The Centers for Medicare & Medicaid Services' Office of Research, Development, and Information (ORDI) strives to make information available to all. Nevertheless, portions of our files including charts, tables, and graphics may be difficult to read using assistive technology. Persons with disabilities experiencing problems accessing portions of any file should contact ORDI through e-mail at ORDI 508 Compliance @cms.hhs.gov.

Disruptions of Continuity: Duals Enrolled in Part D, 2006-2007

Prepared by:
Daniel Gilden, M.S.
Christine E. Bishop, Ph.D.
Angelina Lee, Ph.D.
Cindy Parks Thomas, Ph.D.

Evaluation of Medicare Modernization Act Changes on Dual Eligible Beneficiaries in Demonstration and Other Managed Care and Fee-For-Service Settings

Revised PHASE II: Conduct Impact Analysis of Dual Beneficiaries' Transition to MMA
Part D Pharmacy Coverage

Principal Investigator: Christine E. Bishop, Ph.D. (781) 736-3942 bishop@brandeis.edu

Submitted To
Centers for Medicare and Medicaid Services
Project Officer: William D. Clark, M.S.
Submitted by the
Schneider Institutes for Health Policy
The Heller School for Social Policy and Management
Brandeis University
In collaboration with
JEN Associates, Inc.
November 2010





Table of Contents

1		INTRODUCTION	1
2		METHODS AND DATA	3
	2.1	Methods	3
	Rat	tionale	
	Me	asures	
	Bei	neficiary and Utilization Characteristics	
	Me	thodological Approach	
	2.2	Data	9
3		RESULTS	9
	3.1	Discontinuation and Initiation for All Therapeutic Classes	10
		Exhibit 1: Discontinuation Proportion of Prior Year Users who are Not Users in Current Year:	
	Ranke	d by Increase in 2006 over 2004-5 for Classes with .10+ Increase in Discontinuation Rate	13
		Exhibit 2: Initiation Proportion of Users who are New This Year: Ranked by Increase in 2006 over	er
	2004-	5 for Classes with .10+ Increase in Initiation Rate	16
	3.2	Rates of Use, Initiation and Discontinuation for Defined Disease Subpopulations	20
		Exhibit 3: Calcium Channel Blocker (CCB) Use in Chronic Heart Disease (CHD) Population	22
		Exhibit 4: Angiotensin Converting Enzyme (ACE) Inhibitor Use in a Congestive Heart Failure (CH	F)
	Popula	ation	23
		Exhibit 5: Inhaled Steroid Use in Chronic Respiratory Disease (CRD) Population	24

		Exhibit 6: Cholinesterase Use in Alzheimer's Population	25
		Exhibit 7: Antidepressant Use in a Chronically Mentally III (CMI) Population	26
		Exhibit 8: Insulin Use in a Diabetes Population	28
		Exhibit 9: Percent of Duals Population with Chronic Heart Disease Treated with Calcium Chan	ınel
	Blocke	ers: States	30
		Exhibit 10: Change in Proportion Duals Population with Chronic Heart Disease Treated with C	alcium
	Chann	el Blockers: States, 2004-2005 compared with 2006-7	32
4		DISCUSSION AND POLICY IMPLICATIONS	33
	4.1	Summary and Discussion	33
	4.2	Limitations	34
	4.3	Directions for Further Research	35
	4.4	Policy Implications	35
5		APPENDIX	38
		Appendix Exhibit 1: Discontinuation: Percent Discontinuing Users, Selected Therapeutic Class	ses
	2004-2	2007	38
		Appendix Exhibit 2: Initiation: Percent New Users, All Therapeutic Classes 2005-2007	50
L	ITERAT	TURE CITED	58

ABSTRACT

Research Objective: To assess impact on realized access to prescription drugs of transition from Medicaid programs to Part D plans for beneficiaries dually eligible for both Medicare and Medicaid.

Study Design: A beneficiary-level data file showing Medicaid drug claims prior to Part D implementation and Part D claims (PDE) after Part D implementation was used to identify beneficiaries with consistent eligibility in an observation year and the prior base year who had claims for drugs in specific therapeutic classes. Measures of drug discontinuation and initiation were computed for 121 therapeutic classes for four observation years. For specific chronic disease populations, these measures and a utilization rate for a specific therapeutic class were computed for four observation years; utilization rates for chronic disease populations were also computed for selected states.

Population Studied: A 5% sample of beneficiaries who were dually eligible for both full fee-for-service Medicare and Medicaid for at least one 24-month period spanning implementation of Part D: 2003-4, 2004-5, 2005-6 and 2006-7.

Principal Findings: Comparing 2006 to 2004 and 2005, some therapeutic classes showed substantial increases in the rate of discontinuation, but a number of these classes appear to be substitutes for over-the-counter entities that may not have been covered by Part D pharmacy benefit plans. The rate of initiation increased substantially for 2006 for many classes, returning to the previous rate in 2007, suggesting that Part D increased access for some drugs. The therapeutic classes examined in detail for specific appropriate chronic disease populations

(calcium channel blockers, ACE inhibitors, inhaled steroids, cholinesterase, antidepressants and insulin) showed a consistent pattern of small statistically significant increases in discontinuation in the implementation year but not in the following year; large statistically significant increases in the rate of initiation in the implementation year but not in the following year; and substantial, statistically significant and persistent increases in the rate of program-paid utilization of the therapeutic class. Impacts were greater for beneficiaries in certain states. A limitation of the study is that especially in states with Medicaid formulary limits, beneficiaries may have accessed drugs outside of Medicaid, which could result in systematic underreporting of actual use in the years prior to Part D.

Conclusions: Implementation of Part D appears to have increased realized access to prescription drugs for dually eligible beneficiaries, especially in states with restrictive Medicaid prescription drug policies.

Implications for Policy, Delivery or Practice: By moving dually eligible beneficiaries from Medicaid programs to private drug plans, Medicare Part D appears to have increased access to prescription drugs for this group. The measures developed here can assist in monitoring the program in the future.

1 Introduction

The implementation of the Medicare Part D benefit assured the availability of an outpatient pharmacy benefit for all Medicare beneficiaries. A portion of the Medicare Part D enrolled population was previously also enrolled in Medicaid. Outcomes of the transition from Medicaid coverage to Medicare Part D plans for the approximately 5 million Medicare beneficiaries with concurrent full Medicaid enrollment (dual eligibles)¹ are of special concern. These beneficiaries have high levels of disability and chronic disease. Representing only 15% of the total Medicare population, they account for close to 30% of Medicare fee-for-service payments.

The possibility of disruption of access to medicines for chronic disease taken continually by beneficiaries in the dually eligible population was the focus of concerns that dually eligible beneficiaries might be harmed by the transition from Medicaid to Part D (Hall, Moore and Shireman 2005; Jensen and Kaiser Commission on Medicaid and the Uninsured 2005; Kaiser Family Foundation 2005; U.S. Government Accountability Office 2005). Access to needed medications is especially important for the dually eligible population (Kennedy, Tuleu and Mackay 2008; Law, Soumerai, Ross-Degnan and Adams 2008; Pan, Chernew and Fendrick 2008; Raebel, Delate, Ellis and Bayliss 2008; Briesacher, Andrade, Fouayzi and Chan 2009;

¹ Source: Authors' analysis of Part D enrollment file; Part D enrollees eligible for full Medicaid (including QMB and SLMB qualified beneficiaries with full Medicaid coverage) numbered 5,020,195.

Hassan and Lage 2009; Karve, Cleves, Helm, Hudson et al. 2009; Lage and Hassan 2009; Madden, Graves, Ross-Degnan, Briesacher et al. 2009; Trinacty, Adams, Soumerai, Zhang et al. 2009; Zivin, Madden, Graves, Zhang et al. 2009; Duru, Mangione, Hsu, Steers et al. 2010; Fung, Mangione, Huang, Turk et al. 2010; Zhang, Lave, Donohue, Fischer et al. 2010).

If health status impacts for Medicaid-Medicare dually eligible beneficiaries are to be attributed to the introduction of Medicare Part D, they must be shown to be due to changes to access to medication. To investigate changes in access to prescription drug therapies associated with the transition to Part D for dually eligible beneficiaries, this project adopted a two-part analytic strategy. First, the analysis looked for changes in health outcomes that were concurrent with implementation. The null hypothesis for that portion of the study, discussed in a companion report (Impact of Part D Transition on Dually Eligible Medicare Beneficiaries), was that the transition to Part D had no impact on measures of health outcomes that could be assessed from Medicare claims, including hospital use, emergency department use, ambulatory care sensitive hospitalizations and nursing home entry; these were also examined for subpopulations expected to be especially vulnerable to a change in access to medication therapy. With the exception of hospitalization for one ambulatory care sensitive condition (urinary tract infection), the analysis revealed that the null hypothesis could not be rejected – in other words, the transition to Part D had virtually no discernible negative effect on major health outcomes for dually eligible beneficiaries. In fact, some significant positive effects were discerned: for example, hospitalization rates were reduced for the dually eligible in 2006.

The second portion of the health impact analysis was designed to delve into the phenomenon that caused any observed health impacts, to examine actual utilization of prescription drugs before and after Part D implementation. The original concept was to investigate in more detail *negative* consequences for particular subpopulations, to understand whether disruptions in access had actually occurred that were responsible for any observed poor outcomes for these populations. Because poor outcomes were not found, the second portion of the project became less necessary – but it was decided that analysis of realized access to prescription drugs before and after implementation of Part D could provide corroboration of the findings of the outcome analysis and pave the way for future monitoring and assessment of any access changes.

Therefore this second portion of the analysis of impacts of Part D on dually eligible beneficiaries uses simple measures of realized access to prescription drugs for dually eligible beneficiaries, to investigate whether the absence of negative outcomes found in the first stage of the project is corroborated by few actual changes in access.

2 Methods and Data

2.1 Methods

Rationale

Changes in access to prescription drugs can be identified by observing changes in drug utilization (realized access). Drugs in different therapeutic categories have various expected patterns of utilization, so no single measure of change in utilization can capture the overall impact of the introduction of Part D. Every year beneficiaries continue therapies, begin to use

new drugs and drop therapies. The annual pattern of continuity, new use and discontinued use for a particular drug category depends on many factors, but is expected to exhibit consistent patterns for that category. For example, antibiotics use is typically short term. Many antibiotic users observed in a year are expected to be new users and the year-to-year rate of discontinuation of antibiotic therapy is expected to be very high. In contrast, drug therapies for the treatment of chronic disease are expected to exhibit lower rates of discontinuation and initiation, because the bulk of users take these drugs for a long time. By measuring year-to-year changes in patient level drug utilization it is possible to assess whether the transition from Medicaid-financed pharmacy care to Medicare Part D prescription drug plans in 2006 led to anomalous trends in utilization. Further, utilization rates for particular drugs used in the treatment of particular conditions can be computed to assess patterns of realized access to prescription drugs for subpopulations likely to need specific therapeutic entities.

Based on these observations, three broad-based measures of utilization change were developed for this report.² The first two represent flows into and out of the population using particular drugs and do not require that a disease population be identified. Discontinuation is measured as the proportion of those who use a specific drug in one year who do not use the same drug in the next year. (The obverse of this, continuity, could be computed as the proportion of

² This project did not have the resources or scope to examine fine-grained adherence measures, for example proportion of days covered in a month. See for example (Soumerai, Pierre-Jacques, Zhang, Ross-Degnan et al. 2006; Briesacher, Gurwitz and Soumerai 2007).

users in the prior year who continue as users in the observation or target year.) Initiation is measured as the proportion of users in the current year who are new users. The third measure is the rate of utilization for particular prescription drugs for the disease subpopulations that are likely to use them. This measure requires that disease subpopulations be identified that are appropriate to each prescription drug of interest.

