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The 340B Drug Discount Program in Review:

A Look at the Data and Evidence to Date

Over 15 Years *of* Making a Difference in Cancer Care

Since its inception, the 340B Drug Discount Program has been the subject of countless research studies, white papers, and analyses looking at its substantial growth and role in the United States' health care system. This paper seeks to provide a review of the data and evidence provided by studies of the 340B program to better understand how it has changed over the last 25 years. A necessary and important program for America's most vulnerable patients, 340B has morphed into a substantial profit-generating program for most hospitals that is very different from the noble, original program intended to help patients in need.

A series of legislative missteps has been responsible for the tremendous growth of the 340B program in hospitals. Most of these hospitals make tremendous profits from the program; provide incredibly low levels of charity care; are much more expensive for patients and taxpayers; and are shrinking our nation's cancer care system. 340B has become a classic case of well-intentioned policy causing unintended consequences that adversely affect patient care.

340B is a Good Idea

340B is a federal program that requires drug manufacturers to provide outpatient drugs at significantly reduced prices to eligible health care organizations, known as covered entities, that are supposed to treat high numbers of indigent and uninsured patients. Eligible participants include non-profit hospitals, community health centers, Ryan White HIV/AIDS clinics, black lung clinics, and other designated facilities that treat indigent and uninsured patients. The original concept of the 340B program was that by providing access to deeply discounted drugs (upwards of 50 percent), participants would be able to use savings to provide needed services and medication for the indigent, uninsured, and underserved patient populations they treat.

What Went Wrong?

When it started, the 340B program was aimed at a very small subset of safety-net providers. According to a report by the Medicare Payment Advisory Commission (MedPAC) to Congress, 340B grew very slowly to include just 583 participants after its first 13 years of existence (1992 – 2005).

Since then, however, 340B has exploded, with most of the growth being driven by hospitals.[1] By 2014 there were 2,140 hospitals participating in 340B, a 367 percent increase in just nine years after the Medicare Modernization Act (MMA).

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Today approximately 45 percent of all acute care hospitals participate in the 340B program. [2]

The catalyst for the explosive growth of hospitals in 340B was the passage of the MMA, which was signed into law in late 2003. The MMA fundamentally changed reimbursement for Medicare Part B prescription drugs (those drugs administered by physicians in clinics, hospitals, and other clinical settings) from 95 percent of Average Wholesale Price (AWP) to Average Sales Price (ASP) plus 6 percent.[3]

The shift from AWP to ASP-based reimbursement significantly lowered drug reimbursement for everyone in Part B. However, hospitals soon discovered that the 340B program gave them a loophole that actually allowed them to realize substantial profits from Part B drugs. Hospitals that would have seen significant decreases in payments under the new ASP-based system offset those losses by joining the 340B program and gaining access to tremendously discounted drugs.

At the same time, the severe MMA reimbursement cut forced a significant number of oncology practice closures and mergers into hospital systems. 340B hospitals seized on the

opportunity provided by financial pressures on physician-run community cancer clinics by actively pursuing acquisitions of these providers. 340B hospitals realized the profit to be made by taking advantage of the shutdown or acquisition of their competition: local community cancer clinics. This enabled hospitals to increase the volume of high-cost, high-profit chemotherapy drugs they could deliver in 340B.

Illustrating this trend is Medicare data analyzed by the actuarial firm Milliman in 2016. It shows that from 2004-2014 the proportion of chemotherapy infusions delivered in hospital outpatient departments nearly tripled, increasing from 15.8 to 45.9 percent in the Medicare population. For the commercially insured population, the increase was much more dramatic, going from 5.8 to 45.9 percent. In the Medicare population, the portion of chemotherapy infusions administered in 340B hospital outpatient departments increased by 770 percent rising from 3.0 to 23.1 percent. As of 2014, 340B hospitals accounted for 50.3 percent of all hospital outpatient chemotherapy infusions among the Medicare population.[4]

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340B is Consolidating America's Cancer Care System into Hospitals

In a 2015 white paper examining the rapid growth of the 340B program, Berkeley Research Group (BRG) noted that chemotherapy for cancer patients is often one of the largest, if not the largest, therapeutic area in terms of drug reimbursement, and further states that 340B hospitals have actively expanded the scope of their oncology departments to capitalize on this.[5]

The oncology marketplace is particularly impacted by trends in the 340B program. The same BRG white paper revealed that in 2014, oncology drugs accounted for over 42 percent of Medicare fee for service Part B hospital outpatient drug reimbursement to 340B hospitals.[6] In 2016, Milliman found that 340B hospitals accounted for 50.3 percent of all hospital outpatient chemotherapy infusions in the Medicare population, as of 2014.[7]

> **74.5 percent of the acquisitions of community oncology clinics were by hospitals with 340B drug discount pricing.[9]**

