

Prescription Drug Adherence and Cost-Related Underuse
in the Medicare Population

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Abstract

Underuse of medical care and prescription drug adherence are health behaviors affected by financial pressures, demographic and socioeconomic characteristics, and health status of Medicare beneficiaries. Cost-related underuse is the avoidance of needed medical care or prescription drugs due to financial concerns about the cost of the treatment. The purpose of this project is to determine the characteristics associated with cost-related underuse and to evaluate how health policy changes and prescription drug coverage may affect that behavior. The project aims are threefold: (1) determine the change over time and relationship between prescription drug coverage and the underuse of other medical care due to cost within the Medicare population; (2) examine the effect of enrollment in the Medicare Part D partial Low Income Subsidy (LIS), a program that provides scaled premium assistance and a flat 15% co-insurance, on adherence within drug classes associated with cost-related underuse; and (3) test the effects of financial, patient, and disease characteristics on prescription drug adherence within the Medicare partial LIS population. This study will provide a broader understanding of the policy levers, such as the Medicare Part D Low Income Subsidy, that impact prescription drug behavior and underutilization of medical care by Medicare beneficiaries.

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Project Introduction

This dissertation investigates adherence and cost-related underuse within the Medicare population and focuses on prescription drug-taking behaviors, medical care utilization, drug coverage, and pharmacy assistance programs, such as the Medicare Part D Low Income Subsidy (LIS) or Extra Help program. This study provides a broader understanding of cost-related underutilization within the Medicare population to inform evaluation of the Medicare Part D program and to improve the quality of health within the Medicare population. The findings of this project integrate into the broader medical sociology, health policy, and applied health services research literatures that examine prescription drug adherence and will be useful to health policy makers and practitioners providing care to the Medicare population.

The project goals are threefold: (1) determine the change over time and the relationship between prescription drug coverage and the underuse of other medical care due to cost within the Medicare population; (2) examine the effect of enrollment in the Medicare Part D partial LIS benefit, a program that provides scaled premium assistance and a flat 15% co-insurance, on adherence within drug classes associated with cost-related underuse; and (3) test the effects of financial, patient, and disease characteristics on prescription drug adherence within the Medicare partial LIS population. These three study aims examine prescription drug behavior that may be affected by cost constraints and evaluate the responses of this behavior to health policy changes and prescription drug plan coverage.

Literature Background on Cost-Related Underuse of Prescription Drugs

Prescription drug adherence as a health behavior concept has an extensive health services and clinical research literature.¹ The traditional focus has been the physician-patient dyad, and research findings from this perspective typically suggest patient education strategies to correct non-adherent behaviors.² The issue of cost-related underuse is a relatively recent area of research and broadens the traditional scope of study to include characteristics of the health insurance market and medical care system.³ Conceptually, a person who experiences cost-related underuse would be an adherent patient net the cost constraint and this suggests public policy and programs as possible solutions rather than behavioral or attitudinal interventions. Within this broad literature, the conceptual terms of compliance, adherence, concordance, and underuse have all been used to describe the attitudes and health behaviors of patients who do not follow medical treatment regimens as prescribed. While some⁴⁻⁶ distinguish ideological differences between the applications of the different terms, I use the term underuse to describe sub-optimal medication taking behaviors self-reported from survey data such as skipping doses or splitting pills and non-adherence/adherence to describe health behavior measures using clinical data or administrative claims.

Medication underuse and non-adherence by the elderly is an important topic in health services research and health policy analysis.⁶ Underutilization of prescription drugs in the elderly population is more prevalent due to higher rates of chronic conditions that require medications^{7,8} and more households with fixed incomes.⁹ The most common definition of underutilization of prescription drugs within the health survey literature is

not filling or obtaining medication from the pharmacist.¹⁰ However, underuse may result from a range of behaviors that do not follow the medication-taking regimen, such as increasing the spacing of dosages, skipping doses, or splitting pills to lengthen the prescription fill.^{7,11} A comparison of rates of prescription medication underuse due to cost reasons (as measured by self-report survey questions of not filling a prescription during the previous time period, delaying initiation of medication use, skipping or splitting pills) in the community-dwelling, adult population range from 1.6 to 22 percent and averaged 4.2 percent within the Medicare-only population prior to the implementation of the Medicare Part D benefit.¹⁰ Rates vary due to question wording, look-back periods, survey source, and sample.^{10,12}

The health consequences of underuse include increases in co-morbidity,¹³ worse management of illness,^{14,15} and increased risk of mortality.¹⁶ Health system consequences for service delivery from prescription drug underutilization include increasing rates of hospitalizations, use of the emergency departments, and demand for home health care services.¹⁶ At the population level, the relationship between cost-related underuse and the lack of prescription drug coverage within the Medicare benefit was one of the driving forces for the passage of the Part D legislation.¹⁷⁻¹⁹

Prescription drug utilization and drug plan coverage patterns by the Medicare population have been studied extensively.^{17,18,20-27} Descriptive analyses have documented racial and socioeconomic differences in utilization and drug plan enrollment rates^{19,28-31} and types of medications used by subpopulations stratified by health or co-morbidity conditions.^{23,32-34} The relationship between race/ethnicity and cost-related underuse of

prescription drugs has been shown to be related to financial pressures, such as income.^{17,35} Given that many of the elderly population are retired with fixed incomes, a large number of studies focus on the underuse of prescription medications due to cost reasons^{36–38} based on limited out-of-pocket spending budget constraints.

Several studies of non-Medicare populations have shown that differing levels of coinsurance rates and co-payment levels may reduce prescription drug utilization and increase non-adherence.^{36,39} Stuart and Zacker⁴⁰ show that dual-eligible beneficiaries residing in states with Medicaid drug co-payments have lower overall utilization than dual beneficiaries in states without co-payments. Ku⁴¹ finds that co-payment differences of even a \$1 between brand and generic for beneficiaries with incomes less than \$5000 is equivalent to a \$10 difference for beneficiaries with household incomes of \$50,000.

The relationship between prescription drug non-adherence and the use of other medical care has typically been examined from the perspective of impact on total health care costs: better drug adherence results in net savings from not using other more costly health services or, conversely, poorer adherence results in more costly hospitalizations and emergency services.¹⁶ These offset studies typically focus on a single drug class related to a chronic condition, such as congestive heart failure,⁴² myocardial infarction,⁴³ stroke,⁴⁴ cancer,⁴⁵ or depression.⁴⁶ Data used for the analyses in these studies is frequently administrative claims that allow sequencing of procedures and prescription fills to estimate changes in co-payments and service utilization. Self-reported underuse of medical care within the Medicare population and its relationship with prescription drug coverage has not been examined using this same framework.

Policy Background of Medicare Part D Low Income Subsidy Program

Non-adherence and cost-related medication underuse are important areas of study within the Medicare population. Concerns about underutilization and the importance of drug coverage were demonstrated by the implementation of the Part D program on January 1, 2006, which marked one of the largest coverage expansions in Medicare program history. The outpatient prescription drug benefit allows beneficiaries to choose to enroll in either stand-alone Prescription Drug Plans (PDP) or Medicare Advantage Plans with Part D (MA-PD). Part D coverage is a benefit that has phases based on total out-of-pocket and utilization costs with four different stages: the deductible, initial coverage, the benefit gap, and catastrophic coverage. Congress designed the phased benefit in order to attract private plans to offer prescription drug coverage. Enrolled Part D beneficiaries move through the different stages based on out-of-pocket costs and total drug spending during the calendar year. The importance of the study of cost-related underuse is a primary concern during the benefit gap or “donut hole,” which is the Part D benefit phase when the beneficiary is responsible for the full cost of the medication and plan premium. During the gap phase, the Medicare beneficiary is facing the same cost constraints as someone without drug coverage but the person has the additional cost of continuing to pay the monthly premium. For private plans offering the Medicare prescription drug coverage, the catastrophic coverage phase provides re-insurance of high-cost beneficiaries.

The Part D benefit design provides different incentives for plans to address beneficiary adherence levels, in general, apart from the benefit phase feature. PDPs or

stand-alone drug plans have little or no financial incentive to improve or monitor adherence because better adherence would result in increased drug utilization; any medical utilization offsets would benefit the Medicare program and not PDP profits. MA-PDs, in comparison, do have incentives to improve drug adherence to prevent other more costly health care utilization because the plan is responsible for coverage of the beneficiaries other Medicare-covered medical care; therefore, better adherence levels for MA-PD enrollees have the potential to result in net plan savings or better profits. As such, the examination of drug adherence within the Medicare population is an important research area for all Part D enrollees and not just those select numbers that encounter the donut hole or benefit gap feature.

The Low Income Subsidy (LIS) program is one of the “safety net” features of the Part D program that allows Medicare beneficiaries who qualify based on assets and income levels to be eligible to receive premium subsidies and reduced cost sharing. The LIS program is administered by the Social Security Administration (SSA), which is responsible for the eligibility determination and program enrollment in coordination with state Medicaid programs. Medicare beneficiaries who are dually-enrolled in the Medicaid program are deemed or auto-enrolled into the LIS program. Other non-dual beneficiaries may apply to qualify for enrollment. LIS Medicare beneficiaries are not subject to benefit phase constraints, such as the donut hole, and account for close to two-thirds of all prescription drug enrollees that reach the catastrophic coverage benefit phase.⁴⁷ The LIS program has 8 categories of enrollment that vary based on the premium subsidy amount and the cost sharing proportion.

LIS categories differentiate deemed and non-deemed beneficiaries and the premium subsidy and cost-sharing amounts as shown in Table 1.⁴⁸ The deemed LIS enrollees are Medicare beneficiaries who are enrolled in the Medicare Savings Programs (MSP), or more commonly known as the Medicare-Medicaid duals, and are automatically assigned their corresponding LIS category based on their MSP qualification status. The MSP program has different Medicaid coverage categories based on the individual's asset and income level. Deemed LIS enrollees are autoenrolled in a stand-alone PDP but may elect to enroll in an MA-PD. Non-deemed enrollees must apply for the LIS program and categorical assignment is based on their SSA income level without asset-level certification. The last category in Table 1 is for enrollees in the Part D program that are not in the LIS program and they do not received any premium subsidies or cost sharing but may enroll in a plan with gap coverage. The partial LIS group examined in research aims 2 and 3 of this project are categories 6 through 8.

For 2006 and 2007, programmatic summary statistics show that roughly 25 million beneficiaries or 54% of the total Medicare population enrolled in the Part D program.⁴⁹ Of those enrolled in Part D, 72% in 2006 and 69% in 2007 were enrolled in the stand-alone PDPs.⁴⁹ Approximately 10 million beneficiaries or 40% of the enrolled Part D Medicare population in 2006 and 2007 were enrolled in the Low Income Subsidy program and roughly 85% of LIS enrollees were deemed or auto-enrolled.⁴⁹ The average time from deductible to the benefit gap in 2006 and 2007 was approximately 6 months and the average time in catastrophic coverage was 4 months.⁵⁰ For the LIS enrolled Part

D population, approximately 44% exceeded the initial coverage limit in 2006 and 2007; for the non-LIS enrolled population, approximately 24% reached the benefit gap phase.⁵⁰

Project Aims

The project has three specific research aims: (1) examine the change over time of prescription drug and medical care underutilization within the Medicare population, (2) evaluate the effect of the Medicare Part D Low Income Subsidy (LIS) program for those enrolled within the partial LIS benefit on cost-related underuse of medications, and (3) determine the effects of differing premium subsidization amounts and race/ethnicity on prescription drug adherence controlling for other financial, patient, and diagnostic characteristics within the partial LIS population. Both survey and administrative data are used to address these research aims.

The first research objective examines cost-related underutilization of prescription drugs and medical care and its relationship with prescription drug coverage. This study aim examines the possible policy solutions for minimizing cost-related underutilization. Using both descriptive and statistical analysis of the Medicare Current Beneficiary Survey (MCBS), the findings from this research objective compare over time the phenomena of cost-related underutilization for both medical care and prescription drugs as self-reported by the Medicare beneficiary. The key question is to determine if prescription drug behavior is similar to other health care behaviors or if it is unique. The findings from this study examine responsiveness of cost-related underuse to an extension of prescription drug coverage and whether this pattern is similar for prescription drugs and medical care. The statistical analysis uses longitudinal data to examine the

relationship of prescription drug underutilization and underuse of medical care and the effect of prescription drug coverage over time.

The second research objective evaluates the effect of partial LIS enrollment on adherence within the three drug classes most likely to have cost-related underuse reported in the MCBS data: statins, gastrointestinal agents, and anti-diabetics. Using administrative enrollment and claims data, this research aim examines Part D enrollees' prescription drug adherence levels before and after enrollment in the Low Income Subsidy program to evaluate whether the additional income assistance, through cost sharing and premium assistance, improves adherence with prescribed drug therapy regimens. The dependent variable is the calculated administrative drug adherence measure. The Medicare claims and enrollment administrative data are collected from 2006 through 2010 and allow analysis of the initial implementation period of the Part D program. The analytic sample is composed of Medicare beneficiaries who first enrolled in the Part D benefit and later enrolled in the LIS program between 2006 and 2010 to allow examination of pre-LIS enrollment and post-LIS enrollment adherence levels. Independent variables used in the analysis include financial, patient, and diagnostic characteristics. The implications of the findings from this research aim provide an evaluation of whether the LIS program enrollment improves medication adherence and decreases cost-related underuse of prescription drugs for Medicare beneficiaries.

The third research objective compares the different levels of premium assistance provided to partial LIS enrollees based on their income and asset levels and race/ethnicity of the beneficiary in the examination of prescription drug adherence levels. The partial

LIS program has 3 different categories of eligibility with the same cost sharing but differing premium subsidization amounts based on income. Cost-sharing levels are a flat 15% coinsurance level. Premium assistance ranges from notched levels at 75%, 50%, and 25% assistance. Similar to the second research aim, administrative enrollment and claims data are used for this research aim. The purpose of this research aim is to examine race/ethnicity and the effects of the differing cost sharing and premium subsidization levels on medication adherence for select therapeutic classes, such as gastrointestinal agents, anti-diabetics, and statins. The 2006-2010 administrative enrollment and claims data are used to construct the analytical cohort of all partial LIS enrollees. The findings from this study objective provide information on the effectiveness of the partial LIS program for increasing prescription drug adherence by the Medicare population enrolled in the Part D benefit and needing the additional financial assistance provided by cost sharing and premium subsidization. Taken together, the importance of these last two research aims is to examine the two primary policy levers, cost sharing and premium assistance, for reducing cost-related underuse of prescription drugs within the Medicare population.

Conceptual Model of Prescription Drug Non-Adherence

Given over 50 years of academic research on adherence,⁶ prescription drug underutilization due to cost is a relatively recent focus within the extensive drug adherence literature. Starting in the late 1990s with Soumerai, et al.³⁹ examination of cost-related underuse within the Medicaid population in response to increases in co-payments and benefit caps, researchers have expanded the literature from a focus on the

clinical patient-physician dyad to a broader health services conceptual model that incorporates the health environment context. Piette, et al.⁵¹ accurately summarize the next generation of studies that focus on the bridge between the economic barriers conceptual model and the adherence conceptual model as shown in Figure 1.

The cost-adherence conceptual model links compliance and cost-related underuse in the same model.^{51,52} The direct effect of financial pressures, such as drug coverage, cost-sharing, subsidy programs, income level, interacts with drug regimen characteristics, such as number of prescriptions and refill frequency, and is moderated by patient, drug, health, and health system characteristics and mediated by clinician and health system factors. Patient characteristics are measures of socio-demographic traits, cognitive ability, or health literacy and attitudes. Diagnosis characteristics are health measures such as disease burden or disability status. Drug characteristics include therapeutic class, side effects, drug form, and immediacy of benefits. The patient, diagnosis, and drug characteristics have a direct effect on drug non-adherence and are the main components of the traditional drug adherence conceptual model. The health system factors include pharmacy access, cost assistance programs, or coordination of care programs and have both mediating and moderating effects in the conceptual model. Clinician factors are measures of the patient-physician dyad relationship. The traditional adherence model focused on the patient, drug and diagnosis characteristics and the mediating effects of the clinician factors.

The cost-adherence conceptual model informs the research design of this dissertation project, but the data sources used in the analysis do not have variables that

match all of the separate model concepts. Nonetheless, the model is useful for this project because it addresses the behavior influences that affect the drug adherence decision process. The conceptual model also highlights the groups of key variables and relationships that need to be measured and tested in the statistical models for the research aims. The primary conceptual area that captures the main exposure variables in the empirical models tested in this project is financial pressures, such as income and drug coverage, and patient and diagnostic characteristics are also tested.

Financial characteristics examined in this project that are associated with cost-related underuse include prescription drug coverage, premium and cost-sharing assistance, and income and asset levels of the Medicare beneficiary. Following the conceptual model, it is expected that obtaining prescription drug coverage or having higher income levels decreases the financial pressure for the Medicare beneficiary and increase prescription drug adherence or reduces the likelihood of cost-related underuse.^{34,37,38,52-55}

Patient characteristics examined in this project include demographic variables, such as age, sex, and race/ethnicity. In addition, Study 1 includes socioeconomic variables such as education level, employment status, and metropolitan status. Patient characteristics account for individual differences, such as patient-physician communication patterns, patient beliefs about the efficacy of treatment, patient abilities to understand medical advice, or differences in patterns of medical care seeking behaviors and having a usual source of care.^{30,56,57} Older Medicare beneficiaries are less likely to experience cost-related underuse than younger beneficiaries.⁵⁸⁻⁶¹ Women are

more likely to experience cost-related underuse than men.⁶²⁻⁶⁴ Cost-related underuse has been shown to vary by race/ethnicity groups within the Medicare population,^{56,65-67} and it is expected that non-white racial groups or Hispanic ethnicity are more likely to have cost-related underuse.^{64,68,69}

Diagnostic characteristics associated with cost-related underuse that are examined in this project include chronic conditions or measures of co-morbidity. Having multiple chronic conditions increases the number of prescription medications used to treat Medicare beneficiaries, known as polypharmacy,^{2,12,54,70} and it is expected to increase the likelihood of cost-related underuse and poorer adherence.^{34,71,72} Study 1 also includes self-reported mobility limitations and these limitations are expected to increase the likelihood of cost-related underuse.^{63,73}

One limitation of the Piette, et al.⁵¹ cost-adherence conceptual model is that it does not distinguish between decreases due to overutilization and decreases that are adverse underutilization.⁷⁴ Increased financial pressures, such as higher co-payments, may have a beneficial effect of decreasing overutilization. The drug characteristics have a moderating effect in the model, so the degree to which overutilization is related to particular types of drugs would be captured in the model, but the distinction needs to be clear in the operationalization of the drug non-adherence that decreases in utilization may be reflecting decreases in overutilization. To address this possible conceptual model limitation, Studies 2 and 3 examine therapeutic classes most likely to have cost-related underuse within the Medicare population, and Study 1 examines survey questions that ask about needed medical care and prescribed medications.

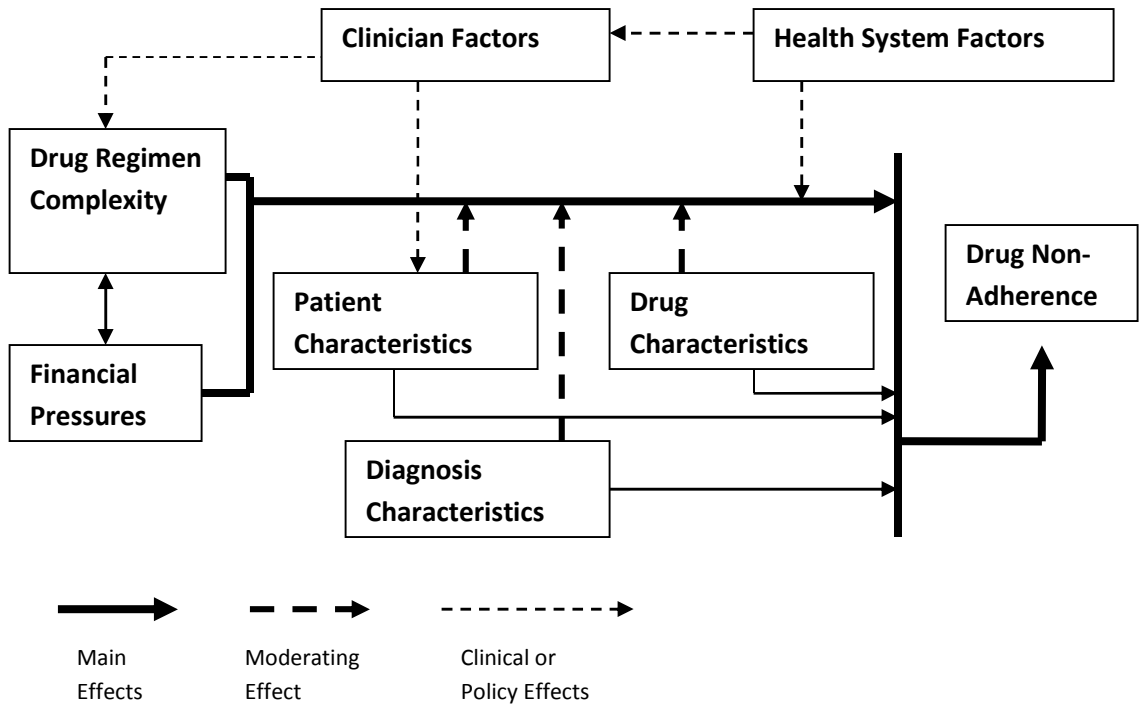
The research aims of this project address different sections of Piette's conceptual model. The first research aim expands the conceptual model by examining other health outcomes, such as cost-related underuse of medical care. The second aim examining pre/post partial LIS enrollment focuses on the health systems factors by examining how a safety net policy lever, which provides premium subsidization and cost-sharing, may reduce financial pressures and affect prescription drug adherence. The third research aim concentrates on the financial pressures and patient characteristics by comparing adherence levels by the income and premium subsidization groups and individual-level characteristics, such as race and ethnicity. For each of the research aims, the explanatory variables tested within the empirical models are grouped within their corresponding conceptual area as related to financial pressures, patient, and diagnostic characteristics.

Table 1: Low Income Subsidy Categories

LIS Category	Deemed	Premium Subsidy	Co-Payment Cost-Sharing
1	Yes	100%	No Co-Payment
2	Yes	100%	Low (\$1-\$3)
3	Yes	100%	High (\$5-\$7)
4	No	100%	High (\$5-\$7)
5	No	100%	15% Co-payment
6	No	75%	15% Co-payment
7	No	50%	15% Co-payment
8	No	25%	15% Co-payment
9	No	None	No Cost Sharing

Source: Centers for Medicare and Medicaid Services (CMS). 2011. “Chapter 13 – Premium and Cost-Sharing Subsidies for Low-Income Individuals” in Medicare Prescription Drug Benefit Manual. Baltimore, MD: U.S. Department of Health & Human Services.

Figure 1. Cost-Adherence Conceptual Model



Source: Piette JD, Heisler M, Horne R, Alexander GC. 2006. "A Conceptually Based Approach to Understanding Chronically Ill Patients' Responses to Medicare Cost Pressures." *Social Science & Medicine* 62(2006):849.

Study 1: Cost-Related Underuse Before and After Medicare Part D

Summary for Study 1

Research Objective: The primary purpose of this study is to examine rates of prescription drug and medical care underutilization due to cost within the Medicare population and to compare these rates before and after the implementation of the Medicare Part D benefit.

Study Design: The Medicare Current Beneficiary Survey (MCBS) Access to Care modules are used to compare a longitudinal cohort from 2005 to 2007. Underutilization is defined as self-reported behaviors to extend prescribed medications, such as skipping doses, splitting pills and not acquiring medication fills, or as foregoing needed medical care by the beneficiary during the previous 12 months. Explanatory variables include prescription drug coverage, demographic and socioeconomic characteristics, chronic conditions, mobility measures, and geography. Logistic regression is used to test cost-related underuse following the implementation of Part D in 2007 in a stratified analysis of Medicare beneficiaries that experienced underuse in 2005 and those that did not.

Population Studied: Community-dwelling, continuously-enrolled Medicare population from 2005 to 2007.

Principal Findings: Medicare beneficiaries had a reduction in cost-related underuse of medical care from 7.6 percent (95% confidence interval(CI), 6.8-8.3) in 2005 to 5.8 percent (95% CI, 5.1-6.6) in 2007 and had a larger reduction in cost-related underuse of prescription drugs from 13.4 percent (95% CI, 12.1-14.7) in 2005 to 9.1 percent (95% CI, 8.1-10.1) in 2007. Medicare beneficiaries who did not experience cost-related underuse of prescription drugs in 2005 had a 0.06 (95% CI, 0.06-0.07) probability of newly experiencing cost-related underuse of prescription drugs in 2007, and of those beneficiaries not obtaining prescription drug coverage had a marginal probability increase of 0.02 (95% CI, 0.003-0.04) in the likelihood of underuse compared to those with continuous drug coverage from 2005 to 2007. In comparison, beneficiaries who did not experience cost-related underuse of medical care in 2005 had a 0.04 probability (95% CI, 0.04-0.05) of newly experiencing it in 2007, and compared to those with continuous drug coverage, those with new prescription drug coverage had a marginal probability increase of 0.012 (95% CI, 0.0004-0.02) and those with no drug coverage in both 2005 and 2007 had a marginal probability increase of 0.014 (95% CI, 0.003-0.03) in the likelihood of medical care underuse in 2007.

Conclusions: The findings suggest the implementation of Part D was associated with an overall decline in cost-related underuse within the Medicare population, and those that did not experience underuse in 2005 and continued to lack drug coverage in 2007 were more likely to newly experience underuse in 2007.

Introduction

Following the implementation of Medicare Part D in 2006, cost-related underuse continued to be a concern, especially for Medicare beneficiaries who encountered the coverage gap.²⁶ Possible consequences for those Medicare beneficiaries that adopted cost saving strategies, such as not filling prescriptions or taking medications less frequently than the prescribed dosage, were potentially adverse effects that affected their health and treatment regimens.³⁸ While there are several corollary concerns that relate to underutilization, such as issues of medical knowledge needed for understanding treatment regimens,^{75,76} doctor-patient communication about reasons for the prescribing the medication,³⁷ and understanding drug interaction effects⁷⁷ that are not addressed in this study, the underutilization of prescription medications due to cost reasons continues to be a major issue for the health of the Medicare population.^{71,78,79}

Prescription drug underutilization within the elderly population has received a vast amount of study.^{12,17,80} Most studies are cross-sectional surveys or compliance evaluations. Longitudinal rates of prescription drug underutilization within the Medicare population have not been examined with the same detailed analysis. Similarly, the relationship between prescription drug coverage and the underuse of other medical care is not as well-studied in the Medicare population. Given that the implementation of Medicare Part D was the largest, recent benefit expansion, it remains important to investigate baseline rates of underuse by Medicare beneficiaries to examine the health behavioral response to the policy change.

Background on Medicare Part D Implementation

The initial implementation of the Medicare Part D benefit was associated with reductions in cost-related underuse of prescription drugs.^{81–86} More recently, however, these initial gains have eroded for the Medicare disabled population⁷⁹ and those with multiple chronic conditions.⁷¹ These recent increases in cost-related underuse do not have a clear reason for the change, such as coverage benefits. The Part D benefit structure remains the same for the disabled Medicare population that are deemed, and the donut hole coverage gap began to close starting in 2011, which benefits high drug utilization groups such as those with multiple chronic conditions. If the trend reversal is related to increased financial pressures experiences from the recession, it would be expected that cost-related underuse would decline as the economy recovers; however, if the trend reversal is related to increased financial pressures from increasing drug prices, then the reversal of the trend would be expected to continue.

Research examining the relationship between Medicare Part D and medical care are broadly grouped as the “offset” studies because they focus on how prescription drug therapy use offsets or reduces the utilization of other medical care, mainly higher cost care.⁸⁷ For example within the Medicaid population, a 1% increase in prescription drug use relates to a 0.04% to 0.17% decrease in inpatient and outpatient costs.⁸⁸ Offset effects within the Medicare population following the implementation of Part D are mixed. Some find no effect,^{89,90} and others find positive effects of reduced hospitalizations⁹¹ or declines in non-drug medical costs,⁹² especially when drug adherence is factored into the model.^{72,93} One recent analysis found the implementation of Medicare Part D reduced

non-urgent and unnecessary emergency department visits.⁹⁴ Offset studies examine administrative claims data for medical care and prescription drugs but have not examined self-reported underuse of medical care from survey data. The relationship between Medicare Part D coverage and self-reported cost-related underuse of medical care has not been examined previously and is a unique contribution to the research literature by this study.

