

What Policies are States Using to Control Medicaid Prescription Drug Spending during 1990-2004, and How Effective are They?

By

Kosali Simon
Assistant Professor
Department of Policy Analysis and Management
106 MVR Hall
Cornell University
Ithaca NY 14853
(607) 255-7103
kis6@cornell.edu

Sharon Tennyson
Associate Professor
Department of Policy Analysis and Management
137 MVR Hall
Cornell University
Ithaca NY 14853
(607) 255-2619
st96@cornell.edu
and

Julie Hudman
Independent Consultant
204 Sunrise Road
Ithaca, NY 14850
607-229-3873
julie_hudman@yahoo.com

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Abstract

We present the first systematic description and analysis of state policies limiting prescription drug access under Medicaid during 1990-2004. We document the range of policy tools that states are using and how this has changed over time, and we analyze the impact of these policies on states' Medicaid prescription spending growth during 1992-2003. Our study reveals that states are increasing their use of nearly all types of restrictions we consider. We see substantial variation in the number and type of policies in existence across states, but a clear upward trend in access restrictions over time. Analysis of state level annual spending growth shows that these restrictions have in general helped in containing costs, and that some approaches, particularly preferred drug lists and tiered copayment systems that have become popular in more recent years, have been more successful than others.

I. Introduction

Spending on prescription drugs is the fastest-growing expense category in Medicaid—growing on average over 16 percent per year between 2000 and 2004 (Holahan and Cohen, 2006).¹ In 2004, state Medicaid programs spent over \$30 billion on prescription drugs (Holahan and Cohen, 2006). In 2005, Medicaid programs anticipate their prescription drug costs to grow 14.3 percent which continues a trend of double-digit growth (Crowley et al, 2005).²

Policymakers' concerns about managing the use and costs of Medicaid prescription drug benefits have grown in response. Surveys of state Medicaid programs in 2000, 2003, and 2005 concluded that states had already introduced many policies to control their drug benefit costs, and the number of states implementing such policies has increased each study year (Crowley et al, 2005). In fiscal year 2005, forty-three states implemented policies to control Medicaid prescription drug costs; in addition, forty-one states plan to adopt such policies in 2006 (Smith et al, 2005). The Medicaid Commission's 2005 report to the Secretary of the Department of Health and Human Services recommends several ways that states can further reform their pharmacy benefits, for example, by the use of a three-tiered copayment system (Medicaid Commission, 2005). Medicaid's drug restrictions are also relevant for understanding drug coverage under Medicare Part D as many of the access

¹ During the same time period, overall Medicaid spending grew a little over 9 percent per year (Holahan and Cohen, 2006).

² Several papers document in more detail the growing costs of Medicaid prescription drug costs. Tepper and Lied (2004) show trends in Medicaid Rx use and costs for 1985 to 2001. Baugh et al (2004) provide further breakdowns of this trend, showing for example that spending amounts are the highest for central nervous system drugs. The most detailed study of trends is Banthin and Miller (2006) who use MEPS 1996-2002 to look at usage of any Medicaid Rx as well as the number of drugs conditional on usage, by drug category as well as by population subgroups. They find that much of the growth comes from the use of certain drugs such as antidepressants and from the use of newer medications.

restrictions seen here (e.g. step therapy, prior authorizations, tiered copayments, quantity limits, generic substitution, and use of formularies) are adopted in Medicare Part D.

Federal rules do not require states to cover prescription drugs under their Medicaid plans, but all states currently provide this benefit to most Medicaid beneficiaries. Federal law sets minimum requirements for prescription drug coverage for those states choosing to provide drug benefits, but states are allowed significant flexibility in administering their programs. Thus the nature and stringency of state policies used to control prescription drug spending vary across states and over time. Although select policy changes have gained widespread attention among media and policy analysts,³ the extent of policies and their changing prevalence over time have not been systematically documented,⁴ nor has there been a study of the effects of these policies on the growth in Medicaid prescription drug expenditures.⁵

This article provides an analysis of changes in states' Medicaid prescription drug policies over the time period 1990-2004, and assesses how these changes affect the growth in Medicaid prescription drug spending in the states. Our focus is on state policies that have the most direct bearing on Medicaid beneficiaries' access to prescription drugs. These include copayments for prescription drugs, prescribing limits, mandating the use of generic drugs, step-therapy requirements, prior authorization of drug use, and preferred drug lists.⁶

³ Examples include Texas and Kentucky's exclusion of the antipsychotic medication Zyprexa from their preferred drug lists; Koyanagi, Forquer and Alfano (2005) who research states' use of cost control policies on a selected group of psychiatric medications; and Lichtenberg (2005), Murawski and Abdelgawad (2005), and Virabhak and Shinogle (2005) who looked at the effects of implementing preferred drug lists in a state.

⁴ Morden and Sullivan (2005) look at state prescription drug policies in 2004; and Crowley et al (2005) update previous surveys in 2000 and 2003 with new data from 2005.

⁵ One study (Fischer and Avorn, 2003) calculated the hypothetical financial impact of states' *greater* use of generic drug policies and found that states could potentially realize an increase in savings by implementing these policies in their Medicaid program.

⁶ There are other efforts being made to control Medicaid drug costs that we do not discuss as they impact the cost per prescription to Medicaid rather than the number or type of medications used by patients. Examples are

Understanding the use and effectiveness of these policies is of particular importance because of their potential to reduce beneficiaries' access to needed prescriptions, and the possible negative health consequences of reduced access.⁷

The article is organized as follows. Section II describes the construction of our dataset documenting states' Medicaid prescription drug policies over time, and uses those data to analyze trends in states' use of pharmacy benefit restrictions. We find an increased use of restrictions in nearly all areas, especially in utilization management policies, but substantial variation across states. Section III analyzes the effects of these state policies on the growth in state Medicaid prescription drug spending. We find that states' benefit restrictions have contained expenditure growth, and that the newer utilization management policies have been most successful in this regard. Section IV of the article summarizes and interprets these findings.

II. State Medicaid Pharmacy Benefit Restrictions

We compile data from secondary and primary sources to analyze state Medicaid prescription drug policies over 1990-2004. We use the database to analyze cross-state and over time patterns in state Medicaid prescription benefit restrictions. We track the prevalence

changes to the reimbursement formula from pharmaceutical companies and extension of the rebate program to Medicaid managed care.

⁷Research has suggested that Medicaid beneficiaries perceive poorer access to prescription drugs than those with private insurance coverage, and that these access disparities have increased over time. Using data from 1994, Berk and Schur (1998) found that after controlling for health status, Medicaid beneficiaries have the same access to a usual source of care and a similar number of doctor visits as those with private coverage, but are twice as likely to report not being able to obtain prescription drugs. This study found that 7 percent of those with Medicaid were unable to obtain a prescription drug when needed, compared to 2.9 percent of those with private coverage or 13.6 percent of those who had no coverage. Estimates based on the 2000 and 2003 Community Tracking Study (CTS) showed much higher percentages of people unable to afford prescription drugs, and similar disparities between Medicaid beneficiaries and the privately insured (Cunningham, 2005). Coughlin et al (2005) analyzed data from the 1999 and 2002 National Survey of America's Families (NSAF) and found that Medicaid beneficiaries reported worse access compared to low-income insured individuals on two measures – access to dental benefits and prescription drugs. The authors conclude that states' flexibility with the prescription drug benefit including an increase in cost containment policies has led to poorer access for Medicaid beneficiaries. One study that found no differences in access is Elam (2004). Using 1996 MEPS data, this study found that Medicaid beneficiaries had about the same access to antidepressant drugs as those with private coverage.

and stringency of each specific policy used by the states over the study's time period, to examine the evolution of state policy instruments to control drug usage and cost. The combined extent and scope of policies employed by each state is also tracked to evaluate how a state's overall approach relates to other states, and how this has changed over time. Taken together, the results of these analyses portray the evolving character of state Medicaid prescription drug policy.

