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## Medicare Part D and Potentially Inappropriate Medication Use in the Elderly

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### Abstract

**Objective**—Inappropriate medication use, which is common in older adults, may be responsive to out-of-pocket costs. We examined the impact of Medicare Part D on inappropriate medication use among Medicare beneficiaries.

**Study design**—Pre-post with comparison group.

**Methods**—Using data from 34,679 elderly beneficiaries in Medicare plans from 2004-2007, we used Healthcare Effectiveness Data and Information Set (HEDIS) measures of prescribing quality: (1) any use of Drugs to Avoid in the Elderly (DAE), (2) proportion of total medication use attributable to DAEs, and (3) any Potentially Harmful Drug-Disease Interactions in the Elderly (DDE). Rates of inappropriate use among 3 groups transitioning from no drug coverage or limited coverage (\$150 or \$350 quarterly caps) to Part D in 2006 were compared to those with constant drug coverage.

**Results**—DAE use increased slightly among those moving from No Coverage to Part D (from 15.72% to 17.61%) whereas the comparison group's use decreased (20.97% to 18.32%) [Relative Odds Ratio (ROR) = 1.34, 95% CI 1.22-1.48,  $p < 0.0001$ ]. However, the proportion of total drug use attributable to DAEs declined among the No Coverage group after Part D (3.01% to 1.98%), a significant difference relative to the comparison group (ROR = 0.84, 95% CI 0.72-0.98,  $p = 0.03$ ). Rates of DDE were low (1%) both before and after Part D.

**Conclusions**—While use of high-risk drugs increased slightly among those gaining Part D drug coverage, high-risk drug use actually declined as a proportion of total drug use, and the prevalence of drug-disease interactions remained stable.

### Keywords

Medicare Part D; inappropriate medication use; drug-disease interactions; benefit design

## INTRODUCTION

Potentially inappropriate medication use, which is common in older adults, can lead to adverse drug events and may increase health care costs.<sup>1-4</sup> Little is known about the factors contributing to inappropriate medication use. In particular, we do not know whether prescription drug coverage influences the quality of prescribing or patients' likelihood of filling prescriptions for inappropriate medications; this gap in knowledge is important given the significant expansion in drug coverage brought about by the Medicare drug benefit (Part D).<sup>5</sup>

Part D, which provides drug coverage to 28 million beneficiaries, cut the number of older adults lacking drug coverage in half, reduced out-of-pocket costs,<sup>6</sup> increased prescription drug use,<sup>7</sup> and improved adherence to treatment of chronic conditions.<sup>8-10</sup> Less is known about Part D's effect on the quality of medication use. By making drugs more affordable, Part D may have increased inappropriate drug use. Alternatively, Part D could have decreased inappropriate use by increasing access to medication therapy management.<sup>11</sup> A previous study estimated the impact of Part D on potentially inappropriate medication use using the Beers criteria.<sup>12</sup> However, because that study compared Part D enrollees with all those not enrolling in Part D, most of whom had other sources of coverage, it likely underestimated the policy's effect among the previously uninsured.

We examined Part D's effect on potentially inappropriate medication use using two National Committee for Quality Assurance (NCQA) Healthcare Effectiveness Data and Information Set (HEDIS) quality measures: (1) use of Drugs to Avoid in the Elderly (DAE), and (2) Potentially Harmful Drug-Disease Interactions in the Elderly (DDE). First, we examined whether the likelihood of use of DAE and of DDE changed with Part D. Second, to gauge the net effect of Part D on the quality of pharmacotherapy (i.e., the extent to which it has increased inappropriate vs. appropriate medication use), we estimated the change in the proportion of total drug use attributable to DAEs.

## METHODS

**Data Source, and Sample, and Study Design**—We obtained claims (pharmacy and medical) and enrollment data from a large health insurer in Pennsylvania from 2004-2007 on a 40% sample (n=35,102) of members enrolled in the insurer's Medicare managed care products. The sample was selected at random based on member ID using the Proc Survey Select function in SAS. We included members in the study sample if they were continuously enrolled and filled at least one prescription in the insurer's network of approximately **65,000** pharmacies during the study period (n=34,679). This approach was used to minimize censoring of due to out-of-network pharmacy use.

