GENDER AND RACIAL DISPARITIES IN COST-RELATED MEDICATION NONADHERENCE: THE EFFECT OF MEDICARE PART D AND FACTORS IMPACTING COMPLIANCE AMONG OLDER WOMEN AND BLACK AMERICANS

By

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ABSTRACT

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The purpose of this dissertation is to better understand how cost-related medication nonadherence (CRN) has been impacted by the implementation of Medicare Part D. CRN can include not filling, stopping, or skipping doses of a prescription because of cost (Gellad, Haas, & Safran, 2007; Safran et al., 2005). Research demonstrating the impact of Medicare Part D on CRN is extremely limited. Studies have primarily investigated the effect of the benefit utilizing pharmaceutical claims and health care plan data (Chen et al., 2008; Joyce, Goldman, Vogt, Sun, & Jena, 2009; Lichtenberg & Sun, 2007; Schneeweiss et al., 2009; Yin et al., 2008) and do not differentiate beneficiaries by demographics or health status. While gender and racial disparities in noncompliance prior to Medicare Part D clearly existed (Gellad, et al., 2007; Heisler, Wagner, & Piette, 2005; Klein, Turvey, & Wallace, 2004; Piette, Heisler, & Wagner, 2004a; Soumerai et al., 2006; Zivin, Ratliff, Heisler, Langa, & Piette, 2010), studies have not examined the prevalence of racial and gender disparities in CRN since the implementation of Medicare Part D.

This dissertation is comprised of three discrete empirical manuscripts, with introductory and concluding essays. Cumulative advantage/disadvantage theory was used as a foundation for understanding the effectiveness of Medicare Part D. Longitudinal and cross-sectional analyses were conducted using data from the Health and Retirement Study (HRS) and the Prescription Drug Study (PDS), a subsample of the HRS, to examine racial and gender differences in CRN before and after the implementation of Medicare Part D and factors associated with the benefit that can potentially impact adherence. In particular, this study addressed the following questions: 1) To what extent do racial and gender disparities in CRN exist since the implementation of Medicare Part D? 2) Do the Medicare Part D Low-Income Subsidy (LIS), coverage gap, and restrictions directly and indirectly affect the relationship between race, gender, and CRN? and 3) How do factors associated with cumulative advantage/disadvantage theory, specifically socioeconomic and health status, directly and indirectly affect the relationship between race, gender, and CRN? The results suggest that older Black Americans and females are more likely to report CRN before and after Medicare Part D than older Whites and males. Applying for the LIS increases the risk of CRN and mediates gender differences. Racial disparities in CRN appear to be driven by having a Medicare Part D plan with a gap in coverage. Poorer health and lower annual income increases the likelihood of CRN, even after controlling for LIS status and Medicare Part D's cost containment provisions. Further, experiencing the coverage gap and restrictions have a direct effect on nonadherence due to cost. The findings provide important insights into Medicare Part D's effectiveness in eliminating racial and gender differentials in CRN. Implications for practice, policy, education, and future research are discussed.

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CHAPTER ONE

INTRODUCTION

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) is considered the largest benefit expansion in the history of the Medicare program. The MMA made substantial changes to the structure of Medicare and provided prescription drug coverage for beneficiaries under Part D. Medicare Part D was crafted as a response to older adults' need for prescription drug insurance. While overall the MMA helped facilitate the purchase of needed medications, core stipulations of the policy can potentially prevent access to medications because out-of-pocket expenditure requirements can be substantial. Provisions contained in the Act allow Medicare Part D plans to utilize coverage restrictions that include limiting the number and/or type of medications that are paid for by the plan and requiring increased cost-sharing for certain drugs. Further, Medicare Part D contains a benefit threshold or coverage gap. Entering the gap means that prescriptions previously covered by the prescription drug plan become the sole responsibility of the Medicare beneficiary after reaching a drug specified spending limit. There is concern that these cost-containment provisions can make it difficult for more vulnerable populations to purchase their medications, particularly older women and Black Americans. This, in turn, could impact their ability to adhere to their medication regimen.

The purpose of this dissertation is to better understand how Medicare Part D affected racial and gender disparities in cost-related medication nonadherence (CRN) and explain factors associated with the benefit that can potentially impact adherence. This chapter briefly outlines cumulative advantage/disadvantage theory, the theoretical perspective used in this dissertation. It then discusses the socioeconomic and health implications of cumulative disadvantage for older women and Black Americans and how adherence can be impacted under the Medicare Part D

benefit. The structure of the dissertation and main objectives of each chapter will be explained followed by a discussion of the significance of the three studies.

Cumulative Advantage/Disadvantage Theory

Cumulative advantage/disadvantage theory can be traced to Robert K. Merton's (1968a) introduction of the "Matthew Effect." This term was developed by Merton, a sociologist, and named after a passage in the Gospel of Matthew 25:29 (Merton, 1968a). The framework was developed to provide a basis for understanding inequality, or the skewed system of recognition and productivity in science (O'Rand, 2003). Merton (1968b) primarily focused on advantage, and asserted that the scientists who are recognized for exceptional performance early in their careers produce returns that grow or accumulate over time. They continue to attract additional resources and rewards such as computers, research assistants, and guidance from colleagues, which provide them with the opportunity to perform research and receive additional recognition (Anderson, Long, & Krauze, 1982; Cole & Cole, 1973; Ross & Wu, 1996). The status of prominent scientists is constantly enhanced, and the system disproportionately advantages those that already maintain a privileged position. Their work is more highly valued than that of scientists who are relatively unknown, and the effects accumulate over time and involve differentiation, or increasing inequality due to the accumulation of resources (Merton, 1968a, 1968b).

Merton's ideas have been integrated into the field of aging. Cumulative advantage/disadvantage theory has increasingly been used as a paradigm to describe stratification and growing trajectories over time (Dannefer, 1987; Farkas, 2003; Kail, Quadagno, & Keene, 2009; A. E. Wilson, Shuey, & Elder, 2007). The concept is based on the accrual of advantages and disadvantages over a lifespan, and considers how systematic disadvantages

impact later life. It is suggested that advantages and disadvantages not only accrue throughout the life course but are magnified and can have a feedback effect (Crystal & Shea, 1990a; Ferraro & Kelley-Moore, 2003). In other words, "the more disadvantages individuals experience, the more likely they are to accrue subsequent and greater disadvantages" (Kail, et al., 2009, p. 557). Because of cumulative advantages and disadvantages throughout the life course, heterogeneity increases with advancing age and inequalities are most pronounced in later life (Crystal & Shea, 1990a, 1990b; Dannefer, 1987; Ross & Wu, 1996). For example, individuals from economically disadvantaged families tend to have fewer years of education. This creates differences in employment opportunities, which can lead to lower wages, unemployment, less advantageous working conditions, and fewer or no accumulated assets, health, or pension benefits. These disadvantages continue to accrue over the life span (Dannefer, 2003). Lower income due to limited employment and educational opportunities is often compounded because of poorer health status (O'Rand & Hamil-Luker, 2005). In this way, economic and health inequalities accumulate and become magnified in later life (Dannefer, 2003; Sambamoorthi, Shea, & Crystal, 2003).

When considering health status in later life, socioeconomic status is strongly related to level of functional impairment (Clark & Maddox, 1992) and is a primary determinant of disparities in health (Williams, 2002; A. E. Wilson, et al., 2007). Consistent with cumulative advantage/disadvantage theory, studies have found that health trajectories continue to diverge across the life course (Clark, 1997; Dannefer, 2003; Hatch, 2005; Kelley-Moore & Ferraro, 2004b). Individuals with a lower level of education often have more functional limitations due to accumulated disadvantages. Level of functioning and the development of acute and chronic health conditions are often dependent on accrued resources, particularly accumulated income and financial assets (Crystal & Shea, 1990a).

Cumulative Advantage/Disadvantage, Race, Gender, and Medicare Part D

This dissertation focuses on racial and gender disparities in CRN under Medicare Part D. Older women and Black Americans are significantly impacted by cumulative disadvantage which can subsequently impact their ability to purchase prescribed medications and maintain adherence with a medication regimen under the MMA. Cost-containment provisions within the policy allow Medicare Part D plans to enforce restrictions by refusing to pay for certain medications or limiting the number, type, and dollar amount of medications that are covered. Additionally, substantial cost sharing is required once a beneficiary reaches the benefit threshold, or enters the coverage gap. These provisions, in turn, can increase out-of-pocket prescription drug expenditures and can disproportionately impact females and Black Americans because of lower SES (Crystal & Shea, 1990a; Finkle, Hartmann, & Lee, 2007; Wright & Devine, 1994) and increased chronic conditions (Clark, 1997; Kelley-Moore & Ferraro, 2004a) due to accumulated disadvantages. Higher expenditures resulting from the Medicare Part D coverage gap and restrictions can subsequently impact their ability to purchase medications and maintain compliance (Wei, Akincigil, Crystal, & Sambamoorthi, 2006).

The ability to afford pharmaceuticals and maintain adherence to a prescribed medication regimen are largely dependent on retirement earnings. Income in later life is essentially based on pre-retirement experiences, and racial and gender inequities continue to increase with advancing age (Crystal & Shea, 1990a; Finkle, et al., 2007; Wright & Devine, 1994). Wages for females and Black Americans have consistently lagged behind those received by White males, and women and Black Americans are more likely to have been segregated into positions without retirement or pension benefits (Gonyea & Hooyman, 2005). Since Social Security is based on a 40-year work history, older women and Black Americans are typically subject to lower benefits

in later life than White males due to lower wages and fewer years in the labor force (Olson, 1994) and thus have less income available to purchase prescribed medications. Income inequalities are even more pronounced for Black Americans because of racial discrimination and the unequal educational, social, and economic opportunities throughout the life course (Calasanti & Slevin, 2001; Kail, et al., 2009; Quinn, 1996). Furthermore, while poverty in old age is twice as likely for women as for older men, it is three times higher for Black Americans than Whites (Finkle, et al., 2007; Gonyea & Hooyman, 2005; Wright & Devine, 1994).

Older women and Blacks Americans' lower income is typically exacerbated by a higher prevalence of chronic health conditions. Racial and gender inequities in morbidity exist throughout the life course and health trajectories continue to diverge with increasing age (Clark, 1997; Kelley-Moore & Ferraro, 2004a). Women are more likely to report functional limitations, a higher number of chronic conditions, and rate their health as poor or fair than their male counterparts (Murtagh & Hubert, 2004). While the gender gap in disability is relatively small at age 65, it widens considerably into older age (M. J. Gibson & Brangan, 1998). Of all racial groups, health status is poorest for older Black Americans (Collins, Estes, & Bradsher, 2001) and compared to Whites, older Black Americans report higher rates of hypertension, diabetes, depression, and difficulty with physical and social functioning (Schoenbaum & Waidmann, 1997; Schoenborn & Heyman, 2009) and have a higher risk of developing cancer, cardiovascular disease, and stroke (Manton & Stallard, 1997).

As the result of increased morbidity, females and Black Americans are more reliant on pharmaceuticals (Goulding, 2005). However, their ability to afford prescribed medications is often compromised because of lower SES due to disadvantages throughout the life course. Compared to White males, older women and Black Americans spend a higher proportion of their

income on pharmaceuticals (Rogowski, Lillard, & Kington, 1997; Sambamoorthi, et al., 2003). It is expected that they will continue to experience a disproportionately heavier financial burden under Medicare Part D and will be adversely impacted by the coverage gap and restrictions (Wei, et al., 2006).

While racial (Bambauer et al., 2007; Gellad, et al., 2007; Heisler, et al., 2005; Klein, et al., 2004; Piette, Heisler, & Wagner, 2004c; Roth, Esserman, Ivey, & Weinberger, 2009; Roth & Ivey, 2005; Soumerai, et al., 2006; Steinman, Sands, & Covinsky, 2001; Zivin, et al., 2010) and gender (Heisler, et al., 2005; Piette, et al., 2004c; Zivin, et al., 2010) disparities in CRN clearly existed before Medicare Part D, studies have not examined whether differentials in CRN exist since the implementation of the MMA. This dissertation addresses this gap in research. It builds on previous studies on racial and gender disparities in CRN by considering how Medicare Part D has impacted compliance, and explores factors associated with the benefit that can potentially affect adherence. Based on existing literature and using cumulative advantage/disadvantage theory as a framework, the specific questions to be explored by this dissertation in three distinct papers are:

- 1. To what extent do racial and gender disparities in CRN exist since the implementation of Medicare Part D?
- 2. How do the Medicare Part D coverage gap, coverage restrictions, and Low-Income Subsidy (LIS) directly and indirectly affect the relationship between race, gender, and CRN?
- 3. How do socioeconomic and health status directly and indirectly affect the relationship between race, gender, and CRN since the implementation of Medicare Part D?

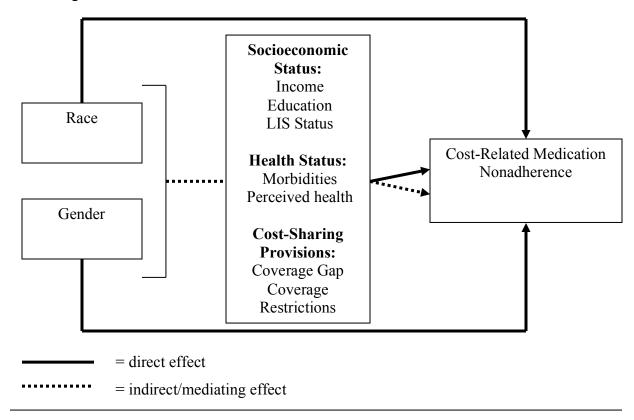


Figure 1.1 is the theoretical model for this dissertation.

Figure 1.1: Theoretical model

As illustrated in this model, it is expected that race and gender will have a direct effect on CRN. The Medicare Part D cost-containment provisions, specifically the coverage gap and restrictions, will have both a direct and indirect effect on CRN. That is, encountering cost-containment provisions will increase CRN and these provisions will mediate the effect of race and gender on CRN if the coefficients decrease or the relationship becomes nonsignificant with the addition of these variables into the models. Further, it is anticipated that CRN will be associated with early disadvantage, measured by income, education, health status, and LIS status. These factors, in turn, will indirectly affect racial and gender differences in CRN.

Overview and Structure of Dissertation

This dissertation is comprised of three discrete empirical papers, with introductory and concluding essays. It uses data from the Health and Retirement Study (HRS) and the Prescription Drug Study (PDS), a subsample of the HRS. The PDS was specifically designed to examine prescription drug utilization as Medicare Part D was implemented. The outcome variable of interest in all studies is CRN, which includes not filling, stopping, or skipping doses of a prescription because of cost.

The objectives of the first paper (Chapter Two) are to examine 1) whether racial and gender disparities in CRN have changed since the implementation of Medicare Part D; and 2) whether socioeconomic status, health status, and prescription insurance coverage directly and indirectly affect the relationship between race and gender and CRN over time. The analytic sample for this longitudinal analysis consists of 3,171 respondents age 65 and older who were Medicare-eligible, taking at least one prescribed medication, and responded to questions about adherence or nonadherence in either 2005 or 2007. While gender and racial disparities in CRN prior to the Medicare prescription drug benefit (Part D) exist, studies have not considered racial and gender disparities in CRN since the policy's enactment. Thus, this study allows for the examination of whether and to what extent nonadherence due to cost has changed for older women and Black Americans since the implementation of the Part D benefit, and how factors associated with cumulative disadvantage affect CRN.

The second paper (Chapter Three) uses a similar methodology as Chapter Two. While the study in Chapter Two included respondents who met study criteria regardless of source of prescription drug coverage, the analytic sample for Chapter Three only includes the subset of these respondents who enrolled in Medicare Part D (n=1,466). In addition to examining racial

and gender differences in CRN over time among enrollees, this paper examines the direct and indirect effects of the Low-Income Subsidy (LIS). Examining disparities among enrollees can help us understand how Medicare Part D enrollment affects CRN for older women and Black Americans over time and the impact of the LIS on adherence, a key provision of the MMA.

The third paper (Chapter Four) focuses specifically on the impact of the Medicare Part D coverage gap and restrictions on racial and gender differences in CRN. The objectives of the fourth chapter are to determine: 1) to what extent race and gender impact the likelihood of CRN under Medicare Part D plans; and 2) to what extent the Medicare Part D coverage gap and coverage restrictions directly and indirectly affect the relationship between race, gender, socioeconomic and health status and CRN. The 2006 wave of the HRS and data from the 2007 wave of the PDS were utilized. The analytic sample for this cross-sectional analysis consists of 1,353 respondents age 65 and older who were enrolled in Medicare Part D, taking at least one prescribed medication, and responded to questions about adherence or nonadherence in 2007. The results of this research can help inform Medicare policy by identifying whether older women and Black Americans are disproportionately nonadherent under the Part D benefit, and how the coverage gap and restrictions directly and indirectly impact CRN.

The final chapter links the previous chapters of the dissertation together, and summarizes and interprets the findings. Conclusions are drawn in relation to racial and gender differences in CRN and Medicare Part D, and implications for social work practice, policy, and education are discussed. The chapter concludes by summarizing the limitations of the study and presenting recommendations for future research.

Significance of the Study

This dissertation will address how Medicare Part D has impacted nonadherence, particularly for older women and Black Americans. CRN with a prescribed medication regimen can have negative health ramifications. Individuals who restrict medication use because of cost have significantly worse health outcomes than those who are adherent, and in one study were twice as likely to exhibit a deterioration in overall health status over time (Heisler et al., 2004). Prior to Medicare Part D, individuals with coverage restrictions were twice as likely to enter a nursing home, and more likely to use hospital and outpatient services than those without restrictions (Soumerai, McLaughlin, Ross-Degnan, Casteris, & Bollini, 1994; Soumerai, Ross-Degnan, Avorn, McLaughlin, & Choodnovskiv, 1991). In a recent study involving mental health patients, approximately one quarter of all patients who were unable to access medications due to Medicare Part D coverage restrictions experienced an adverse clinical event, and in many cases, required an emergency room visit (West et al., 2007). These findings suggest that nonadherence not only affects the health status and well-being of older individuals, but results in an increase in overall health care costs and utilization.

While the body of knowledge pertaining to how Medicare Part D has impacted medication access and adherence is slowly growing, there are several gaps that limit our understanding. This study will begin to address these limitations, and makes the following contributions to our understanding of gender and racial disparities and our ability to promote equitable access to prescription medications.

First, while gender and racial disparities in noncompliance prior to Medicare Part D existed, studies have not examined the prevalence of racial and gender disparities in nonadherence due to cost since the implementation of the MMA. This study is the first to

examine whether and to what extent the policy has affected racial and gender disparities in nonadherence.

Second, previous research primarily utilized pharmaceutical claims data or membership databases associated with Medicare drug plans in an attempt to understand how the Medicare Part D coverage gap has impacted medication use. There are limitations with the methodology utilized in these past studies. First, nonadherence was estimated to occur based on a reduced number of pharmaceutical claims as opposed to being reported by beneficiaries. In other words, studies speculated without clear evidence that lower prescription drug expenditures were associated with noncompliance due to increased cost-sharing resulting from the coverage gap. Second, findings were based on aggregate claims and did not differentiate between beneficiaries by accounting for demographics or health status. It is therefore impossible to determine whether older women and Black Americans are disproportionately experiencing CRN as the result of the coverage gap. This study not only aims to understand whether racial and gender disparities in CRN occur under Medicare Part D, but it is the first to investigate directly whether the coverage gap and restrictions contribute to nonadherence among older females and Black Americans.

Third, the MMA stipulated that prescription drug cost-sharing assistance be provided to beneficiaries that qualify for the LIS. This study is significant in that it is the first to examine how the LIS directly and indirectly impacts nonadherence among older women and Black Americans. This knowledge can inform policymakers about the impact of the LIS on reduced medication nonadherence.

This dissertation has distinct implications for social work practice and policy, and aims to provide information that can help improve the health and well-being of the aging population, in particular, older women and Black Americans. It will enhance our understanding of whether the

Medicare Part D coverage gap and restrictions serve as barriers for cumulatively disadvantaged populations and continue to perpetuate health and economic disparities. Understanding how the Medicare prescription drug benefit affects adherence among older women and Black Americans can help practitioners recognize that clients may need additional resources and assistance in order to avoid nonadherence, which can potentially avert adverse health events and improve well-being.

This topic is particularly relevant given provisions contained within the Patient Protection and Affordable Care Act, or PPACA, of 2010. While the PPACA increased coverage to beneficiaries reaching the coverage gap, the provision will not be fully implemented until 2019 (Kaiser Family Foundation, 2009c). For example, beneficiaries received a 50 percent discount for some brand name medications in 2011, and this discount will gradually increase to 75 percent by 2020. Affording medications can still be problematic for older women and Black Americans because the legislation does nothing to control the increasing cost of medications or Medicare drug plan premium and copayment amounts. Additionally, restrictions will continue to impede access to prescribed medications and if current patterns continue, will be increasingly problematic in the future (Donohue, Huskamp, & Zuvekas, 2009; Polinski, Mohr, & Johnson, 2009). This study can be utilized to inform policymakers on how differential life experiences can impact medication compliance under the MMA. Findings will help substantiate the need to account for race and gender when evaluating policy alternatives in order to promote more equitable access to prescription medications and avoid disparate heath outcomes.

CHAPTER TWO

MANUSCRIPT ONE

ABSTRACT

Purpose: While gender and racial disparities in cost-related medication nonadherence (CRN) existed prior to the Medicare prescription drug benefit (Part D), studies have not examined the prevalence of racial and gender disparities in CRN since the policy's enactment. The objectives of this longitudinal study are to determine: 1) whether racial and gender disparities in CRN have changed since the implementation of Medicare Part D; and 2) whether socioeconomic status, health status, and prescription insurance coverage directly and indirectly effect the relationship between race, gender, and CRN over time. Methods: This study utilizes secondary data from the 2004 and 2006 waves of the Health and Retirement Study (HRS) and data from the 2005 and 2007 waves of the Prescription Drug Study (PDS), a subsample of the HRS, to evaluate changes in CRN before and after Medicare Part D. The analytic sample consisted of 3,171 respondents age 65 and older who were Medicare-eligible and taking at least one prescribed medication. The outcome variable of interest was CRN, which included not filling, stopping, or skipping doses of a prescription because of cost. The main predictors were race (Black and White) and gender (male and female). Covariates included demographics, socioeconomic status, health status, and type of prescription drug coverage. The analysis was conducted using mixed-effects logistic regression models. Results: Results indicated that older Black Americans and females were significantly more likely to report CRN both before and after Medicare Part D compared to older Whites and men. While the rate of CRN for females significantly decreased over time in comparison to males, there was no change in the rate for Black Americans relative to Whites. The introduction of variables related to socioeconomic status, health status, and prescription

insurance coverage had little mediating effect on these findings. Health status, annual income, education, and prescription insurance coverage, however, had a direct effect on CRN over time. *Conclusions:* Despite the implementation of Medicare Part D, racial and gender disparities in CRN continued to persist. In comparison to older males, older females had greater improvement over time. Older adults with poorer health, a lower annual income, or less generous or no prescription drug coverage had a greater likelihood of CRN both before and after Medicare Part D.

CHAPTER TWO

RACIAL AND GENDER DISPARITIES IN MEDICATION NONADHERENCE: A PRE/POST MEDICARE PART D COMPARISON

Background

Prescription drugs are an essential part of medical treatment and play an increasingly important role in health care. When Medicare was initially enacted in 1965, prescription drugs were less central to health care. Today, older adults are more likely to suffer from chronic conditions, such as depression, diabetes, high blood pressure, or arthritis, that are treated through the use of pharmaceuticals (Medicare Payment Advisory Commission, 2000). As a result, prescription drug use and expenditures by older adults have grown substantially. Between 1992 and 2000, the average number of prescriptions utilized by older adults increased 45% and it is projected that trend will continue (Families USA, 2000).

Cost can be a formidable barrier in medication access. Retail prescription drug prices have increased an average of 6.9% annually from 1990 to 2007, far outpacing the rise in inflation (Kaiser Family Foundation, 2008). Older adults are disproportionately impacted by the increasing costs of prescription medications because while they represent 13% of the general population, they account for 34% of all medications that are dispensed and 42% of all prescription drug expenditures (Families USA, 2000). As drug costs and out-of-pocket medication expenses rise, adherence tends to fall (Mojtabai & Olfson, 2003; Safran, et al., 2005). Older adults – particularly individuals with several chronic conditions – often become nonadherent when they are unable to afford medications (Heisler, et al., 2004; Neuman et al., 2007; Soumerai & Ross-Degnan, 1999).

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) was passed in an effort to increase access to prescription drugs for older adults with an emphasis

on the need to provide medications to more vulnerable populations, particularly poor and chronically-ill older individuals (Bass, 2005). To respond to the need to provide older adults with drug coverage, the MMA added the Part D benefit to Medicare (Madden et al., 2008; Mayes, 2005). Part D includes a number of cost-containment provisions such as cost-sharing requirements, plan premiums and a time period, known as the coverage gap, when beneficiaries are responsible for 100 percent of their drug costs. Cost-sharing provisions stipulate that the beneficiary is required to pay a fixed amount for each prescription or copayment, a proportion of the medication price or coinsurance, and/or an annual payment before the plan will provide coverage or deductible. Plan premiums require that individuals pay a monthly amount to receive coverage and averaged \$40.72 in 2011, an increase of 57% since Medicare Part D was implemented in 2006 (Hoadley, Summer, Hargrave, Cubanski, & Neuman, 2010). There is concern that these cost-containment provisions can inhibit the use of medications for older women and Black Americans. Compared to older men and Whites, older women and Black Americans tend to have a greater number of chronic health problems (Clark, 1997; Kelley-Moore & Ferraro, 2004a) and are, therefore, more reliant on prescription medications (Rogowski, et al., 1997; Sambamoorthi, et al., 2003). This means that older women and Black Americans tend to have higher copayments and are more likely to reach the coverage gap each year. Combined with their overall lower socioeconomic status, therefore, older women and Blacks are less able to afford out-of-pocket expenditure requirements (Wei, et al., 2006) and more likely to have difficulties adhering to their medication regimen.

Previous research has shown the connection between cost-related medication nonadherence (CRN) and cost-containment provisions similar to those present in Medicare Part D plans (Adams, Soumerai, & Ross-Degnan, 2001; T. B. Gibson, Ozimkowski, & Goetzel, 2005;

Tseng, Brook, Keeler, Steers, & Mangione, 2004). CRN can include not filling, stopping, or skipping doses of a prescription because of cost. Prior to the MMA, racial and gender disparities in CRN clearly existed (Heisler, et al., 2005; Klein, et al., 2004). Medicare Part D may continue to impede access to medication because the benefit's cost-containment provisions can increase out-of-pocket expenditures (Hsu et al., 2008). These provisions, in turn, can disproportionately impact females and Black Americans who tend to be of lower socioeconomic status and are also living with more chronic conditions both of which subsequently affect their ability to maintain adherence (Wei, et al., 2006). To date, studies have not examined the prevalence of racial and gender disparities in CRN since the implementation of the Medicare prescription drug benefit. This longitudinal study uses a cumulative advantage/disadvantage framework to build upon prior research by examining whether and to what extent racial and gender disparities in CRN have changed since the implementation of Medicare Part D.

Literature Review

Cumulative Advantage/Disadvantage and Medicare Part D

Cumulative advantage/disadvantage theory is useful as a foundation for understanding and evaluating the effectiveness of Medicare Part D. The theory has increasingly been used as a paradigm in the field of aging to describe stratification and growing trajectories over time (Dannefer, 1987; Farkas, 2003; Kail, et al., 2009; A. E. Wilson, et al., 2007). Systematic disadvantages have a considerable impact on later life, and it is suggested that they not only accrue throughout the life course but are magnified and can have a feedback effect (Crystal & Shea, 1990a; Ferraro & Kelley-Moore, 2003). In other words, "the more disadvantages individuals experience, the more likely they are to accrue subsequent and greater disadvantages" (Kail, et al., 2009, p. 557). For example, individuals from economically disadvantaged families

are more likely to have fewer years of education. This creates differences in employment opportunities, and subsequently places them at greater risk for incurring lower wages, unemployment, and less advantageous working conditions. Lower income due to limited employment and educational opportunities is often compounded because of poorer health status, lesser or no health insurance, and greater health care expenditures (Sambamoorthi, et al., 2003). Because of cumulative advantages and disadvantages throughout the life course, heterogeneity increases with age, and inequalities are greatest in later life (Crystal & Shea, 1990a; Dannefer, 1987; Ross & Wu, 1996). For these reasons, the aged should not be stereotyped (Butler, 1985) or treated as a homogeneous group (Neugarten, 1982) when deliberating social policy initiatives intended to target older individuals. Inequities resulting from disadvantages throughout the life course need to be considered in order to ensure equitable access to benefits.

This study will focus on racial and gender disparities in CRN before and after the implementation of the Medicare Part D benefit. As the result of cumulative advantages and disadvantages throughout the life course, it is anticipated that higher out-of-pocket expenditures will be related to personal characteristics associated with early disadvantage, or income, education, and health status. These factors, in turn, can potentially impact CRN under the benefit.

Income and education. The ability to afford pharmaceuticals and maintain adherence to a prescribed medication regimen are largely dependent on retirement earnings. Income in later life is essentially based on pre-retirement experiences, and racial and gender inequities continue to increase with advancing age (Crystal & Shea, 1990a). Wages for females and Black Americans have consistently lagged behind those received by White males, and women and Black Americans are more likely to have been segregated into positions without retirement or

pension benefits (Gonyea & Hooyman, 2005). Since Social Security is based on a 40-year work history, older women and Black Americans are typically subject to lower benefits in later life than White males due to lower wages and fewer years in the labor force (Olson, 1994) and thus have less income available to purchase prescribed medications. Catastrophic changes such as widowhood – which is more common in the lives of women (Moody, 2009) – can be particularly difficult because older females and Black Americans are in a disadvantaged position. Women and Black Americans not only enter old age poorer than men and Whites (Finkle, et al., 2007; Gonyea & Hooyman, 2005; Wright & Devine, 1994) but can become poorer with age as a result of widowhood (Minkler & Stone, 1985). Further, income inequalities are even more pronounced for Black Americans because of racial discrimination and the resulting unequal educational and economic opportunities throughout the life course (Kail, et al., 2009).

Health status. Lower income is typically exacerbated by a higher prevalence of chronic health conditions among older women and Black Americans. Racial and gender inequities in morbidity exist throughout the life course and health trajectories continue to diverge with increasing age (Clark, 1997; Kelley-Moore & Ferraro, 2004a). Women are more likely to report functional limitations, a higher number of chronic conditions, and rate their health as poor or fair than their male counterparts (Murtagh & Hubert, 2004). Of all racial groups, health status is poorest for older Black Americans (Collins, et al., 2001) and compared to Whites, older Black Americans report higher rates of hypertension, diabetes, depression, and difficulty with physical and social functioning (Schoenbaum & Waidmann, 1997; Schoenborn & Heyman, 2009).