A. Data

The primary source of information used in creating our policy database is *Pharmaceutical Benefits under State Medical Assistance Programs*, a report published annually by the National Pharmaceutical Council (NPC) based on their surveys of states. Data on states' preferred drug list policies were not available in the NPC reports, so we obtained these from the National Council of State Legislatures (NCSL), and confirmed the year of implementation by searches of states' Medicaid websites.

The NPC reports are available in hard-copy (1992-1999) or pdf (2000-2004) formats and organized into tables of state comparisons of individual policy variables. To create a database for research, we entered these data into electronic spreadsheet formats and organized the raw information into a state by year dataset. This format facilitated systematic coding and tracking of individual policies and of the entire set of policies employed by each state, allowing us to provide a more complete picture of policy trends and the combination of tools used at the individual state level.

The NPC reports contain detailed charts and descriptions of state Medicaid pharmacy benefit programs, including the features we are interested in studying. However, the surveys do not report all policies in every year. Missing information was added to the database where possible, and the data were checked against and supplemented with data from other published

sources where available.⁸ As a final step, we created individual state profiles from the information we gathered, and mailed this information to each state’s Medicaid office to verify their accuracy and gather information where there were gaps in our data. With some exceptions, we were able to gather data on each state policy for every year in the study period 1990-2004. For clarity of presentation we display data here for only four selected years: 1990, 1996, 2000 and 2004.

B. Trends in States’ Use of Specific Policies

We analyze trends in states use of policies after separating them into four broad areas: copayments, prescribing limits, mandating use of generic or low-cost drugs, and prior authorization policies (including the use of preferred drug lists). Our data include 48 states plus the District of Columbia. We omit Arizona and Tennessee because their Medicaid programs are set up under waivers that allow them to differ along many dimensions relative to other states.

Cost-sharing

Under current Medicaid law, states are permitted to implement “nominal” cost-sharing for certain groups of beneficiaries. This has been defined as copayments from \$.50 to \$3.00 per prescription, though the federal government⁹ has granted waivers allowing for cost-sharing levels up to \$5.00 per prescription.¹⁰ Copayments may be used to shift costs to beneficiaries and to direct them toward cheaper drugs. While current federal law prevents states from denying a beneficiary access to a prescription because of failure to pay the copayment, it does so at presumably a high stigma cost.

⁸ Kaiser Family Foundation surveys of the states (Kaiser Commission on Medicaid and the Uninsured, 2001, 2003) provide the most comprehensive comparison sources.

⁹ State programs are overseen by the Centers for Medicare and Medicaid (CMS).

¹⁰Copayments may vary with eligibility status and service provider. Under current law cost sharing does not apply to drugs used by pregnant women and children. However, the Deficit Reduction Act of 2005 substantially increases the allowable scope of cost-sharing (<http://ccf.georgetown.edu/pdfs/recontable020906.pdf>).

Figure 1 demonstrates that prescription drug cost-sharing requirements have become increasingly prevalent over the study period. The number of states with cost-sharing has doubled since 1990. In 1990, 20 states required a copayment from beneficiaries to receive prescription drugs. By 2004, the number of states with copayment requirements had grown to 40, with eight states adding copayments between 2000 and 2004.

The Figure also shows an increasing use of tiered copayment systems that require higher copayments for brand name drugs. In 1996 (first year data are available) only 3 states charged differential copayments for brand-name and generic drugs. By 2004, 17 states employed a tiered copayment system. The vast majority of states adopting the tiered systems have done so since 2000, when only 4 states used tiered copayments.

In addition to introducing new cost-sharing requirements, states have greatly increased the levels of prescription drug copayments since 1990. In 1990, 18 of the 20 states with cost-sharing had payment levels of \$1.00 or less. In 2004, only five of the 39 states with cost-sharing had copayments of \$1.00 or less, 18 had copayments ranging up to \$3.00 and four states went to \$5.00. The median (maximum) copayment requirement among states with cost-sharing rose from \$1.00 in 1990 to \$3.00 in 2004.

In states with tiered copayment systems, the difference in copayments required for brand versus generic drugs has increased over time. In both 1996 and 2000, the median copayment amount for brand-name drugs among states that used a tiered system was \$2.00, while the median copayment for generics was \$0.50 in both years. By 2004, the median copayment for brand-name drugs was \$3.00 and that for generics was \$1.00.

Prescribing Limits

States have much flexibility in how prescription drugs are dispensed in their Medicaid programs. Medicaid federal law states only that benefits such as prescription drugs must be

provided so they are “sufficient in amount, duration and scope to reasonably achieve their purpose.” (Crowley et al, 2005). Federal regulations also allow for states to place appropriate limits on quantities per prescription and other utilization control methods.

The state policy data in Figure 2 show relatively little change in prescribing limits over the study period. A vast majority of states have some limits on prescribing, and this has remained relatively constant since 1990. In 2004 47 states placed some limits on prescribing; in 1990 43 states had some form of prescribing limits.

Although most states impose prescribing limits, there is variation in the specific nature and the extent. As seen in Figure 2, only a few states impose limits on how many prescriptions per month a beneficiary may receive, and the use of this policy has changed little over the study period. In 2004, 15 states limited the number of prescriptions a beneficiary may receive.¹¹ In 1990 13 states limited the number of prescriptions per month. Limiting the quantity of pills in each prescription is a more commonplace policy, and its use has increased since 1990. In 1990 26 states placed limits on how many pills are allowed in each prescription; this number grew to 43 states in 2004. However, a large number of states introduced these limits between 1990 and 1996 rather than in more recent periods. In both 1996 and 2000, around 40 states placed limits on the quantity of pills per prescription.¹²

Generic and Low-Cost Drugs

Medicaid law requires states to cover all FDA-approved medications by pharmaceutical manufacturers who have rebate agreements with the federal government. However, Medicaid law also allows for states to require or encourage the use of generic

¹¹ New York imposes no monthly limit, but the state does impose an annual limit of 40 prescriptions per beneficiary. This limit may be over-ridden with physician approval.

¹² 22 states also report limits on the number refills per prescription in the 2004 NPC survey, and this number has not changed much since 1990. Moreover, many of the refill limits apply only over a time period, such as 5 refills per 6 month period, and are used in conjunction with quantity limits of 30 day supplies per prescription.

medications, in ways beyond the use of tiered copayment systems already discussed.¹³ States may also require physicians to prescribe the lowest cost multi-source drug first. Often called “fail-first” or step therapy requirement, this policy requires an individual to use and “fail” on a particular drug – the lowest cost one – before Medicaid allows a higher priced alternative.

Analysis of the data reveals that generic drug policies are receiving increased attention from the states. Figure 3 shows that in 1990, only 12 states required that physicians prescribe generics when available. In 2004, this number had grown to 41 states. The period between 2000 and 2004 saw a large increase in states mandating generics – from 31 states in 2000 to 41 in 2004.

The Figure also reveals that states use “fail first” policies less frequently than other generic drug policies, but have increased the use of these policies in recent years. In 1996 (the first year data are available) only 8 states had such a policy in place. By 2004 this number had grown to 15.

Prior Authorization Policies

States have the flexibility to require prior authorization of drugs within their Medicaid prescription drug programs. Under these laws, states may require that physicians request and receive permission before a particular drug can be prescribed and dispensed.¹⁴ Sometimes a prior authorization program works in conjunction with a “formulary” or “preferred drug list”.

