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.

Impact of Part D Transition on Dually Eligible Medicare Beneficiaries

Prepared by:

Daniel Gilden, M.S.

Christine E. Bishop, Ph.D.

Angelina Tong 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

ABSTRACT

Research Objective:

To test the null hypothesis that for dually eligible beneficiaries, the implementation of Part D had no significant negative impact on health outcomes measurable using Medicare claims.

Study Design:

In order to estimate the impact of Part D on dually eligible beneficiaries, population-based rates for health outcomes are first graphed against time for 48 months prior and 12 months post implementation of Part D. Mean annual population-based outcome rates are compared for beneficiaries with full fee-for-service dual eligibility throughout the prior year who survive into the observation year for four observation years before and one observation year after the implementation of Part D. Multivariate panel analysis is then used to estimate the effect on each outcome associated with the indicator for the implementation year for Part D (2006) after adjusting for beneficiary demographic and health characteristics. The outcome (dependent) variables for these analyses include hospital admissions, hospital days, emergency department utilization, physician encounters, nursing home entry (for beneficiaries not already residing in a nursing home) and ambulatory care sensitive hospitalizations. Subanalyses identify differences for populations with identified chronic conditions and in nursing homes.

Population Studied:

Full Medicaid-eligible fee-for-service Medicare beneficiaries, both Aged and Disabled.

Principal Findings:

The null hypothesis of no negative impact for Part D cannot be rejected. Part D implementation did not have a substantive measurable negative impact on health outcomes for fee-for-service full dually eligible Medicare beneficiaries, as a whole or for vulnerable subpopulations. Several comparisons of means showed small but significant increase in a negative outcome after Part D implementation; these were for specialist physician encounters; for one ambulatory care sensitive hospitalization (urinary tract

infection); and beneficiaries with congestive heart failure (CHF) showed slightly elevated rates of hospitalization and emergency department use. Multivariate analysis adjusting for risk factors showed very small but significant negative outcomes in only three instances: hospital admission rates for urinary tract infection; for Aged beneficiaries with CHF; and for nursing home residents. Overall the bulk of the comparisons and multivariate analyses showed no negative effect of Part D.

Conclusions:

Even though some dually eligible Medicare beneficiaries may have had better access to prescription drugs under the Medicaid plans that covered them prior to the implementation of Part D, a panel analysis testing for a discontinuity in health outcomes is unable to identify a meaningful significant negative impact for this population or for vulnerable subpopulations. It is not strictly possible to accept a null hypothesis, but this study adds to growing evidence that Part D "did no harm" for dually eligible beneficiaries.

Implications for Policy, Delivery or Practice:

Medicare Part D has not had an adverse impact on the health of dually eligible Medicare beneficiaries.

1 Introduction

The implementation of the Medicare Part D benefit assured the availability of an outpatient pharmacy benefit for all Medicare beneficiaries and was expected to improve health outcomes to the extent that 1) access to prescription drugs was expanded and 2) expanded access promotes better health outcomes. Beneficiaries as a group have indeed maintained or expanded their prescription drug insurance coverage during this transition.[1] The greatest impacts on prescription drug utilization (realized access) have been observed for beneficiaries who previously did not have insurance coverage for prescription drugs (Goldman and Joyce 2008; Yin, Basu, Zhang, Rabbani et al. 2008; Safran, Strollo, Guterman, Li et al. 2010). The link between expanded access and health outcomes has been the focus of studies conducted prior to Part D assessing the impact of prescription drug coverage on health outcomes. These have found mixed results, with some studies showing that greater access improves health outcomes and others showing little effect (Goldman, Joyce and Zheng 2007; Khan, Kaestner and Lin 2008; Yang, Gilleskie and Norton 2009). Only a few studies to date have examined impacts of Part D on beneficiary health outcomes, and these have encompassed impacts for the general Medicare population (Zhang, Donohue, Lave, O'Donnell et al. 2009; Ingber, Greenwald, Freeman and Healy 2010; Kaestner and Khan 2010) Again, any major impact of Part D coverage is expected to occur for Medicare beneficiaries who previously had no or inadequate insurance coverage for prescription drugs; it is for these beneficiaries that an increase in access to prescription drugs is expected, with a concomitant improvement in health outcomes.

Medicare beneficiaries who transitioned to Part D as dual eligibles, eligible for Medicaid as well as Medicare, were in a somewhat different situation. These beneficiaries, numbering

[1] By April 2010, over 29 million Medicare beneficiaries were enrolled in Medicare Part D (Centers for Medicare and Medicaid Services 2010); many who have not enrolled remain in plans with equivalent ("creditable") coverage. However, some beneficiaries still lack coverage for prescription drugs (Jacobson and Anderson 2010).

approximately 5 million[2] in 2006, 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. In contrast to the general Medicare beneficiary population, the expected impact of Part D on access to drugs and health status for the dually eligible beneficiaries is not attributable to gaining insurance for prescription drugs, because they were already insured: until January 2006, dual beneficiaries received outpatient prescription drug coverage through their states' Medicaid programs. The effect of the transition to Part D for these potentially highly vulnerable beneficiaries was to shift them from 51 state Medicaid programs with benefit designs that varied in restrictiveness and generosity to over 636 Part D plans that also varied in benefit design (Hoadley, Cubanski, Hargrave, Summer et al. 2009). Medicaid drug coverage varied in copayments, prior authorization requirements, formulary restrictions and other elements of benefit design (Crowley, Ashner and Elam 2005; Cunningham 2005). Some state Medicaid plans were very generous, with low or zero copayments, few formulary restrictions, and no limit on the number of prescriptions beneficiaries could access per month or per year. Others were very restrictive, with capped benefits or restricted formularies.

For dually eligible beneficiaries in states with restrictive Medicaid plans, Part D plan coverage may be less restrictive than their past Medicaid coverage; for dually eligible beneficiaries in states with generous Medicaid coverage and low or no copayments, some Part D plans may be more restrictive than the coverage beneficiaries had under Medicaid. As Part D began, dually eligible beneficiaries were automatically enrolled with no out-of-pocket premium in low-cost Part D plans, called benchmark or low-income subsidy plans, whose premium costs were at or below the area average.[3] The benefit design of the Part D plans enrolling dual

[2] 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 in January 2006. This includes dual beneficiaries enrolled in managed care plans.

[3] Benchmark plans were determined by CMS through an elaborate bidding process. Prescription drug plans (PDPs) with a standardized cost at or above the area median were designated as benchmark plans and open for enrollment at no premium by dually eligible beneficiaries. In 2006, 409 of the 1429 total number of PDPs were designated as benchmark plans (Hoadley, Cubanski et al. 2009). Dually eligible beneficiaries eligible for full Medicaid were sent

eligibles may include formulary limitations and prior authorization requirements that diverge substantially from the design of the Medicaid drug program of previous enrollment. In any month, dual beneficiaries are able to switch enrollment to any other area benchmark plan at no cost (or to pay an incremental premium to enroll in an above-benchmark plan, although this is rare). They may also enroll in Medicare Advantage plans that include Part D coverage (MA-PDPs). Dually-eligible beneficiaries pay standard reduced co-payments for prescriptions and do not face the benefit limits applied to non-Medicaid Part D plan enrollees.

Concerns that dually eligible beneficiaries might be harmed by the transition from Medicaid to a Part D plan arose well before the transition date (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). The dually eligible disproportionately include cognitively impaired populations, such as nursing home residents with dementia and persons with developmental disabilities and chronic mental illness. In the short run, confusion about plan membership and variations in drug formularies could lead to interruptions in utilization in important therapies for this autoenrolled population. In the longer run, the capacity of these high risk populations to navigate the administrative transition and safely maintain their access to necessary outpatient therapies was at issue. It was feared that interruptions in prescription drug therapies would lead to increased use of emergency services, hospitals, nursing facility care and even death. Many state Medicaid agencies addressed these concerns by continuing their pharmacy benefit through the first quarter of 2006, enabling the dually eligible to access both a Medicare and a Medicaid financed pharmacy benefits (Fox and Scholfield 2006; Smith, Gifford, Kramer and Elam 2006). Despite these provisions, there were anecdotal reports of difficulties accessing needed prescription medicines, especially psychotropic medicines (Arizpe 2006; Kaiser Commission on Medicaid and the Uninsured 2006; Kaiser Commission on Medicaid and the Uninsured 2006; Morden and Garrison 2006; Bagchi, Esposito and Verdier 2007; Donohue and Frank 2007; Hall, Kurth and Moore 2007; Huskamp, Stevenson, Donohue, Newhouse et al. 2007; West, Wilk, Muszynski, Rae et al. 2007; Wilk, West, Rae, Rubio-Stipec

---

a letter in October 2005 stating their plan of autoenrollment and informing them about their options for choosing a different benchmark, above benchmark or Medicare Advantage prescription drug plan (PDP).

et al. 2008; Donohue, Huskamp and Zuvekas 2009; Huskamp, West, Rae, Rubio-Stipec et al. 2009; Basu, Yin and Alexander 2010; West, Wilk, Rae, Muszynski et al. 2010).

