Medicare Part D Prescription Drug Benefits and Administrative Burden in the Care of Dually Eligible Psychiatric Patients

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Objective: **With implementation of Medicare Part D, concerns were raised that patients with severe mental illness who were dually eligible for both Medicaid and Medicare benefits would be at clinical risk. In addition to concerns about medication access and continuity, there were concerns about administrative burden for physicians and their staffs. This study aimed to quantify the amount of administrative burden for psychiatrists and their staff related to Medicare Part D prescription drug plan administration in a national sample of dually eligible psychiatric patients and to identify factors associated with increased burden.** ***Methods:*** **A total of 5,833 psychiatrists were randomly selected from the American Medical Association's Physicians Masterfile. Responses were obtained from 64% (N=3,247) with a mailed survey using practice-based survey research methods during the first four months of Medicare Part D implementation (January to April 2006); 1,183 psychiatrists met eligibility requirements.** ***Results:*** **Psychiatrists and their staff spent 45 minutes in administrative tasks for every one hour of direct patient care for dually eligible patients. Drug plan features, including prior authorization and preferred drug formularies, and medication access problems were associated with increased administrative time.** ***Conclusions:*** **Results of this study indicate several drug plan features and medication access problems related to Part D implementation were associated with significant increases in administrative burden for psychiatrists and their staff, which may result in less time for direct patient care. Given the vulnerability of this high-risk population, this increased administrative burden may pose a significant risk to the overall quality of care for psychiatric patients. (*Psychiatric Services* 59:34–39, 2008)**

With the January 1, 2006, implementation of the Medicare prescription drug benefit, the mental health community and the Centers for Medicare and Medicaid Services were concerned that patients with severe mental illness who had both Medicaid and Medicare benefits (dually eligible) would be at clinical risk when their previous medication benefit was transferred from state Medicaid programs to the new Medicare program (1). Approximately six million dually eligible patients with numerous chronic, complex medical and psychiatric conditions were to be automatically enrolled in low-premium drug plans, although they were permitted to choose a different plan that would better meet their needs. It is estimated that approximately two million of these dually eligible patients have a psychiatric disorder that significantly impairs their daily functioning. In addition to concerns about clinical risks regarding access and continuity of medications under Part D (2), there were concerns about less time for clinical care associated with increases in administrative burden and difficulties for physicians and their staffs (3).

Administrative burden for mental health clinicians has been assumed to lead to inefficiency, decreases in the quality of clinical care, and greater expense, but there has been little research evidence to support these claims. The few studies done have shown deleterious effects associated with increased burden (4,5). For example, Lemak and colleagues (4) found that as the average administrative burden in outpatient substance abuse treatment units increased, organizational efficiency (measured by operating expenses per therapy hour) and productivity (measured by treatment sessions per full-time equivalent staff) decreased. These findings indicate that as administrative burden increases, resources begin to shift away from patient care.

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Given the uncertainty about changes in medication access and continuity, administrative burden, and other anticipated difficulties associated with Medicare Part D, the American Psychiatric Institute for Research and Education developed and implemented a national study to monitor the functioning of the Medicare Part D prescription drug program among a large, national sample of patients who were dually eligible for Medicaid and Medicare and who were being treated by psychiatrists (2). This study systematically assessed the experiences of these patients. The study, which monitored the functioning of Part D prescription drug plans from January 1, 2006, through April 30, 2006, found that 53% of patients had at least one medication access problem. Of these patients, 27% experienced a significant adverse clinical event.

Using data from this large data collection effort, we aimed to systematically quantify the amount of administrative burden for psychiatrists and their staff related to prescription drug administration as part of the Medicare Part D program among a large, national sample of psychiatric patients eligible for both Medicare and Medicaid. We also sought to identify patient and setting factors, features of Part D prescription drug plans, and medication access problems associated with increased administrative burden.

Methods

A total of 5,833 psychiatrists were randomly selected from the American Medical Association's Physicians Masterfile of all U.S. psychiatrists (N= 55,000). Psychiatry residents and those not listing direct patient care as their type of practice were excluded. After excluding psychiatrists who were not currently practicing (N=291) and those with undeliverable addresses (N=439), we obtained responses from 64% of the target sample, or 3,247 psychiatrists. Of these respondents, 37% (N=1,183) met the study eligibility criteria of treating at least one dually eligible patient during their most recent typical work week.

