

Analysis of 340B hospitals' outpatient department acquisition cost and commercial reimbursement for physician-administered brand medicines

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Executive Summary

The 340B Drug Pricing Program allows qualifying hospitals and safety net clinics to purchase covered outpatient medicines at discounted rates from manufacturers. Since its creation in 1992, the 340B program has grown significantly, spurring increased interest from lawmakers and government oversight groups, which has resulted in significant effort to investigate how hospitals are using the revenue generated by the program.

The 340B program provides qualifying facilities access to discounted prescription medicines and its intent is to allow these providers to “*stretch scarce federal resources as far as possible to provide more care to more patients*,” according to the Health Resources and Services Administration (HRSA). Hospitals and qualified facilities are able to dispense the medicines they purchase at 340B discounted prices to Medicare and commercially insured patients and retain the spread between the purchased and reimbursed price, with no obligation to report to the federal government how they are using those funds. This paper compares the reimbursements 340B hospitals receive from commercial insurers for brand physician-administered medicines to the estimated prices these hospitals pay to acquire the medicines. We also evaluate how differences between estimated acquisition costs and reimbursements for 340B hospitals compare to non-340B hospitals. While several papers have examined the characteristics of 340B hospitals and their

associated outpatient sites (including the growth in number and types of 340B hospitals and associated outpatient sites and the spending at these facilities^{1,2}), this analysis calculates the difference between hospitals' purchase and reimbursement prices for physician-administered 340B medicines used to treat patients with commercial insurance.

Our analysis produced the following observations based on 2016 claims data:

- On average, across all hospital types (including both non-340B and 340B), hospital reimbursements for brand medicines are approximately 247% of their acquisition costs.
- Hospitals participating in the 340B program receive reimbursements of 294% of their respective acquisition costs (340B ceiling price), on average. This means the reimbursement that 340B hospitals receive from payers averages nearly three times the amount the hospitals paid to acquire these brand medicines.³
- On average, the upper quartile of 340B hospitals (by reimbursement) receive at least 3.5 times their acquisition costs for brand medicines from commercial insurers. By comparison, the upper quartile of non-340B hospitals receive at least 2.2 times their acquisition costs.

1 U.S. GAO (June 2018). Report to Congressional Requesters: Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement.

2 Blalock, E. (December 2018). Increases in Part B Drug Utilization at Enrolling 340B Hospitals. Retrieved September 22, 2019, from <https://www.thinkbmg.com/newsroom-publications-increases-part-b.html>.

3 All hospitals analyzed were acute care facilities. We did not separately identify DSH 340B hospitals in our study. However, the majority of covered entities listed in the HRSA database of 340B acute care facilities are DSH. Similarly, in a prior Milliman study of 340B hospitals, a minority of 340B hospitals were identified as non-DSH (see "Commercial payers spend more on hospital outpatient drugs at 340B participating hospitals" at <http://www.milliman.com/payers-spend-more-on-outpatient-drugs-at-340B-hospitals/>).

Background

Created by Congress in 1992, the 340B Drug Pricing Program is intended to help safety net facilities and certain qualifying hospitals (known as “covered entities”) that serve a large proportion of vulnerable or uninsured patients gain access to prescription medicines at discounted rates. Clinics that receive certain grants from the federal government (federal grantees) are eligible to participate in the 340B program⁴, as are hospitals that have a minimum disproportionate share hospital (DSH) adjustment percentage and meet additional requirements.⁵ While grantees are typically required to use revenue from 340B to provide care to vulnerable communities, reinvest any additional resources into services for vulnerable patients, and meet reporting requirements on use of 340B revenue, similar requirements do not apply to 340B hospitals.⁶ The 340B program allows covered entities to purchase certain medicines at discounted prices but dispense these medicines to all eligible patients, including Medicare and commercially insured patients, and have no obligation to report how this revenue is used.

How hospitals use 340B discounts, combined with the program’s significant growth (2,357 hospitals participated in 340B in 2017, a significant increase from 51 hospitals in 1992), has spurred increased interest in the program from lawmakers and government oversight groups.⁷ While several papers have examined the characteristics of 340B hospitals and their associated outpatient sites,⁸ this paper estimates these hospitals’ gross margins for 340B-eligible medicines used to treat patients with commercial insurance. Specifically, to calculate gross margin, our analysis examines the difference between the reimbursements 340B hospitals receive from commercial insurers for brand outpatient medicines and our estimates of the prices hospitals pay to acquire those same medicines. We compare these estimates among 340B hospitals and non-340B hospitals.

