EXAMINING POLICY, ENABLER AND ACCESS FACTOR EFFECTS ON U.S STATE MEDICAID PHARMACEUTICAL UTILIZATION AND EXPENDITURE

By

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ABSTRACT

EMMANUEL KWESI EGHAN. Examining Policy, Enabler and Access Factor Effects on US State Medicaid Pharmaceutical Utilization and Expenditures.
(Under the direction of Dr LOUIS H. AMATO)

Prescription drug expenditures and utilization are the fastest growing and most widely varying expenditures within Medicaid programs across US states. The passage of the Affordable Care Act (ACA) in 2010 and the subsequent Medicaid state expansions resulted in very large coverage gains among several demographics. Prior to the ACA a number of studies highlighting determinants of overall healthcare utilization and expenditures had been undertaken. Most of these studies examined discreet determinants for overall health care. However, these determinants, their interactions have not been tested concurrently in relation to pharmaceutical expenditures. Data from the Centers for Medicare and Medicaid Services (CMS), US Department of Labor, Department of Education, and state Medicaid programs were merged to create a balanced panel data (n=350 observations and 53 variables over a seven (7) period from 2009 to 2015). Based on Andersen's Behavioral Model of Health Services, and using STATA-16 a random effects (RE) panel regression analysis is undertaken to estimate an econometric model for Medicaid pharmaceutical expenditures. A Structure Equation Model is developed to examine the relationships between and test the hypothesized effects of policy, access and predisposing factors on State Medicaid expenditures. The model estimate showed a significant influence on drug expenditures of state non-drug Medicaid expenditures, proportion of males in the population, and provider education programs on generics. Discussions, limitations and future directions for research are stated.

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DEDICATION

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This dissertation is dedicated to my family: my wife Josephine for all her steadfast support and prayers during this doctoral journey, my son Dennis (my IT go to person), my first daughter Maame Esi (my reader and reviewer), and to my second daughter Ewura Esi (my creative inspirer). And to my parents Nana Gyan-Akwandah (VI) Twafohene of the Nkusukum Traditional Area and Joana Oyo Eghan without whom I wouldn't be where I am now, and to all my brothers and sisters for all their support and encouragement.

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LIST OF ABBREVIATIONS

ACA	Patient Protection and Affordable Care Act
ABM	Andersen's Behavior Model of Health Service Utilization
AMP	Average Manufacturers Price
AVE	Average Variance Extracted
AWP	Average Wholesale Price
CMS	Centers for Medicare and Medicaid Services
DAW	Dispense As Written
CR	Composite Reliability
DV	Dependent Variable
FE	Fixed Effects
IV	Independent Variable
MDRP	Medicaid Drug Rebate Program
PA	Prior Authorization
PE	Pharmaceutical Expenditure
PDDL	Preferred Drug Dispensing Lists
PLS	Partial Least Squares
PLS-SEM	Partial Least Square-Structural Equation Modeling
RE	Random Effects
SEM	Structural Equation Modeling

CHAPTER 1: INTRODUCTION

Nations, businesses, and individual reaction to the ongoing COVID-19 pandemic have challenged the pharmaceutical industry to explore new drugs and vaccines that can treat and prevent this menace (Chesbrough, 2020; Ramelli & Wagner, 2020). Pharmaceuticals play a crucial role in health care. Pharmaceutical discoveries have dramatically reduced deaths from HIV-AIDS, cardiovascular, and other chronic diseases. Remdesivir, a recently discovered drug, and others such as azithromycin, hydroxychloroquine, and dexamethasone appear to be hopeful options to reduce number of COVID-19 related deaths. Pharmaceuticals save and improve lives. They also promote trust and participation in health services. However, despite their importance, pharmaceuticals contribute to rising healthcare expenditures because they tend to be costly to health systems, insurance payers, residents, and businesses (Embrey, 2013).

US healthcare expenditures rose steadily over the past two decades. This rise is driven by socio-economic and demographic factors such as increased disposable income, shifts in enrollment from private health insurance to public insurance, continued population aging, and growth in prices of healthcare products and services (Bose 2014). The effects of these drivers on healthcare expenditure, however, vary between US states. In her article on determinants of US health care expenditures, Bose (2014), found strong associations between state-level healthcare expenditure and the demographic composition of states, rates of employment, state GDP, and number of physicians, and the prices of health care products and services (Bose, 2014). Prescription drugs are a sub-component of health goods and services. Prescription drug sales have been growing rapidly in the US. Prescription drug sales, which account for approximately 12% of the total US health expenditures, increased by 5.5% in 2017 to $476.2 billion in 2018 (Schumock et al., 2018). In 2018, three (3) prescription drugs, Adalimumab (Humira®), Insulin

glargine (Toujeo®, or Lantus®), and Etanercept (Enbrel®) accounted for over $ 26.0 billion of national spending on health. Two of these prescription drugs, Adalimumab and Etanercept, for treating rheumatoid arthritis, and Insulin for diabetes management. Although 48% and 14 % of pharmaceutical expenditures were financed through private health insurance and by resident out-of-pocket payments respectively, publicly payers, such as Veterans Administration, Medicaid and Medicare paid for 37% of the national prescription expenditure (Center of Medicare and Medicaid Services,2019). Medicaid, a public payer of health care designed to provide medical care for low-income families, indigent seniors, disabled adults is the main publicly funded insurance program in the US. Enacted in 1967, Medicaid is a joint State and Federal level intervention and part of the Title Nineteen provisions of the 1965 Social Security Act amendments (Moore, 2005). Due to state autonomy, the structure, financing, and benefits package for each Medicaid program varies considerably. Medicaid, accounting for nearly 18% of the national drug expenditure from 2016-2019, was the single most significant sponsor among the publicly funded insurance programs (Centers for Medicare and Medicaid Services). In view of the level of Medicaid expenditures among the publicly funded programs, this, and because pharmaceuticals are also among the covered benefits greatly affected by the recurrent increases in expenditures, Medicaid prescription drug benefits have been a cause for concern for many state payers.

State Medicaid programs, historically adopted a mix of policies and strategies to contain prescription drug spending. The most frequently used state Medicaid cost-containment policies include generic and therapeutic substitution policies, comprehensive drug utilization reviews, and prior authorization of high-priced medications, and utilization of formularies, and most-preferred drug lists (PDL), and mandatory drug price rebates from manufacturers. The Medicaid

Drug Rebate Program (MDRP), enacted as part of the Omnibus Budget Reconciliation Act (OBRA) of 1990, enabled State-Medicaid programs to purchase drugs at the best possible market price provided by manufacturers for wholesalers or labelers (Act, 1990). The MDRP requires that a manufacturer seeking Medicaid drug product coverage agrees to offer rebates on the average manufacturer's price (AMP) for all branded drugs purchased by Medicaid. In turn, the state commits to adding all the manufacturer's FDA approved medicines to the state's pharmacy benefit package. The state also commits to sharing all savings accrued from rebates with the US Department of Health. The Patient Protection and Affordable Care Act (ACA) enacted in 2012, increased the Medicaid drug rebate to states from 15.1 to 23.1 percent of the average price of branded pharmaceuticals (Protection & Act, 2010). The ACA also increased the manufacturer's rebate on generic drugs from 11% to 13 %.

The US pharmaceutical market, the largest in the world, actively regulates market-entry, market exclusivity, and the safety of pharmaceuticals. The pharmaceutical industry is divided into organizations that research and develop new drugs (innovators or brand name firms); and follower organizations that produce generic versions of off-patent medicines (Boehm, Yao, Han, & Zheng, 2013). The typical life cycle of a branded pharmaceutical entails drug discovery and development (including safety testing) receipt of US Food and Drug Authority approval, patent filing and extensions, oligopolistic competition and generic competition, and discontinuation of use (Massinghoff, 1999). Branded pharmaceuticals are granted up to 20 years of patent exclusivity in the US. Lakdwallah D et al., 2018, illustrated the critical effect of exclusivities granted pharmaceutical companies and the bargaining power of large public sector buyers on pharmaceutical price discrimination (Lakdwallah, 2018). Howard (2015) highlighted

the effect of competitive influences of generic companies and companies producing similar but non-identical drugs on price discrimination within the pharmaceutical industry.

The overarching goal of this study is to identify the predictors of state-level Medicaid drug expenditures and examine the effects of the interactions between these predictors on Medicaid drug expenditures. A second objective will be to estimate a model to explain state Medicaid pharmaceutical utilization and expenditure. Previous drug utilization and evaluation studies have shown the impact of race, demographics, income, access to insurance, or cost containment policy factors on drug utilization and expenditures. Most of these studies focused on singular categories of predictors or determinants but do not examine all potential factors together (Roy, S., & Madhavan, S. S. (2012). The previous studies have not studied the inter-relationships and interactions among these predictors and their effect on drug expenditures (Mujasi, P. N., and Puig-Junoy, J. 2015). With the recent ACA expansion, and the introduction of newer cost-containment policies, it is essential that we identify all of the determinants of and their interactive effects on Medicaid pharmaceutical utilization and expenditures.

Conceptual Framework

The two objectives of this thesis will be examined through the lenses of health and economic theory.

Objective one (1): Estimate an econometric model for Medicaid pharmaceutical expenditures and

Objective two (2) examine the effects of the interactions between these predictors on Medicaid drug expenditures will be examined using Andersen's behavioral model (ABM) of health services use as a conceptual framework. ABM was developed to examine predictors of health services utilization and has been applied recurrently in a variety of healthcare use research

(Andersen, 1995; Chen & Chang, 2002; Gotsadze, Tang, Shengelia, & Zoidze, 2017). This framework of the demand for health services will be adopted to help categorize independent variables that are expected to affect state Medicaid drug utilization and expenditures. ABM posits that individual usage of healthcare is a result of the individual's intrinsic disposition to consume healthcare (predisposing factors) in response to a need; and factors that make it possible to access care or act as barriers to use (enabling factors), as well as their inherent or perceived need for medical care (need factors). The Behavioral model has featured in several health use research projects. Chern, Wan, and Begun (2002) also applied the behavioral theory to study the comparative value of factors in forecasting consumption of dentalcare services by HIV patients (Chern, Wan, & Begun, 2002). Roy and Madhavan used Anderson's behavioral theory for the first time in the literature to estimate a pre-ACA model for pharmaceutical expenditures in the United States (Roy & Madhavan, 2012). Majusi and Puig-Junoy (2015) again used this behavioral theory to establish a linear log model of pharmaceutical expenditures for estimation of overall pharmaceutical spending to guide budget formulation in Uganda (Mujasi & Puig-Junoy, 2015).

In the overall process, the study seeks to address the following questions.

- *What are the significant predictors of state Medicaid drug expenditures?*
    - *Based on the pre and post ACA determinants what model best estimates Medicaid pharmaceutical expenditures.*
    - *What, if any, are the interactive effects of these determinant factors/variables/latent constructs on each other and on Medicaid pharmaceutical expenditures?*

CHAPTER 2: LITERATURE REVIEW

Chapter 2 provides a review of the literature relative to the research objectives in Chapter one. This chapter starts with an introduction to Medicaid and highlights the literature on Medicaid cost containment relative to pharmaceutical expenditures. An underlying thread for the study's research objective is the implications on Medicaid of the ACA. Given this, the literature review also highlights the ACA's critical legislative outputs, including pharmaceutical rebates, state level predictors of health service utilization and effects of increased variation in race and ethnicity of Medicaid clients on prescription drug use throughout ACA expansion.

The research questions are examined through the lens of health, or economic theory. The review will be sub-divided into three sections. The opening section offers a review and synthesis of the phenomenon of interest grounded in the relevant theory and calls attention to research gaps. The second section describes the theoretical framework underpinning the study. Building on the literature synthesis and to address research gaps, the final section presents a model and also, states the hypothesis based on the underpinning theory in the context of Medicaid pharmaceutical coverage.

Medicaid

Medicaid is a publicly funded program designed to provide medical care for low-income families, needy seniors, disabled adults, and the medically indigent. Enacted in 1967, Medicaid is a joint state and federal government intervention under Title 19 of the 1965 Social Security Act (Rosenbaum, 2002). The federal government funds majority of Medicaid's costs and sets overall rules for eligibility, minimal benefits to be covered, and rates of provider payments (Kaiser Foundation, 2002). States however make available extra funds and take decisions on their Medicaid programs relative to eligibility, benefits, provider payments, and service delivery

approaches (Han, Luo, & Ku, 2017). There is a direct relationship between the portion of federal Medicaid reimbursement to states and the amount that states spend (Huberfeld, 2011). The federal funding portion of Medicaid, referred to as Federal Medical Assistance Percentage (FMAP), is calculated annually by using the level the state's per resident income as compared to the national income. To guarantee equity, Medicaid programs with higher per capita incomes are reimbursed a smaller share of costs. FMAP reimbursement rates to states have a statutory minimum of 50% and a maximum of 83% of total state Medicaid expenditures (Mitchell & Baumrucker, 2016).

There are several optional services that state Medicaid programs can offer. These services include optometry, dental, and provision of prosthetic devices. As a result of these options and flexibilities in choice of services, Medicaid programs vary substantially across states (Holahan, 2007). Although state Medicaid features vary, a constant feature in all states is prescription drug coverage (Morden & Sullivan, 2005. It is worth noting that as long as states offer outpatient prescription drugs, Medicaid requires coverage for all other the US-Food and Drug Administration (FDA) approved medicines produced by firms who offer rebates to Medicaid. Additionally, Medicaid also requires states participating in a MDRP with the federal government to share savings from the rebate with the federal government (Gencarelli, 2003).

Due to rising expenditures, states have also enacted and implemented various cost-containment measures for pharmaceuticals, which include:

1. **Caps.** A cap is the maximum dollar amount a state plan, e.g., Medicaid will reimburse for an outpatient drug benefit.
2. **Preferred drug lists (PDL)**: PDLs', sometimes referred to as formularies, are usually a list of drugs that Medicaid programs reimburse. When considering a PDL, plan designers

also consider applicable state-level "dispense as written" regulations that specify how a provider can use particular branded products. Although the OBRA (1990) prevents the use of restrictive formularies, State Medicaid programs have established supplementary approaches to induce favorable drug use trends. These supplementary approaches encourage use of less expensive but equally efficacious drugs than more expensive alternatives in any given therapeutic class. They achieve results with the approach by soliciting additional manufacturer rebates for products included on the Preferred Drug Lists (PDL) beyond those rebates mandated by the federal government. PDLs influence decisions on the type of prescription drugs the state believes to be the most cost-beneficial or effective with minimal side effects for Medicaid beneficiaries (Murawski & Abdelgawad, 2005). The approach for selecting PDLs varies with each state. Twenty-five percent of states have in-house drug utilization review teams, including a pharmacy and therapeutic committee whose main activity is to check and upgrade the PDL drug selection, and outsource services (Neumann et al., 2006).

3. **Prior authorization.** Prior Authorization (PA) entails a review of enrollee clinical data before Medicaid authorizes the prescribing or dispensing of a particular non-preferred prescription drug for an enrollee. The intricacies of the PA process vary from state to state. In some states, this can be done by phone, while in others, clinicians are required to submit forms that have to be vetted administratively before approval. State level variations in PA processes determines the degree to which PA programs deters or encourage use of certain prescription drugs on a PDDL (Morden & Sullivan, 2005).
4. **Generic substitution**. Approximately seventy percent of states mandate dispensing of a generic equivalent of drugs when available; however, six (6) out of ten (10) states allow

the physician to nullify this substitution requirement by simply making a “Dispense As Written (DAW)” request on the script to the pharmacist. (Morden & Sullivan, 2005).

5. **Copayment.** Copayments for prescription drugs have been applied in about 36 state Medicaid programs (Lieberman, Polinski, Choudhry, Avorn, & Fischer, 2014). Copayments vary from $0.50 to $3.00 per prescription. While a $0.50 to $3.00 copayment appears small, they can present as hurdles to many disadvantaged users of health services. (Gibson, Ozminkowski, & Goetzel, 2005; Klepser, Huether, Handke, & Williams, 2007; Ku, Deschamps, & Hilman, 2004).

6. **Quantity, duration, and refill limits**.

   This cost containment approach entails instituting a rule on the maximum quantity of drugs to be prescribed and dispensed at one time to a Medicaid recipient. The rationale is to prevent waste if the entire prescription is not needed. All states enforce limits on total days of medicine supply, and it is typically about a month or 3 months for refills. Although longer supply periods may inadvertently raise the potential for medication wastage, earlier studies posit that it may also lessening pharmacy expenditures by dropping dispensing fees and drug ingredient costs (National Pharmaceutical Council, 2015). States with tighter restrictions also cap the quantity of individual prescriptions and the number of brand-name items per period.

7. **Dispensing Fees.**

   State reimbursements for most Medicaid enrollee drug prescriptions are through retail pharmacies. The amount reimbursed to pharmacies is calculated using the ingredient cost of the drug and a pharmacist dispensing fees compensated by Medicaid, in addition to any amounts paid by beneficiaries as cost-sharing. States' dispensing fees per prescription

are usually between $3.50 and $4.50. A common practice by states is to start with the Average Wholesale Prices (AWP) and subtract the discount on the net amount accruing from the deductions (Berndt & Newhouse, 2010). Formulae vary widely by state (Baghdadi, 2017), and this variance includes the use of different formulae for drugs and their substitutes. In a number of cases, pharmaceuticals are reimbursed within a range of AWP: minus 5-18% of AWP (Berndt & Newhouse, 2010). The pharmacy's final reimbursement is calculated as a sum of the professional fee and the medicines approved Medicaid price: (AWP-X percent) + pharmacist professional fee, where X is the negotiated discount. Frequently, high product reimbursement is balanced with lower dispensing fees.

8. **Managed care.**

Medicaid programs vary in how they utilize the managed care provisions (Krieger, Connell, & LoGerfo, 1992). About 42 percent of gross spending was attributable to fee-for-service Medicaid, and the rest to Medicaid managed care in 2015. The proportion of Medicaid enrollees on non-fee for service programs significantly rose post enactment of the Balanced Budget Act (BBA) of 1997. The BBA led to major reduction in Medicaid expenditures by widened states' autonomy to require Medicaid recipients to register in managed care plans (Dickler & Shaw, 2000).

