Changes in Drug Coverage Generosity and Untreated Serious Mental Illness

Original Investigation

Changes in Drug Coverage Generosity and Untreated Serious Mental Illness
Transitioning From Medicaid to Medicare Part D

Jeanne M. Madden, PhD; Alyce S. Adams, PhD; Robert F. LeCates, MA; Dennis Ross-Degnan, ScD; Fang Zhang, PhD; Haiden A. Huskamp, PhD; Daniel M. Gilden, MS; Stephen B. Soumerai, ScD

IMPORTANCE More than 1 in 5 disabled people with dual Medicare-Medicaid enrollment have schizophrenia or a bipolar disorder (ie, a serious mental illness). The effect of their transition from Medicaid drug coverage, which varies in generosity across states, to the Medicare Part D drug benefit is unknown. Many thousands make this transition annually.

OBJECTIVES To determine the effect of transitioning from Medicaid drug benefits to Medicare Part D on medication use by patients with a serious mental illness and to determine the influence of Medicaid drug caps.

DESIGN, SETTING, AND PARTICIPANTS In time-series analysis of continuously enrolled patient cohorts (2004-2007), we estimated changes in medication use before and after transitioning to Part D, comparing states that capped monthly prescription fills with states with no prescription limits. We used Medicaid and Medicare claims from a 5% national sample of community-dwelling, nonelderly disabled dual enrollees with schizophrenia (n = 5554) or bipolar disorder (n = 3675).

MAIN OUTCOMES AND MEASURES Psychotropic treatments included antipsychotics for schizophrenia and antipsychotics, anticonvulsants, and lithium for bipolar disorder. We measured monthly rates of untreated illness, intensity of treatment, and overall prescription medication use.

RESULTS Prior to Part D, the prevalence of untreated illness among patients with a bipolar disorder was 30.0% in strict-cap states and 23.8% in no-cap states. In strict-cap states, the proportion of untreated patients decreased by 17.2% (relatively) 1 year after Part D, whereas there was no change in the proportion of untreated patients in no-cap states. For patients with schizophrenia, the untreated rate (20.6%) did not change in strict-cap states, yet it increased by 23.3% (from 11.6%) in no-cap states. Overall medication use increased substantially after Part D in strict-cap states: prescription fills were 35.5% higher among patients with a bipolar disorder and 17.7% higher than predicted among schizophrenic patients; overall use in no-cap states was unchanged in both cohorts.

CONCLUSIONS AND RELEVANCE The effects of transitioning from Medicaid to Medicare Part D on essential treatment of serious mental illness vary by state. Transition to Part D in states with strict drug benefit limits may reduce rates of untreated illness among patients with bipolar disorders, who have high levels of overall medication use. Access to antipsychotic treatment may decrease after Part D for patients with a serious mental illness living in states with relatively generous uncapped Medicaid coverage.

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Author Affiliations: Department of Population Medicine, Harvard Medical School and Harvard Pilgrim Health Care Institute, Boston, Massachusetts (Madden, LeCates, Ross-Degnan, Zhang, Soumerai); Division of Research, Kaiser Permanente, Oakland, California (Adams); Department of Health Care Policy, Harvard Medical School, Boston, Massachusetts (Huskamp); JEN Associates, Inc, Cambridge, Massachusetts (Gilden).

Corresponding Author: Jeanne M. Madden, PhD, Department of Population Medicine, Harvard Medical School and Harvard Pilgrim Health Care Institute, 133 Brookline Ave, Sixth Floor, Boston, MA 02215 (jeanne_madden@hphc.org).

The availability, since 2006, of subsidized drug coverage for Medicare beneficiaries under the Part D benefit increased the overall use of prescription medications while reducing out-of-pocket expenditures.[1-3] However, to our knowledge, there have been no rigorous national studies of the effect of Part D on treatment for disabled beneficiaries with schizophrenia or bipolar disorder, particularly on changes in access to psychotropic medications following Part D that are associated with variations in state Medicaid coverage policies.[4-7]

Schizophrenia and bipolar disorder (serious mental illnesses) together affect 1% to 2% of the US adult population, often with devastating personal, familial, and societal outcomes.[8,9] Adults who have persistent functional deficits due to a serious mental illness may be eligible for Supplemental Security Income disability and Medicare benefits; more than 20% of nonelderly Supplemental Security Income recipients qualify based on a serious mental illness.[10] Medicaid provides supplemental coverage for Medicare beneficiaries with incomes below eligibility thresholds ("dual enrollees"). In 2006, the responsibility of prescription drug coverage for existing and future dual enrollees transitioned from Medicaid to the Medicare Part D benefit, administered by private prescription drug plans.[3]

Patients with a serious mental illness, who typically have high rates of medication nonadherence (associated with relapse, hospitalization, and suicide),[11-15] are vulnerable to formulary restrictions and prior authorization requirements used by some Medicaid programs and prescription drug plans.[4,16,17] Medicaid benefit restrictions vary substantially across states. Of particular concern, some state Medicaid programs impose monthly caps on the number of prescription fills covered, even today.[18,19] These caps, which are not allowed under Part D, are likely to harm sicker patients who require multiple medications for long-term use.[20-23] Disabled individuals insured by Medicaid who are eligible for Medicare must wait 2 years before receiving Medicare benefits and the accompanying Part D drug coverage. Thus, every year, many thousands of beneficiaries with a serious mental illness face drug benefit caps in Medicaid and eventually transition to Part D drug coverage.