Medicaid prescription drug programs differed across states, and it is possible that dually eligible beneficiaries transitioning from Medicaid to Part D plans in various states experienced varied access impacts. Therefore the measures are examined across states where numbers of beneficiaries are sufficient.

Indicators of continued use, initiation and discontinuation by patient and drug category cannot identify gaps in care and suboptimal utilization. However, trends in these rates do provide a window onto how overall use of drugs shifted in 2006 relative to an historical baseline.

Measures

In order to create consistent measures, populations with two continuous years of fee-for-service dual eligibility in both Medicare and Medicaid with full benefits were identified in four study periods: 2003-2004 (for 2004 use), 2004-2005 (for 2005 use), 2005-2006 (for 2006 use), and 2006-2007 (for 2007 use). The 2003-2004 and 2004-2005 cohorts can support a historical measure of pre-Part D therapy churning. The 2005-2006 cohort experience the impact of the transition and the 2006-2007 cohort is post policy. The cohort definition is quite restrictive in that it excludes beneficiaries who die, lose eligibility or switch to managed care at any time

during the two year period. Such a restrictive population definition is necessary to establish

consistent measures of access continuity that can be compared over time.³

1) Discontinuation: Beneficiaries who dropped use of a drug class in each observation year

were identified as those who-- used a drug in this class in the base year and did not use it

in the target year. This statistic is computed as the number of users who discontinue by

the target year divided by the total number of users in the base year.

2) Initiation: New users were identified by finding beneficiaries who used a drug in the

target year but not the base year, and thus have a "clean period" without utilization. The

statistic for initiation is computed as the number of new users in the target year divided

by the number of total users in the target year.

3) Rate of use. Beneficiaries in specific chronic disease populations were identified based

on prior year Medicare hospitalization and physician claims. Members of these

populations using a drug of interest in the observation year were identified. The rate of

use is computed as the number of users divided by the number of beneficiaries in the

disease population for the observation year.

_

³ Because this approach excludes beneficiaries who die during the two-year observation window, it is not able to

capture changes in access, whether changes in rates of discontinuation or changes in rates of initiation, that are

associated with increased mortality..

Beneficiary and Utilization Characteristics

Chronic conditions. Information on Medicare claims from the standard 5% sample of Medicare beneficiaries was used to determine presence of chronic conditions and diseases. The identification of these conditions for a beneficiary in a given target observation year is based on claims in the prior year, so only beneficiaries with a full prior year of eligibility can be included in any analysis. Diagnosis indicators were set based on the presence of the diagnosis in a physician or hospital claim. The available diagnosis indicators include Alzheimer's disease or dementia; schizophrenia; developmental disability (mental retardation); neurodisability (any diagnosis listed pertaining to a serious neurological disease, for example multiple sclerosis); cancer, any type; Parkinson's disease; congestive heart failure; diabetes; and chronic obstructive pulmonary disease (which here includes asthma, emphysema and chronic bronchitis). Diagnoses selected for investigation in this analysis include chronic heart disease (CHD), congestive heart failure (CHF), chronic respiratory disease, Alzheimer's/ dementia, chronic mental illness (CMI), and diabetes.

<u>State of residence</u> is the only other beneficiary characteristic used in the current analyses.

<u>Therapeutic class.</u> Prescription drugs were classified into therapeutic classes. For this analysis, the classes investigated in depth were calcium channel blockers, angiotensin converting enzyme (ACE) inhibitors, inhaled steroids, cholinesterase, antidepressants and insulin.

Methodological Approach

The approach chosen for the analysis was to compute and display measures of discontinuation and initiation of therapy by therapeutic class for the years prior to and after Part D implementation. This broad-brush descriptive approach can provide a context for further delving into the impact on access to particular drugs. It was beyond the scope and resources of the project to provide class-specific context for the therapeutic trends, effective Medicaid coverage pre- and post-Part D, cost and PDP utilization controls for therapeutic classes. To heighten the focus on therapeutic classes where changes were meaningful, standard comparison of proportions was used to assess differences between the Medicaid period (2004, 2005) and the transition year (2006) for statistical significance. In addition, the measures for the pre-Part D period were compared to the second Part D year (2007), to assess whether rates of discontinuation, initiation and, where possible for a defined disease group, utilization returned to pre-Part D levels after the transition year.⁴

⁴ The method selected requires multiple comparisons. Testing of the overall null hypothesis that measures were no different from pre-Part D rates in the post-Part D period could be identified as an occasion to invoke a Bonferroni adjustment, which would change the standard for statistical significance for any one test from p<.05 to p<z where z is an inverse function of the number of tests conducted. The aim here is also to identify particular therapeutic classes for which dual beneficiaries may have experienced especially large changes in access. Because one in 20 tests of differences where no difference actually exists will be significant at p<.05, the danger of artifactual findings is real. However, the standard of significance achieved here is much greater (generally p<.0001) for all results

2.2 <u>Data</u>

The core data for the study is monthly Part D claims (PDE) and enrollment data (Contract File) for 2006 and 2007 merged with information from the Medicaid Dual Status File prepared by JEN Associates and the Medicare Denominator File for 2003 through 2007.

For a 5% subset of the dually eligible beneficiaries in the core data set, a link was made to the Medicare 5% denominator records. For this 5% sample, a further link was made to Medicaid prescription drug claims in the MAX data using Social Security Number. These links were validated using supporting data fields present in both administrative data sources (date of birth and sex). Medicaid claims from years prior to Part D form the only source of prescription drug utilization prior to Part D implementation.

Jen Associates' Medicaid Dual Status File provided month-to-month Medicaid eligibility so that the study group for each target year could be restricted to full fee-for-service duals who were eligible for the full target year and the full previous year.

3 Results

The analysis of initiation and discontinuity of prescription drug therapy for dually eligible beneficiaries in specific chronic disease groups reveals that the transition to Medicare Part D was associated with *a small but statistically significant increase in discontinuation of therapy* in the

discussed. In addition, current literature raises questions about the value of a Bonferroni adjustment (Perneger 1998).

year of transition for many of the classes of drugs examined but also was associated with a substantial statistically significant increase in the rate of initiation of therapy for the year of transition. In some of the therapeutic class cases that exhibited large changes for the transition year, the rates of discontinuation and initiation for 2007 returned to (were statistically indistinguishable from) pre-Part D levels. For the disease populations available for study, similar phenomena were observed, and in addition a substantial, persistent and statistically significant increase in the proportion of beneficiaries receiving drug treatment in each disease class was observed for the post-Part D years.

3.1 <u>Discontinuation and Initiation for All Therapeutic Classes</u>

Because consistent data are available on Medicaid prescription drug claims for years prior to Part D for the dually eligible population, a broad look at prescription drug initiation and discontinuation was feasible for all therapeutic classes for a broad population of dually eligible beneficiaries regardless of disease or condition. The population was restricted to beneficiaries who were fully dually eligible for both Medicare fee-for-service and Medicaid for both the observation year and the prior year. Note that disease and condition are not used in this broad look at discontinuation and initiation; the population base for each computation is essentially the beneficiaries observed to use the drug in the prior year and the observation year. The base for this analysis is all therapeutic classes available for study that had an average of 1000 users per year in the Jen Associates 5% merged Medicare-Medicaid data. The Appendix Exhibits present findings for discontinuation and initiation rates for this full list.

Exhibits 1 and 2 focus on rates for the therapeutic classes with the greatest changes in their rates of discontinuation and initiation between the years 2004-2005 and 2006. Exhibit 1 presents the 28 therapeutic entities (out of 152 with 1000 users) with more than .10 (ten percentage point) increases in the discontinuation rate for 2006 in comparison over the 2004-5 baseline. Initiation is the focus of Exhibit 2, which shows statistics for 47 entities that showed an increase of .10 (ten percentage points) or more in proportion of users who are new users.

Changes in discontinuation rate relative to past discontinuation rate can indicate disruption in ongoing use. There appear to be substantial increases in the rate of discontinuation for the year 2006 – beneficiaries who were prescribed a drug in 2005 who did not receive it under Part D. Rates of discontinuation spike to between 70 and 90 percent for several classes. However, a closer look reveals that the entities exhibiting the greatest change in rate of discontinuation for 2006 relative to 2004-5 include a number of entities that may have been covered under certain Medicaid programs and were not covered by Part D plans (Michigan Department of Community Health Medicaid Program 2006). These include prescription vitamins and minerals including iron supplements, all benzodiazepines, all barbiturates, and agents used for symptomatic relief of cough and colds (decongestants, expectorants, antitussives). Other classes in the list appear to include over-the-counter products that some Medicaid programs may have covered when prescribed by a physician (for example, laxatives, ophthalmic lubricants, miscellaneous analgesics, antihistamines and topical emollients). Some Medicaid programs continued to cover these excluded products for the dually eligible, but they were not covered under Part D plan formularies (Kaiser Family Foundation 2010). Therefore

realized access cannot be observed without adding Medicaid data for 2006 and 2007 to the PDE data.⁵

Although disruption of ongoing patterns of therapy was a concern as Part D was implemented, increases in the initiation rates (proportion of current users who did not use the drug in the prior year) for some therapeutic entities suggest that many dually eligible beneficiaries were gaining greater access to prescription drugs. Exhibit 2 reveals that for many therapeutic entities, the proportion of users who are new increased markedly in 2006 and then fell back toward 2005 levels by 2007. This suggests a pattern of increased and continuing (but not ever increasing) access supported by Part D – a large group of new users joined the base of users in 2006 and further new users joined them in 2007 in about the same proportion as in 2005. Initiation rate increased for many therapeutic entities.

⁵ It is surprising that any use was found in PDE data (2006, 2007) for benzodiazepines and barbiturates, which were Part D excluded classes. The benzodiazepines show a sustained increase in rates of discontinuation, so population-based rates of Medicare-paid use is declining.

Exhibit 1: Discontinuation-- Proportion of Prior Year Users who are Not Users in Current Year: Ranked by Increase in 2006 over 2004-5 for Classes with .10+ Increase in Discontinuation Rate

Note: Therapeutic classes limited to those averaging 1000 users per year in 5% sample. Discontinuation rate is proportion of last year's users who are not users in current year. All study group beneficiaries are dually eligible for FFS Medicare and full Medicaid throughout the 24 month period.

