First-Year Medicare Part D Prescription Drug Benefits: Medication Access and Continuity Among Dual Eligible Psychiatric Patients

Joyce C. West, PhD, MPP; Joshua E. Wilk, PhD; Donald S. Rae, MS; Irvin L. Muszynski, JD; Maritza Rubio-Stipec, ScD; Carol L. Alter, MD; Karen E. Sanders, MS; Stephen Crystal, PhD; and Darrel A. Regier, MD, MPH

Objective: This study provides national data on medication access and continuity problems experienced during the first year of the Medicare Part D prescription drug program, which was implemented on January 1, 2006, among a national sample of Medicare and Medicaid "dual eligible" psychiatric patients.

Method: Practice-based research methods were used to collect clinician-reported data across the full range of public and private psychiatric treatment settings. A random sample of psychiatrists was selected from the American Medical Association Physician Masterfile. Among these physicians, 1,490 provided clinically detailed data on a systematically selected sample of 2,941 dual eligible psychiatric patients.

Results: Overall, 43.3% of patients were reported to be unable to obtain clinically indicated medication refills or new prescriptions in 2006 because they were not covered or approved; 28.9% discontinued or temporarily stopped their medication(s) as a result of prescription drug coverage or management issues; and 27.7% were reported to be previously stable on their medications but were required to switch medications. Adjusting for case mix to control for sociodemographic and clinical confounders, the predicted probability of an adverse event among patients with medication access problems was 0.64 compared to 0.36 for those without access problems ($P < .0001$). All prescription drug utilization management features studied were associated with increased medication access problems ($P < .0001$). Adjusting for patient case mix, patients with "step therapy" ($P < .0001$), limits on medication number/dosing ($P < .0001$), or prior authorization ($P < .0001$) had 2.4 to 3.4 times the increased likelihood of an adverse event.

Conclusions: More effective Part D policies and management practices are needed to promote clinically safer and appropriate pharmacotherapy for psychiatric patients to enhance treatment outcomes.

J Clin Psychiatry 2010;71(4):400–410

Submitted: *August 8, 2008; accepted January 2, 2009.*
Online ahead of print: *November 17, 2009 (doi:10.4088/JCP.08m04608whi).*
Corresponding author: *Joyce C. West, PhD, American Psychiatric Institute for Research and Education (APIRE) Practice Research Network (PRN), 1000 Wilson Blvd, Suite 1825, Arlington, VA 22209 (jwest@psych.org).*

The Medicare prescription drug benefit (Part D) represented a landmark health policy when it was implemented on January 1, 2006, for the first time providing a federally sponsored prescription drug benefit for Medicare beneficiaries. Although most seniors have been satisfied with this new benefit, problems were encountered in the program's initial implementation for the nation's 6 million "dual eligible" population with Medicare and Medicaid insurance.[1–3] The dual eligibles were transitioned from state Medicaid programs into Part D prescription drug plans (PDPs), shifting half of total state Medicaid prescription drug costs to the federal Part D program.[4]

The initial transition problems were characterized as "impacting a significant number of dual eligibles."[2] The most commonly reported problems included charging beneficiaries incorrect cost-sharing amounts, beneficiaries' not knowing which plans they were randomly assigned to, and pharmacies' not having sufficient information to bill the plans. Dual eligible patients with mental and addictive illnesses—representing nearly one-third of all dual eligibles and those most likely to have cognitive impairments, costly medication regimens, and limited ability to pay for medications—were shown to be at particular risk for medication access problems during this transition period.[2,5–10]

Consistent with other national and state health policies expanding health care benefits over the last 3 decades, including the recent landmark federal mental health parity bill,[11,12] the Medicare Part D prescription drug benefit was made fiscally viable with the use of managed care strategies to contain benefit costs. The Part D regulations mandated the use of prescription drug utilization management to contain costs and utilization. These management or quality assurance features were also designed to provide safety protections for patients by reducing medication errors and to improve the quality of care associated with overutilization or inappropriate utilization of prescription drugs.[13] However,

there were particular concerns regarding the unintended consequences and potential for these care management strategies to limit access and continuity of treatments for psychiatric and other high-cost patients. The Centers for Medicare and Medicaid Services (CMS) recognized the special needs of psychiatric patients, given their reliance on psychopharmacologic medications, and enacted policies to facilitate medication access and continuity. CMS issued a guidance to the PDPs stating that they were expected to cover "all or substantially all" drugs in 6 protected classes, which included 3 medication classes commonly used to treat mental illnesses (ie, antidepressants, antipsychotics, and anticonvulsants).[14] Another CMS transition policy stated that patients "who were on a stable medication regimen" should not be subject to prior authorization or "step therapy" protocols for the "all or substantially all" protected medication classes.[14]

Despite CMS protections, some dual eligible psychiatric patients were reported to have encountered obstacles obtaining medications during the initial program implementation. A national survey[9] of seniors indicated that 1 in 5 dual eligibles had exceptions or appeals pursued to get prescriptions filled during the first year of the program, twice the rate of other enrollees. A 3-state study[8] of dual eligibles' experiences during the first 8 months of Medicare Part D highlighted problems with formularies, utilization management, enrollment, communications with plans, and payment issues. Some patients were reported to be unable to obtain previously prescribed medications and were required to use formulary drugs to which they had previously failed to respond. Other problems included denials and delays in getting medications, difficulties obtaining medications because of administrative complexities, and patients' having to pay premiums and copayments they did not owe. These problems were reported to be time consuming and confusing for many dual eligibles.[8]

Our previous study[10] of psychiatric patients' experiences in the first 4 months of the Part D program reported that 1 in 5 patients had discontinued or temporarily stopped taking their medication because of drug coverage or management issues. One in 5 patients were previously stable on their medication regimens but were required to switch medications because they were not covered or approved. Ten percent of patients were reported to have improved medication access.[10]

Concerns regarding medication access and continuity for this high-cost, vulnerable group remain beyond the program's initial implementation, given this population's reliance on medications and risk of relapse and other adverse events associated with medication disruptions and switches, and given the incentives for Part D PDPs to constrain prescription drug utilization and costs to increase profits, particularly among this high-cost group.[15–21] As Medicare enrollees with mental illness have been shown to have prescription drug costs 61% greater than beneficiaries without mental illness,[7] they are likely targets of prescription drug benefit management, which is a central feature of the Part D program to control prescription drug costs and utilization.

