Medicaid Prescription Drug Policies and Medication Access and Continuity: Findings From Ten States

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Objectives: **The aims of this study were to compare medication access problems among psychiatric patients in ten state Medicaid programs, assess adverse events associated with medication access problems, and determine whether prescription drug utilization management is associated with access problems and adverse events.** ***Methods:*** **Psychiatrists from the American Medical Association's Masterfile were randomly selected (N=4,866). Sixty-two percent responded; 32% treated Medicaid patients and were randomly assigned a start day and time to report on two Medicaid patients (N=1,625 patients).** ***Results:*** **A medication access problem in the past year was reported for a mean±SE of 48.3%±2.0% of the patients, with a 37.6% absolute difference between states with the lowest and highest rates (p<.001). The most common access problems were not being able to access clinically indicated medication refills or new prescriptions because Medicaid would not cover or approve them (34.0%±1.9%), prescribing a medication not clinically preferred because clinically indicated or preferred medications were not covered or approved (29.4%±1.8%), and discontinuing medications as a result of prescription drug coverage or management issues (25.8%±1.6%). With patient case mix adjusted to control for sociodemographic and clinical confounders, patients with medication access problems had 3.6 times greater likelihood of adverse events (p<.001), including emergency visits, hospitalizations, homelessness, suicidal ideation or behavior, or incarceration. Also, all prescription drug management features were significantly associated with increased medication access problems and adverse events (p<.001). States with more access problems had significantly higher adverse event rates (p<.001).** ***Conclusions:*** **These associations indicate that more effective Medicaid prescription drug management and financing practices are needed to promote medication continuity and improve treatment outcomes. (*Psychiatric Services* 60:601–610, 2009)**

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Medicaid provides the largest source of funding for treatment of mental illness in the United States, with $26.4 billion in expenditures in 2003 (1,2). Medicaid is also a major purchaser of prescription drugs (3,4), with antipsychotics, anticonvulsants, and antidepressants accounting for three of the top five therapeutic classes for total Medicaid pharmacy payments (4). Consequently, Medicaid programs are increasingly utilizing prescription drug prior authorization and other utilization management strategies to contain Medicaid costs (5). Because many states are facing significant budget deficits, states will likely continue to seek ways to contain prescription drug utilization.

In general medicine, research has suggested that requiring prior authorization policies for prescription drugs and use of other utilization management policies for select therapeutic medication classes can result in significant cost savings on prescription drugs, with little evidence of unintended utilization or cost increases in other health care sectors (6–8). In psychiatry there has been scant research on these policies. One review indicated that some prescription drug utilization management strategies that Medicaid uses to constrain access to essential drug classes, including psychopharmacologic medications, can reduce appropriate care, adversely affect patient health, and increase costs of care (9). A recent study of

Maine's Medicaid prior authorization and step therapy policy for second-generation antipsychotics indicated that this policy was associated with a 29% greater risk of treatment discontinuity but no associated cost savings for patients with schizophrenia (10).

We previously reported findings from a national study of psychiatric patients dually eligible for Medicare and Medicaid. We examined cases in which these beneficiaries switched from state Medicaid programs to Medicare Part D prescription drug plans and found that medication access problems affected 53.4% of patients. Most of the medication access problems studied, including switching clinically stable patients' medications and discontinuing medication because of issues concerning prescription drug coverage or utilization management, were associated with increased adverse events, including emergency visits (11).

Considerable research has examined the effects of cost sharing with patients, including copayments for prescription drugs. A recent review (12) concluded that increased cost sharing among patients is associated with reduced rates of drug treatment and adherence and increased medication discontinuations. For some chronic conditions, including schizophrenia, higher cost sharing was associated with increased utilization of medical services (13). Prescription drug cost sharing in poor and elderly populations has been shown to be associated with reduced use of essential drugs and higher rates of serious adverse events and emergency visits (14).

This study examined the clinical impact of commonly used prescription drug utilization management policies in ten state Medicaid programs of policy interest. Primary aims of this study included comparing physician-reported rates of psychopharmacologic medication access and continuity problems, assessing whether significant adverse clinical events are associated with medication access problems, and identifying whether specific prescription drug policies or management features are associated with medication access problems and adverse events.

Methods

Five hundred psychiatrists were randomly sampled from the American Medical Association's Physician Masterfile in ten states: California, Florida, Georgia, Massachusetts, Michigan, New York, Ohio, Pennsylvania, Tennessee (only 366 psychiatrists available), and Texas, for a total of 4,866 psychiatrists. Psychiatry residents, those with undeliverable addresses, and those without direct patient care as their practice were excluded (N=584). Each psychiatrist was randomly assigned one of 21 start days and times during their last typical work week to report on their next two Medicaid patients. Responses were obtained from 62% of the sample (N=2,671); 32% (N=857) met the study eligibility criterion of having treated Medicaid-only patients in their last typical work week, thus resulting in clinically detailed data for 1,625 Medicaid patients.

