

© Health Research and Educational Trust DOI: 10.1111/j.1475-6773.2010.01237.x RESEARCH ARTICLE

# Increasing Time Costs and Copayments for Prescription Drugs: An Analysis of Policy Changes in a Complex Environment

Marisa Elena Domino, Bradley C. Martin, Elizabeth Wiley-Exley, Shirley Richards, Abel Henson, Timothy S. Carey, and Betsy Sleath

**Objective.** To estimate the effect of two separate policy changes in the North Carolina Medicaid program: (1) reduced prescription lengths from 100 to 34 days' supply, and (2) increased copayments for brand name medications.

**Data Sources/Study Setting.** Medicaid claims data were obtained from the Centers for Medicare and Medicaid Services for January 1, 2000–December 31, 2002.

**Study Design.** We used a pre–post controlled partial difference-in-difference-indifferences design to examine the effect of the policy change on adults in North Carolina; adult Medicaid recipients from Georgia served as controls. Outcomes examined include medication adherence and Medicaid expenditures.

**Data Collection/Extraction Methods.** Data were aggregated to the person-quarter level. Individuals in HMOs, nursing homes, pregnant, or deceased in the quarter were excluded.

**Principal Findings.** Both policies decreased medication adherence. The days' supply policy had a much larger effect on adherence than did the copayment increase. Total Medicaid spending declined from the days' supply policy, but the copayment policy resulted in a net increase in Medicaid expenditures.

**Conclusions.** Although Medicaid costs decreased with the change in days supply policy, these savings were due to reduced adherence to these chronic medications. Additional research should examine the effect of these policy changes from the perspective of Medicaid enrollees.

Key Words. Medicaid, prescription drugs, chronic medications, days' supply

Over the past 20 years major advances in the pharmacological treatment of hypertension, diabetes, schizophrenia, and depression have led to improved outcomes in these and other chronic conditions (Gray et al. 2000; Pignone, Phillips, and Mulrow 2000; Chobanian et al. 2003; Conley et al. 2003; Sokol

et al. 2005; Lee, Grace, and Taylor 2006; Rasmussen, Chong, and Alter 2007), yet the cost of these treatments is high (Weideman et al. 2002; Kennedy, Coyne, and Sclar 2004; Sokol et al. 2005; Centers for Disease Control and Prevention 2009). The growth of pharmaceutical spending in many of these chronic disease categories is particularly high in state Medicaid programs (Banthin and Miller 2006).

The reasons for increasing pharmaceutical costs to Medicaid are manifold, and attempts to constrain them are common. Multiple strategies have been used by both public and private insurers, including prior authorization, formulary restrictions, tiered formularies with increased copayments for more expensive/nonpreferred medications, mail-order pharmacies, and restrictions of the number of days' supply (Soumerai et al. 1991; Berglin et al. 2003; Soumerai 2004; Ridley and Axelsen 2006; Chernew et al. 2008).

Cost-containment strategies have proven to be effective in altering patterns of care but often spill over to the use of other types of health services, including medication adherence and discontinuation, and hospital and nursing home use, especially in low-income populations or among those with chronic illnesses (Soumerai et al. 1987; Huskamp et al. 2003; Domino et al. 2004a; Hsu et al. 2006; Ridley and Axelsen 2006; Chernew and Newhouse 2008). Individuals with limited benefits often have unfavorable clinical outcomes and lower adherence rates for hypertension, hyperlipidemia, and diabetes medications (Hsu et al. 2006). Yet the evidence about whether these strategies are net cost-saving, or even cost-effective, is scarce (Soumerai 2004).

One restriction that many insurers use is to allow subscribers to fill only a month's supply of medications, even those that are used chronically. Currently, 41 out of 46 states for which information on days' supply restrictions were available restrict the days' supply in their Medicaid programs to 34 days or fewer.<sup>1</sup> Such a strategy may be cost saving if patients undergo frequent

Address correspondence to Marisa Elena Domino, Ph.D., Department of Health Policy and Management, Gillings School of Global Public Health, The University of North Carolina at Chapel Hill, 135 Dauer Dr., 1104G McGavran-Greenberg Hall, Chapel Hill, NC 27599-7411; e-mail: domino@unc.edu. Bradley C. Martin, Pharm.D., Ph.D., is with the Division of Pharmaceutical Evaluation and Policy, University of Arkansas for Medical Sciences, Little Rock, AR. Elizabeth Wiley-Exley, M.P.H., Ph.D. and Shirley Richards, BS, are with the Department of Health Policy and Management, Gillings School of Global Public Health, The University of North Carolina at Chapel Hill, Chapel Hill, NC. Abel Henson, M.S., Statistician, is with the Division of Pharmaceutical Evaluation and Policy, University of Arkansas for Medical Sciences, Little Rock, AR. Timothy S. Carey M.D. M.P.H., is with the Sheps Center for Health Services Research, UNC Chapel Hill CB 7590, Chapel Hill, NC. Betsy Sleath, Ph.D., is with the University of North Carolina School of Pharmacy and Cecil Sheps Center for Health Services Research, Chapel Hill, NC.

medication changes mid-prescription resulting in the discard of unused portions (Domino et al. 2004b). However, once a patient has been established and the dose is titrated for chronic medications, drug doses generally remain stable (Basile 2003; Neuser et al. 2005; Mago 2008) and adherence to consistent dosing is an important part of therapy.

Despite the wide use of limited days' supply policies, little research has examined the use of these policies on pharmaceutical use and costs, and no literature yet contrasts the use of restricted days' supply policies over other demand-side efforts such as increased cost sharing. This paper examines a natural experiment in the North Carolina (NC) Medicaid program in which the allowed days' supply per prescription was decreased from 100 days to 34 days on July 1, 2001, followed by an increase in copayment for brand name drugs on October 1, 2001. We used similar individuals on Georgia Medicaid as a comparison group and examined both medication adherence and total Medicaid expenditures.

