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Heath Ashford

Lauren Valli


William K. Willis

Marshall University, willis23@marshall.edu

Alberto Coustasse

Marshall University, coustassehen@marshall.edu

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Heath Ashford
Healthcare Administration Student
Healthcare Management
College of Business
Marshall University
100 Angus E. Peyton Drive
South Charleston, WV 25303
ashford3@live.marshall.edu

Lauren Valli
Healthcare Administration Student
Healthcare Management
College of Business
Marshall University
100 Angus E. Peyton Drive
South Charleston, WV 25303
valli@live.marshall.edu

William Willis, DrPH, MSHA
Assistant Professor
Health Care Administration Program
College of Business
Marshall University Graduate College
100 Angus E. Peyton Drive
South Charleston, WV 25303
(304) 746-8946
(304) 746-2063 FAX
willis23@marshall.edu

Alberto Coustasse, DrPH, MD, MBA, MPH
Associate Professor
Health Care Administration Program
College of Business
Marshall University Graduate College
100 Angus E. Peyton Drive
South Charleston, WV 25303
(304) 746-1968
(304) 746-2063 FAX
coustassehen@marshall.edu

UTILIZATION OF 340B PROGRAM IN A RURAL HOSPITAL

*Heath Ashford, Marshall University
Lauren Valli, Marshall University
William Willis, Marshall University
Alberto Coustasse, Marshall University*

ABSTRACT

Introduction: *The 340B is a federal program that provides eligible rural hospitals, providers, and clinics the capability to purchase medications at reduced prices for outpatient use. Enrollment in the 340B program requires drug manufacturers to supply covered healthcare entities and eligible healthcare organizations medications at substantially reduced prices and has allowed covered entities to extend federal resources by offering more comprehensive services and reaching more of the vulnerable populations. The purpose of this research study was to examine utilization of 340B program within provider based clinics of a university medical school affiliated with a rural hospital to assess the benefits and barriers of its utilization.*

Methodology: *The methodology for this study was a literature review complemented with a semi-structured interview of an expert in 340B program. Seven electronic databases were utilized with a total of 21 ~~sources~~ ~~articles~~ referenced for this review.*

Results: *The type and volume of care provided in rural areas has been expanded as a result of the 340B program leading to median savings of \$10,000 per month in prescription purchases. Pharmacy savings have ranged from \$600 to \$158,000 per month depending upon whether chemotherapy was available on an outpatient basis or not. In 2010, total cost of drug discounts equaled \$6 billion dollars, and ~~has been is~~ projected to be \$12 billion by 2016 with ~~typical~~ ~~a~~ discount range ~~between being~~ 30% to 50%.*

Discussion/Conclusion: *The results of this study suggest that ~~the~~ ~~The~~ benefits in the types and volume of services provided outweigh the barriers of maintaining separate drug inventories and difficulties in the management of the outpatient pharmacy that include audits at the state and federal levels as well as audits from pharmaceutical manufacturers.*

INTRODUCTION

Background

The 340B is a federal program that provides eligible rural hospitals, providers, and clinics the capability to purchase medications at reduced prices for outpatient use. Hospitals are defined as rural if the hospital has less than 500 beds and the population is less than 50,000 (INSERT REFERENCE). Cabell Huntington Hospital (CHH) is eligible for participation in the 340B program because it is a rural, disproportionate share hospital. Disproportionate share hospitals serve a significantly disproportionate number of low income patients (HRSA, 2014). This program was created in 1992 and has permitted ~~to~~ a group of hospitals which cared for vulnerable populations to acquire prescriptions for their patients at reduced prices. Furthermore, without health insurance that provides prescription drug coverage, patients have been twice as likely to reduce consumption by cutting pills, skipping doses or not filling prescriptions entirely due to cost (Kaiser Permanente, 2008). Enrollment in the 340B program requires drug manufacturers to supply covered healthcare entities and eligible healthcare organizations medications at substantially reduced prices. ~~It also and~~ has allowed covered entities to extend federal resources by offering more comprehensive services and reaching more of the vulnerable populations (Keough & Webster, 2009). Healthcare centers were originally established over 40 years ago to provide primary and preventive care and have endured due to their record of quality and community effectiveness (Lefkowitz, 2005). Two distinctly different cultural and geographical regions, rural Mississippi and inner city Boston, have provided evidence that community health centers have reduced disparities in healthcare provided to minorities and the most economically disadvantaged (Geiger, 2005). Regardless