A preferred drug list (PDL) is a list of drugs available to Medicaid beneficiaries without prior authorization. All other drugs require prior authorization or approval by the state Medicaid office. By Medicaid law, even a drug not on a state’s PDL must be made

¹³ States may also offer pharmacists an incentive fee to distribute generic drugs. These policies are used less often by the states, with only six states having such a policy in 2004. These policies may also indirectly affect beneficiary access to brand name drugs.

¹⁴ If states operate a prior authorization program, they must provide a response within 24 hours of a request for a prescription drug, and must provide a 72-hour emergency supply of the medication.

available through a request for prior approval from the state. PDLs are required to include all drugs made by manufacturers with rebate agreements in effect with the federal Department of Health and Human Services, with some exceptions to this rule (such as if the drug is similar to other drugs on the PDL). Some states have excluded certain drugs under these exceptions.

Figure 4 shows that prior authorization programs have been prevalent among the states throughout the study period: 41 states had prior authorization programs in 1991 (first year data available) and 49 states had a program in place in 2004. However, the past five years have seen rapid adoption of PDLs by the states. Since implementation of a PDL often (but not always) comes with a considerable lag after a state legislature authorizes its development, our data report the implementation dates rather than the authorization dates. In 2000 no states had implemented a preferred drug list operating in their Medicaid program. In 2001, only two states (Florida and Georgia) had implemented a PDL.¹⁵ By 2004 fully 30 states had PDL programs in place.¹⁶

Beyond the widespread implementation of PDLs, other data available from NPC reports indicate that prior authorization scope and activity has increased greatly over the study period. Although not reported in the Figure, these data reveal that states are reviewing a much larger number of prior authorization requests over time. In 1998 (first year of available data), for the 30 states reporting data the number of requests per state ranged from 25 to 895,000 and the median state reviewed 16,000 requests. By 2004, for the 40 states reporting data the number of requests ranged from 28 to 2,900,000 and the median state reviewed 77,500 requests. Among the 27 states that reported in both 1998 and 2004, eight saw a

¹⁵ Michigan had authorized but not implemented a PDL in 2001.

¹⁶ Data compiled by the authors from information on state PDL passage obtained from the National Council of State Legislators (NCSL) found at <http://www.ncsl.org/programs/health/medicaidrx.htm>), with implementation dates determined from states' Medicaid websites. Tennessee also has a PDL but is not included in our data. Our data show that 35 states have implemented PDLs as of 2005.

decrease in prior authorization requests over the time period and 19 states saw an increase in requests. The median change in prior authorization requests from 1998 to 2004 among these states was an increase of 273%.

Additionally, states are approving a lower percentage of prior authorization requests over time. In 1998, for the 24 states reporting data the range of approval percentages was 60% to 98%, with the median state approving 90% of requests. In 2004, for the 39 states reporting data approvals ranged from 27% to 100%, with the median state approving only 82% of requests. Among the 22 states reporting data for both years, the change in approval percentages over time ranged from a decrease of 63% to an increase of 31%, with the median state approving 2% fewer requests in 2004 than in 1998.

C. Trends in the Scope of State Restrictions

We first measure the scope of a state's overall activism in controlling Medicaid prescription drug access by examining the number of policies in place in the state. We examine five important policies for which we have data over the entire study period: copayments, generic substitution, limits on number of prescriptions, limits on quantity per prescription, and the use of prior authorization (data available since 1991). We also consider these five policies plus three additional policies for which we have data for later years only: tiered copayments, fail first policies and PDLs. Figure 5 compares states' use of these policies in 1990, 1996, 2000 and 2004.¹⁷ The figure shows the mean number of policies in place per state in each year of our analysis.

The comparisons in the figure demonstrate a substantial upward trend in states' prescription drug access restrictions over time. Among the five older policies, the mean number of policies per state in 1990 was 2.32. By 2004, the mean number of policies per

¹⁷ Data on prior authorization policies in 1991 is reported in the 1990 count of policies.

state was 3.83. In 1990 only one state (California) had all five policies in place; one state (Indiana) utilized none of the policies; and seven additional states used only one of the five. By 2004 all states employed at least one of these policies and nine states used all five.

Examination of states' adoption of the three newer policies (tiered co-pays, fail-first, PDLs) also shows increasing use over time. States are adopting the three new policies at very different rates, but the majority of states employ at least one of the new policies in 2004. There is nonetheless considerable variation in policy activism across the states. Four states (Georgia, Maryland, Minnesota and Vermont) had adopted all three of the newer policies by 2004, while 13 states had adopted none. We also observe that when states adopt new policy tools, they tend to do so without substantially reducing their use of other policies (Figure 5). The average state had 3.22 of the eight policies in place in 1996, and 5.10 of the eight policies in place in 2004.

Our analysis of state data also showed that states' policy activism relative to other states can change greatly over time. With some exceptions, states that are relatively restrictive in 2004 tend to have been among the more restrictive states in 1990 as well.¹⁸ On the contrary, many states that are among the least restrictive in 2004 would not have been so classified in 1990. For example, Connecticut, Hawaii, Rhode Island and Texas had in place about the median number of policies in 1990, but are among the least restrictive in 2004. This is because the number of policy restrictions has not increased over time in these states, while other states have been more proactive in policy changes.

One shortcoming of using counts of policies is that it assumes each type of restriction is equally stringent. To explore alternative ways to measure a state's policy environment, we

¹⁸ Some states -- including Minnesota, North Carolina and Oklahoma -- have greatly increased their relative use of restrictions over time.

create two index variables by applying each state's pharmacy benefit restrictions to a random sample of privately insured individuals' prescription drug usage. By comparing the hypothetical impact of each state's restrictions on the drug usage of this uniform sample of individuals, we can create a measure of the relative stringency of each state's prescription drug plan.

We construct the index variables using data from the Medical Expenditure Panel Survey (MEPS) household component, a nationally representative dataset on the health care use and expenditures of the civilian non-institutionalized population. Supplementary files of the MEPS provide detailed information on respondent prescription drug use. We draw a random sample of 1000 privately insured individuals from the 1996 MEPS survey.¹⁹ We retain data on the individual's prescription drug usage, including drug name, quantity, dosage, and duration of use. We then compare the hypothetical impact of each state's Medicaid pharmacy benefit restrictions on the individual, by applying each state's restrictions to the individual as if they lived in that state and received Medicaid.

We create one index variable (Index1) that attempts to measure the extent of prescription quantity limits and utilization management restrictions that the person faces in a state. This variable is constructed by first calculating whether the number of drugs a person takes exceeds the state's prescription limit, and whether the individual takes any brand name drugs that might be subject to prior authorization, fail-first requirements, generic substitution or a PDL. We create a second index variable (Index2) that attempts to measure the extent of prescription cost-sharing the person faces under Medicaid in a given state. This variable applies the copayment per prescription to each of the drugs a person takes. The index values for each state and year are then created by averaging the index values that arise for that state

¹⁹ Results are similar if we restrict our sample to privately insured adults.

and year for the individuals in our random sample. Thus, the state by year values of Index1 and Index2 reflect the extent of state pharmacy restrictions relative to other states and years.

Because we do not have detailed data on state policies as they apply to individual drugs, these index variables are somewhat crude approximations. For example, copayment amounts in some states may vary by drug or avenue of Medicaid eligibility. Only select individual drug classes are subject to fail-first requirements or prior authorization, and we do not have detailed lists of the drugs that appear on PDLs for our entire sample period. Nonetheless, we can observe the number and type (brand vs generic) of drugs an individual takes and use this information in conjunction with the state policies to determine the maximum copayment amount an individual would face, and the potential utilization restrictions they could face, if they lived in each state and each year. We believe that these indices serve as an additional validity check on other ways we measure a state's policy environment in this paper. The details of the construction of the index variables are reported in an Appendix available from the authors.