	Mean Users Prior Year	Discontinu	tinuation: Proportion Prior Year Users Dropping Use Difference 2007 vs.			Difference		Difference			
Therapeutic Class	2003-2006	2004	2005	2006	2007	2006 vs.	2004-5	2007			
vitamin and mineral combinations	14,311	0.246	0.236	0.948	0.502	0.707	***	0.261	***		
benzodiazepine anticonvulsants	23,102	0.275	0.270	0.974	0.938	0.701	***	0.665	***		
benzodiazepines	15,360	0.291	0.282	0.981	0.840	0.695	***	0.555	***		
ophthalmic lubricants and irrigations	3,127	0.366	0.369	0.990	0.737	0.622	***	0.369	***		
vitamins	10,433	0.276	0.262	0.864	0.456	0.595	***	0.187	***		
iron products	5,878	0.427	0.415	0.989	0.553	0.569	***	0.133	***		
barbiturate anticonvulsants	3,190	0.245	0.220	0.788	0.190	0.555	***	-0.043	***		
upper respiratory combinations	19,662	0.551	0.529	0.901	0.693	0.360	***	0.152	***		
laxatives	22,056	0.321	0.333	0.680	0.411	0.353	***	0.084	***		
platelet aggregation inhibitors	33,202	0.201	0.194	0.534	0.169	0.336	***	-0.028	***		

	Mean Users Prior Year	Discontinu		portion Prioping Use	or Year Users	Diffe	rence	Differ	
Therapeutic Class	2003-2006	2004	2005	2006	2007	2006 vs.	2004-5	2007	
miscellaneous analgesics	23,638	0.381	0.391	0.707	0.484	0.321	***	0.097	***
decongestants	1,285	0.687	0.695	0.986	0.488	0.295	***	-0.203	***
expectorants	4,152	0.769	0.631	0.981	0.779	0.264	***	0.062	***
antitussives	2,732	0.727	0.673	0.956	0.889	0.254	***	0.188	***
immunologic agents	2,783	0.611	0.440	0.787	0.455	0.251	***	-0.081	***
agents for pulmonary hypertension	2,555	0.255	0.385	0.570	0.960	0.249	***	0.639	***
topical emollients	6,954	0.500	0.546	0.707	0.595	0.183	***	0.071	***
central nervous system (CNS) stimulants	4,279	0.441	0.423	0.613	0.356	0.181	***	-0.075	***
miscellaneous antihyperlipidemic agents	1,824	0.418	0.386	0.580	0.406	0.180	***	0.006	ns
phenothiazine antiemetics	19,201	0.541	0.514	0.702	0.581	0.175	***	0.053	***
anticholinergic antiparkinson agents	11,388	0.364	0.362	0.518	0.266	0.155	***	-0.096	***
antihistamines	35,231	0.397	0.413	0.558	0.409	0.152	***	0.003	ns

	Mean Users Prior Year	Discontinu		portion Prioping Use	or Year Users	Difference 2006 vs. 2004-5		Differo	
Therapeutic Class	2003-2006	2004	2005	2006	2007			2007	
minerals and electrolytes	38,980	0.234	0.238	0.385	0.225	0.149	***	-0.010	**
antidiabetic combinations	5,315	0.216	0.226	0.368	0.203	0.147	***	-0.018	ns
miscellaneous respiratory agents	2,147	0.677	0.680	0.817	0.736	0.139	***	0.058	***
miscellaneous GI agents	8,541	0.520	0.498	0.629	0.509	0.121	***	0.001	ns
topical antibiotics	14,455	0.642	0.641	0.752	0.684	0.110	***	0.043	***
recombinant human erythropoietins	1,606	0.400	0.360	0.485	0.457	0.107	***	0.079	***

Exhibit 2: Initiation-- Proportion of Users who are New This Year: Ranked by Increase in 2006 over 2004-5 for Classes with .10+ Increase in Initiation Rate

Note: Therapeutic classes limited to those averaging 1000 users per year in 5% sample. Initiation rate is proportion of current year's users who were not users in prior year. All study group beneficiaries are dually eligible for FFS Medicare and full Medicaid throughout the 24 month period.

Thereneutic Class	Mean Users Current	Initiation	_	ion Users N ear	ew This	Difference		Difference	
Therapeutic Class	Year 2004-2007	2004	2005	2006	2007	2006	vs. 2004-5	2007 vs	s. 2004-5
agents for pulmonary hypertension	2,555	0.245	0.185	0.743	0.277	0.525	***	0.058	ns
cox-2 inhibitors	27,192	0.301	0.131	0.452	0.373	0.201	***	0.122	***
ophthalmic lubricants and irrigations	3,127	0.411	0.408	0.602	0.762	0.192	***	0.352	***
glucose elevating agents	1,836	0.485	0.467	0.645	0.455	0.170	***	(0.020)	ns
vitamin and mineral combinations	14,311	0.324	0.302	0.479	0.576	0.166	***	0.263	***
estrogens	7,981	0.121	0.101	0.274	0.132	0.162	***	0.020	*
miscellaneous analgesics	23,638	0.432	0.437	0.597	0.538	0.162	***	0.103	***
laxatives	22,056	0.397	0.379	0.544	0.483	0.157	***	0.096	***
antipsoriatics	1,516	0.269	0.240	0.397	0.221	0.144	***	(0.032)	ns
antihistamines	35,231	0.376	0.370	0.516	0.439	0.143	***	0.066	***

Thereneutic Class	Mean Users	Initiation	-	ion Users N ear	ew This	Difference		Difference	
Therapeutic Class	Current Year 2004-2007	2004	2005	2006	2007	2006	vs. 2004-5	2007 vs	s. 2004-5
angiotensin converting enzyme inhibitors	50,905	0.219	0.191	0.348	0.214	0.143	***	0.009	**
gamma-aminobutyric acid analogs	18,517	0.355	0.341	0.488	0.369	0.140	***	0.021	***
thyroid drugs	28,157	0.146	0.107	0.257	0.104	0.130	***	(0.023)	***
inotropic agents	10,694	0.190	0.154	0.302	0.171	0.129	***	(0.002)	ns
sulfonylureas	21,979	0.193	0.165	0.306	0.176	0.127	***	(0.004)	ns
barbiturate anticonvulsants	3,190	0.219	0.221	0.346	0.276	0.126	***	0.056	**
insulin	18,023	0.187	0.170	0.303	0.182	0.125	***	0.004	ns
methylxanthines	3,045	0.217	0.192	0.330	0.201	0.125	***	(0.004)	ns
miscellaneous anxiolytics, sedatives and hypnotics	21,695	0.360	0.364	0.486	0.377	0.124	***	0.015	***
antianginal agents	11,572	0.244	0.216	0.352	0.223	0.122	***	(0.007)	ns
upper respiratory combinations	19,662	0.515	0.532	0.645	0.675	0.121	***	0.152	***
skeletal muscle relaxants	23,613	0.423	0.399	0.532	0.413	0.121	***	0.002	ns

Therapeutic Class	Mean Users Current	Initiation	_	ion Users N ear	ew This	Difference		Difference	
Therapeutic Class	Year 2004-2007	2004	2005	2006	2007	2006	vs. 2004-5	2007 vs	s. 2004-5
sex hormone combinations	2,193	0.198	0.222	0.329	0.265	0.120	***	0.056	**
calcium channel blocking agents	47,673	0.192	0.163	0.297	0.182	0.119	***	0.004	ns
antipsychotics	13,137	0.307	0.316	0.431	0.350	0.119	***	0.039	***
loop diuretics	40,565	0.259	0.227	0.361	0.226	0.118	***	(0.017)	***
cardioselective beta blockers	48,264	0.238	0.189	0.331	0.165	0.118	***	(0.047)	***
hydantoin anticonvulsants	6,822	0.133	0.117	0.242	0.123	0.117	***	(0.002)	ns
antiadrenergic agents, peripherally acting	11,439	0.264	0.239	0.366	0.266	0.114	***	0.015	*
mouth and throat products	2,533	0.566	0.561	0.676	0.634	0.113	***	0.070	***
proton pump inhibitors	60,392	0.280	0.239	0.371	0.249	0.112	***	(0.009)	***
dopaminergic antiparkinsonism agents	6,137	0.315	0.384	0.464	0.379	0.112	***	0.027	***
coumarins and indandiones	13,093	0.288	0.248	0.379	0.247	0.111	***	(0.021)	***
miscellaneous hormones	7,549	0.268	0.221	0.356	0.243	0.110	***	(0.003)	ns

Thereneutic Class	Mean Users	Initiation:	-	ion Users N ear	Difference		Difference		
Therapeutic Class	Current Year 2004-2007	2004	2005	2006	2007	2006	vs. 2004-5	2007 vs. 2004-5	
antihyperuricemic agents	4,976	0.293	0.269	0.390	0.255	0.109	***	(0.026)	**
hormones/antineoplastics	2,178	0.262	0.246	0.362	0.227	0.108	***	(0.027)	ns
antidepressants	58,695	0.215	0.188	0.309	0.199	0.108	***	(0.003)	ns
antiarrhythmic agents	2,999	0.347	0.300	0.431	0.309	0.107	***	(0.015)	ns
antidiabetic combinations	5,315	0.323	0.217	0.377	0.258	0.107	***	(0.012)	ns
5-aminosalicylates	1,270	0.351	0.341	0.452	0.327	0.106	***	(0.019)	ns
phenothiazine antiemetics	19,201	0.537	0.548	0.647	0.593	0.104	***	0.051	***
HMG-CoA reductase inhibitors	65,203	0.229	0.167	0.301	0.170	0.104	***	(0.026)	***
antiadrenergic agents, centrally acting	9,193	0.330	0.305	0.419	0.308	0.102	***	(0.009)	ns
minerals and electrolytes	38,980	0.296	0.280	0.389	0.283	0.100	***	(0.005)	ns
ophthalmic glaucoma agents	14,683	0.196	0.165	0.281	0.180	0.100	***	(0.001)	ns

3.2 Rates of Use, Initiation and Discontinuation for Defined Disease Subpopulations

Rates of use for defined disease populations and the year-to-year rates of initiation and discontinuation for specific drugs for the years before and after implementation of Part D are the focus of the next group of Exhibits. For example, Exhibit 3 shows, for the years 2004 through 2007, the number of beneficiaries with a diagnosis of chronic heart disease (CHD) in the prior year's claims who have a prescription for a calcium channel blocker at some time during the current or observation year. Most of these users also had a prescription for a calcium channel blocker in the previous year, but for 2004, for example, 4,748 or 21% of the current users were new – they did not have a claim for a calcium channel blocker in 2003. Almost 3500 beneficiaries with a CHD diagnosis had a claim for a calcium channel blocker in 2003 but had no claim for this drug class in 2004; the estimated discontinuation rate was thus 16.2% of those in the defined cohort with a calcium channel blocker in 2003. All in all, 29.1% of the full benefit fee-for-service dual beneficiaries with a CHD diagnosis observed in 2003 and eligible throughout 2003 and 2004 were receiving prescriptions for calcium channel blockers.

Any disruptive impact of Part D should be indicated by the discontinuation statistic for 2006 – the proportion of beneficiaries receiving calcium channel blockers in 2005 who did not receive these in 2006. This rate, .178, is indeed slightly elevated above the rates for 2004 and 2005. As shown in the Exhibit, this discontinuation rate is statistically significantly greater than the average rate for 2004 and 2005. However, the discontinuation rate returns to a rate statistically indistinguishable from the prior discontinuation rate by 2007.

The initiation rate for the transition year also is significantly different from past years. In 2006, a full 30% of the dually eligible beneficiaries with CHD receiving calcium channel blockers had not received them in the prior year. This initiation rate is an increase of eleven percentage points over the average for 2004 and 2005. The initiation rate returns to baseline in 2007 (no significant difference between the rate for 2007 and the combined rate for 2005 and 2006). But the impact on the proportion of beneficiaries with a CHD diagnosis who were receiving calcium channel blockers was substantial and significant: this rate rose from .287 for 2004 and 2005 to .318 – and remained elevated at .319 for 2007.

This pattern is repeated in the other subanalyses, presented in Exhibits 4, 5, 6, 7 and 8.

All of the drug entities studied in specific chronic condition subpopulations show 1) a significant increase in the rate of use in the population for 2006 over 2004-5 which is maintained or increased in 2007; 2) a small but significant increase in discontinuation for 2006 over 2004-5 returning to an insignificant or negative change in the rate of discontinuation for 2007 in comparison to 2004-5; and 3) a large and significant increase in initiation, the proportion of drug users who are new users, for 2006 in comparison with 2004-5, returning to a steady state rate in 2007 with no significant difference from 2004-5.

