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# ANALYSIS OF KENTUCKY MEDICAID MANAGED CARE VERSUS FEE-FOR- SERVICE SYSTEMS: MEDICATION ADHERENCE IN PATIENTS WITH PREVALENT CHRONIC DISEASES

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ANALYSIS OF KENTUCKY MEDICAID MANAGED CARE VERSUS  
FEE-FOR-SERVICE SYSTEMS: MEDICATION ADHERENCE IN PATIENTS WITH  
PREVALENT CHRONIC DISEASES

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THESIS

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A thesis submitted in partial fulfillment of the  
requirements for the degree of Master of Science in the  
College of Pharmacy  
at the University of Kentucky

By

Catherine Kerr Herren

Lexington, KY

Director: Dr. Jeffery Talbert, Professor of Pharmacy Practice and Science

Lexington, KY

2016

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## ABSTRACT OF THESIS

### ANALYSIS OF KENTUCKY MEDICAID MANAGED CARE VERSUS FEE-FOR-SERVICE SYSTEMS: MEDICATION ADHERENCE IN PATIENTS WITH PREVALENT CHRONIC DISEASES

*Objectives:* Managed care organizations reduce healthcare costs and may improve patient health outcomes by encouraging better control of prevalent chronic diseases. The purpose of this study was to determine whether changing from a fee-for-service program to a capitated managed care program improved medication adherence for Medicaid patients in Kentucky with hypertension, hypercholesterolemia, or type 2 diabetes.

*Methods:* We conducted a quasi-experimental study of patients enrolled in Kentucky Medicaid to evaluate the impact of transitioning to capitated managed care in November 2011. Medication adherence was measured using the proportion of days covered (PDC) method. Multivariable analyses measured the adjusted differences in adherence as a result of the implementation of capitated managed care.

*Results:* Adjusted analyses indicate an average decrease in PDC by about 17-22 days of therapy coverage in the post-policy time period. However, no significant difference in adherence rate changes between the treatment and control populations were observed.

*Conclusions:* Results indicate clinically inconclusive evidence regarding the immediate effect of the implementation of Medicaid managed care in Kentucky on medication adherence rates in patients with prevalent chronic diseases. There is a need to address the decline in average adherence rates, and the efficacy of Medicaid managed care based on medication adherence.

**KEYWORDS:** Medicaid, managed care, fee-for-service, adherence, chronic disease

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Catherine Herren

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April 28, 2016

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## Section One: Introduction

According to the World Health Organization, poor adherence to chronic disease therapies is a worldwide problem.<sup>1</sup> Adherence is defined as the ability to follow a specified treatment regimen as provided by a healthcare professional in the treatment of an illness or disease.<sup>1</sup> Poor adherence to long-term therapies severely compromises the effectiveness of treatment, making this a critical issue in population health.<sup>1</sup> Studies show that poor adherence is associated with a higher incidence of hospitalizations among patients with hypertension, and increases complications among patients with hypertension and hypercholesterolemia.<sup>2</sup> All-cause hospitalizations among patients with diabetes increase with poor adherence to therapy.<sup>2</sup> Medical costs tend to be lower with higher levels of medication adherence, and are primarily driven by reductions in hospitalization rates.<sup>3</sup> Previous studies have examined rates of adherence to medications for prevalent chronic diseases, and 10-20% of patients with either hypertension, hypercholesterolemia, or type 2 diabetes were found to have less than optimal medication adherence, as measured by the medication possession ratio (MPR < 70%).<sup>4</sup> Therefore, poor adherence to chronic disease medications is an excellent target for health policy makers who desire to improve patient health outcomes.

The Pharmacy Quality Alliance endorses the proportion of days covered (PDC) as the preferred method for calculating adherence.<sup>5</sup> PDC is calculated using prescription claims data by determining the number of days medication was available to a patient, divided by the total number of days during the specified time period.<sup>6,7</sup> It calculates adherence better than the medication possession ratio by adjusting for early fills of medication using arrays. A PDC above 0.8 is considered adherent.<sup>7,8</sup> In this study,

medication adherence will be evaluated using the proportion of days covered (PDC) method.<sup>7,8</sup>

In the past two decades, managed care has been proven to be an effective way to reduce costs and improve the efficiency of health service utilization by controlling provider reimbursement rates and reducing unnecessary hospitalizations and emergency department visits.<sup>9</sup> Managed care organizations (MCOs) have a fundamental interest in primary preventative care for long-term cost reduction due to their structure.<sup>9,10</sup> MCOs will assign patients to a primary care physician within the network, and give these providers a capitated payment for each member they enroll.<sup>9,10</sup> In comparison with traditional fee-for-service (FFS), MCOs can limit provider choices for patients, where FFS patients have no restrictions on which providers can be seen.<sup>9</sup> Additionally, in traditional FFS models, the providers are not restricted to the number of services they provide.<sup>9</sup> Not all FFS patients have access to a primary care provider, thereby leading to increased utilization of unnecessary emergency department visits.<sup>10</sup> Patients enrolled in MCO plans are encouraged to have regular physician visits and screenings for early detection and prevention of disease, thereby encouraging better patient health outcomes and more appropriate health care service utilization.<sup>9,10</sup>

Medicaid managed care has improved the ability of Medicaid programs to obtain better value for their expenditures, while improving provider accessibility and accountability,<sup>11</sup> but little data is available regarding quality of care in this patient population. A case study comparing capitated MCO reimbursement and FFS reimbursement found that for-profit capitation models were more cost-effective than FFS models for Medicaid patients with severe mental illness.<sup>12</sup> Previous studies of shifts to

capitated managed care in commercial insurance and Medicare populations suggest that a shift from FFS to MCO reimbursement did not fundamentally change the patterns or quality of care delivered.<sup>13</sup> A study examining health outcomes for patients with congestive heart failure showed that there was no significant difference in outcomes and quality of care between patients with FFS-based insurance and patients with MCO-based insurance through a health maintenance organization.<sup>14</sup> Finally, results from one study of a Medicare MCO in Pennsylvania showed that patients receiving a common therapeutic procedure for the treatment of coronary artery disease had a clinically meaningful long-term survival benefit in comparison with their FFS counterparts.<sup>15</sup>

The National Committee for Quality Assurance (NCQA) provides accreditation measures for health plans and is widely accepted as an important industry standard.<sup>16</sup> As commercial and government-based payers have become increasingly interested in value, MCOs are held accountable for quality and cost.<sup>16</sup> NCQA developed the Healthcare Effectiveness Data and Information Set (HEDIS) to provide tangible, actionable quality measures.<sup>16,17</sup> By 2012, such measures included improving control of blood pressure, cholesterol management in patients with cardiovascular conditions, and comprehensive diabetes care.<sup>17</sup> Within these measures, adherence to prescribed medication therapy is encouraged.<sup>17</sup> In November 2011, the state of Kentucky implemented a policy to change its Medicaid infrastructure from fee-for-service reimbursement to managed care, in hopes of improving the health of its Medicaid patients while lowering costs.<sup>18</sup> The purpose of this study was to compare patient medication adherence before and after the implementation of capitated managed care for Medicaid patients in Kentucky with prevalent chronic diseases, including hypertension, hypercholesterolemia, and type 2

diabetes. Additionally, this study will be used to inform policy makers of the efficacy of the current Medicaid program in improving medication adherence, and its potential to improve patient health outcomes.