of the patients' insurance status, healthcare centers have provided quality care to vulnerable populations by eliminating barriers to access of care and have improved health outcomes. Also no incentives have existed for physicians to provide care for low income patients lacking insurance within the current United States (U.S.) healthcare system (Wilensky & Roby, 2005). The expansion of ~~managed care~~ health insurance and federal programs such as 340B has led to hospital-physician financial collaboration creating large integrated healthcare organizations (Cuellar & Gertler, 2006). Due to policies passed, including the Patient Protection and Affordable Care Act (PPACA) of 2010, a variety of healthcare entities such as cancer centers and community hospitals can purchase medications under 340B federal program, irrespective of their patients' insurance coverage or lack thereof (HRSA, 2014). In addition, hospital participation has increased from 591 hospitals in 2005 to include approximately one third of all U.S. hospitals or 1673 hospitals in 2011 (Mitka, 2012a).

The implementation of the 340B program in a rural hospital has been driven by market factors leading to expensive medication pricing and the need to provide affordable prescriptions costs to patients discharged from the hospital and patients seen in the hospital's provider based outpatient clinics. Hospitals have maintained profit margins of 7.2% in 2010 because of their business acumen implements ways to procure cost savings on outpatient medications with programs such as 340B, but it has been increasingly faced with barriers of strict government requirements and Medicare provider based rules which develop difficulties in cost saving strategies (Selvam, 2012). With hospital expenditures estimated to increase at a yearly rate of 4.8% the next 5 years, hospital personnel have been faced with the challenge to decrease costs while maintaining patient quality and care (Shactman, Altman, Eilat, Thorpe, & Doonan, 2003). Rates charged by hospitals are governed by negotiation in the private sector and by federal law when Medicare is the primary insurance (Hart & Siegel, 2012).

Costs and Savings of Program 340B

The cost of implementation of 340B program has been justified based upon annual cost savings of \$330,000 achieved with an annual outpatient prescription budget of \$1 million (Endo, 2010). The parent hospital registered for participation has assumed responsibility for compliance to all federal guidelines and regulations for the outpatient clinics and departments on site within the hospital walls. As a result, the clinics and departments must meet requirements set forth by Joint Commission on Accreditation of Healthcare Organizations, including limited access to medications and proper temperature monitoring to ensure safety and integrity (Federal Registry, 2012). Since the 340B program does not require covered entities to provide discounted medications to indigent patients only, patients with excellent prescription coverage are eligible to use the service too. In addition, eligible patients have been defined as those who receive treatment at the parent hospital or outpatient clinics, with the exception of patients covered by Medicaid. Hospitals and outpatient clinics are not required to pass the savings on medications to individual patients or their insurance carrier. Private pay and insurance billing are based upon Average Wholesale Price or list price instead of 340B government mandated purchase price. Simply stated, the 340B program has reduced the acquisition costs of medications but not the reimbursement (Apexus, 2014). As reported in The New York Times in 2013, it is feasible for an oncologist to generate \$1 million in profit by treating his insured patients with medications obtained legally under 340B program (Pollack, 2013).

The purpose of this research was to examine utilization of 340B program within provider based clinics of a university medical school, Joan C. Edwards School of Medicine (JCESOM) in Huntington, West Virginia affiliated with a rural hospital, Cabell Huntington Hospital (CHH), to assess the benefits and barriers of its utilization.

METHODOLOGY

The primary hypothesis was: the benefits of utilization of the 340B program in a rural hospital outweigh the barriers. The secondary hypothesis was: that the 340B program increases access to medications to the uninsured population while maintaining profitability for rural hospitals and affiliated provider based clinics.

