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**Will prescription drug coverage for the low-income elderly pay for itself?
A review of the literature**

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Almost all of the nation's 35 million elderly have health insurance coverage through Medicare. In addition, Medicaid provides assistance with the cost of medical care and long-term care to about 4 million seniors. Medicaid coverage of prescription drugs is particularly important, and addresses one of Medicare's most important gaps. However, many low- and modest-income elderly are not eligible for Medicaid and lack any insurance coverage for prescription drugs. To help fill this gap, 28 states operate pharmaceutical assistance programs for the low-income elderly (National Conference of State Legislatures 2003). Financed with state funds, many of these programs are at risk in the current fiscal environment. Consequently, states have turned to the federal government and the Medicaid program to secure new resources for this coverage.

In early 2002, the Bush Administration announced the Pharmacy Plus waiver initiative, which allows states to secure federal matching funds for the cost of operating these prescription drug programs for seniors who otherwise would not be eligible for Medicaid (Guyer 2003). To secure a Pharmacy Plus waiver, states must agree to place all of their expenditures for the elderly in Medicaid under a global funding cap.

A key assumption underlying the financing of Pharmacy Plus Waivers is that expanding drug coverage through Medicaid will reduce cost pressures on Medicaid. Since the caps require that expenditures under the waiver increase by no more than they would have in the absence of the waiver, states are counting on cost savings from expanded prescription drug coverage (see Guyer 2003 for a full discussion of the financing of Pharmacy Plus Waivers). The expectation is that providing expanded access to prescription drugs will reduce the number of elderly who spend down to Medicaid eligibility levels due to high drug costs. Providing some assistance to the low-income elderly will "divert" them from enrolling for full Medicaid benefits now (because they won't spend down due to high drug costs) and in the future (because better management of chronic illness will prevent acute illness and deterioration in health status that would increase the use of other health care services). Elderly Medicare beneficiaries with chronic conditions will use fewer non-drug medical services, including Medicaid home health and nursing home care and Medicare services, especially inpatient hospital care.¹

¹ Although expanded drug coverage may be expected to reduce hospital spending for this group, cost offsets from reduced hospitalizations are not typically factored into the Pharmacy Plus cost savings calculations because Medicare, not Medicaid, is the primary source of payment for hospital care for the elderly.

Unfortunately, the research literature provides little support for this “diversion” or “cost offsets” theory. Only a few studies have evaluated the impacts of state pharmaceutical assistance plans (drug coverage expansions) on Medicaid spending and enrollment, and those studies provide little evidence to support the assumption of cost offsets. Many more studies examine efforts to limit access to prescription drugs in Medicaid. These studies may test the diversion theory in the inverse (i.e. limiting coverage for drugs will raise spending on other Medicaid-covered services), but the findings from these studies are also of limited relevance since they focus on a narrow subpopulation—older or more chronically ill—who are already enrolled in Medicaid and are at greatest risk when drug benefits are cut. An important lesson from this literature is that states may want to protect drug coverage for the elderly in traditional Medicaid before turning to new coverage expansions for seniors. Finally, a number of studies focus on particular drugs or drug classes and the cost savings from newer drugs. These studies provide some evidence of cost savings, but are also of limited relevance for assessing a broad coverage program for the low-income elderly.

Methods

A Medline search of the research literature (and a manual search of citations in published papers) produced only a very few studies that examined the impacts of prescription drug coverage expansions for the low-income elderly on health and long-term care utilization and spending. With little in the way of direct evidence, I broadened my search to include related evidence: studies of access limits in Medicaid and other insurance plans; studies of specific drugs or drug classes; and studies of the cost effectiveness of newer prescription drugs.

Findings from the Literature

Evidence on cost offsets can be found in four distinct sets of studies: (1) studies of drug coverage expansions; (2) studies of Medicaid cost containment efforts that limited access to prescription drugs; (3) studies of the cost effectiveness of specific drugs or drug classes; and (4) studies of the cost effectiveness of newer drugs. These studies and their key findings are discussed below and summarized in **Table 1**.

Drug coverage expansions

A number of cross-sectional studies provide evidence that the elderly with drug coverage use more prescriptions than those without (U.S. Department of Health and Human Services 2000) and that drug coverage expansions increase the use of prescription drugs among the newly insured (Gianfrancesco, Baines, and Richards 1994; Grootendorst, O'Brien, and Anderson 1997; Lillard, Rogowski, and Kington 1999; Tamblyn 2001). However, many fewer studies examine the impacts of prescription drug coverage expansions on the health status of the elderly, their utilization of other health services, and their overall health and long-term care spending. In the published literature, I could find only one methodologically rigorous study that evaluated the effects of expanded access to a wide range of prescription drugs on the use of Medicaid services and costs by the elderly. That paper, by Bruce Stuart and Daniel Lago, evaluated the impact of a drug assistance plan for the low-income elderly in Pennsylvania (the Pennsylvania

Pharmaceutical Assistance Contract for the Elderly, or PACE) on Medicaid enrollments and expenditures in the mid-1980s (Stuart and Lago 1989).²

With “little known” at time of study about prescription drug use and spending patterns, the authors estimated that the reported levels of drug spending for PACE enrollees “would easily have impoverished over 27 percent of the aged enrollees” in the drug coverage plan (p. 455). Consequently, with the PACE subsidies, the authors expected to find both significantly lower rates of elderly enrollment in Medicaid and lower benefit payments. Had PACE not been available, they argued, some of the enrolled individuals “would now be impoverished, by high out-of-pocket drug costs. Others would be suffering the consequences of forgone or postponed drug therapy in terms of poorer health, higher non-drug medical expenses, and reduced earning power” (pp. 452-3). However, despite the enrollment of more than 460,000 elderly individuals in PACE, the authors could find no evidence of a reduction in Medicaid enrollment and spending in time series data:

“if PACE had averted a Medicaid spend-down by three-tenths of 1% or more of first-year PACE enrollees, we should have detected it. The fact that we did not does not mean that some individuals may have avoided or delayed Medicaid enrollment because of PACE. We still believe that to be the case. However, these instances appear to be rare enough that they have no discernable effect on aggregate welfare enrollments or Medicaid expenditures in the state of Pennsylvania” (p. 465).