In the present study, we examine the effects of transitioning to Part D coverage among disabled dual enrollees with schizophrenia or a bipolar disorder, comparing the experience of enrollees in states with strict Medicaid cap policies with the experience of enrollees in states without caps. A priori, we expected increased use of essential psychotropic therapies after Part D in states with caps; in states with no caps, the transition to private Part D plans, with the potential to use more intensive utilization management techniques, might lead to reduced treatment.

Methods

We used an interrupted time-series analysis with comparison series, the strongest quasi-experimental design,[24,25] to evaluate changes in medication use among disabled dual enrollees with a serious mental illness while controlling for baseline trends. We examined study outcomes for 2 years before and 2 years after the initial large-scale transition to Part D (2004-2007) and stratified results by states' cap policies (strict cap vs no cap).

Our study was approved by the institutional review board of the Harvard Pilgrim Health Care Institute. Patients did not provide consent; the US Centers for Medicaid and Medicare Services provided the de-identified data sets for research under a standard data use agreement.

Study Population and Data

We obtained 2004-2007 Medicare and Medicaid enrollment and claims data from the 5% national sample of dual enrollees. We excluded 2 states with anomalous data (Ohio and Louisiana) and a third state (Arizona) where all beneficiaries were in managed care (claims unavailable). In the 48 remaining states (including the District of Columbia), we identified 29 556 persons who were dually enrolled in 2005, 18 to 64 years of age in all years, and had received at least 1 diagnosis of schizophrenia (*ICD-9* code 295.x) or bipolar disorder (*ICD-9* codes 296.0-296.1 and 296.4-296.8) on a physician or facility Medicare claim. To ensure stable analytic cohorts,[20,26] we then identified 11 318 patients with continuous 4-year enrollment (at least 10 months of fee-for-service Medicare/Medicaid enrollment per year) and no institutionalizations longer than 90 days. We further required 1 institutional or 2 physician claims on different dates to qualify as having either schizophrenia or a bipolar disorder,[17,27] and we assigned patients to 1 condition based on the preponderance of their diagnoses. Our final cohort included 9229 dual enrollees (5554 with schizophrenia and 3675 with a bipolar disorder), representing 184 580 individuals with a serious mental illness nationally.

Study Variables

States' Cap Policies

We used published summaries[28-32] of Medicaid drug benefits to assign 32 states to "no-cap" status, 11 to "soft-cap" status (higher limits on the number of prescriptions or generous overrides), and 5 to "strict-cap" status. Strict-cap states have low limits on monthly fills (≤5 total fills or ≤3 fills of brand-name drugs) and no evidence of generous overrides. Our primary analyses compared 4 strict-cap states with 32 no-cap states. We also present national estimates, including all 48 available states. Finally, we analyzed Tennessee separately because its Medicaid program implemented a strict cap in August 2005, late in our baseline period; the Tennessee case illustrates the effects of initiating and then eliminating (through Part D implementation) a strict cap.[33]

Patient Characteristics and Medication Use

In addition to a diagnosis of schizophrenia or bipolar disorder, patient-level characteristics (from 2005) included age group, sex, race, state of residence, and a comorbidity score based on Medicare's Hierarchical Condition Categories model and Medicare service claims diagnoses.[34] We measured medication use using Medicaid pharmacy data (2004-2005), Medicare Part D data (2006-2007), and Medicare Part B data (2004-2007; antipsychotic depot injections). Our primary outcomes

Table 1. Demographic and Clinical Characteristics of Study Cohorts in 2005[a]

Characteristic	Patients With Schizophrenia				Patients With Bipolar Disorder			
	National (48 States)	No Cap (32 States)	Strict Cap (4 States)	Tennessee	National (48 States)	No Cap (32 States)	Strict Cap (4 States)	Tennessee
Total No.	5554	2718	403	151	3675	1821	233	207
Age group, %								
20-34 y	14.4	13.8	16.4	14.6	17.9	18.9	22.3	19.3
35-44 y	32.3	33.1	30.8	35.8	31.8	30.9	29.2	37.7
45-54 y	38.5	39.0	36.7	39.7	35.7	35.3	33.5	29.0
55-64 y	14.8	14.2	16.1	9.9	14.6	14.8	15.0	14.0
Sex, %								
Female	37.6	37.4	35.0	39.1	62.7	62.8	75.5	61.4
Male	62.4	62.6	65.0	60.9	37.3	37.2	24.5	38.6
Race, %								
White	68.2	74.3	53.6	72.2	84.7	86.9	79.0	92.3
Black	22.4	16.8	35.5	27.2	10.1	8.5	12.9	6.8
Other/Unknown	9.4	8.9	10.9	0.7	5.3	4.6	8.2	1.0
Comorbidity score, mean (SD)	1.05 (0.65)	1.07 (0.67)	1.05 (0.53)	1.01 (0.57)	1.12 (0.80)	1.13 (0.83)	1.22 (0.88)	1.03 (0.66)
Total prescription fills,[b] mean (SD), No.	66.40 (50.51)	74.07 (55.94)	35.84 (25.13)	57.03 (37.41)	74.57 (53.21)	78.62 (54.82)	44.45 (31.14)	75.78 (42.98)
Unique medications,[c] mean (SD), No.	8.94 (5.98)	9.13 (6.19)	7.22 (4.14)	10.23 (6.71)	12.46 (7.05)	12.48 (6.93)	9.91 (5.12)	15.06 (7.57)

