340B GROWTH AND THE IMPACT ON THE ONCOLOGY MARKETPLACE

WHITE PAPER | SEPTEMBER 2015
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This study was funded by Community Oncology Alliance with support through educational grants from Bristol-Myers Squibb and Pharmaceutical Research and Manufacturers of America (PhRMA).
Since May 2015, government agencies have issued a number of significant reports and guidance notices pertaining to the 340B program. In May, the Medicare Payment Advisory Committee (MedPAC) published a report on growth in the 340B program and noted that almost 45 percent of acute care hospitals now participate in the 340B program. The Government Accountability Office (GAO) issued a report in June highlighting that in 2012, 340B-enrolled hospitals received more than twice the amount of Medicare Part B hospital outpatient drug reimbursement on a per-beneficiary basis than non-340B hospitals. The report expressed concern that the profits realized by 340B hospitals on separately payable drugs purchased through the 340B program (including many oncology drugs) may be incentivizing these hospitals to use more expensive drugs and increase utilization of Part B drugs. In response to this report, Senator Chuck Grassley requested the Senate Finance Committee to hold a hearing on the 340B program. Most recently, the Department of Health and Human Services issued its long-anticipated "mega guidance" on the 340B program and explicitly addressed some 340B hospitals’ methods for increasing chemotherapy infusions of 340B purchased drugs.

In light of this renewed focus on the 340B program, and with the acknowledgement that oncology drugs in particular play a significant role in the 340B program, this report seeks to understand the following:

- Historical growth in the 340B program along alternative dimensions such as percentage of hospital outpatient revenue at 340B hospitals
- Current size of the 340B program based on Medicare Part B hospital outpatient drug spend
- Percentage of Part B drug spend at 340B hospitals attributable to oncology drugs
- Historical growth in Part B oncology drug spend at 340B hospitals versus non-340B hospitals
- Medicare Part B oncology drug reimbursements to 340B hospitals and community oncology practices

Using a combination of Medicare fee-for-service (FFS) hospital outpatient claims, Medicare FFS physician office claims, hospital cost reports, and Office of Pharmacy Affairs (OPA) data, the authors developed a set of analyses to address each of the objectives noted above. We observed the following:

- Hospitals enrolled in the 340B program received 58 percent of total Medicare Part B hospital outpatient drug reimbursement in 2013 and over 60 percent of Part B reimbursement for oncology drugs, up from 43 percent and 47 percent, respectively, in 2010
- Historical growth in the 340B program is a function of both newly enrolled 340B entities and expansion of hospital outpatient operations at existing 340B entities
  - Hospitals newly enrolled in the 340B program since 2010 account for almost 23 percent of the total Medicare Part B hospital outpatient drug spend at 340B hospitals in 2013
  - Between 2010 and 2013, the percentage of total hospital outpatient revenue at 340B disproportionate share hospitals (DSH) increased from 37 percent to 40 percent, even though the count of total 340B DSH hospitals remained almost unchanged
- 340B hospitals realized a 123 percent increase in Part B reimbursement for oncology drugs between 2010 and 2013, compared to just 31 percent at non-340B hospitals, while reimbursement to physician offices declined by 5 percent

2 GAO, Medicare Part B Drugs: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals (June 2015).
340B hospitals receive over 50 percent more Part B oncology drug reimbursement per beneficiary per day than community oncology practices.

These results suggest that the 340B program is significantly larger than commonly understood and will likely continue to grow over the next five years. Much of the growth in the 340B program over the last five years has been concentrated in oncology drugs, and the shift in site of care from the physician office to hospital outpatient setting is being driven in large part by 340B hospitals. This has significant cost implications for patients and payers due to the higher per-beneficiary per-day reimbursements when patients are treated in hospital outpatient departments versus physician offices.