In response to these concerns, this analysis uses Medicare claims for other health services to assess whether fee-for-service dually eligible beneficiaries transitioning to Part D in January 2006, both as a group and considered as especially vulnerable subgroups, experienced adverse health events. Because there is no experimental control group which did not undergo the transition to Part D, we use a variety of methods to study patterns of health outcomes over time for all fee-for-service dually eligible beneficiaries and for vulnerable subgroups, to assess whether a break in health outcome trends occurred with Part D implementation. Thus the objective of this study is to test the null hypothesis that health outcomes for dually eligible beneficiaries, after accounting for other factors, were no worse after January 2006.

If any changes in health trends are identified, they cannot logically be attributed to the transition to Part D unless they are also associated with changes in access to prescription drugs, which is the essence of Part D considered as a policy intervention. Thus the strategy of a companion analysis is to assess trends in prescription drug utilization (initiation and discontinuation) for subpopulations with significant health trend differences after the implementation of Part D.

2 Methods and Data

2.1 Methods

Because there is no control group of similar dual beneficiaries who did not transition to Part D, we employed three methodological approaches, ranging from graphical examination of monthly means for all enrolled fee-for-service dually eligible beneficiaries to multivariate adjustment of outcomes for special populations, in order to compare outcomes before and after Part D implementation.

- First, mean monthly outcomes were graphed for all dually eligible Medicare beneficiaries enrolled in fee-for-service Parts A and B for years before and after Part D implementation. This allows visual inspection of the trends in outcomes.
- Second, annual outcomes were compared for carefully defined analogous populations of dually eligible beneficiaries for years before and after Part D implementation, using

standard statistical tests to assess the significance of any differences in means. This analysis is restricted to beneficiaries who were dually eligible for both full Medicaid and fee-for-service Medicare for the full year before the observation year.

- Third, panel data analysis of annual outcomes was carried out for the same restricted groups of dually eligible beneficiaries observed at multiple points in time. Multivariate analysis was used to adjust for personal characteristics and health status indicators, to determine whether adjusted outcomes were significantly different in the post-implementation period.

Each of these statistical methods and the study group used to implement them is described more completely in the sections below.

Graphical Presentation of Mean Monthly Outcomes

Graphing the mean for each outcome variable for all fee-for-service dually eligible beneficiaries for each month in the period between January 2001 and December 2007 provides a first look at outcomes using completely unadjusted data. Outcome measures for any beneficiary who was dually eligible for both full Medicaid and fee-for-service Medicare in any month contributed to the statistics computed for that month. In classic interrupted time series analysis, the analyst looks for a break in the pattern simultaneous with the intervention of interest, in this case the implementation of Part D in January 2006. Graphical presentation of these monthly means reveals any substantial discontinuities in mean monthly outcomes for 2006 that might be attributable to the implementation of Part D. An abrupt change in level or a sharp change in the slope of the trend for an outcome variable at that point in time suggests an impact that warrants further investigation.

Comparison of Mean Outcomes

Monthly means for outcome variables were computed for identically defined cohorts for 2002 through 2006 to provide a time series representing outcomes by year before and after Part D implementation. The annual cohorts consisted of beneficiaries who were dually eligible with Medicare A and B fee for service benefits and full Medicaid benefits for the full year prior to the outcome year. Because the outcome years are 2002 through 2006, the prior years are 2001 through 2005. Although the study group is necessarily reduced by the requirement that each member have a full year of experience as a dually eligible beneficiary, this also allows consistent

identification of special subpopulations using diagnoses and conditions identified in each beneficiary's past year's claims.

Monthly means were computed for specific subpopulations of interest, thus introducing adjustments for some beneficiary characteristics. Occurrences of certain health events during the year (any hospitalization, any emergency department utilization, any nursing home entry) were also identified and presented as a rate per thousand beneficiaries eligible during that year. Unadjusted means for these consistent populations, presented on an annual basis, were compared for periods before and after Part D implementation to assess the impact of Part D on outcomes using standard tests for differences in means or rates.[4]

Multivariate Panel Data Analysis

The multivariate analysis of beneficiary panel data incorporated adjustments for beneficiary characteristics and health status indicators. The analysis was premised on an underlying model which assumes that health outcomes in one year (year t in the notation below) are in general related to (or a function of) personal characteristics (age, sex, other characteristics) and health status in the previous year (designated in the notation as year t-1). A general time trend may also affect outcomes. The impact of Part D was captured by an indicator variable set to 0 for outcome years prior to the implementation of Part D and 1 for years after

[4] The overall approach of testing multiple measures for any evidence of deteriorating health outcomes would be expected to identify a certain proportion of positive findings given the nature of random variables; theoretically, one in twenty tests will show significance at the .05 level where no significant difference exists. This should be kept in mind as results of the analysis are reviewed, and suggests that if our standard for a significant impact is the .05 level, a Bonferroni-based approach would support a higher standard for significance (1/n * .05, where n is the number of tests). However, recent scholarship suggests that the Bonferroni correction "causes more problems than it solves" (Perneger 1998). More important for this analysis, as will be shown below, the analytic strategy pursued here results in virtually *no* significant findings of deleterious outcomes, and we purposely do not emphasize the significant findings that did emerge of improvement in health outcomes. In effect, our "fishing expedition" comes up virtually empty-handed, so a Bonferroni correction would only reinforce the finding of no deleterious effect for Part D.

implementation; this is the effect of Part D on outcomes in addition to the trend. In general terms,

$$(1) \quad Outcome_{it} = \alpha + \beta\, Demog_i + \gamma X_{t-1,i} + \delta\, t + \rho\, PartD_t + c_i + \varepsilon_{it}$$

where $Outcome_{it}$ is a particular outcome for individual i in year t; $Demog_i$ is a vector of time-invariant demographic characteristics for individual i, including indicators for sex, race, and rural residence; $X_{t-1,i}$ is a vector of health status and utilization variables measured for the prior year (t-1); t is time, equal to the outcome year; $PartD_t$ is an indicator equal to 0 when t is less than 2006 and equal to 1 for t equal to 2006; c_i is an error term specific to individual i, accounting for multiple observations on the same individual; and ε_{it} is a standard error term. α, β, γ, δ and ρ are parameters to be estimated.

The functional form of the example model in Equation 1 is linear, but the same variables can be used in other functional forms depending on the dependent variable. For dichotomous outcome variables, which indicate whether or not an outcome occurred during the year (hospitalization, nursing home entry), logistic regression was used. For continuous outcome variables, e.g. annual Medicare expenditures, inpatient hospital episodes, annual number of hospital days, SNF days, etc., values for each beneficiary were computed on a per month basis. Each monthly value was then augmented by .01 before the natural log was computed for use as the dependent variable in an ordinary least squares regression.

Impact of implementation of Part D is shown by ρ, the coefficient for the indicator of the post-implementation period. When the dependent variable is dichotomous, indicating any use of hospitalization or emergency department in the year, for example, the estimate of the impact of Part D, which in this case is estimated using logistic regression, is interpreted using an odds ratio, which shows the estimated impact on the probability that the outcome occurred. For the continuous outcome variables, measured as the logarithm of the individual's monthly mean, the coefficient is interpreted as a percentage impact on the outcome.

Beneficiaries were included in the outcomes analysis only for years (t) when they present a full prior year (t-1) of dually eligible status and participation in fee-for-service Medicare Parts A and B. Only partial years can be observed for dual beneficiaries who left Medicaid or died after January of the outcome year, but these partial observations are assumed to be randomly distributed across years.

Because many individual beneficiaries contribute multiple outcome observations over the observed years, i.e. are members of more than one observed panel, it is necessary to account for clustering of repeated observations for the same individual over time, indicated by the c_i error term in equation (1). This is accomplished through implementation of generalized estimating equations (GEE), which provide standard errors for the coefficients that correct for clustering.

Because a large number of health status and personal characteristics were used to adjust for beneficiary risk for specific outcomes, step-wise methods were used in some of the analyses. Variables were retained in the final models if coefficients were significantly different from zero with a probability of .5 or greater.

In addition, the multivariate models were further adjusted by restricting them to subgroups defined as above. For example, rather than including an indicator variable indicating that the beneficiary met the criteria for schizophrenia, the analysis was restricted to beneficiaries with that indicator. This allowed the impact of demographic and health status variables as well as the impact of Part D implementation to vary across subgroups.

Outcome Variables: Definitions

The outcomes selected for study represent substantive health events that can be identified in claims. The outcome variables are of two types: indicator variables representing any use during the year (yes = 1 and no = 0) and continuous variables representing mean monthly amounts for each beneficiary in the outcome year. The indicator variables include: any acute inpatient stay, any emergency department utilization; nursing home entry;[5] and thirteen types of hospitalization identified as preventable using criteria developed by the Agency for Healthcare Research and Quality Hospital Cost and Utilization Project (HCUP) (Friedman and Basu 2004; Agency for Healthcare Research and Quality 2010). The continuous variables include: Medicare acute hospital inpatient stays; Medicare acute hospital inpatient days; Medicare outpatient

[5] Nursing home entry was determined based on MDS records and Medicare indicators for all years; in addition, because Medicaid data were available for 2001 through 2005, nursing home claims could also be used to verify nursing home use for those years. This may result in a relative undercount of nursing home entry in 2006, although MDS and Medicare indicators appear to be a reliable means to determine whether any nursing home use has occurred.

emergency department (ED) encounters; Medicare specialty and nonspecialty physician utilization; and Medicare skilled nursing facility days.[6] To deal with the skewed distribution, the natural logarithm of each value (augmented by .01 allow inclusion of zero values) was computed for each outcome variable.