A challenge in this analysis—and any analysis of the 340B program—is estimating the discounted price of a covered medicine to determine the hospital’s acquisition cost. The 340B

ceiling price represents the maximum price a manufacturer can charge for a 340B-eligible medicine. The ceiling price is calculated by subtracting the medicine’s unit rebate amount (URA) from its average manufacturer price (AMP). While ceiling prices may be disclosed confidentially to covered entities, they are not otherwise public. Further, the data used to calculate ceiling prices (AMP and URA) are also confidential. However, several analyses approximate 340B discounts:

- The Medicare Payment Advisory Commission (MedPAC) estimated in 2015 that the *minimum* discount 340B hospitals receive for medicines paid under the outpatient prospective payment system is 22.5% of the medicines’ average sales price (ASP).⁹
- The Office of Inspector General (OIG) found that Medicare Part B payments were 58% higher than 340B ceiling prices in 2013.¹⁰
- By law, a brand drug’s 340B ceiling price equals the drug’s AMP minus its Medicaid rebate. The ceiling price, on average in 2013, has been estimated to be 37% of AMP (a 63% of AMP rebate).¹¹

KEY DEFINITIONS

The set of terms and corresponding definitions below are used throughout this report:

REIMBURSEMENT (also referred to as “allowed charges”)	Payment between the health plan and provider (hospital) for covered services Includes both the plan liability and patient copayment or coinsurance Source: 2016 commercial medical claims from Milliman’s Consolidated Health Cost Guidelines™ Source Database
AVERAGE SALES PRICE (ASP)	Reflects the average of nearly all manufacturer U.S. sales prices for Medicare Part B drugs and includes rebates and discounts privately negotiated between manufacturers and purchasers Used as the estimated acquisition cost a non-340B hospital pays for medicines Source: CMS ASP Drug Pricing Files
340B CEILING PRICE	Estimated acquisition cost a covered entity pays for a 340B-eligible outpatient medicine Source: See Methodology section for description of calculation
GROSS HOSPITAL MARGIN	Calculated as: Reimbursement ÷ Acquisition Cost (ASP or 340B Ceiling Price)

4 Federal grantee categories eligible to participate in 340B include: Black Lung Clinics, Comprehensive Hemophilia Diagnostic Treatment Centers, Federally Qualified Health Centers, Federally Qualified Health Center Look-Alikes, Native Hawaiian Health Centers, Ryan White HIV / AIDS Program Grantees, Sexually Transmitted Disease Clinics, Title X Family Planning Clinics, Tribal/Urban Indian Health Centers, and Tuberculosis Clinics.

5 Critical access hospitals (CAHs) are not required to have a minimum DSH adjustment percentage to qualify for 340B but must meet other criteria. Certain children’s hospitals, sole community hospitals, rural referral centers, and freestanding cancer hospitals may also participate if specified criteria are met.

6 Although there are no requirements under the 340B statute for how 340B revenue can be used, covered entities that are federal grantees (such as federally qualified health centers) may be required to use 340B revenue in ways that are consistent with their grant requirements.

7 The U.S. House Energy and Commerce Committee (2018). Review of the 340B Drug Pricing Program. U.S. GAO (2018). Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement.OIG (2018). Examining Oversight Reports on the 340B Drug Pricing Program: Testimony Before the United States Senate Committee on Health, Education, Labor, and Pensions.

8 Nikpay, S., Buntin, M., & Conti. R.M. (2018). Diversity of participants in the 340B Drug Pricing Program for U.S. hospitals. JAMA Intern Med.;178(8):1124–1127. Conti, R.M. & Bach, P.B. (October 1, 2014). The 340B drug discount program: Hospitals generate profits by expanding to reach more affluent communities. Health Affairs;33(10):1786-92.

9 MedPAC (2015). Report to the Congress: Medicare and the Health Care Delivery System. Chapter 3, Part B Drug Payment Policy Issues.

10 U.S. Department of Health and Human Services, Office of Inspector General (November 2015). Part B Payments for 340B-Purchased Drugs. Retrieved September 22, 2019, from <https://oig.hhs.gov/oei/reports/oei-12-14-00030.pdf>.

11 Congressional Budget Office (December 8, 2016). Options for Reducing the Deficit: 2017-2026, p. 255. Retrieved September 22, 2019, from <https://www.cbo.gov/publication/52142>.

Our study focuses on the difference between acquisition costs and the commercial reimbursement of physician-administered brand medicines in the hospital outpatient setting. We used a large claims database of 2016 commercial insurance claims to identify hospital outpatient reimbursements by hospital type (i.e., 340B hospital vs. non-340B hospital). Details regarding how 340B discounts were determined are found in the Methodology and Assumptions section below.