Research Design

Data

The dataset used for this analysis is survey data for a national Medicare sample. The Medicare Current Beneficiary Survey (MCBS) is a multi-purpose panel survey composed of four rotating cohorts interviewed in person, three times per year over a four-year period. The Computer Assisted Personal Interview (CAPI) is conducted in-person at the beneficiary's place of residence. Survey instruments on access and self-reported health measures are administered during the fall interview round. Health care utilization and coverage information is collected each round following the initial interview, which is used for training the panelist in how to track the data that is reported in the subsequent rounds. The sample is constructed from the enrolled Medicare population and includes community and facility beneficiaries in all 50 states, the District of Columbia and Puerto Rico. The primary sampling units are based on zip code clusters, and the strata are beneficiary age groups. MCBS divides the collected data into two different modules for each calendar year: Access to Care and Cost and Use. The Access to Care module

contains that fall round survey instruments, and the Cost and Use modules contains the health care utilization and associated costs reported during each survey round. An entering cohort is trained during the first fall survey round on how to collect utilization and cost information that is reported in each of the subsequent interview rounds. For this reason, panelists may be tracked through four Access to Care modules containing fall round survey data and three Cost and Use modules for the calendar year medical care utilization following that first fall round interview and training. Each module contains the survey weights and variance correction variables for the complex survey design. In addition, the Access to Care module contains two-, three-, and four-year backwards longitudinal weights. MCBS has been continuously fielded since 1991 and allows the examination of historical behavioral data prior to the implementation of Medicare Part D. For this study, the 2005 and 2007 Access to Care modules are used to construct a longitudinal panel.

The benefits of using the MCBS data are threefold. First, the panel allows longitudinal study of prescription drug behavior and underutilization of medical care. Second, the sample is a national representative sample of the entire enrolled Medicare population that includes the disabled and facility dwelling beneficiaries who are typically absent in other survey samples. Lastly, the survey also includes self-reported health conditions and utilization for both the Fee-for-Service (FFS) and Medicare Advantage (MA) populations. The use of self-reported health conditions and health behaviors from survey questionnaires, such as those used by MCBS, have been shown to be valid and

reliable measures of health⁹⁵⁻⁹⁷ and prescription drug behavior^{98,99} compared to measures from administrative claims data and medical charts.

Study Sample

A retrospective longitudinal cohort was constructed from the Access to Care modules from 2005 through 2007 to examine cost-related underuse before and after the implementation of the Medicare Part D benefit. The study examines cost-related underuse of medical care following the implementation of Medicare Part D. Cost-related underuse of prescription drugs provides a comparison for the medical care results and contributes to previous findings of cost-related underused of prescription drug by examining the stratified Medicare population based on prior underuse. Previous findings examining the two-year longitudinal cohort from 2005-2006 cohort found a reduction in prescription drug cost-related underuse following Medicare Part D.^{83,84} Limitations of using a shorter panel, such as the 2005-2006 cohort, are twofold. First, MCBS fields the survey instruments during the fall so the question look-back periods for the underutilization measures include a portion prior to the January 1 start date of the Part D benefit. Secondly, the initial implementation of Medicare Part D had open enrollment through May of 2006, so an examination of Part D drug coverage may only coincide for a partial period of overlap. The 2005-2007 panel cohort does not have these limitations. For the 2005-2007 cohort, Medicare Part D has been shown to be related to declines in prescription drug underuse,^{81,82} but the relationship between Part D coverage and the underuse of medical care has not been previously examined during this same period.

Figure 2 provides the detailed flow chart showing the construction of the analytical sample used in this study. The total sample size for the 2005-2007 MCBS cohort is 6,654 respondents. The retention rate between the 2005 and 2007 fall round interviews was 94.0% for the longitudinal cohort.¹⁰⁰ Most of response decline is due to mortality (approximately 5%). The overall survey response rate for this cohort is 63.9% for the entire panel rotation including the initial refusal rate.¹⁰⁰ Approximately 82% of the Medicare beneficiaries agree to participate in the survey when they are initially contacted and retention declines following that initial agreement are mainly from decedents and respondent moves outside of the CAPI survey clusters that are not tracked.¹⁰⁰

In construction of the analytical cohort used in this study, respondents that were facility-dwelling respondents or refused to reply to the selected survey questions were excluded from the analysis. MCBS survey respondents that were residing in a nursing home or long-term care facility during the fall survey rounds in 2005 or 2007 (unweighted N = 478) are excluded from the analytical sample because facility respondents are not directly interviewed, and different survey instruments that do not include questions of prescription drug or medical care underuse are completed by a proxy respondent for panelists by the designated contact within the residential facility. The second exclusion criteria from the cohort are the small number of respondents with missing data (unweighted N = 72) because of item non-response to the question or they did not complete the entire interview round that included the questions used in the analysis. Since the MCBS is a complex survey design, all respondents (unweighted N = 6,654) are included to have complete strata and cluster information for the Taylor

linearization calculations of standard errors but only the analytical subpopulation (unweighted N = 6,104) provide the information used in the analysis variables. The final analytical sample represents 33,119,862 Medicare beneficiaries continuously enrolled in the Medicare program from 2005 through 2007 and residing in the community.

Outcome Variables

Cost-related underuse is measured separately for medical care and prescription drugs. Table 2 provides the survey instrument questions for the measures used to construct the cost-related underuse outcomes from the MCBS Community Core survey instruments.¹⁰¹ Underutilization of medical care is reported in the Access to Care module and occurs when the survey respondent does not seek medical care due to concerns about the cost of the care at any time during the previous 12 months. Respondents that report “yes” are coded as experiencing cost-related underuse of medical care, and “no” replies are coded as not experiencing it. Respondents that refuse to answer the question or “don’t know” are coded as missing data for cost-related underuse of medical care. Prescription drug cost-related underuse is constructed from three survey questions.⁸²⁻⁸⁴ Cost-related underuse is coded if a respondent reports not acquiring a prescribed medication during the previous 12 months because of the medication cost, or reports “often”/“sometimes” taking smaller doses of a medication to extend the length of the fill, or reports “often”/“sometimes” skipping doses to extend the medication coverage length. The respondents are coded as not experiencing cost-related underuse if they do not report any of those behaviors or as having missing data if they refuse or “don’t know.”

For analytical purposes, the Medicare population is stratified by their underuse behavior in 2005 and the outcome measures are constructed based on their underuse behavior in 2007. The stratification allows an examination of cost-related underuse of medical and prescription drugs in 2005 to compare underuse in 2007 within the subpopulation. Survey respondents in the analytical sample have separate cost-related underuse outcomes for prescription drugs and medical care based on their behavior 2005 and 2007. For those that experience cost-related underuse in 2005, they either continued to experience it in 2007 or resolved the underuse issue and did not experience cost-related underuse in 2007. For those that did not experience cost-related underuse in 2005, they continued to not experience it in 2007 or they experienced cost-related underuse in 2007 as a new health behavior issue.

Explanatory Variables

Financial Characteristics. Prescription drug coverage is queried during the Fall interview round from the administration of the Supplemental Health Insurance instrument.¹⁰⁰ Panelists are asked about prescription drug coverage for up to 5 different supplemental insurance plans that they have listed during the previous year's survey rounds. For dual Medicaid covered panelists and Tricare enrollees, the panelists are asked if their enrollment covers prescriptions drugs. The survey instrument also asks about any other public plan coverage of prescription drugs and enrollment. Drug coverage in 2005 is compared to drug coverage in 2007 to create a four-category variable that indicates continued coverage for those with drug coverage in both 2005 and 2007, new coverage for those without any drug coverage in 2005 but with coverage in 2007, no coverage for

those without any drug coverage in both 2005 and 2007, and lose coverage for those with drug coverage in 2005 but without any reported coverage in 2007. Drug coverage is expected to reduce financial pressure and the likelihood of experiencing cost-related underuse.

The second financial characteristic measures self-reported income above or below \$25,000. Income is the one question with the highest refusal response rate¹⁰⁰ and many survey respondents do provide any additional detail on income level beyond the first question of whether they are above or below \$25,000. Income is part of the questionnaire instruments conducted during the fall round each year. Panelists that refuse to answer the income question in subsequent years have their previous year reply carried forward as their income response for that year.¹⁰⁰ For these reasons, income is coded from the 2005 Access to Care module, at baseline, for analysis because it is not possible to distinguish reliable smaller intervals of income for all panelists nor determine no change in income between years from responses that are carried forward because of current refusal. It is expected that Medicare beneficiaries with higher income levels are less likely to experience cost-related underuse.

Patient Characteristics. Demographic, socioeconomic, and geographic variables are measured as patient characteristics. Demographic variables include age, race/ethnicity, and gender. Age is coded into 5 categories to group the younger, disabled Medicare population (less than 45 years and 45-64 years) and older, age-qualified Medicare populations (65-69 years, 70-74 years, 75 years and older). Race/ethnicity is self-reported by the panelists and combines the race and Hispanic ethnicity questions into

one variable for White, Non-Hispanic; Black, Non-Hispanic; Hispanic, All Races; and Other, Non-Hispanic comparison groups. Male and female are the two gender codes. Socioeconomic variables include education level and current employment status. Geography is the rural/urban status of the county of residence. All patient characteristics are from the baseline in the 2005 Access to Care module.

Diagnostic Characteristics. Health status measures of diagnostic characteristics include self-reported health, chronic conditions, and mobility measures. These measures are coded from the baseline responses in the 2005 Access to Care. It is expected that those with worse health, more chronic conditions, less mobility are more likely to experience cost-related underuse of medical care or prescription drugs.

Self-reported health is a Likert scale question rating health from poor to excellent and recoded into two categories to compare self-reported good/very good/excellent health with fair/poor health. This measure is coded at baseline in 2005.

Chronic conditions are measured as a count variable of all of the self-reported chronic conditions in 2005 and grouped into three categories for comparison: those with none or one chronic condition, those with two or three chronic conditions, and those with four or more self-reported chronic conditions in their medical history.⁸⁴ The chronic conditions include self-reported histories with rheumatoid arthritis, non-rheumatoid arthritis, emphysema, asthma, chronic obstructive pulmonary disease (COPD), diabetes (either Type 1 or Type 2), stroke or brain hemorrhage, hypertension, hardening of arteries, myocardial infarction, heart attack, angina pectoris, coronary heart disease, any non-skin cancer, or skin cancer.

Depression has been shown to be associated with cost-related underuse of prescription drugs.^{46,54,60,86} It is coded as an indicator variable for self-reported history of depression or not in the 2005 Access to Care module.

Mobility measures include instrumental activities of daily living (IADL) and activities of daily living (ADL). IADLs and ADLs are grouped into three comparative categories for none, one, or two or more. IADLs include any difficulty using telephone, doing light housework, doing heavy housework, preparing meals, shopping, or managing money. ADLs include any difficulty bathing or showering, dressing, eating, getting in or out of bed or chair, walking, or using the toilet. Mobility measures are coded from the 2005 baseline survey responses.

Statistical Analysis

Descriptive analysis of the rates of cost-related underuse of medical care and prescription drugs in 2005 and 2007 are compared using a paired t-test for differences in proportions. The bivariate and multivariate results are presented for each of the subpopulations stratified by underuse behavior in 2005 for prescription drugs and medical care, separately. Rates by the stratified underuse subpopulations are calculated for each of the outcome measures of cost-related underuse in 2007 and compared for financial, patient, and diagnostic characteristics from the 2005 baseline year for both medical care and prescription drugs using bivariate χ^2 test statistics. The same explanatory variables are then used to estimate a logistic regression for the categorical outcome variables. Adjusted odds ratios are calculated from the logit parameters and provided with the 95% confidence interval. The adjusted Wald test of joint probability of

the variables for financial, patient, and diagnostics characteristics are equal to zero as a set within the logistic regressions is also calculated. The average marginal probabilities at the means of the explanatory variables are calculated to allow comparisons of financial, patient, and diagnostic variables and presented with their corresponding 95% confidence interval. All descriptive, bivariate, and logistic regression analyses are completed using Stata 12 SVY procedures for complex surveys and subpopulations. Results with $p < 0.05$ are discussed in the finding section below.

Findings

Descriptive Analysis of Cost-Related Underuse

Figure 3 shows that community-dwelling Medicare beneficiaries who were continuously enrolled from 2005 through 2007 had a reduction in cost-related underuse of medical care from 7.6 percent (95% confidence interval(CI), 6.8-8.3) to 5.8 percent (95% CI, 5.1-6.6) in the years before and after the implementation of the Medicare Part D benefit. Cost-related underuse of prescription drugs during this same time period had a larger reduction from 13.4 percent (95% CI, 12.1-14.7) in 2005 to 9.1 percent (95% CI, 8.1-10.1) in 2007 for the continuously enrolled, community-dwelling Medicare population. Cost-related underuse of medical care and prescription drugs both declined during the expansion of Medicare to include the Part D prescription drug benefit in 2006. The net 1.8 ($=7.6-5.8$) percent reduction in medical care cost-related underuse was a 23.7 ($=1.8/7.6$) percent change from 2005 to 2007. In comparison, cost-related underuse of

prescription drugs had a 32.1 percent change or a net 4.3 percent reduction from 2005 to 2007.

Cost-Related Underuse of Prescription Drugs

Table 3 presents the distribution of the financial, patient, and diagnostic characteristics by cost-related underuse of prescription drugs in 2007 for the Medicare subpopulation that experienced cost-related underuse of prescription drugs in 2005. Of the 13.4 percent of the Medicare population that experienced cost-related underuse of prescription drugs in 2005 (Figure 3), 71.3 percent or 3,007,675 Medicare beneficiaries resolved their cost-related underuse by 2007 and 28.7 percent (1,211,449 beneficiaries) continued to experience cost-related underuse of prescription drugs in 2007.

Continued, unresolved cost-related underuse of prescription drugs compared to resolved underuse in 2007 was associated with 2005 baseline measures of patient and diagnosis characteristics. Older Medicare beneficiaries age 75 or more years (32.8 percent) were more likely to resolve their cost-related underuse than not (16.8 percent unresolved). Similarly, disabled Medicare beneficiaries that experienced cost-related underuse of prescription drugs in 2005 were more likely to continue to experience it in 2007 with 38.7 percent ages 45 to 64 years with unresolved compared to 19.7 percent with resolved underuse and 12.2 percent less than 45 years with unresolved compared to 6.1 percent with resolved. Persons with better self-reported health in 2005, the baseline year, were more likely to resolve their underuse of prescription drugs, 31.9 percent, than have unresolved cost-related underuse, 16.3 percent. Medicare beneficiaries with depression were more likely to have unresolved cost-related underuse of prescription

drugs, 47.9 percent, than resolved, 28.4 percent. Those without any instrumental activities of daily living mobility limitations were more likely to have resolved underuse, 61.0 percent, than continued, unresolved cost-related underuse, 47.0 percent.

Table 4 shows the logistic regression of resolved compared to unresolved cost-related underuse of prescription drugs in 2007 for the Medicare population that experienced cost-related underuse of prescription drugs in 2005. The adjusted Wald test of joint probability shows that the set of variables measuring patient characteristics ($F(13,466)=2.58$, $P>|F|=0.002$) and diagnosis characteristics ($F(8,471)=2.22$, $P>|F|=0.025$) are associated with differences between resolved and unresolved cost-related underuse of prescription drugs in 2007. Compared to Medicare beneficiaries ages 75 years and older, disabled beneficiaries less than 45 years (adjusted odds ratio (AOR)=0.36; 95% CI, 0.18-0.72) and ages 45 to 64 years (AOR=0.40; 95% CI, 0.22-0.71) are less likely to resolve cost-related underuse of prescription drugs, controlling for all other financial, patient, and diagnostic characteristics. Medicare beneficiaries with good to excellent self-reported health in 2005 are more likely to have resolved cost-related underuse of prescription drugs (AOR=1.88; 95% CI, 1.26-2.79). Of those that experience underuse in 2005, beneficiaries with depression are less likely to resolve the underuse in 2007 (AOR=0.66; 95% CI, 0.44-0.97).

Table 5 provides the distribution of the financial, patient, and diagnostic characteristics by newly experienced cost-related underuse of prescription drugs or not in 2007 for the Medicare population that did not self-report prescription drug cost-related underuse in 2005. The 86.6 percent of the continuously enrolled from 2005 to 2007,

community-dwelling Medicare population that did experience cost-related underuse of prescription drugs in 2005 (Figure 3) had 1,619,170 beneficiaries, 5.6 percent, self-reported underuse of prescription drugs due to costs in 2007. The remainder of the subpopulation cohort (27,281,568 beneficiaries or 94.4 percent) continued to not experience cost-related underuse of prescription drugs in 2007.

Newly experienced cost-related underuse of prescription drugs in 2007 for those that did not have any in 2005 is associated with income, gender, race/ethnicity, age, self-reported health status, the chronic condition of depression, and mobility limitations. Medicare beneficiaries with incomes less than \$25,000 were more likely to experience cost-related underuse (61.6 percent) than continue to not (53.5 percent) in 2007. Females were more likely, 61.2 percent, to have new cost-related underuse of prescription drugs than those that did not have any cost-related underuse, 54.0 percent. Of those with new cost-related underuse of prescription drugs, a higher proportion (11.7 percent) were black, non-Hispanic and a lower proportion (4.6 percent) were Hispanic than their comparable proportions without any cost-related underuse (black, non-Hispanic 7.5 percent; Hispanic 7.4 percent). White, non-Hispanic Medicare beneficiaries and other, non-Hispanic race/ethnicities had similar proportions with no cost-related underuse compared to new cost-related underuse of prescription drugs (white, non-Hispanic 80.5 percent none, 78.6 percent new cost-related underuse; other, non-Hispanic 4.5 percent none, 5.1 percent new). Medicare beneficiaries ages 75 years and over were less likely to experience cost-related underuse of prescription drugs (31.7 percent new cost-related underuse, 42.0 percent no cost-related underuse). Disabled Medicare beneficiaries aged

45 to 64 years were 20.0 percent of those with new cost-related underuse and 9.1 percent of those without any cost-related underuse of prescription drugs in 2007. The other three age groups have similar proportions with new and no cost-related underuse (less than 45 years 3.0 percent with none, 4.7 percent with new; ages 65 to 69 years 23.0 percent none, 23.3 percent new; ages 70 to 74 years 22.9 percent no cost-related underuse, 20.3 percent new cost-related underuse of prescription drugs). Those that continued to not experience cost-related underuse of prescription drugs had better health (47.7 percent) than those that newly experienced underuse (29.5 percent). Medicare beneficiaries with depression were a larger proportion (29.7 percent) of those with new cost-related underuse than those that did not experience cost-related underuse of prescription drugs in 2007 (16.8 percent). Medicare beneficiaries that did not experience cost-related underuse in 2005 were more likely to continue no cost-related underuse in 2007 if they did not have any IADLs (73.0 percent no underuse, 63.8 percent new underuse) or ADLs (74.1 percent no underuse, 65.3 percent new underuse).

The logistic regression results of new compared to no cost-related underuse of prescription drugs in 2007 for the subpopulation that did not have any cost-related underuse of prescription drugs in 2005 are provided in Table 6. The adjusted Wald test of joint probability for the variable sets measuring patient characteristics ($F(13,466)=2.68$, $P>|F|=0.001$) and diagnosis characteristics ($F(8,471)=4.18$, $P>|F|=0.000$) shows that these sets of variables are associated with the likelihood of experiencing new cost-related underuse in 2007 compared to those that did not. Controlling for all other financial, patient, and diagnostic characteristics, Medicare

beneficiaries that did not have any prescription drug coverage in 2005 or 2007 were more likely to experience cost-related underuse of prescription drugs in 2007 (AOR=1.52; 95% CI, 1.08-2.14) than those with continuous drug coverage in 2005 and 2007 for those Medicare beneficiaries that did not have any cost-related underuse of prescription drugs in 2005. Male beneficiaries (AOR=0.70; 95% CI, 0.54-0.92) are less likely to experience new cost-related underuse than female beneficiaries. Compared to Medicare beneficiaries ages 75 years and over, disabled Medicare beneficiaries less than 45 years (AOR=1.81; 95% CI, 1.13-2.89) and ages 45 to 64 years (AOR=2.20; 95% CI, 1.50-3.23) are more likely to experience new cost-related underuse of prescription drugs, and newly enrolled aged Medicare beneficiaries from ages 65 to 69 years (AOR=1.44; 95% CI, 1.09-1.89) are also more likely to have new cost-related underuse of prescription drugs. Medicare beneficiaries with self-reported good to excellent health status are less likely to experience new underuse than those with fair or poor health (AOR=0.59; 95% CI, 0.43-0.81). Of those without any cost-related underuse of prescription drugs in 2005, beneficiaries with a medical history of depression are more likely to experience cost-related underuse in 2007 (AOR=1.53; 95% CI, 1.09-2.15).

Table 7 presents the adjusted marginal probability of cost-related underuse of prescription drugs in 2007 constructed from the stratified population logistic regression models in Tables 4 and 6. The average marginal effect (AME) is the adjusted marginal probability and is an estimated change in probability given a unit change in the variable while holding all other explanatory measures at their corresponding mean values. Overall, the predicted probability of resolved cost-related underuse of prescription drugs

in 2007 is 0.77 (95% CI, 0.74-0.81) for those Medicare beneficiaries that experienced cost-related underuse of prescription drugs in 2005, and the predicted probability of new cost-related underuse of prescription drugs in 2007 is 0.06 (95% CI, 0.06-0.07) for those Medicare beneficiaries that did not experience cost-related underuse of prescription drugs in 2005.

Medicare beneficiaries that did not have any prescription drug coverage in 2005 or 2007, compared to those with continuous drug coverage, had an increased probability of new cost-related underuse in 2007 (AME=0.02; 95% CI, 0.003-0.04) for those Medicare beneficiaries that did not report cost-related underuse in 2005. All other financial characteristics in the stratified population models are not associated with differences between experiencing or not experiencing cost-related underuse of prescription drugs in 2007.

Patient characteristics associated with cost-related underuse of prescription drugs in 2007 include age for those Medicare beneficiaries that experienced cost-related underuse in 2005 and gender, race/ethnicity, and age for those Medicare beneficiaries that did not have cost-related underuse in 2005. Male beneficiaries have a lower probability of new cost-related underuse in 2007 (AME= -0.02; 95% CI, -0.03 - -0.005) than female beneficiaries. Compared to white, non-Hispanic beneficiaries, Hispanic beneficiaries have a lower probability of new cost-related underuse (AME= -0.02; 95% CI, -0.04 - -0.005). In comparison to Medicare beneficiaries ages 75 years and older, disabled Medicare beneficiaries less than 45 years have a lower probability of resolved cost-related underuse (AME= -0.19; 95% CI, -0.32 - -0.05) and a higher probability of new

cost-related underuse of prescription drugs (AME=0.03; 95% CI, 0.001-0.06). Compared to the same reference age group, Medicare beneficiaries ages 45 to 64 years have a lower probability of resolved underuse (AME= -0.17; 95% CI, -0.28 - -0.06) and a higher probability of new underuse (AME=0.05; 95% CI, 0.02-0.08). Medicare beneficiaries ages 65 to 69 years have a higher probability of new cost-related underuse of prescription drugs in 2007 (AME=0.02; 95% CI, 0.003-0.03) compared to beneficiaries ages 75 years and older.

Both self-reported health status and medical histories of depression are diagnosis characteristics associated with cost-related underuse in 2007. Compared to those with fair or poor health, Medicare beneficiaries with better health have a higher probability of resolved cost-related underuse of prescription drugs (AME=0.10, 95% CI, 0.04-0.16) and a lower probability of newly experiencing underuse in 2007 (AME= -0.03; 95% CI, -0.04 - -0.01). Beneficiaries that have a medical history of depression have a lower probability of resolved underuse (AME= -0.07; 95% CI, -0.15 - -0.002) and a higher probability of new cost-related underuse of prescription drugs in 2007 (AME=0.03; 95% CI, 0.003-0.05).

Cost-Related Underuse of Medical Care

Table 8 presents the distribution of the financial, patient, and diagnostic explanatory variables by resolved and unresolved cost-related underuse of medical care in 2007 for those Medicare beneficiaries that experienced cost-related underuse of medical care in 2005. Of the 7.6 percent of the Medicare population continuously enrolled from 2005 to 2007 (Figure 3) who experienced cost-related underuse of medical

care in 2005, 68.0 percent or 1,613,091 Medicare beneficiaries resolved the underuse and did not experience cost-related underuse of medical care in 2007. Compared to the 2007 resolution rate, 71.3 percent (Table 3), of those who experienced cost-related underuse of prescription drugs in 2005, a smaller percentage resolved cost-related underuse of medical care in 2007 but the estimated 760,100 (Table 8) Medicare beneficiaries who continued to experience cost-related underuse of medical care in 2005 and 2007 (or 32.0 percent) is numerically smaller than the number, 1,211,449 (Table 3), who continued to experience cost-related underuse of prescription drugs in 2005 and 2007.

As shown in the bivariate comparisons in Table 8, prescription drug coverage and age are associated with resolved and unresolved cost-related underuse of medical care in 2007 for those Medicare beneficiaries that experienced cost-related underuse of medical care in 2005. Of those that resolved cost-related underuse of medical care in 2007, 48.0 percent had continued drug coverage in both 2005 and 2007 (compared to 41.0 percent with unresolved), 25.0 percent had new drug coverage in 2007 and no coverage in 2005 (compared to 25.3 percent with unresolved), 21.4 percent had no drug coverage in 2005 or 2007 (compared to 32.1 percent with unresolved), and 5.6 percent did not have drug coverage in 2007 who had coverage in 2005 (compared to 1.6 percent with unresolved). Older Medicare beneficiaries were more likely to have resolved cost-related underuse of medical care with disabled Medicare beneficiaries ages 64 years and younger accounting for the majority, 58.7 percent (42.1 + 16.6 percent), of those with unresolved cost-related underuse of medical care compared to 39.4 percent (28.3 + 11.1 percent) ages 64 years and younger with resolved.

Table 9 presents the logistic regression results of resolved cost-related underuse of medical care in 2007 for those that experienced underuse in 2005. Compared to Medicare beneficiaries who did not have prescription drug coverage in 2007 but had coverage in 2005, beneficiaries that had no drug coverage in both 2005 and 2007 were less likely to have resolved underuse of medical care (AOR=0.19; 95% CI, 0.05-0.77), controlling for all other financial, patient, and diagnostic characteristics.

Table 10 shows the distribution of the financial, patient, and diagnostic explanatory variables by those who had no cost-related underuse of medical care and those who newly experienced cost-related underuse in 2007 for those Medicare beneficiaries who did not have cost-related underuse of medical care in 2005. Of the 30,746,671 Medicare beneficiaries continuously enrolled and community dwelling from 2005 to 2007 and who did not experience cost-related underuse of medical care in 2005, 3.4 percent, or 1,056,827 beneficiaries, had cost-related underuse of medical care in 2007. The bivariate test statistics show that financial, patient, and diagnostic measures are related to new cost-related underuse of medical care in 2007 for those that did not have underuse in 2005.

Both income level and prescription drug coverage are related to cost-related underuse of medical care in 2007 for those Medicare beneficiaries that did not have any cost-related underuse in 2005. Of those with new cost-related underuse of medical care, 21.0 percent had new drug coverage in 2007 that did not in 2005 (compared to 13.6 percent with no cost-related underuse) and 22.3 percent did not have any drug coverage in 2005 or 2007 (compared to 17.6 percent with no cost-related underuse). Of those with

no cost-related underuse of medical care 60.4 percent had continuous drug coverage in 2005 and 2007 compared to 50.2 percent of those with new cost-related underuse.

Medicare beneficiaries with income below \$25,000 are more likely to have new cost-related underuse of medical care, 81.3 percent, than those with incomes above \$25,000, 18.7 percent. Those who did not experience any cost-related underuse of medical care had 53.4 percent with income below \$25,000 and 46.6 percent with income above this level.

Patient characteristics related to new cost-related underuse of medical care include race/ethnicity, age, and education. Medicare beneficiaries who self-identify as white, non-Hispanic are 80.3 percent of those with no cost-related underuse of medical care and 71.6 percent of those with new cost-related underuse of medical care. Almost twice the rate of black, non-Hispanic Medicare beneficiaries had new cost-related underuse, 14.9 percent, than had no cost-related underuse of medical care, 7.8 percent. In stark contrast, Medicare beneficiaries ages 75 years and older were 42.4 percent of those with no cost-related underuse and 22.0 percent of those with new cost-related underuse of medical care while disabled Medicare beneficiaries younger than 64 years were 11.9 percent of those with no cost-related underuse (9.1 + 2.8 percent) and 45.3 percent (36.9 + 8.4 percent) of those with new cost-related underuse of medical care. More than 35 percent of those with new cost-related underuse of medical care had some college education compared to 23.8 percent of those with no cost-related underuse, but those with a highest level of education as a high school diploma were 31.5 percent of those with no

cost-related underuse and 23.9 percent of those with new cost-related underuse of medical care.

All diagnosis characteristic measures are related to new cost-related underuse of medical care in 2007 for those that did not have cost-related underuse in 2005. Medicare beneficiaries with good to excellent self-reported health in 2005 baseline year were 46.6 percent of those with no cost-related underuse and 25.5 percent of those with new cost-related underuse of medical care in 2007. Of those with new cost-related underuse, 30.1 percent had medical histories of four or more chronic conditions, and 21.7 percent of those with no cost-related underuse had four or more chronic conditions. Those with a medical history of depression were more likely to have new cost-related underuse of medical care, 41.3 percent, than those with no cost-related underuse, 17.0 percent. Medicare beneficiaries without any mobility limitations are more likely to have no cost-related underuse of medical care in 2007 with 72.7 percent with no IADLs and 74.2 percent with no ADLs having no cost-related under in 2007 compared to 53.5 percent with no IADLs and 54.6 percent with no ADLs with new cost-related underuse of medical care in 2007.