Data were collected by mail from September to December 2006 with practice-based survey research methods. Data were collected on patient characteristics, prescription drug utilization management practices, medication access problems, and adverse events experienced since January 1, 2006. The number of observations used in the analyses was 1,625, but all estimates were weighted on the basis of clinicians' Medicaid caseloads and the total number of psychiatrists in each state treating Medicaid patients, reflecting a weighted sample of over 43,000 Medicaid patients. Patients had a mean of 10.0 months (95% confidence interval [CI]=9.9–10.0) in which to experience medication access problems or adverse events since January 1, 2006. Participating psychiatrists received $75 as an incentive to respond and thus increase response rates. All study procedures were approved by the institutional review board of the American Psychiatric Institute for Research and Education (APIRE).

Rates of medication access problems and prescription drug utilization management features were examined across the patient subgroups and the ten states. Predictive probabilities of experiencing medication access problems and adverse events were calculated for each state. We adjusted for differences in patient case mix (including patients' age, gender, race, treatment setting, psychiatric diagnosis, and severity of psychotic, depressive, anxiety, alcohol or other substance use, and manic symptoms as well as sleep disturbances to control for patient sociodemographic and clinical confounders. Rates and odds of experiencing adverse events (adjusted for patient case mix) were examined among patients experiencing specific medication access problems and prescription drug utilization management features. In assessing the likelihood that adverse events were associated with the utilization management features, we also included two covariates that were measures of polypharmacy (prescription of three or more medications and coprescription of two or more antipsychotics) because patients with a polypharmacy regimen may have been more likely to have adverse events and to be covered by utilization management policies that applied to their medications. For the state comparisons, Spearman rank-order correlation coefficients were used to examine the relationship between the number of prescription drug utilization management features and number of medication access problems and between the number of medication access problems and number of adverse events.

Results

Patient characteristics

Approximately half the patients were age 35 or under (Table 1). Approximately half were white. Half were female, and nearly half (45.7%) of the patients were treated in public outpatient clinics. The most common diagnoses were schizophrenia (27.9%), childhood disorders (26.2%), and major depression (24.9%).

Medication access problems

Overall, 48.3% of the patients were reported to have experienced at least one medication access problem (Table 2). Rates of access problems varied significantly ($p<.001$) across the states, with a 37.6% absolute difference between the lowest (New York, 27.1%) and highest (Michigan, 64.7%) rates. A similar pattern of significant differences between states was noted when rates of medication access problems

were adjusted for demographic and clinical characteristics of patients (p<.001). The states with the lowest rates of reported medication access problems were New York (27.1%), Texas (31.0%), and California (32.4%), whereas Tennessee (63.3%), Georgia (64.2%), and Michigan (64.7%) had the highest rates. The most common types of medication access problems were as follows: patients were unable to access clinically indicated medication refills or new prescriptions because they were not covered or approved by Medicaid (34.0% of patients overall), clinicians would have preferred to use clinically indicated medications but could not prescribe them because of prescription drug coverage or approval issues or because patients could not make copayments (29.4%), medications were discontinued or temporarily stopped because of prescription drug coverage or administrative or management issues or a problem with patient copayments (25.8%), a medication not clinically preferred was prescribed because another clinically indicated and preferred medication was not covered or approved (25.0%), and problems accessing medications because of copayments were experienced (13.7%).

Patients in New York, Texas, and California had the lowest rates of problems accessing clinically indicated medication refills or new prescriptions because they were not covered or approved (19.0%–22.4%), whereas patients in Tennessee, Georgia, and Michigan had the highest rates of problems (49.3%–55.0%). Patients in New York, Texas, and California also had the lowest reported rates of problems with accessing medications because of patient copayments (6.8%–9.2%), whereas patients in Ohio and Tennessee had the highest (24.2% and 27.4%, respectively). Patients in New York had the lowest reported rates of discontinuing or temporarily stopping medications because of drug coverage, administrative or management issues, or copayment problems (11.9%), whereas patients in Ohio, Florida, Tennessee, Georgia, and Michigan had significantly higher rates of these problems (34.4%–38.4%).

For 29.4% of patients, the physician listed a specific, clinically indicated medication that he or she would have preferred to use but could not because of health plan prescription drug coverage, approval issues, or issues with patient copayments (Table 2). The medications that most commonly could not be prescribed included second-generation antipsychotics (including clozapine, risperidone, olanzapine, quetiapine, ziprasidone, and aripiprazole; 24.8%±2.6%), sedatives (including eszopiclone, zolpidem tartrate, zaleplon, and ramelteon; 21.5%±3.8%), selective serotonin reuptake inhibitor–type antidepressants (15.3%±2.5%), other types of antidepressants (13.5%±1.8%), and stimulants (6.9%±1.4%). Among the patients currently prescribed sedatives, 59.7%±8.1% had moderate to severe sleep problems, 58.2%±8.1% had moderate to severe anxiety symptoms, and 55.5%±8.2% had moderate to severe depressive symptoms.

