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## 340B Program Utilization in Rural US Clinics

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### 340B PROGRAM UTILIZATION IN RURAL US CLINICS

### **ABSTRACT**

Introduction: The 340B program was an effective strategy in reaching more potential patients, providing more comprehensive services, and limiting the gap between affordability and healthcare. The uninsured and underprivileged often are unable to receive medications at the high market price due to the financial situation they face and inflation. The 340B program seeked to mend this issue to help the public and healthcare organizations. The main purpose of this research was to search and evaluate if the 340B program lived up to its purpose of decreasing the cost of medications in rural based clinics.

**Methodology:** The research strategy developed for this qualitative study utilized a mixed methodology of a literature review along with a semi-structured interview with an executive from a rural 340B clinic. Four electronic databases were utilized to form a conclusive analysis. The 21 sources used are referenced for this literature review.

**Results:** The literature review evaluated five studies of the cost and impact of the 340B program in rural locations across the United States.

**Discussion/conclusion:** The 340B program discussed was an effective program in lowering the cost of medications in rural provider based clinics across the United States when utilized.

Key words: Critical Access Hospitals, Entity, Medicaid, Medicare, Non-profit

#### INTRODUCTION

Beginning in 1992, hospitals and pharmacies who are contracted through the 340B government program were able to purchase drugs in the outpatient setting at a heavily discounted price which allowed them to pass those savings onto the patient (MEDPAC.Gov, 2015). The 340B program protected vulnerable patients from the ever-rising costs of their medications through a contract with specific clinics and hospitals across the country (Slafsky, Ross, Krishnamurthy 2018). Those hospitals and clinics that have these government contracts must fall under six distinctive categories to become a covered entity, which allowed them to purchase the drugs at a significant discount directly from the manufacturer (340B Health, 2020). In each category to be considered a covered entity, the facility must have been governmental healthcare facility with a state or local contract in addition to being either a private non-profit hospital who provides care to low-income patients who are not registered for services from Medicaid or Medicare, or a private or public non-profit entity who has a local or state powers (Keough, Webster, 2009).

Data gathered from 2005-2014 demonstrated that hospital participation had more than tripled in 340B program rural-healthcare (Gillard, Shelby, White, 2019). To be considered rural the area in question must have consisted of a population between 2,500 and 50,000 residents (HRSA, 2020). Organizations such as critical access hospitals, Disproportionate Share hospitals (DSH), and other rural hospitals were evaluated. Beginning in 1992, there were only 583 rural facilities participating in the 340B program. This number has since ballooned to over 2,000 rural healthcare facilities partingting in the 340B program as of 2019 (Gillard et al., 2019). A 2018 study completed by the U.S. Government Accountability Office (GAO) revealed that in 2016 of the 2,399 hospitals participating in the 340B program 1,511 (63%) were considered to be rural in their location (Gillard et al., 2019). In West Virginia, there are currently 36 facilities that have

340B participation including St. Mary's Medical Center and Cabell Huntington Hospital (340B Health, 2020).

For a private non-profit facility to become a 340B covered entity, the facility must have provided care for at least 11.75% of low-income patients out of their total patient population during the most recent fiscal quarter (McCaughan, 2017). A low-income patient is someone who lived at or below the poverty line of \$25,465 per year for a family of two adults and two children (Fessler, 2019). Individuals living in the rural community need the 340B due to being low income, non-existing healthcare coverage, and unable to afford the coverage on their own. (Kaiser, 2017). For every Medicaid prescription through 340B, hospitals have estimated savings of more than seven dollars per medication. For larger organizations and healthcare practices that bill for five hundred thousand Medicaid prescriptions a year, this was a reported \$3.6 million in savings (McKesson, 2017).

Tax-exempt hospitals have been required to report the average in which they have helped improve the community. These reports have been completed through the IRS Form 990 Schedule H (Nikpay et al., 2018). In 2016, hospitals participating in the 340B drug savings program that qualified for tax-exemption were able to contribute \$56.1 billion in total benefits to their communities (AHA, 2019).

