OUTCOMES ASSOCIATED WITH A STATE-LEVEL HEALTH POLICY CHANGE FOR THE ATYPICAL ANTIPSYCHOTIC CLASS OF DRUGS WITHIN THE GEORGIA MEDICAID SCHIZOPHRENIC POPULATION

by

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(Under the Direction of Matthew Perri)

ABSTRACT

Background: Schizophrenia is a chronic mental illness affecting approximately 1% of the US population. Currently, pharmacological treatment is the mainstay of therapy for schizophrenia. At nearly $200 million per year, mental health drugs represent a significant component of prescription drug spending within the Georgia Medicaid program. In 2004 the Georgia Medicaid program implemented a prior-authorization policy for the atypical antipsychotic class of drugs resulting in an average savings of $2.7 million per year. **Objectives:** To determine if implementation of a prior-authorization policy for the atypical antipsychotic drugs resulted in increased healthcare utilization in the Georgia Medicaid Program from July 2003 to April 2006. **Research Design:** Segmented regression analysis with time series analysis. **Subjects:** Continuously eligible, adult Georgia Medicaid recipients with a diagnosis of schizophrenia and documented use of an atypical antipsychotic medication. **Measures:** Four healthcare services utilization endpoints were analyzed in this study: emergency room visits, outpatient office visits, hospital admissions and length of stay. Where applicable, analysis of a non-continuously eligible population was also performed to investigate the possibility of disenrollment bias in

significant study results. **Results:** This study found a significant decline in post-policy trend for the average number of emergency room visits ($\beta 3$ = -0.0029) and the average number of hospital admissions per member per month ($\beta 3$ = -0.0010). Baseline starting level and pre-policy trend were also found to be significant predictors for both endpoints. Significant models were not identified for average outpatient office visits per member per month or average length of stay per admission. **Conclusions:** In contrast to much of the published literature on prior-authorization for the atypical antipsychotics, the results in this study indicate patient outcomes may have actually been improved after the initiation of the policy. To the extent that medical utilization reflects patient health outcomes and health status, the results of this study indicate the program has potentially improved the health of schizophrenic patients in the Georgia Medicaid program and lowered program costs.

INDEX WORDS: Atypical Antipsychotic, Schizophrenia, Prior-Authorization, Healthcare Utilization, Segmented Regression Analysis, Time Series Analysis

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DEDICATION

To my husband, Tim – you are an amazing man and I am so proud to be your wife. You have followed God's leading and I will follow you…always and forever. I love you.

To my boys, Elijah and Noah – you have brought such joy into my life and nothing is more special than being called your "Momma". My prayer for each of you is that you accept Jesus at His first call and live a life dedicated to Him.

Finally, I give this work back to God. His guidance made it all possible.

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Thank you, Momma, for teaching me to persevere and never give up; not just in word, but in action and deed. I would not be who I am today without you. I love you.

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CHAPTER ONE

INTRODUCTION OF THE TOPIC AND RELEVANT ISSUES

1.1. Schizophrenia and the Atypical Antipsychotics

Schizophrenia is a chronic mental illness affecting approximately 1% of the US population (www.nimh.nih.gov). Men and women are equally affected; however, the age of onset varies slightly between the sexes (www.nimh.nih.gov). Symptoms of schizophrenia are generally divided into two groups, positive and negative. Positive symptoms include hallucinations and delusions as well as thought and movement disorders. Difficultly or loss of ability to express emotion, speak, plan and execute activities are common negative symptoms. Unfortunately, the cause of schizophrenia is not known and there is no known cure.

Currently, pharmacological treatment is the mainstay of therapy for schizophrenia. Medications prescribed for this disease include the typical (i.e. first-generation) and atypical (i.e. second-generation) antipsychotics. While the typical antipsychotics have been available for use in the US since the 1950s, the atypical antipsychotics have only been available since 1989 when clozapine (Clozaril), the first atypical, was approved for use by the Federal Drug Administration (FDA). Following the introduction of clozapine, several other drugs in this class were developed and approved for use in the US (see Table 1).

Table 1: FDA Regulatory Information for the Atypical Antipsychotic Drugs

	Forms, Routes and Strengths	FDA Approval	Approved Indications (all formulations)	Patent Expiration	Generic Availability
Clozaril (clozapine)	Oral Tablets: 25,100mg	Sept 1989	Chronic: Treatment-resistant Schizophrenia Recurrent suicidal behavior in Schizophrenia	1998	Yes
Risperdal (risperidone)	Oral Tablets: 0.25,0.50,1,2,3,4mg Orally-disintegrating tablets: 0.5,1,2,3,4mg Oral solution: 1mg/mL Long-acting injection/parental: 12.5,25,37.5,50mg vials	Dec 1993	Chronic: Schizophrenia Acute: Manic episodes in Bipolar I Mixed episodes in Bipolar I Irritability associated with Autism	2007	Yes, 2008
Zyprexa (olanzapine)	Tablets: 2.5,5,7.5,10,15,20mg Orally-disintegrating tablets: 5,10,15,20mg Injection/parental: 10mg vial	Sept 1996	Chronic: Schizophrenia Maintenance treatment in Bipolar I Acute: Manic episodes in Bipolar I Mixed episodes in Bipolar I Acute agitation in Schizophrenia Acute agitation in Bipolar I mania	2011	No
Seroquel (quetiapine)	Tablets: 25,50,100,200,300,400mg Extended-release tablets: 50,150,200,300,400mg	Sept 1997	Chronic: Schizophrenia Maintenance treatment in Bipolar I Acute: Manic episodes in Bipolar I Depressive episodes in Bipolar I	2011*	No
Geodon (ziprasidone)	Capsules: 20,40,60,80mg Oral solution: 10mg/mL Single use IM vials: 20mg/mL	Feb 2001	Chronic: Schizophrenia Acute: Manic episodes in Bipolar I Mixed episodes in Bipolar I Acute agitation in Schizophrenia	2012	No
Abilify (aripiprazole)	Tablets: 2,5,10,15,20,30mg Orally-disintegrating tablets: 10,15mg Oral solution: 1mg/mL Single use IM vials: 9.75mg/1.73mL	Nov 2002	Chronic: Schizophrenia Acute: Manic episodes in Bipolar I Mixed episodes in Bipolar I Acute agitation in any of above Adjunct treatment in MDD	2014*	No
Symbyax (olanzapine with fluoxetine)	Capsules: 3,6,12mg with 25mg fluoxetine 6,12mg with 50mg fluoxetine	Dec 2003	Acute: Depressive episodes in Bipolar I Treatment resistant MDD	2017	No
Invega (paliperidone)	Extended-release tablets: 1.5,3,6,9mg	Dec 2006	Chronic: Schizophrenia Acute: Acute agitation in Schizophrenia	2010	No

*Pediatric extensions will delay expiration date slightly

Source: http://www.accessdata.fda.gov/Scripts/cder/DrugsatFDA/

With the exception of Symbyax, all the atypical antipsychotic drugs have been approved by the FDA for long-term use in the treatment of schizophrenia in adults. Other indications may vary by drug including pediatric indications (see Table 1) (www.fda.gov).

Atypical antipsychotics are commonly touted for increased efficacy compared with the typical antipsychotics; however, with the exception of clozapine in the case of refractory schizophrenia, this finding has not been consistently borne out in the literature. In fact, the Clinical Antipsychotic Trials of Intervention Effectiveness (CATIE) found no superior efficacy in terms of treatment discontinuation for any of the atypical antipsychotics versus perphenazine, common typical antipsychotic (Lieberman et al, 2005). Decreased incidence of extrapyramidal side effects is a commonly cited reason for safety gains in the atypical antipsychotics over the typicals; however, the atypical antipsychotics have safety issues of their own that must be acknowledged included weight gain and metabolic side effects (Rosenheck et al, 2003). In the first 18 months of the CATIE trial, olanzapine was found to be associated with increased weight gain as well as increased glycosylated hemoglobin, total cholesterol, triglycerides – all symptoms consistent with the development of metabolic syndrome (Lieberman et al, 2005). In addition, safety concerns are an issue with the atypical antipsychotics as well

One final point regarding the issue of safety – it should be noted that the FDA has issued a black box warning for all atypical antipsychotic labels indicating increased risk of death in the elderly patients with dementia-related psychosis (www.fda.gov). Additionally, Seroquel and Symbyax have a second black box warning for increased suicidal ideation and suicidal behavior in children, adolescents and young adults (www.fda.gov).

1.2. Drug Utilization, Cost and State Medicaid Programs

More individuals are using psychotropic medications—just over 8% of individuals were using a psychotropic drug in 2001 compared with less than 6% in 1996 (Zuvekas, 2005). Spending on psychotropic drugs increased from just under $6 million in 1996 to nearly $15 million in 2001 with the atypical anti-psychotics representing a large portion of this increase in spending—nearly 30% (Zuvekas, 2005).

Psychotropic drug spending places a disproportionate fiscal burden on public health programs including state Medicaid programs: The public and out-of-pocket share of psychotropic drug spending is higher compared to prescription drug spending in general (Zuvekas, 2005). Frank and Conti (2003) report that state Medicaid programs were responsible for over half of all antipsychotic drug spending in the US in 2001.