Two other evaluations of state-financed pharmacy assistance plans for the low-income elderly did report evidence of cost offsets, but both conclude that the majority of cost savings were for hospitalizations—which are covered by Medicare, thus providing little cost saving for Medicaid (EPIC 1996; Lingle, Kirk, and Kelly 1987). Moreover, the significance of these findings is limited by weaknesses in the studies’ research designs.³

A recent careful statistical study of pharmacy assistance programs in Vermont failed to reveal any savings to the Medicare program due to the expansion of drug coverage (Gilman, Gage and Mitchell 2003). There was no evidence of a substitution of drug for non-drug spending. Rather, the central finding was that beneficiaries generally sign up for drug benefits after they experience an acute inpatient episode and a subsequent need for prescription drugs. Medicare spending for enrollees increases sharply in the first year of enrollment in the pharmacy assistance programs before returning to pre-enrollment levels.

² Eligibility for PACE was based on an income test (\$12,000 for single individuals, \$15,000 for married couples)—there was no asset test—and enrollees paid a \$4 co-payment for each prescription for “broad and comprehensive drug coverage” (Stuart and Lago 1989 p. 454).

³ The EPIC study, an evaluation of the pharmaceutical assistance plan for the low-income elderly in New York, was a cross sectional study that did not adequately control for differences in EPIC enrollees and non-enrollees. The Lingle study, an assessment of a drug coverage plan in New Jersey in the late 1970s also used a cross sectional analysis and found that hospital spending in New Jersey was far below spending on elderly Medicare beneficiaries in New York, but the authors did not adequately address the likely impact of the anticipation of a major policy shift in hospital payment policy in New Jersey in 1980.

In the same report, these authors assessed the impact of pharmacy assistance programs on Medicaid “spend down” rates. The number of newly enrolled dual eligibles declined by half (from 2,501 in 1994 to 1,268 in 2001) at the same time that pharmacy assistance enrollments rose from 3,894 to 14,659, “lend[ing] support to the contention that [the pharmacy assistance programs] have helped to lower the rate at which Medicare beneficiaries in Vermont spend down to full Medicaid benefits” (Gilman, Gage and Mitchell 2003, p. 3-16).⁴ These descriptive findings are far from conclusive, however, since a number of factors—demographic trends, health status, and income—can affect the rate at which the elderly enroll in Medicaid.

In part, there are few methodologically rigorous studies of the impact of new coverage on prescription drug use and spending because data on the use and spending patterns of the previously uninsured are hard to come by. However, longitudinal studies of the effects of prescription drug cost containment do not face the same data constraints because Medicaid claims are available for the continuously insured potentially affected by the policy change. Moreover, states have afforded researchers ample opportunity to examine the effects of access restrictions since they have often responded to fiscal pressures by reducing benefit coverage or pharmacy reimbursement levels. These studies are reviewed below.

Access limits in Medicaid

A number of studies “prove” the cost offsets hypothesis in the inverse. Most of these studies suggest that prescription drug cost containment efforts “defeat both coverage and cost-containment goals” (Reutzel 1993). Though designed to slow the growth of prescription drug spending, the reductions instead end up being very costly for the Medicaid program; they lead to increases in the use of other services that more than offset any reductions in prescription drug spending.

The most widely cited findings are those of Soumerai and others in several papers examining the effects of a prescription drug cap implemented in New Hampshire in the early 1980s. An initial study of the effect of a cap of three prescriptions per month found evidence of significant declines in the use of both essential and nonessential medications for a representative sample of the Medicaid population—a 30% drop in number of prescriptions filled. Analyses of selected subgroups revealed that the heaviest prescription drug users experienced the largest declines. There was a 42% drop in the number of prescriptions filled for recipients of multiple drugs (who were mostly elderly and disabled). This study, however, did not assess the clinical consequences of the access restrictions or changes in the use of other services (Soumerai et al. 1987).

A later study examined the impacts on health status and hospital and nursing home use, but for only a small segment of the original sample. The study analyzed the outcomes of chronically ill older Medicaid beneficiaries—those over age 60, with an average of three or more prescriptions per month, who used medication for one or more of five major chronic illnesses (diabetes, heart disease, COPD and asthma, seizures, or conditions requiring the use of anticoagulants). The

⁴ Although the authors refer to this as the “spend down” rate, they use data on the number of new enrollments in Medicaid. New enrollees may include those who may have spent down to Medicaid, as well as those who are categorically eligible, who have not spent down, but have low income and assets that make them financially eligible for Medicaid.

authors found that, for this vulnerable population, nursing home admissions increased after the cap was implemented, although there was no significant change in the hospitalization rate (which would be expected if there was an acute deterioration in disease condition). Higher rates of nursing home admissions, it appeared, were related to efforts by patients to bypass the effect of the policy since long-term care facilities were exempt from the cap (Soumerai et al. 1991).

A third study examined the impact of the cap on the seriously mentally ill. Soumerai and colleagues analyzed the impact of access restrictions on non-institutionalized patients with schizophrenia (Soumerai et al. 1994). For this population, the cap resulted in immediate reductions in the use of antipsychotic drugs, antidepressants and lithium, and anxiolytic and hypnotic drugs. Although there was no evidence of increased admissions to the state psychiatric hospital, there were increases in community mental health center visits, and sharp increases in the use of emergency mental health services and partial hospitalization. All told, the estimated average increase in mental health care costs per patient during the cap exceeded the savings in drug costs by a factor of 17.

A widely cited Canadian study also provides some evidence on the use of hospital and nursing home care following the implementation of cost sharing for prescription drugs in Quebec. In that study, increased cost sharing for the previously insured was associated with increases in emergency room use and in serious adverse events (hospitalization, nursing home admission, and death). Although no cost estimates were provided, the evidence suggests that efforts to reduce the province's drug spending led to higher rather than lower spending (Tamblyn et al. 2001).

