kaiser commission on medicaid and the uninsured

Unintended Consequences: The Potential Impact of Medicare Part D on Dual Eligibles with Disabilities in Medicaid Work Incentive Programs

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THE HENRY J. KAISER FAMILY FOUNDATION

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The Kaiser Commission on Medicaid and the Uninsured provides information and analysis on health care coverage and access for the low-income population, with a special focus on Medicaid's role and coverage of the uninsured. Begun in 1991 and based in the Kaiser Family Foundation's Washington, DC office, the Commission is the largest operating program of the Foundation. The Commission's work is conducted by Foundation staff under the guidance of a bi-partisan group of national leaders and experts in health care and public policy.

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EXECUTIVE SUMMARY

Prescription drug coverage created by Title I of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003[1] (MMA), also known as Medicare Part D, will affect not only 35.4 million elderly enrollees but also 6.5 million younger enrollees with disabilities, 2.4 million of whom have low incomes and currently obtain medications through Medicaid. This younger dually eligible group includes participants in state Medicaid Buy-In programs, which are work incentive programs that allow certain people with disabilities to work and maintain Medicaid coverage. Most Medicaid Buy-In participants are dual eligibles who will transition from Medicaid drug coverage onto Part D on January 1, 2006.

Because Part D was conceived primarily as a benefit for elders and presumably was designed with their needs in mind, it is important to examine how this younger group of beneficiaries with disabilities—who have significantly different, and often unstable, health conditions—may be impacted. Of particular concern is the possibility that low-income persons with disabilities who utilize large numbers and/or expensive types of drugs may be unable to get their needs met under the privately operated Part D prescription drug plans (PDPs).

To explore the potential impact of Part D on these younger dual eligibles, we analyzed Medicaid claims data for three dually-eligible Kansas groups: elders, Buy-In participants, and other disabled adults under age 65. Findings indicate that Buy-In and other disabled adults have fundamentally different health conditions and medication needs than the elderly, with Buy-In participants having the most intensive and expensive drug needs. Highlights include:

- Average monthly prescription costs per person were $404 for Buy-In participants, compared to $387 for other dually-eligible persons with disabilities, $259 for young disabled persons eligible for Medicaid only, and $238 for dually-eligible elders.

- Buy-In participants have high rates of mental illnesses and use many expensive brand-name psychotropic medications, while elders have high rates of cardiovascular diseases and use more generics and over-the-counter medications. Other disabled dual eligibles, while also having high rates of mental illness, appear to have relatively higher rates of physical disabilities than Buy-In participants.
- In the four classes for which off-label drug use was examined (antiulcer drugs, anticonvulsants, antidepressants, and antipsychotics), more than half (51.3%) of Buy-In enrollees used at least one medication for an other than FDA-approved indication.
- Many Buy-In enrollees were discovered to use multiple drugs within a Part D class, with more than two-thirds (68.3%) using two or more drugs in at least one class and more than a quarter (26.5%) using three or more.

People with disabilities are fundamentally different from the majority elder population enrolled in Medicare. With regard to Part D legislation, Buy-In participants use:

- more high-cost medications, which may make it more difficult to access these drugs, given restrictive formularies and other cost-control practices;[2]
- more brand-name medications, making their Part D co-pay obligations higher;
- many drugs off-label, increasing the likelihood that coverage for a prescribed medication may be denied;[3] and
- multiple drugs within classes, decreasing the likelihood that all of their medications will be covered by a single Part D plan.

More than half of Kansas Buy-In participants previously qualified for Medicaid through the spenddown process; nationally, about one-third of Buy-In enrollees transitioned from this

eligibility category. Enrollment in Buy-Ins provides continuous access to Medicaid benefits without spending down income. Continuous access to medications through Medicaid Buy-In programs has proven to be a powerful incentive to work.[4] In fact, a recent multi-state study found prescription drugs to be the single largest Medicaid benefit utilized by Buy-In participants.[5] Under Part D, Buy-In participants who have Medicare coverage may feel less incentive to work and continue paying Buy-In premiums because they will no longer receive Medicaid drug coverage and, in fact, may be financially better off disenrolling. Moreover, if they are less able to gain access to needed medications under Part D, they may experience medical setbacks that make them less able to continue working. In either case, Part D will have the unintended consequence of acting as a barrier to work for thousands of people with disabilities.

The fact that Medicare will risk-adjust premium subsidies according to socioeconomic status and health conditions suggests that the Centers for Medicare and Medicaid Services (CMS) is aware of the greater costs associated with some groups, particularly dual eligibles. However, the success of the proposed safeguards to protect both PDPs and beneficiaries remains to be seen. Because many details about Part D have yet to be determined, it is too early to predict how well the program will work for dual eligibles with disabilities. Other similar programs, however, provide some insights into likely problems. The introduction of managed care formularies for Medicaid recipients in Pennsylvania created many barriers for people to obtain essential medications in a timely manner.[6] Given the managed care structure of Part D plans, similar problems seem likely; e.g., no provision of emergency supplies, waits of weeks to even months for approval of nonformulary prescriptions or those requiring prior authorization, and a host of other administrative issues.

Common sense suggests that a safety net is required for situations in which enrollees are unable to obtain critical or life-sustaining medications. Such situations can arise when either the drug is not on formulary and/or is being used off-label and the appeals process has been exhausted, or when patients cannot afford the co-payments for the numerous medications they need. Given the vulnerability of this population, immediate action is needed to address these issues in the short time remaining before Part D is implemented.

INTRODUCTION

The prescription drug coverage created under Title I of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003[7] (MMA), also known as Medicare Part D, will affect more than 40 million seniors and people with disabilities who are enrolled in Medicare. Some 2.4 million of these are individuals under age 65 with disabilities who, by virtue of their limited assets and income, are also eligible for Medicaid coverage. The people comprising this so-called dually-eligible disabled group currently access prescription drug coverage through their state Medicaid plans. Unfortunately, many of them may be disproportionately and negatively impacted when the Part D program is implemented in January 2006 and they are required to access medications through Medicare. Their drug utilization patterns are markedly different from and their expenditures significantly higher than those of the seniors who constitute the majority of people in Medicare; thus the formularies developed by private providers under Medicare Part D may be inadequate to meet their needs.

To explore how dual eligibles may be affected, this paper discusses the medication needs and utilization patterns of an extremely vulnerable group, people with disabilities who are enrolled in the Kansas Medicaid Buy-In program. Buy-In programs allow qualified people with disabilities to work and maintain Medicaid eligibility. Although Buy-In enrollees account for only a small fraction of the potential Medicare Part D population (about 45,000 people nationally), the issues they present are illustrative of those that many dual eligibles with disabilities may face under the new Part D programs. Further, this study uses experiences in one state to highlight issues of potential importance to disabled Medicare beneficiaries nationwide.

Key Questions

- How do the average per person, per month Medicaid pharmaceutical expenditures for Buy-In participants and other dually-eligible disabled populations differ from those of the elderly?
- How do utilization patterns differ between dually-eligible persons with disabilities and the elderly in terms of classes of drugs used and the proportion of brand-name to generic drugs? Given these utilization patterns, will disabled participants experience a disproportionately greater financial impact from higher co-pays and out-of-pocket expenses under MMA? Will their utilization patterns place them at risk of not being able to access the drugs they need?
- How often do Buy-In populations use certain classes of drugs for indications outside those approved by the FDA? Current guidance indicates that private drug plans will not be obligated to pay for drugs prescribed for off-label uses.
- Do Buy-In participants tend to have high rates of prescription drug utilization within therapeutic classes? Under Part D, PDPs are required to provide only two drugs per category or class, based on the United States Pharmacopeia model guidelines that divide drugs into 146 categories and classes. How will this design affect beneficiaries' access to the drugs they need?