According to the Health Resources and Services Administration (HRSA) since 2013, the 340B program has saved patients an estimated \$3.8 billion in drug copayments (MEDPAC.Gov, 2015). This was done by the program permitting the purchase of individual outpatient medications to contracted 340B pharmacies and facilities (Mulcahy, 2014). The 340B program have not cost the government any money due to being funded by drug company discounts and has greatly enhanced the community (McKesson, 2017).

The purpose of this research paper was to analyze the effect that the utilization of the 340B program had on lowering the cost of medications in rural provider based clinics in the United States.

### METHODOLOGY

The hypothesis developed for this research study was to determine if the 340B program has a positive effect on lowering the cost of prescription drugs in 340B rural clinics within the United States.

The implementation of a conceptual framework was utilized for the study as it focused on the promotion and enrollment of the 340B program for those who qualify and cannot afford their drug copays. For this study, it is imperative to clearly distinguish how a patient would be guided toward applying for 340B benefits. The results finalized from the literature, benefits, and barriers of the 340B application process can be viewed through the conceptual framework in figure 1. As shown in figure 1, the conceptual framework demonstrated the implementation of the 340B program. When a medication is prescribed to a patient in a rural facility the patient then picks up the medication at the pharmacy. When a medication has an unaffordable copay, the pharmacist can then contact the physician to alert them to the unattainable price along with discussing the potential options. The physician can then contact the patient to discuss the 340B program and determine if they qualify. The outcome from this is that the patient qualified for the 340B discount program or the patient does not qualify for the 340B program and the physician will need to consider another medication (Mulder, 2017).

Search Strategy

The research strategy developed for this qualitative study was a literature review with a semi-structured interview with an executive from a rural 340B clinic. The research team was

able to determine how the 340B program was effective in lowering the cost of medications in rural U.S. 340B clinics.

### Step 1: Identifying Literature and Collecting Data

In search of data and articles related to the purpose and hypothesis of the study, several keywords phrases were utilized such as "340B" AND "Medicaid" AND "Medicare" AND "Non-profit" AND "Critical Access Hospitals" OR" Entity". During the search to identify relevant data and literature appropriate to the study several electronic peer-reviewed and electronic search engines were utilized such as Google Scholar, PubMed, ProQuest and, Ebsco Host.

Step 2: Establishing the Criteria for Inclusion and Analysis of Literature and Semi-Structured Interview

The information and data utilized for this study came from 2008-2020 only in the English language. The articles were evaluated and analyzed to ensure the most current and accurate information was included. To verify that all information within the study was accurate WF and HS conducted the literature search and interview. The information was then validated by AC who served as a secondary reader to ensure all information included met the criteria for inclusion.

By employing the Preferred Reporting Items for Systematic Review and Meta-Analysis Approach (PRISMA), the research approach gathered 80 relevant citations for analysis that met the criteria for inclusion. For those who met the criteria, an additional 40 were determined to be a secondary source. Duplicate citations and information had been removed, 40 of 120 were

screened. Twelve sources from screening had been removed, full-text citations were assessed for inclusion eligibility, with an additional 5citations removed after they were deemed to not contain author bias on information or insufficient details related to the study. A total of 21 citations were used in the qualificative synthesis with 10 of the citations being used in the results section of the meta-analysis as shown in figure 2 (PRISMA, 2015).

A semi-structured interview was also utilized in the study to gather additional relevant data and information. Before the interview took place, Marshall University's Institutional Review Board (IRB) examined all material as well as procedures that would be utilized to gather information and granted approval by the board for the study to conduct the interview. The interview was not recorded as both co-investigators present took detailed notes of the executive's answers. The interview was conducted face to face in the office of the director of pharmacy services and chief development officer for the Southern West Virginia Healthcare system, Dr. Christopher Harper, RPH. Social distancing was implemented along with surgical face masks being worn by all parties present to prevent the spread of COVID-19.

#### Step 3: Used As Examples

The research results presented within this study were case studies found utilizing the keywords listed in section one. Case Study 1: Speciality Drug Price Trends in the Federal 340B Program. Case Study 2: The impact of patient assistance programs and the 340B Drug Pricing Program on medication cost. Case Study 3: Rural Hospitals: Are you missing out on drug savings? 4: Utilization of 340B Program in a Rural Hospital Case Study 5: Pharmacy provides critical link in rural care continuum.

