4-2014

A Study on Generic Prescription Substitution Policy as a Cost Containment Approach for Michigan's Medicaid System

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A STUDY ON GENERIC PRESCRIPTION SUBSTITUTION POLICY AS A COST CONTAINMENT APPROACH FOR MICHIGAN'S MEDICAID SYSTEM

by

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A dissertation submitted to the Graduate College
in partial fulfillment of the requirements
for the degree of Doctor of Philosophy
School of Public Affairs and Administration
Western Michigan University
April 2014

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Increasing health care costs have made management of Medicaid services to provide low-income families through Medicaid programs critical in the recent times. The number of Medicaid beneficiaries in Michigan has increased over the years mainly due to the downsizing of auto sectors. Currently, states spend almost 16% of their budget for Medicaid, making it the second largest item in the budget for most (Kaiser Foundation, 2010). Prescription drugs are a significant part of Michigan's Medicaid costs. Higher costs caused a tremendous fiscal burden on Michigan in administering the program and providing prescription drugs for its patients. Michigan has implemented several strategies for Medicaid since 2001, which have brought modest results in terms of Medicaid cost containment. An AARP report (2010) found that 80% of drugs have therapeutic equivalents or generics available in the market while 20% of drugs have no generic substitutions. But depending on the nature of diseases generic substitutions for Medicaid prescription drugs could be much higher than 80%. Previous research suggests that Michigan has the potential to increase generic substitutions at least 10% to 15%. This study examined whether a generic substitution policy would be an efficient and effective

cost-containment strategy for Michigan Medicaid prescription drug programs. This research emphasized three questions: First, would a generic substitution policy be an efficient strategy in containing Medicaid prescription drug program costs for Michigan? Second, did any "heavily used" brand drugs exist which had generic equivalents allowing Michigan to safely reduce Medicaid prescription drug costs by implementing a generic substitution policy? Third, if the answer was 'yes' to both questions, then approximately what amount could Michigan save per year by implementing the generic substitution policy? This research found that Michigan could save $170 million by implementing a generic substitution policy in the prescription drugs program within the selected six-year period between 1999 to 2010 . In 2010, Michigan could save more than 16 million dollars by only prescribing generics, instead of ten brand drugs. A total savings from generics could be approximately $40 million if only generics were prescribed instead of brand drugs. The total amount could be much higher if the multivitamin category was included.

DEDICATION

Dedicated to the three "magi" of my life

A Biblical story tells us about the "three Magi" who brought gifts to the new born Christ from the east. Allah has also blessed me with unending gifts by the "three Magi" in my life. Gifts from my mom and dad have shaped my life. My mom was my first teacher. I can still recall closing my eyes the day she first taught me how to write. I learned from her to be simple, tolerant, and diligent in my personal life. My dad shaped my world view. He taught me the value of education and encouraged me to be an academician. I lost my mom in 2009 shortly after starting the Ph.D. program at the School of Public Affairs Administration (SPAA) in the Fall of 2008, and my dad passed away in 2011. In those very difficult times, my wife, Sania, shared with me all the sorrows and anguish of my personal life. She shielded all the difficulties and kept the daily problems apart from my studies, and helped me be active in pursuing my Ph.D. Without her endless encouragement and endurance, it would have been impossible to accomplish my dream journey towards doctoral degree.

I dedicate this dissertation to my beloved mom, dad, and my wife, Sania—the three "Magi" of my life.

ACKNOWLEDGEMENTS

"Government is like wind in the paddy field"

- Eastern Proverb

My study of Public Administration started with a roomful of students in an undergraduate class at the University of Dhaka, Bangladesh. I became passionate about public administration when our Professor Salahuddin M. Aminuzzaman explained to us that wind does not discriminate, it touches every leaf of the paddy field when it blows. The role of government should be like the flow of the wind and touch the life of every personof a society without any discrimination. Thus I became aware of the significance of public administration in a society like Bangladesh and the necessity of research to develop it. I always dreamed of having my Ph.D. in the USA as an American Scholar, mainly contributing to derive and develop modern Public Administration. I have come to a defining moment in my journey toward the study of Public Administration with the completion of this Ph.D. dissertation. So many memories and names have come together up to this very moment that helped me in completing this huge task.

I contacted Dr. Matthew Mingus, the then Director of the Ph.D. Program at the School of Public Affairs and Administration (SPAA), about my Ph.D. admission. I am humbled that he accepted me into Ph.D. program at the SPAA. I always wanted him to be

part of my Ph.D. dissertation committee. I sincerely thank him for accepting my request to chair my Ph.D. dissertation committee. As the Chair, Dr. Mingus provided me with valuable advice from the proposal stage to my final dissertation submission. Without his support and thoughtful guidance it would be impossible for me to develop and organize my dissertation research in the current fashion.

I also sincerely thank Dr. Han and Dr. Falan. They have made me very grateful, not only for giving their consent to be part of this dissertation committee, but also for providing their precious feedback in every step of my Ph.D. dissertation. They helped me to address many crucial issues, i.e., quality of generic drugs, quality of patient treatment by generics instead of brands et cetera, by their profound knowledge and experience regarding the US health care system.Further, Dr. Han gave me an opportunity to participate in the International Conference on Health Information Technology and Advancements (ICHITA). The experience of participating in ICHITA 2011 and 2013 helped me significantly to investigate issues addressed in the current research. I sincerely express many thanks to Dr. Han for his time and assistance in improving my dissertation presentation. Again, my thanks go to both Drs. Han and Dr. Falan.

I wish to thank all the faculty at SPAA, especially under whom I took my Ph.D. classes, for their support and advice. Surely they have prepared me a much better Ph.D. student than I was before entering this Doctoral program. I want to thank Dr. Barbara Liggett, Director of the School of Public Affairs and Administration. She provided me a

generous financial support for the preparation of the final version of my dissertation. I thank Dr. Wagle and Dr. Higbea for their assistances. Dr. Wagle helped me a lot by providing valuable advice regarding the quantitative analysis part of my dissertation. Dr. Higbea provided me valuable information regarding the Michigan Medicaid and prescription drugs program. In some cases, I received required Medicaid information directly from his contacts of which I was not aware and probably I would not able to find out due to time limitations. I thank Dr. Visser for his kind help. His Ph.D. core course "Contemporary Issues in Public Administration" first introduced me to the issues of Medicaid program. I got a solid idea of my dissertation proposal in his class.

Outside SPAA, I am grateful to Dr. Weilhour of the Political Science department at WMU. He was the professor of the quantitative research course that I took in the Ph.D. program as a required course. I learned so much about the statistical software STATA in his class. Eventually, I used STATA in analyzing the data of my Ph.D. dissertation. He also provided me valuable advice during the data analysis part of my dissertation.

My endless thanks to Dr. Mike Tarn, Chair of the department of Business Information Systems (BIS) at the Haworth College of Business. Dr. Tarn offered me a Graduate Research Assistant (GRA) position at the BIS department almost for the whole period of my Ph.D. program. Without this GRA support it would have been much more difficult for me to continue my doctoral studies smoothly. I also thank all faculty and staffs of the BIS department for their cooperation.

My special thanks go to Michele Behr, the subject librarian of Public Administration at the Waldo Library. Michele helped me so much in finding relevant articles and formatting references from the time from preparing my proposal writing to final dissertation thesis!

My most sincere thank must also be directed to Mr. Abdul Moyeen, my sponsor. His financial and moral support made many things so comforting for me. In addition, I also express gratitude to my family members, relatives and friends both in the United States and back at home for their well wishes and encouragement.

I thank Allysha Choudhury and Yugeng He, two students of the University of Michigan, for developing the computer program "The drug detail gatherer". This program helped me categorize millions of research data almost without any manual intervention. Without this program it would have been very difficult to categorize accurately all these data within my dissertation time period. I am very grateful for their help.

Last, but definitely not the least, I give my sincere thanks to my wife, Sania, my daughter Mayeesha, and my son Mehran. I am sure that my Ph.D. degree would have never been completed without Sania's help. She solely took care of all our family matters when I was busy with my study for all these years without any complaints. She sacrificed all her joys and provided the best support for my Ph.D. I could not spend more time with Mayeesha and Mehran due to my study, busy course works, exams, and other academic

engagements. They all accepted their undeserved deprivation for the sake of my Ph.D. degree. The title page of this dissertation mentions only my name as the author but I am sure that without their sacrifices this dissertation would have never been completed. I am so grateful to them. Sania, Mayeesha, and Mehran—I love you all so much!

Khandaker Nayeemul Islam

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CHAPTER I

INTRODUCTION

1.1.Health Care Costs and Medicaid—the Issue

US health care costs have been increasing over the years at a steady pace. Since 1965, the US national health care costs have increased from $27.5 billion to $2,472 billion within 1965 to 2009. In terms of the percentage of the US GDP, health care costs increased 5.2% in 1965 to 17.6% in 2009 (Falan, Han, Zoeller, Tarn, & Roach, 2010). National health care spending almost quadrupled between 1990 and 2002. Additionally, Pricewaterhouse Coopers (2010) reported that in the last five years health insurance premiums have increased four times faster than wages. The US's $8,160 per capita health care expense has made it the costliest nation in the world in terms of health care costs (World Health Organization, 2009). In the current economic recession, high health care costs have transcended the impact on health alone, and impacted other aspects of people's socio-economic life. Himmelstein, Thorne, Warren, and Woolhandler (2009) mentioned that high health care costs caused almost 50% of all business bankruptcies in the US in 2007. Since the beginning of the current recession, 1.5 million families each year have lost their homes to foreclosure due to high medical bills (Robertson, Egelhof, and Hoke, 2008). In 2010, approximately 47 million people had no health insurance due to high costs of insurance premiums. Rising health care costs, which have been worsened by the current economic downturn, have made increasing numbers of people dependent on

Medicaid over the years for their health care needs, thus causing Medicaid to become one of the most critical problems in federal, state, and local government in current times.

Medicaid is a joint federal and state-funded health insurance program for low-income and medically needy persons (OIG, 2006). In 1965, President Johnson's administration originally conceived Medicaid as a health care supplement only for those eligible to receive cash welfare assistance (Kaiser Foundation, 2010). After its inception for a relatively small targeted group, Medicaid has broadened significantly to minimize the ever-increasing coverage gaps created by the private insurance system. Medicaid is now the nation's publicly financed health and long-term care coverage program for low-income people (Kaiser Foundation, 2010). According to Kaiser Foundation (2013), almost 62 million low-income people received health insurance coverage through the Medicaid program, which included more than one-fourth of the total population of children in the US. In 2011, total Medicaid cost without administrative cost was $413.9 billion. Medicaid provided 65.65% of acute care and 30.25% for long-term care (Kaiser Foundation, 2013). In terms of total national health care spending in 2011, Medicaid provides costs of 16% of total health services and supplies, 18% of hospital care, 8% of professional services, 31% of nursing facility care, and 7% of the prescription drugs (CMS, 2013). Increasing costs have made Medicaid the largest single health insurance program in the country (Simon, Tennyson, and Hudman, 2009).

In attempting to provide health care for the low-income groups in the US, the Medicaid program has gone through various reforms since its initiation. Over time, the structure of Medicaid has changed and its scope and costs have broadened significantly. For example, state responsibility to provide health care to low earning people through the

Medicaid program has been broadened significantly by the Patient Protection and Affordable Care Act 2010 signed by President Obama.

1.2 States and Medicaid Costs

Currently, states spend almost 16% of their budget for Medicaid, which is the second largest item in the budget for most states (Kaiser Foundation, 2010). This responsibility has been broadened significantly by the Patient Protection and Affordable Care Act (P.L. 111-148), commonly known as the health care reform bill or Obamacare, and signed by President Obama on March 23, 2010. The new health reform law will allow 32 million new people who previously had no health insurance to get health insurance. This law will also expand Medicaid coverage for all low-income people except illegal immigrants (Clemmitt, 2010), thus significantly increasing the amount of financial responsibility of the state government. States' roles become crucial in implementing the new health care reforms although suspicions exist—mainly for financial reasons—whether states are capable of carrying out the tasks bestowed on them (Clemmitt, 2010). The Congressional Budget Office (CBO) projected that the new bill will increase states' costs by $20 billion more over the next decade, which is an increase of 1.25% (Kaiser Foundation, 2010). An Urban Institute report by Dorn and Buettgens (2010) projected more fiscal vulnerability of states regarding Medicaid costs in the near future due to the current health care reform bill. The report states that the law will create a huge impact on state budgets. For two main reasons, state Medicaid spending for low-income adults will increase. First, the new act will increase the number of new enrollments of individuals who currently qualify but have not yet signed up for Medicaid. Thus the act will increase states' standard share of Medicaid expenses. Second, by the new legislation Medicaid has to cover all adults with incomes at or below 133% of the federal poverty level (FPL).

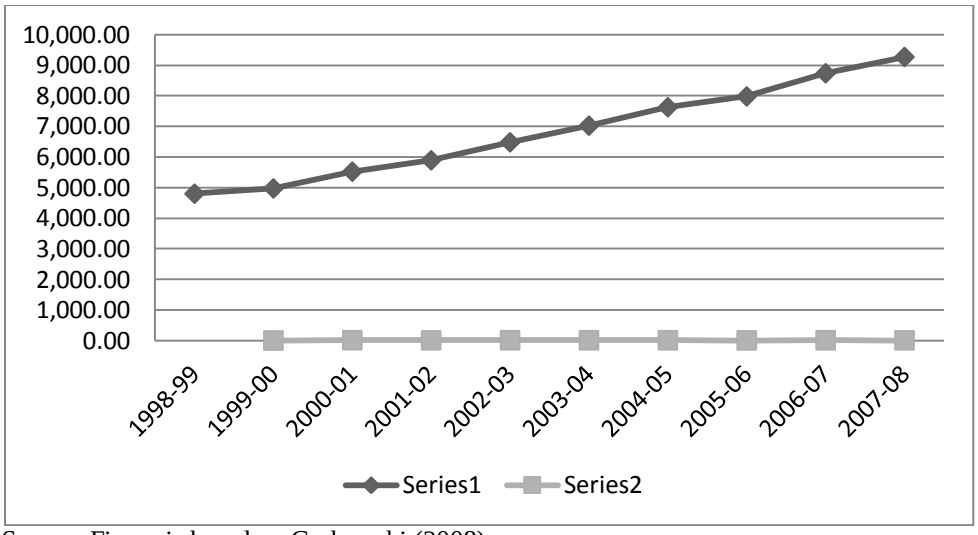
Although the federal government will pay 100% of all health care costs for newly eligible adults during 2014–2016, states will begin paying some of these costs in 2017 and the state share will gradually rise to 10% in 2020 and thereafter. Based on CBO data, the Urban Institute report estimates that state costs for Medicaid will be between $21.1 billion and $43.2 billion during 2014-2019 for people with incomes below 133% FPL (Dorn and Buettgens, 2010).

The cost of rising health care, especially Medicaid costs, have taken a tremendous toll on the fiscal management of the federal and state governments, because of the responsibility of financing the Medicaid program to ensure health care for the low-income groups of the population. Both federal and state governments have launched policies/strategies to control health care costs. Thus, especially in a post-recession economic environment, Medicaid cost containment has become one of the focal points of federal and state governments' fiscal policy. A number of studies are being conducted, searching for reasons for health care cost escalation and ways to contain Medicaid costs (James and Bayley, 2006; Delaune and Everett, 2008; Dalen, 2010, Kelly and Fabius, 2010).

1.3 Medicaid Costs in Michigan—the Problem Statement

Michigan, like other states, financed the Medicaid program with the financial help of the federal government to ensure a health safety net for its people. In 2007, one and a half million Michigan low-income residents received health care coverage through Medicaid at an annual cost of $9 billion (Fairgrive, 2007). One in every seven Michigan residents or 15% of the total Michigan population depends on Medicaid. More than 30% of Michigan's 2.5 million children were enrolled in Medicaid in 2007. Seventy-five

percent of Medicaid recipients are from lower income families, including pregnant women, children, and parents or other care-giver relatives (Fairgrive, 2007). Figure 1 shows a trend of the Michigan Medicaid expenditure from 1998 to 2008. In addition to the steady increase of Medicaid expenditures, beneficiaries of the Michigan Medicaid program have also increased in number.

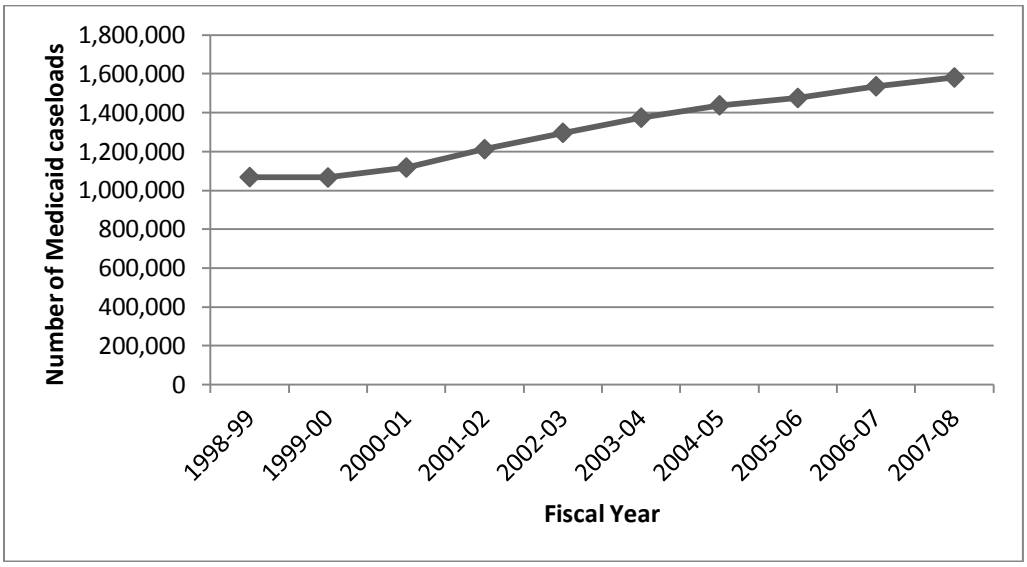


Source: Figure is based on Grabowski (2008)

Figure 1. Michigan Medicaid Expenditure (in million $)

Figure 2 shows a steady growth rate of Michigan Medicaid caseloads over the years, which can provide indication of increase of actual Medicaid beneficiaries. In the near future, the caseloads and costs of the Michigan Medicaid program will increase, because the current economic downturn has worsened state unemployment (Finkbeiner, D. quoted in Opsommer, 2010). This situation has been intensified due to the recent economic slowdown and especially due to the near-collapse of the three Michigan-based American auto giants: General Motors, Chrysler, and Ford. The downsizing of these three Detroit-based auto industries has seriously increased the state unemployment rate while at the same time decreasing wages and salaries. A large portion of the state population has historically been directly or indirectly dependent on the auto industry;

moreover, employees of the manufacturing sector—such as auto industries—received good health care benefits (Fairgrive, 2007). Additionally, in Michigan, due to the effect of the recent federal health care reform bill, it is estimated that the Medicaid expansion will add 375,000 individuals to the Medicaid program (Angelotti and Fosdick, 2010).



Source: Figure is based on Grabowski (2008)

Figure 2. Michigan Medicaid Program Caseloads

The increase in the state's Medicaid beneficiaries and costs and the decrease of the state's ability to use special financing methods to fund Medicaid by generating money for General Funds/General Purpose (GF/GP) also jeopardizes Michigan's ability to finance the future Medicaid program effectively. Michigan has used various payment strategies to enhance the federal financial contribution to the Medicaid program such as Disproportionate Share Hospital Payments (DSH), intergovernmental transfers/adjustor payments, school-based payments, certified public expenditures, and others. For example, the federal government regulations allowed supplemental payments to hospitals that provided higher proportions of their services to Medicaid beneficiaries and the uninsured to count toward the match. This payment method is known as the DSH payment method.

The DSH method was similar in structure to Medicaid reimbursement for health care services provided by the hospitals. State financial contributions were matched by the federal Medicaid funds at the rate of the Federal Medicaid Assistance Percentage (FMAP). As there are no specific services for DSH payments, the state therefore could use DSH payments in flexible ways. For example, Michigan used DSH payments to create funds for safety nets for hospitals and public medical education programs, and also financed County administered low-income health benefit programs. Thus Michigan also used DSH payments as a tool to reduce GF/GP expenditures in the Medicaid program (Fosdick, 2008).Table 1 shows a picture of annual GF/GP savings by DSH payments from fiscal years 1990/1991 to 2004/2005.

In a similar way, Michigan used other special financing strategies to increase federal financing participation in various Medicaid programs, and thus reduced GF/GP expenditures in Medicaid programs. Table 2 shows a total savings to Medicaid in Michigan due to the use of special financing strategies for fiscal years from 1990/91 to 2006/07. The state's inability in using special financing, due to the federal government closure of special financing payment loopholes over the years, has forced Michigan to make necessary adjustments in Medicaid expenditures of significant dollar amounts reaching from $117.5 million to about $166.3 million for each year between fiscal year 2002/03 and 2005/06 (Table 3). In contrast, data shows that- the increased amount of special financing might prevent the state from facing large increases in Medicaid costs.

Table 1

Public Hospital DSH Savings

Fiscal Year	Annual GF/GP Savings
1990-91	$200,000,000
1991-92	$233,500,000
1992-93	$255,523,800
1993-94	$314,703,600
1994-95	$47,175,900
1995-96	$34,463,100
1996-97	$14,488,000
1997-98	$33,396,400
1998-99	$40,777,000
1999-2000	$31,552,600
2000-01	$39,965,800
2001-02	$34,575,200
2002-03	$37,229,800
2003-04	$69,551,800
2004-05	$45,805,700
Total	$1,432,708,700

Source: Fosdick, 2008

Table 2

Total GF/GP Savings to Medicaid by Fiscal Year

Fiscal Year	Annual GF/GP Savings
1990-91	$200,000,000
1991-92	$233,500,000
1992-93	$410,256,500
1993-94	$493,452,900
1994-95	$497,705,900
1995-96	$507,766,800
1996-97	$523,049,500
1997-98	$507,248,600
1998-99	$511,506,600
1999-2000	$744,887,600
2000-01	$782,497,500
2001-02	$732,937,300
2002-03	$615,391,000
2003-04	$496,191,600
2004-05	$329,875,400
2005-06	$172,128,400
2006-07	$169,006,600

Source: Fosdick, 2008

To put it in a context with the rest of the nation, Michigan's unemployment is far higher than the national rate. Its Medicaid caseloads, number of beneficiaries, related costs, and the diminished ability of special financing to supplement Medicaid costs have

made the future of Medicaid in Michigan a critical issue (Fosdick, 2008). Some desperate measures for cost containment are needed to keep the Michigan Medicaid program alive.

In recent years, Michigan has implemented various strategies as part of the state's ongoing cost containment efforts. Of all the policies and strategies for cost containment, savings from prescription drugs in Medicaid has received significant attention as a potential source due to its potential advantages over any other structural or policy adjustment in this regard (Kibicho, 2007). Michigan has implemented the following four specific policies to contain Medicaid prescription drug costs: 1) in February 2002, introduced a preferred drug list for Medicaid beneficiaries known as the Michigan preferred product list (MPPL); 2) in February 2003, implemented the Michigan Multistate Pooling Agreement (MMSPA), a joint purchasing arrangement with Vermont, also known as the National Medicaid Pooling Initiative (NMP); 3) in November 2003, established a maximum allowable cost for pharmacy reimbursement; and 4) in May 2004, coordinated a Michigan multi-state purchasing arrangement (Kibicho, 2007). Although these cost-containment initiatives contributed a considerable savings, in reality, these cost-savings strategies achieved only modest success in limiting the escalation of Medicaid prescription drug expenditures in terms of total state shares (Grabowski, 2008).

To contain costs of prescription drugs, a generic substitution policy has received considerable attention. Increasing use of generic drugs for prescriptions can reduce a significant amount of costs for the Medicaid program. Additionally, the Department of Health and Human Services (DHHS) (2010) stated that the quality of generic drugs is similar to brand-name and non-generic drugs, while generic drugs are priced much less compared to brand-name/non-generic drugs (DHHS, 2010; OIG, 2006). In recent times,

ten states (Florida, Kentucky, Massachusetts, New Jersey, New Mexico, Oregon, Rhode Island, Tennessee, West Virginia, and Wyoming) have implemented a generic substitution policy for Medicaid prescription drugs (Shrank et al., 2010). A survey based on the top six therapeutic drug categories found that the percentage of state generic drug prescriptions dispensed vary from state to state from *i.e.*,44.8% to 60.1% (Cox, Behm and Mager, 2006). One AAA report (2010) found that, in general, 80% drugs have its generic and other 20% drugs have no generic substitutions.

Table 3

Special Financing Change in GF/GP Expenditure for Medicaid

Year	Increase in State Medicaid Expenditure ($)	Annual Change in Financing Savings ($)	Change in State Medicaid Expenditure w/o Special Savings ($)
1998-99	165,282,300	(4,258,000)	169,540,300
1999-2000	82,427,500	(233,381,000)	315,808,500
2000-01	54,801,400	(37,609,900)	92,411,300
2001-02	11,360,800	49,560,200	(38,199,400)
2002-03	324,639,000	117,546,300	207,092,700
2003-04	337,703,800	119,199,400	218,504,400
2004-05	453,159,200	166,316,200	286,843,000
2005-06	300,307,700	157,747,000	142,560,700
2006-07 (est.)	177,609,600	3,121,800	174,487,800

Source: Fosdick, 2008

In the context of Michigan Medicaid prescription drug cost containment, a generic-substitution policy becomes a viable option because Michigan has the potential to use more generic substitutions. The Centers for Medicare and Medicaid Services (CMS) data of 2009 shows that a total of only 66% generic drugs are utilized for Medicaid beneficiaries, which is considered moderate as compare to many other states. A report prepared by DHHS determined that in 2004 55% of drugs prescribed to Michigan Medicaid patients were generic (Grabowski, 2008). According to Cox et al. (2006), the

generic fill rate in Michigan was 52.7% in 2006. Furthermore, it is estimated that switching from brand-name to generic drugs could have a 11% reduction in annual overall drug costs. In monetary terms, according to IMS Health, an estimated 1% increase in generic drug utilization can produce approximately $4 billion per year savings nationally for Medicaid (Jaeger, 2005). According to CMS's data in 2009, a 1% increase of generic drug use could potentially save the Michigan's state share $4,616,125, and 5% increase in generic use could save the state share $ 23,080,624. Based on the CMS estimate, Michigan can save nearly $64,625,750 a year in Medicaid prescription drugs if it can optimize the use of generic drugs instead of the current 66% use of generic. A Lewin Group report (2011) estimated that Michigan can save a net $453,573,163 over the next ten years (*i.e.,* from 2012 to 2021) if the Medicaid pharmacy program—including increased amounts of generics in Medicaid prescription drug use—was optimally managed. All this previous research and data suggest that Michigan can increase generic substitutions at least 14% to 23% and even more to achieve the maximum limit of using generic drugs and thus, can save a significant amount of money from its Medicaid prescription drug expenditures.

Increasing use of generic drugs in generating to cost savings has received significant attention for another very practical reason of provision of specialty drugs or "super drugs." Cost of specialty drugs has become a concern for Medicaid and private employers as well. Greene (2010) mentioned that prescription drug costs in the US increased 3.1% and 5.3% for 2008 and 2009 respectively. Hospital and physician costs also increased by 55% and 4% respectively in 2008 and 2009, which was slightly less than previous years but at the same time costs of specialty drugs increased in 16.3% rate

according to 2011 Medco Drug Trend report. Costs of some specialty drugs have increased at a 20% rate over past several years. Greene (2010) mentioned, by quoted Rebecca McLaughlan, that currently a number of specialty drugs are in the pipeline of FDA approval. Most of these drugs are "over $1,000 per month for rheumatoid arthritis and cancer drugs". In the context of current financial crisis, higher costs of specialty drugs can create huge pressure in managing Michigan Medicaid prescription drug program efficiently.

The present study emphasizes two crucial issues related to the Medicaid cost containment in Michigan. First, this study asks if implementation of a generic substitution policy can be an effective and efficient strategy for containing prescription drugs costs in Michigan Medicaid. Second, if yes, then how much Medicaid prescription drug costs can be saved by the generic substitution policy in Michigan and from which therapeutic classes? Three research questions are proposed based on these two issues.

1.4 Significance of the Study

Cost containment in the Medicaid prescription drugs program has received significant for some obvious reasons. Currently, states spend16- 20% of its budget on Medicaid-related expenses, which creates a serious toll in the fiscal management. Michigan has introduced several strategies to contain Medicaid prescription drug costs and they have brought some modest success. However, no significant studies with a multi-year time frame and data have been conducted in terms of generic substitution and its impact on cost containment for Medicaid prescription drug costs in Michigan. No study to date has been conducted that highlights the pros and cons of formulating a generic substitution policy in Michigan in terms of cost containment in the Medicaid

prescription drugs program. The present study is especially significant for two very distinct reasons. First, it has attempted to show the savings of the Michigan Medicaid prescription drugs program by implementing a generic substitution policy in a monetary amount using comprehensive CMS data of multiple years. Prior studies mostly used data of one quarter to analyze the cost containment issue of the Michigan Medicaid prescription drug issue. This research uses data of several years comparing two other pioneering states regarding implementation of generic substitution policy in their Medicaid prescription drugs programs.

Second, in addition, this study does not only identify the potential savings opportunity by mandating a generic substitution policy at large, but also specifically identifies brand drugs where the Michigan Medicaid prescription drugs program could save a significant amount. It specifically identified brand drugs that have been reimbursed even though having a therapeutically equivalent available in the market. It identified the most expensive ten brand drugs that were reimbursed in the Michigan Medicaid prescription drugs program, and thus identified specific areas of intervention to mandate a generic substitution policy.

From a policy point of view, this research provides a blue print to the stakeholders regarding the Michigan Medicaid prescription drugs program cost containment. It identifies what to do and how to do it, regarding the cost containment issue of the Michigan Medicaid prescription drugs program.

1.5 Organization of the Study

This study is organized in to seven different chapters. The first chapter presents a background of Medicaid and cost issues of its prescription drugs program. This chapter lays out the necessity and the importance of mandating a generic substitution policy for

Michigan Medicaid prescription drugs program. Chapter Two provides a review of the relevant literature of the current research issue of containing cost in Medicaid, as well as the Michigan Medicaid prescription drugs program. Chapter Three deals with the research approach and the research methodology including research questions and research hypotheses, population, data sample, and the collection of data and data analysis. This chapter also discusses regression models, including all variables of the models, to examine various research hypotheses, and the descriptive statistical methods used in examining hypothesis 3. Chapters Four and Five mainly deal with the statistical models of regression analysis to examine hypotheses one and two respectively. Chapter Six deals with hypothesis three using descriptive statistical methods to quantify the savings of the Michigan Medicaid prescription drugs program through generic substitution. Chapter Seven is the conclusion of the dissertation. It discusses findings and recommendations of the current research, as well as potential future research options regarding implementation of a generic substitution policy as a cost containment approach in the Michigan Medicaid prescription drugs program.