The lack of publicly available claims and utilization data has severely limited efforts to examine the clinical impact of Medicare Part D.[22] Consequently, studies of dual eligible psychiatric patients have largely been limited to analyses of PDP plan features, economic modeling estimating medication switching in response to pharmacy benefit management, and qualitative focus groups and survey research with limited data on this population.[1,2,8,21–23]

This study follows up on our previous study,[10] providing clinically detailed data on the experiences of a large national sample of dual eligible patients treated by psychiatrists. The specific aims of this study were to (1) characterize trends in medication access and continuity among dual eligible patients treated by psychiatrists during the first year of the Part D benefit, (2) assess whether adverse events were associated with medication access problems, and (3) identify any patient or PDP features associated with enhanced (or impaired) medication access and significant adverse events.

METHOD

Observational, clinician-reported surveys tracked patient and clinician experiences during the first 12 months of Medicare Part D. Data collection consisted of 3 cross-sectional assessments: January–April 2006, May–August 2006, and September–December 2006. To allow the maximum time for a patient to have experienced a medication access problem, we used data from the third data collection cycle (September–December 2006); however, the trend analyses include data from all 3 data collection cycles. The target population was all practicing psychiatrists in the United States with a deliverable address who treated dual eligible patients.

A total of 5,833 psychiatrists were randomly selected from the American Medical Association Physician Masterfile of US psychiatrists (N = 55,000). After excluding psychiatrists not currently practicing or with undeliverable addresses (n = 734), responses were obtained from 65.9% of the sample (N = 3,361) during the first data collection cycle. Of these respondents, 35.4% (N = 1,189) met the study eligibility criteria of having treated dual eligible patients during their last typical work week and participated in this study, reporting clinically detailed data on 1,193 systematically sampled patients.

Of the psychiatrists who participated in the first data collection cycle, 75.2% (N = 894) participated in the second (May–August 2006), with 85.2% treating dual eligible patients in their last typical work week, providing clinically detailed data on 762 systematically selected patients. For the third data collection cycle (September–December

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2006), the 1,189 psychiatrists who participated in the first data collection cycle and 1,600 new psychiatrists randomly selected from the American Medical Association Physician Masterfile were sampled. The new physician sample was included to offset increased psychiatrist attrition and nonresponse over time in order to maintain the desired sample size and power for the study. The new sample was included also out of concerns related to the potential response bias associated with relying on a sample that had participated in previous data collection cycles. Responses were obtained from 67.5% of the previous physician respondents (N = 803) and 66.8% of the new physician sample (N = 914 [based on 1,600 minus 232 removed for bad addresses, etc]). Of those physicians who responded, 56% met the study eligibility criteria, providing data on 986 systematically selected patients. Across all 3 phases of the study, 1,490 physicians (the number of physicians who participated in at least 1 of the 3 data collection phases) provided clinically detailed data on a systematically selected sample of 2,941 dual eligible psychiatric patients.

The study was approved by the institutional review board of the American Psychiatric Institute for Research and Education (APIRE). Data were collected using through-the-mail, practice-based research methods. Each psychiatrist was randomly assigned one of 21 start days and times to report on their first dual eligible patient they treated during their last typical work week. Data were collected on patient characteristics, PDP features, medication access problems, and adverse events experienced since January 1, 2006, as indicated in Tables 1–5. The survey included a $75 check to increase response.

The average patient in the first data collection sample had 6.0 weeks (95% CI, 5.6–6.4) to accrue a medication access problem or adverse event since January 1, compared to 27.3 weeks (95% CI, 27.0–27.7) and 42.1 weeks (95% CI, 41.8–42.4), respectively, for patients in the second and third data collection cycles. The trend analyses examined rates of reported access problems since January 1, May 1, and September 1 for the 3 data collection cycles.

Rates of medication access problems were examined across the 3 data collection cycles using linear regression, adjusting for time differences to accrue a medication access problem associated with the timing of survey completion. Rates and odds of medication access problems and significant adverse events were examined across different patient sociodemographic and clinical groups. Predicted probabilities of adverse events were adjusted for patient case mix (ie, patient age, sex, race, psychiatric diagnoses, treatment setting, and presence of severe psychotic, depressive, anxiety, manic, sleep disturbance, and substance use symptoms) to control for patient sociodemographic and clinical confounders when assessing whether specific medication access problems were associated with adverse clinical events. Odds ratios (adjusted for patient case mix) examined the relationship between specific PDP utilization management features and the odds of having a medication access problem or significant adverse event (see Table 5). Logistic regressions identified PDP features most highly associated with medication access problems and significant adverse events, adjusting for patient case mix.

Table 1. Patient Sociodemographic, Diagnostic, and Clinical Characteristics

Characteristic	n[a]	% (SE)[b]
Age, y		
≤ 40	222	21.9 (1.9)
41–64	574	56.7 (2.4)
≥ 65	159	21.4 (2.1)
Sex		
Male	421	43.6 (2.4)
Female	550	56.4 (2.4)
Race/ethnicity		
White	723	69.5 (2.2)
Black/African American	156	16.4 (1.7)
Hispanic	62	8.5 (1.4)
Other/mixed/unknown	45	5.5 (1.1)
Treatment setting		
Public clinic outpatient	330	41.7 (2.4)
Private clinic outpatient	197	19.9 (1.8)
Solo/group private office	256	17.2 (1.6)
Private inpatient	41	5.4 (1.2)
Public inpatient	68	5.2 (0.9)
Nursing home/other	78	10.6 (1.7)
Diagnosis		
Schizophrenia	383	43.1 (2.4)
Major depression	322	31.8 (2.2)
Bipolar disorder	212	17.4 (1.7)
Anxiety disorder	194	17.3 (1.7)
Childhood disorder[c]	40	3.1 (0.7)
Substance use disorder	111	9.2 (1.3)
Other disorder	42	4.9 (1.0)
Severe symptoms		
Depressive symptoms	138	13.6 (1.6)
Anxiety symptoms	154	14.5 (1.6)
Psychotic symptoms	116	13.5 (1.8)
Manic symptoms	29	3.3 (0.9)
Alcohol or other substance use symptoms	38	3.7 (0.9)
Sleeping problems	98	10.4 (1.5)
Total	986	100.0 (0)