#### RESULTS

Case Study 1: Speciality Drug Price Trends in the Federal 340B Program

From 2015 to 2017 American's have seen the price of their medications increase by 28.7% (Hass, 2019). A 2019 completed study, examined price increase for speciality medications in Southern California 340B pharmacies. Data was gathered from 2006-2016 and examined the price of speciality medications purchased through the 340B pricing program compared to the Wholesale Acquisition Cost (WAC) pricing model (Lee, Chang, McCombs, 2019).

Patients who purchased their generic speciality medications through the WAC saw an increase of 14.7% in price for their medications. While patients who purchased their generic specialty medications through the 340B program during this study saw an increase of 10.3% in cost. Patients saved on average 4.5% on their generic speciality medication copay over the ten year study period by utilizing the 340B pricing program ( Lee et al., 2019). When brand speciality medication prices were examined, the 340B price of those medications increased 6.4% over the study. The WAC price for brand speciality medications increased more significantly at 14.1%. For brand speciality medications patients were able to save on average 7.8% when purchasing their medications through the 340B program over the timeline of the study (Lee et al., 2019).

Case Study 2: The impact of patient assistance programs and the 340B Drug Pricing Program on medication cost

The objective of this study was to evaluate the key purpose and impact of the 340B Drug Program. Researchers used a retrospective analysis of medication dispensary data. Researchers of the study used data for uninsured patients at 2 community health hospitals. Those measured were 340B patients and patients using prescription assistance programs (Castellon, Bazargan-Hekazi, Masatsugu, Contreras, 2014).

Overall, the study resulted in a total of 1420 prescription assistance program (PAP) individuals and 2772 340B medications to uninsured patients in February 2012. Patients who received PAP on average saved \$617.36 per medication while only paying on average \$0.11 copay per medication. Those patients who qualified for 340B assistance saved on average \$62.31 per medication while having an average copay of \$11.50 per medication. 340B proved to provide significant medication cost savings for uninsured patients (Castellon et al., 2014).

Case Study 3: Rural Hospitals: Are you missing out on drug savings?

According to a study it is predicted that hospitals will increase their overall annual spending from 12% to 14% (Radford, Slifkin, Shur, Cheung, Naernholdt, 2008). In 2018, a proposal to raise the Medicare Disproportionate Share Hospital (DSH) from 11.75% to 18% was introduced into the new congressional bill (Vartorella, 2018). In 2007, when the increase in DSH was passed to 11.75%, rural hospitals with less than 500 acute care beds, who were not previously eligible, had become eligible to apply for 340B participation (Radford et al., 2008).

In 2007, of the 950 rural not-for-profit hospitals in the US, there were 400 who became eligible to apply for approval into the 340B program. However, according to the Health Resources Services Administration's Office of Pharmacy Affairs (OPA), in October of 2007, there were only 200 hospitals that were participating in the 340B program. In comparison urban

hospitals that were eligible for participation in October of 2007 had a participation rate of 72% as compared to rural hospitals who were eligible which had a participation rate of 21% (Radford et al., 2008).

According to the study, the challenges and program requirements of successfully converting the 340B program into a rural hospital or clinic has been the main reason some rural facilities have chosen not to participate. The reported median savings of rural 340B participants per month was \$19,700 (Radford et al., 2008). At the Lincoln Primary Care facility, on average the pharmacy has served on average 5,800 340B patients per year with an average saving of 50% on their medication copay (Christopher Harper, personal communication, Oct. 2, 2020).

Case Study 4: Utilization of 340B Program in a Rural Hospital

A completed 2015 study set out to examine the benefits of participating in the 340B program as a rural entity. By 2016, it is predicted that the total discount on drugs through 340B will top \$12 billion as compared to 2010 when the discounts produced \$6 billion in savings. The authors explained that during 2010, the average discount on medication through 340B ranged from 30% up to 50% (Ashford et al., 2015).

It's estimated that rural hospitals and clinics can bring in supplemental revenue ranging from \$160,000 to \$200,000 per year by utilizing the 340B program. This additional revenue can be used to supplement not only the pharmacy but the clinic outreach programs in the area as well to promote overall better community health (Ashford et al., 2015).