Between 2000 and 2005, total US Medicaid program spending rose an average of 8.9% per year for an increase from $205.7 billion per year to $315.0 billion per year (http://www.kff.org/medicaid/upload/7697.pdf). Pharmaceuticals represent the "fastest growing component of health care expenditure" in the US (Hamel and Epstein, 2004). Prescription drug spending represented greater than 10% of total US Medicaid spending for FY03 – 05 increasing from $27.05 billion in FY03 to $30.97 billion in FY05 (http://www.cms.hhs.gov). Directly pertinent to this current study, US Medicaid spending on antipsychotic medications exceeded $5.5 billion in 2005 – up from less than $1 billion in the mid-90's (Law et al, 2008).

Within the state of GA's Medicaid program, pharmacy expenditures doubled between 2000 and 2004 and currently represent in excess of $1 billion per year in Medicaid spending (Dubberly et al, 2007 Presentation). In addition, FY05 – FY07 represented a time of significant enrollment growth for the program with average monthly enrollment more than doubling going

from an average of 215,215 enrollees to 437,764 enrollees http://dch.georgia.gov/vgn/images/portal/cit_1210/31/32/70650176Medicaid.12.2007.FINAL.pdf

1.3. The Georgia Medicaid Preferred-Drug List and Prior-Authorization Program

The Georgia Department of Community Health (DCH) serves as the lead planning agency for all health and health policy issues throughout the state of Georgia. A nine-member, Governor-appointed, board directs the overall operation of the DCH's two main divisions: health planning and medical assistance. The overall mission of the DCH is three-fold: to (1) ensure "access to affordable, quality health care in our communities," (2) champion "responsible health planning and use of health care resources", and (3) promote "healthy behaviors and improved health outcomes" (Dubberly et al, 2007 Presentation). The DCH has several responsibilities including being charged with insuring 1.5 million (FY2005) Georgians through the state Medicaid program (http://dch.georgia.gov).

In 2001, after considering various strategies for most effectively, efficiently and safely allocating limited healthcare dollars within the state, the DCH initiated a preferred-drug list (PDL) and prior-authorization program within the Georgia State Medicaid Program. The reality of unmet healthcare need within the state of Georgia, combined with limited state healthcare dollars, prompted the DCH to take this action.

In developing a clinically appropriate PDL, the DCH employed the auspices of the Georgia Drug Utilization Review Board (DURB) which consists of various members including medical doctors, pharmacists, clinical academicians, other healthcare professionals as well as a patient advocate. The DCH, in conjunction with the DURB, purposed to develop a clinically

responsible PDL recognizing medical innovation when and where appropriate. Secondarily, the DCH solicited supplemental rebates from pharmaceutical manufacturers. Ultimately, the inclusion of drugs on the PDL relies upon both the clinical expertise provided by the DURB and relevant costing information. Drugs not included on the PDL are available through a PA process within the Medicaid program. Further, an exception and appeals process ensures that no drug deemed medically necessary can be excluded from the program.

As an additional safeguard, the PA program includes a "grandfather clause" allowing individuals already on a non-preferred therapy at the time of PDL development to remain on their medication regardless of formulary decisions. Qualifying members would need to have at least one pharmacy claim for the non-preferred medication in the previous twelve months. This provision serves to minimize disruption of successful drug therapies.

Beginning in April of 2004, the DCH began incorporating mental health drugs into the PA program. Specifically, step-wise initiation of four mental health drug classes proceeded as follows:

Table 2: Prior-Authorization Implementation Schedule

Mental Health Drug Category	Implementation Date
Attention-deficit hyperactivity disorder medications	April 1, 2004
Selective serotonin reuptake inhibitor medications	July 1, 2004
Atypical antipsychotic medications	September 1, 2004
Selective norepinephrine reuptake inhibitor and dopamine agonist medications	January 1, 2005

At nearly $200 million per year, mental health drugs represent a significant component of prescription drug spending within the Georgia Medicaid program (Dubberly et al, 2007

Presentation). In addition, large variations in cost exist within specific drug classes. In the atypical antipsychotics class of drugs, the difference between the least costly and most costly medication is in excess of $200 per monthly prescription (Dubberly et al, 2007 Presentation).

In 2006, the Georgia DCH initiated a preliminary descriptive study to investigate the impact of the inclusion of mental health drugs into the PA program. Several outcome measures were investigated in this study. The results of this analysis suggested that the addition of four classes of mental health drugs to the PA program did not result in an increase in (1) number of mental health prescriptions per member per month (PMPM), (2) number of emergency room visits PMPM, (3) number of outpatient visits PMPM, (4) number of hospital admissions PMPM, (5) average length of stay for hospital admissions, or (6) number of disenrollments due to incarceration (Dubberly et al, 2007). In addition, the study found the net cost per mental health claim was reduced by nearly 8% and net spending decreased by over $16 million per year (Dubberly et al, 2007 Presentation). Of particular relevance to the currently proposed study, the inclusion of the atypical anti-psychotics to the PA program resulted in $2.7 million in savings per year. (Dubberly et al, 2007 Presentation).

The preliminary analysis performed by the Georgia DCH suggests that inclusion of mental health drugs into a PA program may result in the generation of substantial cost-savings without a concurrent increase in healthcare utilization. However, this suggestion requires further validation through a more rigorous scientific analysis which is the purpose of the currently proposed study. The purpose of this study is to more rigorously examine and describe the impact of the atypical antipsychotics PDL and prior-authorization policy on Georgia Medicaid schizophrenic population.

CHAPTER TWO

LITERATURE REVIEW

2.1. Cost-Control Strategies

Limited healthcare resources in the face of unmet healthcare need presents both an economic as well as an ethical dilemma. These dilemmas highlight the necessity for implementing the most economically efficient policies within the bounds of medically responsible and appropriate care (Burton et al, 2001). Ultimately, any program for controlling costs should be developed, implemented and monitored to ensure patient care is not compromised in the process (Bishop, 2005). To that end, numerous strategies have been studied and implemented in an effort to control prescription drug costs.

Some of the most common cost-control strategies include step-therapy, prior-authorization, drug category exclusions (generally lifestyle drugs) and cost-sharing approaches such as capitation or co-payments (Soumerai, 2004). Different approaches present different benefits and challenges. In an effort to better understand the overall implications of the differing approaches, Burton et al.'s (2001) method of grouping strategies by the mechanism of control—direct versus indirect—can be helpful.

Arguably, the most important potential advantage direct mechanisms offer is the ability to tailor programs with a primary focus on health outcomes (Burton et al, 2001). This can be accomplished through a reliance on evidence-based medicine (EBM) as the driving process, rather than manufacturer rebates and drug costs. Rebates and costs will certainly be a factor in

developing responsible programs; however, these considerations can be held secondary to EBM guidelines where available. Challenges to the direct method of control include restrictions on patient and provider autonomy, as well as significant administrative burden. However, these problems have the potential to be minimized by (1) implementing and maintaining transparent programs that include both physicians and patients in the development process, and (2) simplification and streamlining of the prior-authorization process. Finally, direct methods of control present the potential for therapy disruption through periodic changes in program guidelines and preferred drugs. Again, there are mechanisms to eliminate or limit this potential disadvantage such as grandfathering stabilized patients.

Indirect mechanisms for cost-control have the potential to overcome some of the disadvantages of direct mechanisms such as improving patient and physician autonomy and limiting administrative burden. Additionally, methods such as capitation may help physicians resist patient demands for over-prescribed or heavily advertised drugs where these demands are inappropriate. However, potential disadvantages should not be overlooked including shifts in drug costs from insurers to providers and patients irregardless of medical need, disinfrinchment of the sickest and the poorest of patients, and a foundational disregard for ability/inability to pay.

2.2. Prior-Authorization

Prior-authorization is "a [direct] cost-control procedure in which an insurer requires a service or medication to be approved in advance in order for the service or medication to be paid for by the insurer" (http://www.montevideomedical.com/Pages/Page_05.htm). It is a procedural barrier, not an economic barrier (Soumerai, 2004)—a distinction that is important when

considering programs within the Medicaid population. Selected drugs, generally on a preferred-drug list or formulary, do not require prior-authorization and these drugs are available without the need for prior approval. In addition, any drug deemed medically necessary for a given patient must be made available to that patient thereby eliminating the possibility of closed formularies (Koyanagi et al, 2005).

Prior-authorization is useful for many reasons including managing drug costs and encouraging appropriate clinical care (Momani et al, 2002; Soumerai, 2004). When developed according to EBM guidelines and with the expertise of providers, payers and patients, the use of preferred-drug lists and a PA process can limit drug costs related to inappropriate prescribing and related adverse medical events. In addition, preferred-drug lists and the use of prior-authorization can be used as a negotiating tool in determining drug prices with pharmaceutical companies thereby enabling the acquisition of drugs at a lower cost (Hamel and Epstein, 2004).

Drug therapy is a highly cost-effective form of treatment when compared to other medical treatment options; therefore, programs that limit or modulate access to prescription drugs should be approached carefully (Kotzan, 1993; Soumerai, 2004). The use of prior-authorization is most suitable when equally/more effective and less expensive therapy alternatives exist and the development of prior-authorization programs should never be based on cost information alone (Kotzan, 1993; Soumerai, 2004).

2.3. Benefits of Prior-Authorization

As discussed above, the use of prior-authorization offers the benefit that preferred-drug lists and formularies can be developed using EBM guidelines as well as clinical expertise as the foundation, rather than cost information alone (Burton et al, 2001). This is a distinct advantage

that prior-authorization, as well as other direct methods of cost-control, offers over indirect methods such as cost-sharing and capitation.