Prior to Part D (2004-2005) members had one of four levels of prescription drug coverage through the insurer. Two groups had quarterly limits on drug costs covered by the plan of \$150 or \$350 beyond which beneficiaries paid 100% of costs. The level of the quarterly cap depended solely on the county of residence. These two groups are referred to hereafter as the "\$150 Cap" and "\$350 Cap" groups. A third "No Coverage" group had no prescription drug coverage prior to Part D. We are confident that we captured prescription fills for this group, even before Part D, because they received a 15% discount when presenting their insurance card at network pharmacies and because we constrained the sample to those for whom we observed at least one prescription fill. The fourth group, ("No Cap"), had generous drug coverage without quarterly caps through a former employer or union contracting with the insurance company. The three groups with drug coverage (\$150 cap, \$350 cap, and No Cap) paid tiered copayments (\$10/\$20 for a 30-day supply of generic/brand name for No Cap and \$12/\$20 for generic/brand for the \$150 and \$350 cap groups). Other medical benefits (e.g.,

outpatient visit copayments) were similar across the four groups, and beneficiaries were subject to the same care management regardless of pharmacy benefit. Because the No Cap group's coverage depended on decisions by employers to offer supplementary coverage, and individuals seldom decline this coverage because it is typically generous, we believe selection bias into the No Cap plan was minimal.

After Part D went into effect in January 2006, individuals in the No Coverage, \$150 cap and \$350 cap groups obtained Part D drug benefits through the same insurance company. The Medicare Advantage Prescription Drug (MA-PD) plans in this study had no deductible. Plan members faced copayments (e.g., \$8/\$20 generic/brand-name drugs) until their total drug spending reached the coverage gap (\$2,250 in 2006). In the coverage gap, the MA-PD plans covered either nothing or generic drugs only with an \$8/\$10 copayment, depending on the option chosen by the member. After members' annual total drug spending reached the catastrophic coverage limit (\$5,100 in 2006), they paid the greater of five percent coinsurance or a small copayment (\$2 to \$5). Beneficiaries in the No Cap group maintained the same generous drug coverage they had in 2004-05 in 2006-07, facing the same copayments as before, with no gap in coverage.

Using Part D's implementation as a natural experiment, we assessed changes in inappropriate medication use among the three groups who transitioned from no coverage or limited drug coverage (i.e., \$150 cap and \$350 cap) to Part D coverage in 2006. To adjust for secular trends in medication use, we used the No Cap group as a comparison group.

**Outcome measures**—We examined 2 HEDIS quality measures developed by an expert panel who reviewed previously published explicit criteria.<sup>13</sup> The first was a dichotomous indicator of whether an individual filled at least one prescription for one or more drugs in 8 classes or categories to be avoided in older adults (DAE) (Appendix Table 1). There is substantial overlap between the DAE list and drugs on the 1997 and 2003 Beers lists. However, NCQA's Medication Management Technical Advisory Subgroup excluded from the HEDIS list some drugs on the Beers list for which recent evidence supports their use in some elderly patients. In addition, benzodiazepines were removed from this measure since Part D did not cover that class.

In addition to the likelihood of DAE use, we measured the percent of total days supplied for all medications attributable to DAEs to gauge the net effect of Part D on prescribing quality. Our assumption was that Part D would increase use of nearly all drugs (both appropriate and inappropriate) but that the magnitude of those increases would vary.<sup>7,10,14</sup> A change in the percent of total days supplied attributable to DAEs provides an indication of whether Part D had a disproportionately larger (or smaller) effect on potentially inappropriate medication vs. other use.

Lastly, we constructed a dichotomous composite measure for risk of a DDE.<sup>3,15-19</sup> Using another HEDIS measure based on work by Lindblad et al.,<sup>3</sup> we examined the use of medications contraindicated in individuals with the following three diseases: 1) chronic renal failure, 2) dementia; or 3) history of falls or hip fracture. Appendix Table 2 lists the ICD-9 diagnosis codes recommended by NCQA to identify individuals with these conditions and the medications that could exacerbate them. We present DDE rates as a percent of the relevant study population (i.e., proportion of the study sample with the diagnosis who also filled a prescription for a contraindicated drug in the same year).

