How Prescription Drug Use Affects Health Care Utilization and Spending by Older Americans:
A Review of the Literature

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AARP’s Public Policy Institute informs and stimulates public debate on the issues we face as we age. Through research, analysis and dialogue with the nation’s leading experts, PPI promotes development of sound, creative policies to address our common need for economic security, health care, and quality of life.

The views expressed herein are for information, debate, and discussion, and do not necessarily represent official policies of AARP.
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FOREWORD

Prescription drugs are intended to have beneficial clinical effects. One would hope their use might also reduce patients’ need to use other health care services. This effect is often observed in the literature (Chrischilles, Dasbach, Rubenstein et al., 2001; Sokol, McGuigan, Verbrugge, & Epstein, 2005). Sometimes these cost offsets are offered to justify prescription drug prices, particularly in the case of brand-name drugs (Lichtenberg, 2002). Despite several studies demonstrating that specific prescription drugs and/or therapeutic classes can produce offsets in utilization of non-drug medical services and may even result in net savings, evidence is sparse on the effects of expanding prescription drug coverage and changing prescription cost sharing for patients. The 2006 implementation of the Medicare prescription drug benefit has sparked interest in the effects of such coverage expansions.

While some prescription drug use may not produce cost offsets (e.g., some patients may live longer and incur higher health care costs), in other cases, prescription drug use may result in some degree of cost offsets and possibly net savings (e.g., some medications may prevent or delay serious progression of disease and associated costs). The nature and extent to which studies have found these effects is the subject of this paper.

AARP’s Public Policy Institute commissioned this paper to review and summarize evidence in the professional literature regarding the impact of expanding prescription drug coverage on non-drug utilization and associated cost offsets, particularly for older Americans. As used in this paper, the concept of “cost offsets” is intended to mean some level of cost reduction in non-drug spending that is associated with prescription drug use. Net savings is used to mean that prescription drug costs are more than offset by reduced spending on non-drug services.

Although some of the most important effects of prescription drug use include its impact on quality of life and longevity, this paper does not explore these effects fully, largely because they need to be better described in the literature.

While none of the studies reviewed for this paper included findings from the Medicare prescription drug program because such data have not yet been released, the findings have obvious relevance and implications for the Medicare program. To the extent that expanded Medicare coverage for prescription drugs produces cost offsets in other parts of the Medicare program, overall Medicare spending may be affected favorably.

We hope this paper will serve as a resource for analysts, advocates, policy makers and stakeholders who are interested in and concerned about this topic to: (1) establish a baseline regarding areas of basic agreement in study findings; (2) identify areas where consensus is lacking; (3) identify gaps in the literature; and (4) provide guidance on issues that deserve further investigation.

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EXECUTIVE SUMMARY

Background
Prescription drugs play a central role in the health and well-being of older Americans. In spite of the expectation that greater use of prescription drugs should lead to improved health outcomes, fewer complications, decreased disability, and lower overall health care costs, the impact of prescription drug insurance coverage on medical spending has not been well documented. While the literature generally agrees that providing prescription drug coverage increases use of medications, estimates of the overall effect on health and medical costs of providing such coverage have ranged widely. This is particularly true for studies that look at program-level outcomes for Medicare and Medicaid and at broad populations.

Purpose
This paper assesses the professional literature on the impact of prescription drug insurance and the use of prescription drugs on utilization and spending by the elderly on prescription drugs and non-drug health care services, with a particular focus on the contribution of newer research.

Methodology
This paper systematically reviews peer-reviewed and comparable professional literature on the impact of prescription drugs, prescription drug insurance coverage, and benefit design on drug and non-drug medical care utilization and spending in the older population. For a list of studies reviewed, see the appendix and references.

Findings-in-Brief
The studies we reviewed have examined primarily the impact of providing prescription drug insurance and specific benefit design features, such as various cost-sharing approaches. With certain caveats described below, the review finds support for the following:

- Prescription drug coverage can produce cost offsets from reductions in non-drug services, such as hospitalizations and emergency visits.

- Studies that incorporate increased longevity into spending projections suggest that cost offsets may diminish over time.

- Strict benefit limits of all kinds (spending caps or number of prescriptions) decrease prescription drug use and increase use of other medical services, including acute and long-term care services.

- Increased prescription drug cost sharing decreases the use of essential, as well as non-essential, classes of medications.

- In general, increased patient cost sharing reduces use and spending for prescription drugs, with a 10% increase in drug cost sharing being associated with a decrease in drug use of approximately 1%–6%.
Appropriate use of prescription drugs leads to improved health outcomes for many chronic conditions in the elderly.

Prescription drug coverage increases drug use by as much as 20% and improves patient adherence to medication regimens.

The effects of acquiring prescription drug coverage and increased cost sharing on prescription drug use, use of other medical services, and health outcomes are often delayed, so accounting for them warrants at least a 12-month follow-up.

A considerable lack of consensus remains in important areas:

- The magnitude of cost offsets associated with broad changes in prescription drug coverage and/or use has not been determined reliably.
- Whether cost offsets that arise produce net savings after costs associated with increased prescription drug used are taken into account.
- The marginal effects of various drug benefit design features (e.g., caps, cost sharing, formularies, etc.) on cost offsets to non-drug services are not conclusive.

Finally, although it was not the central focus of this paper, the review found a dearth of evidence regarding the effects of broad changes in prescription drug coverage on disability or quality of life.

Several caveats apply to these findings, including:

- Many previous studies, particularly older ones, have relied on small sample sizes and have not used robust methodologies. For instance, many studies have relied on cross-sectional rather than longitudinal data and have not used adequate controls for unobserved factors.
- Few studies take into account the dynamic relationship among prescription drugs, health status, demand for insurance, and spending over time.
- While recent studies have begun to address these dynamic relationships, most studies remain limited by a lack of large, longitudinal databases and by methodological limitations, such as potential selection bias due to difficulty controlling for unobserved factors.
- None of the studies reviewed for this paper included findings from the Medicare prescription drug program because such data have not yet been released.

The consensus findings of this review suggest some important policy implications, including:

- Appropriate prescription drug use should be encouraged, particularly among the elderly with chronic conditions.
- When patient adherence to prescription drug regimens is less than optimal, it can be improved by reducing prescription drug prices for patients by adding coverage for the
uninsured and reducing cost sharing for those who have prescription drug coverage. However, increased adherence may also increase prescription drug spending.

- One may need to target cost sharing for prescription drugs by type of medication and patient condition (through programs such as value-based insurance design) to minimize unintended consequences in other areas, such as non-drug spending and health outcomes.
- We may reduce unintentional increased use and spending for non-drug services by avoiding strict benefit limits on prescription drug use.
- We should view with skepticism study findings that do not take delayed effects into account.

In addition to the policy implications of these study findings, further clarification of the impact of prescription drug coverage and benefit design would enable a range of stakeholders (e.g., patients, payors, and policy makers) to make more informed choices. Questions that need to be addressed include the following:

- What are the effects of high cost sharing and significant gaps in prescription drug coverage, such as those found in high-deductible health plans (i.e., health savings accounts) and the Medicare Part D drug benefit (i.e., the donut hole)?
- What are the effects of prescription drug coverage and patient adherence, not only on cost offsets from other medical services, but also on health status, quality of life, and productivity?
- What are the effects of targeted coverage designs such as differential cost sharing for particular drugs or classes to encourage more use of effective drugs in the patients who would most benefit?

To understand these issues better, researchers should consider undertaking future studies that combine the sophisticated analytic techniques used in some of the recent studies reviewed in this paper with prospective studies and/or data sets representing natural experiments (where legal or policy changes have produced substantial changes in the scope of prescription drug coverage, such as the recent addition of a Medicare prescription drug benefit). While study designs using natural experiments may still suffer from methodological limitations (i.e., bias, limited generalizability, etc.), they do offer important opportunities to sort out the effects of changes in prescription drug coverage and, in particular, different benefit designs.

With implementation of a prescription drug benefit as part of the Medicare program in 2006, analysis of Medicare data may make it possible to better identify longer-term effects of prescription drug coverage on health outcomes as well as on costs (both drug costs and cost offsets from other services). However, Medicare studies will require linking Part D drug data with hospital claims data from Part A and physician claims data from Part B. We may facilitate sorting out the effects of various drug benefit designs by linking Medicare data with non-Medicare data sets, such as claims from Medicare supplemental insurance (i.e., Medigap) and commercial claims for people before they became Medicare eligible. To fully explore the data and parse these and other questions
with important policy implications, government and private researchers will need to have timely access to longitudinal data sets.
I. INTRODUCTION

Prescription drugs play a critical role in the health and well-being of individuals. In particular, for older members of the population, medications are a foundation for treatment of chronic disease: nearly 90% of Americans age 65 and older take prescription medications, with half taking three or more medications regularly (National Center for Health Statistics [NCHS], 2004). Medications, especially those used to treat chronic diseases, are now used routinely to prevent disease progression and avoid complications.

Insurance for prescription drugs, while by no means assuring that individuals will receive needed medications, offers the potential to improve younger and older Americans’ access to medications. The literature has shown quite consistently that having prescription drug coverage is associated with increased use of medications. In spite of the very reasonable expectation that increased use of prescription drugs could lead to fewer complications, fewer instances of disability, improved health outcomes, and lower overall health care costs, the link between these factors is not well established empirically. This is particularly true for studies that look at program-level outcomes for Medicare and Medicaid and at broader populations.

There has been a lack of consensus in professional literature on the extent to which providing insurance coverage for prescription drugs reduces or avoids the use of other medical services. Questions also remain regarding which benefit design features of prescription drug insurance can lead to improved adherence to drug regimens and whether such adherence leads to better health and outcomes for patients.

Since before passage of the Medicare Modernization Act of 2003, there has been a pressing need for, and interest in, understanding and documenting whether providing prescription drug coverage leads to improved health outcomes and/or offsets in utilization and cost of other medical services. Research to assess the aggregate program effects of an expansion in coverage across all therapeutic drug classes is critical for budget projections and program cost effects, but may mask strong effects in particular disease areas. Research focusing on specific clinical areas and on specific insurance design features, such as cost sharing or administrative controls, is also necessary to determine optimal design of coverage.

This paper assesses the literature through 2007 to determine what past and future research can offer both methodologically and for policy purposes. It critically examines research on the impact of prescription drug use and coverage design on health care utilization and costs, to highlight underlying relationships and suggest considerations for future studies. While the clinical benefits of individual prescription drugs are well documented, the focus of this review is the impact of older adults’ prescription drug coverage and use on non-drug health care utilization and costs. However, because the demand for and use of prescription drugs over time is largely intertwined with health status, this relationship cannot be ignored, and studies that address these important links are highlighted. This paper addresses the following questions:

1. Conceptually, what is the effect of prescription drug coverage on the broader health care system?
2. How do changes in older persons’ prescription drug utilization affect their use of and spending for other health services?