Prior-authorization can be used to encourage appropriate use of prescription medications while limiting the potential for patient harm due to over-utilization of newer, less understood or more toxic medications (Soumerai, 2004). This could result in improved health outcomes for patients as well as cost-savings related to the prevention of adverse events. In fact, a 2004 study by Hamel and Epstein found that the use of a prior-authorization program likely saved the lives of many patients by limiting the use of rofecoxib (non-preferred drug requiring prior-authorization) in patients at low risk of gastrointestinal bleeding.

Unlike economic cost-control strategies such as higher co-payments and cost-sharing, prior-authorization does not discriminate based on ability to pay—an advantage of particular importance in the Medicaid population. This particular feature of prior-authorization partially explains why many state Medicaid programs have been increasingly reliant on prior-authorization as a primary strategy to control prescription drug costs (Hamel and Epstein, 2004).

Respect for medical need and flexibility in obtaining necessary medications are two important features of prior-authorization. Many other strategies including utilization limits, cost-sharing and exclusions do not share these characteristics and this is a great benefit that prior-authorization offers. It is the ability of prior-authorization to produce cost-savings while providing access to any medically necessary drug that can be most appealing about this strategy (Momani et al, 2002).

One additional advantage of prior-authorization actually relates to its disadvantages. Specifically, the challenges of prior-authorization (such as administrative burden, mandatory medication changes and limitations on access) may be more easily overcome compared with the

challenges of other cost-control strategies, especially indirect controls which—irregardless of actual medical need—largely shift responsibility to providers and patients once a given cost or utilization threshold has been achieved (Burton et al, 2001). Capitalizing on the benefits that a prior-authorization strategy can offer, acknowledging and minimizing the challenges presented by prior-authorization—all in a transparent, clinically-driven process involving both providers and patients—makes prior-authorization one of the most "justifiable" approaches to controlling prescription drug costs (Burton et al, 2001).

The ability of prior-authorization (1) to be a clinically-driven process based on current medical knowledge and EBM, (2) to improve health outcomes and improve patient safety, and (3) to allow access to any medically necessary prescription drug makes this strategy for controlling prescription drug costs quite appealing.

2.4. Challenges of Prior-Authorization

Numerous challenges have been presented as to the use of prior-authorization. Several of the most notable and widely discussed potential disadvantages are presented here; however, it should be noted that many of these are program-dependent. Program-dependent simply means that a potential disadvantage may or may not be applicable depending on how a given prior-authorization program was developed, implemented and how it is monitored and maintained on an ongoing basis.

One of the most urgent concerns regarding the use of prior-authorization is the potential for compromise in quality of care and patient safety with or without a resultant deterioration in health outcomes (Polinsky et al, 2007; Wilk et al, 2008; Soumerai, 2004; Koyanagi et al, 2005; MaineCare Report, 2005; Bishop, 2005; Hamel and Epstein, 2004). Substitution of cheaper but

less efficacious or more toxic drugs, clinical deterioration during the prior-authorization process, and inappropriately limited access to medically necessary drugs are commonly cited concerns. Substitution may occur (1) prior to the actual prior-authorization process when costing information is given precedence over clinical knowledge and EBM guidelines, or (2) during the prior-authorization process if procedures are inordinately complex and physicians simply opt out of the process by prescribing only preferred medications, even if a non-preferred medication is indicated (Soumerai, 2004). A recent study found that 19.3% of psychiatrists actually discontinued or changed clinically appropriate medications rather than initiate a prior-authorization appeal or exception (West et al, 2007). In addition to inappropriate physician acquiescence, inordinately time-intensive PA processes could result in clinical deterioration or the experience of avoidable side-effect while providers and patients are navigating the clinical and administrative processes necessary in obtaining non-preferred medications (MaineCare Report, 2005).

Inappropriate limitations on access to medically indicated drugs can pose quality concerns and this may occur in several ways. Again, poorly designed preferred-drug lists may present challenges in this regard. Alternatively, inadequate staffing and logistical support, failure to comply with prior-authorization rules and regulations including mandatory turnaround times and poorly trained personnel were factors cited in a 2005 Kaiser Report by Bishop. Additionally, patients may be indirectly denied necessary medications secondary to lack of medical oversight; specifically, physicians may opt to no longer accept patients with prior-authorization intensive health plans or accept only a limited number of these patients (MaineCare Report, 2005).

Non-responsiveness to updates regarding medication safety information presents a patient safety concern as well. A 2007 study of state Medicaid programs' responsiveness to the FDA's advisory reporting increased mortality among elderly patients with dementia taking atypical antipsychotics found that none of the 21 states with prior-authorization policies for atypical antipsychotic medications had reflected this information in their policies or processes up to one year after the advisory (Polinski et al, 2007).

Restricted physician autonomy is another commonly cited concern with regard to prior-authorization. Criticisms regarding the flexibility of state health plans such as Medicaid to limit physician prescribing ability do exist (Koyanagi et al, 2005). In particular, compromise of physician autonomy and potential limitation on prescribing ability have been the cause of much concern in disease states where drug treatment responses are known to be quite variable, such as in mental health populations (Soumerai, 2004; Koyanagi et al, 2005).

Another challenge prior-authorization programs can present is that of economic inefficiency including increased administrative costs and increased overall medical costs. Designing, implementing and administering a prior-authorization program requires time and energy both from the health plan organization itself as well as medical professionals. At the provider level, there is an opportunity cost for medical personnel assigned to administrative tasks that must be absorbed (Wilk et al, 2008; MaineCare Report, 2005). This cost results in inefficiency due to highly trained clinical personnel spending time on non-clinical, administrative tasks and may actually limit the time providers and staff are able to spend in direct patient contact activities including assessment and education. In turn, this may affect patient satisfaction as well as health outcomes and quality of care. Additionally, economic inefficiency can result if a prior-authorization program results in increased use of non-drug medical services

such as office visits, hospital admissions, institutional care, and so forth (Hamel and Epstein, 2004; Soumerai, 2004; MaineCare Report, 2005).

Provider frustration with the prior-authorization process can present an additional burden. Multiple plans and formularies, frequent PDL changes and lack of uniformity in prior-authorization processes all contribute to provider irritation and malcontent with such programs (Bishop, 2005; Hamel and Epstein, 2004). Even when the prior-authorization process flows smoothly and takes only minutes for a given patient, the cumulative effect over a provider's day or week can be very costly and frustrating resulting in provider's viewing the entire process as a "hassle" at best (Brown et al, 2008). Distrust and confusion surrounding the clinical criteria for prior-authorization decision-making as well as the selection of drugs for preferred/non-preferred status is also a source of frustration cited by providers (Brown et al, 2008). Patients can also become frustrated with complex and sluggish prior-authorization processes as well as frequent changes in their program's PDL. Rather than switch drugs or initiate a prior-authorization request, their dissatisfaction may lead to self-directed discontinuation of their medication (MaineCare Report, 2005).

Finally, a 2005 Kaiser Report by Bishop found concerns related to a lack of sufficient monitoring of retail pharmacy compliance with prior-authorization policies and Medicaid laws, lack of continuity between inpatient and outpatient formularies and inability to obtain medications due to the opposing financial interests when two different managed care organizations administer drug and medical services benefits. Huskamp (2005) also highlighted potential limitations on realized cost-savings from mental health prior-authorization programs when health plans use behavioral medicine "carve-out" benefits to provide mental health services. Huskamp explains these carve-outs have little to no incentive for controlling

prescription drug expenditures and, in fact, may actually drive up pharmaceutical costs through increased utilization of drug therapies rather than utilizing potential psychotherapeutic options citing previously published work by Busch (2002).

2.5. Overcoming the Obstacles of Prior-Authorization

As previously discussed, one advantage of prior-authorization over many other cost-control methods is the potential for minimizing or overcoming the challenges presented by such programs. A 2005 prior-authorization study made several key recommendations (The MaineCare Report, 2005). These recommendations are explored here:

- Expanding the involvement of community physicians in the development of prior-authorization programs and allowing their clinical expertise to inform the process may serve to improve quality of care and health outcomes as well as mitigate concerns regarding limitations on physician autonomy in the medical decision-making process. Additional improvements are possible through a greater reliance on EBM with costing concerns being of secondary importance.

- Patient and provider frustration can be attenuated through simplification and streamlining of the prior-authorization process, both within a given health plan as well as across different health plans. Such improvements in the administrative process would also serve to improve the economic efficiency of prior-authorization program.

- Frustrations may be further alleviated simply by making available accurate and understandable information regarding a health plan's prior-authorization process, including criteria for prior-authorization approval and reasons for denial.

- Expediting requests and appeals would improve economic inefficiencies as well as mitigate patient and provider aversion of the prior-authorization process.

- Where reasonable, exempting stabilized patients from PDL changes as well as inpatient/outpatient formulary discrepancies will limit economic inefficiencies due to medical events secondary to medication changes. These events can include increased physician visits as well as crisis management services such as emergency room visits.

In addition to several of the key recommendations above, a 2005 Kaiser Report by Bishop also recommends improvements in pharmacy infrastructure and monitoring and increased continuity of care both from a disease state management standpoint as well as inpatient/outpatient standpoint.

