Effects of Coverage on Antipsychotic Utilization among Medicare Part D Beneficiaries with Schizophrenia and Bipolar Disorders in Washington State

By

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ABSTRACT

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Medicare Part D is health insurance for people who are either disabled or over 65 years old or suffer from End Stage Renal Disease. It provides coverage for outpatient prescription drugs and is a departure from the traditional Medicare program in which the benefits are uniform. Coverage has a minimum drug formulary packaged in standard plans or actuarially equivalent plans that offers varying additional benefits.

Objective: (1) to examine the effects of coverage on utilization of select antipsychotic drugs: olanzapine, quetiapine, risperidone, and haloperidol, (2) to understand out-of-pocket expenditure patterns among beneficiaries with schizophrenic and bipolar disorders in Washington State. Design: a descriptive and analytical cross-sectional, retrospective study design that used 2008 Part D Event data (1922 unique individuals). Measurements: utilization of four antipsychotics (in number of claims and medication adherence measured in Proportion of Days Covered) and out-of-pocket expenditures before the gap-in-coverage period (pre-ICL), during the gap-in-coverage period (ICL), and post gap-in-coverage period (post-ICL). Results: Beneficiaries who experienced all three benefit phases (i.e. pre-ICL, ICL, and post-ICL) comprised a very small percentage, 1.36 percent, of the study population and generated only 141 claims. Among these beneficiaries, 70.92 percent had low PDC adherence that primarily occurred during the ICL period (35.46 percent), followed by the pre-ICL period (21.3 percent), and the post-ICL period (14.19 percent). Only 29 percent of beneficiaries who experienced all three benefit phases had high PDC, with the highest percentage (13.5 percent) occurring in the post-ICL period (13.48 percent), followed by the pre-ICL period (11.35 percent) and the ICL period (4.26 percent). Beneficiaries spent far more in average our-of-pocket expense during the gap period ($36.43) than averages in the pre-gap period and the catastrophic coverage period combined ($14.19). Non-adherent beneficiaries paid a greater average than adherent beneficiaries: low PDC beneficiaries paid an average of $27.95 and a median of $2.25, while high PDC beneficiaries paid an average of $7.50 and a median of $ 0. Conclusion: Utilization of antipsychotics is affected by the extent of Part D plan coverage beneficiaries choose and elements of Part D plans effect medication utilization differently.

DEDICATION

The joys, fears, tears, and hard work in the process of researching and writing this dissertation is dedicated to my three children: Annya, Shantara, and Justin. I take a page from my husband's book on focused determination and hope that I have lead by example that perseverance, dedication, and a genuine conviction in the pursuit of applied knowledge for a better society yields happiness and fulfillment that we all seek in life.

This dissertation is also dedicated to my parents, who did not live to see me finish my doctorate education. In honor of them and my Javanese heritage: *kawula aturaken puniko pinongko sembah bekti poro putro dumateng Romo soho Ibu sekaliyan* (translation: I offer this work as a form of filial devotion to my father and mother).

Closing this dedication is the mantra of Prajñaparamita ("Perfection of Wisdom") from the *Sutra of the Heart of Transcendent Knowledge*, which some Buddhist masters and scholars have interpreted to mean man's continual journey of going and going beyond until enlightenment.

OM GATE GATE PARAGATE PARASAMGATE BODHI SVAHA

(Translation: Gone, gone, gone beyond, gone altogether beyond, O what an awakening, all hail!)

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CHAPTER 1

INTRODUCTION

I. MEDICARE PART D: PRESCRIPTION DRUG COVERAGE

Medicare Part D is an insurance program under Medicare that provides coverage for outpatient brand and generic prescription drugs, which was established by the Medicare Prescription Drug, Improvement and Modernization Act of 2003 and launched in 2006. The fundamental idea behind the program is to expand coverage of prescription drugs through market competition that would benefit the interests of both beneficiaries and providers under the regulatory watch of the Centers for Medicare and Medicaid Services (CMS).

It is a departure from traditional Medicare where the federal government runs the program, benefits are uniform, and payments are based on fee-for-service plans. From the provider side, Medicare Part D is intended to spur competitive drug pricing and plan designs that would curb escalating drug costs and improve quality of care and treatment adherence at the same time. Coverage is offered by private organizations (i.e. health insurance companies, pharmacy benefit managers) that meet CMS requirements to become a Part D plan sponsor. These include a minimum drug formulary requirement, co-sharing of financial risks with CMS, and a standard Part D benefit or an actuarially equivalent Part D plan that may offer more benefits than the standard or stand-alone prescription drug plan (PDP). Standard components of a Part D plan have an annual deductible, coverage up to a CMS pre-determined level, a gap in coverage, and a period of catastrophic coverage.

All Medicare beneficiaries are eligible for Part D, but it is an optional program with an initial seven-month enrollment period that starts three months prior to a beneficiary turning 65 years old. New Medicare beneficiaries under 65 years old who are disabled have a different initial enrollment period, which is good for six months beginning on the twenty-first month after first receiving social security or Railroad Retirement Board (RRB) benefits. Other initial enrollment periods for Part D occur in the period June 1 through June 30 annually for Medicare beneficiaries who already have Part A and/or Part B, and 63 days after termination of another type of drug plan (e.g. Medicare, employer, or retiree drug plans). Failure to enroll in Part D when first becoming eligible will incur a penalty in the form of higher monthly premiums when an eligible individual finally signs up for a Part D plan; the penalty will remain throughout the duration of the prescription drug coverage.

Those who are dually eligible for Medicare and Medicaid, otherwise known as full-benefit dual-eligible beneficiaries, are also covered under this program. A Medicare beneficiary becomes dually eligible by qualifying for Medicaid when his/her income and assets fall below a certain threshold and s/he collects Supplemental Security Income (SSI), while a Medicaid beneficiary becomes dually eligible when s/he qualifies for Medicare at 65 years old or suffers from disability.

Dual eligibles, however, are automatically assigned at random to a prescription drug plan (PDP), but, unlike non-dual eligibles, they have the option to choose a different plan at any time and do not have to wait until the annual open enrollment period. If a dual eligible dis-enrolls

from a PDP without enrolling in a new one, then s/he will lose prescription drug coverage all together. Dual eligibles and other qualified low-income Medicare beneficiaries receive subsidies to help pay for their out-of-pocket costs for prescription drugs and monthly premium up to the level of the low-income benchmark premium.

There are two types of prescription drug plans available through Medicare Part D, namely the stand-alone drug coverage only plan and the Medicare Advantage plan (MA-PD). Private companies offer these two types of plans, with MA-PD offering other benefits, such as Medicare Part A and Part B coverage, in addition to prescription drug coverage, albeit at a higher premium.

The varying drug plan structures can be categorized as (a) basic standard plan, (b) alternative basic standard plan, (c) alternative enhanced plan, (d) alternative enhanced plan with supplemental prescription drug coverage, and (e) alternative enhanced plan with optional prescription drug coverage. Benefits differ from plan to plan, but all plans are required to offer coverage that is at least actuarially equivalent to the basic standard plan. It is in the differential plan design and benefit structure that a provider is expected to compete.

No matter the plan, however, there are eleven categories of drugs that are restricted under the Medicare Prescription Drug, Improvement and Modernization Act, 2003: (1) agents used for anorexia, weight loss, or weight gain, (2) agents used to promote fertility, (3) agents used for cosmetic purposes or hair growth, (4) agents used for the symptomatic relief of coughs or colds, (5) agents used to promote smoking cessation, (6) prescription vitamins and minerals, except prenatal vitamins and fluoride preparations, (7) non-prescription drugs, (8) covered outpatient drugs, which the manufacturer require associated tests or monitoring from the manufacturer or designee as a condition of sale, (9) barbiturates, (10) benzodiazepines, and (11) agents used for treatment of sexual or erectile dysfunction ("Social Security Act," 2006b). Although actual wording in section 1927(d)(2) of the Social Security Act, regulating the limitations on coverage of drugs, states that the aforementioned list of drugs "may be excluded from coverage or otherwise restricted," in reality most plans excluded the classes of drugs all together.

Beneficiaries of Medicare Part D basic standard plans pay a monthly premium as well as annual deductibles and co-payments for each prescription filled, but rates differ by plan and region, totaling 1,824 PDPs nationwide for the year 2008 (Kaiser Family Foundation). Coverage temporarily ceases when a beneficiary reaches a certain cumulative amount in prescription drug purchases, known as the Initial Coverage Limit (ICL), which is set by CMS at $2,510 for 2008. The ICL has increased to $2,840 in 2011and $2,930 in 2012.

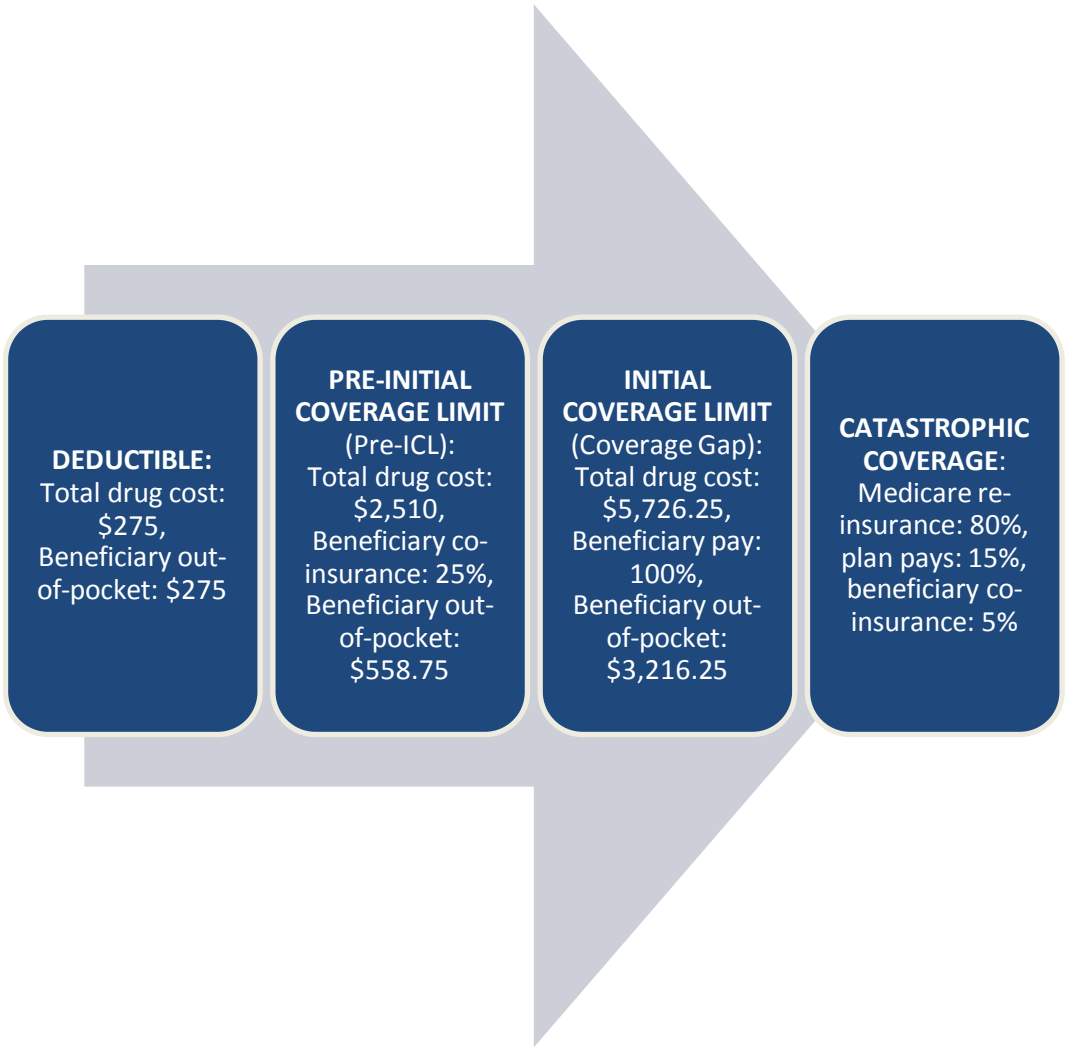
Beneficiaries must then cover their own prescription drug expenses up to a certain amount during the period when coverage ceases, which is otherwise known as the "donut hole." The amount for the year 2008 is capped at $3,216.25 during the no-coverage period, after which coverage resumes at 95 percent for each prescription filled. In 2010, the amount for the gap-in-coverage period was $3,610 and in 2012 is $3,727.50.

Some plans provide very limited coverage for brand-name and generic prescription drugs during the donut hole period, but many do not provide coverage at all. Drug formulary and pharmacy networks also differ by plan and region and may change every year.

Under Medicare Part D, coverage is also offered to low-income beneficiaries with plan characteristics that are similar to regular standard plans, but with lower premiums, deductibles,

co-payments, co-insurance and catastrophic coverage based on level of income. These plans are known as Low Income Subsidy (LIS) plans and Medicare beneficiaries may qualify for full or partial LIS plans depending on their level of income and resources based on the annual Federal Poverty Guidelines. Subsidies for LIS plan beneficiaries help pay for monthly premiums and cost of drugs. In contrast, regular stand-alone plans and enhanced plans do not consider level of income of beneficiaries in their product offerings.

FIGURE 1: MEDICARE PART D STANDARD BENEFIT, 2008



II. MEDICARE PART D AND MENTAL HEALTH CARE

The creation of Part D heralded a major change in Medicare. With the continuous rising cost of health care and prescription drugs, Part D sought to curb federal spending and, at the same time, increase access to prescription drugs. This was accomplished by giving a much greater role to the private sector in administering the program, and competition in bidding for the provision of PDPs on an annual basis. Federal spending is contained through subsidies per beneficiary paid to PDP providers and shifting most of the administrative overhead load to the private sector. The doughnut hole, as another mechanism for cost containment, placed cost of prescription drugs on beneficiaries at 100 percent. Thus, PDP providers were free to design plans and structure benefits that met the standard requirements dictated by CMS.

PDP providers not only compete to win PDP bids, but also compete for beneficiary enrollment and secure lower drug prices through volume purchases. By establishing a program that is administered by private insurance companies, market competition is intended to reduce the costs of prescription drugs. In tandem with competition, consumers are expected to better manage their individual budgets and medication needs when choosing a PDP. A market-driven program, therefore, is anticipated to spur changes on both sides: plan providers and beneficiaries.

In Part D, the federal government is no longer the single-payer in a fee-for-service reimbursement system as in traditional Medicare (i.e. Part A and Part B); instead Part D involves a host of private entities operating alongside PDP providers. These include Pharmacy Benefit Managing companies (PBM), claims processing companies, brick and mortar pharmacies, as well as mail-service pharmacies (see Figure 1 for the various stakeholders in the program).

In practice, the program has expanded overall prescription drugs to its beneficiaries and now includes dual-eligibles, who comprise 29 percent of total Part D participants. In 2003 Medicare accounted for 7 percent of total national spending of $100.3 billion for mental health, while Medicaid accounted for 26 percent. After the implementation of Medicare Part D and with an estimated average annual growth rate of 6.7 percent at the time of the study, the figure for Medicare spending for mental health rose to 11 percent of a total national spending of $121.7 billion. It is projected that the figure will continue to increase to 12 percent of a total national spending on mental health of $203.3 billion in 2014 (Levit et al., 2008). Thus, the role of psychotropic drugs and Medicare Part D are important aspects in mental health treatment among the elderly.

As the frontline treatment for mental illness and with one in four elderly suffering from a mental disorder (Jeste et al., 1999), spending for psychotropic drugs increased 15-17 percent annually from 1991-2001 (Mark et al., 2005). Psychotropic drugs, however, are costly for many elder ages 65 and older. They rank highest compared to younger adults in psychotropic drug usage (Zuvekas, 2005) and the cost of psychotropic drugs is projected to continue to accelerate concurrent with increase in usage as well as the introduction of newer, improved and expensive drugs to the marketplace. Spending on antipsychotic drugs, similarly, has increased from $1.1 billion in 1996/1997 to $4.6 billion in 2004/2005, with overall usage of atypical (second-generation) antipsychotics increasing from 0.15 percent of the population in 1996/1997 to 1.06 percent in 2004/2005, while usage of typical (first-generation) decreased from 0.60 percent to 0.15 percent of the population during the same time period (Domino & Swartz, 2008).

In 2002, 22.6 percent of elderly Medicare beneficiaries who are categorized as not disabled and 31 percent of dual-eligibles used psychotropic drugs, in which anti-depressants were the most used therapeutic category (Donohue, 2006). Compared to the general population, the figure for drug usage in general remains high for the elderly, where 91percent of the elderly ages 65 and older had a prescription drug expense of some kind in 2005 (Kaiser Family Foundation, 2008c). The high rate of prescription drug usage and the importance of psychotropic drugs in mental health treatment are underscored in Medicare Part D, especially when also taking into consideration the high levels of comorbidity of diseases and polypharmacy on this population. Usage of overall antipsychotic drugs have remained stable from the mi-1990s through to early 2000s, from 1.25 percent (1996-1998) to 1.46 percent (2001-2004); however, usage of atypical (or second-generation) antipsychotics, in particular, sharply increased during the same period, from 14.65 percent to 72.73 percent (Jano, Chen, Johnson, & Aparasu, 2007).

Prior to Medicare Part D, mental health coverage under Medicare was lifetime-limited to 190 days of in-patient care at psychiatric hospitals and 50 percent co-payments for psychotherapy, but as treatments for mental health grew to favor out-patient care and pharmacotherapy, psychotropic drugs became predominant in managing mental disorders among the elderly and has outpaced spending in both prescription drugs and health care in general . Furthermore, the role of Medicaid coverage for psychotropic drugs was borne by the states until Medicare Part D was instituted, which meant that out of the 22.5 million Part D enrollees in June 2006, approximately 6.1 million individuals were dual-eligibles automatically assigned to standard PDPs under the new program (McClellan, 2006). The federal government, thus, became the largest public payer for prescription drugs.

Before the implementation of Medicare Part D, lack of prescription drug coverage under Medicare was identified as a barrier to mental health care despite the availability of some degree of prescription drug coverage from supplemental insurance. However, one-third of Medicare beneficiaries are unable to afford the premiums and rely on out-of-pocket spending (Health Care Financing Administration, 2000). Limited or fixed income can often cause intermittent filling of prescriptions, resulting in behaviors that extend medication. Behaviors such as decreasing dosage, skipping intake or delaying filling a prescription have direct consequences to wellbeing. Breaks or sudden termination of psychotropic regimens may have deleterious consequences, particularly in psychiatric conditions that are chronic and severe. In the case of the elderly population, where many take up to six prescribed medications (Larsen & Martin, 1999), out-of-pocket expenses for drugs, even with some form of coverage, can still be prohibitive. Annual expenditure for antipsychotic drugs, for example, quadrupled from $126 million in 1996-1998 to $483 million in 2002-2004 with atypical (or second-generation) antipsychotics experiencing a ten-fold rise from $46 million to $436 million during the same period (Jano et al., 2007).

With pharmacotherapy as the predominant form of treatment for mental illness among the elderly and the inclusion of dual-eligibles for coverage under Medicare Part D, it is reasonable to propose that the program will have both positive and negative consequences to the geriatric mental health landscape. Studies on the effects of Medicare Part D on mental health care are beginning to emerge since data from the Centers for Medicare and Medicaid Services (CMS) became available to external non-CMS researchers in 2008. Annual changes to drug coverage and varying out-of-pocket expenditures among beneficiaries, however, continue to occur, indicating that not only beneficiaries, but insurance companies are also navigating through the complex requirements of the program.

Although there are certain requirements that must be met by PDP providers, there are enormous differences between plans in (a) the number of plans in each state, (b) the benefits offered, (c) the monthly premiums, (d) the coverage during the doughnut period, (e) the formularies, and (f) the utilization management employed.

Early reports on Medicare Part D find that the program is successful in increasing the number of enrollees and, thus, access to prescription drugs. This includes benchmark plans for low-income-subsidy (LIS) beneficiaries who qualify for zero monthly premiums and no gap in coverage (no doughnut hole period). Provisions for LIS beneficiaries in the program is important in the context of mental health, because of the marked vulnerability of this particular population in affording psychotropic drugs for disorders that are most usually chronic. Disruption in filling prescriptions affects adherence to treatment regimen and may increase the burden on public health systems in the long run, such as increase in psychiatric in-patient admissions and emergency room visits.

In looking at changes in PDPs since 2006, among 88 percent of total PDPs offered in 2008, one report (Hoadley, Thompson, Hargrave, Cubanski, & Neuman, 2008) found that there has been an overall 2 percent increase in the number of benchmark plans that allow enrollment of LIS beneficiaries who qualify for zero monthly premiums. However, there is a large range to the number of benchmark plans offered in each state, with Nevada offering only two plans, while Illinois offers 19 benchmark plans.

An unforeseen consequence of allowing PDP providers to change benefit plans annually is that when a PDP no longer meets requirements for a benchmark plan, Medicare is thus forced to reassign LIS beneficiaries to other benchmark plans. Many LIS beneficiaries, however, are unable to navigate the wealth of information that is necessary to assess possible changes in product offerings. In 2008, over 2 million beneficiaries bore the brunt of such reassignment, creating disruption in utilization if a particular drug is no longer on a PDP formulary or under utilization management (i.e. prior authorization, step therapy or quantity limitations). Nevertheless, the onus remains with beneficiaries to review whether a PDP fulfils their medication needs, despite the automatic and random nature of reassignments when a plan provider disqualifies from a benchmark plan.

With regard to psychotropic drugs, although CMS has required PDP providers to include "all or substantially all" drugs categorized as anti-depressants and anti-psychotics, other therapeutic categories that have high usage remain excluded from such requirement. Benzodiazepines, for example, are excluded, even though 6.6 percent of Medicare beneficiaries and 9 percent of dual-eligibles relied on this type of drug more than anti-psychotics (Donohue, 2006). Benzodiazepines (e.g. alprazolam, clonazepam, diazepam, flurazepam, lorazepam, triazolam) are commonly prescribed to treat anxiety, but are also used to treat seizures, depression, and insomnia. As a consequence of non-coverage, beneficiaries on benzodiazepines must pay out-of-pocket or find state assistance, such as Medicaid or state drug assistance programs, if eligible.

From changes in LIS plans, formularies, premiums and coverage during the coverage gap period, any modifications to Medicare Part D, thus, affect beneficiaries in both negative and positive ways. The implications of the program, however, are manifold and far reaching, beyond beneficiaries receiving subsidized prescription drugs.

One example is the impact on the pharmaceutical industry, where patented drugs are a source of profit. With the government prohibited from negotiating drug discounts for Medicare Part D, however, drug makers are free to negotiate price directly with the many pharmacy benefit managers (PBM) involved in the program. Consequently, without pressure from the government for considerable drug discounts, pharmaceutical companies are likely to continue with strategies to extend patented drugs in order to maintain or increase price and prevent generic versions entering the market. The effects on psychotropic drugs would mean that certain drugs would remain patented with no generic alternative that may be more affordable for beneficiary cost-sharing. Similarly, PBMs are also poised to benefit from Medicare Part D through administration fees, spread pricing and drug manufacturer rebates. PBMs would also enforce strict utilization management, such as prior authorization or step therapy, before an expensive patented psychotropic drug is approved. Local pharmacies not listed with any PDP pharmacy networks are affected as well, because PDPs are able to restrict pharmacy networks to pharmacies of their choosing and determine co-payments that are lower than out-of-network pharmacies.

Medicare Part D remains controversial among beneficiaries and regulators alike. Although the voluntary program expands prescription drug coverage to both Medicare and dually eligible Medicare-Medicaid beneficiaries, the program came with enormous skepticism as to its viability. Among the concerns voiced was the infusion of market-based competition where private entities bid to provide coverage of prescription drugs and the instantaneous enrollment of 6.4 million people who are dually eligible for Medicare and Medicaid.

III. MEDICARE PART D IN WASHINGTON STATE

The population of Washington State is approximately 6,574,400 with 14 percent on Medicare and 18 percent on Medicaid in 2010 (Kaiser Family Foundation). Among the Medicare population, most qualified through age (84.4 percent), while the remaining qualified through disability (15.6 percent) in 2009. Beneficiaries in the 65-69 year old age range comprise the largest group at 23.7 percent compared to other beneficiaries in 2004, followed by the 70-74 year old group at 19.5 percent, and the 75-79 year old group at 16.9 percent. In 2007, dual eligibles (i.e. individuals who qualify for both Medicare and Medicaid) made up 17 percent of the Medicare population (Kaiser Family Foundation).

The distribution of Washington Medicare beneficiaries with any kind of prescription drug coverage in 2010 consisted of 35 percent in stand-alone prescription drug plans (PDPs) and 18 percent in Medicare Advantage prescription drug plans (MA-PDs) totaling to 506,734 individuals. The remaining Medicare population have other types of prescription drug coverage, such as through the Federal Employees Health Benefits (FEHB), TRICARE (for active and retired uniformed services members and their families), and the Veterans Administration (VA) (Kaiser Family Foundation). The total number of beneficiaries with Medicare Part D Low Income Subsidy (LIS) in the state increased from 153,826 in 2008 (Q1Group LLC, 2011a) to 164,967 in 2011 (Q1Group LLC, 2011b).

Like many other states, Medicare Part D in Washington experienced numerous plan and benefit changes since its launch in 2006. Statistics indicate that there were 55 plans offered in 2008 with 27 plans offering enhanced coverage (i.e. plans offering more than the defined standard coverage, which may include lower to no deductibles, lower co-insurance or co-payments, and smaller cost-sharing during the gap in coverage period) (Q1Group LLC, 2011a). The overall number of prescription drug plans offered has decreased since then with only 44

plans offered in 2010, 32 plans in 2011, and 30 plans in 2012 (Q1Group LLC, 2011b). Enhanced plans have also decreased during the same time period with 23 plans offered in 2010, 15 plans in 2011, and 14 plans in 2012. Plans with premiums under $20 in 2007/2008 were offered by only three plans and such plans were no longer available during 2010 – 2012. Instead, low-premium plans were plans with premiums under $25, of which only two were available in 2010, one available in 2011, and one available in 2012 (Q1Group LLC, 2011b). While Low Income Subsidy (LIS) plans have increased from seven in 2011 to nine in 2012, the number of LIS plans have decreased since Medicare Part D launched. In 2007 and 2008, there were 16 LIS and 15 LIS plans respectively (Q1Group LLC, 2011a, 2011c).

Similar to the national trend of decreased average monthly premiums among Medicare Part D plans, Washington State premiums also dropped 2.41 percent for the 2011/2012 period; nevertheless, 57 percent of Medicare Part D stand-alone PDP beneficiaries in the state are projected to face an average increase in monthly premiums of $5.42 unless they switch to plans with lower premiums (Q1Group LLC, 2011b).

The body of research on Medicare Part D specific to Washington State is currently sparse. However, a study by Afendulis and Chernew suggests that the change in prescription drug coverage rate due to Medicare Part D increased from 53.6 percent in 2005 to 83.4 percent in 2006 with an estimated 219,680 newly covered individuals in Washington State (2011). The study also estimated the impact of Medicare Part D on avoided hospitalization rates for ambulatory care-sensitive conditions (ACSC) among the Medicare population, concluding that Washington State experienced a reduction of 1,533 ACSC hospitalizations, or 2 percent of avoided ACSC hospitalizations among 50 states and the District of Columbia.

IV. STUDY RATIONALE

Although Medicare Part D is a voluntary program for subsidized prescription drugs, 25 million beneficiaries enrolled within just two years of the program's launch; a figure that underscores the magnitude of the program. Recent numbers estimate the total number of program beneficiary at 27 million with two-thirds enrolled in standard PDPs that mostly do not offer coverage during the gap period (Hoadley, Cubanski, Hargrave, Summer, & Neuman, 2009). Additionally, approximately 3.4 million beneficiaries reached the coverage gap in 2007 (Cubanski, Neuman, Hargrave, Hoadley, & Summer, 2010), which means that beneficiaries' health behaviors and wellbeing are affected when adherence to medications are impacted by out-of-pocket costs and lack of drug coverage during the gap period. Meanwhile, the size of the coverage gap itself is projected to continue to widen to $5,066 by 2013 from the initial $2,850 in 2006 (Congressional Budget Office, 2004) along with continued premium increase at about 20 percent by 2019 (Congressional Budget Office, 2009).

Thus, the rationale behind the specific focus of this study is that pharmacotherapy is the frontline treatment for mental disorders among the elderly population, but the impact of the new program on traditionally underserved population remains unclear. The elderly living on limited disposable income, the elderly living in rural areas and the elderly among minority groups may be particularly vulnerable if there are insufficient number of plans offered in a given region that are affordable in terms of premiums, deductibles, co-pays, and co-insurance. In turn, this may affect accessibility and, thus, adherence to prescribed drugs.

In light of the sparseness of research on Medicare Part D and antipsychotic utilization in Washington State, findings of this study are intended to serve as pilot data for future research on Medicare Part D in the state. Although approximately three-fourths of the population of Washington State resides in eight urban counties, the remaining population is spread across 31 counties that are classified as rural (Mills, 2008), where 13 rural counties are considered distressed during the 2007-2009 period (i.e. counties with three year average unemployment rates equal to or greater than 120 percent of the statewide unemployment rate) (Washington State Employment Security Department, 2010). A greater percentage of older individuals age 55 years old and older are found in rural (27.2 percent) than urban counties (21.8 percent) (Mills, 2008), and the Medicare population in Washington State represents 14 percent of the state population, which is comparable to the national percentage of 15 percent of the Medicare population in terms of the population of the country.

Medicare Part D is implemented with the view that involvement of private entities in a public program will offer better coverage, better prices, and greater choices for prescription drugs through market competition. It was also designed to control prescription drug costs through a number of mechanisms (e.g. deductibles, co-insurance, and tiered drug copayments, etc.) that are enforced by providers; however, all but one of the top ten brand-name drugs without generic availability and most frequently used by Medicare Part D beneficiaries experienced price hikes in the 2009-2010 period (Cubanski et al., 2010). For example, the price paid by beneficiaries during the coverage gap for Aricept, which is a drug to treat the symptoms of Alzheimer's Disease, increased by 7 percent from $ 184 to $ 198.

Along with such mechanisms, Medicare Part D was touted to present more plans for consumers. This means that responsibility is placed on consumers to choose from a myriad of prescription drug plans based on individual medication needs and affordability, which is not an easy decision to make considering the large number of plans and the different drug formularies in a given region. In California in 2008, for example, there were 56 stand-alone PDPs with varying drug formulary, premiums, deductibles, co-insurance and gap coverage, which beneficiaries are expected to peruse annually in order to decide whether to stay in their current plan or switch to a different PDP. In 2010, the total number of stand-alone PDPs in California dropped to 47; similarly, the number of stand-alone PDP in Washington State also dropped from 55 in 2008 to 44 in 2010 (Hoadley et al., 2009). Annual changes in existing PDP frequently occur due to a number of reasons, including drugs that are removed from a formulary or classed in a different tier, adjustments in premiums, co-payment or co-insurance, and changes in pharmacy networks, to name a few. Additionally, not all plans remain available in a given service area.

For a subset of the Medicare Part D population, namely those with serious mental disorders, such a responsibility is burdensome given that most disorders among this particular population are chronic in nature with some involving cognitive impairment. All beneficiaries must take into consideration their individual medication regimen together with their share of deductibles and co-payment/co-insurance and individual plan drug formulary. Thus, the onus of reviewing and choosing a PDP every year and managing out-of-pocket expenses for medications may have a direct impact on clinical outcomes among beneficiaries. Little in the history of the program design indicates special consideration to the effects it may have on mentally ill beneficiaries.

Examining antipsychotic utilization and plan coverage enables: (a) an assessment of accessibility of generic and brand-name antipsychotic drugs, (b) an overview of the distribution of antipsychotics dispensed, which will provide a better understanding of pharmacotherapy for schizophrenic disorders through Medicare Part D, (c) an assessment of the effects of coverage and the gap in coverage ("the donut hole") on the filling of antipsychotic drugs, which will give insight into antipsychotic drug affordability and treatment adherence. Given that atypical antipsychotics were introduced in the late 1990s/early 2000s and utilization of atypical (or second-generation) antipsychotics has grown tremendously over the last ten years, the study focuses on three atypical antipsychotics commonly prescribed for the treatment of schizophrenia: olanzapine, quetiapine, and, risperidone.

This study will analyze coverage and utilization of the three atypical antipsychotics from the newly released Part D Prescription Drug Event (PDE) data with social welfare policy implications in mind. Although in and of themselves prescription drugs are not usually considered a welfare benefit, the program is, nevertheless, designed as an expansion of Medicare, which is the healthcare benefit tied to Social Security. Just as millions of people rely on Social Security, millions – precisely 44,831,390 beneficiaries in 2008 (Mathematica Policy Research) – also rely on Medicare for the provision of health care in their elderly years, which includes not only health and mental health services, but now also expanded coverage for prescription drugs.

CHAPTER 2

LITERATURE REVIEW

Although Medicare Part D is well into its fifth year of implementation, access to Part D data from the Centers of Medicare and Medicaid Services (CMS) only became available to external non-CMS researchers in 2008, thus, published studies using CMS Part D data are currently very limited. As such, there have been no published studies yet on antipsychotic drug utilization based on the Prescription Drug Event (PDE) data.

I. PSYCHOTROPIC DRUG UTILIZATION AMONG THE ELDERLY

Previous studies have investigated the broad category of psychotropic drug utilization, which included antipsychotics, among the elderly using varying data sets, such as Medicaid database (Lakey, Gray, Sales, et al., 2006), retail-specific pharmacy claims data (Chen, Nwangwu, Aparasu, et al., 2008), the Medical Expenditure Panel Survey (Aparasu, Mort, and Brandt, 2003), and publicly available online prescription drug plan and formulary information (Huskamp, Stevenson, Donohue, et al., 2007; Zivin, McCammon, Davis, et al., 2008).

For example, one study, analyzing the 1996 Medical Expenditure Panel Survey (MEPS) data found that 19 percent of 21,571 sample persons of community-dwelling elderly used psychotropic drugs (Aparasu, Mort, & Brandt, 2003). Of that 19 percent, the largest age group found to be utilizing psychotropic drug was the 65-74 year old age bracket at 53.9 percent. In contrast, the older age groups were found to be utilizing lower rates of psychotropic drugs at 37.3 percent for the 75-84 year old age group, and 8.8 percent for the 85 year old and older group. Among the therapeutic classes most widely used were anti-depressants at 9.1 percent, followed by anti-anxiety agents at 7.5 percent, sedatives at 4.8 percent, anti-psychotic agents at 1.8 percent, and psycho-stimulants at 0.1 percent. The study utilized the health behavior model by Anderson and Newman (1973) that considers predisposing (socio-demographic and attitudinal characteristics), enabling (income and insurance), and need factors (measures of existence, severity, or condition of disease) affecting health services utilization. Among the predisposing factors, gender was significantly associated with general psychotropic use as well as with anti-depressants and anti-anxiety agents. Specifically, women were found to be more likely to use psychotropic drugs in general and almost one and a half times more likely to use anti-depressants and anti-anxiety agents than men. Prescription insurance as an enabling factor and health status as a need factor were consistently significant across therapeutic categories. Ethnicity was only significant in the use of sedatives or hypnotics, with Blacks less likely to use sedatives or hypnotics compared to other races. Limitations of this study included: the absence of specific documentation on prescription drug coverage in the MEPS data and the year of data collection (1995).

Zuvekas (2005) also used the Medical Expenditure Panel Survey (MEPS) data and suggests that the increase in national spending for psychotropic drugs between 1996 through to 2001 is due to the greater prevalence of mental illness as well as greater mean spending per

consumer. Psychotropic drug usage during the period increased from 5.9 percent in 1996 to 8.1 percent, with consumers 65 years old and older paying over three-fifths of the cost of their psychotropic drugs and representing the highest usage rate compared to other age groups. Among the 65 years old and older, newer anti-depressants explain 60 percent of the spending growth during the study period; women were more likely than men to use psychotropic drugs; similarly, Whites were more likely to use psychotropic drugs than other ethnic groups.

Later data from the Medical Expenditure Panel Survey (MEPS) 2004 – 2006 was used by Domino and Farley (2010) to compare psychotropic usage with non-psychotropic drug usage before and after implementation of Medicare Part D. Antidepressants and antipsychotics (psychotropics) were compared with lipid-lowering and antihypertensive agents (non-psychotropics), but the study did not find significant differences in drug access associated with the program. For the study period, greater percentages of Medicare beneficiaries filled prescriptions for lipid-lowering and antihypertensive agents annually than for antidepressants and antipsychotics; with 40 – 44 percent filling at least one prescription for lipid-lowering agents each year, 62 – 64 percent for antihypertensive agents, 17 – 19 percent for antidepressant, and 3 – 4 percent for antipsychotics. However, the opposite was found among dual eligible beneficiaries in whom higher usage for psychotropic drugs was greater than non-psychotropic drugs per year for the study period. Antidepressant usage ranged 21-22 percent and antipsychotic usage ranged 7-10 percent, while usage of lipid-lowering agents were lower compared to non-dual eligible beneficiaries at 30 – 38 percent and 53 – 62 percent for antihypertensive agents.

In contrast to the findings by Domino and Farley (2010), a different study using the same data set (Medical Expenditure Panel Survey, 2005 – 2006) suggests that there was an increase in the rate of antidepressants usage among Medicare beneficiaries, excluding dual eligible, that was statistically significant (Donohue, Huskamp, & Zuvekas, 2009). Specifically, medication use for antidepressants among non-institutionalized Medicare beneficiaries increased from 16 percent in 2005 to 18.1 percent in 2006. Analyses for dual eligibles indicate that though there was an increase in antidepressant usage from 18.8 percent in 2005 to 20.8 percent in 2006, the difference between the years was not statistically significant. Similarly, no statistically significant difference was found in overall antipsychotic usage among dual eligibles, who experienced a slight drop from 8.5 percent in 2005 to 8.4 percent in 2006. Atypical antipsychotics, however, increased slightly among this population, from 7.4 percent in 2005 to 7.7 percent in 2006.