Case Study 5: Pharmacy provides critical link in rural care continuum

A completed 2019 study examined the effects that the purchase of a local pharmacy has on a rural healthcare system. In May of 2014, the rural Pender Community Hospital District and Pender Care Center of Pender Nebraska purchased a local pharmacy then relocated the pharmacy to their medical campus which qualified the health system for the 340B program. This purchase was completed to not only generate more revenue for the Pender Care center but to try to deter the mass exodus of pharmacy services to outside entities (Bryan Health, 2020).

In the first six months since the acquisition was finalized, the pharmacy saw an increase in prescriptions by 50% as compared to the previous six months. Patients who qualified for 340B assistance saw a saving on their medication copayment based on the medication anywhere from 30-50%. Since 340B eligibility in 2014, the facility was able to generate a revenue of 1.5 million dollars from their pharmacy services. As shown in figure 4, the additional revenue allowed for the facility to donate \$342,000 in 2016 to their annual charity care, which is more than triple the donation they were able to make in 2015 of \$100,000 (Bryan Health, 2020).

#### **DISCUSSION**

The purpose of this research paper was to analyze the effect that the utilization of the 340B program had on lowering the cost of medications in rural provider based clinics in the United States. The hypothesis developed for this research study was to determine if the 340B program has a positive effect on lowering the cost of prescription drugs in 340B rural clinics within the United States.

Case Study 1 examined the price increase of specialty medications prices purchased through the Wholesale Acquisition Price (WAC) and the 340B pricing program over a ten year period. Data was collected on the purchase price of speciality medications of contracted 340B

pharmacies. One limitation to this study is that the authors didn't analyze all specialty drugs which made the results not comparable to other therapeutic classes across the same timeline (Lee et al., 2019).

Case study 2 compared medications costs and savings of medications on the 340B program against the Patient Assistance Program in two community hospitals during February of 2012. A limitation to this study by focusing solely on the cost the study failed to focus on factors that may have influenced the prices. Additional factors that may have influenced the price of the medications that were not accounted for were market price and medication availability (Castellon et al., 2014). According to the 340B expert, in his rural 340B pharmacy patients will save an overall average of 48% on their monthly medication copay when they utilize the 340B program (Christopher Harper, personal communication, Oct. 2, 2020).

Case study 3 set out to determine why there had been low participation in the 340B program in rural clinics. A limitation within the study was that when the authors gathered their date they failed to include 200 hospitals who had become eligible to use the 340B program (Radford et al., 2008). Depending on the medications prescribed to the patient, when utilizing the 340B program at the Lincoln County Primary Clinic Pharmacy a patient can save an average of 10,000 a month on their medication copayments (Christopher Harper, personal communication, Oct. 2, 2020).

Case study 4 analyzed the benefits of a rural clinic participating in the 340B program.

One limitation that came from this study was the publication bias along with the studies that had been utilized in the study. Along with being able to generate more of a profit margin for the rural facility participating in the 340B program patients are able to save more on their medication copayment (Ashford et al., 2015). The 340B expert said that patients who participate

in their rural 340B pricing program save on average 50% per drug (Christopher Harper, personal communication, Oct. 2, 2020).

Case study 5 examined the benefits of a rural health care facility that had purchased a local pharmacy to become eligible for the 340B program in rural Nebraska. A limitation that arose from this research paper was that the study focused mainly on the increase in prescriptions to the newly acquired pharmacy. Additionally, the study only presented general and average savings of medications for patients not specific savings on patient medication copays (Bryan Health, 2020).

Limitations for the paper included not focusing on more rural areas throughout the United States. A more wide range and conclusive study could have been done to interview more professionals in other rural areas to further analyse the 340B program. A limited sample size, similar publication bias, and studies focusing on one area of the 340B program were all limitations reported throughout the review.

Policy implications that could come from this study are the continuous changes of the 340B system. The Affordable Care Act was one noticeable policy that greatly impacted the results and accessibility of the 340B program. Rural expansion and participation were highly utilized in the program to further the success of the 340B program. Should the Affordable Care Act be replaced or revised, less patients and facilities will be eligible for this program.

## CONCLUSION

The 340B program has shown to have a positive effect on decreasing the cost of prescription medication in rural provider based 340B clinics in the United States. The literature review along with semi-structured interview was able to demonstrate that implementation of the

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340B program in rural 340B provider-based clinics in the United States had an effect on lowering medications costs.