Risk Adjustment Factor Variables: Definitions

Population subgroups were identified to provide one level of adjustment for the descriptive statistical comparisons. These subgroups identified individuals with the following conditions: dementia; chronic mental illness; cancer; mental retardation; congestive heart failure; diabetes; chronic respiratory disease; and high frailty. In addition, nursing home residents were distinguished from community residents and basis of eligibility (Disabled, Aged) was used to further define subgroups.

The multivariate models included the following independent variables, measured in the base year:

Diagnosis indicators were set based on the presence of the diagnosis in a physician or hospital claim in the base year. The diagnosis indicators include Alzheimer's 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).

Health status: An index of frailty, developed by Jen Associates Inc. as a prognostic tool for risk of nursing home entry, was computed for each beneficiary. It is based on the diagnostic indicators. The RxRisk index was developed by Jen Associates Inc. in an effort to use patterns of prescription drug utilization as a proxy for severity of illness. In a population with substantially complete insurance coverage for prescription drug use, it can be assumed that individuals with severe forms of certain illnesses are using drugs that treat those illnesses; and

[6] Another continuous outcome variable available in claims data is per month payments under Medicare Part A and Part B. This could be used to capture overall use of Medicare services if the prices of services could be accounted for. However, it is challenging to purge expenditure data of price changes, especially for administered prices like Medicare payment rates.

the number and mix of drugs prescribed for an individual is therefore associated with complexity of chronic illness status.

The RxRisk index was originally calibrated by Jen Associates Inc. to explain variation in diagnostic complexity in the subsequent year. It is based on Medicaid drug claims for the prior year, and reflects risk deciles computed for the original calibration population. The omitted category is very low risk, for beneficiaries with little or no prescription drug use. It is noteworthy that the dually eligible population is the only broad-based group for whom relatively complete information about prescription drug utilization and access is available from claims prior to the implementation of Part D.

Long-term care status: Nursing home status was estimated by the presence of a nursing home review (Minimum Data Set, MDS) in the last six months of the prior year (1 = evidence of nursing home use in second half of prior year) .[7] Only beneficiaries who were definitely not nursing home residents in the previous year are included in the analyses using nursing home entry as an outcome.

Demographic and location descriptors: were based on information from the Medicare enrollment record. They included sex (female = 1, male = 0); four age categories reflecting age at the end of the base year (<65, 65-74, 75-84, 85+); race (White, Black, Hispanic, other race); rural (based on the Rural-Urban Continuum codes reported in the Area Resource File for county of beneficiary residence; scores above 3 represent rural counties) (United States Department of Agriculture 2004).

2.2 Data

The data for all the analyses were developed from data for a 5% sample of dually eligible Medicaid and Medicare beneficiaries observed in years 2001 through 2007. For analyses requiring risk factors, either as independent variables or to define subgroups, demographic characteristics and health status variables were measured in a base year (t-1) for each observation

[7] This is a conservative and possibly over-inclusive identification of the nursing home resident population, because it includes beneficiaries with a short SNF stay in the previous year as well as long-stay nursing home residents. In presenting the results, the phrase "observed to use nursing home care in the second half of the prior year" is used to describe this population.

year t. Thus the 2001-2007 data set supported adjusted outcomes analyses for outcome years 2002 through 2007, yielding six possible values for time t. However, prescription drug use (RxRisk) was only available from Medicaid data (2001 through 2005). Therefore the outcome years examined are 2002 through 2006.[8]

The 5% data file for dually eligible beneficiaries was derived from a combination of Medicare claims and enrollment data from the national Medicare 5% sample 2001-2007 and 100% Medicaid enrollment data from the national Medicaid MAX data source for the period 2001-2005. Linkages between the Medicare 5% denominator records and the MAX enrollment data were executed using Social Security Number and validated using supporting data fields present in both administrative data sources (date of birth and sex). Part D enrollment data from the period 2006-2007 was integrated into the data to create monthly data fields for Part D and reported Medicaid enrollment status.[9] The linkage between these sources leads to an augmented Medicare denominator record that includes monthly Medicaid status for the period 2001-2005 and Part D enrollment data for 2006-2007. Medicare A and B claims data from the Medicare 5% sample were integrated with the monthly enrollment status to create a detailed person-level longitudinal record that documented by month Medicare program utilization by service type, specific therapy sensitive hospitalization episodes by HCUP Ambulatory Care Sensitive hospitalization type (Friedman and Basu 2004; Agency for Healthcare Research and Quality 2010) and flags for the presence of physician- and hospital-reported diagnoses for selected disabilities and chronic diseases. The records also include nursing home residency indicators based on Medicaid (MAX) nursing home claims and monthly utilization measures of Medicaid-paid pharmaceutical therapies by therapeutic class (Lexicon therapeutic classification system).

3 Results

Using data on service utilization in dually eligible populations, we demonstrate that the Part D transition did not lead to substantial increases in health services utilization, both for the Medicare beneficiary population overall and for specific high risk groups. The impact of the

[8] Recalibration of RxRisk using Part D drug claims (PDE) would permit the analysis to be extended to later years.

[9] The Part D enrollment data were critical to determining full Medicaid dual status because Medicaid status indicators on the Medicare denominator file are known to be flawed (Barosso 2006)

introduction of a national Medicare pharmacy benefit has not increased adverse events for this previously-covered vulnerable group as a whole. Beyond this null finding, the analyses demonstrate *improved* health care outcomes for some of these high risk populations in the first year of the Part D program.

3.1 Graphical Presentation of Outcomes

The data for monthly outcomes for all beneficiaries who were dually eligible for at least one month from 2001 through 2007 were graphed to provide a visional analysis. Exhibits 1 and 2 show monthly rates for inpatient acute days and emergency department visits per dually eligible beneficiary fully eligible in that month. Although substantial seasonal variation is apparent over the seven years shown in these charts, visual inspection does not reveal any change in trend at January 2006, indicated by the red diamond, for either of these important indicators of adverse events.[10]

[10] A regression of the natural logarithm of each outcome variable on a monthly time trend, a month indicator for seasonality and an indicator for observations in the post-Part D period revealed that inpatient episodes per beneficiary were 3.6% lower in the post-Part D period while emergency department visits per user were not significantly different under Part D after accounting for trend (which was significantly negative for hospitalizations and positive for ED use) and seasonality (which showed significant differences among months of the year). The impact of the Part D period was significant at $p<.001$ for the hospitalization rate. Because of anomalous observations, the first and last observations in the hospitalization exhibit are extrapolated.

Exhibit 1: Inpatient Acute Hospitalizations per Month Per Enrolled Beneficiary, 2001 – 2007