The research methodology used for this study was a literature review complemented with a semi-structured interview with an expert in 340B program in a rural hospital in Huntington, West Virginia. Only pertinent answers to questions in Appendix A were included to provide a comprehensive overview in support of relevant academic journal articles. Search engines available through the Marshall University website were used to access the literature that was utilized. The key phrases "340B" AND "rural hospitals" or "critical access hospitals" AND "provider based clinics" OR "provider based facility" OR "FQHC" were used to search online databases for scholarly articles. Scholarly

databases consisted of PubMed, Medline, ProQuest, EBSCOHost, Science Direct, Academia Search Premier, and Google Scholar. Information from healthcare organizations and government websites, such as the Health Resources and Services Administration and Office of Pharmacy Affairs were reviewed. Articles were limited to the English language and published 2004 through 2014 to obtain current information. Primary and secondary data were included from original articles, research studies and reviews. References cited by published sources were also reviewed for relevant articles. One hundred twenty two articles were reviewed and after review of abstracts was performed, 21 articles were chosen for this research study. The search was completed by HA and LV and validated by AC who acted as a second reader and also double checked if references met the research study inclusion criteria.

The conceptual framework for this research is illustrated in Figure 1. The research approach for the comparison of the benefits and the barriers to implementation of the 340B Program followed the systematic steps and conceptual framework utilized by Yao, Chu, & Li (2010). The framework emphasizes the need and demand impacting a hospital's decision to implement the 340B program and the barriers encountered. The benefits and barriers vary according to the level examined: federal, state, local, and rural. Each level impacts the ultimate decision made regarding implementation of 340B program. (Figure 1)

FIGURE 1

The findings are presented in the subsequent sections using categories of utilization under the headings: Collaboration of Cabell Huntington Hospital and Marshall Health, Benefits of 340B Program Utilization, and Barriers of 340B Program Utilization.

RESULTS

Collaboration of Cabell Huntington Hospital and Marshall Health

Due to rapid changes in the healthcare arena, executives at Marshall Health, the practice arm of JCESOM, entered into an agreement with CHH to become provider based clinics and participants in the 340B program. This strategic move has allowed the academic health center to enhance its market share, stabilize the organization's financial position by improving efficiency and quality measures by targeting the needs of its rural patient population. These bold moves have allowed Marshall Health to fulfill its mission of providing care to the vulnerable populations while maintaining fiscal responsibilities in a changing healthcare environment (Joe McGlothlin, personal communication, April 25, 2014). While CHH has been the entity obtaining the 340B status, administrators of CHH and Marshall Health, along with JCESOM and MU School of Pharmacy, have formed a partnership to manage an outpatient pharmacy, Marshall Pharmacy, separate from CHH inpatient pharmacy. Staff of the outpatient pharmacy are employed by Marshall Health and not CHH thereby reducing CHH pharmacy staffing costs. Currently, the outpatient portion of CHH pharmacy fills only prescriptions for CHH employees. Marshall Pharmacy will assume this duty also, allowing CHH pharmacy staff to focus on the needs of hospitalized patients. Medications to stock the outpatient pharmacy have been purchased at 340B prices. While employees of Marshall Health and CHH may utilize Marshall Pharmacy for prescription needs, only the employees who have been discharged from CHH or seen by a physician of Marshall Health, provider based clinics of CHH, are eligible to receive medications covered by the 340B program. All other customers will purchase prescriptions from medications not purchased under the program, similarly to patients with Medicaid coverage.

The type and volume of care provided in rural areas has been expanded as a result of the 340B program leading to median savings of \$10,000 per month in prescription purchases (Radford, Slifkin, Schur, Cheung, & Baernholdt, 2008). Savings has been greatest on cancer chemotherapy and adjunct medications bolstering the immune system secondary to adverse effects of chemotherapy (Warren & Shanker, 2013). Disbursement on clinic-administered prescriptions has been indicated to increase more rapidly than overall hospital disbursement, at annual rates of 12%-14%. Increase in cost of outpatient clinic-administered medications has been linked to implementation of Medicare Part D, as well as newly developed drugs in specialized therapeutic areas (Hoffman, et al., 2008).