In an effort to assess the impact of Medicare Part D on psychotropic drug utilization from claims data, Chen, Nwangwu, Aparasu, Essien, Sun, and Lee (2008) examined claims for over one million individuals nationwide from a large retail pharmacy (Walgreens) twelve months before Medicare Part D became effective (2005) and twelve month after (2006). They analyzed monthly utilization and out-of-pocket expenses for antidepressants, antipsychotics, and benzodiazepines, and found that the number of older individuals (65 years old and older) who filled at least one prescription increased by 7 percent, from 1.19 million (2005) to 1.28 million individuals (2006). Among the three therapeutic classes, antidepressants experienced the biggest growth in usage at 10.6 percent, while antipsychotics usage grew 8.5 percent, and benzodiazepine usage grew only 4.4 percent. With the inclusion of dual eligible beneficiaries under Medicare Part D (i.e. beneficiaries who qualify for both Medicare and Medicaid), Medicare took over prescription drug reimbursement from Medicaid. Prior to implementation of Medicare Part D, Medicaid paid 12 percent of total pharmacy reimbursement for antidepressants and 27 percent for antipsychotics in 2005. After Medicare Part D, Medicaid pharmacy

reimbursement dropped to 1 percent for antidepressants and 2 percent for antipsychotics in 2006. Findings from a separate study using 2005 – 2006 data from the Medical Expenditure Panel survey also found Medicaid's share of dual eligible reimbursement for antidepressants and antipsychotics fell from 70 percent in 2005 to 5 percent in 2006 for antidepressants and from 84 percent to 11 percent for antipsychotics (Donohue, 2006; Donohue et al., 2009). The study highlighted the fact that psychotropic drugs were the most costly therapeutic medication category among dual eligible and the second most costly therapeutic medication category among Medicare beneficiaries in general.

Chen, Nwangwu, and associates (2008) also found a decrease in out-of-pocket costs for both antidepressants and antipsychotics, but an increase for benzodiazepine out-of-pocket costs. Antidepressant out-of-pocket costs decreased 18 percent during the study period, while antipsychotic out-of-pocket cost dropped 21 percent, which translates to a $4.52 savings per prescription for the former and a $5.71 savings per prescription for the latter. This finding is somewhat similar to the study by Donohue and associates (2009) in that there was a slight drop in out-of-pocket cost for antidepressants only, which covered 36 percent of all spending (compared with Medicare, Medicaid, private, and other entities) for antidepressants in 2005 to 35 percent in 2006. Out-of-pocket spending for antipsychotics, however, increased from 23 percent in 2005 to 26 percent in 2006.

The increase for benzodiazepines of 19 percent in out-of-pocket costs and a $2.79 increase per prescription in the study by Chen, Nwangwu, and associates (2008) were due to coverage exclusion of benzodiazepines under Medicare Part D. Although separately Medicaid still pays for benzodiazepine for dual eligibles, nevertheless, it experienced a drop in share of benzodiazepine costs by 50 percent, which is likely due to out-of-pocket costs borne by beneficiaries who are not dually eligible or who have switched to a Medicare Part D plan. A separate study on the effects of Medicare Part D benzodiazepine exclusion on the risk of fractures among elderly individuals living in nursing homes highlight medication substitutions made in lieu of benzodiazepines that included antipsychotics as well as non-benzodiazepine sedative/hypnotics, and anxiolytics (Briesacher, Soumerai, Field, Fouayzi, & Gurwitz, 2010). Specifically, in states where there were no supplemental coverage to obtain benzodiazepine the average monthly number of antipsychotic dispensed increased after Medicare Part D was instituted in 2006 compared to the year prior (0.66 change in monthly fills, 95% CI, 0.65 to 0.67, $p < .001$).

II. ANTIPSYCHOTIC DRUG UTILIZATION AMONG THE ELDERLY

Antipsychotics have long been used to treat mental disorders in the United States since the introduction of Thorazine (chlorpromazine) in 1954 for schizophrenia. Further development of antipsychotic drugs led to the introduction of clozapine in 1989 as the prototypical second-generation (or atypical) antipsychotic. Now there are nine kinds of atypical (or second-generation) antipsychotics available that are commonly used to treat psychosis, schizophrenia, and bipolar disorders, but they are also used to treat other conditions – some of which are considered off-label (i.e. not approved by the Federal Drug Administration) – such as obsessive compulsive disorders, post-traumatic stress disorder, eating disorders, personality disorders, aggressive and other behavioral symptoms related to dementia, irritability associated with autistic disorders, as a supplemental drug with antidepressants for depression, and to reduce suicidal ideation.

Atypical antipsychotic generic names are: aripiprazole, asenapine, clozapine, iloperidone, olanzapine, paliperidone, quetiapine, risperidone, and ziprasidone. They come as both brand-name and generic drugs, and delivered in a variety of forms: tablet, capsule, liquid, and intramuscular injection, with some as extended release, long-acting, and orally disintegrating tablets.

In 1967 total sales for psychoactive drugs topped $692 million with one in three adults using some kind of medication in this category (Swazey, 1974). Recent numbers show that antipsychotics continue to be in strong demand with spending reaching $14.6 billion in 2009 (Gatyas, 2010) and increasing to $16.1 billion in 2010. Antipsychotics, as a therapeutic class, ranks fifth in spending behind anti-diabetes medications (with $16.9 billion in spending in 2010), lipid regulators ($18.7 billion), respiratory agents ($19.3 billion), and oncologic agents ($22.3 billion) (Gatyas, 2011). More than a quarter of Medicare beneficiaries in nursing homes are taking antipsychotics and they are disproportionately used among the elderly population in general (Briesacher et al., 2005; Kamble, Chen, Sherer, & Aparasu, 2008), but fines incurred by the pharmaceutical companies for unlawful promotion of off-label usage pale in comparison to their annual sales. In 2009 Eli Lilly & Co, was fined $1.4 billion for marketing Zyprexa (generic name: olanzapine) to nursing home doctors; Astra Zeneca was fined $520 million for kickbacks to doctors related to Seroquel (quetiapine) prescribing; Pfizer, was fined $301 million for off-label marketing of Geodon (ziprasidone); and Bristol-Myers Squibb was fined $515 million for off-label marketing of Abilify (aripiprazole) (Perrone, 2011; Wilson, 2010). Although drug companies are not permitted by law to promote drugs for specific usages that have not been approved by the Food and Drug Administration (i.e. off-label usage), physicians are allowed to prescribe drugs for off-label purposes.

According to a report by the IMS Institute of Healthcare Informatics (2011), changes in spending was predominantly led by the state of the innovation cycle, with the antipsychotics market growing by $1.4 billion and the filling of 56 million prescriptions in 2010 due to newer, brand-name atypical antipsychotics. The jump in spending by $300 million in 2009 to a dramatic $1.4 billion the following year was driven by the patent expiry of Risperdal (risperidone) in 2008 and the continued growth in spending for Abilify (aripiprazole), Seroquel (quetiapine), and Zyprexa (olanzapine). Both Abilify and Seroquel were among the top ten products by spending for the overall patented drug market in which Abilify ($4.6 billion) and Seroquel ($4.4 billion) ranked fifth and sixth respectively in spending for 2010.

Like studies on psychotropic drugs, studies focusing on antipsychotic drug utilization and insurance coverage among the elderly also use various databases, such as the Medicare Current Beneficiary Survey, the Medical Expenditure Panel Survey, the National Nursing Home Survey, state Medicaid administrative claims data, pharmacy-specific data, and state Veterans Health Care Systems. These studies encompass a variety of foci and measures under the umbrella of drug utilization. Prescribing patterns, duration of usage, single versus multiple drug therapy, dosing, medication possession ratio, drug persistence, prescription rate refills, pill counts, and drug supply gaps are some examples of study foci and drug utilization measures in prior research.

A study by Weissman (2002), for example, analyzed prescribing patterns for antipsychotics derived from pharmacy file prescription data and diagnostic information from outpatient files for veterans with schizophrenia within the Veterans Integrated Service Network (VISN) in New York. Like earlier studies on antipsychotics in general and antipsychotics

specifically prescribed for schizophrenia, Weissman found that prescriptions for atypical antipsychotics increased, while prescriptions for typical antipsychotics decreased during the study period (1998-2000). With the exception of clozapine, atypical antipsychotic increased from one-third to more than one-half of total antipsychotics prescribed, while prescriptions for typical antipsychotics decreased from 61 percent to 44 percent; however, elderly veterans with schizophrenia (i.e. ≥ 65 years old) were more likely to receive single drug therapy of the older generation, typical antipsychotics in contrast to younger veterans with schizophrenia who are more likely to receive multiple drug therapy (also known as polypharmacy) with newer atypical antipsychotics. Additionally, atypical antipsychotics accounted for 95 percent of the proportion of total spending for antipsychotics in 2000, but represented only 61 percent of total antipsychotic prescriptions. Total cost of antipsychotic drugs to the VISN in New York increased from $3.52 million (1998) to $6.68 million (2000) with olanzapine as the costliest atypical antipsychotic at $258.05 per month per patient in 2001.

Antipsychotic usage prior to Medicare Part D was also examined by Wang and Farley (2009) utilizing the Medical Expenditure Panel Survey (MEPS) for 2004 and 2005. They found that typical users were older, non-Hispanic, and female with higher usage among low-income families and beneficiaries of public health insurance. During the study period almost 4 million individuals of all ages utilized antipsychotics with greatest usage found for atypical antipsychotics (80.5 percent), followed by typical antipsychotics (23 percent), and the smallest usage was among individuals taking both atypical and typical antipsychotics (3.5 percent). Among atypical antipsychotics olanzapine, risperidone, and quetiapine were more frequently used compared to other atypical antipsychotics. Compared to younger age groups, however, the study suggests that individuals age 65 years old and older are less likely to receive antipsychotics.

A closer look at the elderly population and antipsychotic utilization, Jano, Johnson, Chen, and Aparasu (2008) found that an average of 0.62 million elderly individuals used antipsychotics annually during the study period from 1996 – 2004. Like the study by Wang and Farley (2009), Jano and associates also analyzed the Medical Expenditure Panel Survey data prior to Medicare Part D and found that the majority of antipsychotic users were female, white, non-Hispanic and living in urban areas. Olanzapine, risperidone, and quetiapine were also more frequently used than other antipsychotics, but overall a slightly greater percentage of typical antipsychotics (51.88 percent) were used compared to atypical antipsychotics (50.39 percent). As with the study by Wang and Farley, perceived mental health status was significantly associated with atypical use. Individuals with poorer perceived mental health status were more likely to use atypical rather than typical antipsychotics.

Specific to elderly individuals living in nursing homes, Crystal, Olfson, Huang, and associates (2009) suggests that much of antipsychotic utilization is employed to manage behavior symptoms associated with dementia, such as agitation, aggression, anxiety, disinhibition , irritability, and wandering. Increase in atypical antipsychotic usage was particularly evident in nursing homes during the mid and late 1990s due to the growth of the atypical antipsychotic market and the reduction in physical restraints on residents in nursing homes. One study found that an elderly nursing home resident taking antipsychotics received a mean of 9.56 medications and can perform a mean of 4.1 activities of daily living (ADL) with the likelihood of receiving an antipsychotic increasing with bowel incontinence, history of falls, behavioral symptoms, depressed mood, and dependence when making decisions on tasks of daily life (Kamble et al.,

2008). As recent as 2011, the Office of Inspector General released a report (Levinson) looking into atypical antipsychotic over-utilization in nursing homes.

In their investigation using claims data for Medicare Part B, D, and the Minimum Data Set, the Office of Inspector General (OIG) discovered that during January – June 2007, 14 percent of elderly nursing home residents had claims for atypical antipsychotic medications (Levinson, 2011). Eighty-three percent of Medicare claims for atypical antipsychotics among nursing home residents were prescribed for off-label purposes, 51 percent were erroneous (i.e. not used for medically accepted indications or not administered to nursing home residents), and 22 percent were not compliant with standards set by the Centers for Medicare and Medicaid Services (i.e. drugs in excessive doses or excessive duration).

Using the Nursing Home Minimum Data Set (MDS) for eight states (CA, FL, GA, IL, NJ, NY, OH, and TX) in 1999 and 2006, Crystal, Olfson, Huang, and associates (2009) also found that 27.6 percent of nursing home residents had received an antipsychotic medication within the past seven days in 2006. Residents with schizophrenia had the highest rate of antipsychotic usage, 74 percent, within the past seven days in 1999 compared to others with bipolar disorders, 57.5 percent, and dementia with aggressive behavioral symptoms, 39.3 percent. In 2006, all three diagnoses remained associated with high rates of antipsychotic usage in the past seven days that were higher than rates recorded in 1999: residents with schizophrenia had 81.2 percent, residents with bipolar disorders had 65.1 percent, and residents with dementia and aggressive behavioral symptoms had 51.2 percent. Private for-profit nursing homes in 2006 had higher rates of antipsychotic use in the past seven days, 28.8 percent, compared to private not-for-profit nursing homes, 24.7 percent, and government facilities, 25.9 percent. The biggest increase in antipsychotic use in the past seven days when comparing 1999 with 2006 numbers occurred in not-for-profit nursing homes, which increased from 17.4 percent to 24.7 percent, while other kinds of facilities had smaller increases: government facilities went from 21.2 percent to 25.9 percent, and for-profit nursing homes went from 21 percent to 28.8 percent. Among the three kinds of nursing homes, the greatest percentage of residents receiving antipsychotics in 2006 were in private for-profit nursing homes at 73.5 percent compared to 22.3 percent in private not-for-profit nursing homes, and 4.3 percent in government facilities.

In a study analyzing the 2004 National Nursing Home Survey, Kamble, Chen, and associates (2008) found similar prevalence rates of antipsychotic usage among elderly nursing home residents, whereby 24.82 percent of nursing home residents were taking antipsychotics. Atypical antipsychotics accounted for most of the usage at 23.45 percent, while only 1.9 percent used typical (first-generation) antipsychotics, and less than one percent used both. The most commonly prescribed atypical antipsychotics were olanzapine (8.29 percent), risperidone (7.89 percent), and quetiapine (6.46 percent). High usage of antipsychotics was also found for managing conditions other than schizophrenia and bipolar disorders, specifically 70 percent for dementia, 40 percent for depression, and 18 percent for anxiety. Antipsychotics for the treatment of schizophrenia and bipolar disorders were much lower at 12 percent for the former and four percent for the latter.

Although the study by Crystal, Olfson, Huang, and associates (2009) and Kamble, Chen, and associates (2008) do not specifically address the effects of Medicare Part D on antipsychotic utilization in nursing homes, residents are guaranteed, by way of the Social Security Act, section §1860D, the right to choose their Medicare prescription drug benefit plan; however, pharmacies contracted by nursing homes might not be included in a prescription drug plan's preferred

network. Consequently, residents might likely pay higher out-of-pocket cost for their medications even though nursing homes are obligated to provide "pharmaceutical services (including procedures that assure the accurate acquiring, receiving, dispensing, and administering of all drugs and biological to meet the needs of each resident)" . Thus, although nursing homes residents are guaranteed the right to choose their own prescription drug plan, they do not have the freedom to choose their own pharmacy.

The body of work on antipsychotic utilization subsequent to the launch of Medicare Part D is slowly growing with earlier studies relying on individual pharmacy claims data soon after the program launched. West, Rae, Mojtabai, and associates (2011), however, conducted a study using clinical reports by psychiatrists on 986 dual eligibles from September – December 2006. They looked at problems with medication access that were due to Medicare Part D coverage or management issues (i.e. approval or co-pay issues) and discovered that 27.6 percent of the clinically indicated medications that could not be prescribed were atypical antipsychotics. Patients who were not able to obtain their atypical antipsychotics had an 82.2 percent rate of adverse events (i.e. emergency room visits, hospitalizations, homelessness, and incarcerations) and patients experiencing problems with obtaining preferred antipsychotics had 17.6 times increased odds (95 % CI = 8.7, 33.3, mean p = 0.0039) of having an adverse event within the past year compared to patients who were able to obtain their medications.

Coverage and management issues also prevented psychiatrists prescribing clinically preferred and intended medications in which 9.3 percent of the 90 patients that were clinically stable had to switch from an atypical to a typical antipsychotic. Medication switching led to significantly higher rates of adverse events (62 percent) compared to both patients with no medication switching and no problem with obtaining clinically indicated medications (36.8 percent). There were especially high rates of adverse events among patients who were switched to a different medication in a different class (82.8 percent), such as from an atypical to a typical antipsychotic, from a selective serotonin reuptake inhibitor (SSRI) to an older antidepressant, or from a newer sleep medication to a benzodiazepine. The study found that there was an 81.2 percent rate of adverse events occurring among individuals who were switched from an atypical to a typical antipsychotic (West et al., 2011).

Similar conclusions regarding medication access difficulties among dual eligibles after Medicare Part D was launched are documented in an earlier study by Huskamp, West, Rae, and associates (2009), although their study did not provide analysis of specific medications. Data from participating psychiatrists were collected for a longer period of time (three waves across 12 months in 2006) than the study by West, Rae, Mojtabai, and associates (September – December 2006) (2011). Thirty five percent of dual eligibles experienced difficulties accessing medications due to no coverage, while 22 percent were due to co-payments. Emergency room visits were also associated with medication access, in which individuals with medication access problems were more likely to have an emergency room visit compared to similar individuals with no problems with medication access (OR = 1.75, mean p = .003). Overall, individuals with medication access problems were more likely to be women, more likely to have major depression or anxiety, and more likely to have severe depressive symptoms, anxiety symptoms, or sleeping problems. A similar profile is drawn from the study by West, Rae, Mojtabai, and associates that individuals with major depression as well as severe symptoms of depression, anxiety, and sleep problems were more likely to have switched medications because of Medicare Part D coverage or management issues (i.e. approval or co-pay issues). Additionally, individuals with a prior

psychiatric emergency visit, individuals with increased suicidal or violent ideations, and a co-occurring psychiatric disorder were also more likely to have switched medications due to prescription coverage or management issues.

III. ANTIPSYCHOTIC DRUG ADHERENCE AMONG THE ELDERLY

Adherence in healthcare is generally understood as the extent to which a person's behavior coincides with medical or health advice (Haynes, Taylor, & Sackett, 1979), thus medication adherence is the ability to take medications as prescribed. The term is often used interchangeably with 'compliance' and together with 'persistence' (i.e. continuation of treatment or duration of time from initiation to discontinuation of therapy), but literature on the subject show a large degree of variation in the ways medication adherence/compliance and persistence are measured. Many analysts claim there exists no gold standard on measuring adherence/compliance and persistence (which is further elaborated in the Methods Chapter) and studies use myriad ways of calculation, such as: Continuous, Single-Interval Measure of Medication Availability (CSA), Continuous Measure of Medication Acquisition (CMA), Compliance Rate (CR), Days between Fills Adherence Rate (DBR), Continuous Measure of Medication Gaps (CMG), Continuous Multiple Interval Measure of Oversupply (CMOS), Medication Possession Ratio (MPR), Medication Possession Ratio, Modified (MPRm), Medication Refill Adherence (MRA), Proportion of Days Covered (PDC), and Refill Compliance Rate (RCR). Standardized medication management assessment tools specifically for the elderly are also used to examine adherence, such as the Medication Administration Test (MAT), the Medication Management Instrument for Deficiencies in the Elderly (MedMaIDE), the Medication Management Ability Assessment (MMAA), and the Drug Regimen Unassisted Grading Scales (DRUGS), and Gurland's Medication Management test (MM Test).

Studies on antipsychotic adherence emphasize the greater risk of experiencing side effects when older individuals take antipsychotics, which have resulted in pharmaceutical manufacturers being required to include a black box warning on their product packaging to alert consumers to potentially serious adverse effects. Some of these serious side effects include agranulocytosis, seizures, myocarditis, orthostatic hypotension, suicidality, and even death. Other side effects that are excluded from black box warnings are tardive dyskinesia (particularly in first-generation antipsychotics), metabolic syndrome, diabetes, extrapyramidal symptoms, weight gain, emotional blunting and sedation.

Atypical antipsychotics are considered to have less serious side effects than first-generation antipsychotics, such as haloperidol, fluphenazine, droperidol, and zuclopenthixol, and, thus better rates of adherence. Among individuals with schizophrenia, discontinuation of antipsychotics results in psychotic relapse, hospitalization, and emergency room visits (Csernansky, Mahmoud, & Brenner, 2002; Dolder, Lacro, Dunn, & Jeste, 2002; Fenton, Blyler, & Heinssen, 1997; Weiden, Kozma, Grogg, & Locklear, 2004).

Medication side effect, however, is one among many factors to consider when examining medication adherence among the elderly. In a study on medication adherence comparing older individuals with bipolar disorders (n = 29, mean age: 61 years old) to older individuals with schizophrenia (n = 219, mean age: 53 years old) and older individuals who were psychiatrically health (n = 54, mean age: 66 years old), researchers examined the effect of cognitive impairment on the ability of older individuals to manage a medication regime (Depp et al., 2008).

Researchers administered the Medication Management Ability Assessment (MMAA), which is a standardized instrument that was specifically designed for middle-aged and older individuals with serious mental illness (Depp et al., 2008). It is a performance-based measure of medication management ability involving role play with an assessor who describes a particular medication regimen. In the study participants were asked to follow a regimen of four medications with their bottles, dosages and instructions 30 minutes after being briefed by the assessor. Errors were then recorded as the number of under or over 21 possible correct doses. Results of the study found that older individuals with bipolar disorders made almost three times as many errors as psychiatrically healthy individuals, but no difference with older individuals with schizophrenia. The errors in the bipolar disorders group were in terms of under counting (vs. over counting) correct doses in which cognitive impairments were the most significant predictor of MMAA scores. A total of 83 percent of the bipolar disorders group made at least two errors compared to 78 percent of the group with schizophrenia and 50 percent of the group that was psychiatrically healthy. Errors of five or more were similar between the bipolar disorders group and the schizophrenia group at 52 percent and 53 percent respectively, while the psychiatrically healthy group made only 17 percent errors of five or more.

Researchers in the study (Depp et al., 2008) hypothesized that cognitive functioning would be the strongest predictor of MMAA performance and that the bipolar disorders group would perform better than the schizophrenia group; however, they found no difference in MMAA scores between the bipolar disorders group and the schizophrenia group even though the former had better cognitive and symptom profiles. Cognitive deficits were measured with the Mattis Dementia Rating Scale (DRS) that had subscales, such as attention, initiation/perseveration, construction, conceptualization, and memory, and scores of the DRS and its subscales were assessed with the MMAA performance scores. Although the researchers hypothesized that three subscales of the DRS – specifically attention, initiation/perseveration, and memory – would correlate with the MMAA scores, they discovered that only memory significantly predicted MMAA performance. Medication profiles of the participants indicate that antipsychotics were the largest therapeutic category used among both the bipolar disorders group (72 percent) and the schizophrenia group (98 percent), in which atypical antipsychotics had the highest usage rate in both groups (75 percent for the bipolar group and 79 percent of the schizophrenia group).

The study by Depp, Cain, Palmer, and associates (2008) highlight cognitive impairment unique to the elderly population that must be taken into consideration with regard to medication adherence. The issue of dosing is another dimension affecting adherence, specifically in terms of potency, frequency and the manner in which medications are meant to be taken (e.g. with or without food and water, together with other medications, etc.). Due to the relative newness of atypical antipsychotics, dosing strategies have primarily occurred based on individual response variability and the avoidance of adverse side effects. This is of particular concern among the elderly population as an older individual is more likely to have more than one chronic condition and likely to take more than one long-term medication. Based on 2005 Medical Expenditure Panel Survey (MEPS) data, a study (Paez, Zhao, & Hwang, 2009) suggests that 45.3 percent of older individuals ages 65 – 79 years old have three or more chronic conditions and 21.5 percent have two chronic conditions; while 54.2 percent of older individuals 80 years old and older have three or more chronic conditions and 20.2 percent have two chronic conditions. One hundred percent of these older individuals with three or more chronic conditions had expenditure for

drugs that averaged $1,292 per person annually, while those with two chronic conditions had an average expenditure of $791 per person annually.

Dosing atypical antipsychotics is particularly problematic for the elderly population with chronic conditions and multiple medication regimens, because prescriptions are not standardized. With atypical antipsychotics, which are known to have less serious side effects than older antipsychotics, dosing strategies are often based on individual response to a particular medication and its side effects. Some studies (Chan, Lane, Yang, & Huang, 2006; Correll, Malhotra, Kaushik, & McMeniman, 2003; Karow et al., 2008; Leucht, Shamsi, Busch, Kissling, & Kane, 2008), for example, suggest two weeks to observe individual response (i.e. through symptom alleviation or adverse effects) before adjusting or switching medications, while other studies (Dando & Keating, 2005; Ketter, Jones, & Paulsson, 2007) highlight dosing based on severity or state of a particular condition (e.g. maintenance treatment of schizophrenia, acute psychosis, acute bipolar mania, etc.). Additionally, dosing in practice do not necessarily follow dosing that have been established in clinical trials, which is further exacerbated when no clinically guidelines have been established for some atypical antipsychotics (Citrome & Volavka, 2002; Kapur, Vanderspek, Brownlee, & Nobrega, 2003; Lieberman et al., 2005).

In a study (Leslie & Rosenheck, 2004) examining antipsychotic dosing among 53,661 individuals with schizophrenia from the Veterans Administration (VA) national outpatient encounter data file and the VA drug benefit management system, researchers found that only 62.1 percent were given doses according to the Schizophrenia Patient Outcomes Research Team (PORT) recommendations, while 27.8 percent were given doses below and 10.1 percent were given doses above PORT recommendations. Among the entire sample, 17.4 percent were 65 years old or older and, along with female individuals, were more likely to be dosed below PORT recommendations and less likely to adhere to the recommendations. Older individuals given first-generation antipsychotics were generally dosed below PORT recommendations, while those given second-generation (or atypical) antipsychotics were generally dosed above PORT recommendations. From the entire sample, 31.8 percent were prescribed with first-generation antipsychotics, while the largest second-generation antipsychotics prescribed was for olanzapine at 30.3 percent, followed by risperidone at 25.2 percent. PORT originated in 1992 to disseminate scientific findings on treatments for schizophrenia that includes antipsychotic medications, adjunctive pharmacotherapies, assertive community treatment/intensive case management, electroconvulsive therapy, psychological interventions, family interventions, and vocational rehabilitation. Since PORT's original recommendations in 1998, updates on treatment recommendations have been released in 2003 and 2010 to keep up with the growing body of empirical data. It is funded by the Agency for Healthcare Research and Quality and the National Institute of Mental Health.

The study above underscores the reality that dosing often do not follow recommended guidelines, which are issued by various entities, such as the schizophrenia Patient Outcomes Research Team (PORT), Clinical Antipsychotic Trials of Intervention Effectiveness (CATIE), the Veterans Administration, individual departments of public health, etcetera. Studies examining dosing and drug-specific antipsychotics for the treatment of schizophrenia among the elderly population, however, remain sparse.

Pfeiffer, Ganoczy, and Valenstein (2008) examined the relationship between change in dosing frequency with adherence in the veterans population with schizophrenia. Using pharmacy data from the Veterans Administration, their sample had a mean age younger (56 years old

individuals receiving once daily dosing, and 55 years old for individuals receiving more than once daily dosing of antipsychotics) than the study on dosing by Leslie and Rosenheck (2004). With a total of 32,612 individuals with schizophrenia, researchers reviewed their prescription antipsychotic data, calculated medication possession ratio, and grouped prescriptions as either once daily or more than once daily. They found that an increase in dosing frequency was significantly associated with a decrease in adherence among individuals who had a 50 percent or greater increase in total dose during the study period (October 2004 – September 2005), while a decrease in dosing frequency was significantly associated with improved adherence among patients who were originally on more than once-daily dosing. In contrast to the study by Leslie and Rosenheck, older age and a larger number of psychotropic prescriptions were associated with better adherence.

An earlier, similar study on antipsychotic adherence also analyzed data from the Veterans Administration using the National Psychosis Registry (Valenstein et al., 2004). The study investigated antipsychotic adherence among 63,214 veterans with schizophrenia or schizoaffective disorder by measuring Medication Possession Ratio (MPR) and examined associated patient factors. Study findings discovered that, in general, there were high levels of poor adherence for both groups that were prescribed typical antipsychotics (37.8 percent) and atypical antipsychotics (41.5 percent) as well as those on single drug therapy (40 percent) and those on dual-drug therapy (38 percent). African Americans on single antipsychotics were more poorly adherent (54 percent) than whites (32 percent), while younger veterans with schizophrenia were also more poorly adherent (46 percent for veterans < 45 years old; 38 percent for veterans 45-64 years old) than older veterans (33 percent for veterans ≥ 65 years old).

The subject of antipsychotic adherence among the elderly covers a wide spectrum of related issues that must be taken into consideration. Chief among them are factors unique to the elderly that affect adherence, such as: antipsychotic usage that are considered off-label (i.e. not approved by the Federal Drug Administration), but widely practiced; cognitive and memory impairments; possible drug-drug interaction from taking multiple medication regimen; as well as serious side effects and adverse drug events due to changing pharmacokinetics with aging. The introduction of Medicare Part D and the way prescription drug plans are designed adds to the already multifaceted nature of antipsychotic utilization and adherence.

IV. ANTIPSYCHOTIC DRUG COVERAGE

In early 2008, two years after Medicare Part D came into effect, the program had 25.4 million beneficiaries enrolled (Kaiser Family Foundation). In mid-2011 the number has reached 29.5 million or more than half of all Medicare beneficiaries (Kaiser Family Foundation, 2011). Overall, the program has expanded prescription drug coverage among the elderly, but studies on specific therapeutic classes of drugs from Medicare Part D claims data itself currently remain sparse.

In terms of coverage for medications in general, Lenderts and Kalali (2010) examined payer data nationwide for branded and generic medications for July 2010. Utilizing private data known as Vector One: Payer (VOPA), which is owned by SDI Health LLC, they found that compared to antidepressants and attention deficit hyperactivity disorder (ADHD) medications, atypical antipsychotics had the highest average out-of-pocket cost and the largest disparity between its brand-name versus its generic versions. The average out-of-pocket costs incurred by individuals covered by commercial third-party prescription plans (excluding Medicaid) was

lower for selective serotonin reuptake inhibitors (SSRI, an antidepressant) compared to serotonin and norepinephrine reuptake inhibitors (SNRI, an antidepressant) and atypical antipsychotics. Average out-of-pocket cost for brand-name SSRI was $37.50, while generic SSRI was $8.16. In contrast, average out-of-pocket cost for brand-name antipsychotics was $46.40, while average out-of-pocket cost for generic antipsychotics was $12.13. Brand-name atypical antipsychotics were typically $34.27 higher than their generic equivalent.

Atypical antipsychotic studies specific to Medicare Part D coverage in Washington State are also very limited. Two studies by Wang, Kennedy, Cohen and Sclar (2009), and Wu, Kennedy, Cohen, and Wang (2009) focused on Medicare Part D coverage of six atypical antipsychotics: aripripazole, clozapine, olanzapine, risperidone, quetiapine, and ziprasidone. The studies utilized information accessible from the CMS online tool to compare prescription drug plans in the region. Findings from these studies found that coverage and drug formulary restrictions of the atypical antipsychotics varied substantially among stand-alone prescription drug plans (PDPs) and Medicare Advantage prescription drug plans (MA-PDs). Although most plans covered all of the six atypical antipsychotics reviewed, most plans also applied coverage tiers (i.e. copayment dependent on tier grouping. Drugs grouped as generic, preferred brand, and non-preferred brand; or drugs grouped as generic and non-generic brand) with higher tiers requiring higher co-payments. Additionally, most plans applied utilization management in the form of quantity limits, which are more likely used by PDPs, or prior authorization, which are more likely used by MA-PDs. From 2007 to 2008 the number of PDPs offered in Washington State dropped from 57 to 53 plans, while the number of MA-PDs grew from 43 to 52 plans. However, both types of plans increased their premiums, specifically by 15 percent, for PDPs, and 20 percent, for MA-PDs. Copayments also increased during the study period, with the highest increase for clozapine, which increased by 52 percent; while aripripazole increased by 31 percent among PDPs during the initial coverage period. Aripripazole copayment also increased the most by 11 percent among MA-PDs during the initial coverage period. The only decline in copayment was seen during the gap coverage for clozapine, which declined by 5 percent among PDPs and 8 percent among MA-PDs; while the highest increase was seen for ziprasidone at a mean increase of 12 percent among PDPs and 14 percent among MA-PDs.

A study by Zivin, McCammon, Davis et al. (2008) compared Medicare Part D plans using the PDP online comparison tool provided by the Centers for Medicare and Medicaid Services (CMS) and assessed which plan would be the least expensive based on cost of all medications and, separately, based on cost of non-psychiatric medications only. Using four hypothetical clinical scenarios (patient with psychiatric disorders: psychosis, bipolar disorders, depression, and dementia with behavioral disturbances; and medical conditions: rheumatoid arthritis, osteoarthritis, hypertension, hypothyroidism, hyperlipidemia, type 2 diabetes, and urinary incontinence), they hypothesized that the lowest cost for PDP for all medications is not the lowest-cost PDP if psychotropic drugs were excluded. The study found that there is considerable variation in lowest cost PDP across regions as well as variations in optimal plan choice based on medication regimen. Psychiatric medications also explained 60 to 80 percent of medication costs across the hypothetical cases, with brand-name psychiatric drugs costing more than other medications.

Studies on the impact of the coverage gap on psychotropic drugs specifically have not yet surfaced, perhaps due to the relatively new availability of Medicare Part D claims data. One study on the effects of the Medicare Part D coverage gap on prescription drugs in general

indicate that beneficiaries with some kind of coverage during the doughnut hole period had a smaller percentage of drug use reduction compared to beneficiaries without any kind of gap coverage (Zhang, Donohue, Newhouse, & Lave, 2009), while other studies (Bayliss, Ellis, Delate, Steiner, & Raebel, 2010; Raebel, Delate, Ellis, & Bayliss, 2008) assessing medication adherence and healthcare utilization in the context of the coverage gap found that in the first two years of implementation Medicare Part D beneficiaries had lower medication adherence during the gap period and they were characteristically older with more morbidity and more medication usage than those who did not reach the coverage gap. A different study (S. Ettner et al., 2010) identified risperidone, quetiapine, and olanzapine as the top three atypical antipsychotics that drive Medicare Advantage Prescription Drug Plan beneficiaries with dementia into the coverage gap. More than 23 percent of beneficiaries with dementia in the study who entered the gap were taking one of the three atypical antipsychotics, surpassing the number of beneficiaries with schizophrenia using the same drugs. A higher figure of 36 percent was found among beneficiaries living in skilled nursing facilities using the three antipsychotics. Average cost in 2006 for a 30-day supply for olanzapine was $225.60, for risperidone $159.90, and for quetiapine $135.30. Beneficiaries with dementia, along with those with diabetes, end-stage renal disease, coronary artery disease, chronic obstructive pulmonary disease, and congestive heart failure were at greater risk to enter the coverage gap.

Evidence from a study that examined data from Medstat MarketScan Commercial Claims and Encounters Database suggest that there is an association between higher cost-sharing and lower levels of atypical antipsychotic compliance in the commercially insured population (Gibson, Jing, Kim, et al., 2010). Examining 7,910 individuals between the ages 18 – 64 years old with either schizophrenia or bipolar disorders, the study found that cost-sharing (i.e. in the form of copayment and co-insurance) becomes a financial barrier when levels exceed $30, resulting in lower probability of adherence and shorter time to discontinuation of medications. Medication adherence rates were 27 percent lower among beneficiaries with antipsychotic cost-sharing greater than or equal to $50 compared to beneficiaries with cost-sharing lower than $10. Similarly, medication adherence rates were also lower by about 10 percent among beneficiaries with cost-sharing in the range of $30-$50.

Zeber, Grazier, Valenstein, Blow, and Lantz (2007) also looked at the mentally ill veterans population and pharmacy utilization. The study investigated the effects of copayment increase on medication refills among veterans with schizophrenia, distinguishing psychiatric fills from medical fills, but did not group antipsychotic fills separately. Analyzing data from the National Psychosis Registry for 2000 - 2003, the study found that there was an overall decline of 25 percent in prescription fills for psychotropic drugs among a sample of 40,737 co-paying veterans with schizophrenia subsequent to a copayment increase from 12.9 percent to 14 percent. In contrast, there was an increase from 0.7 percent to 3.7 percent in prescription psychotropic fills among 39,931 non-co-paying veterans with schizophrenia (i.e. veterans who were exempt from making copayments) as well as 1.7 more prescription psychotropic fills specifically among female veterans. Older veterans ($\geq$ 65 years old) were found to have 5.3 fewer psychotropic fills than younger veterans along with a 50 percent drop in psychiatric admissions during the same period as a result of copayment increase. Similarly ethnic minority veterans also had lower psychotropic fills, with five fewer fills among African American veterans and almost two fewer fills among Hispanic veterans. The study employed the health belief framework by Becker and Maiman (1975) that aided in building the analytical models for medication adherence and risk factors. The study found that veterans preferred to restrict prescription psychotropic fills rather

than prescription medical fills as a response to copayment increase, particularly when there are co-morbid conditions involved. According to the health belief framework, medication adherence reflects balancing perceived benefits of treatment (i.e. prescription fills) with perceived barriers to treatment (i.e. cost increase) and stems from a combination of patient characteristics, beliefs about health as well as provider and system factors.

In considering past studies on schizophrenia in the veterans population several caveats must be noted. First are differences in patient level profiles among the elderly, predominantly male, veterans population and the elderly in the general population. Mentally ill veterans are characteristically poor, homeless, disabled, and socially isolated with higher co-occurrences of substance abuse than the civilian population. Secondly, the health systems in which veterans and non-veterans receive mental health care also differ in terms of health insurance benefits and coverage. For example, there are no monthly premiums in the Veterans Administration (VA) single health system and co-paying veterans comprise only one percent of individuals treated within the VA system, while all non-subsidized Medicare Part D stand-alone PDPs have premiums and some form of copayment and/or co-insurance. Notwithstanding the differences, however, studies on pharmacotherapy for schizophrenia among the elderly in either population suggest that high cost sharing prescription drugs affect pharmacy utilization, medication adherence, and, in the longer term, other health services utilization (see Farley, 2010; Gibson et al., 2010; Marcus & Olfson, 2008; Simoni-Wastila, Zuckerman, Shaffer, Blanchette, & Stuart, 2008; Slade et al., 2005; Soumerai, Ross-Degnan, Casteris, & Bollini, 1994; Taira, Iwane, & Chung, 2003; Zeber et al., 2007).

Previous studies on the effects of cost-sharing and gaps in coverage on the elderly population with schizophrenia are sparse, and limited evidence suggesting higher cost-sharing through tiered formularies bring about proper pharmacy utilization and better health outcomes are inconclusive. Given the chronic nature of schizophrenia, the importance of adhering to medications, the imposition of cost-sharing and gaps in coverage by many prescription drug plans lead to the clear need to examine utilization and adherence of antipsychotics under Medicare Part D.

In summary, there remain gaps in the literature concerning the effects of Medicare Part D coverage of antipsychotics. With the concern raised in Congress (Levinson, 2011) on over-prescribing of antipsychotics among nursing home residents, together with the widespread practice of off-label usage, it is evident that the issue of antipsychotic utilization, adherence, cost, and coverage among the elderly is multi-faceted and complex, particularly as antipsychotics are among the classes of drugs that are required to be covered by the program. Studies to date have provided findings that are inconclusive, and antipsychotic- and disease-specific studies encompassing utilization, adherence, and coverage are even sparser.