The consolidation of community oncology practices into hospital systems has been studied using actual Medicare data. The 2013 analysis by the Moran Group found that physician-owned community oncology clinics administered 87 percent of chemotherapy in 2005. By the end of 2011, chemotherapy administration by community oncology clinics fell to 67 percent, with 33 percent then being administered in outpatient hospital settings.[8]

The Community Oncology Alliance's 2016 Practice Impact Report found that, in the previous two years, 74.5 percent of the acquisitions of community oncology clinics were by hospitals with 340B drug discount pricing.[9]

340B Hospitals Increase Spending on Drugs

Community oncology practices provide cancer care for almost 55 percent of all cancer patients in the United States. One of the hallmarks of community cancer care is the attention to drug costs. To control costs for the patient as well as the health care system, these practices develop cancer treatment protocols that provide the best possible care while limiting drug costs. This is in contrast to research showing that 340B hospitals increase spending on drugs.

An extensive 2015 analysis in the peer-reviewed Food and Drug Law Journal concluded that covered entities have been abusing the 340B Program, unjustly enriching themselves by manipulating the program to serve their financial interests at the expense of drug manufacturers and patients.[10]

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> ***— from the Government Accountability Office***

In 2015, the Government Accountability Office (GAO) reported that in both 2008 and 2012, per beneficiary Medicare Part B drug spending, including oncology drug spending, was substantially higher at 340B DSH hospitals than at non-340B hospitals. This indicates that, "… on average, beneficiaries at 340B DSH hospitals were either prescribed more drugs or more expensive drugs than beneficiaries at the other hospitals in GAO's analysis."[11]

The GAO report also found that, "… there is a financial incentive at hospitals participating in the 340B program to prescribe more drugs or more expensive drugs to Medicare beneficiaries." Unnecessary spending has negative implications, not just for the Medicare program, but for Medicare beneficiaries themselves, who are financially liable for larger copayments when they receive more or more expensive drugs.[12]

Researchers – and even the hospitals themselves – admit that one reason for this rapid growth is the additional revenue that hospitals can realize from deeply discounted 340B drugs.[13] In the program, covered entities can purchase drugs for all eligible patients – including patients with Medicare and fully covered by private insurance – at the 340B discounted price. Today, 340B hospitals are opening up in suburban areas where patients predominantly have private insurance, yet the 340B discounts still apply.[14] This deep margin is another way that tax-exempt 340B hospitals are able to make a substantial profit.

340B Hospitals Provide Negligible Charity Care

A 2016 study by BRG, determined that despite the rapid growth in 340B hospitals, there has been no corresponding increase in the amount of charity care those hospitals provide. Given that most 340B hospitals qualify for the program in part based on the number of Medicaid and low-income Medicare patients they serve, there is a presumption that these hospitals also provide relatively high levels of charity care – such as free or discounted care to low-income uninsured or under-insured patients. However, studies on the amount of charity care provided by 340B hospitals suggest that many of these hospitals are providing relatively low-levels of charity or uncompensated care.[15]

> **Only 24 percent of 340B hospitals provide 80 percent of all charity care delivered by 340B hospitals, despite representing less than half (45 percent) of all hospital beds in the program.[17]**

The current 340B program includes many hospitals that provide only a minimal amount of charity care. In fact, for approximately 24 percent of the 340B hospitals studied, charity care represents 1 percent or less of hospital patient costs. These hospitals provide a level of charity care that is far below the 3.3 percent national average for all hospitals regardless of 340B status, as revealed in an analysis by Avalere Health in 2014. Moreover, the problem is getting worse – since 2011, the number of hospitals with that low level of charity care has grown more than 50 percent.[16]

A 2016 analysis by Avalere of data from 2014 hospital cost reports found that only a very small number of 340B hospitals account for the bulk of overall charity care provided by 340B hospitals. Only 24 percent of 340B hospitals provide 80 percent of all charity care delivered by 340B hospitals, despite representing less than half (45 percent) of all hospital beds in the program.[17]

Cancer Care in 340B Hospitals Costs Patients & Taxpayers a Lot More

The shift of cancer care out of physician-run community-based oncology practices and into hospital-based or affiliated infusion suites costs the health care system a lot more money.