CHAPTER II

LITERATURE REVIEW AND CONCEPTUAL FRAMEWORK

2.1 Introduction

Skyrocketing health care costs have long been a concern for scholars and practitioners. The Nixon administration first raised concern about the crisis of rising health care costs in 1969 (Starr, 1982). Scholars have long been asking the question, "Can we control health care costs?" (Herzlinger, 1978; Weinberger, 1981; Maciosek, Coffield, Flottemesch, Edwards, and Solberg, 2010; Brill, 2010). Additionally, scholars have investigated ways to contain health care expenditures (Delan, 2010; Kelly and Fabious, 2010; Delaune and Everett, 2008; James and Bailey, 2010). In this regard, a major focus is on how to contain costs in the Medicaid program as the single largest health insurance program in the USA. For cost containment of Medicaid, the issue of prescription drug costs has received significant attention by scholars as one of the major factors related to state finance.

This chapter discusses literatures relevant to the Medicaid prescription drugs as well as costs containment of the prescription drugs programs. The main goals of this literature review are: 1) to depict a overall picture of current health care issues especially related to high costs and its impact in managing government run health care programs such as Medicaid prescription drugs program; 2) to identify literatures related to brand drugs and generic use in containing costs of Medicaid prescription drugs program especially related to brand and generic drugs; 3) to identify cost issues,

strategies previously used to encounter prescription drugs cost escalation with strengths and weakness, and potential policy alternative(s) to enhance cost containment efforts specific to Michigan Medicaid prescription drugs program; and 4) to infer inferences related to the current research.

The following review is organized into six sections based on the varied scope and nature of the related literatures. The first section deals, in general, with research and studies related to Medicaid prescription drug costs strategies, generic versus brand quality issues, and especially the strategy of generic drug substitution and issues related to its applicability. The second section of the literature review deals with research and studies related to issues of Michigan's cost containment strategies regarding Medicaid prescription drugs costs. The third section deals with issue of applicability of the generic substitution as cost containment mainly from a policy perspective. Section Four discusses literatures related to necessity of implementing generic substitution policy. Section Five summarizes the findings of the literature review and, finally, the sixth section provides a conclusion of the chapter discussion.

2.2.Brand Drugs, Generic Utilization, and Medicaid Cost Containment

The Public Policy Institute of the American Association of Retired Persons (AARP) (2010) discussed the strategies for increasing generic drug utilization and the associated savings. The report discusses the cost advantages of using generic drugs. It describes various approaches to increasing generic drug use for prescribers and patients, which include designing health benefit packages to attract consumers, educational efforts about generic drugs for both consumers and physicians, e-prescribing, drug pricing/reimbursement in terms of promoting generic drugs by limiting the amount of

reimbursement for certain drugs, redesigning prescription pads, financial benefits for pharmacists and prescribers, and federal legislation in terms of promoting generic utilization. One of the important aspects of this report is that it emphasizes the critical role of government in increasing generic drug utilization. Because physicians have opinions both in favor and against the equivalency of generic drugs to non-generic brand drugs, the government's role may be significant in increasing the utilization of generic drugs, at least in the Medicaid program.

Simon, Tennyson, and Hudman (2009) analyzed state policies such as preferred drug lists, tiered copayment systems, and others in aiming to limit spending on Medicaid prescription drug costs and growth of US states from 1990 to 2004. In examining state strategies in containing Medicaid prescription drugs cost, this study used data of "Pharmaceutical Benefits Under State Medical Assistance Programs" based on annual report of National Pharmaceutical Council (NPC) state surveys of 1990-2004. In addition, data on states preferred drug lists were collected from National Council of State Legislatures (NCSL). These data were checked and supplemented by data available by other published sources. In order to verify these data Medicaid offices of each state were contacted. Based on NPC and NCSL and data provided by state Medicaid offices, individual state data profiles were created to identify state strategies and policies to control prescription drug costs from 1990-2004. The authors found that these policies helped states contain Medicaid prescription drug costs in general, although the study did not show any robust success in term of cost containment. Among the policies initiated by the states to contain prescription drug costs, preferred drug list (PDL), and tiered co-payment systems proved more effective than other policies. This study implies that state

policies regarding control costs may be successful in containing Medicaid prescription drug costs.

A vast number of literature (Kesselheim et.al. 2008, FDA, 2011, American Medical Association, 2007) deal with the quality issue of generic and brand drugs. A number of studies dealt with the issue if quality of generic drugs is similar to brand drugs. In getting FDA approval, generic drugs are required to meet the same quality and performance as the brand drugs in terms of identity, strength, quality, purity, and potency. Generic drugs must meet rigorous standards established by the FDA for their approval. According to FDA approval, standard generic drugs have to contain the same active ingredient, strength, dosage form, and route of administration as the brand name (or reference) product (FDA, 2011). In case of inactive ingredients, generic drugs do not need to contain the same ingredients as the brand drugs. A generic drug must show bioequivalence to its brand drug. By performing review of bioequivalence data and tests, FDA ensures that performance of generic drugs will work as the same as its respective brand name drugs. This approval and performance criteria applies to all generic drugs. Manufacturing, packaging, and testing sites of any generic drugs must pass the same quality standards and exact specifications set for the brand name drugs.

Kesselheim, et al. (2008) examined the issue of bioequivalence of generic and brand drugs. The authors summarized clinical evidence s to compare generic and brand-name drugs used in cardiovascular disease. In doing so, the authors did a systematically searched peer-reviewed publications in MEDLINE, EMBASE, and International Pharmaceutical Abstracts from January 1984 to August 2008. A total of 47 articles were selected to analyze cardiovascular medications, of which 38 or 81% articles were

randomized controlled trials. In addition, the authors categorized authors' positions on generic substitution as negative, positive, or neutral for the study. The result was as follows: clinical equivalence was found in 7 out of 7 or 100% of β -blockers, 10 out of 11 or 91% of diuretics, 5 out of 7 or 71% of calcium channel blockers, 3 out 3 or 100% of antiplatelet agents, 2 out 2 or 100% of statins, 1 out of 1 or 100% of angiotensin-converting enzyme inhibitors, and 1 out of 1 100% of α-blockers. In narrow therapeutic index drugs, clinical equivalence was found in 1 out of 1 RCT or 100% of class 1 antiarrhythmic agents and 5 out of 5 RCTs or 100% of warfarin. Aggregate effect size (n = 837) found −0.03 (with 95% confidence interval, −0.15 to 0.08), which confirmed of no superiority of brand-name to generic drugs. Among 43 editorials, 23 or 53% showed a negative view of generic drug substitution. The authors concluded that "Whereas evidence does not support the notion that brand-name drugs used in cardiovascular disease are superior to generic drugs, a substantial number of editorials counsel against the interchangeability of generic drugs"(Kesselheim et.al. 2008. p.2514).

Davit et al. (2009) analyzed bioequivalence of 2070 generic and brand drugs approved by the FDA from 1996 to 2007. The authors compared the effectiveness of FDA approval process of bioequivalence measures of generic drugs and their brand drug counterparts in the US over a twelve years period within 1996-2007. This analysis compared bioequivalence measures of 2070 FDA approved single dose orally administered generic and brand drugs from 1996 to 2007. In this study of bioequivalence study drug peak plasma concentration (C_{max}) and area under plasma drug concentration versus time curve (AUC), which represents drug rates and absorption rate were evaluated. C_{max} and AUC geometric mean ratios of corresponding 2070 generic and brand drugs that

used 12 to 170 subjects were determined individually through bioequivalence studies. And then the average of GMRs from the 2070 individual study was calculated and besides, the differences between means of generic and brand drugs were calculated for both C_{max} and AUC. The average difference in C_{max} and AUC between generic and brand drugs were calculated as 4.35% and 3.56%, respectively. Besides, almost 98% of the bioequivalence studies within this found the difference between AUC of generic drugs from that of the brand drugs was less than 10%. This study concluded that there is no significant difference between generic and brand drugs and thus supported the FDA claims that generic and brand drugs formulations are therapeutically the same.

Shrank et al. (2010) evaluated the relationship of state policies to cut down Medicaid as well as prescription drug costs and the use of generic drugs in the Medicaid program. State policies of generic substitution policy and the role of pharmacists in dispensing and patients in utilizing drugs regarding Medicaid prescription drug have varied. In doing so, the authors used quarterly data of 2006 and 2007 for forty nine states provided by Centers for Medicare and Medicaid Services (CMS). In addition, annual survey data provided by National Associations of Boards of Pharmacy was also used in the study. Shrank et al. (2010) evaluated the relationship between different generic substitution policies and the use of a cholesterol-lowering generic drug, Simvastatin, and the brand name equivalent drug, Zocor after its patent expired. The authors found that states that implemented policies that required patients' consent prior to generic substitution used generic substitution 25% less than the states that did not have a requirement of prior patient consent. Shrank et al. (2010) concluded that states could save more than $100 million in their Medicaid expenditures by establishing a policy of

eliminating the requirement of patient consent about three leading drugs that are going to expire in 2011 including Zocor. The authors found that although it is appealing, in general, to have more choice of patients regarding use of their drugs, more restrictive strategies such as generic substitution policy with no prior patient consent is more effective in cost savings. The authors also found that cost per prescription is also lower in states that have generic substitution policy without prior patient consent than states with prior patient consent provision and having no generic substitution policy. This study shows that a public policy can make a difference in cost containment of Medicaid prescription drugs by using policy regarding generic substitution.

Brill (2010) examined selected brand drugs used in Medicaid prescription drugs program while generics are available in the market for those brands and quantified over spending on brand drugs. By analyzing a large subset of 2009 Medicaid drug program data related to the Medicaid drug rebate program, Brill (2010) identified that "states' Medicaid programs engaged in a large amount of unnecessary and wasteful drug spending by reimbursing pharmacies for relatively costly brand products when identical generic products are available." Brill studied CMS's 2009 data of 20 heavily used drugs, which contained over 120,000 data points, used in states Medicaid prescription drug programs for which a generic substitute was available in the identical dosage form, strength, package type, and package size. His research found that "Medicaid wasted an average of $96 per prescription. In other words, for these twenty chemicals, every time a Medicaid beneficiary received a brand prescription instead of a generic, Medicaid wasted nearly $100. By this metric, Clozaril and Percocet are the most wasteful, with an average of overspending exceeding $200 per prescription. Fully half of the drugs had an average

waste of over $100 per prescription. Toprol-XL and Zithromax waste averaged only $8 and $12 per prescription, respectively." Brill (2010) estimated $271 million of wasteful spending due to the underutilization of generic substitutions available in the market. He also estimated that if generic substitutions were properly utilized, then total Medicaid spending could be $1.49 billion instead of the actual cost of $1.74 billion in 2009.

The study of Sharnk et al. (2007) aimed to evaluate if the use of generic drugs is influenced by physician, patient, pharmacy benefit design, or pharmacy characteristics. The authors used Anthem Blue Cross and Blue Shield (ABCBS) prescription management in the western United States, specifically Colorado and Nevada region for the study. They analyzed claims of 5,399 patients filling in at least 1 of 6 chronic medications by generics alternatives over the period from 2001 to 2003. The study included drugs classes calcium channel blockers (CCBs), HMG CoA reductase inhibitors (statins), oral contraceptives (OCs), angiotensin converting enzyme inhibitors (ACE-Is), istamine 2 receptor antagonists (H2RA), and proton pump inhibitors (PPIs). These drug classes were chosen due to their common prescription pattern and also the availability of multiple brands options with identical therapeutic equivalence. Results of the study revealed that 1,262 or 23.4% patients out of 5,399 filled new prescriptions with generics. 606 or 14.9% patients switched to a generic drug in the same class in the subsequent year who initiated with brand medications. The study found that patients who live in the 'poorest' zip codes have the least chance of initiating a prescription with the generic substitution. Patients of middle-income and high-income zip codes are 28% and 29% respectively more likely to initiate in therapy with a generic medication. The study also found that older male patients are less likely to be initiated in therapy with a generic

medication than younger patients. Female patients aged 25 to 39 years of age are 36% more likely to be initiated in therapy with generic medication than females aged 25 years and less. The study found that generalist physicians are more willing than medical subspecialists, obstetrician, and gynecologists to prescribe generics. The study did not find any association between pharmacy benefit design and pharmacy type with prescription initiation with generic drugs. One of the crucial findings of the study is that the initial choice of the prescription is the strongest determinant of subsequent use of any medication. This study implies clearly that patients in the lowest-income zip codes (*i.e.*, who are mostly covered by both Medicaid and Medicare) are less likely to received generic substitution at the beginning of the prescription therapy. It also implies that neither physicians nor pharmacies provide adequate advice to these patients about available generic substitution. One of the reasons may be that since Medicaid pays for these prescriptions, pharmacies are indifferent about costs, or pharmacies are more interested in making higher-cost sales.

Liberman and Roebuck (2008), by using plan sponsor data from 2007 to 2009, found that with the increase of generic dispensing ratio (GDR), prescription drug costs have decreased significantly in the years from 2007 to 2009. By analyzing data of almost 14 million beneficiaries, the authors found that a 1% increase of GDR was associated with a 2.5% decrease in gross pharmacy costs, i.e., the Medicaid reimbursement costs. Liberman and Roebuck (2008) concluded that savings in prescription drugs are realized when GDR increased. They estimated that during 2007-2009 period more than one-half of savings was derived from the lower drug prices due to brand to generic conversions. This study substantiated two conclusions: first, states' Medicaid programs can save

prescription drug costs by switching from brand to generic drugs, and second, by limiting the use of brand name drugs.

Miller et al. (2007) examined whether a multi-interventional program can limit in increasing costs of prescription drugs while ensuring delivery of an adequate quantity of medications. Four interventions were introduced to encourage cost effective drug prescription. These interventions were introduction of generic substitutions, removal of prescription of over the counter drugs, quantity limit for medications without indicating for daily use, and a mandatory pill splitting for select drugs. Miller et al. (2007) examined ability of short term cost control by each of these four interventions by comparing class specific spending for all prescription drugs before and after the intervention measures were implemented. By examining data from a three-year period of a health plan in North Carolina that implemented a series of evidence-based interventions in containing costs of prescription drugs in a varied population, Miller et al. (2007) found that at baseline in 2003, 36% of plan members who used prescription drug benefits claimed 2.8 drugs on average per member per quarter and 60% of members claimed brand-name only drugs. Total plan costs of prescription drugs in 2003 were $10.1 million or $37.57 per member per month. In comparison, similar hospital-based health plans had an average of 1.9 claims per member per quarter at a cost of $27.73 per member per month. The implications of this study are that implementation of four cost saving strategies, which Miller et al. (2007) called "easy-to-implement interventions" became successful in containing prescription drugs costs while maintaining a necessary quantity of delivery of selected classes of long-term drugs. In terms of cost containment intervention in Medicaid prescription drugs, the results of this study are quite significant.

West et al. (2009) studied medication access problems, which refers a situation where patients are not being able to access clinically indicated medication refills or new prescriptions due to various institutional and non institutional reasons, of psychiatric patients in ten states' Medicaid programs and adverse events associated with medication access problems, and determined that prescription drug utilization management is associated with the access problems and adverse events. By selecting 4,866 psychiatrists randomly from the American Medical Association's master file who treated Medicaid patients, psychiatrists were randomly assigned a start day and time to report on two Medicaid patients, for a total of 1,625 patients. West et al. (2009) identified the most common access problems as not being able to access clinically indicated medication refills or new prescriptions due to Medicaid restrictions of not covering or approving a specific required drug, prescribing a medication not clinically preferred because of restrictions of covering clinically indicated or preferred medications, and discontinuing medications as a result of prescription drug coverage or management issues. Thus, the authors found that "patients with medication access problems had 3.6 times greater likelihood of adverse events, including emergency visits, hospitalizations, homelessness, suicidal ideation or behavior, or incarceration"(p. 601). According to West et al. (2009), the states that had lowest medication access problems were New York (27.1%), Texas (31.0%), and California (32.4%), while Tennessee (63.3%), Georgia (64.2%) and Michigan (64.7%) had the highest rate of medication access problems in Medicaid. In this regard, West et al. (2009) concluded that patterns of associations of events and medication access problems have an impact on beneficiaries and their illness. Thus, more effective Medicaid prescription drug management and financing practices are needed to

overcome access problems related not only to psychiatric Medicaid patient's medication but also all Medicaid patients. Although this study was conducted on psychiatric patients, the results and conclusions in this regard can be considered in a broader Medicaid context to meet the needs of Medicaid cost containment, especially in the context of prescription drugs in Michigan, which was found as the state with the highest rate of medication access problems.

Cunningham (2005) used data of Community Tracking Study (CTS) household surveys conducted in 2000–01 and 2003 to examine five commonly used strategies in Medicaid cost containment by states including 1) prior authorization in dispensing a drug; 2) copayments that beneficiaries are required to pay for each prescription; 3) quantity limits of prescription, or in other words, states limit the maximum number of prescriptions that Medicaid will cover during a certain period of time; 4) generic substitution law drugs; and 5) step therapy that physicians need to demonstrate that a lower-cost drug is ineffective before prescribing a more costly alternative. These studies included a total of 100,600 people from both 2000-2001 and 2003 surveys to analyze the survey question "During the past twelvemonths, was there any time you needed prescription medicines but didn't get them because you couldn't afford it for?" Then the answers were compared the degree of prescription drug access problems for adult Medicaid beneficiaries with the access problems of those adults with private insurance coverage and those without. Then these access problems were compared against the cost containment policies as well as other factors related to prescription drug access of adult Medicaid beneficiaries and then it also examined outcomes of state cost containment policies on change in access problem within the period of 2000-01 and 2003. Result of

this study found that implementation of all five strategies did not solve problems in Medicaid cost containment. Rather it increased problems in getting prescription drugs in states that implemented all five strategies, as opposed to states that did not implement all five strategies. Among the five strategies implemented in Medicaid cost containment, prior authorization and mandatory generic substitutions had the largest effects on access to prescription drugs.

Wagner, Heisler, and Piette (2008) examined the relationship between amounts of co-payment and a decrease in pharmaceutical spending over a period of time from 2003 to 2008. In doing so, the authors examined the relationship of copayment and four types of cost-related underuse, such as taking fewer doses, postponing taking a medication, failing to fill a prescription at all, and taking lower medication doses as prescribed. A nationwide survey of US adults aged 50 taking medication for a chronic condition was conducted during November and December of 2002. Survey responses of a total of 2,869 persons were included in the study. Information provided by the participants on seventeen chronic conditions (i.e., "arthritis, asthma, chronic back pain or sciatica, high cholesterol, COPD (chronic bronchitis, emphysema, or COPD), depression,diabetes, heartburn, acid reflux, or irritable bowel syndrome, atherosclerosis (blocked arteries in the heart, angina, or chest pain from heart disease), heart failure, high blood pressure or hypertension, myocardial infarction (heart attack), migraine headache, osteoporosis, stomach or duodenal ulcers, and stroke"(Wagner et al. 2008, p.54), medication they take for those conditions, and whether they underused any medication due to cost. By using multivariate logistic regression, the authors analyzed those who reported paying co-payments for their prescriptions. Research data show a strong positive association

between co-payments and cost-related medication underuse. The authors thus concluded that promoting the use of generic drugs may be a potential solution to ensure appropriate amount of doses for Medicaid patients.

A report by DHHS (2010) discusses barriers and opportunities for the use of generic drugs as an important tool to control health care costs. According to the report the use rate of generic prescriptions was almost 75% in 2009. In 2004, the generic use rate was 57%. Barriers to generic drugs derive from state laws on generic substitution, factors related to generic availability in the market, and patients and prescribers' perception and behavior. State laws control the practice of pharmacies, and thus determine when pharmacies should or must dispense generics to the patients. States' approaches differ in terms of dispensing generic substitutions by pharmacists. Some state laws require a pharmacist to substitute generic drugs instead of a brand drugs if the prescriber does not specify brand name drugs, where as some use a more permissive approach for pharmacists and allow them to dispense generic drugs at their discretion when the prescriber does not identify otherwise. In addition, some states require a patient's consent in substituting brand name drugs with generics. Few states - limit delivering generics by the pharmacist if those generics have a Narrow Therapeutic Index (NTI), which refers to a drug that has small differences between the effective dose and a toxic dose (DHHS, 2010), while some states prohibits substitution of brand by generic NTI drugs. The availability of generic drugs may be delayed by a settlement, generally called a "pay for delay" or reverse payment, through which a brand name drug company pays the generic drug company not to enter in to the market with its generic drug for a certain period to avoid competition. In 2009, nineteen "pay for delay" arrangements were reported where

generic drug entries were delayed on an average of 17 months. The consumer's perception is one of the major factors in using generic drugs because in many cases patients have discretion in choosing their drugs. A survey of 2500 commercially insured beneficiaries revealed that 56% believed that Americans should use more generics, while only 36% of the same survey preferred using generics for them. Physician prescribing behavior is also important regarding the use of generic drugs. In many cases physicians do not prescribe generic drugs due to the safety and effectiveness of generic drugs. The National Ambulatory Medical Care Survey found that the majority of physicians referred drugs by their brand name rather than generic names. It implies that physicians often prescribe medicine out of habit, not by intention. DHHS concludes that in these cases allowing pharmacists to substitute generics can be an important factor in promoting generic drugs. The DHHS report emphasizes elimination of "pay for delay" arrangements and speedy review of generic drugs to gain earlier access to generic drugs in the markets. The major implication of this report is that is focuses on various roles that a government can play in increasing the use of generic drugs and thus create savings for Medicaid.

A report from the Office of Inspector General (OIG) (2006) discussed generic drug utilization in state Medicaid programs in 2004. It found that overall state Medicaid programs, on average, 54% of all prescriptions dispensed were generic. The state "generic utilization rate" i.e., the percentage of all dispensed generic prescriptions, varied from 41% to 61%. On average, 20% of prescriptions dispensed were for drugs that had no generic substitute. Use of generic substitution rates was consistent among state Medicaid programs. One of the significant issues in this regard as the OIG report found that within certain therapeutic classes (i.e., a group of drugs that treat the same medical

conditions) the generic substitution rate is significantly higher in some states than others. The report found that the generic drug substitution rate varied significantly among states in the therapeutic classes of psychostimulants, i.e., anti-depressants, diabetic therapy, antiulcer/gastrointestinal preparations, anticoagulants, bronchial dilators, and systemic contraceptives. For example, the generic substitution rate for anticoagulant drugs, which is used as a blood thinner, ranged from 27% in one state to 100% in another, with a difference of 73% in the substitution rate. The OIG report found a strong relationship between lower substitution rate or higher single-source drug prescription and physicians drug prescription pattern, which is not always necessarily related to the absence of generic drugs. The generic utilization was highest in those states where brand prescribing was low. The generic utilization rate was thus influenced by the physician drug prescribing pattern.

Increasing use of generic substitution has received significant attention as a cost saving tool in managing the Medicaid federal and state policy and several researchers have argued for increasing use of generic drugs in the Medicaid program. Despite the support for increasing use of generic drugs in Medicaid by mandatory policy, an opposite view has also emerged. Some physicians questioned about the equivalency of generic drugs to brand drugs and if FDA approval process and monitoring of generic drugs reflect "true pharmacologic-clinical impact of these standards" (Sussman,2010). This group of physicians depicts mandating a generic substitute policy and thus therapeutic substitution as 'harmful' in patient care. These physicians argued that by this system a "patient gets something that the payer, not the physician, deems close to the prescription, but not identical" (O'Connor, 2010). In this vein, Margolese,Wolf,Desmarias, and Beauclaria

(2010) stated that "generic drugs "are not required to undergo efficacy and safety studies before being marketed. A generic is approved if the manufacturer shows an "essential similarity" to the original medication through identical routes of administration, and type and quantity of active compound as shown by bioequivalence studies" (quoted in Sussman, 2010). Thus it is argued that change from brand drugs to generic can cause severe negative impact on patient health and thus overall patient care can be questioned by this cost savings approach in Medicaid prescription drugs (O'Connor, 2010).

The above literature review provides an overall picture of the quality issue of generic and brand drugs, and policies that can influence increasing use of generic drugs and potential savings due to use of generics instead of brand drugs. These issues are crucial to the study of the current context of Michigan as well as the current dissertation. Literatures in the following section detail these issues in the context of the state of Michigan, followed by a discussion that provides a rationale to implement a generic substitution policy as a cost containment strategy for Michigan.

2.3.Medicaid, Generic Utilization, and Prescription Drug Costs in Michigan

Kibicho (2007) studied whether policies implemented by Michigan related to its Medicaid program reduce expenditures of per day's supply (EDS) of drug therapy. She discussed four policies related to curbing prescription drug costs in Michigan, such as 1) a preferred drug list introduced in 2002, 2) a joint purchasing arrangement with Vermont began in 2003, 3) maximum allowable cost for pharmacy reimbursement in 2003, and 4) a multi-state purchasing arrangement in 2004. These policies are discussed in the following section.

2.3.1. "Brand Medically Necessary Edit"

"Brand medically necessary edit" or "prior authorization" requires physician approval that a brand drug is essential for patients, instead of a generic drug prior to payment. Prior authorization is based on the Michigan Department of Community Health (MDCH)-specific definition of brand and generic drugs according to the Michigan Pharmaceutical Product List (MPPL). Primarily, prior authorization is aimed to limit prescriptions of questionable drugs in terms of the therapeutic appropriateness identified through a drug utilization review, but it became a tool to control escalating Medicaid prescription drug costs (Fox, Trail, Reinhard, and Crystal, 2004). In recent years, Michigan, as well as other states, has focused on limiting the prescription of expensive brand drugs through the prior authorization process (Fox et al., 2004). Although a comprehensive process has been designed for prior authorization to limit prescription of brand or drugs outside the preferred drug lists (PDL), in reality, it becomes less effective for other cost containment strategies that appears contradictory to prior authorization. For example, although the Michigan Multi-State Pooling Agreement (MMSPA) has received mixed success, in many cases, it became apparent that drug manufacturers intended to give a rebate for costly brand drugs, rather than generics, and thus, many brand drugs have been included in Michigan's preferred drug lists. As drugs listed in the PDL do not need prior authorization so that physicians prescribe these drugs, rather than generics. Brill (2010) mentioned that the Medicaid program received a rebate on average of 15.1% of the average manufacturer price (AMP) per unit, and for generics, the rebate was 11% of the AMP per unit in 2009. The Government Accountability Office (GAO) indicated that Medicaid reimbursement per unit in reality, on average, is 12% higher than AMP.

Therefore, the actual rebate is expected to be smaller than that reimbursed by Medicaid (Brill, 2010). Thus, it shows a need for streamlining Medicaid cost savings strategies.

2.3.2. Preferred Drug List (PDL)

Michigan introduced the preferred drug list (PDL) provision for the Medicaid prescription drug program in July 2001 by the Michigan legislative Act 60 (PA 60) (Kaiser Commission, 2003). The PDL is a collection of drugs obtainable for Medicaid prescription drugs program beneficiaries. Michigan became the second state in the US to introduce the "Pharmaceutical Product List (PPL)," after Florida. The goal of this PDL is often used to contain costs of the Medicaid prescription drugs, i.e., to limit cost escalation of prescription drugs. Currently almost 70% of Medicaid prescription drugs that are reimbursed by the Medicaid are prescribed according to the list (Kaiser Commission, 2003). Drugs that are included in the PDL do not need any prior authorization. Any drugs that are not included in the PDL need to obtain prior authorization from the state be covered by Michigan Medicaid.

Michigan's Pharmaceutical Product List (MPPL) or PDL is criticized because it, in general, excluded the views of key stakeholders in the Medicaid prescription drug benefit – particularly Medicaid beneficiaries (Kaiser Commission, 2003). It is argued that exclusiveness of the most vulnerable Medicaid beneficiaries in creating the preferred drug lists could jeopardize their health (Kaiser Commission, 2003).

Some groups of people think that the Michigan's Pharmaceutical Product List (MPPL) is not particularly restrictive. Kaiser Commission's report (2003) concluded that the MPPL is more restrictive in selected therapeutic categories when compared to other PDLs or formularies. This report found that MPPL is particularly restrictive in three therapeutic classes: cardiovascular, antidepressants, and diabetes.

2.3.3 Michigan Multi-state Pooling Agreement (MMSPA)

In February 2003, Michigan with Vermont and South Carolina formed a Michigan Multi-State Pooling Agreement (MMSPA) aimed to reduce prescription drug costs for their Medicaid programs. In April 2004, the federal government approved the idea of establishing this drug purchase pool. Soon after its formation and approval from the federal government, Alaska, Hawaii, Minnesota, New Hampshire, Nevada, and Montana (in May 2004) joined the pool and expanded the MMSPA as "National Medicaid Pooling Initiative" (National Conference of State Legislature, 2012). Drug manufacturers also participated in the pool as the key stakeholder of the Medicaid program for participating states of the pool (Reinhart 2004).

The aim of the pool was to negotiate a bigger markdown and supplemental rebates from drug manufacturers, although each state has separate PDL. Through this arrangement, prices and rebates are tied to the volume so that the member states could have a larger price cut for their prescription drugs, because of the larger pool and higher buying power. A total of 26 manufacturers participated in the MMSPA (Reinhart, 2004). Michigan's then Governor Jennifer Granholm stated the goals of this Michigan multi-state pooling agreement: "The states want to tap into multistate prescription drug-buying power to save Michigan and its recession-battered budget as much as $50 million. We expect to cut tens of millions of dollars from our Medicaid drug costs this year "(National Conference of State Legislature, 2012). According to the National Governors Association Center for Best Practices Michigan and Vermont estimated that it would save $8 million and $1 million respectively in 2004 (National Conference of State Legislature, 2012). The then US Department of Health and Human Service (HHS) Secretary Thompson

made a remark at that time about the pool that "this is the first time in the history of the Medicaid program that states have worked together in this manner...By using the proven technique of negotiating lower prices, states will reap important savings on their drug costs…The ability to purchase drugs at a lower cost will help states continue to provide critical medications to the millions of low-income citizens who depend on the Medicaid program" (National Conference of State Legislature, 2012). As of March 2012, ten states are members of National Medicaid Pooling Initiative (NMPI). These states are Alaska, Kentucky, Michigan, Minnesota, Montana, New Hampshire, New York, North Carolina, Rhode Island, and South Carolina. The District of Columbia is also a member of the pool. Soon after the formation, member states showed a mixed reaction to the pool, and five states, including Nevada, Hawaii, Georgia, Arkansas, and Tennessee, discontinued participation as members. Vermont also withdrew from the pool in January 2006 and formed its own "Sovereign State Drug Consortium."