CHAPTER 3

CONCEPTUAL FRAMEWORK

Medicare Part D is a complex program to understand as it involves many entities and mechanisms in its implementation (e.g. pharmacy benefit managers, plan sponsors, pharmacies, competitive bidding for plans, government reimbursements, drug manufacturer rebates, price concessions for drugs, medication therapy management services, utilization management tools, formulary requirements, etc.). As such, analyses of the impact and effectiveness of the program can be approached in many ways. This dissertation focuses on the effects of out-of-pocket expenditure on utilization of antipsychotic drugs among a specific group of beneficiaries as a way to examine choice of plan coverage in the program.

Actual prices of drugs paid by insurance companies (referred to as "plan sponsor" by the Centers for Medicare and Medicaid Services or CMS) in Medicare Part D are neither transparent nor available in Medicare Part D data files collated by the CMS; thus an alternative approach to assess coverage is by looking at the beneficiary cost-sharing component for prescription drugs filled. Such cost-sharing features in Medicare Part D are built into the design of plan benefits that varies considerably between plans; where deductibles, gap in coverage, specialized drug tiers, co-payments, and/or co-insurance may be imposed in part or in whole by plan sponsors. This study emphasizes the ways in which coverage via beneficiary out-of-pocket expenditures affect antipsychotic utilization. Thus, choice – i.e. beneficiaries optimally choosing a prescription drug plan that will enable drug utilization that will meet their medical needs – is a piece in the puzzle of understanding Medicare Part D program effectiveness.

From the above rationale, the conceptual framework underpinning this study is that of consumer behavior from a behavioral economics perspective, specifically in terms of assessing plan choices and drug utilization among beneficiaries. As a program that intended to expand access and insurance coverage of prescription drugs, the design of Medicare Part D relies on market competition among plan sponsors to offer prescription drugs that would meet the very diverse needs of the Medicare population. Thus, choosing the best plan for a beneficiary would mean giving consideration to plans that would meet beneficiary drug needs and monthly budget that greatly varies within this population. A beneficiary, therefore, must assess such factors as: monthly premium, annual deductible, out-of-pocket expenditure during the donut hole, total annual out-of-pocket expenditure, coverage (or lack thereof) during the donut hole, availability of brand-name and generic drugs on plan formulary, mail order options, and plan ratings. Plan choice becomes harder when multiple drugs are needed and when drug needs in one calendar year ahead are unpredictable (particularly among the chronically and co-morbidly ill population); yet the ultimate goal remains, which is to maximize individual utility by selecting a plan with the lowest out-of-pocket cost for a beneficiary, but also have enough built-in coverage should drug needs change during the year.

Traditional economic theories in the context of health insurance assume that prospective enrollees are perfectly rational and forward-thinking in assessing insurance options in terms of costs and benefits. Greater foci are, thus, typically placed on market forces such as prices, coverage information, health insurance options, income, and other factors influencing the supply

and demand of health insurance. For most goods and services increase in price result in decrease in demand, where in the health insurance arena the notion of price is reflected in a number of ways, such as through premiums and cost-sharing mechanisms (i.e. co-payments and co-insurance). In this approach more choices through market competition is thought to benefit consumers.

Behavioral Economics, Choice, and Decision-Making. In contrast, behavioral economics emphasize the ways in which individuals reach economic decisions in order to understand marketplace deviations that are not readily explicable by traditional economic models. A plethora of choices, for example, is conventionally thought to be better, but studies in behavioral economics suggest that *too many* choices become too complex for some consumers resulting in sub-optimal decision-making, inconsistent decision-making, less satisfaction with decisions made, or even no decisions altogether (Abaluck & Gruber, 2009; Hanoch, Wood, Barnes, Liu, & Rice, 2011; Iyengar & Lepper, 2000; Redelmeier & Shafir, 1995; Roswarski & Murray, 2006; Schram & Sonnemans, 2011; Tanius, Wood, Hanoch, & Rice, 2009). In the context of Medicare Part D where stand-alone prescription drug plan offerings (PDPs) among most states number in the 51-55 range (in 2008), the question of how many plans are too many for the Medicare population becomes important.

Health and finance-related studies indicate that older individuals do not always make the most optimal choices compared to younger individuals and faced with an abundance of choice and complexity of information related to choices – otherwise known as "choice overload" – many consumers suffer decision-making paralysis, which is the inability to make decisions due to the overwhelming number of options available. Studies on health insurance from a behavioral economics approach suggest that there is a threshold for the number of plan choices in which consumers make optimal decisions, but there is no consensus on a magic number of plans that conclusively show that beyond a certain choice-set size costs (i.e. costs in terms of errors, time spent, and emotional costs) will outweigh benefits gained (Barnes, Hanoch, Wood, Liu, & Rice, 2012; Bundorf & Szrek, 2010; Elbel, 2007; Frank & Lamiraud, 2008; Gruber, 2009; Hanoch, Rice, Cummings, & Wood, 2009; Hanoch et al., 2011; Loewenstein, 1999; Szrek & Baron, 2007).

In an experimental study examining the effects of age and number of simplified Medicare Part D plans on objective measures of performance and subjective assessment of plan selection experience Hanoch, Rice, Cummings, and Wood (2009) found that older individuals (65 years old and older, n = 90) performed more poorly compared to younger individuals (18-64 years old, n = 90) and exhibited greater confidence in choosing the lowest-cost plan even though the opposite was the case; additionally, decision quality deteriorated as the number of plans increased. In the study participants were randomly assigned into groups of 3, 10, or 20 hypothetical Medicare Part D prescription drug plans. The plans were given single letters as plan identifiers rather than actual plan sponsor names from Medicare Part D, and participants were given print-outs on relevant plan information (except for information on drug formulary and coverage during the gap, which were excluded) prior to making their plan selection in a pen-and-paper format. Objective measures related to performance were presented via four questions to assess comprehension of tabular information and ability to compare plans, while subjective measures were via questions related to self-reported confidence in choosing the best plans according to the scenarios presented. On the subject of performance the study suggests that prior to controlling for socio-demographics variables and health status, older adults are less likely to

choose the correct plan that minimizes total annual costs; however, age was no longer significant once control variables were included. In contrast, before and after controlling for socio-demographic variables and health status, age and the number of plans were significantly associated with the number of correct answers in response to the four questions on objective measures. Specifically, older individuals and those assigned to the larger number of hypothetical plans (10 and 20 plans) were less likely to correctly answer at least three of the four questions on tabular plan information.

In a similar experimental study, Bundorf and Szrek (2010) assigned older individuals (ages 65 years old and older, N = 295) to four groups of plan sizes: 2, 5, 10, and 16 hypothetical plans and asked them to choose two plans based on six plan characteristics (i.e. deductible of $0, $100, $250; formulary breadth of 75, 85, 95, and 100 drugs from the top 100 drugs used by Medicare beneficiaries; the number of drugs with co-payments of $20 or less – 20, 50, 75, and 95; the number of drugs with prior authorization – 0, 10, 20, and 40; gap coverage of none, generic only, or brand and generic; and monthly premium). The second choice, however, was randomly assigned from a different group of plan size than the first choice and after making their selections individuals then answered questions regarding their decision process, choice set, and plan choice. The plans in each set were grouped so that no one plan stood out compared to others in the set. Findings from the study suggest that both the benefits (i.e. in terms of evaluating and choosing a plan that meets participants' preferences) and costs of choice (i.e. costs in error, time, and emotion) increases as choice sets became larger; however, decision-making also became difficult with 61 percent of individuals finding the decision process very to extremely difficult on a Likert scale. As choice sets increased, individuals became less satisfied with the size of their choice set, but were more satisfied with the plan they chose as the number of alternative plans increased. Satisfaction with plan choice peaked at choice set size of 10 plans. Decision-making became easier with the second choice with individuals feeling they had more control during their decision-making process and were more likely to feel well-informed in making their choices.

Another study (Gruber, 2009) using Medicare Part D claims data from Wolters Kluwer Company and the Centers for Medicare and Medicaid Services similarly found that beneficiaries were not making optimal decisions in their plan choices. Using claims data for drug utilization and out-of-pocket expenditure for 55,000 beneficiaries in 2005 and 2006 the study discovered that only nine percent of beneficiaries were choosing the lowest-cost plan available. Savings that could have been made by beneficiaries who did not choose the lowest-cost plan amounted to $360 on average. Even with a broader criterion for low-cost plan set at five percent of prescription drug plans still only 13 percent of beneficiaries chose a low-cost plan. Under this scenario $280 on average could have been saved by those who did not choose a low-cost plan. Further studies by Abaluck and Gruber (2009, 2011) show that beneficiaries do not choose plans efficiently in that too much weight is given to premiums than out-of-pocket costs, individualized risk characteristics of other plan options are not considered, and though plan characteristics are considered in decision-making, they are not considered with respect to their effects on the distribution of out-of-pocket costs.

The studies above and similar studies on the behavioral economics of health insurance suggest that having plan options for consumers is important on various levels. From a market mechanism level a pool of insurance plans creates competition and controls costs among plan sponsors that spurs better plan benefits. Better plan benefits, in turn, will enable consumers to choose a plan that would meet and satisfy individual needs, but a number of studies suggest that

Medicare Part D beneficiaries are less than satisfied. From a panel survey conducted in 2007 comprising 1255 respondents ages 65 years old and older, Morgan and Campbell (2011) found that only 39 percent of Medicare Part D stand-alone prescription drug plan (PDP) beneficiaries and 45 percent of Medicare Advantage prescription drug plan (MA-PD) beneficiaries were very satisfied with their plans. More recent survey findings from 992 respondents ages 65 years old and older (KRC Research, 2011) indicate that satisfaction levels have improved with 52 percent of both stand-alone PDP and MA-PD beneficiaries feeling very satisfied with their drug coverage particularly among beneficiaries with PDP monthly premiums less than $30 and spend less than $50 in monthly out-of-pocket costs.

Improved satisfaction with Medicare Part D may be due to familiarity with the program now that it is in its sixth year and studies on Medicare Part D from a behavioral economics perspective is starting to emerge that provides a better understanding of the program and its effectiveness. Satisfaction of Medicare Part D from this perspective, for example, suggest that satisfaction levels improved not only because of program familiarity, but also the heterogeneity of plan offerings available that enabled beneficiaries to choose plans specific to their medication needs and budgets.

Studies on Medicare Part D from a behavioral economics lens thus far approach the question of beneficiary choice on a prescription drug plan from a behavioral (i.e. decision-making) standpoint with respect to such aspects as: choice set size, plan differentiation, choice complexity, choice overload, decision paralysis, optimality of plan choice from a costs and savings perspective, beneficiary numeracy levels, and beneficiary satisfaction levels with chosen plans. This dissertation examines choice optimality by way of beneficiary prescription drug plan coverage and out-of-pocket expenditure and comparing them to the lowest available plan in the region based on select antipsychotics. Elderly Medicare beneficiaries with schizophrenic disorders are the study population serving as proxy for cognitive deficits, which has not been specifically examined in past studies on plan choice. The study also extends analysis of optimal plan choice to include the ways in which coverage affects drug utilization (i.e. filling of prescriptions and medication adherence). This research, thus, seeks to better understand the relationship between plan choice (i.e. coverage), out-of-pocket expenditure, and select antipsychotic utilization.

I. STUDY QUESTIONS AND HYPOTHESES

Question 1

What are the characteristics of Medicare Part D beneficiaries in Washington State utilizing antipsychotic medications?

Question 2

What types of plans do beneficiaries choose in terms of coverage for antipsychotic medications?

Question 3

What are the characteristics of beneficiaries who enter the gap-in-coverage period, or ICL benefit phase?

Question 4

Do plan choice and antipsychotic coverage impact antipsychotic medication adherence? In what ways do beneficiaries' plan choices and antipsychotic coverage affect medication adherence?

Question 5

Do beneficiaries' out-of-pocket expenditure affect medication adherence?

Question 6

How well do beneficiaries choose their Medicare Part D plans in terms their antipsychotic medication needs?

Hypothesis 1. Beneficiary Plan Choice.

In light of past studies suggesting that the elderly in general make sub-optimal choices in health-related matters, it is hypothesized that most Medicare Part D beneficiaries with schizophrenic and bipolar disorders do not choose the cheapest prescription drug plan available.

Hypothesis 2. Beneficiary Plan Choice.

In terms of coverage during the donut hole, it is hypothesized that most Medicare Part D beneficiaries with schizophrenic and bipolar disorders choose plans that offer some level of coverage during the donut hole.

Hypothesis 3. Beneficiary Reaching the Donut Hole.

Medicare Part D beneficiaries with schizophrenic and bipolar disorders who reach the donut hole have higher overall out-of-pocket expenditure than those who do not reach the donut hole during the study period.

Hypothesis 4. Beneficiary Medication Utilization.

Medicare Part D beneficiaries with schizophrenic and bipolar disorders who reach the donut hole have lower overall medication utilization than those who do not reach the donut hole during the study period.

Hypothesis 5. Beneficiary Medication Adherence.

Medicare Part D beneficiaries with schizophrenic and bipolar disorders with higher out-of-pocket expenses in the gap period have lower levels of medication utilization and adherence than those with lower out-of-pocket expenses in the gap period.

CHAPTER 4

Methods

I. STUDY DESIGN

In seeking to understand the effects of coverage of Medicare Part D among beneficiaries with schizophrenia and bipolar disorder in Washington State, the design of this study is retrospective and cross-sectional using secondary data. The study population is extracted by the Centers for Medicare and Medicaid Services (CMS) and comprised of Medicare Part D beneficiaries with at least one filled prescription of the atypical antipsychotics: olanzapine, risperidone, and quetiapine, or the typical antipsychotic haloperidol. Both descriptive and analytical examinations of data are conducted and findings are reported in the Results chapter.

Funding to obtain Medicare Part D data and provision for a secure data room were provided by Washington State University under the auspices of John Roll, PhD, Senior Vice Chancellor for Academic Affairs and Research. As such, the Institutional Review Board (IRB) at Washington State University reviewed the study proposal and determined that IRB approval or certification of exemption were not required due to the secondary, de-identified, and encrypted nature of the data.

II. DATA SOURCE

This study utilized the Medicare Part D Prescription Drug Event (PDE) data, which are summary records (i.e. claims) of prescriptions filled under Medicare Part D submitted monthly to the Centers for Medicare and Medicaid Services (CMS) by prescription drug plans (PDPs) and Medicare Advantage prescription drug plans (MA-PDs). The PDE data is managed by the Research Data and Assistance Center (ResDAC) at the University of Minnesota and the study population is extracted based upon review of a study proposal. Subsequent to proposal approval, data was requested for the following data files:

- Part D Event Finder file, 2008
- Beneficiary Summary Finder File, 2008
- Carrier Finder File, 2008
- Beneficiary Summary File, 2008
- Part D Event Data (15 variables)
- Drug Characteristics File
- Plan Characteristics File
- BENE_ID Crosswalk

A. THE MEDICARE PART D PRESCRIPTION DRUG EVENT (PDE) DATA

The PDE data is summary records of prescription drug claims of Medicare Part D beneficiaries that are submitted by prescription drug plans participating in the Medicare Part D program and processed (i.e. collect, validate, and store) by the Centers for Medicare and Medicaid Services (CMS). Thus, the PDE data reflects all Medicare Part D prescriptions that are filled at the point-of-service; in other words, it records all prescriptions that are filled by the program's beneficiaries and, thus, it is distinct from prescribing data. PDE data is available to non-CMS researches upon submission and approval of a research proposal, which is followed by a CMS cost estimate of the data files requested for the approved study.

The following variables from the PDE data (Table 1) are used:

TABLE 1: LIST OF PDE VARIABLES

PDE Variable	Purpose
Encrypted Part D Event ID	Unique key for each Part D event
Encrypted 732 Beneficiary ID	Need for linking to other files
Patient Date of Birth (DOB)	To establish age of beneficiaries in sample population
Patient Gender	To establish sex of beneficiaries in sample population
RX Service Date	To determine first fill date of the year studied (2008) for the selected antipsychotics
Product Identifier	This is the National Drug Code (NDC) of a drug and is necessary to identify a specific drug.
Encrypted Plan Contract ID	To link PDE data file with Plan Characteristics file in order to assess whether there are differences in antipsychotic usage by type of plan.
Encrypted Plan Benefit Package ID	To link PDE data file with Plan characteristics file in order to assess whether there are differences in antipsychotic usage by benefit package.
Quantity Dispensed	To determine dosage units dispensed.
Days Supply	To determine number of days supply dispensed.
Patient Pay Amount	To determine beneficiary out-of-pocket expense and entry into various benefit phases. The study will assess whether copayments affect filling of prescriptions and adherence.
Low-Income Cost-Sharing Subsidy Amount (LICS)	To identify low income beneficiary
Benefit Phase	To determine benefit phase status and link with prescription filling.

There are a number of files necessary in order to utilize the PDE data and conduct the proposed analyses. The additional files are: (1) Beneficiary Summary Finder file, (2) Carrier Finder file, Beneficiary Summary file, (3) Drug Characteristics file, (4) Plan Characteristics File, and (5) BENE_ID Crosswalk. The Beneficiary Summary file is constructed by CMS using beneficiary sample criteria provided by the researcher and is run against the claims and enrollment data; the Carrier Finder file is the claims file used by CMS to create the Beneficiary Sample file; the Drug Characteristics file contains drug-related variables (i.e. brand name,

generic name, drug strength, and form of drug); the Plan Characteristics file has information on Medicare Part D plans (i.e. premiums, cost-sharing tiers, plan benefit package, and service area); and the BENE_ID Crosswalk file merges the various files by beneficiaries whose identities have been de-identified and encrypted by CMS.

B. OTHER DATA

Rural-Urban Commuting Area Codes (RUCA) version 2.0 for Washington State was downloaded from the Rural Health Research Center website (Rural Health Research Center, 2009). The RUCA Codes are used to identify beneficiaries' locations of residence, which in this research study is aggregated into four categories: (1) urban areas, (2) large rural areas, (3) small rural areas, and (4) isolated areas.

The RUCA Codes is a Census tract-based rural-urban classification system developed by the Washington, Wyoming, Alaska, Montana, and Idaho (WWAMI) Rural Health Research Center, the Office of Rural Health Policy, and the Economic Research Service of the Department of Agriculture. It defines rural and urban areas based on population density and population work commuting patterns. The codes in this study utilized the ZIP code version of the RUCAs.

III. STUDY POPULATION INCLUSION-EXCLUSION CRITERIA AND DATA EXTRACTION

Data extraction was conducted by Vangent (now General Dynamics Information Technology Company) on behalf of the Centers for Medicare and Medicaid Services (CMS) based on the following criteria:

A. FIRST COHORT SEARCH CRITERIA:

- Search calendar year 2008 Prescription Drug Event file for beneficiaries with an event for one of the researcher-provided National Drug Codes (NDC) for brand and generic olanzapine, risperidone, quetiapine fumarate, and haloperidol. Total number of NDCs: 791.
- Search calendar year 2008 Master Beneficiary Summary File (A/B/D segment) for beneficiaries who are 66 or older in which age is determined at the end of the calendar year, who live in Washington State, and do not have end-stage renal disease.
- Beneficiaries found in both of the above searches make up the first cohort.

Total number of beneficiaries from the first search is 14,346 beneficiaries, of which 8,227 are dually eligible for Medicare and Medicaid (referred to as 'duals').

B. SECOND COHORT SEARCH CRITERIA:

- Beneficiaries in the first cohort are then searched in the Carrier file for researcher-provided diagnoses (i.e. ICD-9 codes for Schizophrenic and Bipolar disorders). Total number of beneficiaries in the second search: 1922.

Additionally, beneficiaries who filled prescriptions for any of the antipsychotics in the study, but died during the study period are excluded from analyses.

IV. VARIABLES AND MEASUREMENTS

All files received from the Centers for Medicare and Medicaid Services (CMS) were merged together with the Rural-Urban Commuting Area Codes (RUCA) file and data cleaning, examination, and descriptive and analytical analyses were conducted using SAS 9.3.

A. OUTCOME VARIABLES.

Two main outcome variables for analyses are medication utilization in the form of claims (i.e. prescriptions filled) and medication adherence as measured in Proportion of Days Covered (PDC).

1. PRESCRIPTION CLAIMS:

For every prescription claim, its corresponding beneficiary data is examined (i.e. age, sex, race, and RUCA code) along with its dispensed dosage, number of days supplied, out-of-pocket-costs, benefit phase, low income cost-sharing status of beneficiary as well as corresponding drug characteristics and plan characteristics.

2. PROPORTION OF DAYS COVERED (PDC):

This is a measure of medication adherence, which in this study is calculated using prescription claims for the antipsychotics: olanzapine, quetiapine, risperidone, and haloperidol. These antipsychotic medications are prescribed for beneficiaries with schizophrenia and bipolar disorder and adherence is estimated for calendar year 2008. For every prescription claim, PDC is calculated using the date when a prescription is filled and the number of days a medication is supplied divided by the number of days in the study period and then multiplied by 100 percent. Variables used to calculate PDC values are: beneficiary identification, date of prescription filled, number of days medication is supplied, start date of the study period, and end date of the study period.

Using SAS 9.3 a macro is prepared and variable values for the macro are set with arrays created for prescription fill dates and the number of days supplied for a particular medication for each beneficiary. The macro also includes calculations to account for early and overlapping refills, and the sum of adjusted number of days supplied for a medication. PDC values ≥ 0.80 are considered adherent and values greater than 1.0 are truncated, while claims for only one filled prescription during the study period are excluded from PDC calculations.

B. COVARIATES.

Recapitulating that the focus of the study is to investigate the effects of coverage on antipsychotic utilization among Medicare Part D beneficiaries with schizophrenia and bipolar disorder in Washington State, the following are covariates of interest:

1. BENEFICIARY:

Using the variable BENE_ID beneficiaries are identified for analyses. This variable consists of both numeric and character values and it serves to cross-reference data for all claims and related variables for each beneficiary. The BENE_ID variable is unique to the Chronic

Condition Warehouse, which is the national database for Medicare, Medicaid, and Part D PDE data.

2. AGE:

Beneficiary age is identified through the variable BENE_AGE_AT_END_REF_YR for every beneficiary in the data file. This variable is the age of a beneficiary at the end of the study period.

3. SEX:

The variable BENE_SEX_IDENT_CD identifies sex of a beneficiary.

4. RACE:

The variable BENE_RACE_CD identifies race of a beneficiary, which is coded for the following groups: Asian, Black, Hispanic, North American Native, and White.

5. RURAL-URBAN AREAS OF RESIDENCE:

The variable for rural-urban areas is aggregated into four categories from the ZIP code version of the Rural-Urban Commuting Area Codes (RUCA) 2.0. The four area categories are: urban, large rural, small rural, and isolated.

6. GENERIC ANTIPSYCHOTIC MEDICATIONS:

There are three atypical and one typical antipsychotic medications examined in this study. Olanzapine, quetiapine, and risperidone are atypical antipsychotics drugs and haloperidol is a typical antipsychotic drug. These medications are identified under the GNN variable.

7. NUMBER OF DAYS OF SUPPLIED MEDICATIONS:

The variable for the number of days of supply for a medication dispensed by a pharmacy when a prescription is filled is DAYS_SUPLY_NUM. It is a numeric variable ranging from 0 – 999.

8. BENEFIT PHASES:

There are 13 benefit phase categories in the variable BENEFIT_PHASE that show the specific benefit phase a beneficiary is in when a prescription is filled. A benefit phase is assigned based on a beneficiary's plan benefit package, out-of-pocket threshold amount, accumulated gross drug, and out-of-pocket costs. Four categories within this variable represents the main benefit phases of the Medicare Part D program: deductible phase, pre-Initial Coverage Limit (pre-ICL) phase, Initial Coverage Limit (ICL) phase, and catastrophic coverage phase. Six are straddle or in-between phases, which is when a beneficiary fills a prescription and exceeds the accumulated monetary value for a particular main benefit phase, but does not yet meet the minimum accumulated monetary value for the next main benefit phase. The remaining three categories for this variable represent fields other than the main benefit phases and straddle phases. For the purpose of this study, straddle phases are grouped together with its nearest

preceding (i.e. lower accumulated costs level) benefit phase: the deductible to Pre-ICL straddle phase is grouped together with the deductible phase; the deductible to ICL straddle phase is grouped together with the deductible phase; the deductible to catastrophic coverage straddle phase is grouped together with the deductible phase; the pre-ICL to ICL straddle phase is grouped together with the pre-ICL phase, the pre-ICL to catastrophic coverage straddle phase is grouped together with pre-ICL phase, and the ICL to catastrophic coverage straddle phase is grouped together with ICL phase.

9. OUT-OF-POCKET COSTS OF MEDICATIONS:

The variable patient pay amount, labeled as PTNT_PAY_AMT, is used to represent beneficiary out-of-pocket medication costs. It is the non-reimbursable dollar amount paid by a beneficiary (i.e. deductible, co-payment, co-insurance, and other non-reimbursable costs).

10. LOW INCOME SUBSIDY STATUS:

The variable LICS_AMT indicates the low income cost-sharing subsidy amount each time a prescription is filled. Assistance to beneficiaries from varying low-income levels is available to supplement Medicare Part D premiums, deductibles, co-payments, and co-insurance. In this study the variable is used to identify beneficiaries with low income subsidy status during the study period.

11. MEDICARE PART D PLAN TYPE:

PLN_TYPE is the variable categorizing the type of Medicare Part D plan (i.e. Medicare prescription drug plan, health maintenance organization (HMO), preferred provider organization (PPO), private fee-for-service plan (PFFS), and National PACE).

12. MEDICARE PART D DRUG BENEFIT TYPE:

The variable DRGBENTP is the type of Medicare Part D benefit structure of a plan. There are four types of benefit structure: defined standard actuarially equivalent, basic alternative, and enhanced alternative.

13. MEDICARE PART D GAP COVERAGE TYPE:

GAPCOVTP is the variable for the type of coverage offered by a plan during the gap period: some generics; some generics and some brands; all preferred generics; all generics; all preferred generics; all preferred generics and some brands; all generics and some brands; all preferred generics and all preferred brands; all generics and all brands; all drugs on a plan formulary; and no gap coverage.

14. MEDICARE PART D PLAN PREMIUMS:

The plan_total_premium_net_rebate is the variable used for plan premiums in this study. It is defined as the dollar amount of the total basic rate and supplemental premium rates after rebates.

V. DATA ANALYSES

A. DESCRIPTIVE ANALYSES.

The first part of the study addresses the first three research questions:

1. What are the characteristics of Medicare Part D beneficiaries in Washington State utilizing antipsychotic medications?
2. What types of plans do beneficiaries choose in terms of coverage for antipsychotic medications?
3. What are the characteristics of beneficiaries who enter the gap-in-coverage period, or ICL benefit phase?

In answering the above questions frequencies and distributions of the demographic characteristics of the study population in general are examined in terms of rural-urban area groupings and dual eligibility (i.e. Medicare and Medicaid). Medicare Part D plans subscribed by beneficiaries are also examined through plan premiums and beneficiary claims for antipsychotic medications. Premiums are examined by drug benefit type and controlled for beneficiary age, while antipsychotic claims are examined by plan type, drug benefit type, gap coverage type, and benefit phases.

Emphasis is placed on the gap-in-coverage period (or ICL phase) because the primary focus of the study is the effects of coverage on antipsychotic utilization. "Coverage" in terms of Medicare Part D is most relevant during the ICL phase, because it is the critical period when a beneficiary would need some level of coverage for their medications or pays out-of-pocket. Thus, coverage broadly means the extent beneficiaries choose the most optimal plan in terms of premiums, which is tied to the type of plan and type of benefit structure, as well as overall out-of-pocket cost of medications. The cumulative amount in out-of-pocket costs a beneficiary pays for prescription medications, therefore, impacts a beneficiary's benefit phase and whether or not a beneficiary enters the ICL phase when costs of medications are at 100 percent if a beneficiary does not have any level of coverage during the ICL phase.

As such, the demographic characteristics of beneficiaries in the ICL phase are examined, specifically in terms of beneficiary age, urban-rural areas, number of days' supply for medication, and out-of-pocket costs. Medication utilization by way of total number of claims during the ICL phase are also given detailed attention from the level of proportion of month covered and out-of-pocket costs for each antipsychotic drug during the pre-ICL, ICL, and catastrophic coverage phases.

B. ANALYTICAL ANALYSES.

The second part of the study addresses the remaining three research questions:

1. Do plan choice and antipsychotic coverage impact antipsychotic medication adherence? In what ways do beneficiaries' plan choices and antipsychotic coverage affect medication adherence?
2. Do beneficiaries' out-of-pocket expenditure affect medication adherence?
3. How well do beneficiaries choose their Medicare Part D plans in terms their antipsychotic medication needs?

The focus of attention in answering the above questions is analyses of medication adherence. As previously mentioned, medication adherence is measured by Proportion of Days Covered (PDC) and PDC values are calculated by medication (i.e. olanzapine, quetiapine, risperidone, and haloperidol) for all beneficiaries according to benefit phases (i.e. pre-ICL, ICL, and catastrophic coverage phases), type of gap coverage, out-of-pocket costs together with the benefit phases, and adherence together with type of plan, type of drug benefit, type of gap coverage, and out-of-pocket costs during the ICL phase.

Bivariate analyses were conducted in order to support the conceptual justification of including the aforementioned covariates as potential predictors in logistic regression models, followed by execution of a simple logistic regression model and a logistic regression model with interactions. PDC values are dichotomized into low PDC (< 0.80) and high PDC (≥ 0.80) for the outcome variable in the regression models.

Findings of the study analyses are presented in the Results chapter and further examined and explained in the Discussion chapter.

CHAPTER 5

RESULTS

Data on antipsychotic utilization among Medicare Part D beneficiaries in Washington State is scarce. Below are findings that address the first two research questions in detail:

Question 1

What are the characteristics of Medicare Part D beneficiaries in Washington State utilizing antipsychotic medications?

Question 2

What types of plans do beneficiaries choose in terms of coverage for antipsychotic medications?

I. STUDY POPULATION

The final study population excludes beneficiaries who died during the analysis year, 2008, and exclude duplicate identification records, which totals 1715 unique individuals who filled at least one prescription for the antipsychotics examined. These individuals were older Medicare Part D beneficiaries (i.e. ≥ 65 years old) with diagnosed schizophrenia and bipolar disorders, and live in Washington State. The number of total unique individuals in the study population is prior to executing medication adherence calculations that would exclude individuals with only one refill during the 2008 period.

Washington State is in the northwest of the United States with a land mass of approximately 66,455 square miles, 39 counties, and a total population of approximately 6,971,406 people in 2013 (U.S. Census Bureau, 2014). The sample population in the study represents 0.33 percent of total Washington State Medicare Part D beneficiaries who are in stand-alone Prescription Drug Plans (PDPs) or in Medicare Advantage Drug Plans (MA-PDs)(The Henry J. Kaiser Family Foundation, 2014).

A. BENEFICIARIES IN THE RURAL-URBAN COMMUTING AREAS

1. RACE AND RURAL-URBAN COMMUTING AREAS

Most beneficiaries (87.11 percent) live in urban areas, while the remainder are spread out between large rural (7 percent), small rural (3.73 percent), and isolated areas (2.16 percent). White beneficiaries (89.21 percent) comprise the largest group in all four rural-urban commuting areas, or RUCA, while only one other race category, North American Natives, also populate all four RUCA areas (1.28 percent). Other races – Blacks, Asian, Hispanic, and 'other' – mostly reside in urban areas (9.98 percent) and a small percentage of Asian (1.56 percent) and Hispanic (1.56 percent) only reside in small rural areas. Even a smaller percentage of beneficiaries live in

isolated areas (mostly Whites 94.59 percent, North American Native 2.7 percent, and 'other' category 2.7 percent).

2. AGE AND RURAL-URBAN COMMUTING AREAS

After grouping beneficiaries in to 'young old' (65-74), 'old' (75-84), and 'oldest old' (85 and older), the largest age group in the study population is the 'young old' that comprise 54.61 percent of the cohort and reside largely in urban areas. Similarly, the 'old' and the 'oldest old' age groups also largely reside in urban areas at 28.06 percent and 11.32 percent respectively. The remaining 12.89 percent of the study population is spread across large and small rural areas as well as isolated areas. In each of the four RUCA areas, the 'young old' is the largest group, while the 'oldest old' is the smallest.

3. SEX AND RURAL-URBAN COMMUTING AREAS

Female beneficiaries outnumber male beneficiaries in the study population, comprising 71.12 percent across all four RUCA areas. In contrast, male beneficiaries number 28.88 percent in the four RUCA areas.

B. DUAL-ELIGIBLE BENEFICIARIES

Dual-eligible beneficiaries are individuals who qualify, at some level, for both Medicare and Medicaid. Different than dual eligible beneficiaries for special needs plan, dual-eligible beneficiaries are identified through the variable DUAL_ELGBL_MOS_NUM, which show the total number of dual eligibility months for a particular beneficiary. In the study population 64.35 percent of beneficiaries were fully dually eligible for 12 months, while 27.48 percent were non-duals. The remaining 8.17 percent were spread across one to 11 months of dual eligibility; with the largest group among these beneficiaries was 1.23 percent for 11 months of dual eligibility. The number of diagnosed beneficiaries with dual eligibility and antipsychotic claims totaled 1243.

1. DUAL ELIGIBILITY AND RACE

Most dual eligible beneficiaries in the study are White at 63.25 percent, followed by 4.20 percent Black, 1.87 percent Asian, 1.05 percent North American Native, 0.70 percent Hispanic, and 1.34 percent 'other'. Among White beneficiaries, 62.39 percent had 12-month dual eligibility, 29.10 percent were non-duals, and the remaining 8.51 were between 1-11 months of dual eligibility. The only other race category that had between 1-11 months of dual eligibility were Blacks at 10.4 percent and 'other' categories at 7.14 percent, while Asian, Hispanic, and North American Native had none. Compared to White beneficiaries, all other beneficiaries had small numbers of 12-month dual eligibility with Black beneficiaries at 5.8 percent, Asian beneficiaries at 2.9 percent, North American Native beneficiaries at 1.63 percent, Hispanic beneficiaries at 1.09 percent, and 'other' at 1.9 percent.

2. DUAL ELIGIBILITY AND AGE

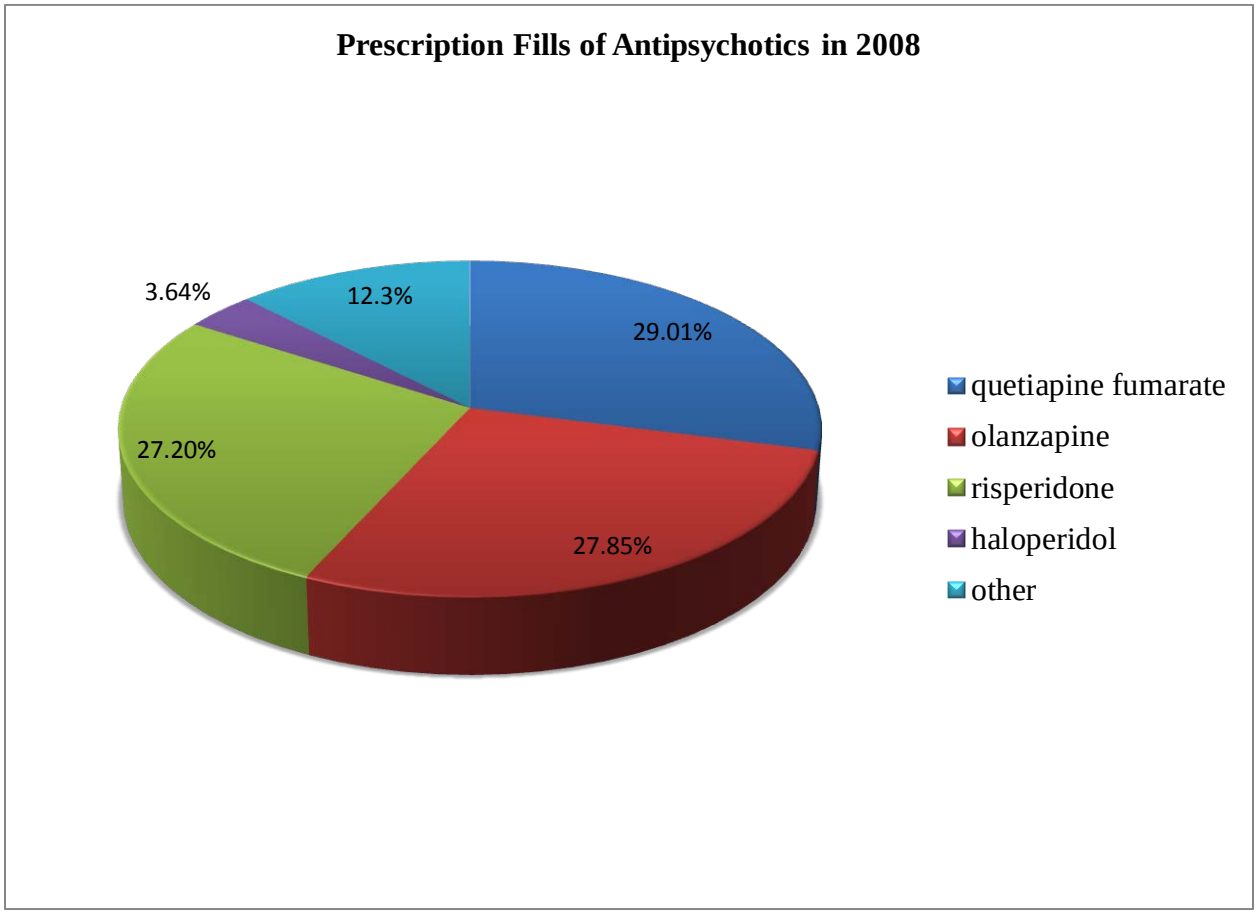
Comparing dual eligibility in total months across the study age range and testing for normality of distribution, only dual eligibility for 11 and 12 months are not normally distributed, having a Kolmogorov-Smirnov D statistic of 0.142 and a p-value = 0.024 for dual eligibility of

11 months and a Kolmogorov-Smirnov D statistic of 0.112 and a p-value < 0.010 for dual eligibility of 12 months. Non-duals across the age range are also not normally distributed, having a Kolmogorov-Smirnov D statistic of 0.119 and a p-value < 0.010.

II. ANTIPSYCHOTIC MEDICATIONS

Four antipsychotic medications are analyzed in the study: olanzapine, quetiapine fumarate, risperidone, and haloperidol. Among the ten antipsychotics filled by beneficiaries, the top three most frequently filled antipsychotics examined are quetiapine fumarate at 29.01 percent, olanzapine at 27.85 percent, and risperidone at 27.20 percent. In contrast, only 3.64 percent of prescriptions filled were for haloperidol, haloperidol decanoate, and haloperidol lactate (Figure 2).

FIGURE 2: PRESCRIPTION FILLS OF ANTIPSYCHOTICS IN 2008



III. MEDICARE PART D PLANS

A. PLAN TYPE

Plan type variable refers to the type of Part D plan. The majority of beneficiaries, 94.75 percent, chose Medicare Part D Prescription Drug Plans, while 4.14 percent opted with Health Maintenance Organization (HMO) plans that offer prescription drugs, 0.53 percent with Private Fee for Service (PFFS) plans, 0.35 with Preferred Provider Organization (PPO) plans, and 0.23 percent with National PACE plans.