Results

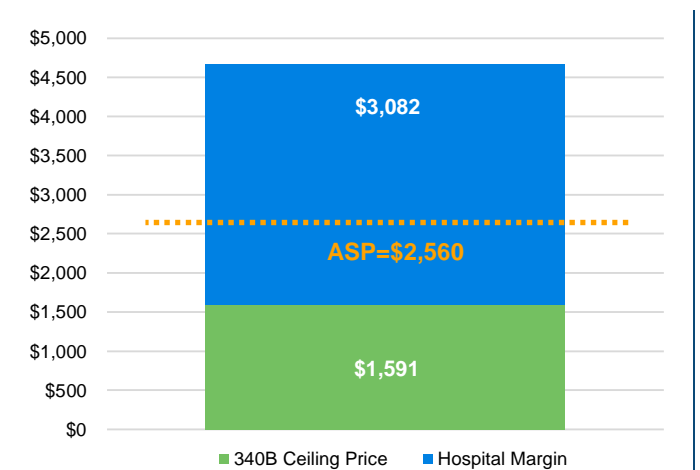
On average, across all hospital types (including both non-340B and 340B), hospital reimbursements for brand medicines are approximately 247% of their acquisition costs (accounting for 340B pricing). Hospitals participating in the 340B program receive reimbursements of 294% of their respective acquisition costs (i.e., 340B ceiling price), while non-340B hospitals receive 170% of their acquisition costs (i.e., ASP, on average for a Part B drug). This means 340B hospitals, on average, receive reimbursement from commercial payers that is almost three times the amount paid to acquire these medicines. In contrast, non-340B hospitals receive reimbursement that is approximately 1.7 times their acquisition costs.¹²

Our data suggest the 340B acquisition cost reflects a 38% discount from ASP on average across brand medicines administered at 340B hospitals. This is in line with other estimates from published studies, specifically the OIG report from 2013, which estimated 340B ceiling prices that year at a 37% discount from then-prevailing Medicare Part B payment rates to hospitals for 340B drugs (i.e., ASP + 6%).

As shown in Figure 1, the average reimbursement for a medicine at a 340B hospital in our sample was \$4,673. Of this amount, we estimate \$3,082 (66%) is retained by the 340B hospital.

In addition to analyzing reimbursements at the claims level, we also analyzed the variation in average reimbursement at the hospital level.

FIGURE 1: ILLUSTRATION OF ESTIMATED RETAINED HOSPITAL GROSS MARGIN¹³ AND ACQUISITION COST FOR AVERAGE COST MEDICINE IN THE ANALYSIS



Figures 2 and 3 on page 4 show the distribution of average hospital gross margins across 340B and non-340B hospitals, respectively.¹⁴

- The distribution of 340B hospitals' gross margins (Figure 2) is skewed slightly to the right and shows a wide range of gross margins. In addition, some large outliers are receiving reimbursements above 700% of their acquisition costs (they may represent hospitals in our data that administer a large portion of "penny-priced" medicines).¹⁵
- In contrast, gross margins at non-340B hospitals are skewed more heavily to the right, with a large percentage of hospitals receiving gross margins between 100% and 250%.

The skewed reimbursement range in the non-340B data indicates a tendency of non-340B hospitals to have lower average reimbursement ratios than 340B hospitals. Fewer outliers in the non-340B data indicates less variation in reimbursement. When ranked by total average gross margin for physician-administered medicines, the upper quartile of 340B hospitals received at least 3.5 times their acquisition costs for brand medicines from commercial insurers. For non-340B hospitals, the upper quartile received at least 2.2 times their acquisition costs.

¹² We also analyzed the ratio of billed charges to respective acquisition cost separately. The Considerations and Limitations section of this paper includes discussion about why allowed charges, and not billed charges, is the focus of this analysis.

¹³ Hospital gross margin is equal to the amount reimbursed to the hospital minus the hospital's estimated acquisition cost. It does not account for the hospital's expenses such as overhead, payroll, or profit.

¹⁴ Figures 2 and 3 exclude hospitals with fewer than 40 total outpatient claims and hospitals that dispensed fewer than three different brand medicines used within our study.

¹⁵ "Penny-pricing" occurs when the 340B ceiling price calculation results in a price of \$0.00. When this occurs, HRSA regulation requires manufacturers to charge 340B-covered entities \$0.01 per unit of measure for the drug. For additional information: U.S. Department of Health and Human Services (November 2018), 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, available at <https://www.federalregister.gov/documents/2018/11/30/2018-26223/340b-drug-pricing-program-ceiling-price-and-manufacturer-civil-monetary-penalties-regulation>.