[a] The 32 no-cap states were Alaska, Colorado, Connecticut, District of Columbia, Delaware, Florida, Hawaii, Iowa, Idaho, Indiana, Massachusetts, Maryland, Michigan, Minnesota, Missouri, Montana, North Dakota, Nebraska, New Hampshire, New Jersey, New Mexico, Nevada, Oregon, Rhode Island, South Dakota, Utah, Virginia, Vermont, Washington, Wisconsin, West Virginia, and Wyoming. The 4 strict-cap states were Arkansas, Mississippi, Oklahoma, and Texas. Eleven states with less restrictive caps (Alabama, California, Georgia, Illinois, Kansas, Kentucky, Maine, North Carolina, New York, Pennsylvania, and South Carolina) were included (along with Tennessee) in national analyses. Three states (Arizona, Louisiana, and Ohio) were excluded from the study.

[b] Based on 2005 Medicaid pharmacy claims.

[c] Unique 8-digit *American Hospital Formulary Service Drug Information* code cross-linked to US National Drug Code on claim.

were lack of treatment with essential psychotropic medications and treatment intensity. The essential psychotropic medications were antipsychotics for schizophrenia and antipsychotics, anticonvulsants, or lithium for bipolar disorders. Antipsychotics included first- and second-generation oral forms and long-acting depot injections. Anticonvulsants included medications recommended[35] for bipolar disorders and medications used in practice to treat bipolar disorders (eg, gabapentin, levetiracetam, and pregabalin). We defined lack of treatment as the enrollee having no available days of medication supplied in the month,[16] and we determined treatment intensity using standard monthly doses. For each unique medication of interest, 1 standard monthly dose equaled the median number of milligrams received per person-month, among person-months with any treatment; standard monthly doses allow for comparisons of treatment intensity over time and between patient groups.[33] To measure overall medication use, we defined adjusted prescription fills per month as total days supplied divided by 30, including all prescription medications covered under Part D.

Statistical Analyses

We aggregated monthly patient-level drug use measures in all states (no-cap states, strict-cap states, and Tennessee) using prevalence rates for no treatment and mean values for standard monthly doses and adjusted fills. To evaluate post–Part D changes in drug use, we constructed interrupted time-series regression models for each study group using SAS PROC AUTOREG.[25] Our main models included an intercept, a term for baseline trend, and terms for change in level and trend after Part D. Four months of observations (from December 2005 through March 2006) were omitted as a policy phase-in period.[36] We applied backward elimination of terms with $P \geq .20$. To report results concisely, we calculated the difference 1 year after the transition between the estimated outcome value from all terms included in the model and the predicted value based solely on baseline trends (ie, the counterfactual).

In sensitivity analyses (data not shown), we modeled changes in all 43 states other than the strict-cap states and all southern states other than strict-cap states; the results were similar to those for no-cap states. We also modeled individual-level time-series outcomes in strict-cap and no-cap states, using generalized estimating equations ; the results were nearly identical to the results from the aggregate models, although with less statistical power. All analyses used SAS statistical software (SAS Institute Inc).

Results

Characteristics of the Study Cohorts

Table 1 presents demographic and clinical characteristics of dual enrollees with schizophrenia or a bipolar disorder, nationally and for individuals residing in no-cap states, strict-cap states, and Tennessee. **Table 2** shows that, immediately

Table 2. Estimated Changes in Use of Psychotropic Treatments for Serious Mental Illness Following Transition From State Medicaid Drug Coverage to Medicare Part D[a]