B. SPECIAL NEEDS PLANS

Special Needs Part D plans (SNP) refers to the specific type of special needs offered in benefit packages, whether chronic or disabling condition, dual eligible (for Medicare and Medicaid), or institutional. Among the study population, most had non-SNP plans at 97.49 percent, while only 2.22 percent were institutional special needs, followed by dual eligible special needs at 0.23 percent, and chronic or disabling condition at 0.06 percent.

C. DRUG BENEFIT TYPE

The variable Drug Benefit Type (DRGBENTP) is the kind of benefit structure of a Part D plan, whether a plan structures its benefits according to the Centers for Medicare and Medicaid Services (CMS) defined standard benefit, an actuarially equivalent standard, a basic alternative, or an enhanced alternative structure.

The type of benefit structure most chosen by beneficiaries in the study is the basic alternative with 36.46 percent, followed by the enhanced alternative at 32.21 percent, and the actuarially equivalent standard at 28.53 percent. Only 2.10 percent of beneficiaries chose the defined standard benefit. No information available for 0.70 percent of the plans chosen by beneficiaries (Figure 3).

1. DRUG BENEFIT TYPE AND GAP COVERAGE TYPE

Coverage during the gap period is offered at varying levels by basic alternative and enhanced alternative type plans. There are 11 levels of coverage that plan sponsors are permitted to offer, such as: some generics, all preferred generics, all generics, some brands and some generics, all preferred generics and all preferred brands, etc., however, the study population mostly opted for no gap coverage through basic alternative plans with no gap coverage (36.52 percent), actuarially equivalent plans with no gap coverage (29.05 percent), and enhanced alternative plans with no gap coverage (23.16 percent) (Figure 4). A much smaller percentage of the population chose enhanced alternative plans that offered some level of coverage during the gap period (8.99 percent), while the defined standard plans that offered no coverage garnered an even smaller percentage (2.10 percent).

FIGURE 3: PLAN D PLAN BENEFIT STRUCTURES IN STUDY POPULATION, 2008

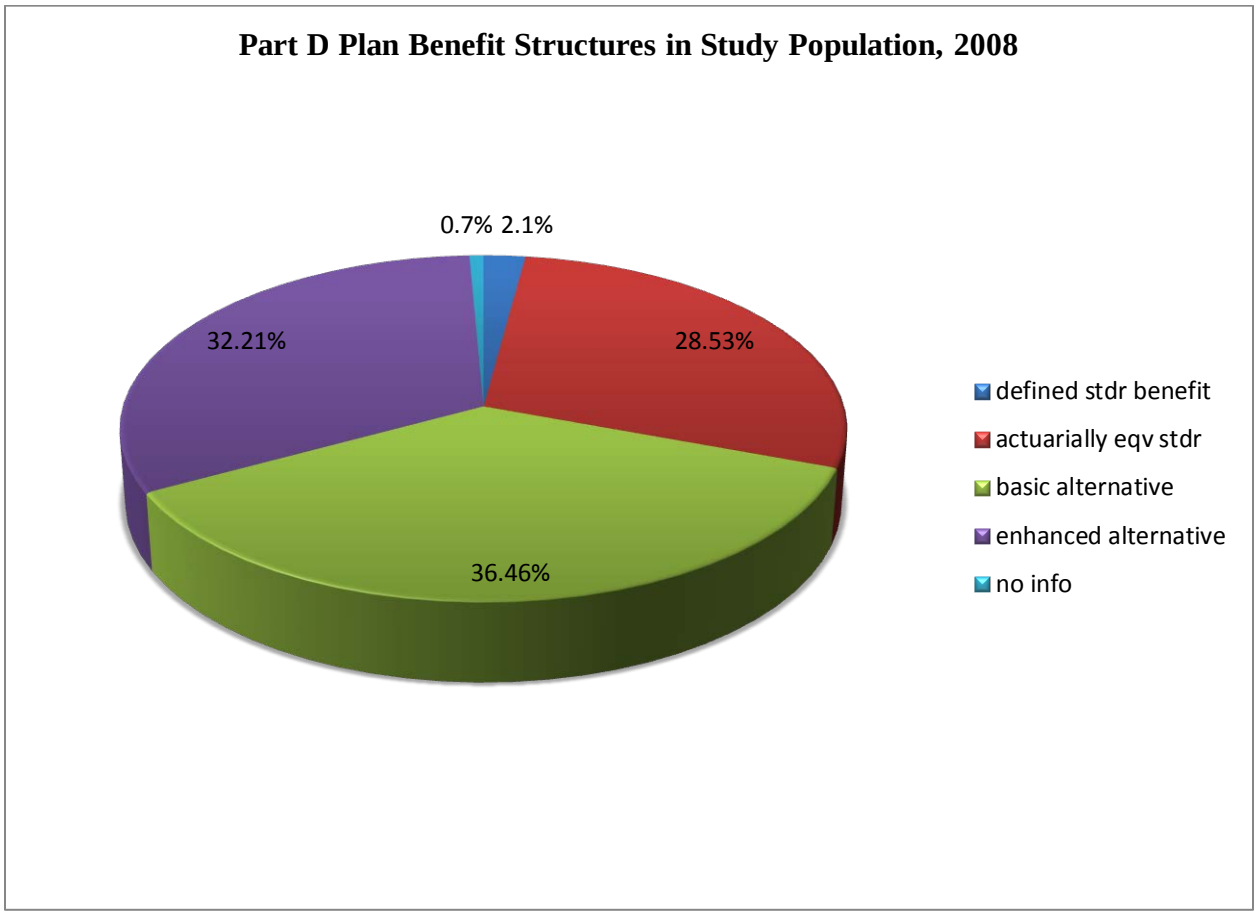
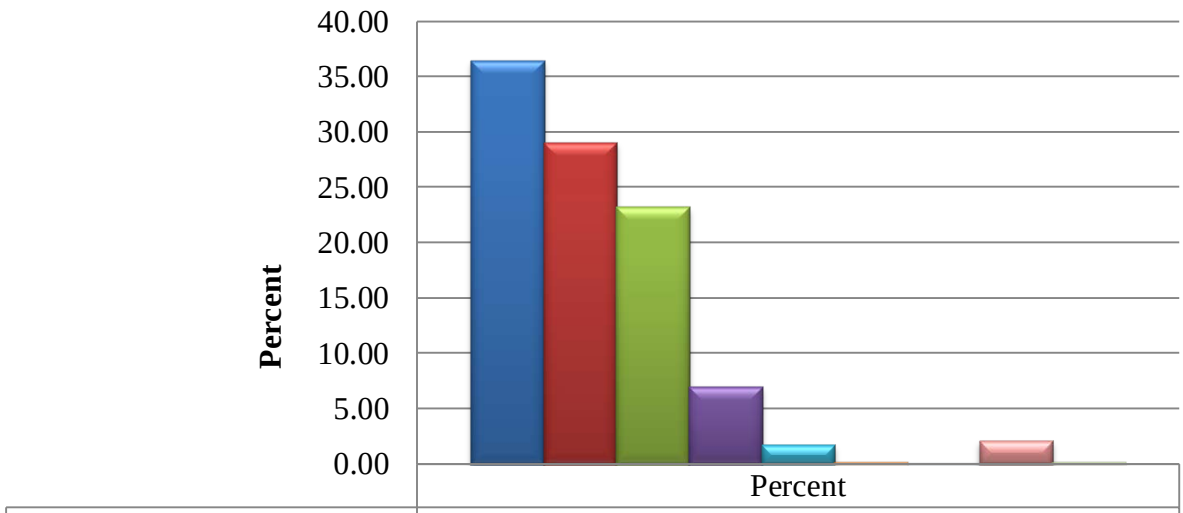


FIGURE 4: TYPE OF DRUG BENEFIT AND TYPE OF GAP COVERAGE



	Percent
basic alternative no gap coverage	36.52
actuarially equivalent no gap coverage	29.05
enhanced alternative no gap coverage	23.16
enhanced alternative all generics	7.00
enhanced alternative all preferred generics	1.75
enhanced alternative some generics some brands	0.18
enhanced alternative some generics	0.06
defined standard no gap coverage	2.10
no info no gap coverage	0.18

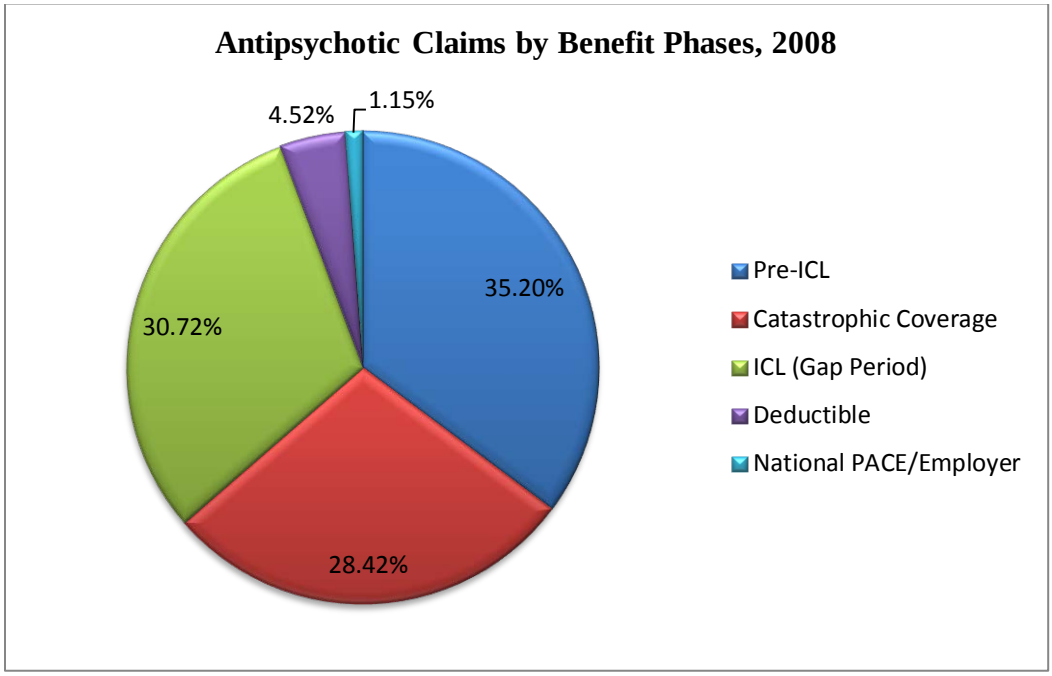
D. BENEFIT PHASES

This variable (BNFTPHAS) is the phase in which a prescription drug claim occurred. It is based on the date when a prescription was filled, accumulated gross drug and out-of-pocket costs, deductible, initial coverage limit (ICL), and out-of-pocket threshold. Benefit phases include straddle prescription drug event (PDE), which is when a claim occurred between two different phases, for example: DP = deductible to pre-ICL straddle PDE, DI = deductible to ICL (coverage gap) straddle PDE, DC = deductible to catastrophic straddle PDE, etc.. Benefit phases show how quickly beneficiaries reach a dollar threshold of out-of-pocket costs for a particular phase, which moves them into another benefit phase and a different dollar threshold.

1. ANTIPSYCHOTIC CLAIMS AND BENEFIT PHASES

In 2008, 35.20 percent of antipsychotic claims in the study (n = 21,001) were made in the pre-initial coverage limit (pre-ICL) phase, 30.72 percent in the ICL phase (i.e. the gap period), and 28.42 percent in the catastrophic coverage phase (Figure 5). These figures include straddle periods in the pre-ICL and ICL phases. Additionally, only 4.52 percent of claims were in the deductible phase and the remaining 1.15 percent was associated with claims through other plans, such as National PACE or employer-sponsored plans. In terms of the number of beneficiaries in the study period there were 1582 individuals in the pre-ICL phase, 1280 individuals in the ICL phase, and 808 individuals in the catastrophic coverage phase. These beneficiaries generated the 21,001 claims examined in this study.

FIGURE 5: ANTIPSYCHOTIC CLAIMS BY BENEFIT PHASES, 2008



2. ANTIPSYCHOTIC CLAIMS AND BENEFIT PHASES BY MONTH.

The largest number of antipsychotic claims in the study was made in the November, 2008 with 2078 claims, which comprised 8.97 percent of total antipsychotic claims made that year. Among these November claims, 56.06 percent were claims during the catastrophic coverage phase, followed by 23.48 percent during the gap in coverage phase, and 15.74 percent during the pre-initial coverage limit (pre-ICL) phase. The remainder of claims for November was made during the various straddle periods and the deductible phase.

Total antipsychotic claims for the last month of 2008 tallied second largest after November at 8.94 percent of total antipsychotic claims in the study. Most claims during December were in the catastrophic coverage phase totaling over 3 percent more than the previous month (Figure 6).

The gap in coverage phase or ICL (Initial Coverage Limit) phase comprised 28.66 percent of total antipsychotic claims for 2008 with the largest number of claims for the ICL phase made in the month of May at 3.73 percent. In the month of January there were only 0.03 percent of total antipsychotic claims in 2008 made during the gap-in-coverage period and increased to 0.60 percent in February, 1.96 percent in March, and 3.02 percent in April. Thus, the number of antipsychotic claims in the ICL phase increased from January and reached its peak in May before decreasing for the remaining months of the year. Total antipsychotic claims during the ICL phase for June was 3.59 percent of total antipsychotic claims in 2008, July 3.40 percent, August 3.06 percent, September 2.60 percent, October 2.51 percent, November 2.11 percent, and December 2.04 percent. The decrease in the number of antipsychotic claims during the ICL phase in the latter half of the year, however, did not reach levels as low as the first quarter of the year.

Excluding claims made through National PACE and employer sponsored plans (1.12 percent), 38.40 percent of total antipsychotic claims were made in benefit phases that preceded the ICL phase, in which the majority of claims were made during the pre-ICL phase at 31.23 percent. Claims made following the ICL phase totaled 31.82 percent (i.e. in the ICL to catastrophic coverage straddle PDE phase and the catastrophic coverage phases).

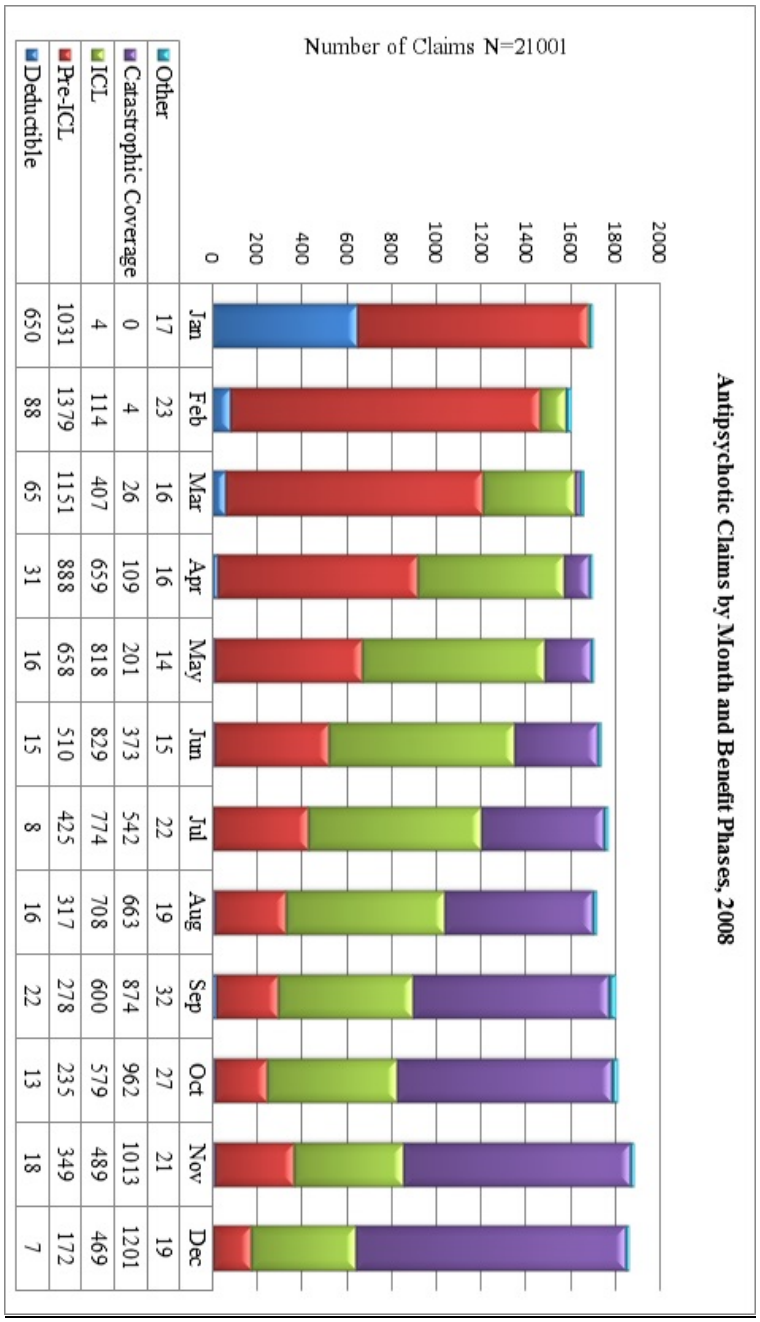
3. BENEFIT PHASES AND TYPE OF GAP COVERAGE

The variable for type of gap coverage offered by a plan is GAPCOVTP with character values ranging from ‘no gap coverage’ to ‘all generics,’ ’some generics’ to ‘all preferred generics and some brands’. Total number of classification for these values is 11.

Beneficiaries are grouped into benefit phases of those who reached the gap period (‘ICL’) versus beneficiaries who only reached the pre-ICL period (‘Pre-ICL’). Beneficiaries who reached the ICL period comprised 74.67 percent of total study population or 1280 individuals, in which 91.17 percent of this group had no coverage during the ICL period, while the remaining 8.83 percent had various kinds of coverage that were mostly for all generics coverage (Figure 7). In contrast, 92.30 percent of the total study population or 1582 individuals reached the pre-ICL period. Among those who did not reach the gap-in-coverage period 90.58 percent did not have any coverage for the gap-in-coverage period, 7.33 percent had all generics covered, while 1.83 percent had all preferred generics, 0.19 percent had some generics and some brands covered, and the remaining 0.06 percent had only some generics covered.

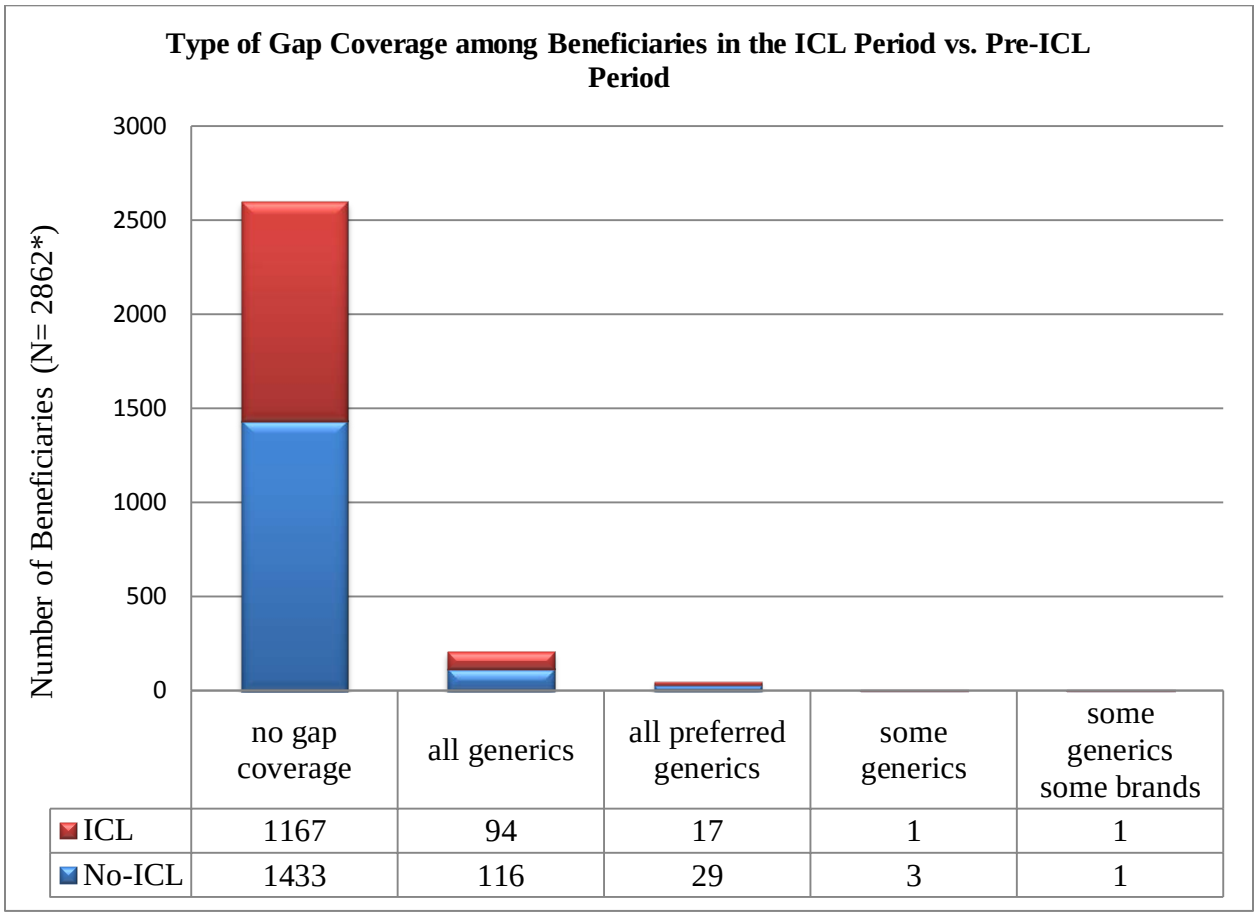
In a 2x2 table for month (column) and benefit phase (row) stratified by type of gap coverage, the Cochran-Mantel-Haenszel statistics were all significant (non-zero correlation: 2321.20, DF: 1, p value < 0.0001, row mean scores differ: 2321.20, DF: 1, p value < 0.0001, general association: 3113.25, DF: 11, p value < 0.0001) indicating the strong association between month of claim submission and benefit phase of either being in the gap-in-coverage period or in the pre-ICL period even after controlling for types of gap coverage.

FIGURE 6: NUMBER OF CLAIMS N=21001



	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Other	17	23	16	16	14	15	22	19	32	27	21	19
Catastrophic Coverage	0	4	26	109	201	373	542	663	874	962	1013	1201
ICL	4	114	407	659	818	829	774	708	600	579	489	469
Pre-ICL	1031	1379	1151	888	658	510	425	317	278	235	349	172
Deductible	650	88	65	31	16	15	8	16	22	13	18	7

FIGURE 7: TYPE OF GAP COVERAGE AMONG BENEFICIARIES IN THE ICL PERIOD VS. PRE-ICL PERIOD



*Excludes deductible phase, deductible straddle, and catastrophic coverage

E. PREMIUMS

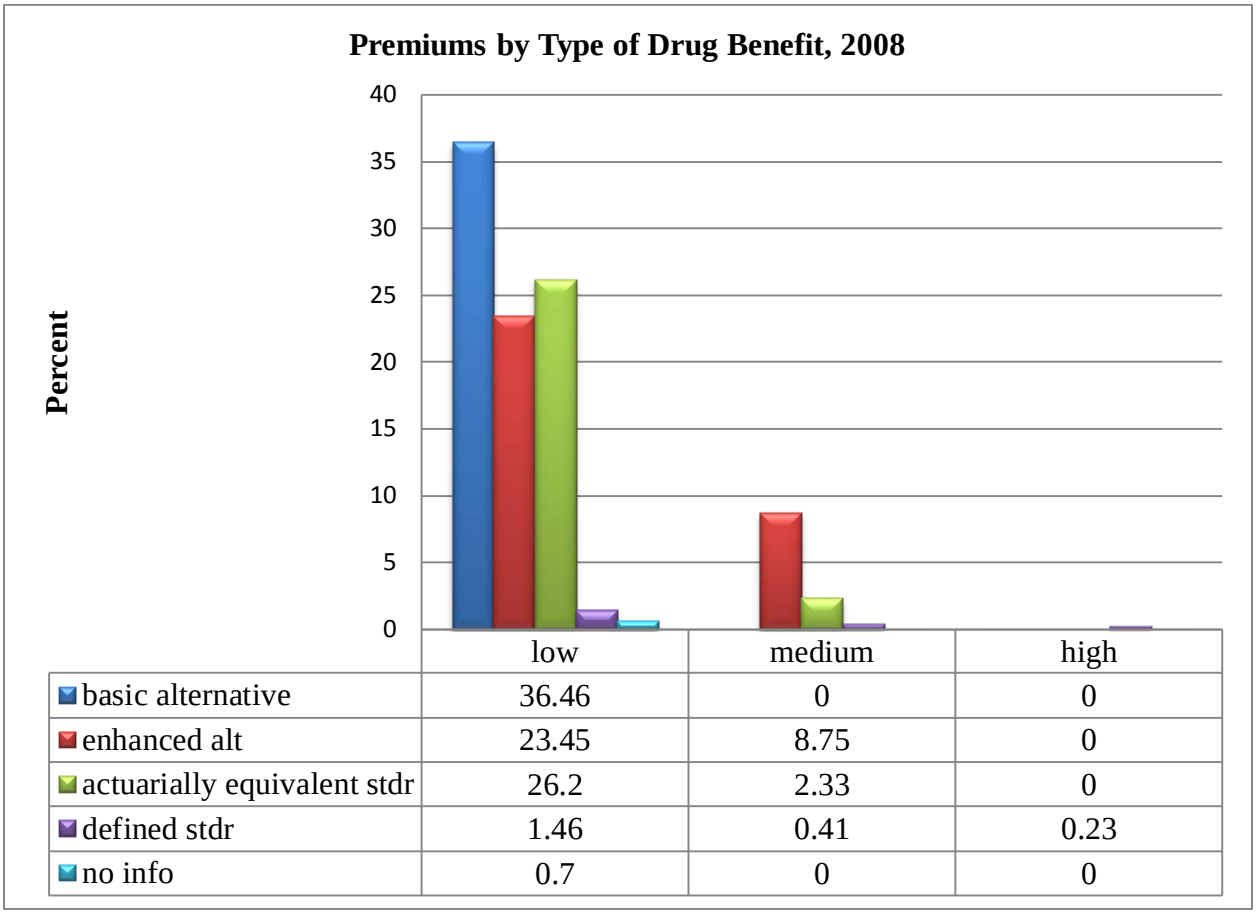
The variable for premiums (plan_total_premium_net_rebate) is the total dollar amount of the Part D basic and supplemental rates that is net of rebates. In the study population 5.08 percent of beneficiaries had the average premium of $29.01 while 80.75 percent of beneficiaries had premium values within one standard deviation (SD = 9.706) of the mean and 90.27 percent within two standard deviations of the mean. Distribution of premiums is positively skewed with a value of 2.594 and a kurtosis of value of 12.467 indicating a non-normal distribution. Only 0.29 percent had $0 premiums (out of 1714 beneficiaries). Average premium in the study population is just over $29 with a maximum of $106.4 and minimum of $0.

1. PREMIUMS AND DRUG BENEFIT TYPE.

Premiums are grouped into 'low' (< $36), 'medium' ($36 - $71.99), high (≥ $72), and 'missing' for missing values and association between premiums and drug benefit structure of plans is examined: 88.28 percent of beneficiaries chose low premiums mostly through basic alternative plans (36.46 percent), followed by actuarially equivalent standard plans (26.2 percent), and enhanced alternative plans (23.45 percent) (Figure 8). Only 1.65 percent of

beneficiaries chose low premiums through defined standard benefit plans. A smaller percentage of beneficiaries (11.49 percent) chose medium level premiums that were mostly offered by enhanced alternative plans (8.75 percent) with the remaining through actuarially equivalent standard plans (2.33 percent), and a very small percentage through defined standard benefit plans (0.41 percent). No beneficiaries opted for medium level premiums through basic alternative plans. Higher premiums only captured 0.23 percent of the study population, which were all through defined standard benefit plans. A Fisher's Exact test show that there is a statistically significant relationship between the level of premiums and type of drug benefit structure that beneficiaries in the study population choose (p = 8.254E-61).

FIGURE 8: PREMIUMS BY TYPE OF DRUG BENEFIT, 2008



	low	medium	high
basic alternative	36.46	0	0
enhanced alt	23.45	8.75	0
actuarially equivalent stdr	26.2	2.33	0
defined stdr	1.46	0.41	0.23
no info	0.7	0	0

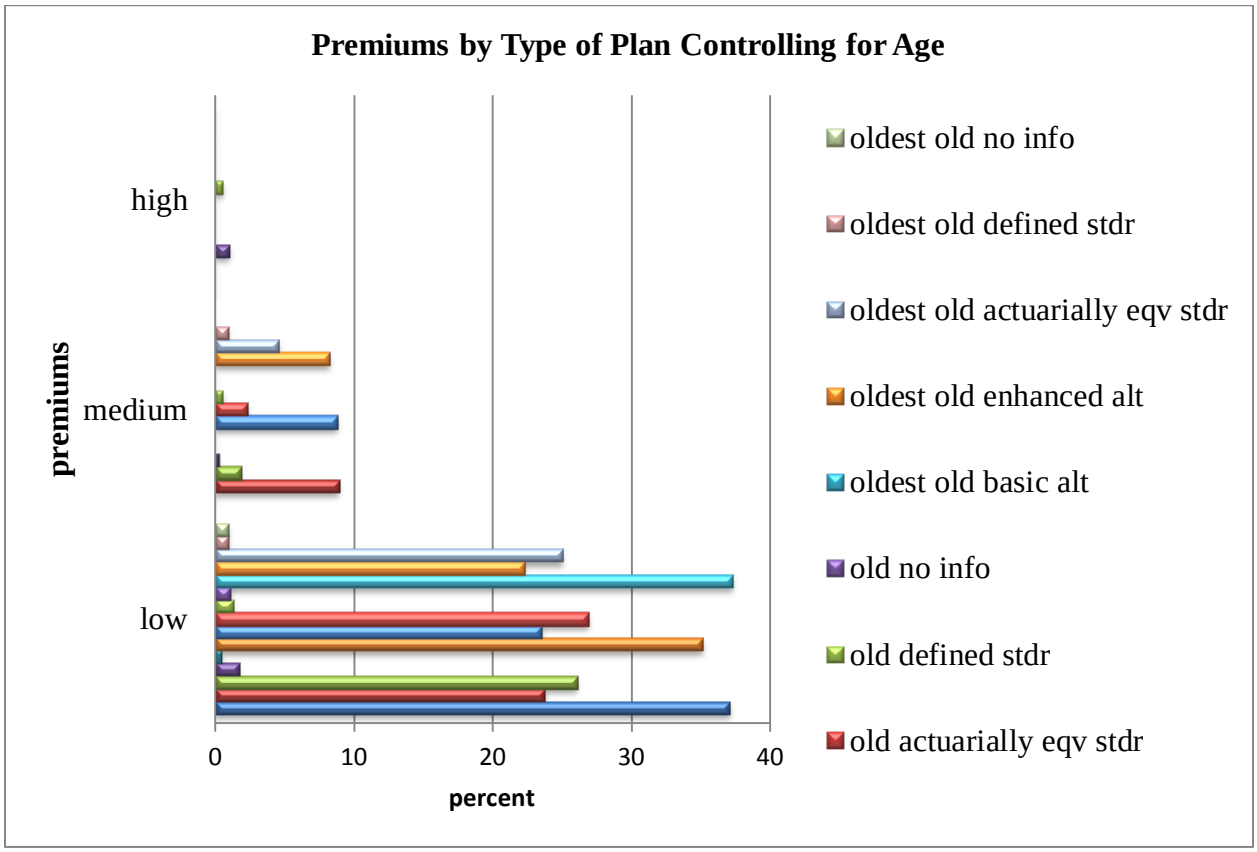
2. PREMIUMS BY TYPE OF PLAN CONTROLLING FOR AGE

The greatest concentrations of beneficiaries across all age groups are found in low premium plans belonging to the basic alternative type plans. Medium-level premiums are chosen by all age groups as well, but are mostly attached to the enhanced alternative type plans; while high premiums are least chosen by beneficiaries (Figure 9).

Among the 'young old' most, at 37.07 percent, chose low premiums through basic alternative plans, followed by 26.07 percent through actuarially equivalent standard plans, and

23.72 percent through enhanced alternative plans. Similarly, among the 'old' group most, at 35.13 percent, also chose low premiums through basic alternative plans, followed by 26.88 percent through actuarially equivalent standard plans, and 23.48 percent through enhanced alternative plans. The same is found among the 'oldest old' group with 37.27 percent with low premiums through basic alternative plans, followed by 25 percent through actuarially equivalent standard plans, and 22.27 percent through enhanced alternative plans. Across all age groups medium level premiums were mostly chosen through enhanced alternative plans, at 27.21 percent for the 'young old,' 27.22 percent for the 'old' group, and 26.87 percent for the 'oldest old' group. Only a minority of beneficiaries in the 'young old' and 'old' age group chose high level premiums through defined standard plans, at 0.11 percent and 0.54 percent respectively; while no beneficiary in the 'oldest old' group chose high level premiums. The Cochran Mantel Haenszel (CMH) statistic for non-zero correlation is 35.3686, DF: 1, and p-value < 0.0001.

FIGURE 9: PREMIUMS BY PLAN CONTROLLING FOR AGE



F. PATIENT PAY AMOUNT

This variable is the dollar amount paid by beneficiaries that is not reimbursable by plans or other third party payers, such as co-payments, co-insurances, and deductibles, but excludes premiums. If payment is for a covered drug, the amount is counted toward a beneficiary's true-out-of-pocket costs (TrOOP). In 2008, the TrOOP amounts mandated through the various

benefit phases are: $275 during the deductible phase, $ 558.75 during the pre-initial coverage limit (pre-ICL) phase, and $ 3,216.25 in the ICL phase.

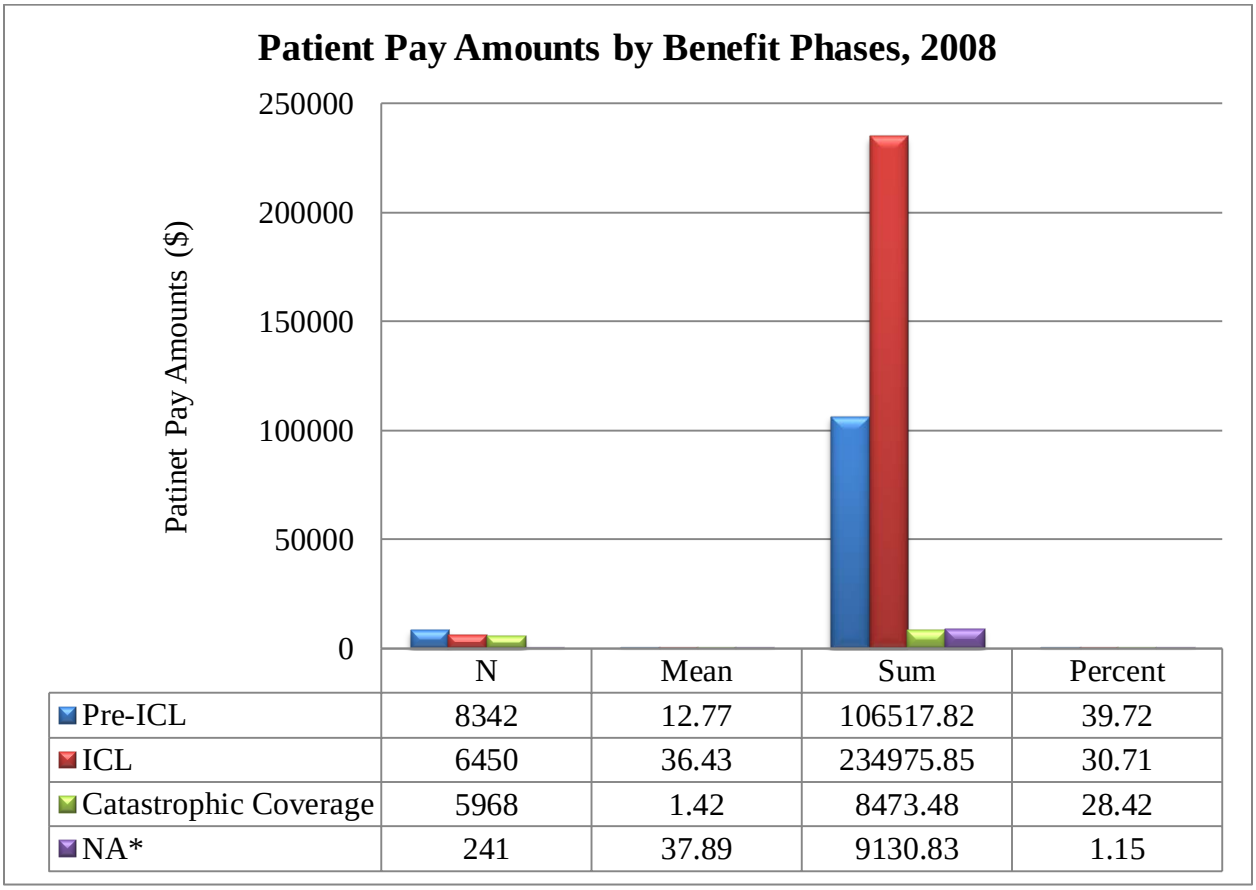
Annual total for patient pay amount in 2008 was $359,098 for 21,001 claims of antipsychotics among 1714 beneficiaries. Total patient pay amount peaked at its highest amount in May at $44,585.67 for 1708 claims and subsequently diminishing each month through to the end of the year with a slight increase in the month of November. By December the total patient pay amount was $22,646.87 for 1868 claims, which is higher still than total patient pay amount in the preceding January that reached $18,499.63 for 1703 claims and February at $17,660.61 for 1609 claims.

Across the benefit phases, the largest average patient pay amount of $41.64 occurred in the ICL period while the smallest average patient pay amount occurred in April, at $0.46 in the catastrophic coverage phase. In the pre-ICL period, beneficiaries largest average patient pay amount was $22.37 that occurred in November.

1. PATIENT PAY AMOUNT AND BENEFIT PHASES

Approximately 30.71 percent of total antipsychotic claims were made during the gap-in-coverage period or initial coverage limit (ICL) phase, which totaled $234,975.85 in patient pay amount. It is the highest patient pay amount compared to any other benefit phases, with the pre-ICL phase accruing the second highest patient pay amount that totaled $106,517.82 (Figure 10). A graph of total number of claims and benefit phases is represented in Figure 11, which shows that during the gap in coverage, or ICL phase, beneficiaries submitted the most number of claims by the middle of the year in sharp contrast to the other benefit phases and that the rise in total number of claims during the ICL phase started very early in the year. In comparison, the number of claims started high in the pre-ICL period and kept declining through the year, except for a small increase in November.