3. What is the nature and quality of the evidence regarding these questions? How methodologically rigorous are the studies that produced it? To what extent are the study results relevant to the Medicare population? Is evidence from recent studies methodologically stronger than that from previous studies?

4. Based on the evidence, can one project potential cost offsets or savings from expanded access to prescription drugs under Medicare’s new prescription drug benefit?

5. What further research would be useful?

To address these questions, this paper first provides a conceptual framework for analysis. Second, it describes the literature regarding direct effects of prescription drug insurance on use and spending and identifies gaps in the literature. After describing methods used for literature selection and review, this paper describes the literature regarding effects of specific drugs and drug classes on use and spending, followed by a discussion of the impact of prescription drug coverage and benefit design on non-drug spending. Finally, the paper summarizes the nature and quality of the evidence, areas of consensus and lack of consensus, policy implications, and recommendations for future research.

II. CONCEPTUAL FRAMEWORK

To better understand the dynamics through which prescription drug insurance contributes to changes in use of drugs and other medical services, it is important to review the basic factors that contribute to prescription drug use and spending. These can be grouped into categories adapted from several health and social behavioral models (Anderson, 1995; Piette, Heisler, Horne, & Alexander, 2006):

- **Patient characteristics:** Demographics, health status, medical need, sociocultural influences, perceived benefits of the prescription, income, health literacy, insurance status (medical and/or prescription drug), and risk preferences in the demand for insurance.

- **Characteristics/insurance benefit design:** Insurance influences use of drugs by changing individuals’ out-of-pocket costs. These costs vary by type of insurance (limited or expansive networks, physician services access); source (public or private); insurance benefit controls (formularies, drug utilization management, benefit limits); cost-sharing structures; and availability/use of other services both previously and concurrently.

- **Health care system factors and complementary inputs:** Availability of providers; organization of care; payment systems; available benefits and coverage, including pharmacy assistance and discount programs; associated non-drug costs of obtaining medications (travel, etc.); and advertising pressures.

- **Provider characteristics:** Physician knowledge of prescription therapy and its costs; practice style; therapeutic preferences; provider prescribing incentives; pharmacist availability; and knowledge.
**Medication characteristics:** Price; ease of administration; associated costs of administration; perceived and actual effectiveness; availability of substitutes; associated risks and potential side effects; and advertising influences.

The above factors contribute to the supply and demand for medical care and the rate at which drugs and other services are consumed. In economic terms, these factors, particularly past and concurrent medical care utilization and health status, contribute to the demand for health care services that produce health (known as the health production function [Grossman, 1972]). However, the interaction among these factors is complex, as many of them change over time or cannot be observed from available data (e.g., individual preferences for insurance, undocumented health care events, individual budgets and spending preferences).

Figure 1 illustrates the relationship among prescription drug insurance, prescription drug consumption, and related medical services. These relationships are the organizing framework for the current literature review.

Economic theory predicts that as insurance lowers a medication’s out-of-pocket cost, use of that medication will increase. The type and features of insurance benefit design influence the demand for prescription drugs and other services. At the same time, the demand for insurance itself is dependent on health status, which, in turn, contributes to changes in the demand for prescription drugs and other medical services. This relationship is particularly strong for prescription drug insurance; if individuals could predict short-term medication use, they could purchase insurance as a prepayment mechanism for their medications.

Prescription drugs may be viewed as substitutes for some services (offsetting the need for some services, such as hospitalizations and emergency care) but complementary to other services (resulting in increases in physician or other services associated with prescribing and managing treatment and adverse events). To the extent that adherence to drug regimens improves health outcomes and longevity (Gowrisankaran & Town, 2005; Heisler, Langa, Eby, & Fendrick, 2005), health care costs incurred during added years of life, in turn, may offset short-term savings from reductions in use and spending for other services.

These dynamics mean that the effect of prescription drugs on health should be accounted for in estimates of future health care spending. Further complicating matters, many of the relevant factors in this process are unobservable and may change over time—for instance, prior health status, risk preferences, provider practice style, health system patterns, natural progression of disease, and the interaction between medical care and health status over time. If the study design and data analysis do not address these issues adequately, the impact of prescription drug coverage on the health care system will be overestimated for some services and underestimated for others.
When estimating the impact of policies on the broader health care system, researchers should take into account such factors as:

- differences between insured and uninsured populations (observed and unobserved selection);
- changes in health status;
- improvements in longevity;
- insurance benefit design characteristics; and
- other observed and unobserved characteristics of patients.

Predictive models (both those that estimate future program costs and those that estimate the impact of particular design features) that do not take these risk factors into account are likely to produce biased estimates of the effects of prescription drugs and insurance coverage on health and medical care utilization.

**III. IDENTIFYING GAPS IN THE LITERATURE**

Numerous studies have shown that having prescription drug insurance (versus having none) is associated with increased use of prescription drugs. Most studies of older Americans have used data from the Medicare Current Beneficiary Survey (MCBS), other national surveys, or retiree health care claims. These studies usually have been based on cross-sectional data (analyses at a fixed time), adjusting for measurable health status, and
other indicators. Such studies show a moderate to strong insurance effect on the likelihood of prescription drug use (insured persons are 6%–17% more likely to use drugs [Gianfresco & Baines, 1994; Stuart & Grana 1998]), with generally larger differences between insured and uninsured for particular drug classes (Adams 2001a; Blustein, 2000; Doshi, Brandt, & Stuart, 2004; Federman, Adams, Ross-Degnan, Soumerai, & Ayanian, 2001; Stuart, Doshi, Briesacher, Wrobel, & Baysac, 2004). Longitudinal studies (time series analysis of individual patient records or aggregate population data) that have followed populations as they gain insurance suggest that it is important to observe this dynamic over time (Briesacher, 2005; Khan, Kaestner, & Lin, 2007; Stuart & Coulson 1993; Stuart et al., 2004).

Numerous studies have also established that changes in beneficiary cost sharing for prescription drugs affects drug utilization and spending by insured populations (Gibson, Ozminkowski, & Goetzal, 2005; Gruber, 2006; Lexchin & Grootendorst 2004; Maio et al., 2005; Rice & Matsuoka 2004). These studies confirm that higher drug cost sharing results in lower utilization of and spending for drugs, but the magnitude of this effect varies. Studies that report price elasticity of demand for drugs (an economic measure of consumer responsiveness to prices) generally range from -0.1 to -0.6 (meaning that a 10% increase in consumer cost sharing results in a 1%–6% decrease in medication utilization) (Goldman, Joyce, & Zheng, 2007; Gruber, 2006; Shea, Terza, Stuart, & Briesacher, 2007). Additional findings from this research include:

- Levels of cost sharing and plan generosity are strongly related to prescription drug consumption (Artz, Hadsall, & Scholdelmeyer, 2002; Doshi & Polsky, 2007; Huskamp, 2003; Joyce, Escarce, Soloman, & Goldman, 2002; Stuart & Zacker, 1999).
- Effects of insurance coverage design on utilization vary across drug classes (Goldman et al., 2004; Stuart & Grana 1998).
- Having insurance for physician visits is critical to using a drug benefit (Coulson & Stuart 1992; Grootendorst, O’Brien, & Anderson, 1997; Rogowski, Lillard, & Kington, 1997).
- Beneficiary cost sharing has a strong impact on drug adherence and/or health outcomes for those with chronic diseases (Cole, Norman, Weatherby, & Walker, 2006; Gibson et al., 2005; Goldman et al., 2004).

Studies that have attempted to distinguish between essential and non-essential drug use have shown that even though non-essential drug use may be more responsive to higher cost sharing, both categories are affected to some extent (Goldman et al., 2004; Johnson, Goodman, Hornbrook, & Eldredge, 1997b; Tamblyn, Laprise, Hanley, Abrahamowicz et al., 2001).

Studies that consider insurer type (e.g., Medicaid, Medigap, private managed care) have shown that:

- Medicaid drug coverage is associated with higher drug consumption and spending compared to other types of supplemental insurance (Adams, 2001a; Rice & Matsuoka, 2004), and
managed care populations use drugs differently from individuals with other types of insurance, including greater use of chronic care drugs, newer drugs, and generic drugs, and the effects of cost sharing may be lower than they are in other populations (Hillman et al., 1999; Lyles & Palumbo, 1999; Stafford et al., 2003; Wallack, Martin, Thomas, & Ryan, 2007).

While studies have clearly established a direct relationship among prescription drug coverage, drug utilization, and spending, the relationship between prescription drug coverage and use of other health care services has not been as well established. For this reason, we undertook this review.

IV. METHODS FOR LITERATURE SELECTION AND REVIEW

Relevant studies for this review included those of the impact of drug coverage on use of non-drug medical services. Specific outcomes of interest included both overall health care utilization and its various components (i.e., hospitalization, physician visits, emergency department visits, and skilled nursing and other long-term care services) and costs associated with these services. We also discuss relevant examples of research examining the effect of optimal use of particular drug classes on the cost of other medical services.

We conducted a systematic literature review following standard approaches (Cochrane Collaborative Center for Reviews and Dissemination, 2006; Fink, 2004). We searched articles through online sources, including National Library of Medicine (PubMed, Medline), EconLit, Web of Science, and Google Scholar, using both standard searches and “reverse” searches of articles citing relevant sources. In addition to the standard journals, we looked for government website publications and published foundation reports that exhibited sufficient methodological rigor. In particular, several of those published by the National Bureau of Economic Research (NBER) fell into this category. Further, we queried outside experts to identify the most influential papers on the topic and methodologies to ensure that we identified all relevant articles.

We considered articles for review only if they directly investigated either the impact of prescription drug use in particular classes on medical or long-term care services, or the impact of prescription drug insurance programs and benefit design (cost sharing, coverage caps, formularies, etc.) on drug use and other medical services.

While an extensive literature exists on the clinical benefits of particular drugs and drug classes in controlled trials, together with a more limited number of studies of their cost effectiveness (Neumann, 2005), we have not attempted to summarize these results for a number of reasons. Most of these studies demonstrate the clinical or cost effectiveness of using a particular prescription drug for a particular patient population. In addition to the narrow scope of these studies, other concerns have been raised regarding the generalizability of these studies to broad expansions of prescription drug insurance coverage (e.g., publication bias—the tendency to publish favorable results and funding from industry sources); limited generalizability outside of trial populations; and lack of benefit design considerations (Congressional Budget Office [CBO], 2002). Nevertheless, we have included selected studies with particular relevance to older populations or chronic disease.
To be included in this review, studies had to meet one of the following criteria: peer reviewed or equivalent; outcomes as noted (acute medical service use and spending, long-term service use and spending, economic evaluations); international studies if comparable and relevant to the U.S. health care system (e.g., Canadian); computer simulation models for forecasting costs and health outcomes; adequate sample size; and transparent methods. We also included studies that examined older populations, exclusively or as a subgroup, or had particular relevance to chronic disease or the Medicare population, as well as relevant methodological papers. Observational studies based on claims data or patient reporting of objective measures, such as diagnoses, were included only if they controlled for patient demographics. We excluded opinion surveys that report subjective information on health status or cost related to prescription drug.