BACKGROUND ON MEDICAID BUY-IN PROGRAMS

Medicaid Buy-In programs allow people with disabilities the opportunity to work and obtain or maintain Medicaid coverage. As of October 2004, 31 states operated Buy-Ins, an optional eligibility category under Medicaid.[8] In the past dual eligibles with disabilities who

opted to work generally lost their eligibility for Medicaid coverage because Medicaid is a means-tested program.[9] Two pieces of legislation—the Balanced Budget Act of 1997 and the Ticket to Work/Work Incentives Improvement Act of 1999—gave states the flexibility to expand Medicaid to people with disabilities whose income or assets would otherwise disqualify them for coverage. The programs were designed as a work incentive to support increased employment and independence of people with disabilities who meet the standard for Social Security disability. Most states with Buy-In programs require cost-sharing for participants, usually through premiums based on a sliding fee scale. The majority (76%) of Buy-In participants are dually eligible for Medicare and Medicaid and will transition to the Part D benefit in January 2006. [10]

Despite the fact that some Buy-In participants may have incomes exceeding 100% of the federal poverty level, the regulations for the Medicare Modernization Act make it clear that Buy-In participants are considered "full benefit dually-eligible" Medicaid participants and will thus qualify for the full Part D premium subsidy and reduced co-pays. The State of Kansas implemented its Medicaid Buy-In program, "Working Healthy," in July 2002 with funding from a Medicaid Infrastructure Change grant from the Centers for Medicare and Medicaid Services (CMS). Working Healthy allows Kansans with disabilities to work, increase their earnings and assets, and obtain or maintain Medicaid coverage. About half of participants in the program had qualified for Medicaid coverage through the state's medically needy program prior to enrollment in the Buy-In, and 98% are dually eligible.

Recent compilations by Liu, Ireys, White and Black[11] indicate that prescription drug costs are the single largest Medicaid expense for Buy-In participants. In California, pharmacy claims represented a full 74% of Buy-In expenditures.[12] Comments from interviews and surveys of Kansas Buy-In participants have repeatedly and overwhelmingly underscored the fact that they

are better able to get their prescription medications because of enrollment in the Buy-In.[13] "I really can't afford my medicine any other way—even working," writes one enrollee who has both diabetes and mental illness. "I get my meds for $12," writes another. "Before, I was paying $200 to $300 a month." These same individuals frequently relate that their conditions are more stable because of consistent access to medications (see "A Buy-In participant who is able to work because of medications" inset).

Depending on an individual Buy-In participant's motivations and needs, implementation of Part D may result in disincentives to work or barriers to work due to exacerbations of their conditions. Due to the complexity of the interplay between Medicaid and Medicare for dual eligibles, the exact effects of Part D are not yet clear. However, some potential

A Buy-In Participant Who Is Able to Work Because of Medications

JB is a 51-year-old woman who has depression and bipolar disorder. She has been enrolled in the Kansas Buy-In since its inception, has worked continuously throughout her enrollment, and has even gone back to school to increase her work skills. Prior to the Buy-In, JB had a $1000+ spenddown every six months.

"My biggest problem at the time was being able to keep my medication to be able to continue to work. That was the thing, if I wasn't able to take my medication, then I was going to be at home. I wasn't going to get out and do what I needed to do. And then I felt bad about myself and everything in life. And I'd get more depressed. So the medication part, being able to take my medication, is very important to be able to get to a place where I can work full time."

She also shared that, often, while in spenddown, "I didn't take my medication. I couldn't afford it." After enrolling, she said she has been "able to get my medication when I need it." She further related that, immediately after her enrollment, she spent a very difficult period of about six months becoming re-stabilized through medication. Moreover, JB explained that, without her spenddown obligation, she has been able to pay off bills and feel less stressed financially.

JB does not have extensive medication needs related to her mental illnesses—she takes Effexor XR and Geodon. She also regularly takes hormone replacement therapy and thyroid medication. Nevertheless, even short-term interruptions in her regimen can result in long-term setbacks to her quality of life and ability to work. Under Part D, JB will no longer have the option of accessing medications through Medicaid even if a Part D plan does not meet all of her needs. She will have the same coverage for prescriptions whether she works or not and, if the coverage is not adequate, may actually be unable to work.

effects include the following:

- Buy-In enrollees who pay a Buy-In premium, especially those who do not need many other Medicaid services, may find it more cost effective to disenroll once medications are available through Part D.
- Individuals who leave the Buy-Ins may choose to work only at the income and asset levels that will keep them eligible for Part D premium subsidies.
- Therapeutic interchange of less expensive and less effective drugs or other access problems may result in destabilization of an individual's condition and inability to work competitively.

METHODS

To examine how Kansas Buy-In participants and other dually-eligible persons with disabilities might be affected by Part D, we analyzed one year of Medicaid claims data for three dually-eligible groups: elders, Buy-In participants, and other disabled adults under age 65.[14] Pharmaceutical claims provided information about the most commonly used and most expensive drugs as well as numbers of prescriptions filled and actual amounts paid by Medicaid. The Buy-In group's drugs also were classified within the United States Pharmacopeia Model Guidelines—the suggested model for Part D formularies—and according to whether a generic version of the drug was available. These data were used to track the proportion of brand-name to generic utilization and the utilization of multiple drugs within Medicare classes.

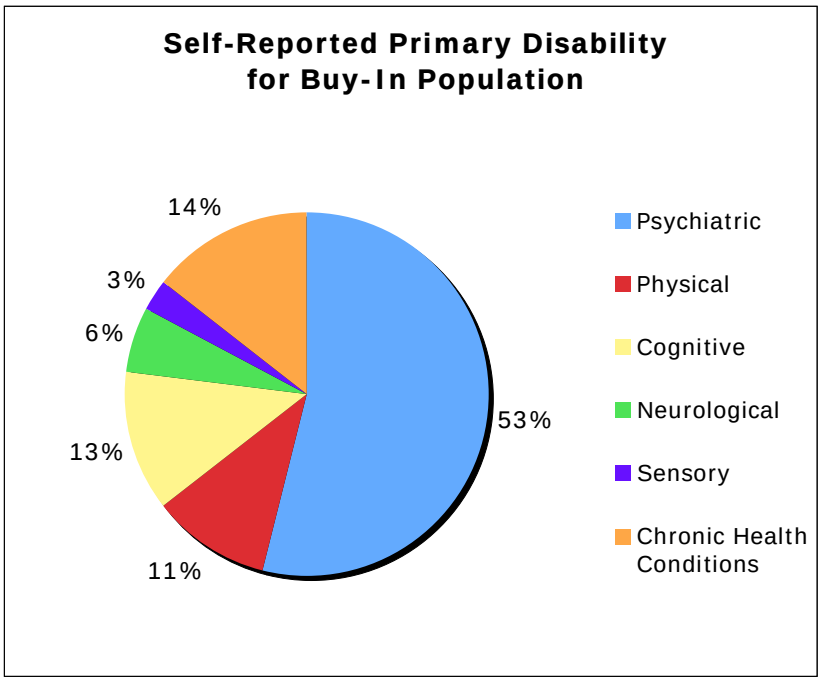
Information on disabilities was obtained in two ways. Self-reported disability declarations were available from a sample of Buy-In participants continuously enrolled in 2003. Outpatient and inpatient claims data were used to identify common comorbidities by aggregating ICD-9 (International Classification of Diseases, 9th revision) codes into 3-digit categories to

create major diagnostic categories. These data were available for all three groups.