As of January 2014, there were 24,769 registered sites utilizing 340B with 11,093 being hospitals and the rest being contract pharmacies (Apexus, 2014). In order to provide prescription service on an outpatient basis, the pharmacy dispensing medications under 340B federal program may be owned by the enrolled hospital or the pharmacy service can be contracted out to local retail pharmacies or mail order provider (Apexus, 2014). The majority of

hospitals utilized in-house pharmacies at 82% while contract pharmacies, either retail or mail order, comprise the other 18% (HRSA, 2014). A third option of a combination of a hospital owned pharmacy working in conjunction with a contract pharmacy to provide medications to patients is being implemented at CHH and Marshall Health. Outpatient service covers prescriptions to be taken by the patient at home and also physician administered medication in clinic practice as part of an outpatient procedure, day surgery or outpatient chemotherapy (Joe McGlothlin, personal communication, April 25, 2014). Currently 340B drug purchases are greater than \$6 billion per year. That is an increase from \$1 billion per year just a decade ago, but pales in comparison to estimates of \$12 billion by 2016 (Conti & Bach, 2013).

Benefits of 340B Program Utilization

By design, the 340B program has required drug manufacturers to offer substantial discounts on medications delivered in outpatient settings. The typical discount has been between 30% to 50%, leading to tremendous prescription cost savings for the covered rural hospital and its provider based clinics (Conti & Bach, 2013) (Table 1).

According to the pharmacy directors of rural hospitals in 2006, the pharmacy savings have ranged from \$600 to \$158,000 per month depending upon whether chemotherapy was available on an outpatient basis or not (Radford, et al., 2008) (Table 1). The 340B program does not prevent hospitals from billing patients or insurance providers the maximum allowable amount or to pass the acquisition cost savings along to consumers. As a result, the savings from participation in 340B program have been used to increase or improve services, offset losses from providing the pharmacy services or offset losses in other hospital departments, fund staff positions, and reduce patient prices for purchased prescriptions (Barlas, 2011) (Table 1).

Barriers of 340B Program Utilization

One of the most commonly documented barriers to implementation of 340B program has been the complexities affiliated with operating a pharmacy in compliance with additional federal statutes, regulations, and guidelines (Barlas, 2011). Transparent communication and work flow between administration, pharmacy, and Pharmacy Benefit Manager have been essential. Pharmacy logistics included, but were not limited to, understanding pharmacy reporting of cost analysis, management software system to track inventory, and implementation of a replenishment system for medications (Wilensky, 2010) (Table 2).

According to Health Resources and Services Administration, all new covered entities and their corresponding outpatient clinics must be registered three month prior to the effective start. The only exception to this rule is when a Public Health Emergency has been declared (Federal Register, 2012). For example, Marshall Pharmacy, providing outpatient prescription delivery under 340B contract beginning April 1, 2014, had to be registered between January 1- January 15, 2014 (Joe McGlothlin, personal communication, April 25, 2014).

There are no specific directions as to how drug delivery under 340B should be implemented, however there is an expectation that all statutes, guidelines, and federal regulations will be adhered to so the entity will be in compliance (Federal Register, 2012). Due to enhanced Congressional oversight, governmental attention to the 340B program has increased. Communications between Republican Congressmen and the Pharmaceutical Manufacturers of America has alleged possible noncompliance. Complaints from the National Community Pharmacists Association has highlighted the need for further education explaining the 340B program and who is eligible to receive medications through the program (Mitka, 2012b). In addition, the PPACA has required recertification on an annual basis and has allowed for audits and penalties for institutions found not to be in compliance (Wallack, 2013) (Table 2). According to McGlothlin (2014), one of the greatest challenges regarding utilization of 340B has been implementing separate records for inpatient, outpatient, and specifically Medicaid medications. CHH is working with their IT departments to create separate virtual drug inventories rather than actual separate physical inventories. To further complicate the matter, hospital employees routinely have received reduced prescription costs as part of union negotiations (Joe McGlothlin, personal communication, April 25, 2014). Employees of the hospital and subsequent facility based clinics can only receive prescriptions obtained under the 340B program if their primary care has been provided by the covered entity. Employees who seek primary care elsewhere are entitled to prescription coverage cannot be provided with drugs purchased on 340B program (Phillipe, Andrus, Sims, & McDaniel, 2010).