As the result of increased morbidity, females and Black Americans are more reliant on pharmaceuticals (Goulding, 2005). However, their ability to afford prescribed medications is often compromised because of lower socioeconomic status. Compared to White males, older

women and Black Americans spend a higher proportion of their income on pharmaceuticals (Rogowski, et al., 1997; Sambamoorthi, et al., 2003). For these reasons, it is expected that they will continue to experience a disproportionately heavier financial burden under Medicare Part D (Wei, et al., 2006). This, in turn, can subsequently affect their ability to purchase prescribed medications and maintain adherence.

Medicare Access and Adherence

Pre-Medicare Part D. Prior to Medicare Part D, CRN was estimated to occur in one fourth of all older adults (Safran, et al., 2005); those without prescription drug coverage or with limited coverage were significantly more likely to be noncompliant because of cost (Blustein, 2000; Fillenbaum, Hanlon, Corder, Brock, & et al., 1993; Rogowski, et al., 1997). Nonadherence due to cost was greater among older women than men (Heisler, et al., 2005; Piette, et al., 2004c; Zivin, et al., 2010). Race was an even stronger predictor of CRN than gender. According to one study, older Black Americans were 1.5 times more likely to report nonadherence to a medication regimen than Whites (Gellad, et al., 2007), and numerous studies have found that Black Americans were more likely than Whites to forgo or delay taking prescribed medications because of cost (Bambauer, et al., 2007; Klein, et al., 2004; Roth, et al., 2009; Roth & Ivey, 2005; Soumerai, et al., 2006; Steinman, et al., 2001).

Post-Medicare Part D. When analyzing the MMA from certain economic perspectives, the policy can appear highly successful. In 2008, 90 percent of Medicare's 45 million beneficiaries had prescription drug coverage (Joyce, et al., 2009) as compared to 76 percent in 2006 (Levy & Weir, 2009). Further, it is estimated that out-of-pocket spending on prescription drugs decreased between 13 and 18.4 percent even as the number of medications used by older adults increased from 5.9 to 12.8 percent since the implementation of the MMA (Chen, et al.,

2008; Joyce, et al., 2009; Lichtenberg & Sun, 2007; Schneeweiss, et al., 2009; Yin, et al., 2008). However, these findings do not take into consideration the implications of the cost-containment provisions - or cost-sharing requirements, plan premiums, or coverage gap - of the MMA, and the impact of those provisions on cumulatively disadvantaged beneficiaries. In other words, there was no differentiation of groups reported in these findings; beneficiaries were regarded as a homogeneous group that gained access to a prescription drug benefit and lowered their medication expenditures. It is important to recognize the potential implications of Medicare Part D cost-sharing provisions on older females and Black Americans. For example, one implication of the cost-sharing requirements is that access to medications is not in fact the same for all beneficiaries. Those with lower income and increased morbidity, such as is often experienced by older women and Black Americans, may be negatively and disproportionately influenced by cost-sharing requirements both because of their higher medication expenses and their limited income. This, in turn, can impact their ability to access medication and maintain adherence. Thus, existing research on the impact of MMA does not recognize the differential consequences of these provisions

Research examining changes in CRN before and after Medicare Part D is extremely limited. One of the main reasons for this limitation is the restrictions placed on the availability of data. The Centers for Medicare and Medicaid Services has historically been a primary source of data for researchers. However, a provision contained in the MMA stipulated that private health care plans were not required to release Medicare Part D claims data for nonpayment-related purposes, which included research, public health purposes, and health care analysis (Crystal, 2008, November; Stuart, 2008). This stipulation largely accounts for the limitation with existing

research. Fortunately, this was modified in 2009, and data are currently in the process of being released.

When considering studies conducted after the implementation of Medicare Part D, Safran et al. (2009) reported that for older individuals with no or a meager drug benefit, enrollment resulted in lower out-of-pocket prescription drug expenditures, higher medication utilization, and overall lower CRN. However, low-income, chronically ill beneficiaries were significantly more likely to report CRN and difficulty affording their medications. Similarly, Madden et al. (2008) found that while there was a modest but significant decrease in overall CRN, no decrease was observed among individuals in fair to poor health, with at least four morbidities, or having an annual income less than \$25,000. Although differences associated with race or gender were not analyzed in either study, the findings shed some light on the experiences of these groups. Because older women and Black Americans are more likely to be low income, rate their health as poor or fair, and experience higher rates of chronic illness and health problems, these studies suggest that the benefit may have little or no impact on CRN for these groups.

While previous studies have not specifically examined the effect of the Medicare drug benefit on racial or gender disparities in CRN, research suggests ethnic disparities continue to exist. One study conducted after the implementation of Medicare Part D, for example, found that Hispanics were more likely to report CRN than non-Hispanics. Further, CRN was significantly greater for non-Hispanic Blacks than non-Hispanic Whites. When examining gender, both Hispanic and non-Hispanic females were more likely to report nonadherence due to cost than males (Frankenfield, Wei, & Anderson, 2010).

CRN and the Coverage Gap. Other studies focused specifically on CRN resulting from the Medicare Part D coverage gap. Provisions contained within the MMA stipulated that once a

beneficiary reaches the benefit threshold, known as the coverage gap, they are responsible for 100% of their prescription drug costs until spending approximately \$4,550 out-of-pocket for prescription medications. Overall, reaching the coverage gap resulted in lower drug consumption (Pedan, Lu, & Varasten, 2009; Sun & Lee, 2007; Zhang, Donohue, Newhouse, & Lave, 2009) and decreased adherence (Hsu, et al., 2008) because of increased out-of-pocket expenditure requirements. Furthermore, Hsu et al. (2008) found that 36% percent of respondents encountering the coverage gap stopped taking their medication, reduced the recommended dosage, or switched to an alternate drug.

While research has not specifically examined the impact of the Medicare Part D coverage gap on older women and Black Americans, beneficiaries with certain chronic illnesses – such as depression and diabetes – have a greater risk of this cost-sharing provision because they spend considerably more on medications and are, therefore, at greater risk of CRN (Hoadley, Hargrave, Cubanski, & Neuman, 2008; Stuart, Simoni-Wastila, & Chauncey, 2005). Fifty-one percent of older diabetics who reached the coverage gap or benefit threshold had a decline in out-of-pocket spending on medications, suggesting that they may have become noncompliant (Hoadley, et al., 2008). In comparing older adults with and without depressive symptoms, individuals with depressive symptoms were more likely to report CRN and forego basic needs to pay for medications following the implementation of Medicare Part D (Zivin, Madden, Graves, Zhang, & Soumerai, 2009). Because older women and Black Americans experience higher rates of diabetes (Gellad, Huskamp, Phillips, & Haas, 2006; Schoenborn & Heyman, 2009) and a greater number of depressive symptoms (Skarupski, Mendes de Leon, Barnes, & Evans, 2009), they may face a greater risk of CRN under Medicare Part D.

Overall, studies suggest that gender and racial disparities in CRN prior to Medicare Part D existed. However, research demonstrating the impact of Medicare Part D on disparities in nonadherence due to cost is limited. Studies have primarily investigated the effect of the Medicare prescription drug benefit utilizing pharmaceutical claims and health care plan data and do not differentiate beneficiaries by demographics. While a few studies have used nationally representative datasets to examine CRN, racial and gender differences in change in medication adherence before and after Medicare Part D have not been examined. Further, the one study examining disparities in CRN after the implementation of the benefit was cross sectional as opposed to longitudinal. Thus, research has not investigated whether racial and gender disparities in CRN have changed since the implementation of the MMA; therefore, the policy's effectiveness in eliminating differentials is currently unknown.

This study will build on existing knowledge in a number of ways. First, it uses data from a nationally representative longitudinal dataset specifically designed to examine prescription drug utilization as Medicare Part D was implemented. This allows for the examination of gender and racial differences in CRN both before and after Medicare Part D. Second, this study examines changes in CRN over time for older women and Black Americans, thus expanding our knowledge of how racial and gender disparities in CRN have increased or decreased since the implementation of Medicare Part D. Third, the study examines whether and to what extent lower socioeconomic status, poorer health status, and little or no prescription insurance coverage directly and indirectly affect the relationship between race and gender and CRN over time, specifically before and after the implementation of Medicare Part D. This furthers our understanding of how factors associated with cumulative disadvantage can impact likelihood of nonadherence due to cost.

Based on existing literature, there are four hypotheses in this study:

- As compared to older males, older females are more likely to report CRN over time and less likely to report a decline in CRN over time.
- As compared to older Whites, older Black Americans are more likely to report CRN over time and less likely to report a decline in CRN over time.
- Socioeconomic status, health status, and prescription insurance coverage will mediate the effect of racial and gender differences in CRN over time.
- Lower socioeconomic status, poorer health status, and less generous or no prescription insurance coverage will increase the likelihood of CRN over time.

Methodology

Sample

This study utilizes secondary data from the 2004 and 2006 waves of The University of Michigan (U-M) Health and Retirement Study (HRS) as well as data from the 2005 and 2007 waves of the HRS Prescription Drug Study (PDS) to conduct a longitudinal analysis. Launched in 1992, the HRS is a nationally representative population study of more than 20,000 Americans over the age of 50 designed to assess the relationship between health and retirement. The core HRS survey collects information pertaining to physical and mental health, insurance coverage, financial status, family support systems, retirement situation, and work status (Juster & Suzman, 1995). The primary mode of data collection is by telephone; however, in situations where health limitations would make the hour-plus telephone session difficult or where there is no telephone in the household, the survey is conducted in the respondent's home (HRS, 2011). Primarily funded through the National Institute on Aging (NIA U01AG009740), the HRS is designed, administered, and conducted by the Institute for Social Research (ISR) at the U-M. The overall

interview response rate for the core 2004 HRS was 86.2% and for the core 2006 HRS, the overall response rate was 88.5% (Ofstedal, 2009, June).

The PDS is a subsample of the HRS, and is a two-wave mail survey conducted in 2005 and 2007. It was specifically designed to examine prescription drug utilization as Medicare Part D was implemented. The baseline wave was administered pre-Medicare Part D in 2005 by the ISR, and captured information pertaining to prescription drug use, coverage, and knowledge of the Medicare prescription drug benefit. The second wave was conducted post-Medicare Part D in 2007, and captured similar information as well as data pertaining to the impact of the MMA costcontainment provisions such as the coverage gap and restrictions. The sample was drawn from respondents who participated in the HRS in 2004. To be eligible for inclusion in the PDS, respondents needed to be age 65 or older in 2007 (born in 1942 or later), or have Medicare or Medicaid coverage at some time between 2002 and 2004. Because the Consumption and Activities Mail Survey (CAMS) was fielded at the same time as the PDS, approximately 40% of eligible participants were excluded because of their involvement in the CAMS. However, the exclusion did not affect the representation of the PDS sample because CAMS participants were randomly selected (J. Faul, Personal Communication, January 4, 2012). Of those who were eligible for inclusion in the PDS, 4,684 individuals or 88.1% completed the PDS in 2005, and 3,536 persons or 74% responded to the survey in 2007 (HRS, 2011). Given that this is a relatively new topic area, there are no reliability or validity measures associated with the PDS (J. Faul, Personal Communication, February 3, 2012).

To be included in the analytic sample for this study, respondents were required to 1) be either non-Hispanic White/Caucasian or non-Hispanic Black/African American; 2) be age 65 or older in 2005 and therefore eligible for Medicare when the PDS was administered; 3) have

reported taking prescription medications in 2005 or 2007; and 4) have responded to questions about prescription drug adherence in the 2005 or 2007 PDS. Of the 4,808 responding to the 2005 or 2007 PDS, 4,248 were either non-Hispanic White/Caucasian or non-Hispanic Black/African American; 3,606 were age 65 and over; 3,323 reported taking prescription medications; and 3,181 reported data on prescription drug adherence or nonadherence. Thus, a total 3,181 respondents to the 2005 (n=2,863) or 2007 (n=2,301) PDS were included in the final analytic sample.

The combination of HRS and PDS provides an excellent source for testing the proposed hypotheses because indicators of cumulative advantage/disadvantage that could decrease or increase older adults' risk of CRN are available through these datasets. Variables from the 2005 and 2007 PDS included CRN, type of prescription drug insurance coverage, and Medicare Part D enrollment status. All other variables were obtained from the 2004 and 2006 RAND HRS data files. These data files contain a broad range of measures across HRS waves, and are developed and maintained by the RAND Center for the Study of Aging, with support provided by the NIA and Social Security Administration (RAND Center for the Study of Aging, 2010).

In regards to Institutional Review Board (IRB) approval, this study relied exclusively on secondary data to complete all analysis. The HRS and PDS files contain de-identified individual data that are available to the public. Therefore, the IRB at Michigan State University (MSU) does not require human subjects review.

Measures

Dependent variable. A summary indicator of any CRN was constructed as the dependent variable. In the 2005 and 2007 PDS, CRN was evaluated using questions about the following three behaviors: 1) not filling a new prescription because of cost; 2) stopping taking a

medication because of cost; or 3) skipping doses of a medication to save money. If the respondent indicated that they engaged in any of these behaviors, they were considered nonadherent in this study. Earlier research typically used a single measure to assess CRN, and focused solely on whether respondents failed to fill a prescription in the past year because of cost. However, this measure did not assess for multiple ways CRN could occur. Thus, the additional questions were developed to help monitor and identify changes in CRN, and have demonstrated test-retest reliability (Pierre-Jacques et al., 2008) and construct validity (Soumerai, et al., 2006). This composite variable approach was originally developed by Safran et al. (2003) based on a series of validated survey questions concerning CRN to prescription regimens, confirmed using factor analysis techniques, and used as a main outcome in subsequent research examining drug nonadherence practices of older adults (Bambauer, et al., 2007; Gellad, et al., 2007; Madden, et al., 2008; Safran, et al., 2005; Soumerai, et al., 2006; I. B. Wilson, Rogers, Chang, & Safran, 2004; Zivin, et al., 2009). Because all three measures of CRN, specifically filling, stopping, or skipping doses of a prescription because of cost, were highly correlated with comorbidity, self-reported health status, and socioeconomic status (Bambauer, et al., 2007; Safran, et al., 2005; Safran, et al., 2003; Soumerai, et al., 2006), it is important that they be included in this study. Older females and Black Americans are more likely to have a lower income and multiple health problems due to disadvantages throughout the life course and thus, accounting for all behaviors can further understanding of CRN before and after the implementation of Medicare Part D.

In this study, a dichotomous variable indicating any nonadherence or no nonadherence to the three CRN behaviors in the PDS – not filling a new prescription because of cost, stopping taking a medication because of cost, or skipping doses of a medication to save money – was

created for each time point, or for both the 2005 and 2007 measures. The CRN variable was initially incorporated as a continuous variable indicating a sum total of the three behaviors. However, results were significantly skewed because the majority of the sample were adherent to their medication regimen and similar to previous research, the variable was dichotomized (Bambauer, et al., 2007; Gellad, et al., 2007; Madden, et al., 2008; Safran, et al., 2005; Soumerai, et al., 2006; I. B. Wilson, et al., 2004; Zivin, et al., 2009). Using this global, dichotomous measure is common in existing literature, and will help provide a meaningful comparison to previous research.

Independent variables. The main predictors of interest were race (Black and White) and gender (female and male). A time variable was also created to evaluate CRN over time (2005 and 2007) using the "reshape" command in Stata version 11 and was used in all regression analyses as a main predictor. The "reshape" command converted the data to a long format and provided a single variable that was used to measure CRN at both time points. Using literature pertaining to cumulative advantage/disadvantage as a guide, other independent variables included socioeconomic characteristics, health status, and variables related to prescription drug insurance coverage. Additionally, age and marital status were used as control variables.

Socioeconomic characteristic indicators included attained education and annual household income. Disadvantages can accumulate throughout the life course as the result of decreased educational attainment and lower income, and result in decreased ability to afford prescription medications and maintain adherence. The level of attained education was a continuous variable ranging from 0 to 17 or more years of education. Cumulatively disadvantaged individuals tend to have lower levels of education. Subsequently, they are less likely to have prescription drug coverage and the financial resources needed to purchase

prescribed medications. Utilizing this measure will help clarify how educational attainment can impact CRN. Additionally, it can further our understanding of how education can indirectly impact CRN among older women and Black Americans. Annual household income was a continuous variable ranging from \$0 to \$2,761,657. Utilizing this variable can help understand how income can impact CRN, and whether the poor and near-poor may be more likely to forego medications because of cost.

Health status variables included number of chronic medical conditions and self-reported health status. Increased morbidity is associated with cumulative disadvantage and increased reliance on pharmaceuticals, particularly among older women and Black Americans. Thus, it is important to understand how health status impacts CRN. First, a continuous variable indicating the number of chronic medical conditions was used. Respondents were asked, "Has a doctor ever told you that you have [name of chronic medical condition]" or "our records from your last interview show that you have [name of chronic medical condition]." This question was asked for a series of eight chronic medical conditions and included: high blood pressure, diabetes, cancer, lung disease, heart disease, stroke, psychiatric problems, and arthritis. The second health-related variable included self-reported health status. Respondents were asked, "Would you say your health is excellent, very good, good, fair, or poor?" Responses ranged from 0 = "excellent" to 4 = "poor" with a higher score indicating that the respondent perceived their health status as being more poor.

Two prescription insurance coverage variables were included. Having less generous prescription drug coverage is related to cumulative disadvantage, and can impact adherence. Respondents were asked, "Which of the following best describes how your insurance works when you buy prescription drugs?" Five levels of drug coverage response options were defined:

no coverage/pay full cost, insurance pays part of cost, prescription discount card, full coverage/pay nothing, and some other type of coverage. In the 2007 PDS, respondents were also asked, "Are you currently enrolled in a Medicare Part D plan or a Medicare HMO or Advantage plan that helps pay for prescription drugs?" Possible responses response options included 'yes,' 'no,' and 'don't know.' Including the 'don't know' option can help illustrate the confusion associated with the Medicare Part D benefit (Heiss, McFadden, & Winter, 2006; Hsu, et al., 2008). A substantial number of respondents chose this option.

Finally, other control variables included age and marital status. Age was a continuous variable ranging from age 65 to 101. Marital status was a seven-category variable: married, married with spouse absent, partnered, separated, divorced, widowed, and never married.

Analytic Strategy

Univariate descriptive statistics summarized all measures at baseline. Cross-tabulations were conducted to determine the bivariate association between respondent characteristics and CRN at baseline and in 2007. The Rao-Scott chi-square, a design-adjusted version of the Pearson chi-square, was used to test the significance of the association (Rao & Scott, 1981). Mixed-effects logistic regression models were used for multivariate analysis to estimate racial and gender differences in CRN over time, and to examine the direct and indirect effect of socioeconomic and demographic characteristics, health status, and prescription insurance coverage on the relationship between race and gender and CRN.

Mixed regression models are useful for this type of analysis for several reasons (Blackwell, Mendes de Leon, & Miller, 2006; Rabe-Hesketh & Skrondal, 2008). First, they do not require that respondents be measured on the same number of time points. In other traditional methods such as repeated-measures ANOVA, cases are dropped if some measurements are

missing (Blackwell, et al., 2006). This is important because some participants did not respond to questions pertaining to CRN in both surveys. In particular, 72.9% of respondents indicated adherence or nonadherence in both the 2005 and 2007 PDS. Of the 27.1% not responding at both waves, 51.4% completed the CRN questions in the 2005 PDS and 48.6% indicated adherence or nonadherence in the 2007 PDS. In general, by allowing the inclusion of cases with missing data, the sample size is larger and thus more closely approximates the general population (Ott & Lngnecker, 2001).

Second, mixed regression models do not require that respondents complete the survey at precisely the same time interval. This, again, is an essential point when considering the administration of the PDS. The survey was mailed to respondents in October, and the field period continued through March. It was completed at varying times over a six-month period. Finally, mixed regression models are advantageous when analyzing repeated-measures data because they provide an estimate of individual-specific change across time and also model patterns of change between individuals. By modeling both fixed and random effects, there is the ability to account for individual differences over time as well as deviations from the group trend (Van Dongen, Olofsen, Dinges, & Maislin, 2004).

A series of six mixed regression models were run with the direct and indirect effects of each set of variables on the relationship between race, gender, and CRN over time examined in each model. Model 1 included only race and gender. Age and marital status variables were added in Model 2 and in Model 3, socioeconomic characteristics were added. Health status variables were added in Model 4. In Model 5, prescription insurance coverage variables were added. Finally, year of adherence or nonadherence due to cost was interacted with race and gender in Model 6 to compare racial and gender differences in change in CRN over time, controlling for all

other variables. A likelihood-ratio test was performed for each model to determine whether including time as a fixed and random effect provided a better fit than the random-intercept only model. A null model was first fit with the dependent variable only to determine the level of between-person variance. Next, the fixed effect of time and a random effect associated with the intercept of each respondent were added to the model. A third model then added a second random effect that allowed each person to have a unique outcome at each time point. With the exception of the null model, this process was repeated for Model 1 through Model 6. An alpha of .05 was used as the cutoff for determining statistical significance. In every analysis, the likelihood-ratio test was not significant. Thus, time was included only as a fixed effect in the regression models.

All statistical analyses were performed in the Stata version 11.0 statistical package (StataCorp). Stata's survey commands were used in univariate statistics and bivariate tests of association to account for the complex multistage clustered sampling design of the HRS when computing standard errors. The PDS questionnaire weights (a product of the HRS sampling weights) were applied to adjust for sample selection probability or oversampling of select minority groups and for interviewee nonresponse in univariate and bivariate analysis only (HRS, 2011). Stata does not allow the incorporation of the survey command or application of probability weights in mixed-effect logistic regression analyses. Thus, mixed regression models did not control for the design effect and were not weighted. A consequence of not utilizing the questionnaire weights or controlling for the design effect is the potential for inaccurate point estimates and/or inaccurate standard errors, which in turn can impact the ability to infer results to the general population. Despite this limitation, mixed-effect regression analyses can provide a strong indication of racial and gender difference in CRN over time because unlike other methods

such as time-series ANOVA, cases are not dropped if there are missing values. Further, there was no substantive difference in outcomes in bivariate models that were weighted and controlled for the design effect as compared to multivariate models. Thus, the potential that the results will inaccurately reflect the general population is minimal. Significance in multivariate analysis was tested at the p<.05 level using a one-tailed test.

Results

Description of Sample at Baseline

A detailed description of the sample in 2005 is provided in Table 2.1. Of the 2,863 individuals responding to the question about medication adherence at baseline, 8.2% self-identified as non-Hispanic African American and the majority (58%) were female. Respondents ranged in age 65 to 101 with a mean age of 74.3 years, and over half (53.3%) were married. The average household income was \$50,614 (SD = \$100,088) and the mean years of education was 12.42 (SD = 2.93). Respondent self-reports indicated that the majority felt their health was good (35%), very good (27.1%), or fair (21.1%), followed by excellent (8.5%), and excellent (8.3%). The average number of chronic health conditions was 2.38 (SD = 1.36). In regards to prescription insurance coverage, most (59.7%) had insurance to pay for part of the cost of medications, 15.3% paid the full cost of their prescriptions or had no coverage, 13.8% had a prescription discount card, 6.7% paid nothing for their medications, and 4.5% listed "other" as their source of coverage. No respondents were enrolled in the Medicare Part D benefit at baseline because it was not yet implemented.

Bivariate Results

Bivariate analyses of medication adherence and nonadherence in 2005 and 2007 are presented in Table 2.2. In regards to the main predictor variables, both race and gender appeared

TABLE 2.1

Variable	\mathbf{N}^{1} / \mathbf{M}	% ¹ / SD
Race		
Black American	422	8.2
White	2,441	91.8
Gender		
Female	1,713	58.0
Male	1,150	42.0
Age (range 65 to 101)	74.38	7.38
Marital status ²		
Married	1,579	53.3
Married, spouse absent	32	1.0
Partnered	52	1.5
Separated	23	1.0
Divorced	222	8.0
Widowed	886	32.5
Never married	68	2.7
Education (range: 0 to 17) ²	12.42	2.93
Annual household income (range: \$0 to \$2,761,657)	50,614	100,088
Number of chronic medical conditions (range: 0 to 7)	2.38	1.36
Self-reported health ²		
Excellent	241	8.5
Very good	749	27.1
Good	989	35.0
Fair	637	21.1
Poor	244	8.3
Prescription drug coverage ²		
Pay full cost or no coverage	504	15.3
Insurance pays part of cost	1,497	59.7
Prescription discount card	436	13.8
Pay nothing	198	6.7
Other	117	4.5
Medicare Part D enrollment		
No	2,863	100
Cost-related adherence or nonadherence		
Adherent	2,390	85.2
Nonadherent	473	14.8
1		

Description of Sample of Individuals Age 65 and Over Reporting Medication Adherence/Nonadherence in 2005 (Baseline) (n=2,863)

¹Weighted %, unweighted N

²Sample size varies slightly due to missing data within PDS or HRS

to be significantly related to CRN. In 2005 and 2007, a higher proportion of Black Americans were nonadherent compared to Whites, and a greater proportion of females were nonadherent compared to males.

In terms of control variables, age was significantly related to CRN. Nonadherent older individuals reported a significantly lower age than adherent older adults before and after Medicare Part D. Marital status was not significantly related to CRN.

In regards to socioeconomic status, educational attainment was significantly related to nonadherence in 2005 and 2007. Respondents who reported CRN had significantly fewer years of education. Further, nonadherent older individuals reported a significantly lower annual income than adherent older adults before and after the implementation of Medicare Part D.

In regards to health status variables, respondents who reported CRN had a significantly greater number of chronic conditions compared to those that maintained adherence in 2005 and 2007. A smaller proportion of respondents in excellent health reported nonadherence before and after Medicare Part D than those in other categories with those in fair or poor health reporting the most nonadherence. Finally, prescription insurance coverage was significantly related to CRN. A much larger proportion of those reporting nonadherence in 2005 and 2007 utilized a prescription discount card or had no coverage/paid the full cost of their medications as compared to those who had insurance, paid nothing for medications, or had some other type of coverage. In 2007, a higher proportion of those enrolled in Medicare Part D or unaware of whether they were enrolled in this benefit reported CRN in 2007 compared to those who were not enrolled in Medicare Part D at that time.

Bivariate analyses suggest that without controlling for other factors, older Black Americans and women were more likely to report CRN than older Whites and men before and

2005 (n=2,863) 2007 (n=2,301) Nonadherence Nonadherence Adherence Adherence $\%^{1}$ $\%^{1}$ $\%^1$ $\%^1$ Ν Ν Ν Ν Race Black American 321 77.3 101 22.7 221 75.0 73 25.0 White 2,069 85.9 372 14.1 1.719 86.8 288 13.2 χ^2 , df=1 14.21***³ 11.95***³ Gender Female 1,382 82.6 84.3 15.7 331 17.4 1,110 232 Male 1,008 88.8 11.1 830 88.0 129 142 12.0 6.47*³ χ^2 , df=1 19.70***³ Age $(M \pm SD)^2$ 74.68 ± 7.69 72.64 ± 6.98 76.03 ± 6.87 74.32 ± 6.24 34.57***³ 15.68***³ df=1, 51 Marital status² Married 1.344 86.8 235 13.2 1,119 87.5 185 12.5 Married, spouse absent 28 90.9 9.1 24 93.1 6.9 4 2 Partnered 44 86.8 8 13.2 24 79.5 9 20.5 Separated 20 86.8 3 13.2 12 81.6 3 18.4 Divorced 47 37 175 81.4 18.6 128 80.8 19.2 Widowed 725 83.7 161 16.3 571 84.3 114 15.7 Never married 53 15 43 81.4 18.6 88.5 6 11.5 1.74³ χ^2 , df=6 1.77³ Education (M±SD)² 12.05 ± 3.09 12.48 ± 3.05 12.56 ± 2.85 11.99 ± 2.82 5.19*³ 12.23***³ df=1, 51

Bivariate Relationships Between Independent Variables and Medication Adherence/Nonadherence, 2005 and 2007

2005 (n=2,863) 2007 (n=2,301) Adherence Nonadherence Adherence Nonadherence $\%^1$ $\%^{1}$ $\%^1$ $\%^1$ Ν Ν Ν Ν **Annual household** income (M±SD)² 53,391 ± 85,825 $34,588 \pm 52,804$ $48,113 \pm 61,358$ $37,948 \pm 50,520$ 21.74***³ 7.91**³ df=1, 51 Number /chronic medical conditions $(M\pm SD)^2$ 2.34 ± 1.35 2.61 ± 1.39 2.46 ± 1.35 2.84 ± 1.38 13.61***³ 24.91***³ df=1, 51 Self-reported health² Excellent 217 90.1 24 9.9 165 93.3 16 6.7 650 88.5 99 11.5 558 Very good 88.5 75 11.5 832 85.5 14.5 701 87.5 118 12.5 Good 157 Fair 505 81.7 132 18.3 348 79.3 106 20.7 Poor 183 77.5 61 22.5 147 81.7 38 18.3 6.49***³ 7.88***³ χ^2 , df=4 Prescription drug coverage² Pay full cost or no 394 88 coverage 79.4 110 20.6 78.2 26 21.8 Insurance pays part of 1,306 88.0 191 12.0 1,542 85.9 285 14.1 cost Prescription discount 306 72.5 130 27.5 73 76.2 27 23.8 card Pay nothing 184 93.6 14 6.4 123 90.2 14 9.8 109 Other 93.8 6.2 86 92.9 7 7.1 8 χ^2 , df=4 20.07***³ 4.18**³

Bivariate Relationships Between In	levendent Variables and Medication A	dherence/Nonadherence, 2005 and 2007

		2005 (n=2,863)				2007 (n=2,301)			
	Adhe	Adherence		Nonadherence		Adherence		Nonadherence	
	Ν	% ¹	Ν	% ¹	Ν	% ¹	Ν	% ¹	
Medicare Part D enro	llment ²								
No	2,390	85.2	473	14.8	788	90.4	97	9.6	
Yes					968	82.7	226	17.3	
Don't know					129	81.0	31	19.0	
χ^2 , df=2		$10.54^{***}{}^3$							

Bivariate Relationships Between Independent Variables and Medication Adherence/Nonadherence, 2005 and 2007

¹Weighted %, unweighted N's

²Sample size varies slightly due to missing data within Prescription Drug Study (PDS) or Health and Retirement Study (HRS)

³Test statistic is Rao-Scott chi-square for categorical variables and F means test for continuous variables

*Significant at p<.05; **Significant at p<.01; ***Significant at p<.001

after the implementation of Medicare Part D as expected. Respondents who were younger, had lower income, fewer years of education, or poorer health status appeared more likely to report CRN over time. Having a prescription discount card or no coverage increased the likelihood of CRN in 2005 and 2007. Finally, older individuals enrolled in Medicare Part D or who were unaware of their enrollment status appeared more likely to report CRN in 2007.

Mixed-Effect Logistic Regression Results

Table 2.3 shows mixed-effects logistic regression models for CRN outcomes. Model 1 estimated the effects of race and gender on CRN over time, controlling for each other and time. Compared to older Whites, Black Americans were over two and a half times more likely to report CRN both before and after the implementation of Medicare Part D (OR=2.55). Females were 1.82 times more likely than males to experience CRN. Further, CRN was not significantly different in 2007 as compared to 2005.