Description of the Sample

Self-reported disabilities of Kansas Medicaid Buy-In participants are shown below. These data reflect 38% of all participants continuously enrolled throughout 2003; however, a similar distribution of conditions was found in an analysis of outpatient and hospital claims covering 98% of those continuously enrolled in 2003 (n=400). The disabilities shown below are those judged to be the most significant by the individual; 40% of participants report having multiple disabling conditions. Based on self-reports, people with mental illnesses constitute the single largest sub-group (53% of participants), followed by people with chronic physical health problems such as lupus, rheumatoid arthritis, and diabetes (14% of participants); people with cognitive impairments (13% of participants); and people with physical disabilities, such as cerebral palsy, paraplegia, amputations, or spinal conditions (11% of participants).

Compared to the overall dually-eligible population in Kansas, people with serious mental illness are somewhat over-represented in the Buy-In. Buy-In programs in other states, including California,[15] Minnesota,[16] and Wisconsin[17] have reported similar discrepancies for this sub-group.



Males and females are equally represented among Buy-In participants, and their average age is 44.9 years, ranging from a low of 21 to a high of 64 (program eligibility begins at age 16 and ends at age 65). Again, this age range is fairly typical for Buy-Ins.[18] Racially, 86.3% of participants are white, 5.3% are black, 3.1% are of another racial or ethnic minority, and 5.3% are unknown (see Table 1). This distribution approximates that of the state in general. The broader dually-eligible disabled population has proportionately more females and African Americans.

Table 1
Demographic characteristics of Kansas Medicaid dually eligible participants by group

Characteristic	Percent of elders (n=4,482)	Percent of Buy-In participants (n=400)	Percent of other dually-eligible disabled (n=1,375)
Gender			
Male	25.3	50.8	46.8
Female	74.7	49.0	53.2
Unknown	0.0	0.2	0.0
Race/Ethnicity			
White	83.2	86.3	84.7
Black	8.7	5.3	12.4
Other	8.1	3.1	2.8
Unknown	0.0	5.6	0.0
Mean Age (SD)	79.7 (9.24)	44.9 (9.65)	45.7 (11.20)
Age groups			
16-21	0.0	0.0	0.7
21-30	0.0	6.3	10.4
31-40	0.0	26.8	23.3
41-50	0.0	37.8	30.2
51-60	0.0	22	25.8
61-64	0.0	6.8	9.5
>=65	100.0	0.0	0.0
Unknown	0.0	0.5	0.0

Notes: Other Race/Ethnicity includes Hispanic, Native American, Asian, and other. Buy-In represents all members continuously enrolled during calendar year 2003; elderly and other dually-eligible disabled represent a cross-sectional sample of persons enrolled at least one month from May 2001 through March 2002.

FINDINGS

Table 2 reports comorbidities according to Medicaid claims, comparing the range of conditions experienced by the Buy-In enrollees with those of elders and other dually-eligible disabled Medicaid enrollees. Buy-In participants experience a range of chronic health conditions that are distinctly different from the types and frequencies of conditions experienced by dually-eligible elders in the state; some of these conditions are related to the Buy-In group's underlying disabilities and some are related to their younger age. Notably, the most frequent mental disorder among elders is organic psychoses, including Alzheimer's disease and dementia, while Buy-In participants most frequently experience schizophrenia and other psychoses. Within chronic physical conditions, the elderly experience much more cardiovascular disease, whereas Buy-In participants have greater rates of diseases of the nervous system (e.g., multiple sclerosis) and systemic or inflammatory arthropathies (e.g., rheumatoid arthritis, systemic lupus erythematosus). People in the other dually-eligible disabled group are generally similar to those in the Buy-In group except that they have relatively higher occurrences of conditions—such as cerebral palsy, paralyses, and mental retardation—that likely qualify them for one of the state's home-and community-based services (HCBS) waivers. Waiver services, such as attendant care, are not yet available to Kansas Buy-In participants, so this discrepancy is not surprising. The differing distribution of conditions among the three groups significantly influences the types of medications used by each.

Table 2
Major ICD category & principal diagnoses of Kansas participants by group

ICD category & principal diagnoses	Percent of elders (n=4,482)	Percent of Buy-In participants (n=400)	Percent of other dually-eligible disabled (n=1,375)
Infectious & parasitic diseases (000-041, 043-140)	11.8	10.5	11.5
HIV infection (042)	0.0	1.0	0.6
Neoplasms			
Benign (210-229)	3.2	9.8	6.9
Malignant (140-209, 230-239)	8.2	5.3	6.0
Endocrine diseases			
Diabetes (250)	22.0	16.8	19.6
Hyperlipidemia (272)	8.8	8.3	11.9
Thyroid (240-246)	9.6	6.0	10.4
Diseases of blood & blood-forming organs (280-289)	14.0	4.0	11.7
Mental Disorders			
Organic psychotic conditions (290-294)	11.2	0.5	3.3
Schizophrenia (295)	3.1	27.3	13.6
Other psychoses (296-299)	7.6	25.3	21.5
Neurotic disorders, including depression (300-316)	13.5	15.8	39.5
Mental retardation (317-319)	1.9	4.0	14.7
Diseases of the nervous system & sense organs			
Disorders of the eye and adnexa (360-379)	23.8	22.0	27.1
Disorders of the ear (380-389)	7.4	13.5	13.5
Multiple sclerosis (340-341)	0.2	1.3	2.1
Cerebral palsy and other paralytic syndromes	1.6	1.3	4.5
Parkinson's disease (332)	3.9	0.5	0.6

continued

Table 2 (*continued*)
Major ICD category & principal diagnoses of Kansas participants by group

ICD category & principal diagnoses	Percent of elders (n=4,482)	Percent of Buy-In participants (n=400)	Percent of other dually-eligible disabled (n=1,375)
Diseases of the circulatory system			
Hypertensive disease (401-405)	38.3	16.3	27.4
Ischemic heart disease, including myocardial infarctions (410-414)	5.4	2.8	4.1
Other heart disease, including heart failure (420-429)	30.9	6.5	15.8
Cerebrovascular disease (430-438)	14.2	0.5	5.3
Diseases of the respiratory system			
Asthma (493)	3.5	10.3	8.1
Other chronic obstructive pulmonary disease (491-492)	5.8	2.5	5.6
Diseases of the digestive system			
Diseases of the esophagus, stomach & duodenum (530-537)	12.4	8.5	18.8
Diseases of the genitourinary system			
Chronic renal disease, including renal failure (580-589)	3.5	2.3	4.7
Other genitourinary conditions (590-630)	21.6	24.0	31.1
Diseases of the skin & subcutaneous tissue (680-710)	15.6	22.5	22.5
Diseases of the musculoskeletal system & connective tissue			
Systemic & inflammatory arthopathies (710-714)	1.8	3.5	3.0
Osteoarthritis & other joint disorders (715-719)	24.5	21.0	27.3
Rheumatism, excluding the back (725-729)	13.8	20.8	24.7
Dorsopathies (720-724)	11.2	15.0	18.8
Osteopathies, chondropathies, & acquired musculoskeletal deformities (730-739)	11.1	4.8	10.4

Source: Kansas Medicaid Buy-In claims records, 2003; Kansas Medicaid elderly and disabled claims records, 2001-2002.

