Transition to Medicare Part D: An Early Snapshot of Barriers Experienced by Younger Dual Eligibles With Disabilities

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Objective: This study assessed the impact of transition from Medicaid drug coverage to Medicare Part D on a sample of dually eligible adults younger than age 65 years with disabilities.

Study Design: Telephone survey of employed adults participating in the Kansas Medicaid Buy-In program, Working Healthy, about their experiences in accessing medications after their transition to Part D.

Methods: A total of 328 (55%) individuals from a random sample of 600 agreed to participate in a survey administered by a university-based research unit during February and March 2006, which included 18 questions with yes/no, multiple choice, and open-ended responses. Participants resembled other Kansas dual eligibles demographically and medically, other than having slightly higher rates of mental illness and lower rates of mental retardation and some physical conditions. Participants' 2004 Medicare and Medicaid claims data were analyzed to obtain an overview of their comorbidities and previous prescription use.

Results: Twenty percent of participants reported difficulty obtaining medications, including drugs in Part D–protected classes; 13% were required to switch medications; and 8% stopped taking at least 1 medication. More than half did not know they could change plans monthly, potentially improving their access to medications.

Conclusion: The high incidence of access problems despite Centers for Medicare & Medicaid Services (CMS) safeguards points to the need for ongoing monitoring of Part D. If the problems persist, CMS must be willing to modify the program and/or better enforce the rules already in place to avoid adverse outcomes for beneficiaries with disabilities.

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For author information and disclosures, see end of text.

The transition to Medicare Part D affected not only 35.4 million elderly enrollees but also 6.4 million younger enrollees with disabilities, 2.5 million of whom have low incomes and previously obtained medications through Medicaid. Because Part D was conceived primarily as a benefit for elders, we sought to examine its effects on a dually eligible, younger group of beneficiaries who have significantly different, more expensive, and often unstable health conditions.

ANTICIPATED ISSUES FOR DUAL ELIGIBLES

CMS Preemptive Policies

The Centers for Medicare & Medicaid Services (CMS) instituted policies intended to "mitigate the risks and complications associated with an interruption of therapy" for dual eligibles taking certain categories of drugs.[1] To ensure continuous coverage, CMS required that dual eligibles be automatically assigned to a Part D plan but permitted them to change plans monthly.

CMS required formularies to cover all or substantially all medications within 6 drug classes: antidepressants, antipsychotics, anticonvulsants, anticancer drugs, immunosuppressants, and antiretrovirals for treating HIV/AIDS.[2] CMS prohibited Part D plan sponsors from implementing prior authorization or step therapy requirements intended to "steer beneficiaries to preferred alternatives within these classes for enrollees who are currently taking a drug."[1] Regulations stipulate that patients stabilized on an antidepressant or antipsychotic drug before switching to Part D "should not be subject to utilization management strategies, such as prior authorization or requirements to first fail a preferred product (fail first), to continue therapy."[3]

Studies of Part D Formularies

After evaluating Part D plans from a medical perspective, Elliott and colleagues anticipated that dual eligibles might discontinue essential medications because of increased cost sharing, or might have difficulty obtaining these medications because of

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formulary restrictions.[4] Hoadley and colleagues found that "some plans do not cover the drugs that would be expected if they were following these (CMS) guidelines without any exceptions."[5] In a 50-state survey of Medicaid officials, researchers found "failure of some plans to adhere to the CMS transition plan requirements or failing to cover all or substantially all of the drugs in the 6 protected categories."[6]

The Department of Health and Human Services, Office of the Inspector General (OIG) investigated the extent to which Part D formularies include 200 drugs commonly used by dual eligibles under Medicaid.[7] The OIG found that some drugs in protected classes were not covered by as many as 41% of the formularies. Twenty-one drugs commonly used by dual eligibles were not covered by at least 25% of formularies and, in some cases, up to 57% of formularies.

EARLY SNAPSHOT OF TRANSITION FOR YOUNGER DUAL ELIGIBLES

Sample

Survey participants consisted of 328 (55%) working adults from a random sample of 600 dually eligible enrollees in Kansas's Medicaid Buy-In program, Working Healthy. Survey participants were more likely to live in an urban/semiurban area and had slightly higher rates of mental illness than the sample population, but were otherwise demographically comparable.