Current Size of the 340B Program

The 340B program provides steeply discounted drug pricing to a variety of participants known as “covered entities.” Covered entities can generally be grouped into two categories: federal grantees (Ryan White clinics, community health centers, tuberculosis centers, etc.) and hospitals. Hospitals account for 85 to 90 percent of all 340B purchases; as a result, estimates of the size of the 340B program are often presented in terms of hospital-based metrics. For example, in its May 2015 report, MedPAC observed that in 2014 about 45 percent of all Medicare acute care hospitals participated in the 340B program. Although there are a variety of different ways to measure the size of the 340B program, this study focuses on two hospital outpatient metrics: hospital outpatient revenue and Medicare Part B drug reimbursement. We have chosen to focus on these metrics for a combination of reasons:

- Hospitals account for about 90 percent of total 340B purchases, and the vast majority of recent growth in the 340B program is attributable to hospital utilization
- The 340B program is limited to outpatient utilization
- Medicare claims data allows for detailed analysis of drug utilization and reimbursement trends

Using hospital cost report data published by the Centers for Medicare and Medicaid Services (CMS), we analyzed hospital outpatient revenue from 2010 through 2013 at 340B-enrolled DSH and non-DSH hospitals, as well as non-340B-enrolled hospitals. Figure 1 depicts how 340B DSH hospitals have grown from 12 percent of hospital outpatient revenues in 2003 to almost 40 percent in 2013. When considering all 340B hospitals (i.e., including critical access, sole community, pediatric, and cancer hospitals), this percentage increases to 47 percent for 2013. This provides a different perspective from the commonly cited figure that the 340B program accounts for just 2 percent of total U.S. drug spend.

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4 Community Oncology Alliance, Community Oncology Practice Impact Report (October 21, 2014); Avalere Health LLC, Hospital Acquisitions of Physician Practices and the 340B Program (June 2015).
7 See Appendix B for a description of our methodology for categorizing hospitals.
At 40 percent, 340B-enrolled DSH hospitals account for a much larger percentage of hospital outpatient revenue than the percentage of total acute care hospitals that they represent (22 percent in 2013). This implies that, on average, 340B DSH hospitals have larger outpatient facilities than their non-340B counterparts, and this gap is widening.

Looking at the scope of the 340B program in terms of hospital outpatient revenue is more targeted than simply evaluating the percentage of all hospitals that participate in the 340B program, because it focuses solely on the outpatient facilities eligible to purchase 340B drugs. However, this metric can still be diluted, because hospital outpatient operations encompass far more than just drug purchases. Analyzing Medicare FFS hospital-outpatient Part B drug reimbursement provides an even more precise estimate of 340B program participation by hospitals, because it focuses more narrowly on drug utilization. Figure 2 reveals that hospitals enrolled in the 340B program received over 58 percent of Medicare Part B hospital outpatient drug reimbursements in 2013. This percentage increases to over 60 percent when looking exclusively at oncology drugs, and both of these metrics have grown significantly since 2010. It is important to note that a small percentage of the Medicare Part B drug reimbursements to 340B hospitals were for drugs purchased outside of the 340B program, due to a small number of orphan drug and dual eligible purchases made at non-340B prices. However, the percentages included in Figure 2 provide useful context for the relative size of the hospitals that participate in the 340B program when considering total purchase volume of outpatient drugs.

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9 See Appendix B for a detailed description of our methodology for calculating Medicare hospital outpatient Part B drug spend at 340B and non-340B hospitals.

10 This figure differs significantly from MedPAC’s May 2015 Report to Congress on 340B, which estimated that 48% of Medicare Part B hospital outpatient drug reimbursements were for 340B purchased drugs. Over 70% of the variance between our estimate (58%) and the MedPAC estimate (48%) is attributable to our inclusion of orphan drugs purchased by entities eligible through ACA, which MedPAC excluded. The remaining difference is attributable to MedPAC’s exclusion of dual eligible utilization for those entities not listed on the Medicaid Exclusion File, which we included.

11 In 2013, about 30% of hospitals, when weighted by total Medicare Part B drug reimbursement, excluded the Medicaid population from 340B purchases. Dual eligibles (i.e., beneficiaries enrolled in both Medicare and Medicaid) account for about 6% of Medicare beneficiaries, so the dual eligibles may account for about 1.8% (0.3 * 0.06 = 0.018) of total Medicare Part B drug reimbursement to 340B hospitals.
Figures 1 and 2 demonstrate a clear growth trend in the size of the 340B program, and this growth has been well documented in other studies. Apexus, the 340B prime vendor, has published statistics on total 340B drug purchases that estimate the 340B program grew from $6.0 billion in drug purchases in 2010 to $7.5 billion in drug purchases by 2013, a 25% increase.12 Our own research of manufacturer 340B chargeback data suggests that the growth rate in 340B gross sales between 2009 and 2012 exceeds 50%.13 Regardless of the specific metric of growth one evaluates, research into the 340B program and the oncology marketplace in particular suggests that 340B program growth is a function of both newly enrolled 340B hospitals and the expansion of hospital outpatient facilities at existing 340B hospitals.