FIGURE 2: DISTRIBUTION OF INDIVIDUAL 340B HOSPITAL GROSS MARGIN¹⁶

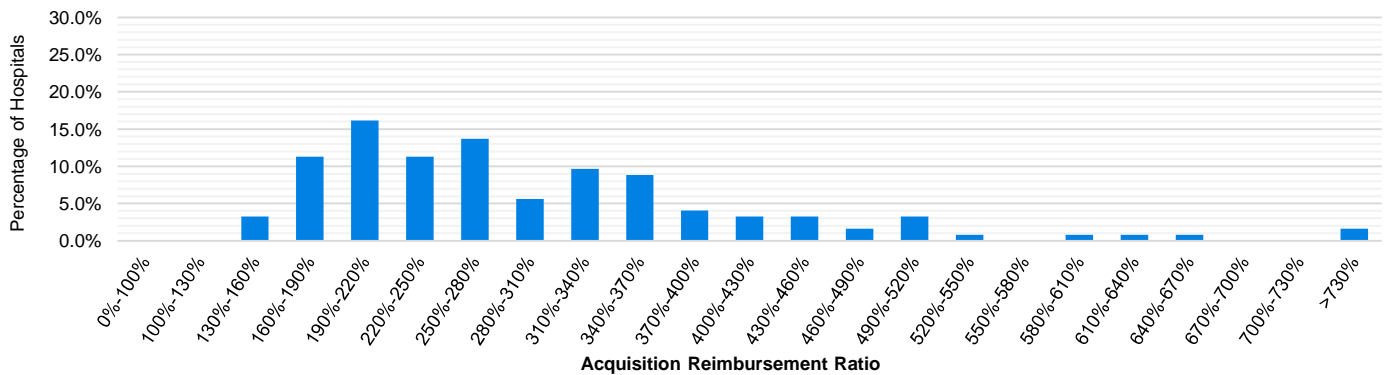
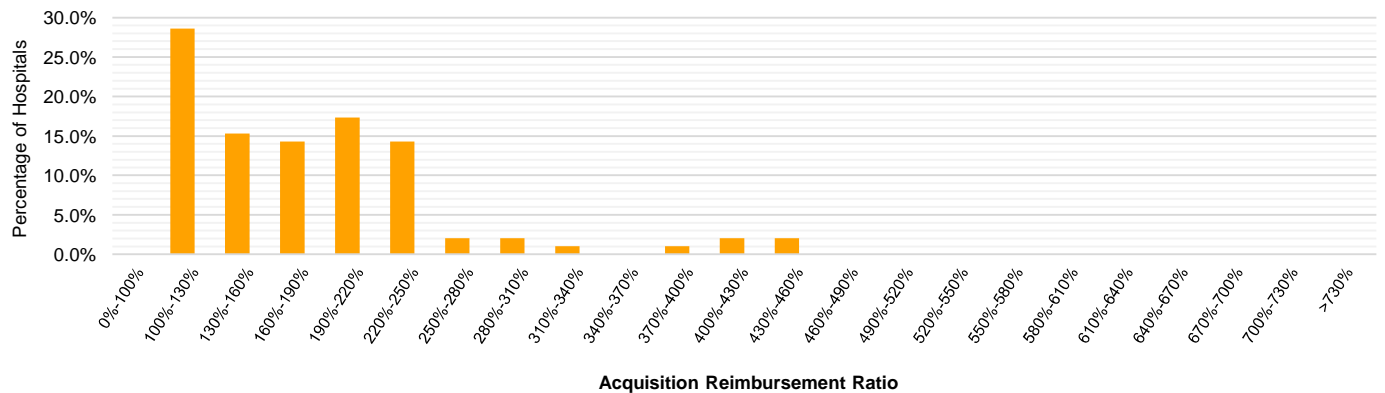


FIGURE 3: DISTRIBUTION OF INDIVIDUAL NON-340B HOSPITAL GROSS MARGIN¹⁷



Methodology and Assumptions

We analyzed 2016 commercial medical claims from Milliman’s Consolidated *Health Cost Guidelines (HCG) Source Database (CHSD)* to evaluate the variation in retained hospital gross margin for outpatient-administered medicines eligible for the Medicaid Drug Rebate Program (covered outpatient drugs, or COD) at 340B and non-340B hospitals. The CHSD contains approximately 30 million commercially insured lives and is a consolidation of member experience data contributed by numerous health plans throughout the nation. Prior to using the data, we validated it for consistency and overall reasonability with external sources. Gross margin, for this report, is defined as the reimbursement to the hospital, as a percentage of the hospital’s estimated acquisition cost. It does not account for hospital expenses, such as overhead, payroll, or profit.

IDENTIFYING 340B HOSPITALS

We used a combination of Medicare IDs and National Provider Identifiers (NPIs) to identify 340B participating and nonparticipating hospitals. Specifically, we identified 340B participating hospitals using the online database of the Health Resources and Services Administration (HRSA) Office of Pharmacy Affairs.¹⁸ We selected hospitals with 340B status in the 48 contiguous states, Hawaii, Alaska, and Washington, D.C., in 2016 or earlier (and for which 340B status was not terminated in 2016 or later). For hospitals that changed status within 2016, we classified them based on their status at the beginning of the year. We compared the HRSA list of 340B hospitals to the list of Acute Care Hospitals from the public use file (PUF) reports from the Centers for Medicare and Medicaid Services (CMS).¹⁹ Hospitals found on both lists were included in our analysis as 340B hospitals while hospitals from the list of Acute Care

¹⁶ Gross margin is the reimbursement paid to the hospital as a percentage of the hospital’s estimated acquisition cost. It does not account for the hospital’s expenses, such as overhead, payroll, or profit.