**Independent Variables**—Our primary independent variables were generosity of pharmacy benefits pre-Part D (No Coverage, \$150 cap, \$350 cap, No Cap), and time period with respect to the policy change (pre- vs. post-Part D). We used time × pharmacy benefit

level interaction terms to assess whether the policy's impact varied by pre-Part D drug benefit level.

**Covariates**—We included covariates for socio-demographic factors [i.e., age, sex, and census block group-level data for race (percent of residents who are black), income (percent with incomes below poverty-level), and residence in a rural area]. To control for differences in health status among the pharmacy benefit groups we included prospective risk score calculated using Risk Grouper software from DxCG. DxCG uses a series of proprietary algorithms based on dozens of ICD-9 diagnosis and/or Healthcare Common Procedure Coding System codes. These scores are similar to the Centers for Medicare and Medicaid Services-Hierarchical Condition Categories (CMS-HCC) weights used to adjust MA-PD payments.<sup>20</sup> A higher prospective score indicates a likelihood of higher **medical and pharmacy** spending in the following year.<sup>21</sup> Risk scores were constructed at the person-year level and were included as a time-varying covariate.

**Statistical analysis**—We calculated descriptive statistics to summarize characteristics of members in the study sample before Part D. We used Pearson chi-square and analysis of variance (ANOVA) to compare characteristics among the groups based on pre-Part D pharmacy benefit. For the multivariable analyses of dichotomous outcomes (any DAE or DDE), we fit a series of generalized estimating equations (GEE) models<sup>22</sup> with a binomial distribution and logit link function. To analyze changes in the proportion of days supplied for DAEs, we had to account for a large number of individuals with zero high-risk drug use and a very low overall proportion. To achieve model convergence we multiplied the proportion by 100, rounded to the nearest integer, and modeled the effect of Part D using a negative binomial GEE. In all models, the main categorical independent variables were time period (pre-/post-Part D), level of pre-Part D pharmacy benefit (e.g., No Coverage, \$150 cap, \$350 cap, No Cap) and the time period × pharmacy benefit level interaction. We used an exchangeable correlation structure to account for multiple observations from the same subjects over time and the resulting stochastic non-independence of observations. We constructed contrasts to obtain post- vs. pre-Part D odds ratios separately for each level of pre-Part D pharmacy benefit; and obtained ratios of our odds ratios to test if the odds ratios for each pharmacy benefit group changed significantly relative to the reference group. We used SAS® version 9.1 (SAS Institute, Inc., Cary, North Carolina) for all statistical analyses.

This study was approved by our University's Institutional Review Board.

## RESULTS

**Sample Characteristics**—Table 1 displays the characteristics of individuals in the analytic sample before Part D's implementation (2005). The No Coverage, \$150 cap and \$350 cap groups were slightly older and more likely to be female than those in the No Cap group. The No Coverage and No Cap groups were comparable in health status. There were no statistically significant differences in the likelihood of hospitalization or non-drug medical expenditures. There were very small, but statistically significant, differences between the \$150 cap and \$350 cap groups' prospective risk scores and those of the No Cap group.

**Likelihood of high-risk drug use**—There were slight changes in use of DAEs across all groups (Table 2). The percent of individuals transitioning from No Coverage to Part D who used DAE increased from 15.72% to 17.61%, a change that was not significant [Odds Ratio (OR)= 1.07, 99% Confidence Interval 0.99-1.17, p=0.10) (Table 2). However, after adjusting for the decline in use of DAEs in the No Cap group with constant coverage (from

20.97% to 18.32%), the relative pre-post Part D increase in the No coverage group was statistically significant [Ratio of Odds Ratios (ROR) = 1.34, 95% CI 1.22-1.48,  $p < 0.0001$ ].