## Section Two: Methods

### *Overview:*

The study took advantage of a natural experiment due to a policy change in the Kentucky Medicaid program. We conducted a retrospective study using a pre-policy and post-policy treatment and comparison group, and quasi-experimental design to estimate the effect of the switch from Medicaid FFS to managed care. We compared adherence rates for populations of Medicaid patients age 18-64 with hypertension, hypercholesterolemia, and/or type 2 diabetes who were insured by FFS and were switched to one of three new MCOs. Only one Medicaid MCO (Region 3) (Appendix A) existed prior to November 2011, and patients from this MCO were used as a control population to account for historic trends.<sup>18</sup> We hypothesized that the implementation of Medicaid managed care would improve overall adherence rates to medications indicated for prevalent chronic diseases, adjusting for other factors.

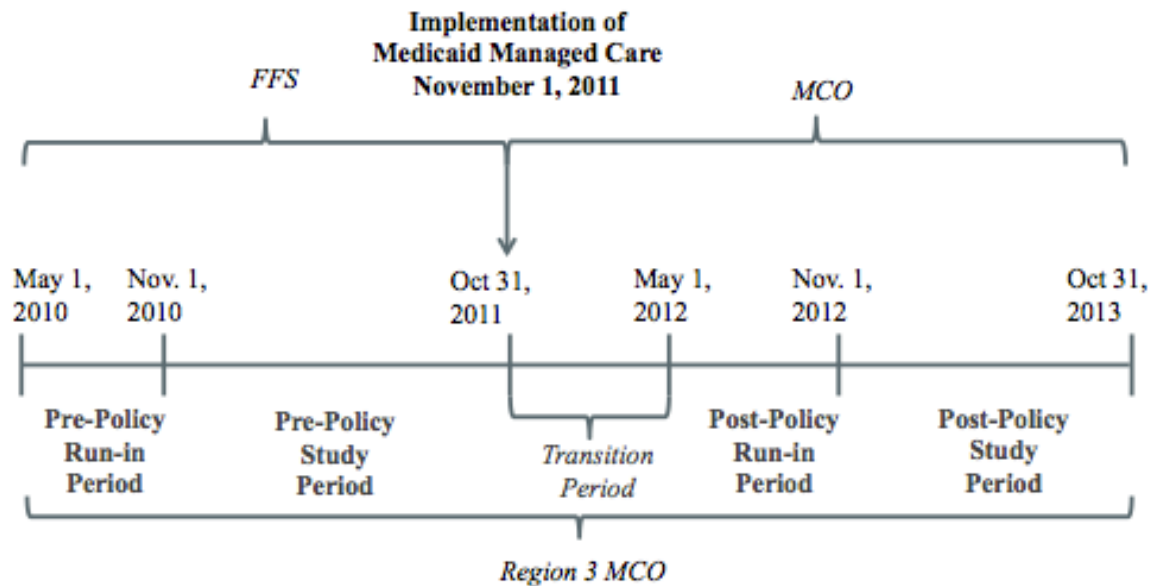
### *Sample Selection:*

The study sample was drawn from patients in Kentucky receiving medical care through Kentucky Medicaid Services during the years 2010 through 2013. Patient demographics, eligibility, and medication claims were obtained from the Kentucky Medicaid administrative claims dataset. The sample was divided into four groups: the pre-policy treatment group, the post-policy treatment group, the pre-policy control group, and the post-policy control group. The treatment group represents Kentucky Medicaid patients enrolled in FFS before the policy, and patients enrolled in a MCO after the policy. The control group represents patients in the Region 3 MCO before and after the policy. The time between November 1, 2010 and October 31, 2011 is defined as the pre-

policy study period. The time between November 1, 2012 and October 31, 2013 is defined as the post-policy study period. The 6 months prior to each study period were considered the run-in periods for determining prevalent users of medications to ensure treatment was initiated prior to the pre-policy and post-policy study periods. This allows for an accurate adherence calculation. These time periods were chosen based on data availability, and to allow time for transition after the policy implementation.

In order to be included in the study, patients had to be continuously eligible for Medicaid benefits from May 1, 2010 through October 31, 2011 and/or from May 1, 2012 through October 31, 2013. Next, patients had to have a diagnosis of hypertension (ICD-9 codes 401.1 or 401.9), hypercholesterolemia (ICD-9 code 272.x), and/or type 2 diabetes (ICD-9 codes 250.x0 and 250.x2) (Appendix B), AND have at least one claim for a first-line prescription medication (Appendix C) indicated for the treatment of their specific chronic disease during either of the run-in periods. The inclusion of diagnosis codes is intended to validate the use of each medication for the indicated disease. Then, for the corresponding pre- or post-policy study period, patients had to have at least one claim for a first-line prescription medication indicated for the treatment of their specific chronic disease. Finally, patients had to be between the ages of 18 and 64 to eliminate dual eligible patients and pediatric patients. Patients in the post-policy study period were excluded if they were not assigned to a managed care organization (i.e. the disabled and those in waiver programs) or if they were not in the existing Region 3 MCO. Figure 2.1 depicts the timeline for sample selection and eligibility requirements. Figure 3.1 is a flow diagram of the study population specification.

Figure 2.1: Timeline for Sample Selection and Eligibility Requirements



#### *Dependent Variables:*

We evaluated medication adherence using the proportion of days covered (PDC) method. The dependent variable can either be continuous or dichotomous, where patients are adherent if they have a PDC above 0.8. In this study, PDC was measured as a continuous variable for increased statistical power. In subsequent studies, PDC will be a dichotomous variable, and the proportion of adherent patients will be determined. The PDC was calculated separately for each patient in the four included groups: the pre-policy treatment group, the post-policy treatment group, the pre-policy control group, and the post-policy control group. Medication claims for the included medication classes were identified using their generic product identifiers (GPI) (Appendix C). Each patient's PDC calculation used all claims for a single medication class as identified by the first 2-4 numbers in the GPI. Therefore, if patients were switched to another medication in the same medication class during the study period, their adherence calculation would account for this change in therapy. For patients who had claims for more than one medication



class in the same study period, they would have several different PDC calculations. These PDCs were averaged to determine the average PDC per patient. Therefore, for the analyses in this study, either average PDC per patient or PDC per medication class per patient could be used as the dependent variable of interest.

#### *Independent Variables:*

The independent variables included in the study were demographic, economic, and health-related. The primary independent variable of interest was an indicator variable determined by whether the individuals were assigned to any managed care organization in November 2011 (post-policy treatment group). Patients enrolled in the Region 3 MCO served as a managed care control population. The control variables included age (continuous variable), gender (dichotomous variable), ethnicity (two dichotomous variables describing the two most prevalent populations), and medication class (categorical variable) (Appendix D). The medication classes included in the study were ACE inhibitors, angiotensin II receptor blockers, beta-blockers, calcium channel blockers, thiazide diuretics, antihypertensive combination products, HMG-CoA reductase inhibitors (statins), and biguanides (metformin) (Appendix B). These medications were included as they were considered first line therapies based on the guidelines active during the time of the study, specifically JNC 7 for hypertension, the 2002 NCEP guidelines for high blood cholesterol, and the 2009 AACE/ACE guidelines for type 2 diabetes.<sup>19,20,21</sup>

#### *Statistical Analysis:*

Descriptive statistics of the adherence measures and control variables, including patient demographics and medication class, for each of the four study groups were determined. The demographic data were determined per patient. The adherence statistic

was calculated as the average PDC per person, and summary statistics for adherence were then calculated in each group. Therefore, mean average PDC is the average of each patient's average PDC in that group. Median average PDC is the middle average PDC calculation for that group. The medication class statistics represent the number of patients receiving each medication class. Several patients took medicines in more than one of these medication classes, so the determined frequencies were greater than the sample size.