For 26.7%±1.7% of patients, the physicians reported initiating prescription drug exceptions and appeals processes, whereas for 20.3%±1.7% of patients, the physicians reported

Table 1

Sociodemographic, diagnostic, and clinical characteristics of Medicaid beneficiaries with serious mental illness from ten states[a]

Characteristic	Total sample (N=1,625)			Patients with any access or continuity problem	
	N	%	SE	%	SE
Age[b]					
<18	382	30.6	1.9	39.5	3.5
18–35	443	25.6	1.7	53.2	3.6
36–45	374	23.3	1.8	53.3	4.6
>45	393	20.6	1.6	51.2	4.1
Gender[c]					
Male	768	50.1	2.0	42.0	2.7
Female	832	49.9	2.0	55.6	2.8
Race or ethnicity					
White	946	53.2	2.0	52.5	2.8
Black or African American	424	26.6	1.6	44.3	3.3
Hispanic	189	14.5	1.5	41.0	5.3
Other, mixed, or unknown	66	5.7	1.2	46.3	11.3
Treatment setting					
Public outpatient clinic	642	45.7	2.0	49.6	2.8
Private outpatient clinic	291	17.5	1.5	55.0	4.7
Solo or group private office	305	16.2	1.6	50.1	5.7
Private inpatient	122	6.6	1.2	42.8	8.9
Public inpatient	119	6.5	.8	42.7	6.4
Nursing home or other	117	7.5	1.1	39.2	7.0
Diagnosis					
Schizophrenia	457	27.9	1.8	47.6	3.8
Major depression[d]	461	24.9	1.7	57.2	3.8
Bipolar disorder	305	18.3	1.5	54.8	4.3
Anxiety disorder	256	14.7	1.6	56.0	5.9
Childhood disorder[b]	326	26.2	1.8	40.3	3.9
Substance use disorder	183	12.0	1.3	46.9	5.8
Other disorder	42	2.1	.5	36.7	11.4
Moderate to severe symptoms					
Depressive symptoms[c]	789	48.7	2.0	56.6	3.0
Anxiety symptoms[d]	820	51.6	2.0	54.0	2.9
Psychotic symptoms[b]	441	29.1	1.9	55.4	3.8
Manic symptoms	216	13.8	1.4	46.9	5.4
Alcohol or other substance use symptoms[c]	272	17.0	1.6	50.9	5.0
Sleeping problems	761	51.9	2.0	59.4	3.0
Total	1,625	100.0		48.3	2.0

[a] Percentages are weighted to an estimated 43,000 Medicaid patients in ten states.
[b] p<.05, comparison group versus total sample
[c] p<.001, comparison group versus total sample
[d] p<.01, comparison group versus total sample

Table 2

Rates of medication access and continuity problems among Medicaid beneficiaries with serious mental illness from ten states[a]

Medication access problem	Overall			N.Y.	Texas	Calif.	Ohio	Florida	Mass.	Penn.	Tenn.	Georgia	Mich.
	N	%	SE	(N=149)	(N=159)	(N=111)	(N=241)	(N=152)	(N=169)	(N=167)	(N=136)	(N=203)	(N=138)
Patient could not access clinically indicated medication refills or new prescriptions because Medicaid would not cover or approve[b]	555	34.0	1.9	20.6	22.4	19.0	37.3	39.1	38.0	38.8	49.3	55.0	50.9
Clinically indicated, preferred medications could not be prescribed because of health plan prescription drug coverage or approval issues or because patient could not make copays[b]	497	29.4	1.8	17.8	15.1	14.7	23.1	38.8	27.8	46.7	45.5	41.5	45.2
Medication was discontinued or temporarily stopped because of drug coverage, administrative, or management issues or patient problem with copays[b]	457	25.8	1.6	11.9	21.0	19.2	34.4	35.1	25.3	21.7	38.4	37.0	35.5
Medicaid limitations resulted in prescribing a medication not clinically preferred[b]	410	25.0	1.8	14.2	12.6	14.1	22.2	35.3	28.1	36.7	32.9	33.0	39.3
Patient had problems accessing medications because of copays[c]	273	13.7	1.2	6.8	9.2	8.0	24.2	11.4	14.0	10.5	27.4	14.0	19.2
One or more medication access or continuity problems[b]	826	48.3	2.0	27.1	31.0	32.4	52.7	56.7	57.1	61.2	63.3	64.2	64.7
Predicted probability of access or continuity problem[b,d]				.284	.306	.339	.530	.593	.568	.615	.647	.645	.645
Any adverse event[e]	1,007	60.4	2.0	50.5	45.1	57.9	62.2	59.4	65.0	68.7	70.0	68.6	68.7
Predicted probability of any adverse event[c,d]				.496	.450	.542	.626	.586	.655	.685	.718	.690	.701

[a] With the exception of the two rows of predicted probabilities, values for states are mean percentages, weighted to the state population. A table that includes standard errors is available as an online supplement to this article at ps.psychiatryonline.org.