## CONCEPTUAL MODEL

Both out-of-pocket and time costs affect demand for prescription medications. A decrease in the allowed days' supply is an increase in time costs because medication users have to take more frequent trips to the pharmacy. There is also a potential increase in out-of-pocket costs when a copayment is required monthly instead of every 3 months. There is unobserved heterogeneity in the benefits of being compliant to medication and in individuals' costs of traveling to the pharmacy, across medication classes and across individuals within medication classes that will affect medication use.

We hypothesized that the increase in both types of cost to the patient of obtaining a prescription will not only decrease adherence, but that decreased adherence will affect the use of other health care services. The direction of the effect of decreasing prescription lengths on other measures of health care use, such as outpatient medical visits, is not obvious a priori. If other services, such as outpatient visits, emergency room (ER) visits, or hospital stays, serve as substitutes for prescription medication use, than an increase in the cost of obtaining a prescription should increase the use of these other services due to declines in health status. The magnitude of the effect from copayment changes may not be the same as the magnitude for changes in time costs.

However, there are at least three situations where decreased adherence could *decrease* the use of other health care expenditures. First, if greater drug costs disproportionately deter inappropriate medication use that may lead to iatrogenic harms, then health expenditures could be reduced (Chernew and Newhouse 2008). Secondly, shorter prescription lengths combined with a fixed number of prescription refills may be desirable if they are linked to greater office visits and greater opportunities to monitor side effects or physical status and improve health. Finally, reduced prescription lengths could increase interactions with pharmacists and thus increase opportunities for monitoring side effects or adjusting dosage, which could lead to reductions in other health care use. We modeled the reduced form effect on total Medicaid expenditures (pharmacy and other health services). The sign of the effect is ambiguous a priori, depending on whether the savings from lower pharmaceutical use outweigh any increases in health care spending.

# METHODS

We used a pre-post controlled partial difference-in-difference-in-differences (DDD) design to examine the effect of the policy changes on adults in NC; adult Medicaid recipients from Georgia (GA) were used as a comparison group. The maximum days' supply changed in NC on July 1, 2001 from 100 to 34 days and the copayment for brand name prescriptions increased from U.S.\$1 to U.S.\$3 on October 1, 2001. GA is an appropriate control group for NC because the maximum days' supply limitation of 31 days did not change during our study period and both states have a similar population size (8.6 M), poverty rate (13 versus 14 m)percent), and percent of the population reporting African American race (29 versus 22 percent) and Hispanic ethnicity (6 versus 5 percent). GA, however, did have an increase in its copayment for nonpreferred prescriptions from U.S.\$0.50 to between U.S.\$0.50 and U.S.\$3.00 for nonpreferred medications on July 1, 2001. While this policy change in our control state during the study period is not necessarily desirable, we believe it had minimal impact on our comparison for several reasons. First, the vast majority (79-94 percent) of chronic medications were in the "preferred" categories before the policy change and thus did not experience an increase in copayments. Second, a number of Medicaid eligibles were excluded from the copayment increase (e.g., under age 21, pregnant women, those in institutions, or under hospice care). Finally, our methodology accounts for this difference between GA and NC in the policy period.

### Data

Claims data for this analysis were obtained from the Centers for Medicare and Medicaid Services for both states and cover the study period from January 1, 2000–December 31, 2002, yielding 18-month pre- and postpolicy periods.

#### Sample

We separately examined individuals in the NC and GA Medicaid programs who use medications for chronic conditions in the following six categories: (1) anti-hypertensives, (2) anti-diabetic medications (sulfonylureas and metformin), (3) lipid-lowering drugs (Gemfibrozil and HMG-CoA reductase inhibitors [statins]), (4) seizure-disorder medications, (5) antidepressants, and (6) antipsychotics. Conditions and medications were selected based on their relatively high prevalence in the Medicaid population; generally stable dosing once therapeutic effect has been achieved; and the potential for observable effects of nonadherence to medications on health services use. Diagnoses were required for associated conditions in all classes except statins and antidiabetic medications because of the potential for off-label use. The range of hypothesized effects on health services is listed in Table 1.

#### Inclusion Criteria

Individuals age 19–64 enrolled in the Medicaid program who received at least 90 days' supply of target medications, not necessarily continuously, over the 18-month prepolicy period were included in each of the six samples. All included individuals were required to be fully eligible for Medicaid benefits, thus ruling out Medicare partial dual enrollees who only received Medicare cost-sharing assistance from Medicaid (often called "SLMB/QMBs").

Data on total Medicaid expenditures and expenditures by service type (outpatient, inpatient, ER, and pharmacy) were aggregated to the quarterly level for each individual enrollee. Quarterly data were only included if the individual was enrolled in Medicaid for at least 90 percent of the quarter.

Drug Classes	Hypothesized Immediacy of Nonadherence	Diagnosis Required
Anti-hypertensives	Low	Yes
Statins	Low	No
Anti-diabetic medications (sulfonylurease and metformin)	Medium	No
Antidepressants	Medium	Yes
Antipsychotics	High	Yes
Seizure-disorder medications	High	Yes

Table 1:Included Drug Classes and Hypothesized Effects of Nonadherenceon Other Health Services Use

Quarters were excluded if the enrollee was enrolled in an HMO, in a nursing home, was pregnant, or died. We removed one quarter (third quarter of 2002) of data in GA from all drug variables due to a suspiciously low level of prescriptions in one month in the raw claims files. All remaining quarters on Medicaid were included, whether or not spending occurred.

We ran sensitivity analyses on individuals who received at least 438 medication days (= 80 percent of the 18 month pre-period) and otherwise met other inclusion and exclusion criteria. We also ran models on individuals who were continuously enrolled, defined as having at least 11 quarters of Medicaid enrollment out of 12 possible, but results were virtually identical to those reported here, due to the large percent (62 percent or greater) of the sample population that was continuously enrolled.