These studies suggest that restrictions in access to prescription drugs lead to unintended effects for Medicaid—increases in the use of and spending on other health care services that more than offsets the reductions in prescription drug spending. Cuts are shown to be particularly problematic for those who were in poorest health and at greatest risk of adverse health effects with changes in medication use. With the exception of the Canadian study, however, these findings are limited to the seriously mentally ill and the chronically ill elderly. There is less evidence on how access limits affect the use of health care and long-term care services for the broader Medicaid population or even for a broad cross-section of the low-income elderly. Moreover, it is not clear whether these studies really help prove the inverse—that improvements in access for the broader elderly population will lower overall Medicaid spending.

Cost effectiveness of specific drugs or drug classes

Evidence for the cost offsets hypothesis can also be found in studies of specific drugs or classes of drugs. For example, there are a large number of studies that examine whether access to new AIDS drugs reduces the use of expensive health care services. Those advocating coverage expansions argue that early access to treatment (specifically, highly active antiretroviral therapy, HAART) will provide “substantial health benefits at affordable costs” (Kahn et al. 2001):

By delaying the progression from HIV to AIDS, not only is the health and quality of life of individuals living with HIV greatly improved, but savings in treatment cost are realized. ... Studies indicate that HAART can significantly lower the costs of patient hospitalization, community care, terminal care, and the costs of treating opportunistic infections. The results of these studies range from a finding

that, with the introduction of HAART, health care expenditures decline to a finding that increased drug costs are offset by savings in non-drug services (Treatment Access Expansion Project 2003).

One study of AIDS patients in a Medicaid waiver program in Florida found that the waiver program enrollees—who received case management and more aggressive drug therapies—had higher drug spending but lower overall medical spending than similar patients not enrolled in the waiver (Mitchell and Anderson 2000). Other studies have also found evidence of cost offsets for those receiving antiretroviral therapies, especially for hospitalizations (Bozzette et al. 2001; Goldman et al. 2001). But just as many studies find that drug coverage expansions cost money. Even so, when total patient spending rises, this spending is found to be cost effective from a societal point of view. The drugs are well worth what they cost—leading to a more efficient use of resources and tremendous improvements in health (Freedberg et al. 2001; Schackman et al. 2001).

There is similarly mixed evidence on cost offsets of expanded access to particular drug therapies for people with mental illness. For example, a study comparing the costs of alternative drug therapies for people with schizophrenia found that those receiving clozapine—a more expensive therapy than the alternative (haloperidol) to which it is compared—had higher medication and outpatient costs, but lower inpatient costs (Rosenheck, Cramer, and al. 1997). Another study, which examined the cost of treating schizophrenia among Medicaid patients, found that having an antipsychotic drug was associated with lower psychiatric hospital costs, but higher nursing home costs (McCombs et al. 2000). A review of the cost effectiveness of antidepressants suggests that more effective medications (SSRIs compared to tricyclics) are associated with reductions in overall treatment costs, although reported cost savings did not meet the standard for statistical significance (Mitchell et al. 1997).

What about the drugs used most frequently by the elderly for conditions that put them at risk of nursing home admission? Is there comparable evidence for drug therapies and the use of institutional care for the elderly? In fact, there are a few studies that examine the cost implications of drug therapies for hip fractures, rheumatoid arthritis, and Alzheimer's disease—all conditions that are associated with an increased risk of nursing home admission among the elderly.

For example, a study of patients with previous hip fractures found that treatment with alendronate significantly reduced the costs associated with fractures. However, this study examined only the fracture-related costs, not all medical and long-term care costs (Chrischilles et al. 2001). Other studies suggest that there are reduced risks of hip fractures and joint destruction with the use of specific therapies—and potentially reduced costs. One study found that the risk of hip fracture decreased significantly with increasing duration of current thiazide use, although no cost estimates were provided (Ray et al. 1989). In another study, it is reported that hospital and nursing home costs account for 70 percent of the expenditures for patients with rheumatoid arthritis in Medicaid. The author implies that receipt of disease modifying antirheumatic drugs may slow the process of joint destruction and offset the use of more expensive nursing home services in the future (Jacobs et al. 1988). Similarly, in another study, drug treatment (alpha-

tocopherol, vitamin E) for patients with mild to moderate Alzheimer's disease was shown to delay the progression to nursing home admission (Reichman 2000).

These studies suggest the potential for reduced expenditures on nursing home care, but not all of the studies suggest savings, and the studies generally do not provide cost estimates and so are of limited use in determining whether expanded access to drugs reduces spending. Moreover, the studies focus on narrow subpopulations with indications for use the suggested therapies. The cost implications of coverage expansions that would likely expand access to a wider population are not explored. This focus on a specific population provides little insight into how expanding access to a broad range of drugs for the low-income elderly would affect their medical care use and costs.

The cost effectiveness of newer drugs

Economist Frank Lichtenberg has provided another set of studies that explores the cost offsets hypothesis. Lichtenberg starts with the observation that there are many pharmaceutical therapies that clearly result in cost offsets, at least in the short term. He points to the role of H2 antagonists in substantially reducing the number of surgeries for peptic ulcers, to antibiotics in reducing long-term hospital stays for patients with tuberculosis, and clozapine in reducing costly institutional stays for the mentally ill (Lichtenberg 1996). In theory, "increased spending on drugs that specifically manage disease, preclude or delay surgeries, or reduce hospital admissions and lengths-of-stay pay for themselves many times over" (Kleinke 2001, p. 46). Lichtenberg sets out to find evidence of these cost offsets in highly aggregated data and finds that the number of hospital stays, bed-days, and surgical procedures declined most rapidly for those with diagnoses with the greatest increase in the total number of drugs prescribed and the greatest change in the distribution of drugs (i.e. the greatest innovation). A \$1 increase in pharmaceutical expenditure is associated with a \$3.65 reduction in hospital care expenditure (Lichtenberg 1996).

In two more recent papers, Lichtenberg examines the hypothesis that people who take newer drugs in 1996 have lower overall health care spending than those taking older drugs (Lichtenberg 2001, 2002). Accounting for patient characteristics and the condition for which the drug is prescribed, Lichtenberg finds that patients who took newer drugs had lower spending. In an update of this study, he estimates that a reduction in the age of drugs reduces non-drug expenditures by all payers by 8.3 times as much as it increases drug expenditure in the Medicare population; it reduces Medicare non-drug expenditure six times as much as it increases drug expenditure. Most of the non-drug Medicare cost reduction (two-thirds) is due to reduced hospital costs; the remaining one-third is approximately evenly divided between reduced Medicare home health care cost and reduced Medicare office-visit cost (Lichtenberg 2002).