V. FINDINGS

A. Use of Individual Prescription Drugs

There is ample evidence from clinical trials that, used correctly in the right patients, individual prescription drugs and drug classes can improve health status. This literature has been reviewed elsewhere (e.g., O’Brien, 2003). The evidence from these studies is mixed on the extent of cost offsets from reductions in other medical service utilization that may be associated with appropriate medication therapy and tends to vary by clinical condition and drug type. As we discuss further below, these findings have led some analysts to attribute substantial increases in the population’s health status over the past few decades to the availability of new prescription drugs (Lichtenberg, 2006). Some have inferred that increased spending associated with improvements in health care technology, including prescription drugs, has been well worth the cost (Cutler, Rosen, & Vijan, 2006). Others have shown through cost-benefit analysis that the use of some drugs produces considerable savings in some areas, but this varies greatly by type of medication, disease, and population (Neumann, 2005).

For many chronic diseases, medication use has produced significant health care cost savings in controlled settings that eliminate the insurance effect. For instance, research has shown that AIDS anti-retroviral therapy can produce savings in less hospital use and lower hospital spending (Bozzette et al., 2001). Other studies have suggested that annual savings from such interventions may be offset by increased longevity (Goldman et al., 2004; Lichtenberg, 2006). The use of drugs in Alzheimer’s disease has also shown sizeable cost offsets through fewer hospitalizations and less residential care in patients with moderate to severe disease (Feldman, Gauthier, Hecker et al., 2004; Hill, Futterman, Mastey, & Fillit, 2002; Lu & Fillit, 2005). In osteoporosis, a randomized controlled trial found that drug therapy reduced the incidence and health care costs associated with fractures by 35% (Chrischilles et al., 2001). Additional conditions for which adequate adherence to medications has been strongly associated with lower health care costs and hospitalization rates include asthma, diabetes, hypertension, high cholesterol, and heart disease (Balkrishnan, Christensen, & Bowton, 2002; Balkrishnan, Rajagopalan, & Camacho, 2003; Fischer & Avorn, 2004; Gibson et al., 2006; Hepke, Martus, & Share, 2004; Sokol et al., 2005; Stephens, Botteman, & Hay, 2006; Stukel, Lucas, & Wennberg, 2005). On the other hand, several economic analyses of prescription drug use for treatment of mental health conditions have shown improved clinical outcomes but mixed
evidence of health care cost offsets (Frank, McGuire, & Normand, 2006; Lave, Frank, Schulberg, & Kamlet, 1998; McCombs, Nichol, Johnstone et al., 2000).

Such studies suggest the potential for prescription drugs prescribed and consumed under controlled circumstances to lead to health care cost offsets, if not net savings. However, because insurance coverage and other factors strongly influence prescription drug use, the remainder of this review focuses on the literature dealing with the effect of insurance coverage and benefit design on prescription drug use and related offsets in use and cost of non-drug health care services.

**B. Overview of Studies Reviewed**

A large volume of published articles address various aspects of prescription drug coverage and health care costs, but only a limited number use robust methods and apply to older populations. We found 10 studies (peer-reviewed or equivalent) that assessed the impact of having or gaining prescription drug coverage. A number of these assessed the effect of payor type (managed care versus other models, and public versus private insurance) on drug and other medical costs for specific clinical conditions.

Twenty-nine studies assessed the effect of insurance benefit design on use of medical and other non-drug services, particularly for older adults. Studies examined the impact of either administrative or financial controls (benefit caps, formularies, and prior authorization) or patient cost sharing (copayments, coinsurance, progressive cost-sharing tiers, or reference pricing). The following section briefly summarizes findings from older studies, then discusses findings from newer studies in more detail.

**C. Prescription Drug Coverage, Health Status, and Non-Drug Medical Spending**

Literature examining the impact of prescription drug coverage and use on non-drug spending is limited, but increasing evidence suggests that providing prescription drug coverage has a small but significant effect on other medical services, at least in the short run. Most studies have used observational data (most often the MCBS, which combines claims data and patient reporting), comparing the insured to the uninsured, to estimate the impact of drug coverage on non-drug services and on the overall costs of the Medicare program. Five studies published since 2004 estimate the program-wide impact of adding drug benefit coverage in terms of cost offsets, either for the Medicare program alone or for the entire population.

All nine studies found that an increase in prescription drug use was associated with insurance coverage, in both probability of prescription drug use and prescription drug spending. Six of these studies showed drug coverage to decrease costs of Part A and/or Part B services significantly. The remaining three showed little or no long-term cost offset from drug coverage. The methods used to estimate drug cost offsets varied in amount and type of data, analytical methods, and follow-up period, as discussed in more detail below.

An earlier study by Lingle, Kirk, and Kelley (1987) showed that low-income seniors enrolled in a state pharmacy assistance program, and thus more likely to fill prescriptions, had lower hospital costs. However, the age of the study, inability to infer a causal
relationship, and restriction of the study population to low-income seniors limit the
validity and relevance of these findings.

Several MCBS-based studies provide important insights into medical cost offsets from
prescription drug coverage, but they have limited generalizability beyond the study
population, due to their methods and small sample size. Briesacher and associates (2005)
showed non-significant decreases in hospital spending for all Medicare beneficiaries who
had acquired drug coverage in several two-year periods. This study adjusted for
differences in health status that might have encouraged sicker patients to gain drug
coverage preferentially, and our review revealed no other obvious evidence of selection
bias. This study estimated that acquiring prescription drug coverage increased drug
spending by up to 66% after the first year. Although the study found some lagging cost
offsets from lower hospital and physician spending, these effects were not statistically
significant. As the study’s authors noted, the results are not generalizable and should not
be considered definitive, but they do suggest that, if this trend continues and becomes
significant, the impact of drug coverage may continue well into the second or third year
after drug coverage is acquired.

Stuart and associates (2004) examined the impact of drug coverage for Medicare
beneficiaries with chronic obstructive pulmonary disease (COPD). A propensity score
approach (i.e., matching or weighting insured and uninsured individuals on observable
characteristics to better account for unobserved differences between the two groups)
based on 1999 morbidity was used to correct for selection bias. Those with drug coverage
paid 61% more for COPD drugs, had 29% less physician spending, and had no significant
differences in hospital spending in 2000, after adjusting for covariates. As in the previous
study, Stuart and associates (2004) relied on a small sample (384 beneficiaries with
coverage and 78 controls), so this study should be considered exploratory.

Atherly (2004) examined the impact of Medicare supplemental drug coverage on
asthmatics, using cross-sectional data from MCBS 2001. While drug coverage was
associated with 21% greater physician spending for all beneficiaries, for those with
asthma, physician spending was actually 7% less. This suggests that drug coverage may
have a differential impact on certain types and severity of disease. Although the analysis
was adjusted for covariates, its findings are still limited because it used cross-sectional
data.

In another estimate of the overall cost impact of adding a prescription drug benefit for
an older population, Gilman, Gage, and Mitchell (2004) used data from the Vermont
Medicaid pharmacy waiver program, which provided prescription drug benefits to non-
Medicaid, low-income seniors. This study, which used a design based on data from one
year before and one year after implementation, found drug coverage for low-income
seniors to be associated with an average increase in Medicare spending of $1,000 during
the enrollment year. The following year, the population experienced a return to baseline
spending, suggesting that a change in health status may have led to enrollment in
this program, but that overall spending was not affected. The study also showed a
simultaneous statewide increase in the number of seniors enrolling in Medicaid, but one
should not infer a causal relationship with drug coverage due to the study’s methodology.
Instead, this finding was more likely the result of low-income individuals signing up for
the state pharmacy assistance program and also enrolling in the state Medicaid program.
Using a very different methodology that relies heavily on assumptions, Rosen and associates (2005) simulated the insurance effect of an anti-hypertensive medication for diabetics, allowing for disease progression and modeling the effect of expected increased drug adherence due to insurance coverage. Based on epidemiological and cost-effectiveness data, this study used no direct patient data; instead, it relied on sensitivity analyses to model the expected patient response to drug coverage. Based on computer simulation of first dollar coverage and estimates of how the addition of drug coverage might increase use of the drug in question, this study found that prescription drug coverage led to lower annual Medicare costs ($1,606 less) and increased longevity (0.23 quality-adjusted life years [QALYs]). However, on a program-wide basis, the study also found that annual savings would be offset by increased use of other health care services during added years of life. In a related sensitivity analysis based on more limited coverage available under the standard Medicare drug benefit, the study found that, in spite of annual savings from fewer hospitalizations, coverage for the drug in question would result in net costs to Medicare, although coverage would be relatively cost effective (i.e., less than $1,000 for the expected increase in QALYs per diabetic).

Several other recent studies also used computer simulation to model future health spending associated with providing drug benefits through the Medicare program. Recognizing the importance of the dynamics of health status and demand for drugs in specifying the impact of drug coverage, Yang, Gilleskie, and Norton (2004) used multiyear MCBS data (1992–1998) to estimate the effect of drug coverage, taking into account the dynamics of insurance choice, health status changes, and unobserved patient characteristics. In doing so, they incorporated the following assumptions:

- Patient preferences for insurance coverage depend on health status.
- Use of different types of medical care correlates with illness.
- Current medical care consumption influences future health and future consumption.
- Past medical care consumption influences current consumption (Yang et al., 2004; Yang, Gilleskie, & Norton, forthcoming).

Using longitudinal data, this study addressed several of the limitations of static, cross-sectional analyses and demonstrated the extent to which other study estimates may have been biased by not adjusting adequately for earlier medical use. Based on this model, the authors found that drug coverage would increase drug spending by 12%–17% over five years, with smaller cost offsets from less use of other services. However, increased drug consumption would increase longevity, which would add to health care spending. As a result, drug coverage was predicted to result in small increases in Medicare Parts A and B spending after five years due to improved longevity. These estimates of the impact of drug coverage on drug spending were slightly lower than those of other study findings.

Updating MCBS data through 2001 and using the same methods, the authors found a similar (7%–27%) increase in drug spending over a five-year interval and similar effects on long-term health and spending (e.g., increased longevity and greater use of other services) (Yang et al, forthcoming). In a separate paper using the same techniques, the authors estimated the impact of different sources of drug coverage, showing a small but
significant subsequent year savings to Medicare from providing drug coverage (Yang & Norton, 2006).