#### Measures

Adherence was measured using the proportion of days covered (PDC) measure (Benner et al. 2002; Peterson et al. 2007), which expresses the fraction of the days in the quarter for which at least one medication in the target class was received. Actual medication-taking behavior among those with dispensed prescriptions is not available in our data. The PDC is preferred to the Medication Possession Ratio (MPR) for adherence to a class of medications since the MPR can overstate adherence if multiple products in the same category are filled (Martin et al. 2009). The PDC instead calculates daily indicators of medication use and divides by the number of days in the quarter, and therefore it cannot be > 1.0. We also created an indicator of quarters in which the PDC is >80 percent, an often-used threshold for adherence (Keene et al. 2005; Andrade et al. 2006; Karve et al. 2009). We removed the first quarter of 2000 from the PDC analyses due to left censoring but retained its drug expenditures.

Expenditures are examined from the state Medicaid program's perspective. We examine expenditures on target medications and total Medicaid expenditures, which includes expenditures on services, pharmaceuticals, and other items recorded in the Medicaid claims files. Expenditures on prescription drugs are before rebates from manufacturers. Because a linear time trend was used, no adjustments were made for inflation.

### Analytic Methods

We examined the influence of the policy changes on measures of Medicaid spending and adherence using partial DDD ordinary least squares regression models with individual fixed effects. The person-level fixed effects will control for any time-invariant differences between patients and prescribers in each state, as well as in the subpopulations described below. Although the time trends in outcomes were similar in the prepolicy period between states, we allowed for separate linear time trends for NC and GA and used state-specific seasonal dummy variables to adjust for seasonal effects.

The partial DDD approach uses not only a comparison state (GA) but also separates out enrollees who were more likely to be affected by the policy changes. We identified individuals in NC who received a prescription in the prepolicy period of longer than 40 days; we anticipated that the effect of the days' supply policy would be concentrated in this group. A similar group is not available in GA due to the restriction of 31 days during the full study period; thus, we refer to this as a *partial* DDD.

We examined the ways in which individuals with long prescriptions (LPs) differ from other individuals in each drug class cohort through logit analysis. Results varied across the six disease categories (not reported; available from authors by request) but generally showed that women, the continuously enrolled, disabled, older, and more comorbid individuals were more likely to receive longer prescriptions, while minorities and those with greater hospital use during the study period were less likely to fill an LP. The use of person-specific fixed effects controls for time-invariant differences and between LPs and others in NC. Of remaining concern is whether the time trends in measures of use were different between LPs and others in NC before the prescription drug policies were implemented. For four of the six cohorts, we found no evidence of different trends in the rate of service access or expenditures for those who accessed services between LPs and others in NC before the policy change. Small differences in trends in service access and expenditures were detected in the remaining two samples (antidepressants and antipsychotics, respectively). This means that for these two samples, our estimated postperiod effects might overstate the actual effect due to the policy change, and thus we urge caution in interpreting results from these cohorts.

State policy making occurs in a complex environment and the days' supply change studied here is no exception. On October 1, 2001, 3 months after the days' supply change, NC raised the copayment amount for brand name prescription drugs from U.S.\$1 to U.S.\$3, leaving the generic medication copayment at U.S.\$1. This copayment change should not have affected those using only generic medications, but it may have affected patterns of care for those using brand name medications. We split medication users into those who used only generic medications (3.0–18.4 percent; Table 3) and those who used brand name medications. Along these two dimensions (LP/not LP;

Time Period and Population	Affected by Days Supply Policy Change?	Affected by Copayment Policy Change?
Transition; SP	No	No
Transition; LP	Yes	No
Post; generic only, SP	No	No
Post; generic only, LP	Yes	No
Post; brand name user, SP	No	Yes
Post; brand name user, LP	Yes	Yes

 Table 2:
 North Carolina Populations Affected by Policy Changes

LP, individuals who received a long prescription ( $\geq 40$  days) in the prepolicy period; Post, the subsequent quarters; SP, those who only received short prescriptions; Transition, the first quarter after the days' supply policy change.

generic/brand users), we can identify individuals who were most likely affected by the two policy changes (Table 2).

We focus on three separate policy periods and their potential effects in NC: (1) the pre-policy period, January 1, 2000–June 30, 2001, with an allowed longer prescription length and U.S.\$1 copayments for both generic and brand-name medications; (2) the transition period, July 1, 2001–September 30, 2001, when the allowed days' supply was shortened; and (3) the postperiod, October 1, 2001–December 31, 2002, where the shortened days' supply policy continued, compounded by the greater copayment for brand name prescriptions.

Empirically, we allowed for a separate effect during the transition period and the postpolicy period. Interactions between the NC indicator, the LP and generic/brand name indicators and the transition and postperiods were the key variables of interest and are reported in the tables. Because of the nontrivial number of quarters without Medicaid expenditures, we used two-part OLS regression models (Duan 1983; Duan et al. 1983), modeling the probability of use in the quarter separately, using a linear probability mode to accommodate the fixed effects, from the level of expenditures among observations with nonzero spending. Robust standard errors are reported.

#### RESULTS

Each of the medication cohorts had 8,300–62,000 unique nonelderly adults per state, with up to 12 observations each, yielding sample sizes for each of the six medication cohorts from 212,000 to almost one million observations (Table 3). All samples were predominately female with varying racial and ethnic