[a]Ns do not add up to 986 in all cases because of missing data.
[b]Percentages are based on weighted data.
[c]The most common childhood disorders were attention-deficit/hyperactivity disorder (2.24%) and pervasive developmental disorder (0.82%).

RESULTS

Patient Characteristics

The majority of patients were white (69.5%) and under 65 years of age (78.6%) (Table 1). Approximately half were female, nearly half (41.7%) were treated in public outpatient clinics, and about one-third were treated in private outpatient settings. The most common diagnoses were schizophrenia (43.1%), major depression (31.8%), bipolar disorder (17.4%), and anxiety disorders (17.3%).

Medication Access Problems

The psychiatrists reported that 43.3% of patients could not access clinically indicated medication refills or new

Table 2. Medication Access Problems and Significant Adverse Events Among Dual Eligible Psychiatric Patients in Medicare Part D in 2006

Medication Access and Continuity Problems	Total Sample		Any Adverse Event[a]		Emergency Room Visit		Hospitalization		Homelessness		Incarcerated or Detained in Jail or Prison	
	n[b]	% (SE)[c]	% (SE)[c]	Predicted Probability[d]	% (SE)[c]	Predicted Probability[d]	% (SE)[c]	Predicted Probability[d]	% (SE)[c]	Predicted Probability[d]	% (SE)[c]	Predicted Probability[d]
Patient could not access refills or new prescriptions because they were not covered or approved												
Yes	347	43.3 (2.4)	75.7 (3.0)	0.706****	42.9 (3.9)	0.427****	28.1 (3.6)	0.275	6.5 (1.9)	0.061*	6.8 (2.0)	0.038*
No	624	56.7 (2.4)	44.8 (2.9)	0.409	29.8 (2.7)	0.292	28.0 (2.7)	0.291	6.0 (1.2)	0.057	3.4 (0.8)	0.033
Patient was stable on clinically desired or indicated medication but was required to switch to a different medication because clinically preferred medication refills were not covered or approved												
Yes	189	27.7 (2.3)	81.3 (3.5)	0.753****	48.1 (5.2)	0.479**	33.8 (5.1)	0.344	5.3 (1.9)	0.049	8.1 (2.9)	0.041
No	782	72.3 (2.3)	49.4 (2.6)	0.459	30.8 (2.4)	0.304	25.9 (2.3)	0.264	6.7 (1.3)	0.063	3.7 (0.8)	0.033
Patient could not access clinically indicated medications or doses because the medications or doses were "off-label"												
Yes	140	18.9 (2.1)	83.8 (4.2)	0.770***	56.1 (6.3)	0.602****	38.6 (6.4)	0.390	7.5 (2.7)	0.072	8.8 (3.6)	0.050
No	828	81.1 (2.1)	52.4 (2.5)	0.491	30.9 (2.3)	0.298	25.7 (2.2)	0.263	6.0 (1.2)	0.056	4.0 (0.9)	0.031
Patient had problems accessing benzodiazepines because they were not covered or approved												
Yes	238	27.9 (2.2)	75.6 (3.5)	0.704****	47.5 (4.9)	0.474**	36.5 (4.8)	0.361**	8.5 (2.4)	0.076	7.1 (2.4)	0.038
No	726	72.1 (2.2)	51.9 (2.7)	0.475	31.1 (2.5)	0.306	25.0 (2.4)	0.258	5.5 (1.2)	0.054	4.1 (1.0)	0.034
Clinically indicated and preferred medications could not be prescribed because of drug coverage or management issues												
Yes	276	34.8 (2.4)	79.3 (3.1)	0.750****	42.5 (4.3)	0.423**	31.1 (4.1)	0.307	6.0 (1.7)	0.057	7.0 (2.3)	0.040*
No	710	65.2 (2.4)	46.5 (2.8)	0.422	31.5 (2.6)	0.312	26.3 (2.5)	0.272	6.5 (1.4)	0.060	3.8 (0.9)	0.033
Medication was discontinued or temporarily stopped because of drug coverage or management/administration issues or copayments												
Yes	219	28.9 (2.3)	82.9 (3.4)	0.792****	48.5 (5.0)	0.462***	32.9 (4.8)	0.311	7.4 (2.3)	0.059	4.5 (1.6)	0.026
No	747	71.1 (2.3)	48.6 (2.7)	0.432	30.8 (2.5)	0.306	26.5 (2.4)	0.276	5.9 (1.2)	0.060	5.2 (1.3)	0.039
Prescribing a medication not clinically preferred due to drug coverage or management issues												
Yes	216	28.6 (2.2)	79.7 (3.2)	0.763****	43.5 (4.8)	0.446***	29.7 (4.3)	0.294*	9.2 (2.6)	0.088**	8.8 (2.8)	0.044
No	770	71.4 (2.2)	49.2 (2.7)	0.447	32.1 (2.6)	0.314	27.2 (2.5)	0.280	5.2 (1.1)	0.049	3.4 (0.8)	0.032
Patient had problems accessing medications because of patient copays												
Yes	211	25.2 (2.2)	77.6 (3.7)	0.727****	59.0 (5.0)	0.572****	36.1 (4.9)	0.354**	8.8 (2.6)	0.068	8.6 (2.7)	0.065**
No	759	74.8 (2.2)	52.0 (2.7)	0.473	27.8 (2.4)	0.279	25.5 (2.4)	0.263	5.5 (1.1)	0.057	3.8 (1.0)	0.026
One or more medication access or continuity problems												
Yes	558	62.2 (2.3)	68.8 (2.6)	0.640****	40.9 (3.1)	0.405***	30.3 (2.9)	0.304*	7.6 (1.5)	0.072**	5.6 (1.5)	0.036
No	428	37.8 (2.3)	40.2 (3.5)	0.358	26.2 (3.1)	0.257	24.1 (3.1)	0.250	4.2 (1.2)	0.039	3.8 (1.0)	0.034