Figure 6 shows the mean value of Index1 and Index2 across states in each year of our analysis. Consistent with our data on the counts of policies per state, the figure shows an increase in state policy restrictions over the study period, particularly since 2000.

III. Do State Restrictions Reduce Prescription Drug Spending?

Our analysis of data from 1990 to 2004 shows that states now employ a much larger set of restrictions to control Medicaid prescription drug expenditures than they did in the past, and that this trend has intensified since 2000. Despite these general trends, the data demonstrate considerable variation across the states – in the specific policies used, the scope of benefit restrictions, and the extent of policy changes over time.

Whether these benefit restrictions as a whole are effective in reducing states' expenditures is a critical question for policy, but we have little evidence to date. This is presumably due to the lack of a systematic compilation of state policies, and to the difficulties of separating out their effect on state expenditures from the numerous other factors that may be operating simultaneously. A variety of studies have examined the effects of state Medicaid pharmacy benefit restrictions, but have generally analyzed the effect of a single policy rather than a state's overall policy environment, and often use data from only one or two states.²⁰ Most of these studies also focus on the effects of a policy on drug access or usage rather than on state expenditures.

A. Related Literature

In one of the earliest studies, a time series study of Medicaid claims data for nearly 18,000 Medicaid beneficiaries (67% were elderly and disabled) in South Carolina found an 11 percent drop in average monthly prescriptions following the 1977 implementation of a \$.50 copay (Nelson et al, 1984). This decline was significantly greater than in the comparison state of Tennessee that did not have cost sharing. In addition, the authors observed a long-term decline in drug use in South Carolina for classes of drugs (including cardiovascular, cholinergic, diuretic, and psychotherapeutic agents) that are often used for life-threatening or hard-to-manage conditions compared to the control state.

Using the 1992 Current Medicare Beneficiary Survey, Stuart and Zacker (1999) examined the impact of Medicaid co-pays ranging between \$.50 and \$3.00 in 38 states. They found that elderly and disabled Medicaid beneficiaries residing in copayment states had lower rates of prescription drug use than their counterparts in non-copayment states. After

²⁰ A comprehensive review of the literature on the impact of pharmacy benefit restrictions in private and public insurance programs is contained in Hoadley (2005).

controlling for demographic and state policy differences, they found that the disparity is due primarily to a reduced likelihood of filling any prescription, and that the disparity was greatest for beneficiaries in fair or poor health.

Additional studies have looked at the effects of limiting the number of prescriptions per month for Medicaid beneficiaries (Soumerai et al, 1991; Soumerai et al, 1994; Martin and McMillan, 1996). These studies have found that limiting the number of prescriptions that are reimbursed was associated with a decreased usage of drugs and increased hospital admissions. Martin and McMillan (1996) looked at a 1991 Georgia policy that limited monthly reimbursable prescriptions from six to five. They utilized a quasi-experimental, retrospective, 12 month interrupted time-series analysis and found that prescription drug usage fell by 9.9 percent and beneficiaries had altered prescription drug regimens with potential for clinical consequences.

Studies that have examined the impact of state pharmacy benefit restrictions on program costs (not access to drugs) include several studies of prior authorization restrictions.²¹ Bloom and Jacobs (1985) used a pre-post design in West Virginia of the drug cimetidine, which decreased in use after prior authorization was required; Kotzan et al (1993) looked at Georgia data and use of H2 blockers and NSAIDs and found that use of these drugs decreased after prior authorization; and Smalley et al (1995) found similar effects of prior authorization for NSAIDs in Tennessee Medicaid claims. Dranove (1989) and Moore and Newman (1993) find evidence that the use of Medicaid formularies substantially changes prescribing behavior, a finding echoed in recent work by Murawski and Abdelgawad (2005) on Medicaid preferred drug lists.

²¹ Some studies have examined the effect of other Medicaid pharmacy benefit program features. Maximum allowable cost (MAC) lists are lists of generic drugs and maximum reimbursements for them similar to the federal upper limit (FUL) list. MAC lists are either more inclusive or list lower prices than the FUL list. Two studies reported that states with MAC lists said they saw lower cost growth (Abramson et al, 2004).

In summary, from the literature above and from several published reviews (MacKinnon and Kumar, 2001; Soumerai, 2004; Soumerai et al, 1993 and Hoadley, 2005), there is evidence that copayments, prescribing limits and utilization management strategies reduce Medicaid beneficiaries' use of drugs. These studies shed light on the impact of state restrictions on drug usage and access, but are of limited scope and in many cases employ a research design that has been subject to criticism (MacKinnon and Kumar, 2001; Soumerai, 2004). Nor do they do not tell us the combined effect of the current extent and scope of restrictions on state Medicaid prescription expenditures.

Our systematic collection of policy data that covers all states over a long time period allows us to test the implications of state benefit restriction policies for state prescription drug expenditure growth, using a research design that allows us to isolate the effect of the policies. We combine our data on state policies with data on each state's annual Medicaid prescription drug expenditures and characteristics of the state Medicaid population, obtained from the Centers for Medicare and Medicaid Services (CMS). Using multivariate regression analysis, we examine whether a state's use of prescription drug benefit restrictions has reduced the pace at which prescription drug expenditures have grown, after controlling for time trends and other influences on these expenditures.

B. Data

The data set used to test our hypotheses comprises of information made publicly available by CMS (formerly the Health Care Financing Administration, HCFA). The key outcome variable is the cost of prescription drugs under the Medicaid program in each year and state. States reported the annual total Medicaid Rx expenditure by state and by year (as

well as other aggregates) until 1998 through what was known as the HCFA-2082 form.²² CMS then compiled these data by state and year 1991-1998 and released the output to researchers. Since January 1999, as a result of the 1997 Balanced Budget Act (BBA), it became mandatory for states to submit data quarterly at the micro level (person-level enrollment and claims data) to CMS which would then create these aggregates themselves using the Medicaid Statistical Information System (MSIS).²³ Figure 7 displays annual nominal prescription drug expenditures (summed over all states) for the years 1992-2003.

The MSIS data also contain measures of the size and characteristics of the enrolled population such as the number of children, the number of disabled and blind Medicaid recipients, the number aged over 65 and the number of beneficiaries with any Medicaid drug utilization that year. Medicaid data from this source have been widely used by researchers studying the Medicaid program and its expenses, including Baugh et al 2004, Liska et al 1997, Holahan and Liska 1997, Holahan and Gosh 2005, although there are several details one must be cautious of depending on the research question (Bruen, 2000).

Prescription drug spending data provided by CMS are nominal dollars, reported by federal fiscal year (Oct-Sept), and represent gross amounts prior to the receipt of rebates by manufacturers. These reports specifically exclude any patient copayments, measuring only the amount that was paid by the state Medicaid system to the pharmacy.²⁴ These only cover Medicaid enrollees under fee-for-service Medicaid, (and not enrollees covered by capitated Medicaid managed care) as Medicaid has to pay the pharmacy claim in order for the expenses to be recorded by the state. If prescription drugs are provided to a Medicaid patient during a hospital stay, those expenses are included in the inpatient hospital claim, thus these are only

²² The official name was "Statistical Report on Medical Care: Eligibles, Recipients, Payments and Services"

²³ Several states had been submitting micro level data to CMS using the MSIS system even prior to 1999.

²⁴ These payments represent the total cost of the medications and do not take into account the Federal Matching Assistance Percent of the total costs which the federal government will refund to the states.

outpatient prescription expenses. Similarly, in most states medications provided in nursing homes are also included in the nursing home's reimbursement rate. As Medicaid restrictions do not apply in an inpatient setting (for example, since something like a fail first or prior approval approach is not feasible), and do not apply to capitated managed care plans, these features of the dataset are not problematic for our study.