Bivariable analyses used non-parametric testing strategies, such as the Wilcoxon Sign-Rank test, the Kruskal-Wallis test, and generalized linear regression to measure the effect of each variable on the change in adherence as a result of the switch from FFS to managed care. The multivariable analysis was conducted as a difference-in-difference model, where the dependent variable of adherence measures the effect of the policy change, or the pre and post average differences in adherence between the treatment and control groups (Appendix D). A difference-in-difference model is a multivariable generalized least squares regression model where an interaction term between the pre-versus post-policy period and the treatment versus control group is the covariate of interest, as this represents the true effect of the policy. The interaction captures the overall effect on the post-policy treatment group. Sensitivity analyses considered the removal of outliers, interaction terms, and transformations to the non-parametric data to determine the robustness of results. The final model represents the multivariate model with the largest explanation of variation in the outcome. We considered P values  $< 0.05$  to be statistically significant. This data for this study represent proprietary information used for research by the Institute for Pharmaceutical Outcomes and Policy at the

University of Kentucky. This study was reviewed and approved by the University of Kentucky Health System's Institutional Review Board. Data analysis was completed using SAS Version 9.4.

### Section Three: Results

#### *Characteristics of the Study Population:*

Figure 3.1 depicts the study population obtained from the Kentucky Medicaid administrative claims dataset. The final treatment group included 41,683 patients, with 22,267 patients in the pre-policy treatment group receiving FFS Medicaid, and 19,416 patients in the post-policy treatment group receiving MCO Medicaid. The final control group included 5,373 patients, with 2,531 patients in the pre-policy control group, and 2,842 patients in the post-policy control group, all receiving MCO Medicaid in Region 3 in Kentucky.

Figure 3.1: Flow Diagram of Study Population Specification

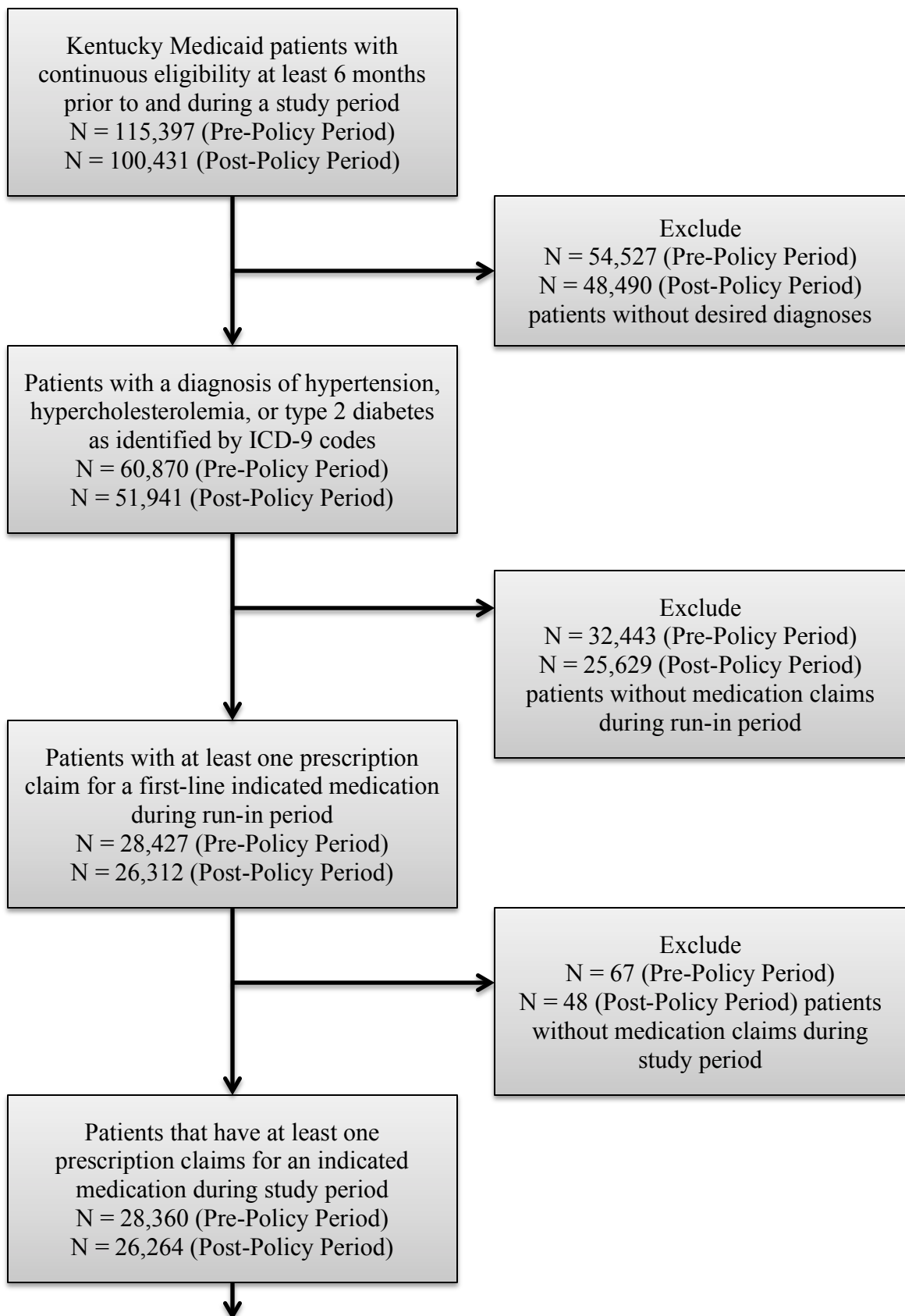
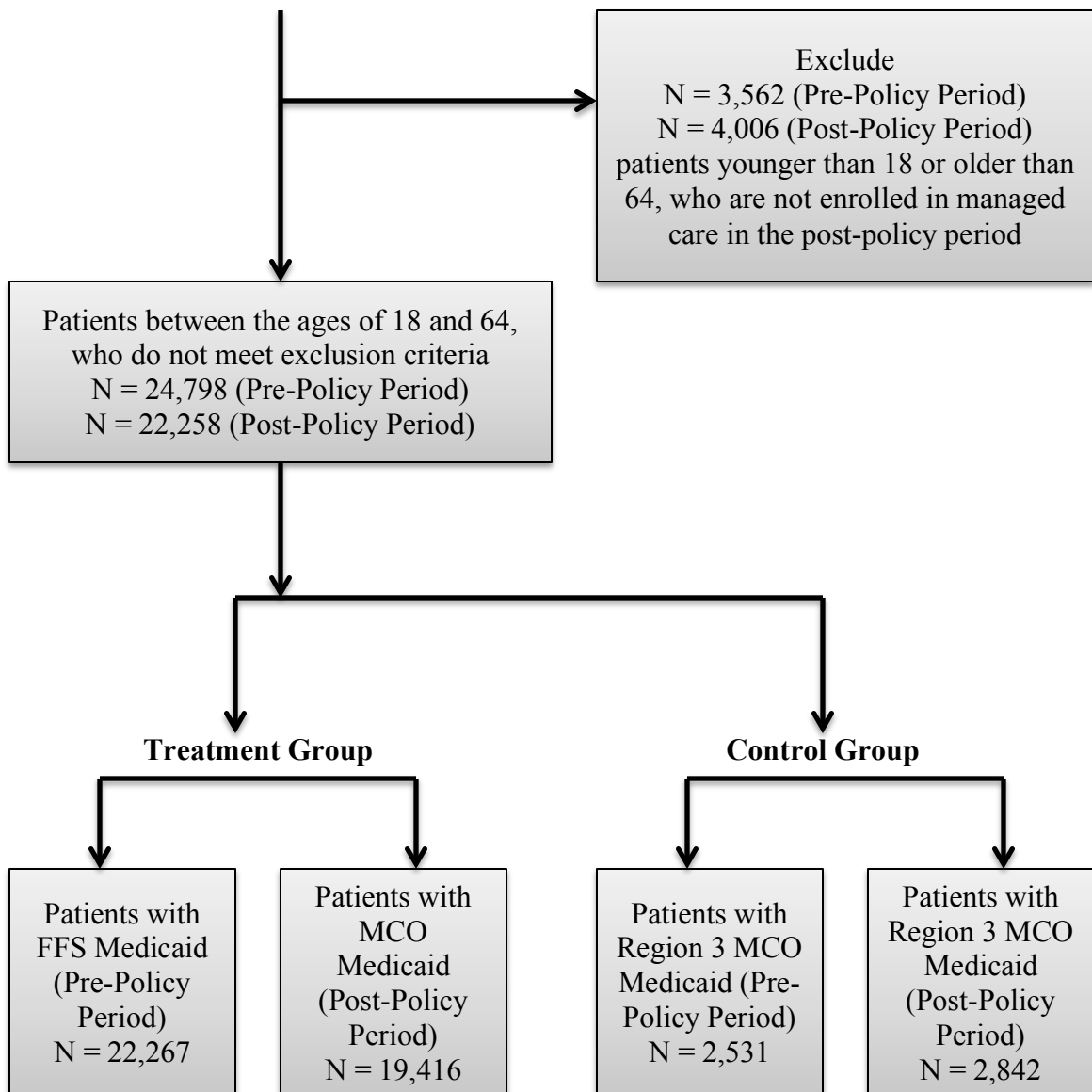