[a]Includes emergency room visits, psychiatric hospitalizations, increase in suicidal or violent ideation or behavior, homelessness, and being incarcerated in jail or prison since January 1, 2006.
[b]Ns do not add up to 986 in all cases because of missing data.
[c]Percentages are based on weighted data.
[d]Adjusting for patient age, sex, race, treatment setting, diagnosis, and presence of severe psychotic, depressive, anxiety, manic, sleep disturbance, and substance use symptoms.
*$P<.05$, **$P<.01$, ***$P<.001$, ****$P<.0001$.

prescriptions because they were not covered or approved, and 28.9% of patients were reported to have discontinued or temporarily stopped their medication(s) as a result of health plan or prescription drug administrative issues, changes in coverage, management of benefits, or patient copayments (Table 2). Approximately 30% were previously stable on clinically desired or indicated medications but were required to be switched to a different medication because clinically preferred medication refills were not covered or approved. Nearly 30% were reported to have had problems accessing benzodiazepines because they were not covered or approved. One-quarter were reported to have had problems accessing medications because of patient copayments, and 18.9% were reported to have been unable to access clinically indicated medications or doses because the medications were "off-label."

For one-third of patients, the physicians listed a specific, clinically indicated medication he or she would have preferred to use but was not able to because of health plan prescription drug coverage or approval issues or because of patient copayments. Atypical antipsychotics were the most common type of medication that could not be prescribed, representing 23.8% (SE = 3.3%) of such medications, followed by selective serotonin reuptake inhibitor (SSRI) antidepressants (21.5%, SE = 2.9%), sedatives (16.5%, SE = 2.8%), other antidepressants (13.2%, SE = 2.5%), benzodiazepines (8.5%, SE = 2.2%), and mood stabilizers (5%, SE = 1.3%).

Rates of problems filling prescriptions (adjusted for length of time) were higher in the last 8 months of 2006 compared to the first 4 months of 2006 ($P<.05$) (Table 3). Rates of initiating prescription drug exceptions or appeals processes were also higher in the last 8 months of 2006, when physicians initiated exceptions or appeals for approximately one-third of patients to facilitate coverage of clinically indicated medications ($P<.01$). During the last 4 months of 2006, the clinicians reported changing or

Table 3. Trends in Access to Medications in 2006 for Dual Eligible Psychiatric Patients in Medicare Part D

Variable	January–April 2006 (since January 1) (N = 1,193), % (95% CI)	May–August 2006 (since May 1) (N = 762), % (95% CI)	September–December 2006 (since September 1) (N = 986), % (95% CI)
Problems filling prescriptions, including questions, calls, or follow-up with patients, pharmacists, health plans, or prescription drug plans	39.8 (35.9–43.8)	47.1 (42.0–52.1)	46.3 (41.7–51.0)*
Initiated health plan or prescription drug exceptions request or appeals process to facilitate coverage or approval of clinically desired medications	27.0 (23.5–30.8)	35.4 (30.6–40.5)	36.3 (31.8–41.1)**
Changed or discontinued medications rather than pursuing exceptions or appeals processes	19.0 (15.9–22.5)	23.2 (19.0–27.9)	25.0 (20.9–29.6)

*$P < .05$, **$P < .01$ (adjusted for differences in length of time to report problems during the data collection cycles).

discontinuing medications rather than pursuing prescription drug appeals for 25% of patients.

Adverse Events

The likelihood of a patient having any adverse event was significantly associated with having a medication access problem (see Table 2). Overall, 68.8% of patients with medication access problems had a significant adverse event reported (ie, an emergency room visit, psychiatric hospitalization, increase in suicidal or violent ideation or behavior, homelessness, or being incarcerated or detained in prison or jail), compared to 40.2% for patients with no access problems. The predicted probability (adjusted for case mix to control for patient sociodemographic and clinical confounders) of an adverse event among patients with medication access problems was 0.64 compared to 0.36 for those without access problems ($P < .0001$). Adjusting for case mix, all the access problems studied were associated with an increased likelihood of an emergency room visit; 40.9% of patients with medication access problems had an emergency room visit versus 26.2% for patients without access problems. Adjusting for case mix, the likelihood of a hospitalization was positively associated with problems accessing benzodiazepines ($P < .01$), problems accessing medications because of copays ($P < .01$), and prescribing a medication not clinically preferred due to drug coverage or management issues ($P < .05$). The likelihood of being homeless was positively associated with not being able to access refills or new prescriptions because they were not covered or approved ($P < .05$) and with prescribing a medication not clinically preferred due to drug coverage or management issues ($P < .01$). Likewise, the likelihood of being incarcerated or detained in jail or prison was positively associated with patients' not being able to access refills or new prescriptions because they were not covered or approved ($P < .05$), not being able to prescribe clinically preferred medications ($P < .05$), and having problems accessing medications because of patient copays ($P < .01$).

Patient and Prescription Drug Plan Features Associated With Medication Access Problems and Adverse Events

Patients with major depression, severe depressive symptoms, or sleep problems were significantly more likely to have medication access problems reported, but rates of access problems were high across all diagnostic groups (48.7%–70.8%) (Table 4). Patients treated in private outpatient clinics had the highest rates of medication access problems (68.4%), while those in public inpatient settings had the lowest (30.2%). Patients with more severe depressive, psychotic, anxiety, and substance use/dependence symptoms and with sleep problems were significantly more likely to have significant adverse events reported.