The relevance of these findings has been questioned because of concerns about the author's methodological approach. He fails, for example, to acknowledge that unmeasured determinants of hospitalization rates may be correlated with the degree of drug innovations—suggesting that factors other than pharmaceutical innovation may in fact account for reductions in hospital use. (The methodological limitations of these studies are described in a recent CBO study (Congressional Budget Office 2002, pp. 51-52). The Lichtenberg studies, moreover, do not shed light on cost offsets for Medicaid-financed nursing home care.

Discussion

Can expanded drug coverage for the low-income elderly in Medicaid pay for itself, or at least partially pay for itself? Some studies do provide evidence of some cost offsets for some prescription drugs for some populations. The strongest evidence, however, “proves” the cost offsets hypothesis only in the inverse, showing that restrictions in access reduce prescription drug costs, but other costs increase and more than offset the prescription drug savings. In addition, to the extent that these studies help make the case, the effects appear to be narrow—with cost offsets for certain vulnerable groups or specific drugs. Clearly, some drugs do save money or are cost-effective, but the issue depends critically on the context in which the drug is used and the intervention with which it is compared (Neumann et al. 2000). Once coverage is expanded beyond a narrow clinical subpopulation, cost offsets may be small relative to total costs. In fact, when access is expanded to the full range of prescription medications for a broad cross section of the low- and modest-income elderly, it is quite likely that access to better medicines will increase, not reduce, costs. The one research study that provided the most direct evidence on the diversion theory, Bruce Stuart’s 1989 study of the Pennsylvania PACE program, could find no evidence of reduced Medicaid enrollment and spending. The 2003 evaluation of Vermont’s pharmacy assistance plans could find no evidence of Medicare cost offsets and provided only inconclusive descriptive trends of reductions in the Medicaid “spend-down” rate (Gilman, Gage and Mitchell 2003).

A comprehensive pharmaceutical assistance program will give prescription drugs to many who need them, but meeting that need will not necessarily reduce other health care spending. In fact, the strongest evidence suggests that it may be important for states to maintain coverage for the elderly in Medicaid before they pursue coverage expansions for other seniors since limits on drug coverage for these more frail and seriously ill have been associated with unintended cost growth in Medicaid.

Fortunately, we don’t need cost offsets to justify coverage expansions. Prescription drugs are a necessary part of a comprehensive health care system, not because of their potential for cost offsets but because there are drug therapies available that can reduce symptoms of disease, cure disease, and improve quality of life. Unfortunately, states agreeing to forgo their entitlement funding on the promise of cost offsets may be expecting more cost savings than they are likely to get—putting coverage for all of the elderly in Medicaid at risk.

TABLE 1. COST OFFSETS FROM EXPANDED ACCESS TO PRESCRIPTION DRUGS: FINDINGS FROM THE LITERATURE

1. Drug Coverage Expansions			
Study	Study Population/Design	Study Period	Key Findings
Prescription Drug Coverage and Medical Indigence Among the Elderly (Stuart and Lago 1989)	Medicaid enrollment and expenditure data for the elderly in Pennsylvania. Statistical analysis of 72 months of aggregated time series data; 10 enrollment and expenditure variables from the HCFA 120 reports.	1980-87	<p>Strong circumstantial evidence that public third-party coverage reduces the risk of medical indigence among the elderly: 30% of enrollees in the pharmaceutical assistance plan for the elderly (PACE) had drug expenditures in excess of \$600; 15% incurred charges of \$1,000 or more. Those with less than \$6,000 in annual income are at particularly high risk of becoming medically indigent – 27% of PACE enrollees fall in this income range.</p> <p>However, substantial direct assistance with the cost of prescription drugs did not reduce the need for Medicaid coverage on behalf of low-income elderly recipients. PACE did not have a statistically significant impact on Medicaid enrollments or expenditures for the elderly (statistical tests did not detect any reduction in the Medicaid spend down rate).</p>
The impact of outpatient drug benefits on the use and costs of health care services for the elderly (Lingle, Kirk, and Kelly 1987)	10,600 Medicare eligibles in PA and NJ Multiple regression analysis; data on utilization and payments for Medicare services and prescription drug payments for the NJ and PA Medicare enrollees.	1975, 1979	<p>Significant savings in inpatient hospital costs for the elderly enrolled in a pharmaceutical assistance plan. New Jersey Medicare recipients used, on average, \$238.50 less in inpatient hospital care under the pharmaceutical assistance program than did their counterparts in eastern Pennsylvania, which did not have a drug payment assistance program in place. The drug assistance program resulted in no overall health care cost increases.</p>
EPIC Evaluation Report to the Governor and Legislature: An Evaluation of New York State's Elderly Pharmaceutical Insurance Coverage Program (EPIC 1996)	Cross sectional observational study of EPIC enrollees compared to nonenrollees.	1987-95	<p>Substantial savings in both hospital inpatient and nursing home costs for EPIC enrollees. Inpatient savings attributable to both fewer admissions than would be expected based on the experience of all NY seniors, and less intensive hospital stays for those admitted. Savings for 1994 estimated at \$73 million. After adjusting for case mix and demographic distributions, savings fall to \$42-46 million. Lower nursing home admission rates produce savings of \$6 million. The annual net cost of operating EPIC in 1993 was \$41 million, therefore the savings to the health care system in one year exceeds the costs of the program.</p>
The Impact of Pharmacotherapy Policy: A Case Study (Tamblyn 2001)	A random sample of 93,950 elderly persons and 55,333 adult welfare medication recipients. Analysis of claims data for the previously insured; survey of physicians and pharmacists for impacts on the newly insured.	1993-97	<p>An increase in cost sharing for previously insured beneficiaries led to a reduction in both essential (senior citizens: 9.1%; income security: 14.4%) and less essential medication (senior citizens: 15.1%; income security: 22.4%). Reductions in the use of essential drugs were associated with an increase in the rate of emergency visits (by 43% in senior citizens and 78% in income security recipients) and adverse events (by over 100% in senior citizens and 88% in income security recipients). The 442 physicians and pharmacists who were surveyed reported that the policy reduced the use of antilipidemics, inhaled steroids and antihypertensives in the previously insured beneficiaries, but improved access to previously unaffordable medications for cardiac disease and asthma in the newly insured beneficiaries.</p>

Drug Coverage Expansions, continued.