The effects of race and gender on CRN over time remained significant with introduction of age and marital status variables in Model 2, although the odds of older Black Americans reporting CRN decreased 33% and for women, there was a 12% decline. Thus, the addition of these variables appeared to have some indirect effect on the relationship between race, gender, and CRN over time. Furthermore, both age and marital status had a direct effect on CRN in 2005 and 2007 when controlling for race, gender, and time. The odds of reporting CRN decreased as age increased. Respondents who were older had a lower likelihood of nonadherence due to cost over time (OR=.94). Additionally, respondents who were divorced (OR=1.47) or widowed (OR=1.53) were more likely than those currently married to experience CRN over time.

The inclusion of socioeconomic characteristic variables in Model 3 appeared to mediate some of the effect of race and gender on CRN over time, although the significant relationships

Mixed-Effects Logistic Regression Results of Cost-Related Medication Nonadherence

	Model 1	Model 2	Model 3	Model 4	Model 5	Model 6
	OR	OR	OR	OR	OR	OR
Race						
Black American	2.55***	2.22***	1.67**	1.51*	1.53*	1.65
White (reference group)						
Gender						
Female	1.82***	1.70***	1.63***	1.65***	1.42**	3.01***
Male (reference group)						
Year						
2007	.88	.96	.98	.95	.91	1.26
2005 (reference group)						
Age (continuous)		.94***	.93***	.93***	.93***	.93***
Marital Status						
Currently married (reference group)						
Married, spouse absent		.58	.50	.48	.51	.52
Partnered		1.72	1.63	1.65	1.91	1.90
Separated		.75	.56	.51	.76	.77
Divorced		1.47*	1.26	1.19	1.33	1.34
Widowed		1.53**	1.22	1.16	1.23	1.24
Never married		.94	.82	0.79	.97	.97
Education (continuous)			.93***	.95*	.95*	.95*
Annual household income (continuous	5)		.99***	.99***	.99***	.99***
Number of chronic medical condition	s (continuous)			1.17***	1.18***	1.18***
Self-reported health						
Excellent (reference group)						
Very good				1.32	1.22	1.24
Good				1.48	1.36	1.37
Fair				2.25**	2.14**	2.18**
Poor				2.27**	2.20**	2.25**

Mixed-Effects Logistic Regression Results of Cost-Related Medication Nonadherence

	Model 1	Model 2	Model 3	Model 4	Model 5 OR	Model 6 OR
	OR	OR	OR	OR		
Prescription drug coverage						
Pay full cost or no coverage (refe	rence group)					
Insurance pays part of cost					.35***	.35***
Prescription discount card					1.42*	1.43*
Pay nothing					.12***	.12***
Other					.17***	.17***
Medicare Part D enrollment						
No (reference group)						
Yes					1.94***	2.01***
Don't know					1.79*	1.91*
Year*Race						.95
Year*Gender						.59**

*Significant at p<.05; **Significant at p<.01; ***Significant at p<.001

Model 1: Race, Gender, and Year (n=3,181)

Model 2: Race, Gender, Year, Age, and Marital Status (n=3,177)

Model 3: Race, Gender, Year, Age, Marital Status, and Socioeconomic Status (n=3,172)

Model 4: Race, Gender, Year, Age, Marital Status, Socioeconomic, and Health Status (n=3,169)

Model 5: Race, Gender, Year, Age, Marital Status, Socioeconomic and Health Status, and Insurance Coverage (n=3,104)

Model 5: Interaction Effect of Race, Gender, and Year, Controlling for Age, Marital Status, Socioeconomic and Health Status, and Insurance Coverage (n=3,104)

were maintained. The odds of older Black Americans experiencing CRN in 2005 and 2007 decreased 55% and for females, there was a 13% decline. Marital status was no longer a significant predictor with the addition of these variables. Furthermore, both educational attainment and annual household income had a direct effect on CRN before and after Medicare Part D when controlling for race, gender, time, age, and marital status. CRN was significantly less for respondents with greater number of years of education (OR=.93). Further, having a greater annual income was associated with a lower likelihood of nonadherence due to cost (OR=.99).

With the addition of health status variables in Model 4, the effects of race and gender on CRN over time remained significant. Number of chronic medical conditions and self-reported health appeared to have very little indirect effect on the relationship between race, gender, and CRN as only a slight change in odds ratios was observed. Respondents with a greater number of chronic medical conditions had an increased likelihood of CRN (OR=1.17). Further, as compared to older individuals who reported their health as being excellent, odds of CRN were greater for those who rated their health as fair (OR=2.25) or poor (OR=2.27).

The significant effects of race and gender on CRN before and after Medicare Part D were maintained with addition of prescription insurance coverage variables in Model 5. The inclusion of prescription drug coverage and Medicare Part D enrollment variables appeared to have some mediating effect on the relationship between race and gender and CRN in 2005 and 2007. Although the odds of older Black Americans reporting CRN increased slightly (2%), a 23% decrease in CRN for women was observed. Furthermore, prescription drug coverage and Medicare Part D enrollment had a direct effect on CRN over time when controlling for race, gender, time, age, marital status, socioeconomic characteristics, and health status. As compared

to respondents that paid for the full cost of their medication(s) or had no prescription drug coverage, individuals with insurance that covered part of the cost were 65% less likely (OR=.35) and those with a prescription drug discount card were nearly one and a half times more likely (OR=1.42) to report CRN before and after Medicare Part D. Furthermore, the odds ratios (.12 and .17, respectively) show that respondents who paid nothing for their medications were 88% less likely to experience CRN and those who had some other type of coverage were 83% less likely to report CRN (compared to respondents who paid for the full cost of their medications). When considering Medicare Part D enrollment, the odds of CRN over time were nearly double (OR=1.94) for individuals enrolled in this benefit than for non-Medicare Part D enrollees. Further, respondents who did not know if they enrolled in Medicare Part D were 1.79 times more likely to experience CRN before and after the implementation of the benefit.

Finally, year of adherence or nonadherence due to cost was interacted with race and gender variables in Model 6 to compare racial and gender differences in change in CRN over time, controlling for age, marital status, socioeconomic characteristics, health status, and prescription insurance coverage. As compared to males, the rate of CRN for females significantly decreased over time (OR=.59). For older Black Americans, the interaction was not significant. Nonadherence due to cost, relative to Whites, did not change over time.

Discussion

The addition of the Part D drug benefit to Medicare was the largest expansion of the program in over 40 years (Madden, et al., 2008). While Medicare Part D was designed to help older persons gain access to needed medications, the extent to which the policy eliminated racial and gender disparities in CRN was unknown. This is the first longitudinal study to examine whether and to what extent nonadherence due to cost has changed for older females and Black

Americans since the implementation of the Medicare prescription drug benefit, and how factors associated with cumulative disadvantage can directly and indirectly affect the likelihood of CRN over time.

In this study, there was a significant disparity in CRN between older Black Americans and Whites both before and after Medicare Part D, and these differences did not change over time. Similarly, older females were significantly more likely than males to report CRN in both 2005 and 2007; however, women experienced a significantly greater decline in nonadherence over time compared to men. Both racial and gender disparities remained significant after controlling for age, marital status, socioeconomic characteristics, health status, and prescription insurance coverage. Further, factors related to cumulative disadvantage, specifically lower socioeconomic status, less education, poorer health status, and less generous or no prescription insurance coverage, had a direct effect on CRN over time.

In terms of hypotheses organizing the present analyses, there are several findings in need of discussion. The first hypothesis stated that compared to older males, older females are more likely to report CRN over time and less likely to report changes in CRN over time. This was partially supported. This study replicates previous findings showing that women were more likely to experience CRN than men (Heisler, et al., 2005; Piette, et al., 2004c; Zivin, et al., 2010), and expands this research by demonstrating that gender disparities existed before and after Medicare Part D. This suggests that although a drug benefit became available under Medicare, women continue to have more difficulty than men affording medications and maintaining adherence. A potential reason why disparities persist is that Medicare Part D's cost-sharing provisions continue to present barriers to maintaining adherence.

The prediction that females would be less likely to have a decline in CRN over time, however, was not supported. On the contrary, women were *more* likely to experience a decline in CRN. Thus, it is suggested that Medicare Part D is more effective in reducing CRN among women than men over time. One potential explanation is the availability of the Low-Income Subsidy (LIS) that was established with the enactment of Medicare Part D. The LIS provides financial assistance for Medicare Part D beneficiaries that have limited income and resources. Those eligible receive assistance with costs associated with the Part D plan (monthly premiums, annual deductible, medication copayments), and have a reduced coverage gap. Additional analyses (not shown) demonstrated that in 2005 and 2007, a significantly higher proportion of females had an annual household income in the lower two quartiles and therefore, they may be closer to the financial guidelines established to receive LIS assistance. One study confirmed that lower income individuals are more likely to participate in the LIS (Davidoff et al., 2010). Thus, it is possible that women may have had a greater reduction in CRN over time than men because of financial status and the availability of this assistance.

In terms of race, it was predicted that compared to older Whites, older Black Americans would be more likely to report CRN over time and less likely to report a decrease in CRN over time. This hypothesis was partially supported. This finding expands previous research illustrating racial disparities in CRN (Gellad, et al., 2007; Klein, et al., 2004; Soumerai, et al., 2006; Steinman, et al., 2001) by demonstrating that despite the presence of a drug benefit under Medicare, older Black Americans were significantly more likely to report CRN both before and after Medicare Part D. It is therefore suggested that cost continues to be a barrier to maintaining adherence for older Black Americans.

When considering change over time, it appears that Medicare Part D may be more effective in improving gender disparities in CRN than racial differentials. The rate of CRN for females significantly decreased over time in comparison to males; however, there was no change in the rate for Black Americans relative to Whites. A possible reason for this finding may be Black Americans' greater reliance on Medicaid for prescription drug coverage. Unlike those who became eligible for LIS assistance with the enactment of Medicare Part D, Medicaid recipients were automatically enrolled in Medicare Part D plans that continued to subsidize drug costs. In other words, the assistance received through Medicaid was retained under Medicare Part D plans. Additional analyses (not shown) revealed that in this study, old Black Americans were significantly more likely to be enrolled in Medicaid in both 2005 and 2007. Despite the presence of drug coverage under Medicaid, Black Americans have experienced problems affording the cost-sharing requirements (Gellad, et al., 2007; Klein, et al., 2004). Thus, very little change in CRN over time could be expected given previous coverage and cost-sharing requirements that existed under Medicaid before Medicare Part D were essentially maintained.

The third hypothesis that socioeconomic status, health status, and prescription insurance coverage would mediate the effect of racial and gender differences in CRN over time was not supported. Although the odds of CRN for older Black Americans and females compared to older Whites and males decreased with the addition of these variables, the effects were small and racial and gender differences in CRN over time remained significant. In other words, disparities continued even after accounting for factors associated with cumulative disadvantage.

It is difficult to assess the reasons why disparities persist after controlling for socioeconomic status, health status, and prescription insurance coverage because of limitations with existing research. There are, however, two potential explanations. First, while this study

controls for whether an individual actually enrolled in Medicare Part D, it could not control for individual differences within Part D plans. There are over 40 Medicare Part D plans (Kaiser Family Foundation, 2011b), and coverage restrictions and cost-sharing requirements vary extensively within plans (Hoadley, Hargrave, Cubanski, & Neuman, 2006). Each plan's coverage policies can impact CRN. For example, antidepressants are often subject to policies designed to reduce access, which can increase CRN (Huskamp, Stevenson, Donohue, Newhouse, & Keating, 2007). Because older women are more likely to have a greater number of depressive symptoms (Skarupski, et al., 2009), their chances of incurring coverage restrictions or other costcontainment measures associated with Part D plans are greater. Similarly, cost-sharing requirements are typically more for individuals with diabetes than most other chronic illnesses under Medicare Part D plans (Ettner et al., 2010). Since older Black Americans are more likely to be diabetic than Whites (Schoenbaum & Waidmann, 1997; Schoenborn & Heyman, 2009), they have a greater likelihood of incurring cost sharing under Part D plans. Further, Black Americans had a significantly greater number of medications in 2005 and 2007 as compared to Whites (additional analysis, not shown). Thus, the variation in cost sharing may have a greater impact on older Black Americans than Whites because their health status is typically poorer and as a result, they often have higher prescription drug needs. This, in turn, can impact their ability to purchase prescribed medications and maintain adherence.

A second explanation involves factors involving the physician-patient relationship and trust. The physician-patient relationship has been found to influence CRN (I. B. Wilson, et al., 2004). Higher out-of-pocket prescription drug expenditures have been associated with a greater likelihood to forgo medications because of cost if trust in the physician is low (Piette, Heisler, Krein, & Kerr, 2005). Further, communication regarding costs can influence CRN. Individuals

who have experienced problems paying for their medications are often not asked if they can afford the cost (Piette, Heisler, & Wagner, 2004b). It is possible that for some older women and Black Americans in this study, physician trust and/or communication were low and contributed to CRN.

Finally, it was predicted that lower socioeconomic status, poorer health status, or little or no prescription insurance coverage would increase the likelihood of CRN over time. When considering socioeconomic status, this prediction was supported. Similar to previous crosssectional studies conducted before the implementation of Medicare Part D, having a greater annual household income and more years of education decreased the likelihood of nonadherence due to cost (Gellad, et al., 2007; Mojtabai & Olfson, 2003; Soumerai, et al., 2006; Steinman, et al., 2001; Zivin, et al., 2010). This study expands these findings and suggests that despite the implementation of Medicare Part D, older individuals with a lower income and less education are especially vulnerable to CRN.

With regard to health status variables, poorer health directly affected CRN as predicted. In this study, older persons with a greater number of chronic medical conditions were more likely to report CRN before and after Medicare Part D. Additionally, nonadherence due to cost was more likely for individuals reporting fair or poor health than those reporting excellent health. This is consistent with previous findings that individuals in poor health with multiple comorbidities have high and persistent CRN over time (Briesacher, Gurwitz, & Soumerai, 2007; Madden, et al., 2008; Safran, et al., 2005). CRN can be caused by higher out-of-pocket expenditures due to multiple medications (Frankenfield, et al., 2010; Zivin, et al., 2010), and generosity of coverage can substantially reduce the risk of nonadherence for those with several comorbidities (Soumerai, et al., 2006). While Medicare Part D may have alleviated some of the

financial burden for sicker beneficiaries, it is suggested that cost-sharing requirements under Medicare Part D can still be problematic and thus, have little impact on CRN.

When considering prescription drug coverage variables, these findings support the hypothesis that having no or less generous drug coverage will increase CRN over time. First, as compared to older adults with no coverage or paying the full cost for their medications, having partial coverage provided by insurance, paying nothing for medications, or having some "other" source of coverage decreased the likelihood of CRN before and after Medicare Part D. This is consistent with previous findings showing that older individuals with drug coverage were less likely to report CRN than those without (Frankenfield, et al., 2010; Mojtabai & Olfson, 2003; Steinman, et al., 2001), and expands research by demonstrating that these differences remained despite the implementation of Medicare Part D. Additionally, CRN was significantly greater over time between older individuals with a prescription discount card – which typically provides minimal coverage – and those without coverage or paying the full cost of their medications. This is a bit perplexing given that a discount card can provide some financial assistance with medication costs. A potential reason for this finding is that those who acquire a discount card may have greater difficulty with medication costs than those without this type of assistance. In other words, they obtain the card because they are struggling with drug costs.

Second, when considering the impact of Medicare Part D on CRN, those enrolled in the benefit or uncertain if they enrolled in the benefit were significantly more likely than those not enrolled to report nonadherence due to cost over time. This finding may seem counterintuitive, particularly because one might expect CRN to *improve* over time if enrolling in the benefit. However, this study included all respondents, regardless of type of prescription drug coverage. In other words, if an individual did not enroll in Medicare Part D, it may be because they had

coverage through an alternative source such as an employer-based plan. Research has shown differential adherence to medications depending on the source of coverage. For example, CRN was significantly greater for those enrolled in Medicare Part D as compared to individuals with employer-based coverage (Safran, et al., 2009). These differences can be explained by out-of-pocket expenditures under Medicare Part D; as compared to employer-based plans, Part D enrollees had higher cost-sharing requirements or a less generous benefit structure (Goedken, Urmie, Farris, & Doucette, 2010; Safran, et al., 2009). Thus, it is suggested that older individuals enrolled in Medicare Part D will continue to experience greater CRN because of cost sharing under this program.

An additional finding worthy of note involves the age variable. It was somewhat surprising that increased age *decreased* the likelihood of CRN over time, particularly because research shows lower prescription drug coverage rates among older age groups (Kanavos & Gemmill-Toyama, 2010). This finding, however, is consistent with cross-sectional studies using HRS to examine CRN before the implementation of Medicare Part D. One potential reason involved the sampling of the HRS and exclusion of institutionalized persons. Because risk of institutionalization or nursing home placement increases with age, it was suggested that the older age groups participating in the HRS are disproportionately healthy (Klein, et al., 2004). This explanation, however, could not be confirmed through additional analysis. Therefore, future research is needed to understand why younger persons were more likely to experience CRN than older age groups.

Strengths of this study include the use of a large nationally representative sample of older adults and its ability to examine multiple predictors simultaneously and over time. However, there are a number of limitations that must be considered. In the future, a longer prepolicy and

postpolicy series would provide more clarity and permit a stronger assessment of Part D enrollment. Other unmeasured factors may have influenced the results. For example, the transition of dual eligibles from Medicaid to Medicare drug plans in 2006 was confusing for many older adults (Kaiser Family Foundation, 2006) and resulted in difficulties obtaining medications (West, et al., 2007). A significantly greater proportion of older Black Americans in this study were dually eligible as compared to Whites, and thus, had a greater likelihood of being impacted by the transition. As a result, CRN may have been overestimated because data collection occurred shortly after the launch of Medicare Part D and at a time of initial confusion. However, the PDS only contained two waves of data at the time this study was conducted. While this research provides important evidence on the impact of the policy on racial and gender disparities in CRN, the results should be considered early evidence until longer-term data become available.

Second, socioeconomic and health status were measured in the 2004 and 2006 HRS, and CRN was measured in the 2005 and 2007 PDS. Thus, there is the potential that income or certain health conditions may have changed because these measures were not taken simultaneously or when CRN was reported. While this seems less likely with income because older adults are largely dependent on Social Security, there is greater potential for fluctuation in health status. Depression, for example, can be transitory (Zivin, et al., 2010). Older females and Black Americans who enrolled in Medicare Part D have a greater prevalence of depression as compared to older males and Whites (Skarupski, et al., 2009). Thus, the indirect effect of health status on the relationship between race, gender, and CRN may have been inaccurately represented in the results.

Third, this study investigated nonadherence due to cost *only* and did not account for other factors that can impact adherence. For example, an individuals' concerns or beliefs regarding treatment through the use of medications can certainly impact adherence (Aikens & Piette, 2009). Some medications may be viewed as more essential than others (Lau et al., 2008; Piette, Heisler, & Wagner, 2006) and there could be racial and gender differences in whether a prescription is perceived as necessary, particularly when faced with cost concerns. As compared to older males and Whites, older females' and Black Americans' ability to afford out-of-pocket expenditure requirements is typically less due to lower socioeconomic status (Wei, et al., 2006). Thus, they may perceive the need for certain medications differently because of economic concerns. Additionally, physician trust and communication can be a factor in medication adherence (Piette, et al., 2005). It is possible that for some older females and Black Americans in this study, physician trust and/or communication were low and contributed to CRN. While this could account for some variation in CRN, these factors were not the focus of this research but will be examined in future studies.

Fourth, older Black Americans had a significantly greater proportion of missing data when asked about CRN in the 2007 PDS than older Whites. Individuals can be confused by the Medicare Part D benefit because of its complexity (Davidoff, et al., 2010; Heiss, et al., 2006; Hsu, et al., 2008). Fewer Black Americans may responded to the CRN question because as stated previously, the survey was administered shortly after the implementation of Medicare Part D – which was a time of confusion for many older persons. This, in turn, could bias the results and underestimate or overestimate the racial effect of CRN over time. Further, this study relied on self-reported survey measures. Self-reporting can be subject to social desirability bias (Nederhof, 2006). Respondents may be reluctant to admit failure to adhere to a prescribed

medication regimen – particularly if it is due to cost factors. Because older women and Black Americans are more likely to be economically disadvantaged, they may incur greater difficulty affording the cost of prescribed medications – and, admitting failure to adhere because of economic reasons. This bias could contribute to underestimating the prevalence of CRN.

Fifth, there are limitations with nonadherence measures contained in the PDS. The survey did not ask respondents whether they took less than the prescribed dosage of a medication or if they cut pills in half to make a medication last longer. The survey question asked if a dosage of a medication was skipped to save money, and this measure could be a potential indicator of these behaviors. However, failure to ask if these behaviors specifically occurred could underestimate CRN.

Finally and as stated previously, this study utilized a composite measure to estimate CRN as opposed to including all three behaviors as separate indicators: 1) not filling a new prescription because of cost; 2) stopping taking a medication because of cost; or 3) skipping doses of a medication to save money. While this is consistent with previous research and therefore useful for cross-study comparison (Bambauer, et al., 2007; Gellad, et al., 2007; Madden, et al., 2008; Safran, et al., 2005; Soumerai, et al., 2006; I. B. Wilson, et al., 2004; Zivin, et al., 2009), measuring each behavior separately may provide important insights for social work practice on racial and gender disparities in CRN. For example, one behavior could be more prevalent than others among older women or Black Americans. By understanding which types or types of nonadherence are more common in older women and Black Americans, interventions that specifically target certain behaviors can be designed. Thus, future research will examine each CRN item as an outcome.

Despite these limitations, the study makes a strong and significant contribution to our understanding of whether and to what extent racial and gender disparities in CRN have changed since the implementation of Medicare Part D. It also extends our understanding of the direct and indirect effect of factors related to cumulative disadvantage on the relationship between CRN and race and gender over time. Medicare Part D reduced out-of-pocket prescription drug expenditures (Millett, Everett, Matheson, Bindman, & Mainous, 2010). This is an important point, but the benefit may not be sufficient for all groups. The older adult population is not homogeneous, and subgroup differences need to be considered. These results suggest that despite the implementation of a drug benefit under Medicare, racial and gender disparities in CRN continue to persist, and poorer health, being lower income, or having less generous or no prescription drug coverage increases the likelihood of CRN. Findings can help substantiate the need to account for race and gender when evaluating policy alternatives in order to promote more equitable access to prescription medications and avoid disparate heath outcomes.

CHAPTER THREE

MANUSCRIPT TWO

ABSTRACT

Purpose: The viability of Medicare Part D and the Low-Income Subsidy (LIS) as a means of reducing or eliminating racial and gender disparities in cost-related medication nonadherence (CRN) is still uncertain. Using cumulative advantage/disadvantage theory as a framework, the objectives of this longitudinal study were to determine: 1) to what extent racial and gender disparities in CRN exist over time for older women and Black Americans enrolled in Medicare Part D; and 2) to what extent the LIS directly and indirectly affects the relationship between race, gender, socioeconomic and health status, and CRN before and after Medicare Part D. Methods: To evaluate changes in CRN before and after Medicare Part D, secondary data from the 2004 and 2006 waves of the Health and Retirement Study (HRS) and data from the 2005 and 2007 waves of the Prescription Drug Study (PDS), a subsample of the HRS, were utilized. The analytic sample for this longitudinal analysis consisted of 1,466 respondents, age 65 and older, who were enrolled in Medicare Part D, taking at least one prescribed medication, and responded to questions about adherence or nonadherence in either 2005 or 2007. The outcome variable of interest was CRN, which included not filling, stopping, or skipping doses of a prescription because of cost. The main predictors were race (Black American and White), gender (male and female) and LIS status (dual eligible/receiving LIS, applied for LIS, and no LIS). Covariates included demographics, socioeconomic, and health status. The analysis was conducted using mixed-effects logistic regression models. Results: Results indicated that racial and gender disparities in CRN persisted after accounting for health and socioeconomic status. While LIS status did not affect racial differentials, applying for the LIS mediated gender differences. Poorer

health, applying for the LIS, and having an annual income between \$12,271 and \$43,479 increased the likelihood of CRN over time. However, differences in between those earning \$12,721 to \$23,363 and the highest income group were mediated by applying for the LIS. *Conclusions:* Gender differences in CRN were substantially driven by whether an individual applied for the LIS as were differentials between lower and higher income groups. However, older Black Americans, the near-poor, and individuals in poor health continue to be disproportionately nonadherent. These findings indicate the need to target outreach towards these groups to raise awareness of the LIS and increase participation. Additionally, policymakers should consider raising the LIS income requirements to 200% FPL.

CHAPTER THREE

COST-RELATED MEDICATION NONADHERNECE UNDER MEDICARE PART D AND THE LOW-INCOME SUBSIDY: A RACIAL AND GENDER COMPARISON

Background

Prescription drug costs can present a significant barrier to older adults in need of medications and, aside from health insurance premiums, represent the leading contributor to outof-pocket health care expenditures (Kaiser Family Foundation, 2010b). Retail prescription drug prices have increased an average of 6.9% annually from 1990 to 2007, far outpacing the rise in inflation (Kaiser Family Foundation, 2008). Older adults are disproportionately impacted by the increasing costs of prescription medications because while they represent 13% of the general population, they account for 34% of all medications that are dispensed and 42% of all prescription drug expenditures (Families USA, 2000). As drug costs and out-of-pocket medication expenses rise, adherence tends to fall (Mojtabai & Olfson, 2003; Safran, et al., 2005). Older adults – particularly individuals with several chronic conditions – often become nonadherent when they are unable to afford medications (Heisler, et al., 2004; Neuman, et al., 2007; Soumerai & Ross-Degnan, 1999).

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) is the largest benefit expansion in the history of the program, and represents the most meaningful health care policy in the past three decades because it reduces out-of-pocket health care costs. To respond to the need to provide older adults with drug coverage, the MMA added the Part D benefit to Medicare (Madden, et al., 2008; Mayes, 2005). Part D includes a number of cost-containment provisions such as cost-sharing requirements, plan premiums and a time period, known as the coverage gap, when beneficiaries are responsible for 100 percent of their drug costs. Cost-sharing provisions stipulate that the beneficiary is required to pay a fixed amount for

each prescription or copayment, a proportion of the medication price or coinsurance, and/or an annual payment before the plan will provide coverage or deductible. Plan premiums require that individuals pay a monthly amount to receive coverage and averaged \$40.72 in 2011, an increase of 57% since Medicare Part D was implemented in 2006 (Hoadley, et al., 2010). There is concern that these cost-containment provisions can inhibit the use of medications for older women and Black Americans. Compared to older men and Whites, older women and Black Americans tend to have a greater number of chronic health problems (Clark, 1997; Kelley-Moore & Ferraro, 2004a) and are, therefore, more reliant on prescription medications (Rogowski, et al., 1997; Sambamoorthi, et al., 2003). This means that older women and Black Americans tend to have higher copayments and are more likely to reach the coverage gap each year. Combined with their overall lower socioeconomic status, therefore, older women and Blacks are less able to afford out-of-pocket expenditure requirements (Wei, et al., 2006) and more likely to have difficulties adhering to their medication regimen.

Previous research has shown the connection between cost-related medication nonadherence (CRN) and cost-containment provisions similar to those present in Medicare Part D plans (Adams, et al., 2001; T. B. Gibson, et al., 2005; Tseng, et al., 2004; Wang et al., 2010). CRN can include not filling, stopping, or skipping doses of a prescription because of cost. Prior to the MMA, racial and gender disparities in CRN clearly existed (Heisler, et al., 2005; Klein, et al., 2004). Medicare Part D may continue to impede access to medications because the benefit's cost-containment provisions can increase out-of-pocket expenditures (Hsu, et al., 2008), and may have a disproportionately greater impact on older females and Black Americans because of their economic status, health status, and greater reliance on prescription medications (Wei, et al., 2006).

Because out-of-pocket expenditure requirements can be a barrier to prescription drug access, the Low-Income Subsidy (LIS) program (also known as "Extra Help"), was created under the MMA. This program was intended to offset prescription drug costs for beneficiaries with limited income and resources. There are two groups of beneficiaries that qualify for this assistance. First, the MMA stipulated that individuals covered by both Medicare and Medicaid, known as dual eligibles, automatically qualify and receive the LIS. Prior to Medicare Part D, dual eligibles received prescription benefits through state Medicaid programs. The MMA required that these beneficiaries enroll in Medicare Part D and the LIS to maintain this assistance. States were no longer allowed to provide prescription drug coverage for dual eligibles. Second, other low-income Medicare beneficiaries whose income and assets are below a specified level can receive assistance; however, they are required to apply for the LIS. Coverage is not automatic for this group.

The LIS reduces or eliminates out-of-pocket expenses associated with Medicare Part D, including premiums, deductibles, copayments, coinsurance, and costs associated with the coverage gap (Kaiser Family Foundation, 2009b). A summary of Medicare prescription drug plan subsidies is provided in Figure 3.1. Though research pertaining to the efficacy of the LIS is lacking, it is suggested that older women and Black Americans in particular will be impacted by the LIS provision because of their lower-income status.

To date, studies have not examined the prevalence of racial and gender disparities in CRN for beneficiaries that enrolled in Medicare Part D or the impact of the LIS on CRN. This longitudinal study builds upon prior research by using a cumulative advantage/disadvantage framework to examine to what extent racial and gender disparities in CRN have changed for older women and Black Americans enrolled in Medicare Part D. Further, this study seeks to

Figure 3.1

Medicare Drug Benefit Subsidies for Low-Income Beneficiaries, 2010					
Low-Income Subsidy Level	Monthly Premium	Annual Deductible	Copayments		
Dual eligibles, or individuals with Medicare and Medicaid: <i>Automatically enrolled and</i> <i>receiving LIS</i>	\$0	\$0	\$1.10-\$2.50/generic \$3.30-\$6.30/brand- name; no copayment after total drug spending reaches \$6,440		
Individuals with income <135% of poverty and resources <\$8,100/individual or \$12,910/couple: <i>Application for LIS required</i>	\$0	\$0	\$2.50/generic \$6.30/brand-name; no copayment after total drug spending reaches \$6,440		
Individuals with income 135% to 150% of poverty and resources <\$12,510/individual or \$25,010/couple: <i>Application for LIS required</i>	Sliding scale up to \$31.94	\$63	15% of total costs up to \$6,440; \$2.50/generic \$6.30/brand-name thereafter		
SOURCE: Kaiser Family Foundation summary of Medicare drug benefit Low-Income Subsidies in 2010. NOTE: 2009 poverty level is \$10,830/individual and \$14,570/couple					

understand to what extent the LIS directly and indirectly affects the relationship between race, gender, socioeconomic and health status, and CRN over time. Examining disparities among enrollees can help us understand how Medicare Part D enrollment has impacted CRN for older women and Black Americans, and the impact of the LIS, a key and costly provision of the MMA.