DISCUSSION

The purpose of this research was to examine the utilization of the 340B program at a rural hospital and its provider based clinics affiliated with a university medical school to assess the benefits and barriers to its implementation. Prior to 2003, few rural hospitals with less than 500 beds qualified for the 340B program. The Medicare Modernization Act corrected this by increasing the disproportionate share hospitals cap from 5.25% to 11.75%. Patients who have been uninsured or underinsured have had limited access to expensive prescriptions which leads to noncompliance due to financial difficulties, hospital admissions due to lack of medications, and ultimately increased burden to the U.S. health care system.

Benefits of 340B Program Utilization

The finding of this study suggest that the Utilization of the 340B program has increased access of affordable prescriptions to the uninsured population who are discharged patients of a rural hospital or its affiliated provider based clinics. The 340B program has required pharmaceutical manufacturers to provide outpatient medications at or below the 340B ceiling prices to enrollees. While acquisition costs have been reduced, reimbursement has not when prescriptions have been filled for patients who have been fully insured.

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A motivating factor to implement the 340B program has been to increase revenues of the rural hospital and its clinics in order to support other underfunded initiatives. According to McGlothlin (2014), Marshall Pharmacy will be owned by CHH, staffed by employees of Marshall Health, and will offer learning opportunities for students of both JCESOM and School of Pharmacy. Marshall Pharmacy has planned to implement a program called “Meds to Beds”. A pharmacist or pharmacy intern will deliver medications to the hospital room when patients have been scheduled for immediate discharge from CHH. In addition to alleviating the need for the patient to pick up prescriptions after leaving the hospital, the pharmacist or intern will provide counseling in a private setting allowing the patient adequate time to ask questions regarding prescription indications, directions, and potential side effects. Future plans include delivery of prescriptions to patients that are seen in Marshall Health provider based clinics of Internal Medicine, Family Practice, Psychiatry, Pediatrics, Orthopedic Surgery, General Surgery, Oral Surgery, and Obstetrics-Gynecology. Patients will have the opportunity to ask questions of both the pharmacist and their physicians prior to leaving the clinic. The additional revenue has helped compensate for the reduced reimbursements from state Medicaid agencies and the projected declining federal support beginning in 2014.

In addition, the benefits of cost savings of \$10,000 average per month and the additional revenue of \$160,000 to \$200,000 per year of the 340B program in rural hospitals suggest that the benefits outweighs the barriers of maintaining separate drug inventories, additional pharmacy staff salaries, and audits.

Barriers to 340B Utilization

Not all eligible rural hospitals have participated in the 340B program due to HRSA regulations, reporting requirements, difficulty in obtaining complete information regarding implementation, costs of start-up inventory, increased pharmacy staffing, and lack of awareness of eligibility. Federal regulations and guidelines established in 2010 by the PPACA have included annual recertification of all enrollees, audits, and penalties for noncompliance.

One of the most daunting barriers to implementation of the 340B program has been the complexity associated with operating an outpatient pharmacy. The inventory may be used to fill prescriptions for patients discharged from the hospital or patients of the provider based clinics regardless of insurance status, excluding patients with Medicaid coverage. Medications used within the clinics to treat patients, including chemotherapy, have been covered under the 340B program as well. Separate records for inpatient and outpatient medications have been necessary because inventory purchased under the 340B program cannot be used for inpatient purposes. Inventory does not need to be separated physically but can be separated virtually through management information systems. Inventory administration and tracking have required additional pharmacy staff.

This research has focused on the utilization of 340B program in a disproportionate share hospital in a rural area. The limitations of this study did not examine the 340B program as it has been applied to critical access hospitals, cancer and children hospitals in urban areas. The ultimate success of the program at Cabell Huntington Hospital has been accomplished due to close partnership with Marshall Health and Marshall University, which may be difficult to replicate at larger institutions. Research bias cannot be excluded from this study. The search strategy also limited this

study due to the select few databases used for article selection. Publication bias may be also present. Most articles reviewed supported the utilization of 340B program.