¹⁷ Gross margin is the reimbursement paid to the hospital as a percentage of the hospital’s estimated acquisition cost. It does not account for hospital expenses, such as overhead, payroll, or profit.

¹⁸ Available at <https://340bopais.hrsa.gov/coveredentitysearch>.

¹⁹ Data.Medicare.gov. Hospital General Information. Retrieved September 22, 2019, from <https://data.medicare.gov/Hospital-Compare/Hospital-General-Information/xubh-q36u>.

Hospitals that were not included in the list of 340B hospitals from HRSA were designated as non-340B.

For this analysis, 340B status was assigned by linking NPI to Medicare ID. Note, that some Medicare IDs from the Acute Care Hospitals list did not map to a hospital in our data set and therefore were excluded from the analysis. Of the 990 Medicare IDs mapped to a hospital in our data, 421 (43%) were identified as 340B and 569 (57%) as non-340B. Each unique Medicare ID is assumed to be a unique hospital.

IDENTIFYING ELIGIBLE HOSPITAL OUTPATIENT PHARMACY SPEND

We started with a list of 1,459 Healthcare Common Procedure Coding System (HCPCS) reimbursement codes in the RJ Health Systems Reimbursement Codes Master Datafile™ (RCMD™), which includes a National Drug Code (NDC) crosswalk listing all active NDCs falling under each HCPCS reimbursement code.

We used Milliman's HCGs grouper to identify hospital outpatient pharmacy claims associated with these HCPCS codes. Milliman's grouper uses a combination of HCPCS code, revenue code, bill type, place of service, and other data to group claims. We removed any non-medicine cost (i.e., administration) and vaccines from the analysis.

We extracted claims associated with these HCPCS codes from Milliman's 2016 CHSD database, assigning each claim a 340B and non-340B hospital status according to the description above. We found that the payer spending associated with the top 383 HCPCS codes represented 99.8% of allowed costs and we focused on those HCPCS codes for the remainder of the analysis.

From this remaining list of HCPCS codes, we excluded:

- HCPCS codes associated with any nondrug codes, according to the RCMD code or the Covered Outpatient Drug (COD) status used for the Medicaid Drug Rebate Program.
- Any HCPCS code not found in CMS's quarterly ASP files.
- Any HCPCS code associated with an NDC not included on the Medicaid Drug Rebate Program list on data.medicaid.gov.
- HCPCS codes for medicines approved as blood-clotting factors and for pediatric indications, as noted in the Medicaid Drug Rebate Program list on data.medicaid.gov.
- HCPCS codes for medicines for which the ceiling price calculation was not reliable or reasonable (e.g., the allowed cost per unit was significantly less than the estimated ceiling price).

From the claims associated with the remaining subset of HCPCS, we further excluded:

- **Commonly bundled medicines, as determined by analyzing the percentage of \$0 claims in the data.** If more than 50% of claims in a HCPCS code were \$0, it was considered commonly bundled and excluded.

- **Claims appearing to be part of a bundled payment.** These claims included several criteria, including those with \$0 or \$1 allowed claims with an allowed amount greater than the billed amount, and claims with unusually low unit amounts.
- **Outlier claims.** We calculated the 3rd and 97th percentiles of reimbursement ratios by claims line (as a percentage of ASP) and removed claims outside of those bounds.

Figure 4 summarizes the impact of these exclusions on our data set. The final analysis included 57% of total outpatient hospital pharmacy spending, mapped to either a 340B or non-340B hospital.

FIGURE 4: SUMMARY OF HCPCS CODES AND CLAIMS EXCLUDED FROM ANALYSIS

	Allowed	% Included
All outpatient medicines mapped to 340 or non-340B hospitals	\$725,691,738	100%
Remove medicines with no HCPCS code ¹	658,797,900	91%
Remove medicine HCPCS codes that are not in study ²	485,070,733	67%
Remove claims with unreliable allowed and / or units		
Remove potential bundles	461,457,372	64%
Remove claims with coordination of benefits (COB)	433,075,027	60%
Remove unit per claims outliers	431,193,658	59%
Remove "Allowed to ASP Ratio" outliers	416,126,615	57%
Final included	416,126,615	57%

¹ These are claims with a pharmacy revenue code such as "0250" but no corresponding HCPCS code. We expect they are primarily bundled claims.