All the PDP utilization management features studied, as reported by the physician, were associated with significantly higher reported rates of medication access or continuity problems ($P < .0001$), even after adjusting for case mix (Table 5). Patients with these PDP features identified, compared to those without, had adjusted odds ratios between 3.7 and 6.2 for a medication access problem to be reported. All the PDP features reported except preferred drug/formulary lists and requirements to use mail order were also associated with increased rates of adverse events. Adjusting for case mix, step therapy or "fail-first" policies, limits on number or dosing of medications, prior authorization, and requirements to switch to generics were all associated with significantly higher adjusted odds of adverse events (ranging from 2.2 to 3.4).

Logistic regression analyses, adjusted for patient case mix and all the PDP features studied, indicated that prior authorization (OR = 2.8; 95% CI, 1.6–4.9), requirements to switch to generics (OR = 2.1; 95% CI, 1.2–3.6), limits on the number or dosing of medications (OR = 1.9; 95% CI, 1.1–3.3), and step therapy or fail-first protocols (OR = 1.8; 95% CI, 1.1–3.3) were the PDP utilization management features most highly associated with medication access problems. Prior authorization (OR = 3.0; 95% CI, 1.8–5.1), step therapy or fail-first protocols (OR = 2.9; 95% CI, 1.7–4.7), and limits on the number or dosing of medications (OR = 1.7; 95% CI, 1.1–2.7) were the features most highly associated with adverse events.

Strengths and Limitations

This study provides clinically detailed data on a large, national sample of dual eligible psychiatric patients treated during the first year of the Medicare Part D program. The study's primary limitation is exclusive reliance on

Table 4. Patient Sociodemographic, Diagnostic, and Clinical Characteristics and Rates of Medication Access Problems

			Any Access or Continuity Problem[a]		Any Adverse Event[b]	
Characteristic	n[c]	% (SE)[d]	% (SE)[d]	OR	% (SE)[d]	OR
Age, y						
≤40	222	21.9 (1.9)	55.6 (4.7)	0.8	55.6 (4.7)	0.9
41–64	574	56.7 (2.4)	64.4 (3.0)	1.1	57.9 (3.1)	0.9
≥65	159	21.4 (2.1)	62.1 (5.4)	…	59.5 (5.4)	…
Sex						
Male	421	43.6 (2.4)	58.6 (3.5)	0.8	57.4 (3.6)	1.0
Female	550	56.4 (2.4)	63.6 (3.0)	…	57.6 (3.1)	…
Race/ethnicity						
White	723	69.5 (2.2)	61.5 (2.7)	…	55.3 (2.8)	…
Black/African American	156	16.4 (1.7)	61.4 (5.5)	1.0	66.7 (5.2)	1.6
Hispanic	62	8.5 (1.4)	62.7 (8.1)	1.1	57.9 (8.4)	1.1
Other/mixed/unknown	45	5.5 (1.1)	71.2 (8.3)	1.5	65.7 (8.6)	1.6
Treatment setting[e]						
Public clinic outpatient	330	41.7 (2.4)	61.6 (3.7)	1.0	47.7 (3.8)	0.9
Private clinic outpatient	197	19.9 (1.8)	68.4 (4.4)	1.3	58.4 (4.9)	1.3
Solo/group private office	256	17.2 (1.6)	61.9 (4.9)	…	51.3 (5.0)	…
Private inpatient	41	5.4 (1.2)	59.8 (11.4)	0.9	100.0 (0)	NA[f]
Public inpatient	68	5.2 (0.9)	30.2 (8.8)	0.3	97.8 (1.6)	42.3
Nursing home/other	78	10.6 (1.7)	63.4 (7.8)	1.1	62.3 (7.9)	1.6
Diagnosis						
Schizophrenia	383	43.1 (2.4)	58.2 (3.7)	0.8	59.6 (3.6)	1.1
Major depression	322	31.8 (2.2)	70.8 (3.6)	1.8**	58.4 (4.1)	1.0
Bipolar disorder	212	17.4 (1.7)	66.2 (4.6)	1.2	61.7 (4.7)	1.2
Anxiety disorder	194	17.3 (1.7)	64.2 (5.1)	1.1	57.8 (5.3)	1.0
Childhood disorder[g]	40	3.1 (0.7)	48.7 (12.1)	0.6	60.5 (11.5)	1.1
Substance use disorder	111	9.2 (1.3)	56.8 (7.7)	0.8	62.2 (8.0)	1.2
Other disorder	42	4.9 (1.0)	48.8 (10.4)	0.6	47.2 (10.5)	0.6
Severe symptoms						
Depressive symptoms	138	13.6 (1.6)	76.0 (5.1)	2.1**	78.9 (5.3)	3.1****
Anxiety symptoms	154	14.5 (1.6)	66.1 (5.7)	1.2	72.0 (5.2)	2.1**
Psychotic symptoms	116	13.5 (1.8)	60.1 (7.0)	0.9	74.9 (6.7)	2.5**
Manic symptoms	29	3.3 (0.9)	61.6 (12.6)	1.0	77.0 (12.1)	2.6
Alcohol or other substance use symptoms	38	3.7 (0.9)	79.6 (7.2)	2.4	87.7 (8.6)	5.5**
Sleeping problems	98	10.4 (1.5)	83.7 (4.5)	3.3***	82.9 (4.9)	3.9****
Total	986	100.0 (0)	62.2 (2.3)	NA	57.9 (2.3)	NA

[a]Includes all medication access problems listed in Table 2.
[b]Includes emergency room visits, psychiatric hospitalizations, increase in suicidal or violent ideation or behavior, homelessness, and being incarcerated in jail or prison since January 1, 2006.
[c]Ns do not add up to 986 in all cases because of missing data.
[d]Percentages are based on weighted data.
[e]Any access or continuity problem, $P < .05$; any adverse event, $P < .0001$.
[f]Since 100% had adverse events, there is no odds ratio.
[g]The most common childhood disorders were attention-deficit/hyperactivity disorder (2.24%) and pervasive developmental disorder (0.82%).
*$P < .05$, **$P < .01$, ***$P < .001$, ****$P < .0001$.
Abbreviation: NA = not applicable.
Symbol: … = reference.