Study	Study Population/Design	Study Period	Key Findings
<p>Evaluation of Vermont's Pharmacy Assistance Programs for Low-Income Medicare Beneficiaries (Gilman, Gage and Mitchell 2003)</p>	<p>Descriptive analysis of trends in enrollment in pharmacy assistance programs in Vermont and trends in new Medicaid enrollments among the elderly.</p> <p>Quasi-experimental design, analysis of pre-post enrollment changes in Medicare expenditures for pharmacy assistance program enrollees, vs. changes in Medicare expenditures for non-enrollees over the same period.</p>	<p>1994-2000 (impact of Pharmacy Assistance programs on Medicaid "spend down" rate)</p> <p>1995-1999 (impact of Pharmacy Assistance programs on Medicare spending)</p>	<p>Data trends "lend support to the contention that [the pharmacy assistance programs] have helped to lower the rate at which Medicare beneficiaries in Vermont spend down to full Medicaid benefits." The number of newly enrolled dual eligibles declined by half (from 2,501 in 1994 to 1,268 in 2001) at the same time that pharmacy assistance enrollments rose from 3,894 to 14,659. These trends are far from conclusive, however, since a number of factors—demographic trends, health status, and income—can affect the rate at which the elderly enroll in Medicaid.</p> <p>No savings to the Medicare program due to the expansion of drug coverage. Beneficiaries generally sign up for drug benefits after they experience an acute inpatient episode and a subsequent need for prescription drugs. Medicare spending for enrollees spikes in the first year of enrollment in the pharmacy assistance programs, before returning to pre-enrollment levels.</p>

2. Access Limits in Medicaid

<p>Payment Restrictions for Prescription Drugs Under Medicaid: Effects of Therapy, Cost and Equity (Soumerai et al. 1987)</p>	<p>Medicaid recipients in NH (n= 10,734) were compared to a cohort in NJ (n= 74,027).</p> <p>The recipients were all enrolled continuously in Medicaid for 10 or more months during the 4 years of study. Nursing home patients were excluded from the study. Multiple-drug recipients were defined as a sub-group (received an average of 3 or more prescriptions per month). Using data on 48 months of claims in the study state and a comparison state, time-series analysis was employed to evaluate patient-level changes in the number of prescriptions filled for 16 drugs that varied in their clinical importance and cost.</p>	<p>1981-85</p>	<p>A limit of three paid prescriptions per month caused a sudden, sustained drop of 30 percent in the number of prescriptions filled (from 1.10 to 0.77 prescriptions per patient per month) among 10,734 continuously enrolled patients in NH; no change was observed in the comparison state (NJ). The 860 recipients of multiple drugs, who were predominantly female and elderly or disabled, were most severely affected; the number of prescriptions per month dropped from 5.2 to 2.8 (46%). The decrease was greatest for "ineffective drugs" (58%), but large drops were also observed for "essential" medications, such as insulin (28%), thiazides (28%), and furosemide (30%). Reductions in Medicaid prescriptions were minimally offset by increases in the size of the prescription or in out-of-pocket payments. When a \$1 copayment replaced the three-prescription cap, prescriptions for most medications increased to just below pre-cap levels. Medicaid's savings on drug costs resulting from both policies were comparable (\$0.4 to \$0.8 million annually), but the copayment policy had less effect on patients receiving multiple drugs.</p>
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Access Limits in Medicaid, continued

Study	Study Population/Design	Study Period	Key Findings
<p>Effects of Medicaid Drug-Payment Limits on Admission to Hospitals and Nursing Homes (Soumerai et al. 1991)</p>	<p>411 Medicaid recipients in NH age 60 or older who, in a baseline year, had been taking 3 or more medications per month, including at least 1 maintenance drug for certain chronic diseases. Matched comparison cohort in of 1,375 people in NJ.</p> <p>Survival (defined as remaining in the community) and time-series analyses were conducted to determine the effect of the reimbursement cap on admissions to hospitals and nursing homes.</p>	<p>1980 –83</p>	<p>Limiting reimbursement for effective drugs puts frail, low-income, elderly patients at increased risk of institutionalization in nursing homes and may increase Medicaid costs. In New Hampshire, the 35% decline in the use of <u>study</u> drugs after the cap was applied was associated with an increase in rates of admission to nursing homes; no changes were observed in the comparison cohort. There was no significantly increased risk of hospitalization. Among the patients in New Hampshire who regularly took 3 or more study medications at base line, the relative risk of admission to a nursing home during the period of the cap was 2.2, and the risk of hospitalization was 1.2. (14.4% of NH patients taking drugs from 3 or more classes had entered nursing homes compared to 6.2% of such patients in NJ). When the cap was discontinued after 11 months, the use of medications returned nearly to base-line levels, and the excess risk of admission to a nursing home ceased. In general, the patients who were admitted to nursing homes did not return to the community.</p>
<p>Effects of Limiting Medicaid Drug-Reimbursement Benefits on the Use of Psychotropic Agents and Acute Mental Health Services by Patients with Schizophrenia (Soumerai et al. 1994)</p>	<p>268 Medicaid recipients in NH who were permanently disabled, non-institutionalized patients with schizophrenia 19-60 years old. Matched comparison cohort of 1,959 people in NJ.</p> <p>Medicaid claims data for a period of 42 months linked with clinical records from two community mental health centers and the single state psychiatric hospital in New Hampshire. The study patients (n = 268) and the comparison patients (n = 1959) were permanently disabled, noninstitutionalized patients with schizophrenia, 19 through 60 years of age, insured by Medicaid. Interrupted time-series regression analyses to estimate the effects of the cap on the use of medications and mental health services.</p>	<p>1980 –83</p>	<p>The cap resulted in immediate reductions (of 15% to 49%) in the use of antipsychotic drugs, antidepressants and lithium, and anxiolytic and hypnotic drugs. It also resulted in coincident increases of one to two visits per patient per month in visits to CMHCs (43% to 57%) and sharp increases in the use of emergency mental health services and partial hospitalization (1.2 to 1.4 episodes per patient per month), but no change in the frequency of hospital admissions. After the cap was discontinued, the use of medications and most mental health services reverted to base-line 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. Drug expenditures decreased by about \$5 per person in NH during the cap, but overall expenditures increased by about \$139 per month.</p>
<p>The Impact of Implementing a More Restrictive Prescription Limit on Medicaid Recipients (Martin and McMillan 1996)</p>	<p>743 ambulatory Medicaid recipients in GA who were high prescription users. Quasi-experimental, retrospective, 12-month interrupted time-series analysis of a cohort. Interrupted time-series analyses were performed to model the effect of the five-prescription limit on total, Medicaid- reimbursed, out-of-pocket, and prescription use across eight therapeutic categories.</p>	<p>1991-92</p>	<p>After the implementation of the five-prescription limit, total prescription use fell 6.6%, prescriptions reimbursed by Medicaid fell 9.9%, and prescriptions paid for out-of-pocket increased 9.7%. Abrupt, permanent decreases were observed for cardiovascular, miscellaneous, pulmonary, and palliative therapeutic drug categories, whereas gastrointestinal, chemotherapy, hormone (insulin), and central nervous system prescription use remained constant. The implementation of a more restrictive prescription limit alters prescription regimens potentially predisposing elderly Medicaid recipients to clinical consequences.</p>