Exhibit 3: Calcium Channel Blocker (CCB) Use in Chronic Heart Disease (CHD) Population

Values	2004*	2005	2006	2007	Difference: 2006 rate less rate for 2004 & 2005		rate les	ence: 2007 ss rate for & 2005
Total CHD population†	77762	78766	82939	89665				
Users	22630	22330	26351	28588				
Prior Year Users	21337	21854	22187	26960				
Dropped Use Since Last Year	3455	3584	3941	4059				
New Users	4748	4060	8105	5687				
Utilization Rate: Proportion of CHD population receiving CCBs	0.291	0.283	0.318	0.319	0.030	p<.0001	0.032	p<.0001
Discontinuation Rate: Discontinuing users as a proportion of prior year users	0.162	0.164	0.178	0.151	0.015	p<.0001	-0.012	ns
Initiation Rate: New users as a proportion of target year users	0.210	0.182	0.308	0.199	0.112	p<.0001	0.003	ns

^{*}Target (observation) years. All beneficiaries in subpopulation in target year were eligible for full FFS Medicare and Medicaid throughout target and prior year.

[†]Diagnosis determined based on Medicare hospital and physician claims, prior year.

Exhibit 4: Angiotensin Converting Enzyme (ACE) Inhibitor Use in a Congestive Heart Failure (CHF) Population

Values	2004*	2005	2006	2007	rate le	ence: 2006 ess rate for 04 & 2005	rate le	ence: 2007 ss rate for 04 & 2005
Total CHF population†	41663	42058	43705	45484				
Users	15041	14632	17944	19024				
Prior Year Users	13968	14154	14259	17719				
Dropped Use Since Last Year	2468	2601	2674	2991				
New Users	3541	3079	6359	4296				
Utilization Rate: Proportion of CHF population receiving ACE inhibitors	0.361	0.348	0.411	0.418	0.056	P<.0001	0.064	p<.0001
Discontinuation Rate: Discontinuing users as a proportion of prior year users	0.177	0.184	0.188	0.169	0.017	p<.05	-0.002	ns
Initiation Rate: New users as a proportion of target year users	0.235	0.210	0.354	0.226	0.131	P<.0001	0.003	ns

^{*}Target (observation) years. All beneficiaries in subpopulation in target year were eligible for full FFS Medicare and Medicaid throughout target and prior year.

[†]Diagnosis determined based on Medicare hospital and physician claims, prior year.

Exhibit 5: Inhaled Steroid Use in Chronic Respiratory Disease (CRD) Population

Values	2004*	2005	2006	2007	Difference: 2006 rate less rate for 2004 & 2005		less rate	e: 2007 rate for 2004 & 005
Total CRD population†	65861	69314	73320	80476				
Users	13546	14791	18396	21355				
Prior Year Users	11158	12946	14676	18613				
Dropped Use Since Last Year	2667	2983	3663	4150				
New Users	5055	4828	7383	6892				
Utilization Rate: Proportion of CRD population receiving inhaled steroids	0.206	0.213	0.251	0.265	0.041	P<.0001	0.056	p<.0001
Discontinuation Rate: Discontinuing users as a proportion of prior year users	0.239	0.230	0.250	0.223	0.015	p<.05	-0.011	p<.05
Initiation Rate: New users as a proportion of target year users	0.373	0.326	0.401	0.323	0.053	P<.0001	-0.026	<.0001

^{*}Target (observation) year. All beneficiaries in subpopulation in target year were eligible for full FFS Medicare and Medicaid throughout target and prior year.

[†]Diagnosis determined based on Medicare hospital and physician claims, prior year.

Exhibit 6: Cholinesterase Use in Alzheimer's Population

Values	2004*	2005	2006	2007	Difference: 2006 rate less rate for 2004 & 2005		Difference: 2007 rate less rate for 2004 & 2005	
Total Alzheimer's population†	28217	28678	30149	32001				
Users	7739	8274	9895	10958				
Prior Year Users	6121	7205	7922	9465				
Dropped Use Since Last Year	842	917	1158	1238				
New Users	2460	1986	3131	2731				
Utilization Rate: Proportion of Alzheimer's population receiving cholinesterase inhibitors	0.274	0.289	0.328	0.342	0.047	p<.0001	0.061	p<.0001
Discontinuation Rate: Discontinuing users as a proportion of prior year users	0.138	0.127	0.146	0.131	0.014	p<.10	-0.001	ns
Initiation Rate: New users as a proportion of target year users	0.318	0.240	0.316	0.249	0.039	p<.0001	-0.028	<.0001

^{*}Target (observation) year. All beneficiaries in subpopulation in target year were eligible for full FFS Medicare and Medicaid throughout target and prior year.

[†]Diagnosis determined based on Medicare hospital and physician claims, prior year.

Exhibit 7: Antidepressant Use in a Chronically Mentally Ill (CMI) Population

Values	2004*	2005	2006	2007	Difference: 2006 rate less rate for 2004 & 2005		Difference: 200 rate less rate fo 2004 & 200	
Total CMI population†	83083	87103	95836	109316				
Users	35298	36020	44857	50105				
Prior Year Users	32976	34739	37036	47566				
Dropped Use Since Last Year	4875	5319	5903	7272				
New Users	7197	6600	13724	9811				
Utilization Rate: Proportion of CMI population receiving antidepressants	0.425	0.414	0.468	0.458	0.049	p<.0001	0.039	p<.0001
Discontinuation Rate: Discontinuing users as a proportion of prior year users	0.148	0.153	0.159	0.153	0.009	p<.05	0.002	ns
Initiation Rate: New users as a proportion of target year users	0.204	0.183	0.306	0.196	0.112	p<.0001	0.002	ns

*Target (observation) year. All beneficiaries in subpopulation in target year were eligible for full FFS Medicare and Medicaid throughout target and prior year.

†Diagnosis determined based on Medicare hospital and physician claims, prior year.

Exhibit 8: Insulin Use in a Diabetes Population

Values	2004*	2005	2006	2007	Difference: 2006 rate less rate for 2004 & 2005		Difference: 2007 rate less rate for 2004 & 2005	
Total diabetes population†	76675	80661	87609	97601				
Users	16914	17676	22452	25599				
Prior Year Users	15052	16016	17304	22760				
Dropped Use Since Last Year	1247	1296	1615	1735				
New Users	3109	2956	6763	4574				
Utilization Rate: Proportion of diabetes population receiving insulin	0.221	0.219	0.256	0.262	0.036	p<.0001	0.042	p<.0001
Discontinuation Rate: Discontinuing users as a proportion of prior year users	0.083	0.081	0.093	0.076	0.011	p<.05	-0.006	ns
Initiation Rate: New users as a proportion of target year users	0.184	0.167	0.301	0.179	0.126	p<.0001	0.003	ns

^{*}Target (observation) year. All beneficiaries in subpopulation in target year were eligible for full FFS Medicare and Medicaid throughout target and prior year.

[†]Diagnosis determined based on Medicare hospital and physician claims, prior year.

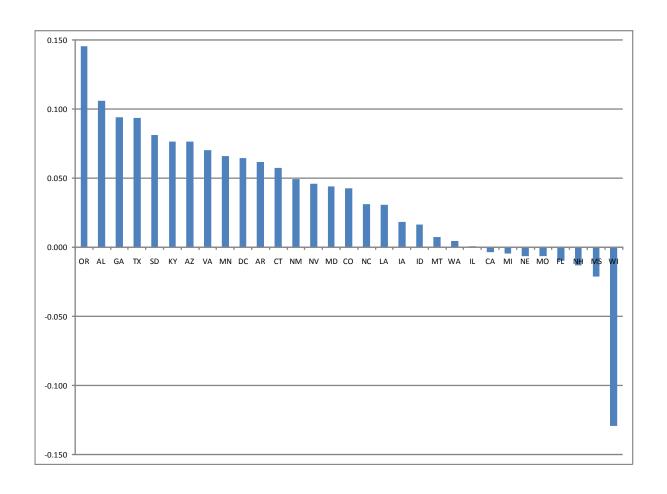
In addition to issues of potential disruption, the transition to Part D was expected to have different impacts for dually eligible beneficiaries depending on the generosity of the Medicaid drug coverage program they transferred *from* in 2006. A descriptive analysis showing rates by state can provide a first look at the variation across states. The diagnosis and drug restrictions create subgroups large enough for aggregate analysis, but do not support analysis at the state level for every state. Restricting analysis to states with at least 100 beneficiaries in the subgroup, the analysis found that the increase in initialization rates were quite different for various states. Exhibit 9 shows the impact on the rate of utilization for states with sufficient size for reporting. In Exhibit 10, the states are ranked by difference between the pre-Part D period and the post-Part D period in the proportion of the CHD population using calcium channel blockers. Oregon, Alabama, Georgia, Texas, South Dakota, Kentucky and Arizona have the largest increases in the population rate of use. Iowa, Idaho, Montana, Washington, Illinois, California, Michigan, Nebraska, Missouri, Florida and New Hampshire had no significant change in utilization rates for their CHD populations. Mississippi and Wisconsin exhibited significant decreases in rates of use. The large decrease for Wisconsin may be a data reporting anomaly.

Exhibit 9: Percent of Duals Population with Chronic Heart Disease Treated with Calcium Channel Blockers: States

	CHD Population		ССВ	Users	Use	Rate		
State	2004 & 2005	2006 & 2007	2004 & 2005	2006 & 2007	Pre- Part D	Post- Part D	Difference	Significance
AL	1748	1708	334	508	0.191	0.297	0.106	<.0001
AR	952	991	227	298	0.239	0.300	0.062	<.0001
AZ	188	314	42	94	0.223	0.300	0.076	<.01
CA	10673	11627	3848	4150	0.361	0.357	-0.004	ns
co	367	439	96	134	0.262	0.304	0.043	<.10
CT	1007	1016	285	346	0.283	0.340	0.058	<.0001
DC	142	186	44	70	0.310	0.375	0.065	<.10
FL	4836	5416	1589	1727	0.329	0.319	-0.010	ns
GA	2127	2367	539	823	0.253	0.348	0.094	<.0001
IA	565	615	170	197	0.301	0.320	0.018	ns
ID	161	194	45	57	0.277	0.294	0.017	ns
IL	4135	5361	1334	1733	0.323	0.323	0.001	ns
KY	1526	1794	345	543	0.226	0.303	0.077	<.0001
LA	1856	1837	482	534	0.260	0.290	0.031	<.01
MD	999	1192	305	417	0.305	0.349	0.044	<.01
MI	2460	2962	776	922	0.316	0.311	-0.004	ns
MN	311	419	66	117	0.212	0.278	0.066	<.01
МО	1656	1893	565	634	0.341	0.335	-0.007	ns
MS	1622	1559	551	496	0.340	0.318	-0.021	<.10

	CHD Po	pulation	ССВ	Users	Use	Rate		
State	2004 & 2005	2006 & 2007	2004 & 2005	2006 & 2007	Pre- Part D	Post- Part D	Difference	Significance
MT	111	126	23	27	0.203	0.210	0.008	ns
NC	2797	2850	895	1001	0.320	0.351	0.031	<.01
NE	348	392	116	128	0.332	0.326	-0.006	ns
NH	195	248	55	66	0.279	0.267	-0.013	ns
NM	311	371	63	94	0.203	0.252	0.049	<.05
NV	217	238	52	68	0.240	0.286	0.046	ns
OR	410	368	50	98	0.121	0.267	0.146	<.0001
SD	140	158	33	50	0.232	0.313	0.081	<.05
TX	5961	6342	1329	2009	0.223	0.317	0.094	<.0001
VA	1416	1545	370	512	0.261	0.331	0.070	<.0001
WA	800	900	252	288	0.315	0.320	0.005	ns
WI	1761	1949	571	380	0.324	0.195	-0.129	<.0001

Exhibit 10: Change in Proportion Duals Population with Chronic Heart Disease Treated with Calcium Channel Blockers: States, 2004-2005 compared with 2006-7



4 Discussion and Policy Implications

4.1 Summary and Discussion

Using relatively simple measures based on populations of dual beneficiaries using prescription drugs by class under Medicaid and Part D, this study was able to display changes in annual rates of discontinuation and increases in realized access for prescription drugs. The analysis of discontinuation rates by therapeutic class suggests that disruption in utilization may have been substantial for certain classes, but some of the classes most affected appear to be drugs that are not covered by Part D plans. Initiation rates also increased substantially for certain therapeutic entities.