Measure, State Group	Outcome Value Before Part D[b]	Level Change After Part D	Trend Change After Part D	Change 1 y Later	
				Absolute	Relative, %
Schizophrenia Cohort					
Untreated patients, %					
National	13.83	1.22[c]	0.08	2.44[d]	19.79[d]
No cap	11.56	1.10	0.09	2.39[d]	23.30[d]
Strict cap	20.61	TD	TD	NC	NC
Mean total SMD of antipsychotic					
National	1.529	TD	−0.005[e]	−0.080[d]	−5.00[d]
No cap	1.620	TD	−0.007[f]	−0.106[d]	−6.20[d]
Strict cap	1.349	TD	TD	NC	NC
Mean total adjusted prescription fills					
National	4.853	TD	0.008	0.114	2.23
No cap	5.133	TD	TD	NC	NC
Strict cap	3.796	0.419[f]	0.019[e]	0.706[d]	17.69[d]
Bipolar Disorder Cohort					
Untreated patients, %					
National	25.22	TD	TD	NC	NC
No cap	23.81	TD	TD	NC	NC
Strict cap	29.95	−4.49[e]	TD	−4.49[d]	−17.20[d]
Mean total SMD of mood stabilizer					
National	1.374	TD	TD	NC	NC
No cap	1.411	0.057	−0.004	−0.002	−0.13
Strict cap	1.201	0.161[c]	TD	0.161[d]	12.20[d]
Mean total adjusted prescription fills					
National	5.429	0.107	0.014[e]	0.322[d]	5.72[d]
No cap	5.622	TD	TD	NC	NC
Strict cap	4.192	0.937[f]	0.043[f]	1.575[d]	35.47[d]

Abbreviations: NC, no change; SMD, standard monthly dose; TD, term dropped from final model because $P \geq .20$.

[a] Attributable changes after 1 year were estimated for March 2007. We defined lack of treatment (ie, untreated patients) as having had no available days in which medication was supplied, apportioned from dispensing date. The mean SMD was calculated across all individuals in the cohort, irrespective of use. Adjusted prescription fills were defined as 30-day supply equivalents. Mood stabilizers included antipsychotics, anticonvulsants, and lithium.

[b] Estimated in November 2005.

[c] $P < .05$.

[d] The 95% CI around the estimate of change does not include 0.

[e] $P < .01$.

[f] $P < .001$.

prior to the Part D transition, untreated illness was much more prevalent among patients with a serious mental illness in states that had strictly capped benefits. In the capped states, 20.6% of patients with schizophrenia received no antipsychotic treatment in November 2005, whereas in no-cap states, 11.6% of patients received no antipsychotic treatment during the same period. For patients with a bipolar disorder, the rates of untreated illness (ie, with no use of antipsychotics, anticonvulsants, or lithium) were 30.0% and 23.8% in capped and no-cap states, respectively. In addition, the average dose of treatment was approximately one-fifth higher, and the average total number of prescription fills per month was approximately one-third higher, in no-cap states than in strict-cap states, for both mental illness cohorts.

Changes in Use of Essential Therapies to Treat Serious Mental Illness

Schizophrenia

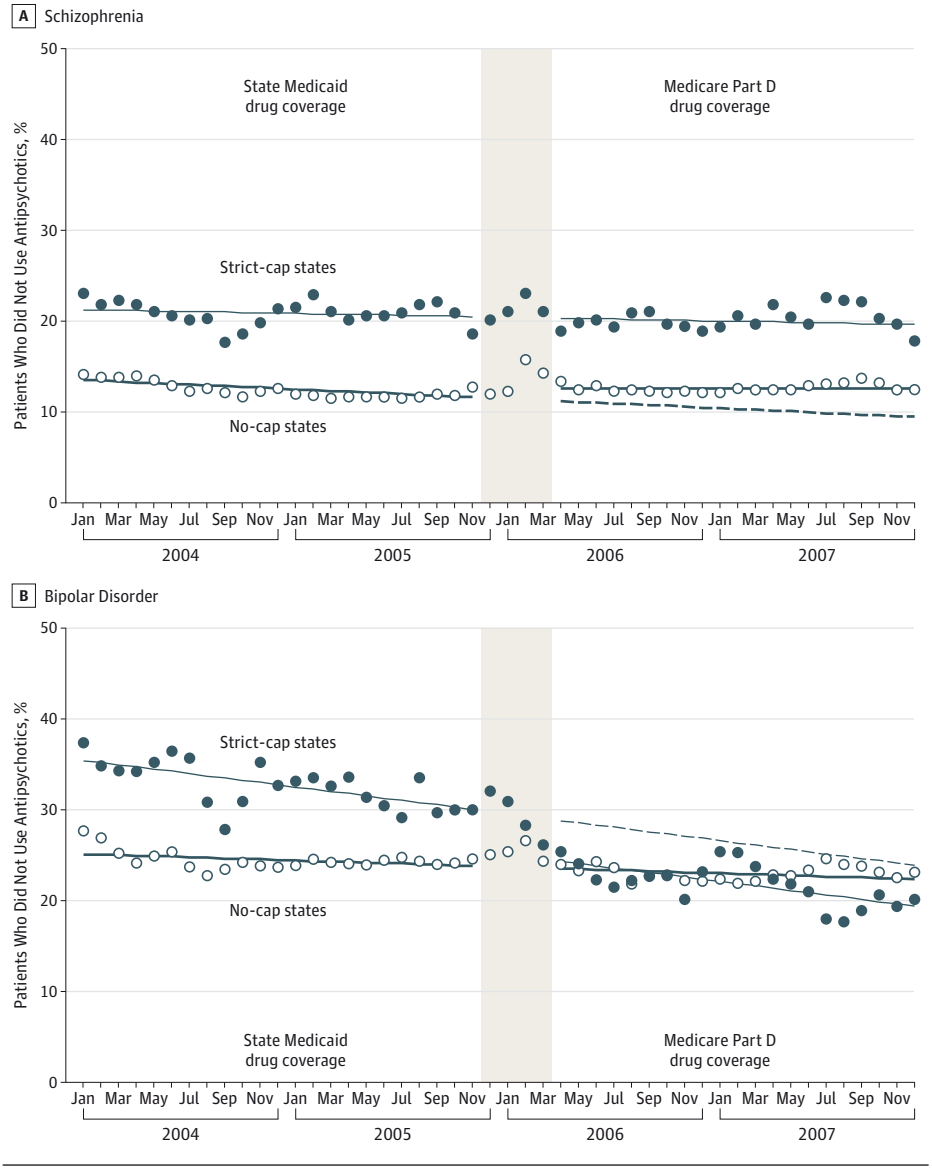
In strict-cap states, we detected no changes in the prevalence of untreated schizophrenia (**Figure 1**A) or in the intensity of treatment following Part D (Table 2). However, in no-cap states, we found small but significant decreases in trend for the intensity of antipsychotic use following Part D, and nonsignificant increases in both level and trend for nontreatment. By 1 year after Part D, these combined effects resulted in a prevalence of untreated illness 23.3% higher, relatively, than predicted based on baseline trends (absolute change, 2.39 percentage points [95% CI, 0.47-4.30 percentage points]).