Access Limits in Medicaid, continued			
Study	Study Population/Design	Study Period	Key Findings
<p>Systemwide Effects of Medicaid Retrospective Drug Utilization Programs (Moore, Gutermuth, and Pracht 2000)</p>	<p>Pooled cross-sectional and time-series analysis of annual state data use to analyze the impact of Retro-DUR on Medicaid drug and non-drug utilization and expenditures. Control group = states not operating Retro-DUR programs in each year.</p>	<p>1985-92</p>	<p>Total drug expenditures are 6.5% lower in states with Medicaid Retro-DUR programs than in states not having such a program. This result is caused primarily through a reduction in the amount of expenditures per recipient, rather than a reduction in the number of recipients. Older programs have greater effects – reduce the number of recipients (by 4.4%) and expenditures (5.4%). Retro-DUR programs do not have significant spillover effects (positive or negative) in other non-drug budgets within the Medicaid system. Older Medicaid DUR programs are more effective: reduce per-recipient drug expenditures by 4.9%, total drug expenditures by 6.9%. Restricted formularies produce only moderate cost savings in drug budgets in Medicaid; significant <u>positive spillover effects</u> in non-drug budgets in Medicaid. Formulary states have 7.3 % more inpatient hospital recipients and 14.1% higher inpatient hospital expenditures.</p>
Access Limitations—Non-Medicaid			
<p>Adverse events associated with prescription drug cost-sharing among poor and elderly persons (Tamblyn et al. 2001)</p>	<p>A random sample of 93,950 elderly persons and 55,333 adult welfare medication recipients. Interrupted time-series analysis of data from 32 months before and 17 months after introduction of a prescription coinsurance and deductible cost-sharing policy in Quebec in 1996.</p>	<p>1993-98</p>	<p>After cost sharing was introduced, the use of essential drugs decreased by 9.1% in elderly persons and by 14.4% in welfare recipients; the use of less essential drugs decreased by 15% and 22.4%, respectively. The rate (per 10,000 person-months) of serious adverse events (hospitalization, nursing home admission, or death) associated with reductions in use of essential drugs increased from 5.8 in the prepolicy control cohort to 12.6 in the postpolicy cohort in elderly persons (net increase of 6.8) and from 14.7 to 27.6 in welfare recipients (net increase of 12.9). Emergency department visit rates related to reductions in the use of essential drugs also increased by 14.2 per 10,000 person-months in elderly persons (prepolicy control cohort, 32.9; postpolicy cohort, 47.1) and by 54.2 among welfare recipients (prepolicy control cohort, 69.6; postpolicy cohort, 123.8). Reductions in the use of less essential drugs were not associated with an increase in risk of adverse events or ED visits.</p>