**Impact of Newly Enrolled Entities**

The Affordable Care Act (ACA) created new eligibility pathways in the 340B program for critical access hospitals, sole community hospitals, rural referral centers, pediatric hospitals, and freestanding cancer hospitals. At the same time, non-profit and government hospitals were achieving 340B eligibility as a result of increases to their DSH percentage. Figure 3 shows cumulative enrollment of newly eligible 340B hospitals from 2010 through 2014. Over 1,500 additional hospitals have enrolled in the 340B program since 2010, with the majority being non-DSH hospitals.

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To better understand how significant the addition of these new hospitals is to overall growth in the 340B program, we analyzed 2013 Medicare FFS hospital-outpatient drug reimbursements to all hospitals enrolled in the 340B program as of December 31, 2014. We segmented these Part B reimbursements into two groups: those made to hospitals that had enrolled in the 340B program by at least December 31, 2009, and those enrolled in the 340B program since January 1, 2010. Figure 4 shows that over 23% of all 2013 Medicare Part B drug reimbursements to 340B covered entities were to hospitals that have enrolled in the 340B program since January 1, 2010.
Even though DSH hospitals made up only 20 percent of the newly enrolled entities, they account for 37 percent of the 2013 Medicare Part B drug reimbursements to newly enrolled 340B hospitals. This is important, because as Medicaid expansion unfolds over the next several years, additional DSH hospitals will become 340B eligible, and these hospitals clearly drive higher volumes of drug reimbursement.\(^\text{14}\) We have previously published estimates that as many as 350 hospitals may become 340B eligible as a result of Medicaid expansion.\(^\text{15}\) This dynamic is already playing out in recent 340B DSH hospital registrations. There were 47 new enrollments of 340B DSH hospitals in 2015. Of these hospitals, 60% experienced an increase in their Medicaid inpatient days between 2013 and 2014, and this percentage is likely to rise as more data becomes available. The growth in Medicaid inpatient days is almost certainly attributable to Medicaid expansion and contributes directly to these hospitals’ 340B eligibility.

**Expansion at Existing 340B Hospitals**

340B hospitals realize substantial margins on Medicare and commercial reimbursement of separately payable drugs purchased at the discounted 340B price. This has led to 340B hospitals expanding outpatient facilities and increasing claims volume for procedures that typically include a sizeable drug reimbursement. Chemotherapy for cancer patients is often one of the largest (if not the largest) therapeutic areas in terms of drug reimbursement, and 340B hospitals have actively expanded the scope of their oncology departments. Several studies have documented the shift in Medicare FFS chemotherapy claims from the community to the hospital outpatient setting, and our most recent analysis indicates that hospital outpatient departments accounted for almost 35 percent of all chemotherapy claims in 2013, up from 21 percent in 2010.\(^\text{16}\) We have also published research on 340B hospital acquisitions of community oncology practices and found that these acquisitions more than double the size of the acquiring hospitals’ oncology services, and that DSH hospitals are driving this acquisition activity.\(^\text{17}\) Building on this research into the shift in site of care, we observed that total Part B drug reimbursements for oncology drugs to 340B hospitals increased by 123 percent from 2010 to 2013 while increasing only 31 percent to non-340B hospitals and decreasing by five percent to community oncology clinics over the same time period.

The focus on expansion of hospital outpatient facilities that specialize in drug administration (e.g., oncology clinics) by 340B hospitals is evident through analysis of hospital cost reports and Medicare FFS hospital outpatient claims data. When measuring growth in hospital outpatient revenues at both hospitals continuously enrolled in the 340B program from 2010 to 2013 and hospitals not enrolled in the program during this time period, we found that 340B hospitals grew by 32 percent compared to 30 percent growth at hospitals not enrolled in the 340B program (see Figure 5). Although 340B hospitals grew at a slightly higher rate, there is not an appreciable difference between the two groups of hospitals.