Per Person Costs

- ***How do the average per person, per month Medicaid pharmaceutical expenditures for Buy-In participants and other dually-eligible populations with disabilities differ from those of the elderly?***

Table 3 summarizes the average per participant, per month Medicaid prescription drug costs of dually-eligible elders, Medicaid-only eligible persons with disabilities, dually-eligible persons with disabilities, and Buy-In participants in Kansas. Costs for dually-eligible persons with disabilities are 62% higher than those of elders, and costs for Buy-In participants are 70% higher than those of elders. The average per participant, per month cost of $404 for Buy-In participants is almost *four* times the estimated $109 national average monthly bid amount for Part D plans.[19]

Table 3
Comparison of per participant per month Medicaid drug costs

Population	Average monthly cost
Kansas Medicaid Buy-In	$404
Other dually-eligible disabled	$387
Medicaid-only disabled	$259
Dually-eligible elders	$238

Note: Costs are based on one year of expenditures; all are based on calendar year 2003.

Utilization Patterns, including Generic versus Brand-name

- **How do utilization patterns differ between dually-eligible persons with disabilities and the elderly in terms of classes of drugs used and the proportion of brand-name to generic drugs? Given these utilization patterns, will Buy-In participants experience a greater financial impact from higher co-pays and out-of-pocket expenses under MMA? Will their utilization patterns place them at risk of not being able to access the drugs they need?**

Using Medicaid administrative data, we compiled lists of the top 20 most frequently prescribed medications for Buy-In participants, dually-eligible elders, and other dually-eligible persons with disabilities. We also compiled lists of the 20 drugs accounting for the highest Medicaid drug expenditures, which reflect a combination of frequency of utilization and average cost of the drug. These lists are shown in Tables 4 through 6 and Tables 8 through 10.

Antipsychotics, antidepressants and anticonvulsants account for 70% of the 20 most frequently prescribed drugs in the Buy-In population and 60% in the other dually-eligible group, compared to 15% in the elderly dual-eligibles. Among the elderly, the distribution is quite different, with drugs used to treat cardiovascular conditions, ulcers, and pain accounting for 80% of the most frequent classes. Only two antidepressants and one antipsychotic medication were among the top 20 for this population. Although the other dually-eligible disabled and Buy-In populations have similar claims utilization, the former has somewhat higher frequency for physical conditions such as pain, cardiac, and respiratory conditions.

Table 4
Most frequent prescriptions filled for Kansas Buy-In participants

Rank	Generic drug name	Common trade name(s)	Drug class	Generic available
1	Clozapine HCL	Clozaril	Antipsychotic	Yes
2	Levothyroxine Sodium	Synthroid [a]	Endocrine/Thyroid	Yes
3	Olanzapine	Zyprexa	Antipsychotic	No
4	Risperidone	Risperdal	Antipsychotic	No
5	Hydrocodone with Acetaminophen	Vicodin, Vicodin ES[b]	Analgesic	Yes
6	Divalproex Sodium	Depakote, Depakote ER	Anticonvulsant	No
7	Clonazepam	Klonopin	Anticonvulsant (benzodiazepine)[c]	Yes
8	Sertraline HCL	Zoloft	Antidepressant	No
9	Quetiapine Fumarate	Seroquel	Antipsychotic	No
10	Venlafaxine HCL	Effexor, Effexor XR	Antidepressant	No
11	Bupropion HCL	Wellbutrin, Wellbutrin SR, Wellbutrin XL	Antidepressant	Yes/No[d]
12	Atorvastatin Calcium	Lipitor	Cardiovascular/ antilipemic	No
13	Paroxetine HCL	Paxil, Paxil CR	Antidepressant	Yes/No[d]
14	Gabapentin	Neurontin	Anticonvulsant	Yes
15	Cetirizine HCL	Zyrtec	Antihistamine	No
16	Lisinopril	Prinivil, Zestril	Cardiovascular/ Ace Inhibitor	Yes
17	Pantoprazole Sodium	Protonix	Antiulcer	No
18	Aripiprazole	Abilify	Antipsychotic	No
19	Trazodone	Trazodone, Desyrel	Antidepressant	Yes
20	Citalopram Hydrobromide	Celexa	Antidepressant	Yes

Notes: [a]Other names include Levothroid, Eltroxin, L-Thyroxine, Levotabs, Levoxyl, Levo-T, Unithroid. [b]Other names include Maxidone, Anexsia, Bancap HC, Lorcet, Lorcet Plus, Lortab, Zydone. [c]Benzodiazepines are excluded from payment under Medicare Part D but may still be covered under Medicaid with federal match. [d]Sustained release (SR) or controlled release (CR) formulation remains under patent. Other forms available as generic.

Table 5
Most frequent prescriptions filled for Kansas elderly Medicaid participants

Rank	Generic drug name	Common trade name(s)	Drug class	Generic available
1	Furosemide	Lasix	Diuretics	Yes
2	Potassium Chloride	Slow K[a]	Potassium Replacement	Yes
3	Levothyroxine Sodium	Synthroid[b]	Endocrine/Thyroid	Yes
4	Digoxin	Digitek, Lanoxin, Digicap	Cardiovascular/ Inotropic	Yes
5	Aspirin		Analgesic, OTC[d]	Yes
6	Warfarin Sodium	Coumadin	Antiplatelet/ Anticoagulant	Yes
7	Celecoxib	Celebrex	Analgesic	No
8	Amlodipine Besylate	Norvasc	Cardiovascular/ Calcium Channel Blocker	No
9	Acetaminophen	Tylenol, Genebs, Panadol[c]	Analgesic, OTC[d]	Yes
10	Sertraline CL	Zoloft	Antidepressant	No
11	Propoxyphene/ Acetaminophen	Darvocet, Wygesic	Analgesic	Yes
12	Omeprazole	Prilosec, Prilosec SA	Antiulcer, OTC[d]	Yes
13	Lisinopril	Prinivil, Zestril	Cardiovascular/ Ace Inhibitor	Yes
14	Nitroglycerin	Nitrobid[e]	Cardiovascular/ Vasodilators	Yes
15	Risperidone	Risperdal	Antipsychotic	No
16	Rofecoxib	Vioxx[f]	Analgesic	No
17	Ranitidine	Zantac	Antiulcer, OTC[d]	Yes
18	Famotidine	Pepcid	Antiulcer, OTC[d]	Yes
19	Atorvastatin Calcium	Lipitor	Cardiovascular/ antilipemic	No
20	Mirtazapine	Remeron	Antidepressant	Yes

Notes: [a]Other names include K Dur, Kaon Cl-10, Klor-Con, Klotrix, K+ 10, K-Norm, K-Tab, Micro K-10 Ex, Pot Cl. [b]Other names include Levothroid, Eltroxin, L-Thyroxine, Levotabs, Levoxyl, Levo-T, Unithroid. [c]Other names include Mapap Acetam, Pediapap, Tempra 1 and Tempra 2. [d]Over-the-counter drugs are excluded from payment under Medicare Part D but may still be covered under Medicaid with federal match. [e]Other names include Nitroquick, Nitrolingual, Nitrol, Nitrodur, Nitrostat Sub, Deponit, Transderm NTG, Nitro Disc, Nitro Trans, Minitran TDS. [f]Withdrawn from the market by manufacturer in 2004.