physician-reported, cross-sectional, observational data with the potential for response, selection, and recall biases. Because of the challenges of collecting data directly from patients using practice-based research methods (eg, the difficulty in obtaining patient informed consent in routine practice settings), we were not able to collect comparative data directly from patients for this study. The study also did not capture data on whether patients were enrolled in Medicare Advantage plans. However, it is important to note that, for many of the primary medication access problems of interest (eg, stable patients required to switch to a different medication because clinically preferred medication refills were not covered or approved, or clinicians' inability to prescribe a clinically indicated and preferred medication because of drug coverage or management issues), physicians would most likely be the best source for this type of information. For example, claims data cannot differentiate between clinically indicated and desired medication switches or selections and those medication switches or selections made as a result of prescription drug policies or utilization management requirements.

The physicians were compensated to increase response rates; however, physicians experiencing medication access problems may have been more likely to respond or deviate from the systematic patient sampling protocol. The clinicians would more likely be aware of specific prescription drug policies when they encounter the policies or when a patient experiences a medication access problem. It is also

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Table 5. Medicare Part D Prescription Drug Plan Utilization Management Features: Rates of Medication Access Problems and Significant Adverse Events (total N = 986)

Prescription Drug Utilization Management Features	n[d]	% (SE)[e]	Any Access or Continuity Problem,[a,b] % (SE)[e]	OR	AOR	Any Adverse Event,[b,c] % (SE)[e]	OR	AOR
Prior authorization								
Yes	518	59.2 (2.3)	78.3 (2.6)	5.7****	6.2****	66.4 (2.9)	2.3****	3.4****
No	468	40.8 (2.3)	38.7 (3.5)	…	…	45.7 (3.6)	…	…
Preferred drug/formulary lists								
Yes	616	67.5 (2.2)	72.7 (2.6)	4.0****	4.4****	59.4 (2.8)	1.2	1.5
No	370	32.5 (2.2)	40.1 (4.2)	…	…	55.0 (4.0)	…	…
Step therapy/fail-first protocols								
Yes	265	31.4 (2.2)	82.4 (3.0)	4.2****	4.4****	72.5 (3.7)	2.5****	3.2****
No	721	68.6 (2.2)	52.9 (2.8)	…	…	51.3 (2.8)	…	…
Requirement to switch to generics								
Yes	378	44.0 (2.4)	79.6 (2.9)	4.2****	4.2****	65.1 (3.4)	1.7**	2.2***
No	608	56.0 (2.4)	48.5 (3.0)	…	…	52.3 (3.0)	…	…
Limits on number or dosing of medications								
Yes	343	38.2 (2.3)	80.7 (2.8)	4.1****	4.5****	68.6 (3.4)	2.1***	2.4****
No	643	61.8 (2.3)	50.7 (3.0)	…	…	51.4 (3.0)	…	…
Requirement to use mail order to fill prescription								
Yes	93	12.0 (1.6)	86.4 (4.3)	4.4****	3.7***	68.4 (6.5)	1.7	1.8
No	893	88.0 (1.6)	58.9 (2.4)	…	…	56.5 (2.5)	…	…
One or more prescription drug utilization management features								
Yes	720	78.8 (1.9)	69.9 (2.4)	4.6****	4.8****	60.6 (2.6)	1.7*	2.2**
No	266	21.2 (1.9)	33.4 (4.9)	…	…	48.1 (5.0)	…	…

[a]Includes all medication access problems listed in Table 2.
[b]Adjusting for patient age, sex, race, treatment setting, diagnosis, and presence of severe psychotic, depressive, anxiety, manic, sleep disturbance, and substance use symptoms.
[c]Includes emergency room visits, psychiatric hospitalizations, increase in suicidal or violent ideation or behavior, homelessness, and being incarcerated in jail or prison since January 1, 2006.
[d]Ns do not add up to 986 in all cases because of missing data.
[e]Percentages are based on weighted data.
*$P < .05$, **$P < .01$, ***$P < .001$, ****$P < .0001$.
Symbol: … = reference.

important to note that many physicians object to managed care utilization management practices and may consider these practices intrusive, interfering with their individual judgment and clinical preferences. They may also resent having to justify medication choices and fill out paperwork that may require a substantial amount of time.[24]

To assess response bias, rates of medication access problems were compared for physicians who previously responded and the new physician sample recruited in the last data collection cycle. No differences were observed, with 62.3% of the old sample and 61.8% of the new sample reporting any access problems for their sampled patients. Unfortunately, there are no available nationally representative data on the characteristics of psychiatrists who treat dual eligible patients to assess the extent to which our sample of respondents may differ from the universe of psychiatrists who treat dual eligible patients. In future studies, we do plan to allocate more resources to collecting these data and to following up with a randomly selected sample of nonrespondents (eg, by offering a higher honorarium) to better ascertain the potential effects of response biases. Collecting data on the physicians' general perceptions of prescription drug utilization management in a sample of responders (and nonresponders) would also help assess the response bias associated with physicians' attitudes toward prescription drug utilization management.

The observational nature of the study limits the ability to make causal inferences. More severely ill patients, who may require more complex medication regimens, may be more likely to experience medication access problems, be subject to PDP utilization management policies, and experience adverse events. The logistic regression analyses did, however, adjust for available patient case mix covariates.

This observational study also examined a large number of associations between medication access problems, PDP utilization management policies, and adverse events. Although we present *P* values as large as $P < .05$ to convey general patterns of associations, if a Bonferroni correction is used to adjust for the multiple tests (52 in total) in Tables 2 and 5, which reflect the primary study analyses, only those findings with a *P* value < .001 would be considered statistically significant.