As Bantlin and Miller (2006) point out, it is important to control for the nature of the population enrolled in Medicaid when looking at trends in Medicaid prescription drug outcomes over time. Accordingly, we account for several features of a state's Medicaid population in our analysis. States generally do not require fully capitated managed care entities that serve Medicaid beneficiaries to submit a break down of the costs to the states. Some forms of Medicaid managed care, such as PCCM, still involve pharmacy claims being paid by the state. We thus include in our analysis data on *fully capitated managed care penetration* in the state. We expect that as states expand programs to cover more enrollees (in ways not picked up by the other controls), costs would naturally rise and thus we incorporate data on the *number of people receiving prescription drugs under the Medicaid program*. Prescription drug use tends to be much higher among the disabled and the costs may have also grown at a faster rate (Baugh et al 2004). For these reasons, we take into account the *percentage of a state's Medicaid beneficiaries that are in different eligibility categories: children, elderly, disabled*. To take into account the changing economy, we include the state's *unemployment rate*.

All of the above measures also come from CMS (except the unemployment rate which comes from the Bureau of Labor Statistics Local Area Unemployment Statistics.) We obtain most of these from the 2082-MSIS forms. The fraction enrolled in Medicaid managed care programs, also comes from CMS but from a different reporting system. CMS reports data

from 1995 onwards showing the percent of the Medicaid population in managed care. As some forms of managed care do not include prescription drugs (i.e. PCCM type managed care), while others do (fully capitated managed care), this means that it is important to know enrollment by type of managed care for the purposes of this study. CMS reports from 1995 onwards in older style pdf format the enrollment numbers in different managed care contracts (and their capitation status) by state, county, and by plan name. A typical year contains about 60 pages of data. These pages were scanned, hand-edited and then aggregated to the state level to compute the percent of the Medicaid population in fully capitated managed care. For data from 1991-1995, we received hard copy tables from CMS which were entered into a database and processed in a similar manner. Because of some missing data for early years, we do not use 1991 information. As our growth rates are calculated from base year to next, we use the first year (1992) in constructing data for 2003, and so the final data set for analysis thus covers 1993-2003, and contains observations on 49 states. Summary statistics are provided in Table 1.

C. Methods

We assume that the annual growth in a state's Medicaid prescription drug expenditures is determined by policy actions taken to control spending growth, as well as by fixed as well as time variant characteristics of the state, and national time trends that affect all states.²⁵ We test our hypotheses about how a state's adoption of policies affects expenditure growth with an empirical model specified in the following way:

²⁵ This study design follows the literature that has looked at the effect of state policies on the growth of costs in other programs, for example, state workers compensation programs (Danzon and Harrington, 2001).

$$\begin{aligned}
\Delta Expenditures_{st} = & \alpha + \beta_1 Restrictions_{st} + \beta_2 \Delta CapitatedManagedCarePenetration_{st} \\
& + \beta_3 \Delta MedicaidRxPopulation_{st} + \beta_4 \Delta \%Kids_{st} + \beta_5 \Delta \%Elderly\&Disabled_{st} + \\
& \beta_6 UnemploymentRate_{st} + State_s + Year_t + State*Time_{st} + e_{st}
\end{aligned} \tag{1}$$

Our dependent variable is the annual growth in Medicaid prescription drug expenditures. We measure expenditure growth as the annual percentage change in a state's spending on prescription drugs expressed as a fraction of the first year's value, $(Expenditures_{st} - Expenditures_{s,t-1}) / Expenditures_{s,t-1}$. Our key independent variables measure the set of pharmacy benefit restrictions ($Restrictions_{st}$) described previously in our study. As discussed above, we expect that policies will differ in their effect on cost containment, and our empirical work uses alternative specifications to look at the general and specific effects of different types of policies.

In studies of the effects of state policies, one must be careful to consider the source of identification (Soumerai, 2004). In a study design that compares outcomes in one state before and after it implements a policy, one could inadvertently attribute the effect of some other phenomenon that occurs in that state during those years to be the effect of a policy. Looking at a cross-section of states at a point in time is also problematic because differences in outcomes between states with and without policies could obviously reflect other underlying differences between states. In our approach, we minimize these concerns by using information both across states and over time for almost all states. We include state fixed effects in all models to account for the fact that different states may be on permanently different growth trajectories (for example, larger states may be more efficient due to economies of scale and every year see lower cost growth rates than a smaller state). We also take account of the fact that in certain years, the entire nation may face cost shocks. Studies that focus just on one

state cannot separate out these effects. We include year fixed effects in all our models to capture the effect of national phenomena that may affect drug spending (e.g. the introduction of a block buster drug).

Although state fixed effects account for the fact that states may be growing at different rates during this time period, they do not account for the possibility that these growth rates themselves may change over time due to some other trends in the state (that may be spuriously correlated with the enactment of a policy). To the extent that a state's Medicaid program changes in composition in ways relevant for costs, the characteristics of the state program are important determinants of cost growth. We include measures such as changes in the proportion of the Medicaid program that is accounted for by children under 21, by those over 65, by those who are disabled or blind, and those in Medicaid managed care, as well as the prescription drug Medicaid enrollment by state by year.

To account for the possibility that other unmeasured state trends (e.g. industrial decline) could be correlated with the timing of policies, in some model specifications we include a separate linear time trend for each state. In this specification, our identification comes from a very robust study design in which we test whether a state that adopts a policy sees a change in its annual pattern of expenditure growth, relative to the nation as a whole, relative to the state's underlying growth rate that is common across all years, and relative to anything else that may be happening in the state that may cause its growth rate to increase or decrease linearly over time relative to other states.

D. Results

We first estimate equation (1) with each state's policy actions measured as a simple count of policies, or as a 0-1 dummy variable indicating whether a state has 4 or more policies (as opposed to 0-3). This approach follows recent work by Cunningham (2005) using the

Community Tracking Study to look at whether state restrictions in the 2000/01-2003 period have affected beneficiaries' perceived access to needed medications.

The results from this model are presented in Table 2. Standard errors are reported in parentheses below coefficients; statistically significant coefficients are indicated with asterixes. The results show that increasing the total number of benefit restrictions appears to reduce expenditure growth, and this effect is statistically significant in all model specifications. The coefficient on the number of policies is consistently in the negative 0.02 range, indicating that states who adopted one additional policy saw annual expenditure growth reduce by about 2 percentage points. The dummy variable for states and years in which 4 or more policies are employed suggests annual expenditure growth is lowered by around 3 percent in both specifications, and this effect is statistically significant when state time trends are excluded from the model.

One might expect that the different policies will have different effects on expenditure growth. Thus the results in Table 2 could mask substantial heterogeneity in the impact of each restriction. However, one should be cautious before entering several separate policies into a single regression model as there could be a high degree of multi-collinearity between them. Our analysis of state actions did not point to a systematic clustering of policy activity, but we nevertheless examined the correlation matrix between the state policies, reported in Table 3. Table 3 shows that the policy variables are not highly collinear: the correlation coefficient between any two laws does not exceed 0.28 and on average it is 0.08 in absolute terms. In the next specifications, we analyze the effects of state benefit restrictions by entering each policy separately in the regression model. Table 4 reports the results of estimation, showing only the coefficients on the policies. Results for controls variables are available upon request.