Bipolar Disorder

Throughout our observation period, the patients with a bipolar disorder were, on average, more likely to go untreated than the schizophrenic patients (Figure 1B). In strict-cap states, we observed a sudden decrease in cases of untreated bipolar disorder after Part D such that, 1 year later, the prevalence of untreated bipolar disorder was 17.2% lower than expected (absolute change, −4.49 percentage points [95% CI, −7.36 to −1.62 percentage points]). Among patients with a bipolar disorder in no-cap states, we observed no net changes in untreated illness following Part D because increases in anticonvulsant use were offset by decreased antipsychotic use; specifically, the prevalence of antipsychotic use had decreased 6.8% (relatively) a year after the transition, while anticonvulsant use had increased 3.2%.

Intensity of mood stabilizer treatment (combining standard monthly doses across antipsychotics, anticonvulsants,

Figure 1. Monthly Time Series (2004-2007) of the Proportion of Patients With Schizophrenia or a Bipolar Disorder Lacking Essential Psychotropic Treatment, by Medicaid Drug-Cap Policy in State of Residence



Shown are the proportions of patients with schizophrenia (A) having no days for which any antipsychotic medication was supplied in the month and of patients with a bipolar disorder (B) having no days for which antipsychotic medication, anticonvulsant medication, or lithium was supplied in the month. The solid lines represent fitted regression estimates. The dashed lines represent predicted results after the transition and based on baseline trends, in the absence of observed effects attributable to Part D.

and lithium; Table 2) increased immediately after Part D in strict-cap states (absolute change after 1 year, 0.16 standard monthly doses per patient [95% CI, 0.04-0.28 standard monthly doses per patient]; relative increase, 12.2%). In the no-cap states, consistent with our results for the prevalence of treatment and nontreatment, we observed a sudden increase in intensity of treatment with anticonvulsants that was offset by a decreasing trend in the intensity of antipsychotic treatment. As a result there was no net change in overall mood stabilizing treatment intensity 1 year after Part D (see eTables 1 and 2 and eFigures 1 and 2 in the Supplement for additional details and graphs).