### Figure 5

<table>
<thead>
<tr>
<th>Year</th>
<th>Non-340B Hospitals</th>
<th>340B Hospitals</th>
</tr>
</thead>
<tbody>
<tr>
<td>2010</td>
<td>425,723,386,299</td>
<td>304,092,115,596</td>
</tr>
<tr>
<td>2011</td>
<td>470,158,081,696</td>
<td>335,962,571,493</td>
</tr>
<tr>
<td>2012</td>
<td>519,093,607,956</td>
<td>368,865,321,114</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>$1,968,707,555,467</strong></td>
<td><strong>$1,411,143,374,508</strong></td>
</tr>
</tbody>
</table>

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14 DSH eligibility is a function of the percentage of Medicaid inpatient days and indigent Medicare inpatient days. As the Medicaid population increases, the percentage of Medicaid inpatient days also increases, which results in newly eligible DSH hospitals.


17 Vandervelde (2014b).
However, the difference between 340B and non-340B hospitals is significant when evaluating the relative growth in oncology drug reimbursement. Figure 6 shows that Medicare Part B oncology drug reimbursement has increased by 86 percent at continuously enrolled 340B hospitals and 58 percent at non-340B hospitals. Although some of this growth is a function of changing demographics and advancements in chemotherapy (which typically come with an increased cost), the disparity in growth rates between 340B and non-340B hospitals speaks to the disproportionate role that 340B hospitals play in the acquisition of community oncology practices. Other studies of hospital acquisitions of community oncology clinics have also demonstrated the outsized role of 340B hospitals in community oncology practice acquisitions.18 This is, in large part, a function of the sizeable profits that 340B hospitals realize on Medicare and commercial reimbursement of oncology drugs.

The shift in site of care comes at a considerable cost to payers and patients due to the higher reimbursement rates in the hospital outpatient versus physician office setting. As noted in several studies, these higher reimbursement rates apply both to the administration of the chemotherapy and the drug reimbursement itself.19 However, differences in reimbursement rates are likely not the only factor that drive increased costs in the hospital outpatient setting. The GAO study found that 340B hospitals received over twice as much Medicare Part B drug reimbursement on a per-beneficiary basis than non-340B hospitals. We evaluated a similar metric, Medicare Part B drug reimbursement on a per-beneficiary per-day basis, and found that in 2013 340B hospitals received 50 percent more Medicare Part B drug reimbursement than physicians practicing in the community setting.20 Figure 7 shows how this comparison has evolved over time.

<table>
<thead>
<tr>
<th>Year</th>
<th>Non-340B Hospitals</th>
<th>340B Hospitals</th>
</tr>
</thead>
<tbody>
<tr>
<td>2010</td>
<td>494,857,666</td>
<td>529,523,686</td>
</tr>
<tr>
<td>2011</td>
<td>633,261,549</td>
<td>690,619,055</td>
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<tr>
<td>2012</td>
<td>761,639,096</td>
<td>861,242,864</td>
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<tr>
<td>2013</td>
<td>781,957,318</td>
<td>982,641,086</td>
</tr>
<tr>
<td>Total</td>
<td>$2,671,715,630</td>
<td>$3,064,026,692</td>
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</tbody>
</table>

18 Community Oncology Alliance (2014); Avalere Health LLC (2015).
20 See Appendix B for a detailed description of our methodology for calculating per-beneficiary per-day Part B oncology drug reimbursement.
These data suggest that the shift in site of care from the physician office to the hospital outpatient department leads to increased costs because of both higher reimbursement rates and higher utilization rates. And, as noted above, this shift in site of care is being driven predominantly by 340B hospitals that realize significant profits on these drug reimbursements.