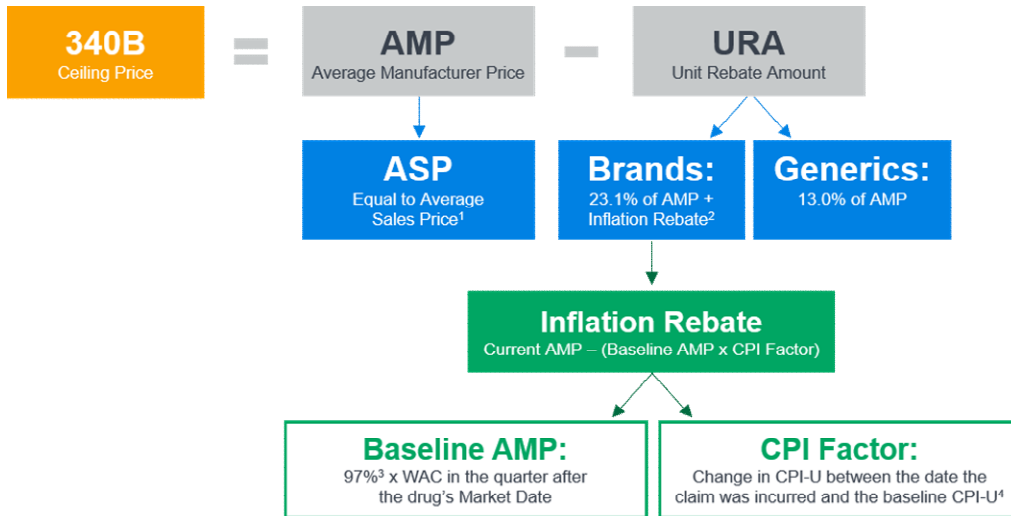
² These include all generics, HCPCS code not found in CMS ASP files, blood-clotting factors or pediatric indication, HCPCS code with high variation in ceiling price, and HCPCS code not found in both 340B and non-340B hospitals.

CALCULATING THE 340B AND NON-340B ACQUISITION PRICE

Non-340B hospitals were assumed to acquire 340B-eligible medicines at the ASP. ASP is published quarterly, but there is a two-quarter lag between the time the sales reflected in the ASP occur and the time when these sales become the basis for reimbursement. Therefore, we used the ASP payment rate files for July 2016, October 2016, January 2017, and April 2017 for quarters one through four, respectively, of 2016. The 340B hospital acquisition price was assumed to be the 340B ceiling price, calculated using the methodology shown in Figure 5.

The ceiling price was calculated on a unit basis. The ceiling price per unit was then multiplied by the number of units reported in the claims data set for that HCPCS code. We evaluated the relationships between allowed cost per unit, wholesale acquisition cost (WAC) per unit, and ASP per unit for reasonability (i.e., we expect that allowed cost is greater than 100% of WAC, and WAC is slightly greater than ASP). Note that we did not include generics in the analysis but included their calculation in Figure 5 for completeness.

FIGURE 5: 340B HOSPITAL ACQUISITION PRICE METHODOLOGY



1. This assumption is based on ASP, a close estimate of AMP.
2. The URA for brands is the *greater of* 23.1% of AMP + Inflation Rebate *or* AMP – Medicaid Best Price + Inflation Rebate. Line extensions have an alternative formula and we did not attempt to account for the additional rebate that may be due, resulting in a potentially conservative estimate of ceiling prices.
3. Accounts for wholesaler discounts equal to 3% of WAC. ASP cannot be used for most NDCs because the market entry date precedes 2005, when ASP use began. Sensitivity testing shows this assumption does not materially affect overall results.
4. Baseline CPI-U is defined as CPI-U for the month prior to the first quarter after the drug's market entry date.

CALCULATING THE 340B AND NON-340B GROSS MARGINS

Our definition of gross margin (i.e., hospital reimbursement as a percentage of the hospital's estimated acquisition cost) does not account for hospital expenses, such as payroll, overhead, profit, or any other charges the hospital may incur related to the acquisition, dispensing, or administration of outpatient prescription medicines. We did not attempt to analyze how the savings generated by the 340B discounts were used. We also did not attempt to account for the health of the underlying patients, because the analysis focused on gross margins, which would only be minimally impacted by the underlying health risk of a population (if at all).

Our analysis excludes medicines included as part of a bundled payment. The data suggested that non-340B hospitals have higher tendencies to bundle medicines with other services: therefore, basing the aggregate margin for each hospital type using their respective utilization mix may not reflect the hospital's true utilization, and also may not be a true direct comparison between hospitals. For this reason, we excluded any HCPCS code where either hospital type had no utilization.