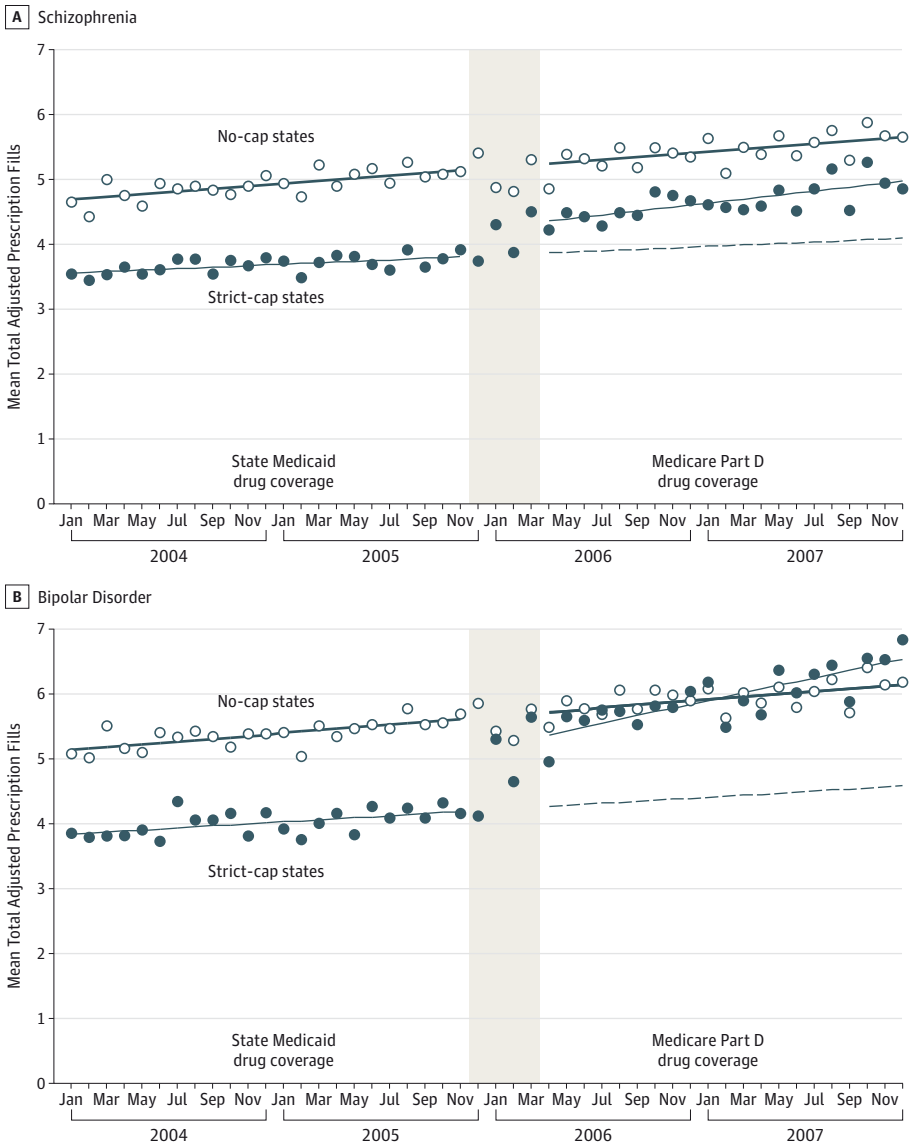
Changes in Overall Medication Use

Use of all medications in strict-cap states increased substantially in both mental illness cohorts after transition to Part D (**Figure 2**). Among patients with schizophrenia, we estimated significant increases in both level and trend after Part D; 1 year after the transition, average monthly use in strict-cap states was 0.71 prescriptions (95% CI, 0.49-0.92 prescriptions; relative change, 17.7%) higher than predicted. Among patients with a bipolar disorder in strict-cap states, overall monthly use increased by 1.57 prescriptions (95% CI, 1.20-1.95 prescriptions), 35.5% higher than predicted. After Part D, medication use among patients with a bipolar disorder in strict-cap states quickly converged with and eventually surpassed levels in the no-cap states. We detected no changes in overall drug use in the no-cap states in either mental illness cohort.

Cap Policy in Tennessee

In June 2005, before Tennessee Medicaid implemented its strict cap, an estimated 21.4% of schizophrenic patients lacked an-

Figure 2. Monthly Time Series (2004-2007) of Average Adjusted Prescription Fills Among Patients With Schizophrenia (A) or a Bipolar Disorder (B), by Medicaid Drug-Cap Policy in State of Residence



The solid lines represent fitted regression estimates. The dashed lines represent predicted results after the transition and based on baseline trends, in the absence of observed effects attributable to Part D.