Figure 3.1: Flow Diagram of Study Population Specification (continued)



*Descriptive Statistics:*

Table 3.1 provides descriptive statistics of the treatment and control groups, in the pre-policy and post-policy study periods, separated into four groups. The average age in the sample was around 50 years old, with a median of 52 years. This was consistent among each of the treatment and control groups. The proportion of male patients was balanced in each group, with around 33% of the groups being male. The ethnicity variables are the only unbalanced demographic variables in Table 3.1. There were a significantly larger proportion of black patients in the control group versus the treatment group. The percentage of each medication class represented was variable among the four groups. Most patients were taking either ACE inhibitors or angiotensin II receptor blockers (around 40-57%), with beta-blockers making up the next most frequently used medication class (around 38-51%). The percentage of ACE inhibitors, angiotensin II receptor blockers, and beta-blockers increased in the post-policy period for both the treatment and control groups. The control group was taking slightly less ACE inhibitors and angiotensin II receptor blockers, and slightly more calcium channel blockers than the treatment group. In the post-policy period, the frequency of thiazide diuretics and HMG-CoA reductase inhibitors increased in both the treatment and control groups. Conversely, the frequency of biguanides and antihypertensive combination medications remained the same in the post-policy period in both the treatment and control groups. Non-parametric tests indicated significant differences between each of the covariates by treatment group and by pre- versus post-policy time period ( $p < 0.0001$ ).

Table 3.1: Descriptive Statistics by Treatment versus Control Group, and by Pre- versus Post-Policy Time Period

Variable	FFS → MCO (Treatment Group)		Region 3 MCO (Control Group)	
	<i>Pre-Policy (FFS Medicaid) N = 22,267</i>	<i>Post-Policy (MCO Medicaid) N = 19,416</i>	<i>Pre-Policy N = 2,531</i>	<i>Post-Policy N = 2,842</i>
<b>Average PDC</b>				
Mean (SD)	0.735 (0.24)	0.689 (0.23)	0.726 (0.23)	0.676 (0.22)
Median (LQ, UQ)	0.816 (0.59, 0.93)	0.734 (0.53, 0.89)	0.795 (0.58, 0.92)	0.721 (0.54, 0.85)
(Min, Max)	(0.01, 1)	(0.01, 1)	(0.05, 1)	(0.04, 1)
<b>Age (years)</b>				
Mean (SD)	50.17 (9.40)	49.95 (8.94)	50.78 (9.02)	50.76 (9.02)
Median (LQ, UQ)	52 (45, 58)	51.5 (45, 57)	52 (46, 58)	53 (46, 58)
(Min, Max)	(18, 63)	(18, 63)	(18, 63)	(18, 63)
<b>Males</b>				
Frequency (%)	7,688 (34.5%)	6,746 (34.7%)	831 (32.8%)	889 (31.3%)
<b>Whites</b>				
Frequency (%)	18,215 (81.8%)	15,947 (82.1%)	1,710 (67.6%)	1,830 (64.4%)
<b>Blacks</b>				
Frequency (%)	1,096 (4.9%)	663 (3.4%)	513 (20.3%)	581 (20.4%)
<b>ACE Inhibitors and Angiotensin II Receptor Blockers</b>				
Frequency (%)	9,781 (43.9%)	11,170 (57.5%)	1,002 (39.6%)	1,438 (50.6%)
<b>Beta Blockers</b>				
Frequency (%)	8,851 (39.7%)	9,960 (51.3%)	963 (38.0%)	1,349 (47.5%)
<b>Calcium Channel Blockers</b>				
Frequency (%)	4,235 (19.0%)	5,118 (26.4%)	639 (25.2%)	881 (31.0%)
<b>Thiazide Diuretics</b>				
Frequency (%)	3,069 (13.8%)	4,102 (21.1%)	346 (13.7%)	578 (20.3%)
<b>Antihypertensive Combinations</b>				
Frequency (%)	2,861 (12.8%)	2,637 (13.6%)	327 (12.9%)	385 (13.5%)
<b>HMG-CoA Reductase Inhibitors (Statins)</b>				
Frequency (%)	10,067 (45.2%)	12,216 (62.9%)	1,082 (42.7%)	1,699 (59.8%)
<b>Biguanides (Metformin)</b>				
Frequency (%)	6,957 (31.2%)	5,882 (30.3%)	793 (31.3%)	882 (31.0%)

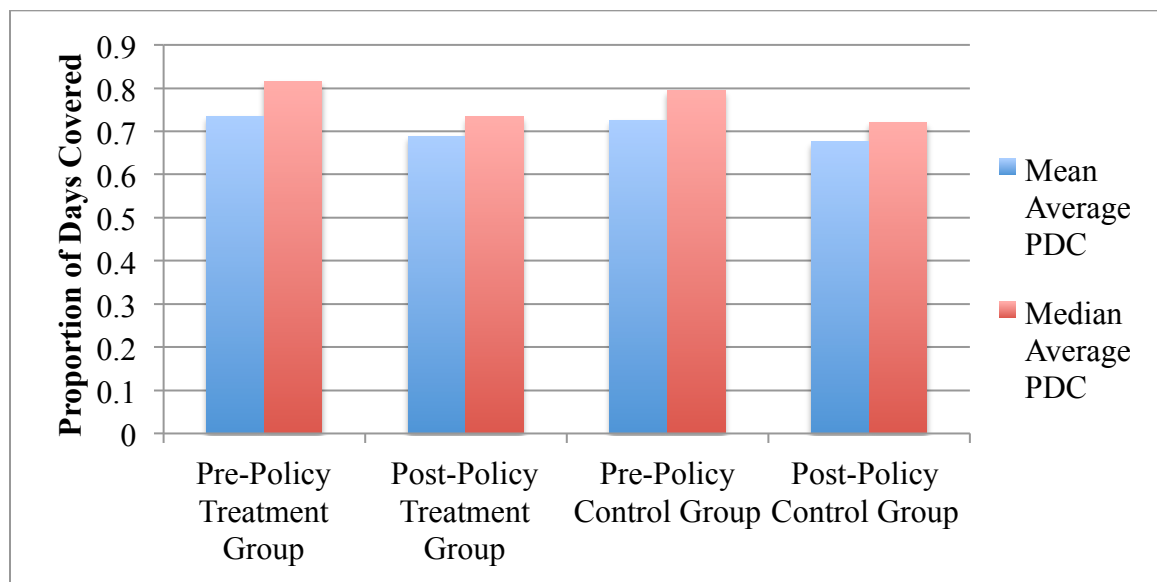
Means and standard deviations (in parentheses) are given for continuous variables, whereas frequencies and percentages (in parentheses) are given for categorical variables.

