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EXAMINING THE BENEFITS OF THE 340B DRUG DISCOUNT PROGRAM

ABSTRACT

Introduction: The 340B Drug Discount Program required drug manufacturers provide discounted outpatient drugs to healthcare organizations which serve vulnerable patient populations to allow these institutions to offer more services to more people. As the 340B program expanded, controversy has centered on which entities have benefited from the program. Many healthcare organizations sold 340B drugs to well insured patients at full price, and thus have been financially rewarded. Amendments to the program have permitted 340B providers to utilize contract pharmacies to dispense 340B medication, which has furthered the debate over which stakeholders are benefiting from the program.

Purpose of the Study: The purpose of this study was to determine which stakeholders benefited because of the 340B Drug Discount Program, and what have been the drivers of recent changes to the program.

Methodology: This study utilized a literature review. One database aggregator and 6 academic databases were used to collect 70 total sources. These sources were reviewed and reduced to 39 sources which were used in the written research. Of these, 20 sources were used in the Results section.

Results: Research showed that 340B eligible entities and contract pharmacies have financially benefited from the 340B program. Patient benefit has been indirect, as qualified providers have expanded service offerings and increased access to healthcare services. Regulatory reform, as well as profit potential, have driven the expansion of 340B as more providers have expanded eligible service lines.

Discussion/Conclusion: The 340B program has realized its purpose in allowing healthcare organizations serving vulnerable populations to expand access opportunities to these patient populations through increased capacity and expanded services. While the goal of the 340B program has often been misconstrued, direct financial benefits to eligible providers have allowed for this expansion of access.

Key Words: 340B, drug pricing program, covered entity, 340B eligible, contract pharmacy, disproportionate share.

INTRODUCTION

As many as one third of Americans living at or below 200% of the federal poverty level have struggled to afford even modest prescription drug expenses. (1) The United States (U.S.) government created the Medicaid Rebate Program in 1990 to provide lower income Americans with assistance with prescription drug expenses. (2) However, this law had the unintended consequence of incentivizing drug manufacturers to discontinue charitable discounts to safety-net providers to ensure that average prices were kept high for purposes of establishing Medicaid rebate rates. (3) Thus, in 1992 Congress created the 340B Drug Discount Program (hereinafter 340B) as part of the Veterans Health Care Act of 1992. (4)

340B mandated that drug manufacturers provide discounted outpatient drugs to certain healthcare organizations which provided services to vulnerable patient populations. (5) These “covered entities” had to either receive money from federal grants or be included in one of six categories of hospitals, the most common of which was called a Disproportionate Share Hospital (DSH), meaning that it served a disproportionate share of the vulnerable patient. (2) The stated purpose of the program has been to allow healthcare providers to stretch federal resources so that these providers could offer more services to more patients. (6)

340B pricing has not been applied to generic drugs, but has been applied to over the counter drugs, prescribed by a physician. (7) 340B pricing has been available to over 18,000 U.S. healthcare entities, and has accounted for 2% of all drugs purchased in the U.S. (7) Only patients of a covered entity have been deemed eligible to receive 340B drugs, covered entities must keep records to ensure that no 340B drugs were being double discounted in the Medicaid Rebate Program. (8) The originally proposed discount for outpatient drugs sold by drug manufacturers to eligible providers was 22%. (9) However, when 340B was eventually passed and instituted, drugs have historically been discounted as much as 51%. (10) The 340B program was expanded in 1996 when the Health Resources and Services Administration (HRSA) allowed eligible entities to use a single outside pharmacy or “contract pharmacy” to dispense 340B prescription drugs. (11) The program was again revised in 2010 as part of the Patient Protection and Affordable Care Act (PPACA), which allowed covered entities to contract with multiple contract pharmacies to fill and dispense 340B prescriptions. (10)