Literature Review

Cumulative Advantage/Disadvantage and Medicare Part D

When deliberating social policy initiatives intended to target older individuals, the aged should not be stereotyped (Butler, 1985) or treated as a homogeneous group (Neugarten, 1982). Inequities resulting from disadvantages throughout the life course need to be considered in order

to ensure equitable access to benefits. Cumulative advantage/disadvantage theory is useful as a foundation for understanding and evaluating the effectiveness of Medicare Part D. The theory has increasingly been used as a paradigm in the field of aging to describe stratification and growing trajectories over time (Dannefer, 1987; Farkas, 2003; Kail, et al., 2009; A. E. Wilson, et al., 2007). Systematic disadvantages have a considerable impact on later life, and it is suggested that they not only accrue throughout the life course but are magnified and can have a feedback effect (Crystal & Shea, 1990a; Ferraro & Kelley-Moore, 2003). In other words, "the more disadvantages individuals experience, the more likely they are to accrue subsequent and greater disadvantages" (Kail, et al., 2009, p. 557). For example, individuals from economically disadvantaged families are more likely to have fewer years of education. This creates differences in employment opportunities, and subsequently places them at greater risk for incurring lower wages, unemployment, and less advantageous working conditions. Lower income due to limited employment and educational opportunities is often compounded because of poorer health status, lesser or no health insurance, and greater health care expenditures (Sambamoorthi, et al., 2003). Because of cumulative advantages and disadvantages throughout the life course, heterogeneity increases with age, and inequalities are greatest in later life (Crystal & Shea, 1990a; Dannefer, 1987; Ross & Wu, 1996).

This study will focus on racial and gender disparities in CRN under Medicare Part D. As the result of cumulative advantages and disadvantages throughout the life course, it is anticipated that higher out-of-pocket expenditures will be related to personal characteristics associated with early disadvantage, or income, education, and health status. These factors, in turn, can potentially impact CRN under the benefit.

Income and education. The ability to afford pharmaceuticals and maintain adherence to a prescribed medication regimen are largely dependent on retirement earnings. Income in later life is essentially based on pre-retirement experiences, and racial and gender inequities continue to increase with advancing age (Crystal & Shea, 1990a). Wages for females and Black Americans have consistently lagged behind those received by White males, and women and Black Americans are more likely to have been segregated into positions without retirement, pension, or health care benefits (Gonyea & Hooyman, 2005). Since Social Security is based on a 40-year work history, older women and Black Americans are typically subject to lower benefits in later life than White males due to lower wages and fewer years in the labor force (Olson, 1994) and thus have less income available to purchase prescribed medications. Further, catastrophic changes such as widowhood – which is more common in the lives of women (Moody, 2009) – can be particularly difficult because older females and Black Americans are in a disadvantaged position. Women and Black Americans not only enter old age poorer than men and Whites but can become poorer with age as a result of widowhood (Minkler & Stone, 1985).

Health status. Lower income is typically accompanied by a higher prevalence of chronic health conditions among older women and Black Americans. Racial and gender inequities in morbidity exist throughout the life course and health trajectories continue to diverge with increasing age (Clark, 1997; Kelley-Moore & Ferraro, 2004a). Women are more likely to report functional limitations, a higher number of chronic conditions, and rate their health as poor or fair than their male counterparts (Murtagh & Hubert, 2004). As the result of increased morbidity, females and Black Americans are more reliant on pharmaceuticals (Goulding, 2005). Yet, their ability to afford prescribed medications is often compromised because of lower socioeconomic status. Compared to White males, older women and Black Americans spend a higher proportion

of their income on pharmaceuticals (Rogowski, et al., 1997; Sambamoorthi, et al., 2003). For these reasons, it is expected that they will continue to experience a disproportionately heavier financial burden under Medicare Part D (Wei, et al., 2006). This, in turn, can subsequently affect their ability to purchase prescribed medications and maintain adherence.

Low-Income Subsidy. Cost-sharing assistance can be considerable for persons who qualify for the LIS (Kaiser Family Foundation, 2009b). The LIS represents a significant policy initiative because overall cost burden associated with prescribed medications can be greater for older females and Black Americans due to disadvantages throughout the life course. Dual eligibles and those applying for the LIS are typically lower-income individuals with multiple chronic illnesses (Davidoff, et al., 2010). Thus, it is possible that older women and Black Americans may be affected by the LIS provision more than older men and Whites because of their financial and health status. Receiving this subsidy substantially reduces or eliminates outof-pocket expenses associated with Medicare Part D, and can potentially impact nonadherence due to cost.

Medication Access and Adherence

Pre-Medicare Part D. Prior to Medicare Part D, CRN was estimated to occur in one fourth of all older adults (Safran, et al., 2005); those without prescription drug coverage or with limited coverage were significantly more likely to be noncompliant because of cost (Blustein, 2000; Fillenbaum, et al., 1993; Rogowski, et al., 1997). Nonadherence due to cost was greater among older women than men (Heisler, et al., 2005; Piette, et al., 2004c; Zivin, et al., 2010). Race was an even stronger predictor of CRN than gender. According to one study, older Black Americans were 1.5 times more likely to report nonadherence to a medication regimen than Whites (Gellad, et al., 2007), and numerous studies have found that Black Americans were more

likely than Whites to forgo or delay taking prescribed medications because of cost (Bambauer, et al., 2007; Klein, et al., 2004; Roth, et al., 2009; Roth & Ivey, 2005; Soumerai, et al., 2006; Steinman, et al., 2001). While Medicare Part D is expected to increase access to medications, it is questionable whether the benefit will eliminate racial and gender disparities in CRN. Older women and Black Americans are more likely to be reliant on prescription medications yet have a decreased ability to afford out-of-pocket expenditure requirements due to lower socioeconomic status. This, in turn, can affect their ability to maintain adherence.

In regards to Medicare and Medicaid recipients, CRN was less for dual eligibles than non-dual eligibles before Medicare Part D (Gellad, et al., 2007; Soumerai, et al., 2006). Despite lower nonadherence among dual eligibles as compared to non-dual eligibles, studies examining CRN within the dual eligible population found that one fourth reported nonadherence (Safran, et al., 2005) and nearly half had difficulties affording their medications (Saver, Doescher, Jackson, & Fishman, 2004). It was suggested that dual eligibles were particularly sensitive to copayment requirements under Medicaid plans because income and asset guidelines for coverage were extremely low (Klein, et al., 2004; Soumerai, Avorn, Ross-Degnan, & Gortmaker, 1987). Medicaid eligibility is dependent on having an annual income at or near the Federal Poverty Level and extremely limited resources such as savings. As a result, affording medications can be difficult even when copayment requirements are minimal. Individuals qualifying for coverage typically have little disposable income left each month after paying for necessities such as food, housing, transportation, or other health care costs – which in turn can impact their ability to purchase prescribed medications (Soumerai, et al., 1987).

Studies conducted before the implementation of Medicare Part D found that older women and Black Americans had higher odds of CRN than older men and Whites after controlling for

the presence of Medicaid coverage, or dual eligibility status (Bambauer, et al., 2007; Soumerai, et al., 2006). Thus, it appears that receiving prescription benefits through state Medicaid programs did little to mediate racial and gender differences in nonadherence due to cost. It is possible that *any* copayment requirements posed difficulties older women and Black Americans – regardless of whether or not they were minimal. It is unclear how CRN will be impacted for dually eligible older women and Black Americans transitioning from Medicaid drug plans to the LIS and Medicare Part D program. There was considerable variation in Medicaid copayment requirements across states (Safran, et al., 2003). For this reason, copayment obligations were expected to be higher under the LIS and Medicare Part D than Medicaid for some beneficiaries, and lower for others (Guyer & Schneider, 2004).

Post-Medicare Part D. When analyzing the MMA from certain economic perspectives, the policy can appear highly successful. In 2008, 90 percent of Medicare's 45 million beneficiaries had prescription drug coverage (Joyce, et al., 2009) as compared to 76 percent in 2006 (Levy & Weir, 2009). Further, it is estimated that out-of-pocket spending on prescription drugs decreased between 13 and 18.4 percent even as the number of medications used by older adults increased from 5.9 to 12.8 percent since the implementation of the MMA (Chen, et al., 2008; Joyce, et al., 2009; Lichtenberg & Sun, 2007; Schneeweiss, et al., 2009; Yin, et al., 2008). However, these findings do not take into consideration the implications of the cost-containment provisions – or cost-sharing requirements, plan premiums, or coverage gap – of the MMA, and the impact of those provisions on cumulatively disadvantaged beneficiaries. In other words, there was no differentiation of groups reported in these findings; beneficiaries were regarded as a homogeneous group that gained access to a prescription drug benefit and lowered their medication expenditures. It is important to recognize the potential implications of Medicare Part

D cost-sharing provisions on older females and Black Americans. For example, one implication of the cost-sharing requirements is that access to medications is not in fact the same for all beneficiaries. Those with lower income and increased morbidity, such as is often experienced by older women and Black Americans, may be negatively and disproportionately influenced by cost-sharing requirements both because of their higher medication expenses and their limited income. This, in turn, can impact their ability to access medication and maintain adherence. Thus, existing research on the impact of MMA does not recognize the differential consequences of these provisions

Research examining changes in CRN before and after Medicare Part D is extremely limited. One of the main reasons for this limitation is the restrictions placed on the availability of data. The Centers for Medicare and Medicaid Services has historically been a primary source of data for researchers. However, a provision contained in the MMA stipulated that private health care plans were not required to release Medicare Part D claims data for nonpayment-related purposes, which included research, public health purposes, and health care analysis (Crystal, 2008, November; Stuart, 2008). This stipulation largely accounts for the limitation with existing research. Fortunately, this was modified in 2009, and data are currently in the process of being released.

When considering studies conducted after the implementation of Medicare Part D, Safran et al. (2009) reported that for older individuals with no or a meager drug benefit, enrollment resulted in lower out-of-pocket prescription drug expenditures, higher medication utilization, and overall lower CRN. However, low-income, chronically ill beneficiaries were significantly more likely to report CRN and difficulty affording their medications. Similarly, Madden et al. (2008) found that while there was a modest but significant decrease in overall CRN, no decrease was

observed among individuals in fair to poor health, with at least four morbidities, or having an annual income less than \$25,000. Although differences associated with race or gender were not analyzed in either study, the findings shed some light on the experiences of these groups. Because older women and Black Americans are more likely to be low income, rate their health as poor or fair, and experience higher rates of chronic illness and health problems, these studies suggest that enrolling in the Medicare Part D benefit may have little or no impact on CRN for these groups.

While previous studies have not specifically examined the effect of the Medicare drug benefit on racial or gender disparities in CRN, research suggests ethnic disparities continue to exist. One study conducted after the implementation of Medicare Part D, for example, found that Hispanics were more likely to report CRN than non-Hispanics. Further, CRN was significantly greater for non-Hispanic Blacks than non-Hispanic Whites. When examining gender, both Hispanic and non-Hispanic females were more likely to report nonadherence due to cost than males (Frankenfield, et al., 2010).

CRN and the Low-Income Subsidy. It remains unknown to what extent the LIS has affected CRN among the non-dual eligible population, or individuals required to apply for this assistance. Further, research has not examined how the provision of this assistance has impacted racial and gender differences in nonadherence. Studies examining the LIS have focused solely on dually eligible beneficiaries transitioning from Medicaid prescription drug plans to Medicare Part D, did not differentiate by age, race, or gender, and only examined out-of-pocket costs, utilization, and access – or factors that can suggest changes in adherence may have occurred – rather than examining adherence itself. Prescription drug claim-based analyses concluded that for dually eligible beneficiaries, mean out-of-pocket expenditures on certain drugs did not change

significantly (Basu, Yin, & Alexander, 2010; Millett, et al., 2010) or were reduced (Chen, et al., 2008; Shrank et al., 2008), and prescription drug utilization remained stable (Shrank, et al., 2008). Other studies utilizing a survey-based approach found that dual eligibles with a mental illness had problems accessing medications because of prior authorization requirements or other restrictions (Hall, Kurth, & Moore, 2007; West, et al., 2007), or increased copayment requirements (Huskamp et al., 2009). Further, while one study reported that prescription drug utilization did not change (Safran, et al., 2009), another found utilization decreased among medications commonly used to treat certain chronic conditions (Farley & Dusetzina, 2010).

It appears that in general, the transition from Medicaid prescription drug plans to Medicare Part D may have had little impact on dually eligible beneficiaries and medication adherence may not have changed. In contrast, certain vulnerable subpopulations such as individuals with a mental illness may have experienced difficulties accessing medications and maintaining adherence because of their health status. Moreover, several studies utilized a claimbased approach, and the results only reflected successfully filled prescriptions and not attempted fills where access problems and subsequent CRN may have occurred (Polinski, et al., 2009). Because of these issues, the lack of differentiation by age, race, or gender within the samples, and the absence of research pertaining to non-dual eligibles, it is difficult to conclude how racial and gender disparities in CRN have been impacted by the LIS. Further, studies have examined factors that can impact adherence, such as out-of-pocket cost, utilization, or access. They did not specifically explore CRN for dual eligibles after the transition from Medicaid to Medicare Part D and the LIS.

Overall, studies suggest that gender and racial disparities in CRN prior to Medicare Part D existed even after accounting for Medicaid drug coverage. However, it remains unknown

whether or to what extent Medicare Part D enrollment or the LIS program has affected disparities in nonadherence due to cost. Studies have primarily investigated the effect of Medicare Part D and the LIS provision utilizing pharmaceutical claims and health care plan data and do not differentiate beneficiaries by demographics. While a few studies have used nationally representative datasets to examine CRN, racial and gender differences in change in medication adherence before and after Medicare Part D have not been examined and the impact of the LIS has not been considered. The one study examining disparities in CRN after the implementation of the benefit was cross sectional as opposed to longitudinal and did not account for LIS status. Thus, research has not investigated whether racial and gender disparities in CRN have changed for individuals enrolled in the Medicare Part D benefit or the impact of the LIS; therefore, the MMA's effectiveness in eliminating racial and gender differences in nonadherence due to cost is currently unknown.

This study builds on existing knowledge and provides important insights about CRN under Medicare Part D. First, it uses data from a nationally representative longitudinal dataset to analyze CRN for beneficiaries that enrolled in Medicare Part D. This allows for the examination of gender and racial differences in CRN both before and after the implementation of this benefit. Second, this study investigates whether the LIS directly and indirectly affects the relationship between race, gender, health, and socioeconomic status, and CRN over time. Examining whether disparities persist despite applying for or automatically receiving the subsidy can help us understand the impact of the LIS, a key provision of the MMA. It also furthers our understanding of how factors associated with cumulative disadvantage can directly and indirectly impact the likelihood of nonadherence due to cost for older females and Black Americans enrolled in this benefit while accounting for LIS status.

Based on existing literature, there are six hypotheses in this study:

- 5) As compared to older Whites, older Black Americans enrolled in Medicare PartD are more likely to report CRN over time
- As compared to older males, older females enrolled in Medicare Part D are more likely to report CRN over time
- LIS status will mediate the effect of racial and gender differences in CRN over time
- Controlling for race and gender, LIS status will decrease the likelihood of CRN over time
- 9) Controlling for LIS status, health and socioeconomic status will mediate the effect of racial and gender differences in CRN over time
- 10) Controlling for race, gender, and LIS status, poorer health status and lower socioeconomic status will increase the likelihood of CRN over time

Methodology

Sample

This study utilizes secondary data from the 2004 and 2006 waves of The University of Michigan (U-M) Health and Retirement Study (HRS) as well as data from the 2005 and 2007 waves of the HRS Prescription Drug Study (PDS) to conduct a longitudinal analysis. Launched in 1992, the HRS is a nationally representative population study of more than 20,000 Americans over the age of 50 designed to assess the relationship between health and retirement. The core HRS survey collects information pertaining to physical and mental health, insurance coverage, financial status, family support systems, retirement situation, and work status (Juster & Suzman, 1995). The primary mode of data collection is by telephone; however, in situations where health

limitations would make the hour-plus telephone session difficult or where there is no telephone in the household, the survey is conducted in the respondent's home (HRS, 2011). Primarily funded through the National Institute on Aging (NIA U01AG009740), the HRS is designed, administered, and conducted by the Institute for Social Research (ISR) at the U-M. The overall interview response rate for the core 2004 HRS was 86.2% and for the core 2006 HRS, the overall response rate was 88.5% (Ofstedal, 2009, June).

The PDS is a subsample of the HRS, and is a two-wave mail survey conducted in 2005 and 2007. It was specifically designed to examine prescription drug utilization as Medicare Part D was implemented. The baseline wave was administered pre-Medicare Part D in 2005 by the ISR, and captured information pertaining to prescription drug use, coverage, and knowledge of the Medicare prescription drug benefit. The second wave was conducted post-Medicare Part D in 2007, and captured similar information as well as data pertaining to the impact of the MMA costcontainment provisions such as the coverage gap and restrictions. The sample was drawn from respondents who participated in the HRS in 2004. To be eligible for inclusion in the PDS, respondents needed to be age 65 or older in 2007 (born in 1942 or later), or have Medicare or Medicaid coverage at some time between 2002 and 2004. Because the Consumption and Activities Mail Survey (CAMS) was fielded at the same time as the PDS, approximately 40% of eligible participants were excluded because of their involvement in the CAMS. However, the exclusion did not affect the representation of the PDS sample because CAMS participants were randomly selected (J. Faul, Personal Communication, January 4, 2012). Of those who were eligible for inclusion in the PDS, 4,684 individuals or 88.1% completed the PDS in 2005, and 3,536 persons or 74% responded to the survey in 2007 (HRS, 2011). Given that this is a relatively new topic area, there are no reliability or validity measures associated with the PDS (J.

Faul, Personal Communication, February 3, 2012).

To be included in the analytic sample for this study, respondents were required to 1) be either non-Hispanic White/Caucasian or non-Hispanic Black/African American; 2) be age 65 or older in 2005 and therefore eligible for Medicare when the PDS was administered; 3) have reported taking prescription medications in 2005 or 2007; 4) have responded to questions about prescription drug adherence in the 2005 or 2007 PDS; and 5) have reported being enrolled in Medicare Part D in 2007 PDS. Of the 4,808 responding to the 2005 or 2007 PDS, 4,248 were either non-Hispanic White/Caucasian or non-Hispanic Black/African American; 3,606 were age 65 and over; 3,323 reported taking prescription medications; 3,181 reported data on prescription drug adherence or nonadherence; and 1,406 reported enrolling in the Part D benefit in the 2007 PDS. Thus, a total 1,466 respondents to the 2005 (n=1,273) or 2007 (n=1,262) PDS were included in the final analytic sample.

The combination of HRS and PDS provides an excellent source of data for testing the proposed hypotheses because indicators of cumulative advantage/disadvantage that could decrease or increase older adults' risk of CRN are available through these datasets. Variables from the 2005 and 2007 PDS included CRN, LIS status, and Medicare Part D enrollment status. All other variables were obtained from the 2004 and 2006 RAND HRS data files. These data files contain a broad range of measures across HRS waves, and are developed and maintained by the RAND Center for the Study of Aging, with support provided by the NIA and Social Security Administration (RAND Center for the Study of Aging, 2010).

In regards to Institutional Review Board (IRB) approval, this study relied exclusively on secondary data to complete all analysis. The HRS and PDS files contain de-identified individual

data that are available to the public. Therefore, the IRB at Michigan State University (MSU) does not require human subjects review.

Measures

Dependent variable. A summary indicator of any CRN was constructed as the dependent variable. In the 2005 and 2007 PDS, CRN was evaluated using questions about the following three behaviors: 1) not filling a new prescription because of cost; 2) stopping taking a medication because of cost; or 3) skipping doses of a medication to save money. If the respondent indicated that they engaged in any of these behaviors, they were considered nonadherent in this study. Earlier research typically used a single measure to assess CRN, and focused solely on whether respondents failed to fill a prescription in the past year because of cost. However, this measure did not assess for multiple ways CRN could occur. Thus, the additional questions were developed to help monitor and identify changes in CRN, and have demonstrated test-retest reliability (Pierre-Jacques, et al., 2008) and construct validity (Soumerai, et al., 2006). This composite variable approach was originally developed by Safran et al. (2003) based on a series of validated survey questions concerning CRN to prescription regimens, confirmed using factor analysis techniques, and used as a main outcome in subsequent research examining drug nonadherence practices of older adults (Bambauer, et al., 2007; Gellad, et al., 2007; Madden, et al., 2008; Safran, et al., 2005; Soumerai, et al., 2006; I. B. Wilson, et al., 2004; Zivin, et al., 2009). Because all three measures of CRN, specifically filling, stopping, or skipping doses of a prescription because of cost, were highly correlated with comorbidity, self-reported health status, and socioeconomic status (Bambauer, et al., 2007; Safran, et al., 2005; Safran, et al., 2003; Soumerai, et al., 2006), it is important that they be included in this study. Older females and Black Americans are more likely to have a lower income and multiple health

problems due to disadvantages throughout the life course and thus, accounting for all behaviors can further understanding of CRN before and after the implementation of Medicare Part D.

In this study, a dichotomous variable indicating any nonadherence or no nonadherence to the three CRN behaviors in the PDS – not filling a new prescription because of cost, stopping taking a medication because of cost, or skipping doses of a medication to save money – was created for each time point, or for both the 2005 and 2007 measures. The CRN variable was initially incorporated as a continuous variable indicating a sum total of the three behaviors. However, results were significantly skewed because the majority of the sample were adherent to their medication regimen and similar to previous research, the variable was dichotomized (Bambauer, et al., 2007; Gellad, et al., 2007; Madden, et al., 2008; Safran, et al., 2005; Soumerai, et al., 2006; I. B. Wilson, et al., 2004; Zivin, et al., 2009). Using this global, dichotomous measure is common in existing literature, and will help provide a meaningful comparison to previous research.

Independent variables. The main predictors of interest were race (1 = "Black American" and 0 = "White"), gender (1 = "female" and 0 = "male"), and LIS status (also referred to as "Extra Help") status. A three-category variable was used to indicate LIS status (0 = "no LIS," 1 = "applied for LIS," "2 = "dual eligible/receiving LIS") at each time point. Individuals whose income and assets exceed Medicaid eligibility criteria are required to apply for the LIS through the Social Security Administration whereas dually eligible beneficiaries automatically receive the LIS because they qualify for both Medicare and Medicaid. Further, level of LIS assistance is dependent on eligibility status, and the subsidy provided to dual eligibles is greater than that provided to non-dual eligibles who applied for assistance. Thus, the including the measure as an ordinal variable is warranted. Respondents were asked three

questions about LIS status. Questions related to whether or not respondents who were not duallyeligible applied for LIS differed slightly in 2005 and 2007. First, in the 2005 PDS, respondents were asked "Do you intend to apply to Social Security for Extra Help paying for prescription drugs?" Responses included 1 = "yes," 5 = "no," and 8 = "I have already applied." Respondents who indicated that they had applied for or intended to apply for the LIS were coded as 1 ="applied for LIS" in the 2005 measure. Separate analyses were conducted using the threecategory variable prior to combining those that actually applied and planned to apply into one category. The results are almost identical; in other words, significance was the same and odds ratios changed slightly. Further, the 2005 PDS was administered during the initial LIS application period when this subsidy first became available to respondents. Considerable outreach efforts by the Social Security Administration were conducted during this timeframe to help beneficiaries apply for and receive this subsidy; for this reason, I believe that intent to apply is a good measure of having applied for LIS. Next, in the 2007 PDS, individuals were asked "Have you ever applied for Extra Help?" Those who said "yes" were coded as 1 = "applied for LIS" for the 2007 measure. Finally, in both the 2005 and 2007 PDS, respondents were asked whether they were receiving Medicaid. Those who said "yes" were coded as 2 = "dual eligible/receiving LIS" at each time point.

A time variable was also created to evaluate CRN over time (2005 and 2007) using the "reshape" command in Stata version 11 and was used in all regression analyses as a main predictor. The "reshape" command converted the data to a long format and provided a single variable that was used to measure CRN at both time points. Using literature pertaining to cumulative advantage/disadvantage as a guide, other independent variables included

socioeconomic characteristics and health status. Additionally, age and marital status were used as control variables.

Socioeconomic characteristic indicators included attained education and annual household income. Disadvantages can accumulate throughout the life course as the result of decreased educational attainment and lower income, and result in decreased ability to afford prescription medications and maintain adherence. The level of attained education was a continuous variable ranging from 0 to 17 or more years of education. Cumulatively disadvantaged individuals tend to have lower levels of education. Subsequently, they are less likely to have prescription drug coverage and the financial resources needed to purchase prescribed medications. Utilizing this measure will help clarify how educational attainment can impact CRN. Additionally, it can further our understanding of how education can indirectly impact CRN among older women and Black Americans. Annual household income was a continuous variable ranging from \$0 to \$1,242,996. The variable was recoded into quartiles: \$12,720 or less; \$12,721 to \$23,363; \$23,364 to \$43,479; and \$43,480 or above. The lower two quartiles roughly correspond to the 100% and 150% federal poverty thresholds, and help understand how CRN has been impacted for the poor and near-poor while controlling for LIS status. Further, the measure was used as a continuous variable in Chapter Two and provided similar results. That is, as income increased, the likelihood of CRN significantly decreased.

Health status variables included number of chronic medical conditions and self-reported health status. Increased morbidity is associated with cumulative disadvantage and increased reliance on pharmaceuticals, particularly among older women and Black Americans. Thus, it is important to understand how health status impacts CRN. First, a continuous variable indicating the number of chronic medical conditions was used. Respondents were asked, "Has a doctor ever

told you that you have [name of chronic medical condition]" or "our records from your last interview show that you have [name of chronic medical condition]." This question was asked for a series of eight chronic medical conditions and included: high blood pressure, diabetes, cancer, lung disease, heart disease, stroke, psychiatric problems, and arthritis. The second health-related variable included self-reported health status. Respondents were asked, "Would you say your health is excellent, very good, good, fair, or poor?" Responses ranged from 0 = "excellent" to 4 ="poor" with a higher score indicating that the respondent perceived their health status as being more poor.

Finally, other control variables included age and marital status. Age was a continuous variable ranging from age 65 to 101. Marital status was a seven-category variable: married, married with spouse absent, partnered, separated, divorced, widowed, and never married.

Analytic strategy

Univariate descriptive statistics summarized all measures at baseline. Cross-tabulations were conducted to determine the bivariate association between respondent characteristics and CRN at baseline and in 2007. The Rao-Scott chi-square, a design-adjusted version of the Pearson chi-square, was used to test the significance of the association (Rao & Scott, 1981). Mixed-effects logistic regression models were used for multivariate analysis to estimate racial and gender differences in CRN over time for those enrolled in Medicare Part D, and to examine the direct and indirect effect of the LIS, health and socioeconomic status, and demographic characteristics on the relationship between race and gender and CRN.

Mixed regression models are useful for this type of analysis for several reasons (Blackwell, et al., 2006; Rabe-Hesketh & Skrondal, 2008). First, they do not require that respondents be measured on the same number of time points. In other traditional methods such as

repeated-measures ANOVA, cases are dropped if some measurements are missing (Blackwell, et al., 2006). This is important because some participants did not respond to questions pertaining to CRN in both surveys. In particular, 72.9% of respondents indicated adherence or nonadherence in both the 2005 and 2007 PDS. Of the 27.1% not responding at both waves, 51.4% completed the CRN questions in the 2005 PDS and 48.6% indicated adherence or nonadherence in the 2007 PDS. In general, by allowing the inclusion of cases with missing data, the sample size is larger and thus more closely approximates the general population (Ott & Lngnecker, 2001).

Second, mixed regression models do not require that respondents complete the survey at precisely the same time interval. This, again, is an essential point when considering the administration of the PDS. The survey was mailed to respondents in October, and the field period continued through March. It was completed at varying times over a six-month period. Finally, mixed regression models are advantageous when analyzing repeated-measures data because they provide an estimate of individual-specific change across time and also model patterns of change between individuals. By modeling both fixed and random effects, there is the ability to account for individual differences over time as well as deviations from the group trend (Van Dongen, et al., 2004).

A series of six mixed regression models were run with the direct and indirect effects of each set of variables on the relationship between race, gender, and CRN over time examined in each model. Model 1 included only the time variable. Race and gender were added in Model 2 and in Model 3, LIS status variables were included. Demographic variables were added in Model 4. Model 5 added the health status variables and in Model 6, socioeconomic status variables were included. A likelihood-ratio test was performed for each model to determine whether including time as a fixed and random effect provided a better fit than the random-intercept only model. A

null model was first fit with the dependent variable only to determine the level of betweenperson variance. Next, the fixed effect of time and a random effect associated with the intercept of each respondent were added to the model. A third model then added a second random effect that allowed each person to have a unique outcome at each time point. With the exception of the null model, this process was repeated for Model 1 through Model 6. An alpha of .05 was used as the cutoff for determining statistical significance. In every analysis, the likelihood-ratio test was not significant. Thus, time was included only as a fixed effect in the regression models.

All statistical analyses were performed in the Stata version 11.0 statistical package (StataCorp). Stata's survey commands were used in univariate statistics and bivariate tests of association to account for the complex multistage clustered sampling design of the HRS when computing standard errors. The PDS questionnaire weights (a product of the HRS sampling weights) were applied to adjust for sample selection probability or oversampling of select minority groups and for interviewee nonresponse in univariate and bivariate analysis only (HRS, 2011). Stata does not allow the incorporation of the survey command or application of probability weights in mixed-effect logistic regression analyses. Thus, mixed regression models did not control for the design effect and were not weighted. A consequence of not utilizing the questionnaire weights or controlling for the design effect is the potential for inaccurate point estimates and/or inaccurate standard errors, which in turn can impact the ability to infer results to the general population. Despite this limitation, mixed-effect regression analyses can provide a strong indication of racial and gender difference in CRN over time because unlike other methods such as time-series ANOVA, cases are not dropped if there are missing values. Further, there was no substantive difference in outcomes in bivariate models that were weighted and controlled for the design effect as compared to multivariate models. Thus, the potential that the results will

inaccurately reflect the general population is minimal. Significance in multivariate analysis was tested at the p<.05 level using a one-tailed test.

Results

Description of Sample at Baseline

A detailed description of the sample at baseline or in 2005 is provided in Table 3.1. Of the 1,273 individuals responding to the question about medication adherence at baseline and enrolling in Medicare Part D in 2007, 10.3% self-identified as non-Hispanic Black or African American and the majority (61.3%) were female. In regards to LIS status, 17.2% applied for the LIS and 15.9% dual eligibles receiving the LIS. Respondents ranged in age from 65 to 101 with a mean age of 73.8 years, and slightly less than half (49.7) were married. Respondent self-reports indicated that the majority felt their health was good (33.2%), very good (27.8%), or fair (21.2%), followed by excellent (9.2%), and poor (8.6%). The average number of chronic health conditions was 2.43 (SD = 1.38). Over a quarter of respondents had annual incomes between \$23,364 and 43,479 (26.7%) or \$43,480 and greater (26.7%), while 22.3% had annual incomes between \$12,721 and \$23,363, and 21.4%% had annual incomes \$12,720 and less. the mean years of education was 12.29 (SD = 2.92). Finally, 18.8% of respondents reported cost-related medication nonadherence in 2005.