FFS = Fee-For-Service; MCO = Managed Care Organization; PDC = proportion of days covered



Average PDC values are similar between the pre-policy treatment group and pre-policy control group. In addition, average PDC values are similar between the post-policy treatment group and post-policy control group. However, average PDC values in the pre-policy period are larger in magnitude than in the post-policy period, regardless of treatment or control group. Median values for PDC are also much larger than mean values for PDC in each of the four groups. In addition, the PDC values are nearly all less than 0.8. Figure 3.2 depicts the summary statistics for the adherence rates calculated in this study.

Figure 3.2: Summary Statistics of PDC Values



#### *Bivariable Analyses:*

Tables 3.2 and 3.3 present the bivariable analyses, which allow for the assessment of unadjusted associations between the covariates and adherence rates. Table 3.2 exhibits the bivariable analyses with the average PDC per patient as the outcome of interest. Table 3.3 uses the PDC per medication class for each patient as the outcome of interest, and includes each medication class examined as a dichotomous covariate. Each of the

covariates examined were found to be significantly associated with adherence. PDC is significantly associated with time period, where the post-policy time period experienced a decrease in the average proportion of days covered corresponding to about 17-22 days of therapy. This particular covariate explains a large proportion of the variation in the PDC outcome compared to the other covariates, though still very small. Being switched from a FFS Medicaid plan to a MCO Medicaid plan (being in the treatment group) increases the PDC significantly by about 5 days of therapy.

The other demographic covariates suggest that being older will increase medication adherence, with one additional year leading to one additional day of coverage. Age is another variable that explains a large proportion of the variation in the outcome compared to the other covariates. Being a male increases medication adherence by about 15 days throughout the year, and being white increases medication adherence by about 4 days throughout the year. Alternatively, being black decreases medication adherence by about 11 days in a year. Ethnicity is expected to be a confounding variable because there are a larger proportion of black patients in the control population. Further, to determine if being black and in the control group is different than being black and in the treatment group, an interaction term between being black and being in the treatment group was added to the final model. Additionally, the variable for white was removed in an attempt to consolidate the ethnicity effect into one dichotomous variable. The dichotomous variables for each medication class were almost all significantly associated with adherence, with the exception of the calcium channel blockers. Patients on thiazide diuretics had decreased adherence by about 30 days in a year compared with each of the other medication classes. Patients taking biguanides and antihypertensive combinations

tend to be less adherent than patients using the other medication classes, as well. Patients taking beta-blockers were the most adherent, with about 12 additional days of therapy coverage per year. Overall, none of the covariates are largely important predictors of adherence based on the explanation of variation in the outcome ( $R^2$ ). Therefore, it is likely that the final model will suffer from omitted variable bias.

Table 3.2: Bivariate Analyses with Average PDC Per Patient as the Outcome of Interest (N = 47,056)

<b>Covariate</b>	<b>Estimate</b>	<b>Standard Error</b>	<b>P-Value</b>	<b>R<sup>2</sup></b>
Post-Policy Indicator	-0.04675	0.00219	<0.0001	0.0096
Treatment Group (FFS → MCO)	0.01386	0.00345	<0.0001	0.0003
Age (years)	0.00414	0.00012	<0.0001	0.0255
Male	0.03995	0.00230	<0.0001	0.0064
White	0.00982	0.00275	0.0004	0.0003
Black	-0.02957	0.00459	<0.0001	0.0009

PDC = proportion of days covered; FFS = Fee-For-Service; MCO = Managed Care Organization

Table 3.3: Bivariate Analyses with PDC Per Medication Class Per Patient as the Outcome of Interest (N = 109,170)

<b>Covariate</b>	<b>Estimate</b>	<b>Standard Error</b>	<b>P-Value</b>	<b>R<sup>2</sup></b>
Post-Policy Indicator	-0.05941	0.00166	<0.0001	0.0116
Treatment Group (FFS → MCO)	0.01532	0.00263	<0.0001	0.0003
Age (years)	0.00438	0.00009	<0.0001	0.0193
Male	0.03990	0.00174	<0.0001	0.0048
White	0.01199	0.00206	<0.0001	0.0003
Black	-0.03301	0.00336	<0.0001	0.0009
ACE Inhibitors and Angiotensin II Receptor Blockers	0.01959	0.00203	<0.0001	0.0009
Beta Blockers	0.03310	0.00211	<0.0001	0.0022
Calcium Channel Blockers	0.00507	0.00278	0.0684	0.0000
Thiazide Diuretics	-0.08271	0.00317	<0.0001	0.0062
Antihypertensive Combinations	-0.01296	0.00360	0.0003	0.0001
HMG-CoA Reductase Inhibitors (Statins)	0.01489	0.00198	<0.0001	0.0005
Biguanides (Metformin)	-0.04476	0.00245	<0.0001	0.0030

PDC = proportion of days covered; FFS = Fee-For-Service; MCO = Managed Care Organization

#### *Multivariable Analyses:*

Tables 3.4 and 3.5 present the results from the final multivariate models. The multivariate model in Table 3.4 uses average PDC per patient as the outcome of interest, and the multivariate model in Table 3.5 uses PDC per medication class per patient as the outcome of interest. For each model, the overall R<sup>2</sup>, or explanation of variation in the outcome, was about 0.04 (4%). Therefore, neither model explains a large proportion of the variation in the adherence outcome of interest. Again, the variable for being in the post-policy period regardless of treatment or control group was significantly associated with a decrease in medication adherence by about 17 to 22 days of therapy per year, other

factors held constant. In the multivariate model, the variable for being in the treatment group is not significantly associated with adherence, nor is the primary outcome of interest of being in the post-policy period and being in the treatment group. Each of the remaining covariates and interaction terms are significantly associated with adherence. Being one year older leads to an increase in medication adherence by 1 to 2 days per year, and being male increases medication adherence by about 13 days per year, other factors held constant. Being black decreases medication adherence by about 15 days per year, on average, if you are in the control population. Being black and being in the treatment population leads to a decrease in medication adherence by about 8 days per year, instead. Therefore, the existing managed care organization in Region 3 has lower medication adherence rates among its black members compared to other black patients in the state Medicaid system.

Each of the effects of the medication classes examined in Table 3.5 was done in comparison to biguanide use. Only patients taking thiazide diuretics had lower adherence rates than patients taking biguanides, other factors held constant. Patients taking thiazide diuretics had on average about 10 fewer days of coverage than patients taking biguanides. Patients taking beta-blockers had the highest adherence rates, with about 24 days of additional therapy compared with those taking biguanides, other factors held constant. Patients taking ACE inhibitors and angiotensin II receptor blockers had the next highest adherence rates, with about 20 days of additional therapy compared to patients taking biguanides, other factors held constant. Patients taking HMG-CoA reductase inhibitors, calcium channel blockers, and antihypertensive combination medications had about 18,

15, and 10 days of additional therapy respectively compared to patients taking biguanides, other factors held constant.