The goal of multiple strategies in containing costs for Medicaid prescription drug program has both benefits as well as limitations. All these policies intend to balance between the need of Medicaid beneficiaries and the costs the state has to pay for prescription drugs (CMS letter, September 9, 2004 as mentioned in Kibicho, 2007). Multiple policies have also reinforced effects of each other. Kibicho (2007) argued that "…the threat of prior authorization makes the PDL an effective tool to negotiate better manufacturer rebates and discounts and when used together with drug utilization review (DUR), they can improve provider prescribing patterns and increase the quality of care".

However, multiple policies cause in tradeoffs in many cases. For example, whereas PDL pursues prescribing higher amount of generic drugs, drug manufacturers

generally propose higher supplemental manufacturer rebates for the more costly brand drugs. Contradictory policies in this case can discourage policy makers from aggressively pursuing policy for low cost therapeutically equivalent generics as alternative (Kibicho, 2007). Besides, some other limitations and consequences of these multiple approaches of cost savings are mentioned. For instance, unaccounted administrative expenses can occur such as processing paperwork, coordination with other providers and other communications for prior authorization of unreimbursed drug. These multiple approaches of cost containment can cause cost shifting from one unit to other units of health care. As costs of physician visits and laboratory services, emergency room visits and hospitalization may occur due to changing patients prescriptions especially for those under complex medical condition, which can also offset the savings by prescription drugs expenditure cost containment policies. In many cases, physicians may choose to prescribe a preferred drug to avoid the excessive processes of prior authorization even though drug according to preferred drug list may not be the best medically effective drug as the non-preferred one (Kibicho, 2007).

Kibicho (2007) finds Michigan's efforts in containing cost in Medicaid prescription drugs are moderate. It was mentioned earlier that in 2003, at the beginning of the MMSPA, there was an estimated savings of $ 8 million for Michigan Medicaid Prescription drug program per year. In this context, it can be safely argued based on previous research such as Brill (2010) that implementing a generic substitution policy has potential to create savings of larger amount for Michigan with clear goals than savings anticipated for the MMSPA at its beginning and other cost containing strategies.

Kibicho (2007) quantified the impact of each policy on the expenditure per day supply of prescription drugs and to identify the most effective policy to reduce EDS. Results of the study found that the preferred drug list of Michigan became successful in changing patterns to more generic product utilization and the maximum allowable costs policy reduced costs of the generic drug. Accroding to Kibicho (2007), findings of the study also suggest that "there may be a limit to cost containment, which is important for policy design" (p. 1). These results reveal that the government's role can impact Medicaid cost containment. It suggests that existing policies may have a limit to contain costs and therefore, looking for new policies is necessary to contain Medicaid costs.

In the context of the Medicaid prescription drug issue, Fairgrive and Stauff (2007) discuss managing Medicaid costs in Michigan in a legislative briefing. By analyzing 12 years of fiscal data from 1995 to 2006, the authors show that Medicaid caseloads and cost trends significantly increased in the period from 2000 to 2006, as compared to the prior period from 1995 to 2000. Within the fiscal period from 2000 to 2006, the Medicaid caseload grew by 33.7%. The challenges Michigan Medicaid face include the economic downturn, along with unemployment, increase in population without health insurance, and decrease in state revenue. The percentage of people with uninsured health insurance increased from 11% in 2002 to 13.2% in 2004. One of the major causes of this increase was that many employers just reduced or dropped health care coverage due to the raising costs, and the elimination of thousands of jobs. Lost jobs in the manufacturing sectors made this situation more critical, since historically health benefits were better in the manufacturing sector than those of other sectors. In the same time, various restrictions imposed by the federal government in using special financing strategies limited

Michigan's scope to maximize federal funding and reducing state GF/GP to fund Medicaid program. Although Michigan introduced a number of cost containment measurements, not all measures were fully implemented. Fairgrive and Stauff (2007) concluded that "one of the major challenges for future Michigan budget planning is addressing the ongoing growth in annual Medicaid costs-which is largely driven by factors outside of the control of state policy makers" (p. 6). The major implication of Fairgrive and Stauff's concluded that, in reality, state government has virtually no control over the growth of beneficiaries, and thus, Medicaid costs. Therefore, Michigan must be innovative and need new strategies that can reduce prescription drug costs.

Fosdick (2008) discussed various restrictions imposed by the federal government regarding the use of special financing in Medicaid and its negative effects on Michigan's ability to maximize special financing, which increased federal participation in reimbursing state Medicaid claims. Michigan used various payment strategies to enhance the federal financial contribution to the Medicaid program, such as Disproportionate Share Hospital (DSH) payments, which included payments to the public hospitals, state psychiatric DSH payments, intergovernmental transfer/adjustor payments, which included outpatient hospital adjustor payments, long-term care adjustor payments; school-based services, and certified public expenditures (Fosdick,2008). These special financing strategies increased federal monetary contributions in financing Michigan's Medicaid program. For example, federal regulations allowed for supplemental payments (called DSH payments) to hospitals that provided higher proportions of their services to Medicaid beneficiaries and uninsured. DSH payments were similar, in structure, to Medicaid reimbursements for health care services provided by the hospitals. State

financial contributions were matched by the federal Medicaid funds at the rate of Federal Medicaid Assistant Percentage (FMAP). Because no specific services are identified for DSH payments, the state could use DSH payments in flexible ways. For example, Michigan used DSH payments to create funds for safety nets for hospitals and public medical education programs, and also used them to finance county-administered low-income health benefit programs. Thus, Michigan also was able to use DSH payments as a tool to reduce GF/GP expenditures in the Medicaid program (Fosdick, 2008). In a similar way, Michigan used other special financing strategies to increase federal financing participation in various Medicaid programs, and again reduce GF/GP expenditures in Medicaid programs. By using special financing strategies successfully up to fiscal year 2005/06, Michigan saved $169 million to $615 million each fiscal year within the fiscal period of 1990/91 to 2005/06 (Fosdick, 2008). The author concludes that, in the context of an increase in the state unemployment rate, Medicaid caseloads, the number of Medicaid beneficiaries, Medicaid costs, and the state's inability to use special financing due to the federal government restrictions to identify and close all loop holes will force Michigan to make necessary adjustments in Medicaid expenditures of significant amounts of dollars.

Literature review of this section reveals that although Michigan has already some measures to contain Medicaid prescription drug costs. Nevertheless, success of these measures is moderate. Besides, the overlapping policies have hampered the goals of cost containment in Medicaid prescription drugs. On the other hand, cost of Medicaid will increase due to the various reasons in future years. Thus, the above literature review provides a rationale for implementing a generic substitution policy as a cost containment

strategy in Michigan. The section below will focus on the issue of necessity of a policy to implement generic substitution as a cost containment approach for the Michigan Medicaid prescription drug program.

2.4.Why Is a Policy Needed for Cost Containment?

Marmor, Oberlander, and White (2009) discussed challenges of the recent health care reform proposed by the Obama administration. The authors view the recent recession as a major factor for the current demand for health care cost control. Due to the recent recession and economic slowdown, millions of people have lost their jobs, and at the same time, employers have had to cut health benefits to their employees in order to cut costs, which have made millions of people dependent on Medicaid. In the context of the recession and the Medicaid program, states face a dilemma of paying for increasing Medicaid beneficiaries while tax revenues are plummeting. In the short term, the federal government has increased investments in health care. It is interesting that, for various reasons, it is hard to control costs, even by the federal government. As pointed out by Marmor, Oberlander, and White (2009), it is due to politics that "Serious attempts at cost control produce a battle with stakeholders who have resources, political clout, and strong incentives to oppose measures that reduce the rate of medical spending growth and their income" (p. 486). According to the authors, in fact, the policy actors from various levels (e.g., pharmaceuticals, physicians, hospitals, nursing homes and many others) related to the political process of policy-making regarding health care, are many and they oppose any reduction in medical spending. Without realistic strategies, it is hard to confront the rising price of health care costs and of Medicaid as well. The authors conclude that proposals in cost containment such as "more research, more prevention screenings, and

better organized patient data" are ineffective in terms of cost-control measures. In containing health care costs, states should emphasize "price restraint, spending targets, and insurance regulation". According to the authors, only efficient and effective strategies at the state level can alter the course of the rising price of health care and Medicaid.

2.5 Summary of the Literature Review

Findings of the existing research are summarized as follows:

1. In getting FDA approval generic drugs are required to meet the same quality and performance standards as the brand name drugs in terms of identity, strength, quality, purity and potency. Generic drugs must meet rigorous standards established by the FDA for their approval. Some scholars disagree with this view because the generic drugs are not required to go through the clinical trial phase of FDA approval.
2. To decrease medical spending by implementing federal government policy is not easy since the major stakeholders are resourceful and they oppose imposing any such policy. One of the reasons for this resistance is financial. In 2008, total Medicaid costs were $339 billion and significant percentage of revenue of nursing homes, health care centers, and public hospitals come from Medicaid (Simon et al., 2009). Thus states should put an emphasis on "price restraint, spending targets, and insurance regulation" (Marmor et al., 2009).
3. The government's role is critical in increasing generic drug utilization regarding cost containment for the Medicaid program. As physicians have opinions both in favor and against about the equivalency of generic drugs to the non-generic brand

drugs, the government's role may be significant and decisive in increasing the utilization of generic drugs in at least the Medicaid program (AARP, 2010).

4. States' strategies to decrease Medicaid prescription drug costs such as preferred drug lists (PDL), tiered copayment systems, joint purchasing arrangement, maximum allowable costs for pharmacy reimbursement, and multi-state purchasing arrangement have modest success (Cunningham, 2005; Tennyson and Hudman, 2009; Hudman, 2009; Kibicho, 2007, 2013). The problem of using a higher copayment is that in many cases higher copayment may force some Medicaid patients to choose to reduce doses less than they need because of financial restraints, as per Simon et al., (2009); Wagner et al., (2008). Although states can save money by creating purchasing pools, these arrangements have their own limitations. While PDLs pursue enhanced use of generic drugs, manufacturers offer larger supplemental manufacturer's discount for more expensive brand drugs (Kibicho, 2007). In addition, success of these strategies depends on the purchasing power and volumes of purchase. The more a state buys, the bigger the rebate it gets (Kibicho, 2007).
5. West et al. (2009) found that adverse events associated with medication access problems in Michigan, along with some other states, have a significant impact on beneficiaries and their illness. Thus, more effective Medicaid prescription drug management and financing practices are needed to overcome access problems related to Medicaid patient medication.
6. In the context of Michigan Medicaid prescription drug costs containment, Michigan's success is modest. Fosdick (2008) and Fairgrive and Stauff (2007)

reported challenges for future Michigan budget planning because of the ongoing growth in the annual Medicaid costs, which is driven largely by factors outside of the control of state policy makers. Additionally, increases in the state unemployment rate, Medicaid caseloads (*i,e.*, the number of Medicaid beneficiaries), and the state's inability to use special financing (due to the federal government restrictions to spot and close all loop holes) have made Michigan's Medicaid financing more critical. Michigan has to make necessary adjustments in Medicaid expenditures of significant amounts of dollars.

7. In the context of higher prescription drug costs, increases of generic drugs may be an efficient and effective alternative strategy used to curb high prescription drug costs with existing strategies in this regard.

2.6 Chapter Summary

As mentioned earlier, Michigan has introduced several strategies to contain Medicaid prescription drug costs, which have brought some modest success. No significant studies with a multi-year timeframe and data have been conducted in terms of generic substitution and its impact on cost containment for Medicaid prescription drug costs in Michigan. No studies to date have investigated the pros and cons of formulating a generic substitution policy in Michigan with actual multi-year data, in terms of savings in the monetary amount for the Michigan Medicaid prescription drugs program. Brill (2010) also concurs the importance of analyzing the issue of Medicaid cost containment by decreasing the use of brand drugs that have generic substitution available on a state-by-state basis.

Fairgrieve and Stauff (2007) also stated regarding Michigan that "one of the major challenges for future state budget planning is addressing the ongoing growth in annual Medicaid costs—which is largely driven by factors outside the control of state policy makers" (p. 6). It is true that, in reality, the state government's role is minimal in determining Medicaid beneficiaries, as Medicaid eligibility is mainly determined by the criteria established by the federal government. Economic slowdowns and recession are major drivers of the increase in Medicaid beneficiaries, the impact of which is largely visible in the current increase in Michigan Medicaid beneficiaries. In 2005/06, Michigan spent nearly $1.4 billion or 40% of the state match requirement for Medicaid services from non-GF/GP funds for Medicaid. In 2006/07, the amount increased to $1.7 billion to match funds from non-GF/GP funds. The above literature reviews suggest that Michigan has to initiate further strategies for cost containment in the Medicaid prescription drugs program without lowering the quality of Medicaid services. In this context, it is believed that a generic substitution policy could be a viable option.

CHAPTER III

RESEARCH APPROACH, METHODOLOGY, DATA SAMPLE AND COLLECTION, AND STATISTICAL MODELS

3.1 Introduction

This chapter discusses the research approach, research methodology, data sample and collection, and statistical models for the identified research issues. It has already been mentioned that this research focuses on two crucial issues of the potential for a generic substitution policy and potential cost savings in Medicaid prescription drugs program in Michigan.

In this current researc a rational choice approach was used to examine the research issues to analyze the potential of implementing a generic substitution policy, and, thus, the cost savings of Medicaid prescription drugs program in Michigan. The section of the rational choice approach of the currenthist chapter discusses the rationale of using a cost-benefit analysis for this research and its advantages in examining issues, such as cost savings for a public program.

The section on research methodology, in general, provides a framework for the current research. It discusses research questions, assumptions about the research questions, hypotheses, definitions of the major terms used in the hypothesis, data collection, sample data set, and data analysis of the current research.

The section on the research models discusses statistical and descriptive statistical models of the current research. It defines dependent and independent variables that are employed in the regression models for testing the research hypotheses.

3.2 Research Approach

3.2.1 Rational Choice Approach

Rational choice is the new classical economic theory used in analyzing issues of public administration (Frederickson and Smith, 2003). It intends to analyze the role of citizens, politicians, and public servants, as well as the performance of public organizations and policies in relation to the actions of self-interested producers and consumers. The rational choice approach in public administration emphasizes that public policy making and its outcomes might be improved if policy goals and implementation strategies of public organizations are based on quantitative data, i.e., scientific data (Hughes, 1998). Thus in formulating and implementing public policy, the rational choice approach uses various quantifiable criteria, referred to as the bases basis of judging or choosing favorable alternatives. The criteria are premises of analysis, and thus help in selecting a preferred alternative over others (Munger, 2000) to address or to find out a solution about research issues. MacRae (1993) and MacRae and Whittington (1997) offer some guidelines for choosing criteria and state that 1) criteria should be emphasized on the ends rather than the means; 2) criteria should imply a clear measure of how well it achieved and satisfied an alternative; 3) if all conditions remain the same, then a set of criteria is better if tradeoffs can be quantified; and 4) a set of criteria should be complete and include all the concerns of all citizens.

3.2.2 Cost -Benefit Analysis

The rational choice approach, especially in public administration, includes various empirical methods such as cost-benefit analysis, decision theory, allocation theory, and time-optimizing models (Hughes, 1998). It is important to note that, although public administration scholars use various empirical methods of the rational choice approach, those methods mostly use economic criteria in choosing any preferred alternatives regarding public policy. These methods are mostly used to determine the economic performance of public organizations and bureaucracy by emphasizing core economic values. In this research, the rational choice approach, specifically, the method of cost-benefit analysis is used to analyze potential savings, or in other words, the efficiency of Michigan state government of using a generic substitute policy in prescription drug in the Michigan Medicaid program. The cost-benefit analysis is "a technique for systematically estimating the efficiency impacts of policies" (Weimer and Vining, 2005, p. 380). In the policy context "a particular matching of resources to use is efficient if and only if there exists no better alternative allocation of those same resources" (Munger, 2000, p. 32). In other words, efficiency can be defined as an effort to achieve as much public good as possible for the available dollars, and accomplish a public goal by using the fewest possible dollars (Fredericson, 1997).

Scholars criticize the use of a rational approach, specifically, the use of cost-benefit analysis in analyzing public policy, arguing that the approach ignores issues of fairness, social equity, social justice, and ethics, which are derived from constitutional, political, and judicial bases of public administration (Rosenbloom, 1983). These aspects greatly influence the structure, functions of public administration, and public agency

leadership. Fairness is referred to as a balanced distribution of resources, costs, and opportunities in social domains (Frederickson, 1997). The notion of social equity in public administration refers to the distribution of public resources, goods, and services by public agency leaders who emphasize and safeguard the rights of poor sections of society who do not have access to policy processes (Frederickson, 1997). Individual obedience to appropriate laws, codes of ethics at work, constitutional principles, and regime values are referred to as ethics in public administration (Denhardt, 2007).

The reason for using cost-benefit analysis in the current research is three-fold. First, the cost containment issue for Medicaid is clearly a monetary issue. In containing costs in a public program, issue of benefit is surely a critical factor. The use of a rational approach helps the current study analyze the efficiency of the policy by analyzing the potential savings of a new generic substitution policy regarding prescription drugs while keeping the benefits to the beneficiaries of the program the same. As this policy does not change the structure of the current program, the rational choice approach using cost-benefit analysis is appropriate for this study. Moreover, the argument of Stokey and Zeckhauser (1978) is noteworthy:

> One of the great virtues of benefit-cost approach is that the interests of individuals who are poorly organized or less closely involved are counted…The benefit and cost accruing to all—to the highway builders, the environmentalists, the 'little people,' the users and providers of services, the taxpaying public—will be counted on a dollar-for-dollar basis. Benefit-cost analysis is a methodology with which we pursue efficiency and which has the effect of limiting the vagaries of the political process. (p. 151)

Although various public administration scholars, most notably Waldo (1948), disputed over the value free mythology of the approach, in reality, cost-benefit analysis has established its firm root in public administration and public policy research.

Second, post positivist and other approaches of public administration work best when dealing with the effectiveness of a public policy, which is Medicaid in our study because, as these approaches emphasize issues such as values and fairness. In contrast, the rational choice approach works better when policy deals with efficiency measures, as its emphasis is on the cost issue of any public policy (Weimer and Vining, 2005). Since the current research deals solely with a financial issue, using a rational choice approach has many advantages over other approaches. As Sen (1990) argued:

> it will not be an easy task to find replacements for the standard assumptions of rational behaviour... both because the identified deficiencies have been seen as calling for rather divergent remedies, and also because there is little hope of finding an alternative assumption structure that will be as simple and usable as the traditional assumptions of self-interest maximization, or of consistency of choice. (p. 206)

Third, although the current study has adopted a cost-benefit model in analyzing generic substitution policy regarding prescription drugs in Medicaid, it does not argue against public administration values such as fairness, social equity, and social justice, as emphasized by scholars such as Frederickson (1997). The current study neither deals with issues such as a reducing number of Medicaid beneficiaries nor it advocates imposing of strict Medicaid eligibility criteria for beneficiaries in containing prescription drug costs due to potential impacts on the wellbeing of poor people. Besides, proposing generic instead of brand drugs do not imply or promote any low-quality treatment because one of the assumptions of this study is that generic drugs are functionally similar to other brand drugs in treating diseases.In specific, the current study focuses on the issue related to Michigan Medicaid prescription drug programs costs because it is crucial for the sustainability of the program. Savings in prescription drugs benefits can help Michigan to administer the Medicaid program more effectively, as it can achieve the same goal to

provide health care to low-income population with the same services more efficiently. A more cost-effective program will be more viable program, especially in the context of Michigan's current and future fiscal budget deficits due to the end of the federal recovery assistance, growing caseloads of Medicaid and other social services, and other unavoidable spending pressures (State Budget Office, 2011). Additionally, any cost savings in Medicaid prescription drugs surely help Michigan's legislature in reallocating surplus money in more beneficial ways to have better returns for the state and the residents. For example, by streamlining tax structure and encouraging investment in and expansion of Michigan, Governor Rick Snyder has revealed a plan of almost $2 billion of corporate income tax relief for companies classified other than as a "C" corporation (i.e., entities that issue public or private stock) in 2013. This provision will exempt an estimated over 95,000 companies to file a state business tax return (State Budget Office, 2011). Savings in Medicaid prescription drugs may help in making up some of the state revenue shortage due to the corporate income tax relief.

3.3 Research Methodology

3.3.1 Research Questions

First, will a generic substitution policy as implemented by Florida and Massachusetts (and eight other states, i.e., Kentucky, New Jersey, New Mexico, Oregon, Rhode Island, Tennessee, West Virginia, and Wyoming) can be an efficient strategy in containing Medicaid prescription drug program costs for Michigan? Second, if not in general, are there any therapeutic classes of prescription drugs or are there any "heavily used" brand drugs for which generic substitutes are available that Michigan can effectively reduce Medicaid costs by implementing a higher use of generic substitution, thus reducing the state prescription drug costs through the generic substitution policy?

Third, if the answer is yes for the above two previous questions, then approximately how much money can Michigan save per year by implementing a generic substitution policy?

3.3.2. Research Assumptions

The current research makes the following assumptions regarding the proposed hypotheses:

1. Generic drugs are similar to single-source or brand drugs in treating diseases. The reason for this assumption is that generic drugs are chemically identical to single-source brand drugs (OIG, 2006). Additionally, the Food and Drug Administration (FDA) states that generic drugs are not only therapeutically equivalent to brand drugs but are also

   > …required to have the same active ingredient and the same strength, dosage form, and route of administration as the brand name (or reference) product. In addition, a generic drug must be bioequivalent to the brand drug; that is, there must be no significant difference between the generic and brand product in the rate or the extent to which the active ingredient is delivered to the patient. There can be some variability between brand name and generic drugs, but the FDA puts limits on how much variability is acceptable. (DHHS, 2010)

2. Pharmacies cannot or will not increase costs of generic drugs to make up the lost profits on single-source brand drugs.

3.3.3 Operational Definitions of Major Terms

This research uses some terms with specific definitions. Although different views and definitions may exist regarding some of these terms, the current study will use these terms in the restricted ways defined as follows:

- *Generic substitute policy* –sets a binding of prescribing generic drugs when available, rather than prescribing brand drugs.

- *Generic drugs*: Generic drugs are copies of brand-name single-source drugs without patent protection, and therefore available to be produced and sold by any FDA-approved manufacturer (FDA, 2006).
- *Single-source or brand-name drugs:* These drugs are produced by one single manufacturer under trademark-protected names. Only a manufacturer that has the patent right of the drugs can produce the brand drugs (AAA, 2010).
- *Generic utilization rate*: The percentage of all prescriptions dispensed in Medicaid that are generics.
- *Single-source drugs prescribing rate:* The percentage of all prescriptions dispensed that are single-source drugs or brand-name drugs in Medicaid.
- *Prescription drug:* Medicaid prescription drugs are defined as those drugs that can be available for Medicaid beneficiaries only through a physician's prescription, and can be either generic or non-generic single-source or brand-name drugs.
- *State share:* The monetary portion that the state matches for prescription drugs for its Medicaid patients in addition to contributions of the federal government to the state Medicaid programs.
- *Efficiency* (in a policy context): Efficiency can be defined as an effort to achieve as much public good as possible for the available dollars, and accomplish a public goal by using the fewest possible dollars (Frederickson, 1997).
- *Effectiveness*: Effectiveness can be defined as whether a policy achieves its preset goals. In the context of Medicaid prescription drugs, effectiveness will be viewed as whether the generic substitution policy serves the beneficiaries of Michigan Medicaid without reducing the existing numbers or the quality of the drugs dispensed.

- *Therapeutic class:* A group of drugs that treat the same medical conditions (OIG, 2006).

3.3.4 Research Hypotheses

Based on the three research questions and the described approach, the current study examines the following specific hypotheses:

1. A potential *generic substitution policy* regarding *prescription drugs* may be an efficient approach to contain prescription drug costs and thus may reduce the *state share* in the Michigan Medicaid program.
2. A mandatory *generic substitution policy* may have more potential in containing Medicaid prescription drug costs than a *generic substitution policy* with conditionality such as prior patient consent.
3. In case of some brand drugs or *therapeutic classes*, Michigan may have the potential to reduce Medicaid costs by mandating a higher use of generic substitution, whenever available, by the generic substitution policy.

3.3.5 Summary of the Discussion

By using the cost benefit analysis based on the research questions and the hypotheses, the current study will analyze the following specific policies regarding Michigan Medicaid prescription drug costs:

1. Status quo or the existing policy (Policy 1) regarding Medicaid prescription drug without mandating generic substitution.
2. Introducing a new alternative policy or generic substitution policy (Policy 2) regarding Medicaid prescription drugs by mandating generic substitution where available.

In analyzing the potential generic substitution policy for Michigan Medicaid prescription drugs, the program's major components of cost and benefit are as follows: yearly costs/expenditures (for sample data set) of prescription drugs, total state share of Michigan in prescription drugs reimbursement, and potential total savings of Michigan in Medicaid prescription drugs reimbursement. A diagrammatic representation of the model is shown in Figure 3.

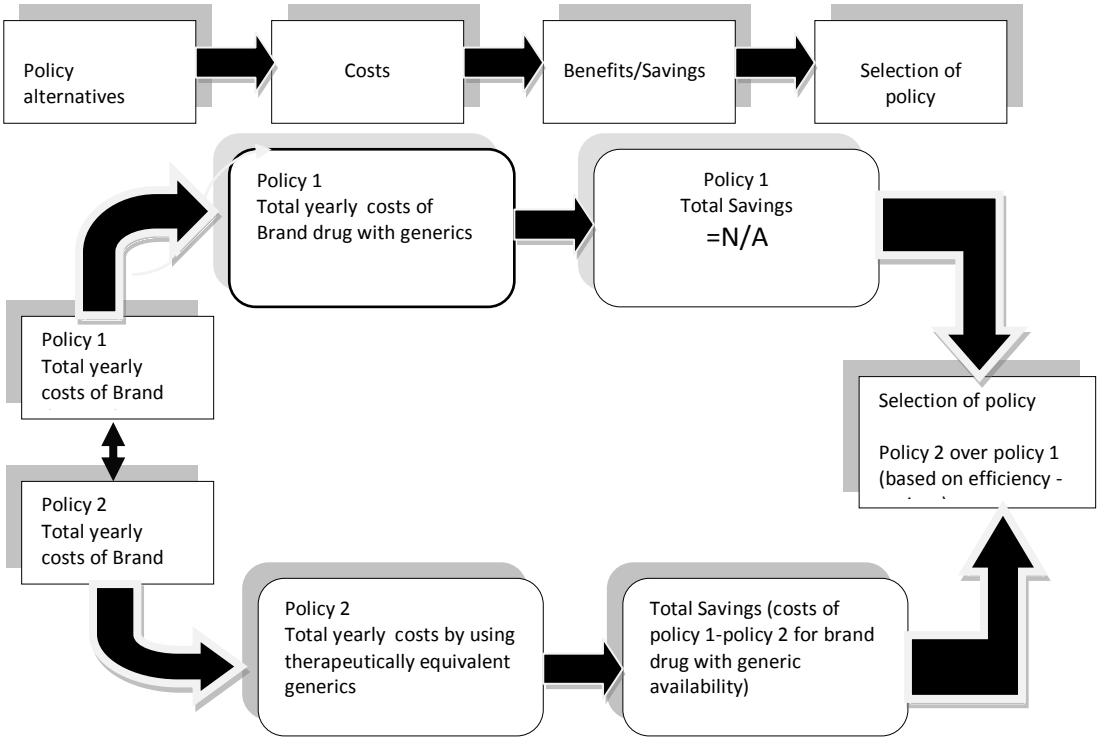


Figure 3. Model of Cost-Benefit Analysis: Status Quo and Mandatory Generic Substitution Policy

The main idea is to examine whether a mandatory generic substitution policy or mandatory use of higher percentage of generic drugs in Medicaid prescription drugs program can benefit the state of Michigan more than the status quo or the existing policy of not mandating the use of generic drugs in the Medicaid prescription drug program in terms of cost savings. If an alternative policy or generic substitution policy (policy 2) can

achieve more benefits, than the status quo is better. The major premise of the analysis can be written by following formula:

$U_i(A) > U_i(S)$ (utility or benefits of A is greater than utility of S)

where, 'S' represents status quo or the current policy without generic substitution, and 'A' represents the alternative policy, which in this case represents a mandatory generic substitution policy in Michigan Medicaid prescription drugs program.

Cost-benefit analysis of a public policy may include various structural-functional and financial aspects resulting from it. Due to limited time and resource constraints, the current research considers only 'costs or expenditures' and 'savings' as the major components in analyzing the efficiency of the current policy regarding prescription drugs in the Michigan Medicaid program. In addition, amid the current recession and state of Michigan's current economic crisis, these two criteria are most crucial in examining the 'efficiency' of any public policy and program.

3.4 Data Collection Method and Sample

3.4.1 Data Collection

In addressing the issues related to the research questions and hypotheses, the current research uses State Drug Utilization data and CMS 64 Quarterly Expense data titled as Medicaid Financial Management Report (yearly) provided by the Centers for Medicaid and Medicare Services (CMS). These data sets are used by Shrank et al. (2008), Shrank et al. (2010), and Brill (2011) in analyzing costs and savings issues of state Medicaid programs.

State Drug Utilization data provides "quarterly reimbursements to pharmacies for each National Drug Code (NDC) and includes the product name, the number of units reimbursed, the number of prescriptions filled, the total amount reimbursed, and the total

amount reimbursed by Medicaid" (Brill, 2010). In order to develop the research data set, brand and generic drugs were categorized separately. In doing so, information provided by the Food and Drug Administration (FDA)'s 'Old National Drug Code Directory' and 'National Drug Code Directory' are used. These two databases provide drug names in juxtaposition of NDC, classification of brand or generic for any specific drug, therapeutic equivalent (brand or generic) if available, and date of therapeutic equivalent to enter in the market. Thus, using these two databases together I developed my sample data set. In addition, the current study has also used State Drug Utilization data, which includes brand total drug unit reimbursed, brand and generic drug unit reimbursed, and corresponding amount reimbursed, for prescription as well as corresponding ratio of these categories.

Table 4

Percentage of Data of Three States Used as Sample

Year	MI	MA	FL
1999	53.89238	60.44772	55.91908
2002	68.57978	75.29672	18.63899
2004	76.70305	75.41825	54.72497
2006	76.7513	80.64172	35.64569
2008	58.58293	82.20229	80.57481
2010	87.02838	87.08079	86.10461

Source: calculated from State Drug Utilization data, CMS, 1999-2010

One issue should be noted that although State Drug Utilization data provides yearly Medicaid reimbursed data for states, I could take account of only roughly half of the drugs for the states of Michigan, Massachusetts, and Florida, because the FDA database

does not categorize any multivitamin as brand or generic, which is prescribed a significant amount in Michigan Medicaid prescription drug program. Biological drug products are provided Biologic License Application (BLA) instead of NDC under the provisions of the 'Public Health Service (PHS) Act' for marketing purposes. Although BLA products go through the same type of FDA approval process, these drugs are categorized neither brand nor generic. So, I excluded all BLA drugs as well as all multi-vitamins from my sample data set and thus included 53.89% to 87.02% drug units reimbursed within the sample years for the state of Michigan as well as Massachusetts and Florida. All together using these two data sets, approximately 2,500,000 drug data points were created, in addition to the existing 3,500,000 Medicaid prescription drug corresponding data points. Approximately, a total of 5,500,000 data points are taken into account to for the current research.