Bivariate Results

Bivariate analyses of medication adherence and nonadherence in 2005 and 2007 are presented in Table 3.2. In regards to the main predictor variables, a higher proportion of Black Americans compared to Whites were nonadherent both before and after Medicare Part D, while a greater proportion of females were nonadherent compared to males before Medicare Part D only.

TABLE 3.1

Variable	N^{1}/M	% ¹ / SE
Race		,
Black American	224	10.3
White	1,049	89.7
Gender	,	
Female	805	61.3
Male	468	38.7
Low-Income Subsidy Status ²		
Dual eligible/receiving Low-Income Subsidy	180	15.9
Applied for Low-Income Subsidy	212	17.2
No Low-Income Subsidy	615	66.9
Age (range 65 to 101)	73.8	7.12
Marital status ²		
Married	653	49.7
Married, spouse absent	13	1.0
Partnered	27	1.8
Separated	17	1.3
Divorced	111	8.9
Widowed	415	33.9
Never married	37	3.4
Number of chronic medical conditions (range: 0 to 7)	2.43	1.38
Self-reported health ²		
Excellent	113	9.2
Very good	333	27.8
Good	421	33.2
Fair	288	21.2
Poor	117	8.6
Education (range: 0 to 17) ²	12.13	3.08
Annual household income		
\$12,720 and less	314	21.4
\$12,721 to \$23,363	309	22.3
\$23,364 to \$43,479	325	26.7
\$43,480 and above	325	29.6
Cost-related adherence or nonadherence		
Adherent	1,007	81.2
Nonadherent	266	18.8

Description of Sample of Individuals Age 65 and Over Reporting Medication Adherence/Nonadherence in 2005 and Enrolling in Medicare Part D (n=1,273)

¹Weighted %, unweighted N

²Sample size varies slightly due to missing data within PDS or HRS

In regards to LIS status, a significantly larger proportion of respondents that applied for the LIS reported nonadherence in both 2005 and 2007.

In terms of control variables, age was significantly related to CRN. Nonadherent older individuals reported a significantly lower age than adherent older adults before and after Medicare Part D. Marital status was not significantly related to CRN.

In regards to health status variables, respondents who reported CRN had a significantly greater number of chronic conditions compared to those that maintained adherence in 2005 and 2007. A smaller proportion of respondents in excellent health reported nonadherence than those in other categories with those in fair or poor health reporting the most nonadherence. This relationship was only significant in 2007.

In terms of socioeconomic status variables, annual household income and educational attainment were not significantly related to nonadherence before or after Medicare Part D.

Bivariate analyses suggest that without controlling for other factors, older Black Americans were more likely to report CRN than older Whites before and after the implementation of Medicare Part D as expected. Gender appeared to impact CRN before Medicare Part D only. Respondents that applied for the LIS were more likely to report CRN over time as compared to those who did not apply. Older individuals who were younger or had a greater number of chronic medical conditions appeared more likely to report nonadherence before and after Medicare Part D. Respondents that self-reported their health as being very good, good, fair, or poor (as compared to excellent) appeared more likely to be nonadherent due to cost in 2007 only.

TABLE 3.2

2007 (n=1,262) 2005 (n=1,273) Adherence Nonadherence Adherence Nonadherence $\%^{1}$ $\%^1$ **%**¹ **%**¹ Ν Ν Ν Ν Race Black American 163 73.5 61 26.5 139 71.6 56 28.4 White 844 82.1 205 17.9 887 84.4 180 15.6 4.03*³ χ^2 , df=1 15.49***³ Gender Female 611 77.5 194 22.5 634 82.3 150 17.7 Male 396 87.1 72 12.9 392 84.2 86 15.8 20.62***³ 0.70*³ χ^2 , df=1 Low-Income Subsidy (LIS) Status² Dual eligible/full LIS 153 88.5 79 11.5 82 81.6 20 18.4 Applied for LIS 133 66.8 27 33.2 127 75.7 54 24.3 No LIS 533 82 12.8 801 84.2 87.2 160 15.8 χ^2 , df=1 18.99***³ 3.18*³ Age $(M \pm SD)^2$ 74.31 ± 7.55 71.74 ± 6.41 76.18 ± 70.3 74.22 ± 5.87 46.42***³ 21.75***³ df=1, 51 Marital status² Married 523 82.3 129 17.7 537 84.3 116 15.7 Married, spouse absent 13 1.0 0.0 93.6 6.4 0 16 1 Partnered 20 77.3 7 22.7 13 66.8 9 33.2 Separated 15 89.9 2 10.1 13.0 11 87.0 2 25 Divorced 86 81.9 18.1 83 23 83.5 17.5

Bivariate Relationships Between	Independent Variables and Medication .	Adherence/Nonadherence, 2005 and 2007

TABLE 3.2

2005 (n=1,273) 2007 (n=1,262) Nonadherence Nonadherence Adherence Adherence **%**¹ **%**¹ **%**¹ **%**¹ Ν Ν Ν Ν Marital status (con't)² Widowed 324 79.9 91 20.1 329 81.5 18.5 76 Never married 25 12 31.0 26 83.9 16.1 69.0 5 χ^2 , df=6 1.24³ 0.96³ Number of chronic medical conditions² 2.38 ± 1.37 2.67 ± 1.43 2.54 ± 1.37 2.95 ± 1.40 8.58**³ 13.82***³ df=1, 51 Self-reported health² Excellent 99 86.1 14 13.9 75 93.0 7.0 9 Very good 277 84.4 56 15.6 282 84.1 15.9 52 Good 330 80.5 91 19.5 354 84.8 75 15.2 Fair 219 79.2 69 20.8 207 76.9 69 23.1 Poor 26.5 95 81 73.5 36 82.3 26 17.7 2.39³ χ^2 , df=4 4.36**³ **Education** (M±SD)² 12.18 ± 3.25 11.92 ± 3.25 12.17 ± 2.96 11.93 ± 3.02 0.84³ 1.38³ df=1, 51 Annual household income² \$12,720 and less 242 80.2 72 19.8 200 81.7 51 18.3 \$12,721 to \$23,363 237 79.2 72 20.8 237 81.5 68 18.5

Bivariate Relationships Between Independent Variables and Medication Adherence/Nonadherence, 2005 and 2007

TABLE 3.2

		2005 (n=1,273)				2007 (n=1,262)			
	Adhe	Adherence		Nonadherence		Adherence		Nonadherence	
	Ν	% ¹	Ν	% 1	Ν	% ¹	Ν	% ¹	
Annual household incom	$e(con't)^2$								
\$23,364 to \$43,479	254	79.2	71	20.8	279	81.6	67	18.4	
\$43,480 and above	274	85.3	51	14.7	299	87.0	46	13.0	
χ^2 , df=3	1.44 ³				1.59 ³				

Bivariate Relationships Between Independent Variables and Medication Adherence/Nonadherence, 2005 and 2007

¹Weighted %, unweighted N

²Sample size varies slightly due to missing data within Prescription Drug Study (PDS) or Health and Retirement Study (HRS)

³Test statistic is Rao-Scott chi-square for categorical variables and F means test for continuous variables

*Significant at p<.05; **Significant at p<.01; ***Significant at p<.001

Mixed-Effect Logistic Regression Results

Table 3.3 shows mixed-effects logistic regression models for CRN outcomes. Model 1 projected CRN over time only. Respondents enrolling in Medicare Part D were 22% (OR=.78) less likely to report CRN in 2007 as compared to 2005. Next, Model 2 estimated the effects of race and gender on CRN over time, controlling for each other and time. Compared to older Whites, Black Americans were over twice as likely to report CRN both before and after the implementation of Medicare Part D (OR=2.22). Females were 1.50 times more likely than males to experience CRN in both 2005 and 2007.

The effect of race on CRN over time remained significant with the addition of LIS status variable in Model 3. Applying for or receiving the LIS appeared to have little indirect effect on the relationship between race and CRN. However, the odds ratio for the relationship between females and males decreased 26% (OR=1.24) and was no longer significant with the inclusion of the LIS status variable. Two separate dichotomous variables indicating whether the respondent applied for the LIS (versus no LIS) and whether the respondent was a dual eligible receiving the LIS (versus no LIS) were created to determine which LIS status category indirectly affected the relationship between gender and CRN over time. The effect of gender on CRN did not change when adding the dual eligible/receiving LIS variable to the model. However, the relationship was no longer significant with the addition of the applied for LIS variable (additional analysis, not shown). This suggests that gender differences in nonadherence over time are driven substantially by whether an individual applied for the LIS. A test of mediation confirmed this finding (Baron & Kenny, 1986). That is, gender was related to applying for the LIS, gender was associated with CRN, and applying for the LIS was related to CRN. Further, time was no longer a significant predictor of CRN with the addition of the applied for LIS variable, indicating that applying for

	Model 1 OR	Model 2 OR	Model 3 OR	Model 4 OR	Model 5 OR	Model 6 OR
Year	011	011	011	011	011	011
2007	.78*	.79*	1.06	1.18	1.10	1.10
2005 (reference group)						
Race						
Black American		2.22***	1.97***	1.75**	1.53*	1.51*
White (reference group)						
Gender						
Female		1.50**	1.24	1.26	1.26	1.24
Male (reference group)						
Low Income Subsidy (LIS) status						
Dual eligible/full LIS			.81	.95	.79	.77
Applied for LIS			3.13***	3.16***	2.63***	2.57***
No LIS						
Age (continuous)				.94***	.94***	.94***
Marital status						
Currently married (reference category)						
Married, spouse absent				.14*	.14*	.13*
Partnered				2.81*	2.94*	2.74*
Separated				.39	.38	.41
Divorced				.80	.76	.79
Widowed				1.14	1.08	1.10
Never married				1.17	1.18	1.22
Number of chronic medical conditions (continuous)					1.22***	1.21**
Self-reported health						
Excellent (reference group)						
Very good					1.36	1.33

TABLE 3.3Mixed-Effects Logistic Regression Results of Medication Nonadherence

	Model 1 OR	Model 2 OR	Model 3 OR	Model 4 OR	Model 5 OR	Model 6 OR
Self-reported health (con't)						
Good					1.47	1.39
Fair					1.96*	1.82*
Poor					1.86*	1.74*
Education (continuous)						.98
Annual household income						
\$12,720 and less						1.08
\$12,721 to \$23,363						1.45
\$23,364 to \$43,479						1.54*
\$43,480 and above						

TABLE 3.3Mixed-Effects Logistic Regression Results of Medication Nonadherence

*Significant at p<.05; **Significant at p<.01; ***Significant at p<.001

Model 1: Year (N=1,466)

Model 2: Year, race, and gender (N=1,466)

Model 3: Year, race, gender, and Low-Income Subsidy status (N=1,425)

Model 4: Year, race, gender, and Low-Income Subsidy status, age, and marital status (N=1,421)

Model 5: Year, race, gender, and Low-Income Subsidy status, age, marital status, and health status (N=1,420)

Model 6: Year, race, gender, and Low-Income Subsidy status, age, marital status, health, and socioeconomic status (N=1,420)

the LIS indirectly affected nonadherence before and after Medicare Part D. It also appears that applying for the LIS had a direct effect on CRN in 2005 and 2007 when controlling for race, gender, and time. As compared to those with no LIS, individuals who applied for the LIS were over three times more likely (OR=3.13) to report CRN before and after Medicare Part D.

The effect of race on CRN over time remained significant with introduction of age and marital status variables in Model 4, although the odds of older Black Americans reporting CRN decreased 22% (OR=1.75). Thus, the addition of these variables appeared to have some indirect effect on the relationship between race and CRN over time. The impact of age and marital status on the relationship between LIS status and CRN over time was minimal. Further, as compared to older individuals who were currently married, odds of CRN were greater for those who were partnered (OR=2.81) and less for those who were married but their spouse was absent (OR=.14). Finally, respondents who were older had a decreased likelihood of CRN (OR=.94).

The inclusion of health status variables in Model 5 appeared to mediate some of the effect of race on CRN over time, although the significant relationship was maintained. The odds of older Black Americans experiencing CRN in 2005 and 2007 decreased 22% (OR=1.53). The effect of applying for the LIS on CRN over time remained significant, though the odds of nonadherence were reduced 53% (OR=2.63) indicating that the addition of these variables indirectly affected CRN before and after Medicare Part D. Further, both number of chronic medical conditions and self-reported health had a direct effect on CRN over time when controlling for race, gender, time, LIS status, age, and marital status. Respondents with a greater number of chronic medical conditions had an increased likelihood of CRN (OR=1.22). Further, as compared to older individuals who reported their health as being excellent, odds of CRN were greater for those who rated their health as fair (OR=1.96) or poor (OR=1.86).

With the addition of socioeconomic status variables in Model 6, the effect of race and LIS status on CRN over time remained significant. Educational attainment and annual household income appeared to have very little indirect effect on the relationship between race and CRN or applying for the LIS and CRN as only a slight change in odds ratios was observed. Further, annual household income had a direct effect on CRN before and after Medicare Part D. As compared to respondents in the highest income group, individuals with an annual income between \$23,364 and \$43,479 were 1.54 times more likely to experience CRN over time.

Discussion

The implementation of the MMA represented an essential policy initiative. The Medicare Part D benefit and LIS program were clearly needed to help older persons gain access to medications and reduce out-of-pocket prescription drug expenditures, yet the extent to which the policy reduced or eliminated racial and gender disparities was unknown. This is the first longitudinal study to examine whether and to what extent nonadherence due to cost over time persists for older females and Black Americans enrolled in Medicare Part D, and how the LIS directly and indirectly affects the relationship between race, gender, and CRN over time. Further, it investigates how factors associated with cumulative disadvantage directly and indirectly affect the likelihood of CRN over time for older individuals enrolled in the benefit while controlling for LIS status.

In terms of hypotheses organizing the present analyses, there are several findings to discuss. The first hypothesis that older Black Americans enrolled in Medicare Part D would be more likely than Whites to report CRN over time was supported. This finding expands previous research illustrating racial disparities in CRN (Gellad, et al., 2007; Klein, et al., 2004; Soumerai, et al., 2006; Steinman, et al., 2001) by demonstrating that despite enrolling in Medicare Part D,

older Black Americans were significantly more likely to report CRN both before and after the implementation of this benefit. It is therefore suggested that cost continues to be a barrier to maintaining adherence for older Black Americans.

The second hypothesis predicted that compared to older males, older females enrolled in Medicare Part D would be more likely to report CRN over time. This hypothesis was supported. This study replicates previous findings showing that women were more likely to experience CRN than men (Heisler, et al., 2005; Piette, et al., 2004c; Zivin, et al., 2010), and expands this research by illustrating that gender disparities existed over time despite Medicare Part D enrollment. This suggests that although a drug benefit became available under Medicare, women continue to have more difficulty than men affording medications and maintaining adherence. A potential reason why disparities persist is that Medicare Part D's cost-sharing provisions continue to present barriers to maintaining adherence.

Next, it was predicted that LIS status would mediate the effect of racial and gender differences in CRN over time. Results for this hypothesis are mixed depending on whether respondents were dually eligible and automatically received the LIS or applied for LIS on their own. Specifically, dual eligibility did not mediate the effect of either race or gender. This finding is similar to research conducted before the MMA that found continuing racial and gender disparities in CRN among Medicaid recipients (Bambauer, et al., 2007; Soumerai, et al., 2006). Though it was anticipated that some out-of-pocket costs could be lower under the LIS than state Medicaid plans (Guyer & Schneider, 2004), it appears that differences in CRN persisted over time despite the transition from Medicaid drug plans to Medicare Part D.

Applying for the LIS mediated the effect of gender on CRN over time, but not the effect of race. This is a bit perplexing given that lower income individuals were more likely to apply

for the LIS (Davidoff, et al., 2010). Additional analyses (not shown) demonstrated that in 2005 and 2007, a significantly higher proportion of Black Americans had an annual household income in the lowest quartile than Whites and thus, had a greater likelihood of qualifying for the LIS. One potential explanation for this is that compared to Whites, Black Americans at or below 150% of poverty are significantly less likely to be aware of the LIS benefit (Neuman, et al., 2007). This is the case among this sample as well (additional analysis, not shown). Only 36% of older Black Americans reported being aware of the LIS in 2007, as compared to 59% of Whites. While research has not specifically examined whether they are more likely to encounter barriers with the LIS applications process, it is suggested that lack of awareness is related barriers within the medical setting which are more common from Black Americans (Smedley, Stith, & Nelson, 2003). Thus, the importance of outreach to increase awareness of the benefit is certainly demonstrated, particularly in light of how applying for the LIS affected gender differences in CRN over time. In this study, 23% of older females applied for the LIS in 2005 as compared to 11% of older males, and in 2007, 18% of older women applied as compared to 8% of older males.

The fourth hypothesis that while controlling for race and gender, LIS status would decrease the likelihood of CRN over time was not supported. While CRN was less for dual eligibles than non-dual eligibles before Medicare Part D (Gellad, et al., 2007; Soumerai, et al., 2006), there was no difference in CRN over time between dually eligible individuals and those with no LIS. A potential reason could involve increased copayment requirements (Huskamp, et al., 2009). It was expected that for some dual eligibles, cost-sharing obligations were expected to be higher under the LIS and Medicare Part D than Medicaid for some beneficiaries (Guyer & Schneider, 2004). This, in turn, could impact CRN differences that previously existed.

Additionally, those non-dual eligibles that applied for the subsidy were significantly *more* likely than those with no LIS to report CRN over time. It seems somewhat counterintuitive that applying for the LIS would result in an *increased* likelihood of CRN given that cost-sharing assistance can substantially reduce out-of-pocket expenditure requirements. However, there are two potential explanations. First, this study included all respondents that enrolled in Medicare Part D, regardless of income, assets, and whether or not they qualified for the LIS. In other words, if an individual did not apply for the LIS, it may be because they exceeded the income or asset guidelines. Those with the greatest need in terms of socioeconomic disadvantage and poorer health status – and therefore, at greater risk of CRN – were most likely to apply for the LIS (Davidoff, et al., 2010). Second, even though an individual applied for the LIS, cost-sharing requirements still exist and can vary depending on income. Though research has not examined how cost-sharing under the LIS affects CRN, it is suggested that copayments could pose difficulties for some beneficiaries and thus impact adherence given that income and asset requirements for LIS coverage are relatively low.

The fifth hypothesis that controlling for LIS status, health and socioeconomic status will mediate the effect of racial and gender differences in CRN over time was not supported. Although the odds of CRN for older Black Americans decreased with the addition of these variables compared to older Whites, the effects were small and racial differences in CRN over time remained significant. In other words, racial disparities continued even after accounting for factors associated with cumulative disadvantage and LIS status. Regarding gender differences, the inclusion of the LIS status variable in Model 3 mediated the relationship between gender and CRN over time. In additional analysis (not shown), the LIS variable was removed in an attempt to understand whether health and socioeconomic status indirectly affected the relationship

between gender and CRN. While the odds of CRN decreased over time, older females were significantly more nonadherent than males. Thus, this suggests that gender differences in CRN were largely influenced by LIS status and factors related to cumulative disadvantage had little impact on this relationship.

With regard to racial disparities, it is difficult to assess the reasons why differences persist after controlling for factors associated with cumulative disadvantage – specifically LIS status, health, and socioeconomic status - because of limitations with existing research. There are, however, two potential explanations. First, this study could not control for individual differences within Part D plans. There are over 40 Medicare Part D plans (Kaiser Family Foundation, 2011b). Cost-sharing can vary extensively within plans (Hoadley, et al., 2006) and exist, regardless of LIS status. Each plan's out-of-pocket expenditure requirements can impact CRN. For example, cost-sharing requirements are typically greater for individuals with diabetes than most other chronic illnesses under Medicare Part D plans (Ettner, et al., 2010). Because older Black Americans are more likely to be diabetic than Whites (Schoenbaum & Waidmann, 1997; Schoenborn & Heyman, 2009) and have comorbid health problems requiring multiple medications (Skarupski, et al., 2009), their chances of incurring cost-sharing under Part D plans is typically greater. Further, Black Americans had a significantly greater number of medications in 2005 and 2007 as compared to Whites (additional analysis, not shown). Thus, the variation in cost-sharing may have a greater impact on older Black Americans than Whites because their health status is typically poorer and as a result, they often have higher prescription drug needs. This, in turn, can impact their ability to purchase prescribed medications and maintain adherence.

A second explanation involves factors involving the physician-patient relationship and trust. The physician-patient relationship has been found to influence CRN (I. B. Wilson, et al.,

2004). Higher out-of-pocket prescription drug expenditures have been associated with a greater likelihood to forgo medications because of cost if trust in the physician is low (Piette, et al., 2005). Further, communication regarding costs can influence CRN. Individuals that have experienced problems paying for their medications are often not asked if they can afford the cost (Piette, et al., 2004b). It is possible that for some older Black Americans in this study, physician trust and/or communication were low and contributed to CRN. For example and as discussed previously, a lower proportion of Black Americans knew about the LIS program than Whites. This could be an indication that physicians are communicating with older Black Americans about the benefit less frequently than they are with Whites. More research is needed to understand the role of physician trust/communication as it relates to CRN under Medicare Part D.

Finally, it was predicted that controlling for race, gender, and LIS status, poorer health status and lower socioeconomic status would increase the likelihood of CRN over time. Regarding health status, poorer health directly affected CRN as predicted. In this study, older persons with two or more chronic medical conditions were more likely than those with no or one medical condition(s) to report CRN before and after Medicare Part D. Additionally, nonadherence due to cost was more likely for individuals reporting fair or poor health than those reporting excellent, very good, or good health. This is consistent with previous findings that individuals in poor health with multiple comorbidities have high and persistent CRN over time (Briesacher, et al., 2007; Madden, et al., 2008; Safran, et al., 2005). CRN can be caused by higher out-of-pocket expenditures due to multiple medications (Frankenfield, et al., 2010; Zivin, et al., 2010). While enrolling in Medicare Part D may have alleviated some of the financial burden for sicker beneficiaries, it is suggested that cost-sharing requirements under the benefit

can still be problematic regardless of whether or not the beneficiary is receiving or has applied for the LIS and thus, have little impact on CRN.

When considering socioeconomic status, this prediction was partially supported. Similar to previous cross-sectional studies conducted before the implementation of Medicare Part D, lower annual household income increased the likelihood of nonadherence due to cost (Gellad, et al., 2007; Mojtabai & Olfson, 2003; Soumerai, et al., 2006; Steinman, et al., 2001; Zivin, et al., 2010). In this study, older adults with an annual household income between \$23,364 and \$43,479 had a greater likelihood of nonadherence compared to those with an income of \$43,480 or more. Interestingly, CRN was not significantly different when comparing individuals with an annual income of \$23,363 or less to those with an income of \$43,480 and above. There are two potential explanations. First, after removing the LIS status variable from the model (additional analysis, not shown), older persons in the second quartile or in the \$12,721 to \$23,363 income range had a significantly greater likelihood of CRN over time than those with an income in the fourth quartile or \$43,480 and above. Differences appeared to be mediated by whether an individual applied for the LIS suggesting that the subsidy may have alleviated some of the medication cost burden for lower income beneficiaries. The LIS can also help us understand why significant differences persist when comparing individuals earning between \$23,364 and \$43,479 annually to those earning \$43,480 or more. Individuals with near-poor incomes of 150% to 200% of the Federal Poverty Level (FPL) were ineligible for the LIS, but typically have greater out-of-pocket health care costs compared to higher income individuals due to poorer health status (Briesacher et al., 2010). Thus, maintaining adherence may be difficult for older adults with annual income between \$23,364 and \$43,479 because while they experience a heavier financial burden for health-related costs, they are minimally ineligible for the LIS. In other words, a portion of

respondents within the income category would have a near-poor income of 150% to 200% FPL which disqualifies them from receiving assistance.

While removing the LIS status variables from the model helps clarify findings regarding the lower income quartiles, it fails to explain the lack of significant difference between the lowest income group and the highest income group or levels of educational attainment. This can be a bit confounding given the significant relationships in Chapter Two. A potential reason involves the representation of the sample. The sample in Chapter Two contained far more variation in source of prescription drug coverage because it included all adults aged 65 and older. The current study only included Medicare Part D enrollees. Those enrolling in the Part D benefit had a greater likelihood of being less educated, lower income, and having multiple morbidities as compared to those who did not enroll (Skarupski, et al., 2009). Thus, respondents may have been more homogenous in terms of income and this could account for the lack of differences observed.

An additional finding worthy of note involves the age variable. As indicated in Chapter Two, it was somewhat surprising that persons the likelihood of CRN over time decreased as age *increased*, particularly because research shows lower prescription drug coverage rates among older age groups (Kanavos & Gemmill-Toyama, 2010). This finding, however, is consistent with cross-sectional studies using HRS to examine CRN before the implementation of Medicare Part D (Klein, et al., 2004; Zivin, et al., 2010). One potential reason involved the sampling of the HRS and exclusion of institutionalized persons. Because risk of institutionalization or nursing home placement increases with age, it was suggested that the older age groups participating in the HRS are disproportionately healthy (Klein, et al., 2004). This explanation, however, could

not be confirmed through additional analysis. Therefore, future research is needed to understand why younger persons were more likely to experience CRN than older age groups.

Strengths of this study include the use of a large nationally representative sample of older adults and its ability to examine multiple predictors simultaneously and over time. However, there are a number of limitations that must be considered. In the future, a longer prepolicy and postpolicy series would provide more clarity and permit a stronger assessment of Part D enrollment. Other unmeasured factors may have influenced the results. For example, the transition of dual eligibles from Medicaid to Medicare drug plans in 2006 was confusing for many older adults (Kaiser Family Foundation, 2006) and resulted in difficulties obtaining medications (West, et al., 2007). A significantly greater proportion of older Black Americans in this study were dually eligible as compared to Whites, and thus, had a greater likelihood of being impacted by the transition. As a result, CRN may have been overestimated because data collection occurred shortly after the launch of Medicare Part D and at a time of initial confusion. However, the PDS only contained two waves of data at the time this study was conducted. While this research provides important evidence on the impact of the policy on racial and gender disparities in CRN, the results should be considered early evidence until longer-term data become available.

Second, socioeconomic and health status were measured in the 2004 and 2006 HRS, and CRN was measured in the 2005 and 2007 PDS. Thus, there is the potential that income or certain health conditions may have changed because these measures were not taken simultaneously or when CRN was reported. While this seems less likely with income because older adults are largely dependent on Social Security, there is greater potential for fluctuation in health status. Depression, for example, can be transitory (Zivin, et al., 2010). Older females and Black

Americans who enrolled in Medicare Part D have a greater prevalence of depression as compared to older males and Whites (Skarupski, et al., 2009). Thus, the indirect effect of health status on the relationship between race, gender, and CRN may have been inaccurately represented in the results.

Third, this study investigated nonadherence due to cost *only* and did not account for other factors that can impact adherence. For example, an individuals' concerns or beliefs regarding treatment through the use of medications can certainly impact adherence (Aikens & Piette, 2009). Some medications may be viewed as more essential than others (Lau, et al., 2008; Piette, et al., 2006) and there could be racial and gender differences in whether a prescription is perceived as necessary, particularly when faced with cost concerns. As compared to older males and Whites, older females' and Black Americans' ability to afford out-of-pocket expenditure requirements is typically less due to lower socioeconomic status (Wei, et al., 2006). Thus, they may perceive the need for certain medications differently because of economic concerns. Additionally, physician trust and communication can be a factor in medication adherence (Piette, et al., 2005). It is possible that for some older females and Black Americans in this study, physician trust and/or communication were low and contributed to CRN. While this could account for some variation in CRN, these factors were not the focus of this research but will be examined in future studies.

Fourth, older Black Americans had a significantly greater proportion of missing data when asked whether they applied for LIS in the 2005 and 2007 PDS than older Whites. Individuals can be confused by or unaware of Medicare Part D and the LIS provision because of its complexity (Davidoff, et al., 2010; Heiss, et al., 2006; Hsu, et al., 2008). As previously stated, older Black Americans were significantly less likely to be aware of the LIS, and lack of

awareness about the subsidy could have contributed to a the greater proportion of missing data. This, in turn, could bias the results and underestimate the racial effect of the LIS on CRN over time. Further, this study relied on self-reported survey measures. Self-reporting can be subject to social desirability bias (Nederhof, 2006). Respondents may be reluctant to admit failure to adhere to a prescribed medication regimen – particularly if it is due to cost factors. Because older women and Black Americans are more likely to be economically disadvantaged, they may incur greater difficulty affording the cost of prescribed medications – and, admitting failure to adhere because of economic reasons. This bias could contribute to underestimating the prevalence of CRN.

Fifth, there are limitations with measures contained in the HRS and PDS. First, there is the need for better representation of non-married partners in the HRS and other samples used in health benefits research. Results suggest that partnered individuals enrolled in Medicare Part D have a greater likelihood of CRN than married individuals. However, less than 2% (n=27) of the sample indicated they were in a partnered relationship when asked about marital status, and it is therefore difficult to generalize these findings. Failure to address this limitation can potentially result in underestimating CRN among partnered individuals. It is important to understand whether differences in CRN exist between partnered and married individuals in order to effectively design social work interventions. Second, the PDS does not ask respondents whether they took less than the prescribed dosage of a medication or if they cut pills in half to make a medication last longer. The survey question asked if a dosage of a medication was skipped to save money, and this measure could be a potential indicator of these behaviors. However, failure to ask if these behaviors specifically occurred could underestimate CRN. Third, the PDS only asks respondents if they applied for or are receiving the LIS. It does not ask individuals if they

use this assistance when purchasing their medications. Respondents who applied for or are receiving the LIS may not necessarily utilize the subsidy; however, an exact measure of LIS utilization was not available within the 2005 or 2007 PDS or the HRS core survey. In my experience as an agency administrator, Medicare beneficiaries who apply for or receive the LIS typically utilize this assistance. For this reason, I believe that these measures of LIS status are an adequate indicator of utilization.

Finally and as stated previously, this study utilized a composite measure to estimate CRN as opposed to including all three behaviors as separate indicators: 1) not filling a new prescription because of cost; 2) stopping taking a medication because of cost; or 3) skipping doses of a medication to save money. While this is consistent with previous research and therefore useful for cross-study comparison (Bambauer, et al., 2007; Gellad, et al., 2007; Madden, et al., 2008; Safran, et al., 2005; Soumerai, et al., 2006; I. B. Wilson, et al., 2004; Zivin, et al., 2009), measuring each behavior separately may provide important insights for social work practice on racial and gender disparities in CRN. For example, one behavior could be more prevalent than others among older women or Black Americans. By understanding which types or types of nonadherence are more common in older women and Black Americans, interventions that specifically target certain behaviors can be designed. Thus, future research will examine each CRN item as an outcome.