Finally, periodic program evaluation studies and ongoing quality control/assurance measures on a program-by-program basis are necessary to ensure the benefits of a prior-authorization program outweigh the costs of the program. If problems are identified, modification of the prior-authorization process may be necessary (Soumerai, 2004; MaineCare Report, 2005). Health plan administrators should recognize that the design, implementation and execution of prior-authorization programs are likely to be important indicators in the program's acceptance by healthcare professionals and patients (Hamel and Epstein, 2004). Additionally, the development of a responsible prior-authorization program must include a clear method for identifying and responding to safety information updates with action taken in a timely manner (Polinsky et al, 2007).

2.6. Prior-Authorization and Mental Health

The use of prior-authorization to contain prescription drug costs and limit inappropriate care is a well-established practice in state Medicaid programs throughout the United States. Psychiatric illness is certainly no exception – all fifty states have restricted access to at least some mental health drugs and forty-nine out of fifty states have implemented prior-authorization policies for at least one class of mental health drugs (Koyanagi et al, 2005).

The use of prior-authorization in mental health is also not without controversy. Drug response heterogeneity is one commonly cited concern. Policies such as prior-authorization that serve to mediate access to particular medications may be particularly problematic given that patient response can be quite variable and unpredictable in mental health disease states (Soumerai, 2004). Heterogeneity in patient response to certain medications makes it "difficult to predict which psychiatric medication will be effective for any one person" (Koyanagi et al, 2005). While this argument is certainly valid and deserves attention, it may be reasonable to argue ***in favor*** of well-designed prior authorization programs on the very same grounds. Specifically, if patient response is largely unpredictable with treatment proceeding by clinical trial and error then responsible management of our limited healthcare dollars seems to dictate that we begin with the most economical drug that a patient may be reasonably expected to respond to in a favorable manner. Additionally, the structure offered by a prior-authorization program allows program-level evaluations and correction – a benefit not possible with provider-level trial-and-error where each individual is left to learn for himself or herself what drug(s) may or may not work best in a given situation/clinical scenario. .

Another concern regarding the use of prior-authorization in mental health relates to patient vulnerability and risk and the perceived need to exempt "high-risk" patients from

prescribing limits such as prior-authorization (Soumerai, 2004). Many mental health patient populations are at an increased risk for co-morbidities and overall mortality. Individuals with schizophrenia, often on an antipsychotic drug, are at increased risk for suicide and substance abuse as well (Tunis et al, 2004). In fact, 10% of all patients with schizophrenia will commit suicide (Siris, 2001). Undoubtedly, it is a serious chronic mental health disorder requiring significant health resources (Tunis et al, 2004). Due to concerns about the appropriateness of limitations on the prescribing of certain mental health drugs, states often offer exemptions for some/all mental health drugs or drug classes (Huskamp, 2005; Bishop, 2005). Antipsychotics and selective serotonin reuptake inhibitors are the two most commonly exempted mental health drugs in state Medicaid prior-authorization and PDL programs (Koyanagi et al, 2005). Such exemptions have made it difficult to fully understand the realized effect of prior-authorization programs on mental health drug use (Huskamp, 2007). While the intent of such exemptions is likely benevolent in nature, there is the potential that such actions may compromise patient safety and quality including a hindrance of mental health parity in the evolution of evidence-based medicine practices. Specifically, while exemption of mental health drugs from access-mediating policies "addresses many of the concerns of psychiatrists and patients, it also exempts them from the prescribing scrutiny being applied to other disciplines and places few checks on the commercial influences of pharmaceutical companies; [instead] states need to search out, and fund, best practice initiatives" (Bishop, 2005).

Specific to this study, many of the concerns with prior-authorization policies in the antipsychotics class of drugs revolves around restrictions that limit initial therapy to only the typical antipsychotics while reserving the atypical anti-psychotic drugs as second-line therapy only. Although typical antipsychotic drugs are generally much less expensive, the atypical

agents have been touted for improved efficacy and patient compliance (Tunis et al, 2004); however, such claims are not consistently borne out in the literature and there is no general consensus on this issue (Luft and Taylor, 2006). In addition to the CATIE trial discussed previously, a 2006 study by Jones et al. found the typical antipsychotics to be better at controlling symptoms and improving quality of life at one year. Rosenheck et al. found no significant advantage in terms of quality of life or symptoms between olanzapine and haloperidol in their 2003 study.

2.7. Previous Studies on the Use of Prior-Authorization in Medicaid Mental Health Populations

Unfortunately, only a limited number of studies have been published examining outcomes associated with the use of prior-authorization for mental health drugs in the Medicaid setting. Generally speaking, the published studies in this area that are available are quite narrow in scope. Several studies and their related findings are summarized in this section.

A California Medicaid study found that upon removal of three atypical antipsychotic drugs from their prior-authorization program, average monthly costs increased for several types of health services in addition to prescription drug costs (McCombs, Mulani and Gibson, 2004). However, it was found that these short-term costs were more than recovered in long-term cost-savings associated with decreased use of nursing home and psychiatric hospital care.

In a 2007 study examining mental health medication access and continuity for dually eligible Medicaid/Medicare in the first four months following implementation of the Medicare Prescription Drug Benefit, it was found that patients on plans requiring prior-authorization for mental health drugs were 2.5 times more likely to experience a medication access/continuity

problem than patients on plans without this feature [after controlling for various seasonal and demographic variables] (West et al). In addition, switching medications on clinically stabilized patients, discontinuing/denying coverage for clinically indicated medications and limiting access to specific dosages or quantities of medications were found to be the most problematic events for mental health patients. In a related study by this same group, it was found that 57.3 additional minutes of physician/staff administration time for each hour of direct patient care was necessary, on average, for patients on plans requiring a prior-authorization (Wilk et al, 2008). It is important to note that in both of these studies recall bias may be a very important limitation on the validity of study results. Specifically, psychiatrists participating in the study were required to recall details from one systematically selected patient previously seen in their office including time spent in direct patient tasks as well as time spent on prescription drug administrative tasks related to that patient.

The effect of Maine's atypical antipsychotic Medicaid prior-authorization program on treatment discontinuation and drug spending found that patients prescribed an atypical antipsychotic after implementation of a prior-authorization policy experienced nearly a 30% increased risk of treatment discontinuation compared with individuals prescribed an atypical antipsychotic prior to the policy change (Soumerai et al, 2008). No increased risk was experienced in a comparator control state without a prior-authorization program. In addition, while a slight decrease in atypical antipsychotic drug spending was experienced in Maine during this time, a similar decrease was experienced in the comparator control state without a prior-authorization program (Soumerai et al, 2008).

Attempting to identify important factors related to the rising costs of antipsychotic use, a 2006 study of California's Medicaid program found that polypharmacy was the single most

expensive form use for this class of drugs (Stahl and Grady). In addition, the authors cite a lack of scientific evidence to support increased effectiveness of polypharmacy in treating patients. It is suggested that limiting polypharmacy may reduce the need for prior-authorization programs. Ultimately, the recommendation made was that at least two first-line atypical monotherapies be attempted, followed by monotherapy with 1st generation drugs or clozapine, before polypharmacy is initiated.

CHAPTER THREE

STUDY RATIONALE AND HYPOTHESES

3.1. Study Rationale

The potential risks and benefits of a prior-authorization program have been well characterized in the literature and a summary of these features have been presented here. Although it is out of the scope of the current proposal to detail the numerous studies that have been conducted evaluating the impact of prior-authorization policies in non-mental health fields of medicine, it is important to recognize that prior-authorization has been used successfully with many classes of drugs. Admittedly, these drugs and patient populations can differ quite significantly from mental health drugs and populations as described here thereby highlighting the need for mental health prior-authorization studies.

The utility of prior-authorization in mental health is not well understood. The current tenor of published literature regarding this practice is largely pessimistic, particularly with regard to antipsychotic drugs. Again, the primary arguments against the use of prior-authorization in mental health populations have been detailed in this proposal. However, additional studies are needed to begin to fully characterize the actual experiences of Medicaid programs applying prior-authorization policies to psychotropic drugs. While the focus is often on prescription drug utilization costs, studies evaluating the impact of prior-authorization programs on pertinent medical services costs, safety and social indicators important in mental health are also important.

The current study will examine the impact of Georgia Medicaid's atypical antipsychotic prior-authorization program on two types of patient outcome indicators: medical service utilization and as well as social indicators, namely, incarceration and suicide (see Table 4).

3.2. Research Questions

This study will attempt to characterize how, if at all, the implementation of the GA Medicaid prior-authorization policy impacted schizophrenic Georgia Medicaid recipients taking an atypical antipsychotic medication. The primary research question for this study is: **Has limiting immediate access to some atypical antipsychotics negatively impacted schizophrenic patients within the Georgia Medicaid Program?** To this end, three questions will be addressed:

1. Has the implementation of an atypical anti-psychotic GA Medicaid PA policy increased utilization of emergency services in the GA Medicaid system?
2. Has the implementation of an atypical anti-psychotic GA Medicaid PA policy increased utilization of outpatient physician services in the GA Medicaid system?
3. Has the implementation of an atypical anti-psychotic GA Medicaid PA policy increased utilization of hospital services in the GA Medicaid system?