Table 6
Most frequent prescriptions filled for Kansas other dually-eligible participants

Rank	Generic drug name	Common trade name(s)	Drug class	Generic available
1	Levothyroxine Sodium	Synthroid[a]	Endocrine/Thyroid	Yes
2	Hydrocodone with Acetaminophen	Vicodin, Vicodin ES[b]	Analgesic	Yes
3	Divalproex Sodium	Depakote, Depakote ER	Anticonvulsant	No
4	Olanzapine	Zyprexa	Antipsychotic	No
5	Clonazepam	Klonopin	Anticonvulsant (benzodiazepine) [c]	Yes
6	Potassium Chloride	Slow K[d]	Potassium Replacement	Yes
7	Furosemide	Lasix	Diuretics	Yes
8	Risperidone	Risperdal	Antipsychotic	No
9	Clozapine HCL	Clozaril	Antipsychotic	Yes
10	Phenytoin Sodium	Dilantin, Phenytek	Anticonvulsant	Yes
11	Omeprazole	Prilosec, Prilosec SA	Antiulcer, OTC[e]	Yes
12	Gabapentin	Neurontin	Anticonvulsant	Yes
13	Albuterol	Proventil, Ventolin	Bronchodilator	Yes
14	Sertraline HCL	Zoloft	Antidepressant	No
15	Quetiapine Fumarate	Seroquel	Antipsychotic	No
16	Estrogens, conjugated	Premarin	Hormone Replacement	Yes
17	Atorvastatin Calcium	Lipitor	Cardiovascular/ antilipemic	No
18	Trazodone	Trazodone, Desyrel	Antidepressant	Yes
19	Fluoxetine HCL	Prozac	Antidepressant	Yes
20	Paroxetine HCL	Paxil, Paxil CR	Antidepressant	Yes/No[f]

Notes: [a]Other names include Levothroid, Eltroxin, L-Thyroxine, Levotabs, Levoxyl, Levo-T, Unithroid. [b]Other names include Maxidone, Anexsia, Bancap HC, Lorcet, Lorcet Plus, Lortab, Zydone. [c]Benzodiazepines are excluded from payment under Medicare Part D but may still be covered under Medicaid with federal match. [d]Other names include K Dur, Kaon Cl-10, Klor-Con, Klotrix, K+ 10, K-Norm, K-Tab, Micro K-10 Ex, Pot Cl. [e]Over-the-counter drugs are excluded from payment under Medicare Part D but may still be covered under Medicaid with federal match. [f]Controlled release (CR) formulation remains under patent. Other forms available as generic.

Clearly, the types of drugs frequently used by younger dual eligibles and the elderly are quite different. From a policy perspective, an equally important finding is that, among these most frequently used drugs, only 50% of those for the Buy-In population are available as generics, compared to 70% of those used by elders and other dually-eligible disabled. This differential is accounted for in part by the higher concentration of psychotic disorders (for which brand-name atypical antipsychotics are often prescribed) among Buy-In participants. To investigate this issue

further, we examined the usage of generic versus brand-name medications across all drugs used by the Buy-In population in 2003 (see Table 7). On average, 58.4% are brand-name. When the analysis is narrowed to maintenance drugs, fully 62.9% of medications used are brand-name, with an average 30.7 maintenance prescriptions filled annually per participant. For full benefit dually-eligible beneficiaries, the Part D co-pay for generic medications will be $1 and for brand-name drugs $3, and these costs will increase each year. Under Medicaid, these individuals would be guaranteed access to their prescriptions regardless of their ability to meet a co-pay requirement. The same protection does not apply under Part D.

Table 7
Overall drug utilization profile for Kansas Buy-In participants for calendar year 2003

	Mean (SD)	Participants	Percent of total
Used any prescription drug		378	94.5
Used at least one maintenance drug[a]		363	90.8
Per person prescriptions per year (range 1-238)	56.5 (41.5)		
Per person maintenance prescriptions (range 1-216)	49.0 (35.3)		
Brand-name prescriptions	33.1 (25.9)		58.4
Brand-name maintenance prescriptions	30.7 (23.3)		62.9
Unique drugs used per person per year (range 1-40)	10.7 (7.9)		
Persons using multiple drugs w/in a Medicare class[b]			
Two or more drugs per class		258	68.3
Three or more drugs per class		100	26.5

Notes: N=400. [a]A maintenance drug is defined as one prescribed in minimum 25-day quantities. Also included are drugs prescribed repetitively in smaller doses that equate to a monthly supply. [b]Determined by classifying 2003 utilization according to United States Pharmacopeia model guidelines.

Among the drugs that resulted in the highest cost to Medicaid, those used by the Buy-In and the other dually-eligible disabled populations are predominantly (70%) psychotropics: antipsychotics, antidepressants, anticonvulsants, and anxiolytics. For the Buy-In population two

immunosuppressants also appear on the high cost list. Cardiovascular, antiulcer, and pain medications round out the top 20. For the elderly, the high cost drugs are more heterogeneous and include antipsychotics, analgesics, antiulcer agents, urinary tract antispasmodics, drugs used to treat cardiovascular conditions, and agents specific to the treatment of Parkinson's disease and dementia. The differences in high cost medications can be directly correlated with the conditions identified as more common within the two groups. More important from a policy perspective, though, is how responsive Part D formularies will be to the fundamentally different suite of high cost drugs used by the disabled population.

A High-Cost User with Low Utilization of Psychotropic Drugs

High cost drug users do not necessarily utilize large numbers of drugs or fill large numbers of prescriptions. The Buy-In participant with the third highest overall annual cost had claims of more than $17,500 for monthly refills of only 3 maintenance drugs. Two of these were atypical antipsychotics (Seroquel and Zyprexa), and the third was a serotonin-specific reuptake inhibitor (Celexa).

Implications for Access

CMS issued final guidelines for formularies that included a list of top drug classes by cost and utilization. CMS stated it would analyze the availability and tier positions of the drugs in this list "to ensure that plans are covering the most widely used medications for the most common conditions."[20] Remarkably, that list did not include three classes encompassing four of the top 20 most costly drugs used by the Buy-In population: norepinephrine and dopamine reuptake inhibitors (Wellbutrin); immunologic agents (Cellcept and Prograf), and glutamate reducing agents (Topamax).

In the same guidance CMS also indicates that they expect formularies to contain a majority of available drugs for certain serious and potentially unstable conditions,

including mental illness. Even if most or all of these drugs are on formularies, however, they could be placed on higher tiers, requiring beneficiaries to file a benefit appeal in order to access them. In addition, according to one legal scholar, "the final regulations preserve considerable discretion on the part of PDP sponsors to deny requests for exceptions to tiered cost sharing and formulary limits, even where the beneficiary submits written evidence from the prescribing physician satisfying the medical necessity standard applicable to such requests under law."[21] Beneficiaries themselves will have to contact their plans to initiate these appeals, which constitutes a potential barrier for low-functioning individuals. In addition, they would be required to pay out of pocket the additional cost-sharing amount pending the appeal and would not be reimbursed if they were unsuccessful. Unlike Medicaid, Part D benefits do not continue pending appeal. Inability to pay these out-of-pocket costs on top of co-payments for Part D drugs, resulting in missed drugs, represents a substantial threat to medical stability and ability to continue in the labor force.