In another study, also using multiple years of MCBS data as the basis for computer simulation, Shang (2005) estimated that Medigap drug coverage increased drug spending by 22%, but was offset by reductions in Medicare Part A (hospital spending) of 10%–13% ($277–$348 per capita per year). This study found the net effect to be that a $1 increase in drug spending was associated with an estimated $1.60–$2.00 decrease in annual Medicare spending. This study went on to model the cost effectiveness of drug treatment for hypertension on overall costs, assuming full patient adherence and accounting for changing morbidity and mortality over five years. In this cost-effectiveness analysis, the study found that, depending on drug price, the increased cost of drug therapy for hypertension was offset entirely by lower Medicare spending on other services, resulting in net annual savings to Medicare and increased longevity of beneficiaries. However, as in some of the other studies described, this study found that the long-term impact on total long-term Medicare spending was small due to greater spending for health care services during increased longevity. In addition to these findings, this study provides important methodological lessons (using a discrete factor econometric model) by demonstrating that adjusting for unobserved as well as observed characteristics of beneficiaries results in lower estimates of the cost of drug coverage, in contrast to models using only observable characteristics.

Using longitudinal MCBS data (1992–2000), Khan and associates (2007) estimated the effect of prescription drug coverage for the elderly on prescription drug use and health status to compare those who changed insurance status to those who did not. This study found that gaining public insurance increased drug use by 14% in the following year, while acquiring employer-sponsored insurance or HMO coverage increased drug use by 6%. Treating insurance coverage as unrelated to health (i.e., random) and adjusting for health status, they did not find drug coverage to be associated with health status, disability, or hospitalization rates in the year following acquisition of coverage.

In summary, available studies of the impact of prescription drug coverage for older Americans on non-drug services have produced a range of findings. However, there is general agreement that prescription drug coverage can produce cost offsets from reductions in non-drug services. Studies that incorporate increased longevity into spending projections suggest that cost offsets may diminish over time. On the other hand, longevity is a positive impact that may not translate to cost offsets or net savings.

Several of these recent studies make sophisticated efforts to account for selection bias as well as changes in health status and demand for insurance, drugs, and other services over time (Khan et al., 2007; Shang, 2005; Yang et al., 2004; Yang et al., forthcoming). By contrast, some studies do not correct adequately for selection bias or time-variant effects, and, as a result, they may overstate the impact of drug insurance on drug spending while understating drug insurance’s impact on other services (Briesacher, 2005; Stuart et al., 2004).

**D. Prescription Drug Benefit Design**

Numerous reviews have reviewed the literature on the impact of prescription drug insurance benefit design on drug use and spending (Adams, 2001b; Gibson et al., 2005; Goldman et al, 2007; Gruber, 2006; Lexchin & Grootendorst, 2004; Maio et al., 2005;
Rice & Matsuoka, 2004) and of administrative controls (Aeserud et al., 2006; Dewa & Hoch, 2003; Hoadley, 2005; Lyles & Palumbo, 1999; Maio et al., 2005; Soumerai, Ross-Degnan, Fortress, & Abelson, 1993; Soumerai, 2004). These studies have generally agreed on the following:

- Increased cost sharing leads to lower drug use and spending.
- Benefit limits, such as caps on drug spending and the number of prescriptions, reduce prescription drug use.
- Hospitalizations, nursing home use, and emergency department visits increase with limits to drug coverage, particularly in frail individuals and those with chronic conditions.

We summarize studies of the impact of benefit design in the following section with respect to particular design elements: administrative controls, benefit limits, cost sharing, and reference pricing.

1. Administrative Controls and Benefit Limits

Administrative controls are important mechanisms by which public and private payors control the type and amount of prescription drug use by patients. Common administrative controls, found in many drug benefit designs, include benefit limits, formulary design, and drug utilization review (prior authorization for drugs, step therapy, dosage unit limits, etc.). Recent less widely adopted administrative controls include financial incentives for providers and pharmacists as well as medication therapy management (a pharmacist’s periodic review and coordination of prescription drugs).

Soumerai et al. (1993) extensively reviewed drug utilization management policies used by state Medicaid programs and concluded that few well-designed studies applied adequate research methods to evaluate prescribing controls. This review found that administrative controls, such as prior authorization in particular, substantially decrease use of the targeted medications, but evidence was lacking on the effect of reduced drug use on health or other medical services. A recent update of the literature found that more research is still needed in this area (Soumerai, 2004).

Studies of prescription benefit caps have concluded that, although they limit use and cost of drug therapy, costs from increased use of other services outweigh savings associated with reduced drug use, at least for such vulnerable populations as the frail elderly. In a series of seminal studies assessing a limit on the number of prescriptions, Soumerai and associates found that restricting drug benefits with a monthly prescription limit reduced use of essential and nonessential drugs and increased overall Medicaid spending (Soumerai, Avorn, Ross-Degnan, & Gortmaker, 1987), and increased use of nursing homes, physician services, and emergency room visits (Soumerai, Ross-Degnan, Avorn, & McLaughlin, 1991)—particularly for mental health services (Soumerai, McLaughlin, Ross-Degnan, Casteris, & Bollini, 1994). Research on other Medicaid programs confirmed many of these findings (Cromwell, Bass, Steinberg et al., 1998; Martin & MacMillan, 1996). Experts often cite studies by Soumerai et al. (1987, 1991, 1994) as evidence that drug utilization controls lead to adverse outcomes and increase acute and long-term care use and spending. However, these studies were limited to frail elderly,
who were at the highest risk of hospitalization and, thus, may not be generalizable to a broader elderly population.

Drug expenditure limits have been evaluated as well. In a methodologically robust study (regression-adjusted, cross-sectional comparison), Hsu, Price, Huang, and Brand (2006) found that an expenditure cap in a health maintenance organization (HMO) was associated with 31% lower drug costs, together with higher emergency department use, more non-elective hospitalizations, and higher death rates. In the group with drug expenditure limits, non-adherence rates were higher for patients with hypertension, diabetes, and high cholesterol, and physiological outcomes were worse. Savings from reduced prescription drug use were offset by increased spending in other areas, and total medical spending did not differ significantly among groups. An important feature of this study was the availability of clinical data to link patient non-adherence to prescribed drug regimens in the group with expenditure caps to indicators of poorer clinical outcomes (higher blood cholesterol levels, higher blood pressure readings, and higher blood sugar levels in diabetics) in the group with expenditure caps. Opinion surveys of patients subject to drug benefit caps, as well as an analysis of insurance claims data, confirm the above findings that patients discontinue their medications after reaching a cap on drug benefits (Cox & Henderson, 2002; Fortress, Soumerai, McLaughlin, & Ross-Degnan, 2001; Joyce, Goldman, Karaca-Mandic, & Zheng, 2007; Schulz, Lingle, Chubon, & Coster-Schulz, 1995; Tseng, Brook, Keeler, & Mangione, 2003; Tseng, Brook, Keeler, Steers, & Mangione, 2004). While these findings may not be directly applicable, they have potentially important implications for the design of Medicare’s prescription drug benefit, which includes a gap in coverage, also known as the “donut hole.”

Formularies (lists of covered drugs) are another feature of most drug benefit plans. In a few controlled studies, closed formularies (those that limit which drugs are covered, versus open formularies, which impose no restrictions) were associated with lower drug expenditures, but the impact on non-drug services has been inconclusive, and generally these studies have not been well controlled for patient selection and differences across health plans. One study of working insured adults (Motheral & Henderson, 1999) indicated that closed formularies did not result in increased spending on other services. However, other studies did show increasing use of medical services in privately insured populations (Horn, Sharkey, & Phillips-Harris, 1998; Murawski & Abdelgawad, 2005) and decreasing use of hospital care in Medicaid (Kozma, Reeder, & Lingle, 1990). Christian-Hermann, Emons, and George (2004) found that a generic-only formulary decreased health plan drug use and costs across several chronic disease categories, increased member out-of-pocket spending, and resulted in an increase in hospital admissions. This study has particular relevance to Medicare because many Part D drug plans provide generic-only coverage, no brand-name drug coverage, in the coverage gap.

Clearly, more work is needed to evaluate the impact of formulary design as it affects use of other health care services and outcomes. In summary, a number of systematic studies have assessed particular administrative controls of drug use on health care spending. Almost all of these studies indicate that broad administrative controls lower drug spending, but do not adequately discriminate between types of drug spending that may be offset by reduced spending in other areas or health effects (either favorable or adverse), especially for individuals with chronic disease or who have low incomes.
2. Prescription Drug Cost Sharing and Spending for Non-Drug Services

Early study findings have varied regarding the effects of changes in copayments or coinsurance for prescription drug coverage on spending for other health care services (Balkrishnan, Byerly, Camacho, Shrestha, & Anderson, 2001; Fairman, Motheral, & Henderson, 2003; Johnson, Goodman, Hornbrook, & Eldredge, 1997a; Johnson et al., 1997b; Motheral & Fairman, 2001; Pilote, Beck, Richard, & Eisenberg, 2002; Tamblyn et al., 2001). Recent studies suggest that savings sought by payors from higher patient cost sharing for prescriptions drugs may be offset by higher medical costs (Chandra, Gruber, & McKnight, 2007; Cole et al., 2006; Dor & Encinosa, 2004; Gaynor, Li, & Vogt, 2006; Goldman et al., 2004; Goldman, Joyce, & Karaca-Mandic, 2006; Li, Guh, Lacaille, Esdaile, & Anis, 2007; Zeber, Grazier, Valenstein, Blow, & Lantz, 2007).

Studies that focus on higher drug cost sharing by patients with particular chronic diseases have found cost offsets from increased hospitalizations (Cole et al., 2006; Goldman et al., 2004; Zeber et al., 2007).

Several observational studies have used a natural experimental design with comparison groups, adjusted for observable patient-related characteristics, to assess the impact of patient cost sharing. Tamblyn and associates (2001) found that introducing 25% coinsurance for an elderly, low-income Canadian population led to a decrease in use of both essential medications (down 9%) and less essential medications (down 14%), while adverse events doubled. Another Canadian study of post-heart attack patients found no significant effects from a modest increase in drug cost sharing on drug use or other services after one year (Pilote et al., 2002). However, the authors note that this finding may be limited to patients who have experienced a serious medical event, such as a heart attack.

A study of elderly HMO enrollees who received prescription drug coverage under two different formularies found that across-the-board limits on patient drug spending were associated with a significant increase in total HMO costs. On the other hand, the formulary that expanded access to generic drugs but did not limit patient drug spending per se was associated with a 6% decline in total HMO costs. However, the results may have been confounded because the formulary changes were implemented at different times, and the study lacked adequate controls (Balkrishnan et al., 2001). Fairman and associates (2003) and Motheral and Fairman (2001) found the greatest effect of a three-tier formulary (e.g., increasing copayments for generic, preferred, and non-preferred brand-name drugs) was shifting drug costs to health plan enrollees. This study found no change in inpatient or outpatient spending after one year or three years; however, cost-sharing increases were quite small.