[b] $p<.001$ between states

[c] $p<.01$ between states

[d] Adjusted for age, sex, race, treatment setting, psychiatric diagnoses, and severity of psychotic, depressive, anxiety, and manic symptoms, sleep disturbances, and substance use symptoms

[e] Includes emergency visits, psychiatric hospitalizations, an increase in suicidal or violent ideation or behavior, homelessness, and incarceration in jail or prison. Comparison between states significant at $p<.05$

changing or discontinuing medications rather than pursuing prescription drug exceptions and appeals processes. The mean number of medication access problems was 1.3±.06 per patient, with patients prescribed 2.1±.05 medications. Patients who were female or age 18 or older were more likely to have had medication access problems (Table 1). Although patients with major depressive disorder, more severe depressive symptoms, or sleep problems were more likely to have medication access problems, rates of access problems were high across all diagnostic groups.

Adverse events

All five medication access problems studied were strongly associated with increased odds of reported adverse events (Table 3). Adjusting for patient case mix, we found that patients with a reported medication access or continuity problem had 3.6 times greater likelihood of a reported significant adverse event ($p<.001$), including an emergency visit, psychiatric hospitalization, increase in suicidal or violent ideation or behavior, homelessness, or incarceration in prison or detention in jail. Overall, 72.2% of patients with medication access problems were reported to have experienced an adverse event, compared with 49.4% for patients with no reported access problems. Adjusting for patient case mix, we also found that patients with problems accessing

Table 3

Medication access problems and significant adverse events reported by physicians of Medicaid beneficiaries with serious mental illness

Medication access or continuity problem	Total sample			Any adverse event[a]			Emergency visit			Psychiatric hospitalization			Homeless			In prison or in jail		
	N	%	SE	%	SE	AOR[b]	%	SE	AOR[b]	%	SE	AOR[b]	%	SE	AOR[b]	%	SE	AOR[b]
Patient could not access clinically indicated medication refills or new prescriptions because Medicaid would not cover or approve																		
Yes	555	34.0	1.9	77.8	3.1	4.4***	42.6	3.4	2.5***	33.8	3.1	2.7***	12.8	2.2	1.7	15.2	2.4	1.5
No	1,037	66.0	1.9	51.8	2.5		30.0	2.2		26.0	2.1		11.4	1.8		12.9	1.6	
Patient had problems accessing medications because of copays																		
Yes	273	13.7	1.2	89.0	2.5	7.8***	53.8	4.7	2.5***	43.4	4.5	3.1***	21.0	3.8	1.9*	20.2	4.0	1.9
No	1,307	86.3	1.2	55.8	2.2		31.3	2.0		26.3	1.9		10.3	1.5		12.7	1.4	
Medication was discontinued or temporarily stopped because of drug coverage, administrative, or management issues or patient problem with copays																		
Yes	457	25.8	1.6	80.8	2.8	4.4***	44.9	3.5	2.2***	37.2	3.3	2.7***	18.2	2.8	3.2***	20.0	3.0	2.4**
No	1,125	74.2	1.6	53.3	2.4		30.7	2.2		25.7	2.1		9.5	1.6		11.5	1.4	
Medicaid limitations resulted in prescribing a medication not clinically preferred																		
Yes	410	25.0	1.8	73.5	4.4	2.4***	43.3	4.1	1.8**	35.0	3.7	1.9*	9.4	2.2	.7	13.1	2.6	1.0
No	1,215	75.1	1.8	56.1	2.3		31.5	2.2		26.9	2.0		12.5	1.7		13.6	1.5	
Clinically indicated, preferred medications could not be prescribed because of health plan prescription drug coverage or approval issues or because patient could not make copays																		
Yes	497	29.4	1.9	75.6	3.8	3.2***	44.6	3.7	2.3***	35.3	3.5	2.4***	9.7	1.8	1.0	12.5	2.1	1.1
No	1,128	70.6	1.9	54.1	2.4		30.2	2.2		26.3	2.1		12.6	1.8		13.9	1.6	
One or more medication access or continuity problems																		
Yes	826	48.3	2.0	72.2	2.8	3.6***	41.5	2.7	2.3***	33.7	2.6	2.6***	13.6	1.8	2.2**	16.0	1.9	2.0*
No	799	51.7	2.0	49.4	2.8		27.7	2.6		24.5	2.5		9.9	2.1		11.1	1.7	

[a] Includes emergency visits, psychiatric hospitalizations, an increase in suicidal or violent ideation or behavior, homelessness, and incarceration in jail or prison

[b] Adjusted odds ratios (AORs) reflect adjustments for patients' age, sex, race, treatment setting, psychiatric diagnoses, and severity of psychotic, depressive, anxiety, and manic symptoms, sleep disturbances, and substance use symptoms.