3. Specific Drugs or Drug Classes

Study	Study Population	Study Period	Key Findings
<p>Effects of Case Management and New Drugs on Medicaid AIDS spending (Mitchell and Anderson 2000)</p>	<p>Florida Medicaid recipients with HIV/AIDS-related illness were identified from claims data.</p>	<p>1993-97</p>	<p>Overall monthly Medicaid expenditures were almost \$843, 42% higher for non-participants than for those enrolled in the waiver. The major reason for the cost difference is that nonwaiver enrollees incurred significantly higher inpatient costs than did those enrolled in the waiver (510% higher). Although waiver enrollees had higher drug spending (twice the amount spent by nonenrollees), these represent only a fraction of the higher inpatient costs incurred by nonwaiver enrollees. Outpatient and physician services costs were also higher for nonenrollees; home health costs were lower for nonenrollees. Adherence to appropriate medications reduces the need for inpatient care. The case management approach of the AIDS waiver may have similar effects for persons with other chronic diseases.</p>
<p>Expenditures for the Care of HIV-infected Patients in the Era of Highly Active Antiretroviral Therapy (Bozzette et al. 2001)</p>	<p>A random sample of 2864 patients who were representative of all American adults receiving care for HIV infection in early 1996 were interviewed and followed for up to 36 months.</p> <p>Estimates of the average expenditure per patient per month were made on the basis of self-reported information about care received.</p>	<p>1996-99</p>	<p>The total cost of care for adults with HIV infection has declined since the introduction of highly active antiretroviral therapy. Expenditures have increased for medications but have declined for other services. However, there are large variations in expenditures across subgroups of patients. The mean expenditure was \$1,792 per patient per month at base line, but it declined to \$1,359 for survivors in 1997, since the increases in pharmaceutical expenditures were smaller than the reductions in hospital costs. After adjustments for the interview date, clinical status, and deaths, the estimated annual expenditure declined from \$20,300 per patient in 1996 to \$18,300 in 1998. Expenditures among subgroups of patients varied by a factor of as much as three. Pharmaceutical costs were lowest and hospital costs highest among underserved groups, including blacks, women, and patients without private insurance.</p>
<p>Cost-effectiveness of earlier initiation of antiretroviral therapy for uninsured HIV-infected adults (Schackman et al. 2001)</p>	<p>A state-transition simulation model of HIV disease was used. Data were derived from the Multicenter AIDS Cohort Study, published randomized trials, and medical care cost estimates for all government payers and for Massachusetts, New York, and Florida.</p>	<p>NA</p>	<p>Antiretroviral therapy initiated at 500 CD4 cells/microL is cost-effective from a societal perspective compared with therapy initiated later. Quality-adjusted life expectancy increased from 7.64 years with therapy initiated at 200 CD4 cells/microL to 8.21 years with therapy initiated at 500 CD4 cells/microL. Initiating therapy at 500 CD4/microL was a more efficient use of resources than initiating therapy at 200 CD4/microL and had an incremental cost-effectiveness ratio of \$17,300 per quality-adjusted life-year gained, compared with no therapy. Costs to state payers in the first 5 years ranged from \$5,500 to \$24,900 because of differences among the states in the availability of federal funds for AIDS drug assistance programs.</p>
<p>The cost effectiveness of combination antiretroviral therapy for HIV disease (Freedberg et al. 2001)</p>	<p>Mathematical simulation model of HIV disease, CD4 cell count and HIV RNA level as predictors of the progression of disease. Outcome measures included life expectancy, life expectancy adjusted for the quality of life, lifetime direct medical costs, and cost effectiveness in dollars per quality-adjusted year of life gained. Clinical data were derived from major clinical trials. Data on costs were based on the national AIDS Cost and Services Utilization Survey, with drug costs obtained from the Red Book.</p>	<p>NA</p>	<p>Treatment of HIV infection with a combination of three antiretroviral drugs is a cost-effective use of resources. For patients similar to those in the AIDS Clinical Trials Group 320 Study (mean CD4 cell count, 87 per cubic millimeter), life expectancy adjusted for the quality of life increased from 1.53 to 2.91 years, and per-person lifetime costs increased from \$45,460 to \$77,300 with three-drug therapy as compared with no therapy. The incremental cost per quality-adjusted year of life gained, as compared with no therapy, was \$23,000. On the basis of additional data from other major studies, the cost-effectiveness ratio for three-drug therapy ranged from \$13,000 to \$23,000 per quality-adjusted year of life gained. The initial CD4 cell count and drug costs were the most important determinants of costs, clinical benefits, and cost effectiveness.</p>

Specific Drugs or Drug Classes, continued			
Study	Study Population/Design	Study Period	Key Findings
The impact of state policy on the costs of HIV infection (Goldman et al. 2001)	This article uses data from a nationally representative sample of HIV+ patients to assess how differences across states in Medicaid and AIDS Drug Assistance Programs (ADAP) affect costs and labor market outcomes for HIV+ patients in care in that state.	NA	Making ADAP programs more generous in terms of drug coverage would reduce per patient total monthly costs, mainly through a reduction in hospitalization costs. In contrast, expanding ADAP eligibility by increasing the income threshold would increase the total cost of care. Expanding eligibility for Medicaid through the medically needy program would increase per patient total costs, but full-time employment would increase and so would monthly earnings. More generous state policies toward HIV+ patients--especially those designed to provide access to efficacious treatment--could improve the economic outcomes associated with HIV.
Mental Illness			
A Comparison of Clozapine and Haloperidol in Hospitalized Patients with Refractory Schizophrenia (Rosenheck, Cramer, et al. 1997)	Male patients at 15 Veterans Affairs medical centers who had refractory schizophrenia and had been hospitalized for the disease 30-364 days in the previous year. Assigned 205 patients to clozapine and 218 patients to haloperidol. Patients received either clozapine or haloperidol for 12 months.	1993-1995	For patients with refractory schizophrenia and high levels of hospital use, clozapine was somewhat more effective than haloperidol and had fewer side effects and similar overall costs. Patients assigned to clozapine had fewer mean days of hospitalization for psychiatric reasons than patients assigned to haloperidol and had lower symptom levels than those in the haloperidol group at follow-up evaluations. Greater cost of clozapine was offset by reductions in the number of days spent in the hospital. Although patients receiving clozapine had higher costs for medication and outpatient care, they spent fewer days in the hospital and, therefore, had lower inpatient costs.
Antipsychotic drug use patterns and the cost of treating schizophrenia (McCombs et al. 2000)	This study investigated the relationships between antipsychotic drug use patterns and direct costs for 3321 Medi-Cal patients with schizophrenia.	NA	Ordinary least-squares regression models were used to estimate the impact on costs of receiving antipsychotic drug treatment, delays in treatment, changes in therapy, and continuous therapy. Average costs were \$25,940 per year per patient. Having used an antipsychotic drug was correlated with lower psychiatric hospital costs (\$2,846 less) but higher nursing home costs. Completing one year of uninterrupted drug therapy was correlated with higher nursing home costs. Delayed drug treatment and changes in therapy increased the cost by \$9,418 and \$9,719, respectively.
Effectiveness and economic impact of antidepressant medications: a review (Mitchell et al. 1997)	Literature Review	NA	This article reviews the existing literature on the pharmacoeconomics and effectiveness of antidepressant medications. Although selective serotonin reuptake inhibitors (SSRIs) have not proved to be more efficacious than the older tricyclics, and their prescription costs are significantly higher, they provide superior effectiveness; i.e., patients are less likely to discontinue taking them or switch antidepressants. Pharmacoeconomic studies consistently demonstrate a relationship between this superior effectiveness and reductions in overall treatment costs, often through decreased utilization of medical and hospital services. The most conservative study found a cost offset that more than negated the extra cost of drugs, although the cost savings were not statistically significant. Other studies found statistically significant lowering of utilization costs by using SSRIs rather than tricyclics. Studies comparing SSRIs with each other present conflicting findings, although fluoxetine appears to have an edge over sertraline and paroxetine with regards to effectiveness and pharmacoeconomics. More studies employing a prospective outcome design and naturalistic study setting need to be conducted with SSRIs and other new antidepressants.