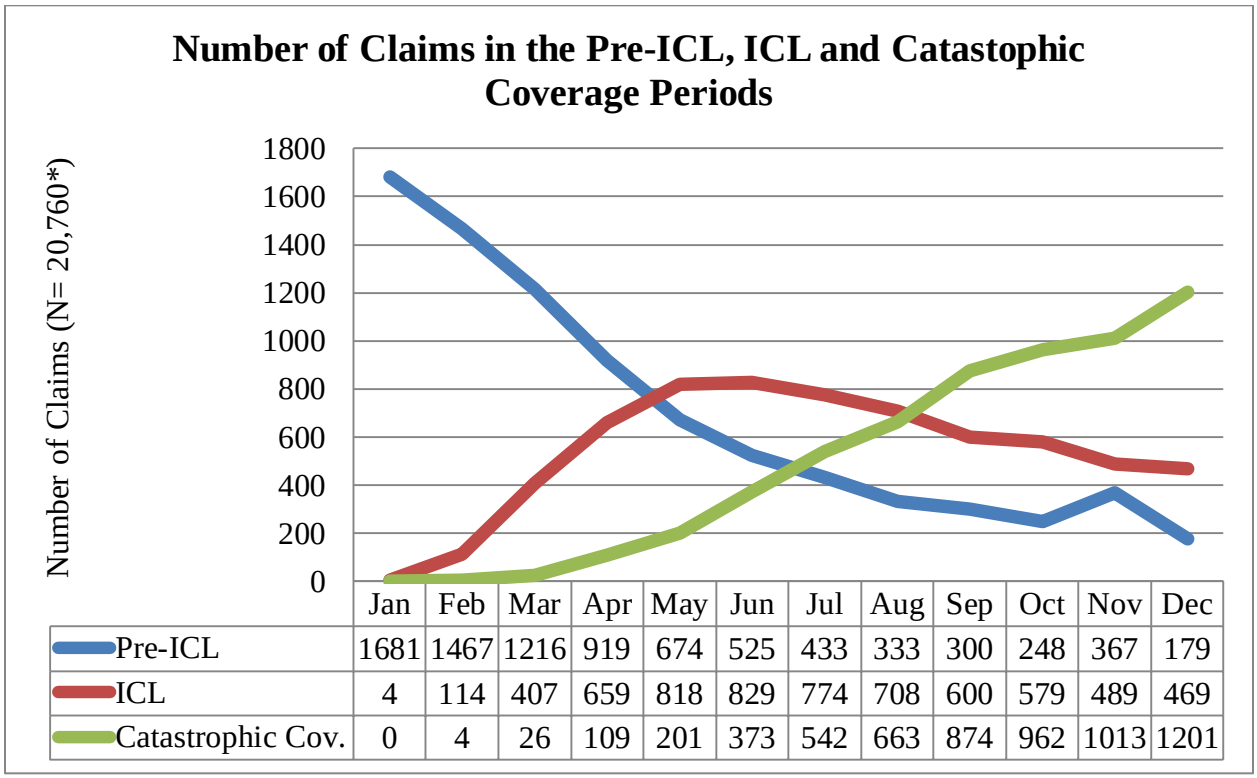
FIGURE 10: PATIENT PAY AMOUNTS BY BENEFIT PHASES, 2008



	N	Mean	Sum	Percent
Pre-ICL	8342	12.77	106517.82	39.72
ICL	6450	36.43	234975.85	30.71
Catastrophic Coverage	5968	1.42	8473.48	28.42
NA*	241	37.89	9130.83	1.15

*National PACE/employer-sponsored plans

FIGURE 11: NUMBER OF CLAIMS IN THE PRE-ICL, ICL AND CATASTROPHIC COVERAGE PERIODS



	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Pre-ICL	1681	1467	1216	919	674	525	433	333	300	248	367	179
ICL	4	114	407	659	818	829	774	708	600	579	489	469
Catastrophic Cov.	0	4	26	109	201	373	542	663	874	962	1013	1201

*Excludes National PACE/employer-sponsored plans

IV. UNDERSTANDING BENEFICIARIES IN THE GAP IN COVERAGE

The following section presents findings that address the research question below:

Question 3

What are the characteristics of beneficiaries who enter the gap-in-coverage period, or ICL benefit phase?

Beneficiaries are grouped into those who entered the gap in coverage period, or ICL benefit phase, and those who did not enter the gap.

A. AGE

The average age in the gap-in-coverage (ICL) group is 74 years old with the median at 73 years old, minimum age at 66, maximum at 98 years old, standard deviation at 6.99 and variance at 48.8. The average age in the group that did not reach the gap-in-coverage (No-ICL) group is 75 years old with the median at 74 years old, minimum age at 66, maximum at 98 years old, standard deviation at 7.42 and variance at 55.03. The Kruskal-Wallis test statistic was not significant for age.

B. URBAN-RURAL RESIDENCY

Beneficiaries reaching the gap-in-coverage period (ICL) were predominantly – 95.83 percent – in urban areas, while the remaining 4.17 percent resided in small rural areas. Similarly, 86.80 percent of beneficiaries not reaching the gap-coverage period resided in urban areas with the remaining 13.20 percent residing in rural or isolated areas.

C. DAYS' SUPPLY OF ANTIPSYCHOTIC MEDICATIONS

In the gap-in-coverage period (ICL), the average antipsychotic dispensed is for 27.99 days with a median of 30 days, a minimum of 1 day, a maximum of 90 days, standard deviation of 7.99 days, and 63.88 variance days. While in beneficiaries not reaching the gap-in-coverage period (No-ICL), the average antipsychotic dispensed is for 28.31 days with a median of 30 days, a minimum of 1 day, a maximum of 100 days, standard deviation 9.96 days, and variance 99.25 days. The Kruskal-Wallis test statistic for days' supply of antipsychotic medications between the ICL versus the No-ICL groups was not statistically significant.

D. PATIENT PAY AMOUNT

The average patient pay amount in the gap-in-coverage (ICL) group is $36.43 with a median of $3.10, a minimum of $0, a maximum of $1445.48, standard deviation $ 110.45, and variance $12,198.93. The average patient pay amount in the pre-ICL group is $12.64 with a median of $3.10, a minimum $0, a maximum $1451.07, standard deviation $43.37 and variance $1881.25. The Kruskal-Wallis test result indicates that patient pay amount between the ICL versus the No-ICL groups were statistically significant (Chi-Square: 157.75, DF: 1, $P < 0.0001$).

E. ANTIPSYCHOTIC MEDICATIONS

1. HALOPERIDOL

Beneficiary Count. Number of beneficiaries with a fill for haloperidol totaled 110 individuals generating 565 claims for the drug in 2008.

Proportion of Month Covered (PMC) in the Pre-ICL Period. Among the 565 claims for haloperidol during the pre-ICL period, 391 claims (69.20 percent) had at least 24 days of supply of medication for the month. The number of claims with such coverage decreased over the months. In January 2008 there were 55 claims, in March there were 39 claims, in June there were 32 claims, in September there were 29 claims, and in December there were 22 claims. Compared to other antipsychotics, claims for haloperidol did not dramatically decrease over the pre-ICL period (Figure K).

Proportion of Month Covered (PMC) in the ICL Period. Among the 204 claims for haloperidol during the ICL period, 143 claims (70.10 percent) had at least 24 days of supply of medication for the month. The number of claims with such coverage did not steadily decrease during the year. Instead, from February to March claims increased from 2 claims to 12 claims, as did claims for April (9 claims), May (11 claims), June (18 claims). In contrast claims decreased from July to September (July: 17 claims, August: 14 claims, September: 14 claims) and October to December (October: 18 claims, November: 14 claims, December: 14 claims). No claims were made in January for haloperidol during the ICL period. The number of claims for haloperidol with at least 24 days of coverage does not dramatically increase during the ICL period (Figure L).

Proportion of Month Covered (PMC) in the Post-ICL Period. Among the 195 claims for haloperidol during the post-ICL period, 147 claims (75.38 percent) had at least 24 days of supply of medication for the month. The number of claims with such coverage increased during the year. From March to July claims increased from 4 claims to 13 claims, as did claims from September to December (September: 20 claims, October: 22 claims, November: 26 claims, December: 28 claims. August claims totaled 11, which is a drop from the preceding month and no claims were made in January and February for haloperidol during the post-ICL period. Unlike the atypical antipsychotics, claims with at least 24 days' supply for haloperidol does not sharply increase by month during the post-ICL period (Figure M). Trends over the 12 month period for haloperidol claims with at least 24 days of coverage do not dramatically rise or fall before, during, and after the gap in coverage period (Figures K, L, and M).

Patient Pay Amount in the Pre-ICL Period. Patient pay amount for 565 claims filling prescriptions for haloperidol before the gap-in-coverage period in 2008 totaled $755.44.

Patient Pay Amount in the ICL and Post-ICL Periods. Gap in coverage for beneficiaries filling prescriptions for haloperidol started as early as mid-February. Patient pay amount for 399 beneficiaries during and after the gap-in-coverage period in 2008 totaled $271.47.

2. QUETIAPINE FUMARATE

Beneficiary Count. Number of beneficiaries with a fill for quetiapine totaled 591 individuals generating 2330 claims before the gap-in-coverage period and 480 individuals with 3579 claims during and after the gap-in-coverage period in 2008.

Proportion of Month Covered (PMC) in the Pre-ICL Period. Among the 2330 claims for quetiapine during the pre-ICL period 2058 claims (88.33 percent) had at least 24 days of supply of medication for the month. The number of claims with such coverage decreased over the months. In January 2008 there were 411 claims, in March there were 303 claims, in June there were 126 claims, in September there were 75 claims, and in December there were 47 claims. Similar to risperidone and olanzapine, claims for quetiapine with at least 24 days of supply sharply decreased from January through to May in the pre-ICL period (Figure K).

Proportion of Month Covered (PMC) in the ICL Period. Among the 1763 claims for quetiapine during the ICL period, 1606 claims (91.09 percent) had at least 24 days of supply of medication for the month. The number of claims with such coverage increased monthly from January to July from 3 claims in January to 224 claims in July, and steadily decreased from July to December from 187 claims to 107 claims respectively. Unlike the pre-ICL period, there is a sharp increase in the number of claims with at least 24 days of coverage for quetiapine during the ICL period that peaks around the middle of the year and then begins to decline (Figure L).

Proportion of Month Covered (PMC) in the Post-ICL Period. Among the 1816 claims for quetiapine during the post-ICL period, 1648 claims (90.75 percent) had at least 24 days of supply of medication for the month. The number of claims with such coverage increased during the year. February claims for quetiapine totaled 4, March 12 claims, April 36 claims, May 56 claims, June 105 claims, July 152 claims, August 191 claims, September 234 claims, October 257 claims, November 274 claims, and December: 327 claims. No claims were made in January for quetiapine during the post-ICL period. Similar to the other atypical antipsychotics, claims for quetiapine with at least 24 days' supply begin to increase a little later, beginning in March, compared to increases during the ICL period (Figure M).

Patient Pay Amount in the Pre-ICL Period. Patient pay amount for 591 beneficiaries filling prescriptions for quetiapine before the gap-in-coverage period in 2008 totaled $33,318.77.

Patient Pay Amount in the ICL and Post-ICL Periods. Gap in coverage for beneficiaries filling prescriptions for quetiapine started as early as mid-February. Patient pay amount for 480 beneficiaries during and after the gap-in-coverage period in 2008 totaled $74,047.31.

3. RISPERIDONE

Beneficiary Count. Number of beneficiaries with a fill for risperidone totaled 590 individuals generating 2673 claims before the gap-in-coverage period and 478 individuals with 3527 claims during and after the gap-in-coverage period in 2008.

Proportion of Month Covered (PMC) in the Pre-ICL Period. Among the 2673 claims for risperidone during the pre-ICL period 2379 claims (89 percent) had at least 24 days of supply of medication for the month. The number of claims with such coverage decreased over the months. In January 2008 there were 433 claims, in March there were 328 claims, in June there were 173 claims, in September there were 103 claims, and in December there were 56 claims. As with quetiapine and olanzapine, claims for risperidone with at least 24 days of supply sharply decreased from January through to May in the pre-ICL period (Figure K).

Proportion of Month Covered (PMC) in the ICL Period. Among the 1929 claims for risperidone during the ICL period, 1674 claims (86.78 percent) had at least 24 days of supply of medication for the month. The number of claims with such coverage increased monthly from

January to May from 1 claim in January to 191 claims in May and again in June, and steadily decreased from July to December from 200 claims to 150 claims by the end of the year. Similar to the other atypical antipsychotics, claims with at least 24 days of supply for risperidone sharply increases during the first five months of the year in the ICL period (Figure L).

Proportion of Month Covered (PMC) in the Post-ICL Period. Among the 1598 claims for risperidone during the post-ICL period, 1322 claims (82.73 percent) had at least 24 days of supply of medication for the month. The number of claims with such coverage increased during the year beginning from March with 7 claims, April 20 claims, May 37 claims, June 84 claims, July 138 claims, August 145 claims, September 182 claims, October 215 claims, November 221 claims, and December: 273 claims. No claims were made in January and February for risperidone during the post-ICL period. Claims with at least 24 days' supply for risperidone sharply increases from March through to the end of the year (Figure M).

Patient Pay Amount in the Pre-ICL Period. Patient pay amount for 591 beneficiaries filling prescriptions for risperidone before the gap-in-coverage period in 2008 totaled $26,799.56.

Patient Pay Amount in the ICL and Post-ICL Periods. Gap in coverage for beneficiaries filling prescriptions for risperidone started as early as mid-March. Patient pay amount for 478 beneficiaries during and after the gap-in-coverage period in 2008 totaled $50,170.80.

4. OLANZAPINE

Beneficiary Count. Number of beneficiaries with a fill for olanzapine totaled 543 individuals generating 2062 claims before the gap-in-coverage period and 486 individuals with 3700 claims during and after the gap-in-coverage period in 2008.

Proportion of Month Covered (PMC) in the Pre-ICL Period. Among the 2062 claims for olanzapine during the pre-ICL period 1877 claims (91.03 percent) had at least 24 days of supply of medication for the month. The number of claims with such coverage was greater in the first six months of the year compared to the remaining six months. In January 2008 there were 440 claims, in March there were 323 claims, in June there were 106 claims, in September there were 36 claims, and in December there were 22 claims. Claims with at least 24 days of olanzapine supply steadily decreased as the months progressed. Compared to other antipsychotics, claims for olanzapine had the steepest decrease from the beginning of the year through to May during the pre-ICL period (Figure 12). Trends for olanzapine claims are similar to risperidone, and quetiapine for the 12 month period, where claims for all three atypical antipsychotics with at least 24 days coverage sharply decreases from the beginning of the year until approximately September when decreases in claims are not as sharp compared to previous months during the pre-ICL period (Figures K, L, and M).

Proportion of Month Covered (PMC) in the ICL Period. Among the 1666 claims for olanzapine during the ICL period, 1501 claims (90.10 percent) had at least 24 days of supply of medication for the month. The number of claims with such coverage increased monthly from February to May from 34 claims to 203 claims, and steadily decreased from June to December from 194 claims to 95 claims by the end of the year. No claims were made for olanzapine in January and February during this period. As with quetiapine and risperidone, claims with at least 24 days of supply for olanzapine sharply increased from January through May during the ICL period (Figure 13).

Proportion of Month Covered (PMC) in the Post-ICL Period. Among the 2034 claims for olanzapine during the post-ICL period, 1867 claims (91.79 percent) had at least 24 days of supply of medication for the month. The number of claims with such coverage increased during the year beginning from February with 1 claim, March 13 claims, April 53 claims, May 78 claims, June 127 claims, July 168 claims, August 220 claims, September 270 claims, October 288 claims, November 297 claims, and December: 352 claims. No claims were made in January for olanzapine during the post-ICL period. Claims with at least 24 days of coverage for olanzapine has the steepest increase from March through to December compared to the other antipsychotics (Figure M). Trends for all atypical antipsychotic claims with at least 24 days' coverage during the post-ICL period show steep increases beginning around April and continues to climb until the end of the year (Figure 14); in contrast, steep increases for these atypical antipsychotics in the ICL period occur from the beginning of the year through to June only before the number of claims begin to decrease through to December (Figure 13).

Patient Pay Amount in the Pre-ICL Period. Patient pay amount for 543 beneficiaries filling prescriptions for olanzapine before the gap-in-coverage period in 2008 totaled $36,854.38.

Patient Pay Amount in the ICL and Post-ICL Periods. Gap in coverage for beneficiaries filling prescriptions for olanzapine started as early as early February. Patient pay amount for 478 beneficiaries during and after the gap-in-coverage period in 2008 totaled $50,170.80.

FIGURE 12: ANTIPSYCHOTIC CLAIMS IN THE PRE-ICL PERIOD

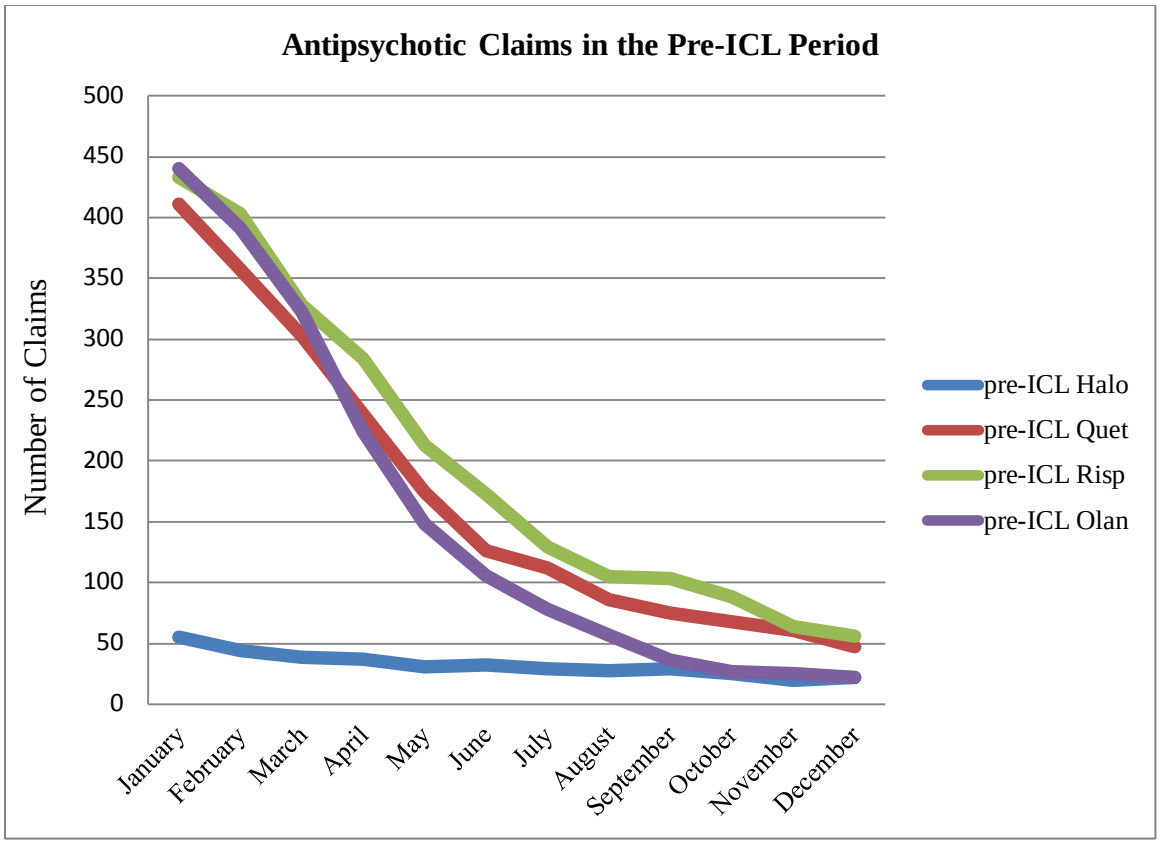


FIGURE 13: ANTIPSYCHOTIC CLAIMS IN THE ICL PERIOD

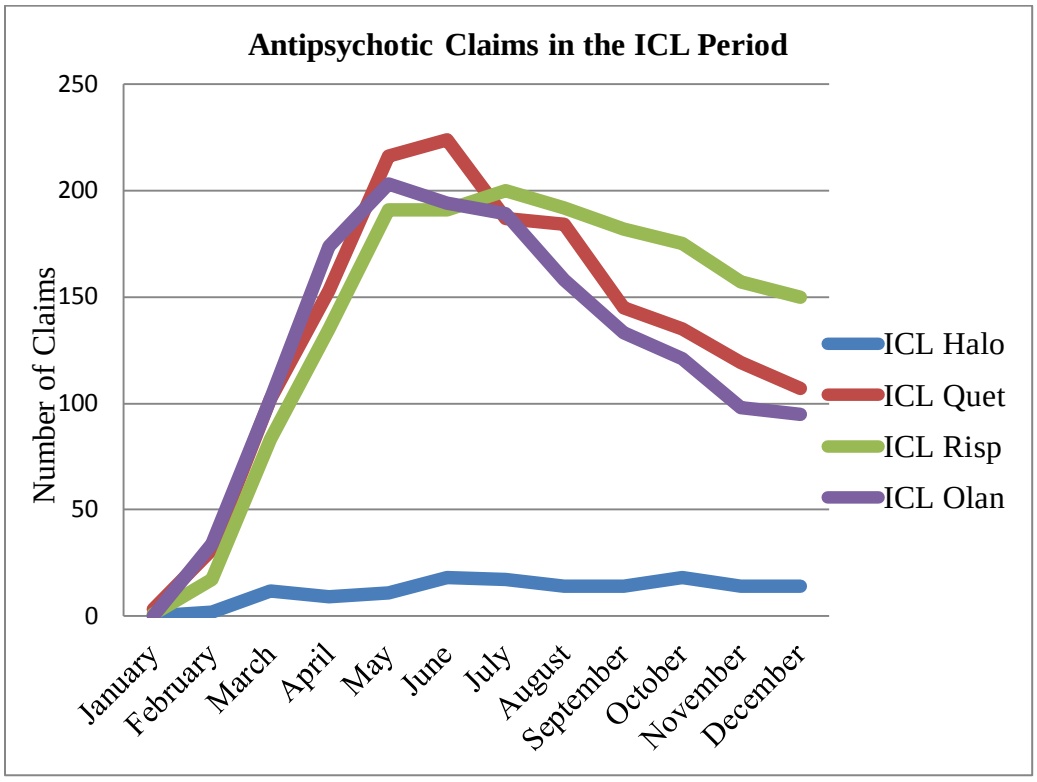
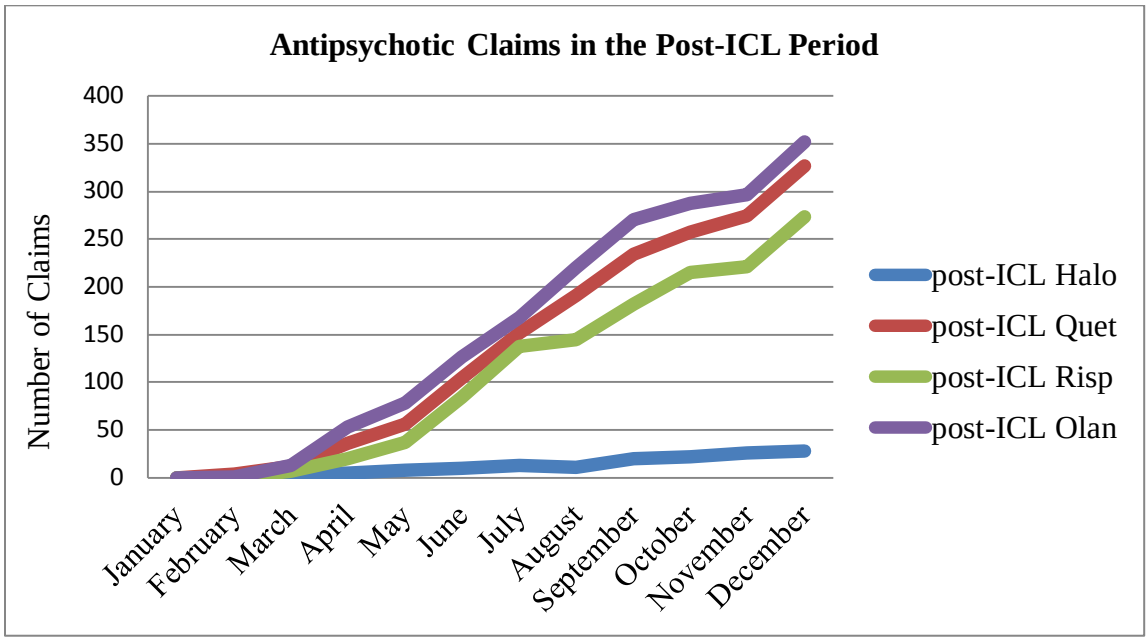


FIGURE 14: ANTIPSYCHOTIC CLAIMS IN THE POST-ICL PERIOD



V. BENEFICIARIES AND MEDICATION ADHERENCE

Adherence to antipsychotics in the study is measured in Proportion of Days Covered (PDC) with values ranging from 0 to 1 and a cut-off value of ≥ 0.80 for adherence. The following research questions are addressed:

Question 4

Do plan choice and antipsychotic coverage impact antipsychotic medication adherence? In what ways do beneficiaries' plan choices and antipsychotic coverage affect medication adherence?

Question 5

Do beneficiaries' out-of-pocket expenditure affect medication adherence?

Question 6

How well do beneficiaries choose their Medicare Part D plans in terms their antipsychotic medication needs?

As a background to answering research questions 3 and 4, demographic characteristics of 1616 beneficiaries with low adherence (PDC value < 0.80) and high adherence (PDC value $\geq$ 0.80) are presented in Table 1. It is also a contingency table showing p values of the variables' Chi statistics in order to support the conceptual justification of including certain variables in a logistic regression model, whereby potential predictors with a significance level higher than 0.05 are excluded. In comparing beneficiaries with low PDCs versus high PDCs a t-test testing the null hypothesis that the mean PDC values of the two groups are the same compared to the alternative that the means are different produced F statistic 261.17, p-value < 0.0001 for the test of equal variances, indicating that there is evidence to reject the null hypothesis that the variances are equal; thus, assuming unequal variances, the Satterthwaite t-test statistic is -74.23, p-value < 0.0001 indicating that the mean PDC values among adherent beneficiaries (i.e. beneficiaries with high PDCs) is significantly higher than the mean PDC values among non-adherent beneficiaries.

A. ADHERENCE AND BENEFIT PHASES

For all antipsychotics, beneficiaries showed the greatest percentage of PDC adherence during the post-ICL period in which 94.06 percent of beneficiaries who filled prescriptions for quetiapine were adherent, followed by 81.11 percent of beneficiaries who filled prescriptions for risperidone were adherent, while lower percentages of adherence were found among beneficiaries who filled prescriptions for haloperidol at 50 percent and beneficiaries who filled for olanzapine at 28.7 percent (Figure N).

During the pre-ICL period, the greatest percentage of adherence is found among beneficiaries on risperidone, 72.2 percent, while the lowest PDC is among beneficiaries on olanzapine, 1.84 percent. The average PDC value was high (PDC value: 1.0) for all antipsychotics with the exception of olanzapine (average PDC value: 0.58). While medication adherence was highest in the post-ICL period, the total number of beneficiaries filling prescriptions for each antipsychotic was lowest during this period (Figure 16). The pre-ICL period had the greatest number of beneficiaries, but declined as coverage moved into the ICL and post-ICL periods.

TABLE 2: DEMOGRAPHIC CHARACTERISTICS OF BENEFICIARIES WITH LOW AND HIGH ADHERENCE

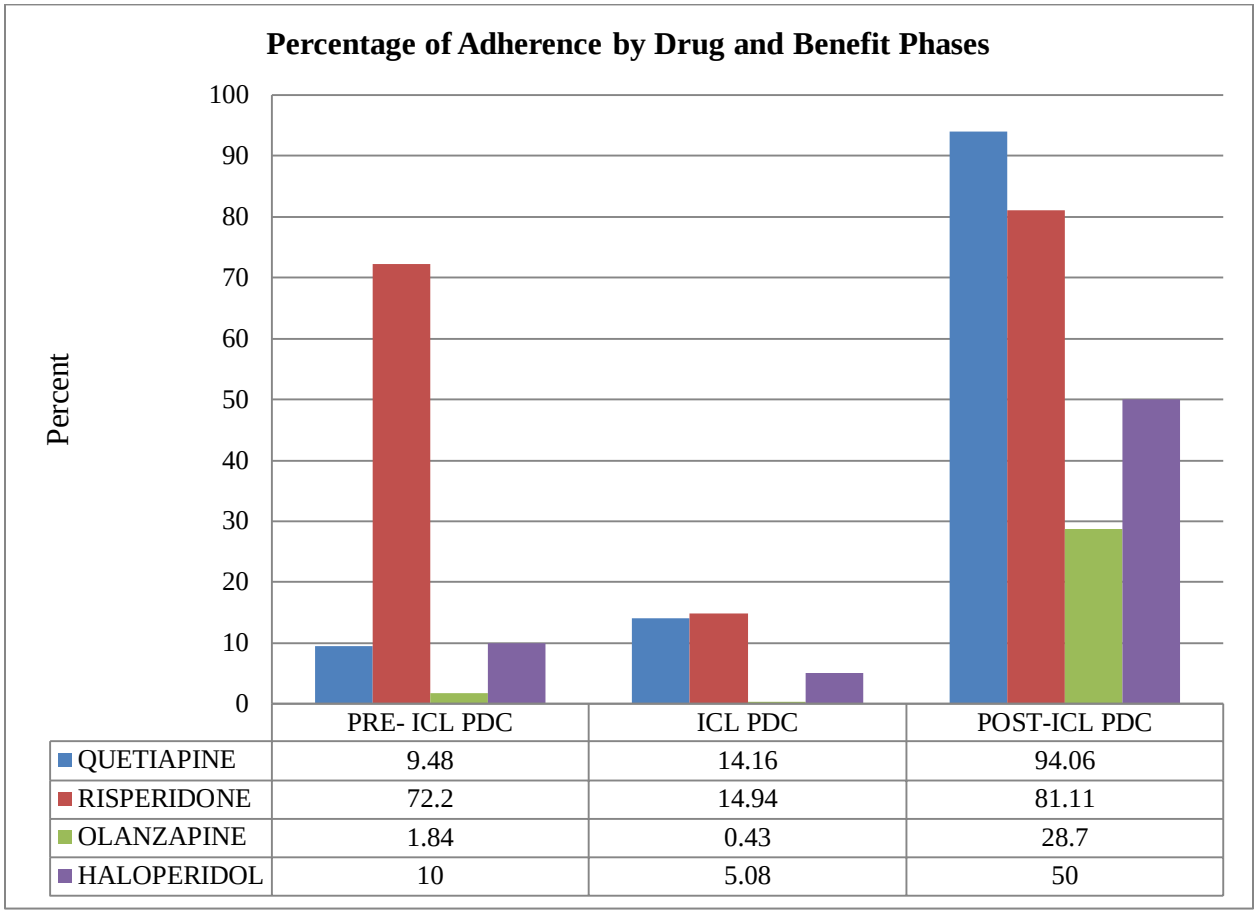
Potential Predictors	PDC Low (n = 909)	PDC High (n=707)	p value
Sex (n = 1616)			0.7094
male	261 (16.15%)	209 (12.93%)	
female	648 (40.10%)	498 (30.82%)	
Age (n=1616)			< 0.0001
young old	452 (27.97%)	432 (26.73%)	
old	326 (20.17%)	202 (12.50%)	
oldest olds	131 (8.11%)	73 (4.52%)	
Race (n = 1616)			0.3569
unknown	0	3 (0.19%)	
White	807 (49.94%)	631 (39.05%)	
Black	44 (2.72%)	31 (1.92%)	
other	18 (1.11%)	9 (0.56%)	
Asian	21 (1.30%)	19 (1.18%)	
Hispanic	6 (0.37%)	7 (0.43%)	
NA Native	13 (0.80%)	7 (0.43%)	
Rural-Urban Areas (n=1616)			0.4877
urban	781 (48.33%)	625 (38.68%)	
large rural	70 (4.33%)	47 (2.91%)	
small rural	37 (2.29%)	21 (1.30 %)	
isolated	21 (1.30%)	14 (0.87%)	

Potential Predictors	PDC Low (n = 4343)	PDC High (n=6136)	p value
Medications (n=10,479)			< 0.0001
olanzapine	1855 (17.70%)	892 (8.51%)	
quetiapine	1070 (10.21%)	2077 (19.82%)	
risperidone	981 (9.36%)	2857 (27.26%)	
haloperidol	437 (4.17%)	310 (2.96%)	
Type of Gap Coverage (n=10,479)			0.0002
all preferred generics	77 (0.73%)	67 (0.64%)	
all generics	274 (2.61%)	501 (4.78%)	
some generics	2 (0.02%)	6 (0.06%)	
some generics, some brands	9 (0.09%)	11 (0.10%)	
no gap coverage	3981 (37.99%)	5551 (52.97%)	
Type of Drug Benefit (n=10,479)			< 0.0001
defined standard	73 (0.70%)	61 (0.58%)	
actuarially equivalent	1281 (12.22%)	2002 (19.10%)	
basic alternative	1575 (15.03%)	2252 (21.49%)	
enhanced alternative	1414 (13.49%)	1821 (17.38%)	
Month Prescription is Filled (n=10,479)			<0.0001
January	93 (0.89%)	90 (0.86%)	
February	98 (0.94%)	114 (1.09%)	
March	130 (1.24%)	184 (1.76%)	
April	179 (1.71%)	257 (2.45%)	
May	207 (1.98%)	352 (3.36%)	
June	269 (2.57%)	510 (4.87%)	
July	362 (3.45%)	652 (6.22%)	
August	494 (4.71%)	710 (6.78%)	
September	562 (5.36%)	811 (7.74%)	
October	612 (5.84%)	834 (7.96%)	
November	617 (5.89%)	797 (7.61%)	
December	720 (6.87%)	825 (7.87%)	
Low Income Cost-Sharing Amount (n=10,479)			< 0.0001
below average	2762 (26.36%)	5299 (50.57%)	
above average	1581 (15.09%)	837 (7.99%)	
Patient Pay Amount (n=10,479)			< 0.0001
below average	3422 (32.66%)	5538 (52.85%)	
above average	921 (8.79%)	598 (5.71%)	

The percentage of PDC adherence dropped for all antipsychotics during the ICL period except for beneficiaries on quetiapine, which had its PDC adherence percentage increase from 9.48 percent in the pre-ICL period to 14.16 percent in the ICL period (Figure 15).

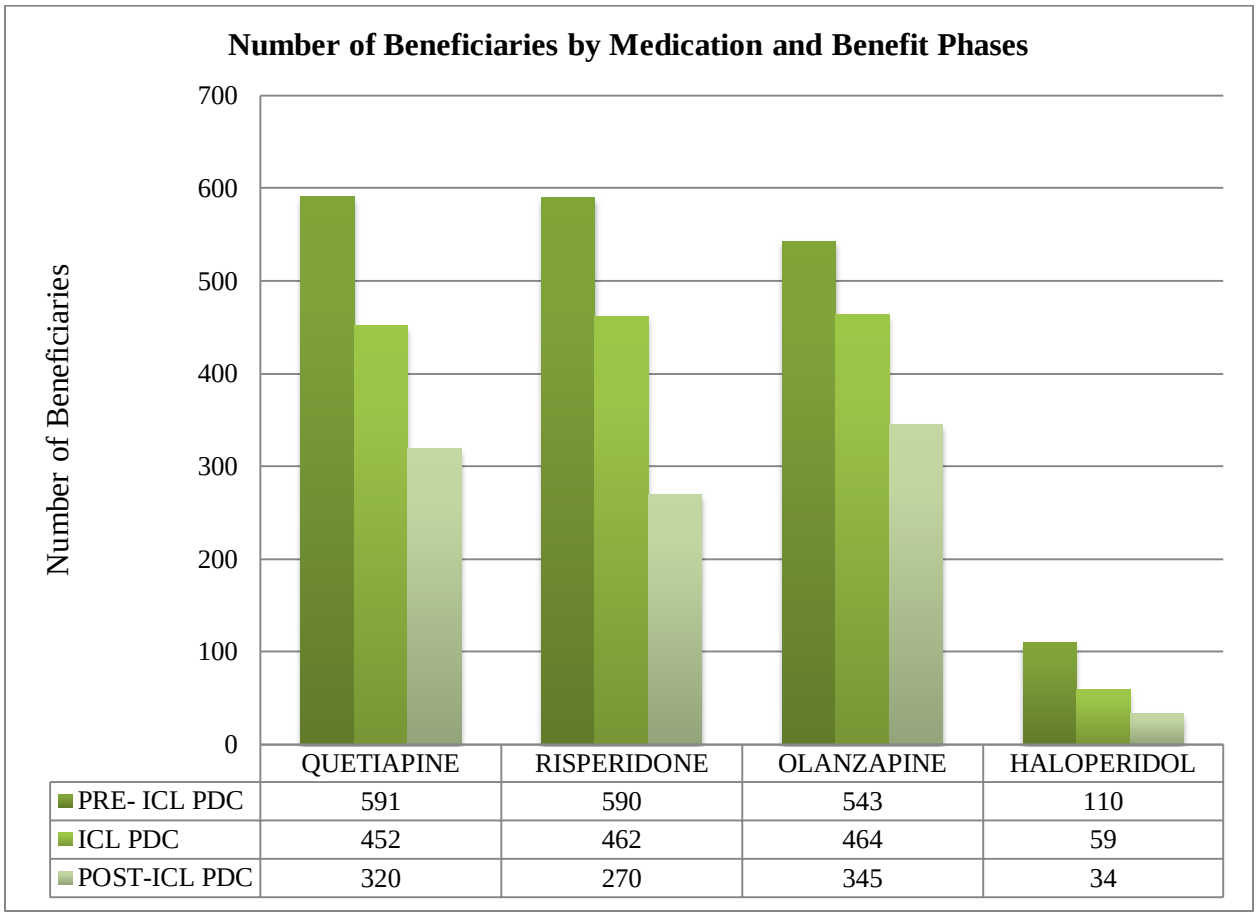
Beneficiaries who experienced all three benefit phases (i.e. pre-ICL, ICL, and post-ICL) during the study period comprised a very small percentage, 1.36 percent, of the study population and generated only 141 claims. Among these beneficiaries, 70.92 percent had low PDC adherence that primarily occurred during the ICL period (35.46 percent), followed by the pre-ICL period (21.3 percent), and the post-ICL period (14.19 percent). In contrast, 29 percent of beneficiaries who experienced all three benefit phases had high PDC, with the highest percentage (13.5 percent) occurring in the post-ICL period (13.48 percent), followed by the pre-ICL period (11.35 percent) and the ICL period (4.26 percent).