Table 11 has the logistic regression results of financial, patient, and diagnostic characteristics on the likelihood of new cost-related underuse of medical care in 2007 for the Medicare population that did not have any cost-related underuse of medical care in 2005. The adjusted Wald test statistic of joint probability for the set of measures for financial characteristics ($F(4,475)=11.77$, $P>|F|=0.000$), patient characteristics ($F(13,466)=5.88$, $P>|F|=0.000$) and diagnosis characteristics ($F(8,471)=5.41$,

$P > |F| = 0.000$) show that as a group of variables the sets are associated with new cost-related underuse of medical care. Controlling for all other explanatory measures, Medicare beneficiaries with new drug coverage (AOR=1.6; 95% CI, 1.1-2.5) or continued lack of drug coverage (AOR=1.7; 95% CI, 1.1-2.6) are more likely to have new cost-related underuse of medical care compared to those Medicare beneficiaries with continuous drug coverage from 2005 to 2007. Those with incomes over \$25,000 are less likely to have new cost-related underuse of medical care (AOR=0.3; 95% CI, 0.2-0.5) than those with incomes below \$25,000. Compared to Medicare beneficiaries age 75 years and older, beneficiaries ages 70 to 74 years (AOR=1.7; 95% CI, 1.0-2.9), ages 45 to 64 years (AOR=4.8; 95% CI, 2.8-8.3), or less than 45 years (AOR=3.6; 95% CI, 2.1-6.0) are more likely to have new cost-related underuse of medical care in 2007. Medicare beneficiaries with some college education in comparison to those without a high school degree are more likely to experience new cost-related underuse (AOR=2.0; 95% CI, 1.3-3.1). Beneficiaries with medical histories with depression are more likely to experience new cost-related underuse of medical care (AOR=1.7; 95% CI, 1.2-2.4).

Table 12 presents the adjusted marginal probability of resolved and new cost-related underuse of medical care by financial, patient, and diagnostic characteristics. Predicted probability of resolved cost-related underuse of medical care in 2007 is 0.74 (95% CI, 0.67-0.80) for those Medicare beneficiaries that experienced cost-related underuse of medical care in 2005. Compared to those Medicare beneficiaries with drug coverage in both 2005 and 2007, beneficiaries that drop coverage (have drug coverage in

2005 but do not in 2007) have a higher probability of resolved cost-related underuse of medical care in 2007 (AME=0.14; 95% CI, 0.01-0.26).

As shown in Table 12, the predicted probability of new cost-related underuse of medical care in 2007 is 0.04 (95% CI, 0.04-0.05) for the stratified population of Medicare beneficiaries that did not have any cost-related underuse of medical care in 2005.

Compared to those with continued drug coverage in both 2005 and 2007, Medicare beneficiaries with new drug coverage in 2007 (AME=0.012; 95% CI, 0.0004-0.02) or no drug coverage in 2005 or 2007 (AME=0.014; 95% CI, 0.003-0.03) had higher probability of new cost-related underuse of medical care in 2007. Medicare beneficiaries with incomes over \$25,000 had a lower probability of new cost-related underuse than beneficiaries with incomes below \$25,000 (AME= -0.03; 95% CI, -0.04 - -0.02). In comparison to Medicare beneficiaries ages 75 year and older, disabled Medicare beneficiaries had higher probabilities of new cost-related underuse of medical care (ages 45 to 64 years AME=0.05; 95% CI, 0.03-0.08; less than 45 years AME=0.04; 95% CI, 0.02-0.06). Those with some college education compared to those without any high school education had a 0.02 higher average marginal probability of cost-related underuse of medical care (95% CI, 0.01-0.03). Medicare beneficiaries with medical histories with depression had a higher probability of new cost-related underuse of medical care than those without depression (AME=0.01; 95% CI, 0.004-0.03).

Discussion

Cost-related underuse is a complex phenomenon. As the findings for those newly experiencing cost-related underuse from this study suggest, financial pressures persist,

even with the largest benefit expansion within the Medicare population in recent years that implemented Medicare Part D. The stratified population analyses show, however, that financial pressures, as measure by the financial characteristics of prescription drug coverage and income, were associated with experiencing new cost-related underuse of medical care in 2007 but not for differences between resolved and unresolved underuse of medical care or prescription drugs (as indicated by the adjusted Wald joint probabilities tests).

Recent research¹⁰² has suggested that anticipatory drug behavior may have overestimated the effects of cost-related underuse of prescription drug prior to the implementation of Part D because Medicare beneficiaries knew benefit would start on January 1, 2006. Given that the Medicare Part D legislation passed in 2003 and the 2006 implementation date was widely publicized in news outlets and beneficiary educational outreach materials, Medicare beneficiaries may have “anticipated” their enrollment in the period prior to implementation and modified their drug utilization behavior by forgoing non-essential medications to avoid the higher costs.¹⁰² The model findings for the stratified Medicare population that experienced cost-related underuse of prescription drugs in 2005 did not show that those with newly obtained drug coverage differed from those that did not in the likelihood of resolved or unresolved underuse and do not support the anticipatory behavior theory.

Perspective pieces marking Medicare’s 50th anniversary brought to light the contrast with a key provision of the Affordable Care Act that subsidizes medical coverage for low income populations under 65 while Medicare does not have an out-of-

pocket limit on medical care.^{78,103} The findings from this study that show the differs by income in the likelihood of experiencing new cost-related underuse of medical care, although examining an historic period of the 2006 Part D implementation, add to the current policy discussions of how policy may affect cost-related underuse of medical care within the Medicare population by showing the association with income and coverage.

Figure 2: Study 1 Analytical Sample Construction

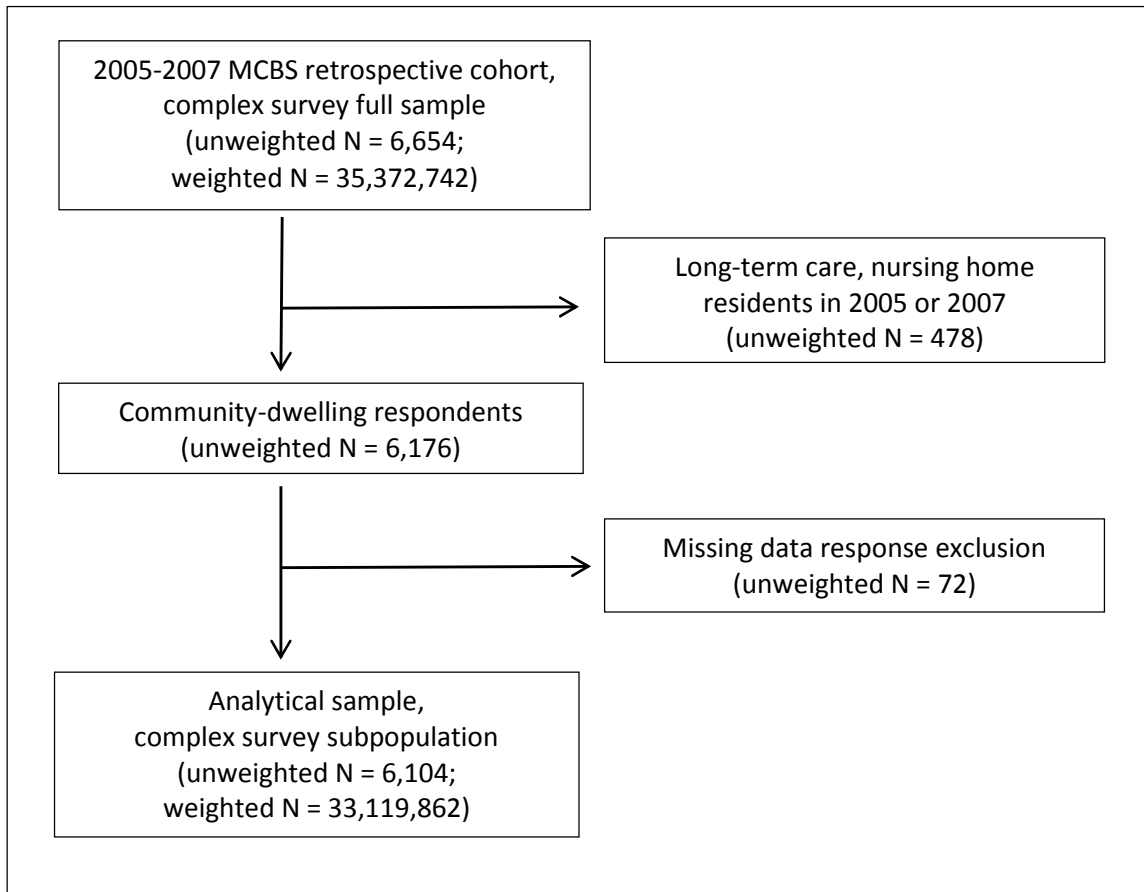
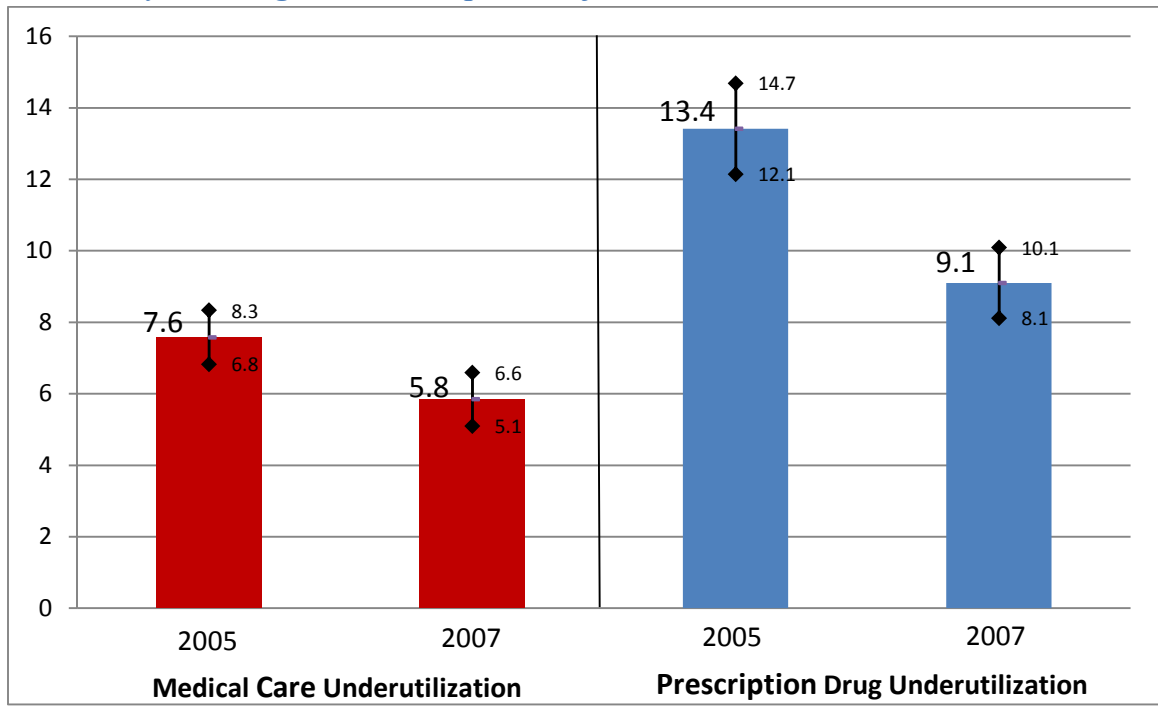


Table 2: Question Wording of Measures Used to Construct Cost-Related Underuse Outcome Variables from the Medicare Current Beneficiary Survey

MCBS Questionnaire Instrument	Question Number	Question Wording [response]
Medical Care Underutilization Due to Cost		
Community Component, Health Status	AC31	In the last year, have you delayed seeking medical care because you were worried about the cost? [yes, no, don't know, refused]
Prescription Drug Underutilization Due to Cost		
Community Component, Satisfaction with Care	SC17	During the past year, were any medicines prescribed for you that you did not get? Which of these reasons explains why you did not obtain the medication? [thought it would cost too much, don't know, refused]
Community Component, Satisfaction with Care	SC20c	Please tell me how often during past year you have taken smaller doses of a medicine to make the medicine last longer? [often, sometimes, never, don't know, refused]
Community Component, Satisfaction with Care	SC20d	Please tell me how often during past year you have skipped doses to make the medicine last longer? [often, sometimes, never, don't know, refused]

Source: Medicare Current Beneficiary Survey (MCBS). 2005. MCBS Main Study – Round 43 – Fall Supplement 2005, Community Component. Baltimore, MD: Centers for Medicare and Medicaid Services.

Figure 3: Unadjusted Rates and 95% Confidence Interval Rates of Cost-Related Underuse of Prescription Drugs or Medical Care within the Continuously-Enrolled, Community-Dwelling Medicare Population from 2005-2007



Note: Data from Medicare Current Beneficiary Survey (MCBS) Access to Care modules. Rates calculated using retrospective longitudinal survey weights. Variance corrected for complex survey design strata and clusters using Taylor Linearization. Differences in rates from 2005 to 2007 are significant at $p < 0.001$.

Table 3: Unadjusted Rates of Cost-Related Underuse of Prescription Drugs in 2007 for the Community-Dwelling Medicare Population Experiencing Cost-Related Underuse of Prescription Drugs in 2005

Variable	Unresolved Cost-Related Underuse	Resolved Cost-Related Underuse	Significance Level
Financial Characteristics			
<i>Drug Coverage</i>			
Continued Coverage	52.0%	49.3%	0.112
New Coverage	24.2%	21.5%	
No Coverage	14.3%	21.6%	
Lose Coverage	9.6%	7.7%	
<i>Income</i>			
Under \$25K	71.0%	71.3%	0.935
Over \$25K	29.0%	28.7%	
Patient Characteristics			
<i>Gender</i>			
Female	67.2%	59.1%	0.052
Male	32.8%	41.0%	
<i>Race/Ethnicity</i>			
White	70.1%	72.8%	0.156
Black	17.3%	12.0%	
Hispanic	6.7%	10.5%	
Other	5.9%	4.8%	
<i>Age</i>			
Less than 45 years	12.2%	6.1%	0.000
45 to 64 years	38.7%	19.7%	
65 to 69 years	17.1%	22.2%	
70 to 74 years	15.2%	19.3%	
75 years and over	16.8%	32.8%	
<i>Education</i>			
No High School	31.2%	36.7%	0.148
High School	22.8%	25.9%	
Some College	32.0%	23.9%	
College Degree	14.0%	13.5%	
<i>Current Employment</i>			
Not Employed	90.4%	88.6%	0.500

Variable	Unresolved Cost- Related Underuse	Resolved Cost- Related Underuse	Significance Level
Employed	9.6%	11.4%	
<i>Geography</i>			
Urban	66.7%	75.5%	0.079
Rural	33.3%	24.5%	
Diagnosis Characteristics			
<i>Self-Reported Health</i>			
Fair/Poor Health	83.7%	68.1%	0.000
Good/Excellent Health	16.3%	31.9%	
<i>Chronic Conditions</i>			
None or One Chronic Condition	26.8%	27.4%	0.585
Two or Three Conditions	46.2%	49.2%	
Four or More Conditions	27.0%	23.4%	
No Depression	52.1%	71.6%	0.000
Depression	47.9%	28.4%	
<i>Mobility</i>			
Instrumental Activities of Daily Living (IADL)			
None	47.0%	61.0%	0.001
One	23.7%	18.5%	
Two or more	29.3%	20.5%	
Activities of Daily Living (ADL)			
None	54.4%	63.4%	0.086
One	16.9%	15.7%	
Two or more	28.7%	21.0%	
Weighted Population	1,211,449	3,007,675	
Percent of Total	28.7%	71.3%	

Note: Data from Medicare Current Beneficiary Survey (MCBS) Access to Care modules. Rates calculated using retrospective longitudinal survey weights. Variance corrected for complex survey design strata and clusters using Taylor Linearization. Significance level from chi-square test statistic reported.

Table 4: Logistic Regression of Resolved Cost-Related Underuse of Prescription Drugs in 2007 for the Community-Dwelling Medicare Population Experiencing Cost-Related Underuse of Prescription Drugs in 2005

Variable	Adjusted Odds Ratio	P> t	95% Confidence Interval	
Financial Characteristics				
<i>Drug Coverage</i>				
Continued Coverage			reference	
New Coverage	1.14	0.517	0.76	1.70
No Coverage	1.45	0.145	0.88	2.38
Lose Coverage	0.73	0.279	0.40	1.30
<i>Income</i>				
Over \$25K	0.83	0.424	0.53	1.31
Patient Characteristics				
<i>Gender</i>				
Male	1.48	0.053	1.00	2.21
<i>Race/Ethnicity</i>				
White			reference	
Black	0.77	0.362	0.44	1.35
Hispanic	1.34	0.402	0.67	2.67
Other	0.94	0.862	0.44	1.99
<i>Age</i>				
Less than 45 years	0.36	0.004	0.18	0.72
45 to 64 years	0.40	0.002	0.22	0.71
65 to 69 years	0.78	0.427	0.43	1.43
70 to 74 years	0.70	0.267	0.37	1.31
75 years and over			reference	
<i>Education</i>				
No High School			reference	
High School	0.93	0.723	0.62	1.39
Some College	0.61	0.051	0.37	1.00
College Degree	0.62	0.117	0.34	1.13
<i>Current Employment</i>				
Employed	0.94	0.851	0.51	1.75
<i>Geography</i>				
Urban			reference	
Rural	0.65	0.080	0.40	1.05

Variable	Adjusted Odds Ratio	P> t	95% Confidence Interval	
Diagnosis Characteristics				
<i>Self-Reported Health</i>				
Fair/Poor Health			reference	
Good/Excellent Health	1.88	0.002	1.26	2.79
<i>Chronic Conditions</i>				
None or One Chronic Condition			reference	
Two or Three Conditions	0.95	0.782	0.63	1.41
Four or More Conditions	0.96	0.884	0.56	1.64
Depression	0.66	0.036	0.44	0.97
<i>Mobility</i>				
Instrumental Activities of Daily Living (IADL)				
None			reference	
One	0.90	0.662	0.57	1.43
Two or more	1.02	0.946	0.61	1.70
Activities of Daily Living (ADL)				
None			reference	
One	1.00	0.998	0.56	1.80
Two or more	0.90	0.658	0.56	1.44
Intercept	5.32	0.000	2.91	9.75

Note: Data from Medicare Current Beneficiary Survey (MCBS) Access to Care modules. Calculated using retrospective longitudinal survey weights. Variance corrected for complex survey design strata and clusters using Taylor Linearization. Model F(25,454)=3.74, P>|F|=0.000. Adjusted Wald test of joint probability for financial characteristics: F(4,475)=1.62, P>|F|=0.167; patient characteristics: F(13,466)=2.58, P>|F|=0.002; diagnosis characteristics: F(8,471)=2.22, P>|F|=0.025.

Table 5: Unadjusted Rates of Cost-Related Underuse of Prescription Drugs in 2007 for the Community-Dwelling Medicare Population Not Experiencing Cost-Related Underuse of Prescription Drugs in 2005

Variable	No Cost-Related Underuse	New Cost-Related Underuse	Significance Level
Financial Characteristics			
<i>Drug Coverage</i>			
Continued Coverage	60.7%	54.9%	0.255
New Coverage	13.5%	15.0%	
No Coverage	17.8%	22.3%	
Lose Coverage	8.0%	7.8%	
<i>Income</i>			
Under \$25K	53.5%	61.6%	0.013
Over \$25K	46.6%	38.4%	
Patient Characteristics			
<i>Gender</i>			
Female	54.0%	61.2%	0.023
Male	46.0%	38.8%	
<i>Race/Ethnicity</i>			
White	80.5%	78.6%	0.047
Black	7.5%	11.7%	
Hispanic	7.4%	4.6%	
Other	4.5%	5.1%	
<i>Age</i>			
Less than 45 years	3.0%	4.7%	0.000
45 to 64 years	9.1%	20.0%	
65 to 69 years	23.0%	23.3%	
70 to 74 years	22.9%	20.3%	
75 years and over	42.0%	31.7%	
<i>Education</i>			
No High School	26.1%	27.7%	0.677
High School	31.4%	33.5%	
Some College	24.4%	22.9%	
College Degree	18.1%	16.0%	
<i>Current Employment</i>			
Not Employed	86.1%	86.4%	0.888

Variable	No Cost-Related Underuse	New Cost-Related Underuse	Significance Level
Employed	13.9%	13.6%	
<i>Geography</i>			
Urban	77.0%	72.9%	0.121
Rural	23.1%	27.1%	
Diagnosis Characteristics			
<i>Self-Reported Health</i>			
Fair/Poor Health	52.3%	70.5%	0.000
Good/Excellent Health	47.7%	29.5%	
<i>Chronic Conditions</i>			
None or One Chronic Condition	32.7%	26.5%	0.089
Two or Three Conditions	46.0%	47.4%	
Four or More Conditions	21.3%	26.2%	
No Depression	83.2%	70.3%	0.000
Depression	16.8%	29.7%	
<i>Mobility</i>			
Instrumental Activities of Daily Living (IADL)			
None	73.0%	63.8%	0.004
One	15.8%	21.1%	
Two or more	11.3%	15.1%	
Activities of Daily Living (ADL)			
None	74.1%	65.3%	0.007
One	12.8%	14.9%	
Two or more	13.2%	19.8%	
Weighted Population	27,281,568	1,619,170	
Percent of Total	94.4%	5.6%	

Note: Data from Medicare Current Beneficiary Survey (MCBS) Access to Care modules. Rates calculated using retrospective longitudinal survey weights. Variance corrected for complex survey design strata and clusters using Taylor Linearization. Significance level from chi-square test statistic reported.

Table 6: Logistic Regression of New Cost-Related Underuse of Prescription Drugs in 2007 for the Community-Dwelling Medicare Population Not Experiencing Cost-Related Underuse of Prescription Drugs in 2005

Variable	Adjusted Odds Ratio	P> t	95% Confidence Interval	
Financial Characteristics				
<i>Drug Coverage</i>				
Continued Coverage			reference	
New Coverage	1.26	0.174	0.90	1.74
No Coverage	1.52	0.017	1.08	2.14
Lose Coverage	1.17	0.622	0.63	2.19
<i>Income</i>				
Over \$25K	0.88	0.400	0.65	1.19
Patient Characteristics				
<i>Gender</i>				
Male	0.70	0.010	0.54	0.92
<i>Race/Ethnicity</i>				
White			reference	
Black	1.34	0.216	0.84	2.12
Hispanic	0.55	0.053	0.30	1.01
Other	1.16	0.642	0.62	2.15
<i>Age</i>				
Less than 45 years	1.81	0.013	1.13	2.89
45 to 64 years	2.20	0.000	1.50	3.23
65 to 69 years	1.44	0.010	1.09	1.89
70 to 74 years	1.26	0.210	0.88	1.81
75 years and over			reference	
<i>Education</i>				
No High School			reference	
High School	1.02	0.891	0.75	1.40
Some College	0.94	0.775	0.63	1.42
College Degree	1.10	0.650	0.73	1.67
<i>Current Employment</i>				
Employed	1.16	0.479	0.77	1.76
<i>Geography</i>				
Urban			reference	
Rural	1.11	0.476	0.83	1.48

Variable	Adjusted Odds Ratio	P> t	95% Confidence Interval	
Diagnosis Characteristics				
<i>Self-Reported Health</i>				
Fair/Poor Health			reference	
Good/Excellent Health	0.59	0.001	0.43	0.81
<i>Chronic Conditions</i>				
None or One Chronic Condition			reference	
Two or Three Conditions	1.20	0.303	0.85	1.69
Four or More Conditions	1.22	0.302	0.84	1.77
Depression	1.53	0.014	1.09	2.15
<i>Mobility</i>				
Instrumental Activities of Daily Living (IADL)				
None			reference	
One	1.12	0.494	0.81	1.53
Two or more	0.85	0.425	0.57	1.27
Activities of Daily Living (ADL)				
None			reference	
One	1.07	0.742	0.73	1.56
Two or more	1.26	0.265	0.84	1.91
Intercept	0.05	0.000	0.03	0.08

Note: Data from Medicare Current Beneficiary Survey (MCBS) Access to Care modules. Calculated using retrospective longitudinal survey weights. Variance corrected for complex survey design strata and clusters using Taylor Linearization. Model $F(25,454)=3.92$, $P>|F|=0.000$. Adjusted Wald test of joint probability for financial characteristics: $F(4,475)=1.82$, $P>|F|=0.123$; patient characteristics: $F(13,466)=2.68$, $P>|F|=0.001$; diagnosis characteristics: $F(8,471)=4.18$, $P>|F|=0.000$.

Table 7: Adjusted Marginal Probability of Cost-Related Underuse of Prescription Drugs in 2007 for Community-Dwelling Medicare Population Stratified by Cost-Related Underuse of Prescription Drugs in 2005

Variable	Resolved Underuse Compared to Unresolved Cost-Related Underuse in 2007 for Subpopulation with Cost-Related Underuse of Prescription Drugs in 2005				New Cost-Related Underuse Compared to No Cost-Related Underuse in 2007 for Subpopulation with No Cost-Related Underuse of Prescription Drugs in 2005				
	AME	P> t	95% Confidence Interval		AME	P> t	95% Confidence Interval		
Financial Characteristics									
<i>Drug Coverage</i>									
			reference				reference		
	Continued Coverage								
	New Coverage	0.0217	0.509	-0.0427	0.0861	0.0117	0.188	-0.0057	0.0292
	No Coverage	0.0566	0.127	-0.0160	0.1291	0.0234	0.027	0.0026	0.0442
	Lose Coverage	-0.0597	0.307	-0.1742	0.0549	0.0079	0.641	-0.0251	0.0408
	<i>Income</i>								
	Over \$25K	-0.0307	0.434	-0.1076	0.0462	-0.0066	0.397	-0.0218	0.0087
Patient Characteristics									
<i>Gender</i>									
	Male	0.0640	0.050	0.0001	0.1280	-0.0180	0.008	-0.0313	-0.0047
<i>Race/Ethnicity</i>									
	White			reference				reference	
	Black	-0.0457	0.385	-0.1487	0.0574	0.0173	0.259	-0.0127	0.0474
	Hispanic	0.0443	0.364	-0.0513	0.1399	-0.0244	0.014	-0.0437	-0.0050

Variable	Resolved Underuse Compared to Unresolved Cost-Related Underuse in 2007 for Subpopulation with Cost-Related Underuse of Prescription Drugs in 2005				New Cost-Related Underuse Compared to No Cost-Related Underuse in 2007 for Subpopulation with No Cost-Related Underuse of Prescription Drugs in 2005			
	AME	P> t	95% Confidence Interval		AME	P> t	95% Confidence Interval	
<i>Self-Reported Health</i>								
Fair/Poor Health			reference				reference	
Good/Excellent Health	0.1015	0.001	0.0404	0.1627	-0.0265	0.001	-0.0423	-0.0108
<i>Chronic Conditions</i>								
None or One Chronic Condition			reference				reference	
Two or Three Conditions	-0.0093	0.781	-0.0745	0.0559	0.0091	0.300	-0.0081	0.0262
Four or More Conditions	-0.0065	0.884	-0.0942	0.0812	0.0100	0.306	-0.0091	0.0291
Depression	-0.0744	0.044	-0.1468	-0.0020	0.0249	0.025	0.0031	0.0466
<i>Mobility</i>								
Instrumental Activities of Daily Living (IADL)								
None			reference				reference	
One	-0.0174	0.668	-0.0970	0.0622	0.0060	0.507	-0.0118	0.0238
Two or more	0.0029	0.946	-0.0803	0.0861	-0.0079	0.404	-0.0264	0.0106
Activities of Daily Living (ADL)								
None			reference				reference	

Variable	Resolved Underuse Compared to Unresolved Cost-Related Underuse in 2007 for Subpopulation with Cost-Related Underuse of Prescription Drugs in 2005				New Cost-Related Underuse Compared to No Cost-Related Underuse in 2007 for Subpopulation with No Cost-Related Underuse of Prescription Drugs in 2005			
	AME	P> t	95% Confidence Interval		AME	P> t	95% Confidence Interval	
One	0.0001	0.998	-0.0956	0.0958	0.0033	0.746	-0.0165	0.0230
Two or more	-0.0178	0.663	-0.0980	0.0623	0.0130	0.292	-0.0112	0.0371

Note: AME is Average Marginal Effect, at means. Probabilities constructed from Tables 4 and 6 logistic regression model estimates with marginal effects calculated with other variables at mean values. Data from Medicare Current Beneficiary Survey (MCBS) Access to Care modules. Calculated using retrospective longitudinal survey weights. Variance corrected for complex survey design strata and clusters using Taylor Linearization. Predicted probability of resolved cost-related underuse of prescription drugs in 2007 is 0.77 (95% Confidence Interval (CI): 0.74-0.81, P>0.000). Predicted probability of new cost-related underuse of prescription drugs in 2007 is 0.06 (95% CI: 0.06-0.07, P>0.000).