Other Indicators of Growth

Analysis of Medicare Part B drug reimbursements covers a large part of the 340B program (i.e., physician-administered drugs), but it does not provide perspective on growth of retail and specialty pharmacy 340B drug utilization. This is becoming an increasingly important aspect of the 340B program as two related trends evolve. First, there has been an increase in the volume of specialty retail drugs, with the most notable of these being in the hepatitis C and oral oncology therapeutic areas. Recent reports suggest that oral oncolytics account for as much as 30 percent of the oncology pipeline and the breakthrough therapies for hepatitis C will further support development of similar drugs. Second, there has been a rapid increase in the number of covered entities contracting with specialty and mail-order pharmacies. The specialty pharmacy marketplace is highly concentrated, and our experience suggests that the six largest specialty pharmacies fill 80 percent to 90 percent of specialty drug prescriptions. This is significant because 340B entities can capture larger volumes of prescriptions at a 340B price, per contract pharmacy arrangement, in a more concentrated market. Using 340B contract pharmacy data from OPA, we isolated registrations of contract specialty and mail-order pharmacies from retail pharmacies and trended these registrations over time. Figure 8 demonstrates the rapid growth in 340B contract specialty pharmacy arrangements since 2013, with the total number of covered entities contracting with at least one specialty or mail-order pharmacy increasing by a factor of 4 between January 2013 and April 2015.


See Appendix B for a detailed description on our methodology for identifying specialty and mail-order pharmacies.
As 340B covered entities generate incremental profits through these contract specialty pharmacy arrangements, the trend of 340B hospitals acquiring oncology practices will be further reinforced. These oncology practices are the source of a large percentage of specialty drug prescriptions (i.e., oral oncolytics) and generate additional profits for the 340B covered entity when contract specialty pharmacies fill these prescriptions. This creates a mutually reinforcing relationship between oncology practice acquisitions and contract specialty pharmacy arrangements, which will further support the trend in acquisition activity by 340B hospitals for years to come.

### Conclusion

The 340B program has grown significantly over the last five years. ACA, contract pharmacy expansion, and oncology practice acquisitions by 340B hospitals have all contributed to this growth. However, this study reveals that the 340B program is even larger than previously understood, with 58 percent of all Medicare Part B hospital outpatient drug reimbursement made to 340B-enrolled hospitals in 2013. Furthermore, the program is poised to grow even larger as more DSH hospitals become 340B eligible due to Medicaid expansion, covered entities expand their contract pharmacy programs to capture specialty drugs, and DSH hospitals continue acquiring community oncology practices.

The oncology marketplace is particularly impacted by trends in the 340B program. In 2013, oncology drugs accounted for over 40 percent of Medicare FFS Part B hospital outpatient drug reimbursement to 340B hospitals. This is partially a function of 340B hospitals’ acquisitions of community oncology practices. The trend in acquisitions, driven in part by the opportunity for sizable profits on the reimbursement of expensive oncology drugs, will be further supported by the inclusion of specialty pharmacies in these entities’ contract pharmacy networks, which will generate even more drug profits. As more oncology-
related encounters are shifted out of the physician office setting and into hospital outpatient departments, costs to patients and payers (including Medicare) will increase due to both higher reimbursement rates in the hospital outpatient setting and greater drug utilization by 340B hospitals compared to both non-340B hospitals and community oncologists.
Appendix A

In order to conduct the analyses presented in this report, we used the following data sets:

**Medicare Outpatient Limited Data Set (LDS) for 2010 to 2013:** These data sets provide 100 percent of Medicare FFS claims submitted by institutional outpatient providers. These data sets were used to:

- Identify total Medicare hospital outpatient chemotherapy claims over time
- Calculate the Medicare payments and Medicare Beneficiary payments on claims provided in hospital outpatient departments at the claim level

**Medicare Carrier Limited Data Sets (LDS) for 2010 to 2013:** These data sets are also known as the Medicare 5 percent Carrier Files or the Physician/Supplier Part B Claims Files. They contain a 5 percent sample of fee-for-service claims submitted on a CMS-1500 claim form, primarily by non-institutional providers. These data sets were used to:

- Identify total physician office chemotherapy claims over time
- Calculate the Medicare payments and Medicare Beneficiary payments on chemotherapy claims provided in physician offices at the encounter level

**CMS Hospital Cost Reports:** These reports provide detailed financial information on all acute care hospitals that receive reimbursement from CMS for healthcare services provided to Medicare FFS beneficiaries. These reports were used to:

- Identify acute care hospitals
- Calculate total hospital outpatient revenue at acute care hospitals over time