Specific Drugs or Drug Classes, continued			
Study	Study Population/Design	Study Period	Key Findings
Hip Fracture; Rheumatoid Arthritis			
The effect of alendronate on fracture-related healthcare utilization and costs: the fracture intervention trial (Chrischilles et al. 2001)	<p>The Vertebral Fracture Arm (VFA) of the Fracture Intervention Trial (FIT) study enrolled 2027 women aged 55-81 with low bone mass and pre-existing vertebral fractures from population-based listings in eleven metropolitan areas in the U.S.</p> <p>Participants were randomly assigned to double-masked treatment with alendronate (5mg/day for two years and then 10mg/day for one year) or a placebo for three years.</p>	NA	Alendronate significantly reduced the proportion of patients utilizing fracture-related healthcare (emergency room, hospital, rehabilitation hospital or nursing home) by 25%. Alendronate significantly reduced the costs associated with hip-fracture-related care by 58%, or \$181 per patient randomized. The reduction in fracture-related total costs was 35% (\$190 per patient randomized) in the alendronate group relative to the placebo group. Alendronate thus not only reduces the incidence of clinical fractures and associated morbidity, but also reduces the proportion of patients utilizing the associated healthcare resources.
Long-term use of thiazide diuretics and risk of hip fracture (Ray et al. 1989)	Residents in the Canadian province of Saskatchewan who were 65 years of age or older and who were not receiving any other drugs thought to affect bone mass.	1984-85	Risk of hip fracture decreased significantly with increasing duration of current thiazide use: relative risk of 1.2 for less than 2 years use, 0.8 for use of 2-5 years, and 0.5 for 6 or more years. In contrast, there was no such trend for use of other antihypertensive-diuretic drugs. This protective effect was not altered by age, sex, nursing home residence, previous hospital admission, or use of other antihypertensive-diuretic drugs or psychotropic drugs. Medical record review for a sample of 235 cases suggested this finding was not due to confounding by body mass, ambulatory status, functional status, or dementia. These results support the hypothesis that thiazides protect against osteoporosis in elderly people.
The total cost of care and the use of pharmaceuticals in the management of rheumatoid arthritis: the Medi-Cal program (Jacobs et al. 1988)	Medi-Cal recipients with rheumatoid arthritis (RA). It was estimated that approximately 24,000 Medi-Cal recipients receive treatment for RA each year.		Medicaid claims data were analyzed to investigate the prevalence and cost of RA in the Medi-Cal program. The sample of Medi-Cal RAs studied averaged more than \$2500 annually in total direct health care expenditures. The total cost of RA to Medi-Cal is projected to be \$19.26 million (+/- \$0.90 million) annually. Inclusion of possible gastrointestinal side effects of drug therapy increases the total cost to \$20.49 million (+/- \$0.91 million). While only 6.5% of the sample of RAs was hospitalized and 4.9% received nursing home care annually, these services are estimated to account for nearly 70% of RA-related expenditures. Less than 7% of Medi-Cal RAs receive disease modifying antirheumatic drugs (DMARDs). More than 75% of Medi-Cal RAs received aspirin or NSAIDs. These relieve pain and inflammation, but have not been demonstrated to halt the process of joint destruction.

Specific Drugs or Drug Classes, continued			
Study	Study Population/Design	Study Period	Key Findings
Alzheimer's Disease			
Alzheimer's disease: clinical treatment options (Reichman 2000)		NA	Comprehensive treatment of Alzheimer's disease requires informed use of medications for cognition enhancement, neuroprotection, and the treatment of disturbed behavior. Current treatments such as the cholinesterase inhibitors donepezil and rivastigmine can slow the progression of cognitive and functional deficits in AD over the short term. Treatment with alpha-tocopherol (vitamin E) has been shown to delay the progression of nursing home admission in patients with mild-to-moderate AD. For managing the behavioral symptoms that commonly accompany AD (e.g., delusions, aggression, depression, anxiety, irritability), various antipsychotics, antidepressants, and anticonvulsants have been effective in carefully selected patients.
4. Newer Drugs			
Do (More and Better) Drugs Keep People Out of Hospitals? (Lichtenberg 1996)	Data on drugs prescribed by physicians in outpatient visits by disease in the National Ambulatory Medical Care Survey (random sample of 30,000-50,000 patients), linked to inpatient and outpatient care utilization, and mortality data.	1980-92	Analysis of the effect of changes in the quantity and type of pharmaceuticals prescribed by physicians in outpatient visits on rates of hospitalization, surgical procedure, mortality and related variables. Estimates indicate that the number of hospital stays, bed-days, and surgical procedures declined most rapidly for those with diagnoses with the greatest increase in the total number of drugs prescribed and the greatest change in the distribution of drugs, by molecule. The estimates imply that an increase of 100 prescriptions is associated with 1.48 fewer hospital admissions, 16.3 fewer hospital days, and 3.36 fewer inpatient procedures. A \$1 increase in pharmaceutical expenditure is associated with a \$3.65 reduction in hospital care expenditure.
Are the benefits of newer drugs worth their cost? Evidence from the 1996 MEPS (Lichtenberg 2001)	This study analyzes data on prescribed medicines from the 1996 Medical Expenditure Panel Survey (MEPS) to examine the association between the use of newer medicines and morbidity, mortality, and health spending	1996	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. Our most notable finding, however, is that the 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.
Benefits and Costs of Newer Drugs: An Update (Lichtenberg 2002)	This study analyzes data on prescribed medicines from the 1996 Medical Expenditure Panel Survey (MEPS) to examine the association between the use of newer medicines and morbidity, mortality, and health spending	1997	In the entire population, a reduction in the age of drugs reduces non-drug expenditure 7.2 times as much as it increases drug expenditure. In the Medicare population, a reduction in the age of drugs reduces non-drug expenditures by all payers by 8.3 times as much as it increases drug expenditure; it reduces Medicare non-drug expenditure 6.0 times as much as it increases drug expenditure. About two-thirds of the non-drug Medicare cost reduction is due to reduced hospital costs. The remaining third is approximately evenly divided between reduced Medicare home health care cost and reduced Medicare office-visit cost. The mean age of drugs used by Medicare enrollees with private Rx insurance is about 9% lower than the mean age of drugs used by Medicare enrollees without either private or public Rx drug insurance.

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