Given the different characteristics between 340B hospitals and non-340B hospitals, we believe it is important to ensure that the utilization mix of the medicines was not affecting the results. To validate our results, we analyzed the impact of differences in utilization mix between the 340B and non-340B hospitals in our data three separate ways:

1. **Raw:** Unique average reimbursement (by HCPCS code) by hospital type applied to each hospital's utilization.
2. **Adjusted, but separate:** Unique average reimbursement (by HCPCS code) by hospital type applied to the utilization of the opposite hospital type.
3. **Aggregate:** Unique average reimbursement (by HCPCS code) by hospital type applied to the combined utilization for both hospital types.

Results are displayed using the first method above. We tested our findings using all three methods and found the results did not materially differ.

Considerations and Limitations

As noted in the Background section of this analysis above, features of the 340B program (such as the confidential nature of AMP and Best Price) limit the ability to estimate hospitals' gross margins on outpatient prescription medicines. We recognize these limitations and the following considerations.

Hospital payment contracting considerations: It is important to consider all hospital service lines when reviewing hospital outpatient pharmacy payment rate results. It is common for hospitals to contract payment rates with payers in totality. If a payer changes contracted payment rates for hospital-administered outpatient medicines, then other hospital services may offset these payment rate changes.

Use of 340B program-generated revenue. We did not evaluate how hospitals use the estimated revenue generated by the program.

Billed charges. For non-340B hospitals, we observed a billed charges ratio of 468% (based on ASP) and for 340B hospitals a billed charges ratio of 576% (based on estimated 340B ceiling prices). Billed charges are the prices for medicines and services that the hospitals initially display to payers. Billed charges function as a starting point for payment negotiations. Rarely (if ever) does the hospital receive this level of payment from a payer. However, while a hospital's billed charge rarely reflects the actual amount paid by a payer or patient, the billed charge has important implications. Many payer contracts are structured as a "percentage off billed charges."²⁰ Additionally, patients who receive care from hospitals outside of their payers' networks may be "balance billed" for the amount not covered by their insurer, and that amount may be based on the billed charge. Because billed charges do not always reflect actual costs to payers and the health system, we did not focus on the metrics obtained by studying the billed charges ratios in this analysis.

HCPCS vs. NDC-11-level data. Outpatient medicines are purchased at the NDC level but reimbursed at the HCPCS code level. Our claims data does not indicate the NDC associated with the outpatient pharmacy claim, only the HCPCS code used for billing purposes. This requires an assumption to be made for the 340B acquisition price when multiple NDCs fall into one HCPCS code because WAC, ASP, and utilization may vary by NDC. This limitation is managed by focusing only on single-source brand medicines in the study.

Estimate of AMP. Due to the confidential nature of the AMP, we estimated both the baseline AMP at the time of market entry and the current AMP for all active, reimbursable NDCs in the HCPCS code of interest at the time of claim incurral. The market date AMP and current AMP are used to calculate the inflation rebate component of the URA for brand medicines (and now generics as well). The *market date AMP* was estimated to be 97% of the WAC price in the first quarter after the market date, according to Medi-Span. We assumed wholesalers may receive discounts of approximately 3% that are not reflected in the WAC price, but would be reflected in the AMP. For the *current AMP* for each quarter in the 2016 claims data, we assumed AMP equals ASP. ASP is available from CMS's website and is derived from the sales from manufacturers to all purchasers and includes practically all discounts. It is therefore a closer estimate of AMP than WAC. ASP could not be used for the *market date AMP* because most products entered the market before 2005, which was the first year ASPs were published. Note that for commonly rebated products, the ASP will be notably lower than WAC because rebates are reflected in ASP. Today, there are two calculations of AMP: standard and "5i." The medicines in this study are "not generally dispensed through retail community pharmacies" and therefore utilize the 5i AMP calculation, which takes into account a much wider range of sales and price concessions than standard AMP and therefore is closer to ASP.²¹ As a result, the ASP is a reasonable estimate of AMP for outpatient hospital products.

Generic vs. brand spending. Our data set includes both brand and generic medicines with each HCPCS code assigned a "brand" or "generic" flag. If all NDCs within a HCPCS code were single-source brands, the "brand" flag was assigned. If there was a multisource brand or only generics available, a "generic" flag was assigned.

Focusing on brands is reasonable because brand medicines made up a majority of the spending in the starting data set. Additionally, studies have shown that brand medicines comprise nearly 90% of 340B utilization,²² compared to 77% in the U.S. market overall.²³ Further research exploring unit cost variations within generic reimbursement under a single HCPCS code would be needed to include generics in any analysis.

Medicines with alternative URA calculations. The URA calculation for medicines approved as blood-clotting factors and for pediatric indications varies from other innovator medicines (17.1% of AMP per unit versus 23.1% of AMP per unit, or AMP minus Best Price, if higher). Prior studies noted that the units billed for blood-clotting factors often underrepresent the number

20 Magellan Rx Management (2017), The Magellan Rx Management Medical Pharmacy Trend Report: 2016 Seventh Edition. EMD Serono (2018), The EMD Serono Specialty Digest 14th Edition.