3.3. Hypotheses

The use of prior authorization to contain prescription drug costs and limit inappropriate care is a well-established practice in state Medicaid programs throughout the United States. Psychiatric illness is certainly no exception – all fifty states have restricted access to at least some mental health drugs and forty-nine out of fifty states have implemented prior authorization

policies for at least one class of mental health drugs (Koyanagi et al, 2005). As an increasingly high number of cost-control policies are being adopted, both in the private and public healthcare sectors, research into the safety, effectiveness and appropriateness of these strategies must be a research priority (Soumerai, 2004). Organizations, including state Medicaid programs, should undertake and promote investigation of the relationship between cost-containment policies and patient outcomes (Momani et al, 2002).

Given the widespread use of PA and other cost-containment strategies, the published literature offers relatively little information on the risks and benefits of this policy approach (Delate et al, 2005; Soumerai, 2004). Even with the limited published information that is available, the overall impact of PA is still not well understood and the usefulness of PA in light of both its benefits and risks is unclear (Hamel and Epstein, 2004). Additional research is needed to investigate the usefulness of prior authorization policies in specific contexts and environments. Ultimately, any cost-containment strategy, including PA, should be developed, implemented and monitored on a program-by-program basis to ensure beneficiary care is not compromised while costs are being controlled (Bishop, 2005; Momani et al, 2002). Additionally, it must be considered that many extraneous variables can and do influence the feasibility and usefulness of PA policies on a program-by-program basis including drug class characteristics as well as patient population characteristics (Soumerai, 2004). This highlights the need for targeted policy evaluations following important policy implementations, such as the GA Medicaid PDL and prior-authorization program. To this end, we will investigate the impact of this policy on several healthcare utilization endpoints for continuously eligible schizophrenic GA Medicaid members who have used an atypical antipsychotic.

We hypothesize:

Ho1: There is no significant difference in the average number of emergency room visits per member per month (PMPM) within the GA Medicaid program before and after implementation of the PDL/PA policy.

Ho2: There is no significant difference in the average number of office visits PMPM within the GA Medicaid program before and after implementation of the PDL/PA policy.

Ho3: There is no significant difference in the average number of hospital admissions within the GA Medicaid program before and after implementation of the PDL/PA policy.

Ho4: There is no significant difference in average length of stay per hospital admission per member within the GA Medicaid program before and after implementation of the PDL/PA policy.

CHAPTER FOUR

RESEARCH METHODOLOGY

4.1. Data

Data analyzed in this study were supplied by the Georgia Department of Community Health (DCH) and Georgia Department of Human Resources (DHR) and made available through a secure file transfer protocol website. Five distinct patient-level files were provided: pharmacy claims file, physician claims file, inpatient claims file, emergency services claims file and a member file containing demographic and personal information on all continuously eligible Medicaid recipients for the study period. Additionally, an eligibility file was provided with Medicaid patient identification numbers for all continuously enrolled Medicaid recipients for the study period.

4.2. Study Period

The study period of interest for this project was July 1, 2003 to April 30, 2006. The pre-policy period examined data from July 1, 2003 up to but not including September 1, 2004 while the post-policy period examined data from September 1, 2004 to April 30, 2006.

4.3. Study Population

Using the eligibility file, all other files were limited to continuously eligible, adult (18 to 65 years of age) Medicaid recipients only. Subsequently, all files were also limited to: (1)

individuals with a schizophrenia-related diagnosis (ICD-9CM code 295) and, (2) individuals who had received at least one prescription for an atypical antipsychotic drug during the study period. Individuals not meeting all these criteria were excluded from the data analysis.

4.4. Statistical Analysis

Segmented regression and time series analysis were utilized for examining the primary study endpoints of interest. The least-squares regression model specified was (Wagner et al. 2002):

$$Yt = \beta 0 + \beta 1(\text{time}) + \beta 2(\text{intervention}) + \beta 3(\text{post-time}) + \varepsilon t \qquad [1]$$

where *Yt* is the mean monthly value for the dependent variable of interest at time *t, time* is time in months from the start of the study period, *intervention* represents the policy period for time *t* (pre-policy period = 0; post-policy period = 1), and *post-time* is time in months since the policy was implemented (value = 0 in the pre-policy period). $\beta 0$ and $\beta 1$ provide estimates of the baseline level and trend for the variable of interest, respectively. $\beta 2$ and $\beta 3$ provide an estimate of the change in baseline level and trend for the variable of interest, respectively. The sum of $\beta 1$ and $\beta 3$ provide an estimate of the post-policy slope. The εt is the error term at time *t*.

Regression model [1] was tested for statistical significance using the proc glm procedure in SAS (SAS Statistical Software). Significant models were further examined for significance of parameter estimates. Where applicable, insignificant parameters were removed and the parsimonious model was re-specified using proc glm in SAS. Significant models on re-specification where further analyzed for residual autocorrelation. Residual analyses included the Durbin-Watson test for autocorrelation and various graphs of the residuals (autocorrelation plot of the residuals, residuals versus time, Q-Q plot, and the white noise plot). If autocorrelation was

detected, time series models suggested by the autocorrelation plot were tested using proc arima in SAS. Where a significant autocorrelation model was identified, segmented regression analysis was repeated with inclusion of the autocorrelation terms and re-tested for significance. Significant models were retained. Where a significant autocorrelation model was not identified, the final model was specified according the initial segmented regression results.

Analysis of a non-continuously eligible population will be done for all variables in which a significant model is identified. Results from the continuously eligible analysis and this analysis will be compared to investigate possible disenrollment bias in study results.

CHAPTER FIVE

STUDY RESULTS

5.1. Emergency Room Visits

9,042 of 12,120 individuals meeting the study criteria presented to an emergency room at least once between July 1, 2003 and April 30, 2006. In total, 65,315 separate emergency room visits were made by this same group of individuals. The average number of emergency room visits by this group ranged from 0.13820 (November 2003) visits PMPM to a high of 0.17475 (July 2004) visits PMPM. No outliers were present in the data.

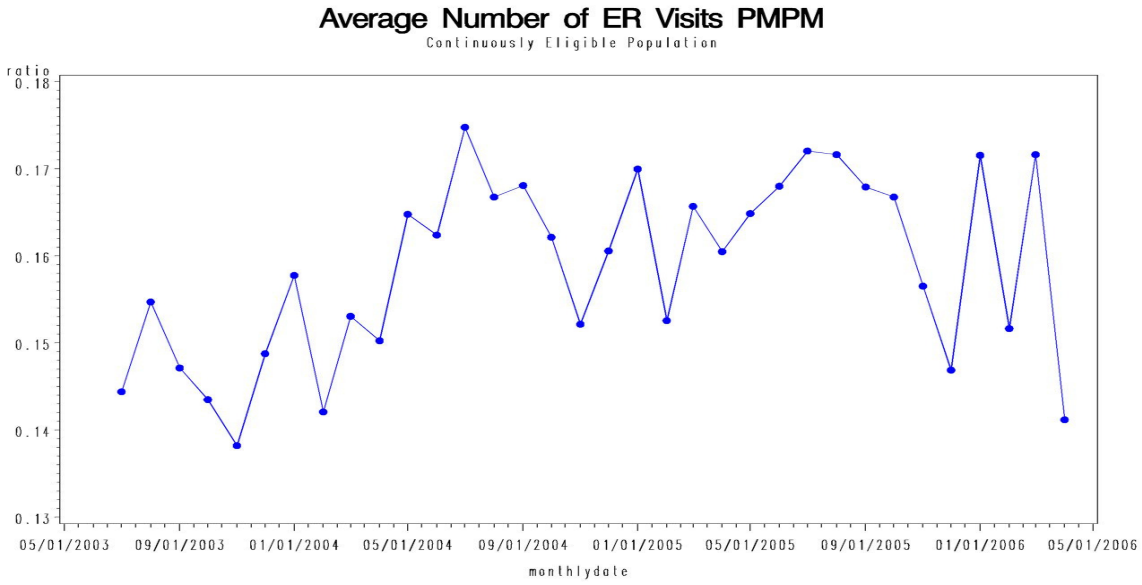

Figure 1: Monthly Data for Emergency Room Visits

Segmented regression analysis revealed model [1] was significant (see Table 3). The $\beta 2$ parameter estimate was not significant and was removed from the model. Subsequent analysis revealed a significant model with significance on all parameters tested.

Table 3: Average Number of ER Visits PMPM, Segmented Regression Results

Full Model	Parsimonious Model
Model Fit:	**Model Fit:**
F = 6.67 (0.0014)	F = 10.32 (0.0004)
Parameter Estimates:	**Parameter Estimates:**
$\beta 0$ = 0.1394 (<0.0001)	$\beta 0$ = 0.1396 (<0.0001)
$\beta 1$ = 0.0019 (0.0025)	$\beta 1$ = 0.0018 (0.0002)
$\beta 2$ = -0.0007 (0.9067)	$\beta 3$ = -0.0021 (0.0019)
$\beta 3$ = -0.0022 (0.0027)	

Residuals obtained from the parsimonious model generally appear to be from a random process (see Figure 2). Homoscedasticity of the errors was supported by the White Test. (p = 0.6560). The Durbin-Watson test statistic for the parsimonious model was 2.06 indicating positive autocorrelation was not present in the first lag. Additionally, 4 – the Durbin-Watson test statistic yielded a value of 1.94 indicating the absence of negative autocorrelation as well. Examination of the residual autocorrelation plot, however, revealed possible evidence for a seasonal time ARMA model (see Figure 3). While the plot was most suggestive of a seasonal MA2 model, testing of this model was not possible due to statistical limitations for a 34 month time series. Instead, a MA1 model was tested and found to be non-significant. The parsimonious model identified using segmented regression was retained as the final model.