Descriptive statistical measures, such as averages, and other statistical methods, such as correlation and regression analysis, are used in this research regarding the cost containment of prescription drugs in the Michigan Medicaid program for the fiscal years of 2000 to 2010. These methods are also used previously by Shrank et al. (2008), Shrank et al. (2010), and Brill (2010).

The current research uses CMS's State Drug utilization Data of Michigan, along with State of Florida and Massachusetts. Using data of Florida and Massachusetts allowesthe current research to estimate the potential effects of generic substitution policy on the Michigan Medicaid prescription drug costs as well as any future efforts in this regard on the basis of comparison.

By using the descriptive measure of averages, the current research calculates percentage of state share in Medicaid, generic utilization rate, generic prescribing rate, average cost of generics, total generic scripts, percent of generic scripts dispensed, single-source drugs prescribing rate, average costs of single-source drugs, total single-source drug scripts, and percent of single-source drug scripts dispensed for Michigan and the other two states as mentioned. Based on the average of the various measures regarding prescription drugs in Michigan and the two other sample states' correlations and a series of multivariate regression analysis, a statistical method that examined relationships between two variables—an independent and a dependent (Singleton and Straits, 2005)—to examine the research hypotheses. The reason for using correlation and regression in the current research is that these methods help examine the relationship between the independent and dependent variables and as mentioned above , a number of authors (e.g., Shrank, 2010) used these methods to show relationship between independent and dependent variables in a similar research.

3.4.2 Sample Data

The current research used mainly secondary data sources from primarily CMS's State Drug Utilization data and CMS 64 Quarterly Financial data as the basis of analyzing the current research issues and hypotheses. CMS's State Drug Utilization data and CMS 64 Quarterly data on Medicaid programs helps identify historic trends in prescription drug costs of Michigan and other two sample states for this study. For this purpose, data of 1999 and every other year from 2002 to 2010 have been accessed for three states -Michigan, Florida and Massachusetts. Both data sets provide different measures of Medicaid data for all sample years. These two databases include more than six million observations points regarding prescriptions of generic and brand name drugs

and reimbursement for each drug for the sample period of the current research. Limiting the sample size to six years allows the development of a large enough dataset to study a trend in cost containment in terms of time. As Sandelowski (1995) argued, "determining an adequate sample size in qualitative research is ultimately a matter of judgment…" (p. 183). Further, within this period Medicaid beneficiaries of sample states have not changed significantly, although in some cases the current recession has accelerated the number faster than at other times. Therefore, the CMS data regarding Medicaid prescription drug costs from 2000 to 2010 is large enough for analyzing the current research issues. Additionally, only CMS databases contain comprehensive Medicaid data on a national level.

Data provided by these databases helps the current study to develop a comprehensive picture of future savings in Michigan's 'state share of Medicaid prescription drugs' regarding the selected independent variables as mentioned above. The current CMS database provides an impression that, if not all classes, at least some specific brand drugs or therapeutic classes can save Michigan a significant amount of money if a generic prescription policy is implemented in terms of Medicaid prescription drugs costs.

Kiecolt and Nathan (1985) have discussed the potential advantages and disadvantages of the secondary data in social research. One of the advantages of using secondary data is that it saves time and money. Using secondary data, researchers can avoid many problems related to data collection. Many data archives contain large quantities of electronic data, which provide data of large spans of time on many social issues, representing national samples and standard items (Kiecolt and Nathan, 1985).

These data sets are relatively easy to access and use. Based on secondary data, researchers can conduct various types of research such as trend, cohort, time series, and comparative analyses on any social issue. Existing data can also be incorporated into other types of newly collected data to investigate a problem with more dimensions than the previous research efforts. Use of the same data can make researchers more effective in explaining phenomenon and issues related to the data.

Despite the great advantages of secondary data, there are also some disadvantages. One of the problems, in this regard, is data availability. Due to the storing of data differently by different data banks, websites, or archives, it can become hard to find the necessary data. Data of some research topics or areas may be more easily available or accessible than other areas. For example, data are more available on health-related issues than for specialized areas such as mental health epidemiology (Kiecolt and Nathan, 1985). Further, despite the existence of data, it is not always publicly available. In many cases, researchers totally depend on the generosity of private data owners, and in many instances, researchers cannot have data without a subscription or membership. Another disadvantage may occur between primary and secondary research objectives. Some methods-related problems may occur in using secondary data, because in many cases, it is hard to verify the errors that have been made in primary data collection, sample design, and measurements. Researchers' biases related to data collection cannot be minimized when using secondary data. Secondary data can also limit the creativity of researchers as repeated use of the same data set prohibits new avenues of research, and thus narrows researchers' research ability as well.

Despite the scope of some potential disadvantages of using secondary data, this study uses secondary data because of specific advantages relevant to the current research. One of the major advantages, in this regard, is that the CMS databases related to Medicaid and other issues related to the current research are reliable, and research communities and other stakeholders acknowledge the validity of these data. As stated by the Kaiser Commission (2004):

> One advantage of Form CMS-64 is that these data are more current than data from MSIS. Based on discussions with many state officials, it is clear that states have long-standing procedures to compile and submit these data. Many of these procedures are automated within the states' own systems for tracking and reporting spending, and CMS indicates that all states now submit their CMS-64 data electronically. Further, states' rational desire to receive federal matching funds gives officials incentive to document and report expenditures in a timely manner. All of these factors contribute to the relative alacrity with which these data are collected and, in turn, are made available by CMS. (p. 3)

This is the most comprehensive database on the issues of the current research. Second, it is difficult to collect data so comprehensive and current on the current research topic by an individual researcher within a limited time period. Due to sufficient resources and other infrastructural advantages of CMS, these data are more comprehensive than any surveys conducted by an individual researcher.

3.4.3 Analysis of Data

In order to examine research hypotheses concerning the efficiency and savings by a generic drug substitution policy in Medicaid prescription drug expenditures, the current research uses descriptive statistical methods, such as average. CMS databases provide quarterly data from the year 2007, and data of earlier years are available on a yearly basis. CMS databases provide number of unit, number of prescriptions for individual drug, reimbursed amount for each drug unit dispensed. CMS databases also do not provide data as percentages. Therefore, this researcher has calculated all Medicaid

measures provided by State Drug Utilization database and CMS 64 Quarterly data as a percentage within 1999-2010 year periods. By using descriptive statistical measures of averages, the following measures were calculated regarding the Michigan Medicaid program on the basis of each fiscal year within the period of 2000 to 2010: 1) total prescription drug spending in Michigan Medicaid, 2) number of total scripts identified as generic and brand drugs, 3) total spending identified as generic, 4) total spending identified as brand drugs, 5) total brand unit, 6) total generic units, 7) total costs of brand drugs, 8) total costs of generic drugs, 9) percent of brand drugs dispensed in total units, 10) percent of generic drugs dispensed in total units, 11) percent of total costs of generic drugs, and xii) percent of total costs of brand drugs.

In categorizing the huge quantity of sample data, a new program "The drug detail gatherer" was developed by using the 'python' script language. The new program helped the current research to categorize CMS's 'state drug utilization data' by 'brand' and 'generic' categories comparatively quickly, with minimal manual intervention. CMS's data base, 'state drug utilization data', provides Medicaid drug reimbursement information for each reimbursed drug by states and year in the prescription drugs program with drug product codes and application number assigned by the FDA. As the 'state drug utilization data' does not categorize drug by 'brand' and 'generic' therefore using the unique drug application number, 'The drug detail gatherer' program cross checks every reimbursed drug in the prescription drugs program with the FDA's old and new databases against unique drug application numbers. The old and new databases of the FDA provide comprehensive information of drugs available in the US market against its application number, such as drug category, generic availability, the date of market

availability of generics, etc. Then ‘The drug detail gatherer’ saves the generic's name, release date, and other relevant information to a file –corresponding to every brand and generic drug reimbursed. Drugs with incomplete information, such as showing no category of brand or generic, are taken off from the sample.

3.4.4 Descriptive Statistics

As mentioned earlier, the current research has examined the potential generic substitution policy as a cost containment method for Michigan’s Medicaid prescription drug program. In determining monetary amounts of savings in Michigan’s Medicaid prescription drug program by generic substitution policy, I chose to calculate the simple average of use of brand drug with therapeutic equivalents or generics available in the market during the prescription periods. In doing so, I first categorized all reimbursed drugs under the Medicaid prescription drugs program into two groups—brand or generic—as State Drug Utilization data or CMS 64 Quarterly database do not provide brand or generic classification. Using the corresponding National Drug Code (NDC) of each drug provided by the State Drug Utilization database, I cross-checked two FDA databases, Old National Drug Code Directory and National Drug Code Directory, to determine if a drug is brand or generic.

In most cases, the process of determining whether a brand drug has a therapeutic equivalent or generic is straight forward. A brand drug that was prescribed before a therapeutic equivalent or generic entered the market was classified under the ‘no generic available’ category. In contrast, a brand drug that was prescribed even though a therapeutic equivalent or generic already existed or entered the market before the prescribing quarter was classified under ‘brand drugs with therapeutically equivalent (BTE)’. In some cases, a specific brand drug was prescription and entrance of its

equivalent generic happened to be in the same quarter of a year. As the State Drug Utilization database does not provide the specific date of prescribing of a specific drug, I therefore developed criteria and used it uniformly for each and every drug classification. In these cases, if a brand was prescribed within the first half of the quarter, for example before February 15 of the first quarter, I classified the drug under the 'no generic available' category. When a brand drug was prescribed in the second half of the quarter, for example after February 15 of the first quarter, I classified the brand under the BTE category. After determining the drug category, I selected all brand drugs that had a therapeutically equivalent or BTE at the time of prescription in Michigan, Massachusetts, and Florida. Then, I calculated the average unit price of those 'brand-to- generic' matches, and I calculated the price difference between the total brand drug dispensed that had the therapeutically equivalent and the price of its generic equivalents, which could be the savings. I calculated this savings as the total amount reimbursed and the Medicaid amount reimbursed in sample years.

Analyses of correlation and regression and calculation of percentage data of earlier-mentioned measures help to show various potential relationships between generic substitute policy and Michigan Medicaid prescription drug cost containment. These measures also help to predict the variation of the various dependent variables, such as percent of 'state share' and 'potential savings' in Medicaid prescription drug costs. Calculation of average costs of generic and brand drugs thus shows variations of costs between generic and brand drugs when generic drugs are available to use in the same therapeutic classes. The cost variations between generic and brand drugs in the same therapeutic classes also provide an opportunity to compare the costs of prescription drugs

in the Michigan Medicaid program from two policy continuums—pharmaceutical expenditures by the current policy (without generic substitution policy) and pharmaceutical expenditures by a potential generic substitution policy (with a mandatory generic substitution policy). Thus analyses of this research provides a basis of the implementation of a potential generic substitute policy as an efficient approach in containing prescription drugs expenditures in the Michigan Medicaid program.

3.5 Statistical Models of the Research

In examining the research hypotheses, statistical models such as regression and descriptive statistics are used. Following sections discuss various statistical models used in the research to examine research hypotheses.

As aforementioned, hypothesis 1 of the current research question is whether a potential generic substitution policy regarding prescription drugs is an efficient approach in containing prescription drug costs and thus reducing the state share in the Michigan Medicaid program. As the state share of Medicaid prescription drugs and thus pharmaceutical costs depends on various factors such as per capita income of state and the US, it is difficult to compare among different states. Furthermore, the total share of state Medicaid pharmaceutical costs also depends on the total number of Medicaid prescription drug beneficiaries of the states. As these factors vary by state, this research has used a "percentage" of different Medicaid measures in regression models instead of using, for example, the total monetary and drug unit reimbursement amounts and state share or pharmaceutical costs.

3.5.1 Regression Analysis: Hypothesis 1

In examining hypothesis 1, three different factors such as price increase, increase in use of prescription drugs, and changes in types of drug use are taken into consideration in relation to the measures of various Medicaid prescription drug costs (Kreling, Mott, and Wiederholt, 2001) and savings as the dependent variable and independent variables such as 'generic substitution policy,' 'percentage of brand drug scripts used,' and 'brand drug with therapeutically equivalent used.' The goal of this analysis is to examine how these factors as independent variables influence the dependent variable or increase or decrease costs and savings of the Medicaid prescription drug program. Four multivariate regression models are employed in examining the first hypothesis. Multivariate regression model can be written as follows:

$$\hat{Y}_i = a + b_1 X_1 + b_2 X_2 + \ldots b_k X_k \quad \ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots \text{(I)}$$

where,

$\hat{Y}$ is the predicted value of the dependent variable; in this case 'percentage of state share in Medicaid prescription drug costs'

a is the intercept or constant, which is the base prediction of Y when all the X variables are fixed at zero

b_1: is coefficient of X_1;

b_2: is coefficient of X_2;

b_k: is coefficient of the last X variable

X is the independent variable, where X= [X_1, X_2,… X_k]

3.5.1.1 Regression Model 1 of Hypothesis 1

In examining hypothesis 1, the first multivariate regression model is employed to examine if there is any significant relationship between the dependent variable 'percentage of state share of total prescription drug costs' ('state share' hereafter) and

independent variables 'generic substitution policy', 'percentage of brand drugs with therapeutically equivalent (BTE) used as of total drug units reimbursement' ('BTE unit reimbursed' hereafter), and 'percentage of brand drug used as of total drug unit reimbursed'('brand unit reimbursement' hereafter). Following independent variables are selected for regression model 1 of hypothesis 1 are listed below:

$X_{1:}$'generic substitution policy

X_2: 'Brand unit reimbursement'

X_3: 'BTE unit reimbursement

$\hat{Y}$: 'percentage of state share as of prescription drug costs' ('state share', hereafter) is the predicted value of the dependent variable of the model.

Thus, similar to equation I, we can rewrite equation of regression model 1 of hypothesis 1 for the current research as following:

'state share' $(\hat{Y}) = a + b_1$ (generic substitution policy)+ b_2 (Brand drug unit reimbursemet) + b_3 (BTE unit reimbursement) ……(extension of I)

Table 5 shows variables of the regression model with STATA code and interpretation.

Table: 5

Dependent and Independent Variables of the Regression Model 1 of Hypothesis 1

Dependent Variable (Y)	
'state share'	
Independent Variables (X)	
X_1	'generic substitution policy'
X_2	'brand unit reimbursement'
X_3	'BTE unit reimbursement'

In this analysis, the dependent variable 'state share' is a continuous variable that refers to a set of data that may take any value within a specified interval of a real number. The goal of this hypothesis is to examine the relationship between a 'generic substitution policy' as well as other independent variables and the dependent variable, "percentage of state share in Medicaid." In doing so, this research uses a dummy variable as the independent variable. The dummy variable is referred to as the variable that is a non-interval level in nature and is usually called a nominal scale. These variables can be assigned numerical numbers to be represented. When this variable has only two categories, then one category can be represented generally by 1, and the other category can be represented by 0, or these two categories can be assigned any other number by the researcher (Allison, 1999). To approach the current analysis, I have created three sets of dummy variables from the original independent variable 'generic substitution policy'. Each of these three dummy variables has two values such as 0 and 1. It helps the regression model (where the dependent variable 'state share' is regressed by the independent variable) to assess the ability to separate our cases into those in which Y=0 and the other in which Y=1. For example, a score of 1 for 'generic substitution policy' regarding the dependent variable 'state share' indicates the states with a current 'generic substitute policy', such as Florida and Massachusetts. A score of 0 on the other hand indicates a state without a 'generic substitute policy', such as Michigan. The "[d]ummy variables are perfectly OK as independent variables in a multiple regression" (Allison, 1999). In reference to the current independent variable "generic substitution policy" one dummy variable represents 'two states with mandatory generic substitution policy' by assigning the number 1, and the other variable represents Michigan, as a 'state without

mandatory generic substitution policy' by assigning the number 0. This type of data is referred to as nominal data, of which the values or observations associated with it can be allocated a code in the form of a number, where the numbers are simply labels. In this regard, it is assumed that the higher percentage of use of generic drugs will lower the state percentage share of prescription drug costs, as generic drugs have a much lower price compared to single-source brand drugs (OIG, 2006). In addition, two more multivariate regression analyses will be employed to examine the first hypothesis.

3.5.1.2 Regression Model 2 of Hypothesis 1

Following three independent variables are employed for a second multivariate regression model to examine if there exist any relationship between and dependent variable, 'potential savings from BTE drug costs at the rate of generic drugs available' ('potential savings', hereafter). Variables of the regression model 2 of hypothesis 1are listed below:

X_1 : 'generic substitution policy'

X_2:'Brand drug unit reimbursement'

X_3 : 'BTE unit reimbursement' and

$\hat{Y}$: 'potential savings'

Thus, we can write regression prediction model 2 of hypothesis 1 as follows:

'potential savings' $\hat{Y}_i$ = a+ b_1 generic substitution policy + b_2 'Brand drug unit reimbursement'+ b_3 'BTE unit reimbursement'……(II)

Table 6

Dependent and Independent Variables of Regression Model 2 of Hypothesis 1

Dependent Variable (Y)	
'potential savings'	
Independent Variables (X)	
X_1	'generic substitution policy'
X_2	'brand unit reimbursement'
X_3	'BTE unit reimbursement'

3.5.1.3 Regression Model 3 of Hypothesis 1

A third multivariate regression model is employed to examine if there exists any relationship and the nature of this relationship between the independent variables as 'generic substitution policy', 'percentage of brand amount reimbursement as of total drug expenditure' ('brand amount reimbursement', hereafter) and 'percentage of BTE amount reimbursement as of total drug expenditure ('BTE amount reimbursement' hereafter) and the dependent variable of 'potential savings'. The regression prediction equation of model 3 of hypothesis 1 can be shown as follows:

'potential savings' ($\hat{Y}_i$)= *a* (constant)+ b_1 'generic substitution policy'(X_1)+ b_2'brand amount reimbursement' (X_2), + b_3'BTE amount reimbursement' (X_3)…….(III)

Table 7

Dependent and Independent Variables of Regression Model 3 of Hypothesis 1

Dependent Variable (Y)	
'potential savings'	
Independent Variables (X)	
X_1	'generic substitution policy'
X_2	''brand amount reimbursement'
X_3	'BTE amount reimbursement'

3.5.1.4 Regression Model 4 of Hypothesis 1

A fourth multivariate regression is employed to examine if there exists any relationship and the nature of this relationship between costs of prescription pattern, for example if prescription suggests generic and or brand drugs and 'potential savings' as the dependent variable. Following the dependent and independent variables of regression model 4 of hypothesis 1are listed below:

X_1 ='per prescription generic reimbursement' ('generic prescription', hereafter)

X_2 = 'per prescription brand reimbursement' ('brand prescription', hereafter)

X_3 = 'per prescription BTE reimbursement' ('BTE prescription', hereafter)

$\hat{Y}_i$ 'potential savings'

The regression prediction equation of model 4 of hypothesis 1 can be shown as follows:

'potential savings'($\hat{Y}_i$) = a+ b_1 ' generic prescription'+ b_2'brand prescription+ b_3 'BTE prescription'……(IV)

Table 8 shows the variables with STATA code and interpretation.

Table 8

Dependent and Independent Variables Regression Model 4 of Hypothesis 1

Dependent Variable (Y)	
'potential savings'	
Independent Variables (X)	
X_1	'generic prescription costs'
X_2	'brand prescription costs'
X_3	'BTE prescription costs'

3.5.2 Regression Analysis: Hypothesis 2

In examining hypothesis 2, the influence of independent variables 'generic substitution policy', 'generic substitution policy with prior consent' ('policy with prior

consent', hereafter) and 'generic substitution policy without prior consent'('policy without prior consent', hereafter) are examined on dependent variables 'state share', and 'potential savings'. Three regression models are employed to examine these relationships.

3.5.2.1 Regression Model 1 of Hypothesis 2

Regression model 1 of hypothesis 2 examines if generic substitution policy with and without mandating provision as independent variables have any influence in increasing or decreasing the dependent variable 'state share'. Thus two independent variables selected for the regression model are defined below:

$X_{1:}$ generic substitution policy with prior consent ('policy with prior consent', hereafter) and

$X_{2:}$ generic substitution policy with no prior consent ('policy with no prior consent', hereafter)

Table 9 shows the dependent and independent variables of the model with STATA Codes and interpretation.

Table 9

Dependent and Independent Variables Regression Model 1 of Hypothesis 2

Dependent Variable (Y)	
'state share'	
Independent Variables (X)	
X_1	'policy with prior consent'
X_2	'policy with no prior consent'

Thus, the regression prediction equation for regression model 2 of hypothesis 2 can be written as follows:

'state share'($\hat{Y}_i$)= *a* (constant)+b_1*'policy with prior consent' + b_2 * 'policy with no prior consent'……..(V)

In this analysis, data related to the dependent variables are continuous in nature and data associated with the independent variables are nominal data, of which values or observations associated with it can be allocated a code in the form of a number where the numbers are simply labels. In examining the relationship between 'policy with prior consent', and 'policy with no prior consent' and the dependent variable, this research Variables included in the regression model 1 of hypothesis 2 uses two categories of dummy variables as independent variables. In reference to the current independent variable, 'policy with no prior consent', a dummy variable represents the state of Florida and is assigned 1 for having 'policy with no prior consent' provision and Massachusetts and Michigan are assigned 0 for not having any 'policy with no prior consent' provisions. In the second case, Massachusetts is assigned a number 1 for having a mandatory generic substitution 'policy with prior consent', and Michigan and Florida have assigned "0" for not having a generic substitution 'policy with prior consent.'

In this regard, it is assumed that the states that have a generic substitution without the provision of prior patient consent have a lower percentage of state share and higher savings potential regarding prescription drug costs than the states that have a generic substitution policy with the provision of prior patient consent. This analysis helps the current research in finding out an efficient policy choice regarding Michigan Medicaid prescription drug program's cost containment.

3.5.2.2 Regression Model 2 of Hypothesis 2

In examining hypothesis 2, a second regression model examines if generic substitution policy with any provisions has any influence in increasing or decreasing of dependent variable. Variables selected for the regression model are listed below:

$X_{1:}$‘policy with prior consent’ and

X_2:‘policy without prior consent’ and dependent variable:

$\hat{Y}_{i:}$ ‘potential savings’

Table 10

Variables Included in the Regression Model 2 of Hypothesis 2

Dependent Variable (Y)	
‘potential savings’	
Independent Variables (X)	
X_1	‘policy with prior consent’
X_2	‘policy without prior consent’

Thus, the regression prediction equation of regression model 2 of hypothesis 2 can be written as follows:

‘potential savings’($\hat{Y}_i$) = a + b_1*‘policy with prior consent’+ b_2* ‘policy with no prior consent’…….…. (VI)

3.5.2.3 Regression Model 3 of Hypothesis 2

The third regression model of hypothesis 2 includes following variables:

X_1: ‘generic substitution policy’

X_2: ‘policy without prior consent’ and

$\hat{Y}_i$: ‘potential savings’

Table 11

Variables Included in the Regression in the Regression Model 3 of Hypothesis 2

Dependent Variable (Y)	
'potential savings'	
Independent Variables (X)	
X_1	'generic substitution policy'
X_2	'policy with no prior consent'

In this regression model, Florida and Massachusetts as state with 'generic substitution policy' assigned a score of 1 and Michigan as state with not having 'generic substitution policy ' has assigned a score of 0. Other independent variable 'policy without prior consent' is defined as it is in the regression model 1 of hypothesis 2 as mentioned. Table11shows the variables of the model with STATA Codes and interpretation

Thus, the regression prediction equation can be shown as follows:

'potential savings' $(\hat{Y}_i) = a + b_1$* 'generic substitution policy' + b_2 *'policy with no prior consent'……(VII)

3.5.3 A Descriptive Statistical Analysis: Hypothesis 3

Hypothesis 3 used descriptive statistical model to examine if Michigan can reduce Medicaid costs in selected therapeutic classes through a higher use of generic substitution. The goal of this analysis is to examine if a mandatory generic substitution policy has any significant effect on the use of generics in selected therapeutic classes whenever available and thus, if Michigan can reduce costs.

In examining how Michigan can save in the Medicaid prescription drugs program by examining broad drug categories, the current research also examines if Michigan can contain costs instead of implementing a higher use of some "popular" brand drugs, which

also have generic substitutions, prescribed by the physicians for Medicaid patients. In doing so, the current research calculates cost differences between ten "popular" or "heavily used" BTE with average generic costs in 2010 by using descriptive statics. As Brill (2010) found, Medicaid overspending of these "heavily used" BTE drugs totaled $329 million in 2009 by the Medicaid programs of forty states.

3.6 Summary of the Chapter

This chapter discussed core issues, methodology of the current research with the hypotheses, data sample and collection methods, data analysis, and statistical models for examining the research models. The discussion of the current chapter has also rationalize cost-benefit analysis as the core approach in determining implementation of a generic substitution policy as an efficient public policy in containing costs of Michigan Medicaid prescription drug program. Regression models and descriptive statistical analysis to examine hypotheses 1, 2, and 3 are discussed in greater detail in chapter 4, 5, and 6 respectively.

CHAPTER IV

REGRESSION MODELS AND HYPOTHESIS 1: A STATISTICAL ANALYSIS

4.1 Introduction

In the following section, this research examines reasons that are mentioned in the literature as key to increasing Medicaid prescription drugs costs by using statistical methods of correlation and regressions and some other supporting techniques. The goal of this analysis is to examine if factors that are mentioned in contemporary literatures as the key factors of increasing prescription drug costs are really related to Medicaid total expenditures effectively and strongly or if these factors have no relationship with increasing prescription drug costs. In examining these reasons, the current research uses Medicaid prescription drug reimbursement data for six years for Michigan, Massachusetts, and Florida. The states of Massachusetts and Florida have implemented generic substitution policy since 2000. Therefore, these two states are included in the current analysis to examine if factors that are selected based on contemporary literature and research findings as independent variables such as generic utilization rate, brand utilization rate, brand drug cost as % of total reimbursement, generic drug cost as % of total reimbursement, costs of per brand prescription, costs of per generic prescription are related to and have any effect on total state reimbursement, total savings in prescription drugs, and savings (at the rate of generic drug unit price) as a percent of

total Medicaid reimbursement total state shares variables that are selected as dependent variables.

Thus, the major goal of this regression analysis is to examine if increases or decreases in independent variables can influence or are related to increases or decreases of dependent variables. The idea, here, is that if these independent variables appear to have significant and strong relationships to dependent variables cost increases of Medicaid prescription drugs, then state government can propose necessary policy changes in relation to these independent variables in containing Michigan Medicaid prescription drug costs.

4.2 Variables in Regression Analysis of Hypothesis 1

Table 12 provides a basic summary of dependent and independent variables selected for regression models employed in examining hypothesis 1.

The total number of observations of two dependent variables employed in examining hypothesis 1 'state share', and 'potential savings' and most independent variables are 18 (in years). In other words, this research deals with a total of 18 years of data for two dependent variables and most of the independent variables related to Medicaid prescription drugs program of Michigan, Massachusetts, and Florida. Out of eight independent variables employed in examining hypothesis 1, five independent variables have observations of 18 years. Three independent variables such as 'per prescription generic reimbursement', 'per prescription brand reimbursement', and 'per prescription BTE reimbursement' have observations of 17 years each.

The average, or mean, of the dependent variable 'state share' as percentage of total prescription drug costs' is 46.64 with a standard deviation of 6.01 and 'state of all sample years are between 38.86 (minimum) and 63.76 (maximum).

Table 12

Summary: Dependent and Independent Variables

Variable	Obs	Mean	Std. Dev.	Min	Max
'state share'	18	46.64	6.01	38.86	63.77
'potential savings'	18	5.27e+07	6.56e+07	6780083	2.51e+08
'generic substitution policy	18	.67	.49	0	1
'BTE unit reimbursement'	18	30.74	20.94	9.25	69.78
'brand unit reimbursement'	18	44.68	15.00	21.36	66.11
'BTE amount reimbursement'	18	13.84	14.19	3.19	50.54
'brand amount reimbursement'	18	83.71	11.04	43.26	94.84
'per prescription generic reimbursement'	17	20.07	12.31	11.95	66.44
'per prescription brand reimbursement'	17	125.75	41.83	69.10	191.59
'per prescription BTE reimbursement'	17	60.67	33.87	29.94	140.44

The average, or mean, score of 'generic substitution policy' (Florida and Massachusetts with generic substitution policy =1; and Michigan, having no generic substitution policy =0), is .67; with a standard deviation of .49 and the minimum and maximum scores are all between 0 (minimum) and 1 (maximum).

The average, or mean, score of 'BTE unit reimbursement' as percentage of total drug units reimbursed, is 30.74 (in %); with a standard deviation of 21.00 and the minimum and maximum scores are all between 9.25 (minimum) and 69.78 (maximum).

The average, or mean score of ‘brand unit reimbursement’ as percentage of brand drug used of total drug unit reimbursed, is 44.68; with a standard deviation of 14.10 and the minimum and maximum scores are between 21.36 (minimum) and 66.11 (maximum). The average, or mean, score of BTE amount reimbursement’ as percentage of total rescription drug costs, is 13.84; with a standard deviation of 14.19 and the minimum and maximum scores are all between 3.19 (minimum) and 50.54 (maximum).

The average, or mean, score of ‘brand amount reimbursement’ as percentage of total prescription drug costs, is 16.96; with a standard deviation of 11.54 and the minimum and maximum scores are all between 5.20 (minimum) and 56.73 (maximum).

Observation of ‘per prescription generic reimbursement’ or percentage of generic drug amount reimbursed per prescription, is 17 (years), while the average, or mean, score is 20.07; with a standard deviation of 12.31 and the minimum and maximum scores are all between 11.95 (minimum) and 66.44 (maximum).

Observation of ‘per prescription brand reimbursement’ or percentage of brand drug amount reimbursed per prescription, is 17 (years), while the average, or mean, score is $125.07; with a standard deviation of $41.83 and the minimum and maximum scores are all between $69.10 (minimum) and $191.58 (maximum).

Observation of ‘per prescription BTE reimbursement’ is 17 (years), while the average, or mean, score is $60.67; with a standard deviation of $33.87 and the minimum and maximum scores are all between $29.94 (minimum) and $140.44 (maximum).