The descriptive statistics for discontinuation, initiation and overall utilization rate for beneficiary populations defined by chronic condition revealed a consistent picture: the transition to Medicaid Part D was associated with a small but statistically significant increase in disruption of therapy in the year of transition for many of the classes of drugs examined but also was associated with a substantial and statistically significant increase in the rate of initiation of therapy for the year of transition and a substantial, persistent and statistically significant increase in the proportion of beneficiaries receiving drug treatment in each disease class that was selected for investigation.

The preliminary analysis by state, for states with sufficient chronic disease population in the condition selected, showed rates of utilization growing substantially in certain states, while others experienced very little increase. Information available on states with large increases in utilization under Part D suggests that restrictiveness of Medicaid drug programs may be responsible for this phenomenon: for example, Oregon Medicaid has a strict preferred drug list

and cost sharing and Texas Medicaid caps the monthly number of prescriptions a beneficiary may fill (Crowley, Ashner and Elam 2005).

4.2 <u>Limitations</u>

This study presents a preliminary look at several aspects of prescription drug utilization prior to and after implementation of Part D, but without in-depth investigation of clinical, market and policy conditions that affect each therapeutic class. The data set melds prescription drug claims from fifty-one Medicaid programs with prescription drug event (PDE) claims under Part D, and underreporting of utilization in either data base, which may vary by state or plan, could affect the accuracy of the statistics. In particular, if dually eligible beneficiaries were consistently accessing additional drugs in states with restrictive Medicaid formularies prior to Part D implementation, either through private payment or drug company subsidy plans, the apparent increase in access observed here is in reality a shift in payment burden. Likewise, detailed knowledge of Medicaid programs to fill in around Part D, through coverage of over-the-counter drugs, barbiturates and benzodiazepines, could reveal whether the apparent declines in access observed for these therapeutic entities are real or merely shifts in payment responsibility.

It would have been preferable to analyze trends in the measures using all the years for which Medicaid prescription drug claims are available in the Jen 5% sample (adding observation years 2002 and 2003), but this was not possible given project scope. Analyses were conducted for only six chronic disease populations, and results may have been different for other conditions, although the results for these six are generally consistent with the overall pattern of discontinuation and initiation when only drug users are considered. State impacts are displayed for only one condition-therapeutic class combination, and it was beyond the scope of the study to

consider in detail why impacts might have been different in different states. A further limitation for interpretation of the results is that especially in states with Medicaid formulary limits, beneficiaries may have accessed drugs outside of Medicaid, which could result in systematic underreporting of actual use in the years prior to Part D.

4.3 <u>Directions for Further Research</u>

The broad measures used here can only provide a preliminary view of the impact of Part D on dually eligible beneficiaries' access to classes of prescription drugs. Using these measures as a base, the next steps for research, after building more contextual background for each therapeutic class of interest, should involve using clinical insights to discern whether any of these changes in pattern were likely to be clinically meaningful. Further investigation of pattern differences by state for particular therapeutic classes of interest could be combined with in-depth knowledge of state policy to shed light on the state differences only touched on here.

4.4 **Policy Implications**

This study was originally developed to seek drug-access correlates for any negative health outcomes found in a companion study, an analysis using Medicare claims to assess the impact of the transition to Part D by dual eligibles. Unexpectedly, the first study found few substantive negative health effects, but instead found positive outcomes for dually eligible beneficiaries even in the first year following implementation of Part D. The current analysis sheds some light on possible reasons for this finding, by providing evidence that the Medicare Part D program may be supplying improved access to many types of prescription drugs for many dually eligible beneficiaries.

The limited disruptions found in the analysis are consistent with the impacts reported in the companion paper and provide further evidence of the "do no harm" impact of Part D implementation.

The patterns of discontinuation for drug classes with large over-the-counter (OTC) components may have implications (and directions for future research) that were outside the focus of this analysis. The goal here was to look for access changes that might have an impact on major health outcomes and other Medicare costs, including hospitalization, emergency department (ED) visits and the like. Although changes in access to over-the-counter products for ordinary dietary supplementation, cold symptoms, constipation, headaches and muscle discomfort may change quality of daily life for beneficiaries, they seem unlikely to result in immediate discernable impacts on hospitalization rates or ED use. Of more concern could be the incentives for both patient and physician to shift prescribing from relatively inexpensive OTC products to expensive but covered prescription analogs. The discontinuation measures (Exhibit 1) show rates in these OTC-including classes rising sharply in 2006 but returning toward baseline for 2007, suggesting that beneficiaries are continuing with these entities but in forms covered by Part D plans. The initiation rates for vitamin and mineral combinations, laxatives and antihistamines were more than 10 percentage points higher in 2006 than in the 2004-5 period (Exhibit 2). After delving into the variations in state Medicaid programs' continuing wraparound coverage for these entities (Kaiser Family Foundation 2010), it would be useful to explore the implications for Medicare cost and beneficiary wellbeing of Part D coverage for OTC products for low-income (and other) beneficiaries.

One hope for the Medicare Part D program was that if prescription drugs were better covered, all Medicare beneficiaries could have better access to technology that could maintain and improve health and substitute for other more costly health services. Researchers and policy makers have long sought evidence about the impact of access to health services technology, and in particular to prescription drugs, on health outcomes. The dually eligible population, with its substantial burden of chronic illness and available data on drug use over time from both Medicaid and Medicare, could provide further insight into this relationship. With government budgets paying so much of their high chronic health care bills, it is especially important that dually eligible beneficiaries have access to efficient and effective technologies. Future studies could be more likely to find the answers to this puzzle if they were designed with a specific focus on those States and sub-populations of duals with the greatest change in access, in comparison to beneficiaries in States with little change.

Perhaps more important than generating knowledge to shape future policy, it is critical that major policy initiatives with the potential for negative health impacts be carefully monitored. Along with the methods developed in the companion analysis in this project, this paper develops relatively simple methods that could support monitoring of Part D over time. Patterns of initiation and discontinuation of drug therapy could be tracked for beneficiaries experiencing disruption in plan assignment due to changes in benchmark status in order to ascertain whether these involuntary plan transitions have therapeutic consequences.

5 Appendix

Appendix Exhibit 1: Discontinuation: Percent Discontinuing Users, Selected Therapeutic Classes 2004-2007

Note: Therapeutic classes limited to those averaging 1000 users per year in 5% sample. Discontinuation rate is proportion of last year's users who are not users in current year. All study group beneficiaries are dually eligible for FFS Medicare and full Medicaid throughout the 24 month period.

Therapeutic Class	Mean Users	% All	Discontinuation: Proportion Last Year's Users Dropping Use This Year			
		Use	2004	2005	2006	2007
5-alpha-reductase inhibitors	2,070	0.1%	0.224	0.205	0.238	0.212
5-aminosalicylates	1,270	0.1%	0.280	0.324	0.350	0.295
adrenergic bronchodilators	30,561	1.5%	0.365	0.354	0.397	0.357
agents for pulmonary hypertension	2,555	0.1%	0.255	0.385	0.570	0.960
aldosterone receptor antagonists	5,675	0.3%	0.264	0.263	0.281	0.239
Aminopenicillins	26,255	1.3%	0.643	0.635	0.648	0.631
analgesic combinations	5,058	0.2%	0.640	0.590	0.665	0.649
angiotensin converting enzyme inhibitors	50,905	2.4%	0.184	0.184	0.193	0.167
angiotensin II inhibitors	21,582	1.0%	0.225	0.214	0.235	0.220

Therapeutic Class	Mean Users	% All		Discontinuation: Proportion Last Year's Users Dropping Use This Year				
	1120011	Use	2004	2005	2006	2007		
antiadrenergic agents, centrally acting	9,193	0.4%	0.267	0.273	0.284	0.260		
antiadrenergic agents, peripherally acting	11,439	0.5%	0.209	0.209	0.217	0.187		
antianginal agents	11,572	0.6%	0.190	0.186	0.198	0.168		
antiarrhythmic agents	2,999	0.1%	0.253	0.241	0.271	0.232		
anticholinergic antiemetics	11,247	0.5%	0.526	0.522	0.555	0.526		
anticholinergic antiparkinson agents	11,388	0.5%	0.364	0.362	0.518	0.266		
anticholinergic bronchodilators	17,121	0.8%	0.346	0.328	0.379	0.323		
anticholinergics/antispasmodics	5,916	0.3%	0.518	0.512	0.545	0.520		
Antidepressants	58,695	2.8%	0.192	0.195	0.202	0.186		
antidiabetic combinations	5,315	0.3%	0.216	0.226	0.368	0.203		
Antidiarrheals	8,555	0.4%	0.566	0.554	0.609	0.568		
antigout agents	2,797	0.1%	0.396	0.366	0.390	0.358		
Antihistamines	35,231	1.7%	0.397	0.413	0.558	0.409		
antihyperlipidemic combinations	5,109	0.2%	0.457	0.220	0.305	0.322		

Therapeutic Class	Mean Users	% All Use	Discontinuatio Dr	on: Proportions		's Users
Therapeutic Class	Wican Oscis		2004	2005	2006	2007
antihypertensive combinations	6,997	0.3%	0.237	0.233	0.241	0.228
antihyperuricemic agents	4,976	0.2%	0.194	0.173	0.194	0.165
antimalarial quinolines	7,061	0.3%	0.365	0.350	0.362	0.668
antimigraine agents	2,542	0.1%	0.415	0.415	0.430	0.373
Antipsoriatics	1,516	0.1%	0.216	0.223	0.237	0.200
Antipsychotics	13,137	0.6%	0.324	0.321	0.335	0.307
Antitussives	2,732	0.1%	0.727	0.673	0.956	0.889
antiviral combinations	1,087	0.1%	0.210	0.098	0.091	0.071
atypical antipsychotics	34,560	1.6%	0.140	0.137	0.153	0.129
azole antifungals	16,396	0.8%	0.606	0.599	0.610	0.575
barbiturate anticonvulsants	3,190	0.2%	0.245	0.220	0.788	0.190
benzodiazepine anticonvulsants	23,102	1.1%	0.275	0.270	0.974	0.938
Benzodiazepines	15,360	0.7%	0.291	0.282	0.981	0.840
beta-lactamase inhibitors	13,660	0.7%	0.748	0.752	0.756	0.724