FIGURE 15: PERCENTAGE OF ADHERENCE BY DRUG AND BENEFIT PHASES



	PRE- ICL PDC	ICL PDC	POST-ICL PDC
QUETIAPINE	9.48	14.16	94.06
RISPERIDONE	72.2	14.94	81.11
OLANZAPINE	1.84	0.43	28.7
HALOPERIDOL	10	5.08	50

FIGURE 16: NUMBER OF BENEFICIARIES BY MEDICATION AND BENEFIT PHASES

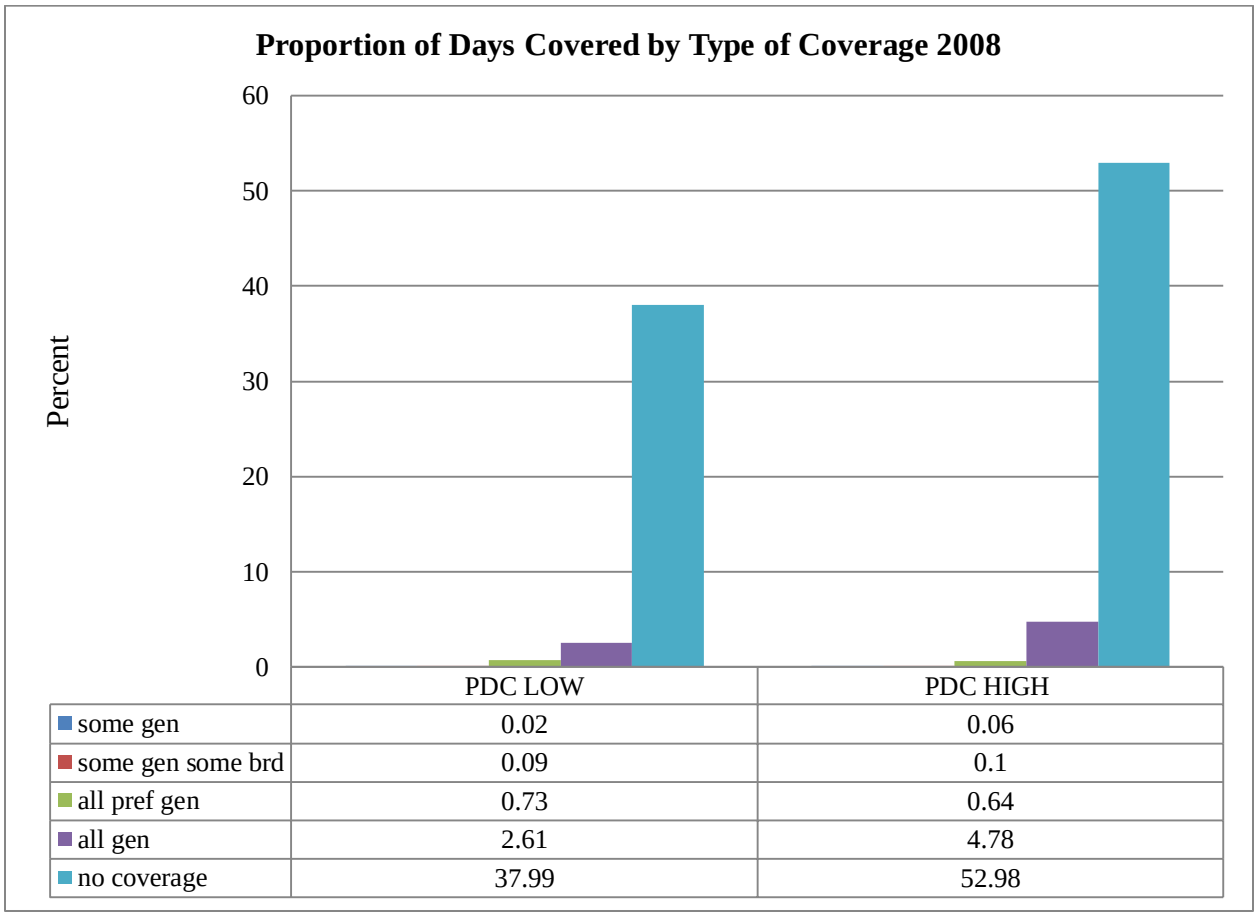


	QUETIAPINE	RISPERIDONE	OLANZAPINE	HALOPERIDOL
PRE- ICL PDC	591	590	543	110
ICL PDC	452	462	464	59
POST-ICL PDC	320	270	345	34

B. ADHERENCE AND TYPE OF GAP COVERAGE

Beneficiaries who were adherent (i.e. high PDCs) comprised a total of 58.55 percent compared to 41.44 percent who were non-adherent (Figure 17). In both high and low PDC groups most beneficiaries had no form of gap coverage (low PDC: 37.99 percent, high PDC: 52.98 percent, Figure 17) and most enrolled in a basic alternative type of drug benefit (low PDC: 15:03 percent, high PDC: 21.49 percent, Figure 18), which is a type of plan that is actuarially equivalent to the standard benefit plan, but may have zero or reduced deductibles, tiered co-payments or co-insurances, and may have modification to the initial coverage limit.

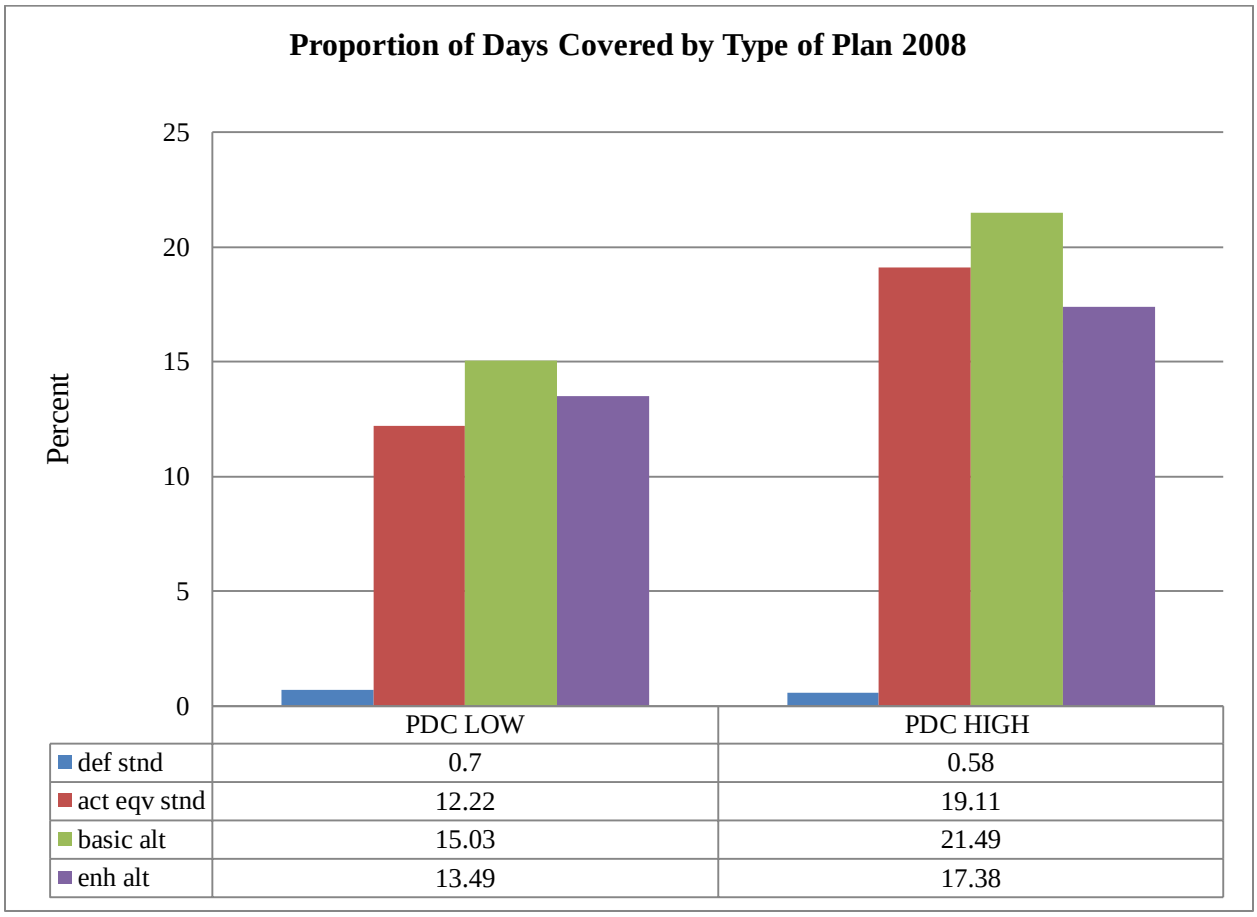
FIGURE 17: PROPORTION OF DAYS COVERED BY TYPE OF COVERAGE, 2008



	PDC LOW	PDC HIGH
some gen	0.02	0.06
some gen some brd	0.09	0.1
all pref gen	0.73	0.64
all gen	2.61	4.78
no coverage	37.99	52.98

* Type of Coverage: some gen = some generics, some gen some brd = some generics, some brands, all pref gen = all preferred generics, all gen = all generics, no coverage = no coverage.

FIGURE 18: PROPORTION OF DAYS COVERED BY TYPE OF PLAN, 2008



	PDC LOW	PDC HIGH
def stnd	0.7	0.58
act eqv stnd	12.22	19.11
basic alt	15.03	21.49
enh alt	13.49	17.38

* Type of Plan: def stnd = defined standard benefit, act eqv stnd = actuarially equivalent standard, basic alt = basic alternative, enh alt = enhanced alternative.

C. ADHERENCE AND PATIENT PAY AMOUNT

Patient pay amount (i.e. the amount a beneficiary pays for a prescription fill that is not reimbursed by a Part D plan and contributes to beneficiary true-out-of-pocket expenses) ranged from $0 to $1451.07, with low PDC beneficiaries paying a greater average than beneficiaries with high PDCs in the ICL period and the catastrophic coverage period. In the pre-ICL period (Table 2) low PDC beneficiaries paid an average of $18.12 (SD = $69.32) for olanzapine, an average of $14.12 (SD = $39.82) for quetiapine, an average of $9.37 (SD = $22) for risperidone, and an average of $1.36 (SD = $2.13) for haloperidol. High PDC beneficiaries paid an average of $13.34 (SD = $ 42.90) for olanzapine, an average of $14.99 (SD = $29.74) for quetiapine, paid an average of $10.13 (SD = $31.20) for risperidone, and an average of $1.28 (SD = $2.17) for haloperidol. The range for patient pay amount in the pre-ICL period was also greater for the low PDC group (min = $0, max = $1451.07) compared to the high PDC group (min = $0, max = $670.38).

In the ICL period (Table 3) low PDC beneficiaries paid an average of $56.75 (SD = $144.45) for olanzapine, an average of $39.84 (SD = $105.48) for quetiapine, paid an average of $27.75 (SD = $94.99) for risperidone, and an average of $1.38 (SD = $2.29) for haloperidol.

High PDC beneficiaries paid an average of $52.89 (SD = $ 55.28) for olanzapine, an average of $35.33 (SD = $90) for quetiapine, paid an average of $13.82 (SD = $55.89) for risperidone, and an average of $0.74 (SD = $1.02) for haloperidol. The range for patient pay amount in the ICL period was greater for the low PDC group (min = $0, max = $1445.48) compared to the high PDC group (min = $0, max = $792.74).

In the catastrophic coverage period (Table 4) low PDC beneficiaries paid an average of $9.13 (SD = $62.45) for olanzapine, an average of $20.75 (SD = $48.87) for quetiapine, an average of $4.31 (SD = $24.25) for risperidone, and an average of $0 (SD = $0) for haloperidol. High PDC beneficiaries paid an average of $1.64 (SD = $ 6.82) for olanzapine, an average of $3.00 (SD = $28.05) for quetiapine, paid an average of $2.21 (SD = $27.86) for risperidone, and an average of $0.02 (SD = $0.20) for haloperidol. The range for patient pay amount in the catastrophic coverage period was greater for the low PDC group (min = $0, max = $1169.82) compared to the high PDC group (min = $0, max = $761.25).

TABLE 3: MEAN PATIENT PAY AMOUNTS DURING PRE-ICL PERIOD

Mean Patient Pay Amounts During Pre-ICL Period					
Olanzapine					
pdc	N Claims	Mean	Std Dev	Minimum	Maximum
low	1957	18.11613	69.31922	0	1451.07
high	105	13.3439	42.90097	0	413.51
Quetiapine					
pdc	N Claims	Mean	Std Dev	Minimum	Maximum
low	1857	14.12449	39.81975	0	1014.79
high	473	14.98856	29.74298	0	384.24
Risperidone					
pdc	N Claims	Mean	Std Dev	Minimum	Maximum
low	349	9.366963	21.99577	0	252.17
high	2324	10.125	31.20372	0	670.38
Haloperidol					
pdc	N Claims	Mean	Std Dev	Minimum	Maximum
low	419	1.357017	2.130895	0	12
high	146	1.279795	2.174401	0	7

TABLE 4: MEAN PATIENT PAY AMONTS DURING ICL PERIOD

Mean Patient Pay Amounts During ICL Period					
Olanzapine					
pdc	N Claims	Mean	Std Dev	Minimum	Maximum
low	1648	56.75426	144.4472	0	1445.48
high	18	52.89056	55.27543	0	112.83
Quetiapine					
pdc	N Claims	Mean	Std Dev	Minimum	Maximum
low	1304	39.84348	105.4793	0	846.25
high	459	35.32721	90.00161	0	792.74
Risperidone					
pdc	N Claims	Mean	Std Dev	Minimum	Maximum
low	1423	27.75285	94.98995	0	1156.69
high	506	13.8147	55.8933	0	427.99
Haloperidol					
pdc	N Claims	Mean	Std Dev	Minimum	Maximum
low	183	1.380164	2.290152	0	12
high	21	0.742857	1.024486	0	2.25

TABLE 5: MEAN PATIENT PAY AMOUNTS DURING CATASTROPHIC COVERAGE PERIOD

Mean Patient Pay Amounts During Catastrophic Coverage Period					
Olanzapine					
pdc	N Claims	Mean	Std Dev	Minimum	Maximum
low	1040	9.132625	62.44887	0	1169.82
high	994	1.642847	6.813369	0	96.8
Quetiapine					
pdc	N Claims	Mean	Std Dev	Minimum	Maximum
low	24	20.745	48.86577	0	168.66
high	1792	3.001306	28.05369	0	663.43
Risperidone					
pdc	N Claims	Mean	Std Dev	Minimum	Maximum
low	74	4.313378	24.2504	0	200.51
high	1524	2.210669	27.85242	0	761.25
Haloperidol					
pdc	N Claims	Mean	Std Dev	Minimum	Maximum
low	40	0	0	0	0
high	155	0.02129	0.198938	0	2.25

D. ADHERENCE AND ANTIPSYCHOTIC MEDICATIONS

1. OLANZAPINE

Proportion of Days Covered (PDC) during the Pre-ICL Period for Olanzapine. Tests for normality for the PDC distribution in 2008 show that olanzapine distribution is not normal. Skewness value of 1.0249 indicates data is highly skewed right and the four tests for goodness-of-fit reject the hypothesis that the PDC is normally distributed: W = 0.9301, p-value < 0.0001; D = 0.1374, p-value < 0.01; W-Sq = 1.5892, p-value < 0.005; A-Sq = 9.5548, p-value < 0.005. During the pre-ICL period the average PDC is 0.3083 among 543 individuals on olanzapine indicating low medication adherence, while the percentage of individuals with high adherence and PDC values of 0.80 or greater totaled 1.84 percent (Figure N). The average number of days covered is 110 days with a median of 90 days. Fitting a lognormal distribution to the data produces a better fit than the normal distribution. A lognormal fit is executed with a lognormal probability plot with sigma estimated from the data (sigma = 0.4038) producing data points that are mostly linearized.

Proportion of Days Covered (PDC) during the ICL Period for Olanzapine. The ICL period is the period when coverage ceases and costs of prescription drugs are borne by beneficiaries. Tests for normality of the PDC distribution in 2008 during this period show that olanzapine distribution is not normal. Skewness value of 0.4158 indicates data is approximately symmetric, but the three tests for goodness-of-fit reject the hypothesis that the PDC is normally distributed: D = 0.0982, p-value < 0.01; W-Sq = 0.5733, p-value < 0.005; A-Sq = 3.3749, p-value < 0.005. During the ICL period the average PDC is 0.3256 among 464 individuals on olanzapine indicating low medication adherence, while the percentage of individuals with good adherence and PDC values of 0.80 or greater totaled 0.43 percent (Figure N). The average number of days covered is 98 days with a median of 90 days. Fitting a lognormal distribution to the data produces a better fit than the normal distribution. A lognormal fit is executed with a lognormal probability plot with sigma estimated from the data (sigma = 0.1905) producing data points that are mostly linearized.

Proportion of Days Covered during the Post-ICL Period for Olanzapine. Post-ICL period comprise of the straddle prescription drug event (PDE) and the catastrophic coverage phase. Tests for normality of the PDC distribution in 2008 show that olanzapine distribution is not normal. Skewness value of 0.1978 indicate that data is near symmetric, but the three tests for goodness-of-fit reject the hypothesis that the PDC is normally distributed: D = 0.0836, p-value < 0.01; W-Sq = 0.3405 , p-value < 0.005; A-Sq = 2.8825, p-value < 0.005. During the post-ICL period the average PDC is 0.5831 among 345 individuals on olanzapine indicating low medication adherence, while the percentage of individuals with good adherence and PDC values of 0.80 or greater totaled 28.70 percent (Figure N). The average number of days covered is 124 days with a median of 121 days. Fitting a lognormal distribution to the data produces a slightly better fit than the normal distribution. A lognormal fit is executed with a lognormal probability plot with sigma estimated from the data (sigma = 0.2128), producing data points that are mostly linearized.

2. QUETIAPINE

Proportion of Days Covered during the Pre-ICL Period for Quetiapine. Tests for normality of the PDC distribution in 2008 show that quetiapine distribution is not normal. Skewness value of 1.1965 indicates that data is highly skewed right and the three tests for goodness-of-fit reject the hypothesis that the PDC is normally distributed: D = 0.1174, p-value < 0.01; W-Sq = 1.6590, p-value < 0.005; A-Sq = 11.197, p-value < 0.005. During the pre-ICL period the average PDC is 0.4475 among 591 individuals on quetiapine indicating low medication adherence, while the percentage of individuals with good adherence and PDC values of 0.80 or greater totaled 9.48 percent (Figure N). The average number of days covered is 105 days with a median of 90 days. Fitting a lognormal distribution to the data produces a better fit than the normal distribution. A lognormal fit is executed with a lognormal probability plot with sigma estimated from the data (sigma = 0.4918), producing data points that are mostly linearized.

Proportion of Days Covered during the ICL Period for Quetiapine. Tests for normality of the PDC distribution in 2008 show that quetiapine distribution is not normal. Skewness value of 0.4375 indicates that data is approximately symmetric and the three tests for goodness-of-fit reject the hypothesis that the PDC is normally distributed: D = 0.0879, p-value < 0.01; W-Sq = 0.4785, p-value < 0.005; A-Sq = 3.1086, p-value < 0.005. During the ICL period the average PDC is 0.5156 among 452 individuals on quetiapine indicating low medication adherence, while the percentage of individuals with good adherence and PDC values of 0.80 or greater totaled 14.16 percent (Figure N). The average number of days covered is 105 days with a median of 98 days. Fitting a lognormal distribution to the data produces a slightly better fit than the normal distribution. A lognormal fit is executed with a lognormal probability plot with sigma estimated from the data (sigma = 0.2302), producing data points that are most nearly linearized.

Proportion of Days Covered during the Post-ICL Period for Quetiapine. Post-ICL period comprise of the straddle prescription drug event (PDE) and the catastrophic coverage phase. Tests for normality of the PDC distribution in 2008 show that quetiapine distribution is not normal. Skewness value of 0.3835 indicate that data is near symmetric, but the three tests for goodness-of-fit reject the hypothesis that the PDC is normally distributed: D = 0.0815, p-value < 0.01; W-Sq = 0.4007 , p-value < 0.005; A-Sq = 2.9436, p-value < 0.005. During the post-ICL period the average PDC is 5.9056 among 320 individuals on quetiapine indicating hyper medication adherence (94.06 percent), while the percentage of individuals with poor adherence and PDCs 0.79 or lower totaled 5.94 percent (Figure N). Hyper adherence could be attributed to stockpiling of medications in these particular phases of benefits. The average number of days covered is 118 days with a median of 111 days. Fitting a lognormal distribution to the data produces a slightly better fit than the normal distribution. A lognormal fit is executed with a lognormal probability plot with sigma estimated from the data (sigma = 0.347), producing data points that are most nearly linearized with the exception of the right tail end of data.

3. RISPERIDONE

Proportion of Days Covered during the Pre-ICL Period for Risperidone. Tests for normality of the PDC distribution in 2008 show that risperidone distribution is not normal. Skewness value of 1.1048 indicates that data is skewed to the right and the three tests for goodness-of-fit reject the hypothesis that the PDC is normally distributed: D = 0.1220, p-value = < 0.01; W-Sq = 2.027, p-value < 0.005; A-Sq = 13.0846, p-value < 0.005. During the pre-ICL

period the average PDC is 1.5262 among 590 individuals on risperidone indicating high medication adherence of 72.2 percent (Figure N), while the percentage of individuals with poor adherence and PDC values of 0.79 or less totaled 27.80 percent. The average number of days covered is 119 days with a median of 101 days. Fitting a lognormal distribution to the data produces a better fit than the normal distribution. A lognormal fit is executed with a lognormal probability plot with sigma estimated from the data (sigma = 0.4700), producing data points that are most nearly linearized.

Proportion of Days Covered during the ICL Period for Risperidone. Tests for normality of the PDC distribution in 2008 show that risperidone distribution is not normal. Skewness value of 0.2846 indicates that data is approximately symmetric and the three tests for goodness-of-fit reject the hypothesis that the PDC is normally distributed: D = 0.0749, p-value < 0.01; W-Sq = 0.3503 , p-value < 0.005; A-Sq = 2.3444, p-value < 0.005. During the ICL period the average PDC is 0.5025 among 462 individuals on risperidone indicating low medication adherence, while the percentage of individuals with high adherence and PDCs 0.80 or greater totaled 14.94 percent (Figure N). The average number of days covered is 107 days with a median of 107 days. Fitting a lognormal distribution to the data produces a better fit than the normal distribution. A lognormal fit is executed with a lognormal probability plot with sigma estimated from the data (sigma = 0.1805), producing data points that are most nearly linearized except for data points approximately less than the 5th percentile and data points approximately greater than the 97th percentile.

Proportion of Days Covered during the Post-ICL Period for Risperidone. Tests for normality of the PDC distribution for 2008 show that the distribution is not normal. Skewness value of 0.1426 indicate that data is approximately symmetric and the three tests for goodness-of-fit reject the hypothesis that the PDC is normally distributed: D = 0.0725, p-value < 0.01; W-Sq = 0.4589, p-value = < 0.005; A-Sq = 2.9231, p-value < 0.005.During the pre-ICL period the average PDC is 2.3770 among 270 individuals on risperidone indicating hyper medication adherence, while the percentage of individuals with poor adherence and PDCs 0.79 or less totaled 18.89 percent. The average number of days covered is 116 days with a median of 112 days. Fitting a lognormal distribution to the data produces a better fit than the normal distribution. A lognormal fit is executed with a lognormal probability plot with sigma estimated from the data (sigma = 0.1804), producing data points that are most nearly linearized.

4. HALOPERIDOL

Proportion of Days Covered during the Pre-ICL Period for Haloperidol. Tests for normality of the PDC distribution for 2008 show that haloperidol distribution is not normal. Skewness value of 0.8128 indicates that data is moderately skewed to the right and the three tests for goodness-of-fit reject the hypothesis that the PDC is normally distributed: D = 0.1683, p-value < 0.01; W-Sq = 0.7924, p-value < 0.005; A-Sq = 4.7504, p-value < 0.005. During the pre-ICL period the average PDC is 0.3416 among 110 individuals on haloperidol indicating low medication adherence, while the percentage of individuals with high adherence and PDCs 0.80 or greater totaled 10 percent (Figure N). The average number of days covered is 122 days with a median of 86 days. Fitting a lognormal distribution to the data produces a better fit than the normal distribution. A lognormal fit is executed with a lognormal probability plot with sigma estimated from the data (sigma = 1.0018), producing data points that are most nearly linearized.

Proportion of Days Covered during the ICL Period for Haloperidol. Tests for normality of the PDC distribution in 2008 show that haloperidol distribution is not normal. Skewness value of 0.5608 indicates that data is slightly skewed to the right and the three tests for goodness-of-fit reject the hypothesis that the PDC is normally distributed: D = 0.1387, p-value < 0.01; W-Sq = 0.2222, p-value < 0.005; A-Sq = 1.3714, p-value < 0.005. During the ICL period the average PDC is 0.3473 among 59 individuals on haloperidol indicating low medication adherence, while the percentage of individuals with high adherence and PDCs 0.80 or greater totaled 5.08 percent (Figure N). The average number of days covered is 77 days with a median of 60 days. Fitting a lognormal distribution to the data produces a better fit than the normal distribution. A lognormal fit is executed with a lognormal probability plot with sigma estimated from the data (sigma = 0.7436), producing data points up to the 70th percentile that are most nearly linearized.

Proportion of Days Covered during the Post-ICL Period for Haloperidol. Tests for normality of the PDC distribution in 2008 show that haloperidol distribution is not normal. Skewness value of 0.5932 indicates that data is slightly skewed to the right and the three tests for goodness-of-fit reject the hypothesis that the PDC is normally distributed: D = 0.1655, p-value = 0.019; W-Sq = 0.2012, p-value < 0.005; A-Sq = 1.2205, p-value < 0.005. During the ICL period the average PDC is 1.075 among 34 individuals on haloperidol indicating high medication adherence, while the percentage of individuals with low adherence and PDCs 0.79 or less totaled 50 percent. The average number of days covered is 105 days with a median of 78 days. Fitting a lognormal distribution to the data produces a better fit than the normal distribution. A lognormal fit is executed with a lognormal probability plot with sigma estimated from the data (sigma = 0.8282), producing data points that are closer to the diagonal reference line.

E. ADHERENCE, TYPE OF PLAN, TYPE OF DRUG BENEFIT, TYPE OF COVERAGE, AND PATIENT PAY AMOUNT DURING THE GAP PERIOD

Specifically for the gap period, means and sums of patient pay amounts are calculated (Table E) taking into consideration subgroups within: PDC (i.e. hi and low), plan type (i.e. Health Maintenance Organization, Preferred Provider Organization, Private Fee for Service plan, and stand-alone Medicare Prescription Drug Plan), drug benefit type (i.e. defined standard, actuarially equivalent, basic alternative, and enhanced alternative), and gap coverage type (i.e.no gap coverage, all generics, all preferred generics, some generics and some brands, some generics).

During the gap period non-adherence by plan type was found most among beneficiaries with stand-alone Medicare prescription drug plans (79.21 percent of all claims, Table E and F) in which beneficiaries filling prescriptions for olanzapine had the highest rate of non-adherence (29.72 percent of all claims), followed by risperidone (25.68 percent), quetiapine (23.48 percent), and haloperidol (3.42 percent). In comparison, much lower percentages were found among non-adherent beneficiaries with other type of plans: HMO plans (2.59 percent), PPO (0.07 percent), and PFFS plans (0.07 percent).

Adherence by plan type overall was also found most among beneficiaries with stand-alone Medicare prescription drug plans (17.03 percent of all claims, Table E and F), however, adherence among beneficiaries with other types of plans were considerably lower (HMO: 0.78 percent, PPO: 0.25 percent), and none were found with PFFS plans. Risperidone (8.95 percent of all claims) and quetiapine (7.57 percent) had the two highest adherences with stand-alone Medicare prescription drug plans, followed by quetiapine with HMO plans at a far lower rate

(0.43 percent).Beneficiary adherence for other antipsychotics through other plans were even lower.

Taking into consideration other benefit design elements (i.e. type of drug benefit and type of gap coverage) and together with plan type and patient pay amount, mean patient pay amount was highest ($776.76) for a single beneficiary filling a prescription for quetiapine who had all generics coverage during the gap through an HMO plan type; this beneficiary was adherent, but made up a very small fraction (0.02 percent) of total beneficiary claims in the gap period. Second highest average patient pay amount ($398.93) was for beneficiaries also filling prescriptions for quetiapine (0.07 percent) who had some generics and some brands coverage through PFFS plans and who were non-adherent, followed by beneficiaries filling prescriptions for olanzapine ($312.93) with all preferred generics coverage through stand-alone Medicare Part D prescription drug plans and who were also non-adherent (0.13 percent). These beneficiaries with some type of coverage during the gap period all had enhanced alternative type of drug benefits.

Among beneficiaries with no gap coverage, the highest average patient pay amount during the gap period ($75.44) was among beneficiaries filling prescriptions for olanzapine, who had basic alternative, stand-alone Medicare prescription drug plans, and were non-adherent (10.05 percent), followed by beneficiaries with enhanced alternative, stand-alone Medicare prescription drug plans ($69.62), who were also non-adherent and filling prescriptions for olanzapine (6.60 percent), and quetiapine ($68.80, 4.40 percent).

Comparing the above figures during the gap period with the pre-gap period non-adherence by plan type in the pre-gap period was found most among beneficiaries with stand-alone Medicare prescription drug plans (57.78 percent of all claims in the pre-gap period, Table E) in which beneficiaries filling prescriptions for olanzapine had the highest rate of non-adherence (24.76 percent of all claims), followed by quetiapine (23.08 percent), haloperidol (5.39 percent) and risperidone (4.55 percent). In comparison, much lower percentages were found among non-adherent beneficiaries with other types of plans in the pre-gap period: HMO plans (1.76 percent), PFFS plans (0.30 percent), and PPO (0.22 percent).

In the catastrophic coverage phase non-adherence by plan type was found most among beneficiaries with stand-alone Medicare prescription drug plans (20.50 percent of all claims in the catastrophic coverage period, Table E and F) in which beneficiaries filling prescriptions for olanzapine had the highest rate of non-adherence (18.15 percent of all claims in the catastrophic coverage period), followed by risperidone (1.28 percent), haloperidol (0.67 percent), and quetiapine (0.41 percent). In comparison, much lower percentages were found among non-adherent beneficiaries with other types of plans in the catastrophic coverage period: HMO plans (0.35 percent), PFFS plans (0.02 percent), and none for PPO.

Adherence by plan type in the pre-gap period overall was also found most among beneficiaries with stand-alone Medicare prescription drug plans (39.12 percent of all claims in the pre-gap period, Table 5 and 6), however, adherence among beneficiaries with other types of plans were considerably lower (HMO: 0.56 percent, PFFS: 0.21 percent, and PPO: 0.05 percent). Risperidone (29.76 percent of all claims) and quetiapine (6.07 percent) had the two highest adherences with stand-alone Medicare prescription drug plans, followed by haloperidol (1.92 percent) and olanzapine (1.38 percent) at lower rates. Beneficiary adherences for other antipsychotics through other plans were even lower.

TABLE 6: ADHERENCE BY TYPE OF PLAN, TYPE OF DRUG BENEFIT, TYPE OF GAP COVERAGE, AND PATIENT AMOUNT DURING THE GAP PERIOD

Patient Pay Amount Sum													
Plan Type HMO													
Drug Benefit Type													
		defined standard					actuarially equivalent				basic alternative		
		Type of gap coverage offered					Type of gap coverage offered				Type of gap coverage offered		
Olanzapine	Mean	no gap coverage	N	PctN	All		Mean	no gap coverage N	PctN	All	Mean	no gap coverage N	PctN	All
pdc														
low		0.78	8	0.48	6.2		3.1	10	0.6	31	1.09	20	1.2	21.7
high	.	.	.	.	.		.	.	.	.	.	.	.	.
All		0.78	8	0.48	6.2		3.1	10	0.6	31	1.09	20	1.2	21.7

	Patient Pay Amount Sum Plan Type **HMO** Drug Benefit Type enhanced alternative Type of gap coverage offered all generics				no gap coverage			
Olanzapine pdc	Mean	N	PctN	All	Mean	N	PctN	All
low	0	4	0.24	0	18.12	15	0.9	271.77
high	.	.	.	.	.	.	.	.
All	0	4	0.24	0	18.12	15	0.9	271.77

	Patient Pay Amount Sum											
	Plan Type **Medicare Prescription Drug Plan**											
	Drug Benefit Type											
	defined standard				actuarially equivalent				basic alternative			
	Type of gap coverage offered				Type of gap coverage offered				Type of gap coverage offered			
	no gap coverage				no gap coverage				no gap coverage			
Olanzapine pdc	Mean	N	PctN	All	Mean	N	PctN	All	Mean	N	PctN	All
low	2.36	37	2.22	87.5	37.68	521	31.27	19631.91	75.44	559	33.55	42171.1
high	.	.	.	.	.	.	.	.	52.89	18	1.08	952.03
All	2.36	37	2.22	87.5	37.68	521	31.27	19631.91	74.74	577	34.63	43123.13

	Patient Pay Amount Sum											
	Plan Type **Medicare Prescription Drug Plan**											
	Drug Benefit Type enhanced alternative											
	Type of gap coverage offered all preferred generics				all generics				no gap coverage			
Olanzapine pdc	Mean	N	PctN	All	Mean	N	PctN	All	Mean	N	PctN	All
low	312.93	7	0.42	2190.51	35.67	100	6	3567.05	69.62	367	22.03	25552.28
high	.	.	.	.	.	.	.	.	.	.	.	.
All	312.93	7	0.42	2190.51	35.67	100	6	3567.05	69.62	367	22.03	25552.28

	Patient Pay Amount Sum											
	Plan Type **HMO** Drug Benefit Type											
	basic alternative Type of gap coverage offered no gap coverage				enhanced alternative Type of gap coverage offered some generics				all generics			
Quetiapine pdc	Mean	N	PctN	All	Mean	N	PctN	All	Mean	N	PctN	All
low	14.66	17	0.96	249.27	0	2	0.11	0	.	.	.	.
high	2.02	23	1.3	46.5	.	.	.	.	776.76	1	0.06	776.76
All	7.39	40	2.27	295.77	0	2	0.11	0	776.76	1	0.06	776.76

	Patient Pay Amount Sum											
	Plan Type **HMO** Drug Benefit Type				Plan Type **PPO** Drug Benefit Type				Plan Type **PFFS** Drug Benefit Type			
	basic alternative Type of gap coverage offered no gap coverage				enhanced alternative Type of gap coverage offered all generics				enhanced alternative Type of gap coverage offered some generics some brands			
Quetiapine pdc	Mean	N	PctN	All	Mean	N	PctN	All	Mean	N	PctN	All
low	29	24	1.36	695.89	.	.	.	.	398.93	4	0.23	1595.72
high	.	.	.	.	94.39	14	0.79	1321.45	.	.	.	.
All	29	24	1.36	695.89	94.39	14	0.79	1321.45	398.93	4	0.23	1595.72

	Patient Pay Amount Sum											
	Plan Type **Medicare Prescription Drug Plan** Drug Benefit Type											
	defined standard				actuarially equivalent				basic alternative			
	Type of gap coverage offered				Type of gap coverage offered				Type of gap coverage offered			
	no gap coverage				no gap coverage				no gap coverage			
Quetiapine pdc	Mean	N	PctN	All	Mean	N	PctN	All	Mean	N	PctN	All
low	1.81	24	1.36	43.4	28.55	404	22.92	11536.09	34.67	476	27	16501.91
high	3.1	6	0.34	18.6	34.78	173	9.81	6017.2	24.18	166	9.42	4013.17
All	2.07	30	1.7	62	30.42	577	32.73	17553.29	31.95	642	36.42	20515.08

	Patient Pay Amount Sum											
	Plan Type **Medicare Prescription Drug Plan** Drug Benefit Type enhanced alternative											
	Type of gap coverage offered all preferred generics				all generics				no gap coverage			
Quetiapine pdc	Mean	N	PctN	All	Mean	N	PctN	All	Mean	N	PctN	All
low	190.93	21	1.19	4009.49	3.88	85	4.82	330.08	68.8	247	14.01	16994.05
high	.	.	.	.	3.1	6	0.34	18.6	57.18	70	3.97	4002.91
All	190.93	21	1.19	4009.49	3.98	91	5.16	348.68	66.24	317	17.98	20996.96

	Patient Pay Amount Sum											
	Plan Type Medicare Prescription Drug Plan											
	Drug Benefit Type											
	basic alternative				enhanced alternative							
	Type of gap coverage offered				Type of gap coverage offered							
	no gap coverage				all preferred generics				all generics			
Risperidone pdc	Mean	N	PctN	All	Mean	N	PctN	All	Mean	N	PctN	All
low	43.44	506	26.23	21983.15	178.88	27	1.4	4829.86	1.24	142	7.36	176.05
high	8.04	176	9.12	1414.89	85.63	6	0.31	513.75	7.05	70	3.63	493.47
All	34.31	682	35.36	23398.04	161.93	33	1.71	5343.61	3.16	212	10.99	669.52

	Patient Pay Amount Sum											
	Plan Type HMO											
	Drug Benefit Type											
	defined standard				basic alternative				enhanced alternative			
	Type of gap coverage offered											
	no gap coverage				no gap coverage				all generics			
Risperidone pdc	Mean	N	PctN	All	Mean	N	PctN	All	Mean	N	PctN	All
low	5.6	4	0.21	22.4	1.78	31	1.61	55.3	.	.	.	.
high	.	.	.	.	1.93	7	0.36	13.5	1.05	1	0.05	1.05
All	5.6	4	0.21	22.4	1.81	38	1.97	68.8	1.05	1	0.05	1.05

	Patient Pay Amount Sum											
	Plan Type HMO				PPO				Medicare Prescription Drug Plan			
	Drug Benefit Type				Drug Benefit Type				Drug Benefit Type			
	enhanced alternative				enhanced alternative				actuarially equivalent			
	Type of gap coverage offered				Type of gap coverage offered				Type of gap coverage offered			
	no gap coverage				all generics				no gap coverage			
Risperidone pdc	Mean	N	PctN	All	Mean	N	PctN	All	Mean	N	PctN	All
low	1	9	0.47	9	128.51	4	0.21	514.05	16.52	427	22.14	7054.32
high	.	.	.	.	.	.	.	.	33.23	96	4.98	3189.91
All	1	9	0.47	9	128.51	4	0.21	514.05	19.59	523	27.11	10244.23

	Patient Pay Amount Sum Plan Type								
	Medicare Prescription Drug Plan Drug Benefit Type enhanced alternative					HMO Drug Benefit Type basic alternative			
	Type of gap coverage offered no gap coverage					Type of gap coverage offered no gap coverage			
Risperidone pdc	Mean	N	PctN	All		Haloperidol pdc	Mean	N	PctN	All
low	17.76	273	14.15	4848.18		low	.	.	.	.
high	9.09	150	7.78	1363.67		high	0.19	11	5.39	2.1
All	14.69	423	21.93	6211.85		All	0.19	11	5.39	2.1

	Patient Pay Amount							
	Sum							
	Plan Type							
	Medicare Prescription Drug Plan							
	Drug Benefit Type							
	actuarially equivalent				basic alternative			
	Type of gap coverage offered				Type of gap coverage offered			
	no gap coverage				no gap coverage			
Haloperidol pdc	Mean	N	PctN	All	Mean	N	PctN	All
low	0.8	81	39.71	64.6	2.13	54	26.47	115.15
high	.	.	.	.	0	4	1.96	0
All	0.8	81	39.71	64.6	1.99	58	28.43	115.15

	Patient Pay Amount							
	Sum							
	Plan Type							
	Medicare Prescription Drug Plan							
	Drug Benefit Type							
	enhanced alternative							
	Type of gap coverage offered				Type of gap coverage offered			
	all generics				no gap coverage			
Haloperidol pdc	Mean	N	PctN	All	Mean	N	PctN	All
low	0.83	14	6.86	11.55	1.8	34	16.67	61.27
high	.	.	.	.	2.25	6	2.94	13.5
All	0.83	14	6.86	11.55	1.87	40	19.61	74.77

TABLE 7: ADHERENCE BY TYPE OF PLAN DURING THE PRE-GAP, GAP, AND CATASTROPHIC COVERAGE PHASES

Adherence by Type of Plan					
Pre-Gap (N= 7630 claims)					
	HMO	**PPO**	**PFFS**	**MPDP**	**Total**
pdc low	134	17	23	4408	4582
% of total in Pre-Gap	1.75623	0.2228	0.30144	57.772	60.0524
pdc hi	43	4	16	2985	3048
% of total in Pre-Gap	0.56356	0.05242	0.2097	39.1219	39.9476
Gap (N = 5562 claims)					
	HMO	**PPO**	**PFFS**	**MPDP**	**Total**
pdc low	144	4	4	4406	4558
% of total in Gap	2.589	0.07192	0.07192	79.2161	81.9489
pdc hi	43	14	0	947	1004
% of total in Gap	0.7731	0.25171	0	17.0262	18.0511
Catastrophic Coverage (CC) (N = 5643 claims)					
	HMO	**PPO**	**PFFS**	**MPDP**	**Total**
pdc low	20	0	1	1157	1178
% of total in CC	0.35442	0	0.01772	20.5033	20.8754
pdc hi	115	2	0	4348	4465
% of total in CC	2.03792	0.03544	0	77.0512	79.1246

F. ADHERENCE IN A LOGISTIC REGRESSION MODEL

Logistic Regression: Model with Interaction Terms. To estimate the coefficients for the dichotomous dependent variable of low PDC versus high PDC a logistic regression model with multiplicative terms is executed. Statistically non-significant variables are excluded (Table 1). Additionally, although the variable type of gap coverage and type of drug benefit are statistically significant in separate bivariate analyses with the dependent variable, they are excluded in the logistic regression model, because they were not statistically significant in a test of the logistic model. Also excluded are the interactions between the variables type of gap coverage and patient pay amount, and age with patient pay amount variables. The interaction of type of drug benefit and patient pay amount is statistically significant in a test of the logistic model and is, thus, included. Given the research questions, the following variables (Table 7) are predictors in the model:

TABLE 8: TABLE OF VARIABLES

Predictor Variable	Variable Label
generic drug name	GNN
date of refill	SRVC_DT
patient pay amount	PTNT_PAY_AMT
low income cost sharing subsidy amount	LICS_AMT
beneficiary age	BENE_AGE_AT_END_REF_YR
Interaction Term	Variable Label
generic drug*patient pay amount	GNN PTNT_PAY_AMT
type of drug benefit *patient pay amount	DRGBENTP PTNT_PAY_AMT
type of drug benefit*low income cost sharing subsidy amount	DRGBENTP LICS_AMT

The model with multiplicative estimates a logistic model predicting the probability of medication adherence measured as proportion of days covered (PDC) with values ≥ 0.80. The model convergence criteria were satisfied and tests for the global null hypothesis that beta = 0 resulted in p-values of < 0.0001 for the predictors (Table 8). Thus, the null hypotheses are rejected and conclude that at least one of the associated coefficients is not equal to zero. The three categorical variables with their interaction terms produced a separate test of the null hypothesis that all of the coefficients associated with the categorical variables and their interaction terms are 0 (Table I). All of the remaining variables are statistically significant. Thus, predictors in the model are statistically significant and indicate strong evidence of their impact on the probability of medication adherence (Table 9). Fit for this model is good as measured by the C statistic: 0.789 and max-rescaled R-Square: 0.2981.