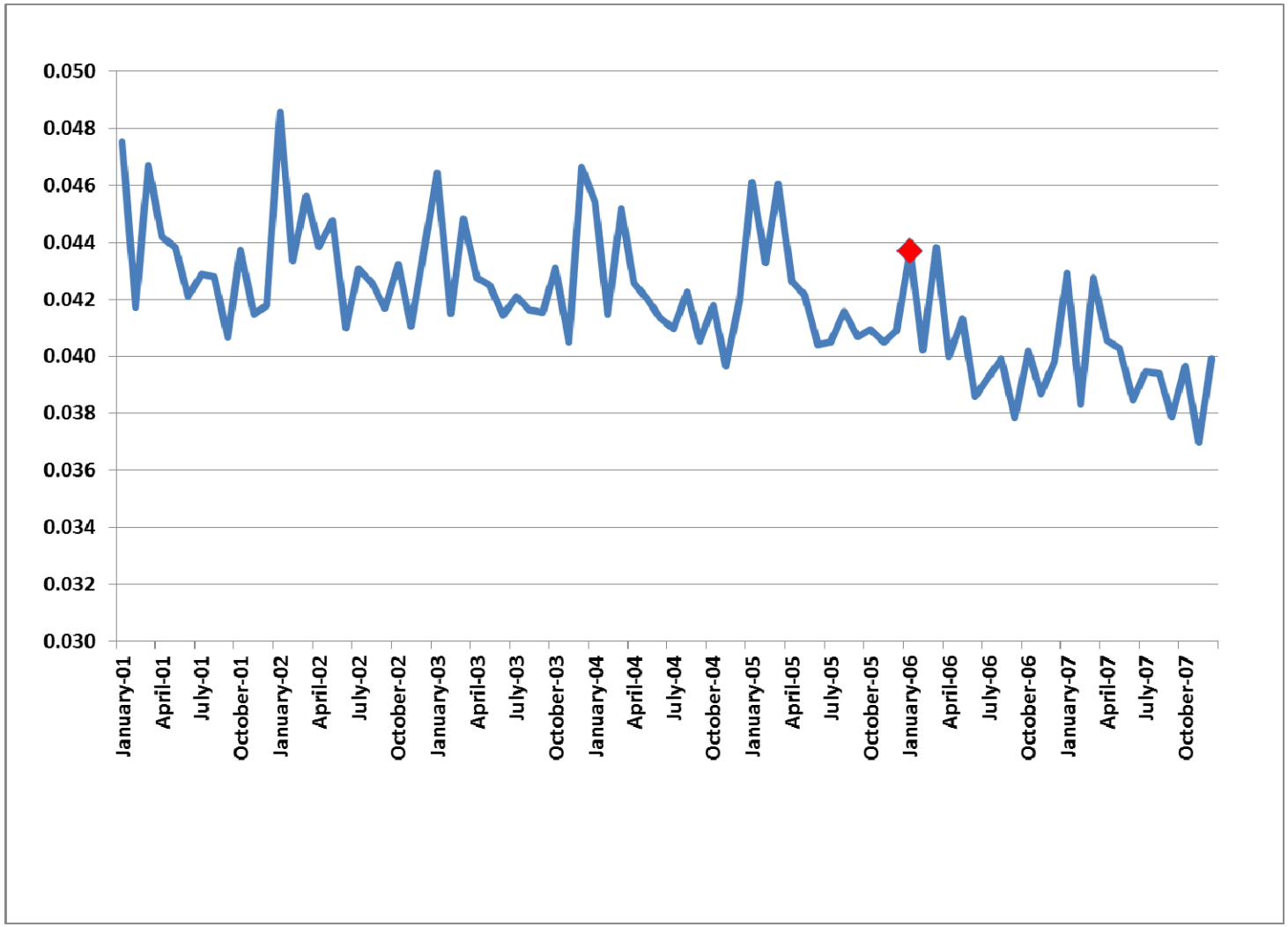
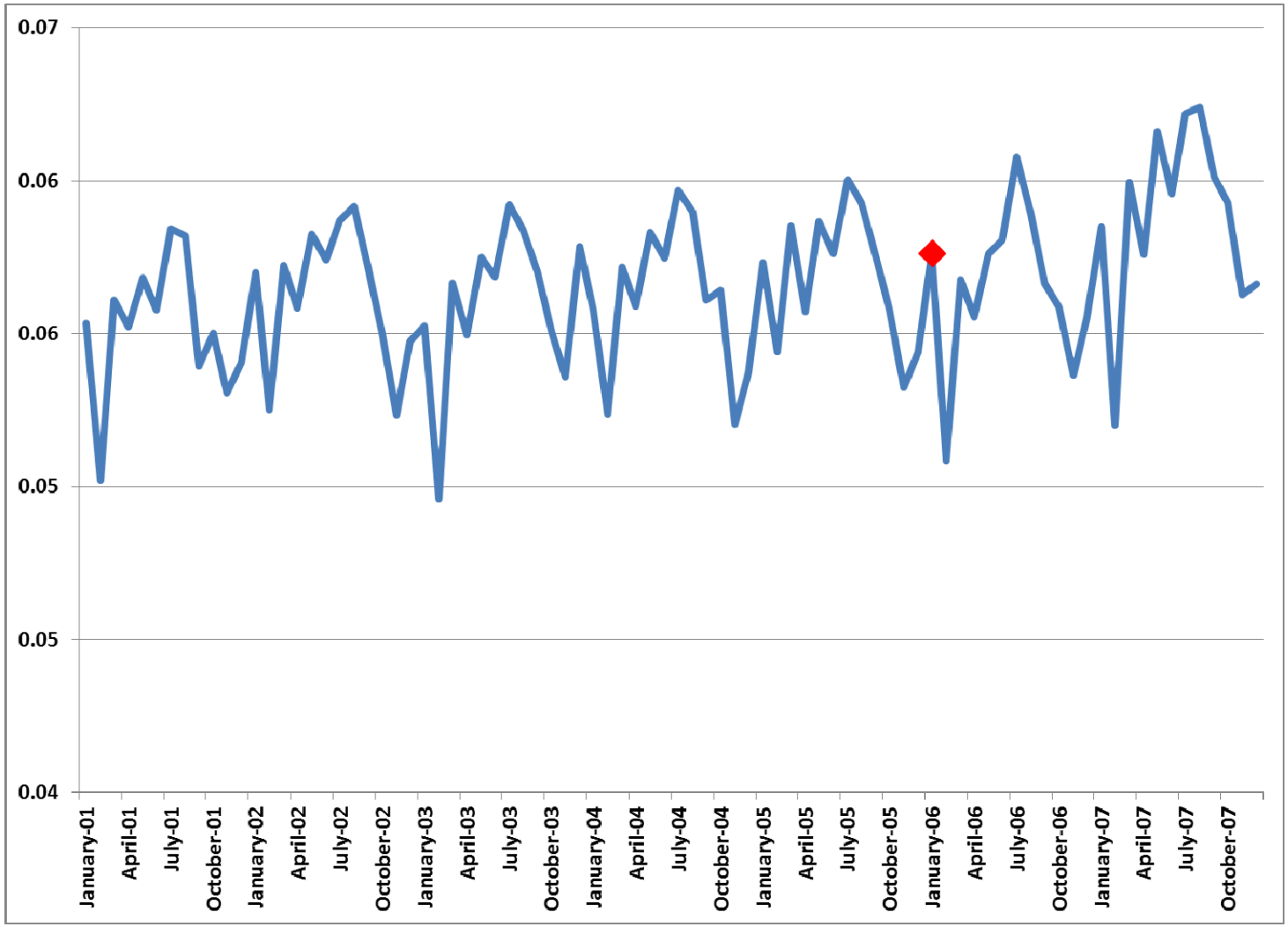


Exhibit 2: Emergency Department Use per Month Dually Enrolled Beneficiary, 2001 - 2007


0.07
0.06
0.06
0.05
0.05
0.04
January-01
April-01
July-01
October-01
January-02
April-02
July-02
October-02
January-03
April-03
July-03
October-03
January-04
April-04
July-04
October-04
January-05
April-05
July-05
October-05
January-06
April-06
July-06
October-06
January-07
April-07
July-07
October-07

3.2 Comparison of Means

The sample restricted to beneficiaries who were full dual eligibles for the entire prior year includes 981,394 annual observations for years 2002 through 2006 on 324,168 different individual Medicare beneficiaries. 212,128 annual observations, or 21.6% of the observations, were for 2006, the year after Medicare Part D was implemented.

Means for outcome variables for the pre-implementation period and the post-implementation period are compared in Exhibit 3. (These are presented for each year in Appendix Exhibit A-1.)

Of the six continuous outcome measures (inpatient acute episodes, inpatient acute days, outpatient emergency department encounters, general physician encounters, specialist physician encounters, and ambulatory care sensitive inpatient episodes) only one (specialist physician encounters) shows a significant increase when 2006 rates of use are compared to utilization in the previous five years. The estimated increase of 263 visits per thousand beneficiaries represents a 4.3% increase over the base period of 2001 through 2005.

None of the three indicator variables (any emergency department use; any hospital admission; nursing home entry) increased significantly in 2006 over the previous period.

Of the HCUP-identified ambulatory care sensitive hospitalizations, one (urinary tract infections, UTI) showed an increase in the rate that reaches statistical significance. Again the increase is small but meaningful, approximately 5% increase in the rate per thousand beneficiaries for this type of hospitalization.

Several of the measures chosen to reflect outcomes show a significant and meaningful *decrease* between 2006 and the base years. Most notable are inpatient acute days per thousand, number of beneficiaries experiencing a hospitalization, and total ambulatory care sensitive hospitalizations as defined by HCUP. Among the ambulatory care sensitive hospitalizations, hospitalization rates fell for dehydration, pneumonia, angina, chronic obstructive pulmonary disease (COPD), congestive heart failure (CHF) and uncontrolled diabetes. Each of these is arguably sensitive to accessibility to prescription drugs, so the fact that these and almost all the other ambulatory care sensitive hospitalization rates (with the exception of UTI) are not

significantly changed or are even falling suggests that the transition to Part D did not reduce access to prescription drugs.

The fee-for-service dually-eligible population encompassed in the full cohort analysis is made up of a number of special populations with substantial medical need. In most states, the dually eligible include both poor individuals and those who become eligible for Medicaid when their medical needs outstrip their ability to pay. Thus the dually eligible population has substantially more medical need than the general Medicare population, with high concentration in certain chronically ill and high frailty populations. Exhibit 4 presents monthly utilization rates for a variety of high risk dual sub-populations that are either reliant on outpatient pharmacy therapies for disease management or are likely to be cognitively challenged.

The exhibit shows that, as observed in the total population, the average monthly utilization rates in the selected high risk subgroups are for the most part not substantially different in the cohort that experienced the Part D transition. Beneficiaries with a congestive heart failure diagnosis in the previous year had elevated rates of outpatient emergency department use and elevated rates of hospital admissions in 2006, but did not have significantly greater numbers of hospital days. Beneficiaries with a diagnosis of dementia or schizophrenia in the previous year had slightly elevated adverse outcomes in the 2006 period, but these differences do not achieve statistical significance and are very small. In contrast, for five of the eight conditions (cancer, MR/DD, chronic respiratory disease, diabetes and high frailty), rates of adverse outcomes *fell* in 2006, and some of these differences were statistically significant.