Recently, Chandra and associates (2007) analyzed the differential impact of prescription drug cost sharing on the Medicare program and private supplemental (Medigap) insurers. This study compared the impact of increased cost sharing for California enrollees in Medicare Advantage plans (HMOs and preferred provider organizations [PPOs]) who also had supplemental drug coverage from their former employer. This study found that demand was highly responsive to cost sharing across drug categories (i.e., drugs for acute, chronic, and discretionary use), particularly for HMO enrollees. At the same time, higher patient cost sharing resulted in a net saving for Medigap insurers. While this study had non-trivial limitations (simultaneous increases in cost sharing across services, and analysis at the plan level rather than the level of individual members), it is the only one to
compare the impact of prescription drug cost sharing on the Medicare program and Medigap insurers. The findings from this study have important policy implications for Medicare, which incurred higher program costs from hospitalizations associated with decreased prescription drug use.

Other studies have shown a strong response to prescription drug cost sharing and a strong offset effect on medical service use. Using cross-sectional data, Goldman and associates (2004) found that doubling copayments for working-age, insured adults decreased prescription drug use by one-third to one-half, but increased emergency visits by 17% and hospital days by 10%. The authors cautioned that copayments for other services may have changed simultaneously with drug copayments, which could have confounded the study results.

In a study based on a large multiemployer database of prescription drug and medical claims (MarketScan), adjusted for changing individual health status and other differences, Gaynor and associates (2006) found that, for insured individuals under age 65, a $1 increase in drug cost sharing reduced drug spending (through fewer prescriptions) by $23.62 in the first year, and $32.57 by the second year. However, because patients substituted outpatient care for drugs, total medical spending decreased by less than that amount: $20.88 in the first year and $21.23 by the second. In the long run, drug savings from higher cost sharing were largely offset by increases in spending for outpatient care. The authors conclude that higher drug cost sharing may not control health spending; however, this finding was revealed only through lagged (i.e., time series) analysis.

Dor and Encinosa (2004) used cross-sectional data from a large insured population to compare the differential impact of drug coverage with flat copayments (a fixed-dollar amount regardless of total price per prescription) to coinsurance (a fixed percent of the full drug price). In an insured adult diabetic population, the study found that coinsurance decreased patient compliance (i.e., reduced refills of diabetes medication) to a greater degree than did fixed-dollar copayments. Drawing on other research, the authors estimated that a $6–$10 increase in drug copayments would result in $125 million per year contemporaneous savings in national spending on diabetes drugs, but would increase spending for other medical services by $360 million per year, for a net national cost of $235 million annually.

In a Canadian study, Li et al. (2007) found that cost sharing by seniors with rheumatoid arthritis had relatively little impact on prescription drug use (i.e., price elasticity for drugs was low), but physician visits increased because, in Canada, such visits require no cost sharing. The authors concluded that there was a strong incentive to substitute physician services for prescription drugs.

In a computer simulation, Goldman et al. (2006) used Medicare (MCBS) data to estimate the effect of “evidence-based copayments” on treatment of high cholesterol. They found that a “value-based insurance design” that eliminated copayments for medium- and high-risk individuals, and increased copayments to $22 for low-risk individuals, would result in net savings by avoiding 80,000 hospitalizations and 31,000 emergency department visits per year.

Other studies of health plans and employer groups have also reported savings from such value-based insurance designs (Chernew, Rosen, & Fendrick, 2007; Mahoney, 2005), but
these have not been rigorous or well controlled. One controlled time-series study assessed the impact of value-based insurance design on drug adherence in a disease management environment (Chernew et al., 2008). Although this study was limited to two employer groups, the authors found that lower copayments for chronic disease treatment resulted in greater adherence to diabetes medications and several categories of heart disease medications. This study did not measure the impact of such a plan design on medical services, but it does suggest that this approach to coverage promotes better adherence to medications for patients most at risk and may prevent disease complications.

3. Reference Pricing

Reference pricing, a cost-sharing approach in which one or several medications within each class is fully covered, but individuals must pay the extra cost of higher-priced drugs in the class, has been evaluated in a series of Canadian studies for anti-hypertensives, anti-ulcer drugs, anti-angina drugs, and non-steroidal anti-inflammatory drugs (Hazlet & Blough, 2001; Grootendorst et al., 2005; Grootendorst & Stewart, 2006; Marshall et al., 2002; Schneeweiss, Dormuth, Grootendorst, Soumerai, & Maclure, 2004; Schneeweiss, Walker, Glynn, Maclure, Dormuth, & Soumerai, 2002). The studies that assessed the impact of reference pricing on non-drug health services found that it resulted in net savings to the province of British Columbia, with either no change in spending for other services (Hazlet & Blough, 2001) or a transitory spending increase in physician and hospital care that subsided after two months (Schneeweiss et al., 2002, 2004).

E. Newer versus Older Drugs

In a series of studies, Lichtenberg (2001, 2002) has attempted to demonstrate that newer (patent-protected, brand-name) drugs that generally cost more than older (brand-name and generic) drugs are associated with greater offsets in non-drug spending. These studies generally have found that newer drugs are more effective, have fewer side effects, and are associated with lower overall medical expenditures than are older drugs. However, these studies suffer from several methodological weaknesses that have raised concerns regarding these findings, including confounding from a concurrent slowdown in overall health care spending, changes in prescribing patterns, and differences in disease severity. Raising additional questions about these findings, other studies using individual-level data of prescription drug use for mental health conditions have found that new antipsychotic medications had the opposite effect on Medicaid populations—that is, while newer drugs may have offered clinical advantages, they did not reduce spending on other medical services (Del Paggio, Finley, & Cavano, 2002; Duggan 2005; Frank et al., 2006). In a literature review, Mintzes and Lexchin (2005) concluded that only 5% of drugs introduced in Canada from 1996 to 2000 offered improved effectiveness over older, less expensive drugs and, thus, credited no net savings to overall health spending.

Our review found no studies of potential cost offsets that may be associated with the relatively new category of specialty drugs, known as biologics.

VI. NATURE AND QUALITY OF THE EVIDENCE

Studies regarding cost offsets that may be associated with broad-based prescription drug coverage and expanded utilization employ a wide range of methodologies to analyze existing data sets retrospectively. While many researchers hold out randomized, controlled trials (RCTs) as the “gold standard” for establishing causation and replicable
results, there is a notable absence of such rigorous studies in the literature regarding prescription drug cost offsets. Further, for a host of reasons (e.g., time, expense, difficulty randomizing, and questions about generalizability), RCTs on this topic are unlikely to be forthcoming anytime soon. While some might find observational studies more reliable if performed prospectively (depending on a variety of factors, such as sample size, size of expected effects, etc.), this review found no such prospective studies of prescription drug coverage or use.

The literature on the topic consists almost entirely of retrospective observational studies based on claims data and/or self-reported data from a variety of sources. These types of studies are quicker and less expensive to perform than are prospective studies. Also, studies that rely on existing data sources are more likely to describe real-world behavior than are prospective studies, which often create artificial conditions. In addition, retrospective studies have the advantage of being able to derive statistical power from large data sets and, thus, are more likely to detect more subtle effects than are prospective studies, which often rely on smaller sample sizes.

As described above, methodological issues, particularly selection bias, associated with this type of research are substantial. Studies that compare analytic techniques indicate that inadequately controlling for selection bias tends to produce overestimates of the impact of insurance on drug use and spending. Several sources of selection bias include incomplete information regarding the extent to which:

- sicker people are more likely to seek drug insurance coverage than are healthier people;
- people are likely to select benefit design features in ways that correlate with their health status;
- changes in health status are likely to influence demand for prescription drugs; and
- use of prescription drugs and non-drug medical services influence each other.

More recent studies have used enhanced methods, such as indirect econometric corrections, to better account for biases and data limitations. Recent studies have revealed the importance of accounting for delayed responses (i.e., lagged effects) to prescription drug coverage and use (Briesacher, 2005; Chandra et al., 2007; Gaynor et al., 2006; Zeber et al., 2007), and unobserved factors, such as health status (Chandra et al., 2007; Yang & Norton, 2006). However, even the most recent observational studies do not entirely agree on the size of cost offsets that may be associated with prescription drug coverage and use—for example, Shang (2005) found significant cost offsets, whereas Yang and associates (2004, forthcoming) found minimal overall cost offsets.

Some recent studies have produced promising results by combining claims data with results from clinical trials in computer simulations that model health and spending effects of prescription drugs on specific clinical conditions (Goldman et al., 2006; Rosen et al., 2005; Shang, 2005). However, examining the impact of drug use on a disease-specific basis has important limitations, since many older Americans have a number of conditions. While some studies of prescription drug effects have simulated the effects of increased longevity and disability, as well as cost offsets (Joyce, Keeler, Shang, &
Goldman, 2005; Yang et al., 2004), these studies have not taken fully into account the value of related benefits (e.g., improved physical and emotional health status, quality of life, and productivity).

VII. CONSENSUS FINDINGS

Based on more rigorous studies, researchers generally agree on and support the following broad findings:

- Prescription drug coverage can produce cost offsets from reductions in non-drug services, such as hospitalizations and emergency visits.
- Studies that incorporate increased longevity into spending projections suggest that cost offsets may diminish over time.
- Strict benefit limits of all kinds (spending caps or number of prescriptions) decrease prescription drug use and increase use of other medical services, including acute and long-term care services.
- Increased prescription drug cost sharing decreases the use of essential, as well as nonessential, classes of medications.
- In general, increased patient cost sharing reduces use and spending for prescription drugs, with a 10% increase in drug cost sharing being associated with a decrease in drug use of approximately 1%–6%.
- Appropriate use of prescription drugs leads to improved health outcomes for many chronic conditions in the elderly.
- Prescription drug coverage increases drug use by as much as 20% and improves patient adherence to medication regimens.
- The effects of acquiring prescription drug coverage and increased cost sharing on prescription drug use, use of other medical services, and health outcomes are often delayed, so accounting for them warrants at least a 12-month follow-up.

A considerable lack of consensus remains in important areas:

- The magnitude of cost offsets associated with broad changes in prescription drug coverage and/or use has not been determined reliably.
- Whether cost offsets that arise produce net savings after costs associated with increased prescription drug used are taken into account.
- The effects of various drug benefit design features (e.g., caps, cost sharing, formularies, etc.) on cost offsets to non-drug services.

Finally, although it was not the central focus of this paper, the review found a dearth of evidence regarding the effects of broad changes on prescription drug coverage on disability or quality of life.
VIII. POLICY IMPLICATIONS
Broadly based consensus findings from this review suggest some important policy implications, including the following:

- Appropriate prescription drug use should be encouraged, particularly among the elderly with chronic conditions.