TABLE 9: TESTING GLOBAL NULL HYPOTHESIS: BETA=0

Testing Global Null Hypothesis: BETA=0			
Test	**Chi-Square**	**DF**	**Pr > ChiSq**
Likelihood Ratio	2621.4275	15	<.0001
Score	2237.8211	15	<.0001
Wald	1684.6851	15	<.0001

TABLE 10: TYPE 3 ANALYSIS OF EFFECTS

Type 3 Analysis of Effects			
Effect	**DF**	**Wald Chi-Square**	**Pr > ChiSq**
GNN	3	909.6272	<.0001
PTNT_PAY_AMT*GNN	3	49.8645	<.0001
SRVC_DT	1	22.4931	<.0001
PTNT_PAY_AMT*DRGBENTP	3	67.5930	<.0001
LICS_AMT	1	525.8492	<.0001
PTNT_PAY_AMT*LICS_AMT	1	9.0731	0.0026
BENE_AGE_AT_END_REF_	2	126.3621	<.0001

In an analysis of maximum likelihood estimates (Table 10), coefficient estimates for the predictors, their standard errors, and Wald Chi-Square test statistics are calculated. All of the predictors are statistically significant, except for olanzapine.

Antipsychotics in the study (GNN as a classification variable for: olanzapine, quetiapine, risperidone, and haloperidol) are statistically significant, except for olanzapine, with Wald Chi-Square: 909.63, DF: 3, $p < 0.0001$, (Table 9). In the Analysis of Maximum Likelihood Estimates (Table 10) the log-odds for the atypical antipsychotics are statistically significant compared to haloperidol as the reference drug, except for olanzapine. A contrast statement is executed to compare individual atypical antipsychotics (Table 12) that also show statistical significance, except contrast for olanzapine versus haloperidol. The largest predicted odds for adherence is contrast for risperidone, which was 5.7673 times than the predicted odds for adherence for haloperidol; followed by the contrast for quetiapine, which was 3.6131 times than the predicted odds for adherence for haloperidol. Predicted odds for adherence for beneficiaries on quetiapine are 0.6265 times than the predicted odds for risperidone (Table 13). Predicted odds for adherence for beneficiaries on olanzapines are 0.2930 times than the predicted odds for quetiapine and 0.1835 times than risperidone (Table 13). Antipsychotics and its interaction with patient pay amount is also statistically significant, Wald Chi-Square: 49.8645, DF: 3, $p < 0.0001$, (Table 9).

Coefficients in the interactions of type of drug benefits with patient pay amount is statistically significant (Wald Chi-square: 67.5930, DF: 3, $p < 0.0001$, Table 9). Type of drug benefit is a classification variable that categorizes plans to: defined standard benefit (coded as 1), actuarially equivalent standard (2), basic alternative (3), and enhanced alternative (4).

Low income cost-sharing subsidy amount (LICS_AMT) and its interaction with patient pay amount in this model are statistically significant (Table 9). Low income cost-sharing subsidy

amount has Wald Chi-square: 527.8492, DF: 1, $p < 0.0001$, while its interaction with patient pay amount has Wald Chi-square: 9.0731, DF: 1, $p = 0.0026$.

Age in the model is statistically significant (Wald Chi-square: 126.3621, DF: 2, $p < 0.0001$, Table 9), but its interaction with patient pay is not statistically significant and, thus, excluded in this model. By running a contrast statement in the model, odds ratio with Wald-Chi square statistics and p values are obtained. Predicted odds for adherence for beneficiaries who are old (i.e. 75-84 years old) are 1.8338 times the predicted odds for beneficiaries who are oldest old (i.e. $\leq$ 85 years old); and predicted odds for adherence for beneficiaries who are old are 1.5876 times the predicted odds for beneficiaries who are young old (i.e. 65-74 years old); while predicted odds for adherence for beneficiaries who are oldest old are 0.8658 times the predicted odds for beneficiaries who are young old (Table 13).

The contrast statement is executed at the 0.05 significance level for all the class variables (i.e. categorical variables) and the output for contrast test results (Table 12) shows the log-odds for comparisons within each categorical variable, while the table for parameter estimates show point estimates for individual comparison and its exponentiated comparison (Table 13). For contrast of categories within generic medications (GNN), all medication contrasts are statistically significant, except for the contrast between olanzapine with haloperidol. In other words, the difference in the log-odds of medication adherence for beneficiaries on a particular medication, such as olanzapine, compared to beneficiaries on a different medication, such as quetiapine, is statistically significant (Wald Chi-Square: 373.4299, DF: 1, $p < 0.0001$); as are contrasts for: old beneficiaries (75-84 years old) versus oldest old beneficiaries ($\geq$ 85 years old) (Wald Chi-Square: 77.1701, DF: 1, $p < 0.0001$).

In order to better understand the continuous variable patient pay amount and its interaction with medications, a table of least squares means is presented (Table 14). Patient pay amount is grouped in to "below average" and "above average" based on the study population average patient pay amount of $16.08. It shows the estimates of the log odds, the odds (i.e. exponentiated column), and the probability of medication adherence (i.e. the mean column) for specific combinations of medication and patient pay amount. The highest estimated odds is for beneficiaries on risperidone with below average patient pay amount (i.e. out-of-pocket cost), which is 2.6720, and an estimated probability of adherence of 0.7277; followed by the estimated odds for quetiapine with below average patient pay amount, which is 2.2284, and an estimated probability adherence of 0.692. While the estimated odds of beneficiary adherence for olanzapine with below average patient pay amount is 0.4805 with an estimated probability of adherence of 0.32; and the estimated odds of beneficiary adherence for haloperidol with below average patient pay amount is 0.3361 with an estimated probability of adherence of just 0.2516. All interactions for medications with above average patient pay amount are not statistically significant.

Similarly, to better understand the effects of type of drug benefit with patient pay amount on medication adherence a table of least squares means is presented (Table 15). Patient pay amount is again grouped in to "below average" and "above average" based on the study population average patient pay amount of $16.08. It shows the estimates of the log odds, the odds (i.e. exponentiated column), and the probability of medication adherence (i.e. the mean column) for specific combinations of medication and patient pay amount. The highest estimated odds is for beneficiaries with basic alternative plans and below average patient pay amount (i.e. out-of-pocket cost), which is 1.2753, and an estimated probability of adherence of 0.5605;

followed by the estimated odds for beneficiaries with enhanced alternative with below average patient pay amount, which is 1.1345, and an estimated probability adherence of 0.5315. While the estimated odds of beneficiary adherence for those with actuarially equivalent plans and below average patient pay amount is 1.0861 with an estimated probability of adherence of 0.5206. In contrast, the estimated odds of beneficiary adherence with above average patient pay amount with any kind of drug benefit type all have estimated odds below 1 and estimated probabilities of adherence below 0.50.

TABLE 11: ANALYSIS OF LIKELIHOOD ESTIMATES

Analysis of Maximum Likelihood Estimates						
Parameter		DF	Estimate	Standard Error	Wald Chi-Square	Pr > ChiSq
Intercept		1	21.9174	4.7183	21.5778	<.0001
GNN	OLANZAPINE	1	0.0569	0.0984	0.3340	0.5633
GNN	QUETIAPINE FUMARATE	1	1.2846	0.0969	175.6937	<.0001
GNN	RISPERIDONE	1	1.7522	0.0966	328.9260	<.0001
GNN	HALOPERIDOL	0	0	.	.	.
PTNT_PAY_AMT*GNN	OLANZAPINE	1	-0.0226	0.00386	34.2633	<.0001
PTNT_PAY_AMT*GNN	QUETIAPINE FUMARATE	1	-0.00289	0.00119	5.8912	0.0152
PTNT_PAY_AMT*GNN	RISPERIDONE	1	-0.00481	0.00120	15.9488	<.0001
PTNT_PAY_AMT*GNN	HALOPERIDOL	1	-0.2434	0.0493	24.3497	<.0001
SRVC_DT		1	-0.00126	0.000266	22.4931	<.0001
PTNT_PAY_AM*DRGBENTP	basic alternative	1	-0.00999	0.00156	41.1423	<.0001
PTNT_PAY_AM*DRGBENTP	defined standard	1	-0.6746	0.1575	18.3562	<.0001
PTNT_PAY_AM*DRGBENTP	enhanced alternative	1	-0.00809	0.00150	28.9203	<.0001
PTNT_PAY_AM*DRGBENTP	actuarially equivalent	0	0	.	.	.
LICS_AMT		1	-0.000646	0.000282	525.8492	<.0001
PTNT_PAY_AM*LICS_AMT		1	0.000050	0.000017	9.0731	0.0026
BENE_AGE_AT_END_REF_	old*	1	0.1441	0.0730	3.8979	0.0483
BENE_AGE_AT_END_REF_	young old*	1	0.6064	0.0690	77.1701	<.0001
BENE_AGE_AT_END_REF_	oldest old*	0	0	.	.	.

* young old = 65-74 y.o., old = 75-84 y.o., oldest old = > = 85 y.o.;

TABLE 12: ODDS RATIO ESTIMATES

Effect	Odds Ratio Estimates		
	Point Estimate	95% Wald Confidence Limits	
SRVC_DT	0.999	0.998	0.999
BENE_AGE_AT_END_REF_old vs oldest old	1.155	1.001	1.333
BENE_AGE_AT_END_REF_young old vs oldest old	1.834	1.602	2.099

* young old = 65-74 y.o., old = 75-84 y.o., oldest old = > = 85 y.

TABLE 13: CONTRAST TEST RESULTS

Contrast Test Results			
Contrast	**DF**	**Wald Chi-Square**	**Pr > ChiSq**
GNN OL vs. QUET	1	373.4299	<.0001
GNN OL vs. RISP	1	741.1077	<.0001
GNN OL vs. HAL	1	0.3340	0.5633
GNN QUET vs. RISP	1	61.4372	<.0001
GNN QUET vs. HAL	1	175.6937	<.0001
GNN RISP vs. HAL	1	328.9260	<.0001
OLD vs. OLDEST OLD*	1	77.1701	<.0001
OLD vs. YOUNG OLD*	1	84.7628	<.0001
OLDEST OLD vs. YOUNG OLD*	1	3.8979	0.0483

* young old = 65-74 y.o., old = 75-84 y.o., oldest old = > = 85 y.o.

TABLE 14: CONTRAST ESTIMATION AND TESTING RESULTS BY ROW

Contrast Estimation and Testing Results by Row									
Contrast	Type	Row	Estimate	Standard Error	Alpha	Confidence Limits		Wald Chi-Square	Pr > ChiSq
GNN OL vs. QUET	PARM	1	-1.2277	0.0635	0.05	-1.3522	-1.1032	373.4299	<0001
GNN OL vs. QUET	EXP	1	0.2930	0.0186	0.05	0.2587	0.3318	373.4299	<0001
GNN OL vs. RISP	PARM	1	-1.6953	0.0623	0.05	-1.8174	-1.5733	741.1077	<0001
GNN OL vs. RISP	EXP	1	0.1835	0.0114	0.05	0.1624	0.2074	741.1077	<0001
GNN OL vs. HAL	PARM	1	0.0569	0.0984	0.05	-0.1360	0.2497	0.3340	0.5633
GNN OL vs. HAL	EXP	1	1.0585	0.1042	0.05	0.8728	1.2837	0.3340	0.5633
GNN QUET vs. RISP	PARM	1	-0.4676	0.0597	0.05	-0.5846	-0.3507	61.4372	<0001
GNN QUET vs. RISP	EXP	1	0.6265	0.0374	0.05	0.5574	0.7042	61.4372	<0001
GNN QUET vs. HAL	PARM	1	1.2846	0.0969	0.05	1.0946	1.4745	175.6937	<0001
GNN QUET vs. HAL	EXP	1	3.6131	0.3502	0.05	2.9881	4.3689	175.6937	<0001
GNN RISP vs. HAL	PARM	1	1.7522	0.0966	0.05	1.5628	1.9416	328.9260	<0001
GNN RISP vs. HAL	EXP	1	5.7673	0.5572	0.05	4.7724	6.9696	328.9260	<0001
OLD vs. OLDEST OLD	PARM	1	0.6064	0.0690	0.05	0.4711	0.7417	77.1701	<0001
OLD vs. OLDEST OLD	EXP	1	1.8338	0.1266	0.05	1.6017	2.0994	77.1701	<0001
OLD vs. YOUNG OLD	PARM	1	0.4622	0.0502	0.05	0.3638	0.5606	84.7628	<0001
OLD vs. YOUNG OLD	EXP	1	1.5876	0.0797	0.05	1.4388	1.7518	84.7628	<0001
OLDEST OLD vs. YOUNG OLD	PARM	1	-0.1441	0.0730	0.05	-0.2872	-0.00105	3.8979	0.0483
OLDEST OLD vs. YOUNG OLD	EXP	1	0.8658	0.0632	0.05	0.7503	0.9990	3.8979	0.0483

* young old = 65-74 y.o., old = 75-84 y.o., oldest old = > = 85 y.o.

TABLE 15: GNN*TNT_PAY_AMT LEAST SQUARES MEANS

GNN*PTNT_PAY_AMT Least Squares Means								
Generic Name - Short Version	Patient Pay Amount	Estimate	Standard Error	z Value	Pr > |z|	Mean	Standard Error of Mean	Exponentiated
OLANZAPINE	below average	-0.7329	0.06832	-10.73	<.0001	0.3246	0.01498	0.4805
OLANZAPINE	above average	-4.5494	36.5006	-0.12	0.9008	0.01046	0.3779	0.01057
QUETIAPINE FUMARATE	below average	0.8013	0.06795	11.79	<.0001	0.6902	0.01453	2.2284
QUETIAPINE FUMARATE	above average	-3.3737	36.5005	-0.09	0.9264	0.03313	1.1691	0.03426
RISPERIDONE	below average	0.9828	0.06642	14.80	<.0001	0.7277	0.01316	2.6720
RISPERIDONE	above average	-2.3160	36.5005	-0.06	0.9494	0.08981	2.9836	0.09867
HALOPERIDOL	below average	-1.0903	0.09331	-11.68	<.0001	0.2516	0.01757	0.3361

TABLE 16: DR GBENTP*PTNT_PAY_AM LEAST SQUARES MEANS

DRGBENTP*PTNT_PAY_AM Least Squares Means								
Drug Benefit Type	Patient Pay Amount	Estimate	Standard Error	z Value	Pr > |z|	Mean	Standard Error of Mean	Exponentiated
basic alternative	below average	0.2432	0.04522	5.38	<.0001	0.5605	0.01114	1.2753
basic alternative	above average	-1.2017	0.1338	-8.98	<.0001	0.2312	0.02377	0.3007
defined standard	below average	-0.4910	0.2008	-2.45	0.0145	0.3797	0.04730	0.6120
defined standard	above average	-12.2052	146.00	-0.08	0.9334	5.004E-6	0.000731	5.004E-6
enhanced alternative	below average	0.1262	0.04941	2.55	0.0107	0.5315	0.01230	1.1345
enhanced alternative	above average	-0.7592	0.1311	-5.79	<.0001	0.3188	0.02847	0.4680
actuarially equivalent	below average	0.08262	0.04690	1.76	0.0781	0.5206	0.01170	1.0861
actuarially equivalent	above average	-0.08459	0.1417	-0.60	0.5506	0.4789	0.03537	0.9189

CHAPTER 6

Discussion

Findings presented in the preceding chapter are discussed below. Additionally, this chapter includes conclusions, strengths and limitations of the study, future research, and implications for the field of social work.

Research questions 1, 2, and 3 in the preceding chapter ask: What are the characteristics of Medicare Part D beneficiaries in Washington State utilizing antipsychotic medications? What types of plans do beneficiaries choose in terms of coverage for antipsychotic medications? And what are the characteristics of beneficiaries who enter the gap-in-coverage period, or ICL benefit phase? These questions explore the descriptive side of the Medicare Part D data that is derived from records submitted by entities administering the Part D benefit (also known as "prescription drug plan sponsors"). In this study, data is extracted only for Washington State comprising Medicare Part D beneficiaries who are 65 years old and older, with diagnoses of schizophrenic and bipolar disorders, and who have had claims of any of the selected antipsychotics: olanzapine, risperidone, quetiapine, and haloperidol.

I. THE STUDY POPULATION IN WASHINGTON STATE

Washington State is geographically almost as large as South Dakota and slightly larger than North Dakota, but its total population of approximately 6.9 million people is 4.5 times larger than South and North Dakota combined (U.S. Census Bureau, 2012); however, 87.6 percent of the population of Washington live in metro areas primarily concentrated in the western and southern areas of the state, while the remaining population reside in areas considered rural and isolated. This is also reflected in the study population where 87.11 percent of beneficiaries live in urban areas. Additionally, the study population is mostly white (89.21 percent), female (71.12 percent), in the young old age category (65-74 years old, 54.61 percent), and fully dual eligible for both Medicare and Medicaid (63.25 percent).

Among the four antipsychotics in the study, prescriptions for quetiapine fumarate was filled the most by beneficiaries (29.01 percent), followed by olanzapine (27.85 percent) and risperidone (27.20 percent). Another 12.3 percent were prescriptions filled for other atypical antipsychotics that are not included in the study analyses. Olanzapine, quetiapine, and risperidone came later to the market in the 1990s compared to haloperidol, an older first-generation antipsychotic drug that was introduced in 1969 and was the lowest filled prescription in the study population (3.64 percent). Newer atypical antipsychotics have lower risks of extrapyramidal symptoms and adverse events and are more frequently prescribed to treat schizophrenia and bipolar disorders than older antipsychotics in the general population (Csernansky et al., 2002; McDonagh, Peterson, Carson, Fu, & Thakurta, 2010). This appears to be the case as well in the study population.

II. THE STUDY POPULATION AND MEDICARE PART D PLANS

Medicare Part D Benefit Types. When Medicare Part D launched in 2006 there was much confusion over the myriad of plans offered with little consumer information, outreach, and ease-of-sign up to support the launch of the program (Connolly, 2006; Kievra, 2006; Olson, 2006; Pear, 2006). Data in this study support claims at the time made by mainstream media and research organizations two years into the program that the uptake of Medicare Part D had stabilized and survived its initial launching problems and (Cubanski & Neuman, 2007) skepticism (Cubanski & Neuman, 2007; Hoadley, Hargrave, Cubanski, & Neuman, 2008; Saul, 2007; Turner, 2007). Medicare Part D plans chosen by the study population were mostly stand-alone Medicare Part D prescription drug plans (94.75 percent) – meaning plans that were offered by prescription drug plan sponsors rather than health maintenance organizations, private-fee-for-service plans, preferred provider organization plans, or national PACE plans – with the basic alternative (36.46 percent) and the enhanced alternative (32.21 percent) drug benefit varieties garnering the most beneficiaries as well as actuarially equivalent standard (28.53 percent). Given that the defined standard benefits plans were designed to offer the cheapest basic coverage, it is surprising that only a very small percentage of the study population opted for it (2.1 percent), while the majority opted for the alternatives (i.e. actuarially equivalent standard, basic alternative, and enhanced alternative). Most beneficiaries opt for basic alternative and enhanced alternative plans, which suggest that they are choosing plans that have reduced or no deductibles, copayment options (versus flat co-insurance only), modifications to the initial coverage limit, and, in the case of enhanced alternative plans, reduction in co-payments during the initial coverage phase, reduction in cost-sharing during the gap period, and more medications on the plans' formulary.

In Washington State in 2008 only less than half of the 55 stand-alone Medicare prescription drug plans offered were enhanced types (49 percent), while just over half of total plans offered (56 percent) were basic alternative or enhanced alternative plans with no deductibles (Q1Group LLC, 2011a). This means that the study population opted for lesser or no deductibles and larger drug formularies even though these types of plans usually have higher premiums, greater initial coverage limit, and greater co-payments for medications that are on varying tiers in the formularies than the defined standard benefits plan. This may be indicative of the broader issue of health reading literacy and numeracy affecting consumer choices in health care and insurance in that low numeric ability is connected with lower overall comprehension and lesser use of health information (Chan & Elbel, 2012; Hibbard, Peters, Dixon, & Tusler, 2007; Howard, Gazmararian, & Parker, 2005; Marcus, 2006; Peters, Hibbard, Slovic, & Dieckmann, 2007). Particularly relevant in the context of consumer decision-making for health insurance are considerations to risks versus benefits, and short-term versus long-term benefits; however, together with cognitive deficits related to severe mental illness and the aged (Baker, Gazmararian, Sudano, & Patterson, 2000; Brosnan, Barron, & Sahm, 2012; Wood et al., 2011), which is also the study population, it is possible that beneficiaries made less than optimal decisions when making their health plan choices.

Benefit Design Elements. Premiums as an example of an aspect of a plan's benefit design that beneficiaries must choose, were mostly low (< $36) in the study population and associated with the basic alternative and actuarially equivalent benefits plans. Most beneficiaries across the age groups chose basic alternative plans in which premiums are above the premiums of defined standard benefits and actuarially equivalent plans, but below the premiums of enhanced

alternative type plans. Beneficiaries in the study population chose above the average premium and the mode available in 2008. The premium range for all types of plans available in Washington State in 2008 was $ 0 to $450.10, a median of $28, a mode of $20.1, and an average of $28 (Centers for Medicare and Medicaid Services, 2013), while the premium range among study beneficiaries was $ 0 to $106.40, a median of $25.40, a mode of $25.20, and an average of $ 29.01. This is consistent with studies on plan choice, which show that consumers have more difficulties choosing optimally when given many choices compared to consumers with fewer choices (Abaluck & Gruber, 2009; Iyengar, Jiang, & Huberman, 2003; Iyengar & Lepper, 2000; Tanius et al., 2009). In Washington State in 2008, eligible beneficiaries had 55 stand-alone Medicare prescription drug plans to consider.

Though most beneficiaries opted for low premiums, medium level premiums ($36 - $71.99) were also chosen across the age groups at a lower rate; with the highest percentage found among the oldest old group (13.64 percent of beneficiaries 85 years old and older chose medium-level premiums) compared to percentages within the old group (11.65 percent) and the young old group (10.9 percent). In contrast, very few beneficiaries chose high premium plans (≥ $72) with only a very small percentage who chose in the old group (0.54 percent) and the young old group (1 percent), and no beneficiaries in the oldest old group opted for high premium plans. Although low premiums were chosen by the majority of beneficiaries in the study this may be indicative of an over emphasis on premiums when choosing plans versus other considerations (Abaluck & Gruber, 2009), such as other elements of a plan's benefit design (drug tiers, co-payments, co-insurance, deductibles, type of coverage during the gap, in-network pharmacies) and projected individual out-of-pocket expenses for the year. For example, the average patient pay amounts (i.e. the dollar amount paid by beneficiaries that is not reimbursable by plans or other third party payers, such as co-payments, co-insurances, and deductibles, but excludes premiums) for both beneficiaries who did not reach the gap period ($12.71) and beneficiaries who did reach the gap period ($19.78) were both lower than the average premium chosen by beneficiaries ($29.01).

Choosing elements within a benefit design that do not lead to an optimal insurance plan for a beneficiary, such as the above, is referred as "choice inconsistencies" by Abaluck and Gruber (2009). Not giving enough consideration to out-of-pocket expenses relative to premiums is also documented in other studies (Kling, Mullainathan, Shafir, Vermeulen, & Wrobel, 2012; McWilliams, Afendulis, McGuire, & Landon, 2011; Zhou & Zhang, 2012); similarly, and central to the Medicare Part D program is the out-of-pocket expenses that occur during the gap-in-coverage period, or also known as "The Doughnut Hole," that is often overlooked or under-estimated.

The Gap in Coverage Period. In launching the Medicare Part D program, much attention was given to inform eligible beneficiaries regarding the period when prescription drug coverage ceases and costs of medications are fully borne by beneficiaries. Only defined standard benefits and actuarially equivalent standard types of plans have a 100 percent gap in coverage, while other benefit types are permitted to offer different levels of coverage for certain drugs in their formularies. There are 11 levels of coverage offered during the gap period, such as: some generic medications only, some generic and brand-name medications, all preferred generics, etc., however, beneficiaries in the study population opted for only five of the available levels of coverage; specifically, coverage for: some generics, some generics and some brands, all preferred generics, all generics, and no gap coverage. Most beneficiaries in the study population

chose the basic alternative benefit type with no gap coverage (36.52 percent), the actuarially equivalent benefit type with no gap coverage (29.05 percent), and the enhanced alternative benefit type with no gap coverage (23.16 percent). In contrast, few beneficiaries (8.99 percent) opted for any kind of gap coverage offered through the alternative benefit types plan. This may also be indicative of the lack of anticipated individual out-of-pocket costs during the gap period and the inattention to gap coverage options attached to alternative plans because of their higher premiums; which underscores the argument that older beneficiaries place too much emphasis on premiums with lesser consideration to other aspects of plan benefits.

Thus, most beneficiaries in the study population enter the gap period with no coverage even though most chose enhanced-type plans (i.e. basic alternative and enhanced alternative benefit types) that actually offers various levels of coverage during the gap period, but chose no gap coverage instead. In 2008, there were 27 enhanced-type plans in Washington State, of which the lowest stand-alone Medicare prescription drug, enhanced-type plan with any kind of generic coverage had a premium of $30 (Q1Group LLC, 2011a). In contrast, the lowest premium in the study population is $ 0 with all generic coverage during the gap period; however, only 0.18 percent of beneficiaries opted for this kind of coverage, which is offered by a Health Maintenance Organization (HMO) and has the most restrictive network compared to other types of organizations offering prescription drugs (e.g. stand-alone Medicare prescription drugs, preferred provider organization, and private fee-for-service). Additionally, in order to qualify for a prescription drug plan offered by an HMO, an enrollee must meet the following criteria: be eligible for Medicare, be enrolled in both Medicare Part A and Part B, reside within a county-defined service area, and must not have end-stage renal disease. Nevertheless, the argument remains that beneficiaries chose premiums over other benefit design elements, because even the cheapest stand-alone Medicare prescription drug, enhanced-type plan with all preferred generic coverage during the gap period and a $30 premium was chosen by only 0.06 percent of the study population.

The gap-in-coverage period, therefore, poses as a major monetary pitfall in light of the fact that 91 percent of study beneficiaries opted for no gap coverage. Beneficiaries spent far more in average our-of-pocket expense during the gap period ($36.43) than averages in the pre-gap period and the catastrophic coverage period combined ($14.19). Compared to the average premium in the study population ($29.01), the average patient pay amount based on claims during the gap period only that had no gap coverage is much higher ($36.23) with a minimum patient pay amount of $ 0 and a maximum of $ 1445.48. At first glance a premium average of $29.01 versus an out-of-pocket average of $36.23 may appear optimal, but a premium is a monthly certainty, applicable even during the gap period, and locked in for the 12-month cycle before the opportunity to switch plan is open, while the gap period is variable depending on individual prescription drug costs that are filled during the gap period. For example, when comparing beneficiaries with no gap coverage versus beneficiaries with all generics coverage during the gap period, total premiums for beneficiaries with no gap coverage based on a $27.30 average monthly premium is $42,287.70; while total premiums for beneficiaries with all generics coverage based on a $42.12 average monthly premium is $65,707.20; however, total out-of-pocket costs during the gap period for beneficiaries without coverage is $200,773.41 compared to $8040.27 for beneficiaries with all generics coverage. Thus, beneficiaries in this study population are under-subscribing offers of gap coverage.

Cost-saving strategies are possible to avoid entering the gap period or minimize beneficiary costs during the gap period compared to premiums that are unchangeable for the whole calendar year. Cost-saving strategies include: switching from expensive brand-name to cheaper brand-name medication, switching from brand-name to generic medication, ordering 90-day supplies by mail order in the beginning of the year, obtaining prescription samples, partial filling of prescriptions, and splitting pills to last longer. Although some studies (Bachynsky, Wiens, & Melnychuk, 2002; Gill, Spain, & Barbara, 2012; Mosena & Van der Merwe, 2009) have raised the problems of splitting pills (e.g. questions on pill potency, adherence, and outcomes), other studies have suggested that pill splitting is frequently practiced by both clinicians and consumers in order to reduce costs (Gee, Hasson, Hahn, & Ryono, 2002; Hamer, Hartung, Haxby, Ketchum, & Pollack, 2006; Parra et al., 2005; Stafford & Radley, 2002); and pill splitting antipsychotics in a few studies do not result in poor outcomes (Freeman, White, & Iranikhah, 2012; Weissman & Dellenbaugh, 2007). Although studies do not conclusively prove that pill splitting antipsychotics is deleterious, pill splitting does not necessarily equate to non-adherence, because small variations of doses from pill splitting do not impact effectiveness due to antipsychotics clinical actions that are dependent on alterations in receptor sensitivity and neurotransmitter production occurring in the long run (Cohen & Cohen, 2000; Stahl, 1998).

Though the duration of individual gap periods are variable, the trend overall in the study population is that claims for olanzapine, quetiapine, and risperidone during the gap peaked in May-June and decreased through the rest of the year, while claims for haloperidol did not change much throughout the study period. For some beneficiaries, the gap period started as early as January (0.03 percent of total antipsychotic claims) and ended as late as December, but the increases in claims up to its peak in May (3.73 percent) were incremental. In comparison, there was an overall downward trend for antipsychotic claims in the pre-gap period – except for haloperidol – from early in the year through to the end of the year, while an upward trend – again except for haloperidol – occurred in the post-gap period from early in the year through to the end of the year.

The gap period also highlights the heterogeneity in out-of-pocket costs for the antipsychotic medications in the study discussed below.

A. MOST EXPENSIVE ANTIPSYCHOTIC MEDICATION IN THE GAP PERIOD

Antipsychotic medication fillings during the gap period decreased from the number of prescription fillings in the pre-gap period and also decreased slightly in percentage for proportion of month covered (PMC, i.e. fills with at least 24 days' supply) except for quetiapine and haloperidol. These two medications also decreased in number of prescription fillings during the gap period, but increased in PMC percentage, specifically from 88.33 percent to 91.09 percent for quetiapine and from 69.2 percent to 70.1 percent for haloperidol. Overall, the percentage of beneficiaries with prescription fills for at least 24 days' supply for atypical antipsychotics: olanzapine (90.1 percent), quetiapine (91.09 percent), and risperidone (86.78 percent) remained high during the gap period compared to the typical antipsychotic haloperidol (70.1 percent).

Quetiapine as the most filled prescription during the gap period is also the most expensive. Beneficiaries with some generic and some brand coverage during the gap period paid most in out-of-pocket cost for quetiapine (average $398.93) compared to beneficiaries paying average out-of-pocket for quetiapine with all preferred generics coverage (average $190.93), and

even more so compared to beneficiaries paying out-of-pocket for quetiapine with all generics coverage (average $21.28) and no gap coverage (average $34.38). Closer examination of the data indicate that the most expensive out-of-pocket average for quetiapine during the gap period, which had coverage for some generic and some brand-name medications, was offered by private-fee-for-service plan sponsors with premiums of $35.30, one claim for 60 days' supply and three claims for 30 days' supply.

In contrast, the cheapest claim for quetiapine during the gap period with all generics coverage were mostly offered by stand-alone Medicare prescription drug plans with an average days' supply of 22 days for 115 claims, in which 13 of these claims came from preferred provider organization plan sponsors for 30 days' supply fills that had high out-of-pocket costs (average $100.31) and one claim from a health maintenance organization for 90 days' supply and had an even higher out-of-pocket ($776.76). During the gap period the average out-of-pocket for quetiapine with no gap coverage ($34.38) is higher than the average out-of-pocket for quetiapine with all generics coverage ($21.28) with a greater total number of claims for quetiapine that had no gap coverage. Quetiapine claims with no gap coverage came mostly from stand-alone Medicare prescription drug plans during the gap period, totaling 1824 claims, an average days' supply of 22 days, but had more claims with high average out-of-pocket costs compared to quetiapine claims with all generics coverage; specifically, 12 claims for 90 days' supply (average $269.17), two claims for 23 days' supply (average $247.82), and one claim for 40 days' supply (average $401.25). Thus, even though all generics coverage through stand-alone Medicare prescription drug plans were available and did provide cheaper out-of-pocket cost for quetiapine during the gap period compared to no gap coverage, only 7 percent of the study population opted for it.

B. MOST EXPENSIVE MEDICATION IN THE PRE-GAP PERIOD

While quetiapine had the highest out-of-pocket average during the gap period for beneficiaries with no gap coverage, its out-of-pocket average with any level of coverage and including no gap coverage was below olanzapine in the period before the gap. The out-of-pocket average for olanzapine during the pre-gap period was the most expensive of all the antipsychotics ($51.78), which had all preferred generics coverage for the gap period for this particular out-of-pocket. Although type of gap coverage does not apply outside the gap period, plans that offer any kind of coverage during the gap have higher premiums than standard benefit plans. In this case, the most expensive out-of-pocket cost in the pre-gap period for olanzapine was for 15 claims of 30 days' supply, offered by stand-alone Medicare prescription drug plans with premiums of $47.20. The cheapest olanzapine in the pre-gap period had an average out-of-pocket of $4.01 that had all generics coverage during the gap period, offered mostly by stand-alone Medicare prescription drug plans but also a few preferred provider organizations (PPO), and health maintenance organizations (HMO). An out-of-pocket average of $4.01 for olanzapine in the pre-gap period had premiums of $41.70 with generics coverage during the gap period. In contrast, beneficiaries with plans that had no coverage during the gap period paid an average out-of-pocket of $13.92 for olanzapine in the pre-gap period with greater options in premiums.

In comparing the most expensive out-of-pocket average in the pre-gap period ($51.78) with the most expensive out-of-pocket average in the gap period ($398.93), both were associated with enhanced alternative plans, while most beneficiaries chose no gap coverage during the gap period, increases in out-of-pocket costs in both pre-gap and gap period were much lower

compared to beneficiaries who chose some level of coverage for the gap period. Specifically, out-of-pocket averages in the pre-gap period attached to plans with no gap coverage for the gap period were: $13.92 (olanzapine), $10.69 (quetiapine), $8.71 (risperidone), and $1.47 (haloperidol) that increased in the gap period to: $57.64 (olanzapine), $34.38 (quetiapine), $22.67 (risperidone). Contrastingly, beneficiaries with all preferred generics coverage in the gap period, for example, had out-of-pocket averages in the pre-gap period of: $51.78 (olanzapine), $24.72 (quetiapine), and $18.15 (risperidone), which increased in the gap period to: $312.93 (olanzapine), $190.93 (quetiapine), and $149.68 (risperidone). Claims for haloperidol in both pre-gap and gap periods were made only by beneficiaries with no gap coverage and all generics coverage for the gap period with out-of-pocket averages remaining very low: $0.63 (pre-gap, all generics coverage) and $1.47 (pre-gap, no gap coverage), which increased only slightly to $0.83 (gap period, all generics coverage) and $1.63 (gap period, no gap coverage). Although pre-gap haloperidol claims were made by beneficiaries with all preferred generics coverage, no claims for haloperidol in the gap period were made by beneficiaries with this type of gap coverage.