Participants' demographic and comorbidity profiles were comparable with those of a random sample of 1375 other dually eligible Kansas Medicaid beneficiaries with disabilities. Participants had somewhat higher rates of serious mental illnesses (psychotic disorders and major depression) and lower rates of mental

Table 1. Principal Diagnoses of Dually Eligible Kansas Medicare Beneficiaries*

Principal Diagnoses (*ICD-9* Category)	Survey Participants (n = 328)	Other Kansas Dual Eligibles Age <65 Years (n = 1375)
HIV infection (042)	0.6	0.4
Malignant neoplasms (140-209, 230-239)	4.6	4.9
Endocrine diseases		
Diabetes (250)	12.5	15.7
Hyperlipidemia (272)†	7.3	3.8
Thyroid (240-246)	4.9	4.5
Blood/blood-forming organ diseases (280-289)	3.4	5.2
Mental disorders		
Organic psychotic conditions (290-294)†	0.6	2.3
Schizophrenia (295)†	26.5	12.2
Other psychoses (296-299)†	25.0	19.1
Neurotic disorders, depression (300-316)	18.6	22.0
Mental retardation (317-319)†	1.2	6.5
Nervous system and sense-organ diseases		
Disorders of the eye and adnexa (360-379)	21.0	24.0
Disorders of the ear (380-389)	8.8	10.6
Multiple sclerosis (340-341)	0.6	1.5
Cerebral palsy and related syndromes (342-344)†	0.9	2.8
Circulatory system diseases		
Hypertensive disease (401-405)	10.4	13.5
Ischemic heart disease, myocardial infarctions (410-414)	0.6	2.1
Heart disease, heart failure (420-429)†	3.4	9.8
Cerebrovascular disease (430-438)†	1.2	3.3
Respiratory system diseases		
Asthma (493)†	7.0	4.3
Chronic obstructive pulmonary disease (491-492)†	0.9	3.1
Digestive system diseases (530-537)	7.0	10.1
Chronic renal disease (580-589)†	0.6	4.0
Skin and subcutaneous tissue diseases (680-710)	15.2	16.0
Musculoskeletal system and connective tissue diseases		
Systemic and inflammatory arthropathies (710-714)	2.7	2.2
Osteoarthritis and other joint disorders (715-719)	17.1	18.4
Rheumatism, excluding the back (725-729)	13.7	15.5
Dorsopathies (720-724)	13.4	14.7
Osteopathies, chondropathies, and acquired musculoskeletal deformities (730-739)	4.3	5.8
Digestive system diseases (530-537)	7.0	10.1

*Data are from the Kansas Medicaid Management Information System, 2004 (survey participants), and 2001-2002 (other dually eligible disabled individuals).
†$P \leq .05$.
Individuals may have reported multiple principal diagnoses.
ICD-9 indicates *International Classification of Diseases, Ninth Revision.*

retardation and physical conditions such as cerebral palsy, respiratory disease, and heart disease, but were otherwise similar to other dually eligible Kansas Medicaid beneficiaries (Table 1).

Participants were 57% female, with a mean age of 47.3 years. Race was reported as 89% white, 5% African American, 5% Native American, and less than 1% Asian and other races; 3% of participants reported Hispanic ethnicity. Demographically, this group closely resembled the general population of Kansas dual eligibles with disabilities, with slightly fewer African American and other races represented.[8] Participants lived in both urban and rural communities similar to the state's general population.

Methods

Telephone interviews were conducted by a university-based research unit during February and March 2006. Participation in the survey was both voluntary and confidential. Each participant received a $10 stipend. An institutional review board approved the study. Administrative data on participants were obtained from calendar year 2004 Medicaid claims files, whereas data for other dual eligibles were from 2001-2002 Medicaid claims files. Comorbidity data were obtained by aggregating *International Classification of Diseases, Ninth Revision*, codes of the primary diagnosis by 3-digit classes.

Instrument

The survey included 18 questions with yes/no, multiple choice, and open-ended responses. The full survey is available from the authors on request.

KEY FINDINGS

Participants experienced 2 major types of issues in the months immediately after implementation of Part D: (1) limited access to medications and (2) limited knowledge of rules and regulations.

Access Limitations

Despite all the preemptive policies to ensure uninterrupted therapies, 20% (66/328) of participants had problems getting prescriptions filled. Moreover, 8% (26/328) reported they stopped taking at least 1 medication due to access issues. Of the 56 respondents who explained their difficulties, 46% (25/56) had to pay either the entire cost of the drug or more out-of-pocket costs than they did under Medicaid; 34% (19/56) needed drugs that were not in the formularies; and 11% (6/56) had difficulty with dosage or refill timing restrictions.

More than one third (15/41) of respondents who identified the drug(s) they could not obtain experienced difficulty acquiring Part D protected class drugs; 4 respondents experienced difficulty getting more than 1 protected drug (Table 2). Nine respondents reported problems obtaining antidepressants; 5 reported limited access to antipsychotics; 4 had difficulty getting anticonvulsants; and 1 reported trouble acquiring an immunosuppressant. Eleven (27%) respondents reported trouble getting benzodiazepines, a drug class not covered by Part D yet covered by Kansas Medicaid, indicating high need for these drugs and lack of information about navigating between Medicaid and Part D. Serious, even life-threatening withdrawal symptoms can result from abrupt cessation in a long-term user.[4]

Fourteen percent (45/328) of survey participants indicated that they were required to get documentation to continue their prescriptions. More than half of these participants reported that documentation took more than 5 days, threatening or interrupting therapy.