The estimates show that most of the policies have a negative effect on expenditure growth, and that the effects of PDLs, tiered copayments and prior authorization are the largest. The coefficients on these latter variables are also statistically significant, while those on the other variables are not. Prior authorization becomes statistically insignificant when state time trends are included in the model. Without state time trends (column 1), the coefficient estimates suggest that the use of PDLs reduces states' annual prescription drug expenditure growth an average of 5.3 percent, tiered copayments reduce annual expenditure growth by 4.9 percent, and prior authorization procedures reduce expenditure growth by 6.4 percent. When state time trends are included, the estimated impact on expenditure growth of PDLs and tiered copayments increases, to -6.0 percent and -6.9 percent, respectively. As noted previously, prior authorization becomes statistically insignificant.

To test the robustness of these effects, we also examined different ways of entering the policy measures in the models (not reported in the tables). For example, we entered the count of policies in each of the four distinct restriction categories (cost-sharing, generics, prescribing limits, prior authorization) rather than the total number of policies. We also tried entering the older, traditional policies (any copayment, generics, prescribing limits, prior authorization) as a count of state restrictions in combination with the newer policies (tiered co-pays, fail-first, PDLs) entered as individual dummy variables. Our main results remain largely the same in all cases. There are some changes in which coefficients reach statistical significance depending on whether we include state linear time trends, but the qualitative story remains the same. Namely, states' pharmacy benefit restrictions tend to decrease cost growth, and utilization management policies such as tiered copayments and PDLs have the greatest impact.

In running our robustness tests, we also specified both our dependent variables and control variables in different ways (not reported in the tables). We ran alternative models in which the dependent variable is the log of expenditure growth ($\ln(\text{Cost}_t/\text{Cost}_{t-1})$) rather than the percentage growth. We also ran models in which the control variables were entered in levels rather than changes, and experimented with different subsets of the control variables. All models produced qualitatively similar results for the policy variables.

Finally, we also run the models using the two policy stringency index variables that we developed using the MEPS data (reported in Table 4). While much weaker, the results from these estimates are not inconsistent with those from the previous specifications. The estimated coefficients on the index variables are negative, though not generally statistically significant. The coefficient on the cost-sharing index (Index2) is statistically significant when state time trends are omitted from the model (column 3). The magnitude of the coefficient estimate is small, but it should be borne in mind that our expenditure data do not incorporate the direct effects of beneficiary copayments. That is, the estimated effect of cost-sharing policies on expenditure growth captures only their effects on reduced drug utilization and shifting to lower cost drugs, if any.

Overall, the results from all specifications are fairly consistent and show that some forms of state restrictions have reduced Medicaid prescription drug expenditure growth in a statistically and economically significant manner. Different specifications suggest slightly different conclusions, but in general it appears that states that have enacted more policies and those that use select utilization management policies such as prior authorization, PDLs, and tiered copayment systems have seen significantly slower prescription expenditure growth over the study period. Thus, this simple econometric exercise lends support to the idea that states

are seeing reductions in prescription drug expenditures after enacting pharmacy benefit restrictions in their Medicaid programs.

IV. Conclusions

Analysis of state data from 1990 to 2004 shows that states now employ a much larger set of restrictions on prescription drug access under Medicaid than they did in the past. This trend has intensified since 2000 as states have faced increasing budgetary pressures overall and in their Medicaid programs.

Analysis of specific policy categories reveals an increased use of restrictions in nearly all areas. The data also show distinct patterns in the timing of different types of policies adopted by the states. Copayments and prescription limits were adopted as relatively early cost-containment strategies— in many states prior to 1996. Mandatory substitution of generic drugs for brand name drugs was also a relatively early policy, although adopted later in many states. In recent years many states have added to these policies a set of utilization management policies that rely on controls on selected drugs or drug classes: tiered copayments, fail first policies, and preferred drug lists.

The extent to which these new restrictions are effective in changing prescribing behavior and reducing costs is a critical question for the states. Our analysis of Medicaid drug expenditure growth suggests that these policies are indeed successful in reducing spending. We conduct a differences-in-differences analysis of states' annual prescription drug expenditure growth, examining whether the rate of a growth is different after state policies are enacted compared to before, in a state that enacted a policy compared to ones that did not, including controls for state, year and state time trend effects as well as program characteristics. The types of restrictions that significantly reduce cost growth are tiered copayments, PDLs and – in some specifications – prior authorization. These policies also

have an economically significant impact on cost growth, reducing annual expenditure growth by 5 to 6 percentage points.

Our findings suggest that policies that provide incentives or requirements for prescription drug users to shift to less expensive drugs are having the greatest impact on reducing states' prescription drug costs under Medicaid. Further research into the impact of these new prescribing hurdles on beneficiary health and health care usage is needed. A related concern is that state policy restrictions may reduce Medicaid drug expenditures but fail to reduce overall Medicaid costs. If prescription drug expenditure reductions are achieved by reducing access to essential medications, then other health care expenditures may rise. Two reviews of the literature conclude that the effects of Medicaid pharmacy benefit restrictions on other Medicaid costs remain largely unknown (Soumerai 2004; Soumerai et al, 1993), but recent research on states' use of Medicaid PDLs shows mixed evidence on their effectiveness from a total program perspective (Lichtenberg, 2005; Virabhad and Shinogle, 2005; Wilson, Axelsen and Tang, 2005) and that there may be some administrative costs shifted to physicians (Ketchum and Epstein, 2006).

It is important to note that our study only considers the effect of policy restrictions on prescription drug costs, and not on access to drugs, health status, or the costs imposed on physicians. Additional research into these questions is facilitated by the policy data compiled for this study. The data show considerable variation across the states in the specific policies used, in the extent and scope of policy restrictions, and the extent of policy changes over time. These differences provide fertile ground for research into the impact of state policies on the growth in Medicaid program costs, on beneficiary access to drugs, and the relationship between access restrictions and beneficiary health outcomes.

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Table 1: Descriptive Statistics

<i>Variable</i>	<i>Mean</i>	<i>Std. Dev.</i>
Percent annual growth rate of Rx costs	0.156	0.130
Log annual growth rate of Rx costs	0.145	0.091
Percent change in number of Rx beneficiaries	0.046	0.323
Percent change in beneficiaries under age 18	0.002	0.007
Percent change in beneficiaries over age 65 or disabled	0.001	0.003
Percent change in beneficiaries in capitated managed care	0.038	0.165
Percent annual growth rate of non-Rx costs	0.091	0.131
Percent of beneficiaries who used Rx services	0.609	0.169
Percent of beneficiaries under age 18	0.487	0.088
Percent of beneficiaries over age 65	0.109	0.038
Percent of beneficiaries who are disabled	0.170	0.048
Percent of beneficiaries in any managed care	0.459	0.301
Percent in capitated managed care	0.306	0.306
State unemployment rate	5.037	1.380
Number of pharmacy benefit restrictions in state	3.436	1.212
Dummy variable for 4 or more restrictions in state	0.442	0.497
State has any copayment (dummy variable)	0.649	0.478
State requires generic substitution (dummy variable)	0.616	0.487
State limits number of Rx (dummy variable)	0.249	0.433
State limits quantity per Rx (dummy variable)	0.829	0.377
State has preferred drug list (PDL) (dummy variable)	0.067	0.250
State has fail-first provision (dummy variable)	0.113	0.317
State has tiered copayment (dummy variable)	0.104	0.305
State has prior authorization (dummy variable)	0.824	0.381
Number of traditional policies in state	1.727	0.758
Number of innovative policies in state	1.724	0.940
Maximum copayment amount	1.151	1.106
Index of state utilization restrictions (Index1)	15.523	14.786
Index of state cost-sharing stringency (Index2)	7.466	5.902
Number of observations	539	

