



# Medicare and Medicaid Prescription Drug Policies: Impact on Access for Psychiatric Patients

*Joyce C. West, PhD, MPP,  
Director, APIRE Psychiatric Research Network*

*April 15, 2008*

# Medicare Part D Prescription Drug Policies: Study Background and Rationale

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Medicare Part D took effect January 1, 2006:

- 6.5 million “dual eligibles” moved from Medicaid to Medicare PDPs.
- Disruptions in medication access and continuity expected due to administrative issues, changes in pharmacy formularies, management and financing.
- 2.5 million dual eligibles with mental illnesses -- greater medication costs/utilization, higher rates of benzodiazepine and off-label prescription drug use not required to be covered.
- Disruptions in medication continuity associated with significant adverse clinical outcomes.
- *Critical to monitor this group to inform future Medicare policies.*

# Medicare Part D Dual Eligibles Study: Evaluation Aims

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Monitor psychopharmacologic management of dual eligible patients treated by psychiatrists to assess:

- 1) Medication access and continuity.
- 2) Administrative functioning/features of PDPs.
- 3) Clinical consequences of unintended medication disruptions.
- 4) Inform future Medicare and Medicaid prescription drug coverage and management policies.

# APIRE's Practice-Based Research Infrastructure to Study Medicare Part D

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- In a given week, psychiatrists treat an estimated:
  - 160,769 Medicare under 65 patients/per week
  - 267,252 Medicaid patients/per week
- Most psychiatrists' patients have serious mental illnesses and on clinically complex medication regimens, with multiple medications.
- Psychiatrists treat most individuals treated for schizophrenia (78%) and many patients with other severe mental illnesses.

# APIRE's Practice-Based Research Infrastructure to Study Medicare Part D

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Claims and administrative data bases have limitations:

- Given Part D complexity, questions regarding availability and timeliness of these data.
- Not able to track medication access and discontinuation problems or clinically undesired switches.
- The full range of other unintended adverse clinical consequences of medication discontinuations or switches difficult or impossible to track.
- Administrative functioning and burdens not captured.

# Proposed Medicare Part D Dual Eligibles Study Design and Approach

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- Observational evaluation design to track and monitor patient and clinician experiences with medication access and continuity:

January-April 2006 1 <sup>st</sup> Post-Implementation Data Collection Cycle	May-August 2006 2 <sup>nd</sup> Post-Implementation Data Collection Cycle	September-December 2006 3 <sup>rd</sup> Post-Implementation Data Collection Cycle
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- Examine relationship between medication access and continuity and key PDP features with practice- and patient-level data.
- Through-the-mail, practice-based research methods successfully used for our other national studies.
- To maximize response rates, multiple mailings utilizing priority mail with a \$75 financial incentive.

# Study Sampling Design

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- 5,833 psychiatrists were randomly selected from the AMA Masterfile of Physicians.
- Clinicians who were not currently practicing (N=291) and those with undeliverable addresses (N=439), were excluded.
- Responses were obtained from 64% of the target sample (N=3,247).
- 35% of the respondents (N=1,183 psychiatrists) reported treating at least one dual eligible patient their last typical work week and provided clinically detailed data for this study.

# Impact of Medicare Part D on Dual Eligibles: Overview of Study Patient Sample (N=1,183)

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## *Sociodemographics:*

- 47% male; 71% white
- 11% age 30 and under; 23% 65 and over

## *Diagnoses:*

- 38% Schizophrenia
- 33% Major Depressive Disorder
- 18% Bipolar Disorder
- 15% Anxiety Disorder
- 11% Substance Use Disorder

# Impact of Medicare Part D on Dual Eligibles: Overview of Preliminary Findings

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- I. Rates of medication access problems.
- II. Problems with PDP administration.
- III. Rates of serious adverse clinical events.
- IV. Characteristics of patients most likely to experience medication access problems.
- V. PDP features associated with medication access problems and adverse events.

# Impact of Medicare Part D on Dual Eligibles: Overview of Preliminary Findings

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- Overall, 53% of all dual eligible psychiatric patients studied had at least one problem with medication access or continuity since January 1<sup>st</sup>. (95% CI 45.7, 56.8)
- As a result, 27% of those w/ medication access problems experienced a serious adverse clinical consequence. (95% CI 21.6, 35.8)
- 20% of those with a medication access problem had an emergency room visit (95% CI 12.4, 27.8); and 11% were hospitalized. (95% CI 5.8, 20.7)

# Preliminary Findings: Access to Medications

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- 39% of patients had problems filling prescriptions.
- 31% had problems accessing medication refills.
- 20% had problems accessing new prescriptions.
- 24% had problems accessing benzodiazepines.
- 18% of patients were previously stable but had to switch to a different medication than clinically desired/preferred.