A 2013 analysis by the Moran Group, found that as more oncology-related encounters are shifted out of the physician office/community oncology practice setting and into hospital outpatient departments, costs to patients and payers (including Medicare) increase. This is 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.[18]

The same Moran study found that chemotherapy days per beneficiary were about 9 to 12 percent higher in the hospital outpatient department than the physician office setting across the 2009 - 2011 period. On a per beneficiary basis, hospital chemotherapy spending was approximately between 25 to 47 percent higher than physician office chemotherapy spending across the same period.[19] In 2012, Avalere found that for patients receiving a full 12 months of chemotherapy, the hospital cost is 53 percent more than in a community practice.[20]

In a landmark 2016 study looking at cost drivers of cancer care, Milliman confirmed that patients who received chemotherapy entirely in the hospital outpatient setting incurred a significantly higher cost than patients whose chemotherapy was delivered entirely in a physician office. For Medicare patients, the difference was $16,208 (34 percent) higher in 2014; for commercially insured patients it was $46,272 (42 percent) higher in 2014. In total, Milliman calculated that the shift of chemotherapy from community oncology practices to hospitals had cost Medicare an extra $2 billion in 2014 alone.[21]

340B Does *Not* Lower Costs for Patients

The 340B program does not require that the savings on drugs be passed on to lower patients' costs. In fact, a 2014 report by the Office of Inspector General (OIG) found that two-thirds of hospitals do not offer the reduced 340B prices to uninsured patients – the very patients 340B was designed to help.[22] For the majority of patients being treated by 340B hospitals their cost of care is not reduced.

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340B Fuels Drug Prices for Everyone

According to a 2014 study in the Journal of the American Medical Association (JAMA), researchers noted that drug manufacturers would likely seek to increase list prices even further to offset discounts – upwards of 50 percent – they incur as a larger number of drug sales become eligible for 340B discounts.[23] For example, a manufacturer pricing a cancer drug at $10,000 list will only realize $5,000 net from 340B hospitals receiving 50 percent discounts. Even worse, 340B hospitals actually benefit when drug prices rise: the $5,000 profit 340B hospitals obtain from a $10,000 list price drug becomes a $5,500 profit when the price rises 10 percent.

> **340B hospitals can even earn more than the drug's manufacturer, due to extreme hospital mark-ups combined with discounted 340B acquisition costs. [25]**

Numerous studies and industry data show that hospitals are profiting from self-defined, grossly inflated list prices for specialty drugs. One study found that hospitals' charges for drugs were marked up 590 percent above the hospitals' costs.[24] A recent analysis of drug benefits spending showed that 340B hospitals can even earn more than the drug's manufacturer, due to these extreme mark-ups combined with discounted 340B acquisition costs.[25]

340B Has Become About Hospital Profits, Not Patient Care

It is clear that many hospitals are entering the 340B program for reasons other than compensation for the charity care they provide.

Highlighting the extent of this problem, the peer-reviewed journal Health Affairs found that in 2012, one 340B entity, Duke University Hospital, "… reported five-year profits of $282 million accrued through its outpatient departments and affiliated clinics as a result of its participation in the 340B program." [26] In response to questions from Sen. Chuck Grassley (R-IA), Duke University Hospital further reported that 340B discounts saved the hospital $48.3 million in 2012, and a total of $158.4 million over 5 years. Meanwhile, only 5 percent of the patients for whom the hospital claimed a 340B discount were uninsured. The other 95 percent had Medicare, Medicaid, or private insurance. [27]

Hospitals themselves have noted that the cost savings on drugs they receive under 340B is a driver toward consolidation or developing affiliations between community-based oncology practices and 340B hospitals.[28] This is not surprising given the upwards of 50 percent discounts 340B hospitals receive on cancer drugs, which equate to 100 percent drug margins. With the average oncologist prescribing more than $4 million in cancer drugs each year, this can represent up to $2 million in pure profit to a hospital's bottom line.

Can the 340B Program Be Fixed?

340B is an invaluable program for community and safety-net providers, including rural hospitals. However, for most 340B hospitals, as documented by the relatively low levels of charity care provided, 340B has become a significant profit generator. Unlike community providers and related entities held to a high level of accountability and transparency in how 340B savings are used to directly help patients in need, 340B in hospitals is a veritable black hole. 340B hospitals can use 340B profits to fund facilities construction and pay CEO salaries and bonuses.

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What is needed to fix the growing and unsustainable 340B is transparency and accountability among 340B hospitals to ensure they are using 340B profits to directly, and solely, help patients in need. A clearer and specific definition of the "340B patient" is also necessary. 340B entities using 340B savings to benefit patient care should not only welcome this transparency and accountability, but should be out front advocating for it. They should want to protect the good they are doing with 340B, not endanger it by misusing the program – especially when that misuse threatens the entire program.

Contrary to misleading claims by 340B hospital advocates that the program only hurts pharmaceutical companies' bottom lines, the facts document that 340B expansion in hospitals is having an adverse impact on patient care and finances, Medicare and taxpayer budgets, and is fueling drug price increases.

ENDNOTES

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About the Community Oncology Alliance

The Community Oncology Alliance (COA) is the only non-profit organization dedicated solely to preserving and protecting access to community cancer care, where the majority of Americans with cancer are treated. COA helps the nation's community cancer clinics navigate a challenging practice environment, improve the quality and value of cancer care, lead patient advocacy, and offer proactive solutions to policymakers. To learn more, visit www.CommunityOncology.org