Exhibit 3: Outcomes for Dual Eligible Cohorts

Value	2002-2005		2006		Difference in Means Post less Pre-Part D	Significance
	Mean	Standard Deviation	Mean	Standard Deviation		
N	769,266		212,128			
Enrolled Months per beneficiary	11.52	1.90	11.56	1.82	-0.04	p<.0001
Annual Inpatient Acute Episodes Per 1,000	469	1012	468	1018	-0.9	ns: p<0.713
Annual Inpatient Acute Days Per 1,000	3433	9535	3320	9269	-113.4	p<.0001
Annual Outpatient Emergency Room Encounters Per 1,000	633	1805	633	1746	0.29	ns :p<0.946
General Physician Encounters Per 1,000	5312	6264	5330	6796	18	ns: p<0.278
Specialist Physician Encounters Per 1,000	6070	8150	6332	8472	263	<.0001
Annual Ambulatory Care Sensitive Inpatient Episodes per 1000	105	356	96	338	-9.2	<.0001
Any ED Use Per 1,000	307	461	304	460	-3.6	0.0016
Any Hospital Admission Per 1,000	276	447	272	445	-3.5	0.0014
Nursing Home Entry Per 1,000†	53	223	47	211	-6	<.0001
HCUP Dehydration Per 1,000	8	91	7	81	-1.9	<.0001
HCUP Pneumonia Per 1,000	27	162	24	153	-2.8	<.0001
HCUP UTI Per 1,000	14	116	14	119	0.66	0.0218
HCUP Perforated Appendix Per 1,000	0	16	0	16	-0.00185	ns: p<0.962
HCUP Angina Per 1,000	1	36	1	29	-0.5	<.0001
HCUP Asthma Per 1,000	5	69	5	70	.15	ns: p<0.381

Value	2002-2005		2006		Difference in Means Post less Pre-Part D	Significance
	Mean	Standard Deviation	Mean	Standard Deviation		
HCUP COPD Per 1,000	15	123	13	114	-2.2	<.0001
HCUP CHF Per 1,000	23	149	21	143	-1.9	<.0001
HCUP Diabetes STC Per 1,000	1	37	1	35	-0.1	ns: p<0.206
HCUP Uncontrolled Diabetes Per 1,000	1	36	1	33	-0.2	p<0.0067
HCUP Diabetes LTC Per 1,000	6	77	6	76	-0.2	ns: p<0.395
HCUP Hypertension Per 1,000	2	43	2	42	-0.1	ns: p<0.413
HCUP Lower extremity amputation Per 1,000	2	38	1	36	-0.1	ns: p<0.105

N = 981,384 except see †

†Nursing home entry analysis is for beneficiaries aged 65+ who are not observed to use nursing home care in the second half of the prior year ; N=475,967 = 373,790 (2002-2005) + 102,177 (2006)

ED: Emergency Department

HCUP: Hospital Cost and Utilization Project, (Agency for Healthcare Research and Quality 2010)

UTI: Urinary Tract Infection

COPD: Chronic Obstructive Pulmonary Disease

CHF: Congestive Heart Failure

STC: Short Term Complications

LTC: Long Term Complications

Exhibit 4: Monthly Mean Continuous Outcomes for 2002-2005 and 2006 by Diagnosis Subgroup

Population Sub-Groups by Cohort	Number of Beneficiaries	Observation Year Months Mean	Outpatient Annual ED Encounters Per 1,000 Beneficiaries Mean	Inpatient Acute Days Annual Per 1,000 Beneficiaries Mean	Inpatient Annual Acute Episodes Per 1,000 Beneficiaries Mean
Dementia 2002-2005	99,665	10.53	560	5,179	652
Dementia 2006	27,661	10.62	577	5,198	672
Cancer 2002-2005	77,707	11.07	640	5,112	670
Cancer 2006	21,671	11.13	612	4,958	665
Schizophrenia 2002-2005	50,164	11.70	1,006	3,302	416
Schizophrenia 2006	13,988	11.73	1,052	3,311	433
MR/DD 2002-2005	49,214	11.70	736	3,051	382
MR/DD 2006	13,669	11.73	728	2,946	376
Congestive Heart Failure 2002-2005	140,435	10.83	774	7,515	964
Congestive Heart Failure 2006	37,655	10.87	776**	7,592	1,003**
Diabetes 2002-2005	236,628	11.39	738	5,196	681
Diabetes 2006	70,010	11.44	725***	4,996	674
Chronic Respiratory Disease 2002-2005	208,435	11.29	932	5,652	758
Chronic Respiratory Disease 2006	60,979	11.35	920***	5,471	756
High Frailty 2002-2005	358,332	11.31	827	4,760	645
High Frailty 2006	101,646	11.37	816***	4,592	638

** p<.05 for difference between 2006 mean and 2001-2005 mean

*** p<.01 for difference between 2006 mean and 2001-2005 mean

ED: Emergency Department

MR/DD: Mental Retardation/ Developmental Disability

In Exhibits 5 and 6, monthly outcomes are presented for dually eligible beneficiaries with two relatively common combinations of disability and disease to provide examples of the experience of very high risk groups before and after the Part D transition period. Impacts for these two vulnerable subpopulations are presented as examples; similar analysis could be carried out for other subpopulations of special interest. The first example population is dual eligible beneficiaries aged less than 65 with both schizophrenia and a diagnosis of a chronic respiratory disease, e.g. asthma, emphysema, chronic bronchitis or COPD. The second example population consists of beneficiaries with a dementia diagnosis, living in a community setting and reporting a diagnosis for chronic ischemic heart disease. Neither of these very ill groups of dual beneficiaries experienced significant increases in outpatient emergency department encounters, acute hospitalizations or acute inpatient days.

Exhibit 5: Continuous Outcomes: Under 65, Schizophrenia and COPD

Value	2002-2005		2006		Difference in Means Post less Pre-Part D	Significance
	Mean	Standard Deviation	Mean	Standard Deviation		
N	9476		2884			
Enrolled Months per Beneficiary in Outcome Year	11.79	1.26	11.78	1.34	-0.01	ns: p<0.8001
Annual Outpatient Emergency Room Encounters Per 1,000	2023.4	5320.6	1956.3	4156.3	-67.1	ns: p<0.5339
Annual Inpatient Acute Days Per 1000	4914.5	12525	4699.7	11754	-214.8	ns: p<0.4135
Annual Inpatient Acute Episodes Per 1,000	660.2	1388.3	672.7	1370.7	12.5	ns: p<0.6715

Exhibit 6: Continuous Outcomes: Over 65, Dementia, CHF Community Resident

Value	2002-2005		2006		Difference in Means Post less Pre-Part D	Significance
	Mean	Standard Deviation	Mean	Standard Deviation		
N	7197		2185			
Enrolled Months per beneficiary	10.55	3.23	10.76	2.98	0.21	p<0.0064
Annual Outpatient Emergency Room Encounters Per 1,000	845.9	1845.3	905.7	2567.8	60	ns: p<0.2292
Annual Inpatient Acute Days Per 1000	7566.6	13060	7235.7	13988	-330.9	ns: p<0.3077
Annual Inpatient Acute Episodes Per 1,000	992.6	1416.1	1002.7	1377.1	10	ns: p<0.7686

***** Community status: not **observed to use nursing home care in the second half of the prior year**, and no nursing home entry during the observation year.

3.3 Multivariate Panel Data Analysis

Comparison of means is somewhat informative, but as described in the Methods section (Multivariate Panel Data Analysis, page 6) it is important to adjust outcomes for any differences in beneficiary characteristics before and after implementation and for trends. The characteristics and number of beneficiaries meeting the criteria for the years prior to and after Part D implementation are shown in Exhibit 7. (Descriptive statistics are presented for each annual cohort in Appendix Exhibit A-2.) Although much remains the same, there are some differences in these characteristics for the pre-Part-D and the post-Part-D dually eligible population. Specifically, the Exhibit reveals that a smaller proportion of the duals in 2006 were diagnosed with congestive heart failure, were observed to use nursing home care in the second half of the prior year, and were eligible for Medicare as Aged; further, a smaller proportion of duals eligible in 2005 died in 2006 than in previous years. The duals observed for 2006 also had higher rates of diabetes, cancer, neurodisability, Parkinson's, and chronic obstructive pulmonary disease. In addition, they were more often found in the highest category of illness severity as indicated by the prescription drugs they obtained in the previous year (RxRisk index). These differences underline the value of multivariate analysis that adjusts for as many risk factors as possible.

Exhibit 7: Demographic and Health Descriptors for Dually Eligible Cohorts, 2002-2005 vs. 2006

Variable Name	All	2002-2005	2006	Significance
N=	981,394	769,266	212,128	--
Alzheimer's/Dementia in base year	0.130	0.130	0.130	ns: p<0.309
Schizophrenia in base year	0.065	0.065	0.066	ns: p<0.229
Mental Retardation/ Developmentally Disability in base year	0.064	0.064	0.064	ns: p<0.442
Neurodisability in base year	0.217	0.217	0.220	p<0.0021
Cancer in base year	0.101	0.101	0.102	ns: p<0.123
Parkinson's in base year	0.023	0.023	0.023	p<0.075
CHF in base year	0.181	0.183	0.178	p<.0001
Diabetes in base year	0.312	0.308	0.330	p<.0001
COPD in base year	0.275	0.271	0.287	p<.0001
RxRisk category=0	0.225	0.223	0.234	p<.0001
RxRisk category 1-3	0.122	0.124	0.112	p<.0001
RxRisk category 4-6	0.184	0.187	0.175	p<.0001
RxRisk category 7-9	0.469	0.466	0.479	p<.0001
Used nursing home care in the second half of the prior year	0.179	0.183	0.164	p<.0001
Female	0.647	0.649	0.638	p<.0001
Male	0.353	0.351	0.362	p<.0001
Age <65	0.368	0.363	0.385	p<.0001
Age 65-74	0.250	0.252	0.243	p<.0001
Age 75-84	0.243	0.244	0.238	p<.0001
Age 85+	0.139	0.140	0.134	p<.0001
White	0.677	0.675	0.687	p<.0001
Black	0.222	0.224	0.215	p<.0001
Hispanic	0.053	0.054	0.049	p<.0001
Other Race	0.048	0.047	0.049	p<0.016
Rural	0.334	0.333	0.337	p<0.0018
Died in outcome year	0.080	0.082	0.076	p<.0001

For the continuous outcome variables, the impact of the implementation of part D, estimated using the natural logarithm of the dependent variable in models fitted for the full dually eligible study group (N= 981394 person years, for 324,168 beneficiaries) is summarized in Exhibit 8.[11] The impact of Part D, shown by the coefficient for the 2006 outcomes, is significant and negative after a continuous annual trend and other factors, listed in the previous table, are taken into account. This shows that dual eligibles used significantly fewer hospital days, emergency department visits, general practitioner visits and specialist visits in 2006 than in previous years after adjusting for other factors including trend.