Table 3: Variable Means or	Frequen	ıcies, by	' Medic	ation C	lass (No	nelderly	y Adult	s)				
	Statins	(xp ou)	Diabete	(xp ou) s	Hyperten. d	sion (with x)	Seizure I (with	Disorder dx)	Antipsych ds	otic (with c)	Antidep (with	ressant : dx)
Variable	NC	GA	NC	GA	NC	GA	NC	GA	NC	GA	NC	GA
Individual characteristics (% of indivi	duals)											
Age	52.6	52.6	50.8	50.8	50.4	49.4	41.9	39.8	42.7	41.3	41.9	41.8
	(9.1)	(9.1)	(10.1)	(10.1)	(10.2)	(10.3)	(12.3)	(12.5)	(11.3)	(11.1)	(11.4)	(11.4)
Male	35.0	31.2	29.7	24.6	32.7	27.3	46.9	43.6	48.4	42.5	20.9	17.8
White $(0/0)$	53.6	48.7	40.2	35.5	37.3	30.1	51.8	47.2	49.3	36.9	66.8	56.2
African American	30.1	36.3	44.3	50.7	47.9	57.4	36.0	43.4	38.9	52.1	20.2	32.7
Other race	16.3	15.0	15.5	13.7	14.9	12.5	12.1	9.5	11.8	11.0	13.3	11.1
Latino/a	0.5	0.4	0.8	0.4	0.4	0.2	0.4	0.3	0.4	0.3	0.6	0.2
Continuously enrolled (%)	72.1	71.7	67.6	68.3	68.0	67.1	74.0	74.6	78.8	79.8	61.5	62.0
Number of diagnoses other	5.8	3.9	5.8	4.0	5.9	4.6	6.5	5.2	6.1	4.5	7.0	5.5
than target condition												
Received long prescription $\cdot$	28.7	ł	31.9	ł	36.8	ł	31.3	ł	21.5	ł	26.6	ł
in prepolicy period (%)	1								1			
Used only generic medications (%)	3.0	ł	4.8	ł	18.4	ł	12.0	ł	9.9	ł	4.2	ł
Outcome measures (person-quarter m	ieans)											
Proportion of days covered (PDC)	0.77	0.78	0.79	0.79	0.82	0.79	0.83	0.82	0.82	0.79	0.74	0.73
	(0.23)	(0.24)	(0.23)	(0.24)	(0.22)	(0.23)	(0.21)	(0.22)	(0.22)	(0.23)	(0.25)	(0.25)
Median PDC	0.87	0.88	0.90	0.89	0.92	0.90	0.93	0.92	0.92	0.89	0.83	0.81
PDC > 0.80 (%)	59.4	60.6	63.0	61.3	67.1	62.8	69.7	67.6	68.2	62.2	53.3	51.3
Target medication expenditures	169	157	189	166	128	120	308	287	710	586	188	169
1	(127)	(128)	(218)	(177)	(141)	(118)	(480)	(420)	(759)	(609)	(208)	(174)
Total expenditures	2,193	2,015	2,238	2,031	2,063	2,031	2,640	2,396	2,815	2,193	2,456	2,273
	(3,605)	(3,609)	(3, 750)	(4, 930)	(3,946)	(4, 720)	(4,634)	(4, 440)	(3,627)	(3, 231)	(4,038)	(4, 148)
Total observations	255,281	161,666	256,601	175,267	618,927	355,910	130, 186	87,066	150,260	116,095	268, 529	139,960
Unique individuals	24,618	15,673	25,654	17,553	61,544	35,685	12,442	8,307	13,863	10,693	27,580	$14,\!438$

compositions. Partly because of the inclusion criteria that required at least 90 days of filled medications, most of the sample was continuously enrolled in Medicaid during the full study period (62–80 percent). Individuals in the sample had a high number of comorbidies, averaging between 3.9 and 7.0 diagnostic groups other than the qualifying condition. Between 22 and 37 percent of individuals in NC received prescriptions of >40 days in the prepolicy period.

Mean adherence, measured by the PDC, was fairly consistent across classes, ranging from 0.73 for antidepressants to 0.83 for seizure disorders. The majority of all quarters with target medication use demonstrated an adherence level of 0.80 PDC or greater, and this figure ranged from 51 percent for antidepressants to 70 percent of quarters for seizure disorder medications. Individuals had average quarterly spending on target medications ranging from U.S.\$120 for hypertension medications in GA to U.S.\$710 for antipsychotic medications in NC. Total Medicaid expenditures ranged from U.S.\$2,015 to U.S.\$2,815 per quarter. Per capita expenditures on most services were higher in NC than GA, but the trends in spending were very similar during the prepolicy period.

DDD models (Table 4) consistently found a significant decrease in medication adherence after the policy changes in all six medication classes. During the transition period, in which only the days supply change was effective, adherence decreased by 1.5-4.6 percentage points across disease categories among individuals with a prior LP. During the postperiod, in which individuals were potentially also affected by the change in brand name copayment, we see a range of effects. The LPs who received generic medications only and thus should be affected only by the days' supply policy had an estimated 2.9-8.0 percentage point decrease in adherence in four of the medication classes; no significant effect on adherence was found among seizure or antipsychotic medication users. Among those who did not receive an LP but used brand name medications and thus were potentially affected by the copayment policy but not the days' supply policy, we find a much smaller decline in adherence, of 0.4-1.8 percentage points in four of the classes, a small increase in adherence among those with a seizure disorder (0.67 percentage point), and the effect on antipsychotic users was not statistically significant. Finally, among those hypothesized to be affected by both policies, the range of the effect was an estimated decline in adherence from 2.1 to 5.7 percentage points. For all classes except statins, this effect was at least as large as the estimated effect of the days' supply only (on LPs with generic use only), indicating compound effects of the two policies.

Adherence decreases substantially reduced the percent of quarters in which individuals were at least 80 percent adherent to target medications.