4.2.1 Regression Model 1 of Hypothesis 1

In hypothesis 1, that a potential generic substitution policy regarding prescription drugs may be an efficient approach in containing prescription drug costs and thus

reducing the state share in the Michigan Medicaid program. Four multivariate regression models are employed to examine hypothesis 1. The major goals of these multivariate regressions are to examine if there any relationship exists and if so, its nature between state Medicaid prescription drug costs and generic substitution policy with different provisions. The main goal of this regression models is to examine if independent variables have any effects on dependent variable. In other words, if increase or decrease of independent variables also increase or decrease value of dependent variable. In examining this relationship, regression model 1 includes following dependent and independent variables are selected:

X_1: 'generic substitution policy'

X_2: 'brand drug unit reimbursement'

X_3: 'BTE unit reimbursement' and

$\hat{Y}$: 'state share'

A multivariate regression model examines if there is any significant relationship between the dependent variable and independent variables. Thus, the regression prediction equation to examine this relationship is as following:

state share $\hat{Y} = a$ (constant)+ b_1*generic substitution policy + b_2 *brand drug unit reimbursement + b_3* BTE unit reimbursement ……(extension of I)

Table 13

Summary Results of the Regression Model 1 of Hypothesis 1

(Y)	Variables (X)	Constant (intercept)	Coef.	(p>|t|)	*β (Beta)*
'state share'	'generic substitution policy'	62.44	1.70	0.70 (non significant)	0.086
	brand unit reimbursement'		-.27	.011 (significant)	-0.63
	'BTE units reimbursement'		-.14	.041(significant)	-0.50

Results

- 1% change in use of brand drugs will decrease 27% state share in monetary amount
- 1% change in BTE used will decrease 14% state share in monetary amount

A brief summary result of the regression mode 1 is presented in Table 13. It shows that among the three independent variables of egression model 1 only two independent variables percentage of brand with therapeutically equivalent (BTE) as of total drug unit reimbursement ('BTE unit reimbursement' here after) with (p>|t|) value of 0.001 and 'percentage of brand drugs (BD) as of total drug unit reimbursement'(brand drug unit reimbursement' here after) with p>|t| value of 0.041 have appeared as significant and the other independent variable 'generic substitution policy' with (p>|t|) value of 0.694 has appeared insignificant. In other words, independent variables 'BTE unit reimbursement' and 'brand drug unit reimbursement' can influence dependent variable 'state Share'.

Result of regression model 1 shows that within the model a 1 unit change in 'brand drug unit reimbursement'(X_2) would decrease 27% 'state share'. It is because the

less money states pay for the brand drugs the less share states need to carry on for the prescription drugs. Similarly, within the regression model a 1 unit change of ‘‘BTE unit reimbursement’(X_3) would decrease 14% in ‘state share’ of prescription drug costs. From β (Beta) value of .63 or 63% and 0.50 or 50% these two independent variables have appeared moderate to strong predictor of dependent variable. In contrast, the other independent variable ‘generic substitution policy’(X_1) has no influence on dependent variable ‘percentage of state share of total prescription drug costs’ or in other words, increase or decrease of ‘percentage of state share of total prescription drug costs’ does not depend significantly on ‘generic substitution policy’ in general. In the following this model is discussed in a greater detail. A statistical result output of STATA analysis of regression Model 1is provided in Appendix A.

Discussion of the regression results. By plugging in the values of independent variables we can write regression prediction equation 1 (extended) as follows:

$$\text{‘state share’ } (\hat{Y}) = 62.44 + 1.70\,(X_1) + \{(-.27)\,(X_2)\} + \{(-.14)\,(X_3)\} \quad \ldots\ldots(I)$$

The value of constant or 62.44 is the base prediction of ‘state share’ or Y when all X variables have 0 value. This regression equation shows that the estimate of ‘state share’ depends differently on selected independent variables. Each additional change of 1 unit in ‘generic substitution policy’ would increase ‘state share’ by 1.7 units. If the change in ‘generic substitution policy, occurs as 10 unit, then Medicaid would have a predicted ‘state share’ decrease by {(1.7) (.10)} or 17 unit, where t is computed 0.40 by using N-1 degrees of freedom. Probability appears as 0.69. So, $t(17)=0.40$, $p>0.55$. This regression appears statistically insignificant. Thus, there do not exist any significant relationship between the ‘state share’ and ‘generic substitution policy’.

Each additional 1 unit change in 'brand drug unit reimbursement' (X_2) would change -.27 unit of state share of prescription drug program, holding all other variables constant. For each additional 10 units change in use of 'brand drug unit reimbursement' (X_2) Medicaid would have a predicted 'state share' change by {(.27) (10)} or 2.7 units, where *t* is computed -2.93 by using N-1 degrees of freedom. Probability appears as 0.011. So we can write this as: t(17)= -2.65, p<0.05. This regression appears statistically significant. Thus, there is a highly significant relationship between 'state share' and 'brand drug unit reimbursement'.

Each additional 1unit change in use of 'BTE unit reimbursement' would change 'state share' by -.14 unit holding all other variables constant. If the change in 'BTE unit reimbursement' of total drug unit reimbursement' occurs 10 units, then Medicaid would have a predicted decrease in {(-.14) (10)} or 1.4 units. *t* is computed -2.25 by using N-1 degrees of freedom. Probability appears as 0.041. So, t(17)=-2.25, p<0.05. This regression appears statistically significant. Thus, there is a highly significant relationship between 'state share' and 'BTE unit reimbursement'.

Beta (β) statistics. From the regression output based on beta statistics among the independent variables, 'brand drug unit reimbursement' appears the strongest predictor of 'state share' with β= 0.63,p< 0.05. It has the strongest effect on the dependent variable 'state share' because its β is higher than any other predictors with significant relationship with the dependent variable.

According to the beta statistics, 'BTE unit reimbursement' appears the second strongest predictor of the dependent variable 'state share' with β= 0.50,p< 0.05. It has the second strongest effects on the dependent variable because its β is higher than the other

independent variable ‘generic substitution policy’ and lower than the β value of ‘brand drug unit reimbursement’.

The other independent variable ‘generic substitution policy’ is not statistically significant, because it has $p > 0.05$.

Regression model summary statistics. The model summary statistics output column labeled as source includes model, which refers to the regression model. In this case, the regression model consists of three predictors, or in other words, independent variables. Thus the degree of freedom becomes equal to the number of the predictors, or 3 in the regression model. The F statistics (3,14)=3.55 is the ratio of the mean square for the model to the mean square for the residual. The probability of F ratio appears as 0.0423 or $p < 0.05$. Thus, F statistic appears as follows:

$$F(3, 14) = 3.55, p < 0.05$$

There is a strong significant relationship between dependent variable ‘state share’ and three independent variables. The model summary statistics output of regression model 1 is shown in Table 14.

R^2 reports how well the model fits the data. This model explains 43% of the variance in ‘percentage of state share of total prescription drug costs’ concern. In this case, STATA reports R^2 as 0.43 in multiple regressions. R^2 measured how close the observations are to the predicted value, based on the set of predictors. We can say that the value .43 for R^2 shows a strong relationship between the dependent variable, percentage of state share of total prescription drug costs’ and independent variables ‘generic substitution policy’, ‘BTE unit reimbursement’ and ‘brand drug unit reimbursement’. Adjusted R^2 appears as 0.31. Adjusted R^2 offsets the ‘chance effects’ or

bias value in a multiple regression with more than one predictor and a small sample R^2 can be big by chance. The value of Adjusted R^2 should be less than value of R^2 as it attempts to reduce chance effects. In case of a substantial difference between R^2 and Adjusted R^2, the value of Adjusted R^2 is reported. Root MSE represents how 'big' or 'less' variables deviate from the regression line. The bigger the Root MSE value, the bigger the difference. The smaller the Root MSE value, the smaller the difference. In this case, Root MSE appears as 4.99. Based on the observations of 18, which we can say is relatively small, Root MSE 4.99 appears small so thus is the difference between the variable and the regression line.

Table 14

Model Summary Statistics of Hypothesis 1

df	3
Number of observation	18
F (3,14)	3.55
Probability>F	0.042
R-Squarded	0.43
Adjusted R-Squarded	0.3106
Root MSE	4.99

4.2.1.1 Multicollinearity Analysis

In addition to examining model statistics, beta statistics, and the value of R^2 to evaluate how strongly dependent and independent variables are related, the current study examines if there exists any collinearity and multicollinearity, and refers to the situation

of high correlation among the independent variables, which makes it difficult to know how important are these independent variables as predictor. In multiple regressions, multicollinearity makes one or more of the variables grossly outmoded due to combination variables (Acock, 2006). The following result shows multicollinearity of the current regression:

Table 15

Multicollinearity: Regression 1, Hypothesis 1

Variable	VIF	1/VIF
'BTE unit reimbursement'	1.24	.80
'brand unit reimbursement'	1.15	.87
'generic substation policy'	1.14	.88
Mean VIF	1.18	

Result shows both variance inflation reflector (VIF) and its reciprocal (1/VIF). In general, statistically if VIF appears more than 10 for any variable, then it is assumed there is multicollinearity for that specific or those variables. If the mean VIF appears substantively greater than 1.00, there could be a multicollinearity problem. Besides, if VIF > 10 or 1/VIF < 0.01, there may be a multicollinearity problem too (Acock, 2006). In the current regression model, VIF appears much lower than 10.0 for each of the independent variables and the mean VIF appears as 1.18, which is not a problem. Therefore, based on the above discussed rules we can say that there is no multicollinearity among the independent variables included in the current regression model.

4.2.2 Regression Model 2 of Hypothesis 1

A second regression model of hypothesis 1 is employed to examine if there exists any relationship between potential savings and use of different types of drugs and the nature of this relationship. In examining this relationship, regression model 1 includes following independent and dependent variables are selected:

X_1: generic substitution policy

X_2: brand drug unit reimbursement

X_3: BTE unit reimbursement and dependent variable

$\hat{Y}$: 'potential savings from BTE costs @ generic' ('potential savings', hereafter).

The regression prediction equation II as follows for hypothesis 1 following:

'potential savings'($\hat{Y}$) = *a* (constant)+ b_1*generic substitution policy + b_2* brand drug unit reimbursement + b_3 *BTE unit reimbursement ……(II)

A brief summary of the results of regression model 2 is presented in Table 16.

Regression model shows that among the three independent variables only one independent variable –'percentage of BTE used as of total drug units reimbursed' ('BTE unit reimbursement' here after) with (p>|t|) value of 0.001 has appeared as significant and the other two independent variables and 'Brand drug unit reimbursement' with p>|t| value of 0.940 'generic substitution policy' with (p>|t|) value of 0.968 have appeared insignificant. In other words, independent variable – 'BTE unit reimbursement' can influence dependent variable 'potential savings' significantly. In the following this model is discussed in a greater detail. A STATA result output is provided for regression model 2 of hypothesis 1 in Appendix B.

Table 16

Summary Statistics of Regression Model 2, Hypothesis 1

Variables		Coef.	Constant	(p>|t|)	*β* *(Beta)*
(Y)	(X)				
'potential savings'	' generic substitution policy'	987,056.6	19,200,000	.97 (non significant)	.007
	'brand drug unit reimbursement'	-64308.28		.94 (non significant)	-.013
	'BTE units reimbursement'	2,411,076		.001 (significant)	0.76

Results:

- 1% change in BTE use could save approximately $2.5 million

Discussion of the regression results. By plugging in the values in the regression prediction equation II we can write it as follows:

'potential savings'($\hat{Y}$) =$19.2 (constant)+ $987,056.6($X_1$) +$(-64,308.28) (X_2)+ $2,411,076 ($X_3$)……(II)

Result of regression model 2 shows that within the regression model value of constant $1.92 million is the base prediction of 'potential savings' from BTE drug costs at the rate of generic drugs available or value of Y when all X variables have 0 value. A 1% change in use of 'percentage of BTE used as of total drug units reimbursed' will decrease approximately $2.5 million of 'potential savings' from BTE drug costs at the

rate of generic drugs available. From β (Beta) value of 0 .76 this independent variable has appeared as a strong predictor of dependent variable 'potential savings' from BTE drug costs at the rate of generic drugs available. In contrast, the other two independent variables 'percentage of brand drug used as of total drug unit reimbursed' and 'generic substitution policy' have no significant influence on dependent variable 'potential savings from BTE drug costs at the rate of generic drugs available' or in other words, increase or decrease of 'potential savings from BTE drug costs at the rate of generic drugs available' does not depend on 'generic substitution policy' in general or 'percentage of brand drug used as of total drug unit reimbursed'.

The value of constant or $ -19.2 million is the base prediction of Y when all X variables have 0 value. This regression equation tells that 'potential savings' depends differently on selected independent variables. This equation tells us if each independent variables contain 0 value and other conditions remain the same then there would be an approximately -$19.2 million (constant) decrease of 'potential savings'.

Each additional unit change in 'generic substitution policy' would increase 'potential savings' by $ 987,056.6 holding all other variables constant. If change occurs in 'generic substitution policy' by ten per unit, then the Medicaid prescription drug program would have a predicted 'potential savings' by ${-$987,056.6 (10)} or $9,870,566, where *t* is computed 0.04 by using N-1 degrees of freedom. Probability appears as 0.96. So, t(17)=0 .04, p>0.55. This regression appears statistically insignificant. Thus, this regression model shows independent variable 'generic substitution policy' has insignificant influence in making any type of change of dependent variable 'potential savings'.

Each additional one unit change in 'brand drug unit reimbursement (X_2) would decrease 'potential savings' by $ 64308.28 holding all other variables constant. If changes in 'brand drug unit reimbursement' occurs in 10 unit then Medicaid prescription drug program would have a predicted decrease in 'potential savings' by ${$ 64308.28 (10)} or $ $ 643,082.8, where *t* is computed 0.08 by using N-1 degrees of freedom. Probability appears as 0.940. So, t (17)=0 .940, p>0.55. This regression appears statistically insignificant. Thus, this regression model does not show any significant relationship between 'brand drug unit reimbursement' and 'potential savings'.

For each additional one unit change in 'BTE unit reimbursement' would change 'potential savings' by approximately $ 2.5 million holding all other variables constant. If change in 'BTE unit reimbursement' occurs by ten unit then Medicaid would have a predicted 'potential savings' ${-$2.5(10)} or approximately $25 million, where *t* is computed 4.10 by using N-1 degrees of freedom. Probability appears as 0.001. So, t (17)=0 .04, p<0.05. This regression appears statistically significant. Thus, this regression model does show an existing significant relationship between BTE unit reimbursement (X_3) and 'potential savings'.

Interpretation of Beta (β) statistics. From the regression output based on beta statistics, among the independent variables) 'BTE unit reimbursement'(X_3) appears the strongest predictor of percent 'potential savings' with β= 0.76,p< 0.05. It has the strongest effects on dependent 'potential savings' because it has the higher β than any other predictors with significant relationship with 'potential savings'.

Other two independent variables 'generic substitution policy' and 'brand drug unit reimbursement (X_2) appear statistically insignificant, because both of these two independent variables have $p > 0.05$.

Regression model summary statistics. Model summary statistics output

Table 17

Model Summary Statistics, Model 2 of Hypothesis 1

df	3
Number of observation	18
F (3,14)	7.11
Probability>F	0.0039
R-Squarded	0.60
Adjusted R-Squarded	0.52
Root MSE	4,600,000

The regression model consists of three independent variables, which are 'generic substitution policy'(X_1), 'brand drug unit reimbursement (X_2), and 'BTE unit reimbursement' (X_3). The source called Residual corresponds to the error components in analysis of variance. In this case degree of freedom is the number of predictors or 3 in this model. The F statistics (3,14)=7.11 is the ratio of the mean square for the model to the mean square for the residual, which is in this case is 1.4724e+16/ 2.0705e+15 =7.11. The probability of the F ratio appears as 0.0039 or $p < 0.05$. Thus, the F statistics appear as follows:

$$F(3, 14) = 2.90, p < 0.05$$

There is a strong significant relationship between 'potential savings' and the independent variables.

R^2 reports how well the model fits the data and this model explains 60% of the variance in 'potential savings' concern. In this case, R^2 appears as 0.60, which shows a strong relationship between the dependent variable, 'potential savings' and the independent variables, 'generic substitution policy'(X_1), 'brand drug unit reimbursement (X_2), and BTE unit reimbursement (X_3). Adjusted R^2 appears as 0.52. Adjusted R^2 offsets the 'chance effects' or bias value in a multiple regression with more than one predictor and a small sample R^2 can be big by chance. The value of Adjusted R^2 should be less than the value of R^2 as it attempts to reduce chance effects. In case of substantial differences between R^2 and Adjusted R^2, the value of Adjusted R^2 is reported. Root MSE represents how big or 'less' variables deviate from the regression line. The bigger the Root MSE value, the bigger the difference. The smaller the Root MSE value, the smaller the difference. In this case, Root MSE appears as 4,600,000.0, which based on the observations of 18 in terms of savings amount, Root MSE appears small so thus the difference between the variable and the regression line.

Table 18

Multicollinearity: Regression 2, Hypothesis 1

Variable	VIF	1/VIF
'BTE unit reimbursement'	1.24	.80
'brand unit reimbursement'	1.15	.87
'generic substation policy'	1.14	.88
Mean VIF	1.18	

4.2.2.1 Multicollinearity Analysis

This regression model uses the same set of independent variables used in the earlier regression model thus multicollinearity is not a problem at all for this regression model as with the previous regression model.

4.2.3 Regression Model 3 of Hypothesis 1

A third regression model of hypothesis 1 is employed to examine if there exists any relationship and the nature of the relationship between Medicaid prescription drugs savings and use of generic substitution policy with different provisions. For this purpose following dependent and independent variables as selected:

$X_{1:}$'generic substitution policy'

$X_{2:}$ 'brand amount reimbursement'

$X_{3:}$ 'BTE amount reimbursement' and dependent variable

$\hat{Y}_i$: 'potential savings'

The goal of this regression is to examine if selected independent variables have any influence in increasing or decreasing the dependence variable. Relationship among the dependent variable and independent variables can be written according to regression prediction equation III and summary of the regression model 3 are shown as follows:

'potential savings' ($\hat{Y}_i$)= *a* (constant)+ b_1 * 'generic substitution policy'+ b_2* 'brand amount reimbursement' + b_3* 'BTE amount reimbursement'…….(III)

Table 19

Summary Statistics of the Regression Model 3, Hypothesis 1

Variables		Constant		(p>|t|)	β
(Y)	(X)		Coef.		*(Beta)*
'potential savings'	'generic substitution policy'	6,338,828	24,800,000	.258 (non significant)	.18
	'brand amount reimbursement'		-241,099.7	.082 (non significant)	-.04
	'BTE amount reimbursement'		3,613,227	.000 (significant)	.78

Results:

- Each additional change of 1 unit in 'BTE amount reimbursement' would increase 'potential savings' by more than $3.5 million.

Result of the regression model 3 shows that among the three independent variables only one independent variable 'percentage of BTE amount as of total drug reimbursement expenditure' ('BTE amount reimbursement' henceforth) with (p>|t|) value of 0.000 has appeared as significant and the other two independent variables 'brand amount reimbursement' with p>|t| value of 0.082 and 'generic substitution policy' with (p>|t|) value of 0.258 have insignificant relationship with dependent variable. In other words, independent variable – 'BTE amount reimbursement' has influence in increasing or decreasing dependent variable 'potential savings' significantly. From β (Beta) value of .7813041 or 78%, this independent variable has appeared as a strong predictor of

dependent variable. In contrast, the other two independent variables 'generic substitution policy' and 'brand amount reimbursement' have no significant influence on dependent variable 'potential savings'. In other words, increase or decrease of 'potential savings' do not depend significantly on 'generic substitution policy' and 'brand amount reimbursement'. Following section discusses the result of the regression model 3 of hypothesis in a greater detail. A STATA result output of regression model 3 is provided in the Appendix C.

Discussion of Regression results. By plugging in the values in the regression prediction equation II we write it as follows:

> 'potential savings' ($\hat{Y}_i$)= 6,338,828 (constant)+{24,800,000* 'generic substitution policy'}+ {-(241,099.7)* 'brand amount reimbursement' }+ 3,613,227 * 'BTE amount reimbursement' ……..…….....(III)

The value of constant or $ 6.33 million is the base prediction of Y when all X variables have 0 value. This regression equation shows that dependent variable 'potential savings' depends differently on selected independent variables. Within the regression framework, this equation shows that if change occurs 0 percent in independent variables then 'potential savings' becomes $6.33 million (the intercept or constant).

Each additional one unit of change in 'generic substitution policy' would increase 'potential savings' by $ $24.8 million holding all other variables unchanged. If the change occurs in 'generic substitution policy, by ten per unit, then Medicaid would have a predicted 'potential savings' ${24,800,000 (10)} or or approximately more than $248 million, where *t* is computed 1.18 by using N-1 degrees of freedom. Probability appears as 0.258. So, t(17)=1.18, p>0.05. This regression appears statistically insignificant. Thus,

this regression model does not show any existing significant relationship between 'potential savings' and 'generic substitution policy'.

Each additional change of one unit in 'brand amount reimbursement' would decrease 'potential savings' by approximately $ 241,099.7 holding all other variables constant. If 'brand amount reimbursement' (X_2) changes by 10 unit then Medicaid prescription drugs would have a predicted 'potential savings' decrease by ${-(241,099.7)(10)} or $2.41 million, where *t* is computed -.26 by using N-1 degrees of freedom. Probability appears as 0.802. So, t (17)=0 .26, p>0.05. This regression appears statistically insignificant. Thus, this regression model does not show any existing significant relationship between independent variable 'brand amount reimbursement' and dependent variable 'potential savings' of prescription drugs program.

Each additional one unit change in 'BTE amount reimbursement'(X_3) would increase 'potential savings'($\hat{Y}_i$) by approximately $ 3.61 million holding all other variables constant. If change occurs in 'BTE amount reimbursement'(X_3) by ten unit then Medicaid prescription drug program would have a predicted 'potential savings' increase by ${$ 3.61(10)} or $ 36.1 million where *t* is computed 5.13 by using N-1 degrees of freedom. Probability appears as 0.00 So, t (17) =5.13, p<0.05. This regression appears statistically significant. Thus, this regression model does show that significant relationship exists between 'BTE amount reimbursement'(X_3) and 'potential savings'($\hat{Y}_i$).

Beta (β) statistics. From the regression output based on beta statistics, among the independent variables 'BTE amount reimbursement' (X_3) appears as the strongest predictor of 'potential savings' ($\hat{Y}_i$) with β= 0.78,p< 0.00. Independent variable 'BTE

amount reimbursement' has the strongest effects on dependent variable 'potential savings' because it has the higher β than any other predictors with significant relationship with the dependent variable.

Two other independent variable 'generic substitution policy' and ' brand amount reimbursement' have appeared statistically insignificant, because both of these two independent variables have p> 0.05.

Model summary statistics. The model summary statistics output shows 3 are the number of predictor or degree of freedom. The F statistics (3,14)=10.43. The probability of the F ratio appears as 0.0007 or p< 0.05. Thus, the F statistics appear as follows:

$$F\ (3,\ 14)=10.43, p<0.05$$

Table 20

Regression Model Summary Statistics, Model 3 of Hypothesis 1

df	3
Number of observation	18
F (3,14)	10.43
Probability>F	0.0007
R-Squarded	0.69
Adjusted R-Squarded	0.62
Root MSE	4,000,000

There is a strong significant relationship between dependent variable 'potential savings' ($\hat{Y}_i$) and independent variables.

R^2 reports how well the model fits the data and this model explains 69% of the variance in 'potential savings' ($\hat{Y}_i$) concern. In this case R^2 appears as 0.69, which shows a strong relationship between the dependent variable 'potential savings' ($\hat{Y}_i$) and independent variables generic substitution policy(X_1), brand amount reimbursement'(X_2), and 'BTE amount reimbursement' (X_3). Adjusted R^2 appears as 0.62. As explained earlier Adjusted R^2 offsets the 'chance effects' or bias value in a multiple regression with more than one predictors and a small sample R^2 can be big by chance. The value of Adjusted R^2 should be less than the value of R^2 as it attempts to reduce chance effects. In case of a substantial difference between R^2 and Adjusted R^2, the value of Adjusted R^2 is reported. Root MSE represents how big or 'less' variables deviate from the regression line. The bigger the Root MSE value, the bigger the difference. The smaller the 'Root MSE' value the smaller the difference. In this case 'Root MSE' appears as $4,000,000.0 million, which based on the observations of 18 in terms of saving's amount, Root MSE appears small in terms of prescription drug expenditures and thus the difference between the variable and the regression line. Following is the result of multicollinearity of the independent variables:

Table 21

Multicollinearity Analysis: Regression 3, Hypothesis 1

Variable	VIF	1/VIF
'brand unit reimbursement'	1.14	.88
'generic substation policy'	1.10	.91
'BTE unit reimbursement'	1.14	.95
Mean VIF	1.10	

Multicollinearity Analysis. As the VIF of independent variables and mean VIF of independent variables appear much lower than 10.0 and 1/VIF value of independent variables appears greater than 0.10, there does not exist any multicollinearity problem in any independent variables of this regression model.

4.2.4 Regression Model 4 of Hypothesis 1

In examining hypothesis 1, a fourth regression is employed to examine if there exists any relationship and the nature of this relationship between the dependent variable 'potential savings at the cost of generic drug' ('potential savings' hereafter) and nature of prescription pattern. This regression model 4 of hypothesis 1 examines if there exists any relationship between 'potential savings' and per prescription costs. Following independent variables are selected to examine the hypothesis:

X_1 'generic prescription costs'

X_2 'brand prescription costs'

X_3 'BTE prescription costs' and dependent variable

$\hat{Y}_i$ 'potential savings'

The regression prediction equation of model 4 of hypothesis 1 can be shown as follows:

'potential savings'($\hat{Y}_i$) = a+ b_1*'generic prescription reimbursement'+ b_2* 'brand prescription reimbursement'+b_3*'BTE prescription reimbursement'.....(IV)

Table 22 presents brief summary results of the regression. Regression model shows that among the three independent variables two independent variables – 'per prescription BTE reimbursement' ('BTE prescription' hereafter) with (p>|t|) value of 0.000 and 'per prescription brand reimbursement' ('brand prescription' hereafter) with p>|t| value of 0.034 have appeared as significant and the other independent variable 'generic prescription' with (p>|t|) value of 0.605 has appeared insignificant. In other

words, independent variables ‘brand prescription’ and ‘BTE prescription’ can influence in increasing or decreasing of dependent variable ‘potential savings’. In contrast, there exists no relationship between independent variable ‘generic prescription’ and ‘potential savings’. Therefore, ‘generic prescription’ as an independent variable has no significant influence on ‘potential savings’ to increase or decrease it.

Table 22

Summary Results of the Regression Model 4 of Hypothesis 1

Variables		Coef.	(p>|t|)	*β*
(Y)	(x)			*(Beta)*
‘potential savings’	‘generic prescription reimbursement’	291239.8	.605 (non significant)	.053
	‘brand prescription reimbursement’	-471634.7	.034 (significant)	-.29
	‘BTE prescription reimbursement	2,156,046	.000 (significant)	1.08

Results

- Each one unit additional change in ‘brand prescription reimbursement’ would decrease ‘potential savings at the cost of generic drug’ by $ 471634.7.
- Each one unit additional change in BTE prescription ‘reimbursement’ would increase ‘potential savings’ by little over $ 2 million.

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Based on *β* (Beta) value, among the three independent variables ‘BTE prescription’ is the strongest predictor of dependent variable ‘potential savings’ and ‘brand prescription’ occurs as the second strongest predictor of the dependent variable.

The other independent variable 'generic prescription' has no influence on dependent variable. In the following this model is discussed in a greater detail and a STATA result of regression summary is provided in Appendix D.

Discussion of Regression results. By plugging in the values of STATA regression analysis in the regression prediction equation IV we can write it as follows:

'potential savings'($\hat{Y}_i$) = 24,400,000+ 291,239.8 (X_1)+ (-471634.7) (X_2)+ 2,156,046 (X_3)……(IV)

The value of constant or $ 24.4 million is the base prediction of Y when all X variables have 0 value. This equation tells us with 0 percent change within the regression model, or in other words, without any changes in any independent variables, 'potential savings' would decrease by $ 24.4 million (the intercept or constant). The regression model shows that 'potential savings' depends on independent variables differently.

Each additional change of one unit occurring in 'generic prescription' would have a predicted increase in 'potential savings' by approximately $291,239.8 holding all other variables unchanged. If change occurs 'generic prescription' by ten units, then Medicaid prescription drug program would have a predicted increase in 'potential savings' by ${291239.8 (10)} or $2.9 million, where *t* is computed 0.53 by using N-1 degrees of freedom. Probability appears as 0.605. So, t(17)= 0.53, p>0.05. This regression appears statistically insignificant. Thus, this regression model does not show any significant relationship between dependent variable 'potential savings at the rate of generic drugs' and independent variable 'generic reimbursement per prescription'.

Each additional change of one unit in 'brand prescription' would decrease 'potential savings' by $ 471,634.7 holding all other variables unchanged. If change occurs in 'brand prescription' by ten units, then Medicaid prescription drug program

would have a predicted decrease in 'potential savings' by ${471,634.7 (10)} or approximately $4.7 million, where *t* is computed -2.37 by using N-1 degrees of freedom. Probability appears as 0.034. So, t(17)=-2.37, p<0.05. This regression appears statistically significant. Thus, this regression model shows significant relationship between dependent variable 'potential savings' and independent variable 'brand prescription'.

Each additional one unit of change in 'BTE prescription' would increase 'potential savings' by approximately $ 2,156,046 holding all other variables unchanged. If change occurs by ten per units, then Medicaid prescription drug program would have a predicted 'potential savings' by ${2,156,046 (10)} or approximately $21.16 million, where *t* is computed 9.10 by using N-1 degrees of freedom. Probability appears as 0.000. So, t(17)=-9.10, p<0.05. This regression appears statistically significant. Thus, this regression model shows significant relationship between dependent variable 'potential savings' and independent variable 'BTE prescription'.

Beta (β) statistics. From the regression output based on beta statistics, among the independent variables 'BTE prescription' appears the strongest predictor of the dependent variable 'potential savings' with β= 1.08,p ≤ 0.00. It has the strongest effects on 'potential savings' at the cost of generic drugs' because it has the higher β value than any other predictors with significant relationship of p< 0.05 with dependent variable 'potential savings'. It has very strong effect in predicting 'potential savings'. In the other hand, 'brand prescription' appears as the second strongest predictor of the dependent variable 'potential savings' with β= 0.29,p< 0.00. The other independent variable 'generic prescription' appears statistically insignificant as it has p>0.05.

Table 23

Regression Model Summary Statistics, Model 4 of Hypothesis 1

df	3
Number of observation	17
F (3,14)	41.44
Probability>F	0.000
R-Squarded	0.91
Adjusted R-Squarded	0.88
Root MSE	2,300,000

Model summary statistics. The model summary statistics output shows 3 are the number of predictors or degree of freedom. The F statistics (3,13)=41.44. The probability of the F ratio appears as 0.000 or $p< 0.05$. Thus, the F statistics appear as follows:

$$F (3, 13)=41.44, p<0.05$$

There is a strong significant relationship between 'potential savings' and three independent variables 'generic prescription', 'brand prescription' and 'BTE prescription'.