9. **Fee-for-service drug spending.**

CMS Medicaid data revealed a wide variation in per capita and total drug expenditure per beneficiary, among states. Compared to managed care programs, Morden and colleagues (2014) detected a difference in the payments equivalent to four times the amounts paid per beneficiary on a fee for services. Ehlert (2014) also report a four and half fold

variance in total medicine spend for fee for service as compared to managed care program (Ehlert & Oberschachtsiek, 2014). Additionally, Baugh (2015) observed wide-ranging variations in drug costs for the elderly and the disabled among states. Although this inconsistency might echo variances in the features of individual state's enrollee utilization of drugs, it appears that this occurs as result of divergent state cost-cutting strategies (Holahan, 2007; Morden & Sullivan, 2005).

10. **Disease management.** The goals of Disease management (DM) are to control the cost of chronic diseases and conditions such as diabetes through use of tested guidelines and approaches that enable patients to understand and prevent diseases from worsening. Successful DM programs require cooperation among patients, prescribers, dispensers, administrators and third-party payers. The prime challenge to DMs has been guiding patients into the program.
11. **Omnibus Drug Rebates (**OBRA 90). This regulation was enacted to enable firms offer rebates to all states offering medicine benefits. OBRA established different pharmaceutical firm rebates for generic (11%) and branded drugs (15.1%).

In a systematic review of the literature, (Soumerai 2004) studied state medication reimbursement policies, and administrative restrictions on prescription drugs. His report highlighted the impact of formularies, and cost containment policies on expenditure and utilization of prescription drugs. Simon, Tennyson, and Hudman (2009) did additional analysis on existing state guidelines that reduce prescription drug access under Medicaid over a period of 14 years (1990-2004), and showed an upward trend in the use of and significant variations in the number and kind of state policies. Again, Simon et al (2009) showed that despite annual spending growth some of these restrictions had helped control Medicaid prescription drug costs.

Indeed, better results were seen with a number of strategies, for example usage of dedicated medicines lists and stratified copay mechanisms. (Simon, Tennyson, & Hudman, 2009). Lexchin (2010) however reported lack of evidence to demonstrate the benefits of restrictive formularies or disadvantages of open formularies on drug costs. Expenditures on outpatient drug coverage have been a source of angst and subject of many Medicaid cost containment strategies.

Patient Protection and Affordable Care and the Health Care and Education Reconciliation ACTs

The expanded eligibility, a key section of the Patient Protection and Affordable Care Act of 2010 and the Health Care and Education Reconciliation Act of 2010—together known as the Affordable Care Act (ACA), was projected to lead to a rise in population insurance coverage. The projection was for a large proportion of these newly covered individuals to sign up in Medicaid. Through its new income thresholds for poverty, the ACA was projected to significantly reduce state-level variations in Medicaid eligibility rules. Nevertheless, a 2012 Supreme Court ruling fundamentally switched ACA Medicaid expansion to a voluntary option for states, consequently reducing variation in eligibility rules among expansion states, while accentuating differences between expansion and non-expansion states (Hong, Holcomb, Bhandari, & Larkin, 2016; Miller & Wherry, 2017). Subsequently, many expansion states received exceptions from the federal government that allowed them to implement changes in some dimensions of their ACA program, further accentuating the state differences. Consequently, the ACA has been perceived as triggering program differences and not just encouraging a rise of Medicaid enrollments (Ghosh, Simon, & Sommers, 2017).

Table 1, below shows a summary of when states took the ACA expansion.

Table 1 State Affordable Care Act Expansion Status-July 2020

Status	State	Year	State	Year	Status	State
Expansion	Alaska	2015	Montana	2016	Non-Expansion	Alabama
	Arizona	2014	Nevada	2014		Florida
	Arkansas	2014	New Hampshire	2014		Georgia
	California	2014	New Jersey	2014		Kansas
	Colorado	2014	New Mexico	2014		Mississippi
	Connecticut	2014	New York	2014		Missouri
	Delaware	2014	North Dakota	2014		Nebraska
	District of Columbia	2014	Ohio	2014		North Carolina
	Idaho	2020	Oregon	2014		South Carolina
	Illinois	2014	Pennsylvania	2015		South Dakota
	Indiana	2015	Rhode Island	2014		Tennessee
	Iowa	2014	Utah	2020		Texas
	Kentucky	2014	Vermont	2014		Wisconsin
	Louisiana	2016	Virginia	2019		Wyoming
	Maine	2019	Washington	2014		
	Maryland	2014	W. Virginia	2014		
	Massachusetts	2014	Michigan	2014		
	Minnesota	2014	Oklahoma	2020		

Source: Kaiser Foundation July 2020

Medicaid Rebates, Prescription Drug Prices, and Pharmaceutical Firm Behavior

This section provides a review of literature on Medicaid drug rebates, prescription drug pricing, and pharmaceutical firm behavior grounded in price discrimination theory. Building

from the review, a hypothesis is developed utilizing price discrimination theory to explain pharmaceutical firm behaviors when setting prices based on Medicaid rebates.

Ambulatory patient medicine benefits are an elective Medicaid packages provided with a comparatively small, federally approved, cost-sharing and deductible rate (Gencarelli, 2003). State Medicaid programs' cost containment strategies include obtaining discounts, and rebates on prescription drug prices from manufacturers. The Medicaid program requires pharmaceutical producers to pay rebates quarterly to state Medicaid programs directly. These quarterly payments are computed on the basis of the AMP reimbursed by drug firms to community through wholesalers for prescription medicines. The statute, focusses on average prices to pharmacies and private insurance programs, and does not include prices charged to the very large federal buyers like Medicare Part D. This exception is significant considering the lower prices both VA and Medicare Part D pay for prescription drugs (Sachs, Bagley, & Lakdawalla, 2018) purchaser.

The Medicaid Drug Rebate Program (MDRP) offers price reliefs opportunities for medicines dispensed to Medicaid ambulatory enrollees. Almost, six hundred pharmaceutical firms take part in the MDRP (CMS 2018). All US states (including the DC) currently provide medicine coverage as a standard benefit in line with the MDRP. The ACA advanced rebate program changes as highlighted in table 3.

Table 2 ACA Medicaid Drug Rebates

	ACA Medicaid Drug Rebates	
1	Brand/innovator Medicines	Changed rebate by 8% to 23.1%
2	Medicines used in the blood clot prevention and for restricted child indications	ACA introduced a rebate of 17.1%
3	Non-proprietary generic medicines	Changed rebate by 2% to 13%

Summary of ACA Rebate Reforms. Source: Centers for Medicare and Medicaid 2010.

Medicaid rebates and their relationship with drug prices have been a subject of previous research (Baghdadi, 2017; Berndt & Newhouse, 2010; Crystal, Akincigil, Bilder, & Walkup, 2007; Ehlert & Oberschachtsiek, 2014; Holahan, 2007; Tehrani & Carroll, 2017). The effects of rebates on prices are particularly important for Medicaid recipients with chronic diseases. Chronic disease such as diabetes have a high prevalence in the US, with over 35 million (10%) of Americans suffering from the disease (US Center for Disease Control, CDC, 2019). Diabetes is 6th out of the ten leading causes of death in the US. The 2017 US Medical Expenditure Panel Survey (MEPS), showed a six-fold rise in spending for insulin among people eighteen years and above with diabetes from over $2.5 billion in 2002 to nearly $16 billion in 2012 (McEwen, Casagrande, Kuo, & Herman, 2017).

A paper by Duggan and Morton (2006) using data on the 200 most utilized drugs between 1997 and 2002, revealed that a ten-percentage-point rise of the market size of Medicaid is accompanied by a seven to ten percent growth in the mean drugs prices. In their 2019 paper, Hwang et al. state that OBRA and the MDRP may have an unfavorable effect on the prices at which other health systems, including safety-net hospitals, buy prescription drugs. They inferred that the price discounts that health facilities receive could suddenly be reduced since those prices were part of the open market data used by Medicaid and pharmaceutical firms to generate rebates. Hwang et al, also posit that pharmaceutical companies would be unwilling to offer rebates to hospitals and other health systems serving low income population as overall rebates and discounts keep increasing for big government buyers (Hwang, Kesselheim, & Sarpatwari, 2017).Furthermore, Hwang et al. surmise that when MDRP increases rebate percentage, pharmaceutical companies knowing that States can identify the high-cost drugs and use the information gleaned to enhance their powers to negotiate supplemental rebates, will be less

willing to provide a discount to other non-Medicaid clients (Hwang, Kesselheim, & Sarpatwari, 2017). Hwang and Kesselheim (2014) further demonstrate growth in average price of the most dispensed innovator cancer drugs in the US, by nearly US$160 after the ACA enactment in 2010. Conversely, generic anti-cancer medicine prices exhibited no substantial variations. This implies that the impact on drug pricing of the ACA rebate may be more pronounced for branded prescription drugs than generics. Indeed, John and Chernuw (2017) argue that despite its intention to secure the "best price" for Medicaid, the Medicaid Drug Rebate Program inadvertently left states vulnerable to high-cost brand-name drugs, especially those with minimal or no market competitors (John & Chernew, 2017).

The MDRP, in particular, does not allow states to exclude high-value drugs from their covered drug lists (potentially restricting opportunities and favoring high-value therapies) and offers no alternatives for Medicaid to negotiate for lower prices except ask for rebates based on set prices (John & Chernew, 2017). This position is further reinforced by other studies suggesting that drug firms may have raised their medicine prices, for example as seen for anti-cancers to counterbalance the increased Medicaid rebate (Tehrani & Carroll, 2017). Ohn and Kaltenbrock (2019) argue that the MDRP program's design exposes programs to the effects pricing decisions by other big players on the market. These players include the Veterans Administration, Medicare, medicine benefit managers, and drug firms. Ohn and Kaltenbrock (2019) infer that states that use open instead of closed drug formularies do not maximize benefits from rebates, and they further surmise that Medicaid purchases may impact overall national US prices of medicines in the near term. Indeed, the argument suggests that in the short term, incremental benefit to the market and to the states using closed Medicaid drug lists would be contingent on whether increases in formulary prices for drugs with lesser rebates exceed the final

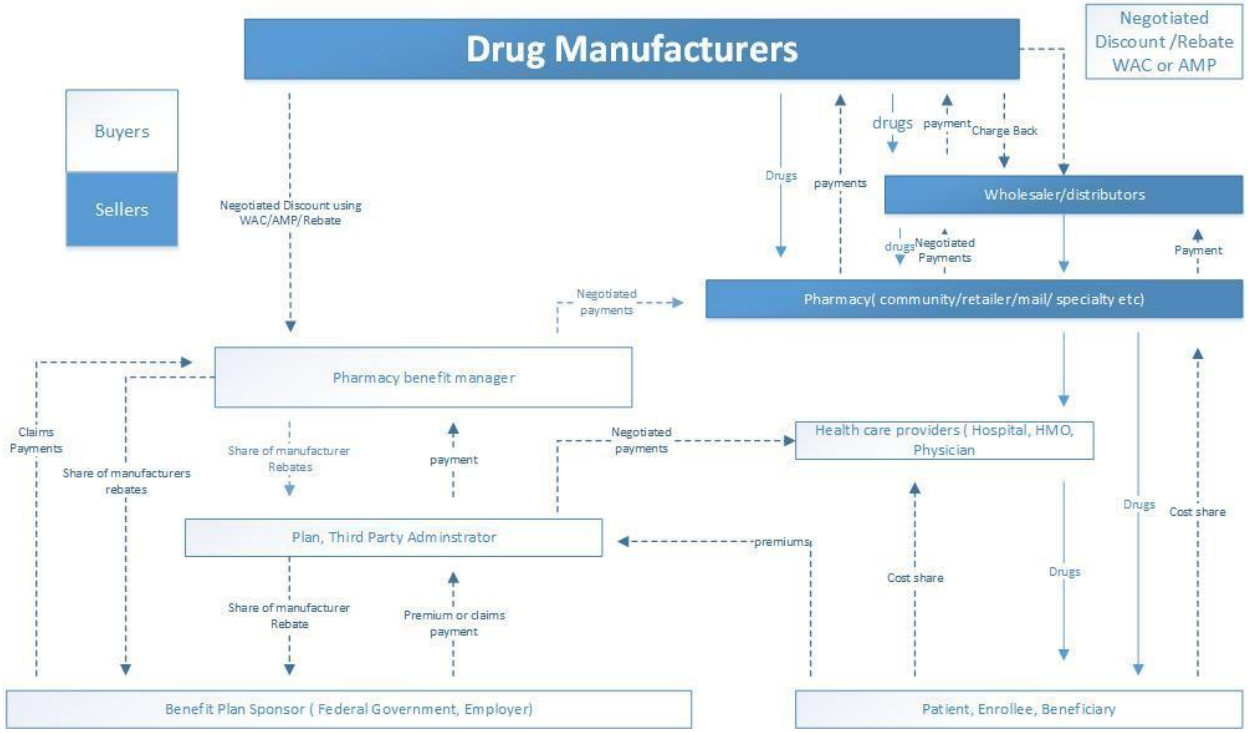
drop in prices for those drugs that do offer significant reductions on commercial health insurance plans.

Irrespective of how they are executed, use of closed drug lists reflect market challenges for brand-name drugs and echo evolving demand on policies that protect Medicaid by utilizing the combined power of other payers (Hwang et al., 2017). Legislators and policy makers need to revisit the MDRP program's fundamental assumption and explore other options to assure long term predictability and steady pattern in Medicaid prescription drug spending (Ohn & Kaltenboeck, 2019).

Some other researchers have confirmed recent increases in wholesaler list prices and manufacturers' WAC. They also confirmed a disproportionate growth in pharmaceutical manufacturers net income as compared reimbursement, in spite of rising public concern about outpatient prescription drug prices (Weinstein & Schulman, 2020). Aitken, Berndt Culter Kleinrock, and Maini (2016) analyzed the effects of drugs firms' rebates on prices. They identified underlying factors such as a growth of the new pipeline of drugs coupled extended patent expiration periods and reduced availability of less expensive generics; as well as the increased trend of mergers among buyers such as wholesalers, pharmacy benefit managers, and health payers; (Aitken, Berndt, Cutler, Kleinrock, & Maini, 2016). Almost 10 million additional Americans enrolled for Medicaid in 2014 across twenty-six expansion states (Kaiser 2015). Wen et al. (2016) shared outcomes of the impact of ACA on medicine utilization. Wen et al (2016) found that state expansions affected level of prescriptions utilized but had no significant effect on per capita Medicaid drug spending (Wen, Borders, & Druss, 2016). This infers that the observed total drug expenditure rises in 2014 could not be solely predicted by the ACA expansion. Indeed, Ghosh et al (2017) also found that the ACA expansions was associated with

a relative rise in units of prescriptions used (Ghosh, Simon, & Sommers, 2017). However, they observed a reduction in per capita drug spending after the expansion. A likely explanation for this insignificant effect of the expansion on medicines expenditures, despite the growth in unis of prescriptions issued, is that expansion states, confronted with the probable budgetary effects of expansions, coupled with the use of newer drugs on a wider population, might have taken proactive cost containment approaches on prescription drug use (Wen, Borders, & Druss, 2016)

Fig 1: Pharmacy Benefit Plans interaction with Pharmaceutical Sector



Source: Pharmacy Benefits Plan and Designs-F Randy Vogenburg 2011

Predictors of Medicaid Prescription Drug Expenditures

This section of the literature review provides a review of and identifies gaps in the literature on the predictors of state Medicaid drug expenditures. Building off the review and gaps observed, the section will present a hypothesis based on ABM in the context of pharmaceutical

expenditures and prescription drug use. Finally, a research model and a hypothesis based on Andersons behavioral model of health services utilization is presented.

Rising prescription drug expenditures raise interest in identifying the factors influencing this growth. Identifying the predictors of Medicaid Pharmaceutical expenditures is very important to State Medicaid policymakers. First, understanding the effect of and the interaction between these predictors on Medicaid expenditures is increasingly important since the ACA's passage led to increased Medicaid enrollments. Second, it is also important for state Medicaid policymakers to better evaluate options for alternate allocation of resources and to evaluate the effects of cost containment strategies Finally, the study will explore explanatory models for pharmaceutical expenditures in the wake of the ACA expansion based on identified predictors.

Over the last two decades, several studies (Danzon (2002), Soumerai (1995), Morgan S (2001), Berndt (2002), and Cleanthous (2011)) have analyzed drug expenditures from different points of view. Danzon and Soumerai (2002) posit that insurance coverage is one of the most consistent predictors of rise in prescription medicine expenditures. A large portion of the pharmaceutical spending increases relates to the records of insurance enrollees in the US, which had a significant increase over a decade of sixty five percent, instead of widened breadth of benefits; and researchers agree that the moral hazard consequence attributed to this increase in numbers explains between twenty to fifty (25-50) percent of the increase in medicines expenditures over the years (Patricia M Danzon & Pauly, 2002) and (Patricia M Danzon & Soumerai, 2002; Soumerai, Ross-Degnan, Fortess, & Abelson, 1993). However, Lillard, Rogowski & Kington (1999) study on the impact of third-party payer programs such as insurance on medicines use and spending showed that medicines benefit implicitly amplified the chances of increased of medicine utilization, rather than an increase in overall spending. (Lillard,

Rogowski, & Kington, 1999). Lakdawalla (2018) highlights the pervasiveness of product patent-driven market power within the pharmaceutical industry and its resulting effect on high prices (Lakdawalla, 2018). Danzon argues that insurance decreases demand elasticity and creates an incentive to charge higher prices than would have occurred with patents drugs only. Therefore, in low- and middle-income countries with limited insurance coverage, patent systems encourage less consumption leading to a welfare loss. However, since welfare loss estimates are sensitive to demand elasticity, they can be decreased by price discrimination (Gogilashvili, 2013). To extend our understanding of pharmaceutical expenditures, Berndt (2014) argues that it is valuable to breakdown the growth in pharmaceutical spending to better understand the components of spending such as price evolution of existing drugs, volume increments of existing medicines, and expenditure growth on newly introduced pharmaceuticals. He indicates that in the US between 1987 and 2000, the core influencers of expenditure rise varied between 1987-1994 and 1994-2000. Although pharmaceutical expenditures rose at approximately equal yearly rates of 11.9 % and 12.9 % in the two sub-periods respectively, increase in price was responsible for above 50% of spending increases in the first period 1987-1994. However, increases in price was responsible for just 25% of spending increase, with the75% reflecting volume/mix changes for the period 1994 to 2000. Meaning that, in the ensuing years, rise in prices were comparatively insignificant, and in place of prices, drug unit increases (larger use of existing and newly introduced medicines) were core influencers of growth in expenditures (Berndt, 2002).