**Table 2: Annual Rx Growth
Models with Policy Counts**

<i>Variable</i>	<i>Counts</i>	<i>Counts</i>	<i>Counts</i>	<i>Four plus</i>	<i>Four plus</i>
Number of policies	-0.025*** (0.01)	-0.022** (0.01)	-0.023** (0.01)	--	--
Has 4 or more policies	--	--	--	-.034** (0.02)	-0.028 (0.02)
Rate of growth of beneficiaries with any Rx	--	0.025 (0.03)	0.029 (0.03)	0.025 (0.03)	0.03 (0.03)
Rate of growth of beneficiaries who are kids	--	1.106 (0.82)	0.971 (0.86)	1.17 (0.86)	0.999 (0.88)
Rate of growth of beneficiaries who are over 65 or disabled	--	2.125 (3.30)	1.774 (3.23)	1.811 (3.34)	1.458 (3.26)
Rate of growth of beneficiaries in capitated MMC	--	-0.056 (0.04)	-0.042 (0.04)	-0.056 (0.04)	-0.043 (0.04)
State unemployment rate	--	-0.018 (0.02)	-0.035 (0.02)	-0.019 (0.02)	-0.037 (0.02)
State and Year fixed effects		Y	Y	Y	Y
Linear state time trends		N	N	N	Y
Observations	535	528	528	528	528
Number of states	49	49	49	49	49
R-squared	0.12	0.14	0.25	0.14	0.25

Robust standard errors in parentheses

* significant at 10%; ** significant at 5%; *** significant at 1%

Table 3: Policy Correlation Matrix

<i>Variable</i>	<i>R1</i>	<i>R2</i>	<i>R3</i>	<i>R4</i>	<i>R5</i>	<i>R6</i>	<i>R7</i>	<i>R8</i>
R1: Any copayment	1.000							
R2: Mandatory generics	-0.101	1.000						
R3: Limit on # of Rx	0.171	0.057	1.000					
R4: Limit on quantity per Rx	-0.023	-0.085	-0.138	1.000				
R5: Preferred drug list (PDL)	0.056	0.059	0.052	0.062	1.000			
R6: Fail-first provision	0.017	0.053	-0.029	-0.025	0.163	1.000		
R7: Tiered copayment	0.250	0.069	0.057	-0.023	0.128	0.090	1.000	
R8: Prior authorization	-0.085	0.276	0.018	0.075	0.124	-0.035	0.062	1.000

Table 4: Annual Rx Growth
Models with Policy Measures

<i>Variable</i>	<i>Separate Indicators</i>	<i>Separate Indicators</i>	<i>MEPS Indices</i>	<i>MEPS Indices</i>
Any copayment	0.012 (0.02)	0.006 (0.03)	--	--
Mandatory substitution of generic for brand name	-0.008 (0.02)	0.001 (0.03)	--	--
Limits on number of prescriptions	-0.008 (0.02)	-0.018 (0.04)	--	--
Limits on quantity per prescription	0.012 (0.02)	0.005 (0.02)	--	--
Preferred Drug List	-0.053* (0.03)	-0.060* (0.03)	--	--
Any fail-first requirement	-0.006 (0.02)	-0.006 (0.03)	--	--
Tiered copayment	-0.049** (0.02)	-0.069** (0.03)	--	--
Any prior authorization	-0.064*** (0.02)	-0.049 (0.04)	--	--
Utilization Policy Index	--	--	-0.003 (0.00)	-0.003 (0.00)
Cost-sharing Policy Index	--	--	-0.001* (0.00)	-0.001 (0.00)
State and Year fixed effects	Y	Y	Y	Y
Linear state time trends	N	Y	N	Y
Observations	528	528	528	528
Number of state	49	49	49	49
R-squared	0.16	0.26	0.14	0.25