Many participants experienced limited access to drugs under the assigned plans. In fact, 23% (77/328) changed plans. Forty-four percent (34/77) of those who switched plans did so because their assigned plan did not meet their needs or cover needed medications, and 18% (14/77) switched because their local pharmacy did not accept the plan to which they had been assigned.

Thirteen percent (43/328) of participants reported being required to change a medication. Sixty percent (26/43) of these respondents were required to switch to a generic form. Forty-four percent (19/43) were switched to a completely different drug or to a different formulation (eg, from an extended-release form to a regular form). Among the 35 respondents who could recall specific drugs from which they were required to switch, 37% (13/35) of the changes were in a protected drug class.

Knowledge

More than half of the participants did not know that, as full-benefit dual eligibles, they could change plans monthly, if needed. Although some knew they could change plans, they did not know how to do so, nor whom to ask for help.

DISCUSSION AND CONCLUSIONS

Despite the small, geographically limited sample, this study is important to policy makers and plan sponsors as an early warning of possible trends. As high users of psychotropic

medications, these participants serve as a barometer for the success of policies to protect continued access to certain classes of critical drugs. Although some of our findings appear to be transition related, they have the potential to seriously disrupt individuals' drug regimens and long-term well-being. For example, many individuals who were not required to make copayments under Medicaid were suddenly faced with multiple copayments and no protection if they were unable to meet them. Under Part D, the copayments are indexed and likely to rise each year, making the copayments a long-term issue of great importance. Other issues, such as lack of knowledge about the ability to change plans, can be addressed through additional outreach and educational efforts. However, the ability to better negotiate different plans is of little relevance if one's local pharmacy accepts only a single plan. As one participant noted, Part D is difficult when one lives in a small town, especially when one has a disability and, often, transportation difficulties.

The fact that numerous people were unable to obtain medications included in protected drug classes is especially troubling and may have long-term implications. Further, drug substitutions that make economic sense may have therapeutic implications for people with disabilities (eg, those who need assistance taking medication may not have this assistance available multiple times throughout the day). Physical and cognitive limitations may make extended-release forms the only effective modality and may make the difference between the ability to live in the community and the necessity of being institutionalized.

In combination, the barriers to access cited by survey participants may result in the inability to get needed medications. Indeed, 8% of our sample had completely stopped taking at least 1 medication since Part D implementation.

■ **Table 2.** Difficulties Reported by Dual-Eligible Survey Participants in Obtaining Medications During Transition to Part D*

Drug Class	Reports of Difficulty Obtaining Medication	Percentage of Reports (n = 67)	Percentage of Respondents (n = 41)
Part D–protected Drugs			
Antidepressant†	9	13.4	22.0
Antipsychotic‡	5	7.5	12.2
Anticonvulsant§	4	6.0	9.8
Immunosuppressant‖	1	1.5	2.4
Other Part D Drugs			
Analgesic	6	9.0	14.6
Antiulcer	5	7.5	12.2
Cardiovascular	4	6.0	9.8
Central nervous system stimulant	4	6.0	9.8
Antihistamine	2	3.0	4.9
Thyroid	2	3.0	4.9
Asthma/anti-inflammatory	2	3.0	4.9
Anxiolytic	1	1.5	2.4
Other Part D¶	6	9.0	19.2
Non–Part D Drugs			
Benzodiazepines	11	16.4	26.8
Nonprescription	2	3.0	4.9
Barbiturate	1	1.5	2.4
Erectile dysfunction drug	1	1.5	2.4
Vitamin	1	1.5	2.4
Total	**67**	**100.0**	**100.0**

*Respondents were permitted to report multiple medications.
†Antidepressants included Lexapro, Cymbalta, Prozac, Ludiomil, Paxil, and Tofranil.
‡Antipsychotics included Abilify, Geodon, Zyprexa, Clozaril, and Lithium.
§Anticonvulsants included Topamax, Neurontin, and Trileptal.
‖Immunosuppressants included Imuran.
¶Other included drug classes: antibiotic, muscle relaxant, antispasmodic, migraine agent, sleep agent, and pituitary hormone.

The Future of Part D

Continued monitoring of Part D in the coming months and years is imperative. As state initiatives have emerged to fill the gaps in coverage left in the wake of Part D implementation, it is important not to lose sight of what can be done on a federal level to improve Part D. If the issues identified here persist, CMS must implement remedies. At the very least, Part D should maintain a level of coverage commensurate with that received by dual eligibles under Medicaid.

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Take-away Points

Problems experienced by dual eligibles with disabilities during transition to Part D are an early warning of possible trends for other Medicare recipients.

- Beneficiary access to medications was limited by plan availability, restrictive formularies, higher out-of-pocket costs, and documentation delays.
- One in 5 beneficiaries were unable to obtain certain medications, including those in CMS-protected drug classes.
- One in 12 beneficiaries stopped taking at least 1 medication due to Part D transition barriers.

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