Morgan (2002) also quantified the importance of various factors that affect growth prescription drug costs per beneficiary for a population of elderly Canadians using prescription claim data from a publicly financed drug plan (Morgan, 2002). Morgan (2002) highlighted that prescription drug expenditures at the population or health system level fall into a number of

categories. These categories include a need for therapy (level of disease incidence in the population, the burden of illness and demographics), the level of drug use (which includes elements such as number of medicines per prescription, frequency, and duration of episodes requiring drug use), the therapeutic choices (namely decisions made by physicians to select particular drugs, treatment regimen, choice of generic vs. brands) and the health policies (access to health and medicines policies, and cost containment strategies, e.g., formularies, and copayments) implemented by the health systems or state plan (Morgan, 2002, 2005, 2006, https://www.pmprb-cepmb.gc.ca).

In addition to prices and quantity of drugs, other studies have shown that socio-demographic structures, disease incidence within the population, variables associated with health care utilization (Garcia-Sempere & Peiro, 2001; Morton-Jones & Pringle, 1993; Mujasi & Puig-Junoy, 2015; Rodríguez et al., 2001) location and organizational factors (Alonso Rodriguez, Calvo Müller, Mataix Sanjuan, & Brown Asenjo, 2001) and prescription quality (Copeland, 1999) are associated with pharmaceutical expenditures in health care services. Bose et al. (2014) also showed that US state-level health expenditures were directly associated with state Medicaid spending, the relative numbers of persons above 65 years, and the registered prescribers per hundred thousand residents. Bose revealed that the incidence level of poverty had significant effect on health expenditures per resident; and that the state GDP, the proportion of elderly, and poverty levels have a negative but significant effect on bordering states' health spending per residents (Bose, 2014). Using pre-ACA Medicaid data, Roy et al. (2012) also found that levels of federal Medicaid assistance funds, primary care access, disease incidence among other factors were predictors of medicine spending under Medicaid (Roy & Madhavan, 2012). In addition, Wrobel (2003), using Medicare data, showed that it was feasible to predict roughly 23 percent of

the variation in Medicare drug expenditures using a predictive model that included essential health care indicators (Wrobel, Doshi, Stuart, & Briesacher, 2003). Mousnad, Shafie, and Ibrahim (2014) review statistically significant factors affecting pharmaceutical expenditures globally (Mousnad, Shafie, & Ibrahim, 2014).

Table 3 Pharmaceutical Expenditure-Significant Predictors

No	Authors	Year	Journal Source	Country	Predictors of pharmaceutical expenditures
1	Chernew et al	2001	American Journal of Managed Care 7(7):667	US	Price variation, quantity differences in prescriptions
2	Dubois et al	2000	Health Affairs,19 (2):231-9	US	Volume rises in use existing& innovator medicines, Average duration of treatment, Change in price factors, Introduction of new and varied treatment mix
3	Hoffman et al	2010	American Journal of the health system-pharmacy 67:919-28	US	Introduction of biologics, & biosimilars, dispersion of innovator pharmaceuticals, use of generic counterparts of the top selling innovator medicines.
4	Hoffman et al	2008	American Journal of the health system-pharmacy 65:234-53	US	Price, utilization of innovator medicines
5	Mueller et al	1997	Journal of Public Health	US	Disease, age, and therapeutic classification s
6	Mullins et al	2001	Health Affairs	US	Price changes in existing drugs, increased use of existing drugs, and clinical guideline shifts to newer formulation of drugs
7	Sherman	1999	Health Policy	US	DTCA of innovator drugs, average price per prescription
8	Steinberg et al	2000	Health Affairs	US	Aging, gender, type of diseases

No	Authors	Year	Journal Source	Country	Predictors of pharmaceutical expenditures
9	Suh et al	1999	American Journal of the health system-pharmacy 65:234-53	US	General price increases, population, growth in the number of prescriptions
10	Vandegrift and Datta	2000	South Economic Journal	US	Overweightness, aging, innovator medicine approved resident income

However, many of the drug expenditure evaluations have analyzed solitary sets of determinants, for example need, demographics, or policy predictors. Alberts, Sanderman, Eimer and Heuxel 1997, Campbell & Roland 1996, Hulka and Wheat 1985, Kandruck, Grant and Segall 1991 Roy & Madhaven 2012, Paschal& Junoy 2015), shows individuals visit a prescriber's following an intricate multi-level communication between factors such as diverse demographic, disease profiles, social and economic factors, emotive decision making, and availability and accessibility to healthcare services. There is a need for a more comprehensive methodology to categorizing core predicators of Medicaid prescription medicine expenditures and the effect of their interaction with each other. Anderson's behavioral health care use model developed in 1981, has been applied to study determinants of individual health-seeking decisions. The Anderson behavioral model (Andersen, 1995) is a multi-level model that incorporates both individual and population determinants of health services use. This model identifies independent variables likely to influence pharmaceutical services and drug use within the state and hence expenditure. The assumptions are that since these independent variables determine the use of health services by the population, they will impact medicine spending as a result healthcare service use. The model theorizes that healthcare utilization is generally predicted based on a set of determinants including but not limited to socio economic, healthcare-system related, and or population factors. Personal level and or population level predictors are

clustered into predisposing, need, and enabling factors. Predisposing predictors denote social, economic, demographics and comprise of age-distribution, gender, marital-status, education, race and ethnicity, and occupation. Enabling determinants are those that back or obstruct health care services use for example income, health insurance, health and pharmaceutical management policies, fee for service, managed care policies, distribution of health facilities, pharmacies). Furthermore, need factors at the individual level include perceived and evaluated state of health and financial capacity. At the population level, need includes the level of mortality, disease morbidity.

The model has been applied for healthcare use and expenditure research. Using medical panel expenditure data, Heider, Mastchinger, Muller, and Suam (2014) used the Anderson theory to examine healthcare spending costs among adults over 65 years of age in Germany (Heider et al., 2014). In this study, Heider et al. analyzed the relationship of overall healthcare spending with population variables determined based on Anderson's theory. Kubrin, (1995) used Anderson's theory to advance and examine forecast about the implication's financial protection on the utilization of health facility and doctor services (Kubrin, 1995) . Chen and Chang (2014) also applied Anderson's theory to examine variables related to medicine spending among children. Roy and Madevan (2012) explored the use of Anderson's theory to model an explanation for pre -ACA state Medicaid medicine expenditures (Roy & Madhavan, 2012). Paschal and Piug-Junoy (2015) also applied the model to determine factors that explain medicine spend for primary care services in Uganda (Mujasi & Puig-Junoy, 2015).

- *What are the significant predictors of state Medicaid drug expenditures?*
    - *What, if any, are the interaction effects of these determinant factors/variables/latent constructs on Medicaid pharmaceutical expenditures?*

What explanatory model best explains state pharmaceutical expenditures

Classification of the literature

The research papers used for this literature survey are classified using first, the type of Journal in which the study has been published, and the theoretical background, for example the literature on price discrimination, and Anderson's behavioral model as it relates to pharmaceutical expenditures (Table 6). Second, the literature is also classified based on the region of the world the study was conducted. US, Europe/Asia. Generally, I limited my scope by attending to examples in the US and Canada. A few examples from Europe, Asia and Africa are included. In a total of 28 Journals including *Lancet*, *Pharmacoeconomic*; *Value in Health*, *Health Policy*, *Health Affairs, International Journal of Health Economics; Journal of the American Medical Association (JAMA)*; *and Social and Medicine; Journal of Health Economic Policy and Law*; *European Journal of Health Economics'*, *Journal of Managed Care. Critical care*,

Table 4: Pharmaceutical Pricing, Price discrimination, Medicaid, Research by Journal Type and Location of Research

Journal	Number of Articles	North America	International/ Europe/Asia	Qualitative and Descriptive	Quantitative
Health Care	3	2		6	2
Harvard Business Review	1	1		3	
Health Policy	5	3	2	2	3
Journal of Economic perspectives,	2	2			
Health Economics	15	5	10	5	10

Journal	Number of Articles	North America	International/ Europe/Asia	Qualitative and Descriptive	Quantitative
Applied health economics and health policy	10	6	4		9
Pharmacoeconomics	7	3	9	5	7
Pharmacology	1	1		1	
Economics	5			6	
Journal of Public Health	5	5	1		
Journal of Law and Economics	3	3		2	1
Journal of health politics, policy and law	2	1		1	1

Hypothesis and Models

Objective 1 *Based on the pre and post ACA determinants what model best estimates Medicaid pharmaceutical expenditures*

H1: State Medicaid program drug expenditures are explained using need, enabling, and predisposing and policy factors following Medicaid ACA expansion

Ho: State Medicaid program drug expenditures are not explained using need, enabling, and predisposing and policy factors following Medicaid ACA expansion

Panel Regression model to estimate drug expenditures for Medicaid at the state level

$$Y_{it} =$$

$$\beta_1 StateUnEmploy_{it} + \beta_2 StateGradRates_{it} + \beta ACA\_ExpansionAmt_{3it} +$$

$$\beta_4 Mandatory\_Generic\_Sub_{it} + \beta_5 Prop\_Medicaid_{it} + \beta_6 Prop\_Black_{it} +$$

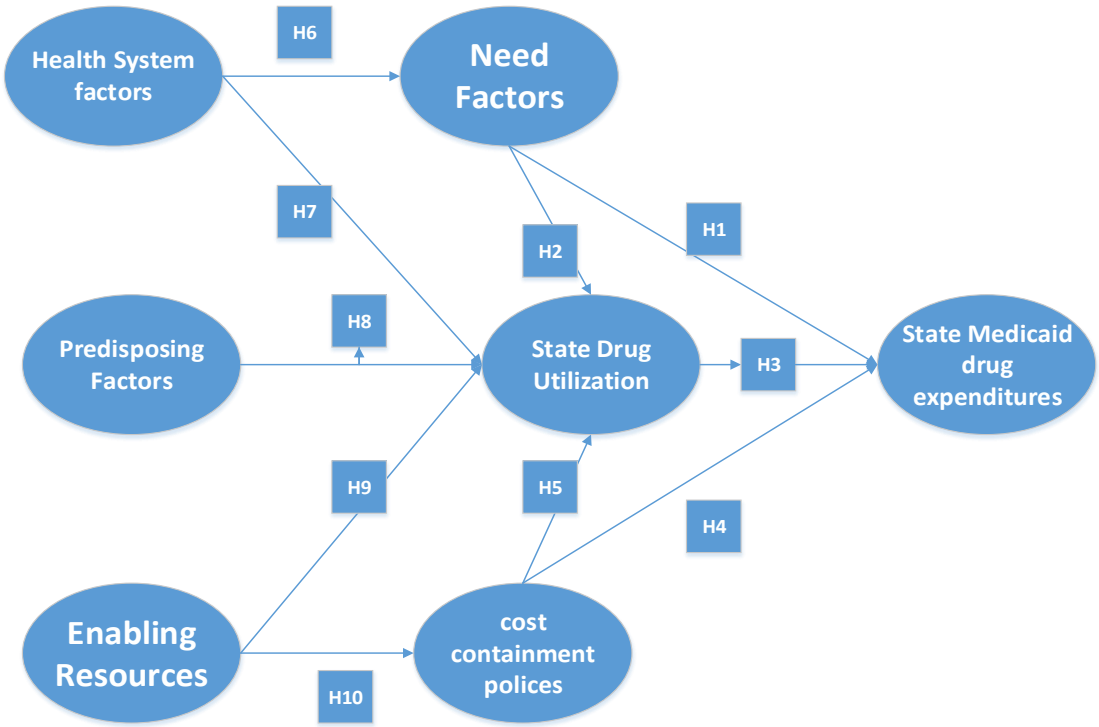
$$\beta_7 Acc\_Pharmacies_{it} + \beta_8 PrimaryCareAccess_{it} + \beta_9 ACA\_Expansion_{it} +$$

$$\beta_{10}State\_Proc\_Elderly_{it} + \beta_{11}FPL\_100_{it} + \beta_{12}FedMedAssProg_{it} + \beta_{13}Highdispensing\_Fee4generics + \beta_{15}ProviderGeneri\_educ + \beta_{16}NonMedicaid\_Hosp + \bar{e}_{it}$$

Where Y=PerCapitaDrugExp per state per year; t, (Year_t) =1 to 7 years and i= State_ID =1 to 50 states

Objective 2 *Based on Anderson's Health Care Utilization Model we posit a conceptual model for State Level Drug Expenditures as illustrated below Fig 2.*

Fig 2: Pharmaceutical utilization and expenditure conceptual model



Hypothesis

Based on Anderson's conceptual framework it is proposed that:

H1: *State need factors has an impact on level prescription drug expenditures*

H2: *State need factors has an effect on State level drug utilization*

H3: *State drug utilization has an impact on State level drug expenditures*

H4: *State cost containment policies have an effect on level medicine expenditures.*

H5*: State cost containment policies have an effect on state medicine utilization*

H6*: State health system factors has an impact on state predisposing factors*

H7: *State health system factors has an impact on state medicine utilization*

H8: *State predisposing factors has an effect on state medicine utilization*

H9: *State enabling resources has an effect on state medicine utilization*

H10: *State enabling resources has a significant impact on state cost containment policies*

CHAPTER 3: METHODOLOGY

Introduction

Chapter 3 provides an overview of the methodological approaches relative to research objectives highlighted in chapters 1 and 2. This chapter has three sections. The first section describes the study population and targeted sample for analysis. The second section states and defines the dependent, independent variables, and the controls for the objectives, and finally, the 3rd section describes the data sources and analytical approach used for the study.

The first objective examines the relative importance of determinants of utilization at the state level in predicting state-level Medicaid drug expenditures and provides a starting focus for the second research objective. Anderson's behavioral theory of healthcare use is modified to examine potential predictors of drug spending in the Medicaid program. The determinants will include the level of federal matching funds, prior authorization, expansion, or non-expansion status of the state. Other determinants will include the proportion of race, e.g., whites and non-whites in the total Medicaid population, the use or non-use of a preferred drug list, level of copays, etc. All these will be grouped broadly as policy, demographic, and need factors, and will be used to evaluate the relationship between these determinants and state-level drug expenditures. The study employs State drug utilization data compiled by CMS.

Study Variables

This section identifies and operationalizes the study's variables. In examining the association between drug expenditures and state level determinants, the following variables will be used:

Dependent Variable

The dependent variable (DV) will be the *Total Drug Expenditure measured as the prescription medicines reimbursement per eligible resident per year.*

Independent Variables

Table 5 below summarizes the independent variables (IVs) identified based on Anderson's Health Utilization model. The columns highlight the health care, population, and resource characteristics of state health systems and the groups of independent variables according to the Anderson health utilization model into :

- Policy variables denote information on all the essential pharmaceutical interventions the states have implemented to control drug expenditures, as shown in the third column in the table below.
- Health care resource indicators that capture or define access to critical medical and pharmaceutical services in the state
- Predisposing characteristics that describe the demographic distribution and structure of the state residents and
- Enabling and health need variables that will include a composite of chronic disease incidence in the state.

The independent variables are computed as illustrated from the Medicaid database and the demographic, education, and health statistics data based for each state. The last column, variable type, categorizes variables as continuous or categorical values.

Table 5: Policy, Enabling and Access Determinant of Pharmaceutical Utilization and Expenditures

#	Health system factors	Policy/ Predisposing and enabling factors	Indicators Variable (IV)	Computation of independent variables	Variable Type
1	Health System Characteristics	Policy factors	Managed care	% of state Medicaid enrollees on Managed care vs. fee for services	Continuous variable
			PDDL (Preferred Drug Dispensing List)	Indicates whether the state implements or doesn't implement an approved drug list	Dichotomous variable No= 0, Yes=1
			Federal Medicaid Assistance	% of total expenditure paid by federal gov yearly	
			Multisource drugs substitution policies	Measures the existent of mandatory exchange of the brand by generic during dispensary	Dichotomous Yes=1, No=0
			Use of Prior Authorization	An indicator for the presence or absence of a policy requiring approval by Medicaid for the use of particular medicines	Dichotomous Yes=1 No=0
		Health care resources	Accessibility of pharmacies	A measure of access to drug dispensing points	Total number of pharmacies as the proportion of eligible Medicaid recipients
			Accessibility of primary care physicians	Measure access by Medicaid beneficiaries to primarycare	The ratio of total primary care physicians to Medicaid

#	Health system factors	Policy/ Predisposing and enabling factors	Indicators Variable (IV)	Computation of independent variables	Variable Type
					eligible beneficiaries
2	Population characteristics	Age distribution of population	Proportion of elderly	Percentage of elderly 65 years or above in state Medicaid population	Continuous variable
			The proportion of race .e g whites, black	The proportion of whites and the proportion of non-whites	Continuous variable
		Enabling resources	High school education level in the state	Percentage of the graduates in the state	Continuous variable
		Financial resources	The proportion of state population below the ACA federal poverty level (FPL)	Percentage below FPL	Continuous variable
3	Need for health care	State Medicaid health risk	Composite % of top chronic diseases in the state	Addictive % of the incidence of top 10 diseases in the state	Continuous variable
		The severity of diseases in the Medicaid population	Total non-drug payments as a proportion of total Medicaid eligible	Measures the percentage difference between the drug expenditure and the overall total health expenditure per eligible Medicaid beneficiary	Continuous variable

Source: Author Nov 2020

The final section of the methods chapter highlights the data sources and analytical approach for the research objectives.

Data sources

This section will retrospectively analyze publicly available medical and pharmacy claims data from the Centers for Medicare and Medicaid (CMS) for the calendar years 2009-2015. The data will not have identifiable patient information. The CMS study sample will potentially include data for all US states except those states that do have fee for service Medicaid systems itemized drug prescription data are unavailable under a managed care system.