*p<.05
**p<.01
***p<.001

medications because of copayments had 7.8 times greater odds of experiencing an adverse event (p<.001) and that patients who discontinued or temporarily stopped their medications as a result of prescription drug coverage or management issues had 4.4 times greater odds of experiencing an adverse event (p<.001).

With patient case mix adjusted, all five of the access problems studied were found to be associated with increased odds of emergency visits and psychiatric hospitalizations. Patients who were reported to have discontinued or temporarily stopped taking their medications because of prescription drug coverage, utilization management, or copayment issues also had 3.2 times greater odds of being homeless (p<.001). Patients reported to have discontinued or temporarily stopped their medications had more than twice the odds of being incarcerated in prison or detained in jail (p<.01).

Prescription drug policies and access and adverse events

Use of preferred drug or formulary lists was the most commonly reported prescription drug utilization management feature (70.0%; state range 35.0%–87.2%), followed by prior authorization (59.5%; state range 25.7%–80.7%), requirements to switch to generics (53.1%; state range 38.0%–76.0%), limits on the number or dosing of medications (49.2%; state range 20.9%–79.7%), and use of step therapy or fail-first protocols (38.9%; state range 14.8%–73.8%) (Table 4). Overall, patients in New York, Texas, and California generally had significantly lower rates of having these management features apply to their medications compared with patients residing in the other states.

With adjustments for patient case mix, all five prescription drug utilization management features studied were highly associated with significantly increased adjusted odds of medication access problems (p<.001) (Table 5). Overall, among patients reported to have a utilization management policy apply to their prescription drugs, 56.7% had a medication access or continuity problem; among patients without prescription drug utilization management, 13.6% had a medication access problem. Prior authorization was associated with 7.8 times higher adjusted odds of experiencing a medication access problem (p<.001). Use of preferred drug or formulary lists was associated with 5.4 times higher adjusted odds (p<.001). Step therapy and fail-first protocols were associated with 4.7 times greater odds of a medication access or continuity problem (p<.001). Adjusting for patient case mix and all the utilization management features studied, we found that patients required to have prior authorization had 4.4 times greater odds (AOR=4.4, CI=4.4–2.7) of a reported medication access problem, whereas patients with step therapy had 1.6 times greater odds (AOR=1.6, CI=1.1–2.4).

With adjustment for patient case mix, all the prescription drug utilization management policies studied were associated with increased odds of adverse events. Rates of adverse events ranged from 66.0% to 72.4% among patients with prescription drug utilization management and from 47.4% to 52.9% among patients without (Table 5). Four of the five prescription drug utilization management features studied were associated with increased emergency visits and psychiatric hospitalizations. Patients with prior authorization had 2.2 times greater likelihood of being reported homeless (p<.05). Adjusting for patient case mix and all the utilization management features studied, we found that patients subject to prior authorization had 3.8 times the odds (AOR=2.3, CI=1.5–3.6) of experiencing a significant adverse event, and those with requirements to switch to generics had 2.7 times greater odds (AOR=1.7, CI=1.1–2.4).

Patients in states with more reported medication access problems had significantly higher rates of adverse events (p<.001). With adjustment for case mix, patients in the seven states with the highest rates of medication access problems had 2.3 times greater odds of experiencing an adverse event (AOR=2.3, CI=1.6–3.5) than patients in the three states with the lowest rates. Spearman rank-order correlations indicated that the number of prescription drug management features was correlated with the number of access problems in states (r=.70, p=.025), which was correlated with the number of adverse events observed in the states (r=.79, p=.006).