- When patient adherence to prescription drug regimens is less than optimal, it can be improved by reducing prescription drug prices for patients by adding coverage for the uninsured and reducing cost sharing for those who have prescription drug coverage. However, increased adherence will increase prescription drug spending.

- One may need to target cost sharing for prescription drugs may by type of medication and patient condition (through programs such as value-based insurance design) to minimize unintended consequences in other areas, such as non-drug spending and health outcomes.

- We may reduce unintentional increased use and spending for non-drug services by avoiding strict benefits limits on prescription drug use.

- We should view with skepticism study findings that do not take delayed effects into account.

In addition to the policy implications of these study findings, further clarification of the impact of prescription drug coverage and benefit design would enable a range of stakeholders (e.g., patients, payors, and policy makers) to make more informed choices. Questions that need to be addressed include the following:

- What are the effects of high cost sharing and significant gaps in prescription drug coverage, such as those found in high-deductible health plans (i.e., health savings accounts) and the Medicare Part D drug benefit (i.e., the donut hole)?

- What are the effects of prescription drug coverage and patient adherence, not only on cost offsets from other medical services, but also on health status, quality of life, and productivity?

- What are the effects of targeted coverage designs such as differential cost sharing for particular drugs or classes to encourage more use of effective drugs in the patients who would most benefit?

IX. RECOMMENDATIONS FOR FUTURE RESEARCH
To understand these issues better, researchers should consider undertaking future studies that combine the sophisticated analytic techniques used in some of the recent studies reviewed in this paper with prospective studies and/or data sets representing natural experiments (where legal or policy changes have produced substantial changes in the scope of prescription drug coverage, such as the recent addition of a Medicare prescription drug benefit). While study designs using natural experiments may still suffer from methodological limitations (i.e., bias, limited generalizability, etc.), they do offer important opportunities to sort out the effects of changes in prescription drug coverage.
and, in particular, different benefit designs. Future studies that rely on retrospective observational data should account for the following:

- trends over time based on longitudinal data (preferably based on individual patient records, rather than on aggregate data);
- interactions between use of medical services and unobserved variables, such as health status;
- interactions among changes in prescription drug coverage, drug use, and use of and spending for non-drug services; and
- delayed or lagged effects of changes in prescription drug coverage, drug use and its effects on health, disability (and function), longevity, quality of life, and productivity (based on follow-up for at least 12 months).

Implementation of Medicare Part D’s prescription drug benefit under the Medicare Modernization Act of 2003 offers a potentially rich database and new challenges for understanding the impact of prescription drug use in real-world settings. However, data from Medicare Part D which was implemented in 2006 have not been released. In addition, wide variations in benefit designs allowed under Part D (e.g., different cost sharing, coverage gaps, formularies, and medication therapy management) will make it challenging to sort out the effects on prescription drug use and cost offsets from the effects on other non-drug services.

Future studies will need to assess the impact of the new Part D drug benefit on:

- access of Medicare beneficiaries to different types of prescription drugs,
- effects on subpopulations within Medicare, and
- effects of different health care delivery arrangements (i.e., HMOs versus fee-for-service, freestanding drug plans versus integrated health plans).

Responses to these questions will have important implications for policy and budget purposes. In addition, Part D data may make it possible to better identify longer-term effects of prescription drug coverage on health outcomes, such as disability and quality of life, as well as costs (both drug costs and cost offsets from other services). However, Medicare studies will require linking drug data from Part D with hospital claims data from Part A and physician claims data from Part B. Sorting out the effects of various benefit designs may be facilitated by linking Medicare data with non-Medicare data sets, such as Medicare supplemental insurance (i.e., Medigap) and commercial claims for patients before they became Medicare eligible.

To fully explore the data and parse these and other questions with important policy implications, academic and other private researchers will need to have timely access to longitudinal combined Medicare data sets.
X. CONCLUSION

Overall, it appears reasonable to conclude that prescription drug coverage improves health outcomes for many chronic conditions in the elderly and increases drug spending. It also appears to produce cost offsets from reduced utilization of non-drug services, at least to some extent. However, many questions remain about the extent and focus of these effects and how best to increase desired effects and minimize unintended and undesirable consequences.

If finding answers to relevant questions in this area is left to uncoordinated, underfunded research, studies are likely to produce piecemeal results and unlikely to provide definitive answers to many questions of interest to researchers and other stakeholders. As a result, policy makers and payors should consider funding research specifically designed to better estimate the broad population effects of prescription drug use on overall spending and health.
REFERENCES


How Prescription Drug Use Affects Health Care Utilization and Spending by Older Americans: A Review of the Literature