The other secondary sources of data will be Kaiser Family Foundation (KFF as well as other were obtained from several data sources including the US Departments of Labor (Statistics, 2014) and Education (Education, Vocational, Education, & America, 1985

CMS Medicaid data

State drug utilization data typically includes all outpatients' medicine usage. The CMS Ambulatory (Outpatients) medicine use records contain a ten (10) or eleven (11) digit National Drug Code (NDC), a set of letters signifying the initial of reimbursing state, and the medication's name (Gencarelli, 2003; Simonaitis & McDonald, 2009). Each NDC number has 3 segments and serves as a common product identifier for the drug (drugs.com). The first segment of the NDC classifies the labelling entity, such as the drug firm, re-packager, or distributor. The next set of numbers is the code for the product, that catalogs the identifies the strength in milligrams as well as whether the product is a capsule, tablet or liquid formulation. The third segment, is the package code, that identifies size of the pack for example 10's, or 28's. The NDC labelling code is allocated by the US FDA (Yang, Ma, Niu, & Xu, 2019), while the drug manufacturer or labeler assigns the product and pack size codes. The NDC directory covers all non-prescription

and prescription drugs, as well as insulin sets and is regularly published in the US. Center of Medicare and Medicaid data tracks period of Medicaid spending on each NDC. The data also includes the total value medicines paid out by the state to pharmacies, the total units of drug on each prescription, and the amounts paid out for Medicaid and non-Medicaid residents' drugs in the state (Roy & Madhavan, 2012; Tehrani & Carroll, 2017).

Using the CMS database, the dissertation will retrospectively analyze publicly available medical and pharmacy claims data for the calendar years 2009-2015.

Analytical approach

First, all drug claims data in the Medicaid program data from 2009-2015 were compiled to obtain the quarterly, and annual per state drug reimbursements. Based on additional data from other state sources the dependent variable per capita drug expenditure was computed.

A modified version of Anderson's model, as illustrated in Chapters 2, will be used as the operational framework for identifying variables/indicators of Medicaid pharmaceutical expenditures. This will be state-level analysis and all data management and analysis will be performed using two (2) statistical software packages , a) STATA and b) SMART PLS-3.

The Model is based on the five (5) latent variables of state need, enabling, predisposing, health and policy/cost containment factors. Each of these have indicator variables and were analyzed over a period of 5 years.

Measurement, Data Analysis and Structural Theory

First, the STATA software program will be used for a descriptive statistics analysis of the data.

Using panel regression analysis an econometric model is estimated for state level drug expenditures and to analyze and test the model, Partial Least Squares-Structural Equation

Modelling (PLS-SEM) analysis using SMART PLS 3.0 Software will be used. PLS SEM will be used because of the hierarchical modelling constrains, and the number of exogenous indicator variables (21) (Hair, Statsedt, Pieper & Ringle (2012 In addition, using SMART-PLS3, a multivariate approach will be applied using the PLS-SEM methodology (Ringle, Wende, & Becker, 2015).

First, assuming model indicators to be reflective, the outer-measurement model was tested for the factor loadings, composite reliability (CR), Average-Variance-Extracted (AVE) as a measure of convergent validity and discriminant validity. Similar tests was run based on a second assumption that indicators are formative. Internal consistency reliability will be evaluated through an examination of the composite reliability and the loading for each assumption. The analysis then looked at the each of the five (5) reflective constructs of state need, enabling, predisposing, health and policy/cost containment factors to check for the composite reliability and for the presence of redundant items (Hair ,2014). Following the test for indicator reliability, recommended by Hair et al redundant indicators were removed where the loading factors are less the recommended 0.70. The average variance extracted (AVE) which is an indicator of convergent validity was then assessed for all constructs and paths as indicator by Hypothesis labelled H1 through to H10. The constructs and paths with p-values less than 0.5 were kept in the final outer- model. Using 5000 sub-sample iterations the structural model tested and all associated quality indicator checked for significance using the SMART-PLS

Discriminant Validity

Using the Fornell-Lacker Criterion, the models discriminant validity will be assessed to show the extent to which the indicators and the latent constructs are a reflection of all the other variables. The discriminant validity is indicated by level of associations between the variables of

interest and the other constructs. In the event that the crosswise values are larger than its corresponding coefficients of correlation (Fornell-Lacker) criterion, an alternative approach based on the multirait-multimethod matrix, to assess the discriminant validity using the Heterotrait - monotriat (HTMT) ratio of correlations will be applied (Heneseler and Ringle).

Finally, to ascertain representative nature of the structural model, the path coefficients, R2, and corresponding t-values as well as p-values was assessed via a booth strapping procedure with a re-sampling of up to 5000 iterations to evaluate the underlying theory of the model, hypothesis, R2 values and the predictive relevance. This will enable the analysis of the path coefficients, testing the hypothesis (H1--→ H10) and accepting or rejecting each hypothesis as needed to confirm a final structural model of drug expenditure based on Anderson's theoretical model.

Ethical considerations

Not all the data expected from the Center for Medicare and Medicaid will be publicly available data. Any additional data to enable analysis will be encrypted to anonymize the name of clients. The statistical softwares, STATA 16 and SMART-PLS-3 , will be used for the descriptive and inferential statistics regression analysis and structural equation. The claims data and analysis files will be kept in a secure computer in Arlington, Virginia. Access to the files will only be granted to the investigator, including the UNCC Dissertation Chair and Committee members.

Potential Limitations of the Study

The data received did not include information on additional, confidential discounts on the prices of medicines used by the insurance. The data may not have all the diagnoses and related

drugs used for Medicaid insured. The sample data will be stratified to reflect the states' overall disease morbidity trends to improve the findings' generalizability.

CHAPTER 4: DATA ANALYSIS AND RESULTS

The chapter presents the outcomes of testing the hypothesized relationships in the study's model. The Chapter also describes the study data and provides an overview of the descriptive statistics, regression analysis and structural equation modeling undertaken.

Sample Characteristics

The primary data source was the medical and drug reimbursement claims data (Act, 1990) from the CMS. Drug claims data, with no identifiable patient information for the calendar years 2009 -2015 for all 50 US states were obtained. However, due to several missing fields, Washington DC Medicaid data was excluded from the analysis. The second dataset, was obtained from the Kaiser Family Foundation (KFF), an independent US health policy research firm that tracks provides Medicaid data on plan policies, pharmaceutical benefit management rules, including the type of copays, type of reimbursement mechanisms, including but not limited to capitation and fee for services in insurance plans for enrollees across the United States. State demographic data, and variables such as ACA expansion status, total residents, proportion of residents living below Federal poverty line (FPL), high school graduation rates, as well as distribution of residents by race per state were obtained from several data sources including the US Departments of Labor (Statistics, 2014) and Education (Education, Vocational, Education, & America, 1985), as shown in Table 1.

In all, 26,815,541 Medicaid drug claims, equivalent to an average of 76,615 claims per state and 2,100 observations of state demographic and access to health care variables over a seven (7) year period, were obtained. The CMS Medicaid database includes provider claims submitted to State Medicaid plans, merged into a harmonized data warehouse that contained data fields indicating the type of payment mechanism used for each claim, a unique 11-digit National

drug code (NDC) for each drug, a code for the manufacturer or labeler of the drug, pack size, total number of prescriptions, and quantity of each drug issued in a given quarter. The CMS data also contains the total dollar amount of state drug and non-drug reimbursements. Using Creswell (Creswell & Creswell, 2017) guidelines, a number of statistical numerous stages were executed to ascertain completeness of data. The states' demographic and access to health care data were merged with the Medicaid expenditure data once both data sets were cleaned. Using state ID, a series of excel data base were created for each source of data- High school graduation rates, state employment rates per year, total Medicaid drug and non-drug reimbursements, total number of prescription and total cost per Medicaid claim per quarter per year. These multiple sources of data were then merged to yield a long format panel data set. This was then used to model the state level drug expenditures and to explore common behaviors and heterogeneities. The resulting strongly balanced panel data obtained included 2,100 observations made up of 350 rows, and 53 columns with a mix of categorical and numerical variables.

As previously noted, data for the study covered 2009 to 2015. Panel data regressions were used because they enable us study individual variable trajectories and explore how an event changes outcome (Brüderl & Ludwig, 2015) over seven years. Panel data regression has also been used for several other Medicaid studies including for policy analysis (Garcia-Sempere & Peiro, 2001; Gogilashvili, 2013).

Dependent Variable (DV)

The dependent variable (DV), the ***PerCapita Drug Expenditure***, was obtained after dividing the total Medicaid yearly state medicines reimbursement by the total population/residents in the state (Foundation, 2012) for each year. Expenditure is expressed relative to total state population to ensure comparability across varying state populations . Using

the figures for state residents as the denominator and annual state drug reimbursement eliminates variability in the dependent variable due to quarterly variation in Medicaid enrollment Using per capita drug expenditures provide a measure for access and equity. Prior research related to Medicaid pharmacy benefits have also used per capita expenditures including work done by Wen et al who used Medicaid spending per state resident as an outcome variable to examine effects of ACA expansion on drug spending (Wen, Borders, & Druss, 2016) ; and Heffler et al , Gilmer and colleagues in 2011 explore variations in Medicaid pharmacy benefits and spending using per capita spending on prescription drugs as one the outcome variables (Gilmer & Kronick, 2011; Heffler et al., 2005)

Independent Variables (IV)

Anderson's behavioral theory of health utilization provides the foundation for the model's variables. These variables are presented below and included in table 1.

Poverty level: represented by the proportion of the residents with incomes 100-400% below Federal poverty line (FPL), are considered eligible for Medicaid. Some previous literature considers poverty as an enabling factor for health-seeking behavior. Indicators for FPL100% to FPL 400% for each state was utilized to estimate their potential explanatory power on US Medicaid pharmaceutical expenditures.

Unemployment rates: literature suggests that unemployment directly impacts the total number of persons falling below the Federal Poverty line (Cylus, Glymour, & Avendano, 2015) leading to increased enrollment in health coverage programs such as Medicaid. Unemployment rates were cyclical and varied from month to month within each state. To compensate for that variability, the average unemployment rate per state was used.

State high school graduation rates: there is a recognized and persistent relationship between an individual's level of education and health status. In their 2009 review of the association between education and health status, Cutler and Lleras-Muney showed that the mortality rate of high school dropouts (age 25-64) was double the rate for individuals with high school qualifications. They also showed that a further four years of education drops the five-year death rates by 1.8 percentage points, while reducing the risks for heart disease and diabetes by 2.16 and 1.3 percentage points, respectively.

Race: Measures of the proportion of white, black, and Hispanics as a proportion of total state residents obtained from the department of human services and the KFF Medicaid site are included. Over Medicaid's lifespan, there have been considerable changes in US racial composition. and it is anticipated that implementation of the ACA may encourage more racial diversity among enrollees. A 2008 Pew Research Center study projects that the US population will rise to about 450 million by 2050 with eighty two percent of this growth attributed to migrants (Pew Research Center, 2008). Ghosh and Sommers (Ghosh, Simon, & Sommers, 2017) confirmed growths in prescription medicine use in areas with large populations which were not insured before the ACA. They also found evidence suggesting that rise in medicines use were more significant in zones with greater Hispanic and black populations, a finding which supports Anderson's theory.

Cost containment policies: State cost containment policies such as presence or absence of copays, use of Pharmacy benefit management schemes, mandatory use of generics instead of brands were included to estimate an explanatory model for pharmaceutical expenditures.

Table 6: Independent Variable Description

Factor	Variable	Description	Measurement	Data Source
Predisposing	Proportion_Ma_Pop	Medicaid Male Population	% of male state Medicaid population	CMS, KFF
Predisposing	Proportion_Medicaid	State Medicaid population	% of residents on Medicaid	CMS, KFF
Predisposing	Pop_Prop_Uninsured	State Uninsured population	% of residents uninsured	KFF
Predisposing	Percent_Elderly	Proportion of Elderly	% of population > 65yr	KFF
Enabling	Pop_100_Below_FPL	The proportion of Population 100% below Federal Poverty Level	% of people in the state below 100% of the Federal poverty level	KFF, US Labor Statistics
Enabling	Pop_400_Below_FPL	The proportion of Population 400% below the recommended national poverty levels	% of people in the state below 400% of the national poverty level	KFF, US Labor Statistics
Enabling	ACA_Expansion	State ACA expansion status	Indicate if state had expanded ACA in the year under review	CMS
Enabling	Percent_ACA	% Medicaid exp. utilized on expansion coverage	% of total Medicaid expenditure utilized on new enrollees during expansion	KFF
Enabling	State_Unemployment	% unemployed	Yearly State-level employment rates	US Department of Labor
Enabling	State_HSGrad	% High School graduation	State graduation rates	US Department of Education

Factor	Variable	Description	Measurement	Data Source
Policy	Federal_MedAssistant	% FMAP	% of state Medicaid expenses reimbursed by Federal Gov.	CMS
Policy	State_Use_PBM	State use of third-party pharmacy benefit program	Exists/does not exist	KFF
Policy	DUR_Implemented	Does state implement Drug Utilization reviews	Yes/no	KFF
Policy	State_Pool_Proc	Does state utilize pooled procurement programs	Yes/no	KFF
Policy	Copays	Does the Medicaid program implement copays	Implemented or not implemented	KFF
Policy	Mandatory_Generic	Mandatory generic dispensing policy	Obligatory/Non-obligatory	KFF
Policy	LowerCopays_Generics	Is there an incentive for use of generics through lower copays	Utilized or not utilized	KFF
Policy	HighDispensing_fees_gen	higher dispensing fees for generic	Utilized or not utilized	KFF
Policy	UseofPrefferredDruglist	Medicaid use of PDL or open lists	Utilized or not utilized	KFF
Policy	ProviderEducationProg_Generics	Are provider education program on generics being implemented	Implemented or not implemented	CMS
Need	Adult__Chronic	% of adults with diabetes	Measures need for chronic care	KFF

Factor	Variable	Description	Measurement	Data Source
Need	Adults_Blacks	% of white non-Hispanic with diabetes	A proxy measure for population health risk	KFF
Need	PerCapita_Non_Drug Medicaid_Amt	The proportion of state health care exp for non-drug activities such as immunization and surgeries.	Expenditure in other health care services other than drugs	KFF, CMS
Healthcare Resources	Acc_Primarycare_facilities	#of primary care facilities per 10,000 residents	Total primary health facilities per 10,000 state residents	KFF
Healthcare resources	Access_Pharmacies	#of pharmacies per 10,000 residents	Total number of pharmacies per 10,000 state residents	KFF

Other demographic variables such as gender, age category (child or elderly) were included as categorical variables. Although a wide range of race/ethnicity data was available, the analysis was limited to more populous race categories of white nonHispanics, black nonHispanics, and Hispanics. Remaining racial groups yield insufficient numbers to include in the model. States which implemented copays also had different levels of copay categorized as single, double or multitiered. To facilitate the analysis, dummy variables were created for these state policy and time variables and included as categorical variables. For example, the indicator "presence or absence of copay policies" was categorized using 0,1 dummy variables.

The study's unit of analysis is the state during a particular year. Panel regression and structural equation modeling were used to study the relationships between the Dependent Variable Drug Expenditure (PerCapitaDrugExp), and the Independent Variables. All statistical

analysis was performed using two (2) Software programs: STATA 16 (StataCorp, LLC, College Station, TX, USA) and SMART PLS-3.0 (SmartPLS GmbH, Germany).

Without an *a priori* knowledge on which model will best estimate drug expenditures, both fixed effects (FE) and random effects (RE) panel regression models were estimated. Hausmann's FE vs. RE test was then applied to determine the suitable model. The Hausman test helps choose the suitable model to control for unseen heterogeneity intrinsic to the panel data. The null hypothesis for the Hausman test is that there is no correlation between the unobserved effects and the included fixed effects. Failing to reject the null hypothesis indicates that the fixed effects specification is inefficient and confirms that the random effects model provides a more efficient estimator. Rejecting the null hypothesis leads to the opposite conclusion (Cameron & Trivedi, 2010). In this study, the Hausmann test failed to reject the null. Further confirmation was obtained from the Breusch -Lagan test which indicated that the random-effects model was a more consistent and efficient estimator for the PerCapitaDrugExp model.

Panel data regression equation for estimating the PerCapitaDrugExp – Equation 1

$$Y_{it} = \beta_1 StateUnEmploy_{it} + \beta_2 StateGradRates_{it} + \beta ACA\_ExpansionAmt_{3it} + \beta_4 Mandatory\_Generic\_Sub_{it} + \beta_5 Prop\_Medicaid_{it} + \beta_6 Prop\_Black_{it} + \beta_7 Acc\_Pharmacies_{it} + \beta_8 PrimaryCareAccess_{it} + \beta_9 ACA\_Expansion_{it} + \beta_{10} State\_Proc\_Elderly_{it} + \beta_{11} FPL\_100_{it} + \beta_{12} FedMedAssProg_{it} + \beta_{13} Highdispensing\_Fee4generics + \beta_{15} ProviderGeneri\_educ + \beta_{16} NonMedicaid\_Hosp + \bar{e}_{it}$$

Where Y=PerCapitaDrugExp per state per year; t, (Year_t) =1 to 7 years and i= State_ID =1 to 50 states

PANEL REGRESSION ANALYSIS RESULTS

Panel regression results were obtained using the STATA command $Sort_{it}$ Year-t and xt command after ensuring no missing data within the data set. The state drug reimbursement panel data was balanced as shown below with 350 observations and T=7 years

Output

xtset State_ID Year_t
panel variable: State_ID (strongly balanced)
time variable: Year_t, 2009 to 2015
delta: 1 unit
State_ID: 1, 2, ..., 51 *n = 50*

Year_t: 2009, 2010, ..., 2015 *T = 7*
Delta (Year_t) = 1 unit
Span (Year_t) = 7 periods
*(State_ID*Year_t uniquely identifies each observation)*

Distribution of T_i: min 5% 25% 50% 75% 95% max
7 7 7 7 7 7 7

Freq.	Percent	Cum.	Pattern
50	100.00	100.00	1111111
50	100.00		XXXXXXX

Descriptive Statistics

A descriptive analysis using STATA was executed on the data of the dependent and independent variables. The descriptive analysis comprised reports on standard errors and means of all study variables as shown in Table 2. Over the period 2009-2015, the mean graduation rates across states were 53.78 %, with a range of 32 to 76% with a mean state unemployment rate of 6.98%. The range of proportion residents living below 100% of federal poverty level was found to be between 7.5% and 24.4%, with a mean of 14.4 %. On average, Medicaid enrollees received

1.6 prescriptions per year with a maximum of 19 prescriptions per enrollee and a minimum of zero.