The groups transitioning from limited drug coverage to Part D saw small but significant reductions in DAE use (from 22.00% to 20.83% for \$150 cap group,  $p = 0.004$ ; from 20.46% to 18.94%,  $p < 0.0001$  in the \$350 cap group). Both reductions were smaller than that in the No Cap comparison group leading to higher relative odds of DAE use post-Part D (ROR = 1.11, 95% CI 1.00-1.22,  $p = 0.04$  for \$150 cap; ROR = 1.08, 95% CI 1.02-1.14,  $p = 0.009$  for \$350 cap). The 5 most commonly prescribed DAEs were: 1) propoxyphene-containing products, 2) nitrofurantoin; 3) oral estrogen containing products; 4) desiccated thyroid products and 5) hydroxyzine (not shown).

**Proportion of total use attributable to high-risk drugs**—The proportion of overall drug use that was for DAEs was quite small (1-3%) before Part D and actually declined slightly in all groups after Part D's implementation (Table 3). Those transitioning from No Coverage to Part D saw the proportion of medication use attributable to DAEs decline from 3.01% to 1.98%, a decrease that remained significant even after adjusting for a slight decline in the No Cap group (ROR = 0.84, 95% CI 0.72-0.98,  $p = 0.03$ ). This indicates that while Part D was associated with a slight increase in likelihood of DAE use (as seen in Table 2), the magnitude of the increase in other medication use was larger. The \$150 Cap and \$350 Cap groups experienced reductions in the proportion of medication use attributable to DAEs similar to that of the comparison group.

**Drug-Disease Interactions**—The prevalence of DDEs was low both before and after Medicare Part D in all four groups (Table 4). In the No Coverage group, only 1.17% had DDEs before Part D vs. 1.27% post-Part D, a change that was not statistically significant relative to the comparison group (ROR = 1.06, 95% CI 0.78-1.44,  $p = 0.69$ ). Only the \$350 cap group experienced a statistically significant change, reducing the prevalence of DDEs from 1.25% to 1.18% ( $p = 0.05$ ), however, this change was not significant relative to the comparison group (ROR = 1.00, 95% CI 0.83-1.20,  $p = 0.967$ ). In rank order, the most commonly prescribed DDE drugs in all four groups post-Part D were those discouraged from use in patients with dementia, history of falls/fracture and chronic renal failure (data not shown).

## DISCUSSION

This study examines Medicare Part D's impact on potentially inappropriate medication use among older adults using HEDIS prescribing quality measures. Our findings point to mixed effects of Part D on quality. On the one hand, Part D was associated with a small but statistically significant increase in the use of high-risk medications (DAEs) in older adults who transitioned from no drug coverage to Part D compared to declining rates of DAE use in a group with stable drug coverage. On the other hand, the percent of all medication use attributable to DAEs was actually smaller after Part D than before. Furthermore, potentially harmful drug-disease interactions (DDEs) appeared unaffected by Part D.

We found that Part D was associated with a small relative increase in use of DAEs for those moving from no prior drug coverage to Part D. Increased use of these high-risk medications drive poor health outcomes, and increased hospitalizations **and health care costs**.<sup>23</sup> This finding suggests that older adults' use of medications whose risks may outweigh their benefits is responsive to changes in out-of-pocket cost. Most drugs on the HEDIS DAE list are available in generic form. Thus, older adults enrolled in Part D face very low copayments for these drugs. The vast majority of health plans administering Part D benefits use three- or four-tiered formularies with very low copayments for first-tier generic drugs

(\$7), and higher copays for branded drugs in the second (\$42) and third tiers (\$78).<sup>24</sup> Part D plans may consider moving the HEDIS DAE drugs (even those that are generic) to a tier with higher cost-sharing or requiring prior authorization for these drugs to discourage their use.