Table 4

State Medicaid prescription drug utilization management policies of ten states

	Overall			N.Y. (N=149)		Texas (N=159)		Calif. (N=111)		Ohio (N=241)		Florida (N=152)		Mass. (N=169)		Penn. (N=167)		Tenn. (N=136)		Georgia (N=203)		Mich. (N=138)	
Policy	N	%	SE	%	SE	%	SE	%	SE	%	SE	%	SE	%	SE	%	SE	%	SE	%	SE	%	SE
Any	1,267	80.5	1.4	53.2	5.6	90.4	2.4	80.4	5.2	71.3	4.0	90.2	2.8	93.9	1.7	90.1	2.6	89.3	4.1	87.3	3.1	79.0	4.8
Preferred drug or formulary lists[a]	1,123	70.0	1.8	35.0	5.4	76.1	5.5	60.9	7.0	61.8	4.3	86.0	3.4	80.7	4.4	85.2	3.3	87.2	4.2	81.4	3.8	74.4	5.0
Prior authorization[a]	965	59.5	1.9	25.7	4.8	62.9	5.6	43.7	6.6	55.6	4.5	68.5	5.5	80.0	4.6	71.0	5.1	80.7	4.7	76.0	4.1	70.0	5.3
Switch to generics[a]	820	53.1	2.0	41.5	5.5	38.0	6.2	53.7	6.8	51.8	4.5	57.8	5.9	72.7	4.9	55.3	5.9	76.0	4.9	58.8	4.9	50.0	6.1
Limits on number or dosing of medications[a]	793	49.2	2.0	20.9	4.2	42.6	6.1	54.2	7.0	41.8	4.6	63.6	5.8	62.7	5.3	56.7	6.2	79.7	4.9	62.6	5.0	37.9	6.1
Step therapy or fail-first protocols[a]	638	38.9	2.0	14.8	4.1	29.5	5.7	32.8	6.1	35.8	4.5	36.4	5.6	48.8	5.7	44.9	6.3	73.8	5.0	70.5	4.4	45.4	6.3

[a] p<.001 for comparisons between states

Table 5

Rates of medication access problems and significant adverse events associated with state Medicaid prescription drug utilization management[a]

Utilization management feature	Total			Any access or continuity problem[b]		Any adverse event[c]		Emergency visit		Psychiatric hospitalization		Homeless		In jail or or in prison	
	N	%	SE	%	AOR[d]	%	AOR[d]	%	AOR[d]	%	AOR[d]	%	AOR[d]	%	AOR[d]
Prior authorization															
Yes	965	59.5	1.9	64.7	7.8***	69.0	3.8***	37.8	2.0***	32.3	3.1***	13.4	2.2*	13.4	1.3
No	660	40.5	1.9	24.2		47.7		29.4		24.1		9.2		13.6	
Preferred drug or formulary lists															
Yes	1,123	70.0	1.8	59.0	5.4***	66.0	2.6***	37.5	1.8**	31.9	2.3***	11.7	1.2	13.2	1.0
No	502	30.0	1.8	23.3		47.4		27.2		22.1		11.9		14.1	
Step therapy and fail-first protocols															
Yes	638	38.9	2.0	69.6	4.7***	72.4	2.4***	40.8	1.4	34.5	1.6*	14.5	1.1	14.2	1.2
No	987	61.1	2.0	34.7		52.8		30.3		25.4		9.9		13.0	
Requirement to switch to generics															
Yes	820	53.1	2.0	61.5	3.1***	69.8	2.7***	41.0	1.9**	33.2	1.6*	12.3	.9	11.5	.7
No	805	46.9	2.0	33.4		49.8		26.9		24.1		11.1		15.7	
Limits on number or dosing of medications															
Yes	793	49.2	2.0	59.5	2.5***	68.1	2.1***	38.1	1.6*	30.9	1.3	12.3	1.4	14.9	1.5
No	832	50.8	2.0	37.4		52.9		30.8		27.1		11.1		12.1	
One or more features															
Yes	1,267	80.5	1.4	56.7	9.7***	63.2	2.5***	36.4	1.9*	30.9	2.5**	12.0	1.4	12.9	1.0
No	358	19.5	1.4	13.6		48.8		26.2		21.1		10.6		16.0	

[a] Percentage values are weighted. A table that includes standard errors is available as an online supplement to this article at ps.psychiatryonline.org.

[b] Includes all medication access problems listed in Table 2

[c] Includes emergency visits, psychiatric hospitalizations, an increase in suicidal or violent ideation or behavior, homelessness, and incarceration in jail or prison

[d] Adjusted odds ratios (AORs) reflect adjustments for patients' age, sex, race, treatment setting, psychiatric diagnoses, and severity of psychotic, depressive, anxiety, and manic symptoms, sleep disturbances, substance use symptoms, and polypharmacy measures (that is, three or more medications prescribed or two or more antipsychotics prescribed).

*p<.05
**p<.01
***p<.001

Discussion

Strengths and limitations

This study provided clinically detailed data on the experiences of a large, ten-state sample of psychiatric patients receiving Medicaid benefits. The primary limitation is this study's exclusive reliance on physician-reported, cross-sectional, observational data, which have potential response and recall biases. However, it is important to note that for many of the primary medication access problems of interest (such as clinicians' inability to prescribe a clinically indicated and preferred medication because of drug coverage or management issues), physicians would likely be the best source for this type of information. The physicians were compensated to help increase the response rates; however, physicians whose patients were experiencing medication access problems may have been more likely to respond to our survey or to deviate from the systematic patient sampling protocol.