In addition to this regulatory expansion, 340B has experienced organic growth by expanding clinical and oncology services to meet the expanding numbers of vulnerable patients over the last dozen years, as covered entities spent 3 times more (over \$7 billion) on 340B drugs in 2013 as compared to 2005 (\$2 billion). (12) It was reported that in 2015, 340B sales in the U.S. at wholesale acquisition costs were estimated at 5% of outpatient drug sales, or \$15 billion, and projected to reach \$25 billion by 2019. (13) The number of participating hospitals, pharmacies, and healthcare organizations in the program has also increased substantially, with approximately 1,365 organizations participating in the program as of 2014. (14) This represented a 134% increase when compared to 583 organizations that were participants in the program in 2005. (15)

The rapid growth of the 340B program, coupled with the fact that the law did not direct to which patients, or at what price, covered entities could sell 340B drugs has caused controversy over the possibility that covered entities have offered the drugs at full price to well-insured patients to reap a windfall profit. (4) Further, nothing within the law directed how covered entities had to use 340B savings. (5) This lack of specification has left a wide array of possible uses for 340B savings open to hospitals, including overall facility support, offsetting losses, maintaining current programs, or expanding services. (3)

The purpose of this study was to determine which stakeholders benefited because of the 340B Drug Discount Program, and what have been the drivers of recent changes to the program.

METHODOLOGY

The primary hypothesis of this study was that the 340B Drug Discount Program provides direct positive financial benefit to eligible providers and an indirect benefit to vulnerable patient populations. This study examined data and experiences of 340B entities to determine where the financial benefits of the program were being realized, with a secondary aim that explored recent changes to the 340B program.

This study utilized a literature review. Peer reviewed sources, government statistics, and law review articles from accredited academic institutions were used where possible, with industry advocacy data used as a supplement where necessary. The academic database aggregator service “MUSummon” at Marshall University, the biomedical literature database “PubMed”, EBSCOhost, Academic Search Premier, Alt-HealthWatch, LexisNexis Academic, and CQ Researcher were primarily used to identify relevant scholarship. In addition, a basic Google search of news and publications was utilized to identify non-academic data from industry sources. The primary search terms utilized to identify relevant scholarship were: “340B”, AND “drug pricing program”, OR

“hospitals”, OR “benefits”, OR “financial impact”, OR “contract pharmacies” OR “discount outpatient drugs”.

The inclusion criteria for data on the U.S. healthcare system’s 340B Drug Pricing Program was any scholarly articles, references, or websites, written in English, published from 2005 to 2017. A total of 70 sources were collected and reviewed. After a thorough review, the most relevant and useful scholarship was reduced to 39 total data sources, 20 of which were selected to use in the results section. The literature search was conducted by JG, SM, and AS, and validated by AC who also acted as a second reader and verified literature met inclusion criteria.

RESULTS

Impact of 340B to Providers

While exact figures vary, the amount outpatient drugs that have been discounted to eligible providers have changed since 340B’s inception in 1992. Considering outpatient prescription medicine caters towards a significant number of conditions that affect the low-income populations, discounts on such medications have allowed pharmacies to realize substantial cost savings as they would have purchased the drugs at a higher price if they opted out of the program. (16) Due to the variability in the type of outpatient drugs and their importance in terms of curing common illnesses among low-income populations, the amount of discount on eligible drugs has remained between 20% and 30%. (17) Hospitals and large healthcare organizations such as, Fenway Community Health Center, Inc. in Massachusetts, and Cedars-Sinai Medical Center in California, have reported discounts between 30% and 50%. (18)

Large hospitals, such as Duke University Health System have derived close to \$300 million in savings or profits from 340B. (19) In 2011, an oncologist in Memphis, Tennessee, who operated as a single provider practice reported there was potential for, as much as, \$1 million in savings

from 340B annually. (20) According to a 2016 review, hospitals represented only 46% of 340B covered entities yet accounted for almost 90% of 340B purchases. According to the author, hospitals received a 340B discount on a 25% of their 2013 drug purchases, which was an increase over only 3% of such purchases in 2004. Furthermore, 340B eligible hospitals have realized increased Medicare profits because of 340B. (21) A 2010 study by the Department of Health and Human Services revealed that Medicare payments to 340B eligible hospitals were 31% higher than acquisition costs, as compared to only 1% for non-eligible hospitals. (22)