Table 8: Unadjusted Rates of Cost-Related Underuse of Medical Care in 2007 for the Community-Dwelling Medicare Population Experiencing Cost-Related Underuse of Medical Care in 2005

Variable	Unresolved Cost-Related Underuse	Resolved Cost-Related Underuse	Significance Level
Financial Characteristics			
<i>Drug Coverage</i>			
Continued Coverage	41.0%	48.0%	0.038
New Coverage	25.3%	25.0%	
No Coverage	32.1%	21.4%	
Lose Coverage	1.6%	5.6%	
<i>Income</i>			
Under \$25K	78.1%	79.4%	0.779
Over \$25K	21.9%	20.6%	
Patient Characteristics			
<i>Gender</i>			
Female	55.1%	58.5%	0.562
Male	44.9%	41.5%	
<i>Race/Ethnicity</i>			
White	75.0%	69.0%	0.402
Black	12.7%	15.5%	
Hispanic	6.0%	10.8%	
Other	6.4%	4.6%	
<i>Age</i>			
Less than 45 years	16.6%	11.1%	0.011
45 to 64 years	42.1%	28.3%	
65 to 69 years	18.2%	29.1%	
70 to 74 years	13.3%	15.9%	
75 years and over	9.8%	15.7%	
<i>Education</i>			
No High School	29.4%	39.5%	0.295
High School	25.7%	22.2%	
Some College	31.4%	28.4%	

Variable	Unresolved Cost- Related Underuse	Resolved Cost- Related Underuse	Significance Level
College Degree	13.6%	10.0%	
<i>Current Employment</i>			
Not Employed	89.3%	87.5%	0.588
Employed	10.8%	12.5%	
<i>Geography</i>			
Urban	70.0%	70.2%	0.983
Rural	30.0%	29.9%	
Diagnosis Characteristics			
<i>Self-Reported Health</i>			
Fair/Poor Health	81.2%	76.1%	0.265
Good/Excellent Health	18.8%	23.9%	
<i>Chronic Conditions</i>			
None or One Chronic Condition	36.6%	27.7%	0.090
Two or Three Conditions	38.2%	51.3%	
Four or More Conditions	25.3%	21.0%	
<i>Mobility</i>			
Instrumental Activities of Daily Living (IADL)			
None	45.2%	51.7%	0.416
One	20.6%	20.3%	
Two or more	34.3%	28.1%	
Activities of Daily Living (ADL)			
None	48.6%	52.9%	0.153
One	14.8%	20.3%	
Two or more	36.6%	26.8%	
Weighted Population	760,100	1,613,091	
Percent of Total	32.0%	68.0%	

Note: Data from Medicare Current Beneficiary Survey (MCBS) Access to Care modules. Rates calculated using retrospective longitudinal survey weights. Variance corrected for complex survey design strata and clusters using Taylor Linearization. Significance level from chi-square test statistic reported.

Table 9: Logistic Regression of Resolved Cost-Related Underuse of Medical Care in 2007 for the Community-Dwelling Medicare Population Experiencing Cost-Related Underuse of Medical Care in 2005

Variable	Adjusted Odds Ratio	P> t	95% Confidence Interval	
Financial Characteristics				
<i>Drug Coverage</i>				
Continued Coverage	0.35	0.095	0.10	1.20
New Coverage	0.29	0.063	0.79	1.07
No Coverage	0.19	0.020	0.05	0.77
Lose Coverage			reference	
<i>Income</i>				
Over \$25K	0.97	0.920	0.51	1.82
Patient Characteristics				
<i>Gender</i>				
Male	0.96	0.848	0.60	1.53
<i>Race/Ethnicity</i>				
White			reference	
Black	1.28	0.586	0.53	3.08
Hispanic	1.63	0.352	0.58	4.61
Other	0.73	0.452	0.32	1.66
<i>Age</i>				
Less than 45 years	0.53	0.203	0.20	1.41
45 to 64 years	0.48	0.131	0.19	1.24
65 to 69 years	1.11	0.826	0.44	2.78
70 to 74 years	0.69	0.547	0.21	2.29
75 years and over			reference	
<i>Education</i>				
No High School			reference	
High School	0.77	0.470	0.38	1.56
Some College	0.84	0.618	0.42	1.67
College Degree	0.58	0.159	0.27	1.24
<i>Current Employment</i>				
Employed	0.95	0.887	0.48	1.88
<i>Geography</i>				

Variable	Adjusted Odds Ratio	P> t	95% Confidence Interval	
Urban		reference		
Rural	0.98	0.937	0.57	1.68
Diagnosis Characteristics				
<i>Self-Reported Health</i>				
Fair/Poor Health		reference		
Good/Excellent Health	0.94	0.844	0.51	1.73
<i>Chronic Conditions</i>				
None or One Chronic Condition		reference		
Two or Three Conditions	1.67	0.106	0.90	3.11
Four or More Conditions	1.07	0.845	0.54	2.12
Depression	0.73	0.248	0.42	1.25
<i>Mobility</i>				
Instrumental Activities of Daily Living (IADL)				
None		reference		
One	1.07	0.829	0.58	1.97
Two or more	1.09	0.780	0.61	1.93
Activities of Daily Living (ADL)				
None		reference		
One	1.28	0.510	0.62	2.64
Two or more	0.72	0.328	0.38	1.38
Intercept	4.03	0.015	1.31	12.39

Note: Data from Medicare Current Beneficiary Survey (MCBS) Access to Care modules. Calculated using retrospective longitudinal survey weights. Variance corrected for complex survey design strata and clusters using Taylor Linearization. Model $F(25,436)=2.10$, $P>|F|=0.002$. Adjusted Wald test of joint probability for financial characteristics: $F(4,457)=1.61$, $P>|F|=0.171$; patient characteristics: $F(13,448)=1.42$, $P>|F|=0.147$; diagnosis characteristics: $F(8,453)=0.94$, $P>|F|=0.480$.

Table 10: Unadjusted Rates of Cost-Related Underuse of Medical Care in 2007 for the Community-Dwelling Medicare Population Not Experiencing Cost-Related Underuse of Medical Care in 2005

Variable	No Cost-Related Underuse	New Cost-Related Underuse	Significance Level
Financial Characteristics			
<i>Drug Coverage</i>			
Continued Coverage	60.4%	50.2%	0.006
New Coverage	13.6%	21.0%	
No Coverage	17.6%	22.3%	
Lose Coverage	8.4%	6.5%	
<i>Income</i>			
Under \$25K	53.4%	81.3%	0.000
Over \$25K	46.6%	18.7%	
Patient Characteristics			
<i>Gender</i>			
Female	55.1%	59.1%	0.327
Male	44.9%	40.9%	
<i>Race/Ethnicity</i>			
White	80.3%	71.6%	0.012
Black	7.8%	14.9%	
Hispanic	7.4%	8.0%	
Other	4.5%	5.5%	
<i>Age</i>			
Less than 45 years	2.8%	8.4%	0.000
45 to 64 years	9.1%	36.9%	
65 to 69 years	22.8%	15.2%	
70 to 74 years	22.9%	17.5%	
75 years and over	42.4%	22.0%	
<i>Education</i>			
No High School	26.6%	28.6%	0.002
High School	31.5%	23.9%	
Some College	23.8%	35.1%	

Variable	No Cost-Related Underuse	New Cost-Related Underuse	Significance Level
College Degree	18.1%	12.5%	
<i>Current Employment</i>			
Not Employed	86.3%	88.0%	0.521
Employed	13.7%	12.0%	
<i>Geography</i>			
Urban	76.9%	70.5%	0.072
Rural	23.1%	29.5%	
Diagnosis Characteristics			
<i>Self-Reported Health</i>			
Fair/Poor Health	53.4%	74.5%	0.000
Good/Excellent Health	46.6%	25.5%	
<i>Chronic Conditions</i>			
None or One Chronic Condition	31.7%	32.7%	0.014
Two or Three Conditions	46.7%	37.2%	
Four or More Conditions	21.7%	30.1%	
<i>Mobility</i>			
Instrumental Activities of Daily Living (IADL)			
None	72.7%	53.5%	0.000
One	16.1%	21.8%	
Two or more	11.2%	24.6%	
Activities of Daily Living (ADL)			
None	74.2%	54.6%	0.000
One	12.8%	16.5%	
Two or more	13.1%	29.0%	
Weighted Population	29,689,844	1,056,827	
Percent of Total	96.6%	3.4%	

Note: Data from Medicare Current Beneficiary Survey (MCBS) Access to Care modules. Rates calculated using retrospective longitudinal survey weights. Variance corrected for complex survey design strata and clusters using Taylor Linearization. Significance level from chi-square test statistic reported.

Table 11: Logistic Regression of New Cost-Related Underuse of Medical Care in 2007 for the Community-Dwelling Medicare Population Not Experiencing Cost-Related Underuse of Medical Care in 2005

Variable	Adjusted Odds Ratio	P> t	95% Confidence Interval	
Financial Characteristics				
<i>Drug Coverage</i>				
Continued Coverage			reference	
New Coverage	1.64	0.021	1.08	2.50
No Coverage	1.73	0.010	1.14	2.62
Lose Coverage	1.15	0.656	0.63	2.09
<i>Income</i>				
Over \$25K	0.32	0.000	0.22	0.49
Patient Characteristics				
<i>Gender</i>				
Male	0.80	0.210	0.56	1.13
<i>Race/Ethnicity</i>				
White			reference	
Black	1.36	0.264	0.79	2.33
Hispanic	0.81	0.459	0.46	1.42
Other	1.15	0.704	0.55	2.40
<i>Age</i>				
Less than 45 years	3.60	0.000	2.14	6.04
45 to 64 years	4.82	0.000	2.81	8.28
65 to 69 years	1.55	0.108	0.91	2.64
70 to 74 years	1.72	0.044	1.02	2.92
75 years and over			reference	
<i>Education</i>				
No High School			reference	
High School	0.89	0.563	0.60	1.32
Some College	2.00	0.001	1.31	3.06
College Degree	1.58	0.123	0.88	2.82
<i>Current Employment</i>				
Employed	1.28	0.291	0.81	2.03
<i>Geography</i>				

Variable	Adjusted Odds Ratio	P> t	95% Confidence Interval	
Urban			reference	
Rural	1.23	0.328	0.81	1.86
Diagnosis Characteristics				
<i>Self-Reported Health</i>				
Fair/Poor Health			reference	
Good/Excellent Health	0.77	0.208	0.51	1.16
<i>Chronic Conditions</i>				
None or One Chronic Condition			reference	
Two or Three Conditions	0.80	0.288	0.53	1.21
Four or More Conditions	1.10	0.692	0.69	1.74
Depression	1.71	0.002	1.22	2.39
<i>Mobility</i>				
Instrumental Activities of Daily Living (IADL)				
None			reference	
One	1.07	0.709	0.76	1.49
Two or more	1.06	0.827	0.61	1.85
Activities of Daily Living (ADL)				
None			reference	
One	1.37	0.244	0.81	2.31
Two or more	1.75	0.059	0.98	3.14
Intercept	0.02	0.000	0.01	0.03

Note: Data from Medicare Current Beneficiary Survey (MCBS) Access to Care modules. Calculated using retrospective longitudinal survey weights. Variance corrected for complex survey design strata and clusters using Taylor Linearization. Model $F(25,454)=12.16$, $P>|F|=0.000$. Adjusted Wald test of joint probability for financial characteristics: $F(4,475)=11.77$, $P>|F|=0.000$; patient characteristics: $F(13,466)=5.88$, $P>|F|=0.000$; diagnosis characteristics: $F(8,471)=5.41$, $P>|F|=0.000$.

Table 12: Adjusted Marginal Probability of Cost-Related Underuse of Medical Care in 2007 for Community-Dwelling Medicare Population Stratified by Cost-Related Underuse of Medical Care in 2005

Variable	Resolved Underuse Compared to Unresolved Cost-Related Underuse in 2007 for Subpopulation with Cost-Related Underuse of Medical Care in 2005				New Cost-Related Underuse Compared to No Cost-Related Underuse in 2007 for Subpopulation with No Cost-Related Underuse of Medical Care in 2005				
	AME	P> t	95% Confidence Interval		AME	P> t	95% Confidence Interval		
Financial Characteristics									
<i>Drug Coverage</i>									
			reference				reference		
	Continued Coverage								
	New Coverage	-0.0374	0.495	-0.1448	0.0701	0.0124	0.043	0.0004	0.0243
	No Coverage	-0.1273	0.051	-0.2550	0.0005	0.0139	0.017	0.0025	0.0254
	Lose Coverage	0.1371	0.032	0.0120	0.2621	0.0028	0.670	-0.0102	0.0159
	<i>Income</i>								
	Over \$25K	-0.0060	0.921	-0.1236	0.1116	-0.0255	0.000	-0.0350	-0.0159
Patient Characteristics									
<i>Gender</i>									
	Male	-0.0085	0.848	-0.0953	0.0784	-0.0051	0.211	-0.0132	0.0029
<i>Race/Ethnicity</i>									
	White			reference				reference	
	Black	0.0433	0.563	-0.1033	0.1899	0.0081	0.312	-0.0076	0.0239

Variable	Resolved Underuse Compared to Unresolved Cost-Related Underuse in 2007 for Subpopulation with Cost-Related Underuse of Medical Care in 2005					New Cost-Related Underuse Compared to No Cost-Related Underuse in 2007 for Subpopulation with No Cost-Related Underuse of Medical Care in 2005			
	AME	P> t	95% Confidence Interval		AME	P> t	95% Confidence Interval		
	Hispanic	0.0813	0.291	-0.0695	0.2321	-0.0044	0.429	-0.0152	0.0065
	Other	-0.0637	0.476	-0.2388	0.1114	0.0035	0.717	-0.0153	0.0223
<i>Age</i>	Less than 45 years	-0.1275	0.183	-0.3150	0.0601	0.0377	0.001	0.0164	0.0591
	45 to 64 years	-0.1460	0.108	-0.3239	0.0319	0.0545	0.000	0.0290	0.0801
	65 to 69 years	0.0169	0.829	-0.1365	0.1702	0.0082	0.128	-0.0024	0.0188
	70 to 74 years	-0.0681	0.540	-0.2859	0.1498	0.0108	0.066	-0.0007	0.0223
	75 years and over		reference				reference		
<i>Education</i>	No High School		reference				reference		
	High School	-0.0458	0.474	-0.1711	0.0796	-0.0021	0.571	-0.0093	0.0051
	Some College	-0.0300	0.626	-0.1509	0.0908	0.0187	0.002	0.0071	0.0302
	College Degree	-0.1031	0.175	-0.2520	0.0458	0.0108	0.148	-0.0038	0.0255
<i>Current Employment</i>	Employed	-0.0092	0.889	-0.1376	0.1192	0.0063	0.329	-0.0064	0.0190
<i>Geography</i>	Urban		reference				reference		

Variable	Resolved Underuse Compared to Unresolved Cost-Related Underuse in 2007 for Subpopulation with Cost-Related Underuse of Medical Care in 2005				New Cost-Related Underuse Compared to No Cost-Related Underuse in 2007 for Subpopulation with No Cost-Related Underuse of Medical Care in 2005			
	AME	P> t	95% Confidence Interval		AME	P> t	95% Confidence Interval	
Rural	-0.0040	0.938	-0.1036	0.0957	0.0051	0.361	-0.0058	0.0160
Diagnosis Characteristics								
<i>Self-Reported Health</i>								
Fair/Poor Health			reference				reference	
Good/Excellent Health	-0.0113	0.845	-0.1241	0.1016	-0.0060	0.206	-0.0154	0.0033
<i>Chronic Conditions</i>								
None or One Chronic Condition			reference				reference	
Two or Three Conditions	0.0945	0.120	-0.0246	0.2135	-0.0051	0.303	-0.0147	0.0046
Four or More Conditions	0.0140	0.844	-0.1258	0.1538	0.0024	0.694	-0.0097	0.0145
<i>Mobility</i>								
Instrumental Activities of Daily Living (IADL)								
None			reference				reference	
One	0.0124	0.826	-0.0981	0.1228	0.0015	0.711	-0.0064	0.0094
Two or more	0.0150	0.776	-0.0883	0.1183	0.0014	0.830	-0.0117	0.0146
Activities of Daily Living (ADL)								
None			reference				reference	

Variable	Resolved Underuse Compared to Unresolved Cost-Related Underuse in 2007 for Subpopulation with Cost-Related Underuse of Medical Care in 2005				New Cost-Related Underuse Compared to No Cost-Related Underuse in 2007 for Subpopulation with No Cost-Related Underuse of Medical Care in 2005			
	AME	P> t	95% Confidence Interval		AME	P> t	95% Confidence Interval	
One	0.0418	0.497	-0.0787	0.1622	0.0075	0.287	-0.0063	0.0212
Two or more	-0.0638	0.344	-0.1959	0.0683	0.0153	0.113	-0.0036	0.0341

Note: AME is Average Marginal Effect, at means. Probabilities constructed from Tables 9 and 11 logistic regression model estimates with marginal effects calculated with other variables at mean values. Data from Medicare Current Beneficiary Survey (MCBS) Access to Care modules. Calculated using retrospective longitudinal survey weights. Variance corrected for complex survey design strata and clusters using Taylor Linearization. Predicted probability of resolved cost-related underuse of medical care in 2007 is 0.74 (95% Confidence Interval (CI): 0.67-0.80, P>0.000). Predicted probability of new cost-related underuse of medical care in 2007 is 0.04 (95% CI: 0.04-0.05, P>0.000).

Study 2: Drug Adherence Before and After Enrollment in Medicare Part D Partial Low Income Subsidy

Summary for Study 2

Objectives: To evaluate the Medicare Partial Low Income Subsidy (LIS) benefit and to determine its association with prescription drug adherence for three therapeutic cohorts of beneficiaries prescribed statins, oral anti-diabetic agents, or proton pump inhibitors.

Background: The partial LIS benefit has three levels of premium subsidization (25%, 50%, 75%) based on the beneficiary's income level and enrollees face the same uniform 15% coinsurance level and small deductible.

Data: Medicare administrative enrollment and claims data are used from the national 5% enhanced sample from 2006 through 2010.

Methods: Medicare beneficiaries continuously enrolled in the stand alone prescription drug plans in the Part D benefit that transition from the non-LIS to partial LIS enrollment at any time during the initial implementation of Part D in 2006 through the end of the

study data in December 2010 are the analytical cohort. Three therapeutic cohorts are selected from the enrollment analytical file based on having prescription drug fills in the pre- and post-partial LIS enrollment periods for proton pump inhibitors, statins, or oral anti-diabetic medications. Demographic measures, health risk adjusters, and Part D plan and benefit variables are used as explanatory variables. A regression analysis examines the relationship of the explanatory measures and before and after partial LIS enrollment change in prescription drug proportional days covered (PDC) adherence measure for each therapeutic cohort.

Results: After enrollment in the partial LIS benefit, average unadjusted adherence levels increased 0.24 (95% confidence interval (CI), 0.21-0.27) for proton pump inhibitors (PPIs), 0.19 (95% CI, 0.17-0.21) for statins, and 0.12 (95% CI, 0.09-0.15) for oral anti-diabetic medications. On average, the oral anti-diabetic therapeutic cohort was adherent, as measured by PDC greater than 0.80, post-partial LIS enrollment but the other two cohorts, although improved, were not at adherent levels on average. Comparing change in adherence among the three premium subsidization groups found insignificant differences for the statin and oral anti-diabetic cohorts, but the 25% premium subsidization group within the PPI cohort had a 0.07 (95% CI, 0.006-0.14) increase in adherence compared to

the 50% subsidization group, adjusted for other financial, patient, and diagnostic characteristics. Partial LIS enrollees residing in more competitive Part D plan markets had lower adjusted change in PPI adherence ($\beta = -0.02$; 95% CI, -0.06 - -0.0001), in statin adherence levels ($\beta = -0.04$; 95% CI, -0.06 - -0.02), and in oral anti-diabetic ($\beta = -0.04$; 95% CI, -0.06 - -0.005) adherence, which suggests they may have experienced less cost pressure during the pre-transition period.

Conclusions: Overall, partial LIS enrollees improved adherence rates following enrollment in the benefit in the three therapeutic classes most likely to have cost-related underuse.

Introduction

The Centers for Medicare and Medicaid Services (CMS) estimate that approximately 20 percent of Medicare beneficiaries eligible to receive extra help with premium subsidies and drug cost sharing have not applied for the Low Income Subsidy benefit.⁴⁹ Cost-related underuse has had marginal declines within the Medicare population since the implementation of Part D, but a sizeable number of eligible beneficiaries have not enrolled within the LIS benefit and are experiencing higher out-of-pocket costs when they may qualify for premium or cost-sharing assistance. A survey of potentially LIS eligible seniors found that 77% were not aware of the subsidy availability, 83% did not know how to apply for it, and 48% were reluctant to apply for a “welfare” program,¹⁰⁴ which suggests some Medicare beneficiaries may be experiencing higher cost sharing and monthly premiums for drug coverage that may unnecessarily lead to cost-related underuse. Overall self-reported, cost-related underuse of prescription drugs has declined slightly within the Medicare populations since expansion of coverage and the implementation of Medicare Part D; however, Medicare beneficiaries with multiple chronic conditions and higher drug utilization remain vulnerable to skipping doses, splitting pills, or delaying refills due to limited income.⁸²⁻⁸⁴ In this study, we examine Part D enrollees’ prescription drug behavior before and after enrollment in the Partial

Low Income Subsidy program to evaluate whether premium assistance and reduced cost-sharing provided by the benefit is associated with better adherence to prescribed drug therapy regimens.

Policy Background of Partial Low Income Subsidy Program

The Low Income Subsidy (LIS) program provides premium payment assistance and reduced cost-sharing/co-payment rates for Medicare Part D beneficiaries who qualify based on income and asset levels. The income limits for LIS qualification are up to 150% of the federal poverty limit (FPL) and, in 2011, assets that do not exceed \$12,640 for individuals or \$25,260 for married couples. Medicare beneficiaries who are dually enrolled in Medicaid, Medicare Savings Program (MSP), or Supplemental Security Income (SSI) are auto-enrolled or deemed into LIS and receive a full 100% premium subsidy. Non-deemed LIS recipients must apply for program enrollment and receive premium assistance on a sliding scale based on their income level. In addition to premium and cost-sharing assistance, LIS program enrollees do not experience the coverage gap during the year and may change drug plans at any time.

Partial LIS enrollees are non-deemed LIS beneficiaries divided into three categories of premium subsidization amounts based on income. The 25%, 50%, and 75% premium subsidization categories are based on qualification into the categories by 5%

increments of income between 135% and 150% of the federal poverty level. Partial LIS enrollees have the same asset level threshold for qualification. All partial LIS beneficiaries have a uniform, small deductible (e.g., \$63 in 2010) and 15% coinsurance rate for prescription drugs. Variation among the three groups is solely the differences in income levels and premium subsidization amounts.

Health services research examining LIS has addressed enrollment differences and eligibility rates¹⁰⁵⁻¹⁰⁹ but has not examined specific prescription drug behavioral outcomes for the partial LIS program population. Instead, most research on the LIS population has been examined using it as a control population of Part D beneficiaries who do not face the coverage gap or donut hole and examined as a broad population rather than individual LIS categories.¹¹⁰⁻¹¹⁵ Examining the LIS population as a single group is similar to how Medicare/Medicaid dual eligible beneficiaries were examined before Medicare Part D and does not distinguish the programmatic differences within these two groups based on qualification differences in enrollment. Lin, et al.,¹¹⁶ notable for its analytical comparison of the LIS cost sharing groups, examine drug initiation of osteoporosis medications comparing full and partial LIS categories with non-LIS Part D beneficiaries and did not find differences in out-of-pocket expenses affecting initiation. Survey analysis of self-reported cost-related drug underuse has shown that LIS

enrollment is associated with reduced underuse,^{117,118} but prescription drug adherence has not been examined by LIS enrollment categories, such as the partial LIS benefit.

Partial LIS enrollees are approximately 13% of all LIS beneficiaries, but it is estimated that only 40% of those eligible for the non-deemed LIS benefit are enrolled.¹⁰⁹ With 60% of the eligible population not enrolled, a large number of new partial LIS enrollees may be more likely to have experienced cost-related underuse of prescription drugs prior to enrolling for the benefit.

Given the relationship between cost-related underuse and Medicare beneficiaries with limited resources, the objective of this paper is to examine medication adherence levels before and after enrollment in the partial LIS benefit. The partial LIS benefit provides premium subsidization and cost-sharing assistance for the enrolled beneficiaries, and it is expected, therefore, that adherence, as measured by the proportion of days covered (PDC), will improve with partial LIS enrollment.

Research Design

Data

The Chronic Condition Warehouse (CCW) 5% enhanced sample from 2006 through 2010 is used to examine prescription drug adherence for the non-deemed, partial LIS recipients with a comparison before and after enrollment. The administrative

Medicare files used in the analysis are the denominator data, prescription drug event (PDE) file, Minimum Data Set (MDS) long-term care assessment, MedPAR, and the plan characteristics data. The Part D Denominator file is used to identify enrollment in Part D and the partial LIS benefit and includes beneficiary demographic data. The MDS data are used to identify and exclude nursing home residents. MedPAR data are used for diagnosis and hospitalizations information. The PDE data are merged with RxNorm to determine the drug therapy cohorts and used to determine their corresponding adherence levels. Health risk adjusters are computed using the AHRQ comorbidity index constructed from the MedPAR data files. The plan characteristics data provide information on the types of Part D plans, such as enhanced benefit plans or stand-alone prescription drug plans (PDPs) and Medicare Advantage prescription drug plans (MAPDs). All Medicare claims data used in the analysis were obtained from the Centers for Medicare and Medicaid Services (CMS) prior to the current substance use disorder (SUD) suppression,¹¹⁹ and study results are not affected by missing SUD data.

Study Sample

The analytical extracts for the enrollment cohorts selected all beneficiaries during the five years of data that were continuously enrolled first in the Part D program but not in the LIS benefit and then enrolled in the partial LIS benefit consecutively. Only those

beneficiaries who transition from non-LIS Part D enrollment one month to partial LIS status the next month are included in the analysis, but that transition may occur at any time during the 2006 to 2010 period. The post partial LIS enrollment period ends when the data ends in 2010 or if the beneficiary is no longer enrolled within the partial LIS categories due to disenrollment in Part D, transition to full LIS, return transition to non-LIS Part D enrollment, or death. Beneficiaries who are not enrolled in the Part D benefit, are enrolled in an MA-PD, or are enrolled in the full LIS benefit prior to a transition into the partial LIS program are not included in the analysis.

Figure 4 provides a flow chart illustration of the construction of the analytical sample for Study 2. Within the enhanced 5% Medicare sample, there are 1,985,653 Part D Medicare beneficiaries from 2006 through 2010. Medicare beneficiaries who enter the partial LIS benefit at their initiation of their Part D enrollment are excluded from the analysis (n=38,488 beneficiaries), and beneficiaries who are deemed into the full LIS benefit without any preceding partial LIS transition from Part D are also excluded (n=780,974 beneficiaries). Long-term care and nursing home residents (n=160,918 beneficiaries) are excluded because their prescription drug behavior is monitored by their residential institution. Lastly, MA-PD enrollees are excluded because their hospital encounter data are not fully included within the MedPAR data file that is used for

adjusting the outcome variable and determining chronic condition co-morbidities. The final analytical file is composed of 552,511 Medicare Part D beneficiaries who are community-dwelling, FFS-enrolled, and do not have any prior LIS transitions. From this analytical population, a total of 3,322 beneficiaries transition from Medicare Part D into the partial LIS program from 2006 through 2010. Of these 3,322 beneficiaries, 1,005 have a proton pump inhibitor filled before and after the transition, 1,606 have a statin filled in both periods, and 747 beneficiaries have oral anti-diabetic medication fills pre- and post-partial LIS transition. The consecutive periods before and after enrollment in the partial LIS benefit are used for extracting the corresponding prescription drug data, demographic, plan, and enrollment variables.

Therapeutic Classes

Therapeutic classes were selected based on medications most likely to not be filled due to cost concerns. The Medicare Current Beneficiary Survey (MCBS) began asking about cost-related underuse in 1997 and collected the prescription drug name that was not filled due to concerns about the cost of the medication. By pooling this data from multiple years of MCBS, the frequency of top medication classes most likely to have cost-related underuse are: (1) gastrointestinal agents, (2) statins, (3) anti-depressants, and (4) oral anti-diabetics. After consultation with project advisors, the three therapeutic drug

classes examined in this study were selected as proton pump inhibitors, statins, and oral anti-diabetics.

The selection of therapeutic beneficiary cohorts is from prescription drug data in the PDE data files that are merged with RxNorm to select three therapeutic classes of drugs - statins, oral anti-diabetics, and gastrointestinal agents - to use for comparison of clinical cohorts of the partial LIS beneficiary sample. RxNorm classifies the 11-digit national drug codes (NDCs) by common code for active ingredients.¹²⁰ The active ingredients used to select the therapeutic cohorts are listed in Table 13. To be included in the clinical cohorts, beneficiaries had to have at least one prescription drug fill for the class in both the pre- and post-enrollment periods.