The physicians may have lacked accurate information on their states' utilization management methods and policies or misattributed medication access problems to these policies, which are complex and can vary across and within medication classes. Because respondents were asked about plan features in general (that is, not specific to particular medication types or classes), the responses are best interpreted as general perceptions by clinicians of policies affecting their patients. Clinicians may be more inclined to report prescription drug policies when they encounter them or a medication access problem.

Although some data on state Medicaid prescription drug management policies are publicly available, the sources of information we identified were limited and not readily comparable across the states or specific to psychopharmacologic medications (5,15, 16). State prescription drug policies also vary between managed and fee-for-service plans within states; this variance was not assessed in this study. Pharmacies may also vary in implementation of prescription drug copayment or other policies. With a particular policy, such as prior authorization, utilization management practices may vary widely in application among patients. The ability to capture these complexities through provider or key informant reports and other sources is

limited given the complexity of these arrangements and variations in policy implementation.

This observational study did not capture data on the timing of medication access problems and adverse events and allowed examination of only the associations between Medicaid policies, medication access problems, and adverse events (as reported by the physicians), thus limiting the ability to make causal inferences. Patients with more severe illness, who may require more complex medication regimens, may be more likely to experience medication access problems, to be subject to prescription drug utilization management policies, and to experience adverse events. The logistic regression analyses did, however, adjust for available patient-related covariates. In addition, the logistic regression analyses of the association between adverse events and utilization management features adjusted for two polypharmacy measures because patients with a polypharmacy regimen may be more likely to face adverse events and to have utilization management apply to their medications. Finally, although we presented p values as large as $p<.05$ to convey general patterns of associations, if a Bonferroni correction was used to adjust for the multiple tests (66 in total) in Tables 3 and 5, which provide results from the primary study analyses, only those findings with a p value <.00078 would be considered statistically significant.

Key findings and policy implications

Approximately half the Medicaid patients were reported by their physician to have experienced at least one medication access or continuity problem, with one-quarter discontinuing or temporarily stopping their medications because of drug coverage, prescription drug utilization management, or copayment issues. Reported rates of medication access problems varied substantially across states, ranging from 27.1% to 64.7% of sampled patients. Clinician-reported adverse events, which were strongly associated with medication access problems, also varied significantly across states, from 45.1% to 70.0%.

States with the highest rates of prescription drug utilization management had significantly higher medication access problems. With adjustment for patient case mix, Medicaid patients in states with the highest rates of medication access problems had 2.3 times greater likelihood of experiencing adverse events compared with patients in states with the lowest rates of access problems. Overall, the prescription drug policies in New York, Texas, and California warrant careful consideration, because they appeared to have a favorable impact on medication access and continuity and on adverse events. Patients in these states generally had significantly lower rates of having the prescription drug utilization management features we studied (including step therapy and fail-first protocols, limits on the number or dosing of medications, generic requirements, prior authorization, and preferred drug or formulary lists) apply to their care, compared with patients in the other states. Other state policies and factors may also be important. For example, better communication through interagency state information systems, more effective policies for waiving copayments, and prompter responses to prior authorization or appeals and exemption requests may also play a role in the lower observed rates of medication access problems and adverse events in these states.

Our study showed a strong, consistent pattern in which all the clinician-reported prescription drug utilization management policies and all the medication access problems studied were highly associated with significant adverse events. Patients reported to have a medication access problem were 3.6 times more likely than patients without access problems to experience an adverse event. Although rates of access problems in this study were generally lower than in our previous study of psychiatric patients who were dually eligible for Medicaid and Medicare Part D (11), the patterns of associations were highly similar. The transition of patients with dual eligibility to Medicare Part D caused significant problems for states, which may have contributed to access problems observed in this study.

Although prior research has identified significant opportunities for management strategies to improve quality and continuity of psychopharmacologic treatment (16–19), this study indicated that current Medicaid prescription drug management features as reported by physicians were not associated with enhanced continuity of medication. Patients reported to be subject to prescription drug utilization management policies had 9.7 times greater odds of having a medication access problem. Medicaid prescription drug utilization management features—such as prior authorization, preferred drug lists, step therapy, and limits on the number and dosing of medications—raise concerns about their effect on quality and continuity of care, given their strong associations with medication access problems, discontinuations, and adverse events. Our data are consistent with prior research indicating that prescription drug utilization management strategies may have significant cost implications; medication access problems have been associated with greater health care services utilization and costs (12,13,20), as well as costs to the social services sector (for example, unemployment and workers' disability and compensation associated with impaired functional status) and criminal justice sector. Given significant research highlighting the challenges of medication adherence in this seriously ill and vulnerable population (21–23) and the deleterious clinical and other consequences of discontinuing or switching psychopharmacologic medications (22,24–27), these findings raise important concerns, particularly given the clinical challenges of restabilizing patients who relapse.