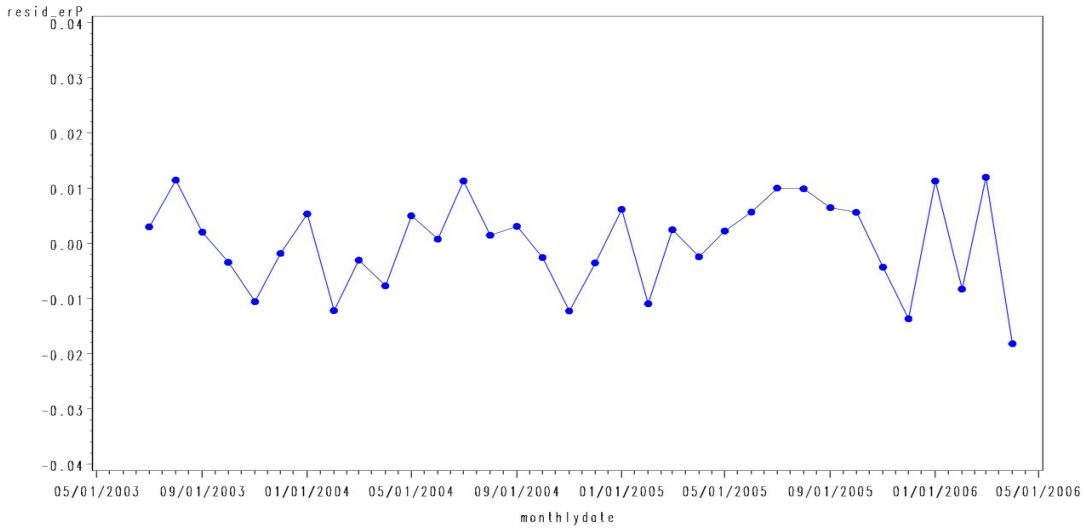

Figure 2: Residual values for Average Number of ER Visits PMPM, Parsimonious Model

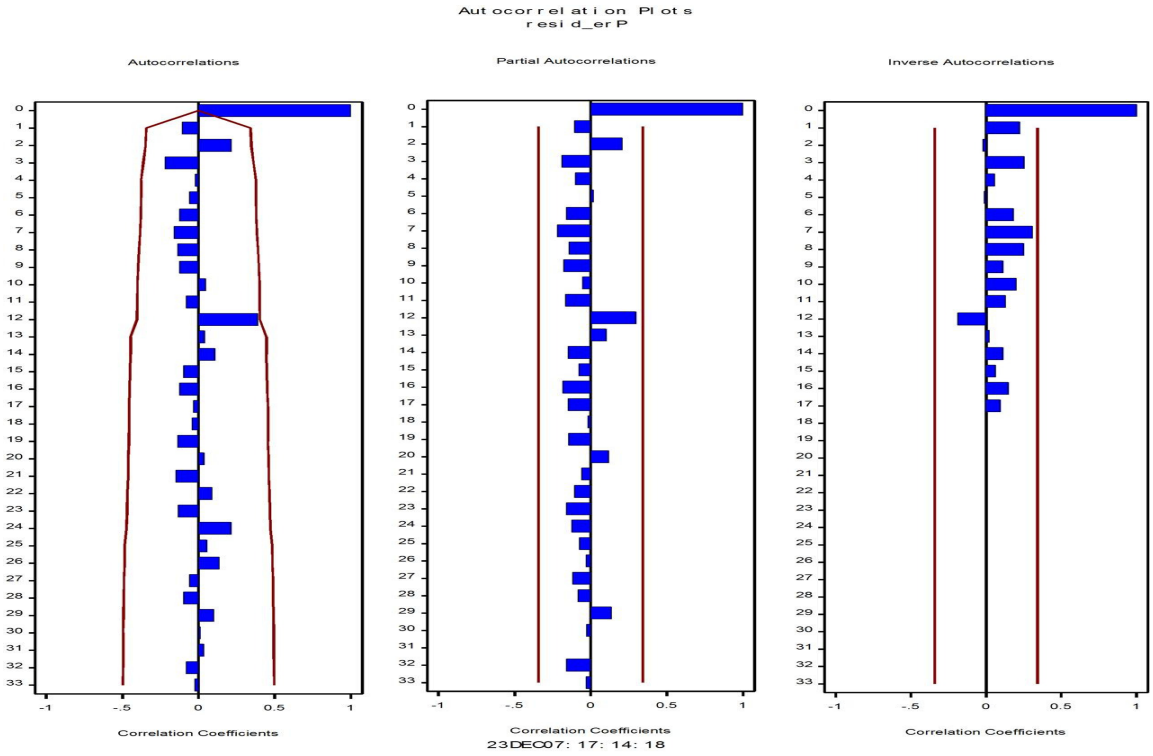

Figure 3: Residual Autocorrelation Plot (ER Visits, parsimonious SR model)

5.2. Office Visits

10,801 individuals meeting the study criteria had one or more claims for a physician office visit (CPT codes 99201-99205; 99211-99215; 99241-99245; 99271-99275) from July 1, 2003 – April 30, 2006. In total, this group experienced 166,360 office visits during the study period. The average number of office visits made by this group ranged from 0.294 (April 2006) to 0.345 (December 2004) visits PMPM, excluding one outlier in March 2006 (see Figure 4).

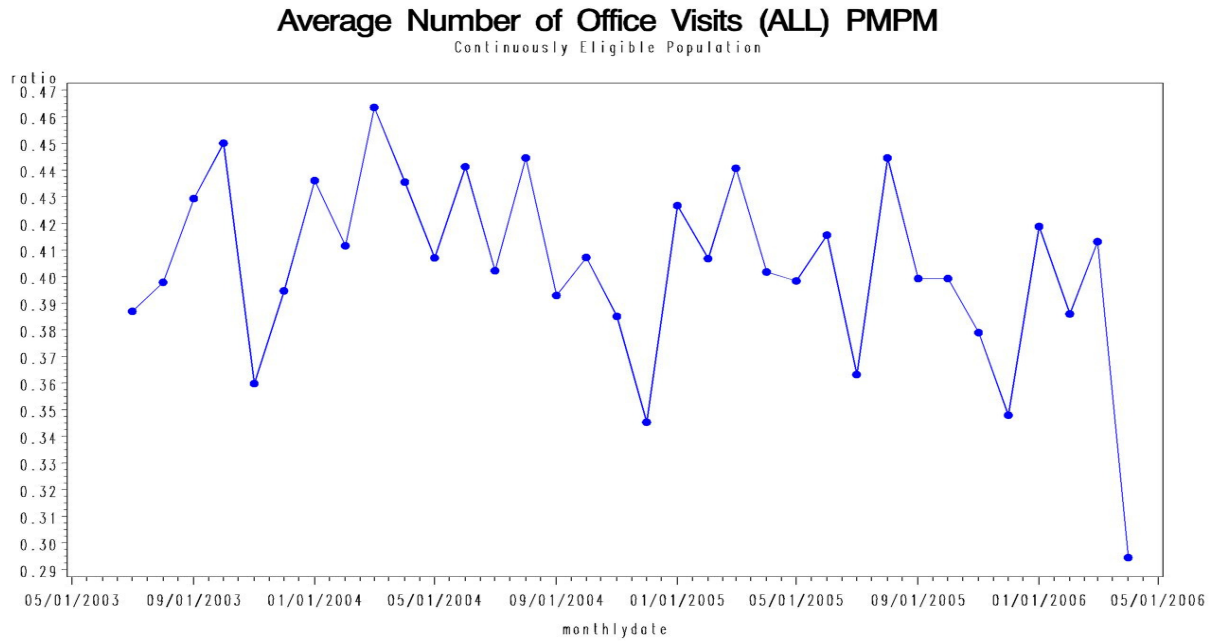

Figure 4: Monthly Data for Office Visits

Segmented regression analysis was done on both the data with the outlier and the data with the outlier minimized (average of values for February 2006 and April 2006). Results for model [1] were not significant in either case (see Tables 4 and 5).

Table 4: Average Number of Office Visits PMPM, Segmented Regression Results
(Outlier)

Full Model
Model Fit:
F = 2.73 (0.0614)

Table 5: Average Number of Office Visits PMPM, Segmented Regression Results
(Outlier Minimized)

Full Model
Model Fit:
F = 2.43 (0.0844)

5.3. Hospital Admissions

Of the 12,210 individuals meeting the study criteria, 5,496 were admitted to a hospital at least once between July 1, 2003 and April, 30, 2006. In total, there were 13,563 total admissions for this group of individuals. The average number of admissions ranged from 0.027 admissions PMPM to a high of 0.039 PMPM (July 2003 and August 2005, respectively) (see Figure 5). No outliers were detected in the data.