As one example of the type of financial impact 340B has had on a hospital, a 2013 media report found that Duke University Hospital purchased \$65.8 million in 340B discounted drugs in a single year and sold the drugs to patients for \$135.5 million. (23) While such profit margins on 340B drugs have been the source of controversy since 2015 due to the program savings having accrued to hospitals and not patients, proponents of the program have argued that it has been crucial in expanding the availability and quality of care to vulnerable patient populations by financially benefiting safety net hospitals. (24)

In a second example, Ozark Medical Center in Missouri has been one of the hospitals that have benefited from taking part in the 340B program. In 2011, the hospital's Medicaid funding was cut by \$1.3 million, a phenomenon that has become common among many health care institutions. However, due to a well-managed 340B program, the hospital received funds of up to \$200,000 per year, partly offsetting the Medicaid losses. (16)

Impact of 340B on Contract Pharmacies

Contract pharmacies have also driven the growth experienced in the 340B drug pricing program. (25) (26) (21) Contract pharmacies are no longer required to have a specific geographical relationship with a health organization. (27) The move has significantly contributed to the growth

of the program by increasing the number of different pharmacies serving as contract pharmacies by over 200% between 2010 and 2017. (28) As of January 2017, HRSA reported that there were 75,080 unique pharmacy locations that were registered under the 340B program. (28) It has also been reported that 4.1% of covered entities had a network of contract pharmacies with 6 to 25 pharmacies. (28)

A management pharmacy vendor, Talyst, reported that retail pharmacy contracts have allowed pharmacies to increase covered entities participation in the 340B program, and in return the covered entity offered a per-prescription dispense fee that induced retail pharmacies to participate. (29) It was also noted by Talyst that retail pharmacies make money through these agreements as the negotiated dispense fee from the hospital was in addition to the normal profit margin. While there were no reported figures on the total financial impact that the retail pharmacy industry's achieved, fees paid to a contract pharmacy to cover the cost of dispensing and other administrative services ranged between \$9 - \$12 per prescription. (30) One example of the impact to pharmacies was illustrated in the participation of the large, for-profit retail pharmacy, Walgreens. In 2014, Walgreens made up 38% of all contract pharmacy arrangements in the 340B program as over 70% of the chain's locations participated in at least one contract pharmacy arrangement. (31) Furthermore, in 2014, *340B Reform* cited a Walgreens analyst who posted on his LinkedIn webpage that 340B will likely add at least \$250 million in incremental revenue over the next five years, making the company more profitable.

Impact of 340B on Patients

Both insured and uninsured patients at an eligible 340B entity can be treated with deeply discounted drugs under the 340B program. These discounts have ranged from 30% - 50% off the drug's list price though these discounts were not necessarily directly passed on to the patient. (20)

Hospitals have noted that while not all discounts were directly passed to patients, the 340B program has allowed covered entities to provide an indirect benefit to impoverished patients by providing potential lifesaving and otherwise uncompensated care. (32) Eligible hospitals and healthcare organizations have provided additional health services such as uncompensated care, which has eliminated the financial burden of accessing such care in other non-eligible institutions. The program has also improved access to medications used to treat chronic conditions such as diabetes and asthma among the indigent. (33) The management of such chronic conditions cost an average of \$3,000 per patient annually that has created a financial burden on (34)¹.

Health Reform and Medicaid Expansion

The primary driver of overall growth in the 340B program has been health reform due to the implementation of the PPACA which expanded Medicaid eligibility. This expansion has allowed hospitals that had not previously qualified for the 340B program to become eligible to take part in the program and register with HRSA. (35) In 2013, there were 970 DSH hospitals under the program compared to 185 in 2003 and it has been projected to grow significantly over the next 5 year as more eligible hospitals seek registration in the coming years. (36)