Therapeutic Class	Mean Users	% All		Discontinuation: Proportion Last Year's Users Dropping Use This Year				
	1.2002	Use	2004	2005	2006	2007		
bile acid sequestrants	1,785	0.1%	0.539	0.528	0.558	0.527		
Bisphosphonates	20,591	1.0%	0.213	0.192	0.215	0.198		
calcium channel blocking agents	47,673	2.3%	0.156	0.156	0.173	0.146		
carbonic anhydrase inhibitor anticonvulsants	4,932	0.2%	0.351	0.344	0.358	0.315		
cardioselective beta blockers	48,264	2.3%	0.147	0.148	0.151	0.124		
chelating agents	1,991	0.1%	0.158	0.186	0.217	0.179		
cholesterol absorption inhibitors	5,263	0.3%	0.251	0.300	0.378	0.245		
cholinesterase inhibitors	11,131	0.5%	0.177	0.172	0.188	0.168		
central nervous system (CNS) stimulants	4,279	0.2%	0.441	0.423	0.613	0.356		
coumarins and indandiones	13,093	0.6%	0.183	0.194	0.211	0.183		
cox-2 inhibitors	27,192	1.3%	0.330	0.640	0.569	0.472		
Decongestants	1,285	0.1%	0.687	0.695	0.986	0.488		
dibenzazepine anticonvulsants	6,536	0.3%	0.190	0.185	0.201	0.192		

Therapeutic Class	Mean Users	% All Use	Discontinuati Dr	on: Proportion on the Troportion of the Troportion of Troportion of Troportion on Trop		's Users
Therapeutic Class			2004	2005	2006	2007
digestive enzymes	1,816	0.1%	0.356	0.328	0.399	0.324
dopaminergic antiparkinsonism agents	6,137	0.3%	0.280	0.232	0.303	0.208
Estrogens	7,981	0.4%	0.311	0.281	0.254	0.202
Expectorants	4,152	0.2%	0.769	0.631	0.981	0.779
fatty acid derivative anticonvulsants	10,538	0.5%	0.173	0.171	0.179	0.165
fibric acid derivatives	7,809	0.4%	0.256	0.257	0.269	0.231
first generation cephalosporins	26,006	1.2%	0.694	0.686	0.711	0.703
gamma-aminobutyric acid analogs	18,517	0.9%	0.319	0.327	0.292	0.286
Glucocorticoids	26,355	1.3%	0.498	0.495	0.515	0.494
glucose elevating agents	1,836	0.1%	0.406	0.376	0.407	0.317
H2 antagonists	27,930	1.3%	0.338	0.325	0.346	0.336
Heparins	2,442	0.1%	0.740	0.757	0.807	0.792
HMG-CoA reductase inhibitors	65,203	3.1%	0.113	0.134	0.160	0.127
hormones/antineoplastics	2,178	0.1%	0.195	0.190	0.204	0.184

Therapeutic Class	Mean Users	% All Use	Discontinuatio Dr	on: Proportions		's Users
Therapeutic Class	Wican Oscis		2004	2005	2006	2007
hydantoin anticonvulsants	6,822	0.3%	0.110	0.114	0.120	0.109
immunologic agents	2,783	0.1%	0.611	0.440	0.787	0.455
inhaled corticosteroids	16,963	0.8%	0.286	0.273	0.303	0.267
inotropic agents	10,694	0.5%	0.138	0.145	0.164	0.132
Insulin	18,023	0.9%	0.088	0.087	0.101	0.084
intravenous nutritional products	1,028	0.0%	0.770	0.764	0.858	0.791
iron products	5,878	0.3%	0.427	0.415	0.989	0.553
ketolides	1,160	0.1%	#DIV/0!	0.786	0.925	0.964
laxatives	22,056	1.1%	0.321	0.333	0.680	0.411
leukotriene modifiers	9,858	0.5%	0.247	0.264	0.276	0.249
lincomycin derivatives	5,047	0.2%	0.788	0.769	0.786	0.758
local injectable anesthetics	1,012	0.0%	0.777	0.740	0.780	0.763
loop diuretics	40,565	1.9%	0.168	0.170	0.179	0.158
Macrolides	37,709	1.8%	0.617	0.597	0.626	0.587

Therapeutic Class	Mean Users	% All		Discontinuation: Proportion Last Year's Users Dropping Use This Year			
Therapeant class	1/2001	Use	2004	2005	2006	2007	
Meglitinides	2,099	0.1%	0.277	0.300	0.313	0.302	
Methylxanthines	3,045	0.1%	0.244	0.234	0.245	0.226	
minerals and electrolytes	38,980	1.9%	0.234	0.238	0.385	0.225	
miscellaneous analgesics	23,638	1.1%	0.381	0.391	0.707	0.484	
miscellaneous antibiotics	7,312	0.3%	0.805	0.792	0.806	0.799	
miscellaneous antiemetics	10,214	0.5%	0.434	0.434	0.457	0.443	
miscellaneous antifungals	2,085	0.1%	0.760	0.770	0.830	0.812	
miscellaneous antihyperlipidemic agents	1,824	0.1%	0.418	0.386	0.580	0.406	
miscellaneous antimalarials	9,021	0.4%	0.755	0.742	0.753	0.728	
miscellaneous anxiolytics, sedatives and hypnotics	21,695	1.0%	0.349	0.369	0.340	0.324	
miscellaneous central nervous system agents	3,083	0.1%	0.366	0.210	0.207	0.156	
miscellaneous coagulation modifiers	2,166	0.1%	0.360	0.353	0.358	0.324	
miscellaneous genitourinary tract	4,986	0.2%	0.696	0.688	0.706	0.681	

Therapeutic Class	Mean Users	% All Use		Discontinuation: Proportion Last Year's Users Dropping Use This Year				
Therapeane class	Nicum Caera		2004	2005	2006	2007		
agents								
miscellaneous GI agents	8,541	0.4%	0.520	0.498	0.629	0.509		
miscellaneous hormones	7,549	0.4%	0.276	0.270	0.294	0.268		
miscellaneous otic agents	3,825	0.2%	0.753	0.743	0.836	0.761		
miscellaneous respiratory agents	2,147	0.1%	0.677	0.680	0.817	0.736		
miscellaneous topical agents	8,135	0.4%	0.543	0.527	0.631	0.677		
miscellaneous uncategorized agents	3,818	0.2%	0.425	0.391	0.462	0.359		
miscellaneous vaginal agents	2,933	0.1%	0.593	0.569	0.591	0.561		
mouth and throat products	2,533	0.1%	0.557	0.553	0.598	0.576		
narcotic analgesic combinations	74,297	3.5%	0.350	0.338	0.333	0.303		
narcotic analgesics	12,804	0.6%	0.318	0.302	0.315	0.287		
nasal preparations	23,016	1.1%	0.415	0.407	0.442	0.411		
natural penicillins	5,931	0.3%	0.824	0.819	0.822	0.798		
neuraminidase inhibitors	1,248	0.1%	0.933	0.859	0.925	0.927		

Therapeutic Class	Mean Users	% All Use	Discontinuatio Dr	on: Proportions		's Users
Therapeutic Class			2004	2005	2006	2007
non-cardioselective beta blockers	12,691	0.6%	0.200	0.184	0.209	0.170
nonsteroidal anti-inflammatory agents	49,740	2.4%	0.425	0.379	0.422	0.389
non-sulfonylureas	20,714	1.0%	0.189	0.160	0.173	0.159
NRTIs	1,296	0.1%	0.098	0.167	0.211	0.190
ophthalmic antihistamines and decongestants	8,726	0.4%	0.482	0.469	0.514	0.486
ophthalmic anti-infectives	14,755	0.7%	0.732	0.727	0.752	0.735
ophthalmic anti-inflammatory agents	4,277	0.2%	0.666	0.627	0.648	0.622
ophthalmic glaucoma agents	14,683	0.7%	0.132	0.136	0.155	0.128
ophthalmic lubricants and irrigations	3,127	0.1%	0.366	0.369	0.990	0.737
ophthalmic steroids	6,830	0.3%	0.636	0.623	0.679	0.640
ophthalmic steroids with anti- infectives	6,403	0.3%	0.743	0.738	0.769	0.741
otic anti-infectives	1,017	0.0%	0.808	0.795	0.832	0.829
phenothiazine antiemetics	19,201	0.9%	0.541	0.514	0.702	0.581

Therapeutic Class	Mean Users	% All Use	Discontinuation Dr	on: Proportions		's Users
Therapeutic Class	TYZCHIN CSCIS		2004	2005	2006	2007
phenylpiperazine antidepressants	12,061	0.6%	0.325	0.325	0.333	0.311
platelet aggregation inhibitors	33,202	1.6%	0.201	0.194	0.534	0.169
Polyenes	6,606	0.3%	0.655	0.669	0.697	0.670
Progestins	6,603	0.3%	0.418	0.425	0.460	0.412
protease inhibitors	1,272	0.1%	0.103	0.087	0.069	0.072
proton pump inhibitors	60,392	2.9%	0.197	0.184	0.238	0.176
purine nucleosides	5,029	0.2%	0.672	0.649	0.658	0.637
pyrrolidine anticonvulsants	1,681	0.1%	0.212	0.206	0.192	0.158
Quinolones	50,142	2.4%	0.512	0.501	0.522	0.512
recombinant human erythropoietins	1,606	0.1%	0.400	0.360	0.485	0.457
Salicylates	1,164	0.1%	0.520	0.500	0.591	0.553
second generation cephalosporins	4,907	0.2%	0.800	0.796	0.809	0.769
sex hormone combinations	2,193	0.1%	0.474	0.384	0.365	0.311
skeletal muscle relaxants	23,613	1.1%	0.404	0.401	0.399	0.376

Therapeutic Class	Mean Users	% All Use	Discontinuatio Dr	on: Proportions		's Users
Therapeutic Class	Witan Oscis		2004	2005	2006	2007
smoking cessation agents	9,152	0.4%	0.416	0.403	0.437	0.328
SSNRI antidepressants	9,404	0.4%	0.296	0.269	0.303	0.262
Sulfonylureas	21,979	1.0%	0.157	0.152	0.166	0.144
tetracyclic antidepressants	7,657	0.4%	0.313	0.296	0.302	0.274
Tetracyclines	2,471	0.1%	0.690	0.684	0.698	0.688
thiazide diuretics	48,181	2.3%	0.206	0.205	0.217	0.184
Thiazolidinediones	16,461	0.8%	0.182	0.163	0.193	0.198
third generation cephalosporins	4,688	0.2%	0.768	0.766	0.797	0.785
thyroid drugs	28,157	1.3%	0.052	0.051	0.059	0.040
topical anesthetics	8,083	0.4%	0.531	0.503	0.538	0.508
topical antibiotics	14,455	0.7%	0.642	0.641	0.752	0.684
topical antifungals	20,499	1.0%	0.520	0.518	0.609	0.530
topical anti-infectives	6,017	0.3%	0.747	0.745	0.760	0.742
topical antivirals	1,680	0.1%	0.730	0.673	0.724	0.699

Continuity Report

Therapeutic Class	Mean Users	% All Use	Discontinuation: Proportion Last Year's Users Dropping Use This Year			
Therapeatic Glass	Wiedli Osers		2004	2005	2006	2007
topical emollients	6,954	0.3%	0.500	0.546	0.707	0.595
topical steroids	29,386	1.4%	0.492	0.489	0.535	0.502
triazine anticonvulsants	2,693	0.1%	0.213	0.225	0.231	0.216
upper respiratory combinations	19,662	0.9%	0.551	0.529	0.901	0.693
urinary anti-infectives	24,820	1.2%	0.600	0.577	0.588	0.566
urinary antispasmodics	13,577	0.6%	0.279	0.260	0.275	0.252
urinary pH modifiers	5,411	0.3%	0.805	0.808	0.871	0.870
vaginal anti-infectives	4,777	0.2%	0.649	0.641	0.679	0.640
Vasodilators	18,026	0.9%	0.354	0.368	0.397	0.357
vitamin and mineral combinations	14,311	0.7%	0.246	0.236	0.948	0.502
Vitamins	10,433	0.5%	0.276	0.262	0.864	0.456