Table 3.4: Difference-In-Difference Analysis with Average PDC Per Patient as the Outcome of Interest (N=47,056)

<b>Covariate</b>	<b>Estimate</b>	<b>Standard Error</b>	<b>P-Value</b>
Intercept	0.51392	0.00773	<0.0001
Post-Policy Indicator	-0.04862	0.00637	<0.0001
Treatment Group (FFS → MCO)	0.00309	0.00512	0.5488
Interaction (Post-Policy Indicator * Treatment Group)	0.00304	0.00677	0.6536
Age (years)	0.00410	0.00012	<0.0001
Male	0.03818	0.00226	<0.0001
Black	-0.04428	0.00789	<0.0001
Interaction (Black * Treatment Group)	0.02448	0.00972	0.0118

PDC = proportion of days covered; FFS = Fee-For-Service; MCO = Managed Care Organization

Table 3.5: Difference-In-Difference Analysis with PDC Per Medication Class Per Patient as the Outcome of Interest (N=109,170)

<b>Covariate</b>	<b>Estimate</b>	<b>Standard Error</b>	<b>P-Value</b>
Intercept	0.47322	0.00656	<0.0001
Post-Policy Indicator	-0.06037	0.00491	<0.0001
Treatment Group (FFS → MCO)	0.00435	0.00416	0.2952
Interaction (Post-Policy Indicator * Treatment Group)	0.0015	0.00521	0.7664
Age (years)	0.00423	0.00009	<0.0001
Male	0.03545	0.00170	<0.0001
Black	-0.04128	0.00582	<0.0001
Interaction (Black * Treatment Group)	0.01936	0.00714	0.0067
Medication Class:			
ACE/ARB	0.05582	0.00285	<0.0001
BB	0.06661	0.00291	<0.0001
CCB	0.04199	0.00342	<0.0001
Diuretic	-0.02837	0.00374	<0.0001
Combo	0.02755	0.00408	<0.0001
Statin	0.05015	0.00281	<0.0001
Metformin	<i>reference</i>	<i>reference</i>	<i>reference</i>

PDC = proportion of days covered; FFS = Fee-For-Service; MCO = Managed Care Organization; ACE/ARB = ACE Inhibitors and Angiotensin II Receptor Blockers; BB = Beta Blockers; CCB = Calcium Channel Blockers; Diuretic = Thiazide Diuretics; Combo = Antihypertensive Combinations; Statin = HMG-CoA Reductase Inhibitors (Statins); Metformin = Biguanides (Metformin)

#### Section Four: Discussion

To our knowledge, this is the first study that uses medication adherence to examine the effect of the switch from Medicaid fee-for-service to managed care in Kentucky. This study design was a basic evaluation of the immediate effects of the policy implementation. It gives policy makers a basic understanding of the success or failure of the Medicaid managed care program after its first year, and allows them to make decisions regarding managed care as a viable option for Medicaid patients in Kentucky.

Descriptive statistics show consistency with the expected demographics of a Medicaid population. There is a larger proportion of female members, and Medicaid generally enrolls more women of childbearing age than any other demographic group.<sup>22</sup> The control group for this study was located in an urban area in Kentucky, and the variable for ethnicity is consistent with the racial population in this area.<sup>18</sup> Additionally, utilization of certain medication classes were expected, as well. The hypertension treatment guidelines recommend initiating ACE inhibitors and angiotensin II receptor blockers in white patients due to a more active renin-angiotensin system, and recommend calcium channel blockers in black patients due to their less active renin-angiotensin system.<sup>19</sup> Therefore, the frequencies presented are consistent with the hypertension treatment guidelines based on the primary ethnicities in each group. The summary statistics of the average PDC variable indicate that most patients have relatively good adherence, but there are significant number of patients with very low adherence who pull the mean PDC toward zero. Therefore, the distribution is heavy tailed, or negatively skewed, indicating a non-parametric distribution. The PDC values presented in Table 3.1 are nearly all less than 0.8, meaning the average adherence rates for the patients in the



study is less than the optimal adherence rate for these chronic medications. This is consistent with other studies examining adherence.<sup>1,2,4</sup> The large sample size in this study allowed for significant non-parametric tests for differences in the baseline characteristics among the four groups.

The demographic variables and medication variables were all significantly associated with adherence rates. This information can be leveraged to target populations at greater risk of having poor adherence. Most specifically, the black population in an urban setting, where managed care has been around since 1997, will take 15 days fewer medication compared with other Medicaid patients. Because this is an urban setting, access to care is not likely the cause of non-adherence. This particular MCO should recognize the importance of targeting these members in hopes to increase adherence and decrease disease-related complications. Males in the Kentucky Medicaid program make up about one-third of the overall population, but they are taking their medicine 13 more days each year than the females. Because females are a large proportion of the Medicaid population, they represent a large target for adherence improvement. Finally, patients who are taking thiazide diuretics, biguanides, and/or antihypertensive combination medications are at greatest risk of having poor adherence rates. Antihypertensive combination medications are already a useful tool in encouraging adherence because they decrease pill burden. Therefore, they represent a particularly difficult group of patients, and arguably the most at risk for developing disease-related complications. Patients taking biguanides usually have a large pill burden, due to both the size of the medication and the frequency at which it is taken.<sup>23</sup> There are extended-release formulations available that decrease this pill burden and may help improve adherence. Those patients

taking thiazide diuretics have the lowest adherence rates, and it is possibly due to either the adverse effects of the medicine (frequent urination), or possibly because their provider recommended they use it as needed.<sup>23</sup> Technically, the as-needed use of thiazide diuretics is off-label,<sup>23</sup> but not uncommon. Educational outreach programs, medication therapy management services, and provider visits are great ways to encourage each of these populations to become more adherent to their long-term medication therapy.

Multivariable data analyses indicate a decrease in PDC between 0.049 and 0.06 (17 to 22 fewer days of therapy coverage) after the implementation of Medicaid managed care in Kentucky, regardless of reimbursement model, controlling for other factors. When comparing those who were impacted by the policy (treatment group) to those who were not (control group), there was no significant difference in the average adherence rates, other factors held constant. Therefore, at this time, there is clinically inconclusive evidence regarding the effect of the implementation of Medicaid managed care in Kentucky. There is, however, a need to improve medication adherence among the Kentucky Medicaid population. Overall, the state Medicaid program can use the results of this study as evidence that additional work needs to be done to improve patient outcomes in the Medicaid population.

It is arguable that this study suggests that medication persistence is a widespread issue, as well. Medication persistence is defined as the duration of time from initiation to discontinuation of therapy.<sup>8</sup> This study attempted to control for persistence by obtaining two separate sample populations of prevalent users in the pre-policy study period and the post-policy study period. However, many of the patients in the pre-policy study period were also included in the post-policy study period. It is possible that a lower adherence

rate in the post-policy study period is related to time to discontinuation of therapy, potentially for a legitimate reason that is not documentable in the administrative claims dataset. A sensitivity analysis of the data examined the effect of the policy after removing outliers. Outliers were considered to be data points two standard deviations away from the mean. Several data points from the heavy tail were removed as a result, but the data remained non-parametric. Analyses did not lead to any additional explanation of variation in the outcome, so the final model included all the data points. Interestingly, this analysis led to a significant effect for the interaction between the post-policy study period and the treatment group. Adherence rates for those impacted by the policy increased by 3-4 days of therapy coverage per year, other factors held constant. Clinically, it is difficult to determine whether 3-4 days of therapy per year will significantly change patient outcomes. Therefore, additional studies should examine rates of complications as a result of missed therapy. Additional sensitivity analyses examined transformations of the data in an attempt to remove skewness and provide a true linear model to better determine the effect of the covariates on adherence. A quadratic transformed model decreased skewness and kurtosis in the data, but the final model is not transformed as this model still explained the greatest amount of variation in the outcome.

