Hospital Acquisitions of Physician Practices and the 340B Program

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Summary

Avalere Health conducted an analysis to examine the relationship between hospital participation in the 340B Drug Pricing Program (the 340B program) and a recent trend of hospital acquisitions of physician practices. The 340B program requires manufacturers to provide certain healthcare providers with discounts on outpatient drugs. Over the past few years, the 340B program has grown significantly and this paper examines one potential reason for that growth.

Our analysis focused on hospitals and their possible acquisitions of all types of physician practices between 2009 and 2013. The analysis was limited to hospital categories that are eligible for 340B (e.g., disproportionate share hospitals and critical access hospitals) and included both for-profit and non-profit hospitals. We found that 340B-participating hospitals were more likely than non-340B hospitals to acquire independent physician practices during this period of time. Specifically, 61 percent of hospitals in the study that were identified as potentially acquiring physician practices participated in the 340B Program during the analysis timeframe compared to a 45 percent 340B participation rate among all hospitals included in the analysis. As discussed more fully in the Appendix, hospitals were identified as having a potential acquisition of a physician practice when the adjusted monthly volume of patients receiving outpatient drug administration increased 5 times over both the national and the hospital referral region increase for the same month.

There are numerous reasons why a hospital would decide to acquire a physician practice. These findings do not necessarily mean that the acquisition of physician practices by 340B hospitals is driven solely by the drug discounts available in the 340B Program. The analysis merely indicates that there appear to be differences between 340B and non-340B hospitals with regards to possible physician acquisitions.

Background

The 340B Program was created by Congress in 1992 and mandates that manufacturers provide certain providers with discounts on outpatient drugs as a condition of participating in Medicaid. Certain non-profit and public hospitals can participate in the 340B program if they meet the applicable eligibility criteria. Non-profit hospitals with a high percentage of Medicaid and low-income Medicare patients, sometimes referred to as disproportionate share hospitals (DSH), account for 81 percent of total sales volume in the 340B program.

Over the past several years, the 340B program has expanded significantly. There are numerous possible reasons for this growth, including the expansion of eligibility in 2010 under the Affordable Care Act (ACA) to include new entity types, broader awareness of the 340B Program, and use of contract pharmacies. As a result of these and other factors, the program has grown significantly. The expansion of eligibility under the Affordable Care Act in 2010 included new entity types, such as hospital owned clinics and physician groups. This expansion allowed more healthcare providers to participate in the program and access the discounts available. Additionally, broader awareness of the program has led to increased participation among eligible entities.

1 Government Accountability Office. “Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement” September 2011; Link
2 For-profit entities are not eligible to participate in 340B, see 42 U.S.C. § 256b(a)(4)(L)(i); Link
4 Government Accountability Office. “Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement” September 2011; Link
factors, the number of 340B-participating sites has more than doubled over the past decade as illustrated by the Figure 1 below.

**Figure 1: Number of 340B-Participating Sites, 2004-2015**

![Figure 1: Number of 340B-Participating Sites, 2004-2015](chart)

*Participation as of December 31 of each year; for 2015, all entities participating as of March are included. Source: Avalere Health analysis of the 340B Database, [http://opanet.hrsa.gov/340B/Default](http://opanet.hrsa.gov/340B/Default)*

Some researchers point to hospital acquisitions of physician practices as one potential way hospitals can increase their profits from the 340B program. Medicines prescribed by the physicians in the acquired practice may become eligible for the 340B discount following the acquisition, allowing the hospital to potentially capture the difference between the 340B discounted price and the price paid by the patient or his/her insurer. Specifically, when an independent physician provides drug therapy, the claim submitted to the payer indicates a physician office as the site of care. When a physician practice is acquired by a hospital, the hospital will generally bill for this same care using the hospital outpatient department (HOPD) as the location of care by certifying the practice location as part of the hospital. Effectively, the acquired physician practice may become an integral part of the hospital included on the

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6 A 340B site is an outpatient clinic enrolled by the participating entity as a location where the discounted drugs are administered.

hospital’s Medicare cost report, and therefore may be eligible to participate in the 340B program.\textsuperscript{7}

The hospital’s enrollment of the acquired physician practices as an additional 340B site creates more opportunity for the hospital to access 340B prices for outpatient pharmaceutical medicines as a result of the additional patient volume flowing through the acquired practice. 340B providers need to annually attest to their continuous eligibility, but they can enroll new sites in the 340B program on a quarterly basis.\textsuperscript{8} The site-of-care shifts associated with the physician practice acquisition also may lead to higher overall costs of care as services provided in the HOPD setting often have a higher reimbursement than services provided in the physician’s office.\textsuperscript{9}

Researchers also have identified hospital acquisitions of physician-based oncology practices in particular as being a key driver of 340B program growth.\textsuperscript{10} Some have found that about three quarters of community oncology practices that were acquired were purchased by a hospital participating in the 340B program and that these acquisitions have been increasing over the past several years.\textsuperscript{11} Avalere Health conducted this analysis to further examine the relationship between 340B participation and hospital acquisitions of physician practices.