An important question facing policy makers is – what is the impact of adding a drug benefit on overall Medicare spending? This question turns, in part, on whether expanding drug coverage increases demand for appropriate drug treatment that leads to reductions in other medical care use,<sup>25,26</sup> or for inappropriate treatment that leads to increases in medical spending.<sup>27</sup> Our finding that the proportion of overall drug use made up by use of DAEs declined after Part D points to a positive ‘net effect’ of Part D on the quality of pharmacotherapy. Furthermore, recent studies show that, while the medical costs associated with adverse drug events in the elderly are substantial, only a fraction of them arise from use of drugs contraindicated in the elderly such as those we studied.<sup>28,29</sup> In combination with several studies showing Part D to have a positive effect on refill adherence for essential medicines to treat chronic conditions,<sup>9,25,30</sup> our findings point to a disproportionately larger effect of Part D on appropriate medication use. This suggests that Part D will have a cost-neutral or cost-cutting effect on non-drug medical care.

We found that the prevalence of potentially harmful drug-disease interactions for those with a history of falls/fracture, dementia or chronic renal failure was unaffected by Part D. Of concern, however, is the continued use of drugs with anticholinergic activity in those with dementia. Evidence suggests that with increasing age there is increased blood brain barrier permeability with medications as well as decreased central cholinergic activities.<sup>31</sup> Moreover, in those with dementia the use of anticholinergics may negate any of the potential benefit of treatment with acetylcholinesterase inhibitors.<sup>32</sup> Part D plans could discourage the use of these medications in those with dementia through cost-sharing or utilization management.

There are a number of potential limitations to our study. First, explicit quality criteria like the HEDIS measures may overestimate inappropriate use (because they may not apply to some patients) or underestimate inappropriate use (because they are infrequently updated and may not include all high-risk drugs). Second, some persons without drug benefits pre-Part D may have filled prescriptions at non-network pharmacies. We believe that any resulting bias is likely quite small due to the price discount afforded patients who use network pharmacies and because we only included in our sample individuals who filled at least one prescription in a network pharmacy. However, the effects we estimated were also small and could be partially explained by censoring during the pre-Part D period. Third, selection bias might result from individuals with poorer health status enrolling in plans with more generous drug coverage. Because the level of coverage pre-Part D depended on where beneficiaries lived or whether they were eligible for retiree drug coverage, we believe the degree of selection bias across study groups is small. Finally, the generalizability of our data from a single region to other parts of the US is unknown. We note, however, that our pre-Part D rates of DAEs and DDEs were comparable to those reported in other studies.<sup>1,3,33</sup> Furthermore, according to recent analyses of national data the region from which we obtain data has the median rate of high-risk drug use.<sup>34</sup>

In summary, we found that Medicare Part D was associated with a small increase in high-risk drug use but no change in potentially harmful drug-disease interactions among those with no coverage prior to Part D. However, when assessed as a proportion of overall drug use, the use of high-risk drugs actually declined after Part D implementation. In order to maximize the potential for Part D to improve the quality of medication use among older

adults, additional changes in to pharmacy benefit design (cost-sharing) and health professional education may be necessary.

## Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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**Table 1**

## Characteristics of Study Sample, 2005

	No Coverage N=3,499	\$150 Cap N=2,519	\$350 cap N=18,199	No Cap N=9,053
	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)
<b>65-74 years</b>	46.96 *	48.91 *	52.39 *	60.44
<b>75-84 years</b>	44.33 *	41.21 *	39.40 *	34.30
<b>&gt;=85 years</b>	8.72 *	9.88 *	8.21 *	5.26
<b>% Female</b>	56.99	63.12	62.67	53.01
<b>% Rural</b>	26.10 *	42.15 *	20.85 *	20.23
<b>% Black</b>	5.23 *	2.39 *	6.03 *	5.71
<b>Median Income (\$)</b>	37,468 (9,852) *	34,860 (5,755) *	38,993 (10,838) *	39,512 (10,762)
<b>% with any hospitalization</b>	19%	18%	19%	18%
<b>Total non-drug medical costs, (SD)</b>	\$6,283 (\$12,055)	\$6,088 (\$11,911)	\$6,426 (\$12,238)	\$6,509 (\$12,919)
<b>Total prescriptions (SD)</b>	19.7 (24.4)	33.8 (26.6)	36.3 (24.9)	45.6 (32.8)
<b>Risk Score</b>	0.94 (0.79)	0.98 (0.83) *	0.96 (0.82) *	0.95 (0.86)

\* differences are statistically significant at p<0.05 level compared to no cap group