Robust standard errors in parentheses

* significant at 10%; ** significant at 5%; *** significant at 1%

Figure 1
State Copayment Policies
1990-2004

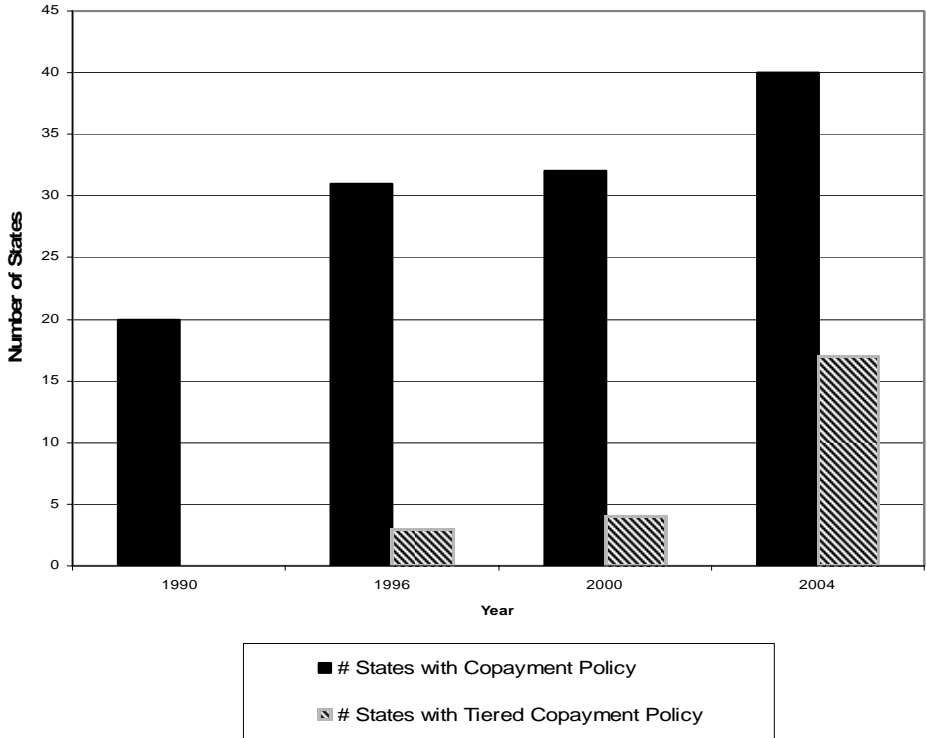


Figure 2
State Prescription Limit Policies
1990-2004

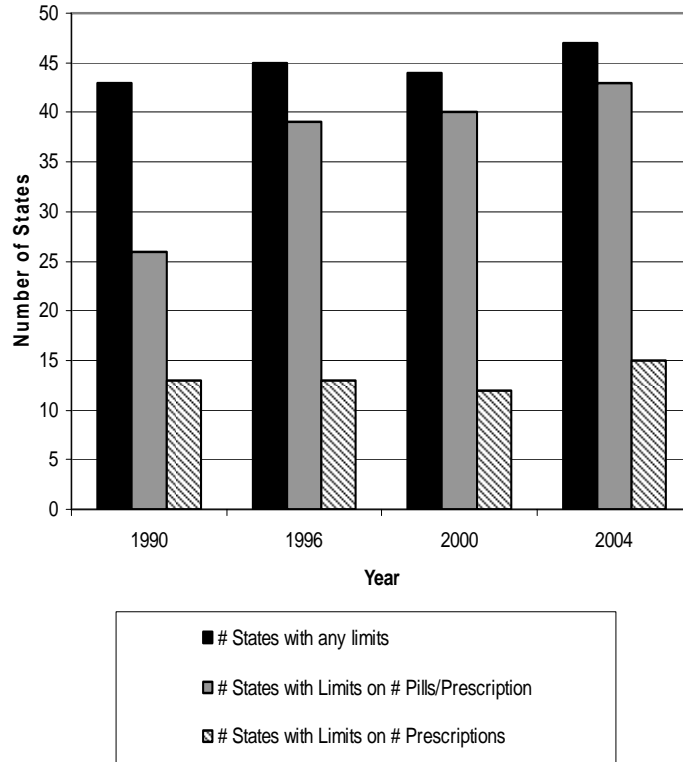


Figure 3
State Generic Management Policies
1990-2004

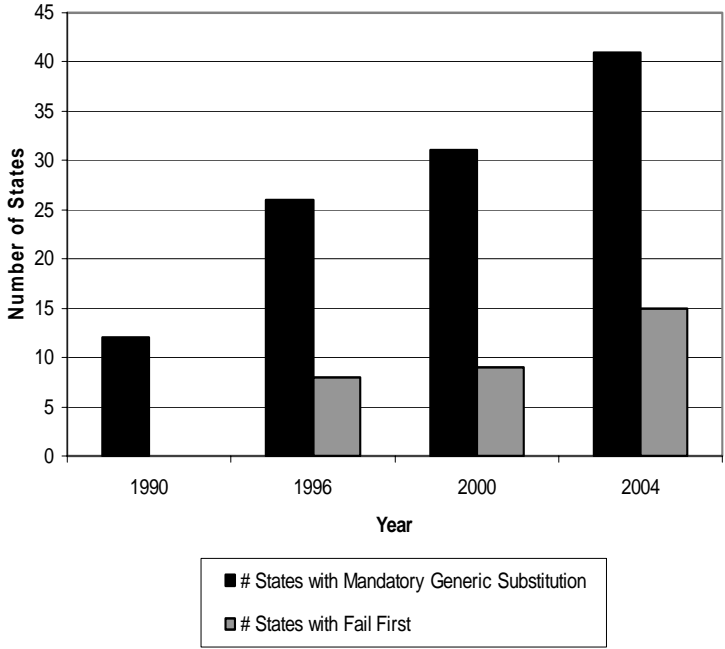


Figure 4
State Prior Authorization Policies
1990-2004

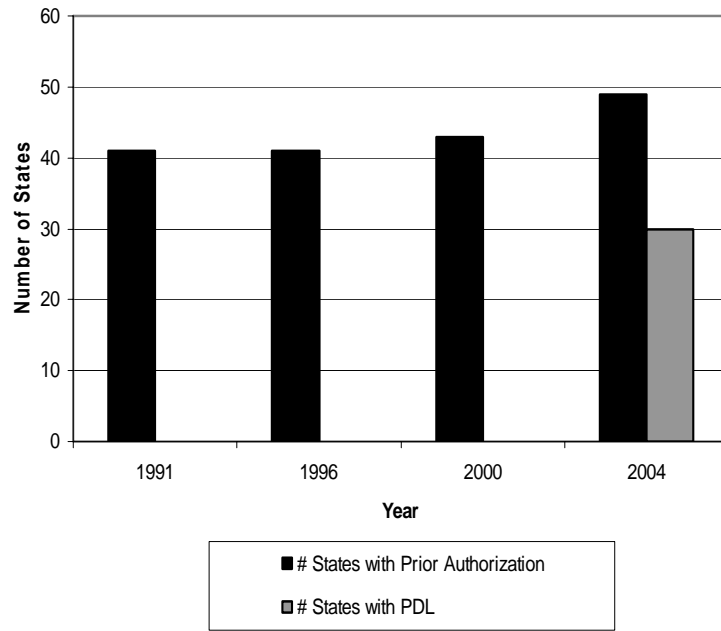


Figure 5
Mean Number of Policies per State
1990-2004

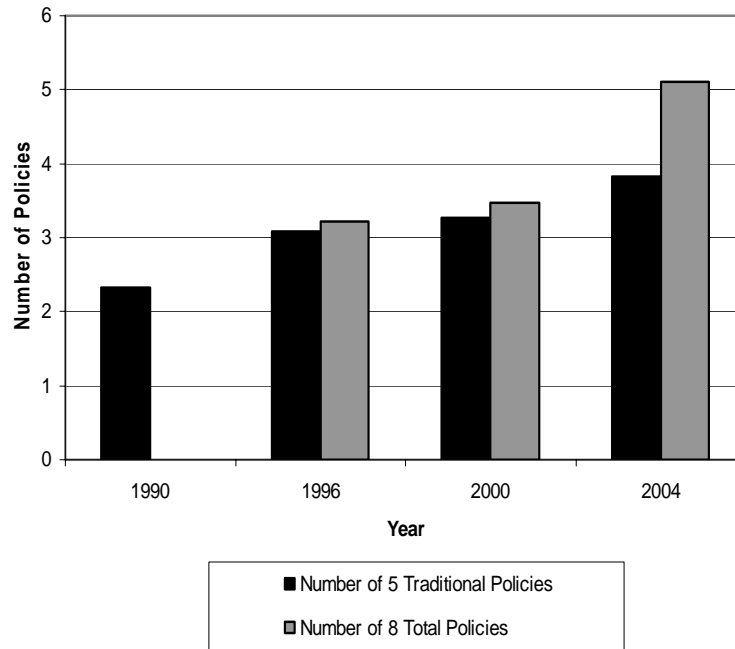


Figure 6
Mean Value of Constructed Policy Index Variables
1996-2004

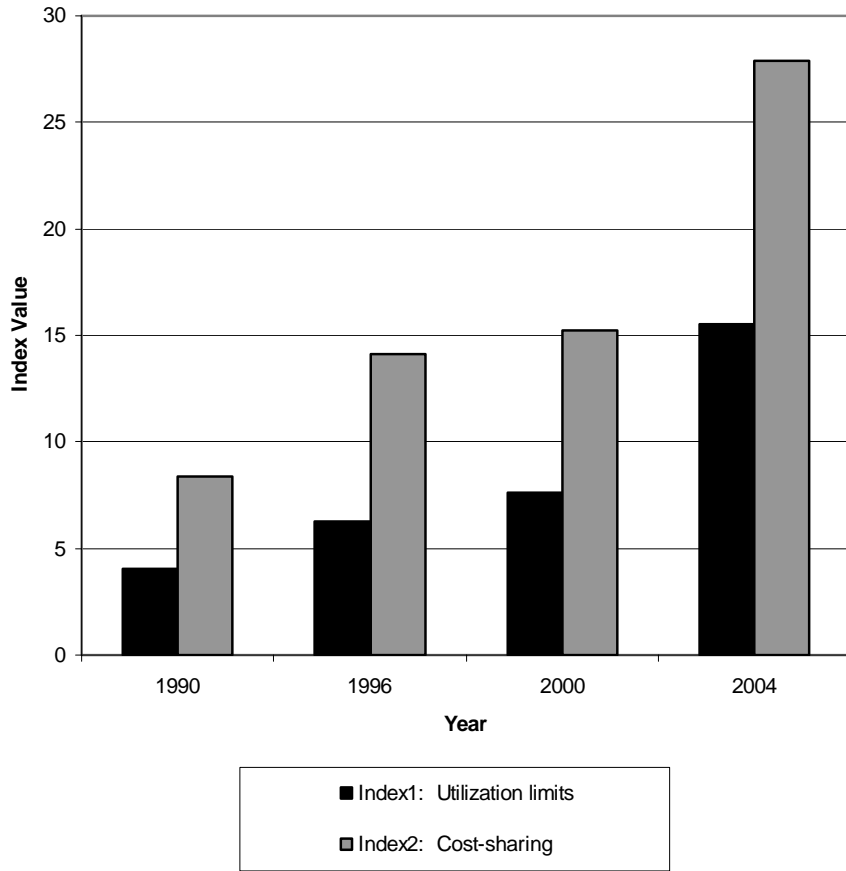


Figure 7
Total Medicaid Prescription Drug Expenditures
1992-2003