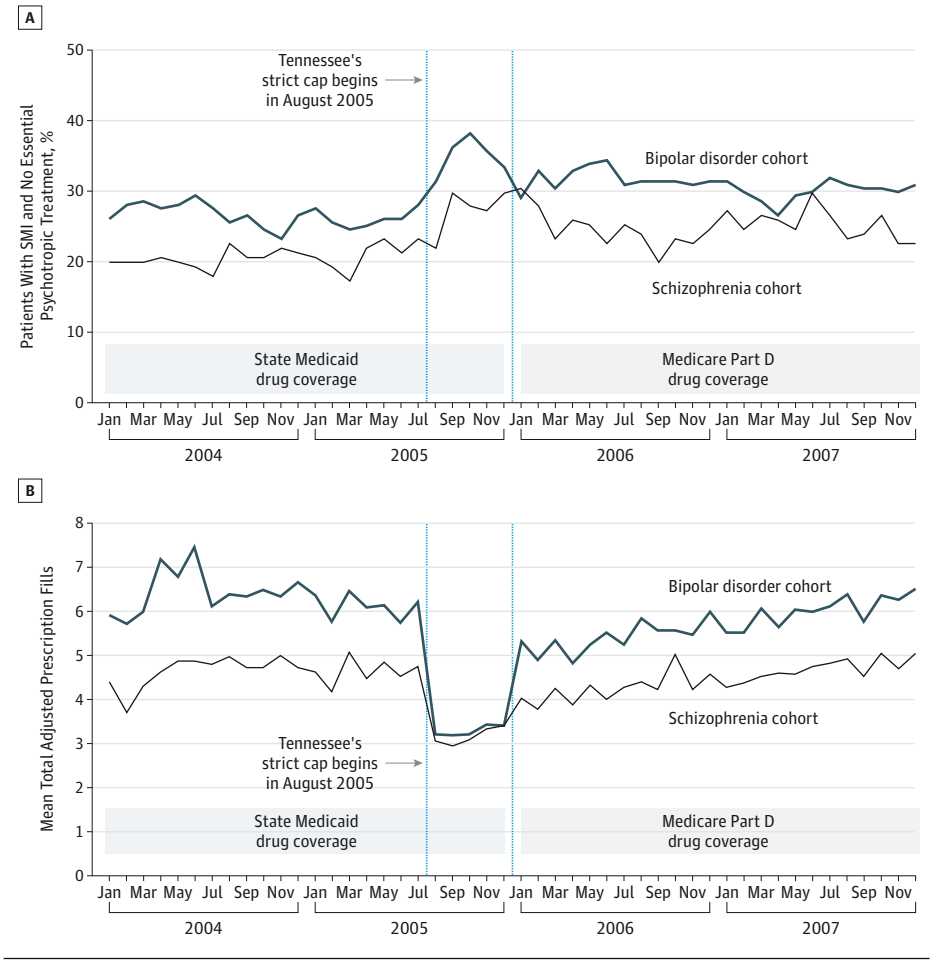
tipsychotic treatment (**Figure 3**A); after the cap, the prevalence of untreated cases increased suddenly by 7.3 percentage points (relative change, 33.9%), while after transition to Medicare Part D, the prevalence of untreated cases immediately decreased by 3.0 percentage points (−10.7%). Among patients with a bipolar disorder, the cap was associated with a 9.9 percentage point increase in the rate of nontreatment over the precap prevalence of 26.5% (37.5%). This rate subsequently decreased by 3.8 percentage points following transition to Part D (−10.6%). Overall medication use decreased sharply after the cap, by 1.8 prescriptions (−36.7%) among patients with schizophrenia and 3.2 prescriptions (−50.6%) among those with a bipolar disorder. Thereafter, we observed increasing trends and Part D–related level increases for both mental illness cohorts (Figure 3B) (see eTable 3 and eFigure 3 in the Supplement for treatment intensity and full model results).

Discussion

Under state Medicaid drug coverage, dual enrollees in strict-cap states used fewer medications overall and, especially important, were more likely to go without psychotropic drug treatment for a serious mental illness than those living in states without caps. After their transition to Part D, we observed improved access to treatment among patients with a bipolar disorder in strict-cap states. Conversely, access to antipsychotics appeared to decrease after Part D for dual enrollees in both mental illness cohorts living in no-cap states. Overall use of prescription medications increased sharply after Part D in strict-cap states, while in no-cap states, overall use did not change.

These findings are consistent with our prior hypotheses and research[20,33,37] regarding the effects of cap policies, and

Figure 3. Monthly Time Series (2004-2007) of the Proportion of Patients With SMI Lacking Treatment (A) and the Mean Adjusted Prescription Fills Among Patients With SMI in Tennessee (B), by Mental Illness Cohort



In Tennessee, we defined a 19-month baseline time segment with an uncapped state Medicaid drug benefit. Tennessee's Medicaid program implemented a strict cap starting in August 2005. Drug coverage responsibility shifted to the Medicare Part D drug benefit in January 2006. SMI indicates serious mental illness.

they may validate widespread concerns[22,23,38] about access to costly antipsychotics within private prescription drug plans. To our knowledge, the present study is the first rigorous national study of changes in access to essential psychotropic treatment after Part D for patients with a serious mental illness living in states with different Medicaid policy environments.

Previous national studies[5-7] of the effects of Part D may have masked important state-level differences. In our study, overall prescription fill rates rapidly converged in the 2 sets of states after drug benefits became more standardized. The sudden improvements in mood stabilizer treatment in strict-cap states after Part D are especially noteworthy; lifelong psychotropic maintenance is critical for preventing relapse and other adverse outcomes of serious mental illness.[11-15] The sizable proportion of patients who do not receive essential medications observed in our study is consistent with prior published reports and is a major concern.

Strict caps remain important barriers to access to essential treatment. In late 2013,[18,19] the Kaiser Family Foundation, which tracks the rapidly changing landscape of US health care coverage, counted 18 states that currently cap Medicaid drug benefits; our own follow-up indicates that, of those 18 states, 6 have highly restrictive caps, such as the caps highlighted in this research, that can adversely affect disabled adult beneficiaries. Currently in states with restrictive caps, patients with a serious mental illness who have only Medicaid coverage are at risk of potentially harmful undertreatment. Transitions to Medicare Part D, similar to the transitions examined here, continue to occur for approximately 170 000 disabled individuals per year following the mandatory 2-year waiting period for Medicare eligibility. Medicaid coverage limits represent 1 source of geographic inequity in US health care. Although the Affordable Care Act should increase the proportion of persons insured nationwide, states must approve Medicaid expansion and partly define the scope of benefits. State-level decisions in these areas could increase existing geographic disparities in access to care.[39-41] In addition, the Affordable Care Act has effectively encouraged the growth of low-premium, high-deductible commercial plans that pose new, largely unexamined barriers to treatment[42]; close monitoring of their effects on vulnerable populations is warranted.