R^2 reports how well the model fits the data and this model explains 91% of the variance in dependent variable 'potential savings' concern. R^2 as 0.905 shows a strong relationship between the dependent variable 'potential savings' and independent variables 'generic prescription', 'brand prescription' and 'BTE prescription'. Adjusted R^2 appears as 0.88 and therefore there does not exist any 'chance effects' or bias value in predicting the dependent variable by the independent variables. Root MSE value as appears as $2,300,000 is relatively small in terms of potential savings amount in

Medicaid prescription drug programs and thus the difference between the variable and the regression line.

Table 24

Multicollinearity: Regression 4, Hypothesis 1

Variable	VIF	1/VIF
'brand prescription reimbursement'	2.09	.48
'BTE prescription reimbursement'	1.93	.52
'generic prescription reimbursement'	1.38	.73
Mean VIF	1.80	

Multicollinearity Analysis. In this regression model as the VIF value of independent variables and mean VIF of independent variables appears much lower than 10.0 and 1/VIF value of independent variables appears greater than 0.10, there does not exist any multicollinearity problem in any independent variables.

4.3. Summary of the Chapter

In examining hypothesis 1, the main goal was to examine relationships among the generic substitution policy, along with other independent variables and dependent variables of the Medicaid expenditures and savings regarding Medicaid prescription drugs program. All the regression models employed in examining the hypothesis tried to find out if selected independent variables have any significant relationship with the dependent variables. In other words, the models tried to identify if these independent variables have any influence in increasing or decreasing the dependent variables. Table

25 presents a brief summary of significant relationship between independent and dependent variables of the regression models of hypothesis 1.

Table 25

Summary Table of Findings of Regression Models of Hypothesis 1

	Variable (Y)	Variable (X)	(p>|t|)	Results
Regression Model 1.	'state share'	'brand drug unit reimbursement'	Significant	1 unit change in use of brand drugs will decrease 26% state share in monetary amount
		'BTE units reimbursement'	Significant	1 unit change in BTE used will decrease 14% of 'state share' in monetary amount
Regression Model 2.	'potential savings'	BTE units reimbursed	Significant	1 unit change in BTE use could save approximately $2.5 million
Regression Model 3.	'potential savings'	'BTE amount reimbursement'	Significant	Each additional 1 unit change in 'BTE amount reimbursement' would increase 'potential savings' of prescription drugs by more than $3.5 million.
Regression Model 4.	'potential savings'	'brand prescription'	Significant	Every additional change in 1 unit in 'brand prescription' would decrease 'potential savings' by $ 471,634.7
		'BTE prescription'	Significant	Each additional change of 1 unit in 'BTE prescription' would increase 'potential savings' by approximately over $2 million

Determining the relationship between 'generic substitution policy' and 'potential savings', and 'state share' of Medicaid prescription drugs as dependent variables is

important, because if a generic substitution policy has any influence in increasing or decreasing Medicaid prescription drug savings and expenditures, then it also implies that implementing a generic substitution policy will be able to contain the Medicaid prescription drug program costs and savings. The findings of Table 25 reveal that:

1. 'BTE unit reimbursement' and 'brand unit reimbursed' have significant relationships with the dependent variable 'state share'. In other words, these two independent variables can influence increasing or decreasing 'state share'. Regression model 1 shows that an additional 1 unit change in use of brand drugs will decrease 26% of the state share in monetary amount and 1 unit change in BTE used will decrease 14% of the state share in monetary amount. There exists no significant relationship between the independent variable 'generic substitution policy' and the dependent variable (regression model 1).
2. 'BTE units reimbursement' as an independent variable has a significant relationship with the dependent variable 'potential savings,' and an additional 1 unit change in BTE use could save approximately $2.5 million (regression model 2).
3. A significant relationship exists between 'potential savings' as a dependent variable and 'BTE amount reimbursement' as an independent variable and each additional 1 unit change in 'BTE amount reimbursement' would increase 'potential savings' of prescription drugs by more than $3.5 million(regression model 3).
4. The dependent variable 'potential savings' has a significant relationship with 'brand prescription' and 'BTE prescription' as independent variables. Each

additional change in one unit in brand prescription' would decrease 'potential savings' by

$ 471,634.7. Each additional change of one unit in 'BTE prescription' would increase 'potential savings' by approximately over $2 million (regression model 4).

5. A 'generic substitution policy' without any provisions as an independent variable has no significant relationship with the dependent variables 'state share' and 'potential savings' (regression model 1, 2,3and 4).

CHAPTER V

REGRESSION MODELS AND HYPOTHESIS 2: A STATISTICAL ANALYSIS

5.1 Regression Analysis: Hypothesis 2

In examining hypothesis 1, one of the goals was to find out if 'generic substitution policy' with other independent variables had any influence on increasing or decreasing Medicaid prescription drug costs and savings in general. Three regression models out of four that were employed in examining hypothesis 1 reveal that there existed no significant relationship between 'generic substitution policy' without any provisions as independent variables and dependent variables 'state share' and 'potential savings'. Therefore, regression models in hypothesis 2 aimed to examine if generic substitution policy with or without 'prior consent' have any influence in containing Medicaid prescription drug costs especially on 'state share' and 'potential savings'.

Thus in examining hypothesis 2, the influence of independent variables 'generic substitution policy', 'policy with prior consent', and 'policy with no prior consent' are examined on the dependent variables 'state share' and 'potential savings'

5.1.1 Regression Model 1 of Hypothesis 2

For first regression model 1 of hypothesis 2 examines if generic substitution policy with provisions of prior consent and without prior consent have any influence in increasing or decreasing on the dependent variable 'state share'. Following independent variables are selected for the regression analysis:

$X_{1:}$ 'policy with prior consent'
$X_{2:}$ 'policy with no prior consent' and dependent variable
$\hat{Y}_i$: 'state share'

A regression prediction equation for regression model 1 of hypothesis 2 can be written as follows:

'state share'($\hat{Y}_i$)= *a* (constant)+b_1 'policy with prior consent' + b_2 'policy with no prior consent'……(V)

A brief statistical output of regression model 1 of hypothesis 2 is shown in Table 26.

Table 26

Statistical Output of Regression Model 1 of Hypothesis 2

Variables		Constant	Coef.	t	(p>|t|)	*β*
(y)	(x)					*(Beta)*
'state share'	'policy with prior consent'	249 million	-78.4 million	0.89	0.388 (not significant)	.1745859
	'policy with no prior consent'		371 million	4.20	.001 (significant)	.8247634

Results

- 'policy with prior consent' would have a predicted decrease in 'potential savings' by approximately $78.5 million
- 'policy with no prior consent' would have a predicted increase in 'state share' by approximately $371 million

Regression model 1 of hypothesis 2 shows that between the two independent variables generic 'policy with no prior consent' with (p>|t|) value of 0.001 has appeared as

significant and the other independent variable generic 'policy with prior consent' with (p>|t|) value of 0.89 has appeared insignificant. In other words, independent variable generic 'policy with no prior consent' can influence in increasing or decreasing of dependent variable 'state share'. In contrast, there exists no relationship between independent variable generic 'policy with prior consent' and 'state share'. Therefore, generic 'policy with prior consent' as an independent variable has no significant influence on 'state share' to increase or decrease it. Based on β (Beta) value, between the two independent variables generic 'policy with no prior consent' is the strongest predictor of dependent variable 'state share' and generic 'policy with prior consent' occurs as a relatively weak predictor of the dependent variable. In the following this model is discussed in a greater detail and a STATA result of regression summary is provided in Appendix E.

Discussion of Regression results. By plugging in the values of STATA regression analysis in the regression prediction equation V we can write it as follows:

'state share'($\hat{Y}_i$)= 249,000,000 (constant)+78,400,000 (X_1) + 371,000,000 (X_2)……(V)

The value of constant or $ 249 million is the base prediction of Y when all X variables have 0 value. This equation tells us with 0 percent change changes in any independent variables within the regression model 'state share' would increase $ 249 million (the intercept or constant). The regression model shows that 'state share' in prescription drug costs depends on independent variables differently.

Each additional one unit changes in generic 'policy with no prior consent' would have a predicted increase in 'state share' in prescription drug costs by $ $371 million holding other variables unchanged. If changes of generic 'policy without prior consent'

occurs by ten units, then the Medicaid prescription drug program would have a predicted 'state share' in prescription drug costs increase by $ million {371 (10)} or 3710 million, where *t* is computed 0.89 by using N-1 degrees of freedom. Probability appears as 0.388. So, t(17)= 4.20, p<0.001. This regression appears statistically significant. Thus, this regression model shows that generic 'policy with no prior consent' has a significant influence in increasing or decreasing of 'state share' in prescription drug costs.

Each additional one unit of change in generic substitution 'policy with prior consent' would increase 'state share' in prescription drug costs by $78. 4 million holding all other variables unchanged. For example, if changes occur in generic 'policy without prior consent' by ten units, then Medicaid prescription drug program would have a predicted 'state share' increase by $ {78.4(10)} million or $784 million, where *t* is computed .89 by using N-1 degrees of freedom. Probability appears as 0.388. So, t (17)= 0.89, p>0.05. This regression does not show any significant relationship between 'state share' and generic substitution 'policy with prior consent'.

Beta (β) statistics. From the regression output based on beta statistics, between the two independent variables generic substitution 'policy with no prior consent' appears the strongest predictor of the dependent variable 'state share' of prescription drug costs with β= 0.82,p< 0.001. It has the strongest effects on 'state share' of prescription drug costs because it has the higher β value than other predictors with a significant relationship of p< 0.05 with 'state share' prescription drug costs'. The other independent variable generic substitution 'policy with prior consent' has appeared statistically insignificant, because it has p> 0.05.

Model summary statistics (hypothesis 2). The model summary statistics output show 2 is the number of predictor or degree of freedom. The F statistics (2,15)=9.81. Probability of F ratio appears as 0.001 or $p< 0.05$. Thus, the F statistics appear as follows:

$$F (2, 15)=9.81, p<0.05$$

There is a strong significant relationship between 'state share' of prescription drug costs and independent variables.

Table 27

Summary Statistics of Regression Model 1 of Hypothesis 2

df	3
Number of observation	17
F (2,14)	9.81
Probability>F	0.001
R-Squarded	0.57
Adjusted R-Squarded	0.51
Root MSE	15,000,000

R^2 shows that this model explains 57% of the variance in 'state share' of prescription drug costs concern. In this case STATA reports R^2 as 0.566, which shows a strong relationship between the dependent variable 'state share' of prescription drug costs and independent variables generic substitution 'policy with prior consent' and generic substitution 'policy with no prior consent'. Adjusted R^2 appears as 0.88 and therefore there does not exist any 'chance effects' or bias value in predicting dependent variable by the independent variables. Root MSE value as appears as (1.5e+ 08) or $ 15,000, 000, which is a relatively small amount in terms of 'state share' of prescription drug costs in

Medicaid prescription drug programs of sample states, and, thus, the difference between the variable and the regression line.

Multicollinearity Analysis. As the VIF value of independent variables and mean VIF of independent variables appear much lower than 10.0 and 1/VIF value of independent variables appears greater than 0.10, there does not exist any multicollinearity problem between the two selected independent variables of this regression model. Multicollinearity result of the independent variables of the model is shown below:

Table 28

Multicollinearity Analysis: Regression Model 2 of Hypothesis 2

Variable	VIF	1/VIF
'policy with prior consent'	1.33	.75
'policy without prior consent'	1.33	.75
Mean VIF	1.33	

5.1.2 Regression Model 2 of Hypothesis 2

In examining hypothesis 2, a second regression model is employed to examine the influence of the independent variables generic substitution with two opposite provisions on dependent variable. Following independent and dependent variables are selected:
A regression prediction equation for regression model 1 of hypothesis 2 can be written as follows:

$X_{1:}$ 'policy with prior consent'

X_2 :'policy with no prior consent' and

$\hat{Y}_i$: 'potential savings'

Regression equation of this model can be written as follows:

'potential savings'($\hat{Y}_i$)= *a* (constant)+b_1 'policy with prior consent' (X_1) + b_2 'policy with no prior consent'(X_2)……(VI)

Table 29 presents the brief summary results of the regression model 2 of hypothesis 2. It shows that between the two independent variables, generic 'policy with no prior consent' with (p>|t|) value of 0.011 has appeared as significant and the other independent variable, generic 'policy with prior consent' with (p>|t|) value of 0.68 has appeared insignificant. In other words, independent variable generic substitution 'policy with no prior consent' can influence increasing or decreasing of the dependent variable 'potential savings'.

In contrast, there exists no relationship between independent variable generic substitution 'policy with prior consent' and 'potential savings'. Therefore, generic 'policy with prior consent' as an independent variable has no significant influence to increase or decrease on 'potential savings'. Based on β (Beta) value, generic 'policy with no prior consent' occurs as the strongest predictor of dependent variable 'potential savings' with β value of .63. In contrast, generic substitution 'policy with prior consent' occurs as a week predictor of the dependent variable with β value of .09. In the following this model is discussed in a greater detail and a STATA result of regression summary is provided in Appendix F.

Table 29

Statistical Output of Regression Model 2 of Hypothesis 2

Variables					(p>|t|)	
(x)	(y)	Constant	Coef.	t		*β (Beta)*
'potential savings'	'policy with prior consent'	28,400,000	-12,400,000	-0.42	.680 (not significant)	-.0918832
	'policy with no prior consent'		85,200,000	2.89	.011 (significant)	.6303019

Results of the regression model

- 'policy with prior consent' would have a predicted decrease in 'potential savings' by approximately $12 million.
- 'policy with no prior consent' would have a predicted increase in 'potential saving' by approximately $85 million.

Result of the regression model. By plugging in the values of STATA regression analysis in the regression prediction equation V we can write it as follows:

'potential savings'($\hat{Y}_i$)= 28,400,000 (constant)+{- (12,400,000)*'policy with prior consent'} + 85,200,000*'policy with no prior consent'……(VI)

The value of constant or $ 284 million is the base prediction of Y when all X variables have 0 value. This equation tells us with 0 percent change changes in any independent variables within the regression model 'potential savings' would increase $

284 million (the intercept or constant). The regression model shows that 'potential savings' in prescription drug costs depends on independent variables differently.

Each additional change of one unit in generic substitution 'policy without prior consent' would have a predicted increase in 'potential savings' in prescription drugs costs by $85.2 million holding other variables unchanged. If changes occur in generic substitution 'policy without prior consent' by ten units, then Medicaid prescription drug program would have a predicted 'potential savings' in prescription drugs costs increase by ${85. 2 (10)} or $852 million, where *t* is computed 2.89 by using N-1 degrees of freedom. Probability appears as 0.001. So, t(17)= 2.89, p<0.011. This regression appears statistically significant. Thus, this regression model shows a significant relationship between generic substitution 'policy without prior consent' and dependent variable 'potential savings' in prescription drugs costs.

Each additional change in one unit in generic substitution 'policy with prior consent' would decrease 'potential savings' in prescription drugs costs by $(1.24e+07) million or $12.4 million holding all other variables unchanged. If changes occur in generic substitution 'policy with prior consent' by ten units, then the Medicaid prescription drug program would have a predicted 'potential savings' by ${12.4 (10)} or 124 million, where *t* is computed - .42 by using N-1 degrees of freedom. Probability appears as 0.680. So, t(17)=-0.42, p>0.05. This regression appears statistically insignificant. Thus, this regression model does not show any significant relationship between generic substitution 'policy with prior consent' and 'potential savings'.

Beta (β) statistics. From the regression output based on beta statistics, between the independent variables generic substitution 'policy with no prior consent' appears the

strongest predictor of the dependent variable 'potential savings' with β= 0.63,p< 0.011. It has the strongest effects on 'potential savings at the cost of generic drug' because it has the higher β than other predictors with a significant relationship of p< 0.05 with 'potential savings'. The other independent variable generic substitution 'policy with prior consent' has appeared statistically insignificant because it has p> 0.05.

Regression model summary statistics. The model summary statistics output show 2 is the number of predictor or degree of freedom. The F statistics (2,15)=6.48. Probability of F ratio appears as 0.0094 or p< 0.05.

Thus, the F statistics appear as follows:

$$F(3, 15) = 9.88, p < 0.05$$

Table 30 shows that there is a strong significant relationship among 'potential savings' and the independent variables. R^2 reports that this model explains 46% of the variance in 'potential savings at the cost of generic drug.' In this case, R^2 appears as 0.463, which shows as a relatively strong to a strong relationship between the dependent variable 'potential savings' and independent variables generic substitution 'policy with prior consent' and generic substitution 'policy with no prior consent'.

Table 30 shows that there is a strong significant relationship among 'potential savings' and the independent variables. R^2 reports that this model explains 46% of the variance in 'potential savings at the cost of generic drug.' In this case R^2 appears as 0.463, which shows as a relatively strong to a strong relationship between the dependent variable 'potential savings' and independent variables generic substitution 'policy with prior consent' and generic substitution 'policy with no prior consent'. Adjusted R^2 appears as 0.39 and therefore there does not exist any 'chance effects' or bias value in predicting the

Table 30

Model Summary Statistics, Regression Model 2 of Hypothesis 2

df	3
Number of observation	17
F (2,15)	6.48
Probability>F	0.009
R-Squarded	0.46
Adjusted R-Squarded	0.39
Root MSE	15,000,000

dependent variable by the independent variables. Root MSE value as appears as $ 5,100,000 million, which is a relatively small amount in terms of 'potential savings' in the Medicaid prescription drug programs and thus the difference between the variable and the regression line.

Multicollinearity Analysis. Multicollinearity result of the independent variables of the model is shown in Table 31. As the VIF value of independent variables and mean VIF of independent variables appear much lower than 10.0 and 1/VIF value of independent variables appears greater than 0.10 thus there does not exist any multicollinearity problem between the two selected independent variables of this regression model.

Table 31

Multicollinearity Analysis: Regression 2, Hypothesis 2

Variable	VIF	1/VIF
'policy with prior consent'	1.33	.75
'policy without prior consent'	1.33	.75
Mean VIF	1.33	

5.1.3 Regression Model 3 of Hypothesis 2

In examining hypothesis 1, and hypothesis 2, the goals were to examine the influence of 'generic substitution policy' without any provisions as independent variables on various dependent variables appeared insignificant for all the regression models. In addition to regression models 1 and 2, a third regression model is employed to examine if 'generic substitution policy' and generic substitution 'policy with no prior consent' have any ifluence on the dependent variable 'potential savings'. Following independent variables are selected for the regression model:

X_1:'generic substitution policy'

X_2:'policy with no prior consent' and

$\hat{Y}_i$: 'potential savings'

The regression prediction equation for model 3 of hypothesis 2 can be as follows:

'potential savings' ($\hat{Y}_i$) = a + b_1* 'generic substitution policy' + b_2* 'policy with no prior consent'(X_2) ……..(VII)

A brief statistical result output of regression model 3 of hypothesis 2 is shown in Table 32.

Table 32

Statistical Output of Regression Model 3 of Hypothesis 2

Variables		*Constatnt*	Coef.	t	(p>|t|)	*β (Beta)*
(Y)	(X)					
'potential savings'	'generic substitution policy'	28,400,000	-12,400,000	-0.42	.680	-.0918832
	'policy with no prior consent		97,700,000	3.31	.005	.7221851

Results

- generic substitution 'policy with no prior consent' would have a predicted increase in 'potential savings' approximately by over $97.5 million.

Regression model 3 of hypothesis 2 shows that between the two independent variables 'policy with no prior consent' with (p>|t|) value of 0.005 has appeared as significant and the other independent variable 'generic substitution policy' with (p>|t|) value of 0.68 has appeared insignificant. In other words, independent variable generic substitution 'policy with no prior consent' can influence in increasing or decreasing of dependent variable 'potential savings'. In contrast, independent variable 'generic substitution policy' without any provisions has no influence in increasing or decreasing dependent variable 'potential savings'. Based on β (Beta) value, generic substitution 'policy with no prior consent' occurs as the strongest predictor of dependent variable 'potential savings' with β value of .72. In contrast, 'generic substitution policy' occurs has a week predictor of the dependent variable with β value of .09. In the following this model is discussed in a greater detail and a STATA result of regression summary is provided in Appendix G.

Regression results. By plugging in the values of STATA regression analysis in the regression prediction equation VII we can write it as follows:

'potential savings' ($\hat{Y}_i$) = 28,400,000 +(-12,400,000) ('generic substitution policy') + 97,700,000 ('policy with no prior consent').....VII)

The value of constant or $ 28.4 million is the base prediction of Y when all X variables have 0 value. This equation tells us with 0 percent changes in any independent variables within the regression model 'potential savings' would increase $ 28.4 million (the intercept or constant). The regression model also shows that 'potential savings' in prescription drug costs depends on independent variables differently.

Each additional change of one unit in 'generic substitution policy' would have a predicted decrease in 'potential savings' in prescription drugs costs by $12.4 million holding other variables unchanged. If changes occur in generic substitution 'generic substitution policy' by ten units, then Medicaid prescription drug program would have a predicted 'potential savings' in prescription drugs costs decrease by ${12.4 (10)} or $124 million, where *t* is computed 0.42 by using N-1 degrees of freedom. Probability appears as 0. So, t(17)= 0.42, p>0.68. This regression appears statistically insignificant. Thus, this regression model shows an insignificant relationship between 'generic substitution policy' and dependent variable 'potential savings' in prescription drugs costs.

Each additional change in one unit in generic substitution 'policy with no prior consent' would increase 'potential savings' in prescription drugs costs by $97.7 million holding all other variables unchanged. If changes occur in generic substitution 'policy with no prior consent' by ten units, then the Medicaid prescription drug program would have a predicted 'potential savings' by ${97.7 (10)} or 970 million, where *t* is computed 3.31 by using N-1 degrees of freedom. Probability appears as 0.005. So, t (17)=-0.42,

$p<0.05$. This regression appears statistically significant. Thus, this regression model reveals 'policy with no prior consent' has significant influence in increasing or decreasing 'potential savings' of prescription drug costs.

Beta (β) statistics. From the regression output based on beta statistics, between the two independent variables generic substitution 'policy with no prior consent' appears the strongest predictor of the dependent variable 'potential savings' with $\beta= 0.72, p< 0.011$. It has the strongest effects on 'potential savings at the cost of generic drug' because it has the higher β than other predictors with a significant relationship of $p< 0.05$ with 'potential savings'. The other independent variable 'generic substitution policy' has appeared statistically insignificant because it has $p> 0.05$.

Table 33

Model Summary Statistics, Regression Model 3 of Hypothesis 2

df	3
Number of observation	17
F (2,15)	6.48
Probability>F	0.01
R-Squarded	0.46
Adjusted R-Squarded	0.39
Root MSE	5,100,000

Model summary statistics. The model summary statistics output show 2 is the the number of predictor or degree of freedom. The F statistics (2,15)=6.48. Probability of F ratio appears as 0.0094 or $p< 0.05$. Thus, the F statistics appear as follows:

$$F (3, 15) =6.48, p<0.05$$

There is a strong significant relationship among 'potential savings' and the independent variables. R^2 reports that this model explains 46% of the variance in 'potential savings' at the cost of generic drug. In this case R^2 appears as 0.463, which shows as relatively strong to a strong relationship between the dependent variable 'potential savings' and independent variables 'generic substitution policy' and generic substitution 'policy with no prior consent'. Adjusted R^2 appears as 0.39 and therefore there does not exist any 'chance effects' or bias value in predicting the dependent variable by the independent variables. Root MSE value has appeared as $ 5.1 million, which is a relatively small amount in terms of 'potential savings' in the Medicaid prescription drug programs and thus the difference between the variable and the regression line.

Multicollinearity Analysis. Multicollinearity result of the independent variables of the model is shown below:

Table 34

Multicollinearity Analysis: Regression 3, Hypothesis 2

Variable	VIF	1/VIF
'generic substitution policy'	1.33	.75
'policy with no prior consent'	1.33	.75
Mean VIF	1.33	

As the VIF value of independent variables and mean VIF of independent variables appear much lower than 10.0 and 1/VIF value of independent variables appears greater than 0.10 thus there does not exist any multicollinearity problem between the two selected independent variables of this regression model.

5.2 Summary Findings of Hypothesis 2

Results of regression models employed in examining hypothesis 2 reveal the following results:

Regression models employed in examining hypothesis 2 reveal the following results:

1. Generic substitution 'policy with no prior consent' as an independent variable has a significant relationship with the dependent variable 'state share' in prescription drug costs and 1 unit change in generic substitution 'policy with no prior consent' would have a predicted increase 'state share' by approximately $371 million (regression 1).
2. A generic substitution 'policy without any provisions' as an independent variable does not have any significant relationship with 'potential savings' at the cost of generic drug as an dependent variable. One unit change in generic substitution 'policy with no prior consent' would have a predicted increase in 'potential savings' at the cost of a generic drug by approximately $85 million (regression 2).

In contrast, a generic substitution 'policy with prior consent' as an independent variable does not have any significant relationship with the dependent variable 'state share' in prescription drug costs' (regression 1).

A generic substitution 'policy with no prior consent' as an independent variable (different set of independent variable) has a significant relationship with the dependent variable 'potential savings' at the cost of generic drug (regression 2).

Table 35

Summary Results of Regression Models of Hypothesis 2

Regression	Variables		(p>|t|)	Results/findings
	Y	X		
Regression Model 1.	'state share'	'policy with no prior consent'	significant	▪ 1 unit change in generic substitution 'policy with no prior consent' would have a predicted increase of 'state share' by approximately $371 million.
Regression Model 2.	'potential savings'	'policy with no prior consent'	significant	▪ 1 unit change in generic substitution 'policy with no prior consent' would have a predicted increase in 'potential savings' at the cost of generic drugs by approximately $85 million.
Regression Model 3.	'potential savings'	'policy with no prior consent'	significant	▪ 1 unit change in 'generic substitution 'policy with no prior consent would have a predicted increase in 'potential savings' at the cost of generic drug approximately by over $97.5 million.

CHAPTER VI

HYPOTHESIS 3: A DESCRIPTIVE STATISTICAL ANALYSIS

6.1 Introduction

Findings of the regression models of hypothesis 1 and 2 of previous chapters have revealed significant relationships of 'BTE unit reimbursement' and 'brand unit reimbursement' as independent variables with dependent 'state share' (regression model 1 of hypothesis 1). These regression models also showed significant relationships of 'BTE unit reimbursement', and 'BTE amount reimbursement' with the dependent variable 'potential savings' (regression model 2 of hypothesis 1) and 'potential savings' (regression model 3 of hypothesis 1). There also exists significant relationship among 'brand prescription' and 'BTE prescription' with the dependent variable 'potential savings'. Results of regression model 2 of hypothesis 2 although revealed that although there exists no significant relationship between generic substitution policy without any provisions with 'potential savings' at the cost of generic drug as an dependent variable yet generic substitution 'policy with no prior consent' maintains a significant relationship with the dependent variables 'state share' (regression model1), and 'potential savings' in prescription drug costs (regression model 2).

These findings draw the conclusion that independent variables 'BTE unit reimbursement', 'BTE amount reimbursement', 'brand prescription', 'BTE prescription', and generic substitution 'policy with no prior consent' can influence in increasing or decreasing of dependent variables 'state share', and 'potential savings' of Medicaid

prescription drugs. From a public policy point of view these findings are significant. As generic drug is relatively much cheaper than that of brand drugs so it can be safely assume that a higher use of 'BTE unit reimbursement' or generic drugs mandated by a generic substitution policy could contain Medicaid prescription drugs program costs. Thus, the policy could also increase 'potential savings' and could decreased 'state share' of Medicaid prescription drugs.

6.2 Descriptive Statistics—Savings by Generic Utilization

The third research question of the current research asked how much money could Michigan approximately save per year by implementing the generic substitution policy? Findings of the regression models have bridged between third research question and hypothesis 3. One of the main goals of hypothesis 3 was to examine if there existed any drug areas, even in general, where the Medicaid prescription drug program could enhance savings. Two approaches are used to answer the issue of cost savings in monetary amount. First, it examined in general, potential total monetary amount of savings

Table 36

Drug Units Reimbursement-Actual and Percentage in Michigan Medicaid Prescription Drugs Program

Year	Total units reimbursed	Brand units reimbursed	% of brand units as of total drug unit reimbursed	Generic drug unit used	% of generic units as of total drug unit reimbursed
1999	305,816,310.7	197,937,208.3	64.72	107,879,102.4	35.28
2002	579,294,000.1	328,690,232.1	56.74	250,603,768	43.26
2004	719,217,135.9	351,236,145	48.84	367,980,990.9	51.16
2006	304,193,547.2	131,065,985.7	43.09	173,127,561.5	56.91
2008	233,975,864.9	134,273,125.4	57.39	99,702,739.48	42.61
2010	650,376,695.6	138,921,427.3	21.36	511,455,268.3	78.64

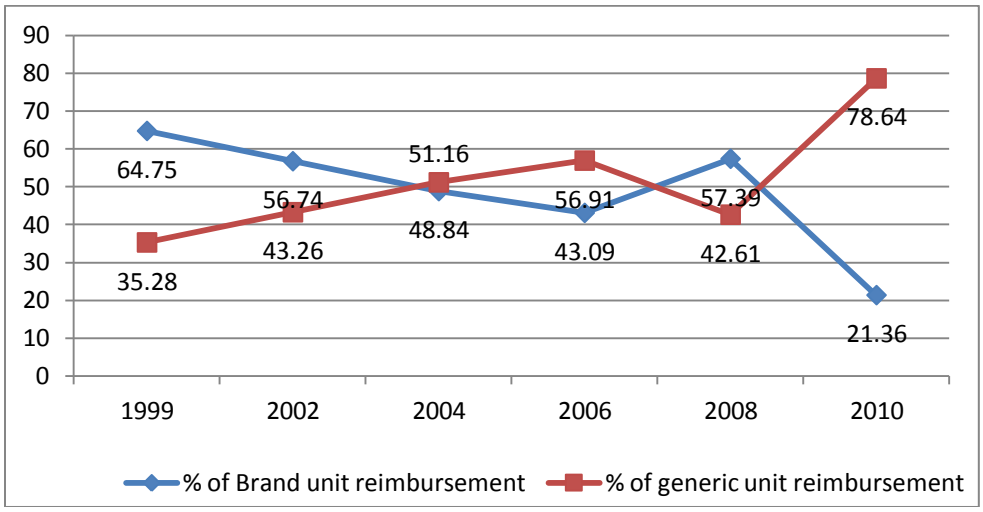
Source: Calculation based on CMS State Drug Utilization Data 1999-2010

By using CMS's yearly state drug utilization data, the current research first calculated the total using optimum generics and second, identified "heavily used" brand drugs while generic substitutions were available in the market for those brands during prescription time. It found that the Medicaid prescription drug programs could save by controlling BTE use when generics are available in the market.