Our analysis examines whether 340B hospitals are more likely to acquire physician practices than non-340B hospitals, while past studies have largely focused on the cost implications of these acquisitions.\textsuperscript{12} Our study analyzed a universe of both 340B and non-340B hospitals and then asked whether 340B hospitals were more likely to have potentially acquired a physician practice. We flagged hospitals as having potentially acquired a physician practice if there was an increase in the volume of patients receiving infused or intravenous drugs administered in the HOPD (see Appendix for a more detailed explanation of the study methodology). By contrast, a recent study by the Berkeley Research Group (BRG) identified physician practice acquisitions by 340B hospitals between 2009 and 2012 by using a dataset of such acquisitions that was provided by the Community Oncology Alliance or derived from the Office of Pharmacy Affairs database through correlation of 340B site registrations and increases in Medicare fee-for-service (FFS) chemotherapy claims.\textsuperscript{13} Due to the differences in the methodology,

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the BRG study may have included physician practice acquisitions that were not captured in our study.

**Findings**

Out of 4,865 hospitals included in the analysis, 143 were identified as possibly acquiring at least one physician practice between 2009 and 2013 based on the monthly patient volume analysis. Detailed findings describing the number of hospitals identified after each analytical step are discussed in the Appendix. Almost all of the identified hospitals were DSH\(^{14}\) (138) and the remaining 5 were critical access hospitals (CAH)\(^{15}\)—another category of hospitals that are potentially eligible for the 340B program. Of these hospitals, 61 percent (87 facilities) participated in the 340B program during the analysis timeframe, compared to 45 percent of the 4,865 total hospitals included in the analysis (Figure 2). The majority of 340B hospitals that appear to have acquired a physician practice did so while eligible to receive discounts for any drugs prescribed by the physician. Of the 87 340B facilities, 71 participated in 340B both during and prior to the acquisition month, 13 enrolled in 340B after the acquisition month, and 3 acquired a practice after their 340B participation was terminated.

*Figure 2: 340B Participation Among Hospitals in the Analysis*

\(^{14}\) A DSH hospital is an entity that serves a disproportionate number of low-income patients as reflected by the disproportionate patient percentage (DPP) equal to the sum of the percentage of Medicare inpatient days (including Medicare Advantage inpatient days) attributable to patients entitled to both Medicare Part A and Supplemental Security Income (SSI) and the percentage of total inpatient days attributable to patients eligible for Medicaid but not entitled to Medicare Part A.

\(^{15}\) A CAH is an entity designated as such by the Centers for Medicare & Medicaid Services based on their rural location and provision of access to critical care. CAHs are paid by Medicare on cost basis.
We also identified the types of patients receiving physician-administered drugs at hospitals identified as potentially acquiring physician practices. Cancer patients represented by far the largest share (35 percent, on average) of all patients receiving drug administration in an acquisition month, followed by patients with blood diseases (19 percent, on average) and patients with musculoskeletal system and connective tissue diseases (11 percent, on average).

Even though the hospitals identified as potentially acquiring physician practices account for only 3 percent of all hospitals included in the study, they represent 12 percent of the total value of medicines infused at hospitals as reflected by total Medicare payment amounts for claims with drug administration over the 2009-2013 period.

Limitations

Publicly available data do not allow for the identification of the acquisition of physician practices at the individual hospital level. As such, we developed a methodology to estimate hospital acquisition of physician practices by identifying increases in monthly volume of patients receiving drugs in the HOPD above a certain threshold. There are several reasons for patient volume shifts at a hospital not associated with physician practice acquisition. These include: physicians exiting a given local market; potential changes in the types of pharmaceuticals being administered including differential use of newly launched products; shifts in patient care patterns (e.g. more patients being treated in the hospital outpatient department than inpatient); and other market consolidation issues.

It is possible that these patient volume trends interact with 340B program incentives as well. For example, many 340B hospitals operate in lower-income areas, where community physicians may be less likely to administer higher cost products for fear of not being able to collect cost sharing from patients. This would suggest that 340B hospitals could see an increase in patient volume due to the launch of a new product if the hospital outpatient setting is the only place where patients can obtain the therapy. Finally, this analysis was not able to establish if the drug administration was provided on the campus of the hospital or at an off-site location. This information is needed to draw a direct relationship between a practice acquisition and enrollment of an additional outpatient site in the 340B program. Notably, per the FY2015 Outpatient Prospective Payment System (OPPS) final rule, the Centers for Medicare & Medicaid Services (CMS) has stated it will start collecting information regarding off-campus, provider-based clinics as a site of care for hospital outpatient services at some point in 2015.16