Primary data collection was conducted from January through April 2006 by using a mailed survey and practice-based survey research methods. Psychiatrists reported clinically detailed data on one systematically selected patient with dual eligibility. Each psychiatrist was randomly assigned a start time to report on the next such patient he or she treated. Psychiatrists were asked to report the number of total minutes they or their staff spent on prescription drug administration for the selected patient. They were also asked the number of total minutes in direct patient clinical care for the selected patient. Additional key variables, described below, included descriptions of the features of Medicare prescription drug plans and the extent of disruptions in medication access or continuity since January 1, 2006, resulting from coverage or administrative issues related to the plan. The survey included a $75 check to increase response. All study procedures were approved by the institutional review board of the American Psychiatric Institute for Research and Education.

Table 1

Characteristics of 1,183 psychiatric patients who were dually eligible for Medicaid and Medicare benefits[a]

Characteristic	Unweighted N	Weighted %	SE (%)
Patient gender			
Male	536	47	2.2
Female	612	53	2.2
Age			
45 and under	433	35	2.0
46–64	472	42	2.1
65 and over	233	23	1.9
Race or ethnicity			
White	860	71	1.9
Black or African American	203	17	1.6
Hispanic	55	6	1.1
Other or unknown	75	6	1.0
Diagnosis[b]			
Schizophrenia	446	41	2.1
Major depressive disorder	405	33	2.0
Bipolar disorder	230	18	1.6
Anxiety disorder	236	15	1.5
Substance use disorder	130	11	1.3
Treatment setting			
Public clinic, outpatient setting	373	42	2.1
Private clinic, outpatient setting	231	18	1.6
Private solo or group practice	294	17	1.5
Public facility, inpatient	78	7	1.1
Private facility, inpatient	76	6	1.1
Nursing home or other[c]	98	10	1.3

[a] Percentages are weighted to reflect all dually eligible psychiatric patients in the United States. Data were missing for some variables.
[b] Some patients had more than one diagnosis.
[c] Includes emergency room, veterans hospital, jail, or university clinic

Administrative burden was calculated for descriptive analyses by using the ratio of the total number of minutes psychiatrists and their staff spent on prescription drug administration for the selected patient to the number of total minutes in direct patient clinical care for the selected patient—that is, minutes of administrative time associated with prescription drug benefits for clinicians and their staff per one hour of direct patient care. Weighted bivariate statistical tests using the RATIO procedure in SUDAAN (6) assessed differences in the amount of administrative burden across patient sociodemographic characteristics, treatment settings, clinical characteristics, drug plan features and administration, and medication access problems.

Multiple (stepwise) regression with the percentage of overall time in administrative tasks as the dependent variable examined the association between the aforementioned factors and administrative burden after statistically adjusting for other factors in the model.

Table 2

Administrative time per hour of direct patient care among psychiatric patients who were dually eligible for Medicaid and Medicare benefits, by patient and setting factors

Variable	Administrative time per hour of direct patient care (minutes)	
	M	SE
Age		
45 and under	48.6	9.2
46–64	42.7	4.7
65 and over	37.7	5.3
Race or ethnicity		
White	43.2	3.6
Black or African American	58.5	21.5
Hispanic	34.6	5.7
Other or unknown	57.0	23.8
Gender		
Male	53.1*	7.5
Female	36.7	3.8
Diagnosis		
Major depressive disorder	44.6	5.4
Schizophrenia	43.4	4.9
Bipolar disorder	40.9	5.7
Anxiety disorder	41.3	6.2
Substance use disorder	61.1	14.2
Symptom severity of moderate or severe		
Depressive	42.2	4.1
Anxiety	42.8	5.7
Psychotic	45.4	5.0
Manic	44.8	7.9
Substance abuse	58.4	13.6
Treatment setting		
Public clinic, outpatient setting	59.2**	6.9
Private clinic, outpatient setting	66.3	20.0
Private solo or group practice	38.1	6.3
Inpatient facility or nursing home	22.8	4.4
Other	23.6	6.5
Total	45.4	4.1

*p<.05, for the difference between male and female
**p<.01, for the difference between public clinic, outpatient setting, and those not in that setting

Results

Patient characteristics

As shown in Table 1, approximately half of the 1,183 patients were men, and most were white. Ages ranged from 31 to 64 years. Forty-one percent had a diagnosis of schizophrenia, and more than 50% had a serious mood disorder of either major depression or bipolar disorder. Forty-two percent of the patients were treated in a public clinic or outpatient facility, and 35% were treated in private outpatient clinics or solo or group practice settings. Thirteen percent were seen in inpatient hospital settings during the sampled visit; Medicare Part D does not apply in hospital settings.