The high rates at which patients were reported not to be able to access clinically indicated, preferred medications because of drug coverage or management issues (affecting 29.4% of patients) or to get medication refills or new prescriptions because they were not covered or approved (34.0%) are of particular concern. It is noteworthy that for 25% of patients, clinicians reported prescribing a medication not clinically preferred because drug coverage or management issues prevented them from doing so and that 20.3% of physicians reported

changing or discontinuing medications rather than pursuing exceptions or appeals, possibly because of administrative burdens (28).

Prescription drug utilization management strategies that are based primarily on cost (29) rather than on clinical considerations, such as patients' symptomatology, comorbidities, and prior treatment history and response, as well as the therapeutic risks and benefits of different medications, can result in suboptimal care and pose serious risks to patients (9,10,30). Psychopharmacologic medications within a class (such as antidepressants, antipsychotic medications, anticonvulsants, or antianxiety medications) are not directly interchangeable. Psychiatric patients generally have differential responses and tolerance or side effect reactions to different medications within a class. Patients with psychiatric illnesses often do not respond to their initial medication but do respond to subsequent trials with a different medication within the same or different class (30). Although the impact of prescription drug utilization management varies depending on the drug and available alternatives, access to a full range of medications facilitates clinical management for this population. Especially worrisome are policies that could lead to medication discontinuations or treatment gaps among stabilized patients, which affected one-quarter of the patents in this study. Fail-first policies requiring documentation within current or past claims databases of failing to improve with a preferred medication can also have major unintended consequences. Such policies may require repeating a medication trial in which a patient previously did poorly or switching a clinically stable patient's medication, which may result in patient relapse or other adverse consequences.

Treatment protocols for evidence-based prescription drug utilization management, such as the Texas Medication Algorithm Project (31), offer potential to improve outcomes of care. Prescription drug utilization management strategies should be based on evidence-based, patient-centered, clinically appropriate care management strategies and rendered in "real time" (without delay) to minimize disruptions in continuity of medication. Continued investments in comparative clinical effectiveness studies and publicly available databases of results of clinical trials are needed to inform evidence-based treatment protocols (32–35). More effective information systems are also needed to better utilize existing Medicaid administrative data to systematically evaluate medication patterns and outcomes and correlate findings with prescription drug utilization management policies (36).

The association between requirements to switch to generics and increased adverse events raises concerns. This study did not, however, distinguish between requirements to switch to the same versus different generic compounds. If generic medications are true bioequivalents to branded products, one would not expect differential treatment responses. In a seriously ill, cognitively impaired population, switching to generics may create confusion among patients (9), which may be associated with dosing or administration changes and result in medication discontinuations. Further investigation is needed to understand this dynamic.

Our findings that psychiatric patients with Medicaid coverage that places limits on the number or dosing of medications had higher rates of adverse events are consistent with prior research (11–14,20). Although dosing limits may provide some clinical safety protections for patients, there may be clinical risks to psychiatric patients, particularly for those prescribed second-generation antipsychotics, given that the upper dosing limits have not been well established (30).

The finding that one in seven patients was reported to have problems accessing medications because of copayments is troubling, particularly because this consumer issue frequently does not come to clinicians' attention (37). States should strengthen policies and pharmacy practices to waive copayments for Medicaid patients for whom copayments provide a financial barrier to clinically needed medications, particularly for beneficiaries with severe mental illness who are at risk of decompensation and adverse events.

States should consider other best practices to improve the management and continuity of prescription drugs for this population. The use of medication support and adherence strategies shown to be effective in assertive community treatment models (23,38,39) should be explored. This includes ordering and delivering medications to patients, providing education about medications, and monitoring medication compliance and side effects. Disease management strategies (40) and more effective use of technology, such as pill boxes with paging systems, have also been suggested to enhance medication continuity (41).

Conclusions

Medications are among the first-line, evidence-based treatments for most mental illnesses (30). Although prescription drugs are an increasingly costly component of state Medicaid budgets, current state prescription drug utilization management strategies are associated with significant adverse clinical consequences for this population. Medication disruptions or switches that are not clinically indicated have been shown in this and other studies to be associated with significant adverse effects for psychiatric patients. It is therefore of concern that reported rates of these problems varied widely across the states we studied, even after we adjusted for patient case mix. These patterns of associations suggest that state prescription drug policies may have a major impact on outcomes for beneficiaries with mental illness and highlight the need for more effective prescription drug management strategies and policies to promote medication continuity and more cost-effective treatment. Clinical and fiscal accountability and transparency are critical in pharmacy benefit management, especially with the limited evidence base for current utilization management strategies. Further data development and sharing are vital in establishing an evidence base to inform these formulary management approaches. Medicaid prescription drug utilization management policies based primarily on cost rather than on clinical considerations may ultimately result in significant human, economic, and social costs.

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