Outcome Variables

The proportional days covered (PDC) was calculated to measure the adherence level for each period and drug class.¹²¹⁻¹²³ The construction of PDC started the counting clock with the first day of the period if the beneficiary had drug stock that carried over into the start of the period or on the first day of the first fill within the period for the medication. The pre-partial LIS period starts on the first month observed enrollment in the non-partial LIS Part D benefit and the post-partial LIS period starts in the first month of partial LIS enrollment. The PDC clock begins within each of the pre and post periods

with the first prescription fill for the therapeutic class and ends with the close of the period. Beneficiaries were limited to carrying a maximum of 30 days of surplus drug stock at any time during the period. Gap days occur whenever the beneficiary does not have days' supply or surplus stock covered and are adjusted for hospitalizations.¹²⁴ Gaps of 90 consecutive days are considered a discontinuation and the end of the PDC calculation period.^{125,126} If the drug is refilled during the pre- or post-transition period after discontinuation, then a second PDC period is calculated for the beneficiary and added to the first period for the adherence calculation.¹ PDC ranges from greater than 0, perfect non-adherence, to 1, perfect adherence during the period. PDC levels greater than or equal to 0.80 are considered as adherent behavior.^{2,126-131} The post-transition PDC is subtracted from the pre-transition PDC to calculate the change in adherence before and after partial LIS enrollment as the outcome measure.

Explanatory Measures

Financial Characteristics. Two different measures of premium subsidization are created for analysis. The first one is an indicator variable for the partial LIS categories. The 25%, 50%, and 75% premium subsidy levels vary by income qualification in the range for the percent above federal poverty level (FPL) for the category, and it is expected that Medicare beneficiaries with higher incomes would have better adherence

rates. The second measure is an indicator variable if the beneficiary enrolls in a plan with a premium above the subsidy level. Partial LIS enrollees receive a subsidy amount up to the benchmark subsidy without their region. If they enroll in a plan with premiums above that amount, they pay 100 percent of the premium above the subsidy limit. Beneficiaries who enroll in plans above the subsidy level are expected to have better adherence because they have more financial resources to cover premium costs above the regional rate.

Two measures of drug plan enrollment are created to capture differing expectations of their effects on adherence behavior: plan switching at the time of benefit enrollment and during the benefit enrollment period. Beneficiaries who switch plans at the transition change the Part D plan they are enrolled in between the last month of non-partial LIS enrollment and the first month of partial LIS enrollment. The plan identifiers contained within the administrative data provided to academic researchers are encrypted specific to the calendar year and a crosswalk file provides plan identifier tracking from one year to the next. Plan switching at the time of enrollment is expected to be associated with improved adherence rates because the beneficiary is enrolling in a plan with a better suited formulary or cost sharing for their prescription drug therapies.¹³² Changing plans during the partial LIS enrollment period, listed as change plans within benefit in the tables, is coded as an indicator variable for one or more plan changes. Plan switching

within the benefit during the year is expected to be related to lower adherence levels because the beneficiary is enrolled in a poor quality plan or mismatched plan formulary.

Another key plan measure captures the degree of competition within the Part D market for the beneficiary and measures the percent of plans offered as enhanced benefit plans within the beneficiary's county. Karaca-Mandic, et al.²⁰ found the level of plan generosity was associated with more competitive Part D markets. It is expected that beneficiaries residing in more competitive markets may have more generous plans benefits and thereby better adherence levels in the period prior to enrollment in the partial LIS benefit.

Patient Characteristics. Demographic measures are created from the denominator data. Age is calculated for the beneficiary for the transition month. The denominator files from CMS changed the reference period for age provided in the annual files from January to December (begin of year to end of year switch) between the 2008 and 2009 files, so age was recalculated to be age at transition for this analysis. Gender is male or female sex from the denominator data. Race/ethnicity is from the Research Triangle Institute race variable in the denominator data.¹³³ Black, non-Hispanic and Hispanic, all races beneficiaries are compared to White, non-Hispanic and Other, non-Hispanic beneficiaries in the regression estimation models. Other, non-Hispanic Medicare beneficiaries were not

examined separately due to the CMS data use agreement restrictions that limit cell size reporting.

Diagnosis Characteristics. Chronic conditions are classified using the Healthcare Cost and Utilization Project (HCUP) algorithm.¹³⁴ Using all of the diagnosis codes provided within the MedPAR data, the following chronic condition indicators are created by the algorithm: congestive heart failure, valvular disease, pulmonary circulation disease, peripheral vascular disease, hypertension, paralysis, other neurological disorders, chronic pulmonary disease, diabetes without chronic complications, diabetes with chronic complications, hypothyroidism, renal failure, liver disease, peptic ulcer disease and bleeding, acquired immune deficiency syndrome, lymphoma, metastatic cancer, solid tumor without metastasis, rheumatoid arthritis/collagen vas, coagulopathy, obesity, weight loss, fluid and electrolyte disorders, chronic blood loss anemia, deficiency anemias, alcohol abuse, drug abuse, psychoses, depression. The chronic condition indicators are summed to create a co-morbidity index and used in the analysis as a three category measure comparing beneficiaries with no co-morbidities, 1 to 2 co-morbidities, and 3 or more co-morbidities.^{70,135} Medicare beneficiaries with more chronic conditions or co-morbidities are expected to have poorer adherence levels from complicated management of polypharmacy or from poorer health limitations.

Exposure variable. The analysis examines transitions that may occur at any time during the period covered by available data. As control measures, the duration in enrollment months before and after transition are used in the regression models as pre and post-partial LIS exposure variables.

Statistical Model

Descriptive analysis of the single treatment-only cohort research design is tested by comparing the average adherence level, as measured by PDC, before and after enrollment in the partial LIS program. A paired t-Test for difference in means compares the unadjusted, pre-partial LIS PDC mean to the unadjusted, post-partial LIS PDC mean. For the bivariate analysis of the explanatory variables, the outcome measure was collapsed into two categories to compare Medicare beneficiaries with improved adherence with those that had the same or worse adherence. The outcome measure was recoded into two categories because it is a continuous variable measuring the individual's change in PDC levels before and after partial LIS enrollment. The bivariate analysis of those with improved adherence following partial LIS enrollment and those that did not improve compares the explanatory measures of financial, patient, and diagnostic characteristics using χ^2 test statistics for the categorical explanatory measures and a t-test for difference in means for the continuous explanatory measures. Heckman's selection

model was estimated to correct for unobservable bias of the self-selection into the partial LIS program by the Medicare beneficiaries, but the Rho value from the two part model indicated that the correction was not needed and a regression model was suitable. The results of the Heckman selection model are provided in Appendix A. The financial, patient, and diagnostic explanatory measures are regressed on the continuous outcome measure of change in adherence before and after enrollment in the partial LIS program. The adjusted Wald test of joint probability of the variables for financial, patient, and diagnostics characteristics are equal to zero as a set is also tested for each regression model. The descriptive and bivariate statistics and regression model are estimated using Stata 12. All results with $p < 0.05$ are discussed in the findings section.

Findings

The findings section discussion is divided into each of the three therapeutic cohort analyses of the descriptive, bivariate, and regression results.

Proton Pump Inhibitor Cohort

Enrollment in the partial LIS benefit does result in statistically significant improvement in levels of prescription drug adherence for those Medicare beneficiaries using prescribed proton pump inhibitors. As shown in Table 14, the average adherence level is 0.44 (95% confidence interval (CI), 0.42-0.47) before enrollment in the partial

LIS program when the Medicare beneficiary is enrolled in a stand-alone PDP in the regular Part D benefit and the average PDC level increases to 0.69 (95% CI, 0.67-0.70) in the period after enrolling in the partial LIS program. The differences between pre- and post-partial LIS enrollment is an improvement of 0.24 (95% CI, 0.21-0.27) in the average adherence level of PPIs.

Table 15 provides the bivariate statistics for the explanatory variables of financial, patient, and diagnostic characteristics with the exposure variable for duration of post-partial LIS enrollment for the outcome measure divided into two categories to compare beneficiaries with improved adherence following the transition in the partial LIS program with those beneficiaries who did not improve. Within the PPI cohort, 68.3 percent improved their adherence levels following enrollment in the partial LIS program. Medicare beneficiaries in the highest income threshold from 145% to 150% of FPL with 25% premium subsidy level were more likely to have improved adherence levels (37.2 percent improved compared to 28.5 percent with same or worse adherence levels). Medicare beneficiaries with the 50% premium subsidy are a larger proportional share of the PPI cohort with same or worse adherence following partial LIS enrollment (39.8 percent with same or worse PDC and 32.4 percent with improved PDC levels). The lowest income group with the highest level of premium subsidization, 75% premium

subsidy, have similar proportional shares with improved and worse adherence levels (31.7 percent with same or worse and 30.5 percent with improved). Differences between improved adherence and same or worse adherence for PPI medications were not statistically significant for the other financial characteristics or the patient and diagnosis characteristics. On average, Medicare beneficiaries in the PPI cohort with improved adherence had 6 more months of enrollment in the partial LIS benefit than those with same or worse adherence. For those Medicare beneficiaries with same or worse PPI adherence, they are enrolled an average of 24.1 months before the transition and 21.4 months after the transition, and those with improved PPI adherence have been enrolled 19.7 months, on average, before partial LIS enrollment and in the benefit 27.7 months on average following the partial LIS transition.

Table 16 provides the regression model results of financial, patient, and diagnosis characteristics on change in PPI adherence before and after partial LIS enrollment. Medicare beneficiaries with incomes between 140% and 145% FPL receiving the 50% premium subsidy had lower change in their PDC adherence levels before and after enrollment in the partial LIS benefit ($\beta = -0.07$; 95% CI, -0.14 - -0.006) than beneficiaries with income between 145% and 150% FPL. Medicare beneficiaries in more competitive Part D markets had lower change in PPI adherence levels before and after partial LIS

enrollment ($\beta = -0.03$; 95% CI, -0.06 - -0.0001). Medicare beneficiaries with 1-2 comorbidities had lower change in their PPI adherence levels than those with 3 or more comorbidities ($\beta = -0.10$; 95% CI, -0.18 - -0.02). Medicare beneficiaries enrolled longer in Medicare Part D before the partial LIS benefit for lower change in their adherence levels compared before and after enrollment ($\beta = -0.003$; 95% CI, -0.005 - -0.001). Medicare beneficiaries enrolled in the partial LIS benefit for longer periods have more improvement in their adherence levels compared to before and after enrollment ($\beta = 0.005$; 95% CI, 0.003-0.007). The adjusted Wald tests on the joint probability that the set of variables for financial, patient, or diagnosis characteristics are equal to zero shows that the diagnosis characteristics are significantly different.

Statin Cohort

Similar to the PPI cohort, enrollment in the partial LIS benefit results in statistically significant improvement in levels of prescription drug adherence for those Medicare beneficiaries using prescribed statins. Table 17 shows the average unadjusted PDC levels for the statin cohort before and after enrolling in the partial LIS program. The average adherence level is 0.59 (95% CI, 0.57-0.61) before enrollment in the partial LIS program and the average PDC level increases to 0.78 (95% CI, 0.77-0.79) in the period

after enrolling in the partial LIS program. The difference before and after enrollment in the partial LIS benefit is 0.19 (95% CI, 0.17-0.21) in statin PDC levels.

Bivariate statistics for the explanatory variables of financial, patient, and diagnostic characteristics with the exposure variable for duration of post-partial LIS enrollment for the outcome measure divided into two categories to compare beneficiaries with improved statin adherence following the transition in the partial LIS program with those beneficiaries who did not improve are provided in Table 18. Within the statin cohort, 63.0 percent had improved adherence levels following enrollment in the partial LIS benefit and 37.1 percent had the same or worse adherence. On average, Medicare beneficiaries with improved statin adherence are younger than those with the same or worse adherence. The average age of Medicare beneficiaries with improved statin adherence is 72.2 years, and the average age of those with same or worse adherence is 73.8 years. Differences between improved adherence and same or worse adherence for statin medications were not statistically significant for the other financial, patient, or diagnosis characteristics. Medicare beneficiaries in the statin cohort with improved adherence had, on average, 4 more months enrolled in the partial LIS benefit than those with same or worse adherence. Medicare beneficiaries with improved statin adherence are enrolled in the Part D before the partial LIS benefit enrollment less time, on average,

than those with the same or worse adherence (23.1 months compared to 25.2 months, on average). For those Medicare beneficiaries with same or worse statin adherence, they are post-partial LIS enrolled an average of 20.9 months, and those with improved statin adherence have been enrolled in the benefit 25.0 months on average following the partial LIS transition.

The regression model results of change in statin adherence levels with financial, patient, and diagnosis characteristics explanatory variables is provided in Table 19. Medicare beneficiaries residing in counties with more Part D plan competition as measured by a larger proportion with gap plans have lower change in their PDC levels ($\beta = -0.04$; 95% CI, -0.06 - -0.02). Controlling for all other explanatory measures, Medicare beneficiaries have 0.003 (95% CI, -0.01 - -0.001) lower change in their statin adherence levels for each year older, and male beneficiaries have 0.05 (95% CI, -0.09 - -0.004) lower change in their statin PDC levels than females. Similar to the PPI therapeutic cohort, partial LIS enrollees with longer periods within the partial LIS benefit have more improvement in the difference between their adherence levels before and after the transition ($\beta = 0.006$; 95% CI, 0.004-0.007) and those with longer periods prior to partial LIS enrollment in the Part D benefit have less improvement in statin adherence ($\beta = -0.003$; 95% CI, -0.004 - -0.001). The adjusted Wald tests on the joint probability tests for

the financial, patient, or diagnosis characteristics show that the financial and patient characteristics are significantly different from zero.

Oral Anti-Diabetics Cohort

For those Medicare beneficiaries taking oral anti-diabetic medications, enrollment in the partial LIS benefit had statistically significant improvement in levels of prescription drug adherence. Table 20 shows the average unadjusted PDC levels for the oral anti-diabetic medication cohort before and after enrolling in the partial LIS program. The average adherence level is 0.68 (95% CI, 0.65-0.71) before enrollment in the partial LIS program and the average PDC level increases to 0.80 (95% CI, 0.78-0.82) in the period after enrolling in the partial LIS program. The pre- and post-enrollment difference of 0.12 (95% CI, 0.09-0.15) shows improved oral anti-diabetic adherence for partial LIS beneficiaries. Compared to the other two cohorts, this therapeutic cohort had the least amount of change before and after enrollment but qualitatively they are the only cohort that changed from an average, non-adherent level below 0.80 PDC to on average, adherent PDC levels after enrolling in the partial LIS program. The 0.80 average PDC level post-partial LIS is exactly on the adherence threshold but both the PPI and statin therapeutic cohorts were below this level before and after partial LIS enrollment.

Table 21 provides the bivariate statistics for the explanatory variables of financial, patient, and diagnostic characteristics with the exposure variable for duration of post-partial LIS enrollment for the oral anti-diabetic cohort. For analytical purposes, the outcome measure is divided into two categories to compare beneficiaries with improved adherence to oral anti-diabetics following the transition in the partial LIS program with those beneficiaries who did not improve. Within the oral anti-diabetic cohort, 47.9 percent had improved adherence levels following enrollment in the partial LIS benefit and 52.1 percent had the same or worse adherence. Similar to the statin therapeutic cohort, Medicare beneficiaries with improved adherence to oral anti-diabetic medications are, on average, younger than those with the same or worse adherence. The average age of Medicare beneficiaries with improved adherence to oral anti-diabetic medications is 71.1 years, and the average age of those with same or worse adherence is 72.9 years. All other outcome category differences were not statistically significant for the other financial, patient, or diagnosis characteristics explanatory measures. On average, those Medicare beneficiaries with same or worse oral anti-diabetic adherence have been enrolled 21.3 months in the partial LIS benefit and 22.5 months before partial LIS, and those with improved adherence have been enrolled in the benefit 26.8 months and 19.8 months, on average, before partial LIS enrollment.

Table 22 presents the regression model estimates of change in oral anti-diabetic medication PDC levels by financial, patient, and diagnosis characteristics explanatory variables. Similar to the statin drug therapeutic cohort, Medicare beneficiaries residing in counties with more gap plans competing within the Part D plan market have lower change in their oral anti-diabetic PDC levels ($\beta = -0.04$; 95% CI, -0.06 - -0.005). Controlling for all other explanatory measures, Medicare beneficiaries have 0.004 (95% CI, -0.01 - -0.001) lower change in their oral anti-diabetic adherence levels for each year older in age. Medicare beneficiaries with longer durations enrolled in the partial LIS benefit have more improvement in their post-LIS oral anti-diabetic adherence levels compared to their pre-LIS adherence ($\beta = 0.005$; 95% CI, 0.002-0.007).

Discussion

The Partial Low Income Subsidy (LIS) provides Medicare beneficiaries, who have incomes between 135% and 150% of the federal poverty level and assets less than \$12,640 for individuals or \$25,260 for married couples in 2011, assistance with premium subsidization and lower cost-sharing for prescription drugs. The purpose of the analysis in this study was to examine if the financial assistance provided by the partial LIS benefit resulted in improvements to adherence of prescription drug therapies.

One limitation of the findings from this analysis for purposes of an overall evaluation of the partial LIS benefit was the focus on three clinical cohorts of drug classes most likely to have cost-related underuse. To the extent that beneficiaries were experiencing cost-related underuse prior to enrolling in the partial LIS benefit, the selection of these three drug classes are more likely to show larger changes in adherence levels than drug classes less likely to have cost-related underuse. In addition to being the drug categories most likely to have cost-related underuse reported, the three therapeutic classes are among the most common medications taken by the Medicare Part D population.⁵⁰

Another important limitation is that the beneficiaries examined transitioned from non-LIS enrollment into the partial LIS benefit. Most partial LIS enrollees begin receiving the benefit at the same time they initiate Part D enrollment. Davidoff, Stuart, et al.¹⁰⁸ found that the most vulnerable Medicare beneficiaries enroll in the LIS benefit at the initiation of Part D coverage. As shown in Figure 4, the numbers of Medicare beneficiaries who enroll in the partial LIS benefit directly are nearly 10 times more than the numbers who transition from non-LIS Part D into the partial LIS benefit. Therefore, the findings for those that transition onto the benefit may not be similar to those that enroll with Part D coverage initiation. More importantly, reducing the administrative

burden of re-enrollment once a beneficiary has enrolled within the partial LIS program may provide health benefits through improved adherence rates for the Medicare programs as shown by the common finding for all three drug therapy cohorts that the longer a beneficiary was enrolled within partial LIS, or exposed to the benefit, the better the adherence level.

Lastly, the findings are limited to the PDP Part D population and may not apply to the MA-PD population enrolled within the partial LIS program. As discussed in Figure 4, Medicare beneficiaries enrolled in PDP and MA-PD plans are roughly evenly split between the two categories of plans. Since MA-PD plans provide prescription drug and medical care coverage, they may have more incentive to assist enrollees to have better prescription drug adherence to avoid more costly medical care utilization.¹³⁶

Williams, et al.¹³⁷ find diabetes and cholesterol-lowering drugs were more likely to have cost-related non-adherence than symptom-relief drugs such as proton-pump inhibitors for Medicare Part D enrollees with diabetes. While this study was not limited to diabetic Medicare beneficiaries, the post-transition partial LIS adherence levels were larger and the cohort average adherence levels were at or near the 0.80 threshold of adherent prescription drug behavior for the diabetic and statin therapy groups compared to the PPI cohort. The results clearly suggest that following their transition the partial LIS

enrollees improved prescription drug adherence levels within three therapeutic classes most likely to have cost-related underuse and may in turn experience health gains that follow from improved drug adherence.

Figure 4: Study 2 Analytical Sample Construction

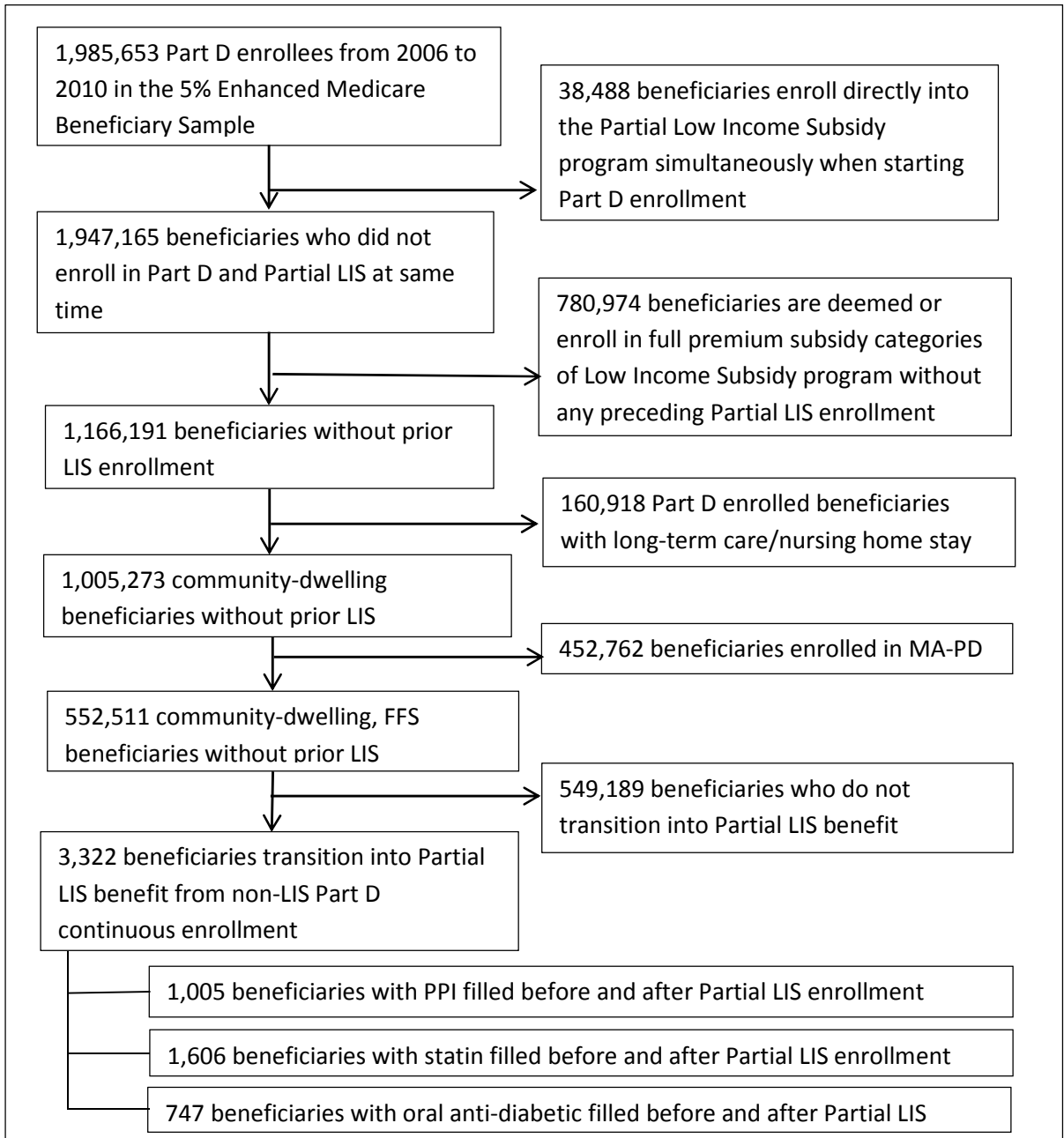


Table 13: Active Ingredients of Selected Therapeutic Classes

Therapeutic Class	Active Ingredients
Proton Pump Inhibitors (PPIs)	Dexlansoprazole, Esomeprazole, Lansoprazole, Omeprazole, Pantoprazole, Rabeprazole
Statins	Atorvastatin, Cerivastatin, Fluvastatin, Lovastatin, Pitavastatin, Pravastatin, Rosuvastatin, Simvastatin
Oral Anti-Diabetics	Acarbose, Acetohexamide, Chlorpropamide, Glibenclamide, Glimepiride, Glipizide, Glyburide, Meglitinides, Metformin, Miglitol, Nateglinide, Pioglitazone, Repaglinide, Rosiglitazone, Saxagliptin, Sitagliptin, Tolazamide, Tolbutamide

Source: Food and Drug Administration (FDA). 2014. Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Silver Spring, MD: U.S. Department of Health & Human Services.

Table 14: Average Unadjusted Drug Adherence Levels of Proton Pump Inhibitors (PPIs) Before and After Medicare Part D Partial Low Income Subsidy (LIS) Enrollment for Continuously Enrolled in Stand-Alone Prescription Drug Plan (PDP), Community-Dwelling Medicare Beneficiaries

Therapeutic Class	Mean (95% Confidence Interval [CI])		Difference (95% CI)	P> t
	Pre-Partial LIS	Post-Partial LIS		
Proton Pump Inhibitors	0.44 (0.42,0.47)	0.69 (0.67,0.70)	0.24 (0.21,0.27)	0.000

Note: Data from enhanced 5% sample of Medicare beneficiaries, 2006-2010.

Table 15: Bivariate Comparison Tests of Explanatory Variables and Improved Change in Adherence Levels of Proton Pump Inhibitors (PPIs)

Variable, Value Labels (units for mean, when applicable)	Change in Adherence Level		P value
	Same or Worse	Improved	
<i>Financial Characteristics</i>			
<u>Partial LIS Income/Subsidy Category</u>			
75% Premium Subsidy	31.7%	30.5%	0.016 ^a
50% Premium Subsidy	39.8%	32.4%	
25% Premium Subsidy	28.5%	37.2%	
Does not switch plans	99.7%	98.8%	0.182 ^a
Switch Plans at Transition	0.4%	1.2%	
Does not change plans	96.6%	96.8%	0.842 ^a
Change Plans Post-Enrollment	3.5%	3.2%	
Plan Premium Not Above Subsidy	66.5%	69.7%	0.305 ^a
Plan Premium Above Subsidy Level	33.5%	30.3%	
Market Percent of Gap Plans (μ , percent)	4.0	3.9	0.130 ^b
<i>Patient Characteristics</i>			
Age (μ , years)	72.4	72.1	0.752 ^b
Female	73.0%	75.4%	0.431 ^a
Male	27.0%	24.6%	
White/Other	89.0%	85.0%	0.128 ^a
Black	8.5%	10.1%	
Hispanic	2.5%	5.0%	

Variable, Value Labels (units for mean, when applicable)	Change in Adherence Level		P value
	Same or Worse	Improved	
<i>Diagnosis Characteristics</i>			
No Co-Morbidities	32.6%	32.2%	0.208 ^a
1-2 Co-morbidities	17.9%	13.9%	
3 or more Co-Morbidities	49.5%	53.9%	
<i>Exposure variable</i>			
Duration Before Transition (μ , months)	24.1	19.7	0.000 ^b
Duration After Transition (μ , months)	21.4	27.7	0.000 ^b
Number of Medicare Beneficiaries	319	686	
Percent	31.7%	68.3%	

Note: Statistical test denoted by ^a is chi-square test and by ^b is paired t-test of difference in means. Data from enhanced 5% sample of Medicare beneficiaries, 2006-2010.

Table 16: Regression Model Results of Financial, Patient, and Diagnosis Characteristics on Change in PPI Adherence Levels Before and After Partial LIS Enrollment

Variable	Parameter Coefficient	Significance Level	95% Confidence Interval	
Financial Characteristics				
<i>Partial LIS Income/Subsidy Category</i>				
75% Premium Subsidy	-0.0348	0.324	-0.1038	0.0343
50% Premium Subsidy	-0.0728	0.034	-0.1399	-0.0056
25% Premium Subsidy		reference		
Switch Plans at Transition	0.2121	0.164	-0.0864	0.5107
Change Plans Post-Enrollment	-0.0502	0.530	-0.2069	0.1066
Plan Premium Above Subsidy Level	-0.0388	0.212	-0.0998	0.0221
Market Percent of Gap Plans	-0.0284	0.049	-0.0566	-0.0001
Patient Characteristics				
Age	-0.0003	0.817	-0.0031	0.0024
Female		reference		
Male	-0.0072	0.831	-0.0736	0.0592
White/Other		reference		
Black	0.0043	0.929	-0.0913	0.1000
Hispanic	0.0036	0.960	-0.1365	0.1437
Diagnosis Characteristics				
No Co-Morbidities	-0.0355	0.270	-0.0986	0.0276
1-2 Co-morbidities	-0.1013	0.015	-0.1826	-0.0199
3 or more Co-Morbidities		reference		
<i>Exposure Variable</i>				
Duration Before Transition	-0.0032	0.004	-0.0054	-0.0010

Variable	Parameter Coefficient	Significance Level	95% Confidence Interval	
Duration After Transition	0.0050	0.000	0.0028	0.0073
Intercept	0.3287	0.005	0.1006	0.5567

Note: Data from the enhanced 5% sample of Medicare beneficiaries, 2006-2010. Model statistics: $F(14,987)=6.79$, $P>|F|=0.000$; $R\text{-squared}=0.09$; $\text{Adjusted } R\text{-squared}=0.08$. Adjusted Wald test of joint probability for financial characteristics: $F(6,987)=2.10$, $P>|F|=0.051$; patient characteristics: $F(4,987)=0.20$, $P>|F|=0.990$; diagnosis characteristics: $F(2,987)=3.06$, $P>|F|=0.047$.

Table 17: Average Unadjusted Drug Adherence Levels of Statins Before and After Medicare Part D Partial Low Income Subsidy (LIS) Enrollment for Continuously Enrolled in Stand-Alone Prescription Drug Plan (PDP), Community-Dwelling Medicare Beneficiaries

Therapeutic Class	Mean (95% Confidence Interval [CI])		Difference (95% CI)	P> t
	Pre-Partial LIS	Post-Partial LIS		
Statins	0.59 (0.57,0.61)	0.78 (0.77,0.79)	0.19 (0.17,0.21)	0.000

Note: Data from enhanced 5% sample of Medicare beneficiaries, 2006-2010.