Although formularies may start out with relatively generous benefits, nothing guarantees they will remain generous over time, especially as drug costs continue to rise. PDPs are allowed to remove drugs from formularies with a 60-day notice. Although full-benefit dual eligibles are not locked into plans like other Medicare beneficiaries and may switch at any time, they may be unable to find a plan that better meets their needs.

Beneficiaries also face potential additional out-of-pocket expenses for drugs previously paid for by Medicaid but excluded from Part D coverage. These include benzodiazepines, weight loss and weight gain agents, barbiturates, and over-the-counter drugs. Clonazepam, a type of benzodiazepine that is used to treat several psychiatric disorders, is the seventh most frequently

used medication by Kansas Buy-In enrollees and fifth most frequently used by other dual eligibles.[22] States may choose to pay for excluded drugs and receive federal match (other than for over-the-counter drugs), but may be unable to do so given their obligation to pay the federal government a clawback payment for dual eligibles' Part D coverage and recently legislated cuts in state Medicaid funding.

In its final guidelines on formularies, CMS states that PDPs are expected to apply utilization management tools for cost control, such as step therapy and therapeutic interchange. Both the law and regulations make clear that a high use of generic medications is a goal for the Part D program.[23,24] These drug utilization review practices represent a particular threat to Buy-In participants because they use more brand-name drugs (Tables 4-6).

Buy-In participants and other dually eligible disabled persons have high rates of serious and persistent mental illnesses (SPMI). We found the mean annual cost of drug treatment for Buy-In participants with any SPMI diagnosis to be more than double the average for participants without SPMI ($6,183 vs. $2,829, p=.000). This is primarily due to the high cost of the newer antipsychotic agents and antidepressants, most of which are still under patent. These drugs are often considered the treatment of choice because of reduced side effects and, in some cases, greater effectiveness. However, the clinical superiority of these drugs has recently been questioned,[25] and this fact in combination with their high costs makes them likely targets for utilization review and therapeutic interchange in Part D plans. Despite the fact that drugs within a class (e.g., serotonin-specific reuptake inhibitors, atypical antipsychotics) may be regarded by Part D formularies as therapeutically equivalent, they have different side-effect profiles and

patient responses. The clinical substitution of older, lower-cost drugs could therefore be destabilizing and increase the risk of serious side effects.[26] Kansas Buy-In participants have reported destabilization of their conditions when access to medications is interrupted.[27]

Dually eligible populations also have high rates of musculoskeletal and inflammatory conditions (Table 2), such as osteoarthritis, auto-immune diseases, rheumatism, and spinal diseases. At least 22 different nonsteroidal anti-inflammatory drugs (NSAIDs) are used in treating these conditions. The cost of a 30-day supply of these medications ranges from a few dollars to more than $100. The difference in anti-inflammatory activity between different groups of NSAIDs is small; however, patient response is highly individualized, and trials of several drugs are often necessary before the right drug is found.[28,29] If patients are unable to access the NSAID they need due to restrictive formularies or cost-control practices such as therapeutic interchange, increased pain or disease activity may lead to increased disability and inability to work.

Table 8

Drugs accounting for the highest aggregate cost to Medicaid for Kansas Buy-in participants

Rank	Generic drug name	Common trade name(s)	Drug class	Generic available
1	Olanzapine	Zyprexa	Antipsychotic	No
2	Clozapine HCL	Clozaril	Antipsychotic	Yes
3	Risperidone	Risperdal	Antipsychotic	No
4	Quetiapine Fumarate	Seroquel	Antipsychotic	No
5	Aripriprazole	Abilify	Antipsychotic	No
6	Divalproex Sodium	Depakote, Depakote ER	Anticonvulsant	No
7	Topiramate	Topamax	Anticonvulsant	No
8	Ziprasidone HCL	Geodon	Antipsychotic	No
9	Venlafaxine HCL	Effexor, Effexor XR	Antidepressant	No
10	Gabapentin	Neurontin	Anticonvulsant	Yes
11	Buproprion HCL	Wellbutrin, Wellbutrin SR, Wellbutrin XL	Antidepressant	Yes/No[a]
12	Sertraline HCL	Zoloft	Antidepressant	No
13	Lansoprazole	Prevacid	Antiulcer	No
14	Tacrolimus Anhydrous	Prograf	Immunologic Agent	No
15	Simvastatin	Zocor	Cardiovascular/ Antilipemic	No
16	Paroxetine HCL	Paxil, Paxil CR	Antidepressant	Yes/No[a]
17	Pantoprazole Sodium	Protonix	Antiulcer	No
18	Atorvastatin Calcium	Lipitor	Cardiovascular/ Antilipemic	No
19	Citalopram Hydrobromide	Celexa	Antidepressant	Yes
20	Mycophenolate Mofetil	Cellcept	Immunologic Agent	No

Note: [a]Sustained release (SR) or controlled release (CR) formulation remains under patent. Other forms available as generic.

Table 9

Drugs accounting for the highest aggregate cost to Medicaid for Kansas's elderly participants

Rank	Generic drug name	Common trade name(s)	Drug class	Generic available
1	Olanzapine	Zyprexa	Antipsychotic	No
2	Omeprazole	Prilosec, Prilosec SA	Antiulcer, OTC[a]	Yes
3	Risperidone	Risperdal	Antipsychotic	No
4	Celecoxib	Celebrex	Analgesic	No
5	Sertraline HCL	Zoloft	Antidepressant	No
6	Lansoprazole	Prevacid	Antiulcer	No
7	Donepezil HCL	Aricept	Antidementia	No
8	Clopidogrel Bisulfate	Plavix	Antiplatelet/ anticoagulant	No
9	Potassium Chloride	Slow K[b]	Potassium Replacement	Yes
10	Rofecoxib	Vioxx[c]	Analgesic	No
11	Mirtazapine	Remeron	Antidepressant	Yes
12	Amlodipine Besylate	Norvasc	Cardiovascular/ Calcium Channel Blocker	No
13	Atorvastatin Calcium	Lipitor	Cardiovascular/ antilipemic	No
14	Fentanyl	Duragesic, Actiq	Analgesic	Yes
15	Quetiapine Fumarate	Seroquel	Antipsychotic	No
16	Tolterodine Tartrate	Detrol	Urinary tract antispasmodic agent	No
17	Paroxetine HCL	Paxil, Paxil CR	Antidepressant	Yes/No[d]
18	Simvastatin	Zocor	Cardiovascular/ antilipemic	No
19	Gabapentin	Neurontin	Anticonvulsant	Yes
20	Carbidopa/Levodopa	Sinemet, Sinemet CR	Antiparkinson Agent	Yes

Notes: [a]Over-the-counter drugs are excluded from payment under Medicare Part D but may still be covered under Medicaid with federal match. [b]Other names include K Dur, Kaon Cl-10, Klor-Con, Klotrix, K+ 10, K-Norm, K-Tab, Micro K-10 Ex, Pot Cl [c]Withdrawn from the market by manufacturer in 2004.[d]Extended release or controlled release formulation remains under patent. Other forms available as generic.