Table 4: Difference-i Target Medication ExJ	n-Difference-in penditures, and	-Differences   Total Medic	Results of Policy caid Spending	, Changes on Me	asures of Adhere	nce Measures,
	Proportion of Days Covered (PDC) for Target Medications	$PDC \ge 0.80$	Probability of Having a Prescription of Target Medication Per Quarter	Medicaid Expenditures on Target Prescriptions for Those with Prescriptions	Probability of Having Any Medicaid Expenditure in Quarter	Total Expenditures for Those with Claims
Statins						
Transition – LP	$-0.0457^{**}$	-0.0787	-0.0480 ***	-94.12**	-0.0022	-245.27**
	(0.0035)	(0.0079)	(0.0055)	(1.97)	(0.0013)	(44.89)
Post; generic only – LP	$-0.080^{**}$	$-0.132^{**}$	-0.006	$-24.62^{**}$	0.0030	-100.38
	(0.012)	(0.025)	(0.019)	(3.73)	(0.0042)	(130.15)
Post; brand user – LP	-0.0570	$-0.0901^{**}$	$0.127^{**}$	$-29.02^{**}$	0.0029	-54.72
	(0.0026)	(0.0058)	(0.010)	(2.09)	(0.0028)	(90.75)
Post; brand user – SP	-0.0180	$-0.0273^{**}$	$0.110^{**}$	$36.48^{**}$	0.0033	159.02
	(0.0021)	(0.0046)	(0.010)	(1.64)	(0.0027)	(89.16)
Diabetes						
Transition - LP	$-0.0342^{**}$	$-0.0623^{**}$	-0.0307***	$-114.86^{**}$	-0.0017	$-348.81^{**}$
	(0.0029)	(0.0067)	(0.0045)	(2.47)	(0.0012)	(44.94)
Post; generic only – LP	$-0.0343^{**}$	$-0.0528^{**}$	0.007	$-20.21^{**}$	0.0030	-57.79
	(0.0077)	(0.0171)	(0.013)	(1.78)	(0.0039)	(168.59)
Post; brand user – LP	$-0.0504^{**}$	$-0.0823^{**}$	0.0423 ***	$-72.43^{**}$	0.0042	$-389.10^{**}$
	(0.0023)	(0.0051)	(0.0076)	(1.95)	(0.0022)	(104.62)
Post; brand user – SP	$-0.0094^{**}$	-0.0097*	$0.0470^{***}$	$30.86^{**}$	0.0053*	-77.49
	(0.0019)	(0.0043)	(0.0074)	(1.06)	(0.0022)	(103.10)

910

HSR: Health Services Research 46:3 (June 2011)

Anti-hypertensives Transition – LP	$-0.0357^{**}$	- 0.0646**	$-0.072^{***}$	- 75.75***	$-0.00296^{**}$	-270.32**
	(0.0017)	(0.0039)	(0.0026)	(0.088)	(0.00076)	(35.73)
Post; generic only – LP	$-0.0445^{**}$	$-0.0831^{**}$	$0.0427^{**}$	$-18.90^{**}$	0.0020	$-170.63^{**}$
	(0.0027)	(0.0059)	(0.0047)	(0.59)	(0.0015)	(35.10)
Post; brand user – LP	$-0.0455^{**}$	$-0.0735^{**}$	$0.0384^{***}$	-62.58***	0.0010	$-178.32^{**}$
	(0.0013)	(0.0028)	(0.0031)	(0.70)	(0.0011)	(28.23)
Post; brand user – SP	$-0.0040^{**}$	-0.0025	0.0320***	$6.20^{**}$	$0.0035^{**}$	$114.60^{**}$
	(0.0011)	(0.0025)	(0.0029)	(0.34)	(0.0010)	(24.86)
Seizure disorder						
Transition – LP	$-0.0219^{**}$	$-0.0411^{**}$	-0.0055	$-155.25^{***}$	-20.0003	$-288.33^{**}$
	(0.0032)	(0.0079)	(0.0047)	(5.42)	(0.0015)	(72.08)
Post; generic only – LP	0.0089	-0.022	$0.0545^{**}$	$-38.42^{***}$	0.0032	-83.13
	(0.0057)	(0.014)	(0.0084)	(2.19)	(0.0035)	(110.28)
Post; brand user – LP	$-0.0212^{**}$	$-0.0319^{**}$	$0.0373^{***}$	$-86.18^{***}$	0.0030	-156.46
	(0.0024)	(0.0056)	(0.0051)	(4.14)	(0.0020)	(70.81)
Post; brand user – SP	$0.0067^{**}$	$0.0106^{*}$	0.0273 **	$64.49^{**}$	0.0035	9.38
	(0.0021)	(0.0049)	(0.0048)	(1.52)	(0.0019)	(66.06)
Antidepressants						
Transition – LP	$-0.0352^{**}$	$-0.0662^{**}$	$-0.0212^{**}$	$-104.61^{**}$	$-0.0025^{*}$	$-439.98^{**}$
	(0.0035)	(0.0079)	(0.0052)	(2.80)	(0.0013)	(50.70)
Post; generic only – LP	$0.0295^{**}$	-0.027	0.030*	$-23.71^{**}$	0.0089*	-253.87
	(0.0098)	(0.021)	(0.015)	(2.39)	(0.0041)	(142.83)
Post; brand user – LP	$-0.0507^{**}$	$-0.0865^{**}$	$0.0531^{**}$	$-93.76^{***}$	$0.0118^{**}$	$-388.29^{**}$
	(0.0027)	(0.0057)	(0.0080)	(2.16)	(0.0025)	(72.97)
Post; brand user – SP	$-0.0086^{**}$	-0.009*	$0.0475^{***}$	-1.82	$0.0123^{**}$	-21.57
	(0.0021)	(0.0046)	(0.0077)	(1.05)	(0.0024)	(69.28)
Antipsychotics						
Transition – LP	-0.0153	$-0.0259^{**}$	-0.0054	$-257.05^{**}$	-0.0028	$-279.74^{**}$
	(0.0039)	(0.0095)	(0.0053)	(11.08)	(0.0019)	(97.20)
Post; generic only – LP	-0.0096	0.004	$0.042^{**}$	-65.69**	0.0056	-108.80
	(0.0075)	(0.018)	(0.010)	(7.11)	(0.0035)	(85.08)
						continued

Table 4. Continued						
	Proportion of Days Covered (PDC) for Target Medications	$PDC \ge 0.80$	Probability of Having a Prescription of Target Medication Per Quarter	Medicaid Expenditures on Target Prescriptions for Those with Prescriptions	Probability of Having Any Medicaid Expenditure in Quarter	Total Expenditures for Those with Claims
Post; brand user – LP	$-0.0218^{**}$ (0.0028)	$-0.0230^{**}$ (0.0065)	$0.0264^{***}$ (0.00.51)	-115.13*** (8.79)	$0.0052^{***}$ (0.0019)	-139.68*** (48.76)
Post; brand user – SP	(0.0021) $ (0.0021)$	(0.0087) (0.0049)	$(0.0044^{\text{set}})$	$162.26^{\text{set}}$ (3.40)	(0.0017) $(0.0017)$	214.30*** (37.99)
*b < .05.						