Appendix Exhibit 2: Initiation: Percent New Users, All Therapeutic Classes 2005-2007

Therapeutic Class	M II	% All	Initiation	New Thi	This Year	
Therapeutic Class	Mean Users	Use	2004	2005	2006	2007
5-alpha-reductase inhibitors	2,070	0.1%	38.0%	39.9%	47.5%	36.1%
5-aminosalicylates	1,270	0.1%	35.1%	34.1%	45.2%	32.7%
adrenergic bronchodilators	30,561	1.5%	39.2%	41.0%	47.9%	40.3%
agents for pulmonary hypertension	2,555	0.1%	24.5%	18.5%	74.3%	27.7%
aldosterone receptor antagonists	5,675	0.3%	38.9%	33.5%	43.5%	32.4%
aminopenicillins	26,255	1.3%	63.4%	64.1%	68.7%	64.1%
analgesic combinations	5,058	0.2%	63.3%	58.8%	65.6%	60.8%
androgens and anabolic steroids	916	0.0%	38.4%	34.8%	43.0%	35.7%
angiotensin converting enzyme inhibitors	50,905	2.4%	21.9%	19.1%	34.8%	21.4%
angiotensin II inhibitors	21,582	1.0%	32.2%	26.6%	35.7%	22.7%
antiadrenergic agents, centrally acting	9,193	0.4%	33.0%	30.5%	41.9%	30.8%
antiadrenergic agents, peripherally acting	11,439	0.5%	26.4%	23.9%	36.6%	26.6%
antianginal agents	11,572	0.6%	24.4%	21.6%	35.2%	22.3%
antiarrhythmic agents	2,999	0.1%	34.7%	30.0%	43.1%	30.9%
anticholinergic antiemetics	11,247	0.5%	54.1%	51.6%	60.2%	55.1%
anticholinergic antiparkinson agents	11,388	0.5%	36.4%	36.2%	35.4%	30.2%

		% All	Initiation	: % Users	New Thi	is Year	
Therapeutic Class	Mean Users	Use	2004	2005	2006	2007	
anticholinergic bronchodilators	17,121	0.8%	44.8%	41.0%	47.7%	38.5%	
anticholinergics/antispasmodics	5,916	0.3%	51.7%	52.4%	61.1%	54.3%	
antidepressants	58,695	2.8%	21.5%	18.8%	30.9%	19.9%	
antidiabetic combinations	5,315	0.3%	32.3%	21.7%	37.7%	25.8%	
antidiarrheals	8,555	0.4%	56.9%	56.6%	63.8%	60.8%	
antigout agents	2,797	0.1%	45.0%	44.9%	52.4%	44.0%	
antihistamines	35,231	1.7%	37.6%	37.0%	51.6%	43.9%	
antihyperlipidemic combinations	5,109	0.2%	85.8%	80.6%	54.5%	31.8%	
antihypertensive combinations	6,997	0.3%	32.8%	26.7%	36.8%	19.2%	
antihyperuricemic agents	4,976	0.2%	29.3%	26.9%	39.0%	25.5%	
antimalarial quinolines	7,061	0.3%	40.3%	37.1%	46.3%	21.8%	
antimigraine agents	2,542	0.1%	42.7%	38.1%	47.2%	37.0%	
antipsoriatics	1,516	0.1%	26.9%	24.0%	39.7%	22.1%	
antipsychotics	13,137	0.6%	30.7%	31.6%	43.1%	35.0%	
antitussives	2,732	0.1%	70.4%	71.2%	70.6%	70.5%	
antiviral combinations	1,087	0.1%	26.4%	32.3%	29.2%	16.0%	
atypical antipsychotics	34,560	1.6%	18.7%	16.1%	24.1%	16.1%	
azole antifungals	16,396	0.8%	59.7%	59.9%	67.8%	62.6%	
barbiturate anticonvulsants	3,190	0.2%	21.9%	22.1%	34.6%	27.6%	
benzodiazepine anticonvulsants	23,102	1.1%	32.0%	30.8%	20.2%	91.3%	
benzodiazepines	15,360	0.7%	34.4%	31.4%	21.8%	84.4%	
beta-lactamase inhibitors	13,660	0.7%	75.5%	76.1%	79.7%	75.9%	

Therenoutic Class		% All	Initiation	: % Users	New Thi	his Year	
Therapeutic Class	Mean Users	Use	2004	2005	2006	2007	
bile acid sequestrants	1,785	0.1%	55.9%	56.3%	63.4%	56.4%	
bisphosphonates	20,591	1.0%	32.6%	28.1%	34.1%	22.3%	
calcium channel blocking agents	47,673	2.3%	19.2%	16.3%	29.7%	18.2%	
carbonic anhydrase inhibitor anticonvulsants	4,932	0.2%	38.9%	35.5%	41.6%	31.5%	
cardioselective beta blockers	48,264	2.3%	23.8%	18.9%	33.1%	16.5%	
chelating agents	1,991	0.1%	26.9%	23.4%	34.9%	26.5%	
cholesterol absorption inhibitors	5,263	0.3%	56.7%	40.6%	52.5%	35.8%	
cholinesterase inhibitors	11,131	0.5%	33.5%	26.2%	32.7%	26.8%	
central nervous system (CNS) stimulants	4,279	0.2%	46.6%	40.9%	43.4%	30.8%	
coumarins and indandiones	13,093	0.6%	28.8%	24.8%	37.9%	24.7%	
cox-2 inhibitors	27,192	1.3%	30.1%	13.1%	45.2%	37.3%	
decongestants	1,285	0.1%	68.5%	67.8%	41.5%	69.6%	
dibenzazepine anticonvulsants	6,536	0.3%	19.3%	17.1%	28.0%	15.0%	
digestive enzymes	1,816	0.1%	37.4%	35.3%	38.6%	39.1%	
dopaminergic antiparkinsonism agents	6,137	0.3%	31.5%	38.4%	46.4%	37.9%	
estrogens	7,981	0.4%	12.1%	10.1%	27.4%	13.2%	
expectorants	4,152	0.2%	63.4%	69.5%	63.3%	83.4%	
fatty acid derivative anticonvulsants	10,538	0.5%	19.2%	19.0%	28.7%	19.6%	
fibric acid derivatives	7,809	0.4%	34.6%	32.4%	40.6%	29.2%	
first generation cephalosporins	26,006	1.2%	69.9%	69.9%	74.6%	70.8%	

	3.5	% All	Initiation	ı: % Users	New Thi	his Year	
Therapeutic Class	Mean Users	Use	2004	2005	2006	2007	
gamma-aminobutyric acid analogs	18,517	0.9%	35.5%	34.1%	48.8%	36.9%	
glucocorticoids	26,355	1.3%	52.5%	52.7%	61.5%	54.2%	
glucose elevating agents	1,836	0.1%	48.5%	46.7%	64.5%	45.5%	
H2 antagonists	27,930	1.3%	30.8%	33.4%	38.7%	34.2%	
heparins	2,442	0.1%	78.8%	78.6%	82.3%	82.9%	
HMG-CoA reductase inhibitors	65,203	3.1%	22.9%	16.7%	30.1%	17.0%	
hormones/antineoplastics	2,178	0.1%	26.2%	24.6%	36.2%	22.7%	
hydantoin anticonvulsants	6,822	0.3%	13.3%	11.7%	24.2%	12.3%	
immunologic agents	2,783	0.1%	51.7%	64.7%	45.4%	67.8%	
impotence agents	840	0.0%	77.6%	45.3%	84.8%	33.3%	
inhaled corticosteroids	16,963	0.8%	38.5%	33.7%	40.9%	33.0%	
inotropic agents	10,694	0.5%	19.0%	15.4%	30.2%	17.1%	
insulin	18,023	0.9%	18.7%	17.0%	30.3%	18.2%	
intravenous nutritional products	1,028	0.0%	81.1%	82.7%	87.7%	86.9%	
iron products	5,878	0.3%	49.0%	45.1%	37.1%	71.0%	
ketolides	1,160	0.1%	100.0%	91.0%	88.6%	71.6%	
laxatives	22,056	1.1%	39.7%	37.9%	54.4%	48.3%	
leukotriene modifiers	9,858	0.5%	36.3%	32.3%	39.2%	29.2%	
lincomycin derivatives	5,047	0.2%	81.0%	80.3%	83.5%	79.5%	
local injectable anesthetics	1,012	0.0%	83.9%	83.3%	84.1%	83.4%	
loop diuretics	40,565	1.9%	25.9%	22.7%	36.1%	22.6%	
macrolides	37,709	1.8%	60.6%	62.1%	66.1%	62.2%	

TI CI	NA VI	% All	Initiation	n: % Users	New Thi	s Year
Therapeutic Class	Mean Users	Use	2004	2005	2006	2007
meglitinides	2,099	0.1%	35.5%	33.1%	37.7%	31.1%
methylxanthines	3,045	0.1%	21.7%	19.2%	33.0%	20.1%
minerals and electrolytes	38,980	1.9%	29.6%	28.0%	38.9%	28.3%
miscellaneous analgesics	23,638	1.1%	43.2%	43.7%	59.7%	53.8%
miscellaneous antibiotics	7,312	0.3%	82.4%	80.8%	85.2%	81.9%
miscellaneous antiemetics	10,214	0.5%	49.2%	47.6%	55.8%	50.0%
miscellaneous antifungals	2,085	0.1%	78.1%	73.0%	76.9%	71.9%
miscellaneous antihyperlipidemic agents	1,824	0.1%	53.2%	48.2%	51.1%	45.8%
miscellaneous antimalarials	9,021	0.4%	75.8%	76.9%	81.2%	75.7%
miscellaneous anxiolytics, sedatives and hypnotics	21,695	1.0%	36.0%	36.4%	48.6%	37.7%
miscellaneous central nervous system agents	3,083	0.1%	97.4%	48.0%	45.1%	33.7%
miscellaneous coagulation modifiers	2,166	0.1%	33.8%	32.0%	39.2%	32.5%
miscellaneous genitourinary tract agents	4,986	0.2%	70.2%	69.5%	75.2%	70.9%
miscellaneous GI agents	8,541	0.4%	53.0%	53.8%	59.6%	48.9%
miscellaneous hormones	7,549	0.4%	26.8%	22.1%	35.6%	24.3%
miscellaneous otic agents	3,825	0.2%	76.2%	74.3%	79.0%	77.3%
miscellaneous respiratory agents	2,147	0.1%	71.6%	69.9%	74.4%	76.4%
miscellaneous topical agents	8,135	0.4%	62.8%	57.5%	63.0%	55.9%
miscellaneous uncategorized agents	3,818	0.2%	53.8%	49.2%	58.6%	46.9%
miscellaneous vaginal agents	2,933	0.1%	56.5%	56.1%	63.4%	58.0%