Tennessee's cap policy demonstrated particularly large negative effects on medication use. In addition, the beneficial effects of Part D on the use of treatments of serious men-

tal illnesses were even clearer in Tennessee than in other strict-cap states. Unmeasured waivers in the other cap states may have mitigated some of the effects of the caps, or patients and health care providers may have developed strategies to work around them. For example, during the baseline, patients in Texas, which has a strict 3-drug cap, had an unusually high average number of days supplied per fill, which decreased after their transition to Part D (data not shown).

Although a comparison of the schizophrenia and bipolar disorder cohorts was not a research question, we observed that the effects of imposing a cap, and eliminating it via transition from state Medicaid to Part D drug coverage, appeared larger in the bipolar disorder cohort. One reason might be that patients with a bipolar disorder took more medications in 2005 (Table 1), so they may have had greater pent-up demand for medication under Medicaid caps and more pronounced increases after these caps were removed. Alternatively, schizophrenic patients, because their diagnosis is considered more severe, may have received more waivers under the caps that we are unable to observe. Patients in the bipolar disorder cohort were also more likely to be white and female. Recent research on the effect of Part D indicates that white dual enrollees with diabetes mellitus were more likely than black dual enrollees to increase their medication use after leaving strictly capped Medicaid coverage.[43] The influence of sex and race on the effect of the Part D transition among patients with a serious mental illness merits further investigation.

Despite differences, the effects of the transition to Part D in the 2 cohorts may be more similar than is at first apparent. Detailed results for treatment with antipsychotics (see eTables 1-3 in the Supplement) were consistent across measures in both cohorts: antipsychotic use increased in the cap states and decreased in the no-cap states 1 year after the transition to Part D. Other studies[4,44] have documented that antipsychotics, many still on patent at that time, were more likely than anticonvulsants to be targets of utilization management techniques (eg, prior authorization requirements) under Part D. A broader range of psychotropic medications is often used in the treatment of bipolar disorders; obtaining multiple distinct medications is especially difficult when drug benefits are restrictively capped.

We did not investigate changes in use of other specific therapeutic categories beyond the psychotropic medications of interest. Future analyses should examine changes in other essential therapies, such as cardiovascular treatments among patients with a serious mental illness and comorbid cardiovascular conditions.

Our study has several limitations. We included only continuously enrolled, community-dwelling, fee-for-service patients, which may limit the generalizability of our findings. These criteria were necessary for accurate outcome measurement and to ensure stable population characteristics. Our study does not take into account the full complexity of changes in drug cost containment policies that accompanied the transition, nor the variation[4] in restrictions on access to medications among different private Part D plans. External interventions that are coincident in time with the intervention of interest are the only major threat to validity of interrupted time-series designs,[24] which readily accommodate and account for underlying secular trends in study outcomes. While changes in the patent status of key medications at the time of the Part D transition could have been associated with changing patterns of use, we carefully examined the antipsychotic and anticonvulsant market during this period and found no changes near the time of the transition. Data were not available to identify individual patients who may have experienced increases or decreases in drug-specific formulary restrictions when transitioning from 48-state Medicaid programs to hundreds of Medicare drug plans. We focused on strict prescription limits, which are specific to Medicaid and which prior studies[17,21,28,34] have indicated may have particularly strong effects on the use of essential medications and may have the potential to harm patients and increase other costs. Because we used both Medicaid and Medicare Part D dispensing data, systematic differences in data sources might result in discontinuities at the time of Part D; however, we checked extensively for potential data irregularities, and the smooth overall utilization trends and the consistency of observed changes following Part D suggest that the data sources were reliable. Our data captured only Medicaid and Medicare dispensing, so we were unable to measure the possible receipt of medications through other sources, such as free samples or patient assistance programs. Other data suggest that out-of-pocket purchases and free samples are rare among such low-income patients in Medicaid.[20,45]

Conclusions

In summary, our research highlights important state-level differences when disabled adults transition from Medicaid pharmacy coverage to Part D, as thousands still do annually. We found significant reductions in the number of people with a serious mental illness who were not treated owing to the transition to Part D from strictly capped Medicaid coverage. Patients who reside in less restrictive states, by contrast, may experience more difficulty accessing treatment under private Part D drug plans than they did with Medicaid drug coverage; this is an important area for future study because recent reports suggest that restrictions in Part D coverage have increased since 2007.[46,47] Policy makers need to understand the treatment barriers in both Medicaid and Medicare Part D that can interfere with the care of highly vulnerable patients.

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Acquisition, analysis, or interpretation of data: Madden, Adams, LeCates, Zhang, Huskamp, Gilden, Soumerai.
Drafting of the manuscript: Madden, Soumerai.
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