4\*

<sup>\*\*</sup>p<.01. LP, individuals who received a long prescription ( $\geq$  40 days) in the prepolicy period; SP, those who only received short prescriptions; Transition, the quarter immediately after the days' supply policy change and before the brand name copay change.

Decreases were observed in all six categories for at least some of the affected categories and ranged from 2.6 to 13.2 percentage point reductions, indicating that both policies increased the rate at which chronic medication users were not adherent to their prescribed medication. The estimated declines were again larger for those affected by the days' supply policy than the increase in copays and were larger still for those affected by both policies.

The NC days' supply policy change was associated with a decrease of 1.7– 5.5 percentage points in the probability of filling a target medication in four classes during the transition quarter (all except seizure disorder and antipsychotic medications) followed by an increase of 3.0–5.5 percentage points in the probability of filling a target prescription each quarter during the postperiod by generic-only LPs, probably because prescription lengths no longer spanned an entire quarter. We cannot reject the hypothesis of no effect of the days' supply policy during the postperiod in two of the six categories (diabetes and statins). Surprisingly, we find an increase in the probability of filling medications from the copayment policy in all six classes, ranging from 2.4 to 11.0 percentage points. This could be due to medication switches that might bring individuals to the pharmacy more often. Finally, among those affected by both polices, we again find a substantially greater probability of filling a prescription for a target medication, ranging from 2.6 to 12.7 percentage points higher.

Medicaid expenditures for those with a target prescription decrease substantially among those affected by the days' supply policy. This effect ranged from -U.S.<sup>\$76</sup> to -U.S.<sup>\$257</sup> during the transition period for LPs to -U.S.<sup>\$19</sup> to -U.S.<sup>\$66</sup> during the postperiod. In contrast, we find increases in spending among target medication users affected only by the copayment policy in five of the six classes, ranging from U.S.<sup>\$67</sup>/quarter to U.S.<sup>\$162</sup>/quarter. Finally, among those affected by both policies, we again see overall declines in target medication expenditures, ranging from -U.S.<sup>\$29</sup> to -U.S.<sup>\$115</sup> per quarter across all six classes.

We examined whether the policy changes in NC were associated with spillovers to other types of services, such as outpatient care, inpatient use, or ER visits and found little evidence of spillovers across all medication classes (results not reported; available upon request).

Overall, total Medicaid spending on all services declined during the transition period in all six classes, ranging from -U.S.\$245 to -U.S.\$440 per person per quarter for service users. Because of high levels of service use each quarter, we find little effect of the days' supply policy on the probability of using Medicaid funded services each quarter. During the postperiod, however, we find almost no effect of the days' supply policy alone in most

medication categories. Among those exposed only to the copayment increase, we find mixed results across medication classes. The probability of using services increased in four of the six categories (all except statins and seizure medications), while the level of spending among service users increased for only two categories (antipsychotics and antihypertensives). Among those exposed to both policies, however, we again find small increases in the probability of accessing Medicaid services in only two categories (antidepressants and antipsychotics) but decreases in expenditures for five of the six categories (only statins showed no change). Since very little spillover effects on services were found, the fact that the magnitude of the change in total Medicaid expenditures was greater than the change in expenditures on target medication may point to changes in the utilization of other medications outside the classes examined here, which would also be exposed to the policy changes.

## DISCUSSION

The decrease in allowed days' supply and the increase in the brand name copayment in the North Carolina Medicaid program substantially decreased adherence across individuals using a broad range of medications for chronic conditions. The observed decreases from the days' supply policy were larger than those from the copayment policy, indicating that the increase in the time costs from more frequent trips to the pharmacy were more of a barrier to medication adherence than the increased copayment. The effects of the policy changes were weaker in the two medication classes in which decreased adherence is thought to have a more immediate and severe impact on health (seizure disorder and antipsychotic medications). The decreases in adherence occurred at a mean level of usage generally thought to show clinical effects. The probability of being 80 percent adherent decreased between 1 and 13 percentage points, implying that the policy changes resulted in a substantial decrease in medication adherence for chronic medication users in NC.

The cost savings associated with the policy change were substantial. We estimate a reduction in total spending on the order of 10–18 percent per LP during the transition period, and a steady state decrease in spending of between 1.3 and 8.0 percent during the full postperiod from the days' supply policy alone. The copayment increase, however, was associated with total cost increases in five of the six medication classes, ranging from 0.4 to 8.0 percent; a modest decrease in total expenditures was only observed among users of diabetic medications. Among those subject to both policy changes, cost declines were again consistently observed across all medication classes and ranged from 2.2 to 16.8 percent of mean expenditures.

The order of the two policy changes may have important implications. Had the copayment increase been implemented before the days' supply change, its effect would be expected to be lessened from that estimated here, as the additional charge for brand-name medications would be experienced less frequently. The implementation of the copayment change during the shorter days' supply period increases the generalizability of these results, because the vast majority of state Medicaid programs have shorter prescription lengths.

The fact that these lower levels of adherence did not seem to translate to increases in the cost of other health services may have several explanations. First, it is possible that the level of changes in adherence observed here may not be sufficiently large to result in adverse health effects; our administrative data do not contain clinical information such as blood pressures or measures of diabetic control that might be more sensitive to adherence changes. Individuals who do experience a clinical effect, such as a worsening of symptoms from reduced medication use, may simply absorb these effects, using either informal care or treatments or possibly tolerating greater disease burden. Alternatively, the 18-month postperiod may not be long enough for decreased medication adherence to spillover to the greater use of other services.