Sociodemographic factors

Overall, psychiatrists and their staff spent 45 minutes in administrative tasks for every one hour of direct patient care (referred to here as "administrative burden") with dually eligible patients in the Medicare Part D program (Table 2). No significant increases were noted in the amount of administrative burden associated with patient age or ethnicity; however, administrative burden was greater for male patients than for female patients (53 minutes compared with 37 minutes, p<.05).

Clinical characteristics

Neither diagnosis nor symptom severity was significantly related to increases in administrative burden (Table 2). More administrative burden was associated with patients treated in public outpatient clinics than with patients seen in any other setting (59 minutes compared with 37 minutes, p<.01).

Prescription drug plan features

Several features of prescription drug plans were associated with significant increases in administrative burden. As shown in Table 3, psychiatrists and their staff whose patients were in plans with dosing limits experienced significantly more administrative burden than those whose patients were in plans without dosing limits (61 minutes compared with 36 minutes, p<.01). In addition, there was significantly more administrative burden associated with patients in plans with prior authorization than with those in plans without prior authorization (57 minutes compared with 32 minutes, p<.01), as well as with patients in plans with preferred drug lists (53 minutes compared with 31 minutes for those in plans without lists, p<.01). Also, patients in drug plans with step therapy or "fail-first" policies had significantly more administrative burden associated with their care than those in plans without these features (71 minutes compared with 37 minutes, p<.05).

Drug plan administration problems and access problems

As shown in Table 3, significant increases in administrative burden were associated with the care of patients in drug plans with administration problems. The care of patients who had problems filling prescriptions presented a greater administrative burden than the care of patients who did not (62 minutes compared with 32 minutes, p<.01). Similarly, the care of patients for whom appeals requests had to be initiated was more burdensome than the care of those for whom such requests were not made (62 minutes compared with 37 minutes, p<.05).

In addition, approximately half of the specific medication access problems studied were associated with significant increases in administrative burden. Psychiatrists and their staff had significantly more administrative burden in treating patients who could

not access refills because they were not covered or approved than in treating patients who did not have this problem (66 minutes compared with 33 minutes, p<.01). Also, there was significantly more administrative burden associated with patients who had copayment problems compared with patients who did not have such problems (66 minutes compared with 37 minutes, p<.01), with those who could not access new prescriptions because they were not covered or approved (63 minutes compared with 39 minutes, p<.05), with those whose medications were switched because their refills were not covered (62 minutes compared with 40 minutes, p<.05), and with those whose medications were temporarily stopped as a result of health plan administrative issues (62 minutes compared with 39 minutes, p<.05).

Table 3

Administrative time per hour of direct patient care among psychiatric patients who were dually eligible for Medicaid and Medicare benefits, by Medicare Part D prescription drug plan features and medication access problems

Variable	Administrative time per hour of direct patient care (minutes)	
	M	SE
Prescription drug plan feature		
Care management to improve safety	54.5	8.7
Prior authorization	57.3**	7.2
Preferred drug list	53.4**	6.2
Step therapy	71.4*	13.9
Emergency refills	49.6	8.8
Mandatory generic medications	55.3	9.4
Dosing limits	60.9**	9.2
Grandfathering of previously prescribed medication	44.0	7.0
Prescription drug administration		
Problems filling prescriptions	61.9**	8.6
Initiated appeals request	62.1*	10.5
Changed or discontinued medications instead of appealing	53.5	8.7
Medication access problem		
Cannot access refills, not covered	65.6**	10.6
Cannot access new prescriptions, not covered	62.6*	9.1
Medication switched, refills not covered	62.1*	10.2
Had to be started on a different medication than desired	56.5	9.3
Could not access benzodiazepines	53.3	8.1
Copayment problems	66.1**	8.8
Medication temporarily stopped, administrative issues	61.7*	8.1
Total	45.4	4.1

*p<.05, compared with patients in plans without the indicated feature or problem
**p<.01, compared with patients in plans without the indicated feature or problem

Results of multiple regressions

Multiple (stepwise) regressions with the percentage of overall time in administrative tasks as the dependent variable were conducted to examine the association with administrative burden of patient demographic characteristics, clinical characteristics, drug plan features, and medication access problems after statistically adjusting for other factors in the model (Table 4). Time to completion of the survey was added as a factor because psychiatrists were asked to report on patient care between January 1 and April 30, 2006. This was not a significant predictor of administrative time. Diagnosis was not included in the regression because of its high correlation with symptom severity.