*Study Strengths and Limitations:*

This is the first study to explore the impact of reimbursement models on quality of care in a large population and with a long-term outcome. As previously mentioned, most research in this area has been focused on short-term outcomes, within a year of a policy change. This study looks beyond a year after the policy implementation, and allows time for providers to transition into the new practice model. Additional strengths of this study

include the natural quasi-experimental design and the large sample size, which provides large power for making statistical inferences. The use of a Medicaid population minimizes misclassification of exposure when using administrative claims to determine patient outcomes. The Kentucky Medicaid benefit allows for no copay for generic products in the medication classes included in this study. Therefore, most patients who receive these medications will use their benefit consistently, allowing for accurate capture of claims data.

This study has numerous limitations alongside its strengths. As with any observational study using administrative claims data, adherence calculations do not actually predict whether or not a patient is taking their medication. Instead, claims data just predicts whether or not a patient has medication available to them. If a patient is consistently filling their medication at the pharmacy, then it is presumed that true adherence approaches the adherence rate calculated from the claims data. Another downfall of claims data is the inability to capture primary non-adherence, where a patient fails to ever have a prescription filled. The inclusion criteria for this study required that patients have a diagnosis code, at least one claim for a medication in the run-in period, and at least one claim for a medication in the study period of interest. Therefore, patients who never fill their medication are excluded from the study.

The determination of the adherence measure is also prone to potential bias. The calculation was based on the medication generic product identifier (GPI) code. Any medications that fall within the same GPI code based on the first 2 to 4 digits in the code were considered therapeutically equivalent. Therefore, if a patient were to switch to a medication in the same class based on GPI, then this therapy switch would be accounted

for. However, if a patient switched to a new medication in a different medication class, then this switch is not accounted for. This consideration applies to switches among the medication classes indicated for hypertension, and medication classes outside those included in this study. Patients that are impacted by this issue are more likely to have very small adherence rates. The use of the average PDC was intended to eliminate some of this effect. Sensitivity analyses considered removal of outliers to reduce the impact of potential switched therapy, but instead led to a reduction in the explanation of variation in adherence rate, so these values remained in the model. Finally, the calculation of adherence is based on the days supply value recorded in the database. For the post-policy study period, in both the treatment and control groups, several missing days supply values had to be imputed. These were imputed to 30 days, which was the most common days supply recorded in the dataset. This imputation could be a cause of the primary difference in adherence between the pre- and post-policy periods.

Other limitations of this study include the control population, the generalizability of the study, the use of both diagnosis codes and medication claims, and the limited data available in the post-policy study period. First, the control population was small with varying demographic and medication-related variables, and not necessarily the best for comparisons to determine the true impact of the policy. The expected effect was that adherence in the control population would be higher in the pre-policy study period, but similar to the treatment population in the post-policy study period. Instead, the control population had generally lower adherence rates than the treatment population throughout the study. An alternative control population would be a state close to the state of Kentucky that implemented Medicaid managed care before Kentucky, or continues to

have a fee-for-service structure. This would allow for a larger sample size to strengthen comparisons. The Medicaid structure and population in Kentucky is not necessarily the same as that of other states. Therefore, a new control population would have additional covariates to consider. Similarly, the results of this study do not imply that Medicaid managed care is unsuccessful in improving patient health outcomes.

Using both diagnosis codes and medication claims as inclusion criteria can limit the number of patients included in the study. This was intended to reduce misclassification of exposure to the medication if the diagnosis for use is not of interest. For example, especially because women of childbearing age are a large proportion of the Medicaid population, claims for metformin may be for polycystic ovarian syndrome (PCOS) and not type 2 diabetes, as desired. Future studies will test these inclusion criteria by including patients with either a diagnosis or a medication claim to determine if results are robust. While the follow-up time is a benefit of this study, improvement in adherence rates may be an even longer-term outcome, requiring 5 or 10 years of data beyond the policy change to determine its true effect. As we continue to obtain data from the Kentucky Medicaid dataset, we will continue to test this outcome to determine if adherence rates improve in the future.

#### *Future Directions:*

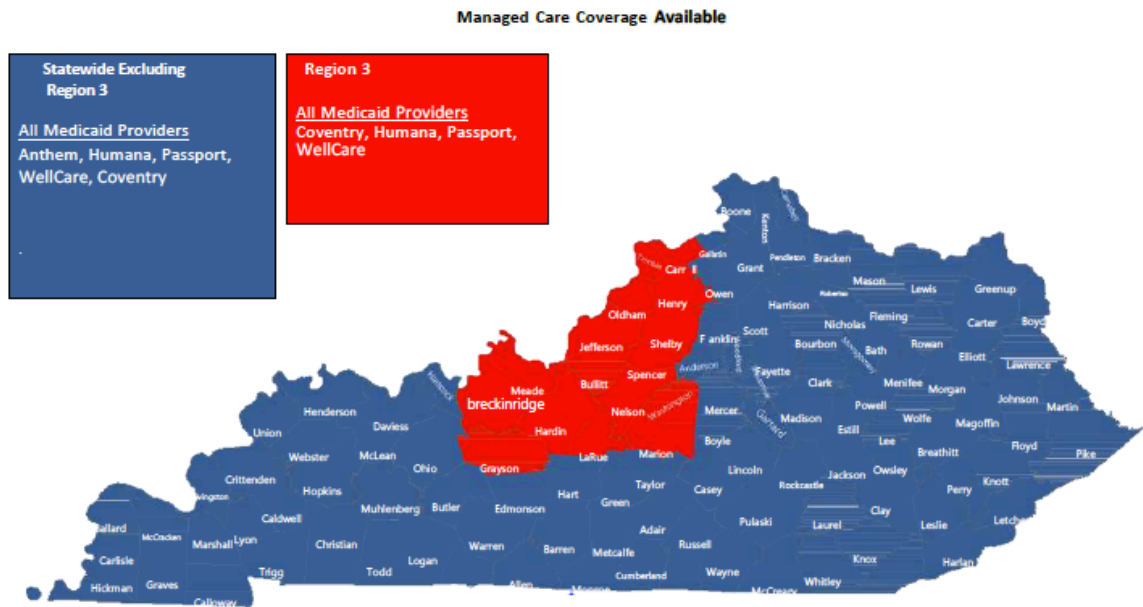
Subsequent analyses will first examine PDC as a categorical variable to determine the change in the percentage of adherent patients in each population. Additionally, subsequent analyses will attempt to define a cohort of patients in both the treatment and control groups that meet the inclusion criteria in both the pre-policy and post-policy time periods. Further studies will examine alternative inclusion criteria, and alternative long-

term outcomes related to these prevalent chronic disease states, such as hospitalizations and mortality rates. These outcomes can be compared to the cost of care under a managed care organization model versus a fee-for-service model to determine cost-efficacy. As discussed, additional follow-up time may be required to determine the true impact of the policy, as changes in adherence rates may not have a clinically significant effect for several years after such a policy change.

*Conclusions:*

Results indicate clinically inconclusive evidence regarding the immediate effect of the implementation of Medicaid managed care in Kentucky on medication adherence rates in patients with prevalent chronic diseases. There is a need to address the decline in average adherence rates, and the efficacy of Medicaid managed care based on medication adherence.

## Appendix A: Kentucky Medicaid Regions of Coverage



This map is a representation of Medicaid coverage in 2016. Prior to the implementation of Medicaid managed care in November 2011, only Region 3 (red) had an available Medicaid managed care plan: Passport Health. The statewide area excluding Region 3 (blue) was entirely fee-for-service reimbursement.