Table 18: Bivariate Comparison Tests of Explanatory Variables and Improved Change in Adherence Levels of Statins

Variable, Value Labels (units for mean, when applicable)	Change in Adherence Level		P value
	Same or Worse	Improved	
<i>Financial Characteristics</i>			
<u>Partial LIS Income/Subsidy Category</u>			
75% Premium Subsidy	32.8%	31.0%	0.232 ^a
50% Premium Subsidy	36.5%	34.1%	
25% Premium Subsidy	30.8%	34.9%	
Does not switch plans	99.5%	98.9%	0.224 ^a
Switch Plans at Transition	0.5%	1.1%	
Does not change plans	96.5%	97.9%	0.078 ^a
Change Plans Post-Enrollment	3.5%	2.1%	
Plan Premium Not Above Subsidy	71.4%	67.5%	0.097 ^a
Plan Premium Above Subsidy Level	28.6%	32.5%	
Market Percent of Gap Plans (μ , percent)	4.2	4.0	0.050 ^b
<i>Patient Characteristics</i>			
Age (μ , years)	73.8	72.2	0.003 ^b
Female	71.8%	72.3%	0.816 ^a
Male	28.2%	27.7%	
White/Other	85.2%	82.9%	0.177 ^a
Black	11.4%	11.8%	
Hispanic	3.4%	5.3%	

Variable, Value Labels (units for mean, when applicable)	Change in Adherence Level		P value
	Same or Worse	Improved	
<i>Diagnosis Characteristics</i>			
No Co-Morbidities	36.8%	38.2%	0.760 ^a
1-2 Co-morbidities	18.8%	17.5%	
3 or more Co-Morbidities	44.4%	44.3%	
<i>Exposure variable</i>			
Duration Before Transition (μ , months)	25.2	23.1	0.023 ^b
Duration After Transition (μ , months)	20.9	25.0	0.000 ^b
Number of Medicare Beneficiaries	595	1,011	
Percent	37.1%	63.0%	

Note: Statistical test denoted by ^a is chi-square test and by ^b is paired t-test of difference in means. Data from enhanced 5% sample of Medicare beneficiaries, 2006-2010.

Table 19: Regression Model Results of Financial, Patient, and Diagnosis Characteristics on Change in Statin Adherence Levels Before and After Partial LIS Enrollment

Variable	Parameter Coefficient	Significance Level	95% Confidence Interval	
Financial Characteristics				
<u>Partial LIS Income/Subsidy Category</u>				
75% Premium Subsidy	-0.0341	0.163	-0.0820	0.0138
50% Premium Subsidy	-0.0318	0.183	-0.0787	0.0150
25% Premium Subsidy		reference		
Switch Plans at Transition	0.0555	0.601	-0.1527	0.2638
Change Plans Post-Enrollment	-0.0242	0.698	-0.1466	0.0981
Plan Premium Above Subsidy Level	0.0204	0.344	-0.0219	0.0627
Market Percent of Gap Plans	-0.0380	0.000	-0.0577	-0.0184
Patient Characteristics				
Age	-0.0030	0.006	-0.0051	-0.0009
Female		reference		
Male	-0.0490	0.032	-0.0937	-0.0043
White/Other		reference		
Black	0.0050	0.872	-0.0555	0.0655
Hispanic	0.0811	0.086	-0.0114	0.1737
Diagnosis Characteristics				
No Co-Morbidities	-0.0155	0.479	-0.0586	0.0275
1-2 Co-morbidities	-0.0193	0.482	-0.0732	0.0346
3 or more Co-Morbidities		reference		
<i>Exposure Variable</i>				
Duration Before Transition	-0.0027	0.000	-0.0041	-0.0012

Variable	Parameter Coefficient	Significance Level	95% Confidence Interval	
Duration After Transition	0.0055	0.000	0.0039	0.0071
Intercept	0.4393	0.000	0.2620	0.6166

Note: Data from the enhanced 5% sample of Medicare beneficiaries, 2006-2010. Model statistics: $F(14,1588)=14.08$, $P>|F|=0.000$; R-squared=0.11; Adjusted R-squared=0.10. Adjusted Wald test of joint probability for financial characteristics: $F(6,1588)=3.08$, $P>|F|=0.005$; patient characteristics: $F(4,1588)=3.24$, $P>|F|=0.012$; diagnosis characteristics: $F(2,1588)=0.36$, $P>|F|=0.695$.

Table 20: Average Unadjusted Drug Adherence Levels of Oral Anti-Diabetic Medications Before and After Medicare Part D Partial Low Income Subsidy (LIS) Enrollment for Continuously Enrolled in Stand-Alone Prescription Drug Plan (PDP), Community-Dwelling Medicare Beneficiaries

Therapeutic Class	Mean (95% Confidence Interval [CI])		Difference (95% CI)	P> t
	Pre-Partial LIS	Post-Partial LIS		
Oral Anti-Diabetics	0.68 (0.65,0.71)	0.80 (0.78,0.82)	0.12 (0.09,0.15)	0.000

Note: Data from enhanced 5% sample of Medicare beneficiaries, 2006-2010.

Table 21: Bivariate Comparison Tests of Explanatory Variables and Improved Change in Adherence Levels of Oral Anti-Diabetic Medications

Variable, Value Labels (units for mean, when applicable)	Change in Adherence Level		P value
	Same or Worse	Improved	
<i>Financial Characteristics</i>			
<u>Partial LIS Income/Subsidy Category</u>			
75% Premium Subsidy	27.8%	33.0%	0.098 ^a
50% Premium Subsidy	36.8%	38.6%	
25% Premium Subsidy	35.5%	28.5%	
Does not switch plans	98.2%	99.2%	0.253 ^a
Switch Plans at Transition	1.8%	0.8%	
Does not change plans	95.6%	96.7%	0.472 ^a
Change Plans Post-Enrollment	4.4%	3.4%	
Plan Premium Not Above Subsidy	69.4%	70.7%	0.707 ^a
Plan Premium Above Subsidy Level	30.6%	29.3%	
Market Percent of Gap Plans (μ , percent)	4.2	3.9	0.055 ^b
<i>Patient Characteristics</i>			
Age (μ , years)	72.9	71.1	0.014 ^b
Female	68.1%	69.8%	0.614 ^a
Male	31.9%	30.2%	
White/Other	79.7%	80.5%	0.668 ^a
Black	14.4%	12.6%	
Hispanic	5.9%	7.0%	

Variable, Value Labels (units for mean, when applicable)	Change in Adherence Level		P value
	Same or Worse	Improved	
<i>Diagnosis Characteristics</i>			
No Co-Morbidities	36.3%	37.4%	0.478 ^a
1-2 Co-morbidities	14.1%	11.2%	
3 or more Co-Morbidities	49.6%	51.4%	
<i>Exposure variable</i>			
Duration Before Transition (μ , months)	22.5	19.8	0.030 ^b
Duration After Transition (μ , months)	21.3	26.8	0.000 ^b
Number of Medicare Beneficiaries	389	358	
Percent	52.1%	47.9%	

Note: Statistical test denoted by ^a is chi-square test and by ^b is paired t-test of difference in means. Data from enhanced 5% sample of Medicare beneficiaries, 2006-2010.

Table 22: Regression Model Results of Financial, Patient, and Diagnosis Characteristics on Change in Oral Anti-Diabetic Adherence Levels Before and After Partial LIS Enrollment

Variable	Parameter Coefficient	Significance Level	95% Confidence Interval	
Financial Characteristics				
<i>Partial LIS Income/Subsidy Category</i>				
75% Premium Subsidy	0.0589	0.126	-0.0166	0.1344
50% Premium Subsidy	0.0205	0.575	-0.0512	0.0921
25% Premium Subsidy		reference		
Switch Plans at Transition	0.0192	0.885	-0.2423	0.2808
Change Plans Post-Enrollment	0.0913	0.253	-0.0653	0.2480
Plan Premium Above Subsidy Level	-0.0394	0.247	-0.1060	0.0273
Market Percent of Gap Plans	-0.0351	0.021	-0.0649	-0.0053
Patient Characteristics				
Age	-0.0043	0.011	-0.0076	-0.0010
Female		reference		
Male	-0.0165	0.632	-0.0840	0.0510
White/Other		reference		
Black	-0.0312	0.489	-0.1197	0.0573
Hispanic	0.0540	0.388	-0.0686	0.1765
Diagnosis Characteristics				
No Co-Morbidities	0.0189	0.568	-0.0461	0.0839
1-2 Co-morbidities	-0.0436	0.359	-0.1369	0.0496
3 or more Co-Morbidities		reference		
<i>Exposure Variable</i>				
Duration Before Transition	-0.0018	0.116	-0.0039	0.0004

Variable	Parameter Coefficient	Significance Level	95% Confidence Interval	
Duration After Transition	0.0047	0.000	0.0024	0.0070
Intercept	0.4079	0.003	0.1364	0.6794

Note: Data from the enhanced 5% sample of Medicare beneficiaries, 2006-2010. Model statistics: $F(14,731)=4.87$, $P>|F|=0.000$; $R\text{-squared}=0.09$; $\text{Adjusted } R\text{-squared}=0.07$. Adjusted Wald test of joint probability for financial characteristics: $F(6,731)=1.81$, $P>|F|=0.094$; patient characteristics: $F(4,731)=2.02$, $P>|F|=0.090$; diagnosis characteristics: $F(2,731)=0.80$, $P>|F|=0.448$.

Study 3: Income and Race/Ethnicity Effects on Drug Adherence of the Medicare Part D Low Income Partial Subsidy Population

Summary for Study 3

Objective: To examine income and race/ethnicity and their association with prescription drug adherence within the Medicare Part D Partial Low Income Subsidy (LIS) for three selected therapeutic cohorts that frequently experience cost-related underuse.

Background: Health services research has demonstrated the association of income gradients and race/ethnicity differences on health behaviors. However, these effects have not been examined for prescription drug behavior within the national Medicare population for partial low-income elderly beneficiaries nor by race/ethnicity.

Data and Methods: Medicare administrative data from 2006 through 2010 is used to determine Partial LIS continuous, calendar year enrollees within the 5% enhanced national sample for statin, proton pump inhibitors (PPI), and oral anti-diabetic therapeutic classes. The unit of analysis is the beneficiary-year. Logistic regression analysis with robust standard errors for individual-level panel effects is used to examine adherent

(proportional days covered ≥ 0.80) prescription drug behavior and the association to financial, demographic, and diagnostic explanatory measures.

Findings: For PPI cohort, the 25 percent subsidy group has a higher probability of adherence than the 75 percent subsidy group (AME = 0.04; 95% confidence interval (CI), 0.01-0.07). All three therapeutic cohorts have race/ethnicity differences in likelihood of adherent behavior. In comparison to white, non-Hispanic partial LIS enrollees, black, non-Hispanic beneficiaries had lower probability of adherence (PPI AME = -0.14; 95% CI, -0.18 - -0.10; statin AME = -0.15; 95% CI, -0.18 - -0.12; oral anti-diabetic AME = -0.11; 95% CI, -0.15 - -0.07) as did Hispanic beneficiaries (PPI AME = -0.16; 95% CI, -0.21 - -0.11; statin AME = -0.15; 95% CI, -0.19 - -0.10; oral anti-diabetic AME = -0.09; 95% CI, -0.14 - -0.04).

Conclusions: Within the partial low income subsidy program even modest income differences may affect drug adherence for some therapeutic classes, but race/ethnicity differences are common across all three clinical cohorts.

Introduction

The Medicare Part D benefit provided numerous plan design options for demand side approaches to limiting prescription drug costs, such as deductibles and varying out-of-pocket cost sharing by formulary. To mitigate some of these approaches for low-income beneficiaries, Medicare provided lower cost-sharing and premium subsidization within the existing Medicare Shared Savings Programs (MSP, also known as dual Medicare-Medicaid program) and an expansion coverage program for incomes up to 150% poverty and limited assets that would not qualify above the threshold within the existing MSP income and asset limits. The expanded coverage group is provided premium subsidies based on income level and reduced cost sharing and deductible amounts. Similar approaches to premium subsidization and cost-sharing assistance for low-income populations have been provided within the Affordable Care Act (ACA) insurance exchange options.

Health services research has demonstrated the effects of income gradients on health behaviors¹³⁸⁻¹⁴³ and price sensitivity in response to out-of-pocket cost sharing.^{3,144,145} However, these effects have not been examined within the national Medicare population for low-income elderly beneficiaries. Examination of the Medicare Part D partial low-income program enrollees allows a comparison of narrow income

segments facing the same benefit design for cost sharing and deductibles and their corresponding health behaviors measured by prescription drug adherence.

Differences in health behaviors and health care utilization patterns by racial and ethnic groups have been closely examined by health services researchers to develop health policy and programs to increase health equity.^{146,147} Given Medicare's prominent role in assisting with desegregation of hospitals in the 1960s when the program was first implemented,¹⁴⁸ it is important to examine the role the implementation of Medicare Part D, the largest expansion of its program benefits in recent history, as a policy and program for reducing race/ethnicity differences in prescription drug behavior within the Medicare population,¹⁴⁹⁻¹⁵² especially enrollment within the low income subsidy program.¹⁵³ Long-standing problems associated with the coding of race/ethnicity within Medicare administrative claims data are discussed below to highlight current updates to improve the validity and reliability of its measurement.

Literature Background on Income and Race/Ethnicity Association with Prescription Adherence within the Medicare Population

The low-income subsidy program for Medicare Part D enrollees is now renamed Extra Help and includes reduced cost sharing and premium assistance for beneficiaries who qualify based on income and asset levels. Lower socioeconomic status groups are

less likely to adhere to long-term treatments for chronic conditions.¹⁵⁴ When faced with tighter budget constraints, lower income populations may cut back on needed care and experience adverse health.¹⁵⁵ Increased drug and office visit co-pays caused increased hospitalization for elderly patients with chronic diseases.¹⁵⁶ While income may affect responses to differing cost sharing, another large difference for elderly Medicare beneficiaries are asset levels, especially differences by racial and ethnic groups. Median asset levels among white Medicare beneficiaries (\$89K) were more than eight times higher than non-white beneficiaries (\$10K).¹⁵⁷

Findings on the relationship between prescription drug adherence and race/ethnicity has been shown to be mixed at the population level,¹⁵⁸ but within the elderly population non-white racial groups or Hispanic ethnic groups tend to have poorer adherence.^{2,35,159-162} In their study of elderly Medicare beneficiaries following an episode of acute myocardial infarction, Lauffenburger et al.¹⁶⁰ found no difference in the initiation of drug therapies post-discharge but Hispanic and Black beneficiaries had lower adherence levels than White patients. Medicare Part D has had mixed results on reducing cost-related nonadherence¹⁶³ and drug spending^{149,150} by race/ethnicity but has been shown to reduce the offset differences in other medical care.^{164,165} While the probability of having drug coverage did not differ by race/ethnicity before or after Part D,¹⁶⁶ non-

White racial and ethnic groups have been shown to have greater price sensitivity in the Part D coverage gap.¹⁵¹

Programmatic Background of Race/Ethnicity Coding in Medicare Enrollment Data

Problems with Medicare race/ethnicity coding are well documented within the academic literature.^{167–172} Arday, et al.¹⁷¹ have found that the iterative updates to the CMS race/ethnicity data have had marked improvements in accuracy. Comparing data from before and after the 1997 update, Arday et al.¹⁷¹ found that sensitivity for white persons was 97 percent, 95 percent for black persons, and less than 60 percent for all others, but these groups had the largest improvements in specificity following the update. There are at least two issues that need to be addressed when attempting to describe the accuracy of the race code in CMS data files: administrative error and self-report bias.

Historically, race data coding in the Medicare enrollment data are transferred from the Social Security Administration (SSA) or the Railroad Retirement Board (RRB). The RRB does not collect information on race and, therefore, many of the CMS enrollment records coded as “unknown” race are RRB beneficiaries. The majority of enrollment records, however, are derived from the SSA's Master Beneficiary Record File.

The SSA collects race on an application form called the SS-5.¹⁷³ From 1936 to 1980, the SS-5 form included three categories for race (white, black, and other). This

information was transferred to a SSA database called the master beneficiary record file, which had four categories of white, black, other, and unknown. In November 1980, the race choice on the SS-5 form was expanded in order to comply with a federal directive. As a result of the federal directive, the “other” category on the SS-5 form was replaced by the following three categories: Asian, Asian American, or Pacific Islander; Hispanic; and Northern American Indian or Alaskan Native. This directive did not, however, require a differentiation between race and ethnicity (i.e., Hispanic is listed as a choice for a single race/ethnicity question). Unfortunately, the SSA did not restructure their Master Beneficiary Record database to accommodate these new choices; instead the new race categories were collapsed into one of the original four choices (White/Black/Other/Unknown).

In regard to those with Hispanic race/ethnicity, prior to 1980, Hispanics may have identified their racial category as white, black, or other; whereas, after 1980, Hispanic was a category choice but administratively it was collapsed into the “other” category. As a result, Hispanic individuals constituted a large portion of the “other” category, and some Hispanic individuals may have continued in the White/Black categories.

In addition to problems associated with collapsed codes, the SSA master beneficiary data stores demographic information associated with the SSN that the person claims benefits

under. Approximately 20 percent of total beneficiaries qualify for social security benefits based on their relation to another wage earner (e.g., spouses or disabled children), and for this group the race/ethnicity variable listed for this beneficiary is that of the qualifying wage earner.

Administrative errors in the race/ethnicity coding in CMS data may result from the SSA and RRB data from which it is compiled. As such, CMS has initiated corrective remedies on three different occasions. In 1994, CMS sent a mailing to all those beneficiaries classified as “other” or “unknown” in the database asking them to self-report their race. In 1997 and 2001, CMS changed the SSA database source they were transferring race data from the Master beneficiary record file (collapsed fields) to the SS-5 file directly.^{174,175} The effect was that those individuals that had marked themselves as Hispanic, Asian, or Native American after 1980 in the SS-5 file would be changed in the CMS enrollment file to these matching codes.¹⁷⁶ In addition, spouses or disabled children qualifying for social security benefits under a different wage earner would have their data corrected with their original SSN category.

The new, updated race/ethnicity measure that was released by the Centers for Medicare and Medicaid (CMS) in 2007 was created from a project sponsored by the Agency for Healthcare Research and Quality (AHRQ).^{133,177} Using surname recoding

and probability modeling, the new race/ethnicity variable released with the administrative data was seen as corrective for mainframe administrative race variable.¹⁷⁸ Known as the Research Triangle Institute Race Code, the new measure has an estimated Kappa value of 0.79 and improved sensitivity (greater than 77%) compared to the administrative race variable.¹³³

Study Design

Data

The administrative data used in this analysis was obtained from the Chronic Condition Warehouse for the 5% enhanced sample from 2006 through 2010. The analytical sample was created from Medicare administrative claims, assessment, and enrollment data files including beneficiary enrollment data, prescription drug event (PDE) file, Minimum Data Set (MDS) long-term care assessment, MedPAR, and the Part D plan characteristics data. The Part D enrollment file is used to identify enrollment in Part D and the partial LIS benefit and includes beneficiary demographic data. The MDS data are used to identify and exclude nursing home residents for the calendar year. MedPAR data are used for capturing co-morbidity diagnoses and to adjust drug adherence for hospitalization periods. The PDE data are merged with RxNorm to determine the drug therapy cohorts by active ingredients and the adherence levels within

those drug cohorts. RxNorm is produced by National Medical Library association and classifies each drug entity by the individual nation drug code (NDC). Health risk adjusters are computed using the AHRQ comorbidity index constructed from diagnoses in the MedPAR data files. The plan characteristics data provide information on characteristics of Part D plans, such as enhanced benefit plans, plan types such as stand-alone prescription drug plans (PDPs) and Medicare Advantage prescription drug plans (MAPDs), benchmark status, premiums, and drug tier information. All Medicare claims data used in the analysis were obtained from the Centers for Medicare and Medicaid Services (CMS) prior to the current substance use disorder (SUD) suppression,¹¹⁹ and the findings are not limited from missing SUD data.

The historical 5% Medicare sample is extracted from the CMS administrative enrollment data in the same manner every year by pulling the same two-digit set from the 11-digit beneficiary identifier. The first 9 digits of a beneficiary Medicare identifier are the Social Security Number (SSN) from which the person claims Social Security payments. Since the last 4 digits of the SSN are random digits, the systematic sampling of five sets of the last two digits pulls a 5% random sample from the Medicare population. One limitation of a random sample from a systematic pull for longitudinal analysis is that Medicare beneficiaries may change their Medicare identifier (for reasons, such as,

identity theft). For the one to two percent that change identifier, the new identifier may not have the two-digits that belong in the set pulled for the sample. To correct this limitation, the Chronic Condition Warehouse (CCW) created the 5% enhanced Medicare sample, where once a beneficiary meets the criterion for inclusion in the sample they are retained in the prospective cohort regardless of whether the current identifier meets the sample pull conditions.

The benefits of using the CMS administrative data are that a large, representative sample is used and that the data contain the actual programmatic measures of utilization. The limitations are that the data quality of the PDE is still relatively untested and measures that can be examined are limited to variables that are collected for enrollment or payment reconciliation. The unknown data quality of the PDE are due to differences in how plans reported the information to CMS and due to possible prescription drug omissions if the beneficiary does not file a paper claim for reimbursement from an out-of-network pharmacy or a fill for a cash-only generic. Possible prescription omissions would result in an upward bias of non-adherence or an overestimation of non-adherence as calculated from the PDE data. Since the analysis is focusing on the LIS enrolled group, this bias is expected to be less because the group does not encounter the benefit gap.

Study Sample

The analytical extracts for the enrollment cohorts selected all beneficiaries during the five years of data that were continuously enrolled during the calendar year within the partial LIS benefit, were not nursing home residents, were not enrolled in MA-PDs, and had a prescription drug fill within the selected clinical cohorts. The unit of analysis is the beneficiary-year observation. The PDE data are merged with RxNorm to select three therapeutic classes of drugs following the same procedures outlined in Study 2 for statin, oral anti-diabetic, and proton pump inhibitor drugs, the drug therapies most commonly associated with cost-related underuse within the Medicare population. To be included in the clinical cohorts, beneficiaries had to have at least one prescription drug fill for the class during the calendar year.

Figure 5 shows the flow chart illustration of the construction steps followed to create the analytical cohorts for Study 3. Within the 2006 through 2010 enhanced 5% sample of Medicare beneficiaries, there are 107,100 beneficiary-year combinations with partial LIS enrollment. Beneficiary-year combinations are excluded for any year the beneficiary is not continuously enrolled within any of the partial LIS benefit categories for the entire calendar year (n=41,502 beneficiary-years). If beneficiaries transition between partial LIS categories, they are still included for that year, but if they transition

out of the partial LIS benefit, disenroll from Medicare Part D, or die at any time during the year, they would be excluded. Next partial LIS beneficiaries are excluded if they reside in a nursing home (n=2,545 beneficiary-years) during the calendar year because they receive monitored care within the facility setting. The final exclusion is partial LIS beneficiaries enrolled within an MA-PD during the calendar year (n=23,934 beneficiary-years). The resulting analytical population is 39,119 beneficiary-years with continuous partial LIS enrollment during the calendar year that reside in the community and are covered by FFS for the year. From this analytical population, subpopulations are selected for the therapeutic cohorts based on prescription drugs filled during the year: 10,468 beneficiary-years have a proton pump inhibitor fill during the year; 16,872 beneficiary-years have a statin; and 8,625 beneficiary-years use oral anti-diabetic medications.

Outcome Variable

The proportional days covered (PDC) was calculated to measure the adherence level for each drug class during the calendar year. The same methodology for calculating PDC in Study 2 was followed for the calculation of calendar year PDC levels for Study 3. The construction of the PDC started the counting clock with the first day of the calendar year if the beneficiary had drug stock that carried over into the start of the year or on the first day of the first fill within the calendar year for the medication. Beneficiaries were

limited to carrying a maximum of 30 days of surplus drug stock at any time during the year. Gap days occur whenever the beneficiary does not have days supply or surplus stock covered and are adjusted for hospitalizations. Gaps of 90 consecutive days are considered a discontinuation and the end of the PDC calculation period. If the drug is refilled during the calendar year after discontinuation, then a second PDC period is calculated for the beneficiary and added to the first period for the calendar year adherence calculation. PDC ranges from greater than 0, perfect non-adherence, to 1, perfect adherence during the period. PDC levels greater than or equal to 0.80 are considered as adherent behavior. The outcome measure is coded as an indicator variable for adherent (PDC \geq 0.80) prescription drug behavior.

Explanatory Measures

Financial Characteristics. The partial low income subsidy group allows a comparison of a narrow income gradient between 135% and 150% of the federal poverty level. The social gradient of morbidity and mortality has been shown to persist into retirement,¹⁴² and the steep inverse relationship is such that even those in the middle of the distribution have an association with poorer health than those above them.^{140,143,179} Thus, it is expected that Medicare beneficiaries in the 75% premium subsidy group will have poorer adherence levels than those in the 25% premium subsidy group, with the

50% premium subsidy group in between them, based on differences in income levels.

The partial LIS category is based on the December enrollment category.

Partial LIS enrollees may enroll in plans with premiums above the subsidy amount and pay the full premium amount above the subsidy level. It is expected that beneficiaries who enroll in plans with premiums above the subsidy level may have more resources in income or assets than those they enroll in plans at or below the premium subsidy amount and may have better adherence rates given the additional resources.

Key control variables measure plan switching during the re-enrollment period or from one year to the next and during the benefit enrollment period.¹⁸⁰ The plan identifiers contained within the administrative data provided to academic researchers are encrypted specific to the calendar year and a crosswalk file provides plan identifier tracking from one year to the next. Changing plans during the partial LIS enrollment period, listed as change plans during year in the tables, is coded as an indicator variable for one or more plan changes.

Another key plan measure captures the degree of competition within the Part D market for the beneficiary and measures the percent of plans offered as enhanced benefit plans within the beneficiary's county. Karaca-Mandic, et al.²⁰ found this measure to be a useful instrument for capturing the level of plan generosity offered within competitive

Part D markets. It is expected that beneficiaries residing in more competitive markets may have more generous plans benefits and thereby better adherence levels.

Patient Characteristics. Demographic measures are created from the denominator data. Age is calculated based on the end of the year. The denominator files from CMS changed the reference period for age provided in the annual files from January to December (begin of year to end of year switch) between the 2008 and 2009 files, so age was recalculated to be age at end of year to be at the same time point. Gender is male or female sex from the denominator data. Race/ethnicity is from the Research Triangle Institute race variable¹³³ in the denominator data and divided into four groups for analysis: white, non-Hispanic; black, non-Hispanic; Hispanic, all races; and other, non-Hispanic.

Diagnosis Characteristics. Chronic conditions are classified using the Healthcare Cost and Utilization Project (HCUP) algorithm.¹³⁴ Using all of the diagnosis codes provided within the MedPAR data, the chronic condition indicators are created and then summed to create a co-morbidity index and used in the analysis as a three category measure comparing beneficiaries with no co-morbidities, 1 to 2 co-morbidities, and 3 or more co-morbidities.^{70,135} Medicare beneficiaries with more chronic conditions or co-

morbidities are expected to have poorer adherence levels from complicated management of polypharmacy or from poorer health limitations.

Statistical Model

The bivariate analysis of the adherent (PDC \geq 0.80) outcome measure compared for the explanatory measures of financial, patient, and diagnostic characteristics using χ^2 test statistics for the categorical explanatory measures and a t-test for difference in means for the continuous explanatory measures. The panel data cohort is tested using logistic regression analysis with indicator variables for calendar year and robust standard errors clustered by individual beneficiaries. The unit of analysis is the beneficiary-year, and three drug therapy classes are run as separate models. The logistic regression model estimates the effects of the financial, patient, and diagnostic characteristics on the calendar year measure of prescription drug adherence with PDC levels greater than or equal to 0.80 and those below that level. The adjusted Wald test of joint probability of the variables for financial, patient, and diagnostics characteristics are equal to zero as a set is also tested for each logistic regression model. The average marginal probabilities at the means of the explanatory variables are calculated from the logistic regression models to allow comparisons of financial, patient, and diagnostic variables across the three therapeutic drug cohorts. The bivariate statistics, logistic regression models, and marginal

effects are estimated using Stata 12. All results with $p < 0.05$ are discussed in the findings section.

Findings

The bivariate statistics and logistic regression model of adherent behavior for each of the three drug classes are discussed by therapeutic cohort below and followed by a discussion of the marginal effects calculated from the logistic regression models and compared across all cohorts.

Proton Pump Inhibitor Cohort

Table 23 presents the bivariate comparison statistics for PPI adherent behavior by financial, patient, and diagnostic explanatory variables. For partial LIS enrollees in stand-alone PDPs and continuously enrolled for the calendar year, 51.2 percent of the PPI cohort have PDC levels greater than or equal to 0.80 and are considered adherent and 48.9 percent of the cohort is non-adherent.