APPENDIX
## Summary Table of Studies Reviewed

<table>
<thead>
<tr>
<th>Reference</th>
<th>Population / Location</th>
<th>Rx Drug or Class</th>
<th>Outcome Measures / Statistical Method</th>
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<td><strong>Effects of Prescription Drug Coverage</strong></td>
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<td>Atherly, A. (2004). The effect of prescription drug coverage on the cost of care to Medicare beneficiaries with asthma. Expert Review of Pharmacoeconomics Outcomes and Research, 4, 421-428.</td>
<td>U.S., Medicare, elderly</td>
<td>N/A</td>
<td>Outcome variable: medical expenditures. Linear probability models; instrumental variables; MCBS data source.</td>
<td>For individual plans, there was unobserved adverse selection of plans with drug benefits and unobserved favorable selection of plans without. Individual supplemental plans without Rx drugs increased Medicare expenditures by $914 annually; those with drugs increased Medicare expenditures by $491. Employer policies also significantly increased Medicare expenditures ($207 without drug coverage and $447 with drug coverage), but the increase was less than that associated with individual policies.</td>
</tr>
<tr>
<td>Briesacher, B. Medicare beneficiaries and the impact of gaining prescription drug coverage on inpatient and physician spending. (2005) Health Services Research, 40 [5 part 1], 1279-1296.</td>
<td>U.S., Medicare</td>
<td>N/A</td>
<td>Outcome variables: total Rx drug expenditures, Medicare hospital expenditures, &amp; Medicare MD expenditures; estimated by a series of fixed-effects, 2-year panel models (1995 and 2000 MCBS data), multivariate models.</td>
<td>Persons gaining drug coverage at any point spent 20% more on drugs than those with none; a subsample gaining year-end coverage (and followed up longer) spent 66% more after the first year with coverage, compared to 8% more for those with no coverage. No consistent evidence that drug coverage either increases or reduces spending for hospital or MD services. Findings from small sample, only suggestive.</td>
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<td>Lingle, et al. (1987). The impact of outpatient drug benefits on the use and costs of health care services for the elderly. Inquiry, 24, 203-211.</td>
<td>U.S., Medicare, elderly, NJ &amp; PA</td>
<td>N/A</td>
<td>Outcome variables: total utilization &amp; cost for Medicare services, total PAA program drug costs, total PAA program administrative costs. Quasi-experimental design; regression analysis.</td>
<td>NJ Medicare recipients used, on average, $238.50 less in inpatient hospital care under the Rx assistance (PAA) program than did their counterparts in eastern PA, who did not have access to the program. Two points in time with limited causal evidence.</td>
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<td>Stuart, et al. (2004) Impact of prescription coverage on hospital and physician costs: A case study of Medicare beneficiaries with chronic obstructive pulmonary disease. <em>Clinical Therapeutics</em>, 26, 1688-99.</td>
<td>U.S., Medicare, elderly</td>
<td>COPD</td>
<td>Outcome variables: drug spending, hospitalizations, MD services. MCBS data. Logistic regression with propensity scoring to adjust for selection.</td>
<td>After adjustment, drug coverage was associated with 61% higher spending on medications and 29% lower spending on MD services (both, P &lt; 0.05). Hospital costs appeared slightly lower for those with drug benefits, but the difference was not statistically significant.</td>
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<td>Balkrishnan et al. (2001). Effect of prescription benefit changes on medical care utilization in a Medicare HMO population. <em>American Journal of Managed Care</em>, 7, 1093-1100.</td>
<td>U.S., Medicare, HMO</td>
<td>N/A</td>
<td>Bivariate and multivariate analyses. Outcome variables: health care services, Rx costs, total annual costs. Panel data, random-effects regression model.</td>
<td>An evidence-based formulary with expanded generic coverage was associated with a significant decrease of 27% in Rx costs, a 4% decrease in MD visits, and a 6% decrease in total costs. A formulary with coverage limits resulted in a 29% increase in Rx costs and a 38% increase in total costs for the HMO.</td>
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<tr>
<td>Chandra et al. (2007). Patient cost-sharing, hospitalization offsets, and the design of optimal health insurance for the elderly. National Bureau of Economic Research, Working paper no. 12972. Retrieved from <a href="http://www.nber.org/papers/12972">http://www.nber.org/papers/12972</a>.</td>
<td>Retired Public Employees, California (CalPERS) Medicare population</td>
<td>N/A</td>
<td>Plan-level data. Regression-adjusted effects of increased cost sharing on MD services, pharmaceuticals and hospitalizations/ separate impact for Medicare; continuously enrolled for three years, 1/2000 - 9/2003. HMO and PPO design changes analyzed separately.</td>
<td>MD visits and Rx drugs are highly price-sensitive among the elderly in both types of plans regardless of policy changes. Higher cost sharing for Rx and MD visits in HMO increased hospital use, especially for those with chronic illness or high previous medical spenders. Supplemental (Medigap) insurer received savings due to cost sharing and decreased use while Medicare had net cost increase due to hospitalization increases. Results are confounded by simultaneous change in cost sharing for and decrease in MD visits.</td>
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<tr>
<td>Christian-Herman, et al. (2004). Effects of generic-only drug coverage in a Medicare HMO. <em>Health Affairs</em>, web exclusive, w4-455-68. Retrieved December 1, 2006 from <a href="http://www.healthaffairs.org">http://www.healthaffairs.org</a>.</td>
<td>U.S. Medicare HMO, CA</td>
<td>N/A</td>
<td>Outcome variables: out-of-pocket costs, hospital admissions, generic Rxs. Case group/control group using administrative HMO data.</td>
<td>Out-of-pocket spending increased for case group by $16.60 between 2001 and 2002 (from $30.90 - $47.50) but only by $14.22 for control group (from $26.27 - $40.49) (p &lt;.0001). In 2002, the case group had an increase of 3.02 admissions/1,000 while the control group had a decrease of 0.22 admissions/1,000. Both the case and control groups increased their use of generic medications between 2001 and 2002, but the increase was larger in the case group.</td>
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<td>Cole, et al. (2006). Drug copayment and adherence in chronic heart failure: Effect on cost and outcomes. <em>Pharmacotherapy</em>, 26(8), 1157-1164.</td>
<td>U.S. insured population, 2002 - 2003</td>
<td>Congestive heart failure (CHF) - ACE inhibitors and beta blockers</td>
<td>Outcome variables: risk of hospitalization, medical costs. Two-stage regression, one-year post-implementation.</td>
<td>ACE inhibitors (anti-hypertensives): $10 increase in copayment led to 2.6% decrease in adherence, 0.8% decrease in medical costs, 6.1% increase in risk of hospitalization. Beta blockers: $10 increase in copayment led to 1.8% decrease in adherence, 2.8% decrease in medical costs, and 8.7% increase in risk of hospitalization.</td>
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<td>Dor, A. &amp; Encinosa, W. (2004, August). Does cost sharing affect compliance? The case of prescription drugs. National Bureau of Economic Research, Working paper no.10738. Retrieved from <a href="http://www.nber.org/papers/w10738">http://www.nber.org/papers/w10738</a>.</td>
<td>U.S., Adults age 18+, diabetics, commercial insurance</td>
<td>Diabetes</td>
<td>Outcome variables: full, partial, or non-compliance with refill for diabetic medication, using MarketScan drug claims data and Employer Eligibility data. Cross-sectional data, ordered logit model.</td>
<td>In the coinsurance model, an increase in the coinsurance rate from 20% to 75% increased non-compliance by 9.9%, and reduced full compliance by 24.6%. For copayments, an increase in copay from $6 to $10 resulted in a 6.2% increase in never-compliers and a 9% reduction in full compliers. Using available aggregate estimates of the cost of diabetic complications, a $6 - $10 increase in copayment would have the direct effect of reducing national drug spending for diabetes by $125 million. However, the increase in non-compliance rates is expected to increase the rate of diabetic complications, resulting in an additional $360 million in treatment costs (net cost = $235 million annually).</td>
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<tr>
<td>Duggan, M. (2005). Do the new prescription drugs pay for themselves? The case of second-generation antipsychotics. <em>Journal of Health Economics</em>, 24, 1-31.</td>
<td>U.S., CA, Medicaid, age 18+</td>
<td>Anti-psychotics in schizophrenia</td>
<td>Outcome variables: cost of antipsychotic drugs, total inpatient/outpatient Medicaid spending. Logistic regression used.</td>
<td>The 610% increase in Medicaid spending on antipsychotic drugs during the study period caused by the shift to three new treatments has not reduced spending on other types of medical care. Because of data limitations, the findings for health outcomes are speculative but suggest that the new medications have increased the prevalence of diabetes while reducing the prevalence of extrapyramidal symptoms among the mentally ill.</td>
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<td>Fairman, K.A. et al. (2003). Retrospective, long-term follow-up study of the effect of a three-tier prescription drug copayment system on pharmaceutical and other medical utilization and costs. <em>Clinical Therapeutics</em>, 25, 3147-3161.</td>
<td>U.S., commercially insured PPO members</td>
<td>All, including estrogens, anti-hypertensives, and anti-hyperlipidemics</td>
<td>Outcome variables: total drug cost; net insurer cost (drug cost - copayment); number of Rx claims; number of MD visits, inpatient hospitalizations, and ER visits; and rates of continuing with chronic medication therapy. Quasi experimental, pre-post with comparison group; Logistic and Cox regression.</td>
<td>Relative to the comparison group (n = 4132), the intervention group (n = 3577) showed less growth in net cost and lower use of third-tier (non-formulary) medications (P &lt; 0.001 and P &lt; 0.01, respectively). The intervention and comparison groups did not differ significantly in numbers of office visits, ER visits, or inpatient hospitalizations. Rx continuation rates were lower for the intervention than for the comparison group at 6 months for oral contraceptives (P &lt; 0.05), but chronic Rx continuation rates did not differ significantly at any other time or for estrogens, anti-hypertensives, or anti-hyperlipidemics.</td>
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<td>Goldman et al. (2004). Pharmacy benefits and the use of drugs by the chronically ill. <em>Journal of the American Medical Association</em>, 291(19), 2344-2350.</td>
<td>U.S., adults age 18 - 64, commercial insurance</td>
<td>Anti-inflammatories (NSAIDs), anti-histamines, anti-hypertensives, anti-asthmatics, anti-ulcerant, anti-diabetic, anti-hyperlipidemic, anti-depressant</td>
<td>Outcome variable: relative change in drug days supplied. Retrospective study, pharmacy claims data. 2-part model: probit plus generalized linear model regression.</td>
<td>Doubling copayments was associated with reductions in use of 8 Rx classes. The largest decreases occurred for NSAIDs (45%) and anti-histamines (44%). Reductions in overall days supplied of anti-hyperlipidemics (34%), anti-ulcers (33%), anti-asthmatics (32%), anti-hypertensives (26%), anti-depressants (26%), and anti-diabetes (25%) were also observed. Among patients diagnosed with a chronic illness and receiving ongoing care, use was less responsive to copayment changes. Use of anti-depressants declined by 8%; use of anti-hypertensives decreased by 10%. Larger reductions were observed for NSAIDs (27%), anti-histamines (31%), and anti-diabetes drugs (23%).</td>
</tr>
<tr>
<td>Hazlet, T.K. &amp; Blough, D.K. (2001). Health services utilization with reference drug pricing of histamine 2 receptor antagonists in British Columbia elderly. <em>Medical Care</em>, 40, 640-649.</td>
<td>Pharmacare beneficiaries, British Columbia, Canada</td>
<td>Five therapeutic classes of drugs, including histamine-2 receptor antagonists (H-2 RAs)</td>
<td>Outcome variables: medical services. Longitudinal generalized linear model, controlling for age, sex, and Rxs in unique drug classes; trend lines in each of these time series were compared for 3 periods.</td>
<td>For Rxs, MD office visits, lab, ER visits, hospitalizations, and hospital length of stay, no worsening of health outcomes associated with implementing the reference pricing policy.</td>
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<td>Hsu, et al. (2006). Unintended consequences of caps on Medicare drug benefits. <em>The New England Journal of Medicine</em>, 354 (22), 2349-2359.</td>
<td>U.S., Medicare, HMO</td>
<td>Multiple</td>
<td>Outcome variables: Rx costs, total medical costs, ED visit rate, non-elective hospitalization rate, death rate. Prospective cohort design. Medicare+Choice claims data, 2-part model with logistic regression for probability of any cost and linear regression of costs.</td>
<td>Subjects whose benefits were capped had pharmacy costs for drugs that were 31% lower than those of subjects whose benefits were not capped but had total medical costs that were only 1% lower. Subjects whose benefits were capped had higher relative rates of visits to the ER (relative rate, 1.09), non-elective hospitalizations (relative rate, 1.13), and death (relative rate, 1.22); difference, 0.68 per 100 person-years (0.30 to 1.07).</td>
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<tr>
<td>Johnson, et al. (1997a). The effect of increased prescription drug cost-sharing on medical care utilization and expenses of elderly health maintenance organization members. <em>Medical Care</em>, 35, 1119-1131.</td>
<td>Medicare, HMO</td>
<td>Multiple</td>
<td>Outcome variables: Rx expenses, copayments, medical care expenses; ANCOVA analysis on 2 years of Kaiser-Permanente claims data.</td>
<td>Increased copayment of $1 - $3, from $3 - $5 and from 50% per dispensing to 70% per dispensing with a maximum payment per Rx resulted in lower annual per capita Rx drug use and expenses. No consistent effect on medical care use (MD visits, ER visits, home healthcare visits, hospitalizations) or total medical care expenses.</td>
</tr>
<tr>
<td>Johnson et al. (1997b). The impact of increasing patient prescription drug cost sharing on therapeutic classes of drugs received and on the health status of elderly HMO members. <em>Health Services Research</em>, 32(1), 103-122.</td>
<td>Medicare, HMO</td>
<td>Multiple</td>
<td>Outcome variables: annual change in dispensing, Rx expenses, copayments, medical care expenses; ANCOVA analysis on 2 years of Kaiser-Permanente claims data.</td>
<td>See above for design. Relative exposure, annual days of use, and Rx drug costs for drugs used in self-limiting conditions and in progressive chronic conditions were not affected consistently. Health status may have been adversely affected. Larger increases in copayments appeared to generate more changes. Small changes in copayments did not appear to affect outcomes substantially.</td>
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<td>Kozma, et al. (1990). Expanding Medicaid drug formulary coverage. Effects on utilization of related services. <em>Medical Care</em>, 28, 963-977.</td>
<td>U.S., Medicaid N/A</td>
<td>N/A</td>
<td>Outcome variables: number of Rxs, MD visits, outpatient visits, and inpatient hospital admissions. Repeated measures design; multivariate ANOVA.</td>
<td>Increases were observed in the number of Rxs, MD visits, and outpatient visits, while the number of inpatient hospital admissions declined. Similarly, expenditures increased for all services except the inpatient hospital. The proportion of variance explained by the formulary change was small in all service areas, but would be of practical significance because of the large number of Medicaid recipients affected. From a theoretical perspective, a reduction in inpatient hospital use and expenditures following the elimination of drug formulary restrictions is particularly noteworthy.</td>
</tr>
<tr>
<td>Li et al. (2007). The impact of cost sharing of prescription drug expenditures on health care utilization by the elderly: Own- and cross-price elasticities. <em>Health Policy</em>, 82, 340-347.</td>
<td>8,107 Canadian seniors with rheumatoid arthritis, 2001 - 2002</td>
<td>Rheumatoid arthritis (RA)</td>
<td>Estimated own-price and cross-price elasticities for Rx drugs and MD visits, using instrumental variables to adjust for RA severity.</td>
<td>Price elasticity for Rx drugs was (-0.11) (plan A) and (-0.20) (plan A1); cross-price elasticity for MD visits was positive and significant: 0.04 (plan A) and 0.06 (Plan A1) one year following change. No analysis of cost offsets, total savings, or hospitalization.</td>
</tr>
<tr>
<td>Lichtenberg, F. (2001). Are the benefits of newer drugs worth their cost? Evidence from the 1996 MEPS. <em>Health Affairs</em>, 20(5), 241-251.</td>
<td>U.S., all ages</td>
<td>New drugs</td>
<td>Outcome variables: mortality, morbidity indicators, and spending on non-drug medical events. MEPS data. Pooled data, multivariate analysis.</td>
<td>People consuming newer drugs were significantly less likely to die by the end of the survey and were significantly less likely to experience work-loss days than were people consuming older drugs. Use of newer drugs tends to lower all types of non-drug medical spending, resulting in a substantial net reduction in the total cost of treating a given condition. Does not adjust for other unrelated system changes over time.</td>
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<td>Motheral, B. &amp; Fairman, K. (2001). Effect of a three-tier prescription copay on pharmaceutical and other medical utilization. <em>Medical Care</em>, 39(12), 1293-1304.</td>
<td>U.S., commercial insurance, PPO</td>
<td>N/A</td>
<td>Outcome variables: total Rx claims and costs, net costs (total - copay), medication continuation, MD visits, and inpatient and ER use. Quasi-experimental with pre-post comparison group. Mann-Whitney test. Logistic, linear and Cox regression analysis.</td>
<td>Relative to the comparison group, the intervention group experienced lower Rx use and expenditures and reduced net costs. Rx continuation rates were lower at 6 and 11 months in one of four chronic therapy classes examined; however, discontinuation could not be clearly linked to tier-three medication use. No significant differences in MD office visits, inpatient, or ER use rates were found.</td>
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<tr>
<td>Murawski, M.M. &amp; Abdelgawad, T. (2005). Exploration of the impact of preferred drug lists (PDL) on hospital and physician visits and the costs to Medicaid. <em>American Journal of Managed Care</em>, 11, sp35-sp42.</td>
<td>U.S., Medicaid Cardiovascular patients</td>
<td>Outcome variables: cardiovascular-related inpatient and outpatient hospital visits and procedures, and MD visits and procedures. A regression-based, difference-in-differences retrospective analysis using patient-level claims data.</td>
<td>There was a statistically significant increase in the number of outpatient hospital visits and MD visits for the test group compared to the control group in the first 6 months after PDL implementation. There was a positive but statistically insignificant increase in the number of inpatient hospital visits. In the second 6 months, MD visits for the test group increased but the increase was not statistically significant. As a result, estimated average Medicaid reimbursement costs for cardiovascular patients in the state increased during that year.</td>
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<tr>
<td>Pilote, et al. (2002).</td>
<td>Canada, age 65+</td>
<td>AMI treatment, including β-blockers, lipid lowering agents, ACE inhibitors, and aspirin</td>
<td>Outcome variables: Rx rates for essential cardiac medications for patients admitted before and after the policy reform, and cardiac procedures, readmissions for cardiac-related complications, outpatient visits to MDs and ERs, and mortality rate. Claims data, logistic regressions with Bonferroni correction.</td>
<td>The proportion of patients who received Rxs for β-blockers, ACE inhibitors, and lipid-lowering drugs increased over time and, more specifically, did not appear to decline with the change in drug policy. In addition, the policy reform did not appear to affect persistence of drug therapy (the proportion of time for which patients were covered by Rxs over the year after discharge). There was no within-class shift from more to less expensive drugs. Use of cardiac procedures increased over time, but this increase was unrelated to the date of the policy reform. Finally, rates of readmission for complications, visits to individual MDs and ERs, and mortality rate were unchanged.</td>
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<td>Popovian, et al. (1999).</td>
<td>U.S., Medicare, HMO</td>
<td>N/A</td>
<td>Outcome variables: Rx expenditures; total health care costs. Retrospective analysis of claims data; 2-part model - logistic regression of use of benefits; linear regression of amount of costs.</td>
<td>Medicare HMO enrollees with two pharmaceutical capitation MD medical groups (PMGs) had 10% higher mean total health care costs and 20% higher Rx costs, and a greater percentage of these patients had Rx expenditures than did patients in the non-Rx capitation PMG. The Rx capitation patients were also 70% more likely to incur higher total health care expenditures and 69% more likely to incur higher Rx expenditures. When controlling for age, gender, and severity of illness, Rx capitation patients had 14% higher total health costs than non-capitated patients (an additional $376 per patient per year) and 29% higher Rx costs ($110 per patient per year).</td>
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**Effects of Prescription Drug Cost Sharing and Other Benefit Design Features on Insured Populations**