Within the constraints of these limitations, the study makes a strong and significant contribution to our understanding of whether and to what extent racial and gender disparities exist in CRN before and after enrolling in Medicare Part D. It also extends our understanding of how the LIS directly and indirectly affects the relationship between race, gender, socioeconomic and health status, and CRN over time. Evidence has shown that the MMA provided much-

needed assistance to those previously lacking prescription drug coverage, and has been effective in reducing out-of-pocket prescription costs. However, it was unclear whether the policy eliminated racial and gender differences in CRN for those enrolled in the Part D benefit. Overall, the study suggests that racial and gender disparities in CRN persisted after accounting for health and socioeconomic status. The LIS mediated gender differences. However, the subsidy did not affect racial differentials. Applying for the LIS, poorer health status, and having a lower annual income increased the likelihood of CRN, however differences between those earning \$12,721 to \$23,363 and the highest income group were mediated by applying for the LIS. Findings are consistent with policy expectations that the LIS would lower prescription drug costs for beneficiaries with limited income and increase access to medications. As demonstrated, gender differences in CRN were substantially driven by whether an individual applied for the LIS as were differentials between lower and higher income groups. However, older Black Americans, the near-poor, and individuals in poor health continue to be disproportionately nonadherent. These findings indicate the need to target outreach efforts towards these groups to raise awareness of the LIS and increase participation. Additionally, policymakers should consider raising the LIS income requirements to 200% FPL.

CHAPTER FOUR MANUSCRIPT THREE ABSTRACT

The objectives of the fourth chapter of this multiple manuscript dissertation were to determine: 1) to what extent race and gender impact the likelihood of cost-related medication nonadherence (CRN) under Medicare Part D plans; and 2) to what extent the Medicare Part D coverage gap and coverage restrictions directly and indirectly affect the relationship between race, gender, socioeconomic and health status and CRN. To evaluate CRN, secondary data from the 2006 wave of the Health and Retirement Study (HRS) and data from the 2007 wave of the Prescription Drug Study (PDS) were utilized. The analytic sample for this cross-sectional analysis consisted of 1,353 respondents age 65 and older who were enrolled in Medicare Part D, taking at least one prescribed medication, and who responded to questions about adherence or nonadherence in 2007. The outcome variable of interest was CRN, which included not filling, stopping, or skipping doses of a prescription because of cost. The main predictors were race (Black American and White), gender (male and female), Medicare Part D coverage gap (reached gap, did not reach gap, and no coverage gap), and coverage restrictions (experienced restrictions and did not experience restrictions). Covariates included demographics, socioeconomic, and health status. The analysis was conducted using logistic regression models. Results indicated that racial disparities in CRN existed under Medicare Part D after accounting for demographics, health status, socioeconomic status, and the coverage restrictions. However, the inclusion of the coverage gap variable mediated differences in CRN between older Black Americans and Whites. Having a coverage gap or coverage restrictions had a direct effect on CRN. Poorer health status, lower income, and having applied for the Low-Income Subsidy (LIS) increased the likelihood of

nonadherence, even after accounting for the coverage gap and coverage restrictions. In conclusion, racial differences in CRN were substantially driven by the Medicare Part D coverage gap. The coverage gap and restrictions, having a lower annual income, poorer health, and applying for the LIS were associated with CRN under Medicare Part D.

CHAPTER FOUR

MEDICARE PART D COVERAGE GAP AND RESTRICTIONS: RACE, GENDER, AND COST-RELATED MEDICATION NONADHERENCE

Background

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) is the largest benefit expansion in the history of the program, and represents the most meaningful health care policy in the past three decades because it reduces out-of-pocket health care costs. To respond to the need to provide older adults with drug coverage, the MMA added the Part D benefit to Medicare (Madden, et al., 2008; Mayes, 2005). In 2008, it was estimated that 90 percent of Medicare's 45 million beneficiaries had prescription drug coverage (Joyce, et al., 2009) as compared to 76 percent before the implementation of the benefit (Levy & Weir, 2009). While overall the MMA helped facilitate the purchase of needed health services, core stipulations of the Act can potentially prevent access to medications because out-of-pocket expenditure requirements can be substantial.

As a means of controlling the cost of the benefit, provisions contained in the MMA allow Medicare Part D plans to utilize coverage restrictions. The vast majority of Medicare Part D plans do not offer coverage within the gap (Hoadley, et al., 2008). Entering the gap means that prescriptions that were previously covered become the sole responsibility of the Medicare beneficiary. Under the 2010 standard benefit, beneficiaries pay a \$310 deductible and 25 percent copay per prescription until they incur \$2,830 in total drug cost at which point they enter the coverage gap. Once beneficiaries incur \$6,440 in total drug costs, they then become eligible for "catastrophic coverage," and Medicare and the benefit provider pay for 95 percent of their drug

costs for the remainder of the year (Kaiser Family Foundation, 2009a). The cycle renews annually.

There is concern that these cost-containment provisions can inhibit the use of medications particularly for older women and Black Americans. Compared to older men and Whites, older women and Black Americans tend to have a greater number of chronic health problems (Clark, 1997; Kelley-Moore & Ferraro, 2004a) and are, therefore, more reliant on prescription medications (Rogowski, et al., 1997; Sambamoorthi, et al., 2003). This means that older women and Black Americans tend to have higher copayments and are more likely to reach the coverage gap each year. Further, they have a greater likelihood of encountering coverage restrictions, such as limitations on the number and/or type of medications paid for by the plan and increased costsharing for certain drugs, because their utilization is higher. Combined with their overall lower socioeconomic status, therefore, older women and Blacks are less able to afford out-of-pocket expenditure requirements associated with the MMA's cost-containment provisions (Wei, et al., 2006) and more likely to have difficulties adhering to their medication regimen.

Previous research has shown the connection between cost-related medication nonadherence (CRN) and cost-containment provisions similar to those present in Medicare Part D plans (Adams, et al., 2001; T. B. Gibson, et al., 2005; Tseng, et al., 2004; Wang, et al., 2010). CRN can include not filling, stopping, or skipping doses of a prescription because of cost. Prior to the MMA, racial and gender disparities in CRN clearly existed (Heisler, et al., 2005; Klein, et al., 2004). Medicare Part D may continue to impede access to medications because the benefit's cost-containment provisions can increase out-of-pocket expenditures (Hsu, et al., 2008), and may have a disproportionately greater impact on older females and Black Americans because of their economic status, health status, and greater reliance on prescription medications (Wei, et al., 2006).

To date, studies have not examined whether racial and gender disparities in CRN persist under Medicare Part D plans or how the coverage gap and restrictions affect differences in nonadherence. This cross-sectional analysis builds upon prior research by using a cumulative advantage/disadvantage framework to examine to what extent racial and gender disparities in CRN exist for older women and Black Americans enrolled in the benefit. Further, this study seeks to understand whether the coverage gap and restrictions directly and indirectly affect the relationship between race, gender, socioeconomic and health status and CRN. The results of this research can help inform Medicare policy by identifying whether older women and Black Americans are disproportionately nonadherent under the Part D benefit, and how the coverage gap and restrictions directly and indirectly impact CRN.

Literature Review

Cumulative Advantage/Disadvantage and Medicare Part D

Cumulative advantage/disadvantage theory is useful as a foundation for understanding and evaluating the effectiveness of Medicare Part D. The theory has increasingly been used as a paradigm in the field of aging to describe stratification and growing trajectories over time (Dannefer, 1987; Farkas, 2003; Kail, et al., 2009; A. E. Wilson, et al., 2007). Systematic disadvantages have a considerable impact on later life, and it is suggested that they not only accrue throughout the life course but are magnified and can have a feedback effect (Crystal & Shea, 1990a; Ferraro & Kelley-Moore, 2003). In other words, "the more disadvantages individuals experience, the more likely they are to accrue subsequent and greater disadvantages" (Kail, et al., 2009, p. 557). Because of cumulative advantages and disadvantages throughout the life course, heterogeneity increases with age, and inequalities are greatest in later life (Crystal & Shea, 1990a; Dannefer, 1987; Ross & Wu, 1996). When deliberating social policy initiatives intended to target older individuals, the aged should not be stereotyped (Butler, 1985) or treated as a homogeneous group (Neugarten, 1982). Inequities resulting from disadvantages throughout the life course need to be considered in order to ensure equitable access to benefits.

This study will focus on racial and gender disparities in CRN that result from one particular social policy, Medicare Part D. As the result of cumulative advantages and disadvantages throughout the life course, it is anticipated that higher out-of-pocket expenditures will be related to personal characteristics associated with early disadvantage as measured by income, education, health insurance coverage, and health status. These factors, in turn, can potentially impact CRN under the benefit.

Income, education, and prescription insurance coverage. The ability to afford pharmaceuticals and maintain adherence to a prescribed medication regimen are largely dependent on retirement earnings. Income in later life is essentially based on pre-retirement experiences, and racial and gender inequities continue to increase with advancing age (Crystal & Shea, 1990a). Wages for females and Black Americans have consistently lagged behind those received by White males, and women and Black Americans are more likely to have been segregated into positions without retirement or pension benefits (Gonyea & Hooyman, 2005). Since Social Security is based on a 35-year work history, older women and Black Americans are typically subject to lower benefits in later life than White males due to lower wages and fewer years in the labor force (Olson, 1994) and thus have less income available to purchase prescribed medications.

Source of prescription insurance coverage in later life is often determined by past employment experiences and those who are disadvantaged – or have lower income and education - typically have a greater dependence on public sources for drug insurance (Hopkins & Kidd, 1996; Kanavos & Gemmill-Toyama, 2010; Lillard, Rogowski, & Kington, 1997; Pourat, Rice, Kominski, & Snyder, 2000). Older males (Gonyea & Hooyman, 2005) and Whites (Zuvekas & Taliaferro, 2003) are more likely to have employer-provided prescription drug coverage, largely due to higher-paying positions that provide subsidized drug benefits in retirement. Comparatively, older females and Black Americans are more likely to have held positions without health benefits (Marquis & Long, 1995; Pol, Mueller, & Adidam, 2002) and as a consequence, were more likely to enroll in Medicare Part D (Bakk, 2012b; Davidoff, et al., 2010; Millett, et al., 2010; Neuman, et al., 2007; Rudolph & Montgomery, 2010; Skarupski, et al., 2009). Source of coverage can directly impact cost sharing and ability to maintain adherence. Compared to older individuals enrolled in Medicare Part D, out-of-pocket expenditures and nonadherence due to cost were substantially lower for those with employer-sponsored coverage (Bakk, 2012b; Neuman, et al., 2007; Safran, et al., 2009). Thus, older women and Black Americans' disproportionately greater reliance on the Medicare Part D can place them at an overall increased risk of CRN because cost sharing is greater under Part D than employer-based plans. Further, older females and Black Americans are less able to afford out-of-pocket expenditure requirements due to their lower socioeconomic status (Wei, et al., 2006), which can also impact ability to afford medications and maintain adherence within Medicare Part D.

Health status. Lower income is typically accompanied by a higher prevalence of chronic health conditions among older women and Black Americans. Racial and gender inequities in morbidity exist throughout the life course and health trajectories continue to diverge with

increasing age (Clark, 1997; Kelley-Moore & Ferraro, 2004a). Women are more likely to report functional limitations, a higher number of chronic conditions, and rate their health as poor or fair than their male counterparts (Murtagh & Hubert, 2004). As the result of increased morbidity, females and Black Americans are more reliant on pharmaceuticals (Goulding, 2005). Yet, their ability to afford prescribed medications is often compromised because of lower socioeconomic status. Compared to White males, older women and Black Americans spend a higher proportion of their income on pharmaceuticals (Rogowski, et al., 1997; Sambamoorthi, et al., 2003). For these reasons, it is expected that they will continue to experience a disproportionately heavier financial burden under Medicare Part D (Wei, et al., 2006) and have a greater risk of incurring the benefit's cost-containment provisions. This, in turn, can subsequently affect their ability to purchase prescribed medications and maintain adherence.

Medication Access and Adherence Under Medicare Part D

When analyzing the MMA from certain economic perspectives, the policy can appear highly successful. Before Medicare Part D, older adults lacking prescription drug insurance spent more on their medications than those with coverage, despite filling fewer prescriptions (Safran, et al., 2005; Soumerai, et al., 2006). Further, it is estimated that out-of-pocket spending on prescription drugs decreased between 13 and 18.4 percent even as the number of medications used by older adults increased from 5.9 to 12.8 percent since the implementation of the MMA (Chen, et al., 2008; Joyce, et al., 2009; Lichtenberg & Sun, 2007; Schneeweiss, et al., 2009; Yin, et al., 2008). However, these findings do not take into consideration the implications of race or gender. Further, cost-containment provisions – or the coverage gap or coverage restrictions – of the MMA are not accounted for in these studies, and the potential impact of those provisions on cumulatively disadvantaged beneficiaries is not recognized. In other words, there was no differentiation of groups reported in these findings; beneficiaries were regarded as a homogeneous group that gained access to a prescription drug benefit and lowered their medication expenditures. It is important to recognize the potential implications of Medicare Part D cost-sharing provisions on older females and Black Americans. For example, one implication of the cost-sharing requirements is that access to medications is not in fact the same for all beneficiaries. Those with lower income and increased morbidity, such as is often experienced by older women and Black Americans, may be negatively and disproportionately influenced by cost-sharing requirements both because of their higher medication expenses and their limited income. This, in turn, can impact their ability to access medication and maintain adherence. Thus, existing research on the impact of MMA does not recognize the differential consequences of these provisions.

While studies demonstrated that racial (Bambauer, et al., 2007; Gellad, et al., 2007; Heisler, et al., 2005; Klein, et al., 2004; Piette, et al., 2004c; Roth, et al., 2009; Roth & Ivey, 2005; Soumerai, et al., 2006; Steinman, et al., 2001; Zivin, et al., 2010) and gender (Heisler, et al., 2005; Piette, et al., 2004c; Zivin, et al., 2010) disparities in CRN existed before Medicare Part D, research examining CRN after the implementation of the benefit is limited. One of the main reasons for this limitation is the restrictions placed on the availability of data. The Centers for Medicare and Medicaid Services has historically been a primary source of data for researchers. However, a provision contained in the MMA stipulated that private health care plans were not required to release Medicare Part D claims data for nonpayment-related purposes, which included research, public health purposes, and health care analysis (Crystal, 2008, November; Stuart, 2008). While this was modified in 2009 and data are currently in the process of being released, this stipulation largely accounts for the limitation with existing research.

When considering studies conducted after the implementation of Medicare Part D, Safran et al. (2009) reported that for older individuals with no or a meager drug benefit, enrollment resulted in lower out-of-pocket prescription drug expenditures, higher medication utilization, and overall lower CRN. However, low-income, chronically ill beneficiaries were significantly more likely to report CRN and difficulty affording their medications. Similarly, Madden et al. (2008) found that individuals in fair to poor health, with at least four morbidities, or having an annual income less than \$25,000 continued to report greater CRN under Medicare Part D. Although differences associated with race or gender were not analyzed in either study, the findings shed some light on the experiences of these groups. Because older women and Black Americans are more likely to be low income, rate their health as poor or fair, and experience higher rates of chronic illness and health problems, these studies suggest that enrolling in the Medicare Part D benefit may have little or no impact on CRN for these groups.

While previous studies have not specifically examined the effect of the Medicare drug benefit on racial or gender disparities in CRN, research suggests ethnic disparities continue to exist. One study conducted after the implementation of Medicare Part D, for example, found that Hispanics were more likely to report CRN than non-Hispanics. Further, CRN was significantly greater for non-Hispanic Blacks than non-Hispanic Whites. When examining gender, both Hispanic and non-Hispanic females were more likely to report nonadherence due to cost than males (Frankenfield, et al., 2010).

Medicare Part D Cost-Containment Provisions and Adherence

Due to declining state budgets and cost increases in the area of prescription medications particularly over the last decade, most state Medicaid programs utilize cost-containment mechanisms or coverage restrictions and coverage caps similar to those present in Medicare Part

D plans in an effort to contain spending (Cunningham, 2005). Coverage restrictions are intended to reduce non-essential drug use and plan expenditures, and include restricting the number and/or type of medications paid for by the plan and requiring increased cost-sharing or a copayment for certain drugs (Nelson, Reeder, & Dickson, 1984; Reeder & Nelson, 1985; Soumerai, et al., 1987). Similarly, coverage caps limit the number of prescriptions paid for by a plan on a yearly basis and are used to control the annual cost of a benefit (Cox, Jerigan, Coons, & Draugalis, 2001). While coverage caps and restrictions have provided considerable savings for state Medicaid programs (Cunningham, 2005; Soumerai, et al., 1987), they also produced unintended consequences. For example, requiring a small copayment (fifty cents per prescription) in Medicaid drug plans reduced prescription drug use and spending across several essential medications (Reeder & Nelson, 1985; Soumerai, et al., 1987). Yearly coverage gaps – similar to the Medicare Part D coverage gap – have resulted in decreased utilization and nonadherence (Cox, et al., 2001; Joyce, Goldman, Karaca-Mandic, & Zheng, 2007; Tseng, et al., 2004).

The impact of coverage caps and restrictions under state Medicaid programs can help clarify beneficiary behavior when faced with out-of-pocket expenditure requirements due to cost-containment policies. Despite the potential consequences of cost-sharing provisions, studies examining whether experiencing the Medicare Part D coverage gap and restrictions are limited, and even less is known about how these provisions indirectly affect racial and gender differences in adherence. This is important because those with a lower income and increased morbidity – which are more common for older females and Black Americans – have a greater risk of encountering the benefit's cost-containment provisions and subsequent difficulty affording their medications.

CRN and the Coverage Gap. Affording medications is a primary concern of Medicare Part D beneficiaries experiencing the coverage gap (Neuman & Cubanski, 2009). Once a beneficiary reaches this benefit threshold, they are responsible for 100% of their prescription drug costs until spending approximately \$4,550 out-of-pocket for prescription medications. Overall, reaching the coverage gap resulted in lower drug consumption (Pedan, et al., 2009; Sun & Lee, 2007; Zhang, et al., 2009) and decreased adherence (Cronk, Humphries, Delate, Clark, & Morris, 2008; Hsu, et al., 2008; Raebel, Delate, Ellis, & Bayliss, 2008) because of increased outof-pocket expenditure requirements. Furthermore, Hsu et al. (2008) found that 36% percent of respondents encountering the coverage gap stopped taking their medication, reduced the recommended dosage, or switched to an alternate drug.

While research has not specifically examined the impact of the Medicare Part D coverage gap on older women and Black Americans, beneficiaries with certain chronic illnesses – such as depression and diabetes – have a greater risk of this cost-sharing provision because they spend considerably more on medications and are, therefore, at greater risk of CRN (Duru et al., 2010; Ettner, et al., 2010; Hoadley, et al., 2008; Schmittdiel et al., 2009; Stuart, et al., 2005). For example, 51% of older diabetics who reached the coverage gap or benefit threshold had a decline in out-of-pocket spending on medications, suggesting that they may have become noncompliant (Hoadley, et al., 2008). In comparing older adults with and without depressive symptoms, individuals with depressive symptoms were more likely to report CRN and forego basic needs to pay for medications after reaching this benefit threshold (Zivin, et al., 2009). Because older women and Black Americans experience higher rates of diabetes (Gellad, et al., 2006; Schoenborn & Heyman, 2009), they may face a greater risk of CRN under Medicare Part D. While depression is more prevalent in females than males (Skarupski, et al., 2009), the severity

and persistence of depressive disorders is higher in Black Americans as compared to Whites (Williams et al., 2007). Thus, greater prevalence, severity, and persistence of depressive symptoms can increase the need for pharmaceuticals and subsequent risk of CRN due to the coverage gap.

Coverage restrictions. Only one study examined Medicare Part D coverage restrictions and found that cost-sharing requirements did not impact the number of prescriptions used by Medicare Part D enrollees. Further, having a copayment requirement did not affect gender differences in drug use (Goedken, et al., 2010). While this study can provide insights on how cost sharing impacts medication use under Medicare Part D plans, there are several limitations. First, the sample consisted of Medicare beneficiaries with *higher* than average income and education and therefore, generalization of results to older women and Black Americans is difficult due to their increased likelihood of having a *lower* socioeconomic status (Crystal, 1986; Crystal & Shea, 1990a; Olson, 1994). Second, the study only assessed drug use and did not specifically examine adherence. Finally, racial differences in medication use were not investigated. Thus, the ability to understand how the Medicare Part D coverage restrictions directly or indirectly affect CRN is largely unknown.

In sum, research has not investigated whether or to what extent racial and gender disparities in CRN exist under Medicare Part D, or how the benefit's cost-containment impacts racial and gender differences in nonadherence due to cost. Studies primarily investigated the effect of Medicare Part D utilizing pharmaceutical claims and health care plan data and did not differentiate beneficiaries by demographics. While a few studies have used nationally representative datasets to investigate CRN, racial and gender differences have not been examined and the indirect effect of the cost-containment provisions has not been considered. The one study

examining disparities in CRN after the implementation of the benefit focused on ethnic differences and did not account for the coverage gap or restrictions (Frankenfield, et al., 2010). Further, the impact of the Medicare Part D coverage restrictions on CRN is essentially unknown.

This study builds on existing knowledge and provides important insights about CRN under Medicare Part D. First, it uses data from a nationally representative dataset to analyze CRN for beneficiaries who enrolled in Medicare Part D. In particular, this study examines whether and to what extent race and gender increase the likelihood of CRN under the Medicare Part D benefit. Second, this study investigates whether and to what extent the Medicare Part D cost-containment provisions directly and indirectly affect the relationship between race, gender, socioeconomic and health status and CRN. This allows us to consider how the coverage gap and restrictions influence racial and gender differences in CRN. It also expands our knowledge of how the Medicare Part D cost-containment provisions impact the likelihood of nonadherence due to cost, and whether these provisions affect the relationship between factors associated with cumulative disadvantage and CRN.

Based on existing literature, there are four hypotheses in this study:

- 11) As compared to older Whites, older Black Americans enrolled in Medicare PartD are more likely to report CRN
- 12) As compared to older males, older females enrolled in Medicare Part D are more likely to report CRN
- Experiencing the Medicare Part D coverage gap and restrictions will increase the likelihood of CRN
- 14) Experiencing the Medicare Part D coverage gap and restrictions will mediate the effect of racial, gender, socioeconomic, and health differences in CRN

Methodology

Sample

This study utilizes secondary data from the 2006 wave of The University of Michigan (U-M) Health and Retirement Study (HRS) and 2007 wave of the HRS Prescription Drug Study (PDS) to conduct a cross-sectional analysis. Launched in 1992, the HRS is a nationally representative population study of more than 20,000 Americans over the age of 50 designed to assess the relationship between health and retirement. The core HRS survey collects information pertaining to physical and mental health, insurance coverage, financial status, family support systems, retirement situation, and work status (Juster & Suzman, 1995). The primary mode of data collection is by telephone; however, in situations where health limitations would make the hour-plus telephone session difficult or where there is no telephone in the household, the survey is conducted in the respondent's home (HRS, 2011). Primarily funded through the National Institute on Aging (NIA U01AG009740), the HRS is designed, administered, and conducted by the Institute for Social Research (ISR) at the U-M. The overall interview response rate for the core 2006 HRS was 88.5% (Ofstedal, 2009, June).

The PDS is a subsample of the HRS, and is a two-wave mail survey conducted in 2005 and 2007. It was specifically designed to examine prescription drug utilization as Medicare Part D was implemented. The baseline wave was administered pre-Medicare Part D in 2005 by the ISR, and captured information pertaining to prescription drug use, coverage, and knowledge of the Medicare prescription drug benefit. The second wave was conducted post-Medicare Part D in 2007, and captured similar information as well as data pertaining to the impact of the MMA cost-containment provisions or coverage gap and restrictions. The sample was drawn from respondents who participated in the HRS in 2004. To be eligible for inclusion in the PDS,

respondents needed to be age 65 or older in 2007 (born in 1942 or later), or have Medicare or Medicaid coverage at some time between 2002 and 2004. Because the Consumption and Activities Mail Survey (CAMS) was fielded at the same time as the PDS, approximately 40% of eligible participants were excluded because of their involvement in the CAMS. However, the exclusion did not affect the representation of the PDS sample because CAMS participants were randomly selected (J. Faul, Personal Communication, January 4, 2012). Of those who were eligible, 3,536 individuals or 74% completed the PDS in 2007 (HRS, 2011). Given that this is a relatively new topic area, there are no reliability or validity measures associated with the PDS (J. Faul, Personal Communication, February 3, 2012).

To be included in the analytic sample for this study, respondents were required to 1) be either non-Hispanic White/Caucasian or non-Hispanic Black/African American; 2) be age 65 or older in 2007 and therefore eligible for Medicare when the PDS was administered; 3) have reported taking prescription medications in 2007; 4) have responded to questions about prescription drug adherence in the 2007 PDS; and 5) have reported being enrolled in Medicare Part D in 2007 PDS. Of the 3,536 responding to the 2007 PDS, 3,139 were either non-Hispanic White/Caucasian or non-Hispanic Black/African American; 2,996 were age 65 and over; 2,797 reported taking prescription medications; 1,419 reported Medicare Part D enrollment; and 1,352 reported data on prescription drug adherence or nonadherence. Thus, the final analytic sample consisted of 1,352 respondents.

The combination of HRS and PDS provides an excellent source for testing the proposed hypotheses because indicators of cumulative advantage/disadvantage that could decrease or increase older adults' risk of CRN are available through these datasets. Variables from the PDS included CRN, Low-Income Subsidy status, plan restrictions, coverage gap status, and Medicare

Part D enrollment status. All other variables were obtained from the 2006 RAND HRS data files. These data files contain a broad range of measures across HRS waves, and are developed and maintained by the RAND Center for the Study of Aging, with support provided by the NIA and Social Security Administration (RAND Center for the Study of Aging, 2010).

In regards to Institutional Review Board (IRB) approval, this study relied exclusively on secondary data to complete all analyses. The HRS and PDS files contain de-identified individual data that are available to the public. Therefore, the IRB at Michigan State University (MSU) does not require human subjects review.

Measures

Dependent variable. A summary indicator of any CRN was constructed as the dependent variable. In the 2007 PDS, CRN was evaluated using questions about the following three behaviors: 1) not filling a new prescription because of cost; 2) stopping taking a medication because of cost; or 3) skipping doses of a medication to save money. If the respondent indicated that they engaged in any of these behaviors, they were considered nonadherent in this study. Earlier research typically used a single measure to assess CRN, and focused solely on whether respondents failed to fill a prescription in the past year because of cost. However, this measure did not assess for multiple ways CRN could occur. Thus, the additional questions were developed to help monitor and identify changes in CRN, and have demonstrated test-retest reliability (Pierre-Jacques, et al., 2008) and construct validity (Soumerai, et al., 2006). This composite variable approach was originally developed by Safran et al. (2003) based on a series of validated survey questions concerning CRN to prescription regimens, confirmed using factor analysis techniques, and used as a main outcome in subsequent research examining drug nonadherence practices of older adults (Bambauer, et al., 2007; Gellad, et al., 2007; Madden, et

al., 2008; Safran, et al., 2005; Soumerai, et al., 2006; I. B. Wilson, et al., 2004; Zivin, et al., 2009). Because all three measures of CRN, specifically filling, stopping, or skipping doses of a prescription because of cost, were highly correlated with comorbidity, self-reported health status, and socioeconomic status (Bambauer, et al., 2007; Safran, et al., 2005; Safran, et al., 2003; Soumerai, et al., 2006), it is important that they be included in this study. Older females and Black Americans are more likely to have a lower income and multiple health problems due to disadvantages throughout the life course and thus, accounting for all behaviors can further understanding of CRN before and after the implementation of Medicare Part D.

In this study, a dichotomous variable indicating any nonadherence or no nonadherence to the three CRN behaviors in the PDS – not filling a new prescription because of cost, stopping taking a medication because of cost, or skipping doses of a medication to save money – was created. The CRN variable was initially incorporated as a continuous variable indicating a sum total of the three behaviors. However, results were significantly skewed and similar to previous research, the variable was dichotomized (Bambauer, et al., 2007; Gellad, et al., 2007; Madden, et al., 2008; Safran, et al., 2005; Soumerai, et al., 2006; I. B. Wilson, et al., 2004; Zivin, et al., 2009). Using this global, dichotomous measure is common in existing literature, and will help provide a meaningful comparison to previous research.

Independent variables. The main predictors of interest were race (Black and White), gender (female and male), coverage restrictions, and coverage gap status. The Medicare Part D coverage gap and restrictions can impact CRN because they require that the beneficiary pay an additional cost to receive their medication(s). Since older women and Black Americans often have a greater number of prescribed medications, their risk of incurring these cost-sharing requirements is greater. Thus, it is important to understand how these provisions affect CRN.

First, three dichotomous variables indicating the types of coverage restrictions present in the respondents' Medicare Part D plan were used. Respondents to the PDS were asked, "Some prescription drug insurance plans restrict the number, type, or dollar amount of prescriptions they will pay for. Check any of the following types of restrictions that your plan has [Mark (X) all that apply]." This question included the following response choices: "My plan won't pay at all for some types of drugs, "My plan makes me pay more for some types of drugs," and "My plan only pays up to a certain amount of money each year." Responses were coded 0 = "no/beneficiary does not have restriction" and 1 = "yes/beneficiary has restriction."

Although having a plan restriction does not mean the respondent will incur that restriction when attempting to purchase a prescribed medication, a more precise measure indicating that the respondent actually incurred the restriction was not available in either the 2007 PDS or the HRS core survey. However, in my experience as an agency administrator, Medicare beneficiaries are often unaware that their plan has a restriction until it is incurred, or until they are required to pay an additional cost for their medication. For this reason, I believe these measures are an adequate indicator of experience with plan restrictions.

Respondents to the 2007 PDS were also asked, "Some prescription drug insurance plans have what's called a coverage gap, or doughnut hole, where you have to pay all or nearly all of the costs of your drugs for part of the year after the insurance has paid up to a certain amount. Have you reached the coverage gap in your prescription drug plan this year? [Mark (X) ONE]." Responses included "yes," "no," and "my plan does not have a coverage gap."

Using literature pertaining to cumulative advantage/disadvantage as a guide, other independent variables included socioeconomic characteristics and health status. Additionally, age and marital status were used as control variables.

Socioeconomic characteristic indicators included education, annual household income, and Low-Income Subsidy (LIS) status. Cumulatively disadvantaged individuals tend to have lower levels of education. Subsequently, they are less likely to have prescription drug coverage and the financial resources needed to purchase prescribed medications. Utilizing these measures will help clarify how income and educational attainment can directly and indirectly impact CRN among older women and Black Americans. The level of attained education was a continuous variable ranging from 0 to 17 or more years of education. Annual household income was a continuous variable ranging from \$228 to \$1,242,996. Finally, a three-category variable was used to indicate LIS status (0 = "no LIS, "1 = "applied for LIS," 2 = "dual eligible/receiving" LIS"). Individuals whose income and assets exceed Medicaid eligibility criteria are required to apply for the LIS whereas dually eligible beneficiaries automatically receive the LIS because they qualify for both Medicare and Medicaid. Further, level of LIS assistance is dependent on eligibility status, and the subsidy provided to dual eligibles is greater than that provided to nondual eligibles who applied for assistance. The LIS was intended to offset prescription drug costs for beneficiaries with limited income and resources by providing financial assistance. Thus, it is expected that older women and Black Americans in particular are impacted by the LIS because of their lower-income status.