**Table 2**

Any Use of Drugs to Avoid in the Elderly (DAE) before and after Part D

	<i>Unadjusted</i>		<i>Adjusted Impact of Part D</i>		<i>Comparison of Adjusted Impact of Part D</i>	
	<b>Pre-Part D (%)</b>	<b>Post-Part D (%)</b>	<b>Adjusted Odds Ratio (95% Confidence Interval)</b>	<b>p-value</b>	<b>Ratio of Odds Ratios (95% Confidence Interval)</b>	<b>p-value</b>
<b>No coverage</b>	15.72	17.61	1.07 (0.99-1.17)	0.10	1.34 (1.22-1.48)	<.0001
<b>\$150 cap</b>	22.00	20.83	0.88 (0.81-0.96)	0.004	1.11 (1.00-1.22)	0.040
<b>\$350 cap</b>	20.46	18.94	0.86 (0.83-0.89)	<.0001	1.08 (1.02-1.14)	0.009
<b>No Cap</b>	20.97	18.32	0.80 (0.76-0.83)	<.0001	reference	

Adjusted for age, sex, prospective risk score, census block group-level data on race, education and income using GEE binomial model.

Pre-Part D time period is January 1, 2004-December 31, 2005. Post-Part D time period is January 1, 2006-December 31, 2007. Benzodiazepines were excluded from the measure before and after Part D

**Table 3**

Percent of total days supplied attributable to Drugs to Avoid in the Elderly (DAE) before and after Part D

	<i>Unadjusted</i>		<i>Adjusted Impact of Part D</i>		<i>Comparison of Adjusted Impact of Part D</i>	
	<b>Pre-Part D (%)</b>	<b>Post-Part D (%)</b>	<b>Adjusted Odds Ratio (95% Confidence Interval)</b>	<b>p-value</b>	<b>Ratio of Odds Ratios (95% Confidence Interval)</b>	<b>p-value</b>
<b>No coverage</b>	3.01	1.98	0.68 (0.59-0.78)	<0.0001	0.84 (0.72-0.98)	0.03
<b>\$150 cap</b>	2.08	1.78	0.84 (0.75-0.95)	0.004	1.04 (0.91-1.20)	0.553
<b>\$350 cap</b>	1.80	1.45	0.82 (0.78-0.86)	<0.0001	1.01 (0.93-1.10)	0.794
<b>No Cap</b>	1.72	1.34	0.81 (0.75-0.87)	<0.0001	reference group	

Adjusted for age, sex, prospective risk score, census block group-level data on race, education and income using GEE negative binomial model.

Pre-Part D time period is January 1, 2004-December 31, 2005. Post-Part D time period is January 1, 2006-December 31, 2007. DAE measure excludes benzodiazepines which were not covered by Part D

**Table 4**

Prevalence of Potentially Harmful Drug-Disease Interactions in the Elderly (DDE) before and after Part D

	<i>Unadjusted</i>		<i>Adjusted Impact of Part D</i>		<i>Comparison of Adjusted Impact of Part D</i>	
	<b>Pre-Part D (%)</b>	<b>Post-Part D (%)</b>	<b>Adjusted Odds Ratio (95% Confidence Interval)</b>	<b>p-value</b>	<b>Ratio of Odds Ratios (95% Confidence Interval)</b>	<b>p-value</b>
<b>No coverage</b>	1.17	1.27	0.96 (0.73-1.25)	0.740	1.06 (0.78-1.44)	0.693
<b>\$150 cap</b>	1.73	1.53	0.84 (0.64-1.11)	0.226	0.94 (0.69-1.28)	0.694
<b>\$350 cap</b>	1.25	1.18	0.90 (0.80-1.00)	0.050	1.00 (0.83-1.20)	0.967
<b>No Cap</b>	1.22	1.18	0.90 (0.77-1.05)	0.177	reference	

Adjusted for age, sex, prospective risk score, census block group-level data on race, education and income using GEE binomial model.

Pre-Part D time period is January 1, 2004-December 31, 2005. Post-Part D time period is January 1, 2006-December 31, 2007.