Table 36 shows drug units reimbursement including brand and generic drugs for the Michigan Medicaid prescription drugs program. It shows that number of total drug unit reimbursements in Michigan Medicaid prescription drugs program was 305.5 million, 579.2 million and 719.2 million in 1999, 2002 and 2004 respectively. In 2006 and 2008, total drug units reimbursement dropped as 304.19 million and 233.97 million respectively. In 2010, total unit reimbursement again increased in 650.37 million. Within the period of sample years 1999-2010 reimbursement of brand drug units was 64.72%, 56.74%, 48.84%, 43.09%, 57.39% and 21.36% respectively. In contrast, generic utilization rate in Michigan Medicaid prescription drug program was 35.28% in 1999. In 2002, 2004 and 2006 generic utilization rate increased in 43.46%, 51.16% and 56.915 respectively for three consecutive years and then dropped in 42.61% in 2008 and again the generic utilization rate then increased in 2010 at 78.63%.

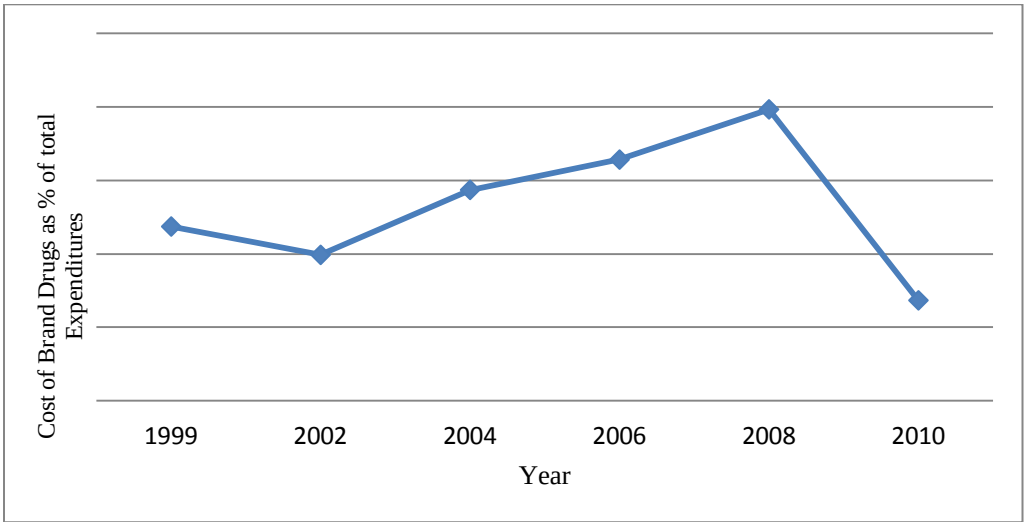
Figure 4 shows that generic utilization rate of Michigan has increased within the period of 1999 – 2010 and at the same period of time reimbursement of brand drugs has increased. Although Michigan has improved the use of generic utilization rate over the years still it is important to recognize the costs issue of brand drugs. One of the major issues in Medicaid prescription drugs cost containment is that costs of brand drugs include major shares of total expenditure of Medicaid prescription drug programs as

shown in Figure 5. For example, approximately 53% brand drugs contained almost 95% costs of Medicaid prescription drug programs in Michigan in 2008.



Source: Calculation based on the CMS's State Drug Utilization database

Figure 4. Brand and Generic Unit Reimbursement (%)



Source: CMS State Drug Utilization data

Figure 5. Brand Drug Costs of Total Prescription Drug Expenditures (%)

In 2010, approximately 21% brand drugs accounted for almost 82% costs of Medicaid prescription drug programs in Michigan. Thus it is important in containing prescription drug costs to ensure not only higher use of generics but to control brand drug, especially BTE, use in the Medicaid prescription drugs program. As already mentioned that approximately 20% drugs have no generics available and Michigan has improved generic use over the years. Therefore BTE can be a potential area of potential costs containment.

`In examining more specific area of saving in Michigan Medicaid prescription drugs program reimbursement of BTE units are calculated in actual number and percentage as of total drug unit and total brand unit reimbursement as shown in Table 37.

Table 37

BTE Reimbursement and Percentage in Michigan Prescription Drugs Program

Year	BTE unit reimbursement	% BTE unit as of total brand unit reimbursement	% BTE unit as of total drug unit reimbursement
1999	96,644,743.02	48.83	31.60
2002	88,991,515.14	27.07	15.36
2004	91,553,571.26	26.07	12.73
2006	30,153,814.88	23.01	9.91
2008	43,394,872.2	32.31	18.55
2010	60,138,530.47	43.29	9.25

Source: Calculation based on the CMS's State Drug Utilization database

Table 37 shows the unit reimbursement of BTE in the Michigan Medicaid prescription drugs program in period of sample years. In 1999, BTE reimbursement was 48.83% of total brand unit reimbursement in the Michigan Medicaid prescription drugs program. Within the year 2002, 2004 and 2006 BTE reimbursement was decreased at 27.07%, 26.07% and 23.01% respectively for consecutive three years. Then in 2008 and 2010,

reimbursement of BTE increased at 32.31% and 43.29% respectively of total brand unit reimbursement. Costs of BTE reimbursement could be much lower if generics were prescribed instead of BTE in the Medicaid prescription drugs program. In other words, data of Table 38 reveals that Michigan Medicaid prescription drugs program prescribed such brand drugs 32.31% and 43.29% in 2008 and 2010 respectively, which could be replaced by much cheaper generic drugs. Similarly reimbursement of brand drugs of 48.83%, 27.07%, 26.07% and 23.01% in 1999, 2002,2004 and 2006 respectively could be replaced by generic drugs and thus Michigan Medicaid prescription drugs program could save a significant amount of money. Table 38 shows average costs and differences between BTE and generic drugs in selected sample years. Data of Table 38 clearly

Table 38

Average Unit Price of BTE and Generic Used in Michigan Prescription Drug Program, 2010

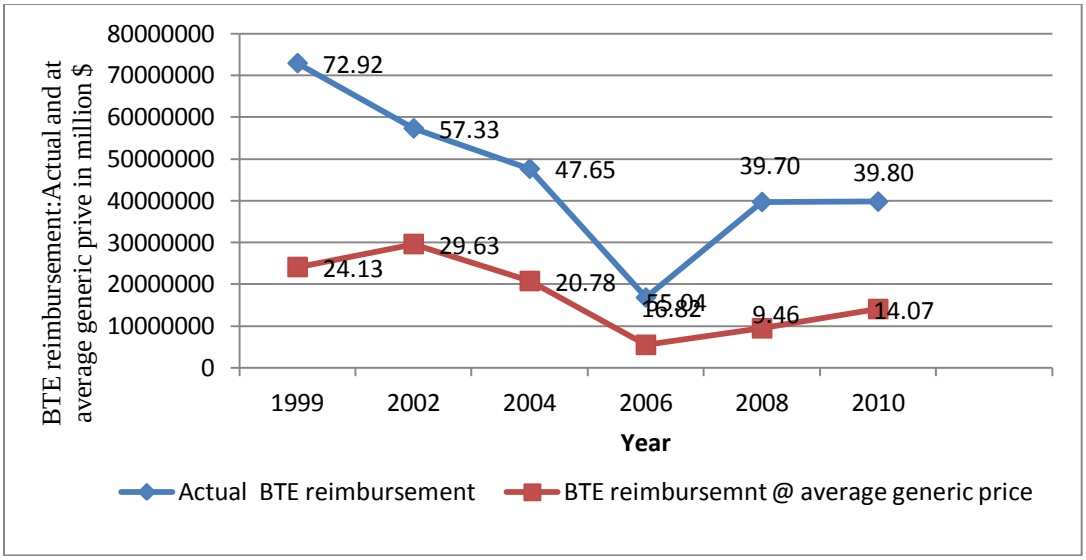
Year	MI Average per unit cost of BTE drugs	MI Average per unit cost of generic drugs	Avg.costs difference between BTE and generics	Avg. costs difference between brand and generics
1999	0.75	0.25	.50	.65
2002	0.64	0.33	.31	1.09
2004	0.52	0.23	.29	1.77
2006	0.56	0.18	.38	2.39
2008	0.91	0.21	.70	2.76
2010	0.66	0.23	.43	3.65

Source: Calculation based on CMS State Drug Utilization Data 1999-2010

indicates BTE as a potential area where Michigan Medicaid prescription drugs program could save due to a significant price difference between brand drug and generic drugs. Figure 6 shows a comparative picture of actual BTE costs and costs of BTE at the rate of average generics of the same selected sample years. Figure 6 shows the difference of actual BTE costs and costs at the rate of generic drugs that were available at the time of

brand prescription between the years 1999-2010. These findings are shown more elaborately in Table 39 with the savings by using generic instead of BTE in Michigan prescription drugs program.

Research findings in Table 39 reveal that within the sample years of 1999-2010, the Michigan Medicaid prescription drug program spent over a total of $274.20 million



Source: Calculation based on CMS State Drug Utilization Data 1999-2010

Figure 6. BTE Reimbursement: Actual, and at Average Generic Price

for brand drugs that had generic or therapeutically equivalent drugs available in the prescription period. At the average rate of available generic drugs within the corresponding sample years, these brand drugs could cost a total of $103.57 million.

Table 39

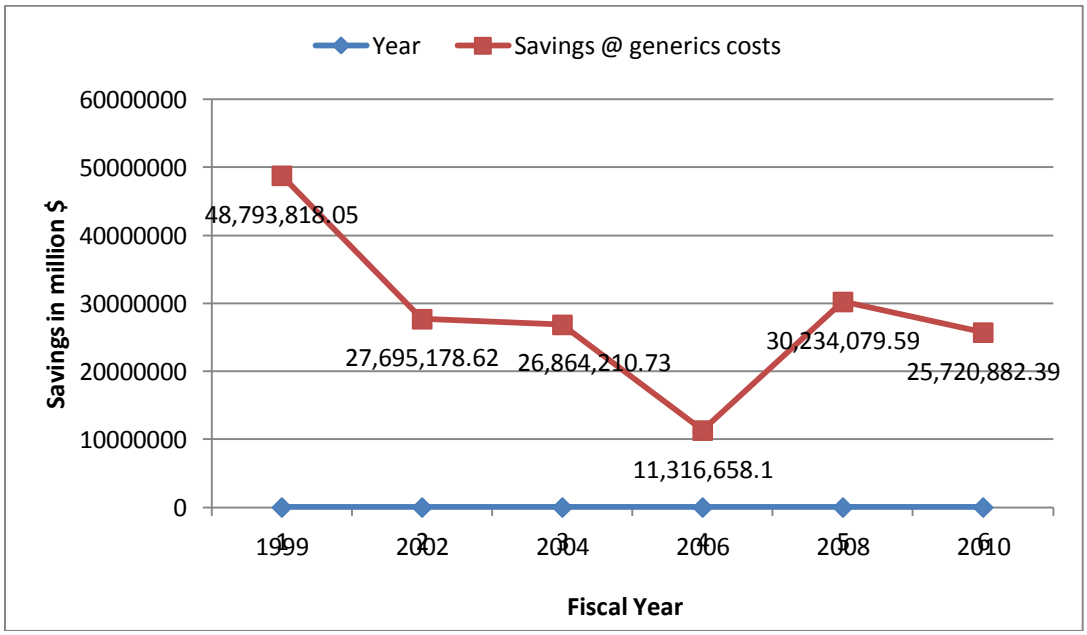
Michigan Medicaid Prescription Drugs Program Potential Savings ($)

Year	MI BTE unit reimbursement	BTE amount reimbursement ($)	Costs @ avg. generics ($)	Savings @ generics ($)
1999	96,644,743.02	72,921,904.31	24,128,086.3	48,793,818.05
2002	88,991,515.14	57,326,219.59	29,631,041	27,695,178.62
2004	91,553,571.26	47,645,639.14	20,781,428.4	26,864,210.73
2006	30,153,814.88	16,820,737.41	5,504,079.31	11,316,658.1
2008	43,394,872.2	39,698,035.96	9,463,956.37	30,234,079.59
2010	60,138,530.47	39,790,835.66	14,069,953.3	25,720,882.39
Total		$274203372.1	$103,578,545	$170,624,827.5

Source: Calculation based on CMS State Drug Utilization Data 1999-2010

Thus Michigan Medicaid prescription drugs program could save a total of over $170.62 million by only prescribing generics instead of brand drugs.

From a public policy context, some other findings of these descriptive statistics appear as valuable. For example, the average cost of per unit brand drug was 90 cents in 1999 and $3.88 in 2010, whereas the average costs of per unit generic drugs was estimated at 18 cents to 33 cents within 1999-2010. Similarly, average costs of per prescription with brand drugs is estimated at $37.75 to $75.58 within 1999-2010, whereas average costs of per generic prescription contained therapeutically equivalent generics varied from $11.94 to $20.43 within 1999-2010. Thus Michigan Medicaid prescription drug program could save approximately $49million, $28 million, $27 million, $11 million, $30 million and $25 million in 1999, 2002,2004,2006, 2008 and 2010 respectively by using generic drugs instead of brand drugs used that had generic equivalent available at the time of prescription (Figure 7).



Source: Calculation based on CMS State Utilization Data 1999-2010

Figure 7. Michigan Prescription Drugs Program Savings at the Rate of Generic Drugs

Findings of the descriptive analysis are similar to other recent research findings. Brill (2010) analyzed 2009 Medicaid data reimbursement of all states for a selected twenty brand drugs and found $271 million in overspending in Medicaid prescription drug programs due to the use of brand drugs instead of generic.

6.3 Savings by Drug Area/Therapeutic Group

In examining hypothesis 3, one of the goals was to find out any specific drug area, in general, where Medicaid prescription drugs programs could save costs. Findings of the results, in general, found that areas such as brand drugs prescribed in the prescription drug programs that already have therapeutic equivalents available in the market could be a potential area where Medicaid prescription drug program could contain costs. Results of these regression models make sense as average costs of brand drugs with therapeutically equivalent are much lower than the brand drugs without therapeutic equivalents available in the market. However, this analysis provides only a broad

potential area where Medicaid prescription drugs program can have savings. This research extends further in identifying specific drugs or 'therapeutic classes' area of savings for Medicaid prescription drug programs by employing a descriptive statistical method.

In doing so, this research uses Michigan 2010 Medicaid prescription drugs program reimbursement data of CMS as the reference. All brand drugs with therapeutically equivalent prescribed are identified with total number of units, number of prescriptions, total reimbursement amount. The ten most costly and highly prescribed brand drugs with therapeutic equivalents available in the market are identified. For each of these ten brand drugs with therapeutic equivalents actual prescription drug program costs, average costs of actual per unit drugs, average costs of actual per prescription for brand drugs with therapeutically equivalent drugs; average costs of per generic drug unit in Michigan in 2010 are calculated. Then average costs of per unit brand drugs with therapeutically equivalent are calculated at the rate of average per unit generic drug costs, and finally savings are calculated by deducting the amount from actual reimbursement costs of brand drugs with the therapeutically equivalent and calculated amount at the rate of average per unit generic drug costs. Then the total amount of savings are calculated by adding savings of all ten brand drugs with therapeutically equivalent prescribed in Michigan Medicaid prescription drugs program in 2010 as presented in Table 40.

Table 40

Selected BTE Reimbursement and Potential Savings in Michigan Medicaid Prescription Drugs Program

Drug name	Units Reimbursed	Actual BTE Amount Reimbursement ($)	Avg. cost per generic unit ($)	Costs @ average per generic unit ($)	Savings of BTE cost s@ average per unit generic ($)
Plavix	839193	4,443,039.27	0.23	196,336.7874	4,246,702
Prograf	416732.1	2,223,677.36	0.23	97,498.24959	2,126,179
Lamictal	374526	1,867,966.3	0.23	87,623.74599	1,780,343
Duragesic	38524	1,743,863.81	0.23	9,013.038321	1,734,851
Zithromax	1136136	1,623,367.64	0.23	265,809.2489	1,357,558
Risperidon	1620172	1,374,779.71	0.23	379,053.7799	995,725.9
Topamax	284168.2	1,312,345.86	0.23	66,483.7259	1,245,862
Trileptal	1375522	1,196,764.6	0.23	321,815.8161	874,948.8
Pulmicort	190,546.1	1,030,490.95	0.23	44,579.97458	985,911
Depakotes	547865	947,883.82	0.23	128,177.9732	819,705.8
Total	6823384	17,764,179.3		1,596,392.34	16,167,787

Source: calculated based on CMS's 'State Drug Utilization data' 2010

Table 40 shows that in the Michigan Medicaid prescription drug programs in 2010, 'Plavix' was reimbursed 839193 units at a total cost of $ 4.44 million. The average cost of per unit 'Plavix' costs is estimated at $5.29. A total of 27561 prescriptions were written for all 'Plavix' during the same time period. In 2010, the average cost of per unit generic drug is estimated at $.23 based on the total costs of generic $119,659,587.09 or $119.66 million for a total number of 511,455,268.319997 generic units reimbursed. At

the costs of per unit generic, the total cost of 839193 units of 'Plavix' is estimated at $196,336.7874 and thus savings is estimated as $4,246,702 or $4.3 million.

'Prograf' is estimated as the second most reimbursed brand drug in Michigan Medicaid prescription drug program in 2010 with a total cost of $ 2,223,677.36. A total 416732.1 units of 'Prograf' were reimbursed with the average cost of $5.335987 per unit. At the costs of per unit average generic, which is estimated $ 0.23, 416732.1 units of 'Prograf' is estimated only $ 97498.24959, and thus savings is estimated $ 2,126,179 or $2.1 million. Figure 8 shows the cost difference between actual BTE reimbursement and the costs of the same BTE at average generic price in 2010.

'Lamictal' is estimated as the third most reimbursed brand drug in the Michigan Medicaid prescription drug program in 2010 with a total cost of $ 1,867,966.3. A total of 374526 units of 'Lamictal' were reimbursed with an average cost of $ 4.987548 per unit. At the costs of per unit average generic as $ 0 .23 total costs of 374526 units 'Lamictal' is estimated only $ 87623.74599, and thus savings is estimated $1,780,343 or $1.78 million.

Actual costs of 'Duragesic', the fourth most reimbursed brand drug in the Michigan Medicaid prescription drug program in 2010, was estimated at $1,743,863.81 with a total reimbursement of 38524 'Duragesic' units. The average cost of per unit 'Duragesic' is estimated at $ 45.27 per unit. At rate of $ 0 .23 per unit generic total costs of 38524 units of 'Duragesic' is estimated as low as $ 9013.038321, and thus savings is estimated $ 1,734,851 or $1.74 million.

Actual costs of 'Zithromax', the fifth most reimbursed brand drug in the Michigan Medicaid prescription drug program in 2010 were estimated at $1,623,367.64 with a total reimbursement of 1136136 'Zithromax' units. Average cost of per unit 'Zithromax' is

estimated at $ 1.42885 per unit. At the rate of average costs of $ 0 .23 per unit generic total costs of 1136136 units of 'Zithromax' is estimated as $ 265809.2489, and thus savings is calculated $ 995725.9.

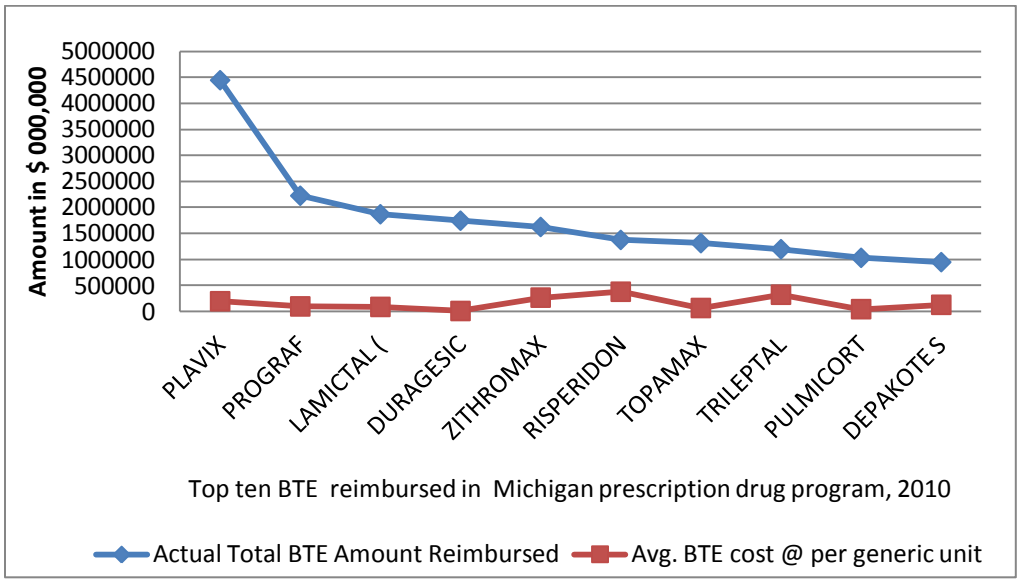


Figure 8. Costs Differences of Reimbursed BTE and Generics: Actual and at the Average Rate of Generics

Similarly, actual costs of 'Risperidon', 'Topamax', 'Trileptal', 'Pulmicort' and 'Depakotes', all high-use brand drugs, are $1,374,779.71; $1,312,345.86; $1,196,764.6; $1,030,490.95, and $947,883.82 respectively. At the rate of average costs of per unit generic as $ 0.23 total costs of these five brand drugs as mentioned above are estimated $379,053.78; $66,483.73; $321,815.82; $44,579.978; and $128,177.97 respectively. Thus savings is estimated for these five brands are $995,725.9; $1,245,862; $874948.8; $985911; and $819,705.8 respectively.

Significant cost difference between brand drugs and generics have made a significant difference between total costs of actual BTE reimbursements and the costs of its generics, which are therapeutically equivalent. This significant cost differences have

provided opportunity to Michigan Medicaid prescription drugs program specific potential area to use more generics than brand drugs in containing costs of Michigan prescription drugs program as shown in Figure 8.

Above discussion showed that Michigan Medicaid prescription drugs program could save from over half a million US dollar to more than four million US dollar from each of the top ten 'heavily used' drugs reimbursement in 2010 as shown in Figure 9.

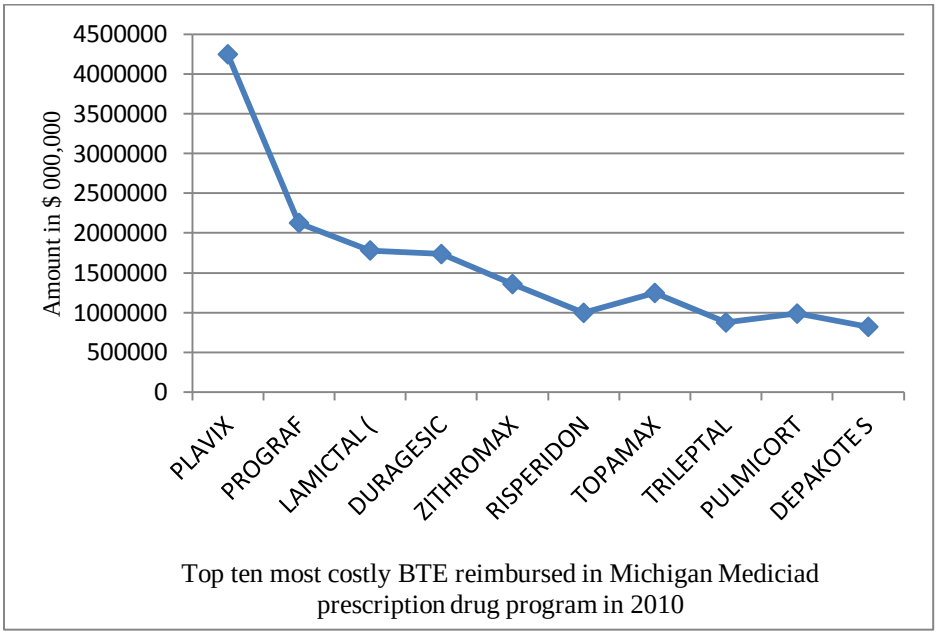


Figure 9. Cost of Brand Drugs with Generic Availability: Savings at the Rate of Per Unit Generic Price

Thus a potential of a total savings of $16,167,787 or $16.17 million is estimated by the use of generics instead of the top ten brand drugs, in terms of reimbursement amounts for the Michigan Medicaid prescription drugs programs in 2010. This finding is similar to the findings of Brill (2010). Furthermore, the following seven out of ten most highly reimbursed brand drugs such as 'Lamictal' 'Duragesic' 'Zithromax' 'Risperidon', 'Topamax', 'Trileptal', and 'Depakotes' have appeared the leading cost savings drugs for Michigan Medicaid prescription drug programs, as also identified by Brill (2010) for the

most cost saving brand drugs prescribed in the Medicaid prescription drug programs of forty states in 2009.

Thus, analysis of hypothesis 3 reveals that:

1. Brand drugs with therapeutically equivalent drugs that are prescribed could be a potential area of savings in the case of Michigan's Medicaid prescription drugs program.
2. The more specific area for potential savings in the Michigan Medicaid prescription drug program could be using more generic drugs instead of prescribing brand drugs such as 'Plavix', 'Prograf', Lamictal' 'Duragesic' 'Zithromax' 'Risperidon', 'Topamax', 'Trileptal', 'Pulmicort' and 'Depakotes'. These are the top ten most expensive brand drugs, which have been prescribed in the Michigan Medicaid prescription drugs program even though generic therapeutically equivalent drugs are available in the market for all these brands.
3. An estimated total of $ 17,764,179.3 was reimbursed for these ten brand drugs in the Michigan Medicaid prescription drug program in 2010, which have generic equivalents. Research findings show that an average $ 0.23 per unit generic drug price in 2010 Michigan prescription drug program could save an estimated $4,246,702; $2,126,179; $1,780,343; $ 1,734,851; $ 995725.9 ,$995,725.9; $1,245,862; $874948.8; $985911; and $819,705.8 respectively from these most reimbursed ten brand drugs such as 'Plavix', 'Prograf', Lamictal' 'Duragesic' 'Zithromax' 'Risperidon', 'Topamax', 'Trileptal', 'Pulmicort' and 'Depakotes' as shown in Figure 10. At an average rate of generic, these top ten brand drugs

could cost only $1,596,392.34. In other words, 90% costs for these ten drugs could be offset by using generics.

4. Thus, Michigan Medicaid prescription drugs program could save an estimated $16,167,787 or $16.17 million in 2010 by only prescribing generic instead of those top ten most expensive drugs, which is 91% savings from the actual costs of these ten brand drugs.

6.4 Summary of the Chapter

Chapter 6 discussed the ten 'heavily used' brand drugs that were reimbursed in Michigan Medicaid prescription drugs program in 2010. Each of these brand drug cost more than half a million US dollars to over four million dollars and a total of $ 17,764,179.3 to Michigan Medicaid prescription drug program in 2010. All these brand drugs had therapeutically equivalent generics available in the market during the prescription periods. Current research finds that Michigan Medicaid prescription drugs program could save $16.17 million in 2010 by only prescribing generic instead of those top ten most expensive drugs, which is 91% savings from the actual costs of these ten brand drugs.

CHAPTER VII

FINDINGS, RECOMMENDATIONS, AND CONCLUSION

7.1 Introduction

After its inception in 1965, scope of the Medicaid program has broadened significantly to minimize the ever-increasing coverage gaps created by the private insurance system through various structural and functional reforms. Medicaid now is the largest publicly financed health and long-term care coverage program for low- income people in the nation (Kaiser Foundation, 2010). Currently almost 62 million low-income people or 1 in every 5 American and 1 in every 3 children received health insurance coverage through the Medicaid program, with a total Medicaid cost of $414 (Kaiser Foundation, 2013). Medicaid also provides costs of 16% of total health services and supplies, 18% of hospital care, 8% of professional services, 31% of nursing facility care and 7% of the prescription drugs (CMS, 2013). Medicaid prescription drug program is a crucial component of Medicaid health care.

Scholars have long been asking the question, "Can we control health care costs?" (Brill, 2010; Flottemesch, Edwards, and Solberg, 2010). Additionally, scholars have investigated ways to contain health care expenditures (Delan, 2010; Kelly and Fabious,2010; Delaune and Everett, 2008; James and Bailey, 2010). In fact, the Nixon administration first raised concern about the crisis of rising health care costs in 1969 (Starr, 1982). Skyrocketing health care costs have raised a serious fiscal toll on state government in managing the Medicaid effectively. In this regard, a major focus is on how

to contain costs in the Medicaid program as well as the costs of prescription drugs program.

A large number of literature, as discussed in the chapter 2 and outside the current discussion, suggest that increasing use of generics instead of brand drugs could be a viable solution for the states in containing costs in Medicaid prescription drugs program. In the recent years some states have already implemented generic substitution policy in its Medicaid prescription drug programs as a cost containment effort. Some studies evaluate potential cost savings by increasing use of generic drugs based on selected drugs used by quarter in the Medicaid prescription drugs program data provided by CMS (Brill 2010, Sharnk, 2010). Brill (2010) thought that individual states based study is necessary to get a more complete picture of cost savings. However, no comprehensive study has been conducted to examine the issue of the increasing use of generic drugs in the Michigan Medicaid prescription drugs program by implementing a generic substitution policy or its impact on potential cost savings in the Medicaid prescription drugs program. This study is therefore an endeavor to progress the conclusions of previous research with both a more comprehensive time frame and data analysis.

7.2 Discussion

This research began with the objective to examine if a generic substitution policy could be an efficient cost containment approach for Michigan Medicaid prescription drug program. In examining so, following research questions were considered.

1. First, will a generic substitution policy be an efficient alternative strategy in containing Medicaid prescription drug program costs for Michigan?
2. If not in general, are there any therapeutic classes of prescription drugs or are there any “heavily used” brand drugs for which generic substitutes are available

that Michigan can effectively reduce Medicaid costs by implementing a higher use of generic substitution, thus saving the state share in prescription drug costs through the generic substitution policy?

3. Third, if the answer is 'yes' for the two previous questions, then approximately how much money can Michigan save per year by implementing the generic substitution policy?

Two basic assumptions were also taken into consideration for this research as follows:

1. Generic drugs are similar to single-source brand drugs in treating diseases. The reason for this assumption is that generic drugs are chemically identical to single-source brand drugs (OIG, 2006).
2. Pharmacies cannot or will not increase costs of generic drugs to make up for lost profits on single-source brand drugs.

Based on the research questions and the assumptions of the research, the current study has examined the following specific hypotheses:

1. A potential *generic substitution policy* regarding *prescription drugs* may be an *efficient* approach in containing prescription drug costs and thus reduce the *state share* in the Michigan Medicaid prescription drug program.
2. A mandatory generic substitution policy with no prior consent may have more potential in containing prescription drug costs than a generic substitution policy with prior patient consent.

3. In some *therapeutic classes* Michigan may have the potential to reduce Medicaid costs by mandating a higher use of generic substitution whenever available by the generic substitution policy.