**OPA 340B Covered Entity Database:** This database includes registration information for 340B covered entities including the timing of the registration and the eligibility pathway (e.g. DSH hospital, Ryan White clinic, etc.) used for the registration. This database was used to:

- Identify 340B hospitals over time and distinguish between DSH, critical access, sole community and free standing cancer hospitals
- Link 340B covered entities to 340B contract pharmacy registrations

**OPA 340B Contract Pharmacy Database:** This database includes registration information for 340B contract pharmacies including the timing of the registration and the name of the pharmacy. This database was used to:

- Distinguish between retail, mail-order, and specialty contract pharmacies
- Calculate the number of covered entities contracting with retail pharmacies and mail-order or specialty pharmacies over time
Appendix B

This section describes in more detail the methodology used to conduct the analyses presented in this report. Specific topics include:

- Definition of a 340B covered entity
- Definition of an oncology drug
- Definition of an oncology claim

**Definition of a Covered Entity**

We relied on the OPA covered entity database to identify 340B covered entities. 340B hospitals included all covered entities that registered in the 340B program with a covered entity type of DSH, CAH, SCH, RRC, PED, CAN, or RRC. 340B grantees included all entity types not included in the 340B hospital category.

For analyses that presented covered entity statistics on an annual basis, we included covered entities registered at any point during the calendar year. When categorizing a Medicare FFS claim as originating from a 340B-covered entity, we compared the date of service on the claim with the specific registration period of the covered entity. For example, if an actively enrolled covered entity registered in the 340B program on July 1, 2011, then claims with dates of service prior to July 1, 2011, are considered non-340B claims, and claims on or after July 1, 2011, are considered 340B claims.

**Definition of an Oncology Drug**

To calculate Medicare FFS hospital outpatient Part B drug reimbursement for oncology drugs, we included all HCPCS codes in the range from J9000 to J9999. This is a conservative methodology that excludes many drugs (e.g., anti-emetics) frequently used in combination with chemotherapy, as well as oncology drugs that are reimbursed using a temporary code prior to the issuance of a J9XXX code.

**Definition of a Chemotherapy Claim**

For purposes of this study, we defined chemotherapy claims within the Medicare Outpatient LDS as claims with bill type 131 or 851 (interim and adjusted claims excluded) with chemotherapy administration codes and a diagnosis of cancer. Chemotherapy claims in the 5 Percent Medicare Carrier File were also identified by the presence of a chemotherapy administration code and a diagnosis of cancer. Chemotherapy administration codes include therapeutic infusions of chemotherapy drugs and other IV hydration infusions in the CPT code range from 96360 to 96549.

A diagnosis of cancer includes both primary and secondary ICD-9 diagnosis codes in the following ranges:

<table>
<thead>
<tr>
<th>Description</th>
<th>ICD-9 Diagnosis Codes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cancer</td>
<td>140-239</td>
</tr>
<tr>
<td>Thrombocytopenia</td>
<td>287.30, 287.31, 287.39, 287.49</td>
</tr>
<tr>
<td>Neutropenia</td>
<td>288.00, 288.02, 288.03, 288.09</td>
</tr>
<tr>
<td>Lymphadenitis</td>
<td>289.1, 289.2, 289.3, 289.53, 289.83, 289.89</td>
</tr>
<tr>
<td>Encounter for chemotherapy</td>
<td>V07.2, V07.39, V58.11, V58.12</td>
</tr>
<tr>
<td>Personal History of Cancer</td>
<td>V10.00-V10.91</td>
</tr>
</tbody>
</table>
About the Author

Aaron Vandervelde
Aaron Vandervelde has over 12 years of experience providing strategy, health policy and litigation consulting services to clients in the healthcare 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 healthcare entities and with the federal government. Specifically, he focuses on deriving strategic insight through the integration and analysis of large, complex data sets including claims data, risk adjustment data, internal and external sales data and publicly available health data.

Mr. Vandervelde’s practice is focused primarily on clients across the healthcare continuum, including Fortune 500 health insurers, pharmaceutical manufacturers and biotech companies, PBM’s, and others. He has advised clients in a variety of federal investigations, contract disputes, litigation, and strategic health policy analyses.

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