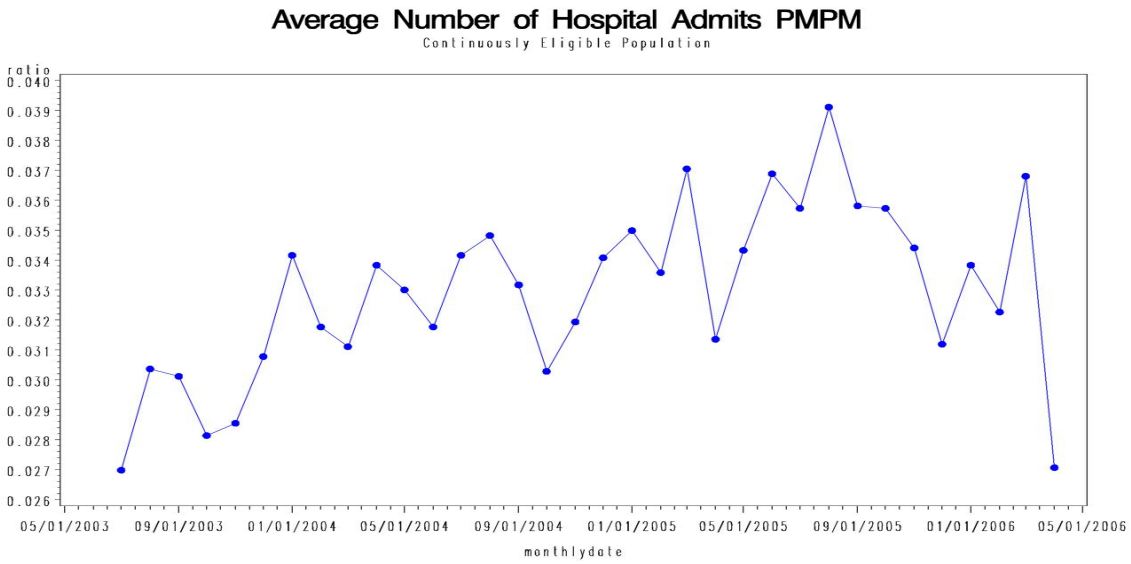

Figure 5: Monthly Data for Hospital Admissions

Segmented regression analysis revealed model [1] was significant (see Table 6). The $\beta 2$ parameter estimate was not significant and was removed from the model. Subsequent analysis revealed a significant model with significance on all parameters tested.

Table 6: Average Number of Hospital Admissions PMPM, Segmented Regression Results

Full Model	**Parsimonious Model**
Model Fit:	**Model Fit:**
F = 6.22 (0.0021)	F = 9.58 (0.0006)
Parameter Estimates:	**Parameter Estimates:**
$\beta 0$ = 0.0278 (<0.0001)	$\beta 0$ = 0.0279 (<0.0001)
$\beta 1$ = 0.0005 (0.0052)	$\beta 1$ = 0.0005 (0.0008)
$\beta 2$ = -0.0004 (0.7938)	$\beta 3$ = -0.0005 (0.0111)
$\beta 3$ = -0.0005 (0.0128)	

Residuals obtained from the parsimonious model generally appear to be from a random process (see Figure 6). Homoscedasticity of the errors was supported by the White Test. ($p = 0.4186$). The Durbin-Watson test statistic for the parsimonious model was 1.69 indicating positive autocorrelation was not present in the first lag. Additionally, 4 – the Durbin-Watson test statistic yielded a value of 2.31 indicating the absence of negative autocorrelation as well. Lack of significant autocorrelation was supported by ACF plots in SAS Time Series Viewer (see Figure 7).

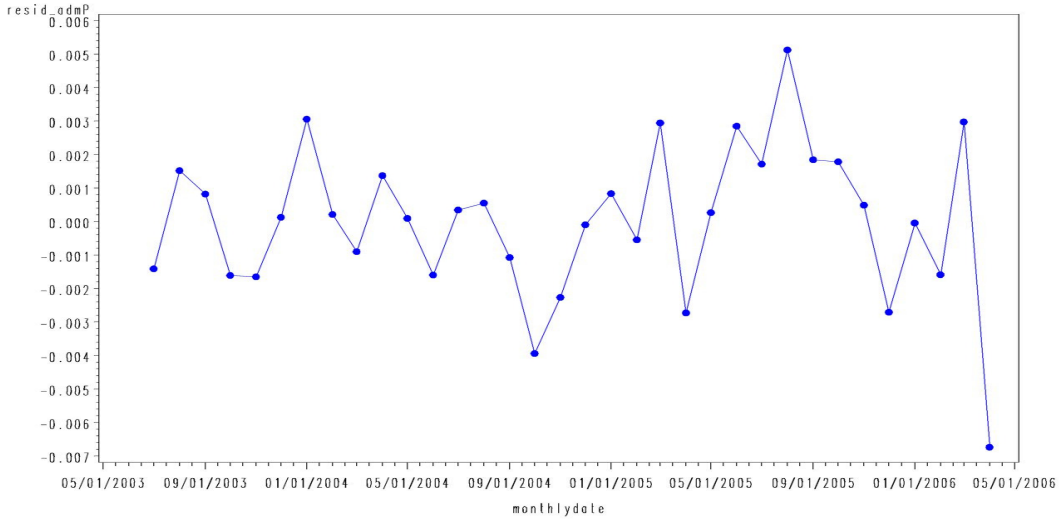

Figure 6: Residual Values for Average Number of Hospital Admissions PMPM, Parsimonious Model

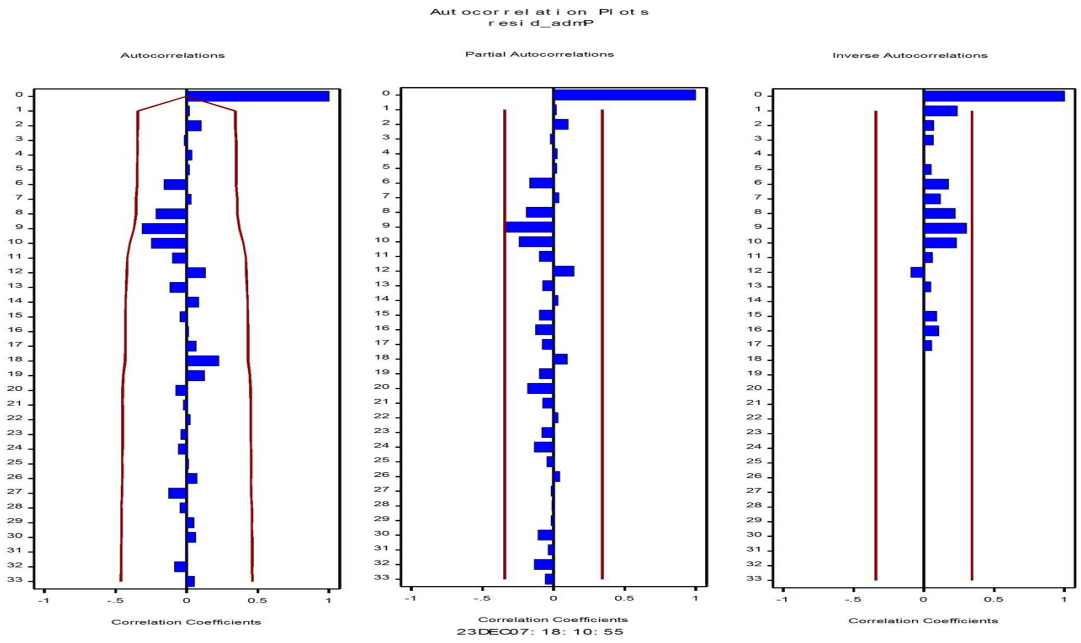

Figure 7: Residual Autocorrelation Plot (Hospital Admissions, parsimonious SR model)

5.4. Length of Stay

Of the 13,563 hospital admissions discussed above, the average length of stay ranged from 5.724 days per month (March 2006) to 7.235 days per month (October 2003) (see Figure 8). No outliers were present in the data.

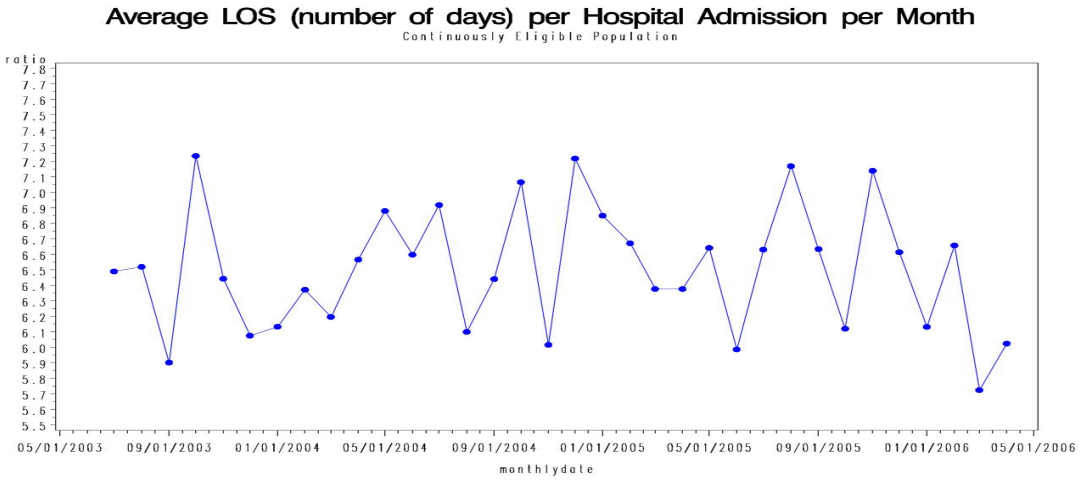

Figure 8: Monthly Data for Length of Stay (Days)

Segmented regression analysis for model [1] was not significant so no further analysis was done for this variable (see Table 7).