For the dichotomous outcome variables, the impact of the implementation of Part D, estimated in models fitted for the full dually eligible study group is summarized in Exhibit 9. This Exhibit reports the estimated odds ratios computed from the coefficients for the indicator for the 2006 year, i.e. the impact observed after implementation, for each logistic regression analysis. The method of general estimating equations (GEE) accounts appropriately for the fact that one beneficiary meeting the criteria for more than one cohort contributes multiple observations to the analysis.[12] None of the three major outcomes, hospital admissions, ED use and nursing home entry, show any significant increase for the outcome year 2006 in comparison to previous years, consistent with no significant worsening of outcomes for dual beneficiaries under Part D. Dually eligible beneficiaries were significantly less likely to visit the emergency department or to have a hospital admission for dehydration, pneumonia or congestive heart failure. However, consistent with the descriptive findings, the Part D implementation year is associated with a significantly greater risk of hospitalization for urinary tract infections, after accounting for beneficiary demographics.

[11] This analysis does not account for multiple observations on the same individual.

[12] These analyses did not include a time trend.

Exhibit 8: Estimated Effects of Part D Implementation, Continuous Outcomes Accounting for Annual Trend

Outcome (natural log)	Impact of Part D	Standard Error	t	Significance
Inpatient Acute Episodes	-0.029	0.007	-3.96	<.0001
Inpatient Acute Days	-0.044	0.010	4.42	<.0001
Outpatient Emergency Room Encounters	-0.013	0.008	-1.68	0.093
General Physician Encounters	-0.096	0.008	-11.29	<.0001
Specialist Physician Encounters	-0.027	0.009	-3.1	0.002
Medicare Skilled Nursing Facility Days	-0.021	0.007	-2.86	0.004

N= 981,394 person years

Source: Impact is coefficient for indicator of Part D (2006) in ordinary least squares regressions using the natural logarithm of each outcome (plus .01) as the dependent variable and including all independent variables achieving a significance level of p<..5.

Exhibit 9: Effect of Part D Implementation on Likelihood of Outcome

Outcome Variable	Odds Ratio (95% confidence interval)	Percent with Outcome
Any Hospital Admission:	1.00 (0.99-1.01)	27.51%
Any ED Use	0.96 (0.95-0.97)	30.65%
Nursing Home Entry*	0.88 (.86-.91)	5.12%
HCUP Dehydration	0.76 (0.72-0.81)	0.80%
HCUP Pneumonia	0.89 (0.87-0.92)	2.62%
HCUP UTI	1.05 (1.01-1.09)	1.38%
HCUP Perforated Appendix	--	0.02%
HCUP Angina	--	0.12%
HCUP Asthma	--	0.48%
HCUP COPD	--	1.50%
HCUP CHF	0.95 (0.92-0.98)	2.24%
HCUP Diabetes STC		0.13%
HCUP Uncontrolled Diabetes	--	0.12%
HCUP Diabetes LTC		0.59%
HCUP Hypertension	--	0.18%
HCUP Lower extremity amputation	--	0.14%

N= 981,394 person years for all analyses except nursing home entry*

*Population at risk of nursing home entry is beneficiaries aged 65 and older who are not observed to use nursing home care in the second half of the prior year; N = 475,967

Source: Coefficient for indicator of Part D in general estimating equation logistic regressions using each outcome as the dependent variable, including all independent variables achieving a significance level of $p<.5$, and accounting for multiple observations on beneficiaries.

Blank table cells indicate there was no significant difference between the transition year and comparison years.

ED: Emergency Department

HCUP: Hospital Cost and Utilization Project, (Agency for Healthcare Research and Quality 2010)

UTI: Urinary Tract Infection; COPD: Chronic Obstructive Pulmonary Disease

CHF: Congestive Heart Failure

STC: Short Term Complications

LTC: Long Term Complications

Estimates of Impact of Part D for Dual Subpopulations

Because of the concern that some dually eligible subpopulations might be especially vulnerable to disruptions in access to prescription medicines, analyses were also conducted for subpopulations. Exhibit 10 reveals that Disabled dually eligible beneficiaries with schizophrenia, developmental disabilities or cancer, and Aged dual beneficiaries with Alzheimer's disease or dementia, Parkinson's disease, chronic obstructive pulmonary disease or diabetes did not experience significantly more inpatient hospital stays or outpatient emergency department visits. Hospitalization became slightly more likely for beneficiaries with congestive heart failure.

Finally, the estimation indicates that dual beneficiaries observed to use nursing home care in the second half of the prior year were more likely to be hospitalized after Part D implementation.

Exhibit 10: Effect of Part D Implementation on Likelihood of Outcome, Selected Populations

Population, Outcomes	N	GEE Estimation Odds Ratio (95% confidence interval)
Aged < 65, Schizophrenia		
Any Hospital Admission	46,869	0.99 (0.94-1.04)
Any ED Use	46,869	0.99 (0.95-1.03)
Nursing Home Entry	39,836	0.86 (0.78-.0.95)
Aged <65 with MR or DD		
Any Hospital Admission	49,414	0.97 (0.92-1.02)
Any ED Use	49,414	0.95 (0.91-0.99)
Nursing Home Entry	36,018	0.80 (0.71-0.91)
Aged <65 with Neurodisability		
Any Hospital Admission	59,107	0.95 (0.91-0.99)
Any ED Use	59,107	0.96 (0.93-1.00)
Nursing Home Entry	45,780	
Aged <65 with Cancer		
Any Hospital Admission	19,117	0.92 (0.85-0.98)
Any ED Use	19,117	0.92 (0.86-0.99)
Nursing Home Entry	17,438	0.71 (0.57-0.89)
Aged 65+ with Alzheimer's/Dementia		
Any Hospital Admission	116,051	1.00 (0.97-1.03)
Any ED Use	116,051	0.95 (0.92-0.98)
Nursing Home Entry	36,150	0.85 (0.80-0.91)
Aged 65+ with Parkinson's		
Any Hospital Admission	20,585	1.06 (0.99-1.14)
Any ED Use	20,585	1.03 (0.96-1.10)
Nursing Home Entry	7,934	0.88 (0.76-1.03)
Aged 65+ with Congestive Heart Failure		
Any Hospital Admission	147,457	1.03 (1.01-1.06)
Any ED Use	147,457	0.95 (0.93-0.98)
Nursing Home Entry	91,815	0.87 (0.82-0.92)
Aged 65+ with Chronic Obstructive Pulmonary Disease		
Any Hospital Admission	178,242	1.01 (0.98-1.03)
Any ED Use	178,242	0.95 (0.93-0.98)

Population, Outcomes	N	GEE Estimation Odds Ratio (95% confidence interval)
Nursing Home Entry	134,584	0.84 (0.80-0.89)
Aged 65+ with Diabetes		
Any Hospital Admission	218,720	1.00 (0.98-1.02)
Any ED Use	218,720	0.96 (0.94-0.98)
Nursing Home Entry	164,485	0.82 (0.78-0.87)
Used Nursing Home Care in Second Half of **Base Year**		
Any Hospital Admission	144,393	1.04 (1.01-1.07)
Any ED Use	144,393	0.97 (0.94-1.00)

* Observations (N) are beneficiary-years; average number of beneficiaries in any year is one-fifth of stated N. Nursing home entry analysis is restricted to beneficiaries not observed to use nursing home care in the second half of the prior year.

4 Summary and Discussion

Graphical presentation of monthly outcomes for all dually eligible beneficiaries over a seven year period did not show a marked change in pattern for outcomes of interest. Comparison of means for consistently defined annual cohorts revealed evidence that use of specialty physicians increased significantly in the year Part D was implemented. Comparison of means showed no significant increase in the rate of ambulatory care sensitive hospitalizations except for urinary tract infection. Comparison of means for subgroups expected to be especially vulnerable to changes in access to prescription drugs showed that ED encounters and inpatient stays rose significantly for dually eligible beneficiaries with congestive heart failure; but ED use declined significantly for beneficiaries with chronic respiratory disease and high frailty, and was not significantly different for any other special group examined.