To answer the first research question and the corresponding hypothesis one, namely that if a generic substitution policy is an "efficient" alternative, the research findings reveal a positive response in the regression models of hypothesis one. Regression analyses of hypothesis one showed that 'BTE units reimbursement' (percentage of brand with therapeutically equivalent (BTE) as of total drug unit reimbursement) and 'brand drug unit reimbursement' ('percentage of brand drugs (BD) as of total drug unit reimbursement') as independent variables have significant relationships with the dependent variable 'state share'. Similarly, findings of regression model two shows that 'BTE unit reimbursement' as an independent variable has a significant relationship with the dependent variable 'potential savings'. Regression model three shows that a significant relationship exists between 'BTE amount reimbursement' as an independent variable and potential savings' as a dependent variable. Similarly, regression model three shows a significant relationship exists between 'brand prescription' and 'BTE prescription' and the dependent variable 'potential savings'. In contrast, regression analyses showed that a 'generic substitution policy' without any provisions as an independent variable has no significant relationship with the dependent variables 'state share' and 'potential savings' (regression model 1, 2, 3, and 4). Similarly, there does not exist any significant relationship between 'generic reimbursement per prescription' and the dependent variable (regression model 4).

In other words, the findings of the regression models of hypothesis one reveal that independent variables such as 'BTE unit reimbursement', 'brand drug unit reimbursement', 'brand prescription', and 'BTE prescription' can influence increasing or decreasing 'state share' and 'potential savings' in the Medicaid prescription drugs program. These findings have indicated generic substitution as a potential policy intervention for the Medicaid prescription drugs cost containment. A generic substitution policy can prevent the unnecessary use of brand drugs where generic drugs are available. 'BTE unit reimbursement', 'brand drug unit reimbursement', 'brand prescription' and 'BTE prescription' have reverse effect on 'state share' and 'potential savings' in Michigan Medicaid prescription drugs program. Thus, the higher the number of 'BTE unit reimbursement', the lower the number of 'brand drug unit reimbursement' in the Medicaid prescription drugs program. Similarly, a generic substitution policy can limit the number of 'brand prescription' and increase the number of 'BTE prescription'. As these two types of prescriptions have an opposite effect on 'state share' and 'potential savings,' the higher the number of 'BTE prescription', the lower the number of 'brand prescription' will be issued in the Medicaid prescription drugs program. Thus, limiting 'brand drug unit reimbursement' and 'brand prescription' through a generic substitution policy will decrease 'state share' and will increase 'potential savings'.

In answering the first research question more extensively, with the corresponding hypothesis two that if a mandatory generic substitution policy with no prior consent may have more potential in containing prescription drug costs than a generic substitution policy with prior patient consent, regression models reveal positive responses. Regression analyses of hypothesis two finds that generic substitution 'policy with no prior consent'

as an independent variable maintains a significant relationship with the dependent variable 'state share' and 'potential savings of prescription drug costs' (regression model 1 of hypothesis 2). Further, generic substitution 'policy with prior consent' as an independent variable does not have any significant relationship with the dependent variable 'state share' and 'potential savings in prescription drug costs' (regression 1 of hypothesis 2). A 'generic substitution policy' without any provisions as an independent variable has no significant relationship with the dependent variable 'potential savings' at the cost of generic drug (regression 2 of hypothesis 2).

In answering the second research question with the corresponding hypothesis three that if not in general, are there any therapeutic classes of prescription drugs or are there any "heavily used" brand drugs for which generic substitutes are available that Michigan can effectively reduce Medicaid costs by implementing a higher use of generic substitution, thus saving the state share in prescription drug costs through the generic substitution policy descriptive statistics reveals a positive response. Findings of hypothesis three shows the more specific area where the Michigan Medicaid prescription drug program can save a large amount of money by using more generic drugs, instead of prescribing brand drugs. The current research identifies ten most heavily used drugs such as 'Plavix', 'Prograf', Lamictal' 'Duragesic' 'Zithromax' 'Risperidon', 'Topamax', 'Trileptal', 'Pulmicort' and 'Depakotes'. These are the top ten most expensive brand drugs, which have prescribed in the Michigan Medicaid prescription drugs program even though generic therapeutically equivalent available in the market for all these brands.

Findings of the descriptive research also reveals the response to research question three and further analyzes the question of hypothesis three of how much Michigan can

save effectively if a generic substitution policy is implemented. Significance of this section is that it shows the potential savings for Michigan Medicaid prescription drugs program in a monetary amount.

Findings of the regression models of hypothesis two have indicated a potential policy intervention area in containing costs efforts in the Michigan Medicaid prescription drug program. Cost increase in prescription drugs is a complex phenomenon. Many factors contribute to the cost escalation, which includes high costs of research and development, advance treatment, promotional and advertisement costs, growing groups of an aging population with more needs for prescription drugs, and higher insurance coverage costs for prescriptions. These factors and many others influence the escalating drug price and its utilization and thus, the overall costs for Medicaid prescription drug programs (Kreling, Mott, and Wiederholt, 2001).Thus, cost containment in Medicaid drug programs also needs multifaceted policies and actions. As already mentioned, Medicaid costs have appeared as the second largest expenditure for Michigan state government, and has created severe pressure on its fiscal management. In the midst of cost escalation of Medicaid prescription drug programs, the Michigan state government must implement appropriate measures to tackle this issue. Implementation of a generic substitution policy could be a viable policy option for the state government of Michigan.

From a public policy point of view, implementation of a generic substitution policy has several advantages in containing costs of the Michigan Medicaid prescription drugs program. One of the major goals of the current research to examine if a generic substitution policy is efficient and effective in containing costs of Michigan Medicaid prescription drugs program. Following sections discuss relative advantages of

implementation of a generic substitution policy in containing costs in Michigan Medicaid prescription drugs program.

7.2.1 Efficiency and Generic Substitution Policy

As mentioned earlier that the current research uses a rational choice approach model to analyze if a generic substitution policy be an efficient strategy in containing Medicaid prescription drug program costs for Michigan Medicaid prescription drugs program. It is also mentioned that in examining the efficiency of generic substitution policy as a cost containment approach, this research would use a cost-benefit model. The reason of using a cost-benefit model for the current research is that this model is especially useful in analyzing policy issues related to program expenditure. In analyzing the cost issue of a public policy such as the Medicaid prescription drugs program, a cost-benefit analysis is especially useful as a criteria because it emphasizes the efficiency, or, in other words, how a policy can fulfill the same goals by using less money. From a public policy point of view, efficiency is an important criterion to choose a policy, because it emphasizes the ends, not the means, which is the single most important goal of the current research . Cost-benefit analysis emphasizes stakeholders' advantages in monetary term to implement a new policy over the existing policy. Figure 10, which is a modification of Figure 1, shows a comparative cost difference between a potential generic substitution policy and the current prescription drugs policy without generic substitution.

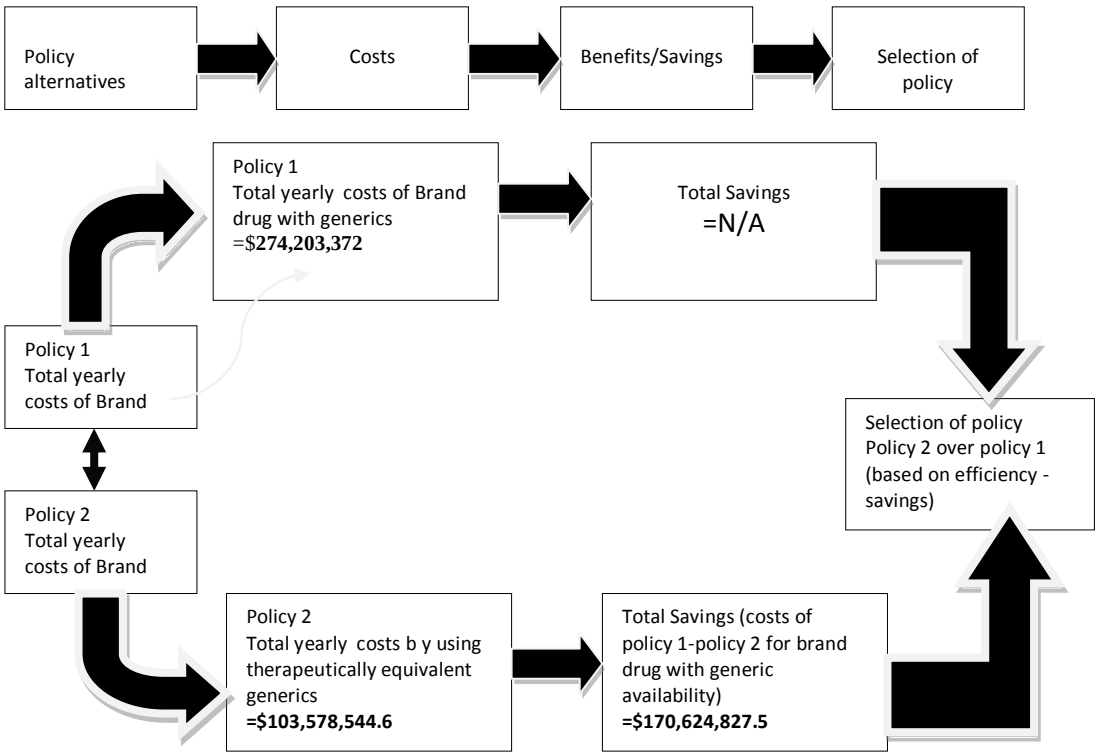


Figure 10. Model of Cost Benefit Analysis in Real Monetary Term- Status Quo and Mandatory Generic Substitution Policy

Figure 10 depicts the cost benefit model in real monetary term between policy 1 or status quo and policy 2 or mandatory generic substitution policy. It shows that Michigan could save $170,624,827.5 million by using therapeutically equivalent generics instead of using brand drugs through a mandating a generic substitution policy within sample years of 1999-2010. More specifically as mentioned that Michigan Medicaid prescription drugs program could save an estimated $16,167,787 or $16.17 million in 2010 by only prescribing generic instead of prescribing top ten most expensive drugs such as 'Plavix', 'Prograf', Lamictal' 'Duragesic' 'Zithromax' 'Risperidon', 'Topamax', 'Trileptal', 'Pulmicort' and 'Depakotes'.

Thus, a cost-benefit model of policy analysis shows that implementation of a generic substitution policy can be more efficient for Michigan Medicaid prescription

drugs program and it could achieve the goals of Michigan Medicaid prescription drugs program with much lower costs.

7.2.2. Effectiveness and Generic Substitution Policy

Besides, one of the major advantages of implementation of a generic substitution from public policy perspective is that implementation of a generic substitution is not only efficient but also effective. The current research defined "effectiveness" as if a policy achieves its preset goals. In the context of the Medicaid prescription drugs program serving the beneficiaries without reducing the existing numbers, savings, and maintaining the quality of the drugs dispensed, the Michigan Medicaid prescription drug program can be considered effective.

Implementation of a generic substitution policy in containing prescription drugs costs does not need any new rules to limit numbers of beneficiaries by imposing new Medicaid eligibility criteria. To contain prescription drugs program costs, state share, and to increase potential savings, this policy only needs to ensure higher use of generic drugs, which is available in the market for treatment of the same symptoms as brand drugs, by imposing a law. One of the major advantages of implementation of the generic substitution policy over any other proposed strategies is that it is comparatively simple to implement by using the current administrative structure. For example, implementing a generic substitution policy does not need to make huge fundamental structural changes, such as creating a new bureau or agency for Medicaid cost control.

One of the major goals of the current research is to examine if a generic substitution policy can save costs in the Michigan Medicaid prescription drugs program. Research findings show that Michigan could save $170,624,827.5 million by using

therapeutically equivalent generics instead of using brand drugs through a mandating a generic substitution policy within sample years of 1999-2010. It also shows that an estimated $ 17,764,179.3 was reimbursed for total ten most expensive brand drugs in the Michigan Medicaid prescription drug program in 2010, which have generic equivalent. At an average rate of generic these top ten brand drugs could cost only $1,596,392.34.Thus, Michigan Medicaid prescription drugs program could save an estimated $16,167,787 or $16.17 million in 2010 by only prescribing generic instead of those top ten most expensive drugs. Thus a generic substitution policy can fulfill the goal of savings for Michigan Medicaid prescription drugs program.

Further, implementation of a generic substitution policy most probably has the lowest potential as a political challenge for state government than any other policy implementation that includes such huge numbers of beneficiaries (Kibicho, 2007). It should be less time consuming to implement, as it does not include any huge structural reorganization. One of the most intriguing advantages of implementation of a generic policy is that its outcomes are not uncertain, as some other states have already been implementing the same policy for years with known results.

7.2.3. Generic Substitution Policy with No Prior Consent Provision

In containing Medicaid prescription drugs costs by implementing a generic substitution policy, one crucial issue is that a policy with no prior consent is more efficient than a policy with prior consent. A generic substitution policy with no prior consent has more chances to utilize generics in treating patients than the generic policy with prior consent, as discussed earlier that for various reasons many physicians prescribe brand drugs. Patients' preferences and requests are one of the major issues in prescribing

brand drugs in the absence of a generic substitution policy. Further, an ongoing debate has also taken place regarding increasing use of generics in recent times. Physicians have expressed different, and in some cases totally opposite, views regarding quality of generic use and its effects on patients. Some physicians hold the idea that generics can be a viable alternatives of brand drugs and the other view questions the effectiveness of generics in treating patients. As already discussed, a number of studies such as Kesselheim et.al. 2008; FDA, 2011; American Medical Association, 2007 and many others have argued for the use of generics, as these studies found no significant or different effect of generics in treating the same symptoms. A generic substitution policy with no prior consent can ensure the use of unnecessary prescription of costly brand drugs as a "no prior consent" provision minimizes physician and patient preferences and limits prescribing brand drugs.

Thus implementation of a generic substitution 'policy with no prior consent' can achieve two major criteria, efficiency and effectiveness, set for the generic substitution policy in containing costs of Michigan Medicaid prescription drugs program.

7.3 Recommendations

The following section discusses the research questions once again based on which this research has initiated.

1. Will a generic substitution policy as implemented by ten states (Florida, Massachusetts, Kentucky, New Jersey, New Mexico, Oregon, Rhode Island, Tennessee, West Virginia, and Wyoming) be an efficient strategy in containing Medicaid prescription drug program costs for Michigan?

2. If not in general, are there any therapeutic classes of prescription drugs or are there any "heavily used" brand drugs for which generic substitutes are available that Michigan can safely reduce Medicaid costs by implementing a higher use of generic substitution, thus saving the state share in prescription drug costs through the generic substitution policy?
3. If the answer is 'yes' for the two previous questions, then approximately how much money can Michigan save per year by implementing the generic substitution policy?

Answers of these research questions are discussed in the following section based on the previous discussion, findings of regression analysis, and descriptive statistics.

1. The current research shows that potential relationship between 'generic substitution policy' and Medicaid prescription drugs costs exists.
2. The costs variation between brand drugs and the brand drugs with therapeutic equivalent classes reveals an opportunity for the Michigan Medicaid program to save a significant amount by implementing 'generic substitution policy.'
3. It also reveals from two policy continuums that generic substitution 'policy with no prior consent' can be more effective in cost containment in the Michigan Medicaid program than generic substitution 'policy with prior consent'.
4. Research findings reveal that within the sample years of 1999-2010 Michigan Medicaid prescription drug program spent $274,203,372.1 or $274.20 million for brand drugs that had generic or therapeutically equivalent drugs available in prescription period. At the rate of average rate of generic drugs in those respective years these brand drugs could cost a total of $103.58 million. Thus, Michigan

Medicaid could save a total of $170.62 million by prescribing only generics instead of those brand drugs.

Based on the findings of the current research, the following recommendations are proposed:

1. Physicians should be encouraged to use more generics in the Medicaid prescription drugs program.
2. It should be mandated to prescribe generics where available, rather than prescribing brand drugs.
3. In mandating use of more generics, Michigan should introduce a generic substitution policy.
4. As a cost containment approach, Michigan should introduce a generic substitution a "policy with no prior consent" provision rather than a "policy with prior consent". The current research reveals that a generic substitution "policy with no prior consent" provision is more efficient in containing costs and thus in creating savings in the Michigan Medicaid prescription drugs program.

7.4 Conclusion and Future Research Scope

Analysis of this research provides a basis for the implementation of a potential generic substitution policy as an efficient and effective approach in containing the prescription drugs expenditure in the Michigan Medicaid program. This research, therefore, strongly suggests implementing a generic substitution policy without a prior consent provision for Michigan in containing costs of its Medicaid prescription drug program. Local, city, and state Medicaid officials should pursue this new policy option to

the state legislature, especially to the legislative committee responsible for agency budgets to implement it.

One of the major limitations of this research is that it uses a subset of total Medicaid drug-related costs and savings. Cost issues of Medicaid prescription drugs could include hundreds of additional brand drugs in this analysis, which cannot be included in this research due to time and financial limitations.

One of the limitations of this study is that it can only portray a partial picture of prescription drug cost containment in Michigan. CMS databases that the current study uses do not maintain pharmaceutical expenditure data of managed care organizations (MCOs) and pharmacy benefits managers (PBMs). Therefore, this study has a limited scope to include data of MCOs and pharmacy benefit managers under contract with state Medicaid agencies in its analysis regarding issues of the Medicaid prescription drug expenditure. As different MCOs use different criteria for prescription drug benefits for their patients, it is difficult to compare performance among MCOs regarding cost savings. Another issue is that the FDA does not categorize multivitamins in generic and brand categories. Therefore, this study excludes a large amount of money reimbursed for multivitamins in the Michigan Medicaid prescription drugs program. The savings amount that is found in this research for the Michigan Medicaid prescription drugs program could be much higher if all drugs, especially the multivitamins category, were included. Further research is needed to identify costs spent for multivitamins so that a more comprehensive Medicaid cost containment potential can be estimated.

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Appendix A

STATA Summary Results- Regression Model 1, Hypothesis 1

Table: STATA Summary Results- Regression Model 1, Hypothesis 1

```
. regress pct_sshare_tot_presdrug_cost gen_sub_pol pct_bdrug_reim_tdrug_unit_reim pct_bte_reim_tdrug_unit_reim,beta

      Source |       SS       df       MS              Number of obs =      18
-------------+------------------------------           F(  3,    14) =    3.55
       Model |  265.447897     3  88.4826324           Prob > F      =  0.0423
    Residual |  348.604081    14  24.9002915           R-squared     =  0.4323
-------------+------------------------------           Adj R-squared =  0.3106
       Total |  614.051978    17  36.1207046           Root MSE      =    4.99

------------------------------------------------------------------------------
pct_sshare~t |      Coef.   Std. Err.      t    P>|t|                     Beta
-------------+----------------------------------------------------------------
 gen_sub_pol |    1.069645   2.663326     0.40   0.694                 .086331
pct_bdrug_~m |    -.269868   .0921271    -2.93   0.011                -.6329671
pct_bte_re~m |   -.1447398   .0644356    -2.25   0.041                -.5042738
       _cons |     62.4357   5.460254    11.43   0.000                        .
```

Key of the variable used in the regression are shown in the following table.

Table: Variables used in STATA regression model 1 of Hypothesis One with interpretation

	STATA Code	STATA Code as regression variable
Dependent Variable (Y)	'pct_sshare_tot_presdrug_cost'	'state share'
Independent Variables		
X*1*	'gen_sub_pol'	'generic substitution policy'
X*2*	'pct_bdrug_reim_ tdrug_ unit_ reim'	'brand unit reimbursement'
X*3*	'pct_bte_reim_ tdrug_unit_reim'	'BTE unit reimbursement'

Appendix B

STATA Summary Results- Regression Model 2, Hypothesis 1

Table: STATA Summary Results- Regression Model 2 (Hypothesis One)

```
. regress pot_sav_avgcost_per_unit_gdrug gen_sub_pol pct_bdrug_reim_tdrug_unit_reim pct_bte_reim_tdrug_unit_reim,beta

      Source |       SS       df       MS              Number of obs =      18
-------------+------------------------------           F(  3,    14) =    7.11
       Model |  4.4172e+16     3  1.4724e+16           Prob > F      =  0.0039
    Residual |  2.8987e+16    14  2.0705e+15           R-squared     =  0.6038
-------------+------------------------------           Adj R-squared =  0.5189
       Total |  7.3159e+16    17  4.3035e+15           Root MSE      =  4.6e+07

------------------------------------------------------------------------------
pot_sav_av~g |      Coef.   Std. Err.      t    P>|t|                     Beta
-------------+----------------------------------------------------------------
 gen_sub_pol |   987056.6   2.43e+07     0.04   0.968                .0072986
pct_bdrug_~m |  -64308.28   840085.7    -0.08   0.940               -.0138187
pct_bte_re~m |    2411076   587573.3     4.10   0.001                .7695884
       _cons |  -1.92e+07   4.98e+07    -0.39   0.706                       .
------------------------------------------------------------------------------
```

Key of the variable used in the regression are shown in the following table

Table: Variables used in STATA regression model 2 of Hypothesis One with interpretation

	STATA Code	STATA Code as regression variable
Dependent Variable (Y)	'pot_sav_avgcost_ per_unit_ gdrug'	'potential savings'
Independent Variables		
X_1	'gen_sub_pol'	'generic substitution policy'
X_2	'pct_bdrug_reim_ tdrug_ unit_ reim'	'brand unit reimbursement'
X_3	'pct_bte_reim_ tdrug_unit_reim'	'BTE unit reimbursement'

Appendix C

STATA Summary Results- Regression Model 3, Hypothesis 1

Table: STATA Summary Results- Regression Model 3, Hypothesis One

```
. regress pot_sav_avgcost_per_unit_gdrug gen_sub_pol   pct_bdrug_amo_tot_expen pct_bte_amo_tot_expen,beta

      Source |       SS       df       MS              Number of obs =      18
-------------+------------------------------           F(  3,    14) =   10.43
       Model |  5.0547e+16     3  1.6849e+16           Prob > F      =  0.0007
    Residual |  2.2612e+16    14  1.6152e+15           R-squared     =  0.6909
-------------+------------------------------           Adj R-squared =  0.6247
       Total |  7.3159e+16    17  4.3035e+15           Root MSE      =  4.0e+07

------------------------------------------------------------------------------
pot_sav_av~g |      Coef.   Std. Err.      t    P>|t|                     Beta
-------------+----------------------------------------------------------------
 gen_sub_pol |    2.48e+07   2.10e+07     1.18   0.258                .1835854
pct_bdrug_~n |   -241099.7   942878.2    -0.26   0.802                -.04058
pct_bte_am~n |     3613227   704115.8     5.13   0.000                .7813041
       _cons |     6338828   8.68e+07     0.07   0.943                       .
------------------------------------------------------------------------------
```

Key of the variable used in the regression are shown in the following table.

Table: Variables used in STATA regression model 3 of Hypothesis One with interpretation

	STATA Code	STATA Code as regression variable
Dependent Variable (Y)	'pot_sav_avgcost_ per_unit_ gdrug'	'potential savings'
Independent Variables		
X_1	'gen_sub_pol'	'generic substitution policy'
X_2	'pct_bdrug_amo_tot_expen'	''brand amount reimbursement'
X_3	'pct_bte_amo _ tot _expen'	'BTE amount reimbursement'

Appendix D

STATA Summary Results- Regression Model 4, Hypothesis 1

Table: STATA Summary Results- Regression Model 4, Hypothesis 1

```
. regress pot_sav_avgcost_per_unit_gdrug per_presc_gen_reim per_pres_bdrug_costs perpres_bte_costs,beta

      Source |       SS       df       MS              Number of obs =      17
-------------+------------------------------           F(  3,    13) =   41.44
       Model |  6.6218e+16     3  2.2073e+16           Prob > F      =  0.0000
    Residual |  6.9246e+15    13  5.3266e+14           R-squared     =  0.9053
-------------+------------------------------           Adj R-squared =  0.8835
       Total |  7.3143e+16    16  4.5714e+15           Root MSE      =  2.3e+07

------------------------------------------------------------------------------
pot_sav_av~g |      Coef.   Std. Err.      t    P>|t|                     Beta
-------------+----------------------------------------------------------------
per_presc_~m |   291239.8   549640.9     0.53   0.605                .0530443
per_pres_b~s |  -471634.7   199300.6    -2.37   0.034               -.2917691
perpres_bt~s |    2156046   236885.2     9.10   0.000                    1.08
       _cons |  -2.44e+07   2.52e+07    -0.97   0.350                       .
------------------------------------------------------------------------------
```

Key of the variable used in the regression are shown in the following table.

Table: Variables used in STATA regression model 4 of Hypothesis One with interpretation

	STATA Code	STATA Code as regression variable
Dependent Variable (Y)	'pot_sav_avgcost_ per_unit_ gdrug'	'potential savings'
Independent Variables		
X_1	'per_presc_gen_reim'	'generic prescription costs'
X_2	'perpres_bdrug_costs'	'brand prescription costs'
X_3	'perpres_bte_ costs'	'BTE prescription costs'

Appendix E

STATA Summary Results- Regression Model 1, Hypothesis 2

Table: STATA Summary Results- Regression Model 1 (Hypothesis 2)

```
. regress sshare_presdrug_costs sgensub_pol_wiconst sgensub_pol_winocons,beta

      Source |       SS       df       MS              Number of obs =      18
-------------+------------------------------           F(  2,    15) =    9.81
       Model |  4.5770e+17     2  2.2885e+17            Prob > F      =  0.0019
    Residual |  3.4992e+17    15  2.3328e+16            R-squared     =  0.5667
-------------+------------------------------           Adj R-squared =  0.5090
       Total |  8.0762e+17    17  4.7507e+16            Root MSE      =  1.5e+08

------------------------------------------------------------------------------
sshare_pre~s |      Coef.   Std. Err.      t    P>|t|                     Beta
-------------+----------------------------------------------------------------
sgensub_po~t |   7.84e+07   8.82e+07     0.89   0.388                .1745859
sgensub_po~s |   3.71e+08   8.82e+07     4.20   0.001                .8247634
       _cons |   2.49e+08   6.24e+07     4.00   0.001                       .
------------------------------------------------------------------------------
```

Key of the variable used in the regression are shown in the following table.

Table: Variables used in STATA regression model 1 of Hypothesis two with interpretation

	STATA Code	STATA Code as regression variable
Dependent Variable (Y)	'pct_sshare_tot_presdrug_cost'	'state share'
Independent Variables		
X_1	'sgensub _ pol_wiconst'	'policy with prior consent'
X_2	'sgensub_pol_ winocons'	'policy without prior consent'

Appendix F

STATA Summary Results- Regression Model 2, Hypothesis 2

Table: STATA Summary Results- Regression Model 2, Hypothesis 2

```
. regress pot_sav_by_gdrug_rate sgensub_pol_wiconst sgensub_pol_winocons,beta

      Source |       SS       df       MS              Number of obs =      18
-------------+------------------------------           F(  2,    15) =    6.48
       Model |  3.3919e+16     2  1.6960e+16           Prob > F      =  0.0094
    Residual |  3.9240e+16    15  2.6160e+15           R-squared     =  0.4636
-------------+------------------------------           Adj R-squared =  0.3921
       Total |  7.3159e+16    17  4.3035e+15           Root MSE      =  5.1e+07

------------------------------------------------------------------------------
pot_sav_by~e |      Coef.   Std. Err.      t    P>|t|                     Beta
-------------+----------------------------------------------------------------
sgensub_po~t |  -1.24e+07   2.95e+07    -0.42   0.680                -.0918832
sgensub_po~s |   8.52e+07   2.95e+07     2.89   0.011                 .6303019
       _cons |   2.84e+07   2.09e+07     1.36   0.193                        .
```

Key of the variable used in the regression are shown in the following table.

Table: Variables used in STATA regression model 2 of Hypothesis two with interpretation

	STATA Code	STATA Code as regression variable
Dependent Variable (Y)	'pct_sshare_tot_presdrug_cost'	'potential savings'
Independent Variables		
X_1	'sgensub _ pol_wiconst'	'policy with prior consent'
X_2	'sgensub_pol_ winocons'	'policy with no prior consent'

Appendix G

STATA Summary Results- Regression Model 3, Hypothesis 2

Table: STATA Summary Results- Regression Model 3 (Hypothesis 2)

```
. regress pot_sav_by_gdrug_rate gen_sub_pol  sgensub_pol_winocons,beta

      Source |       SS       df       MS              Number of obs =      18
-------------+------------------------------           F(  2,    15) =    6.48
       Model |  3.3919e+16     2  1.6960e+16           Prob > F      =  0.0094
    Residual |  3.9240e+16    15  2.6160e+15           R-squared     =  0.4636
-------------+------------------------------           Adj R-squared =  0.3921
       Total |  7.3159e+16    17  4.3035e+15           Root MSE      =  5.1e+07

------------------------------------------------------------------------------
pot_sav_by~e |      Coef.   Std. Err.      t    P>|t|                     Beta
-------------+----------------------------------------------------------------
 gen_sub_pol |  -1.24e+07   2.95e+07    -0.42   0.680                -.0918832
sgensub_po~s |   9.77e+07   2.95e+07     3.31   0.005                 .7221851
       _cons |   2.84e+07   2.09e+07     1.36   0.193                        .
```

Key of the variable used in the regression are shown in the following table.

Table: Variables used in STATA regression model 3 of Hypothesis two with interpretation

	STATA Code	STATA Code as regression variable
Dependent Variable (Y)	'pct_sshare_tot_presdrug_cost'	'potential savings'
Independent Variables		
X_1	'gen_sub _ pol'	'generic substitution policy'
X_2	'sgensub_pol_ winocons'	'policy with no prior consent'

Appendix H

Summary: Dependent and Independent Variables of Regression Models, Hypothesis 1

Table of Summary: Dependent and Independent Variables of regression models (hypothesis 1)

```
. . summarize pct_sshare_tot_presdrug_cost pot_sav_avgcost_per_unit_gdrug gen_sub_pol  pct_bte_reim_tdrug_unit_reim pct_bdrug_reim_tdru
> g_unit_reim   pct_bte_amo_tot_expen pct_bdrug_amo_tot_expen per_presc_gen_reim per_pres_bdrug_costs perpres_bte_costs
```

Variable	Obs	Mean	Std. Dev.	Min	Max
pct_sshare~t	18	46.6426	6.01005	38.86214	63.76553
pot_sav_av~g	18	5.27e+07	6.56e+07	6780083	2.51e+08
gen_sub_pol	18	.6666667	.4850713	0	1
pct_bte_re~m	18	30.74288	20.93902	9.246723	69.77654
pct_bdrug_~m	18	44.67543	14.09639	21.36015	66.10802
pct_bte_am~n	18	13.83858	14.18514	3.185417	50.54027
pct_bdrug_~n	18	83.71422	11.0414	43.26241	94.84048
per_presc_~m	17	20.06574	12.31439	11.94557	66.44014
per_pres_b~s	17	125.7492	41.82719	69.10338	191.5877
perpres_bt~s	17	60.6702	33.86812	29.93969	140.4415