likely better reflects growth that will continue to accelerate in the coming one to two years before moderating slightly. The nature of the calculation also makes it possible to define growth drivers at a more granular level. For this reason, this approach was relied upon in this paper. Relative alignment with the results from the alternative forecast offers support for the final estimates, particularly looking out four to five years.

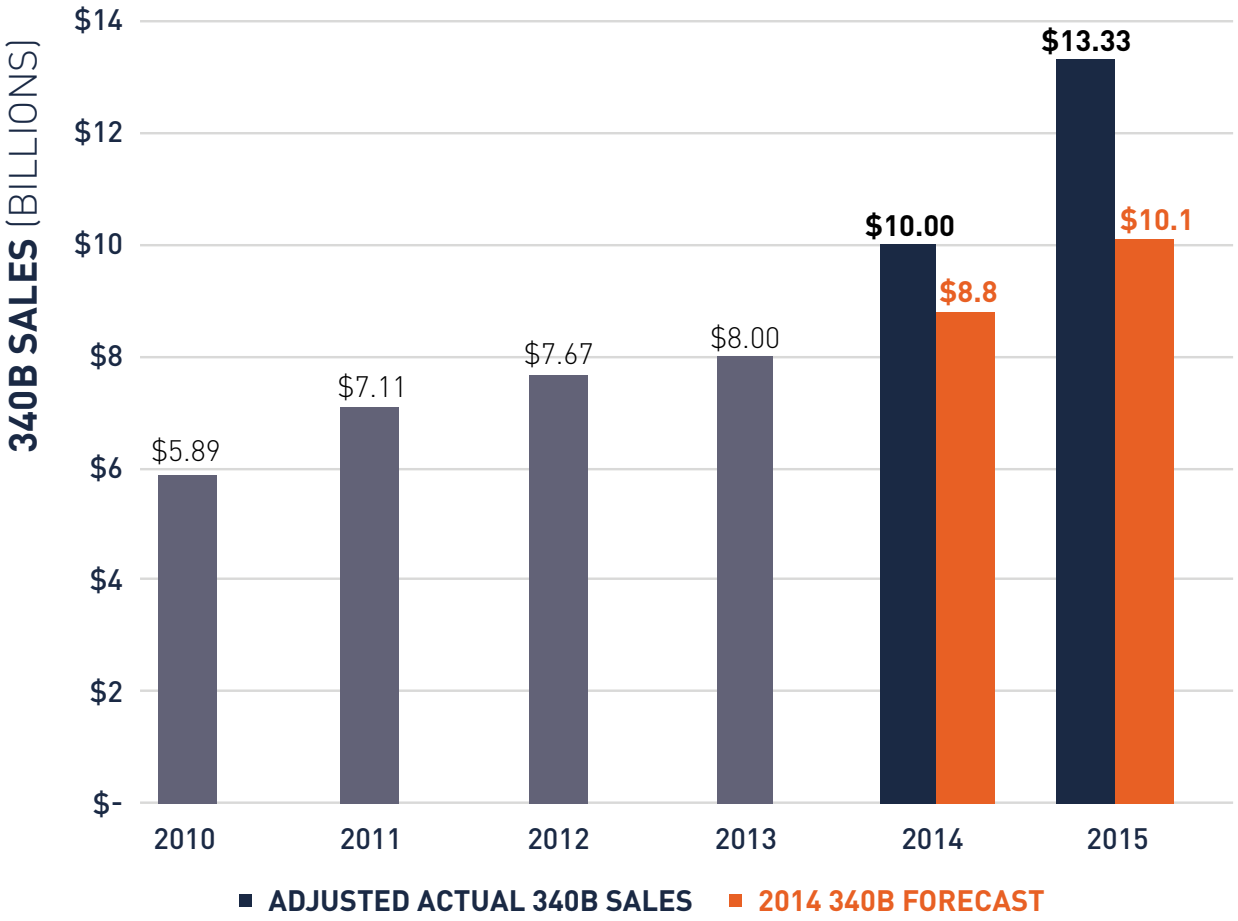
21 *340B Purchases Hit $12 Billion in 2015—and Almost Half of the Hospital Market* (February 2016), accessed at: http://www.drugchannels.net/2016/02/340b-purchases-hit-12-billion-in.html

22 Because the impact of contract pharmacy on the 340B program was minimal in 2010, sales extrapolated using annual hospital growth metrics based on a 2010 starting point will exclude contract pharmacy volume.

Appendix 3: 2014 340B Forecast Comparison

In November 2014, we published a study evaluating factors that had contributed to growth in the 340B program between 2004 and 2013. Our analysis identified historical growth drivers including 340B contract pharmacy expansion, private physician practice acquisitions, and enrollment of newly eligible hospitals resulting from passage of the Medicare Modernization Act and ACA. Based on this analysis and the expected impact of Medicaid expansion on hospital eligibility, we forecasted growth in the program through 2019. Figure 5 compares actual 340B sales as reported by Apexus (adjusted to reflect direct sales of 340B priced drugs) with our 2014 forecast.

FIGURE 5: 340B SALES - ADJUSTED ACTUALS VS 2014 340B FORECAST[23]



Despite forecasting growth in the 340B program that substantially exceeds prior-year growth rates, actual growth in 2014 and 2015 340B sales far outpaced our estimates. In fact, 2015 actual 340B sales approached forecasted sales for 2017.

Subsequent research that we have conducted with covered entities, private medical practices, contract pharmacies, and pharmaceutical manufacturers indicates that the rapid program growth in 2014 and 2015 is a function of many factors. The most prominent of these include practice affiliations with covered entities, adoption of new technology due to GPO prohibition enforcement, increased participation of specialty contract pharmacies, and introduction of new medicines. Further, our research suggests that these factors will continue to drive growth in the 340B program for at least the next five years. As a result, we believe that our 2014 forecast underestimates total 340B sales and we have developed a revised forecast to better understand how the program is likely to grow over the next five years.

23 Aaron Vandervelde, *Growth of the 340B Program: Past Trends, Future Projections*, BRG white paper (November 2014), accessed at: http://www.thinkbrg.com/newsroom-publications-vandervelde-growth-340B-program.html; *340B Purchases Hit $12 Billion in 2015—and Almost Half of the Hospital Market* (February 2016), accessed at: http://www.drugchannels.net/2016/02/340b-purchases-hit-12-billion-in.html.