Table 7: Descriptive Statistics

Variable	Variable Description	Mean	Std Dev	Min	Max	Observations
State_Unemploy_Rate	State Unemployment Rates	6.98	2.12	0.00	14.9	N = 350
State_HSGrad_Rates	State Grad Rates	53.78	9.78	0.00	70.9	N = 350
Pop__Medicaid	Proportion on Medicaid	17.32	4.20	8.7	43	N = 350
Pop_Prop_Uninsured	Proportion Uninsured	12.70	4.31	2.8	23.9	N = 350
Perc_Elderly_Medicaid	Proportion Elderly	43.25	8.11	26.3	64.8	N = 350
Percentage_Adult_white	Percent_Adult_White	51.85	18.53	10.1	92.5	N = 350
FederalMed_Assistance	Federal_MedAss_Percent	61.74	9.11	50.00	84.86	N = 350
TotalMedicaid_PerCapSpending	TotalMedicaid spendingpercapital	1553.23	562.74	0.00	4032.20	N = 350
totalmedicaidexpSpending	totalmedicaidexpansionspending	111.13	221.79	0.00	1231.32	N = 350
TotalnonExpspendperCap	Total_NonExpansionSpendperCap	1438.72	514.75	0.00	4006.67	N = 350
Access_PrimaryCarePer10000	Acc_primarycare per10000 residents	16.44	6.27	10.32	56.85	N = 350
Adult_Whites_Chronicdisease	Adults_Whites_With Chronic Disease Diabetes	9.39	1.84	4.20	14.6	N = 350

Variable	Variable Description	Mean	Std Dev	Min	Max	Observations
Adult_Blacks_Chronicdisease	Adults_Blacks_With Chronic Disease Diabetes	13.24	3.45	2.10	23.2	N = 350
Adult_HispChronic_disease	Adults_Hispanics_With Chronic Disease Diabetes	9.88	3.41	2.00	30	N = 350
Prop_Male_Pop	Proportion_Male_population	49.03	0.74	47.7	51.7	N = 350
Prop_Female_Pop	Proportion_Female_population	50.97	0.74	48.3	52.3	N = 350
Pop_100 FPL	Proportion of the Population living 100% of Federal Poverty level	14.47	3.27	7.50	24.4	N = 350
Pop_400 FPL	Proportion of the Population living 400% of Federal	36.21	7.19	22.9	55.9	N = 350
Access_Pharmacy_10000	Access_to_pharm_10000	0.23	0.14	0.08	0.68	N = 350
PerCapPrescription	PerCapitaPrescription	1.66	1.27	0.00	19.76	N = 350
PerCapNonMedicaid_Reimbursed	PerCapita_NonMedicaid_Amt_reim	4.62	4.75	0.00	40.31	N = 350
PerCapDrugExp	PerCapitaDrugEXP	112.63	71.28	71.28	742.69	N = 350

The mean PerCapDrugExp was $ 112.63 with a range of $71.28 -$742.69 . The mean percent of males in the Medicaid population was 49.03 % The proportion of adults with chronic diseases (diabetes) was highest on the average among blacks (13.2%) white (9.39%) and

Hispanics (9.89%). Further examination of the state Mean PerCapitaDrugExp expenditures additional statistics showed that the lowest quintile (10 states per quintile) included Utah ($49.10per capita), and Nebraska with a mean drug expenditure of $ 75.95 per capita Table 3

Table 8:States with the lowest per Capita Drug Expenditures

#	State	Mean PerCapitaDrugExp ($)
1.	Utah	49.10
2.	North Dakota	52.20
3.	Nevada	54.00
4.	Wyoming	56.65
5.	South Dakota	60.88
6.	Washington	63.44
7.	Montana	64.08
8.	South Carolina	68.07
9.	Rhode Island	71.74
10.	Nebraska	75.95

Within the top quintile i.e., the ten states with highest mean spending per enrollee was Missouri 10th at $139.66 per capita with highest in that quintile being Hawaii ($ 274.96) Table 4.

Table 9: States with the highest per Capita Drugs Expenditures

#	State	Mean PerCapPharmExp
1.	Missouri	139.66
2.	Maine	153.31
3.	Alaska	159.24
4.	Vermont	177.74
5.	Louisiana	179.78
6.	Delaware	180.94
7.	West Virginia	190.80
8.	Connecticut	202.88

#	State	Mean PerCapPharmExp
9.	New York	240.90
50.	Hawaii	274.96

Fixed effects panel regression analysis

The first step in our analysis is to estimate the model for PerCapitaDrugEXP by running a fixed effect panel regression which includes the independent variables listed in Table 5. Prior to estimating the panel regression, a missing variable check and multicollinearity test were conducted. For the fixed effects model the variables LowerCopaysforGeneric and Highdispfee4generic_substitution was omitted due to perfect multicollinearity with the states. This multicollinearity was due to a lack of variation of these attributes across states.

Table 10: Parameter Estimates from Panel data fixed effects regression analysis

PerCapita DrugEXP	Coef.	Std. Err.	t	P>|t|
PerCapitaPrescription	13.26265	2.605328	5.09	0.000
PerCapita_NonMedicaid_Amt_reim	3.83132	.8365377	4.58	0.000
Access_to_pharm_1000hospitals	-7.504869	19.86977	-0.38	0.706
Pop_100_Below_PL	-.237635	2.575427	-0.09	0.927
Proportion_Male_pop	-14.05167	13.107	1.07	0.285
Acc_primarycareper10000	-5.496206	4.91192	-1.12	0.264
Adults_Blacks_Chronic_diabetes	-3.174031	1.117281	-2.84	0.005
Multitiered_Copay	23.02775	14.41275	1.60	0.111

PerCapita DrugEXP	**Coef.**	**Std. Err.**	**t**	**P>|t|**
FFS_4_PDL	-32.59792	15.59311	-2.09	-0.037
DUR_Implemented	28.76671	22.77419	1.26	0.208
ACAExpanded	10.71393	8.768508	1.22	0.223
Federal_MedAss_Percent	-1.234605	.6097712	-2.02	0.044
Percent_Adult_White	1.883174	1.68136	1.12	0.264
State_HSGrad_Rates	-.0101576	0.640736	-0.02	0.987
State_Unemploy_Rate	-7.800592	2.399402	-3.25	0.001
Constant	930.7223	662.5273	1.40	0.161

sigma_u	74.277239
sigma_e	46.381305
rho	.71946638 (proportion of variance due to u_i)

Fixed-effects (within) regression Number of obs = 350 Group variable: State_ID #of groups=50 R-sq within= 0.3670 between= 0.0315 overall= 0.092 F (15,285) =11.02corr (u_i, Xb) = -0.6884 Prob > F = 0.0000:

The second step in the analysis was to run a random effect within regression analysis on the panel data using the independent variables which yielded the parameter estimates below in Table 11. This was then followed by a stepwise inclusion of a series of interactive terms while checking for improvement in R^2.

Table 11: Parameter Estimates from Panel data random effect regression analysis

Variable	Coef	Std.Err	z	P>|z|	
PerCapitaPrescriptions	16.071	2.498	6.430	0.000	
PerCapitaNonMedicaidAmt Reimbursed	3.210	0.732	4.390	0.000	
Access_to_Pharm_10,000	-23.353	20.108	-1.160	0.245	
Pop_100% Below_FPL	0.296	1.446	0.200	0.838	
Proportion_Male_inPop	-26.152	7.538	-3.470	0.001	
Access_to_Primarycare_10,000	-1.240	0.782	-1.590	0.113	
Adult_Blacks_Chronic_diabetes	-2.473	1.017	-2.430	0.015	
Mandatory_Gen_Prescribing	-2.138	12.822	-0.170	0.868	
LowerCopaysforGeneric	16.836	10.367	1.620	0.104	
Multitiered_Copay	3.691	9.008	0.410	0.682	
Highdispfee4generic_subs	8.477	17.472	0.490	0.628	
Providegenericeduc	-32.234	11.765	-2.740	0.006	
FFS_4_PDL	-16.111	11.866	-1.360	0.175	
DUR_Implemented	14.014	10.434	1.340	0.179	
ACAexpanded	14.056	8.091	1.740	0.082	
Federal_MedAss_Percent	-1.560	0.514	-3.040	0.002	
Percent_Adult_White	-0.022	0.312	-0.070	0.943	
State_HSGrad_Rates	-0.510	0.487	-1.050	0.295	
State_Unemploy_Rate	-6.217	1.910	-3.260	0.001	
Cons	1582.193	401.039	3.950	0.000	

sigma_u	23.417702
sigma_e	46.381305
rho	.20313597 (proportion of variance due to u_i)

Random-effects GLS regression # of obs=350 Group variable: State_ID # of groups=50
R-sq: within = 0.3449 between = 0.5261 overall = 0.4237 Wald chi2(19) = 205.77 corer (u_i, X) = 0 (assumed) rob > chi2 = 0.0000

Hausman test for fixed effects

To confirm whether fixed or random- effects offer the best model for PerCapitaDrugExp a Hausmann test for fixed effects was run. The first step in the Hausman test, estimated the fixed effects panel regression, stored estimates and compared the FE estimates with the stored random general least square GLS random regression estimates. The output of the Hausman test provides a side-by-side comparison.

Table 12: Hausman Test

Variables	Coefficients			
	Fixed (b)	Random (B)	Difference b-B	qrt[dig
PerCapitaPrescriptions	13.263	16.071	-2.809	0.739
PerCapitaNonMedicaidAmt Reimbursed	3.831	3.210	0.622	0.406
Access_to_Pharm_10,000	-7.505	-23.353	15.848	
Pop_100% Below_FPL	-0.238	0.296	-0.534	2.131
Proportion_Male_inPop	-14.052	-26.152	12.100	10.730
Access_to_Primarycare_10,000	-5.496	-1.240	-4.256	4.849
Adult_Blacks_Chronic_diabetes	-3.174	-2.473	-0.701	0.463
Multitiered_Copay	23.028	3.692	19.336	11.251
FFS_4_PDL	-32.598	-16.111	-16.487	10.117
DUR_Implemented	28.767	14.014	14.753	20.243
ACAexpanded	10.714	14.056	-3.342	3.379
Federal_MedAss_Percent	-1.235	-1.560	0.325	0.328
Percent_Adult_White	1.883	-0.0225	1.906	1.65
State_HSGrad_Rates	-0.010	-0.510	0.499	0.418
State_Unemploy_Rate	-7.801	-6.217	-1.583	1.453

The coefficients of fixed effects model (b) is consistent under the null hypothesis (Ho) and the alternate (Ha) from the regression and is denoted as follows-

b = consistent under Ho and Ha; obtained from ***xtreg***.

The expect threshold is that chi ^{2}Chi< 0 for the hypothesis to hold.

When the random coefficients denoted as B are inconsistent under the alternative hypothesis as written as B = inconsistent under Ha, efficient under Ho; obtained from xtreg then the test of the original hypothesis will be deemed not systematic

Test: Ho: difference in coefficients not systematic.

For this test, the Chi^2 (-106.99) was less than zero as shown chi^2(15) = (b-B)'[(V_b-V_B)^(-1)](b-B) = -106.99 chi^2<0 ==> Chi ^{2} < 0 implies that model fitted on these data fail to meet the asymptotic assumptions of the Hausman test; meaning a fixed effects estimation was the not the most efficient model for this panel data. The superiority of the random-effects model was further confirmed by using the Breusch et al Lagrangian random effects multiplier test.

Breusch and Pagan Lagrangian multiplier test for random effects

PerCapitaDrugEXP[State_ID,t] = Xb + u[State_ID] + e[State_ID,t]

Estimated results:

	Var	sd = sqrt(Var)
	5080.727	71.279
e	2151.225	46.381
u	548.389	23.418

Test: Var(u) = 0 chibar2(01) = 47.40 Prob > chibar^2 = 0.0000

The overall statistic Chi X^2 has a P= 0.0000 which leads to a strong rejection of the fixed-effects model in favor of a random-effects model (Brüderl & Ludwig, 2015)

Analysis of random estimation results

Table 5 shows the final empirical estimations using a random-effects panel data regression for the parameter coefficients for equation-1. Table 5 shows that the coefficient of Per Capita non drug Medicaid expenditures was 3.2 and significant ($p < 0.000$) significant. The positive coefficient of state non-drug Medicaid expenditures implies that an increase in state non-drug Medicaid expenditures leads to an increase of $3.2 per capita drug expenditure. The non-drug Medicaid per Capita expenditure is a proxy for health care services utilization such as general practitioner consultations, public health interventions such as immunizations, routine and elective surgeries as well as a variety measures for health care activity. It is expected that a high non-Medicaid health expenditure correlates positively with high drug expenditures however in the long run this correlation should change as activities such as immunization should lead to decreased incidence of diseases and hence need for drug treatments. This calls for further long term research to investigate the long term effect of non-drug expenditures on actual use of drug treatments within health systems (Gogilashvili, 2013).

The coefficient for the regressor, proportion of males, in the Medicaid population is -0.26 and significant ($p< 0.001$). The negative coefficient of 0.26 for the proportion of males implies that a one (1) percentage point increase in the proportion of male Medicaid enrollees leads to a $26 reduction in per capita drug expenditure. The study's output confirms *a priori* expectations based on prior literature which indicates that health consumption tends to increase with increasing number of females. The negative coefficient for unemployment rate of -6.2 and significance ($p<0.001$), indicates that a one percentage point increase in the unemployment rate will reduce per drug expenditures by approximately $6. This does not fit our a priori expectation based on Anderson's health seeking behavioral model (Ross & Wu 1995, Rodriguez and

Stoyanova 2004) The expectation is that increased unemployment leads to an increased proportion of persons below the federal poverty level (FPL), which should increase Medicaid enrollee numbers and hence expenditures (Ross & Wu 1995). The negative coefficient for unemployment could probably be related to the dependent value being measured as per capita expenditure. This is an interesting result and will require additional study. Indeed, the number of enrollees with income below the federal poverty level had no significant effect on the PerCapitaDrugExp per state as shown by the model estimates.

A number of policy interventions such as use of multitiered copay (3.691, p=0.682), enrollee payment of Lower Copays for Generics (16.83, p=0.104), prescriber Mandatory generic prescribing (-2.2, p=0.848), and high dispensing fees for generics for pharmacists when they dispense generics (8.6, p=0.628) had no significant effects on per capita drug expenditures as shown by p values accompanying the coefficients. t. The use of copays as a cost containment measure has had mixed reviews. Positive effects have been reported in many employers based private sector schemes. Joyce, Scarce, Solomom and Goldman (2002) report that including another level of copay, requiring pharmacists to substitute generics for all brand products reduced overall payment plans and drug expenditures in employer-based programs (Joyce 2002) Since it starts, policy interventions such as enrollee cost share and influencing prescriber patterns have been part of cost containment strategies in Medicaid. Nelson et al (2008) indicated that copays for instance had differential effects on different categories of diseases and drugs (Nelson, 2008 Wallace et al (1984) in a study focused on Oregon Medicaid showed that despite a reduction in the utilization of medicines after the introduction of copay, per capita expenditures did not change and that applying copays shifted treatment patterns but did not offer any reduction in expenditures. This study also showed that copays, mandatory substitutions and

multitiered copays had no effects on the per capita expenditure In line with Wallace et all it is recommended that policy makers be it cautious in implementing copayments, especially for programs for low-income populations such as Medicaid. The study did not have data to examine the impact of income use of effects of copays.

The ACA expansion also did not show a significant impact on Medicaid drug expenditures, although the coefficient for variable denoting ACA expenditures was positive it was non-significant (14.014 p=082). Similar results were obtained by Sommers (2017) Wen et al (2014) using a difference-in-difference, methodology confirmed that prescription utilization in terms of the number of prescriptions increased under the ACA, but the increases did not necessarily lead to increased total expenditures (Ghosh et al., 2017). This is contrary to the pre-ACA projection of potential increase Medicaid drug costs.

The policy interventions that influence clinical prescribing practices are usually two-fold, either directly targeted to the prescriber, such as education, managerial, administrative tactics, or targeted at the general system and focused on regulations, or economic strategies to minimize health expenditures at the system level. A negative and significant coefficient of -32.16 for provider education on the use of generics is in line with expectation. The results show that per drug expenditures in states with provider education program on use of generics was $ 32 less than states with provider education on use of generics. Again, this is consistent with the literature since brand products tend to be more expensive than their generic counterparts and it is not unexpected that a rise in generic utilization will lead to a drop in expenditure. However, mandatory generic dispensing policy had a negative coefficient of -0.214, but no significant effect (p= 0.868) on expenditures.t. As of 2013, twenty-one (21) states had ‘mandatory generic dispensing and substitution policies” that necessitated that generic equivalents of drugs be

dispensed every time a generic version of the innovator brand was available (Foundation, 2015). Most of these states also have lists of non-substitutable drugs mostly based on the narrow-therapeutic index of the drugs. Physicians argue that it is safer to stick one brand when the drug has a narrow therapeutic index. Most states also have regulation in place permitting a physician to stop generic substitution either by necessitating that the prescriber signs a unique form or by demanding a written request for Brand name dispensing for example "Dispense as written" (DAW), "Brand medically necessary" or "Do not substitute" (Berg, Gross, Haskins, Zingaro, & Tomaszewski, 2008; Socal, Bai, & Anderson, 2021). A second potential reason for the nonsignificant effect of mandatory dispensing of generics will be the increase in the availability and prescriptions of new biologics, that technically have no "therapeutic equivalents" and therefore no generics. Very few "therapeutic equivalents" known as biosimilars are registered by the US Food & Drugs Administration. In addition, the governance arrangements the MDRP requires that Medicaid covers new specialty or biologic drugs introduced by pharmaceutical companies that provide rebates through the MDRP. Finally, literature shows that attempts at curbing brand prescribing through enforcement is seen as an infringement on prescriber autonomy and potential loss of revenue for dispensing doctors (Emanuel & Pearson, 2012). There have been instances within health systems when mandatory rules led to over utilization services or use of other services in order to compensate for the lost autonomy. The mandatory generic requirement may lead to a rise in the units of products per prescription to compensate for lost income in the case of dispensing providers (Meyer, 2016). There could be supplier-induced demand effects emanating from physicians or hospitals which needs further investigation (Peckham & Gousia, 2014). The value of prescribers' imperfect agency was verified using prescribers who were allowed to dispense drugs on their own (dispensing physicians). These

studies found a significant and positive association between prescriber dispensing and growth in the quantity of innovator brands dispensed when restrictions were implemented (Rischatsch, Trottmann, & Zweifel, 2013).

The coefficient of state HSgraduation rates was positive but nonsignificant. Level education was expected to impact health seeking status., A percentage point increase in the Federal matching assistance percentage (FMAP) leads to a $1.5 reduction in per capita drug expenditures. The FMAP . A rise in Federal Med Assistance is likely to decrease medicine reimbursements up to $1.5. This negative and significant coefficient for the Federal Medicaid Assistance Program was counter to what had been observed in practice as prior studies suggested that overall increase in health expenditures led to increase FMAP. The current study did not have enough data to test these assumptions. Further studies need to be done to completely understand the relationship between overall Medicaid expenditures and the pharmaceutical component.