Health status variables included number of chronic medical conditions and self-reported health status. Increased morbidity is associated with cumulative disadvantage and increased reliance on pharmaceuticals, particularly among older women and Black Americans. Thus, it is important to understand how health status impacts CRN. First, a continuous variable indicating the number of chronic medical conditions was used. Respondents were asked, "Has a doctor ever told you that you have [name of chronic medical condition]" or "our records from your last

interview show that you have [name of chronic medical condition]." This question was asked for a series of eight chronic medical conditions and included: high blood pressure, diabetes, cancer, lung disease, heart disease, stroke, psychiatric problems, and arthritis. The second health-related variable included self-reported health status. Respondents were asked, "Would you say your health is excellent, very good, good, fair, or poor?" Responses ranged from 0 = "excellent" to 4 ="poor" with a higher score indicating that the respondent perceived their health status as being more poor.

Finally, other control variables included age and marital status. Age was a continuous variable ranging from age 65 to 99. The variable was recoded into a three-category measure to analyze CRN in relation to the respondent's age cohort (65 to 74, 75 to 84, and 85 or above). Research conducted before the implementation of Medicare Part D found that older-aged individuals were less likely to have prescription drug coverage (Kanavos & Gemmill-Toyama, 2010). For this study, three age groups were utilized to analyze differences in adherence between age cohorts after the Part D benefit became available, and to determine how the benefit may have impacted adherence. Further, the measure was used as a continuous variable in Chapter Two and provided similar results. That is, as income increased, the likelihood of CRN significantly decreased.

It was expected lack of coverage could impact CRN. Marital status was a seven-category variable: married, married with spouse absent, partnered, separated, divorced, widowed, and never married.

Analytic strategy

Univariate descriptive statistics summarized all measures. To determine the bivariate association between respondent characteristics and CRN in 2007, the Rao-Scott chi-square, a

design-adjusted version of the Pearson chi-square, was used for categorical variables (Rao & Scott, 1981) and an F means test for continuous variables. Logistic regression models were used for multivariate analysis to estimate racial and gender differences in CRN under Medicare Part D plans, and to examine whether and to what extent the Medicare Part D coverage gap and coverage restrictions directly and indirectly affect the relationship between race, gender, socioeconomic and health status and CRN. A series of eight regression models were run. Model 1 included only race and gender. Model 2 introduced the age and marital status variables. Socioeconomic status variables were added in Model 3 and in Model 4, health status variables were included. Models 5, 6, 7 and 8 added the coverage restriction and coverage gap measures separately to assess how each mediates the effect of race, gender, socioeconomic status, and health status on CRN, as well as determine how the individual measures directly impact adherence.

All statistical analyses were performed in the Stata version 11.0 statistical package (StataCorp). Stata's survey commands were used in all statistical analyses to account for the complex sampling design (stratification and clustering) of the HRS when computing standard errors for calculated estimates. The PDS questionnaire weights (a product of the HRS sampling weights) were applied to adjust for sample selection probability or oversampling of select minority groups and for interviewee nonresponse (HRS, 2011), and to obtain estimates that reflect the general population age 65 and older. Significance in all analyses was tested at the p<.05 level using a one-tailed test.

Results

Description of Sample at Baseline

A detailed description of the sample is provided in Table 4.1. Of the 1,352 individuals reporting medication adherence (81.7%) or nonadherence (18.3%) due to cost, 9.6% selfidentified as non-Hispanic Black or African American and the majority (60.2%) were female. Respondents ranged in age from 65 to 96 with a mean age of 75.2 years (SD = 7.35), and slightly more than half (53.6%) were married. The average household income was \$46,752 (SD = \$64,747) and the mean years of education was 12.29 (SD = 2.92). In regards to LIS status, 13% applied for the LIS and 4.8% were dual eligibles receiving the LIS. Respondent self-reports indicated that the majority felt their health was good (33.3%), very good (26.9%), or fair (22.7%), followed by poor (10.1%), and excellent (7.0%). The average number of chronic health conditions was 2.55 (SD = 1.38). In regards to coverage restrictions under Medicare Part D plans, over a third (35.8%) of respondents were required to pay more for some drugs, 26.3% had a yearly cost limitation, and 21.8% had drugs that were not covered. Finally, 15% reported reaching the coverage gap, 67% did not reach the gap, while the remainder (18%) did not have a gap in coverage.

Bivariate Results

Bivariate analyses of medication adherence and nonadherence are presented in Table 4.2. In regards to the main predictor variables, a higher proportion of Black Americans compared to Whites were nonadherent. Gender was not significantly related to CRN. In terms of the coverage restriction variables, a significantly greater proportion of respondents whose plans did not pay for some medications, were required to pay more for some drugs, or had yearly cost limitations reported nonadherence as compared to those without these restrictions. A much larger proportion

Variable	\mathbf{N}^{1} / \mathbf{M}	% ¹ / SD
D		
Race Black American	200	9.6
White		9.0 90.1
Gender	1,152	90.1
Female	831	60.2
Male	521	39.8
Age	521	57.0
65 to 74	704	47.9
75 to 84	469	36.7
85 and above	179	15.4
Marital status ²		
Married	749	52.6
Married, spouse absent	16	1.0
Partnered	23	1.4
Separated	9	1.0
Divorced	111	8.0
Widowed	395	33.0
Never married	34	3.0
Education (range: 0 to 17) ²	12.29	2.92
Annual household income (range: 228 to 1,242,996) ²	46,752	64,747
Low-Income Subsidy (LIS) status ²		
Dual eligible receiving LIS	69	4.8
Applied for LIS	196	13.0
No LIS	1,071	82.2
Number of chronic medical conditions (range: 0 to 7) ²	2.55	1.38
Self-reported health ²		
Excellent	94	7.0
Very good	364	26.9
Good	468	33.3
Fair	293	22.7
Poor	116	10.1

TABLE 4.1Description of Sample of Individuals Age 65 and Over Reporting MedicationAdherence/Nonadherence Under Medicare Part D or MA Plan in 2007 (N=1,352)

TABLE 4.1

Variable	\mathbf{N}^{1} / \mathbf{M}	% ¹ / SD
Coverage Restriction		
Plan won't pay for some drugs		
Yes	300	21.8
No	1,052	78.2
Plan requires paying more for some drugs		
Yes	461	35.8
No	891	64.2
Plan has cost limit per year		
Yes	362	26.3
No	990	73.7
Coverage Gap status ²		
Reached gap	176	15.0
Did not reach gap	774	67.0
Do not have coverage gap	190	18.0

Description of Sample of Individuals Age 65 and Over Reporting Medication Adherence/Nonadherence Under Medicare Part D or MA Plan in 2007 (N=1,352)

¹Weighted %, unweighted N

²Sample size varies slightly due to missing data within Prescription Drug Study (PDS) or Health and Retirement Study (HRS) of respondents that reached the coverage gap reported CRN than those not reaching or without this benefit threshold.

In terms of control variables, age was significantly related to CRN. The highest proportion of respondents reporting nonadherence occurred among the young-old, or those age 65 to 74, and CRN decreased as age increased. Marital status was not significantly related to CRN.

In terms of socioeconomic status variables, LIS status was significantly related to CRN. A greater proportion of those that applied for the LIS or were dual eligibles receiving the LIS reported nonadherence. Nonadherent older individuals reported a significantly lower annual income (M = \$35,608, SD = \$34,310) than adherent older adults (M = \$49,244, SD = \$69,973).

In regards to health status variables, respondents who reported CRN had a significantly greater number of chronic conditions (M = 2.96, SD = 1.40) compared to those that maintained adherence (M = 2.46, SD = 1.35). A smaller proportion of respondents in excellent health reported nonadherence than those in other categories with those in fair or poor health reporting the most nonadherence.

Bivariate analyses suggest that without controlling for other factors, older Black Americans were more likely to report CRN under Medicare Part D than older Whites as expected. Respondents whose plan did not pay for certain medications, required paying more for some medications, or had yearly cost limitations, were more likely to report CRN as compared to those without these restrictions. Reaching the coverage gap increased the likelihood of CRN. Older individuals that were younger (age 65 to 74), had a lower annual income, greater number of chronic medications, or self-reported their health as being very good, good, fair, or poor (as compared to excellent) appeared more likely to be nonadherent due to cost.

TABLE 4.2

Bivariate Relationships Between Independent Variables and Medication Adherence/Nonadherence Under Medicare Part D or MA Plan in 2007 (N=1,352)

	Adhe	Adherence Nonadherence		Test			
	Ν	% ¹	Ν	% ¹	Statistic ²	df	р
Race							
Black American	138	69.6	62	30.4	18.02	1	<.001
White	947	83.0	205	17.0			
Gender							
Female	660	79.4	171	20.6	1.67	1	0.202
Male	425	81.6	96	18.4			
Age							
65 to 74	549	79.3	155	20.7	5.49	2	<.01
75 to 84	375	80.9	94	19.1			
85 and above	161	91.1	18	8.9			
Marital status ³							
Currently married	609	82.8	140	17.2	0.50	6	0.788
Married, spouse absent	15	93.1	1	6.9			
Partnered	16	78.6	7	21.4			
Separated	7	79.2	2	20.8			
Divorced	84	80.6	27	19.4			
Widowed	315	79.9	80	20.1			
Never married	28	83.5	6	16.5			
Education (M±SD) ³	12.35	12.35±2.82 12.04±		±2.90	1.73	1, 51	0.195
Annual household income (M±SD) ³	49,244±	4±69,973 35,608±34,310		13.88	1, 51	<.001	
Low Income Subsidy (LIS) status ³							
Dual eligible receiving LIS	52	73.5	17	26.5	7.77	2	<.01
Applied for LIS	130	70.8	66	29.2			
No LIS	890	83.8	181	16.2			

TABLE 4.2

Bivariate Relationships Between Independent Variables and Medication Adherence/Nonadherence Under Medicare Part D or MA Plan in 2007 (N=1,352)

	Adhe	rence	Nonadherence		Test		
	Ν	% ¹	Ν	% ¹	Statistic ²	df	р
Number/chronic conditions (M±SD) ³	2.46=	±1.35	2.96	±1.40	17.04	1, 51	<.001
Self-reported health ³							
Excellent	84	93.0	10	7.0	4.64	4	<.01
Very good	305	83.8	59	16.2			
Good	382	83.4	86	16.6			
Fair	217	75.5	76	24.5			
Poor	75	77.1	31	22.9			
Coverage Restrictions							
Plan won't pay for some drugs							
Yes	201	69.9	99	30.1	28.45	1	<.001
No	884	85.0	168	15.0			
Plan requires paying more for some di	rugs						
Yes	340	75.2	121	24.8	17.14	1	<.001
No	745	85.3	146	14.7			
Plan has yearly cost limit							
Yes	269	75.6	93	24.4	11.05	1	<.01
No	816	83.8	174	16.2			
Coverage Gap status ³							
Reached gap	118	68.1	58	31.9	10.39	2	<.001
Did not reach gap	631	83.0	143	17.0			
Do not have coverage gap	165	88.3	25	11.7			

¹Weighted %, unweighted N; ²Test statistic is Rao-Scott chi-square for categorical variable/F means test for continuous variables ³Sample size varies slightly due to missing data within Prescription Drug Study (PDS) or Health and Retirement Study (HRS)

Logistic Regression Results

Table 4.3 shows logistic regression models for CRN outcomes. Model 1 estimated the effects of race and gender on CRN, controlling for each other. Compared to older Whites, older Black Americans were over twice as likely to report CRN under Medicare Part D (OR=2.09). Gender was not related to nonadherence. The relationship between race and CRN remained the same with the inclusion of demographic, socioeconomic, and health status variables in Models 2, 3 and 4 (not shown).

TABLE 4.3

Logistic Regression Results of Cost-Related Medication Nonadherence Under Medicare Part D or MA Plan in 2007: Race and Gender (N=1,353)

Model 1
OR
2.09***
1.18

***Significant at p<.001

Table 4.4 presents the logistic regression results after the inclusion of the Medicare Part D cost-containment provision measures. The effect of race on CRN was maintained with the addition of the coverage restriction measures in Model 5 (OR=1.57), Model 6 (OR=1.68), and Model 7 (OR=1.58). However, when the coverage gap variable was added in Model 8, the relationship between race and CRN was no longer statistically significant. A test of mediation (Baron & Kenny, 1986) was performed. While reaching the coverage gap was not associated with race, the test confirmed that not reaching the gap mediated the relationship between race and CRN. That is, race was related to not reaching the coverage gap, race was associated with

	Model 5	Model 6	Model 7	Model 8
	OR	OR	OR	OR
Race				
Black American	1.57*	1.68*	1.58*	1.25
White (reference group)				
Gender				
Female	1.12	1.03	1.04	1.06
Male (reference group)				
Age				
65 to 74 (reference group)				
75 to 84	.80	.80	.77	.76
85 and above	.31***	.31***	.30***	.27***
Marital status				
Currently married (reference category)				
Married, spouse absent	.39	.28	.28	.37
Partnered	1.50	1.41	1.56	1.33
Separated	.93	1.07	1.19	1.67
Divorced	.85	.90	.79	.83
Widowed	1.09	1.15	1.10	.96
Never married	.80	.74	.76	.69
Education (continuous)	1.03	1.03	1.04	1.03
Annual household income (continuous)	.99*	.99**	.99*	.99*
Low Income Subsidy (LIS) status				
Dual eligible receiving LIS	1.09	1.46	1.38	2.11
Applied for LIS	1.49*	1.60**	1.57**	1.58*
No LIS				
Number of Chronic Medical Conditions (continuous)	1.20**	1.22**	1.22**	1.23**

TABLE 4.4

Logistic Regression Results of Cost-Related Medication Nonadherence Under Medicare Part D or MA Plan in 2007

Model 5	Model 6	<u>Plan in 2007</u> Model 7 OR	Model 8 OR
OR	OR		
2.57*	2.63*	2.33	2.20*
2.33*	2.24*	2.08*	1.85*
3.04*	3.15*	2.91*	2.36*
2.57*	2.16*	2.42*	2.43*
2.20***			
	2.33***		
		1.82***	
			4.34***
			1.92*
	OR 2.57* 2.33* 3.04* 2.57* 2.20***	OR OR 2.57* 2.63* 2.33* 2.24* 3.04* 3.15* 2.57* 2.16* 2.20***	OR OR OR 2.57^* 2.63^* 2.33 2.33^* 2.24^* 2.08^* 3.04^* 3.15^* 2.91^* 2.57^* 2.16^* 2.42^* 2.20^{***} $$ 2.33^{***} $$

TABLE 4.4

Logistic Regression Results of Cost-Related Medication Nonadherence Under Medicare Part D or MA Plan in 2007

*Significant at p<.05; **Significant at p<.01; ***Significant at p<.001

Model 5: Race, gender, age, marital, socioeconomic, LIS, and health status, and restriction (some drugs not covered) (N=1,317) Model 6: Race, gender, age, marital, socioeconomic, LIS, and health status, and restriction (addn'l pymt./some drugs) (N=1,317) Model 7: Race, gender, age, marital, socioeconomic, LIS, and health status, and restriction (yearly cost limit) (N=1,317) Model 8: Race, gender, age, marital, socioeconomic, LIS, and health status, and coverage gap (N=1,118) CRN, and not reaching the coverage gap was related to CRN. Thus, this suggests that racial disparities in nonadherence are driven substantially by not reaching this benefit threshold. In other words, simply having a gap in coverage can be associated with CRN - even if this benefit threshold is not reached. Individuals often engage in cost-coping behaviors to postpone or delay reaching this benefit threshold, which include becoming nonadherent to a prescribed medication regimen, particularly if medication costs are problematic (Bakk, McGuire, & Woodward, 2012). The coverage gap and restrictions seemed to have very little indirect effect on the relationship between socioeconomic status and CRN or health status and CRN. No significant changes were found. Further, both coverage restrictions and the coverage gap had a direct effect on CRN. Respondents whose plan did not pay for certain medications (OR 2.20), required paying more for some medications (OR 2.33), and had a yearly cost limitation (1.82), had a greater likelihood of reporting CRN than those without these restrictions. The odds of CRN were over four times greater (OR 4.34) for respondents that reached the coverage gap and nearly twice as likely (OR=1.92) for those who did not reach the coverage gap as compared to respondents without this benefit threshold.

In terms of socioeconomic and health status variables, annual income, LIS status, number of chronic medical conditions, and self-reported health had a direct effect on CRN. Having a greater annual income was associated with a lower likelihood of nonadherence due to cost (OR=.99). As compared to those with no LIS, individuals who applied for the LIS were over one and a half times as likely (OR=1.58) to report CRN. Respondents with a greater number of chronic medical conditions had an increased likelihood of CRN (OR=1.23). Further, as compared to older individuals who reported their health as being excellent, odds of CRN were

greater for those who rated their health as very good (OR=2.20), good (1.95), fair (OR=2.36) or poor (OR=2.43).

Finally, those aged 85 and older were 73% (OR=.27) as likely to report CRN as compared to the youngest respondents.

Discussion

Medicare Part D represents the most significant change to the program since its inception. While the benefit provided much-needed coverage to older adults struggling with prescription drug expenses, it includes cost-containment provisions that can potentially inhibit access to medications for more vulnerable populations, most notably older women and Black Americans. This is the first study to examine whether and to what extent racial and gender disparities in nonadherence due to cost exist under Medicare Part D, and how the coverage gap and restrictions affect the relationship between race, gender, socioeconomic and health status and CRN.

In this study, there was a significant disparity in CRN between older Black Americans and Whites enrolled in Medicare Part D. Racial differences remained significant after controlling for age, marital status, socioeconomic status, health status, and the coverage restrictions, but were mediated by not reaching Medicare Part D coverage gap. Experiencing the coverage gap and restrictions had a direct effect on CRN. Further, applying for the Low-Income Subsidy (LIS) or having a lower annual income or poorer health increased the likelihood of nonadherence, even after accounting for the coverage gap and coverage restrictions.

In terms of hypotheses organizing the present analyses, there are several findings to discuss. The first hypothesis that compared to older Whites, older Black Americans enrolled in Medicare Part D are more likely to report CRN was supported. This finding expands previous research conducted before the implementation of the MMA illustrating racial disparities in CRN

(Gellad, et al., 2007; Klein, et al., 2004; Soumerai, et al., 2006; Steinman, et al., 2001) and demonstrates that despite enrolling in Medicare Part D, older Black Americans reported significantly greater nonadherence due to cost. This finding is important, particularly given that older Black Americans have disproportionately greater reliance on Medicare Part D as compared to Whites (Bakk, 2012b; Davidoff, et al., 2010; Millett, et al., 2010; Neuman, et al., 2007; Rudolph & Montgomery, 2010; Skarupski, et al., 2009). While the benefit was intended to increase access to medications, it appears that cost continues to pose barriers to adherence for older Black Americans.

The lack of gender differences in CRN contrasts with previous research conducted before Medicare Part D that found that older women had a greater likelihood of CRN than men (Heisler, et al., 2005; Piette, et al., 2004c; Zivin, et al., 2010). One potential explanation involves the availability of the Low-Income Subsidy (LIS). The LIS was established with the enactment of the MMA and provides assistance with Part D costs (monthly premiums, annual deductible, medication copayments) for beneficiaries with limited income and resources. As demonstrated in Manuscript Two (Bakk, 2012a), gender differences in CRN over time were substantially driven by whether an individual applied for the LIS. Further, subanalysis (not shown) confirmed that in this study, 18% of older women applied for the LIS as compared to 8% of older males. Thus, it is suggested that the availability of the LIS with the enactment of the MMA largely accounts for nonsignificant relationship between gender and CRN under Medicare Part D in this study. Older women were more likely than old men to apply for the subsidy, and this in turn appears to have had an impact on gender differences in nonadherence.

Next, the prediction that experiencing the Medicare Part D coverage gap and restrictions will increase the likelihood of CRN was supported. This study replicates previous findings

showing that compared to older adults without a gap in coverage, those reaching this benefit threshold are more likely to report CRN (Cronk, et al., 2008; Hsu, et al., 2008; Raebel, et al., 2008), and expands this research by illustrating that beneficiaries not reaching the coverage gap also have a greater likelihood of nonadherence due to cost. It may seem counterintuitive that not reaching the coverage gap increases the risk of CRN because Medicare Part D plans pay approximately 75% of the cost of medications before reaching the gap. However, beneficiaries who are aware that their plan has a gap in coverage often engage in cost-coping behaviors which includes decreasing their adherence to certain medications - to postpone or delay reaching this benefit threshold, particularly if they experienced the gap during the prior year (Bakk, et al., 2012). Thus, simply having a gap in coverage appears to have an impact on maintaining adherence, even if a beneficiary has not incurred additional spending. When considering the coverage restrictions, older adults whose plan did not pay for certain medications, required paying more for some medications, or had yearly cost limitations were more likely to report CRN as compared to those without these restrictions as expected. This finding is consistent with research examining implications of cost-sharing requirements under state Medicaid plans (Reeder & Nelson, 1985; Soumerai, et al., 1987), and provides important insights on how each of these Medicare Part D restrictions impact adherence.

Finally, it was predicted that experiencing the Medicare Part D coverage gap and restrictions would mediate the effect of racial, gender, socioeconomic, and health differences in CRN. Support for this hypothesis was limited. Racial differences in CRN were primarily driven *not* reaching the coverage gap. Findings suggest that having a gap in coverage can be associated with CRN – even if this benefit threshold is not reached. Individuals often engage in cost-coping behaviors to postpone or delay reaching this benefit threshold, which include becoming

nonadherent to a prescribed medication regimen, particularly if medication costs are problematic (Bakk, McGuire, & Woodward, 2012). Interestingly, reaching the coverage gap was not associated with race. It is difficult to determine why this relationship was not significant because of the lack of research examining racial difference in CRN under Medicare Part D. A potential explanation could be missing data. Older Black Americans in this study had a significantly greater proportion of missing data when asked whether they reached the coverage gap than older Whites. This could underestimate the findings. Future research is needed to better understand the implications of both reaching and not reaching the coverage gap for older Black Americans.

In regards to the coverage restrictions, having this cost-sharing provision did not impact the relationship between race and CRN. This is a bit confounding – particularly considering that the gap had an indirect effect on the relationship between race and CRN but the coverage restrictions did not. In other words, both the coverage gap and coverage restrictions can potentially increase out-of-pocket expenditures, yet only the gap had an impact on racial differences in CRN. A potential explanation for this finding involves the amount of cost sharing required when entering the coverage gap. Under Medicare Part D, beneficiaries pay a 25% copayment until reaching this benefit threshold; they then become responsible for 100% of their medication costs. The coverage restrictions examined in this study - not paying for or requiring an additional copayment for certain drugs and only paying for a certain number of medications each year – may have presented less of a financial burden. For example, it is possible that the coverage restrictions required a minimal copayment amount or only excluded certain medications. An additional explanation involves potential confusion regarding whether coverage restrictions exist under a beneficiaries' Medicare Part D plan. Subanalyses (not shown) found that a significantly higher proportion of older Black Americans had missing data because they

did not know if they had a gap in coverage. The PDS did not allow beneficiaries to respond that they were unsure if they had coverage restrictions; they were only asked to check the specific restrictions within their plan. Individuals are often uncertain whether cost-sharing requirements exist within their Part D plan because of its complexity (Davidoff, et al., 2010; Heiss, et al., 2006; Hsu, et al., 2008). Given that a greater proportion of older Black Americans were uncertain whether they had a gap in coverage, it is speculated that this same uncertainty could exist for coverage restrictions, thus underestimating the impact of this cost-containment provision.

In regards to socioeconomic and health status, the coverage gap and restrictions had little indirect effect on these relationships. Slight decreases in odds ratios were observed with the addition of the cost-containment provision variables but the significance did not change. A potential explanation involves higher medication costs due to comorbid chronic health problems. Individuals in poor health with multiple comorbidities have high and persistent CRN over time (Briesacher, et al., 2007; Madden, et al., 2008; Safran, et al., 2005). CRN can be caused by higher out-of-pocket expenditures due to multiple medications (Frankenfield, et al., 2010; Zivin, et al., 2010), and having a lower annual household income can further diminish ability to pay for medications and increase the likelihood of nonadherence (Gellad, et al., 2007; Mojtabai & Olfson, 2003; Soumerai, et al., 2006; Steinman, et al., 2001; Zivin, et al., 2010). It is suggested that *any* cost-sharing under the Medicare Part D can be problematic – regardless of whether or not it increases due to reaching the gap or incurring a coverage restriction. For lower-income, chronically ill older adults, affording medications can be difficult even when copayment requirements are minimal (Klein, et al., 2004; Soumerai, et al., 1987).

An additional finding worthy of note involves the impact of factors associated with cumulative disadvantage on the relationship between race and CRN. Though the odds of CRN for older Black Americans decreased with the addition of the socioeconomic and health status variables, racial differences in CRN remained significant. A potential explanation involves factors involving the physician-patient relationship and trust. The physician-patient relationship has been found to influence CRN (I. B. Wilson, et al., 2004). Higher out-of-pocket prescription drug expenditures have been associated with a greater likelihood to forgo medications because of cost if trust in the physician is low (Piette, et al., 2005). Further, prior research has found that Black Americans view their physician less favorably (Doescher, Saver, Franks, & Fiscella, 2000) and have had worse experiences with primary care providers than Whites (Shi, 1999). Thus, for older Black Americans in this study, physician trust may have played a contributing role in CRN. They may have been less willing to discuss cost concerns or perceived benefit of a prescribed medication because the physician-patient relationship was not satisfactory.

Strengths of this study include the use of a large nationally representative sample of older adults and its ability to examine multiple predictors simultaneously. However, there are a number of limitations that must be considered. First, the PDS was administered one year after the implementation of the MMA. In the future, a longer post-policy period would provide more clarity and permit a stronger assessment of Part D enrollment. Other unmeasured factors may have influenced the results. For example, the implementation of Medicare Part D was a confusing time for many older adults (Davidoff, et al., 2010; Heiss, et al., 2006; Hsu, et al., 2008; Kaiser Family Foundation, 2006). As a result, CRN may have been overestimated because data collection occurred shortly after the launch of Medicare Part D and at a time of initial confusion. Additionally, this study was cross-sectional and thus, only provides a snapshot of CRN at one

point in time. Other factors such as the development of an acute health condition or sudden change in economic status could have impacted ability to afford prescribed medications. An examination of CRN over time would provide a stronger assessment of whether differences in nonadherence persist under Medicare Part D. While this research provides important evidence on the impact of the policy on racial and gender disparities in CRN and the impact of the MMA's coverage gap and restrictions, the results should be considered early evidence until longer-term data become available.

Second, socioeconomic and health status were measured in 2006 HRS, and CRN was measured in the 2007 PDS. There is the potential that income or certain health conditions may have changed because these measures were not taken simultaneously or when CRN was reported. While this seems less likely with income because older adults are largely dependent on Social Security, there is greater potential for fluctuation in health status. Depression, for example, can be transitory (Zivin, et al., 2010). Older Black Americans who enrolled in Medicare Part D have a greater prevalence of depression as compared to older Whites (Skarupski, et al., 2009). Thus, the indirect effect of health status on the relationship between race and CRN may have been inaccurately represented in the results.

Third, this study investigated nonadherence due to cost *only* and did not account for other factors that can impact adherence. For example, an individuals' concerns or beliefs regarding treatment through the use of medications can certainly impact adherence (Aikens & Piette, 2009). Some medications may be viewed as more essential than others (Lau, et al., 2008; Piette, et al., 2006) and there could be racial differences in whether a prescription is perceived as necessary, particularly when faced with cost concerns. As compared to older Whites, older Black Americans' ability to afford out-of-pocket expenditure requirements is typically less due to lower

socioeconomic status (Wei, et al., 2006). Thus, they may perceive the need for certain medications differently because of economic concerns. Additionally, physician trust and communication can be a factor in medication adherence (Piette, et al., 2005). It is possible that for some older Black Americans in this study, physician trust and/or communication were low and contributed to CRN. While this could account for some variation in CRN, these factors were not the focus of this research but will be examined in future studies.

Fourth and as described above, older Black Americans had a significantly greater proportion of missing data when asked whether they reached the coverage gap than older Whites. Individuals can be confused by or unaware of the Medicare Part D coverage gap because of its complexity (Davidoff, et al., 2010; Heiss, et al., 2006; Hsu, et al., 2008). This, in turn, could bias the results and overestimate or underestimate the racial effect of the coverage gap. Further, this study relied on self-reported survey measures. Self-reporting can be subject to social desirability bias (Nederhof, 2006). Respondents may be reluctant to admit failure to adhere to a prescribed medication regimen – particularly if it is due to cost factors. Because older Black Americans are more likely to be economically disadvantaged, they may incur greater difficulty affording the cost of prescribed medications – and, admitting failure to adhere because of economic reasons. This bias could contribute to underestimating the prevalence of CRN.

Fifth, there are limitations with adherence measures. The PDS did not ask respondents whether they took less than the prescribed dosage of a medication or if they cut pills in half to make a medication last longer. The survey questioned if a dosage of a medication was skipped to save money, and this measure could be a potential indicator of these behaviors. However, failure to ask if these behaviors specifically occurred could have underestimated CRN.

Finally and as stated previously, this study utilized a composite measure to estimate CRN as opposed to including all three behaviors as separate indicators: 1) not filling a new prescription because of cost; 2) stopping taking a medication because of cost; or 3) skipping doses of a medication to save money. While this is consistent with previous research and therefore useful for cross-study comparison (Bambauer, et al., 2007; Gellad, et al., 2007; Madden, et al., 2008; Safran, et al., 2005; Soumerai, et al., 2006; I. B. Wilson, et al., 2004; Zivin, et al., 2009), measuring each behavior separately may provide important insights for social work practice on racial and gender disparities in CRN. For example, one behavior could be more prevalent than others among older women or Black Americans. Future research will examine each CRN item as an outcome.

In conclusion, the study makes a strong and significant contribution to our understanding of whether and to what extent racial and gender disparities in CRN exist under Medicare Part D despite these limitations. It extends our knowledge of how the benefit's cost-containment provisions – or coverage gap and restrictions – directly and indirectly affect the relationship between race, gender, socioeconomic and health status, and CRN. While the MMA provided much-needed assistance to those previously lacking prescription drug coverage, the Part D benefit contains high levels of cost sharing that can impact adherence among vulnerable subpopulations. Overall, the study suggests that while gender differences did not exist in CRN for those enrolled in the Medicare Part D benefit, racial disparities in CRN existed after accounting for demographics, health status, socioeconomic status, and the coverage restrictions. Reaching and not reaching the coverage gap substantially accounted for racial differences in CRN. The coverage gap and restrictions, having a lower annual income, poorer health, and applying for the LIS was associated with CRN under the Medicare Part D benefit.