For the PPI cohort, adherence is related to the financial characteristics for premium subsidy level and plan switching behavior. Medicare beneficiaries with higher income levels and receiving the 25% premium subsidy are more likely to be adherent (30.0 percent adherent, 27.7 percent non-adherent). Medicare beneficiaries receiving the 50% premium subsidy are equally divided with 35.3 percent non-adherent and 35.7

percent adherent. Beneficiaries with the lowest income levels receiving the 75% premium subsidy are less likely to be adherent (37.0 percent non-adherent, 34.2 percent adherent). For those Medicare beneficiaries who change drug plans during the year, 3.9 percent are non-adherent compared to 2.9 percent that are adherent.

All patient characteristics are related to PPI adherence in the bivariate comparisons. PPI adherent beneficiaries have an average age of 72.7 years and non-adherent beneficiaries have an average age of 70.4 years. Males are more likely to be non-adherent (28.8 percent) than adherent (27.1 percent). White non-Hispanic Medicare beneficiaries have a higher proportional share adherent (86.9 percent) than non-adherent (78.1 percent). Black, non-Hispanic beneficiaries have a larger proportional share that is non-adherent (13.8 percent) than adherent (8.4 percent). Similar to Black, non-Hispanic beneficiaries, partial LIS enrollees with race/ethnicity of Hispanic, all races (non-adherent 7.1 percent; adherent 4.1 percent) and other, non-Hispanic (non-adherent 1.1 percent; adherent 0.6 percent).

The bivariate comparison shows that diagnosis characteristics are related to PPI adherence. Medicare beneficiaries with 3 or more co-morbidities are more likely to be adherent than non-adherent (non-adherent 52.1 percent; adherent 55.8 percent). Those with 1 to 2 co-morbidities have 15.7 percent non-adherent and 14.9 percent adherent.

Medicare beneficiaries without any co-morbidities have a higher share non-adherent, 32.3 percent, than adherent, 29.3 percent.

Table 24 provides the logistic regression results for the PPI therapeutic cohort estimating adherence by financial, patient, and diagnosis explanatory variables. Financial characteristics for the subsidy level and plan changing during the year are associated PPI adherence. Partial LIS enrollees with highest incomes levels and receiving the 25% premium subsidy (AOR = 1.2; 95% CI, 1.0-1.3) are more likely to be adherent than those with the lowest income levels and receiving the 75% premium subsidy. Beneficiaries who change drug plans during the year are less likely to be adherent (AOR = 0.8; 95% CI, 0.6-1.0). Older Medicare beneficiaries are more likely to be adherent to PPIs (AOR = 1.0; 95% CI, 1.0-1.0). In comparison with white, non-Hispanic Medicare beneficiaries, other race/ethnicity groups are less likely to be adherent to PPIs (Black AOR = 0.6; 95% CI, 0.5-0.7; Hispanic AOR = 0.5; 95% CI, 0.4-0.7; Other AOR = 0.5; 95% CI, 0.3-0.9). Unlike the bivariate findings, gender and co-morbidities are not significantly related to PPI adherence when the other financial and patient characteristics are controlled for in the model. The adjusted Wald statistics shows that the financial and patient characteristics, as a group, are related to PPI adherent behavior.

Statin Cohort

The bivariate comparison statistics for the statin drug therapy cohort are listed in Table 25. For the statin therapeutic cohort, 61.4 percent are adherent with PDC levels above the 0.80 threshold and 38.6 percent are non-adherent. Changing prescription drugs plans during the year have a larger proportional share non-adherent, 3.4 percent, than adherent, 2.8 percent, and this explanatory variable is the only financial characteristic related to statin adherence. The average age for partial LIS enrollees that are adherent, 72.8 years, is older than the average age of the non-adherent group, 70.7 years. Similar to the PPI cohort, adherence to statin drugs varies by race/ethnicity group. White, non-Hispanic beneficiaries are a larger proportion of adherent, 84.5 percent, than non-adherent, 74.2 percent. Black, non-Hispanic beneficiaries have a higher share non-adherent, 17.1 percent than adherent, 10.0 percent. Hispanic Medicare beneficiaries are more likely to be non-adherent, 7.1 percent, to statin drugs than adherent, 4.3 percent. Other, non-Hispanic beneficiaries are more likely to be non-adherent, 1.5 percent, but the proportional share adherent, 1.3 percent, is close to the same rate.

Table 26 provides the logistic regression results for the statin therapeutic cohort predicting PDC levels greater than 0.80 or adherent by financial, patient, and diagnosis explanatory variables. The adjusted Wald test statistics show that patient characteristics

are the only set of explanatory measures that as a group are related to statin adherent behavior for the partial LIS enrollees. Older Medicare beneficiaries are more likely to be adherent (AOR = 1.0; 95% CI, 1.0-1.0). In comparison with white, non-Hispanic Medicare beneficiaries, black beneficiaries (AOR = 0.5; 95% CI, 0.5-0.6) and Hispanic beneficiaries (AOR = 0.5; 95% CI, 0.5-0.7) are less likely to be adherent. Controlling for all other financial and patient characteristics, Medicare beneficiaries with 3 or more co-morbidities (AOR = 0.9; 95% CI, 0.8-1.0) are less likely to be adherent with statin drug therapies than beneficiaries without any co-morbidities.

Oral Anti-Diabetics Cohort

Table 27 shows the bivariate comparison statistics for oral anti-diabetic adherence groups by financial, patient, and diagnostic explanatory variables. For partial LIS enrollees taking oral anti-diabetic medications, 70.5 percent have PDC levels greater than or equal to 0.80 and are considered adherent and 29.5 percent of the cohort is non-adherent.

Financial characteristics related to adherent behavior for the oral anti-diabetic cohort include for premium subsidy level and drug plan market competition as measured by the percent of gap plan offerings. Medicare beneficiaries receiving the 25% premium subsidy have the highest income levels among partial LIS enrollees and are more likely to

be adherent (29.9 percent adherent, 26.9 percent non-adherent). Medicare beneficiaries receiving the 50% premium subsidy have a higher proportion with non-adherent, 36.0 percent, than adherent, 34.7 percent. Beneficiaries with the lowest income levels among partial LIS enrollees are receiving the 75% premium subsidy and are less likely to be adherent (37.1 percent non-adherent, 35.4 percent adherent). The average market portion of gap plan offerings for adherent oral anti-diabetic medications (average 4.1 percent) is higher than non-adherents (average 4.0 percent).

Patient characteristics related to oral anti-diabetic adherence in the bivariate comparisons include age and race/ethnicity. Oral anti-diabetic adherent beneficiaries have an average age of 71.5 years and non-adherent beneficiaries have an average age of 69.4 years. White non-Hispanic partial LIS enrollees have a higher proportional share adherent (78.7 percent) than non-adherent (69.6 percent). Black, non-Hispanic beneficiaries have a larger proportional share that is non-adherent (19.5 percent) than adherent (12.9 percent). Hispanic beneficiaries also have a larger percent who are non-adherent, 9.1 percent, than adherent, 6.8 percent. Other, non-Hispanic partial LIS enrollees have similar shares in the oral anti-diabetic adherence groups with 1.8 percent non-adherent and 1.6 percent adherent.

Diagnosis characteristics are also related to oral anti-diabetic adherent behavior. Medicare beneficiaries with more chronic conditions are less likely to be adherent on oral anti-diabetic medications. Partial LIS enrollees with 3 or more co-morbidities are 56.4 percent of non-adherent and 50.0 percent of adherent group. Those with 1 to 2 co-morbidities have more evenly distributed in each of the two statin adherent behavior groups with 11.2 percent non-adherent and 11.4 percent adherent. Medicare beneficiaries with no co-morbidities have a higher share adherent, 38.6 percent, than non-adherent, 32.4 percent.

Table 28 presents the adjusted odds ratio from the logistic regression results for the oral anti-diabetic therapeutic cohort. The adjusted Wald test statistics show that patient and diagnosis characteristics are related to oral anti-diabetic adherence. The likelihood of adherent oral anti-diabetic behavior increases with age (AOR = 1.0; 95% CI, 1.0-1.0). In comparison with white, non-Hispanic beneficiaries, black, non-Hispanic partial LIS enrollees are likely to be adherent to oral anti-diabetic drug therapies (AOR = 0.6; 95% CI, 0.5-0.7). Hispanic beneficiaries are also less likely to be adherent (AOR = 0.7; 95% CI, 0.5-0.8). Medicare beneficiaries with 1 to 2 co-morbidities, in reference to those with no co-morbidities, are less likely to be adherent (AOR = 0.8; 95% CI, 0.6-1.0),

and those with 3 or more co-morbidities are less likely to be adherent (AOR = 0.7; 95% CI, 0.6-0.8).

Marginal Effects Comparison of Clinical Cohorts

Table 29 shows the adjusted marginal probability of adherent prescription drug behavior by financial, patient, and diagnostic characteristics for each of the therapeutic drug cohorts as estimated from their corresponding logistic regression results presented in Tables 24, 26, and 28. The average marginal effect (AME) is the estimated change in probability for the measure holding all other model variables at their mean values.

Financial characteristics are associated with adherent behavior for the PPI cohort. Partial LIS enrollees with the 25% premium subsidy have a 0.04 (95% CI, 0.01-0.07) increase in probability of adherent behavior than the 75% premium subsidy group. Beneficiaries than change plans during the year have a 0.07 (95% CI, -0.12 - -0.01) lower probability than those that do not change plans.

Age and race/ethnicity are patient characteristics related to adherent behavior within all three cohorts. For each additional year in age, the probability of adherent drug behavior increases 0.004 for all three drug therapy cohorts (PPI CI, 0.003-0.005; statin CI, 0.003-0.01; oral anti-diabetic CI, 0.003-0.01). Non-white race/ethnicity groups in reference to the white, non-Hispanic group have lower probability of adherence within all

three therapeutic classes. For the statin and oral anti-diabetic cohorts, Medicare beneficiaries who are black, non-Hispanic (statin AME = -0.15; 95% CI, -0.18 - -0.12; oral anti-diabetic AME = -0.11; 95% CI, -0.15 - -0.07) have lower probabilities of adherence than Hispanic beneficiaries (statin AME = -0.15; 95% CI, -0.19 - -0.10; oral anti-diabetic AME = -0.09; 95% CI, -0.14 - -0.04). Within the PPI cohort, Hispanic beneficiaries (AME = -0.16; 95% CI, -0.21 - -0.11) and other, non-Hispanic partial LIS enrollees (AME = -0.16; 95% CI, -0.29 - -0.02) have lower probabilities of adherence than black, non-Hispanic beneficiaries (AME = -0.14; 95% CI, -0.18 - -0.10).

Diagnostic characteristics are related to the probability of statin and oral anti-diabetic adherence but are not associated with PPI adherent behavior. In reference to beneficiaries with no co-morbidities, beneficiaries with 1 to 2 co-morbidities have a lower probability of oral anti-diabetic adherence (AME = -0.05; 95% CI, -0.09 - -0.004) while beneficiaries with 3 or more co-morbidities have a lower probability of statin adherence (AME = -0.02; 95% CI, -0.05 - -0.00) and oral anti-diabetic adherence (AME = -0.08; 95% CI, -0.11 - -0.05).

Discussion

The study shows that within the partial low income subsidy program even modest income differences between the highest and lowest income thresholds may affect drug

adherence, but these differences only statistical significance for the PPI cohort, the therapeutic cohort most likely to be associated with self-reported, cost-related underuse. The more recent facilitated plan enrollment for the partial LIS group¹⁸¹ making it comparable to the same offering of facilitated enrollment for full LIS beneficiaries in low quality or discontinued plans should be beneficial for the PPI cohort changing plans during the year.

Race/ethnicity differences for black and Hispanic Medicare beneficiaries are common across all three clinical cohorts. Race/ethnicity differences may be related to long-term factors that do not have readily available policy solutions to address, such as cost-sharing and premium subsidization for difference in income and assets. Previous research examining race/ethnicity difference in adherence following heart failure found similar persistent effects,¹⁵⁹ but that study population included disabled and aged Medicare qualified beneficiaries who have different confounding influences. The findings, controlling for specifically identified income groups, from this study for an aged-qualified Medicare population suggest additional research is needed to understand if improvements in pharmacy access issues or better physician-patient relationships would provide more targeted solutions to address the racial and ethnic differences in adherence for this low income Medicare population.

Testing of income effects has been limited due to the confounding effects of differences in benefit designs linked to income levels. By focusing on the partial low income subsidy group, marginal differences in income levels can be tested among beneficiaries who face the same coinsurance rates. The main contribution of this study is the analysis of income and race/ethnicity effects on adherence while controlling for benefit design features with the Medicare population.

One of the key features of the ACA is premium subsidization for lower income populations. The Medicare Part D partial Low Income Subsidy program provides a useful scale comparison, with the limitation of focus on an elderly population, of subsidization based on income levels for an expansion population. The findings from this study show income effects have been minimized, but race/ethnicity differences remain.

Figure 5: Study 3 Analytical Sample Construction

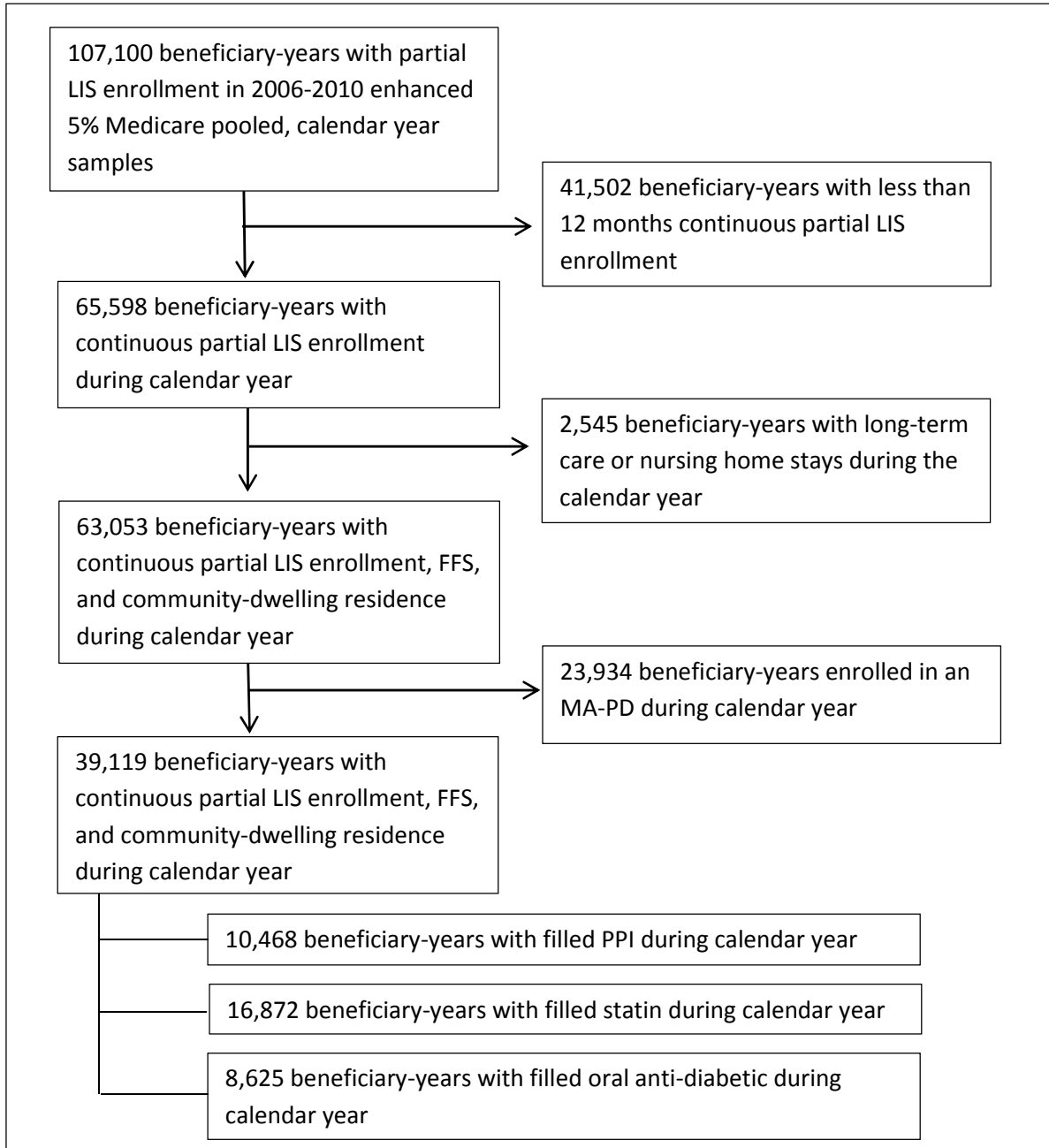


Table 23: Bivariate Comparison Statistics of Explanatory Variables by Proton Pump Inhibitor (PPI) Adherence Behavior for Community-Dwelling Medicare Beneficiaries Enrolled in the Part D Partial Low Income Subsidy (LIS) Program and in Stand-Alone Prescription Drug Plans

Variable	Nonadherent PDC < 0.8	Adherent PDC >= 0.8	P value
<i>Financial Characteristics</i>			
<u>Partial LIS Income/Subsidy Category</u>			
75% Premium Subsidy	37.0%	34.2%	0.005 ^a
50% Premium Subsidy	35.3%	35.7%	
25% Premium Subsidy	27.7%	30.0%	
Does not change plans	96.1%	97.2%	0.003 ^a
Change Plans During Year	3.9%	2.9%	
Does not switch plans	89.0%	88.0%	0.117 ^a
Switch Plans at Re-Enrollment	11.0%	12.0%	
Plan Premium Not Above Subsidy	81.7%	81.0%	0.393 ^a
Plan Premium Above Subsidy Level	18.3%	19.0%	
Market Percent of Gap Plans (μ , percent)	3.9	4.0	0.815 ^b
<i>Patient Characteristics</i>			
Age (μ , years)	70.4	72.7	0.000 ^b
Female	71.2%	73.0%	0.042 ^a
Male	28.8%	27.1%	
White	78.1%	86.9%	0.000 ^a
Black	13.8%	8.4%	

Variable	Nonadherent PDC < 0.8	Adherent PDC >= 0.8	P value
Hispanic	7.1%	4.1%	
Other	1.1%	0.6%	
<i>Diagnosis Characteristics</i>			
No Co-Morbidities	32.3%	29.3%	0.001 ^a
1-2 Co-morbidities	15.7%	14.9%	
3 or more Co-Morbidities	52.1%	55.8%	
Number of Beneficiary-Years	5,120	5,361	
Percent	48.9%	51.2%	

Note: Statistical test denoted by ^a is chi-square test and by ^b is paired t-test of difference in means. Data from enhanced 5% sample of Medicare beneficiaries, 2006-2010.

Table 24: Logistic Regression of Financial, Patient, and Diagnosis Characteristics on PPI Adherent Behavior for Community-Dwelling Partial LIS Medicare Beneficiaries Enrolled in Stand-Alone PDPs

Variable	Adjusted Odds Ratio	P> z	95% Confidence Interval	
Financial Characteristics				
<u>Partial LIS Income/Subsidy Category</u>				
75% Premium Subsidy		reference		
50% Premium Subsidy	1.08	0.177	0.96	1.22
25% Premium Subsidy	1.16	0.020	1.02	1.31
Change Plans During Year	0.76	0.016	0.61	0.95
Switch Plans at Re-Enrollment	1.11	0.113	0.98	1.26
Plan Premium Above Subsidy Level	1.02	0.753	0.90	1.15
Market Percent of Gap Plans	1.00	0.834	0.98	1.02
Patient Characteristics				
Age	1.01	0.000	1.01	1.02
Female		reference		
Male	1.04	0.518	0.92	1.17
White		reference		
Black	0.58	0.000	0.49	0.68
Hispanic	0.53	0.000	0.42	0.66
Other	0.53	0.030	0.30	0.94
Diagnosis Characteristics				
No Co-Morbidities		reference		
1-2 Co-morbidities	0.98	0.806	0.83	1.15
3 or more Co-Morbidities	1.08	0.192	0.96	1.21

Variable	Adjusted Odds Ratio	P> z	95% Confidence Interval	
<i>Control Variables</i>				
	2006		reference	
	2007	0.83	0.021	0.71 0.97
	2008	0.98	0.802	0.83 1.16
	2009	0.97	0.709	0.83 1.13
	2010	0.79	0.004	0.68 0.93
<u>Intercept</u>		0.41	0.000	0.29 0.59

Note: Data from the enhanced 5% sample of Medicare beneficiaries, 2006-2010. The unit of analysis is the beneficiary-year. Robust standard errors clustered by individual beneficiaries. Model statistics: Wald $\chi^2(17)=174.88$, $P>|\chi^2|=0.000$; Pseudo R-squared=0.0185. Adjusted Wald test of joint probability for financial characteristics: $\chi^2(6)=13.88$, $P>|\chi^2|=0.031$; patient characteristics: $\chi^2(5)=122.26$, $P>|\chi^2|=0.000$; diagnosis characteristics: $\chi^2(2)=2.69$, $P>|\chi^2|=0.260$.

Table 25: Bivariate Comparison Statistics of Explanatory Variables by Statin Adherence Behavior for Community-Dwelling Medicare Beneficiaries Enrolled in the Part D Partial Low Income Subsidy (LIS) Program and in Stand-Alone Prescription Drug Plans

Variable	Nonadherent PDC < 0.8	Adherent PDC >= 0.8	P value
<i>Financial Characteristics</i>			
<u>Partial LIS Income/Subsidy Category</u>			
75% Premium Subsidy	36.3%	35.1%	0.077 ^a
50% Premium Subsidy	36.0%	35.6%	
25% Premium Subsidy	27.7%	29.3%	
Does not change plans	96.6%	97.2%	0.025 ^a
Change Plans During Year	3.4%	2.8%	
Does not switch plans	89.9%	89.3%	0.173 ^a
Switch Plans at Re-Enrollment	10.1%	10.7%	
Plan Premium Not Above Subsidy	82.2%	81.1%	0.053 ^a
Plan Premium Above Subsidy Level	17.8%	19.0%	
Market Percent of Gap Plans (μ , percent)	4.1	4.0	0.083 ^b
<i>Patient Characteristics</i>			
Age (μ , years)	70.7	72.8	0.000 ^b
Female	67.1%	68.4%	0.088 ^a
Male	32.9%	31.7%	
White	74.2%	84.5%	0.000 ^a
Black	17.1%	10.0%	

Variable	Nonadherent PDC < 0.8	Adherent PDC >= 0.8	P value
Hispanic	7.1%	4.3%	
Other	1.5%	1.3%	
<i>Diagnosis Characteristics</i>			
No Co-Morbidities	38.8%	39.4%	0.744 ^a
1-2 Co-morbidities	15.8%	15.7%	
3 or more Co-Morbidities	45.4%	44.9%	
Number of Beneficiary-Years	6,518	10,373	
Percent	38.6%	61.4%	

Note: Statistical test denoted by ^a is chi-square test and by ^b is paired t-test of difference in means. Data from enhanced 5% sample of Medicare beneficiaries, 2006-2010.

Table 26: Logistic Regression of Financial, Patient, and Diagnosis Characteristics on Statin Adherent Behavior for Community-Dwelling Partial LIS Medicare Beneficiaries Enrolled in Stand-Alone PDPs

Variable	Adjusted Odds Ratio	P> z	95% Confidence Interval	
Financial Characteristics				
<u>Partial LIS Income/Subsidy Category</u>				
75% Premium Subsidy		reference		
50% Premium Subsidy	1.01	0.875	0.92	1.11
25% Premium Subsidy	1.08	0.136	0.98	1.19
Change Plans During Year	0.86	0.105	0.71	1.03
Switch Plans at Re-Enrollment	1.06	0.303	0.95	1.18
Plan Premium Above Subsidy Level	1.06	0.280	0.96	1.17
Market Percent of Gap Plans	1.00	0.631	0.98	1.01
Patient Characteristics				
Age	1.02	0.000	1.01	1.02
Female		reference		
Male	1.08	0.079	0.99	1.19
White		reference		
Black	0.53	0.000	0.47	0.60
Hispanic	0.54	0.000	0.45	0.65
Other	0.72	0.060	0.51	1.01
Diagnosis Characteristics				
No Co-Morbidities		reference		
1-2 Co-morbidities	0.91	0.143	0.81	1.03
3 or more Co-Morbidities	0.90	0.024	0.82	0.99

Variable	Adjusted Odds Ratio	P> z	95% Confidence Interval	
<i>Control Variables</i>				
	2006		reference	
	2007	0.95	0.443	0.84 1.08
	2008	1.08	0.233	0.95 1.24
	2009	1.10	0.128	0.97 1.24
	2010	1.02	0.725	0.90 1.16
<u>Intercept</u>		0.49	0.000	0.36 0.67

Note: Data from the enhanced 5% sample of Medicare beneficiaries, 2006-2010. The unit of analysis is the beneficiary-year. Robust standard errors clustered by individual beneficiaries. Model statistics: Wald $\chi^2(17)=256.55$, $P>|\chi^2|=0.000$; Pseudo R-squared=0.0188. Adjusted Wald test of joint probability for financial characteristics: $\chi^2(6)=7.96$, $P>|\chi^2|=0.241$; patient characteristics: $\chi^2(5)=229.69$, $P>|\chi^2|=0.000$; diagnosis characteristics: $\chi^2(2)=5.41$, $P>|\chi^2|=0.067$.

Table 27: Bivariate Comparison Statistics of Explanatory Variables by Oral Anti-Diabetic Medication Adherence Behavior for Community-Dwelling Medicare Beneficiaries Enrolled in the Part D Partial Low Income Subsidy (LIS) Program and in Stand-Alone Prescription Drug Plans

Variable	Nonadherent PDC < 0.8	Adherent PDC >= 0.8	P value
<i>Financial Characteristics</i>			
<u>Partial LIS Income/Subsidy Category</u>			
75% Premium Subsidy	37.1%	35.4%	0.024 ^a
50% Premium Subsidy	36.0%	34.7%	
25% Premium Subsidy	26.9%	29.9%	
Does not change plans	96.7%	96.7%	0.986 ^a
Change Plans During Year	3.3%	3.3%	
Does not switch plans	89.5%	89.2%	0.751 ^a
Switch Plans at Re-Enrollment	10.6%	10.8%	
Plan Premium Not Above Subsidy	81.4%	81.7%	0.745 ^a
Plan Premium Above Subsidy Level	18.6%	18.3%	
Market Percent of Gap Plans (μ , percent)	4.0	4.1	0.038 ^b
<i>Patient Characteristics</i>			
Age (μ , years)	69.4	71.5	0.000 ^b
Female	65.0%	65.7%	0.523 ^a
Male	35.0%	34.3%	
White	69.6%	78.7%	0.000 ^a
Black	19.5%	12.9%	

Variable	Nonadherent PDC < 0.8	Adherent PDC >= 0.8	P value
Hispanic	9.1%	6.8%	
Other	1.8%	1.6%	
<i>Diagnosis Characteristics</i>			
No Co-Morbidities	32.4%	38.6%	0.000 ^a
1-2 Co-morbidities	11.2%	11.4%	
3 or more Co-Morbidities	56.4%	50.0%	
Number of Beneficiary-Years	2,550	6,085	
Percent	29.5%	70.5%	

Note: Statistical test denoted by ^a is chi-square test and by ^b is paired t-test of difference in means. Data from enhanced 5% sample of Medicare beneficiaries, 2006-2010.

Table 28: Logistic Regression of Financial, Patient, and Diagnosis Characteristics on Oral Anti-Diabetic Adherent Behavior for Community-Dwelling Partial LIS Medicare Beneficiaries Enrolled in Stand-Alone PDPs

Variable	Adjusted Odds Ratio	P> z	95% Confidence Interval	
Financial Characteristics				
<u>Partial LIS Income/Subsidy Category</u>				
75% Premium Subsidy			reference	
50% Premium Subsidy	0.98	0.820	0.86	1.13
25% Premium Subsidy	1.13	0.107	0.97	1.31
Change Plans During Year	1.02	0.897	0.78	1.32
Switch Plans at Re-Enrollment	1.01	0.867	0.86	1.19
Plan Premium Above Subsidy Level	0.97	0.680	0.84	1.12
Market Percent of Gap Plans	1.02	0.119	1.00	1.04
Patient Characteristics				
Age	1.02	0.000	1.01	1.03
Female			reference	
Male	1.10	0.160	0.96	1.25
White			reference	
Black	0.60	0.000	0.51	0.71
Hispanic	0.65	0.000	0.52	0.81
Other	0.74	0.215	0.46	1.19
Diagnosis Characteristics				
No Co-Morbidities			reference	
1-2 Co-morbidities	0.79	0.026	0.64	0.97
3 or more Co-Morbidities	0.67	0.000	0.59	0.77

Variable	Adjusted Odds Ratio	P> z	95% Confidence Interval	
<i>Control Variables</i>				
	2006		reference	
	2007	0.73	0.001	0.60 0.88
	2008	0.70	0.001	0.57 0.86
	2009	0.76	0.006	0.63 0.92
	2010	0.61	0.000	0.50 0.74
<u>Intercept</u>		1.06	0.821	0.66 1.69

Note: Data from the enhanced 5% sample of Medicare beneficiaries, 2006-2010. The unit of analysis is the beneficiary-year. Robust standard errors clustered by individual beneficiaries. Model statistics: Wald $\chi^2(17)=156.43$, $P>|\chi^2|=0.000$; Pseudo R-squared=0.0227. Adjusted Wald test of joint probability for financial characteristics: $\chi^2(6)=6.65$, $P>|\chi^2|=0.355$; patient characteristics: $\chi^2(5)=98.76$, $P>|\chi^2|=0.000$; diagnosis characteristics: $\chi^2(2)=33.97$, $P>|\chi^2|=0.000$.