The factors that explained the most variance in the model were drug plan features (R^2=.103). Specifically, plans reported to have step therapy or "fail-first" policies (p=.02) and to have preferred drug formularies (p=.04) were associated with significantly more administrative burden. In fact, step therapy policies were associated with a nearly 10% increase in administrative burden over plans without these policies. In addition, problems with medication access were significantly related to increased administrative burden. Problems accessing medication refills (p=.009) and problems with copayments (p=.003) were associated with a nearly 10% increase in administrative burden for psychiatrists. The largest increase in administrative burden was associated with patients with moderate to severe substance use symptoms (p=.020).

Discussion

Significant concerns were voiced regarding the transition to Medicare Part D of patients dually eligible for Medicare and Medicaid—a high-risk, high-cost vulnerable population—and regarding the effects of this large policy shift on the administrative burden placed on psychiatrists treating these patients. Results of this study indicate that several features of Part D prescription drug plans as well as access problems related to the implementation of Part D were associated with significant administrative burden for psychiatrists. The finding that medication access problems associated with Part D implementation were related to significantly higher levels of administrative burden is a particularly troubling finding in that nearly one-half of all dually eligible patients of psychiatrists experienced medication access problems in the first four months of the implementation of Medicare Part D, according to their psychiatrists (2). In many cases, for every one hour of direct patient care there was one hour or more of administrative time for psychiatrists and their staff when certain drug plan policies applied.

The Centers for Medicare and Medicaid Services permitted Medicare prescription drug plans participating in the implementation of the Part D benefit to use a range of management strategies that have some support in improving drug safety and containing prescription drug costs (7–9). However, several of these strategies, including prior authorization, preferred drug lists, and step therapy strategies, were associated in this study with significantly greater

Table 4

Stepwise regression of variables to predict administrative time per hour of direct patient care among psychiatric patients who were dually eligible for Medicaid and Medicare benefits

Step and variable added	Coefficient	R^2	Significant variables	Wald F	df	p
1. Time		.002	None			
2. Demographic characteristics		.015	None			
3. Symptom severity		.028	None			
4. Treatment setting	6.11	.117	Psychotic symptoms	4.53	1, 1,143	.034
	9.04		Substance abuse symptoms	4.69	1, 1,143	.031
	—[a]		Treatment setting	13.16	4, 1,143	<.001
5. Drug plan features	9.62	.220	Substance abuse symptoms	5.58	1, 1,143	.018
	—[a]		Treatment setting	9.14	4, 1,143	<.001
	7.70		Preferred drug formulary	7.12	1, 1,143	.008
	9.39		Step therapy (fail first)	6.74	1, 1,143	.010
6. Drug plan administration	10.55	.270	Substance abuse symptoms	5.94	1, 1,143	.015
	—[a]		Treatment setting	7.12	4, 1,143	<.001
	8.61		Preferred drug formulary	9.56	1, 1,143	.002
	9.12		Step therapy (fail first)	6.84	1, 1,143	.009
	7.99		Problems filling prescriptions	5.45	1, 1,143	.020
7. Access and continuity problems	–4.97	.309	Anxiety symptoms	3.98	1, 1,143	.046
	9.28		Substance abuse symptoms	5.47	1, 1,143	.020
	—[a]		Treatment setting	4.98	4, 1,143	.001
	5.81		Preferred drug formulary	4.07	1, 1,143	.044
	7.99		Step therapy (fail first)	5.21	1, 1,143	.023
	8.51		Could not access refills because not covered	6.81	1, 1,143	.009
	8.29		Problems with copayments	8.76	1, 1,143	.003

[a] Multiple levels

administrative burden. The additional administrative burden associated with these strategies is likely to have a negative effect on patient care, particularly in the case of dually eligible patients, who tend to be severely ill with complex medical and psychiatric illnesses.

The care of many of the patients in this study requires medication management and psychosocial treatments at a minimum (10). Studies of the quality of psychiatric care provided in routine clinical practice, as measured by conformance with evidence-based practice guideline recommendations, have shown significant gaps in quality of psychopharmacologic and psychosocial treatment provided to patients with schizophrenia (11), major depression (12), and other mental illnesses (13, 14). As administrative burden increases, shifting time away from direct patient care, gaps in the provision of guideline-recommended treatments are likely to widen, further diminishing quality of care.