# Preliminary Findings: Access to Medications (cont.)

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- 20% of all patients were not able to have clinically indicated, preferred medications prescribed due to drug coverage/approval issues.
- 18% had to be started on a different medication than the one clinically preferred because new prescriptions were not covered or approved.
- 22% had problems accessing medications because of copayments.
- 9% reported to have had improved medication access/continuity.

# Clinically Indicated/Preferred Medications Most Commonly Could Not be Used

(For 20% of All Patients)

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Atypical Antipsychotics	22%
SSRIs	21%
Benzodiazepines	14%
Other Antidepressants	17%
Other Antianxiety Medications	11%
Other Anticonvulsants	5%
Mood Stabilizers	5%

# Clinically Undesired Medication Discontinuations

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*22% of all patients had clinically indicated medications discontinued or temporarily stopped due to the changes in prescription drug plan administration.*

# Problems with PDP Administration

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- 30% of all patients had problems with plan enrollment or changing to a desired plan.
- 27% of all patients had to have exceptions requests or appeals initiated on their behalf.
- 19% changed or discontinued clinically indicated medications rather than pursue appeals or exceptions.

# Prescription Drug Administrative Time

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- 45.6 minutes per every hour of patient care spent by psychiatrists and their staff on prescription drug administrative issues since 1/1/06.
- Patients with *Medication Access Problems* required significantly more administrative time -- 56 vs. 30 minutes per patient care hour.
- *Prior Authorization, Preferred Drug Lists, and Limits on Number and Dosing of Medications* associated with two-fold increase in administrative time.

# Serious Adverse Events After Medication Access Problems/Medication Discontinuations (N=579)

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- 20% had an Emergency Room visit.
- 11% were hospitalized.
- 23% had side effects significantly worsen – interfering with functioning/out-weighting therapeutic benefit.
- 22% had an increase in suicidal ideation or behavior.
- 15% had an increase in violent ideation or behavior.
- 3% became homeless for more than 48 hours.

# Specific Medication Access Problems and Rates of ER and Hospitalizations

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	<u>% ER</u>	<u>% Hospitalized</u>
Had to Switch Medication	35%	16%
Discontinued Medication	32%	14%
Could Not Prescribe Clinically Indicated/Preferred Medication	30%	16%

# Patients Most Likely to Experience Medication Access/Continuity Problems and Adverse Events

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- Patients with more severe depressive or anxiety symptoms were significantly more likely to experience problems accessing clinically indicated medications.
- Patients with more severe psychotic symptoms were significantly more likely to experience serious adverse events after medication access/continuity problems.

## PDP Features Associated with Medication Access/Continuity Problems

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	<u>Yes</u>	<u>No</u>
■ <b>Prior Authorization*</b>	75%	32%
■ Preferred Drug/Formulary	68%	31%
■ Early/Emergency Refill Policies	69%	45%
■ <b>Requirements to Use Generics*</b>	79%	38%
■ <b>Limits on Number/Dosing of Meds*</b>	76%	38%
■ Protocols for Transitioning Patients	69%	48%

*\*After adjusting for sociodemographic and clinical factors, these UM features most highly associated with Medication Access Problems.*

## PDP Features Associated with Serious Adverse Events

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	<u>Yes</u>	<u>No</u>
■ Prior Authorization	34%	17%
■ Preferred Drug/formulary	32%	18%
■ Requirements to Use Generics	36%	20%
■ Limits on Number/Dosing of Meds	39%	17%

# Medicare Part D Study: Summary of Study Strengths and Limitations

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## Strengths

- Large national sample.
- Clinically detailed data, including data not readily available from claims and other sources.

## Limitations

- Potential for response/selection biases:
  - Physicians compensated to help minimize response bias.
  - Patient-level data internally consistent w/ caseload-level data.

# Medicare Part D Study: Summary of Key Study Findings

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- Significant and widespread problems accessing medications – problems most common among those most severely ill.
- High rates of medication discontinuations and inability to prescribe clinically indicated medications (even among previously stable patients) pose major risks to these patients.
- Problems accessing benzodiazepines, commonly used to treat anxiety, agitation, and sleep problems, also poses a serious clinical problem.
- PDP UM features highly associated with significant medication access problems as well as serious and costly adverse clinical events.

# Policy Implications

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- Current PD UM strategies may have significant cost-offset implications for this population.
- Especially worrisome are policies leading to medication discontinuations or treatment gaps – copays, delays in prior authorizations.
- “Fail First” or “Step Therapy” policies problematic if leads to repeating a previously failed medication or use of clinically inappropriate medications.
- Limits on number or dosing of medications may offer safety protections generally – but problematic for this population.

# Policy Implications

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More effective PD management strategies and policies are needed to promote medication continuity and more cost-effective treatment:

- Evidence-based, patient-centered treatment essential.
- Assertive Community Treatment (ACT) Models
- Disease Management Programs

# Policy Implications

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*“Medicare and Medicaid prescription drug utilization management policies based primarily on cost rather than clinical considerations may ultimately result in significant human, economic, and social costs.”*