Additional estimations of the random-effects model included potentially important interactions. The new variable, an interaction term between ACAExpansion and FMAP was included in the random effect estimates of drug expenditures which yielded a negative -0.177 coefficient and a non-significant effect 0.838 on drug expenditures and did not impact the $R^{2.}$ The lack of statistical significance and absence of an effect on the R^2 is determined by comparing R^2 values for models with the interaction terms both included and excluded. Overall, the random effects panel regression model estimates explained 52% of the dependent variable, drug expenditure's, variance in the data and hence model is a great fit. Many of the coefficients of variables e.g., Per capita prescriptions, proportion of males, and provider generic education theoretically expected to predict the PerCapitaDrugExp were not statistically different from zero.

Model estimates for PerCapitaDrugExp

The theoretical arguments presented above suggest the following model:

$$\text{PerCapitaDrugEXP}_{it} = \beta o + \beta_1 \text{PerCapitaPrescription}_{it} + \beta_2 \text{PerCapita\_NonMedicaid\_Amt\_reim} + \beta_3 \text{Proportion\_Male\_pop}_{it} + \beta_4 \text{Adults\_Blacks\_Chronic\_diabetes} + \beta_5 \text{Providegenericeduc}_{it} + \beta_6 \text{Federal\_MedAss\_Percent}_{it} - \beta_7 \text{State\_Unemploy\_Rate}_{t} + \bar{e}_{it}$$

Parameters obtained from the estimation of random effects model are found in table 8.

Table 13: Model parameters for PerCapitaDrugExp

PerCapitaDrugExp	Coeff	Std.Err	z	P>|z|
PerCapitaPrescriptions	16.071	2.498	6.430	0.000
PerCapitaNonMedicaidAmt Reimbursed	3.210	0.732	4.390	0.000
Proportion_Male_inPop	-26.152	7.538	-3.470	0.001
Adult_Blacks_Chronic_diabetes	-2.473	1.017	-2.430	0.015
Providegenericeduc	-32.234	11.765	-2.740	0.006
Federal_MedAss_Percent	-1.560	0.514	-3.040	0.002
State_Unemploy_Rate	-6.217	1.910	-3.260	0.001
cons	1582.193	401.039	3.950	0.000

sigma_u	23.417702
sigma_e	46.381305
rho	.20313597 (fraction of variance due to u_i)

Random-effects GLS regression # of obs=350 Group variable: State_ID # of groups=50
R-sq: within = 0.3449 between = 0.52.61 overall = 0.4237 Wald chi2(19) = 205.77 corer (u_i, X) = 0 (assumed) rob > chi2 = 0.0000

Overall, the model estimate shows that only two policy variables, provider education on using generics and Federal Medicaid Assistance percentage demonstrated significant influence on drug

expenditures. Provider education remains a key policy intervention strategy that influences clinical prescribing and ultimately minimizes health expenditures at the system level. Among the need variables Adults blacks with chronic disease (diabetes) and the proportion of non-drug Medicaid reimbursement had significant effect on drug expenditures. The presence of chronic diseases will lead to increase drug use so one would have expected the direction to be positive and not negative. However, with the advent of newer biologics and more effective drugs which may require shorter treatment periods, the overall numbers and cost of drugs may be reduced if the right prescription is given so as to reduce drug cost to health systems. Serving as a proxy indicator of how severe diseases are in the community, the non-drug Medicaid reimbursement and its positive coefficient indicates that a $1 increase would lead to about $3 increase in drug expenditures, which is the expected effect of the association and highlights the needs for increased preventive interventions in community. The model estimates shows effects of variables like per capita prescriptions, non-drug Medicaid expenditures, incidence of chronic diseases in the study suggest that promoting good health in the community, increasing provider education on generics could lower Medicaid drug expenditures.

Figure 3: Description of variables and variable label generated by Stata

Contains data
Obs: 350
Vars: 54

Variable name	***Storage type***	***Display format***	***Value Label***	***Variable label***
States	str15	%15s		States
StateACAExpSt~s	str10	%10s		StateACAExpStatus
State_ID	byte	%14.2f		State_ID
Year_t	int	%10.0g		Year_t
State_HSGrad_~s	double	%10.0g		State_HSGrad_Rates

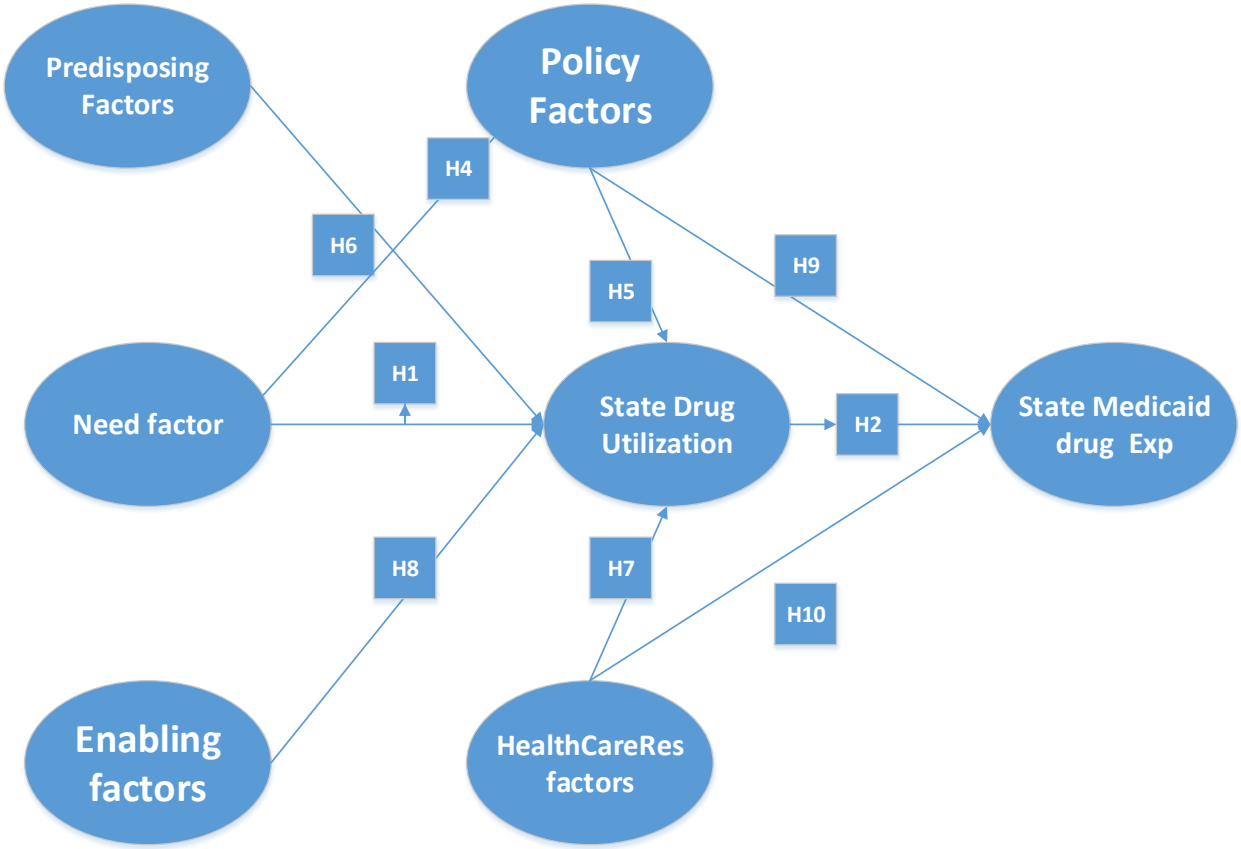
State_Unemplo~e	double	%10.0g	State_Unemploy_Rate
Pop__Medicaid	double	%14.2f	Pop_% _Medicaid
Pop_Prop_unin~d	double	%14.2f	Pop_Prop_uninsured
Perc_Elderly_~d	double	%14.2f	Perc_Elderly_Medicaid
Percent_Adult~e	double	%14.2f	Percent _Adult_White
Federal_MedAs~t	double	%14.2f	Federal_Med Ass_ Percent
Percentchange~A	double	%14.2f	Percentchange_ACA
ACAExpanded	byte	%14.2f	ACAExpanded
TotalMedicaid~i	double	%14.2f	Total per capita Medicaid spending
totalmedicaid~p	double	%14.2f	total Medicaid expansion spend per capita
Totalnonexpan~p	double	%14.2f	Total nonexpansion spend per capita
StateUseofPBM	byte	%14.2f	StateUseofPBM
DUR_Implemented	byte	%14.2f	DUR_Implemented
PDL	byte	%14.2f	PDL
Copays	byte	%14.2f	Copays
No_copays	byte	%14.2f	No _copays
SingleTiered_~y	byte	%14.2f	SingleTiered_Copay
DoubleTiered_~y	byte	%14.2f	DoubleTiered_Copay
Multitiered_C~y	byte	%14.2f	Multitiered_Copay
Supplemental_~s	byte	%14.2f	Supplemental_rebates exist
No_Supplement~s	byte	%14.2f	No _Supplemental_ Rebates
State_Pool_Pr~t	byte	%14.2f	State_Pool_Procurement
State_Non_Poo~c	byte	%14.2f	State_Non_Pool_Proc
FFS_4_PDL	byte	%14.2f	FFS_4_PDL
No_FFS_PDL	byte	%14.2f	No _FFS_PDL
Mandatory_Gen~g	byte	%14.2f	Mandatory _Gen_Precribing
Non_mandatory~n	byte	%14.2f	Non_mandatory_Presc_Gen
LowerCopaysfo~c	byte	%14.2f	LowerCopaysforGeneric
Non_lowerCopa~n	byte	%14.2f	No n_lowerCopays_gen
Highdispfee4g~s	byte	%14.2f	Highdispfee4generic_subs
NonHigh_dispf~b	byte	%14.2f	No n-High_dispfee4gen_sub
Providegeneri~c	byte	%14.2f	Provide generic educ
NonproviderGe~c	byte	%14.2f	No n provider Generic Educ

Useofpreferre~t	byte	%14.2f	Use of preferredDrugist
Nonuseofprefe~s	byte	%14.2f	Non-use of preferred drug lists
Adults_Whites~s	double	%14.2f	Adults_Whites_Chronic_diabetes
Adults_Blacks~s	double	%14.2f	Adults_Blacks_Chronic_diabetes
Adult_Hispani~s	double	%14.2f	Adult_Hispanics_chronic_diabetes
Acc_prima~10000	double	%14.2f	Acc_primary care per10,000
Proportion_Ma~p	double	%14.2f	Proportion_Male_pop
Proportion_Fe~p	double	%14.2f	Proportion_Female_pop
Pop_100_Below~L	double	%14.2f	Pop_100_Below_PL
Pop_100_199_P~L	double	%14.2f	Pop_100_199_Percent BelowPL
Pop_200_399_B~L	double	%14.2f	Pop_200_399_Below_PL
Pop_400_Below~L	double	%14.2f	Pop_400_Below_PL
Access_to_pha~s	double	%14.2f	Access_to_pharm_1000hospitals
PerCapitaDrug~P	double	%14.2f	PerCapitaDrugEXP
PerCapitaPres~n	double	%14.2f	PerCapitaPrescription
PerCapita_Non~m	double	%14.2f	PerCapita_NonMedicaid_Amt_reim

Partial Least Squares (PLS) Structural Equation Modelling and Analysis

Partial Least Square -Structural Equation Modelling (PLS-SEM) using SMARTPLS was used to test the hypothesis **H1-H10** as shown in Figure 2 and stated below

Fig 2: Structure and path model for drug expenditure based conceptual model



Hypothesis

Based on Anderson's conceptual framework, it is proposed to test the following hypothesis:

Based on Anderson's conceptual framework it is proposed that:

H1: *State need factors has an impact on level prescription drug expenditures*

H2: *State need factors has an effect on State level drug utilization*

H3: *State drug utilization has an impact on State level drug expenditures*

H4: *State cost containment policies have an effect on level medicine expenditures.*

H5*: State cost containment policies have an effect on state medicine utilization*

H6*: State health system factors has an impact on state predisposing factors*

H7: *State health system factors has an impact on state medicine utilization*

H8: *State predisposing factors has an effect on state medicine utilization*

H9: *State enabling resources has an effect on state medicine utilization*

H10: *State enabling resources has a significant impact on state cost containment policies*

Partial Least Squares -Structural Equation Modeling is a modeling method that maximizes the explicated variance of dependent variable constructs (Hair, Matthews, Matthews, & Sarstedt, 2017). PLS-SEM is very useful when the research goal is to predict the target indicators of identified "driver constructs" (Joseph F Hair Jr, Hult, Ringle, & Sarstedt, 2016 & Sarstedt, 2016) and testing for significance of path relationships between multiple latent variables. The test for normality of data was not conducted since non-normally distributed data concerns are effectively addressed using a bootstrapping methodology in partial least square analysis. Given the complexity of the theoretical model, in this study, PLS-SEM was chosen, to validate Anderson's theory and to illuminate any latent variances of the vital constructs. PLS-SEM also makes no distributional assumptions in the computation of the model parameters.

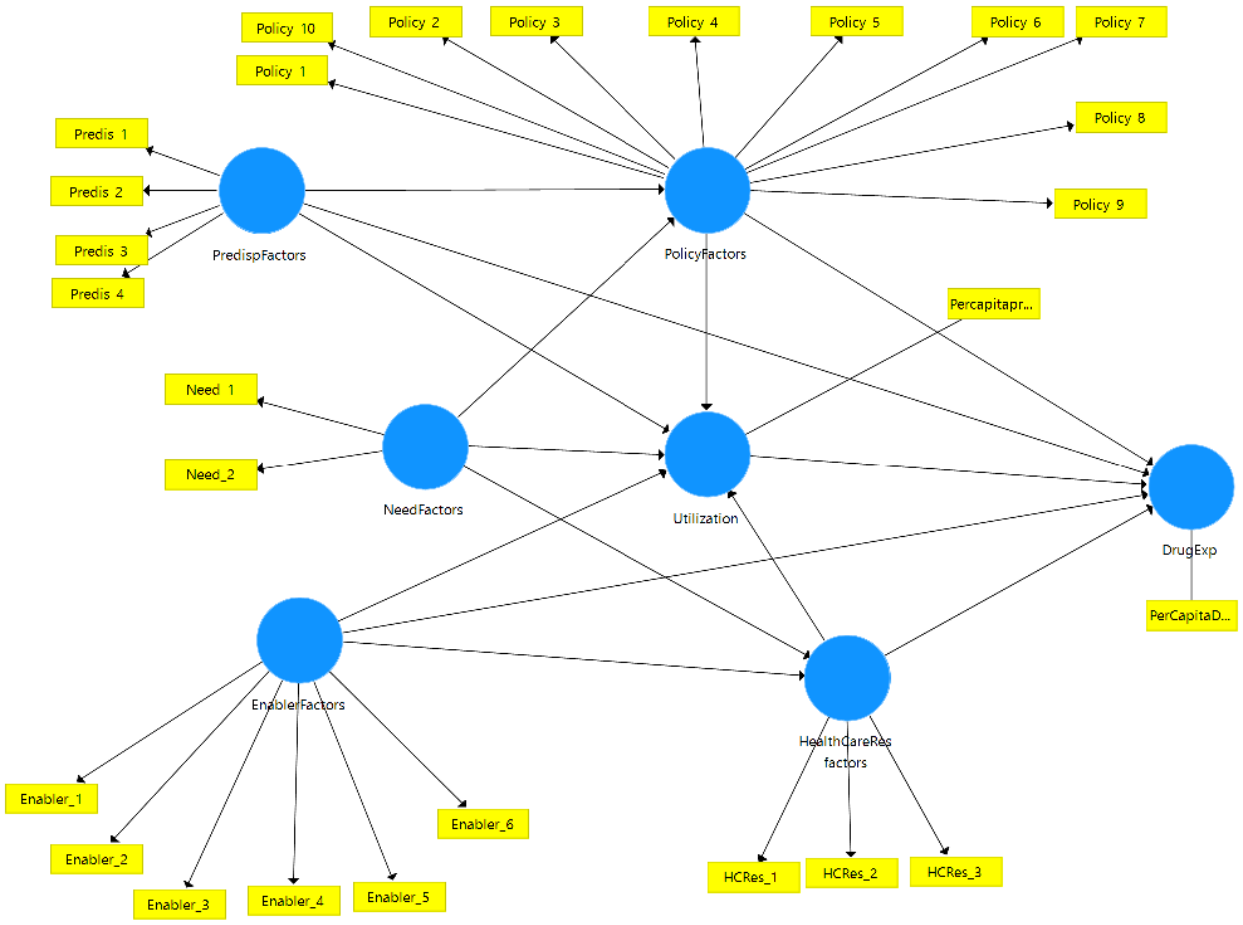
The PLS-SEM has two sub models or components: a) the outer model's measurement and b) the structural or inner-model. The outer-measurement model specifies the relationship between the latent variables and their measurement items or observed indicators. SMART-PLS enables the analysis of the loadings of the outer model measurement items. The structural model, also called the inner-model specifies the relationships (paths) between the independent and dependent latent variables constructs. An essential first step was to prepare the model diagram using SMART PLS. The standard convention represents constructs as circles or ovals and the construct's manifest or observed variables/ indicators as rectangles. Directional arrows represent relationships in both the outer/measurement and inner/structural models, as shown in Figure 3.