DISCUSSION

The findings from this year-long study indicate that the medication access and continuity problems reported among dual eligible psychiatric patients during the first 4 months

of the Medicare Part D program did not decline—and actually increased—over the program's first year.[10] Overall, 43.3% of patients were reported by their physicians not to be able to access medication refills or new prescriptions in 2006 because they were not covered or approved; 29% were reported to have discontinued or temporarily stopped their medications as a result of PDP drug coverage or management issues or copays; and 28% were reported to have been clinically stable but required to switch medications. The problems reported increased slightly during the year and were highly associated with the PDP's ongoing utilization management policies and strategies as perceived by the physicians participating in this study.

The medication access problems and PDP management practices observed in this study were strongly associated (even after adjusting for patient case mix) with significant adverse events, including emergency room visits, hospitalizations, increases in suicidal or violent ideation or behavior, homelessness, and being incarcerated or detained in prison or jail. Overall, rates of adverse events were 28.6% higher among patients with medication access problems. Despite the explicit policies of CMS prohibiting switching clinically stable patients—a policy CMS implemented in recognition of the potential for adverse events when psychiatric patients discontinue or switch their medications[16,25,26]—nearly 1 in 3 patients who were previously stable was reported to be required by their PDP to switch medications. These patients had adverse event rates 31.9% higher than those patients who were not required to switch.

It has been well established that psychiatric patients typically do not respond to their initial medication trial and may require multiple trials with different medications, which may require months or even years, before patients respond adequately.[27] The practice of switching clinically stable psychiatric patients' medications poses a considerable threat to a clinically complex, vulnerable patient group that is generally difficult to treat and stabilize,[27,28] particularly dual eligible psychiatric patients as the majority have diagnoses of schizophrenia or bipolar disorder.

Similarly, PDP management features and policies that are associated with or may lead to clinically unintended medication discontinuations, including temporarily stopping medications due to delays resulting from PDP management or administration, may have grave consequences.[28,29] Prior research has documented that medication disruptions are associated with symptom relapse or exacerbation, hospitalization, and other unintended adverse consequences among psychiatric patients.[15,17,30–32] Our study indicated that 3 of 10 patients were reported by their physicians to have discontinued or temporarily stopped their medications as a result of PDP coverage or management issues or copayments. These patients had adverse event rates 34.3% higher compared to those without medication disruptions, highlighting the importance of implementing utilization management in real time in as nonburdensome a fashion as feasible. Compelling prior research and sound clinical practice dictate that PDP management strategies for this population should foster medication adherence and continuity rather than imposing barriers or delays in accessing clinically indicated medications essential to maintaining patients' functioning and well-being.

Prescription drug plan management strategies should promote improved quality and outcomes of psychopharmacologic treatment as significant gaps in physicians' evidence-based best practices have been identified.[33–36] It is important to note that some patients—or a significant proportion of patients—may have benefited from the PDP's care management practices (eg, through safety edits, reductions in clinically inappropriate polypharmacy, and increased use of evidence-based pharmacotherapies for target conditions). However, the overall findings from this study raise concerns regarding the management practices and protocols now being used, as all the PDP features identified were highly associated with medication access problems and most were highly associated with adverse events rather than enhanced clinical outcomes. After adjusting for patient severity and case mix and all the PDP features studied, prior authorization, requirements to switch to generics, step therapy, and limits on the number or dosing of medications were the PDP utilization management strategies most highly associated with significant adverse events. Greater transparency is needed in PDP management processes to evaluate the extent to which care decisions are being made primarily on cost considerations rather than being guided by evidence-based best practices reflecting patients' clinical considerations. Increased monitoring and oversight of these processes is critically needed given plans' incentives to contain costs and utilization.

Prescribing a different medication rather than a medication clinically preferred by the physician or using fail-first policies or prior authorizations based on preferred drugs or formularies could result in improved quality of care and prescription drug cost savings without negative effects on patient outcomes or quality.[6] However, there have been no systematic studies evaluating the impact of such policies on clinical or economic outcomes for this population, including adverse clinical events and increased costs to other health care and social services sectors. To the extent these policies result in clinically suboptimal treatment through use of medications that do not most appropriately match the needs of patients' symptomatology, prior treatment history, or the therapeutic or side effect profiles of medications most clinically appropriate, they may pose significant risks to psychiatric patients. For some patients, older, less expensive medications may prove as tolerable and effective as newer medications; however, for other patients, newer medications may be more cost-effective.[6] The current challenge for PDPs is to be able to make these distinctions with a limited evidence base on the relative therapeutic benefits and risks of different medications for different patients.[6] Findings from

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this study suggest that current PDP utilization management strategies are not effective in making these distinctions. Prescription drug plans' coverage and management practices were commonly reported to result in use of medications that were not clinically preferred by the treating psychiatrists (affecting 28.6% of patients), with these patients much more likely to have a significant adverse event reported.

Patient cost sharing under Medicare Part D has raised concerns for dual eligibles, given substantial research showing that cost sharing decreases medication adherence and increases use of other medical services.[37,38] Although the Part D benefit exempts dual eligibles from paying premiums or deductibles, those with incomes below 100% of the federal poverty level are to pay a copayment of $1 for generic prescriptions and $3 for brand-name prescriptions; those above 100% of the poverty level have copayments of $2 for generic prescriptions and $5 for brand-name prescriptions.[39] Under most state Medicaid programs, prior to Medicare Part D, pharmacists were allowed to waive copayments; under Part D, pharmacists are not required to waive copayments. Our findings showing that 1 in 4 dual eligible patients had problems accessing medications because of copayments, which was significantly associated with adverse clinical events, indicate that current Part D copayments presented barriers to treatment, particularly detrimental for psychiatric patients. Although for some patients incorrect cost sharing may have been applied, resulting in incorrect copayments,[2] the magnitude of the problem suggests the need for Congress, CMS, and state Medicaid agencies to consider implementing policies and standardizing pharmacy practices to waive copayments for this population.