A number of limitations should be noted. Administrative measures of adherence such as the PDC may not reflect actual medication adherence. These measures may also not be sophisticated enough to pick up changes in recorded adherence that may affect health care use. For example, PDC will equal 0.5 for someone who takes the recommended dose for only half the days in the month as well as for someone who takes half the recommended daily dose for all the days in the month, although these two strategies may have substantially different clinical outcomes. In addition, estimated effects of the separate policy changes were identified through somewhat different subpopulations; as with all difference-in-difference analyses, if other policies disproportionately affected these subpopulations during the post or transition periods, we are at risk of attributing the effects to the policy changes studied herein.

This analysis focused only on costs to the Medicaid program and did not factor in the additional costs such a policy change imposes on individuals using medications through more frequent trips to the pharmacy. The cost of these trips may be compounded when travel is difficult, such as in rural areas or in populations such as the elderly or disabled.

Although we found evidence of Medicaid cost-savings in these six categories of chronic medication users as a result of the shorter prescription length, previous analyses (Domino et al. 2004b) found through a simulation exercise that if compliance were unaffected, the reduced days' supply would actually increase medication expenditures. This was because more frequent visits to the pharmacy substantially increased the pharmacy dispensing fees, outweighing the estimated savings from the differed wastage of drug products. Here, we found that adherence was affected and was critical to the cost implications of this policy.

Beginning on October 1, 2003, NC Medicaid recipients were allowed to obtain 90 days' supply of generic, noncontrolled medications following a 30 days' supply prescription for the same medication. This policy change may be an efficient option that will likely both deter wastage from switching prescriptions as well as maintain lower costs for both the program and Medicaid recipients; the actual effects, of course, remain to be evaluated.

While increasing fiscal pressure faced by states to trim Medicaid expenditures may have motivated the broad dissemination of shorter days' supply and higher copayment policies, the associated decrease in adherence should be followed closely. Lower rates of medication adherence among the chronically ill may eventually reduce the savings to Medicaid budgets demonstrated here, or possibly affect other outcomes, such as employment or even mortality. Shortened days' supply policies are not limited to Medicaid programs and the trade-off among shorter prescription lengths, short-run costs, and adherence has implications for private payors and Medicare Part D policies as well.

## ACKNOWLEDGMENTS

Joint Acknowledgment/Disclosure Statement: Support from the Changes in Health Care Financing & Organization Initiative at RWJF and AcademyHealth and NIMH 5K01MH65639 are gratefully acknowledged. Helpful comments were received from participants at an HCFO grantee briefing and an anonymous reviewer. Assistance from staff at CMS and ResDAC is appreciated.

Dr. Bradley Martin reports that he is a consultant for EMax Health and Daiichi Sankyo for a study on warfarin associated bleeding risk, and Bayer Inc., for a cost study of pulmonary hypertension, but these are not related to the subject matter of this article.

No other conflicts of interest by any of the authors are reported. *Disclosures*: None. *Disclaimers*: None.

# NOTE

1. The authors' calculation based on materials from the Kaiser website and our review of State Medicaid websites.

## REFERENCES

- Andrade, S. E., K. H. Kahler, F. Frech, and K. A. Chan. 2006. "Methods for Evaluation of Medication Adherence and Persistence Using Automated Databases." *Pharmacoepidemiology and Drug Safety* 15 (8): 565–74.
- Banthin, J. S., and G. E. Miller. 2006. "Trends in Prescription Drug Expenditures by Medicaid Enrollees." *Medical Care* 44 (5): 127–35.
- Basile, J. N. 2003. "Titration of Beta-Blockers in Heart Failure: How to Maximize Benefit While Minimizing Adverse Events." *Postgraduate Medicine* 113 (3): 63–70.
- Benner, J., R. Glynn, H. Mogun, P. J. Neumann, M. C. Weinstein, and J. Avorn. 2002. "Long-Term Persistence in Use of Statin Therapy in Elderly Patients." *Journal of American Medical Association* 288: 455–6.
- Berglin, I., N. Bergsman, C. Brown, H. L. Chandler, B. F. Christiaens, E. L. Cody, and A. Coron. 2003. "State Initiatives on Prescription Drugs: Creating a More Functional Market." *Health Affairs* 22: 128–36.
- Centers for Disease Control and Prevention. 2009. "Chronic Disease Overview" [accessed on June 11, 2009, 2009]. Available at http://www.cdc.gov/nccdphp/ overview.htm
- Chernew, M. E., and J. P. Newhouse. 2008. "What Does the RAND Health Insurance Experiment Tell Us about the Impact of Patient Cost Sharing on Health Outcomes?" *The American Journal of Managed Care* 14 (7): 412–4.
- Chernew, M. E., M. R. Shah, A. Wegh, S. N. Rosenberg, I. A. Juster, A. B. Rosen, M. C. Sokol, K. Yu-Isenberg, and A. M. Fendrick. 2008. "Impact of Decreasing Copayments on Medication Adherence within a Disease Management Environment." *Health Affairs* 27 (1): 103–12.
- Chobanian, A. V., G. L. Bakris, H. R. Black, W. C. Cushman, L. A. Green, J. L. Izzo, D. W. Jones, B. J. Materson, S. Oparil, and J. T. Wright. 2003. "Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure." *Hypertension* 42 (6): 1206–52.
- Conley, R., D. Kelly, R. Love, and R. McMahon. 2003. "Rehospitalization Risk with Second-Generation and Depot Antipsychotics." *Annals of Clinical Psychiatry* 15 (1): 23–31.
- Domino, M. E., E. C. Norton, J. P. Morrissey, and N. Thakur. 2004a. "Cost Shifting to Jails after a Change to Managed Mental Health Care." *Health Services Research* 39 (5): 1379–401.
- Domino, M. E., J. Olinick, B. Sleath, S. Leinwand, P. J. Byrns, and T. Carey. 2004b. "Restricting Patients' Medication Supply to One Month: Saving or Wasting Money?" *Amiercan Journal of Health-System Pharmacy* 61: 1375–9.