III. SUMMARY

Summarizing answers to research questions 1, 2, and 3 that pose the questions: What are the characteristics of Medicare Part D beneficiaries in Washington State utilizing antipsychotic medications? What types of plans do beneficiaries choose in terms of coverage for antipsychotic medications? And what are the characteristics of beneficiaries who enter the gap-in-coverage period, or ICL benefit phase? Data show that Medicare Part D beneficiaries with schizophrenia and bipolar disorders in Washington State who are utilizing antipsychotics are mostly white, female, in the 65-74 years old age category, reside in urban areas, and over half are fully dual eligible for both Medicare and Medicaid. These beneficiaries predominantly choose stand-alone Medicare prescription drug plans with drug benefit types that are basic alternatives, enhanced alternatives, and actuarially equivalent. Only a minority of the study population choose the drug benefit type that is defined standard (2.1 percent); however, although more than a quarter (34.19 percent) of the study population chose enhanced alternatives drug benefits that offers various levels of coverage during the gap period, almost three quarters (72.05 percent) of these beneficiaries opted for no coverage during the gap period. These figures suggest the research hypothesis is true that most Medicare Part D beneficiaries in Washington State with schizophrenic and bipolar disorders do not choose the cheapest prescription drug plan available, particularly given that very few beneficiaries chose the defined standard benefit type plan and even fewer opted for the cheapest premium in this type of benefit design (only 1.34 percent chose defined standard benefit plans with premiums of $19.20). Additionally, compared to the state average premium ($28) in 2008, the study population chose premiums above the state average ($29.01).

The research hypothesis that most Medicare Part D beneficiaries with schizophrenic and bipolar disorders in Washington State choose plans that offer some level of coverage during “the doughnut hole” is not confirmed in this study, as most beneficiaries opted for no gap coverage through basic alternative type plans (36.52 percent), actuarially equivalent type plans (29.05), enhanced alternative type plans (23.16 percent), and defined standard plans (2.10 percent). The remaining beneficiaries chose plans with other types of benefit design outside of the Medicare Part D options.

Out-of-pocket expenses is also considered alongside premiums when assessing optimal choices made by beneficiaries, especially in the context of the gap period, when coverage ceases, and in light of the fact that the majority of the study population opted for no gap coverage. Almost three quarters of the study population (74.21 percent) entered the gap period, in which their claims were over three times higher in average out-of-pocket ($36.52) than the average out-of-pocket during the pre-gap period ($10.17). Beneficiaries' out-of-pocket total during the gap period ($252,510.97) surpassed the other benefit phases combined ($137,831.22).These figures suggest the hypothesis is true that Medicare Part D beneficiaries with schizophrenic and bipolar disorders in Washington State who reach the donut hole have higher overall out-of-pocket expenditure than those who reached the pre-gap phase during the study period.

Why beneficiaries failed to choose the cheapest prescription drug plan available or not opt for coverage during the gap period is outside the objective of this study, but other studies have shown that it is not uncommon for beneficiaries to choose higher cost Medicare Part D plan (Heiss, Leive, McFadden, & Winter, 2012; Wood et al., 2011; Zhou & Zhang, 2012). In this particular study population in which beneficiaries have diagnoses of schizophrenia and bipolar disorder, cognitive deficits may also affect assessment, choice of plan, and medication adherence.

Research questions 4 and 5 ask: Do plan choice and antipsychotic coverage impact antipsychotic medication adherence; and in what ways do beneficiaries' plan choices and antipsychotic coverage affect medication adherence in the gap period? Do beneficiaries' out-of-pocket expenditure affect medication adherence in the gap period?

IV. The Study Population and Their Medication Adherence in the Gap Period

An overwhelming majority of beneficiaries in the study were non-adherent (90.4 percent, i.e. measured in Proportion of Days Covered (PDC) with values less than 0.80) during the gap period. These beneficiaries in the gap period comprised over three quarters (78.35 percent) of beneficiaries who were in the pre-gap period, of which more than half (67.43 percent) transitioned out of the gap period into catastrophic coverage.

Regardless of benefit phase, beneficiaries with the highest adherence are among the young old age group (26.73 percent), who filled prescriptions for risperidone (27.26 percent), who chose the basic alternative type of drug benefit (21.49 percent), opted for no coverage during the gap period (52.97 percent), and paid below average in out-of-pocket costs (52.85 percent).

Predicted odds for medication adherence for beneficiaries who are old (i.e. 75-84 years old) is only 0.643 times the predicted odds for beneficiaries who are young old (i.e. 65-74 years old); while the predicted odds for adherence among the oldest old (i.e. $\leq$ 85 years old) is lower at 0.556 times the predicted odds for beneficiaries who are young old.

As with the most number of prescriptions filled, beneficiaries filling risperidone also had the highest predicted odds for medication adherence, specifically, 7.348 times the predicted odds than for haloperidol; while those filling prescriptions for quetiapine and olanzapine had lower predicted odds: 4.721 times the predicted odds than haloperidol for the former and 1.2 times the predicted odds for the latter.

Compared to the odds for enhanced alternative plans, the predicted odds for actuarially equivalent plans and basic alternative plans are 1.202 and 1.107 times greater, respectively; while the predicted odds of medication adherence for defined standard benefit plans is just 0.618 times the odds for enhanced alternative plans.

The predicted odds of medication adherence for type of gap coverage that covers some generic drugs is 1.677 times the odds for no gap coverage and the odds for coverage of all generics during the gap is 1.216 times the odds for no gap coverage. In contrast, the predicted odds of medication adherence for coverage during the gap of all preferred generics is 0.409 times the odds for no gap coverage, and 0.479 times the odds for coverage of some generics and some brand-name drugs during the gap.

Beneficiaries who were non-adherent paid a greater average in out-of-pocket costs in the gap and catastrophic coverage periods compared to beneficiaries who were adherent; with total number of claims increasing and average out-of-pocket-costs decreasing due to the small five percent out-of-pocket co-insurance in the catastrophic coverage period. In contrast, among both adherent and non-adherent beneficiaries total number of claims decreased from the pre-gap period to the gap period while average out-of-pocket costs increased over twice as much for all of the atypical antipsychotics except for risperidone. Unlike other beneficiaries filling prescriptions for olanzapine and quetiapine whose total number of claims dropped, beneficiaries filling prescriptions for risperidone who were also non-adherent had more than a four-fold increase in total number of claims and a near three-fold increase in average out-of-pocket cost from the pre-gap period to the gap period. In contrast, total number of claims dropped by almost 78 percent for beneficiaries filling prescriptions for risperidone who were adherent, but average out-of-pocket cost increased 3.64 percent from the pre-gap period to the gap period.

Overall trend of adherence across antipsychotics and benefit phases show that adherence percentage in the pre-gap period was low (27.43 percent), dropped even lower in the gap period (9.6 percent), and dramatically increased in the catastrophic coverage period (65.63 percent). This suggests that the research hypothesis is true that Medicare Part D beneficiaries with schizophrenic and bipolar disorders who reach the donut hole have lower overall medication utilization than those who do not reach the donut hole during the study period. Medication utilization, in this context, is not only in terms of total number of claims, but also rates of adherence.

V. ADHERENCE AND TYPE OF GAP COVERAGE IN THE GAP PERIOD

The vast majority (90.95 percent) of beneficiaries who entered the gap period did not have any type of coverage for this phase. Most of these beneficiaries with no gap coverage were also non-adherent (91.15 percent). Although alternative and enhanced types of drug benefits offered varying levels of gap coverage, less than a tenth of beneficiaries (9.05 percent) in the gap period chose any kind of coverage. Additionally, even though the basic plans that are defined standard drug benefit type of plans offered no coverage during the gap, only a small minority (1.47 percent) of beneficiaries in the gap period opted for such type of plan. Most beneficiaries with no gap coverage chose basic alternative (36.67), actuarially equivalent (31.10 percent), and enhanced alternative plans (21.72 percent). The type of plan sponsors (i.e. Health Maintenance Organization, Preferred Provider Organizations, Private Fee for Service Organizations, stand-alone Medicare prescription drug plans, etc.) do not appear to drive beneficiary choice as all of these types of plan sponsors offer various types of drug benefits (i.e. defined standard, actuarially

equivalent, basic alternative, and enhanced alternative plans) and various levels of gap coverage. Though most prescriptions were filled through stand-alone Medicare prescriptions drug plans (96.24 percent) – which is the new type of plan created for the Medicare Part D program – most beneficiaries in the gap period (90.95 percent) did not take advantage of the numerous types of gap coverage offered.

Beneficiaries filling prescriptions for risperidone had the most coverage during the gap period (11.9 percent) with most opting for all generics coverage through enhanced alternative plans (9.74 percent) and a small percentage through enhanced alternative plans with all preferred generics coverage (2.17 percent); their corresponding adherence, however, remained lower (2.38 percent) than non-adherence (9.53 percent). Beneficiaries filling prescriptions for quetiapine also had coverage during the gap period (8.62 percent), although at a lower rate than beneficiaries on risperidone and an even lower rate for adherence (0.88 percent) through enhanced alternative plans with all generics coverage. In contrast, beneficiaries filling prescriptions for olanzapine and haloperidol did not have any adherence with gap coverage. Adherence in the gap period, therefore, comprised just over a fraction of beneficiaries having gap coverage (1.04 percent), while adherence with no gap coverage was over eight times higher (8.56 percent). Non-adherence across gap coverage types during the gap period was prevalent (90.4 percent) with the majority of these non-adherent beneficiaries having plans that had no coverage during the gap period (82.39 percent).

VI. Adherence, Type of Gap Coverage, and Out-of-Pocket Expenses in the Gap Period

Across all antipsychotics mean out-of-pocket expenses were highest ($398.93) for beneficiaries filling prescriptions for quetiapine with some generic and some brand-name medications coverage during the gap period; however these beneficiaries were non-adherent and made up a small fraction (0.07 percent) of total beneficiary claims in the gap period. The lowest mean out-of-pocket ($0) were also for beneficiaries filling prescriptions for quetiapine and, similarly, made up a very small fraction (0.04 percent) of total beneficiary claims, whose beneficiaries had some generics gap coverage through a Health Maintenance Organization (HMO) plan type, but were non-adherent as well. Beneficiaries filling prescriptions for haloperidol also had low mean out-of-pocket expenses and non-adherence during the gap period, but some had all generics coverage (0.25 percent of total claims with $0.83 mean out-of-pocket expenses), while most had no gap coverage (3.03 percent of total claims with $1.43 mean out-of-pocket expenses) through stand-alone Medicare prescription drug plans.

Most beneficiaries who were adherent were beneficiaries filling prescriptions for quetiapine (7.88 percent of total claims) who did not opt for coverage during the gap period and whose mean out-of-pocket expenses was $32.19. These beneficiaries opted for no gap coverage through HMOs and stand –alone Medicare prescription drug plans. Adherence for risperidone (7.71 percent) was just below adherence for quetiapine and well above adherence for olanzapine (0.32 percent), but with mean out-of-pocket ($13.94) that was less costly than quetiapine ($32.19) and olanzapine ($52.89). These beneficiaries also did not have coverage during the gap mostly through stand-alone Medicare prescription drug plan and a minority through HMOs. Adherence for haloperidol comprised of beneficiary fills that had no gap coverage all through stand-alone Medicare prescription drug plans, that had a very low mean out-of-pocket ($0.74), but a low percentage of adherence as well (0.38 percent).

Adherence among beneficiaries with coverage during the gap period was highest for beneficiaries filling prescriptions for risperidone (1.28 percent of total claims) who had all generics coverage mostly through stand-alone Medicare prescription drug plans, and mean out-of-pocket expenses ($6.97) far lower than adherent beneficiaries with no gap coverage; however, adherent beneficiaries filling prescriptions for quetiapine who had all generics coverage (0.38 percent of total claims) primarily through Preferred Provider Organizations (PPOs) and stand-alone Medicare prescription drug plans, had mean out-of-pocket expenses far higher ($100.8) than other adherent beneficiaries.

Thus, adherence across antipsychotics that had any kind of gap coverage comprised only a small percentage (1.77 percent) of total claims filled by beneficiaries in the gap period with both high ($100.8 and $85.63) and low ($6.97) mean out-of-pocket expenses, and provided mostly through stand-alone Medicare prescription drug plans, a few PPOs, and a small number of HMOs. In comparison, adherence with no gap coverage had a higher percentage (16.29 percent) with a range of mean out-of-pocket expenses that were not as high ($52.89, $32.19, and $13.94) as adherent beneficiaries with gap coverage and also lower mean out-of-pocket expenses ($0.74) than the lowest mean out-of-pocket expenses for adherent beneficiaries with gap coverage ($6.97). Adherence with no gap coverage was predominantly through stand-alone Medicare prescription drug plans and a small number of HMOs.

Non-adherence was found most among beneficiaries filling prescriptions for olanzapine who had no gap coverage mostly through stand-alone Medicare prescription drug plans and a number of HMOs (27.64 percent of total claims) and a mean out-of-pocket ($57.11) that was almost two times the mean out-of-pocket for adherent beneficiaries filling prescriptions for quetiapine with no gap coverage ($32.19) and four times the mean out-of-pocket for adherent beneficiaries filling prescriptions for risperidone with no gap coverage ($13.94); however, compared to adherent beneficiaries also filling prescriptions for olanzapine with no gap coverage through stand-alone Medicare prescription drug plans, the mean out-of-pocket ($52.89) was just over one percent higher.

Non-adherence was prevalent across antipsychotics with the majority having no gap coverage (74.58 percent of total claims) through stand-alone Medicare prescription drug plans, and a much smaller percentage having gap coverage (7.38 percent) through various plan types, but the mean out-of-pocket expenses were greater in range for beneficiaries with gap coverage ($398.93, $312.93, $190.93, $178.88, $34.3,$4.73, $3.88, $0.83,and $0) than beneficiaries with no gap coverage ($57,11, $38.61, $27.18, and $1.43).

When considering adherence together with the number or percentages of claims, mean out-of-pocket expenses, type of gap coverage, type of drug benefit, and type of plan, this study finds only partial support of the research hypothesis that Medicare Part D beneficiaries with schizophrenic and bipolar disorders with higher out-of-pocket expenses in the gap period have lower levels of medication utilization and adherence than those with lower out-of-pocket expenses in the gap period. Specifically, based on mean out-of-pocket expenses, type of gap coverage, and adherence during the gap period, beneficiaries in the study with higher mean out-of-pocket expenses and some form of coverage during the gap have higher medication utilization – in the form of total prescriptions filled (i.e. claims) – than beneficiaries who have lower mean out-of-pocket expenses even though they also have some kind of coverage; however, in terms of adherence, these beneficiaries with higher mean out-of-pocket expenses and some form of

coverage during the gap have greater non-adherence than beneficiaries who also have some type of gap coverage.

Mean out-of-pocket expenses for beneficiaries with no coverage during the gap period were similar in range between those who were adherent and those who were non-adherent; however, prescriptions filled for non-adherent beneficiaries with no gap coverage were four and a half times than that of adherent beneficiaries who also did not have coverage during the gap.

In a logistic regression model in which adherence is a dichotomous outcome variable (adherent vs. non-adherent) with 6 selected predictors (medication, date of fill/refill, out-of-pocket expense, type of drug benefit, low income cost sharing subsidy amount, and age) all variables were statistically significant and show strong evidence that they impact the probability of medication adherence. Quetiapine, and risperidone – had predicted odds for medication adherence that were much higher than the typical antipsychotic, haloperidol. The highest among them was risperidone in comparison to haloperidol (OR = 5.77, 95% CI = 4.78, 6.97), followed by quetiapine compared to haloperidol (OR = 1.29, 95% CI = 1.09, 1.48). Although olanzapine was found to have 1.06 times the predicted odds for adherence than haloperidol, it was not statistically significant. Analyses of adherence during the gap phase of the study period also show that beneficiaries on haloperidol had the lowest rate of adherence (0.38 percent of total claims) compared to beneficiaries on other antipsychotics, while risperidone had the highest rate of adherence (9.10 percent).

In terms of mean out-of-pocket expenses and medication adherence during the gap period, high mean out-of-pocket expenses were most found among non-adherent beneficiaries. Logistic regression with adherence as a dichotomous outcome variable (adherent vs. non-adherent) and interaction terms also found that the interaction of out-of-pocket expenses with medications was statistically significant (Wald Chi-Square: 49.86, DF: 3, $p < 0.0001$) as was the interaction of out-of-pocket expenses with type of drug benefit (Wald Chi-Square: 67.60, DF: 3, $p < 0.0001$). This further highlights the importance and impact of specific medications and specific drug benefit type (i.e. defined standard, actuarially equivalent, basic alternative, and enhanced alternative) on medication adherence. Comparing mean out-of-pocket costs during the gap period with the pre-gap period and the catastrophic coverage period, the highest mean out-of-pocket cost in the gap period ($56.75 for olanzapine among non-adherent beneficiaries) was over three times the highest mean out-of-pocket cost in the pre-gap period ($18.12 for olanzapine among non-adherent beneficiaries) and over 2.7 times the highest mean out-of-pocket cost in the catastrophic coverage period ($20.75 for quetiapine among non-adherent beneficiaries).

Adherence, therefore, is multi-faceted, especially when examined through the lens of various design elements of Medicare Part D (i.e. types of plans, types of benefit designs, level of gap coverage, out-of-pocket costs). Studies examining antipsychotic coverage in Medicare Part D and the effects of various benefit design elements are still scarce; however, one study (S. L. Ettner et al., 2010) examining gap entry and exit among Medicare Advantage prescription drug plan beneficiaries with dementia in 2006 in eight states found that the atypical antipsychotics quetiapine, risperidone, and olanzapine were among the 12 medications that accounted for over half (50.48 percent) of the study populations' (N= 4,091) pre-gap drug expenditure. Specifically, risperidone was fourth highest behind three dementia medications in pre-gap costs that amounted to $267,247 (or 2.75 percent of total pre-gap expenditures), followed by quetiapine totaling $237,272 (or 2.44 percent). In comparison, olanzapine pre-gap total cost was slightly less at $217,209 (or 2.24 percent). Beneficiaries taking these antipsychotics comprised 23.12 percent of

the study population suggesting that antipsychotics are part of the medication regimen for beneficiaries with dementia, as other studies have also shown (Guthrie, Clark, & McCowan, 2010; Kamble, Chen, Sherer, & Aparasu, 2009; Rosenberg et al., 2012).

Another study (Kim et al., 2010) examining the impact of copayments on antipsychotic adherence among individuals with schizophrenia found that copayment burden affect adherence. Specifically, copayment burden had an inverse correlation with complete adherence and a positive relationship with lower rates of adherence. Individuals with copayment burdens were less than half as likely to report complete adherence (OR = 0.43, p = 0.001) and likelihood of forgetting to take medication (OR = 2.06, p = 0.003) than those without copayment burden.

Overall, poor adherence has become a public health concern such that it has become a crisis, according to the National Council on Patient Information and Education (National Council on Patient Information and Education, 2007); where medication non-adherence is estimated to be around 43 percent in the general population and 55 percent among the elderly, and as much as 74 percent among individuals with schizophrenia taking antipsychotics (Gladman, 1997; Lieberman et al., 2005).

The broader literature on adherence covers wide ranging issues that affect medication adherence, such as medication access, medication management, health literacy, provider-patient relationship, cultural barriers, financial hardship, and cognitive deficits, for example. In the context of this study non-adherence among Medicare Part D beneficiaries is inextricably linked to the type of prescription drug plan and the level of coverage a beneficiary chooses.

Findings of this study suggest that offerings of Medicare Part D plans vary greatly and studies on health plan choice find that older consumers encounter difficulties in making optimal choices (Abaluck & Gruber, 2009; Barnes et al., 2012; Bundorf & Szrek, 2010), which may affect medication adherence. Additionally, given that the study population comprise of beneficiaries with diagnosed schizophrenia and bipolar disorder, adherence to medication may be even more negatively affected due to cognitive impairment among individuals with mental disorders. Studies in the new field of neuroeconomics may hold promising avenues to better understand decision-making processes, particularly in populations with mental disorders, as the field brings together the approaches of psychology, neuroscience, and behavioral economics into a unified framework. Though neuroeconomics studies have not been done specifically on Medicare Part D and populations with mental disorders, some hypotheses may lead the way for future research. For example, studies in behavioral economics suggest that individuals with bipolar disorders make more risky choices for more gains rather than fewer risky choices to avoid losses (Chandler, Wakeley, Goodwin, & Rogers, 2009; Najt et al., 2007). Such behavior is indicative of the reduced diminishing sensitivity that result in steeper loss and gain functions in bipolar individuals, in which the neuroeconomics approach additionally highlight the regions of the brain that govern such dysfunction and the impact on decision-making. Similarly, studies on decision-making among individuals with schizophrenia show that there are deficits in the ability to weigh effort for reward due to apathy, which is a negative symptom occurring in schizophrenia, and caused by dysfunctions in the brain's dopamine systems (Hartmann et al., 2014; Tom, Fox, Trepel, & Poldrack, 2007; Trémeau et al., 2008). Thus, such studies may eventually lead to more research encompassing brain mechanism, behavior, and performance outcomes that may better explain a wider array of health behavior and outcomes, such as choices and decision-making in health plans and health care, and medication adherence, all of which

involve varying levels of choice, decision-making, and reward (i.e. better coverage and better health).

VII. SUMMARY

In summary and as answer to research question 6: How well do beneficiaries choose their Medicare Part D plans in terms their antipsychotic medication needs? This study finds that very few beneficiaries (2.1 percent) chose plans that were defined standard plans, which, typically, provide basic prescription drug coverage and cheaper premiums compared to other types of drug benefit types. By law (i.e. The Medicare Modernization Act, 2003) antipsychotic medications are among the classes of medication required to be covered by plan sponsors, including the standard plans, yet most beneficiaries chose the more expensive plans instead (basic alternative plans: 36.52 percent, enhanced alternative: 34.19 percent, and actuarially equivalent standard: 23.16 percent). Beneficiaries who could forecast entering the gap period would be inclined to select plans that provide some coverage; however, although the more expensive enhanced alternative plans offered various levels of coverage during the gap period, very few beneficiaries (9.13 percent) chose any form of coverage during the gap period. Beneficiary claims made during the gap period predominantly had no gap coverage. These types of drug benefits along with out-of-pocket expenses impact medication adherence among beneficiaries, particularly in the gap period when coverage ceases. A considerable drop in medication adherence during the gap period further underlines the consequences of high out-of-pocket costs that vary across types of drug benefits. Even among the small number of beneficiaries (1.36 percent of study population) who experience all three benefit phases (i.e. before gap-in-coverage/pre-ICL, gap-in-coverage/ICL, and catastrophic coverage/post-ICL) during the study period, adherence was noticeably lowest during the gap period (4.26 percent) compared to adherence during other benefit phases.

The small number of beneficiaries in the study who experienced all three benefit phases (i.e. pre-gap/pre-ICL, gap/ICL, and catastrophic coverage/post-ICL) is likely due to the following reasons: (a) beneficiaries reaching catastrophic coverage do not necessarily go through the gap-in-coverage phase (i.e. ICL period), because the particular benefit phase in which beneficiaries fall into at any given time when a prescription is filled is dependent on their individual true-out-of-pocket expenses (TrOOP) and whether a benefit phase threshold has been reached. Thus, it is possible for a beneficiary to reach catastrophic coverage directly from a preceding benefit phase by meeting the minimum threshold for catastrophic coverage (i.e. after $3,216.25 in TrOOP or after $5,726.25 in total drug costs in 2008). So beneficiaries with extremely high medication costs may find themselves transitioning into catastrophic coverage phase immediately from the deductible period or the pre-gap period (i.e. pre-ICL) and bypass the gap-in-coverage period altogether. It is also important to note that the study population is comprised of beneficiaries with antipsychotic claims defined in the research objective and do not include their claims for other medications that may have been filled during the study period; however, the study data file received from the Centers for Medicare and Medicaid Services (CMS) reflect accumulated TrOOP for individual beneficiaries and all of their medications under Medicare Part D as recorded at the time a prescription is filled that contribute to the determination of a beneficiary's benefit phase; (b) in addition to the three benefit phases (i.e. pre-gap/pre-ICL, gap/ICL, and catastrophic coverage/post-ICL) CMS also assign straddle phases when a beneficiary fills a prescription and his/her TrOOP does not exactly fall into any of the three benefit phases due to the beneficiary's accumulated dollar amount exceeding one benefit

phase, but not quite meeting the minimum of another benefit phase. A switch in Medicare Part D plan in the middle of a calendar year may also cause a beneficiary to fall into a straddle phase due to the differences in benefit structure of a new health plan in terms of deductibles, co-payment, co-insurance, and out-of-pocket payments even though a beneficiary's medication regimen do not change.

Thus, because of sub-optimal coverage and variability of out-of-pocket costs of antipsychotics during the gap period for most beneficiaries in the study population, it would be reasonable to suggest that beneficiaries in the study population are less than satisfied with their plan choice; however, a telephone survey of beneficiaries' (N=1007) opinions regarding the Medicare Part D program in 2008 found that 90 percent were satisfied with their prescription drug coverage (KRC Research, 2008). Even among beneficiaries taking six or more prescription medications the satisfaction rate remained high (91 percent) and among beneficiaries taking one to five prescription medications the satisfaction rate was higher (93 percent). The satisfaction rate is higher among beneficiaries spending less than $50 per month (97 percent) compared to beneficiaries spending $50 or more per month (86 percent). Furthermore, over half of the beneficiaries (54 percent) in the survey strongly agreed that their total out-of-pocket costs are reasonable and also strongly agreed (61 percent) that their plan covers all their prescribed medications. The same telephone survey conducted last year (KRC Research, 2013) showed levels of satisfactions among beneficiaries remained high (90 percent overall satisfaction), although at slightly lower rates for beneficiaries taking one to five prescriptions (91 percent) and beneficiaries taking six or more prescriptions (89 percent).

Such survey results do not support this study's suggestion that suboptimal Medicare Part D plans were chosen and that beneficiaries would necessarily be less than satisfied; however, this may be due to the limited and general nature of the survey questions that do not ask questions regarding satisfaction of costs and gap coverage of antipsychotics in particular or other protected drugs in Medicare Part D. Contrary to the cited KRC survey results, a number of studies found that high out-of-pocket and co-sharing costs affected adherence among beneficiaries using antipsychotics (Bakk, Woodward, & Dunkle, 2014; Kim et al., 2010; Zeber et al., 2007) and that beneficiary preferences and satisfaction with plan choice were related to low premiums and out-of-pocket costs (Han, Ko, & Urmie, 2013; Hargrave, Piya, Hoadley, Summer, & Thompson, 2008).

Alternatively, beneficiary satisfaction might not necessarily equate to the most cost-effective plan selection as behavioral economists suggest that consumers routinely discount the future for the present, which is a process that is also known as "hyperbolic discounting" (Hough, 2013). Thus, in the context of selecting plans, discounting or failure to anticipate future expenses (e.g. out-of-pocket costs in the gap period) for present or near-term preferences (e.g. low premiums) may result in sub-optimal plan selection, which is further amplified if non-adherence occurs as a result of co-sharing costs or out-of-pocket expenses that are outside beneficiaries' financial reach.

Thus, recapitulating the question: How well do beneficiaries choose their Medicare Part D plans in terms their antipsychotic medication needs? This study can only highlight findings based on data that is administrative/claims in nature, which cannot directly address issues such as beneficiary satisfaction of their plan choice or the processes beneficiaries go through in deciding which plan they choose; however, this study underscores the complexity of many elements within the design of Medicare Part D plans that must be considered by beneficiaries when

enrolling in a prescription drug plan that impacts their medication utilization and adherence. Studies on plan selection suggest that too many plans to choose from make decision-making harder for older beneficiaries (Barnes et al., 2012; Hanoch et al., 2009; Heiss, Leive, McFadden, & Winter, 2013; Iyengar et al., 2003); similarly too many benefit design elements to consider in the decision-making process would also make plan selection difficult, even for individuals with high numeracy skills (Szrek & Bundorf, 2014; Wood et al., 2011).

Certainly beneficiary satisfaction is not the sole measure of optimal plan choice, as studies in behavioral economics suggest that choice inconsistencies – and, therefore, sub-optimal plan selection – are common, especially among the elderly; such as beneficiaries putting more weight on: financial characteristics of a plan (e.g. premiums) rather than anticipated cost-sharing costs and out-of-pocket expenses (Abaluck & Gruber, 2009) or focusing more on attributes of one particular plan rather than across plans as well as failure to identify the lowest-cost plan (Hanoch et al., 2011).

VIII. CONCLUSIONS

Findings in this study suggest that lack of coverage during the gap affects medication utilization among Medicare Part D beneficiaries with schizophrenic and bipolar disorders in Washington State. Coverage for antipsychotics during the gap period was very low due to beneficiaries opting out of any kind of gap coverage. This does not necessarily mean that by having no gap coverage beneficiaries obtained the cheapest or most cost-effective plans, because the average premium chosen by beneficiaries proved to be above the state average in 2008. Consequently, medication utilization and adherence are affected by the absence of coverage during the gap, because out-of-pocket expenses increased considerably. However, out-of-pocket expenses are not the sole driver of medication non-adherence, rather the combination of out-of-pocket expenses, type of drug benefit, and type of gap coverage contribute as well. The prevalence of non-adherence among beneficiaries suggest that plan choices were not made optimally as evident also by the high mean out-of-pocket expenses of beneficiaries with some kind of gap coverage and lower mean out-of-pocket, but with no gap coverage through more expensive types of drug benefit other than the defined standard type of plan.

IX. STRENGTHS AND LIMITATIONS OF THE STUDY

This study provides an examination of the effects of coverage on antipsychotics for a very specific subset of the Medicare Part D population in Washington State. To the author's knowledge, it is the first study on Medicare Part D in the state that uses administrative claims data from the Prescription Drug Event file from the Centers for Medicare and Medicaid Services (CMS), and it is the first study in the state that captures the Medicare Part D sub-population with schizophrenia and bipolar disorders filling for select antipsychotics through the program. Using CMS claims data enabled the study on a detailed sub-population with their demographic characteristics that has same diagnoses, same medication regimen, and same sets of Part D plan characteristics, which would have been extremely difficult to obtain through other data sources. Though other studies have used organization specific claims data (e.g. Walgreens, CVS, Kaiser Permanente), these data do not include beneficiaries outside their membership. Findings in this study provide a nuanced assessment of beneficiaries' plan choices and the effects of their choice of various elements of plan design (i.e. plan type, drug benefit type, gap coverage type, drug tier, etc.) on antipsychotic utilization and adherence that focus on the older population with

schizophrenia and bipolar disorders. This study support findings by others that beneficiaries do not pay as much attention to design elements that might reduce their overall cost-sharing and out-of-pocket expenses (e.g. type of gap coverage, drug tier placement) compared to other plan features (e.g. premiums) that do not affect beneficiary total out-of-pocket costs as much (Abaluck & Gruber, 2009; Heiss et al., 2012; Heiss, McFadden, & Winter, 2010); and it also furthers existing studies on Medicare Part D and antipsychotic utilization by explicating the elements of Medicare Part D benefit designs (that includes choice in level of prescription drug coverage) and their effects on adherence and utilization. Where Heiss, Leive, McFadden and Winter's (2012) used a combination of claims data and simulated data to construct benefit designs of Medicare Part D plans, this study used actual Medicare Part D plan characteristics file (from the Centers for Medicare and Medicaid Services) that is linked to Medicare Part D beneficiaries Prescription Drug Event file. Additionally, Heiss and associates simulated data to calculate out-of-pocket expenses and linked to their simulated benefit designs, while this study assessed actual out-of-pocket costs derived from different types of plan benefit designs.

Due to the particular study population (older with severe mental illness) and the differences of plan offerings by county, this study is not generalizable. Additionally, there are limitations in using CMS claims data in this type of study; for example, the cost of data is not cheap and data does not include beneficiaries who have their prescriptions filled covered by other private, non-creditable sources. Limited funding has allowed for only one year of Medicare Part D claims for analyses. Limitations on the cross-sectional design of this study are due to only one year of data for analyses, thus analyses over a longer period of time was not possible. Additionally, because data is derived from claims information submitted by Medicare Part D sponsors and collated by the Centers for Medicare and Medicaid Services (CMS), there was no control over method of data collection in this study. Further, because data extraction for the study population was executed by CMS based on a submitted research proposal, there was also no control over sampling and data extraction. Additionally, although Proportion of Days Covered (PDC) based on claims data is commonly used as a measure of medication adherence, in reality it is an indirect method that may be regarded as distinct from medication adherence measured directly (i.e. through observation of medication intake and detection in bodily fluids).

X. FUTURE RESEARCH

The body of research on Medicare Part D continues to grow since the program launched in 2006, however, studies specifically on Washington State and its sub-populations remain scarce. Future research that would be beneficial for various state agencies might include studies that are unique to the state and would contribute to a clearer picture of the earlier years of the program through to its current stage, especially in light of the variations of plan offerings across counties. Additionally, with more Medicare data files recently becoming available, future studies might link various data sets that have not been linked before that would lead to better understanding of patterns and variations unique to the state. Such studies might be, for example, longitudinal, multi-year analyses; inclusion of prescriber and pharmacy characteristics; differences in beneficiaries out-of-pocket costs through plan networks of preferred pharmacies compared to non-preferred pharmacies; and changes in drug tier placement that affect out-of-pocket payments.

Equally important is monitoring the direction of future policy changes in Medicare Part D so that existing studies might serve informative for law-makers and regulators. One example of

possible future change is the proposed rules to amend, among others, the requirement that plan sponsors must broadly cover certain classes of drugs (Centers for Medicare and Medicaid Services, 2014). Antipsychotic medications are one of the classes of drugs that may be removed from required broad coverage in the future allowing for greater utilization managements (i.e. restrictions) by plan sponsors. If such proposed changes become law, the impact on vulnerable Medicare sub-populations unique to the state would be unknown without sufficient research findings representative of beneficiaries and plan providers in the state.

Similarly, the phasing out of the gap period, otherwise known as the "Doughnut Hole," which was part of the 2010 Affordable Care Act, gradually reduces beneficiary cost-sharing during the gap period down to 25 percent by 2020; however, few beneficiaries are aware that reductions down to the eventual 25 percent will be greater for brand-name medications than for generic medications (Medicare Rights Center, 2010). For example, current reductions in cost-sharing during the gap period are 47.5 percent out-of-pocket cost for beneficiaries filling prescriptions for brand-name drugs versus 72 percent for generic drugs, and, in 2018, 35 percent for brand-name drugs versus 44 percent for generic drugs. More studies looking into prescribing patterns, plan-specific drug formularies, and generic versus brand-name medication utilization are needed; because of the many variations in plan offerings by counties and the changes in plan offerings that occur annually. Additionally, though phasing out of the gap in coverage is good for beneficiaries, this may lead to increases in costs carried by plan sponsors, which may be passed back to beneficiaries in the form of increases in premiums, higher and more expensive tier placements for certain medications, and more restrictive drug formularies. Some suggest that plan sponsors spending may increase by as much as 30 percent with closing of the gap, while beneficiary total drug spending may also increase by as much as 10 percent (Einave, Finkelstein, & Schrimpf, 2013; Jung, Feldman, & McBean, 2013).

Medicare Part D will continue to be fine-tuned over the years, because of the push for cost control as well as prevention and reduction of overpayment and fraud in the program's administration. As such, research on Medicare Part D and its various populations will need to consider the impact of regulatory changes that directly affect the original intent of the program, which is better access and expansion of prescription drug coverage for eligible beneficiaries.

XI. IMPLICATIONS FOR SOCIAL WORK PRACTICE

Medicare Part D is considered to be the largest expansion of entitlement programs since the Great Society era, as such its relevance for social workers working with the elderly and the disabled cannot be overlooked. Although Medicare Part D online plan finders are now available online, social workers still play a role in facilitating enrollment and provide assistance to beneficiaries who do not fully understand the particulars of the program. This may be even more so with beneficiaries with cognitive deficits, such as those with schizophrenia, bipolar disorders, and other mental disorders; as well as for beneficiaries needing to qualify for extra help (i.e. low income subsidy). Findings from this study highlight the difficulties that beneficiaries encounter in optimally choosing plans and provide a more in-depth look into aspects of plan and benefit designs that beneficiaries might consider or ignore when making their decisions that may, ultimately, affect their medication adherence.

Implications for policy and social work practice in light of findings of this study underscore the complex nature of assessing the wide ranging offerings of Medicare Part D plans that is especially difficult for beneficiaries with mental disorders. Non-adherence as a result of

the burden of medication costs need to be better addressed through policy and practice that could be in the form of expanded medication therapy management (MTM) beyond those offered by pharmacists. Although MTM services are required under the Medicare Modernization Act 2003, very few health providers other than pharmacists offer MTM and certification for MTM is currently offered only for pharmacists. Changes in policy and practice are needed to expand MTM beyond pharmacies and pharmacists to include other health care professions. Social workers in this regard have the potential to offer MTM as they work in more health care settings than pharmacists and can offer value-added assistance and referrals for beneficiaries needing extra help in such things as affording and obtaining medications as well as implementing strategies for adherence to medications. Social workers working with the older population are found in a variety of settings, such as nursing homes, assisted living communities, hospitals, and community agencies that now offer integrated health, behavioral health, and social services. Similarly, changes in policy and practice are needed to better facilitate Medicare Part D enrollment through in-person assistance to help prospective beneficiaries with mental disorders assess coverage offerings based on individual budget and medication regimen. Such in-person assistance can be modeled on the new health insurance exchanges mandated by the Affordable Care Act 2010 that allots federal grant funds to train and certify in-person assistance or navigators and application counselors who are tasked to facilitate health insurance enrollment through eligibility assessment, review of plan offerings, and application completion both in electronic and paper form. Furthermore, these navigators and counselors provide outreach and health insurance-related referrals for additional consumer assistance.

As evident in the study population, studies of this nature may be useful not only for social workers, but other health care providers as well who are in positions to help eligible beneficiaries understand their plan options given their individual medication needs and budget, and helping enrolled beneficiaries review their existing plans because plan benefits often change annually, as do medication needs. This study and other similar studies may also be informative for social work education to increase awareness on public health insurance and medication issues among individuals with schizophrenia and bipolar disorders.

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