Multivariate analysis to adjust impacts for any change in the mix of beneficiaries from year to year revealed strong negative impacts of Part D implementation on all the continuous utilization variables (inpatient acute episodes, inpatient acute days, outpatient emergency department encounters, general physician encounters and specialist physician encounters). For the dichotomous outcome variables, the results remain similar to those found in comparison of means: ambulatory care sensitive hospitalization for UTI is more likely after implementation of

Part D. However, hospital admissions were not significantly affected by Part D, and the probability of using the emergency department was significantly lower after Part D implementation. Similar results are seen for subpopulations with complex needs and multiple diagnoses: poorer outcomes are, with a few exceptions (hospital admission for those aged 65 and older with congestive heart failure and for those observed to use nursing home care in the second half of the prior year), not significantly associated with the Part D year. But there are also unexpected positive results: beneficiaries aged less than 65 with a cancer diagnosis were less likely to experience a hospitalization, an ED visit, or nursing home entry in 2006; beneficiaries aged 65 and older with congestive heart failure were significantly less likely to use the ED in 2006, even though they were significantly more likely to be hospitalized. No significant impact on the measured health outcomes was observed for several populations considered at great risk by observers at the time of implementation, namely dually eligibles with schizophrenia, those with developmental disabilities, those with neurodisability, those with Alzheimer's/ dementia, and those with Parkinson's.

One vulnerable population, beneficiaries observed to use nursing home care in the second half of the prior year, was found in multivariate analysis adjusting for other factors (but not for trends) to be more likely to experience a hospitalization in 2006. However, this finding may not represent a true deterioration of health outcomes under Part D. As noted above, the method used to identify the nursing home population may have been overly inclusive, and certainly includes users of post-acute services, who are very likely to be rehospitalized. The mix of post-acute and long-stay nursing home residents may be changing over time in a manner not captured by beneficiary characteristics available to this study. In addition, access to prescription drugs did not change for beneficiaries using SNF services, because drugs are included in the Medicare SNF service.

This study joins several others which have taken varying approaches to early assessment of the impact of Part D on health outcomes for varying populations (Zhang, Donohue et al. 2009; Ingber, Greenwald et al. 2010; Kaestner and Khan 2010). In contrast to this study, their hypothesis has been that beneficiaries who gained insurance coverage through Part D would experience an improvement in health and reduction of utilization of other health services. This hypothesis has not been supported to date. We find, in contrast, that for a group of beneficiaries

who previously received prescription drug insurance coverage from Medicaid programs, a few health services utilization measures have increased suggesting worsening health outcomes, but most utilization-based outcome measures have improved or shown no significant change.

Other researchers have begun to address the impact of the transition to Part D on access to prescription drugs (linked to health outcomes) for dually eligible beneficiaries (Basu, Yin et al. 2010; Kaestner and Khan 2010). As noted above, the impact on realized access for dually eligible beneficiaries is the subject of a companion study in this project.

Limitations

Panel data analyses must be undertaken with care because changes in payment policy and clinical practices over time have an impact on specific utilization rates. This limitation is not addressed by a time trend, which assumes that effects over time are monotonic. Unaccounted for changes in population health, policies unrelated to Medicare Part D or care practices could lead to a finding of significant difference for the post-implementation year that is not necessarily attributable to Part D implementation. Inclusion of cross section data for five outcome years militates against this, by reducing the probability that aberrations in any one year will influence the analysis.

Directions for Future Research

The analysis here treats a policy intervention, the implementation of Part D, as a "black box" that is expected to have impacts on health outcomes, represented here by the utilization of other health services, for the population under study. This study did not investigate the mechanism of action of this policy intervention, which may have changed access (positive or negative) to prescription drugs for this population. The most important next step for research is to investigate whether the impacts identified by this study, mostly favorable reductions in health services utilization, can be attributed to a change in access to prescription drugs. This is feasible for the population under study, because in contrast to many other groups, prescription drug data is available for both the pre- and post-Part D periods for the dually eligible population -- from Medicaid claims prior to part D and from prescription drug event (PDE) data after implementation. Indeed, a companion analysis to this work presents initial descriptive analysis of rates of therapy initiation and discontinuation by class of drug for years 2004 through 2007, as

a first step toward a full analysis of the impact of Part D on access to and utilization of classes of prescription drugs.

Because impact on access likely differs by state, due to initial differences in the restrictiveness or generosity of Medicaid prescription drug programs, analyses of outcomes should be carried out for certain large states; research should also investigate any changes in utilization of prescription drugs by state. In-depth state analysis was beyond the scope of the current study. Several other studies are underway, funded by other funders, which will address some aspects of this issue.

Additional refinements to the analysis reported here that should be carried out include: further investigation of trend and seasonal effects in the monthly data reported in Exhibits 1 and 2; extension of the multivariate analyses to additional years, which would require use of Medicare PDE drug claims to assign beneficiaries to RxRisk groups for years after 2005; inclusion of a time trend in all the multivariate analyses; adjustment of the multivariate analyses for the continuous dependent variable outcomes (Exhibit 8) for the repeated measures on individual beneficiaries; and exploration of the impact of methods appropriate to count dependent variables for the analyses involving number of hospitalizations, ED visits, and hospital days. Any changes in the probability of death due to Part D should also be investigated by using death as a dependent outcome variable.

5 Policy Implications

By building a lengthy baseline period for defined subpopulations of dually eligible beneficiaries, this study has introduced and implemented an approach that was able to follow these populations as they moved from Medicaid prescription drug coverage to Part D coverage. In the absence of a control group, this appears to be a viable systematic method for monitoring the impact of Part D for the dually eligible population. This approach to tracking impacts could and should be continued for several additional years. The approach could also be applied in other situations where a policy has the potential to alter the links between beneficiary characteristics and health outcomes.

Results of this study provide strong indication that, contrary to the fears of a number of observers, Part D was for the most part implemented without major negative health impacts for

dually eligible beneficiaries. This was perhaps due in part to the autoenrollment policy that assured that every dually eligible beneficiary was enrolled in a prescription drug plan before Part D took effect and, in addition, the efforts of various states to support access to prescription drugs for dually eligible beneficiaries during the transition. All involved should feel relieved that the axiom for physicians "to do no harm" also appears to have been achieved in the implementation of this path-breaking reform. There were many opportunities for errors and disasters, but these either did not occur or did not reach a level of disruption that affected health outcomes that could be measured with the proxies used here. The study did uncover several adverse trends which may be exceptions to this overall rosy picture. These should be investigated further, to determine whether further policy intervention is needed to protect access for certain vulnerable groups.

Beyond the neutral finding of little significant worsening of health outcome measures, the study revealed a number of unexpectedly favorable significant impacts, for example lower hospital admissions and emergency department use. Further investigation is needed to determine whether improved outcomes were more likely for beneficiaries who moved from the restrictive drug coverage provided by certain state Medicaid plans to more generous coverage under Part D; and to document any impact on prescription drug access and utilization for these populations, which would support attribution of these effects to the transition to Part D.

Similar ongoing research based on this approach may be considered as a way to continue to assess the longer range impact of Part D on Medicare and Medicaid dually eligible beneficiaries over time, assessing, for example, whether lower hospital admissions continue to be achieved.

In the longer run, savings in health services resources represent savings to Medicare. Previous studies have shown that increased insurance coverage for prescription drugs leads to increased utilization of drugs but not to better health outcomes nor to reduction in other health costs. It is possible that for the subpopulations that make up the dually eligible, with their high rates of disability, chronic illness and advance age, the payoff of better access to prescription drugs will instead provide net savings to Medicare.

Appendix Exhibits

Exhibit A-1: Outcomes for Dual Eligible Cohorts, 2002-2006

Outcome Variable Name	2002	2003	2004	2005	2006
N	169,644	176,909	209,261	213,452	212,128
Enrolled Months per beneficiary	11.48	11.52	11.54	11.53	11.56
Medicare Expenditures per Beneficiary in Year	$ 8,690	$ 9,144	$ 9,858	$ 10,551	$ 11,018
Annual Inpatient Acute Episodes Per 1,000	469	467	466	475	468
Annual Inpatient Acute Days Per 1,000	3514	3428	3382	3423	3320
Annual Outpatient Emergency Department Encounters Per 1,000	631	633	628	638	633
General Physician Encounters Per 1,000	5135	5297	5391	5389	5330
Specialist Physician Encounters Per 1,000	5933	5929	6121	6244	6332
Annual Ambulatory Care Sensitive Inpatient Episodes per 1000	111	108	101	102	96
Any Emergency Department Use Per 1,000	308	307	306	308	304
Any Hospital Admission Per 1,000	275	274	275	279	272
Nursing Home Entry Per 1,000†	56	56	56	56	56
HCUP Dehydration Per 1,000	10	9	8	7	7
HCUP Pneumonia Per 1,000	29	28	24	27	24
HCUP UTI Per 1,000	14	13	13	14	14
HCUP Perforated Appendix Per 1,000	0	0	0	0	0
HCUP Angina Per 1,000	2	1	1	1	1
HCUP Asthma Per 1,000	4	5	5	5	5
HCUP COPD Per 1,000	17	16	15	14	13
HCUP CHF Per 1,000	23	23	23	22	21
HCUP Diabetes STC Per 1,000	2	1	1	1	1
HCUP Uncontrolled Diabetes Per 1,000	1	1	1	1	1

Outcome Variable Name	2002	2003	2004	2005	2006
HCUP Diabetes LTC Per 1,000	6	6	6	6	6
HCUP Hypertension Per 1,000	2	2	2	2	2
HCUP Lower extremity amputation Per 1,000	2	1	1	1	1

†Nursing home entry is computed only for beneficiaries not observed to use nursing home care in the second half of the prior year. Ns are