Table 29: Adjusted Marginal Probability of Adherent Prescription Drug Behavior by Drug Therapy Class Cohorts

Variable	Proton Pump Inhibitor Therapeutic Class Cohort		Statin Therapeutic Class Cohort		Oral Anti-Diabetic Therapeutic Class Cohort	
	AME (95% CI)	P> z	AME (95% CI)	P> z	AME (95% CI)	P> z
Financial Characteristics						
<u>Partial LIS Income/Subsidy Category</u>						
75% Premium Subsidy	reference		reference		reference	
50% Premium Subsidy	0.0201 (-0.01,0.05)	0.177	0.0018 (-0.02,0.02)	0.875	-0.0033 (-0.03,0.03)	0.820
25% Premium Subsidy	0.0366 (0.01,0.07)	0.020	0.0181 (-0.01,0.04)	0.135	0.0249 (-0.01,0.06)	0.106
Change Plans During Year	-0.0680 (-0.12,-0.01)	0.015	-0.0365 (-0.08,0.01)	0.110	0.0036 (-0.05,0.06)	0.897
Switch Plans at Re-Enrollment	0.0256 (-0.01,0.06)	0.112	0.0133 (-0.01,0.04)	0.300	0.0028 (-0.03,0.04)	0.866
Plan Premium Above Subsidy Level	0.0048 (-0.03,0.03)	0.753	0.0131 (-0.01,0.04)	0.277	-0.0063 (-0.04,0.02)	0.681
Market Percent of Gap Plans	-0.0005 (-0.01,0.004)	0.834	-0.0009 (-0.004,0.003)	0.631	0.0036 (-0.001,0.01)	0.119
Patient Characteristics						
Age	0.0036 (0.003,0.005)	0.000	0.0042 (0.003,0.01)	0.000	0.0040 (0.003,0.01)	0.000

Variable	Proton Pump Inhibitor Therapeutic Class Cohort		Statin Therapeutic Class Cohort		Oral Anti-Diabetic Therapeutic Class Cohort	
	AME (95% CI)	P> z	AME (95% CI)	P> z	AME (95% CI)	P> z
Female	reference		reference		reference	
Male	0.0096 (-0.02,0.04)	0.518	0.0190 (-0.002,0.04)	0.078	0.0189 (-0.01,0.05)	0.157
White	reference		reference		reference	
Black	-0.1365 (-0.18,-0.10)	0.000	-0.1542 (-0.18,-0.12)	0.000	-0.1095 (-0.15,-0.07)	0.000
Hispanic	-0.1571 (-0.21,-0.11)	0.000	-0.1479 (-0.19,-0.10)	0.000	-0.0927 (-0.14,-0.04)	0.000
Other	-0.1560 (-0.29,-0.02)	0.024	-0.0784 (-0.16,0.01)	0.067	-0.0634 (-0.17,0.04)	0.241
Diagnosis Characteristics						
No Co-Morbidities	reference		reference		reference	
1-2 Co-morbidities	-0.0051 (-0.05,0.04)	0.806	-0.0214 (-0.05,0.01)	0.144	-0.0462 (-0.09,-0.004)	0.031
3 or more Co-Morbidities	0.0193 (-0.01,0.05)	0.192	-0.0247 (-0.05,0.00)	0.024	-0.0800 (-0.11,-0.05)	0.000

Note: AME is Average Marginal Effect, at means. CI is Confidence Interval. Probabilities are constructed from Tables 24, 26, and 28 logit model estimates by therapeutic class cohorts. Data are Medicare claims and enrollment for the enhanced 5% standard sample, 2006-2010. Predicted probability of PPI adherence is 0.51 (95% CI: 0.50-0.52, P>0.000). Predicted probability of statin adherence is 0.61 (95% CI: 0.60-0.62, P>0.000). Predicted probability of oral anti-diabetic adherence is 0.70 (95% CI: 0.69-0.72, P>0.000).

Project Conclusions

The three research aims of this project examined cost-related underuse of prescription drugs and medical care within the Medicare population and explored how financial, patient, and diagnostic characteristics were associated with those health behaviors.

Summary of Research Aims

The first research aim examined the relationship between prescription drug coverage and medical care cost underutilization. The primary purpose was to examine rates of health care underutilization within the Medicare population and to compare these rates before and after the implementation of the Medicare Part D benefit.

Cost-related underuse is a concern within the Medicare population with limited household budgets and no additional financial resources. The implementation of Medicare Part D resulted in a reduction of cost-related nonadherence to prescription drugs during the initial years, but the relationship to cost-related underuse of medical care within the household has not received the same attention.

The findings demonstrated that the implementation of Medicare Part D benefit reduced the rates of cost-related underuse of medical care and prescription drugs. Nonetheless, the analysis of the stratified, subpopulations based on underuse behavior in 2005 showed that prescription drug coverage was not associated with resolving cost-related underuse of prescription drugs or medical care. Instead, the findings highlighted differences between Medicare beneficiaries that continued to have no drug coverage

following the implementation of Part D and those that had continued drug coverage in both 2005 and 2007 by showing that those without coverage were associated with an increased probability of experiencing new cost-related underuse of prescription drugs or medical care in comparison to those Medicare beneficiaries that did not have any self-reported underuse in 2005 or 2007.

The strengths of this study are the use of a nationally representative longitudinal sample of community-dwelling Medicare beneficiaries that allows comparison of behaviors before and after the implementation of Part D. One weakness of the study is that it measures association and not causality.

While cost related underuse of drugs has been examined following the Part D implementation, the phenomenon of medical care underutilization due to cost has not received the same attention. The main contribution this study makes is the comparison with medical care underuse and prescription drug underuse.

The second research aim evaluated the effects of the Medicare Partial Low Income Subsidy benefit on drug adherence. The purpose of this aim was to evaluate the Medicare Partial Low Income Subsidy (LIS) benefit and to determine its effect on prescription drug adherence for three therapeutic cohorts of beneficiaries prescribed statins, anti-diabetic agents, or proton pump inhibitors (PPIs).

After enrollment in the partial LIS benefit, adherence levels increased on average within all three therapeutic cohorts. Comparing the three premium subsidization groups found insignificant differences for the statin and oral anti-diabetic cohorts, but small differences between the subsidization groups were statistically significant for the PPI

cohort, which found that the highest income group had more improvement in adherence levels. For all three of the therapeutic cohorts, Medicare beneficiaries residing in more competitive Part D plan markets may have experienced less cost pressure from plans with more generous benefits.

Overall, partial LIS enrollees improved adherence rates in the three therapeutic classes most likely to have cost-related underuse following enrollment in the benefit. This suggests that the partial LIS benefit may be offering financial protections for Medicare beneficiaries with out-of-pocket spending for prescription drugs.

The strengths of this study are the use of national claims data for the 5 percent Medicare sample for community-dwelling beneficiaries. The weaknesses of the study are the findings are limited to the three drug classes and may not generalize to other partial LIS enrollees that do not transition into the benefit from Part D or are enrolled in Medicare Advantage plans.

The partial low income subsidy group has not received much specific attention within the literature to date, most likely due to the relatively small size, but this study provides an important first step by examining the basic question of enrollee adherence. The main contribution of this study is the application of existing health services research hypotheses and theory onto an understudied programmatic area.

The partial low income subsidy extended subsidized benefits to a Medicare population that previously did not have any additional assistance, essentially serving as an expansion population. The findings from this study suggest that the additional assistance has provided clinical improvement, as measured by increased adherence, for

these three therapeutic cohorts. In addition, the finding within all three drug therapy cohorts that increased exposure or longer enrollment within the partial LIS benefit was associated with better adherence levels suggests that process changes that reduce the administrative burden of re-enrollment may improve the health of the Medicare population with low incomes.

The third research aim analyzed the effects of differing subsidization levels by income levels and race/ethnicity. The purpose was to examine income effects within the Medicare Part D Low Income Partial Subsidy and their effect on prescription drug adherence within three selected therapeutic cohorts that frequently experience cost-related underuse.

Health services research has demonstrated the effects of income gradients on health behaviors and price sensitivity in response to out-of-pocket cost sharing. However, these effects have not been examined within the national Medicare population for partial low-income subsidy.

For the PPI cohorts, the 25 percent subsidy group had a higher probability of adherent behavior than the 75 percent subsidy group, but the 50 percent subsidy group was not significantly different. For the statin and oral anti-diabetic medication cohorts, the financial characteristics were not significant. Across all three therapeutic cohorts race/ethnicity differences remained and decreased the likelihood of adherent behavior. Within the partial low income subsidy program even small income differences may affect drug adherence for some therapeutic classes, but race/ethnicity differences are statistically significant for all three clinical cohorts.

The strengths of this study are the partial low income subsidy groups face the same benefit design so that the income effects may be isolated. The weaknesses are the findings are examine by selected therapeutic class and need to be replicated for other drug therapies.

Testing of income effects has been limited due to the confounding effects of differences in benefit designs linked to income levels. By focusing on the partial low income subsidy group, marginal differences in income levels can be tested among beneficiaries who face the same coinsurance rates. The main contribution of this study is the analysis of income and race/ethnicity effects on adherence while controlling for benefit design features with the Medicare population. The Affordable Care Act (ACA) eliminated assets restrictions by using modified adjusted gross income (MAGI) eligibility, but Medicare savings programs (Medicare-Medicaid duals) and the LIS benefit continue to use assets. The limited findings on income differences in this study but the sharp contrasts by race/ethnicity may be capturing these asset differences. Within the Medicare population, the spend down of asset levels is most frequently associated with needing Medicaid wrap-around coverage for nursing home care as a result of declining health that requires long term care assistance. Eliminating the asset qualification would provide Part D cost sharing assistance for the beneficiary, and the reduced financial pressure may maintain and increase health within Medicare population with low incomes.

One of the key features of the ACA is premium subsidization for lower income populations. The Medicare Part D partial Low Income Subsidy program provides a useful

scale comparison, with the limitation of focus on an elderly population, of subsidization based on income levels for an expansion population. The findings from this study show that income effects have been minimized, but race/ethnicity differences remain.

A summary of financial, patient, and diagnosis characteristics across the three studies are listed in Table 30. The application of the conceptual model from Piette's et al.⁵¹ development of cost-related non-adherence in Study 1, which directly measure self-reported cost-related underuse, shows a comparison of the financial characteristics by the stratification of the Medicare population based on underuse and no underuse were only significant for those experiencing new cost-related underuse of medical care. For the other subpopulations, resolved underuse or new cost-related prescription drug underuse was associated with patient characteristics and their diagnosis characteristics. For Studies 2 and 3, the use of therapeutic classes most likely to have cost-related underuse to examine adherence within a low-income Medicare population was an attempt to keep the same framework, but financial characteristics were not significant for either Study 2 or 3's oral anti-diabetic cohorts and were not significant for Study 2's PPI cohort or Study 3's statin cohort. It may be the case that medically-sensitive therapeutic classes would show different results.

Policy Implications

The LIS program provides premium payment assistance and reduced cost-sharing for Medicare Part D beneficiaries who qualify based on income and asset levels. The income limits for LIS qualification are up to 150% of the federal poverty limit (FPL) and, in 2011, assets that do not exceed \$12,640 for individuals or \$25,260 for married couples.

Medicare beneficiaries who are dually enrolled in Medicaid are auto-enrolled or deemed into LIS and receive a full 100% premium subsidy. Non-deemed LIS recipients must apply for program enrollment and receive partial premium assistance on a sliding scale based on their income level and a set 15% co-insurance rate. In addition to premium and cost-sharing assistance, LIS program enrollees do not experience the coverage gap during the year and may change drug plans at any time. The findings from Study 1 suggest that programs that target those without drug coverage to enroll in the Part D benefit would help to reduce new cost-related underuse of prescription drugs or medical care. The implications of the study 2 findings suggest that efforts to improve awareness of the availability of the LIS program to increase enrollment will benefit Medicare population health by improving adherence levels for drugs most likely to have cost-related underuse. From Study 3, the findings suggest the importance of targeting programs and policy changes to improve patient-physician communication about prescription drug treatment efficacy to increase drug adherence levels and reduce differences by race/ethnicity.

Future Research

Additional research related to these research aims includes examining how financial, patient, and diagnostic characteristics affect additional outcomes, study populations, and time periods.

Following from the first research aim examining how cost-related underuse of medical care was affected by reduced financial constraints from obtaining drug coverage, it is important to test the model during other time periods to examine how changes in

drug coverage that are not from a nationwide benefit expansion may affect underuse of medical care.

The next top priority following from the findings of the second research aim on the transition into the partial LIS program is to examine other outcomes, such as drug initiation and discontinuation, and other therapeutic classes, such as medications for medically sensitive conditions. In addition based on understanding the dynamic enrollment patterns of the partial LIS beneficiaries learned in creating the analytical dataset for Study 2, a new research aim examining preventable hospital admissions and readmissions for medication sensitive conditions comparing partial LIS beneficiaries who enroll and disenroll in the Part D benefit is an important area of future study.

Adding the Medicare Advantage population is the next step for the third research aim study. Schneeweiss, et al.¹⁸² have shown using the New Jersey Medicaid population that prescription drug therapeutic risk adjusters are adequate substitutes for diagnosis developed adjusters. With the use of a commercial therapeutic classification of prescription drugs to create risk adjusters for the diagnostic characteristic measures, the Medicare Advantage and stand-alone prescription drug populations could be studied together for a more complete picture of the partial LIS program and further examination of the race/ethnicity differences within the partial LIS enrollment population.

Table 30: Project Summary of Adjusted Wald Test of Financial, Patient, and Diagnosis Characteristics Model Findings on Cost-Related Underuse and Therapeutic Drug Classes More Likely to have Cost-Related Underuse

Study, Outcome (Table)	Financial Characteristics	Patient Characteristics	Diagnosis Characteristics
Study 1: Cost-Related Underuse of Prescription Drugs in 2007 for those Experiencing Cost-Related Underuse of Prescription Drugs in 2005 (Table 4)	Not Significant	Significant	Significant
Study 1: Cost-Related Underuse of Prescription Drugs in 2007 for those Not Experiencing Cost-Related Underuse of Prescription Drugs in 2005 (Table 6)	Not Significant	Significant	Significant
Study 1: Cost-Related Underuse of Medical Care in 2007 for those Experiencing Cost-Related Underuse of Medical Care in 2005 (Table 9)	Not Significant	Not Significant	Not Significant
Study 1: Cost-Related Underuse of Medical Care in 2007 for those Not Experiencing Cost-Related Underuse of Medical Care in 2005 (Table 11)	Significant	Significant	Significant
Study 2: PPI Adherence Before and After Partial LIS Enrollment (Table 16)	Not Significant	Not Significant	Significant
Study 2: Statin Adherence Before and After Partial LIS Enrollment (Table 19)	Significant	Significant	Not Significant

Study, Outcome (Table)	Financial Characteristics	Patient Characteristics	Diagnosis Characteristics
Study 2: Oral Anti-Diabetic Adherence Before and After Partial LIS Enrollment (Table 22)	Not Significant	Not Significant	Not Significant
Study 3: PPI Adherence for Continuous Partial LIS Enrollees During Calendar Year (Table 24)	Significant	Significant	Not Significant
Study 3: Statin Adherence for Continuous Partial LIS Enrollees During Calendar Year (Table 26)	Not Significant	Significant	Not Significant
Study 3: Oral Anti-Diabetic Adherence for Continuous Partial LIS Enrollees During Calendar Year (Table 28)	Not Significant	Significant	Significant

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Appendix A for Study 2

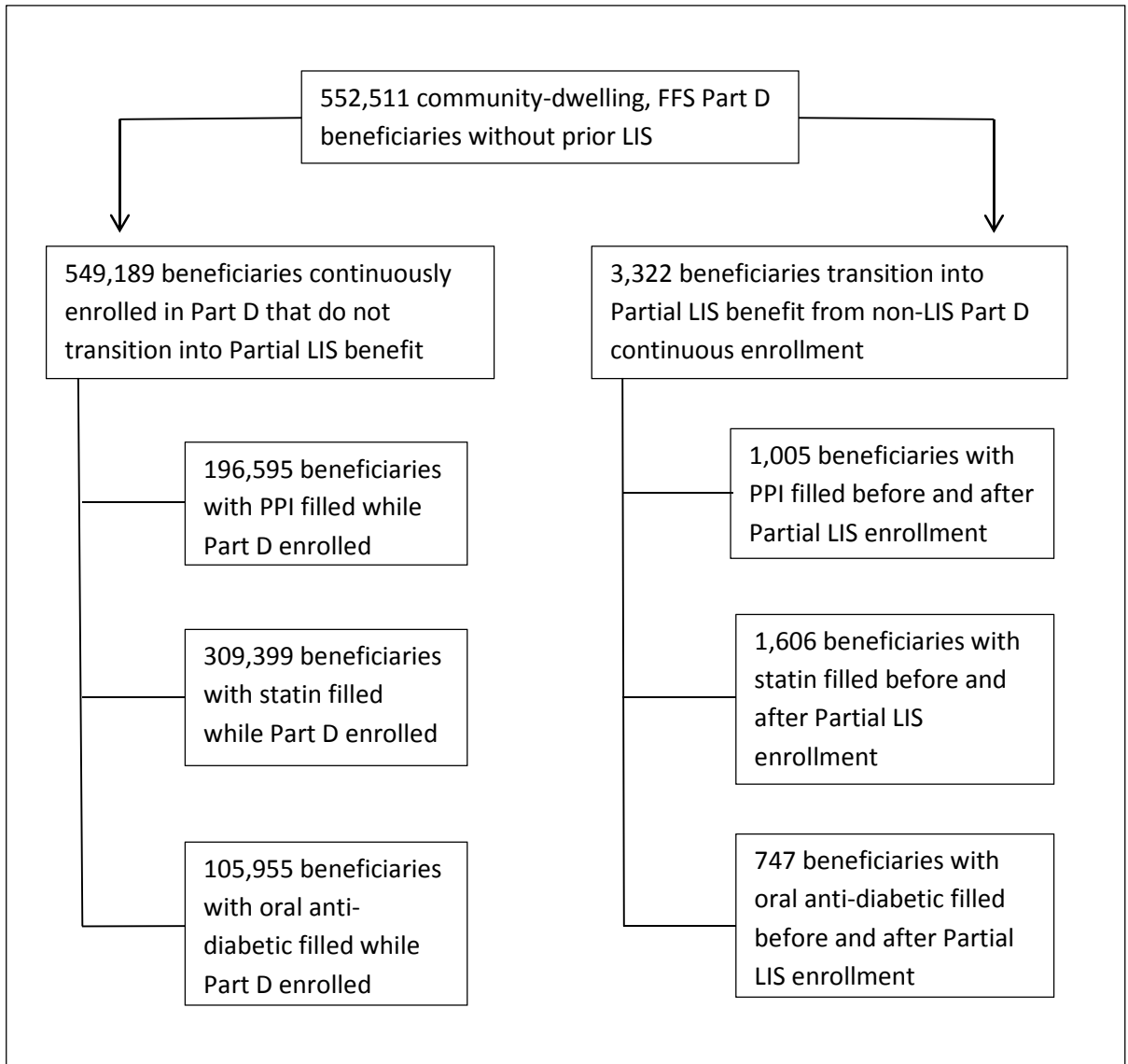
The single treatment-only cohort research design is tested using Heckman's selection model with the observational data. The two-part model tests for unobservable bias of the self-selection into the partial Low Income Subsidy (LIS) program by the Medicare beneficiaries. The first part of the model is a discrete model of enrollment in partial LIS for all Part D enrollees within each therapeutic drug cohort. Two variables included within this discrete model, in addition to the financial, personal, and diagnostic explanatory variables, are a measure of hospitalizations and a measure of full LIS enrollment by three-digit zip code or ZCTA (zip code tabulation area). These two measures are expected to capture the increased likelihood that a beneficiary may transition into LIS enrollment. The second part of the model is a regression analysis of the change in adherence level before and after partial LIS enrollment. Heckman's two-part selection model is performed using SAS 9.4.

Appendix Figure A-1 shows the final stages of the analytical sample construction for the selection data model analyses. The 552,511 Medicare beneficiaries from the enhanced 5% Medicare sample that have not previously transitioned into the LIS program, are community-dwelling, and continuously enrolled in stand-alone Medicare Part D prescription drug plans (PDPs) form the basis for the analytical sample. A total of 3,322 Medicare beneficiaries transition into the partial LIS program from this core group, and the remaining 549,189 beneficiaries do not have any transitions before the end of the study period in December, 2010. The three therapeutic cohorts from these two groups of partial LIS transition and non-transition are then selected based on prescription drug fills

for proton pump inhibitors, statins, or oral anti-diabetic medications within the claims data.

Full selection model results by therapeutic class are provided in Appendix Tables A-1 through A-3. Based on the lack of statistical significance of the Rho computation from the selection models, the model results for Study 2 are run using regression and the Heckman model is not needed for estimation of a correction for self-selection into the partial LIS program.

Figure A-1: Heckman Selection Model Analytical Sample Construction



Appendix Table A-1: Heckman Selection Model Results of Discrete Choice of Transition into Partial Low Income Subsidy (LIS) Program and Continuous Measure of Change in Adherence Before and After Partial LIS Enrollment for 2006-2010 Cohort of 5% Enhanced Sample of Medicare Beneficiaries Taking Proton Pump Inhibitors (PPIs) Medications

Variable Name	Parameter	Standard Error	P-value
Discrete Choice Model, Part 1			
Intercept	-1.126	0.090	<.0001
<i>Transition Measures</i>			
Hospitalization in Prior 6 Months	-0.277	0.029	<.0001
ZCAT Full LIS Enrollment Rate	-0.146	0.011	<.0001
<i>Financial Characteristics</i>			
Market Percent of Gap Plans	0.212	0.016	<.0001
<i>Patient Characteristics</i>			
Age	-0.022	0.001	<.0001
Female	reference		
Male	-0.199	0.026	<.0001
White	reference		
Black	0.309	0.044	<.0001
Hispanic	0.010	0.062	0.8781
Other Race/Ethnicity	-0.232	0.131	0.0768
<i>Disease Characteristics</i>			
No Co-Morbidities	reference		
1-2 Co-morbidities	-0.019	0.053	0.7268
3 or more Co-Morbidities	0.270	0.028	<.0001
Regression Model, Part 2			
Intercept	0.437	0.184	0.0176
<i>Financial Characteristics</i>			
75% Premium Subsidy	reference		
50% Premium Subsidy	-0.040	0.035	0.2530
25% Premium Subsidy	0.030	0.035	0.3976
Switch Plans at Transition	0.221	0.151	0.1439
Change Plans Post-Enrollment	-0.046	0.079	0.5580
Market Percent of Gap Plans	-0.046	0.021	0.0250
Plan Premium Above Subsidy Level	-0.042	0.031	0.1712
<i>Patient Characteristics</i>			

Variable Name	Parameter	Standard Error	P-value
Age	0.002	0.002	0.4439
Female	reference		
Male	0.010	0.037	0.7770
White	reference		
Black	-0.019	0.053	0.7155
Hispanic	-0.015	0.071	0.8341
Other Race/Ethnicity	-0.140	0.170	0.4122
<i>Disease Characteristics</i>			
No Co-Morbidities	reference		
1-2 Co-morbidities	-0.099	0.069	0.1560
3 or more Co-Morbidities	0.004	0.034	0.9095
<i>Control Variable</i>			
Duration Before Transition	-0.003	0.001	0.0033
Duration After Transition	0.005	0.001	<.0001
Rho	-0.222	0.182	0.2210

Note: Data from the enhanced 5% sample of Medicare beneficiaries, 2006-2010.

Appendix Table A-2: Heckman Selection Model Results of Discrete Choice of Transition into Partial Low Income Subsidy (LIS) Program and Continuous Measure of Change in Adherence Before and After Partial LIS Enrollment for 2006-2010 Cohort of 5% Enhanced Sample of Medicare Beneficiaries Taking Statin Medications

Variable Name	Parameter	Standard Error	P-value
Discrete Choice Model, Part 1			
Intercept	-1.385	0.081	<.0001
<i>Transition Measures</i>			
Hospitalization in Prior 6 Months	-0.291	0.025	<.0001
ZCAT Full LIS Enrollment Rate	-0.140	0.009	<.0001
<i>Financial Characteristics</i>			
Market Percent of Gap Plans	0.283	0.013	<.0001
<i>Patient Characteristics</i>			
Age	-0.021	0.001	<.0001
Female		reference	
Male	-0.241	0.020	<.0001
White		reference	
Black	0.407	0.032	<.0001
Hispanic	0.076	0.048	0.1157
Other Race/Ethnicity	-0.152	0.092	0.0996
<i>Disease Characteristics</i>			
No Co-Morbidities		reference	
1-2 Co-morbidities	0.138	0.037	0.0002
3 or more Co-Morbidities	0.339	0.022	<.0001
Regression Model, Part 2			
Intercept	0.221	0.144	0.1239
<i>Financial Characteristics</i>			
75% Premium Subsidy		reference	
50% Premium Subsidy	0.002	0.024	0.9292
25% Premium Subsidy	0.033	0.024	0.1764
Switch Plans at Transition	0.056	0.106	0.5959
Change Plans Post-Enrollment	-0.022	0.062	0.7224
Market Percent of Gap Plans	-0.016	0.018	0.3511
Plan Premium Above Subsidy Level	0.022	0.021	0.3149
<i>Patient Characteristics</i>			

Variable Name	Parameter	Standard Error	P-value
Age	-0.005	0.002	0.0024
Female		reference	
Male	-0.070	0.027	0.0099
White		reference	
Black	0.034	0.037	0.3520
Hispanic	0.084	0.047	0.0744
Other Race/Ethnicity	-0.059	0.106	0.5736
<i>Disease Characteristics</i>			
No Co-Morbidities		reference	
1-2 Co-morbidities	-0.018	0.041	0.6677
3 or more Co-Morbidities	0.033	0.024	0.1749
<i>Control Variable</i>			
Duration Before Transition	-0.003	0.001	0.0002
Duration After Transition	0.006	0.001	<.0001
Rho	0.226	0.143	0.1149

Note: Data from the enhanced 5% sample of Medicare beneficiaries, 2006-2010.

Appendix Table A-3: Heckman Selection Model Results of Discrete Choice of Transition into Partial Low Income Subsidy (LIS) Program and Continuous Measure of Change in Adherence Before and After Partial LIS Enrollment for 2006-2010 Cohort of 5% Enhanced Sample of Medicare Beneficiaries Taking Oral Anti-Diabetic Medications

Variable Name	Parameter	Standard Error	P-value
Discrete Choice Model, Part 1			
Intercept	-1.209	0.118	<.0001
<i>Transition Measures</i>			
Hospitalization in Prior 6 Months	-0.305	0.036	<.0001
ZCAT Full LIS Enrollment Rate	-0.149	0.013	<.0001
<i>Financial Characteristics</i>			
Market Percent of Gap Plans	0.250	0.018	<.0001
<i>Patient Characteristics</i>			
Age	-0.020	0.002	<.0001
Female		reference	
Male	-0.265	0.030	<.0001
White		reference	
Black	0.271	0.044	<.0001
Hispanic	0.095	0.062	0.1268
Other Race/Ethnicity	-0.213	0.131	0.1028
<i>Disease Characteristics</i>			
No Co-Morbidities		reference	
1-2 Co-morbidities	0.073	0.087	0.4012
3 or more Co-Morbidities	0.240	0.033	<.0001
Regression Model, Part 2			
Intercept	0.604	0.197	0.0022
<i>Financial Characteristics</i>			
75% Premium Subsidy		reference	
50% Premium Subsidy	-0.039	0.037	0.2837
25% Premium Subsidy	-0.061	0.038	0.1117
Switch Plans at Transition	0.021	0.132	0.8747
Change Plans Post-Enrollment	0.096	0.079	0.2237
Market Percent of Gap Plans	-0.049	0.022	0.0283
Plan Premium Above Subsidy Level	-0.037	0.034	0.2676
<i>Patient Characteristics</i>			
Age	-0.003	0.002	0.1349

Variable Name	Parameter	Standard Error	P-value
Female		reference	
Male	0.001	0.040	0.9771
White		reference	
Black	-0.048	0.048	0.3179
Hispanic	0.047	0.062	0.4529
Other Race/Ethnicity	-0.015	0.157	0.9252
<i>Disease Characteristics</i>			
No Co-Morbidities		reference	
1-2 Co-morbidities	-0.108	0.098	0.2695
3 or more Co-Morbidities	-0.032	0.033	0.3342
<i>Control Variable</i>			
Duration Before Transition	-0.002	0.001	0.1278
Duration After Transition	0.005	0.001	<.0001
Rho	-0.159	0.191	0.4063

Note: Data from the enhanced 5% sample of Medicare beneficiaries, 2006-2010.