CHAPTER FIVE

CONCLUSIONS

Overview

The purpose of this dissertation was to better understand how racial and gender disparities in cost-related medication nonadherence (CRN) have been impacted by Medicare Part D. Prior to the implementation of the Part D benefit, CRN was greater among older women than men (Heisler, et al., 2005; Piette, et al., 2004c; Zivin, et al., 2010), and numerous studies found that Black Americans were more likely than Whites to forgo or delay taking prescribed medications because of cost (Bambauer, et al., 2007; Klein, et al., 2004; Roth, et al., 2009; Roth & Ivey, 2005; Soumerai, et al., 2006; Steinman, et al., 2001). While gender and racial disparities in CRN prior to Medicare Part D clearly existed, studies had not examined whether these differences persist since the implementation of the Part D benefit.

The research in this dissertation addresses this current gap in literature. Hypotheses were developed based on previous research. Cumulative advantage/disadvantage theory was used as a foundation for understanding the effectiveness of Medicare Part D, and both longitudinal and cross-sectional analyses were conducted using a nationally representative secondary dataset. The findings in Chapters Two, Three, and Four shed light on how racial and gender differences in CRN have been impacted by the Part D benefit, and deepen our understanding of how factors associated with the benefit impact adherence. In this chapter, key findings are summarized and the linkages between studies are considered. Conclusions are drawn in relation to racial and gender differences in CRN and Medicare Part D, and implications for social work practice, policy and education are discussed. The chapter concludes by summarizing the limitations of this study and presenting recommendations for future research.

Summary of Findings

The first paper (Chapter Two) examined whether racial and gender disparities in CRN have changed since the implementation of Medicare Part D. Specifically, it was expected that compared to older males and Whites, older females and Black Americans would be more likely to report CRN before and after the implementation of Medicare Part D and less likely to report a decline in CRN over time. Additionally, it was anticipated that socioeconomic status, health status, and prescription insurance coverage would affect CRN over time and explain racial and gender variations.

As expected, there was a significant disparity in CRN between older Black Americans and Whites both before and after the implementation of the benefit; however, these differences did not change over time. Similarly, older females were more likely than males to report CRN in both 2005 and 2007. Interestingly, contrary to expectations, older women experienced a significantly *greater* decline in nonadherence over time compared to men. The availability of the Low-Income Subsidy (LIS) may be one reason one reason for this finding because older women tend to have fewer financial resources and, therefore, are more likely to qualify for the subsidy. Also contrary to expectations, disparities remained significant after controlling for factors associated with cumulative advantage/disadvantage – specifically, socioeconomic status and health status. This was true across all three studies and potential reasons for this finding will be explored later in this section. Finally, as predicted, lower socioeconomic status, poorer health status, and less generous or no prescription insurance coverage had a direct effect on CRN over time.

While Chapter Two included respondents who met study criteria regardless of source of prescription drug coverage, Chapter Three included only a subset respondents that enrolled in

Medicare Part D. Racial and gender disparities in CRN existed over time among enrollees were examined as well as the direct and indirect effects of the Low-Income Subsidy (LIS). Hypotheses were similar to Chapter Two, with the additional hypothesis that LIS status would mediate racial and gender differences in CRN and decrease the likelihood of nonadherence over time.

As in Chapter Two, racial and gender disparities in CRN persisted even after accounting for health and socioeconomic status. Also, lower income and poorer health status increased the likelihood of nonadherence. There was limited support for the predictions regarding LIS status. As was speculated in Chapter Two, gender differences in CRN were largely driven by whether an individual applied for the LIS. However, LIS status did not affect racial differences in CRN. Previous studies found that Black Americans at or below 150% of poverty were significantly less likely to be aware of the LIS benefit (Neuman, et al., 2007; Skarupski, et al., 2009). Bivariate analysis established that this may be the case in the present sample as well. Further, applying for the LIS resulted in an *increased* likelihood of CRN. This may be because all respondents enrolling in Medicare Part D were included in the sample, regardless of income and assets.

Unlike the other chapters, Chapter Four used cross-sectional analysis to focus specifically on the impact of the Medicare Part D coverage gap and restrictions on racial and gender differences in CRN. In addition to racial and gender differences in CRN, it was expected that experiencing the Medicare Part D coverage gap and restrictions would mediate the effects of race, gender, socioeconomic and health status differences in CRN and increase the likelihood of nonadherence.

As with previous chapters, racial disparities in CRN existed after controlling for socioeconomic and health status. While the coverage restrictions did not affect differences in CRN between older Black Americans and Whites, the coverage gap mediated racial differences.

As predicted, both the coverage gap and restrictions directly affected CRN. Contrary to expectations, poorer health and lower income resulted in an increased likelihood of CRN after controlling for the coverage gap and restrictions. Higher medication costs due to comorbidities could be a reason for this. CRN is often caused by higher out-of-pocket spending resulting from the use of several medications (Frankenfield, et al., 2010; Zivin, et al., 2010). Low income individuals often have more difficulty affording medications and have a greater risk of CRN (Gellad, et al., 2007; Mojtabai & Olfson, 2003; Soumerai, et al., 2006; Steinman, et al., 2001; Zivin, et al., 2010), even when copayment requirements are small (Klein, et al., 2004; Soumerai, et al., 1987). Finally, gender differences in CRN did not exist in this study. The availability of the LIS could be a reason for this finding.

Cumulative Advantage/Disadvantage Theory and CRN

This study used cumulative advantage/disadvantage theory as a foundation for understanding how Medicare Part D impacted CRN. There were interesting findings with regards covariates related to cumulative advantage/disadvantage theory across all three studies. It was hypothesized that CRN would be associated with early disadvantage – measured by income, education, and health status – and these factors, in turn, would have an indirect effect on the relationship between race, gender, and CRN. In all studies, racial differences persisted after controlling for these variables. Further, in Chapters Two and Three, gender disparities existed both before and after Medicare Part D after accounting for these covariates.

There are several reasons why factors related to cumulative disadvantage had little impact on these relationships. First, the physician-patient relationship has been found to influence CRN (I. B. Wilson, et al., 2004). Higher out-of-pocket prescription drug expenditures have been associated with a greater likelihood to forgo medications because of cost if trust in the physician is low (Piette, et al., 2005). It is possible that for some older Black Americans and females in this study, trust was low and contributed to CRN. Physician trust may hold particular relevance when considering Black Americans given their experiences with the health care system. Older Black Americans first-contact experiences with primary care providers have been worse than Whites, and they have experienced greater barriers obtaining appointments and longer wait times during an appointment (Shi, 1999). Further, Black Americans are more likely to perceive race-based discrimination in their interactions with providers (Bird & Bogart, 2001). These experiences, in turn, could impact physician trust and subsequent desire to maintain adherence, particularly when faced with cost difficulties.

Second, physician-patient communication regarding costs can influence CRN. Individuals experiencing problems paying for their medications are typically not asked if they can afford the cost by their physician (Alexander, Casalino, & Meltzer, 2003; Piette, et al., 2004b), and almost half of persons reporting CRN did not discuss cost concerns their physicians (Piette, et al., 2004b; I. B. Wilson et al., 2007). For older Black Americans, physician-patient communication could be even lower because the relationship may be less patient-centered (Johnson, Roter, Powe, & Cooper, 2004) and participatory (Cooper-Patrick et al., 1999). In other words, the physicians may be more directive and therefore less likely to engage older Black Americans in a conversation about ability to afford prescribed medications, particularly in racediscordant dyads (Cooper-Patrick, et al., 1999). Physicians can also hold unconscious racial biases or negative beliefs that can influence their interactions with patients (Doescher, et al., 2000; van Ryn & Burke, 2000). For example, physicians may view Blacks as being less willing to comply with treatment (Gregory, Wells, & Leake, 1987) and thus, be less likely to discuss cost concerns when prescribing a medication.

Third, cultural factors can play a role in adherence with a medication regimen. A patient's personal beliefs or values regarding the use of pharmaceuticals to treat a certain condition can subsequently impact CRN, and they may respond differentially when facing costs for essential versus nonessential treatments (Piette, et al., 2006). For example, if a prescribed medication is perceived as unnecessary (Bakk, et al., 2012) or harmful (Aikens & Piette, 2009), nonadherence can increase – especially if cost is an issue.

Finally, other unexplored cost-related factors may have accounted for the lack of effect. This study could not control for individual differences within Part D plans. There are over 40 Medicare Part D plans (Kaiser Family Foundation, 2011b). Cost-sharing can vary extensively within plans (Hoadley, et al., 2006). Each plan's out-of-pocket expenditure requirements can impact CRN. For example, cost-sharing requirements are typically greater for individuals with diabetes than most other chronic illnesses under Medicare Part D plans (Ettner, et al., 2010). Because older Black Americans are more likely to be diabetic than Whites (Schoenbaum & Waidmann, 1997; Schoenborn & Heyman, 2009) and have comorbid health problems requiring multiple medications (Skarupski, et al., 2009), their chances of incurring cost-sharing under Part D plans are typically greater. Further, in this study, older females and Black Americans had a significantly greater number of medications in both 2005 and 2007 as compared to older males and Whites. Thus, the variation in cost sharing between plans may have a greater impact on older women and Black Americans because their health status is typically poorer and as a result, they often have higher prescription drug needs. This, in turn, can impact their ability to purchase prescribed medications and maintain adherence.

Implications for Social Work Practice, Policy, and Education

This dissertation provides important insights into Medicare Part D's effectiveness in eliminating racial and gender differences in CRN and factors associated with the benefit that impact compliance. The collective and individual findings suggest implications for practice, policy, and education.

Social Work Practice

Communication about difficulties affording medications is essential in order to lower or prevent instances of CRN, particularly given the association between CRN, worse health outcomes (Heisler, et al., 2004), and increased medical costs (Soumerai, et al., 1994; Soumerai, et al., 1991; West, et al., 2007). Social work literature has not examined communication patterns regarding adherence between practitioners and clients, and studies examining physician-patient dialogue about CRN are quite limited. Only 35 percent of physicians asked patients about their ability to afford a prescribed drug (Alexander, et al., 2003), and nearly 40 percent of older adults reporting CRN did not discuss problems affording medications with their physicians (Piette, et al., 2004b; I. B. Wilson, et al., 2007). As suggested previously, physician-patient communication could be even worse older Black Americans. Thus, lack of dialogue about ability to afford prescribed medications has specific implications for direct practice as more attention to and discussion about adherence appears needed. Physicians should not be the sole source of communication about cost difficulties. As described below, there are multiple avenues where social workers have the ability to intervene and provide this much-needed assistance.

First, findings suggest that older Black Americans and females were more likely to report CRN before and after Medicare Part D than older Whites and males. Further, having poorer health and lower annual income – which is more common for older Black Americans and

females - increased the likelihood of nonadherence due to cost. Despite the establishment of a drug benefit under Medicare, social workers should be aware that CRN can still be problematic, and racial and gender differences in the ability to maintain adherence continue to exist. Because social workers often assume positions where they actively participate in performing biopsychosocial assessments and linking persons to needed services and resources, they are among the first to come in contact with older adults struggling with prescription drug costs. For example, social workers may work in Area Agencies on Aging or county-specific aging organizations providing information and assistance which includes locating resources to meet the identified needs of callers. As part of the intake and referral process, questions pertaining to prescription drug use and adherence could be integrated into the assessment instrument. Resources such as pharmaceutical company prescription assistance programs and county prescription drug discount programs can then be provided to older individuals unable to afford medications, thus increasing their ability to maintain adherence. An additional personal example involving practice implications pertains to a Home-Delivered Meals (HDM) program in southeast Michigan. This research directly informed organizational practices and how older adults are assessed for the program. It was discovered that despite its mandate to serve older individuals most in need - primarily, low-income and minority persons (Gelfand, 2006) - the HDM program was not asking participants about medication adherence during intake. The screening instrument has since been modified, and individuals having difficulty affording medications are now referred to their local Area Agency on Aging Information and Referral program for pharmaceutical resources that can assist during periods of non-coverage or limited coverage.

Second, emphasis on the use of a collaborative, interdisciplinary model for service delivery is becoming more prevalent in social work (Bronstein, 2003; Mizrahi & Abramson, 2000). For example, section 3026 of the Patient Protection and Affordable Care Act of 2009 (PPACA) provided substantial funding to community-based aging organizations to reduce hospitalizations for high-risk Medicare beneficiaries through collaboration with hospitals, physicians, nurses, health care organizations, and community organizations. This five-year program is slated to begin in mid-2012 and stresses an interdisciplinary approach to improve quality of care for comorbid older adults. Findings from this dissertation may have particular relevance not only in settings such as these where collaboration is encouraged, but also demonstrate the need to form interdisciplinary relationships. In Chapter Four, racial differences in CRN were substantially driven by having a gap in coverage. Further, having a coverage gap or restrictions, poorer health status, or lower income increased the likelihood of nonadherence. By collaborating with other disciplines, social workers can help older clients that have a greater risk of CRN – those having a coverage gap, restrictions, poorer health, or lower income – avoid CRN. For example, by discussing at-risk clients with physicians, less costly generic alternatives, therapeutic substitutions (Sharkey, Ory, & Browne, 2005; I. B. Wilson, et al., 2007) or medication samples (Bakk, et al., 2012) may be provided. Further, hospitals and community mental health often have programs or resources that can assist persons struggling with medication costs. Social workers can work with these organizations to help clients that are more likely to have problems affording their medications. By forming collaborative relationships with other disciplines, practitioners can help clients identified by this research as having more difficulty with prescription drug costs to maintain adherence.

Third, findings illustrate the importance of outreach to increase awareness of the LIS benefit. In Chapters Two and Three provided evidence that the LIS influenced gender, but not racial, differences. These findings indicate that the LIS can potentially impact adherence. A reason why racial disparities persisted after accounting for whether or not they applied for the subsidy is awareness. As compared to older Whites, Black Americans were less likely to know about the LIS benefit (Neuman, et al., 2007). In this study, only 36% of older Black Americans reported being aware of the LIS in 2007 as compared to 59% of Whites. Further, 57% of older females were aware of the LIS in 2007 compared to 43% of males. Thus, the importance of outreach to increase awareness of the benefit is certainly demonstrated, particularly in light of how applying for the LIS affected gender differences in CRN over time. Despite efforts to promote the LIS, nonparticipation of eligible beneficiaries was estimated at 3 million or slightly less than 50% (Federman et al., 2009). Social work can assume a key role by conducting aggressive, targeted outreach efforts to increase LIS awareness and enrollment. This can include providing information and education about the benefit in senior centers, physicians' offices, churches, hospitals, public health departments, community-based organizations and places that may have high concentrations of lower income individuals, particularly Black Americans. Additionally, since health insurance presentations were associated with greater awareness of pharmaceutical cost-assistance programs among low-income older adults (Federman, et al., 2009), this could be a particularly important strategy to promote knowledge of the program. Finally, questions pertaining to LIS eligibility and assistance should also be incorporated into screening tools used by programs such as care management and Home Delivered Meals as an attempt to increase awareness of this important program.

Another area where social work should consider providing outreach and assistance is Medicare Part D plan enrollment. Each year, Part D plans have the opportunity to change benefit packages. Some of these changes are substantial. For example, the monthly premium for the Humana Standard plan – the largest Medicare Part D plan – increased 329 percent from 2006 to 2009. Additionally, plan restrictions and amount of cost-sharing required when reaching the gap change from year to year (Cahill, 2010). These changes, in turn, can significantly increase beneficiaries' out-of-pocket costs and lead to difficulties affording medications, particularly among older women and Black Americans because of their lower income and higher utilization. Despite increased costs, most beneficiaries are not changing their coverage plans (Jackson & Axelsen, 2008), in part because of plan complexity (Bakk, et al., 2012; Heiss, et al., 2006). The Part D benefit is very confusing, and older adults often have difficulty understanding how the benefit is structured, plan restrictions, and the coverage gap (Heiss, et al., 2006; Hsu, et al., 2008; Rosenbaum & Teitelbaum, 2005; Wilk et al., 2008). As a result, less than 10 percent are in the most cost-effective plan for their medication regimen (Hanoch, Rice, Cummings, & Wood, 2009; Neuman & Cubanski, 2009). Because plans can vary significantly, enrolling in the most appropriate plan is critical. For example, in 2009, the cost of Aricept (a commonly prescribed drug for Alzheimer's disease) ranged from as little as \$20 in one plan to \$88 in another (Neuman & Cubanski, 2009). Finally, the best way to choose the most appropriate Part D plan is through the Centers for Medicare and Medicaid Services (CMS) website. This form of delivery can pose barriers because computer and Internet use can vary by age, income, education, and comorbidity status (Cutler, Hendricks, & Guyer, 2003; Morris, 1996). For example, individuals with more income and education are more likely to own a computer (Cheeseman Day, Janus, & Davis, 2005). Further, for many older adults, Internet access is either unaffordable or unavailable

(Woodward et al., 2011). It cannot be assumed that all groups are able to access the benefit equally or have the ability or desire to use computer technology.

Thus, social workers should not only educate older adults about the need to evaluate their coverage plan on a yearly basis, but also need to provide assistance with the enrollment process. For example, Medicare Part D enrollment days could be conducted in the community at venues such as Area Agencies on Aging, hospitals, or senior centers where social workers provide one-on-one assistance in evaluating coverage options and plan enrollment. Additionally, community-based case managers should evaluate older clients' Medicare Part D plans on an annual basis to ensure they are in the most appropriate plan based on their prescription drug regimen. Finally, while all older persons may not have a desire to use the computer and Internet (Cheeseman Day, et al., 2005), those that want utilize Medicare's online resource to choose their Part D plan should receive the training needed to annually evaluate their options. Social work can assume a key role in providing computer education and training to older adults so they are empowered to make this choice.

Social Work Policy

The results of Chapter Four hold particular relevance as we consider social work's role in public policy. As demonstrated, racial differences in CRN were substantially driven by having a gap in coverage. The need to reduce or eliminate the Part D coverage gap has been recognized in this dissertation as well as previous research (Kaiser Family Foundation, 2010a, 2011a; Pedan, et al., 2009; Sun & Lee, 2007; Zhang, et al., 2009). The PPACA called for a gradual "phasing out" of the Medicare Part D coverage gap by reducing cost sharing for brand-name medications and providing partial coverage for generic medications (Cahill, 2010; Kaiser Family Foundation, 2011a; Traynor, 2010) and is an important step toward reconciling racial, gender, economic, and

health disparities CRN. In 2011, beneficiaries received a 50 percent discount for some brand name prescription medications in the coverage gap. By 2020, the discount will increase to 75 percent. This is significant, but perhaps a bit misleading because "phasing out" the gap could be construed as eliminating copayment requirements altogether. Phasing out the gap simply brings the benefit in line with the coverage before the gap began; beneficiaries will be responsible for 25 percent of their prescription drug costs. Further, the PPACA does not address those problems faced by near-poor older adults who experience difficulty affording copayments because they minimally exceed LIS income or asset limitations (Bakk, et al., 2012). As demonstrated in Chapter Three, beneficiaries whose income minimally exceeded LIS income requirements continued to have a greater likelihood of CRN as compared to the highest income group.

While the PPACA is certainly a positive step in reducing disparities, there are several reasons to be cautious. First, insurers could react to these provisions by increasing Part D premiums to manage the change (Davidoff, et al., 2010). Because the cost of prescription drugs continues to increase faster than inflation (Kaiser Family Foundation, 2009a), medication costs may still pose significant difficulties for economically vulnerable populations, especially those who exceed the LIS income/asset thresholds because cost-sharing is still required. Second, while the law in its final form calls for a significant reduction in cost sharing (to 25 percent), the remaining costs will still be out of reach for many Part D beneficiaries (Ettner, et al., 2010). Failing to completely close the coverage gap will still present economic burdens that lead to older adults rationing their own medications (Bakk, et al., 2012). Finally, given mounting pressure to reduce the nation's debt and federal deficit, there are currently threats to repeal the law (Herszenhorn & Pear, 2011, January 19). While a full repeal is extremely unlikely because the Senate has not passed the bill and President Obama has promised to veto it (Kaiser Health

News, 2011, January 6), some parts of the bill may be in danger. If reforms to Part D provisions that assist the worst off beneficiaries, such as narrowing the coverage gap, are not maintained, the most vulnerable adults will face even greater economic hardship and more serious health outcomes (Bakk & Sosulski, in press) because of the increasing cost of medications coupled with their greater susceptibility to CRN due to poorer health status and lower income.

Social workers need to be vigilant and continually monitor the progress of Medicare policy and Part D benefits, in particular. The profession holds a critical role in advocating for greater social justice, and fair and equitable access to benefits and services. The Medicare Part D coverage gap can cause the most vulnerable groups to become nonadherent to their medication regimen and potentially result in a deterioration in health status (Heisler, et al., 2004) as well as increased health care expenditures (Soumerai, et al., 1994; Soumerai, et al., 1991; West, et al., 2007). Social service providers and other policymakers should advocate not only that the PPACA coverage gap provisions remain intact, but also that greater consideration be placed on how the gap provision impacts more vulnerable groups in future policy decisions. Failure to address these differentials can unintentionally perpetuate racial and gender disparities. Further, given that the LIS mediated gender differences and differences in between those earning \$12,721 to \$23,363 and the highest income group, it is important to advocate for the expansion of this program. Finally, advocacy efforts are needed to simplify the structure of the benefit. As illustrated in the previous section, there are multiple problems faced by older adults because of the complexity of the benefit, and these issues are particularly relevant for more vulnerable populations. Policymakers should considering decreasing the number of Medicare Part D plans and delivering the benefit in a less complicated manner. In this age of reform, gender and race

should be fully considered in order to create changes that enhance older adults' health and wellbeing and reduce rather than increase overall medical spending.

Social Work Education

Social workers will assume a key role in providing assistance to older adults with health care benefits as the population continues to grow. By 2050, it is projected that the number of Americans age 65 and older will be 88.5 million, or over double the 2010 population of 40.2 (Vincent & Velkoff, 2010). It is also anticipated that the older adult population will be much more racially diverse. In 2006, Black Americans represented 9 percent of all those age 65 and over; by 2050, Black Americans will comprise 12 percent of the older adult population (The Federal Interagency Forum on Aging-Related Statistics, 2008). One area that will increasingly demand the attention of the profession is access to pharmaceuticals under Medicare Part D because prescription drugs are an increasingly important part of a treatment regimen (Medicare Payment Advisory Commission, 2006).

The results of this dissertation have distinct implications for social work education. Despite the implementation of Medicare Part D, maintaining adherence continues to be problematic for older females and Black Americans. Thus, it is important to include this topic in policy, practice, and continuing education curricula in order to facilitate medication access and avoid nonadherence, particularly among vulnerable older adults, as well as exercise sensitivity to the differences within the population. Social workers should be educated on the intricacies of the benefit so they have the ability to assist older persons in choosing the most feasible drug plan for their medication regimen, and recognize that benefit choice – which determines the amount of cost sharing required when encountering the coverage gap or restrictions – can subsequently influence medication compliance. Additionally, findings demonstrate the need to include this

topic in social work curriculum in order to raise awareness of resources available to older adults, such as the LIS program, prescription assistance programs and medication samples, which can benefit persons during periods of non-coverage. Finally, social workers should understand that older adults cannot be treated a homogeneous group when considering social policy initiatives (Neugarten, 1982), in particular Medicare Part D. Disparities need to be recognized in order to ensure equitable access to benefits.

Limitations and Future Research

As discussed in each chapter, this dissertation has several limitations. This section discusses limitations that are common in Chapters Two, Three, and Four, and provides suggestions for future research.

First, a longer post-policy period would provide more clarity and permit a stronger assessment of Part D enrollment. Other unmeasured factors may have influenced the results. For example, the transition of dual eligibles from Medicaid to Medicare drug plans in 2006 was confusing for many older adults (Kaiser Family Foundation, 2006) and resulted in difficulties obtaining medications (West, et al., 2007). A significantly greater proportion of older Black Americans in this study were dually eligible as compared to Whites, and thus, had a greater likelihood of being impacted by the transition. As a result, CRN may have been overestimated because data collection occurred shortly after the launch of Medicare Part D and at a time of initial confusion. While this research provides important evidence on the impact of the policy on racial and gender disparities in CRN, the results should be considered early evidence until longer-term data become available. Thus, future studies should provide a longer post-policy series to more adequately assess how Medicare Part D has impacted disparities in CRN. Second, variables were measured at differing time points. For example, socioeconomic and health status were measured in the 2004 and 2006 HRS, and CRN was measured in the 2005 and 2007 PDS. Thus, there is the potential that income or certain health conditions may have changed because these measures were not taken simultaneously or when CRN was reported. While this seems less likely with income because older adults are largely dependent on Social Security, there is greater potential for fluctuation in health status. Depression, for example, can be transitory (Zivin, et al., 2010). Older females and Black Americans who enrolled in Medicare Part D have a greater prevalence of depression as compared to older males and Whites (Skarupski, et al., 2009). Thus, the indirect effect of health status on the relationship between race, gender, and CRN may have been inaccurately represented in the results. Future research should contain measures taken at the same time point.

Third, this study investigated nonadherence due to cost *only* and did not account for other factors that can impact adherence. As stated previously, an individuals' concerns or beliefs regarding treatment through the use of medications can certainly impact adherence (Aikens & Piette, 2009). Some medications may be viewed as more essential than others (Lau, et al., 2008; Piette, et al., 2006) and there could be racial and gender differences in whether a prescription is perceived as necessary, particularly when faced with cost concerns. As compared to older males and Whites, older females' and Black Americans' ability to afford out-of-pocket expenditure requirements is typically less due to lower socioeconomic status (Wei, et al., 2006). Thus, they may perceive the need for certain medications differently because of economic concerns. Additionally, physician trust and communication can be a factor in medication adherence (Piette, et al., 2005). It is possible that for some older females and Black Americans in this study, physician trust and/or communication were low and contributed to CRN. While this could

account for some variation in CRN, these factors were not the focus of this research but should be examined in future studies.

Fourth, this study relied on self-reported survey measures. Self-reporting can be subject to social desirability bias (Nederhof, 2006). Respondents may be reluctant to admit failure to adhere to a prescribed medication regimen – particularly if it is due to cost factors. Because older women and Black Americans are more likely to be economically disadvantaged, they may incur greater difficulty affording the cost of prescribed medications – and, admitting failure to adhere because of economic reasons. This bias could contribute to underestimating the prevalence of CRN. Other methods of measurement, such as the use of Medicare claims data, should be considered in future studies.

Fifth, there are limitations with adherence measures. The PDS did not ask respondents whether they took less than the prescribed dosage of a medication or if they cut pills in half to make a medication last longer. The survey questioned if a dosage of a medication was skipped to save money, and this measure could be a potential indicator of these behaviors. However, failure to ask if these behaviors specifically occurred could have underestimated CRN. Future studies should account for these factors as they can impact adherence.

Sixth, mixed-effect logistic regression models were used in Chapters Two and Three to examine racial and gender differences in CRN over time. The analyses were performed in the Stata version 11.0 statistical package (StataCorp). Stata's survey commands do not allow the incorporation of the survey command or application of HRS probability weights in mixed-effect logistic regression analyses. Thus, the models did not control for the design effect and were not weighted. A consequence of not utilizing the questionnaire weights or controlling for the design effect is the potential for inaccurate point estimates and/or inaccurate standard errors, which in

turn can impact the ability to infer results to the general population. Future research is needed to determine whether there are any substantive differences between these findings and comparative analyses using a methodology that accounts for the design effect and probability weights.

Finally, this study utilized a composite measure to estimate CRN as opposed to including all three behaviors as separate indicators: 1) not filling a new prescription because of cost; 2) stopping taking a medication because of cost; or 3) skipping doses of a medication to save money. While this is consistent with previous research and therefore useful for cross-study comparison (Bambauer, et al., 2007; Gellad, et al., 2007; Madden, et al., 2008; Safran, et al., 2005; Soumerai, et al., 2006; I. B. Wilson, et al., 2004; Zivin, et al., 2009), measuring each behavior separately may provide important insights for social work practice on racial and gender disparities in CRN. For example, one behavior could be more prevalent than others among older women or Black Americans. By understanding which types or types of nonadherence are more common in older women and Black Americans, interventions that specifically target certain behaviors can be designed. Future research should examine each CRN item as an outcome.

In addition to the above suggestions for future studies, there are other areas where more research is needed. First, it was somewhat surprising that persons over the age of 75 were *less* likely to experience CRN than those age 65 to 74, particularly because research shows lower prescription drug coverage rates among older age groups (Kanavos & Gemmill-Toyama, 2010). This finding, however, is consistent with cross-sectional studies using HRS to examine CRN before the implementation of Medicare Part D (Klein, et al., 2004; Zivin, et al., 2010). One potential reason involved the sampling of the HRS and exclusion of institutionalized persons within the sample. Because risk of institutionalization or nursing home placement increases with age, older age groups residing within the community and participating in the HRS may be

disproportionately healthy (Klein, et al., 2004). This explanation, however, could not be confirmed through additional analysis. Therefore, future research is needed to understand why younger persons were more likely to experience CRN than older age groups.

Second, this study examined racial disparities in CRN between older Whites and Black Americans only. The need to reduce health disparities between Whites and minority racial and ethnic groups, which includes Blacks, Hispanics, Asian/Pacific Islanders, and American Indians/Alaska Natives, has increasingly garnered the attention of the federal government (U.S. Department of Health and Human Services, 2011, April 8; Walker, Mays, & Warren, 2004). Overall, racial and ethnic minority groups are less likely to receive needed health services, even after accounting for factors associated with cumulative disadvantage (Institute of Medicine of the National Academies, 2003). Thus, in order to more fully understand how Medicare Part D has impacted disparate access to medications, future research should broaden this comparison.

Finally, the ramifications of CRN with a prescribed medication regimen prior to Medicare Part D have been established. Individuals who restricted medication use because of cost were more likely to exhibit a deterioration in overall health status over time (Heisler, et al., 2004). Further, persons with coverage restrictions were twice as likely to enter a nursing home, and more likely to use hospital and outpatient services than those without restrictions (Soumerai, et al., 1994Soumerai, et al., 1994; Soumerai, et al., 1991). Given that the addition of the Part D benefit represented the largest expansion in the history of the Medicare program, future research should consider the long-term health implications associated with enrollment in the benefit. This is particularly relevant when considering how the LIS mediated gender differences. In other words, it is important to understand whether improved health outcomes are associated with this reduction in CRN and whether the policy has lowered health care costs.

Conclusions

The findings presented in this dissertation raise questions of whether the Part D benefit is sufficient for older adults with increased risk of CRN. It is important to look at not only the overall effect of Medicare Part D but also the relative effect for vulnerable populations. Results suggest that older Black Americans and females were more likely to report CRN before and after Medicare Part D than older Whites and males. While applying for the LIS mediated gender differences in CRN, racial disparities appeared to be driven by having a Medicare Part D plan with a gap in coverage. Poorer health, lower annual income, less generous or no prescription drug coverage, applying for the LIS, and experiencing coverage gap and restrictions increased the likelihood of CRN.

Understanding how Medicare Part D has affected adherence can help social work practitioners recognize that clients may need additional resources and assistance in order to avoid CRN. Additionally, findings can help substantiate the need to account for race and gender when evaluating policy alternatives in order to promote more equitable access to medications and avoid disparate health outcomes. Equity and fairness should receive consideration as policy debates continue. BIBLIOGRAPHY

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