Organic Growth of the 340B Program

Through expansion of services, hospitals have driven organic growth in 340B through increased volumes that would qualify for 340B savings. (37) Duke University reported having generated profits of \$282 million for drugs under the 340B program by increasing its locations over a 5-year period. (20) A 2012 study found that 340B eligible entities may have driven rationale for affiliations and mergers among hospitals and outpatient physician's practices. (20) For example, hospitals without oncology services have decided to set up an oncology practice to

benefit from the discounted outpatient drugs for cancer patients. The motivation behind such a move was to generate additional savings from the discounts offered on such drugs. Additionally, as noted by Hinkley and Kung, (38) chemotherapy services were costlier when offered from an outpatient hospital department, a 37.7% - 52.5% increase, as compared to a physician practice setting. The ability of a single oncologist to produce up to \$1 million in earnings for a hospital, discussed above, has provided incentives to create research departments and grow the 340B program. (39)

DISCUSSION

The 340B Drug Discount Program has greatly expanded since its inception in 1992. This was partly due to regulatory changes, but the program has also grown organically as covered entities have used 340B profits to meet increased numbers of vulnerable patients by expanding healthcare offerings, thereby making these covered entities eligible for even more 340B drugs, further expanding profits. As the debate has focused on expanding access and coverage in recent years, the practice of 340B covered entities essentially subsidizing their operations and growth by virtue of 340B profits has become controversial. This is due in large part to the political advocacy of the pharmaceutical industry which has argued that covered 340B entities have unjustly enriched themselves as opposed to passing the 340B savings and discounts on to vulnerable patients.

It is true that covered 340B entities have experienced a direct financial boon² because of the 340B program. By offering 340B drugs to well insured patients at full price, covered entities are effectively subsidizing the budgets of the covered entities. This sort of profit realization has also been true for contract pharmacies, which have been brought into the 340B equation after the PPACA's 2010 changes to the 340B program. Detractors of the 340B program, led by

² Boon is the correct word here. It refers to a financial benefit or improvement.

pharmaceutical companies resentful of the forced discounted drugs, have argued that the 340B program has merely served to enrich hospitals and pharmacies, without helping poor and vulnerable patient populations. However, this criticism has failed to acknowledge that vulnerable patient populations have benefited by 340B in an indirect manner.

The main criticism of the 340B program has fundamentally misunderstood the purpose and effect of 340B. The program was designed to allow healthcare organizations which were serving a high percentage of the vulnerable patient population to expand healthcare services in a way that they would not be able to do absent the financial insulation provided by 340B. While covered entities may not be directly passing 340B savings on to vulnerable populations, the 340B program was never intended to be an entitlement program for vulnerable populations to receive cheaper drugs, subsidized by pharmaceutical companies. The program was designed for covered entities to stretch scarce resources and expand services, whereby they would be enabled to reach more in the vulnerable patient population. In this respect, the 340B program has functioned as intended, as proved by the organic growth of the program. By using 340B profits and designing strategic growth to realize additional profits, covered 340B entities could expand services and healthcare offerings in the way of more satellite clinics and expanded oncology offerings. This type of organic growth has allowed covered entities to stretch their resources, offer more services in more locations, and therefor fulfil the stated goal of the 340B program. Despite this reality, the misunderstanding of the purpose of the 340B program as well as the significant profits which have inured to contract pharmacies since 2010, have made the 340B program continually controversial.

This study was limited in that it did not include primary research into how individual hospitals and other covered entities were utilizing 340B drugs and accompanying profits in 2017. The industry has continued to change and react to the political climate. The state by state

restrictions on 340B drug pricing are happening in real time, as this research review has been conducted. As such, this study is limited by the timeliness of the topic and the ongoing political and legal activity surrounding 340B. Further, this study was limited by the bias of the researchers, bias of the available publications, limitations of the chosen research strategy, and the number of databases utilized for the secondary research.

This study concerned a timely topic that is a vital importance to many hospitals and other 340B covered entities. Many healthcare organizations rely on 340B profits to subsidize their budget, allowing them to expand and increase services to vulnerable populations. It is critically important that the ongoing debate over the 340B program consider the original purpose of the program and the myriad of ways vulnerable populations are benefiting from the program.

CONCLUSION

As 340B has continued to expand, political advocacy has been successful in creating controversy over the direct financial benefit that healthcare providers and contract pharmacies have realized because of the program. However, vulnerable and underserved patient populations have also benefited in the form of expanded services and increased access to healthcare. This type of benefit, while indirect, has fulfilled the intent of the 340B program at its inception.

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