16 79 FR 66910. November 10, 2014; [Link]
Conclusion

This analysis found that 61 percent of hospitals identified as potentially acquiring physician practices between 2009 and 2013 participated in the 340B Program. This 61 percent 340B participation rate among the acquiring hospitals is higher than the overall 45 percent 340B participation rate among all hospitals in the study. It is beyond the scope of this study to determine whether 340B itself is contributing to physician practice acquisitions. However, the results suggest that policy makers may want to consider whether the 340B program creates financial incentives for hospitals to acquire a community-based physician practice.
Appendix:

METHODOLOGY

Due to the lack of publicly available information on practice ownership changes, Avalere developed a methodology to estimate hospital acquisitions by analyzing monthly volume of Medicare fee-for-service (FFS) patients receiving infused or intravenous drug administration in the HOPD. The methodology assumes that significant increases in patient volume from month to month may indicate hospital-physician practice consolidation.

Avalere used the 100 percent Medicare Outpatient Standard Analytic Files (SAF) to assess the monthly volume of Medicare patients with claims submitted by each HOPD in the United States for drug administration between January 2009 and December 2013. The analysis included only hospital entity categories eligible for 340B participation: DSH, CAH, children’s hospitals (PED), sole community hospitals (SCH), rural referral centers (RRC), and free-standing cancer hospitals (CAN). We did not exclude for-profit hospitals from the analysis. In total, 4,865 hospitals were identified that were both in a 340B-eligible category and administered some infusion medicines outside the emergency department (ED) of the hospital.

For this analysis, all hospital outpatient visits for drug administration were included except visits where drugs were administered in the hospital’s ED. For each hospital, the monthly volume of patients receiving drug infusion was calculated and adjusted based on the number of weekdays in each month and year of the analysis to normalize the data. Further, patients were categorized based on the disease category as reflected by the 18 rolled-up Clinical Classifications Software (CCS) categories calculated using the primary diagnosis recorded by the hospital during drug administration. The percent change in the adjusted monthly patient volume was calculated by comparing a given month to the average from the previous 6 months. Hospitals’ data were excluded from the analysis when the hospital had fewer than 10 patients receiving drug administration in a month and/or when the average from the prior 6 months was less than 10 patients. Average national and average hospital referral region (HRR) percent changes in monthly patient volume receiving infused or intravenous drug administration in the HOPD also were calculated to account for national trends in patient volume (e.g., changes in care-delivery patterns, new drugs on the market) as well as trends specific to the hospital’s local market (e.g., hospital mergers, seasonality of the patient flow).

Hospitals were identified as having a potential acquisition of a physician practice when the adjusted monthly volume of patients receiving drug administration increased 5 times over both the national and the HRR average increase for the same month. The 5-fold increase requirement was selected upon analysis of the data.

17 HCPCS/CPT codes for drug administration “96360” thru “96549” present in any position on the claim.
18 Claims were removed where the revenue code was ‘045x’ or 0981, which indicates ED visit. We were unable to differentiate between ED visits that resulted in admissions versus those that did not, therefore we decided to exclude all those cases from the analysis.
19 The Clinical Classifications Software (CCS) was developed as part of the Healthcare Cost and Utilization Project (HCUP); Link
20 The Dartmouth Atlas Of Health Care; Link
distribution with the goal of setting a conservative threshold to indicate likely hospital acquisition of a physician practice. In total, 143 hospitals were identified as potentially acquiring a physician practice using these criteria. Hospitals were excluded from the analysis that did not maintain a constant (±10 percent) new level of patients 6 months after assumed acquisition and hospitals whose percent change in patient volume fell below the average for all hospitals identified as having a potential acquisition. Detailed findings describing the number of hospitals identified after each analytical step are shown in the appendix table.

Table 1: Number of Hospitals Identified as Acquiring Physician Practices

<table>
<thead>
<tr>
<th>Analytical Steps</th>
<th>Number of Hospitals (Unique Entities Defined by the Medicare Provider Number)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inclusion in the analysis based on the facility type and drug administration requirements</td>
<td>4,865</td>
</tr>
<tr>
<td>Total hospitals identified as potentially acquiring a physician practice</td>
<td>143</td>
</tr>
<tr>
<td>340B hospitals identified as potentially acquiring a physician practice</td>
<td>87</td>
</tr>
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Source: Avalere Health analysis of 2009-2013 100% Outpatient Hospital SAF and the 340B Database.

Finally, the 340B participation status was determined for the identified hospitals to test if there was any relationship between 340B participation and potential physician practice acquisition. The date of 340B participation also was assessed to determine whether a hospital was participating in 340B before, during, or after the month in which it was identified as having a substantial increase in patient volume.

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21 A 10-fold increase was also analyzed and the similar number of hospitals was identified (116) as with the 5-fold increase suggesting that the latter threshold is conservative enough.