*Photo Credit:* Kentucky Cabinet for Health and Family Services: Department for Medicaid Services: Medicaid Member Managed Care Organization Option Information



Appendix B: ICD-9 Diagnosis Codes for Hypertension, Hypercholesterolemia, and Type 2 Diabetes

<b>Prevalent Chronic Disease</b>	<b>ICD-9-CM Diagnosis Codes</b>
Hypertension	401.1, 401.9
Hypercholesterolemia	272.0, 272.1, 272.2, 272.3, 272.4
Type 2 Diabetes	250.00, 250.02, 250.10, 250.12, 250.20, 250.22, 250.30, 250.32, 250.40, 250.42, 250.50, 250.52, 250.60, 250.62, 250.70, 250.72, 250.80, 250.82, 250.90, 250.92

Appendix C: Medication Classes and GPI Codes Indicated First-Line for Hypertension, Hypercholesterolemia, and Type 2 Diabetes

<b>Prevalent Chronic Disease</b>	<b>Medication Class</b>	<b>GPI Code</b>
Hypertension	ACE inhibitors and angiotensin II receptor blockers	361xxxxxxx
	Beta-blockers	33xxxxxxx
	Calcium channel blockers	34xxxxxxx
	Thiazide diuretics	376xxxxxxx
	Antihypertensive combination medications	369xxxxxxx
Hypercholesterolemia	HMG-CoA reductase inhibitors (statins)	39xxxxxxx
Type 2 Diabetes	Biguanides (metformin)	2725xxxxxx

## Appendix D: List of Variables, Model Specification, and Graphical Representation of the Expected Difference-In-Difference Model

**Final Model:**  $Y_i = \beta_0 + \beta_1 I_i(\text{Post-Policy Indicator}) + \beta_2 I_i(\text{Treatment Group}) + \beta_3 I_i(\text{Post-Policy Indicator} * \text{Treatment Group}) + \beta_4 \text{Age}_i + \beta_5 I_i(\text{Male}) + \beta_6 I_i(\text{Black}) + \beta_7 I_i(\text{Black} * \text{Treatment Group}) + \beta_8 I_i(\text{Medication Class: ACE inhibitors and angiotensin II receptor blockers}) + \beta_9 I_i(\text{Medication Class: beta-blockers}) + \beta_{10} I_i(\text{Medication Class: calcium channel blockers}) + \beta_{11} I_i(\text{Medication Class: thiazide diuretics}) + \beta_{12} I_i(\text{Medication Class: antihypertensive combination medications}) + \beta_{13} I_i(\text{Medication Class: HMG-CoA reductase inhibitors}) + \varepsilon_i$

Here are the statistical null and alternative hypotheses of primary interest:  $H_0: \beta_3 = 0$   
 $H_1: \beta_3 \neq 0$

Specifically, the null hypothesis is that the policy implementing Medicaid managed care has no impact on adherence rates in the treatment group. The alternative hypothesis is that the policy implementing Medicaid managed care impacts adherence rates in the treatment group.

$Y_i$  is the primary outcome of interest, or adherence as measured by the proportion of days covered (PDC). PDC is in the final model shown above represents the PDC per medication class per patient.

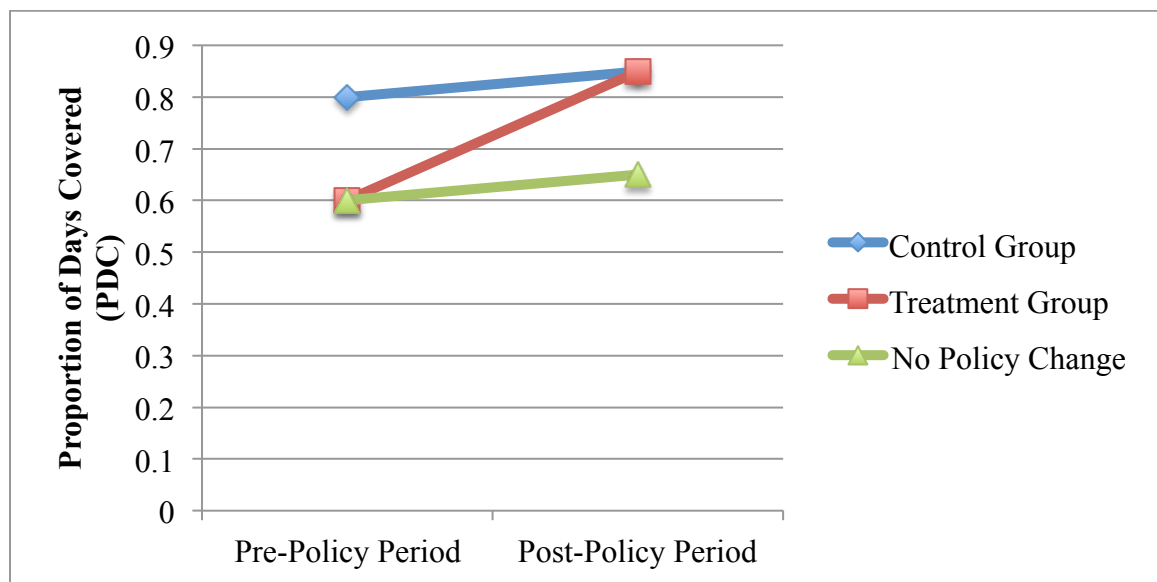
### Covariates used in the Final Model:

1. Post-Policy Indicator → dichotomous variable where patients in the post-policy period = 1, and patients in the pre-policy time period = 0.
2. Treatment Group → dichotomous variable where patients impacted by the policy (FFS → MCO) = 1, and patients in the Region 3 MCO = 0.
3. Post-Policy Indicator \* Treatment Group → interaction term where patients in the post-policy treatment group = 1, and patients in all other groups = 0.
4. Age → continuous variable representing patient age in years
5. Male → dichotomous variable where male patients = 1, and female patients = 0.
6. Black → dichotomous variable where black patients = 1, and all other races = 0.
7. Black \* Treatment Group → interaction term where black patients in the treatment group only = 1, and all other patients = 0.
8. Medication Class: ACE inhibitors and angiotensin II receptor blockers → patients with medication claims for ACE inhibitors and angiotensin II receptor blockers
9. Medication Class: beta-blockers → patients with medication claims for beta-blockers
10. Medication Class: calcium channel blockers → patients with medication claims for calcium channel blockers
11. Medication Class: thiazide diuretics → patients with medication claims for thiazide diuretics
12. Medication Class: antihypertensive combination medications → patients with medication claims for antihypertensive combination medications
13. Medication Class: HMG-CoA reductase inhibitors → patients with medication claims for HMG-CoA reductase inhibitors

**Covariates not used in the Final Model:**

1. White → dichotomous variable where white patients = 1, and all other races = 0.
2. Medication Class: Biguanides → patients with medication claims for biguanides (used as the reference population in the final model).

$\varepsilon_i$  represents the error term, or the leftover variation in the response variable ( $Y_i$ ) that the explanatory variables in the model cannot explain. More specifically, it is the difference in the observed and predicted response of adherence to the policy implementation.

**Graphical Representation of Expected Difference-In-Difference Model:**

Control Group: Expected change in adherence for the Region 3 MCO

- The expected change in adherence is a slight increase for this managed care population with good baseline adherence rates

Treatment Group: Expected change in adherence for those impacted by the policy

- The expected change in adherence is a significant increase for patients who were receiving FFS in the pre-policy period, and are now receiving managed care in the post-policy period.

No Policy Change: Expected change in adherence rates if no policy was implemented

- The expected change in adherence is a slight increase for this fee-for-service population with poor baseline adherence rates

The difference-in-difference model will determine the true change in adherence rates for the treatment group while accounting for changes in adherence that happen naturally after a fixed period of time, as represented by the control group. It is expected that the policy change will increase adherence rates to near that of the control group for this study.

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