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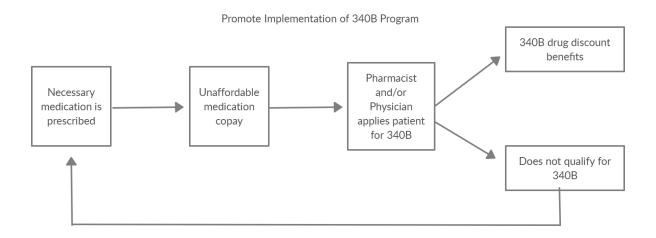


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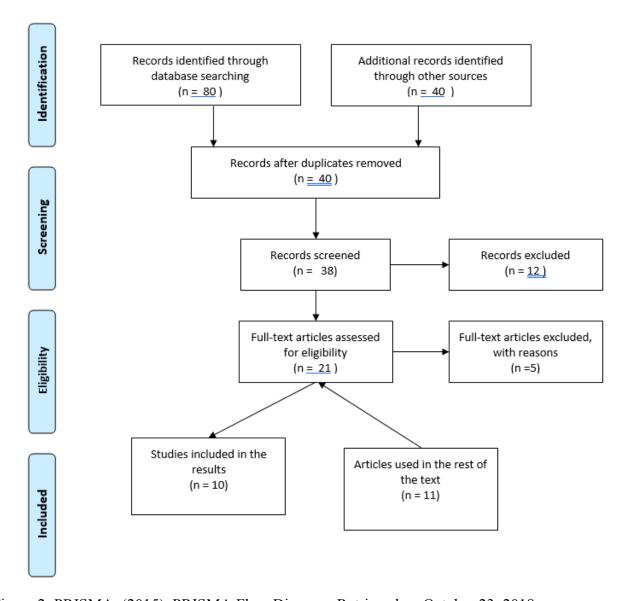


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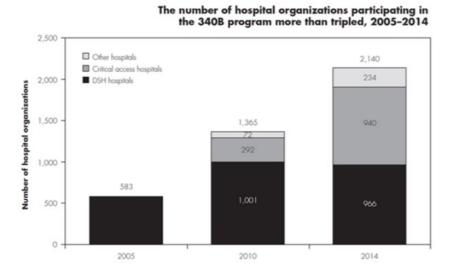


Figure 3: Statistics From Implementation

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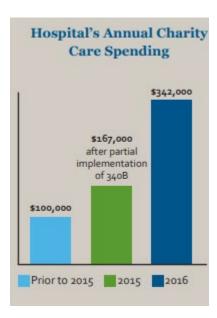


Figure 4: Hospital Annual Charity Care Spending

"Case Study: Pharmacy Provides Critical Link in Rural Care Continuum" Bryan Health, 2020.

https://www.bryanhealth.com/app/files/public/2650/rural-bryan-health-pender-compendium.pdf

## Appendix A

Semi-structured interview of Dr. Christopher Harper, PharmD, Director of Pharmacy Services and Chief Development Officer, Southern West Virginia Health System- Lincoln County Primary Care Center:

- When did the rural clinic start to implement the 340B program? Why?
- How much do entities covered utilizing the 340B program save on average when purchasing the approved medications? Why?
- How do patients in the rural clinic find out about the 340B program? Why?
- Are uninsured or self-pay patients able to receive 340B medications at the 340B reduced rate? Why? / Why not?
- What is your estimate of the percentage of income the 340B program has saved uninsured patients? Why?
- Are revenues impacted positively or negatively due to 340B program implementation?
   Why?
- Do you feel that the utilization of the 340B program has met the goal of providing greater access to medications? Why? / Why not?
- What is your estimate for the number of 340B patients your pharmacy currently assists?
   Why?
- As of September 1<sup>st</sup>, the drug manufacturer Eli Lilly has stated they will pull their medications from their contracted 340B pharmacies. Including drugs such as the popular insulin Humalog and Humulin. If this happens how will that affect 340B patients on those medications? Why? / Why not?

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• What producers, if any, are in place to ensure that patients and/or providers do not overuse or abuse the 340B program? Why?/Why not?