2002: 80,880; 2003: 84874; 2004: 103768; 2005:104,268; 2006: 102,177

HCUP: Hospital Cost and Utilization Project, (Agency for Healthcare Research and Quality 2010)

UTI: Urinary Tract Infection

COPD: Chronic Obstructive Pulmonary Disease

CHF: Congestive Heart Failure

STC: Short Term Complications

LTC: Long Term Complications

Exhibit A-2: Characteristics of Dual Eligible Outcome Cohorts, All Years

Variable Name	2002	2003	2004	2005	2006
N	169,644	176,909	209,261	213,452	212,128
Alzheimer's/Dementia in base year	13%	13%	13%	13%	13%
Schizophrenia in base year	7%	7%	6%	6%	7%
Mental Retardation/ Developmentally Disability in base year	7%	7%	6%	6%	6%
Neurodisability in base year	22%	22%	21%	22%	22%
Cancer in base year	10%	10%	10%	10%	10%
Parkinson's in base year	2%	2%	2%	2%	2%
CHF in base year	19%	18%	18%	18%	18%
Diabetes in base year	29%	30%	31%	32%	33%
COPD in base year	26%	27%	28%	28%	29%
RxRisk category=0	20%	21%	25%	23%	23%
RxRisk category 1-3	14%	13%	12%	12%	11%
RxRisk category 4-6	20%	19%	18%	18%	17%
RxRisk category 7-9	46%	47%	46%	48%	48%
Nursing home resident: observed to use nursing home care in the second half of the prior year	20%	19%	17%	17%	16%
Female	66%	65%	65%	64%	64%
Male	34%	35%	35%	36%	36%
Age <65	35%	36%	36%	37%	38%
Age 65-74	25%	25%	25%	25%	24%
Age 75-84	24%	24%	25%	24%	24%
Age 85+	15%	14%	14%	13%	13%
White	67%	66%	68%	68%	69%
Black	22%	23%	22%	22%	21%
Hispanic	6%	6%	5%	5%	5%
Other Race	5%	5%	5%	5%	5%
Rural	33%	33%	34%	34%	34%
Died in outcome year	9%	8%	8%	8%	8%

Literature Cited

Agency for Healthcare Research and Quality. (2010). "Agency for Healthcare Research and Quality (AHRQ) Quality Indicators " Retrieved 6/1/2010, 2010, from http://www.qualityindicators.ahrq.gov/index.htm.

Arizpe, M. (2006). "Managing depressed patients with comorbidities and dual-eligibility benefit status." J Manag Care Pharm **12**(2 Suppl): 24-29.

Bagchi, A. D., D. Esposito, et al. (2007). "Prescription drug use and expenditures among dually eligible beneficiaries." Health Care Financ Rev **28**(4): 43-56.

Barosso, G. (2006). Dual Medicare-Medicaid Enrollees and the Medicare Denominator File. Minneapolis, MN, Research Data Assistance Center, University of Minnesota.

Basu, A., W. Yin, et al. (2010). "Impact of Medicare Part D on Medicare-Medicaid dual-eligible beneficiaries' prescription utilization and expenditures." Health Serv Res **45**(1): 133-151.

Centers for Medicare and Medicaid Services. (2010). "Monthly Contract Summary and Total Report, April 2010." Retrieved 5/18/2010, 2010, from http://www.cms.gov/MCRAdvPartDEnrolData/MCESR/itemdetail.asp?filterType=none&filterByDID=-99&sortByDID=2&sortOrder=descending&itemID=CMS1234511&intNumPerPage=10.

Crowley, J. S., D. Ashner, et al. (2005). State Medicaid Outpatient Prescription Drug Policies: Findings from a National Survey, 2005 Update, Kaiser Family Foundation.

Cunningham, P. J. (2005). "Medicaid cost containment and access to prescription drugs." Health Aff (Millwood) **24**(3): 780-789.

Donohue, J. M. and R. G. Frank (2007). "Estimating Medicare Part D's impact on medication access among dually eligible beneficiaries with mental disorders." Psychiatr Serv **58**(10): 1285-1291.

Donohue, J. M., H. A. Huskamp, et al. (2009). "Dual eligibles with mental disorders and Medicare part D: how are they faring?" Health Aff (Millwood) **28**(3): 746-759.

Fox, K. and L. Scholfield (2006). Pharmacy Coverage Safety Net: Variations in State Responses to Supplement Medicare Part D, University of Southern Maine, Edmund S. Muskie School of Public Service, Institute for Health Policy.

Friedman, B. and J. Basu (2004). "The rate and cost of hospital readmissions for preventable conditions." Med Care Res Rev **61**(2): 225-240.

Goldman, D. P. and G. F. Joyce (2008). "Medicare Part D: a successful start with room for improvement." Jama **299**(16): 1954-1955.

Goldman, D. P., G. F. Joyce, et al. (2007). "Prescription drug cost sharing: associations with medication and medical utilization and spending and health." Jama-Journal Of The American Medical Association **298**(1): 61-69.

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., Washington, DC: Henry J. Kaiser Family Foundation, Kaiser Commission on Medicaid and the Uninsured; June 2005. Report No. 7330.

Hall, J. P., N. K. Kurth, et al. (2007). "Transition to Medicare part D: an early snapshot of barriers experienced by younger dual eligibles with disabilities." Am J Manag Care **13**(1): 14-18.

HHoadley, J., J. Cubanski, et al. (2009). Medicare Part D Spotlight: Part D Plan Availability in 2010 and Key Changes Since 2006, Kaiser Family Foundation (KFF).

Huskamp, H. A., D. G. Stevenson, et al. (2007). "Coverage and prior authorization of psychotropic drugs under Medicare Part D." Psychiatr Serv **58**(3): 308-310.

Huskamp, H. A., J. C. West, et al. (2009). "Part D and dually eligible patients with mental illness: medication access problems and use of intensive services." Psychiatr Serv **60**(9): 1169-1174.

Ingber, M., L. Greenwald, et al. (2010). Medicare Part D Program Evaluation: Analysis of the Impact of Medicare Part D on the FFS Program, RTI International.

Jacobson, G. and G. Anderson (2010). "Medicare part D: ongoing challenges for doctors and patients." Annu Rev Med **61**: 469-476.

Jensen and Kaiser Commission on Medicaid and the Uninsured (2005). The New Medicare Prescription Drug Law: Issues for Enrolling Dual Eligibles into Drug Plans.

Kaestner, R. and N. Khan (2010). Medicare Part D and its Effect on the Use of Prescription Drugs, Use of Other Health Care Services and Health of the Elderly, National Bureau of Economic Research, Inc, NBER Working Papers: 16011.

Kaiser Commission on Medicaid and the Uninsured (2006). Dual Eligibles and Medicare Part D, Kaiser Commission on Medicaid and the Uninsured.

Kaiser Commission on Medicaid and the Uninsured (2006). The Transition of Dual Eligibles to Medicare Part D Prescription Drug Coverage: State Actions During Implementation, Kaiser Commission on Medicaid and the Uninsured.

Kaiser Family Foundation (2005). Medicare's New Prescription Drug Benefit: The Voices of People Dually Covered by Medicare and Medicaid.

Khan, N., R. Kaestner, et al. (2008). "Effect of Prescription Drug Coverage on Health of the Elderly." Health Serv Res.

Morden, N. E. and L. P. Garrison, Jr. (2006). "Implications Of Part D For Mentally Ill Dual Eligibles: A Challenge For Medicare." Health Aff **25**(2): 491-500.

Perneger, T. V. (1998). "What's wrong with Bonferroni adjustments." BMJ **316**(7139): 1236-1238.

Safran, D. G., M. K. Strollo, et al. (2010). "Prescription coverage, use and spending before and after part d implementation: a national longitudinal panel study." J Gen Intern Med **25**(1): 10-17.

Smith, V., K. Gifford, et al. (2006). The Transition of Dual Eligibles to Medicare Part D Prescription Drug Coverage: State Actions During Implementation, Kaiser Commission for Medicaid and the Uninsured.

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.

United States Department of Agriculture. (2004). "Measuring Rurality: Rural-Urban Continuum Codes." Retrieved 9/30, 2010, from http://www.ers.usda.gov/briefing/rurality/ruralurbcon/.

West, J. C., J. E. Wilk, et al. (2007). "Medication access and continuity: the experiences of dual-eligible psychiatric patients during the first 4 months of the Medicare prescription drug benefit." Am J Psychiatry **164**(5): 789-796.

West, J. C., J. E. Wilk, et al. (2010). "First-year Medicare Part D prescription drug benefits: medication access and continuity among dual eligible psychiatric patients." J Clin Psychiatry **71**(4): 400-410.

Wilk, J. E., J. C. West, et al. (2008). "Medicare Part D prescription drug benefits and administrative burden in the care of dually eligible psychiatric patients." Psychiatr Serv **59**(1): 34-39.

Yang, Z., D. B. Gilleskie, et al. (2009). "Health Insurance, Medical Care, and Health Outcomes: A Model of Elderly Health Dynamics." Journal of Human Resources **44**(1): 47-114.

Yin, W., A. Basu, et al. (2008). "The effect of the Medicare Part D prescription benefit on drug utilization and expenditures." Ann Intern Med **148**(3): 169-177.

Zhang, Y., J. M. Donohue, et al. (2009). "The effect of Medicare Part D on drug and medical spending." N Engl J Med **361**(1): 52-61.