Table 10
Drugs accounting for the highest aggregate cost to Medicaid for Kansas other dually-eligible participants

Rank	Generic drug name	Common trade name(s)	Drug class	Generic available
1	Olanzapine	Zyprexa	Antipsychotic	No
2	Phenytoin Sodium	Dilantin, Phenytek	Anticonvulsant	Yes
3	Risperidone	Risperdal	Antipsychotic	No
4	Divalproex Sodium	Depakote, Depakote ER	Anticonvulsant	No
5	Oxycodone HCL	Oxycontin	Analgesic	Yes
6	Quetiapine Fumarate	Seroquel	Antipsychotic	No
7	Omeprazole	Prilosec, Prilosec SA	Antiulcer, OTC[a]	Yes
8	Gabapentin	Neurontin	Anticonvulsant	Yes
9	Clozapine HCL	Clozaril	Antipsychotic	Yes
10	Fluoxetine HCL	Prozac	Antidepressant	Yes
11	Sertraline HCL	Zoloft	Antidepressant	No
12	Buspirone HCL	Buspar	Anxiolytic	Yes
13	Celecoxib	Celebrex	Analgesic	No
14	Lansoprazole	Prevacid	Antiulcer	No
15	Venlafaxine HCL	Effexor, Effexor XR	Antidepressant	No
16	Paroxetine HCL	Paxil, Paxil CR	Antidepressant	Yes/No[b]
17	Topiramate	Topamax	Anticonvulsant	No
18	Atorvastatin Calcium	Lipitor	Cardiovascular/antilipemic	No
19	Bupropion HCL	Wellbutrin, Wellbutrin SR, Wellbutrin XL	Antidepressant	Yes/No[b]
20	Rofecoxib	Vioxx[c]	Analgesic	No

Notes: [a]Over-the-counter drugs are excluded from payment under Medicare Part D but may still be covered under Medicaid with federal match . [b]Sustained release (SR) or controlled release (CR) formulation remains under patent. Other forms available as generic. [c]Withdrawn from the market by manufacturer in 2004.

Off-Label Utilization of Drugs

- **How often do Buy-In populations use certain classes of drugs for indications outside those approved by the FDA? Current guidance indicates that private drug plans will not be obligated to pay for drugs prescribed for off-label uses.**

Nowhere in the regulations for MMA are Part D providers required to cover off-label utilization of drugs by plan participants. In fact, CMS states, "We do not have the authority to require that Part D plans cover the off-label use of certain Part D drugs."[30] Plans will have flexibility to determine an acceptable use of a drug and the required documentation to support that use.

In order to gauge the extent of off-label drug utilization among Buy-In participants, we selected four classes of drugs that are commonly used for purposes other than the FDA-approved indication: anti-ulcer agents, anticonvulsants, antidepressants, and antipsychotics.[31] We then aggregated all inpatient and outpatient ICD-9 codes for participants for calendar year 2003. A drug was considered to be used off-label if no supporting diagnosis was recorded for the year. The resulting off-label utilization counts are shown in Table 11. Over all, more than half of prescriptions for these medications were not supported by a recorded diagnosis code.[32] This finding is even more troubling in light of the fact that these four classes account for the great majority of the 20 most expensive drugs used, making it likely that Part D providers will carefully scrutinize their usage, with the onus being on the physician—and patient—to fully and persuasively document the need. Other drugs were also used off-label within the Buy-In population. People with autoimmune conditions, such as lupus and rheumatoid arthritis, often use antineoplastic and immunosuppressant drugs. Strict adherence to FDA-approved uses would allow PDPs to refuse these expensive medications for these individuals (see also "A Buy-In Participant with Multiple Sclerosis," page 30).

Of course, PDPs may elect to cover drugs used for indications beyond those approved by the FDA. However, they are not required to do so. The standard industry practice is to use one of four federally-approved drug compendia that report potential therapeutic uses of each drug, including those discovered after FDA approval. These compendia are based on research reported in medical literature and at medical conferences. However, they vary widely in comprehensiveness. For instance, the *Wall Street Journal* reports that Drugdex, the most comprehensive compendium, contains 203 off-label uses for the 12 most popular drugs in the U.S., while AHFS Drug Information contains 68 and U.S. Pharmacopeia 9.[33] Given the need to

control costs, PDPs may decide to exercise restrictive definitions of appropriate off-label use in basic benefit plans.

A concern with any additional documentation requirements for prescriptions is that the added administrative burden will cause even fewer practitioners to accept publicly insured patients. Patients also may be reluctant to ask for this help. A study of California's Medicaid Buy-In program cited a participant who was reluctant to ask for prior authorization because her doctor "does not get paid very much" and "she feels badly asking her doctor to do this."[34]

Table 11
Rate of off-label drug use among Kansas Medicaid Buy-In participants

Drug class	Off-label users	Total users	Percent of off-label use
Antiulcer drugs	80	109	73.4
Anticonvulsants	105	153	68.6
Antidepressants	104	210	49.5
Antipsychotics	23	176	13.1
Any off-label use in above classes	194	378	51.3

Note: Off-label use is defined as any use outside FDA-labeled indication. Off-label use is computed as percent of those for whom drug was prescribed.

Use of Multiple Drugs within a Class

- **Do Buy-In participants tend to have high rates of prescription drug utilization within therapeutic classes? Under Part D, PDPs are required to provide only two drugs per category or class, based on the United States Pharmacopeia model guidelines that divide drugs into 146 categories and classes. How will this design affect beneficiaries' access to the drugs they need?**

Although PDPs have wide latitude in the design of their formularies, the CMS model guidelines require that a Part D plan cover a minimum of only two drugs within each therapeutic class, or one if there is only one drug in the class. Basic benefit plans could thus be very restrictive, with more generous benefits provided only for the critical classes identified by CMS (i.e., antidepressants, antipsychotics, anticonvulsants, antiretrovirals, immunosuppressants, and antineoplastics).

A Buy-In Participant with Multiple Sclerosis

Although people with MS make up a small percentage of the Buy-In population, their potentially high drug costs and off-label use of medications present a good case study of the potential impact of Part D on non-elderly persons with disabilities. At this writing, five disease-modifying treatments for multiple sclerosis have been approved by the U.S. Food and Drug Administration. None of these is currently available in generic form and their average monthly cost is $1,382. Numerous other drugs are used off-label to treat the symptoms of MS, such as gabapentin for spasticity, amitriptyline for pain, and SSRIs and amantadine for fatigue.[*] Part D plans will likely have little incentive to compete for these high-cost users and cover more than the mandatory two drugs in the MS-specific drug class. Moreover, the off-label uses may be more carefully scrutinized to hold down overall costs and because less research may be available to support the usage.