Practical Implications

The 340B program has been a comprehensive plan to improve health outcomes in the population who are uninsured or underinsured in rural area. In addition, JCESOM and MU School of Pharmacy will utilize this program to educate their students. This model could be duplicated at other hospitals, both urban and rural, affiliated with medical schools to educate all students in healthcare, medical, pharmacy, and nursing, regarding collaboration for improving patient outcomes and reducing unnecessary hospitalizations within 30 days of discharge.

Future research should focus on the impact of orphan drug exclusion on the utilization of 340B program. With Medicaid expansion, the consequences of using 340B drugs for Medicaid patients with subsequent cost savings being passed on to individual states should be examined.

CONCLUSION

The utilization of the 340B program might increase access to medications to the uninsured population while it may maintain ing profitability for rural hospitals and affiliated provider based clinics. ~~In addition, the benefits of cost savings of \$10,000 average per month and the additional revenue of \$160,000 to \$200,000 per year of the 340B program in rural hospitals outweighs the barriers of maintaining separate drug inventories, additional pharmacy staff salaries, and audits.~~

^a Personal Communication, J. McGlothlin, April 25, 2014

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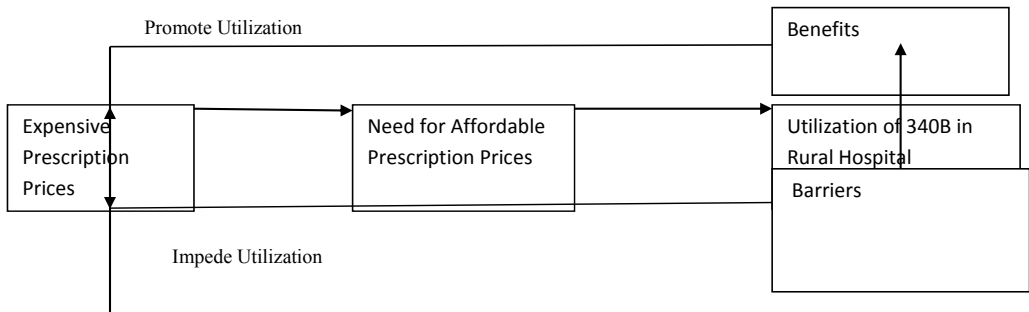


Figure 1 Conceptual framework: Benefits and Barriers to 340B utilization
 Source: Yao, Chu, & Li, 2010.

Table 1 : Benefits of Utilization of 340B Program

Author & Year	Benefits
Radford, et al., 2008	Savings : \$10,000 average per month \$600-\$158,000 per month depending upon practice
Barlas, 2011	Additional revenue of \$160,000- \$200,00 per year permitted staff positions to be funded
Hart & Siegel, 2012	Bill Medicaid & commercial insurers at standard rate of average wholesale price plus dispensing fee
Conti & Bach, 2013	Prescription discounts 30%- 50%

Table 2: Barriers of Utilization of 340B Program

Author & Year	Barriers

Young, 2006	Lack of pricing transparency from pharmaceutical manufacturers
Wilensky, 2010	Pharmacy tracking to prevent diversion and duplicate discount due to mixed use inventory
Wallack, 2013	Certification of 340B entity on annual basis Audits & penalties for noncompliance

APPENDIX A

Semi-structured interview of Joe McGlothlin, RPh, Director of Marshall Pharmacy, Outpatient Pharmacy of Cabell Huntington Hospital:

- How have you implemented the 340B program into your practice in your healthcare entity?
- What method do you use to provide 340B program to your patients in an outpatient/inpatient setting?
- How is responsibility delegated to who is involved in 340B implementation in your facility?
- What services are provided via 340B?
- How have patients reacted to the utilization of 340B?
- How has 340B benefitted your practice?
- How has the utilization of 340B affected patient access to medications?
- How has the utilization of 340B affected the cost of providing prescriptions to patients in your practice?
- Are there any other significant benefits or barriers to 340B utilization in your practice that we have not discussed?