Not only does increased administrative burden increase the likelihood that psychiatrists will not have time to provide needed treatments to their patients, but in order to avoid these increases it may also cause them to minimize the number of patients they are able to treat with characteristics associated with greater administrative burden (15). In addition, 19% of psychiatrists in this study reported changing or discontinuing clinically indicated medications rather than pursuing appeals or exceptions processes for their patients (2). These findings clearly indicate the risk that quality of care may be diminished when physicians are faced with cumbersome administrative procedures. Utilization management protocols of prescription drug plans should balance current evidence and professional standards of care with a thorough consideration of the administrative impact on physicians and the resulting consequences for quality of care.

This study has several limitations. The primary limitation is exclusive reliance on physician-reported, cross-sectional data with potential for response, selection, and recall biases. In particular, psychiatrists may have been inaccurate in estimating their administrative time as well as that of the staff. Also, the study did not measure the outcomes and quality of care associated with increased administrative burden, which may or may not be adverse. Although previous studies have shown negative effects of increased administrative burden, it is possible that increased burden could be associated with positive effects. Several of the policies that are associated with increased burden, such as prior authorization, were designed to improve quality of care and have some support in improving quality, such as drug safety, in the non–mental health care sector (7).

Conclusions

Given the increased vulnerability of patients in this population and their need for intensive clinical care, the significant administrative burden associated with Part D implementation and prescription drug plan policies is a potentially considerable risk to the quality of care of these patients as a result of diminished time that psychiatrists and their staff have to attend to patients' other medical and psychosocial issues.

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The authors report no competing interests.

References

1. The New Medicare Prescription Drug Law: Issues for Dual Eligibles With Disabilities and Serious Conditions. Menlo Park, Calif, Kaiser Commission on Medicaid and the Uninsured, 2004. Available at www.kff.org/medicaid
2. West JC, Wilk JE, Muszynski IL, et al: Medication access and continuity: the experiences of dual eligible psychiatric patients during the first four months of the Medicare prescription drug benefit. American Journal of Psychiatry 164:789–796, 2007
3. Huskamp HA, Keating NL: The new Medicare drug benefit: formularies and their potential effects on access to medications. Journal of General Internal Medicine 20:662–665, 2005
4. Lemak CH, Alexander JA, Campbell C: Administrative burden and its implications for outpatient substance abuse treatment organizations. Psychiatric Services 54:705–711, 2003
5. Galanter M: The impact of managed care on addiction treatment: evaluating physicians' views and the value of health plan benefits. Journal of Addictive Diseases 18 (4):1–4, 1999
6. Shah B, Barnwell B, Bieler G: SUDAAN User's Manual, Release 7.0. Research Triangle Park, NC, Research Triangle Institute, 1996
7. Smalley WE, Griffin MR, Fought RL, et al: Effect of a prior-authorization requirement on the use of nonsteroidal anti-inflammatory drugs by Medicaid patients. New England Journal of Medicine 332:1612–1617, 1995
8. Delate T, Mager DE, Sheth J, et al: Clinical and financial outcomes associated with a proton pump inhibitor prior-authorization program in a Medicaid population. American Journal of Managed Care 11:29–36, 2005
9. Hansen LB, Fernald D, Araya-Guerra R, et al: Pharmacy clarification of prescriptions ordered in primary care: a report from the Applied Strategies for Improving Patient Safety (ASIPS) collaborative. Journal of the American Board of Family Medicine 19: 24–30, 2006
10. American Psychiatric Association Practice Guidelines for the Treatment of Psychiatric Disorders: Compendium 2000. Washington, DC, American Psychiatric Association, 2000
11. West JC, Wilk JE, Olfson M, et al: Patterns and quality of treatment for patients with schizophrenia in routine psychiatric practice. Psychiatric Services 56:283–291, 2005
12. West JC, Duffy F, Wilk JE, et al: Patterns and quality of treatment for patients with major depressive disorder in routine psychiatric practice. Focus 3:43–50, 2005
13. Wilk JE, West JC, Rae DS, et al: Patterns of adult psychotherapy in psychiatric practice. Psychiatric Services 57:472–476, 2006
14. Wang PS, Lane M, Olfson M, et al: Twelve-month use of mental health services in the United States: results from the National Comorbidity Survey Replication. Archives of General Psychiatry 62:629–640, 2005
15. Clark TR: Access to Medications Under Medicare Part D. Washington, DC, National Long Term Care Ombudsman Resource Center, 2005. Available at www.ltcombudsman.org/uploads/ascppartdmedaccess.pdf

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