21 42 CFR Part 447, 2016. The full text is available at <https://www.govinfo.gov/content/pkg/FR-2016-02-01/pdf/2016-01274.pdf>.

22 Clark, B.L., Hou, J., Chou, C.H., Huang, E.S., & Conti, R. (November 1, 2014). The 340B discount program: Outpatient prescription dispensing patterns through contract pharmacies in 2012. Health Affairs;33(11):2012-7.; Office of Inspector General (2011). States' Collection of Medicaid Rebates for Physician-Administered Drugs.

23 IQVIA Institute (2018). Medicines Use and Spending in the U.S.: A Review of 2017 and Outlook to 2022.

of units reimbursed.²⁴ Determining whether a medicine was used for a pediatric indication was outside the scope of this analysis and, as noted above, we are unable to determine which NDC was used for a given HCPCS code in the claims data. Given these factors, we excluded HCPCS codes that included NDCs identified in the Medicaid Drug Rebate Program drug list as blood-clotting factors or as approved for pediatric indications.

Line extensions also have an alternative URA calculation that may lower the 340B ceiling price. We did not attempt to account for line extensions, which results in a higher estimate of 340B ceiling prices for any medicine in the data for which a line extension was used.

Consistency with prior analyses. As noted in the Background section above, previous studies—including those by the OIG, MedPAC, and the U.S. Government Accountability Office (GAO)—have explored dynamics in the 340B program. Any differences in results between this study and prior studies are due to differences in the study time periods (relevant due to the growth in the 340B market), patient populations (e.g., claims incurred by a commercially insured population versus a Medicare population), subsets of 340B hospitals, access to proprietary metrics (e.g., actual 340B ceiling prices), and types of medicines (e.g., brand versus generic medicines). **Variation in utilization patterns.** We did not account for generic utilization patterns, including whether 340B hospitals have higher or lower generic utilization patterns than non-340B hospitals. There are instances when 340B hospitals may have lower acquisition costs for multisource brand medicines at the “penny-price,” when available, as opposed to the generic alternative, which could create incentives lowering generic utilization at 340B hospitals.

Overestimating ceiling prices. Our estimate of 340B acquisition costs using the 340B ceiling price required several assumptions and decisions to operationalize and may have resulted in overestimating ceiling prices or 340B hospital acquisition costs on certain drugs:

- For brand medicines, the URA is equal to the *greater of* the difference between the AMP and the Medicaid Best Price or 23.1% of AMP. We did not account for Best Price rebates potentially exceeding 23.1% of AMP, as this information is not publicly available.
- Covered entities participating in the Apexus Prime Discount Program receive additional discounts from the 340B ceiling price, estimated at approximately 10%. We did not account for additional discounts received through the Prime Discount Program.^{25,25}
- We did not account for the alternative URA calculation for line extensions, which may lower the 340B ceiling price.

Due to these factors, our estimates of 340B savings are potentially understated (i.e., potentially overestimating the aggregate 340B acquisition cost or underestimating the 340B discount), thus underestimating the retained hospital margin for 340B hospitals.

24 OIG (2013). Part B Payments for 340B-Purchased Drugs.

25 Apexus. 340B Prime Vendor Program. Available at: <https://www.340bpvp.com/resource-center/faqs/prime-vendor-program/>

Caveats and Qualifications

This report was developed to estimate the differences in hospital outpatient department pharmacy reimbursement and spend between 340B participating and nonparticipating hospitals for commercially insured patients. This work is not intended to be used for other purposes. This report is provided for PhRMA, but PhRMA may share this information with external parties with Milliman's permission. We do not intend this information to benefit, and assume no duty or liability to, any third party that receives this work product. Any third party recipient of this report who desires professional guidance should not rely upon Milliman's work product, but should engage qualified professionals for advice appropriate to its specific needs. Any releases of this report to a third party should be in its entirety.

In preparing our results, we relied upon public information from the HRSA website and the Medicaid Drug Rebate Program as well as information from Medi Span, the RJ Health Systems Reimbursement Codes Master Datafile™ (RCMD™), and Milliman's commercial claims database. We did not audit or independently verify any of the information furnished, except that we did review the data for reasonableness and consistency. Actual results will vary due to differences in commercial reimbursement, estimate versus actual 340B ceiling prices, and any potential changes to the 340B program.

Anna Bunger is a consulting actuary for Milliman, Inc. She is a member of the American Academy of Actuaries and meets the qualification standards of the American Academy of Actuaries to render the actuarial opinion contained herein. The terms of Milliman's Master Services Agreement with PhRMA, effective January 19, 2016 and extended effective December 19, 2018, apply to this report and its use.



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