Table 10: Independent Variables

	Health system factors	Policy/ Predisposing and enabling factors ©	Indicators Variable (IV)	Computation of independent variables	Variable Type
1	Health System Characteristics	Policy factors	Managed care	% of state Medicaid enrollees on Managed care vs. fee for services	Continuous variable
			PDDL (Preferred Drug Dispensing List)	Indicates whether the state implements or doesn't implement an approved drug list	Dichotomous variable No= 0, Yes=1
			Federal Medicaid Assistance	% of total expenditure paid by federal gov yearly	
			Multisource drugs substitution policies	Measures the existent of mandatory exchange of the brand by generic during dispensary	Dichotomous Yes=1, No=0
			Use of Prior Authorization	An indicator for the presence or absence of a policy requiring approval by Medicaid for the use of particular medicines	Dichotomous Yes=1 No=0
		Health care resources	Accessibility of pharmacies	A measure of access to drug dispensing points	Total number of pharmacies as the proportion of eligible Medicaid recipients

	Health system factors	Policy/ Predisposing and enabling factors ©	Indicators Variable (IV)	Computation of independent variables	Variable Type
			Accessibility of primary care physicians	Measure access by Medicaid beneficiaries to primarycare	The ratio of total primary care physicians to Medicaid eligible beneficiaries
2	Population characteristics	Age distribution of population	Proportion of elderly	Percentage of elderly 65 years or above in state Medicaid population	Continuous variable
			The proportion of race. e g whites, black	The proportion of whites and the proportion of non-whites	Continuous variable
		Enabling resources	High school education level in the state	Percentage of the graduates in the state	Continuous variable
		Financial resources	The proportion of state population below the ACA federal poverty level (FPL)	Percentage below FPL	Continuous variable
3	Need for health care	State Medicaid health risk	Composite % of top chronic diseases in the state	Addictive % of the incidence of top 10 diseases in the state	Continuous variable
		The severity of diseases in the Medicaid population	Total non-drug payments as a proportion of total Medicaid eligible	Measures the percentage difference between the drug expenditure and the overall total health expenditure per eligible Medicaid beneficiary	Continuous variable

Fig 4: Inner and Outer Model For Medicaid Drug Expenditures



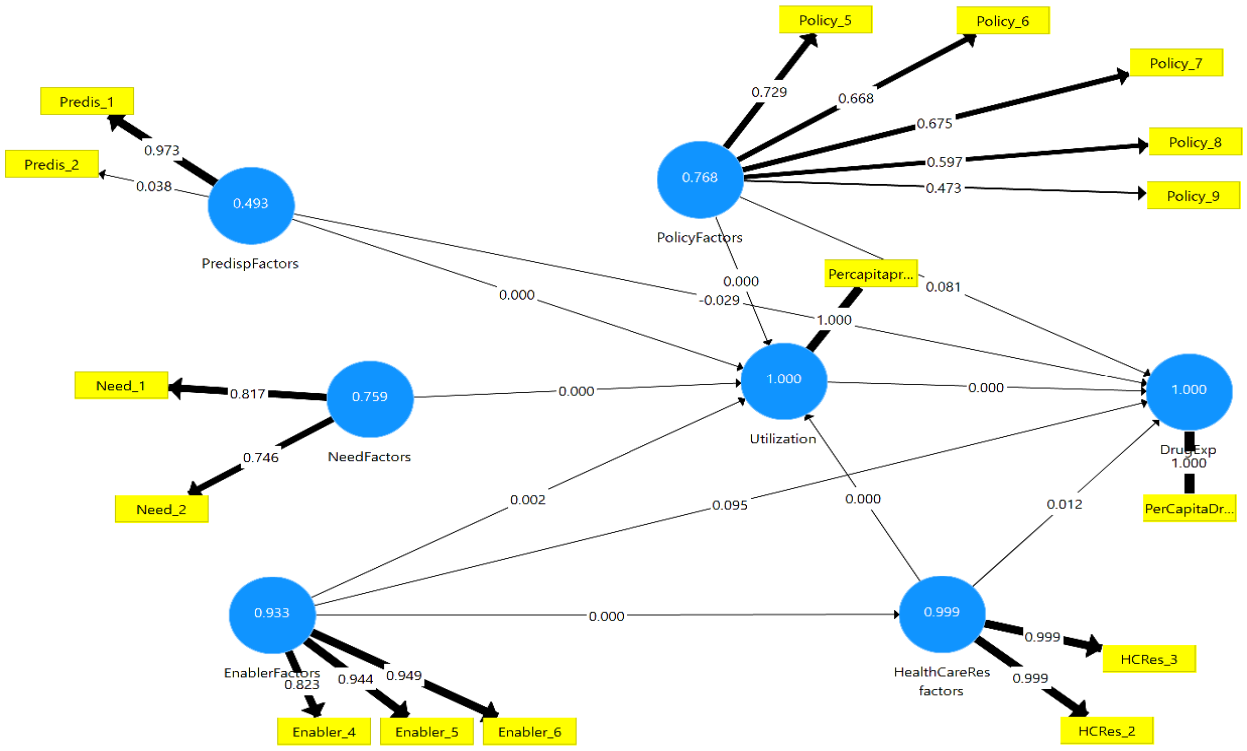
Estimation of the Measurement model

The Partial Least Squares procedure was initially run using SMART PLS-3 (Ringle 2018) by means of a pathway weighting process on the model through three hundred iterations with an end criterion of $10^{\wedge 7}$ to find pathway coefficients, direct, indirect, outer weights and loadings for the distinct modeled latent constructs in figure 3.

The measurement model estimates the unobserved latent constructs or variable factors, such as need, policy, or healthcare resource factors, using the observed variables from the data. The measurement model's construct reliability was assessed and an interactive process applied

to confirm that the mean of the outer loadings for each latent variable was equivalent to or higher than the suggested threshold of > 0.70 (Hair, Black, Babin, Anderson, & Tatham, 2006) . The measurement items with loading equal to or higher than the recommended threshold 0.70 were maintained. Outer loading of indicators with less than 0.7 were removed in a step-by-step manner to arrange the model by initially removing those indicators with the lowermost loading scores. After separate iterations the model was estimated to confirm that the residual indicators in the same construct were not unfavorably affected, meaning, their numerical values did not decline below the recommended threshold of 0.70, while also preserving at least two indicators for each construct and a mean loading of at least 0.65 shown in Figure 4.

Fig 5: Final Structural model with indicator weights



Composite Reliability (CR), Average Variance Extracted (AVE) and Cronbach's alpha (CA)

Further quality checks on the model, together with path coefficients, latent variable correlations/covariances, CR and CV, discriminant validity as well as collinearity statistics, were also run using SMART PLS-3 algorithms. Table 9 shows the CR, AVE and CA of the model as estimated using SmartPLS-S and based on Anderson's theory. A few items were slightly below the 0.7 threshold. Following the recommendation for outer loading test by Hair, Hult, Ringle, indicator Enabler_1 (high school graduates, proportion below 100% FPL) was removed since its loadings was very low (0.345). Predis_1 and Predis_4 for uninsured population and percent of elderly in the population respectively were also deleted due to low outer loadings. Finally, the policy indicators, Policy_1, Policy_2, Policy_9 and Policy_10 related to federal Medicaid percentage, use of pharmacy benefit management (PBM), provider education were deleted, resulting in the final structure equation with the outer and inner models shown in figure 4.
The Composite Reliability (CR) values found for each construct exceeding 0.7 for the policy construct, need factor, and health care resource factors indicated sufficient construct reliability for those 3 constructs. The composite reliability for the predisposing factor was too low, indicating poor reliability of the measurement items even though two measurement items Predis_3 and Predis_1 relating to proportion of the state population insured and proportion of male with Medicaid had strong and high loadings. The average variance extracted (AVE) values for the HealthCare Resource and Enabling factors were higher than the recommended threshold of 0.5. However, based on these results, the items with outer loadings slightly below 0.7 were maintained since their omission did not enhance or worsen the AVE and CR's. (Hair 2017).

Table 14: SMART-PLS Composite Reliability and Convergent Validity

Measurement Items	Variable Description	Loading	Composite Reliability	Average Variance Extracted	Cronbach's Alpha
Enabling Factor			0.679	0.277	0.442
Enabler_2	StateUnemploymentRate	0.572			
Enabler_4	Percentage increase in Medicaid expenditure due to ACA	0.746			
Enabler_5	ACA expansion status	0.862			
Enabler_6	$ amount on expansion	0.874			
Predisposing Factors			.024	0	0.629
Predis_2	Population of Adults who are white	0.627			
Predis_3	Proportion of male in the state population	0.618			
Need Factors			0.757	0.611	0.368
Need_1	Proportion of adult blacks with diabetes	0.835			
Need_2	Total non-Medicaid expenditures	0.724			
Policy Factors			0.743	0.276	0.629
Policy_3	DrugUtilizationReviewsImplemented	0.678			
Policy_4	State Use of Preferred drug List	0.684			
Policy_5	StateMedicaid Copays implemented or not	0.707			
Policy_6	Supplementary discounts received on Drugs	0.787			
Policy_7	StateUse of Pooled procurementsstrategies	0.580			
Policy_8		0.614			

Health Care Resource Factors			0.822	0.663	0.627
HCRes_2	Access to primary care physician per 10000	0.988			
HCRes_3	Access to PhySpecialist	0.989			
PerCapitaDrugExp	PerCapitaDrugExp	1			
Percapitaprescription_1	Percapitaprescription	1			

Discriminant Validity

To determine whether the reflective constructs of the model were empirically different from one another, a discriminant validity was assessed using the Heterotrait-Montrait ratio of correlations (HTMT) (Henseler 2015), with values below the threshold of 0.85. Hence discriminant validity is established see table 10)

Table 15: Discriminant Validity Heterotrait-Monotrait (HTMT)

	DrugExp	**Enabler Factors**	**HealthCare Resfactors**	**NeedFactors**	**PolicyFactors**	**PredispFactors**	**Utilization**
DrugExp							
EnablerFactors	*0.2562*						
HealthCareResfactors	0.0913	*0.0697*					
NeedFactors	0.3862	0.1983	*0.2529*				
PolicyFactors	0.1490	0.0966	0.2714	*0.5498*			
PredispFactors	0.4968	0.5082	0.5228	0.7355	*0.7711*		
Utilization	0.5001	0.2543	0.0505	0.4777	0.2467	*0.2145*	

Note: Values in italics are square root of the Average Variance Extracted (AVE)

All HTMT figures fell below 0.85 thus meeting the HTMT guidelines

Fornell-Larcker Criterion

Discriminant validity was also assessed using the Fornell-larcker criterion, the table shows that the square root of AVE for the constructs was greater than the inter construct correlation.

Table 16: Discriminant Validity using Fornell-Larcker Criterion

	DrugExp	EnablerFactors	HealthCareResfactors	NeedFactors	PolicyFactors	PredispFactors	Utilization
DrugExp	1.0000						
EnablerFactors	0.2483	0.9071					
HealthCareResfactors	0.0921	0.0578	0.9989				
NeedFactors	0.2276	0.1114	0.1628	0.7822			
PolicyFactors	0.1377	-0.0700	-0.1298	0.2053	0.6346		
PredispFactors	-0.3660	-0.4016	-0.0039	-0.0583	-0.1517	0.6886	
Utilization	0.5001	0.2480	0.0511	0.2906	0.2225	-0.1903	1.0000

A cross- loading was also undertaken as shown in table 12. The resulting of cross loading showed each outer indicator was loading appropriately on its constructs.

Table 17: Factor Cross Loading

	DrugExp	EnablerFactors	HealthResfactors	NeedFactors	PolicyFactors	PredispFactors	Utilization
Enabler_4	0.1610	**0.8226**	0.0946	0.1300	-0.0878	-0.2769	0.1492
Enabler_5	0.2445	**0.9443**	0.0814	0.0407	-0.0603	-0.4320	0.2502
Enabler_6	0.2537	**0.9488**	-0.0030	0.1458	-0.0524	-0.3626	0.2550
HCRes_2	0.0810	0.0595	**0.9987**	0.1661	-0.1417	0.0101	0.0436
HCRes_3	0.1012	0.0563	**0.9991**	0.1597	-0.1195	-0.0157	0.0573

	DrugExp	EnablerFactors	HealthResfactors	NeedFactors	PolicyFactors	PredispFactors	Utilization
Need_1	0.1155	0.1137	0.2313	**0.8167**	0.1173	-0.0048	0.2429
Need_2	0.2510	0.0569	0.0080	**0.7461**	0.2114	-0.0930	0.2105
Policy_5	0.1044	-0.0375	0.0029	0.1828	**0.7290**	-0.1662	0.1579
Policy_6	0.0086	-0.0443	0.1479	0.2171	**0.6679**	0.0503	0.1247
Policy_7	0.1094	-0.0418	-0.2909	-0.0026	**0.6754**	-0.1321	0.1691
Policy_8	-0.0401	-0.0574	0.1287	0.1652	**0.5971**	0.0867	0.0813
Policy_9	0.1304	-0.0518	-0.1407	0.1641	**0.4727**	-0.1238	0.1179
Predis_1	-0.3361	-0.3833	0.0827	-0.0417	**-0.2105**	**0.9731**	-0.1872
Predis_2	-0.1007	-0.0477	-0.3752	-0.0678	**0.2670**	**0.0379**	0.0014

Hypothesis Testing and Estimation of Structural Model

Having analyzed the outer model for consistency, we examine the structural and hypothesized relationships **H1 to H10.** The bootstrapping algorithm with a 5000-resampling procedure (Hair , Matthews, Matthews, & Sarstedt) was utilized. During bootstrapping, random samples are drawn from larger original data set with iterative replacements. This iterative procedure is repeated until it yielded five thousand (5,000) samples. These re-sampled subs are then utilized to estimate the structural pathways of model.

The estimates of standard errors, t-values, p-values, and confidence intervals are calculated to assess PLS-SEM indicators and path significance. Since PLS-SEM is a nonparametric method and does not require that data meets certain distributional assumptions to test the structural model and the hypothesized statements. Rather PLS-SEM, depends on the

nonparametric bootstrap processes (Efron and Tibshirani, 1986; Davison and Hinkley, 1997) to ascertain posited significance of relationships and hypothesis as well as results such $R^{2.}$ The 5000 resamples are generated at a 95% confidence interval with the hypothesis test as shown in table 18

Table 18: Hypothesis Test Results

	Hypothesis	Original Sample (O)	(STDEV)	T Statistics	P Values	2.5%	97.5%
H1	**NeedFactors -> Utilization**	0.2109	0.0513	4.1119	***0.000***	0.085	0.292
H2	**Utilization -> DrugExp**	0.4105	0.1940	2.1162	***0.034***	0.238	0.836
H3	**NeedFactors -> DrugExp**	0.0721	0.0794	0.9088	***0.363***	-0.046	0.273
H4	**policyfactors -> NeedFactors**	0.2480	0.0398	6.2318	***0.000***	0.161	0.319
H5	**policyfactors -> Utilization**	0.1426	0.0348	4.0981	***0.000***	0.074	0.212
H6	**PredisposingFactors -> DrugExp**	0.2674	0.1918	1.3939	***0.163***	-0.042	0.436
H7	**PredisposingFactors -> Utilization**	0.0641	0.1572	0.4079	***0.683***	-0.042	0.436
H8	**EnablingFactors -> Utilization**	0.2198	0.0467	4.7052	***0.000***	0.111	0.299
H9	**EnablingFactors -> DrugExp**	0.0662	0.0447	1.4819	***0.138***	-0.012	0.158
H10	**HealthCareRes->Utilization**	0.0467	0.1801	.7901	***0.216***	-.0231	0.421

Assuming a 0.05 significance level, we find that all structural relationships within the model are significant except (Need Factors -> DrugExp (p =0.363), Predisposing Factors -> DrugExp (p=0.163) Predisposing Factors -> Utilization (p=0.683) Enabling Factors -> DrugExp(0.138) and Healthcare->Utilization (0.216)).

Using Anderson's theory, we emphasis that individual health seeking behaviors and the effects of the various constructs are hypothesized to influence utilization and ultimately drug expenditures. What is not clear is the extent to which these constructs interact with each other, or the extent to which one or more of these factors mediates in the processes that lead to drug expenditure. PLS_SEM enables this test based on the p-values and significance of the paths/relationships**.**

H1: evaluates whether State need factors have an impact on level prescription drug utilization. The results revealed that Need Factors have a positive coefficient and significant impact on utilization (β=0.2109 t=4.1119, p< 0.001). This is consistent with the literature. The utilization of health care services is the core output or end result of individual's help seeking behaviors or processes to address the need for health care.

H2: Proposes that utilization has a positive association with DrugExp. The results show a positive but non-significant effect on drug expenditures (β= 0.4105 t=2.1162 p=034). This is consistent with results from a number of studies (Ghosh, 2017) that indicated that an increase in utilization of services does not necessarily reflect in increased expenditures. This effect would probably be due to parallel interventions such as pricing policies, quantity caps, use of generics and other supply chain interventions at play within health systems

H3: Argues that need factors have a positive and significant effect on impact Drug Expenditure. The results show a non-significant effect with a T value of 0.9. Need does not directly influence drug expenditure. This is confirmed by the coefficient of the path and levels of significance. The path Need-→ Utilization--> Drug expenditure is however significant indicating a mediating role of utilization between and expenditures.

H4: Argues that policy factors have a significant effect on need factors. The results reveal that policy has a significant and positive relationship with need factors (β =0.2480 t=6.2318 p< 0.001) Again, this is consistent with theory, policy factors influence equitable access to health care services and assure utilization. Policy here connotes both interventions at the system and individual level.

H5: Argues that policy factors have a significant effect on utilization. The results reveal that policy has a positive and significant effect on utilization factors (β =0.1426 t=4.0981 p< 0.001)

H6: Argues that predisposing factors have a positive impact on drug expenditures. Results show that predisposing factors do not significantly affect Drug Expenditures with a p-value of 0.163 and T-value of less 1.96. Predisposing factors have no significant effects, Drug Expenditures with a p-value of 0.163 and T-value of less 1.96. This is not surprising since predisposing factors also have no effect on drug utilization (see H7). Having a predisposing factor does not predict service use or expenditure generation. For instance, in the situation where people have pre-existing risk such as diabetes and do not utilize adequate health services because of inability to pay an existing co pay or because of inequitable access to health care services is reflective of this result. This is also in line with Lengerke et al's criticism of Anderson model in their paper "Re visiting the behavioral model of health care utilization by Anderson – a review of theoretical advances and perspectives "(von Lengerke, 2014) where they posit limitations of the explanatory power of Andersons model on utilization

H7: Predisposing factors have no significant effect on drug utilization. The results show that (β= 0.0641 t= 0.4079 p=0.683). This is not consistent with a priori expectation even though

Mujasi et al (2015) reported a positive effect of predisposing factors on utilization[3] and drug expenditure in their study of pharmaceutical expenditures in Uganda.

H8: Evaluates the effects of enabling factors on drug utilization. The results show that enabling factors had a positive and significant effect on utilization (β =0.2198 t=4.7052 p< 0.001)

H9: Enabling factors did not have a positive and significant effect on drug expenditures

H10: **S**tate health care resources had no significant effect on expenditures

R-Squared Analysis and overall model fit

The remaining structural analysis is the R^2 values of the endogenous latent constructs. The R^2 values indicated a relatively solid predictive association of policy, and utilization policy with Drug expenditures ($R^2 = 0.3416$), indicating that these factors could explain 34.2% of the variance in drug expenditures observed within states shown in table 20 below.