Another major concern is the lack of coverage under Part D for benzodiazepines, which are not currently required to be covered by Part D plans. Because benzodiazepines are an evidence-based, recommended treatment for agitation, mood stabilization, anxiety, and sleep problems for patients with schizophrenia and other severe forms of mental illness, their initial exclusion in Part D is particularly problematic for this severely ill population.[27] Although most state Medicaid programs had policies to continue providing benzodiazepine coverage, nearly 3 in 10 patients were reportedly having problems accessing benzodiazepines, a problem that was significantly associated with reports of adverse events. These findings reinforce the new Part D legislative reforms that will provide coverage for benzodiazepines, but not until January 1, 2013.

As there continues to be increasing competition in the Part D market with the number of PDPs increasing significantly while financial risks for the PDPs also increase, further incentivizing plans to contain utilization and costs, it is unlikely that medication access problems will decline dramatically for this dual eligible population unless there are substantial changes in monitoring and implementing of the Part D benefit.[40] Prescription drug plans' increasing use of the utilization management features we studied (with utilization management applying to 30% of the most commonly used medications in 2008, compared to 20% in 2006) raises concerns given the strong and consistent associations of these utilization management features with medication access problems and adverse events.[41]

Prescription drug plans are also likely to maintain formularies and utilization management strategies to minimize adverse selection (enrollment of more severely ill beneficiaries with high prescription drug utilization).[6] Increased transparency and timely monitoring of PDP utilization management practices are needed to detect these practices, which are prohibited by CMS. Prescription drug plans' formularies, prior authorization, and step therapy policies are likely to change each year depending on the drug prices the PDPs negotiate. As PDPs are not responsible for costs of additional health services mentally ill beneficiaries use if their conditions are not adequately stabilized with optimal medication regimens, the PDPs will most likely continue to have incentives to switch clinically stable patients' medications or manage access to promote use of lower cost medications that for some patients may not be clinically preferred. Our findings indicate that these practices may result in suboptimal clinical care and harmful outcomes for psychiatric patients.

Although Medicare Part D was intended to reflect a market-driven approach in which beneficiary choice would constrain providers to meet beneficiary needs, it is unlikely that consumer choice functions effectively in this population. Similarly, while the care management features were intended to provide a *value-driven* approach in containing costs and utilization while assuring safety and quality of care provided, these data indicate that these strategies may have some unintended adverse consequences. There is a considerable lack of transparency as to crucial details of administrative cost-containment policies such as prior authorization and step therapy policies. Further, many dual eligibles lack the ability to effectively evaluate complex choices among plans. Thus, effective governmental monitoring and regulation in this area are essential, particularly since plans that pay only for prescribed medications may be subject to perverse financial incentives to limit access, incentives that are misaligned with optimal long-term outcomes for patients and controlling overall Medicare costs. The final regulations for Part D express the intent of CMS to monitor the economic as well as clinical impact of the benefit, specifically stating, "…in our subsequent guidance we intend to make clear that to the extent that the Part D plan considers costs in making its decision, it will take into account total health care costs rather than just drug costs."[39(p4257)]

CONCLUSION

The Medicare Part D PDP utilization management policies examined in this study were associated with high

rates of medication access problems and, in turn, associated adverse events, including emergency room visits, psychiatric hospitalizations, increases in suicidal or violent ideation or behavior, homelessness, and being incarcerated or detained in jail or prison—resulting in significant human, economic, and social costs. More effective monitoring of Part D plans and current CMS policies is critically needed to prevent the switching of medications for clinically stable patients and to facilitate access to evidence-based, clinically indicated medications for this dual eligible population. In addition, CMS and the states need to develop more effective prescription drug policies and management practices based on data examining both cost and clinical outcomes to promote clinically safer and appropriate prescription drug management practices to enhance medication continuity and outcomes of treatment for psychiatric patients.

Author affiliations: American Psychiatric Institute for Research and Education (APIRE) Practice Research Network (Drs West, Wilk, Rubio-Stipec, and Regier and Mr Rae) and Office of Healthcare Systems and Financing (Mr Muszynski and Ms Sanders), American Psychiatric Association, Arlington, Virginia; Department of Psychiatry, Georgetown University, Washington, DC (Dr Alter); and Center for Pharmacotherapy, Rutgers University, New Brunswick, New Jersey (Dr Crystal). Dr Wilk is currently employed at the Division of Psychiatry and Neuroscience, Walter Reed Army Institute of Research, Silver Spring, Maryland.
Potential conflicts of interest: None reported.
Funding/support: This study was funded by grants from the American Psychiatric Foundation (APF) and the Agency for Healthcare Research and Quality (AHRQ; grant U18HS016097) under a subcontract with Rutgers University's Center for Education and Research on Mental Health Therapeutics. The AHRQ funding provided support for analyses of the data and manuscript development. Although a consortium of industry supporters, including AstraZeneca, Bristol-Myers Squibb, Eli Lilly, Forest, Janssen, Pfizer, and Wyeth, provided financial support to the APF for the development and implementation of this study, APIRE had complete discretion and control over the design and conduct of this study, the analyses, the interpretation of the resulting database, and the reporting of the findings, with no input into or approval of the manuscript from the study's funders. The principal investigator for this study was Joyce C. West, PhD, MPP. These grants provided partial salary support for Drs West and Wilk and Mr Rae (all APIRE research staff) and support for Dr Rubio-Stipec, who is an APIRE consultant. Dr Regier, executive director of APIRE, oversees all federal and industry-sponsored research and research training grants in APIRE but receives no external salary funding or honoraria from any government or industry sources. Dr Crystal received support from National Institutes of Health grants MH60831 and MH058984.
Acknowledgment: The authors acknowledge the considerable efforts and talents of Lisa Countis and Jennifer J. Chen, BS, APIRE staff, who were responsible for fielding this study. Ms Chen also provided excellent research assistance in developing this manuscript. Farifteh F. Duffy, PhD, and William E. Narrow, MD, MPH, also APIRE staff, provided helpful comments on the study's data collection instrument. Please note that the principal investigator for this study, Dr West, takes responsibility for the integrity of the data and the accuracy of the data analyses and confirms that all authors had full access to the data in the study.

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