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<td>Schneeweiss, S., et al. (2003). Clinical and economic consequences of reference pricing for dihydropyridine calcium channel blockers. <em>Clin Pharmacol Ther</em>, 74(4), 388-400.</td>
<td>Canada, age 65+, British Columbia</td>
<td>Calcium channel blockers (CCBs)</td>
<td>Outcome variables: Rx use, Rx expenditures, MD visits, hospitalizations, long-term care, and net savings. Quasi-experimental longitudinal study using Pharmacare claims data; logistic &amp; Poisson regression.</td>
<td>The start of reference pricing was followed by a significant reduction in high-priced CCBs (-150 doses per month per 10,000 elderly persons), with a corresponding increase in fully covered CCBs (+116). Overall, anti-hypertensive use did not decline (P = .46). Low-income status was a risk factor for discontinuing treatment; however, this was already observed to a similar extent 12 months before the start of reference pricing. In the overall study cohort, there was no increase in rates of MD visits, hospitalizations, or long-term care admissions. However, the 9% of patients who switched medications showed an 18% increase (95% CI, 8% to 28%) in MD visits and an increase in costs of MD visits per patient ($13 Canadian; 95% CI, $3 - $24) compared with non-switchers during the transition but not afterward.</td>
</tr>
<tr>
<td>Schneeweiss, et al. (2004). Net health plan savings from reference pricing for angiotensin-converting enzyme (ACE) inhibitors in elderly British Columbia residents. <em>Medical Care</em>, 42, 653-660.</td>
<td>Canada, age 65+, British Columbia</td>
<td>ACE inhibitors (anti-hypertensive)</td>
<td>Outcome variable: net health plan savings. Modeling approach: spending changes were identified, quantified through claims analysis, and arranged into 4 major components similar to Mason’s work on policy cost effectiveness.</td>
<td>During the first year after implementation of reference pricing, savings for continuous users were $6 million Canadian. Savings for new users were $200,000 Canadian. Approximately 5/6 of savings were achieved by use changes and 1/6 by cost shifting to patients. There were no savings through drug price changes. Administering reference pricing cost $420,000 Canadian. Overall net savings were estimated to be $5.8 million Canadian during the first year. The magnitude of these savings is equal to 6% of all cardiovascular drug expenditures for seniors in the province. After 10 years, approximately 50% of savings will be achieved by new users.</td>
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<tr>
<td>Schneeweiss, et al. (2002). Outcomes of reference pricing for angiotensin-converting-enzyme (ACE) inhibitors. <em>The New England Journal of Medicine</em>, 346(11), 822-829.</td>
<td>Canada, age 65+, British Columbia</td>
<td>ACE inhibitors (anti-hypertensive)</td>
<td>Outcome variables: drug use, drug expenditures, MD visits, hospitalizations, long-term care, and et savings. Quasi-experimental longitudinal study using Pharmacare claims data; logistic &amp; Poisson regression.</td>
<td>Reference pricing for ACE inhibitors was not associated with changes in the rates of MD visits, hospitalizations, long-term care, or mortality. The probability of stopping anti-hypertensive therapy decreased compared to the probability before the change in policy. Eighteen percent of patients who had been prescribed ACE inhibitors subject to cost sharing switched to lower-priced alternatives. Compared to patients who did not switch, those who did had a moderate transitory increase in the rates of MD visits and hospital admissions through the ER during the 2 months after switching, but not subsequently.</td>
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<tr>
<td>Soumerai, et al. (1991). Effects of Medicaid drug payment limits on admissions to hospitals and nursing homes. <em>The New England Journal of Medicine</em>, 325(15), 1072-1077.</td>
<td>U.S., Medicaid</td>
<td>Survival (defined as remaining in the community) and time-series analyses</td>
<td>A 35% decline in use of study drugs after the cap was applied was associated with an increase in rates of nursing home admissions. No changes were seen in the comparison cohort (RR = 1.8; 95% CI, 1.2 to 2.6). Limiting reimbursement for effective drugs puts frail, low-income, elderly patients at increased risk of institutionalization in nursing homes and may increase Medicaid costs.</td>
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<td>Soumerai, et al. (1987). Payment restrictions for prescription drugs under Medicaid. Effects on therapy, cost, and equity. <em>The New England Journal of Medicine</em>, 317(9), 550-556.</td>
<td>U.S., Medicaid</td>
<td>Interrupted time-series analysis</td>
<td>Among 10,734 continuously enrolled patients, the limit of 3 Rxs per month caused a sudden, sustained drop of 30% in the number of Rxs filled (from 1.10 to 0.77 Rxs per patient per month); no change was observed in the comparison state.</td>
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<tr>
<td>Reference</td>
<td>Population / Location</td>
<td>Rx Drug or Class</td>
<td>Outcome Measures / Statistical Method</td>
<td>Findings</td>
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<td>Soumerai, et al. (1994). Effects of a limit on Medicaid drug reimbursement on the use of psychotropic agents and acute mental health services by patients with schizophrenia. <em>The New England Journal of Medicine</em>, 331, 650-655.</td>
<td>U.S., Medicaid</td>
<td>Psychotropic Rx and MH services for schizophrenia</td>
<td>Interrupted time-series analysis</td>
<td>Reimbursement limits were associated with a 15% to 49% reduction in use of mental health drugs, increases of one to two visits per patient per month to CMHCs, use of emergency mental health services and partial hospitalization (1.2 to 1.4 episodes per patient per month) but no change in frequency of hospital admission. After the cap was discontinued, use of medications and most mental health services reverted to baseline levels. The estimated average increase in mental health care costs per patient during the cap ($1,530) exceeded the savings in drug costs to Medicaid by a factor of 17.</td>
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<td>Tamblyn et al. (2001). Adverse events associated with prescription drug cost-sharing among poor and elderly persons. <em>Journal of the American Medical Association</em>, 285(4), 421-429.</td>
<td>U.S. &amp; Canada, elderly, poor</td>
<td>Multiple Rxs</td>
<td>Outcome variables: Mean daily number of essential and less essential drugs per month, ER visits, hospitalizations, nursing home admissions, and mortality. Interrupted time-series analysis; random effects and Cox hazard modeling.</td>
<td>After cost-sharing was introduced, use of essential drugs decreased by 9.12% in elderly persons and by 14.42% in welfare recipients; use of less essential drugs decreased by 15.14% and 22.39%, respectively. The rate (per 10,000 person-months) of serious adverse events associated with reductions in use of essential drugs increased from 5.8 in the pre-policy control cohort to 12.6 in the post-policy cohort in elderly persons, and from 14.7 to 27.6 in welfare recipients. Increases in ER visits correlated with reductions in the use of essential drugs.</td>
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<td>Zeber et al. (2007). Effect of a medication copayment increase in veterans with schizophrenia. <em>American Journal of Managed Care</em>, 13(6), 335-346.</td>
<td>U.S. Veterans</td>
<td>Data from VA national psychosis registry, 2000 - 2003. Veterans with schizophrenia receiving medical care through VA</td>
<td>Pre-post longitudinal design with controls. Regression-adjusted impact of increase Rx cost sharing on Rx use and cost and health services use, with 40,000 cases; 20-month follow-up.</td>
<td>Rx copayment increase from $2 to $7 led to 9% fewer Rxs overall, and 25% fewer psychotropic Rx refills. No effect on outpatient visits. Psychiatric hospital admissions 5% more likely post-intervention, particularly 10 - 20 months after policy change. Estimated $14.7 million net savings for VA from this population by 20 months post copay increase. However, higher inpatient utilization is troubling in this high risk population.</td>
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