We present here the utilization profile for a Buy-In participant with MS (see below). During 2003, our subject filled 81 prescriptions comprising 18 unique drugs. The total Medicaid expenditure on these drugs was more than $15,000—substantially greater than the projected average annual Part D participant cost of $1,308. The only medication used by this participant that is specific to MS is Copaxone, with an average monthly cost in our file of $1,029, perhaps reflecting a lower Medicaid-negotiated rate than the higher retail price of $1,261 cited by Calabresi.[*] This person's utilization is also remarkable in the off-label use of all four categories of drugs we examined for off-label utilization and an additional fifth drug particular to this case. The first of these is amantadine, an antiviral medication used primarily to treat influenza. It is also on-label in the treatment of Parkinson's disease. However, through an as yet unknown mechanism, amantadine is sometimes effective in treating the fatigue associated with MS. The second off-label prescription used by this subject is Neurontin, which can be used to alleviate pain and spasticity. Our subject also used both Zyprexa and Zoloft, though she had no psychiatric diagnoses recorded for the year. Depression is a common symptom of MS, but Zoloft can also be used to reduce MS-related fatigue. The final off-label use by this person was for Protonix. During the year, she did use two ulcer-sparing NSAIDs—Arthrotec and Celebrex—perhaps indicating a tendency toward gastric symptoms, but one not documented in her claims records.

Our case study also used a variety of medications for on-label treatment of both acute and chronic conditions, including hypertension and a bone fracture, as shown. One of the drugs used regularly was sulfamethoxazole/trimethoprim, presumably as a prophylaxis against urinary tract infections common in MS and also documented by diagnoses codes.

Utilization profile for a Buy-In participant with Multiple Sclerosis

Medication	Total cost	Times filled	Medication	Total cost	Times filled
Copaxone	$9264.59	9	Tequin	$115.32	2
Lamisil	1,743.80	7	Maxair Autoinhaler	80.12	1
Zoloft	965.29	12	Sulfamethoxazole/		
Zyprexa	849.50	6	Trimethoprim	62.68	12
Plendil	595.93	9	Tramadol HCL	39.60	4
Neurontin	485.32	4	Percocet	34.23	1
Arthrotec 75	300.60	3	Amantadine	5.99	1
Protonix	295.45	3	Furosemide	3.05	2
Arthrotec 50	190.90	2	Prednisone	2.15	1
Celebrex	138.38	2	**Total**	**$15,172.90**	**81**

[*] Calabresi, P. (2004). Diagnosis and management of multiple sclerosis. *American Family Physican, 70*(10), 1935-1946.

More than two-thirds (68.3%) of Buy-In participants used at least two medications within at least one Medicare drug class. More than a quarter (26.5%) used three or more medications within at least one Medicare drug class. If the standard remains two drugs per class, then the odds increase that these individuals will not have coverage for all of their needed medications.

A Person with HIV Needing to Gain Weight

The second-highest-cost individual in our Buy-In sample, with total drug expenditures exceeding $20,000 a year, is a person with HIV infection. Although this person used numerous costly anti-viral medications, the drug with the single highest cost per prescription was a weight-gain agent, Oxandrin, an anabolic steroid costing more than $900. Oxandrin is specifically FDA-approved for weight gain, a use that is categorically excluded under Part D regulations. In this case, however, it is being used for the treatment of HIV-related wasting. The Part D regulations regarding this situation are somewhat ambiguous. On the one hand, they state that the definition of a Part D drug excludes "agents when used for anorexia, weight loss, or weight gain" (page 4360). On the other, they also allow excluded drugs to be covered when used for a medically accepted indication (e.g., weight loss drugs used to treat morbid obesity). CMS seems to recognize the potential complexity of the issue in its statement that an "IRE [independent review entity] may be called upon to review whether an agent was in fact used for anorexia, weight loss or weight gain (and therefore excluded from the definition of Part D drug), or whether it was used for some other purpose" (page 4360). Given the somewhat equivocal nature of the regulations on this topic and the potential high costs involved, PDPs might choose not to cover these medications.

The individual we cite is currently able to work full time and pay a premium to maintain Medicaid coverage. Should he, or anyone else with HIV, cancer, or other conditions that can result in wasting, be unable to access weight gain treatment, the ability to continue working competitively could be threatened. States have the option to continue covering drug classes excluded under Part D but may have limited ability to do so.

DISCUSSION

Part D legislation was passed "to provide for a voluntary program for prescription drug coverage";[35] yet, for dually-eligible people with disabilities, participation is mandatory. Those who do not voluntarily enroll in a plan will be automatically enrolled and will not have the option to waive coverage and continue accessing drugs through Medicaid, even with their continued eligibility for Medicaid. Our findings indicate that the drug utilization patterns and costs for Medicaid Buy-In participants are fundamentally different from those of seniors. Moreover, their

utilization patterns put them at high risk for greater out-of-pocket costs and inability to find a Part D plan that matches their needs.

First, the dually-eligible Buy-In population has substantially higher overall costs than other disabled populations and elders. In fact, Buy-In participants' per person drug costs approach four times the projected national average $109/month.[36] Despite risk-adjustments that are designed to serve as safeguards, Part D plans will have little incentive to enroll these people with the highest drug costs. In addition, premium subsidies for dual eligibles will only cover enrollment in low-cost plans. Higher-cost, more comprehensive plans will require additional out-of-pocket premium payments.

Next, our findings indicate that the Buy-In population uses relatively more brand-name medications than do elders and other dually-eligible disabled. Much of this discrepancy is attributable to the different medical conditions experienced by the populations. Generics are simply not available in many of the drug classes more heavily utilized by Buy-In participants, such as MS-specific agents or many atypical antipsychotics. With a $1 co-pay for generics and a $3 co-pay for brand-names—in addition to simply needing more medications—the Buy-In participants will likely pay more out of pocket than will elders with similar income and asset levels. This inequity will likely grow as co-pay amounts increase over time.

Buy-In participants also use many drugs off-label. CMS has stated unequivocally that it cannot require Part D plans to cover these uses. Although plans are required to have appeals processes in place for disputes regarding the appropriate use of a medication, the burden will be on patients and their physicians to prove medical necessity. Adding to the physician's burden of treating dually-eligible persons is likely to further erode the number of physicians, especially specialists, willing to treat publicly insured populations. Moreover, if the appeal

results in a denial, the individual will be responsible for the full cost of the medication.

Although Part D plans have wide discretion in designing their formularies, they are required to cover only a minimum of two drugs per therapeutic class. For people who use multiple drugs within a therapeutic class, this design could prove to be problematic. More than half of Buy-In participants use at least two drugs within a Medicare class and a quarter use three or more. This utilization pattern puts Buy-In participants at high risk for not having all of their medications covered by a particular provider.

Despite the intention to increase access to medications for Medicare beneficiaries through Part D, many dual eligibles may actually experience decreased access. Current safety net provisions in the CMS regulations leave many holes through which dually-eligible disabled persons may fall. Coverage may not be as comprehensive as under Medicaid because, unlike Medicaid, Part D plans are not at financial risk for negative outcomes. Dual eligibles may benefit from utilization review for appropriate use of medications, but certain other drug utilization review practices, such as therapeutic interchange, may be detrimental to those with serious and unstable health conditions. Holes in the safety net in the form of non-covered drugs and higher co-pays for brand-name medications also increase out-of-pocket expenses for low-income dual eligibles and the risk for missed medications. For dual eligibles currently working and participating in Medicaid Buy-Ins, work incentive and ability to work may both be eroded. Immediate action is needed if these unintended consequences are to be avoided.

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[14] Buy-In data represent all participants continuously enrolled throughout 2003. Data for elderly and other dually-eligible persons with disabilities represent a cohort sample followed longitudinally from 1999 to 2002. Average monthly costs for those groups are from 2001-2002 data, with costs adjusted to 2003 levels using the Consumer Price Index for Medical Care.

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