Table 19: SEM R squared

	Original Sample (O)
DrugExp	**0.3416**
NeedFactors	0.0615
Utilization	0.1542

CHAPTER 5: DISCUSSION AND CONCLUSION

This section includes a discussion of the study's findings presented in six subsections. The first section provides an overview of the dissertation study. The second section describes the findings relative to the hypothesis. Section three highlights the study's contribution to the literature. Limitations and proposals for future research are included in the fourth and fifth sections. The final section concludes the study.

Overview

U.S. Healthcare expenditures have been rising steadily over the past two decades (Berndt, 2002; Lakdawalla, 2018). This rise is driven by several factors (Bose, 2014). Bose et al (2014) identify increasing personal disposable income, population aging, prices of healthcare goods and services as factors influencing the expenditure growth (Bose 2014). The effects of these healthcare expenditure drivers vary between US states. Previous studies have found strong associations between state-level healthcare expenditure and state demographic composition and unemployment rates, per capita gross domestic product (GDP), and supply factors such as the number of active physicians, and the prices of health care goods and services (Bose, 2014).

Prescription drug use and spending represent one of the most heterogenous spending categories across states within the US Medicaid program. (CMS,2015). The ACA enactment in 2012, coupled with subsequent state expansions resulted in large coverage extensions to several people. Prior to the ACA expansion, studies focused on exploring determinants of the overall health system expenditures and not pharmaceutical utilization or expenditures. Despite this paucity of literature on Medicaid pharmaceutical expenditure, the few pharmaceutical expenditures studies undertaken focused on singular categories of predictors or determinants and did not examine all potential predictors concurrently (Roy, S., & Madhavan, S. S. (2012). The

previous studies with the exception of one by Roy et al (Roy & Madhavan, 2012) failed to study the inter-relationships and interactions among these predictors and their effects on drug expenditures (Mujasi & Puig-Junoy, 2015) Furthermore, with the recent ACA expansion, and the increased heterogeneity across Medicaid programs signaled by the varying levels of success of cost containment policies, it is essential to understand and test the relationships between the identified determinants and their concurrent effects on pharmaceutical expenditures

The overarching goal for this study was to identify determinants of Medicaid drug expenditure, examine the effects of interaction between the determinants and estimate a model for state level Medicaid drug expenditures. Anderson's Behavioral model for health services utilization provides the theoretical framework for the selection of explanatory variables incorporated into the model estimates. Variables used include state unemployment rates and state poverty rates represented by the percentage of the state residents with sustenance level below recommended federal standards. Cylus et al previously showed that poverty had a positive relationship with health services utilization (Cylus, Glymour, & Avendano, 2015). State high school graduation rates were also included in line with Cutter and Lleras-Muney 1999 paper that identified a positive relationship between health care status and individual level of education(Cylus et al., 2015). Several other factors such as racial distribution of Medicaid enrollees and dichotomous state cost containment policy interventions such as use of copayments, mandatory generic substitution policies were included to estimate a model for pharmaceutical expenditures.

The ensuing section describes the findings and contributions of the study

Research Findings

The results from the panel regression analysis and Partial Least Square-Structural Equation Modeling (PLS-SEM) as described in the section on results confirm heterogeneities in prescription drug utilization and expenditures within Medicaid. The study showed that on average Medicaid enrollees received 1.6 prescriptions per year within a range of zero to a maximum of 19 prescriptions per enrollee. The mean Per Capita Drug Expenditure was $ 112.63 within a range of $71.28 –$742.69. The state with the lowest average spending was Utah, with an average state per capita drug expenditure of $49.10. Hawaii was the highest spending with an average per capita drug expenditure of $ 274.96.

Based on theoretical arguments from Anderson's behavioral model for health services use, and using a random effects panel data regression analysis, the model below is estimated:

$$\begin{aligned} PerCapitaDrugEXP_{it} = \beta o + \beta_1\ PerCapitaPrescription_{it} + \beta_2\ PerCapita\_NonMedicaid\_Amt\_reim \\ + \beta_3 Proportion\_Male\_pop_{it} + \beta_4 Adults\_Blacks\_Chronic\_diabetes \\ + \beta_5\ Providegenericeduc_{it} + \beta_6\ Federal\_MedAss\_Percent_{it} \\ -\beta_7 State\_Unemploy\_Rate_{t} + \bar{e}_{it} \end{aligned}$$

The factors with significant influence on drug expenditures included state unemployment rates, Federal Medical Assistant percentage, proportion of population with chronic diseases given race, proportion of males in the population, non-drug Medicaid expenditures, and provider education programs on generics.

The study also showed that the coefficient of non-drug Medicaid amount reimbursed was positive 3.2 and significant ($p<0.000$). This implies that a $1 increase in state non-drug Medicaid expenditures leads to an increase of $3.2 increase in per capita drug expenditure. The non-drug Medicaid per Capita expenditure is a proxy for health care services utilization such as

general practitioner consultations, routine and elective surgeries as well as a variety measures for health care activity. Generally, it is expected that a high non-drug Medicaid health expenditure will positively impact drug expenditures. However, in the long run the direction of the coefficient should change since activities such as immunization will lead to decreased incidence of diseases and a drop-in need for drug therapies. This calls for further research beyond the current study's scope. The coefficient for the variable, proportion of males in the Medicaid population was -0.26, and significant ($p<0.001$). This implies that a one (1) percentage point increase in the proportion of male Medicaid enrollees is associated with a $26 reduction in per capita expenditures. This finding as explained earlier, validates *an a priori* expectation based on extant literature which indicates that health consumption tends to increase with increasing number of females (Correa-De-Araujo & Trinth 2005; Murphy & Hepworth, 1994). The negative coefficient for unemployment rate of -6.2, and significance ($p<0.001$), indicates that a percentage point increase in the unemployment rate will reduce per capita drug expenditures by approximately $6. This, however, does not fit our *a priori* expectation based on Anderson's health utilization behavioral model. The expectation is that increased unemployment will lead to an increased proportion of persons falling below the federal poverty level (FPL), which should inherently increase Medicaid enrollee numbers and hence expenditures. This result will require additional study.

A number of the policy interventions such as use of multitiered copays (3.691, $p=0.682$), enrollee payment of Lower Copays for Generics (16.83, $p=0.104$), prescriber Mandatory generic substitution (-2.2, $p=0.848$), and high dispensing fees for generics for pharmacists when they dispense generics (8.6, $p=0.628$) had a non-significant effect on per capita drug expenditure. The use of copays as a cost containment measure has had mixed reviews. Positive effects have been

reported with employer based private sector schemes. Joyce, Escarce, Solomom and Goldman (2002) report that introducing different levels of copay, requiring pharmacists to substitute generics for all brand products were shown to reduce overall payment plans and drug expenditures in employer-based programs (Joyce 2002). On the other hand, Wallace et al (1984) in a study focused on Oregon Medicaid showed that despite a reduction in the utilization of medicines after the introduction of copay, per capita expenditures did not change and that applying copays shifted treatment patterns but did not offer any reduction in expenditures. This study also showed that copays, mandatory substitutions and multitiered copays had no effects on the per capita expenditure. Nelson et al (2008) also indicated that copays had differential effects on different categories of diseases the related drugs used to treat them (Nelson, 2008). In line with Wallace et al it is recommended that policy makers re-analyze options to investments in implementing copayments, especially for program for geared toward low-income populations such as Medicaid. Data were not available to examine the impact of income effects on copays.

The ACA expansion had a positive coefficient but a non-significant (14.014 p=0.082) effect on per capita drug expenditures. Similar results had been obtained by Sommers et al using a difference-in-difference methodology that confirmed that post ACA there was an increase in number of prescriptions (utilization), but no increase in drug expenditures (Ghosh et al., 2017). Wen, Borders and Druss (2016) examined variations in Medicaid medicine expenditures and in unit's prescription between the pre-(2011-2013) and post (2014) ACA among states who had undertaken expansion and those who had not. Wen et al observed that the per capita spending in the twenty-three states that had either not undertaken expansion or were late to take up the expansion states was $3.21 per quarter and in $4.75 per quarter in the remain twenty-six expansion states, but the difference between the two groups of states in spending remained

insignificant (Wen, 2016). Indeed, in Mahendrartnam, Dusetzina and Farley (2015) indicate a similar study that even though enrollment in expansions state increase by 17.5% in a year after ACA, there wasn't a corresponding per member per quarter prescription in prescription they also posited that increases in per member per quarter reimbursement could be due to introduction of new more expensive medicines such as Sofosbuvir and increased prices and not from ACA expansion (Mahendraratnam, 2017). Further study is however required to track changes in drug expenditures in expansion states after the earlier assessment highlighted

Clinical prescribing practices can be managed by third party payers either by directly targeting prescriber actions through education, managerial, administrative tactics, or by using regulatory, or economic strategies to minimize prescribing actions that may have the potential to increase health expenditures at the system level. This study showed a negative and significant coefficient (-32.16, $p<0.006$) for provider education on the use of generics. The results show that per capita expenditures in states with provider education programs on used of generics was $32 less than states without provider education programs on use of generics. Again, this is consistent with the literature since brand products tend to be more expensive than their generic counterparts and it is not unexpected that a rise utilization of generic drugs will ultimately lead to a drop-in expenditure. Somewhat surprisingly, and as mentioned earlier, the effect of the mandatory generic dispensing substitution policies on expenditures was non-significant. Lack of significance for mandatory generic substitution during dispensing could be due to the existence of competing policies require encourage exceptions to the policy such as dispensing as written. Approximately seventy percent of states mandate generic dispensing of substitutes for innovator medicines a generic equivalent is readily available in the pharmacy; however, 65% of states with such laws allow the physician to nullify this requirement by merely entering a "Dispense as

Written" statement on the script (Morden & Sullivan, 2005). It is not surprising that drug expenditures were not significantly affected the mandatory generic dispensing policy. The increased introduction and coverage of biologics with very few generic alternatives or biosimilars could also help to explain the nonsignificant influence of generic dispensing policies on drug expenditures Finally, literature suggests that attempts at curbing brand prescribing through enforcement is seen as an infringement on prescriber autonomy and potential loss of revenue for dispensing doctors (Emanuel & Pearson, 2012). It is therefore possible that physicians respond by increasing the use of exceptions that allow dispense as written prescriptions. There have been instances within health systems when mandatory rules led to over utilization of the service or use of other services to compensate for the lost autonomy. The mandatory generic requirement may also be associated with a rise in the units of products per prescription to compensate for lost income in the case of dispensing providers (Meyer, 2016). There could be supplier-induced demand effects emanating from physicians or hospitals, a question which requires further investigation (Peckham & Gousia, 2014) in the form of additional research to identify or better understand any potential supplier induced incentives. The data to investigate this problem was unavailable for this study.

Using the Structural equation modeling approach with a 0.05 significance level, we find that all paths within the postulated structural model for drug expenditures are significant except (Need Factors ----> DrugExp, Predisposing Factors ----> DrugExp Predisposing Factors -----> Utilization Enabling Factors ------> DrugExp (0.138) and Healthcare------>Utilization). The PLS-SEM analysis component of the study hypothesized that need factors had a significant impact on utilization (H1). The results revealed that need factors have a positive coefficient and significant impact on utilization. This result supports previous literature (Andersen, 2005,

Geitona, 2007) In fact, the utilization of health care services is the core output or end result of individual's health and help seeking behavior or processes that take place to address the need for health care (Law, 2005).

Using the PLS-SEM findings revealed that utilization had a positive and significant effect on drug expenditures. This conflicts with other studies such as Ghosh (2017) who found that an increase in utilization of services does not necessarily reflect in increased expenditures. This observation could be due to parallel interventions such as pricing policies, quantity caps, use of biologics with few generics and other supply chain interventions at play within health systems. Hypothesis H4 tested whether policy factors have a significant effect on need factors. The results revealed that policy factors also generally had a significant effect on need factors Again, the result supports the theory which suggests that policy factors influence equitable access to health care services and assure utilization. In this context, policy connotes both system and individual level factors and indicators. Finally, hypothesis, H5, tests whether policy factors have a significant effect on utilization factors. The results for H6 which argues that predisposing factors had a positive and significant effect on drug expenditure was not surprising the effect of predisposing factors on drug utilization (H7) were also nonsignificant. Indeed, the presence a predisposing factor does not predict service use or expenditure generation. Enrollees with pre-existing risk such as diabetes may utilize health services because of inability to cover an existing co pay or because of inequitable access to health care services. Overall, the hypothesis testing suggests that with the exception of policy factors that directly influences drug expenditures all the other constructs influence drug expenditure mainly through the mediating effect of utilization. The results reveal that policy has a significant effect on utilization factors

However, the remaining hypotheses, hypothesis H3, testing whether need factors impact drug Expenditure, H6 testing predisposing factor effect on drug expenditures, H7 evaluation predisposing factor effect on drug utilization, H9 testing enabling factor effect on drug expenditures and H10, testing state health care resource factor on drug expenditures revealed no significant effects

Overall, the random effects panel regression model estimates explained 52% of dependent variable drug expenditure and hence a very good fit for drug expenditures. Many of the coefficients of variables e.g., Per capita prescriptions, proportion of males, and provider generic education theoretically expected to predict the PerCapitaDrugExp were not statistically different from zero

Contributions and management implications

This study findings should be of interest to researchers, stakeholder and policy makers involved in Medicaid expansion and those interested in ensuring that key access and equity metrics are achieved within the US health system and globally.

The study adds to the conceptual understanding of the determinants of pharmaceutical expenditures within health systems and within third party health payer programs such as Medicaid. The study extends Anderson Behavioral health service utilization model to include pharmaceutical use and expenditure, in line with previous work done by Roy and Madevan 2012 and Mujasi & Puig Junoy(2014) This study also extends knowledge about the interactive effects between various determinants of drug utilization and spending using a new approach of structure equation modeling (Garcia-Sempere & Peiro) with latent variables determined using Andersons behavioral model

Overall, using partial least squares structure equation modeling for medicine use expenditure analysis allowed us to develop and test elaborate models and interactions between various latent constructs than just a discreet regression analysis. For example, PLS-SEM approach shows the diverse paths that each of the latent constructs takes in their effects on drug expenditure instead of just a display of the single path as in other models.

Though some of the coefficients and the direction of some explanatory variables were not as expected, the results demonstrated the importance of these factor. It remains important for policy makers and researchers to ask why a number of cost containment strategies such mandatory generic prescribing do not significantly affect drug expenditures as revealed in this study. The ACA expansion did not have the expected positive and significant association with drug expenditure. The results of the study will assist policymakers to design policies targeted at factors that have significant impact on expenditures.

A key management implication relates to the use of policy constraints such as multitiered copays in low-income programs. The study showed that these policies had a non-significant effect on drug expenditures especially in a low-income program such as Medicaid. The need to reconcile policies that such as mandatory generic substitution and ability of provider to override such provisions with a Dispense as written request has managerial and policy implications cost containment. Both the availability of pharmacies (-23.35, p=0.245) and access to primary care facilities (-1.24 , p=0.113) had negative coefficients and had a non-significant effect on per capita drug expenditures. It may be useful for public policy experts to review and adopt strategies to optimize the level of investments into these areas since appears that for Medicaid enrollee additional investments in metrics to enhance access to pharmacies and primary care may not have an incremental effect on drug utilization and expenditures.

. It was also postulated that policy indicators such as mandatory generic dispensing will have a significant effect on drug expenditures but the results suggest that it did not. Both the STATA panel regression results and the SMART_PLS SEM showed that this policy had no significant effect on drug expenditures. Clearly additional factors such price changes, supply induced demand outside the database used for this study need to be explored as they may also have significant impact on drug expenditures This result provides an opportunity for researchers and policy makers to explore further any supplier induced demand activities which offsets the price reduction Medicaid obtains through rebates and negotiated supplementary discounts. The next section highlights the study's limitations.

Limitations

The study had a number of limitations. First, data sources focused only on publicly available data. Additional proprietary data on drug rebates, additional or supplementary discounts received, and actual price changes to Medicaid programs were sought but were ultimately unavailable. While the outputs of the study situated pharmaceutical expenditure and pharmaceutical utilization in the context of Anderson's Behavioral model of health services utilization, there were limited validated indicators and scales for some of the determinants of pharmaceutical expenditures used in the partial least square structure equation modeling. For instance, need factor latent construct had only three indicators, access to pharmaceutical services construct had two indicators while policy factor latent construct had 10 indicators. Again, using overall state level data to measure effects on Medicaid may not capture of the dynamics that influence Medicaid drug expenditures.

The relatively small sample size was addressed in part by the use of boot strapping technique which re-generated samples (5000 iterations) for PLS-SEM analysis.

However, with all SEM, the modeling includes a sequence of assumptions on the observations.

Future research

Aside from contrasting the interactive effects of the various determinants and estimating a model for drug expenditures there remain other research options. Future investigations could take a look at estimating separate models pre and post ACA for comparisons. Beyond the initial work completed by Roy and Madhaven (2012) on Medicaid drug expenditures, several other variables of interest such supplemental rebates, state pooled procurement, ACA expansion, and Medicaid levels of copayments were included. The results revealed varied levels of significance for these variables. Other variables such as percentage increase in actual prices of drugs to Medicaid, state level Gross domestic product and income levels of enrollee could be useful determinants in future research

Understanding the extent to which race and gender influence type of drugs prescribed and their resulting impact on expenditure and utilization is worth pursuing. This research provides some initial evidence that the proportion of males in the Medicaid population and proportion of blacks with chronic diseases have significant influence on drug expenditure. Deeper investigation of these relationships may offer further clues that reveal how race and gender shape drug use and expenditures in health systems.

Conclusion

Overall, the random effects panel regression model estimates explained 52% of dependent variable drug expenditure and hence a great fit for the drug expenditure panel data. Many of the coefficients of variables, for example Per capita prescriptions, proportion of males, and provider generic education theoretically expected to predict the PerCapitaDrugExp were

statistically different from zero. Among health seeking constructs and other variables only policy, utilization variables demonstrate statistical significance in structural equation modeling of drug expenditure. Results underscore the importance of latent need factors and policy factors and hence should be given equal considerations by policy maker in understanding and controlling drug cost within Medicaid.

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