Table 7: Average LOS per Admission, Segmented Regression Results

Full Model
Model Fit:
F = 0.88 (0.4615)

5.5. Disenrollment from the Medicaid Program

Non-continuously enrolled analysis of the average number of emergency room visits PMPM supported results from the continuously enrolled analysis of this variable. Specifically, a parsimonious model with significant $\beta 0$, $\beta 1$ and $\beta 3$ parameters was found to be significant (see Tables 4 and 9). Parameter estimates support a significant negative change in post-policy trend in both models.

Analysis of hospital admissions for a non-continuously eligible population revealed a potential outlier at month 34 (April 2006). Segmented regression analysis was done on both the full dataset and a dataset with the outlier removed. Results for both analyses were similar and both were supportive of the significant negative change in post-policy trend found in the continuously eligible population (see Tables 6 and 8).

Table 8: Non-Continuously Enrolled Analysis, Parsimonious Models

ER Visits	Hospital Admits (with outlier)	Hospital Admits (without outlier)
Model Fit:	**Model Fit:**	**Model Fit:**
F= 14.32 (<0.0001)	F = 14.80 (<0.0001)	F = 12.63 (<0.0001)
Parameter Estimates:	**Parameter Estimates:**	**Parameter Estimates:**
$\beta 0$ = 0.1394 (<0.0001)	$\beta 0$ = 0.0286 (<0.0001)	$\beta 0$ = 0.0289 (<0.0001)
$\beta 1$ = 0.0023 (<0.0001)	$\beta 1$ = 0.0006 (<0.0001)	$\beta 1$ = 0.0006 (<0.0001)
$\beta 3$ = -0.0031 (<0.0001)	$\beta 3$ = -0.0009 (<0.0001)	$\beta 3$ = -0.0007 (<0.0001)

CHAPTER SIX

DISCUSSION

6.1. Intervention Effects

Implementation of an atypical antipsychotic prior-authorization policy in the Georgia Medicaid program was found to be associated with a significant decline in post-policy trend for the average number of emergency room visits PMPM ($\beta 3$ = -0.0021). Baseline starting level and pre-policy trend were also found to be significant predictors ($\beta 0$ = 0.1396; $\beta 1$ = 0.0018).

Using the segmented regression model, the impact of the policy can be estimated both in absolute and relative terms. The absolute difference can be estimated by comparing model results with post-intervention effects to model results without post-intervention effects. This is illustrated below for month 34, the last month in the study period:

$$AD_{(Month\ 34)} =$$

$$[(0.1396 + 0.0018*34 - 0.0021*20) - (0.1396 + 0.0018*34)] = -0.042$$

For the study population of interest, the average number of ER visits PMPM decreased by 0.042 in association with the atypical antipsychotic PA program.

The relative change can be expressed by dividing the absolute difference by model results without post-intervention effects. This is illustrated here:

$$RD_{(Month\ 34)} = [(AD_{(Month\ 34)} / (0.1396 + 0.0018*34)] * 100 =$$

$$[0.042/ (0.1396 + 0.0018*34)] * 100 = -20.92\%$$

Therefore, it is estimated that the average number of ER visits PMPM decreased by 20.92% in month 34 compared to what it would have been in the same month had the policy not been implemented.

In addition to ER visits, the implementation of the atypical antipsychotic prior-authorization policy was also found to be associated with a significant decline in post-policy trend for the average number of hospital admissions PMPM ($\beta 3$ = -0.0005). Baseline starting level and pre-policy trend were also found to be significant predictors ($\beta 0$ = 0.0279; $\beta 1$ = 0.0005).

The absolute difference can again be estimated on a month-by-month basis by comparing the post-intervention model results to model results without post-intervention effects. This is illustrated here, again for month 34:

$$AD_{(Month\ 34)} =$$

$$[(0.0279 + 0.0005*34 - 0.0005*20) - (0.0279 + 0.0005*34)] = -0.010$$

The relative change for the average number of hospital admissions is calculated here:

$$RD_{(Month\ 34)} = (AD_{(Month\ 34)} / [(0.0279 + 0.0005*34)] =$$

$$[-0.010 / (0.0279 + 0.0005*34)] * 100 = -22.27\%$$

Therefore, it is estimated that the average number of hospital admissions PMPM decreased by 22.27% in month 34 compared to what it would have been in the same month had the policy not been implemented.

The use of prior-authorization in mental health is controversial and while this cost-containment theory has been researched the implications of prior-authorization on patient health outcomes are not well understood. The current tenor of published literature regarding this practice is largely pessimistic, particularly with regard to antipsychotic drugs (McCombs et al,

2004; West et al, 2007; Wilk et al, 2008; Soumerai et al, 2008; Stahl and Grady, 2006). From its implementation in September 2004 through April 2006, the Georgia Medicaid atypical antipsychotic prior-authorization program was found to be associated with significant declines in trend for the average number of emergency room visits PMPM as well as the average number of hospital admissions PMPM. At the same time, the Georgia Medicaid program experienced, on average, cost-savings of $2.7 million per year for this class of drugs (Dubberly et al, 2007). In contrast to some of the published literature on prior-authorization for the atypical antipsychotics, the results of this study indicate patient outcomes actually may have been improved after the initiation of the policy.

Segmented regression for model [1] was not found to be significant for office visits and length of stay. Given routine patient follow up visits and monitoring, it would not be expected that office visits would significantly decline with a prior-authorization program for this class of drugs, but a negative impact on health could certainly create an increase in office visits. In this case, grandfathering of existing medications was provided for individuals with prior use of an atypical antipsychotic in the last twelve months. For individuals starting on a new therapy, similar monitoring and maintenance of drug therapy would be required with and without such a program. Likewise, a non-significant finding for length of stay seems reasonable given the assumption of little or no difference between the preferred and non-preferred medications in terms of time to re-stabilization and discharge from the hospital.

The findings of this study provide evidence for the utility of prior-authorization in a mental health context. The challenges of prior authorization programs have been well described in the literature (Soumerai, 2004; MaineCare Report, 2005; West et al, 2007; Bishop, 2005; Hamel and Epstein, 2004). However, many of these challenges may be surmountable with well-

designed prior-authorization programs. The Georgia Medicaid program has attempted to minimize the challenges presented by prior authorization in several ways. Lack of continuity of care between inpatient and outpatient formularies and concern with therapy disruption in stabilized patients are concerns cited in the 2005 Kaiser Report by Bishop. This has been addressed by the Georgia Medicaid Program for the atypical antipsychotics through a mandatory prior-authorization approval clause for patients stabilized on non-preferred medications in the hospital. In addition, the program provides grandfathering of prescriptions for stabilized patients (generally requiring only one claim within the last twelve months for eligibility of this benefit). Furthermore, disruptions in therapy related to PDL changes are virtually non-existent for the Medicaid recipients in the state of Georgia – not one single atypical antipsychotic has been pulled from preferred status and moved to non-preferred status since its development in 2004.

It is unclear how the prior-authorization policy was associated with declines in emergency room visits and hospital admissions. It is possible that the results may demonstrate that safe and effective substitutability of the atypical antipsychotics is more plausible that previously thought. Alternatively, the results could indicate that the clinical "trial-and-error" process associated with finding the most effective atypical antipsychotic offers no benefit over a well-designed prior-authorization program in terms of finding the most effective medication for a schizophrenic individual. To the extent that prior-authorization programs do limit "timely" access to non-preferred medications, one additional explanation is plausible. Specifically, in instances where earlier substitution may have occurred in the absence of a prior-authorization program, physician and/or patient aversion to the prior-authorization process may result in sufficient time for first-line medications to reach optimal therapeutic levels in some patients.

6.2. Limitations

The findings of this study may reflect the presence of some unidentified event or process that was not measured in this study. It could be that the decline observed in emergency room visits and hospital admissions are actually related to such an event or process, rather than to the Georgia Medicaid policy. Additional studies are needed to characterize the long-term effects associated with the policy.

This study examined the association between Georgia Medicaid's atypical antipsychotic prior-authorization program and emergency room visits, outpatient physician visits, hospital admissions and length of stay for hospital admissions. This study does not provide information on other utilization endpoints. In addition, this study investigated the association between important healthcare utilization endpoints and an atypical antipsychotic prior-authorization policy in Georgia Medicaid's continuously-eligible, schizophrenic adult population. Only individuals meeting these criteria, and with a history of atypical antipsychotic drug use, were included in the analysis. This study does not provide information on other users of atypical antipsychotics, including individuals with bipolar disorder and major depressive disorder. Generalizations should not be made to these or any other populations.

6.3. Conclusions

The Georgia Medicaid prior-authorization program for the atypical antipsychotics appears to have resulted in lower costs (as reported by the Department of Community Health; Dubberly et al, 2007) while causing no deleterious effects in the utilization of other medical resources. To the extent that medical utilization reflects patient health outcomes and health status, the results of this study indicate the program has improved the health of schizophrenic

patients in the Georgia Medicaid program and lowered program costs. Limited healthcare resources in the face of shrinking state budgets make clear the stark reality that completely open access to drugs may be unsustainable. In addition, the Medicaid population provides challenges with regard to cost-sharing and utilization limits as mechanisms for cost-control. Clinically-driven prior-authorization programs that acknowledge and work to minimize challenges presented by this type of cost-control may offer the most appealing option for prescription drug cost-control in this population of individuals. This study provides evidence that such efforts may be within our reach.

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