- Duan, N. 1983. "Smearing Estimate: A Nonparametric Retransformation Method." Journal of the American Statistical Association 78 (383): 605–10.
- Duan, N., W. G. Manning Jr., C. N. Morris, and J. P. Newhouse. 1983. "A Comparison of Alternative Models for the Demand for Medical Care." *Journal of Business and Economic Statistics* 1 (2): 115–26.
- Gray, A., M. Raikou, A. McGuire, P. Fenn, R. Stevens, C. Cull, I. Stratton, A. Adler, R. Holman, and R. Turner. 2000. "Cost Effectiveness of an Intensive Blood Glucose Control Policy in Patients with Type 2 Diabetes: Economic Analysis Alongside Randomised Controlled Trial (UKPDS 41)." *British Medical Journal* 320 (7246): 1373–8.
- Hsu, J., M. Price, J. Huang, R. Brand, V. Fung, R. Hui, B. Fireman, J. P. Newhouse, and J. V. Selby. 2006. "Unintended Consequences of Caps on Medicare Drug Benefits." *The New England Journal of Medicine* 354 (22): 2349–59.
- Huskamp, H. A., P. A. Deverka, A. M. Epstein, R. S. Epstein, K. A. McGuigan, and R. G. Frank. 2003. "The Effect of Incentive-Based Formularies on Prescription-Drug Utilization and Spending." *The New England Journal of Medicine* 349 (23): 2224–32.
- Karve, S., M. Cleves, M. Helm, T. Hudson, D. West, and B. Martin. 2009. "The Line between Good and Poor Adherence: The Optimal Cut Point for Adherence Measures Using Administrative Claims Data." *Current Medical Research and Opinion* 25 (9): 2303–10.
- Keene, M. S., M. T. Eaddy, W. W. Nelson, and M. W. Sarnes. 2005. "Adherence to Paroxetine CR Compared with Paroxetine IR in a Medicare-Eligible Population with Anxiety Disorders." *The American Journal of Managed Care* 11 (12, suppl): S362–9.
- Kennedy, J., J. Coyne, and D. Sclar. 2004. "Drug Affordability and Prescription Noncompliance in the United States: 1997–2002." *Clinical Therapeutics* 26 (4): 607– 14.
- Lee, J. K., K. A. Grace, and A. J. Taylor. 2006. "Effect of a Pharmacy Care Program on Medication Adherence and Persistence, Blood Pressure, and Low-Density Lipoprotein Cholesterol: A Randomized Controlled Trial." *Journal of American Medical Association* 296 (21): 2563–71.
- Mago, R. 2008. "Proposed Strategies for Successful Clinical Management with Aripiprazole." *Expert Opinion on Pharmacotherapy* 9 (8): 1279–90.
- Martin, B. C., E. K. Wiley-Exley, S. Richards, M. E. Domino, T. S. Carey, and B. L. Sleath. 2009. "Contrasting Measures of Adherence with Simple Drug Use, Medication Switching, and Therapeutic Duplication." *The Annals of Pharmacotherapy* 43: 36–44.
- Neuser, D., A. Benson, A. Brückner, R. B. Goldberg, B. J. Hoogwerf, and D. Petzinna. 2005. "Safety and Tolerability of Acarbose in the Treatment of Type 1 and Type 2 Diabetes Mellitus." *Clinical Drug Investigation* 25 (9): 579–88.
- Peterson, A., D. Nau, J. Cramer, J. Benner, F. Gwadry-Sridhar, and M. Nichol. 2007. "A Checklist for Medication Compliance and Persistence Studies Using Retrospective Databases." *Value in Health* 10 (1): 3–12.

- Pignone, M., C. Phillips, and C. Mulrow. 2000. "Use of Lipid Lowering Drugs for Primary Prevention of Coronary Heart Disease: Meta-Analysis of Randomised Trials." *British Medical Journal* 321 (7267): 983–6.
- Rasmussen, J. N., A. Chong, and D. A. Alter. 2007. "Relationship between Adherence to Evidence-Based Pharmacotherapy and Long-Term Mortality after Acute Myocardial Infarction." *Journal of American Medical Association* 297 (2): 177–86.
- Ridley, D. B., and K. J. Axelsen. 2006. "Impact of Medicaid Preferred Drug Lists on Therapeutic Adherence." *PharmacoEconomics* 24 (suppl 3): 65–78.
- Sokol, M. C., K. A. McGuigan, R. R. Verbrugge, and R. S. Epstein. 2005. "Impact of Medication Adherence on Hospitalization Risk and Healthcare Cost." *Medical Care* 43 (6): 521–30.
- Soumerai, S. B. 2004. "Benefits and Risks of Increasing Restrictions on Access to Costly Drugs in Medicaid." *Health Affairs* 23 (1): 135–46.
- Soumerai, S. B., J. Avorn, D. Ross-Degnan, and S. Gortmaker. 1987. "Payment Restrictions for Prescription Drugs under Medicaid: Effects on Therapy, Cost, and Equity." *New England Journal of Medicine* 37 (9): 550–6.
- Soumerai, S. B. S. D., D. S. D. Ross-Degnan, J. M. D. Avorn, T. J. S. D. McLaughlin, and I. B. S. Choodnovskiy. 1991. "Effects of Medicaid Drug-Payment Limits on Admission to Hospitals and Nursing Homes." *The New England Journal of Medicine* 325 (15): 1072–7.
- Weideman, R. A., K. C. Kelly, C. L. Kelley, and B. Cryer. 2002. "COX-2-Specific Inhibitors: Prescribing Patterns in a Large Managed Care Health System and Strategies to Minimize Costs." *The American Journal of Managed Care* 8 (10): 869–77.

# SUPPORTING INFORMATION

Additional supporting information may be found in the online version of this article:

Appendix SA1: Author Matrix.

Please note: Wiley-Blackwell is not responsible for the content or functionality of any supporting materials supplied by the authors. Any queries (other than missing material) should be directed to the corresponding author for the article.