The state of	No. 11	% All	Initiation	n: % Users	New Thi	his Year	
Therapeutic Class	Mean Users	Use	2004	2005	2006	2007	
mouth and throat products	2,533	0.1%	56.6%	56.1%	67.6%	63.4%	
mydriatics	827	0.0%	65.8%	65.7%	70.1%	68.2%	
narcotic analgesic combinations	74,297	3.5%	37.4%	35.9%	45.5%	34.0%	
narcotic analgesics	12,804	0.6%	40.8%	39.5%	47.9%	37.9%	
nasal preparations	23,016	1.1%	44.1%	42.5%	50.0%	44.2%	
natural penicillins	5,931	0.3%	80.8%	80.6%	82.6%	80.2%	
neuraminidase inhibitors	1,248	0.1%	87.6%	94.8%	93.3%	87.7%	
non-cardioselective beta blockers	12,691	0.6%	32.9%	30.4%	38.4%	23.6%	
nonsteroidal anti-inflammatory agents	49,740	2.4%	46.4%	46.8%	46.4%	40.4%	
non-sulfonylureas	20,714	1.0%	23.0%	24.2%	33.5%	22.2%	
nucleoside reverse transcriptase inhibitors (NRTIs)	1,296	0.1%	10.9%	6.7%	18.4%	11.4%	
ophthalmic antihistamines and decongestants	8,726	0.4%	50.6%	49.0%	52.2%	50.0%	
ophthalmic anti-infectives	14,755	0.7%	74.8%	74.0%	78.3%	76.0%	
ophthalmic anti-inflammatory agents	4,277	0.2%	72.8%	68.0%	71.3%	67.8%	
ophthalmic glaucoma agents	14,683	0.7%	19.6%	16.5%	28.1%	18.0%	
ophthalmic lubricants and irrigations	3,127	0.1%	41.1%	40.8%	60.2%	76.2%	
ophthalmic steroids	6,830	0.3%	63.8%	62.6%	67.7%	65.9%	
ophthalmic steroids with anti- infectives	6,403	0.3%	72.8%	73.5%	78.9%	76.2%	
otic anti-infectives	1,017	0.0%	78.9%	79.8%	84.0%	80.7%	
phenothiazine antiemetics	19,201	0.9%	53.7%	54.8%	64.7%	59.3%	

		% All	Initiation	nitiation: % Users New This Year			
Therapeutic Class	Mean Users	Use	2004	2005	2006	2007	
phenylpiperazine antidepressants	12,06	61 0.6%	34.0%	32.1%	42.9%	33.4%	
platelet aggregation inhibitors	33,20	1.6%	28.3%	23.0%	31.6%	24.5%	
polyenes	6,60	06 0.3%	70.5%	69.4%	76.4%	69.6%	
progestins	6,60	0.3%	48.4%	46.9%	52.6%	50.6%	
protease inhibitors	1,27	2 0.1%	16.8%	11.1%	21.3%	9.7%	
proton pump inhibitors	60,39	2.9%	28.0%	23.9%	37.1%	24.9%	
purine nucleosides	5,02	0.2%	67.9%	66.7%	71.1%	66.1%	
pyrrolidine anticonvulsants	1,68	0.1%	39.9%	33.6%	41.3%	32.2%	
quinolones	50,14	2.4%	53.3%	54.2%	60.4%	54.7%	
recombinant human erythropoietins	1,60	0.1%	56.9%	53.7%	51.8%	46.6%	
salicylates	1,16	64 0.1%	52.7%	58.5%	59.7%	51.6%	
second generation cephalosporins	4,90	0.2%	78.3%	80.0%	83.9%	79.5%	
sex hormone combinations	2,19	0.1%	19.8%	22.2%	32.9%	26.5%	
skeletal muscle relaxants	23,613	1.1%	42.3%	39.9%	53.2%	41.3%	
smoking cessation agents	9,152	0.4%	43.0%	39.4%	47.7%	49.6%	
SSNRI antidepressants	9,404	0.4%	38.2%	41.5%	47.6%	33.9%	
sulfonylureas	21,979	1.0%	19.3%	16.5%	30.6%	17.6%	
tetracyclic antidepressants	7,657	0.4%	37.6%	35.7%	43.9%	35.1%	
tetracyclines	2,471	0.1%	67.5%	68.3%	74.4%	69.6%	
thiazide diuretics	48,181	2.3%	27.4%	21.5%	34.2%	20.4%	
thiazolidinediones	16,461	0.8%	25.4%	26.5%	30.5%	16.5%	
third generation cephalosporins	4,688	0.2%	82.4%	81.6%	83.4%	81.3%	

TIL CL	M. H	% All	Initiation	: % Users	New Thi	is Year	
Therapeutic Class	Mean Users	Use	2004	2005	2006	2007	
thyroid drugs	28,157	1.3%	14.6%	10.7%	25.7%	10.4%	
topical acne agents	881	0.0%	56.9%	50.6%	68.3%	86.7%	
topical anesthetics	8,083	0.4%	65.7%	59.0%	63.5%	56.9%	
topical antibiotics	14,455	0.7%	66.3%	66.0%	73.5%	72.3%	
topical antifungals	20,499	1.0%	55.0%	53.5%	58.7%	57.6%	
topical anti-infectives	6,017	0.3%	76.9%	76.1%	79.0%	77.8%	
topical antivirals	1,680	0.1%	73.2%	68.7%	75.2%	73.2%	
topical emollients	6,954	0.3%	57.2%	57.4%	63.5%	68.1%	
topical steroids	29,386	1.4%	50.5%	49.6%	58.1%	52.9%	
triazine anticonvulsants	2,693	0.1%	38.9%	34.3%	41.7%	30.0%	
upper respiratory combinations	19,662	0.9%	51.5%	53.2%	64.5%	67.5%	
urinary anti-infectives	24,820	1.2%	62.7%	62.2%	68.6%	62.3%	
urinary antispasmodics	13,577	0.6%	32.1%	30.7%	39.5%	29.6%	
urinary pH modifiers	5,411	0.3%	81.0%	82.3%	89.8%	88.6%	
vaginal anti-infectives	4,777	0.2%	62.6%	61.6%	67.9%	64.2%	
vasodilators	18,026	0.9%	39.5%	36.9%	47.9%	43.6%	
vitamin and mineral combinations	14,311	0.7%	32.4%	30.2%	47.9%	57.6%	
vitamins	10,433	0.5%	37.4%	35.0%	38.9%	57.8%	

Literature Cited

- Briesacher, B. A., S. E. Andrade, et al. (2009). "Medication adherence and use of generic drug therapies." Am J Manag Care 15(7): 450-456.
- Briesacher, B. A., J. H. Gurwitz, et al. (2007). "Patients at-risk for cost-related medication nonadherence: a review of the literature." J Gen Intern Med **22**(6): 864-871.
- Crowley, J. S., D. Ashner, et al. (2005). State Medicaid Outpatient Prescription Drug Policies: Findings from a National Survey, 2005 Update. 7381. http://www.kff.org/medicaid/upload/State-Medicaid-Outpatient-Prescription-Drug-Policies-Findings-from-a-National-Survey-2005-Update-report.pdf
- Duru, O. K., C. M. Mangione, et al. (2010). "Generic-Only Drug Coverage in the Medicare Part D Gap and Effect on Medication Cost-Cutting Behaviors for Patients with Diabetes Mellitus: The Translating Research into Action for Diabetes Study." J Am Geriatr Soc.
- Fung, V., C. M. Mangione, et al. (2010). "Falling into the coverage gap: part D drug costs and adherence for medicare advantage prescription drug plan beneficiaries with diabetes." <u>Health Serv Res</u> **45**(2): 355-375.
- Hall, J., J. Moore, et al. (2005). Unintended Consequences: The Potential Impact of Medicare Part D on Dual Eligibles with Disabilities in Medicaid Work Incentive Programs.
- Hassan, M. and M. J. Lage (2009). "Risk of rehospitalization among bipolar disorder patients who are nonadherent to antipsychotic therapy after hospital discharge." <u>Am J Health Syst</u> Pharm **66**(4): 358-365.
- Jensen and Kaiser Commission on Medicaid and the Uninsured (2005). The New Medicare Prescription Drug Law: Issues for Enrolling Dual Eligibles into Drug Plans. http://www.kff.org/medicare/upload/The-New-Medicare-Prescription-Drug-Law-Issue-for-Enrolling-Dual-Eligibles-into-Drug-Plans-Issue-Paper.pdf
- Kaiser Family Foundation (2005). Medicare's New Prescription Drug Benefit: The Voices of People Dually Covered by Medicare and Medicaid. http://www.kff.org/medicare/7243.cfm
- Kaiser Family Foundation. (2010). "Medicaid Coverage of Medicare Part D Excluded Drugs 2009." Retrieved 11/14, 2010, from http://www.statehealthfacts.org/comparemaptable.jsp?ind=820&cat=6.
- Karve, S., M. A. Cleves, et al. (2009). "Prospective Validation of Eight Different Adherence Measures for Use with Administrative Claims Data among Patients with Schizophrenia." Value Health.
- Kennedy, J., I. Tuleu, et al. (2008). "Unfilled prescriptions of medicare beneficiaries: prevalence, reasons, and types of medicines prescribed." J Manag Care Pharm **14**(6): 553-560.
- Lage, M. J. and M. K. Hassan (2009). "The relationship between antipsychotic medication adherence and patient outcomes among individuals diagnosed with bipolar disorder: a retrospective study." <u>Ann Gen Psychiatry</u> **8**: 7.

- Law, M. R., S. B. Soumerai, et al. (2008). "A longitudinal study of medication nonadherence and hospitalization risk in schizophrenia." <u>J Clin Psychiatry</u> **69**(1): 47-53.
- Madden, J. M., A. J. Graves, et al. (2009). "Cost-related medication nonadherence after implementation of Medicare Part D, 2006-2007." Jama 302(16): 1755-1756.
- Michigan Department of Community Health Medicaid Program (2006). Part D Drugs/Part D Excluded Drugs. https://michigan.fhsc.com/Downloads/Part_D_Drugs_Excluded_drugs-20090812.pdf
- Pan, F., M. E. Chernew, et al. (2008). "Impact of fixed-dose combination drugs on adherence to prescription medications." <u>J Gen Intern Med</u> **23**(5): 611-614.
- Perneger, T. V. (1998). "What's wrong with Bonferroni adjustments." <u>BMJ</u> **316**(7139): 1236-1238.
- Raebel, M. A., T. Delate, et al. (2008). "Effects of reaching the drug benefit threshold on Medicare members' healthcare utilization during the first year of Medicare Part D." Med Care 46(10): 1116-1122.
- Soumerai, S. B., M. Pierre-Jacques, et al. (2006). "Cost-related medication nonadherence among elderly and disabled medicare beneficiaries A national survey 1 year before the medicare drug benefit." <u>Archives Of Internal Medicine</u> **166**(17): 1829-1835.
- Trinacty, C. M., A. S. Adams, et al. (2009). "Racial differences in long-term adherence to oral antidiabetic drug therapy: a longitudinal cohort study." <u>BMC Health Serv Res</u> **9**: 24.
- U.S. Government Accountability Office (2005). Medicare: Contingency Plans to Address Potential Problems with the Transition of Dual-Eligible Beneficiaries from Medicaid to Medicare Drug Coverage. GAO-06-278R http://www.gao.gov/new.items/d06278r.pdf
- Zhang, Y., J. R. Lave, et al. (2010). "The impact of Medicare Part D on medication adherence among older adults enrolled in Medicare-Advantage products." Med Care 48(5): 409-417.
- Zivin, K., J. M. Madden, et al. (2009). "Cost-related medication nonadherence among beneficiaries with depression following Medicare Part D." <u>Am J Geriatr Psychiatry</u> **17**(12): 1068-1076.