Estimates of Medicare Part D Out-of-Pocket Cap–Associated Prescription Adherence and Affordability Under the Inflation Reduction Act (IRA)

Introduction

A recent report revealed that over 4,200 drug products experienced price increases, with 46% exceeding inflation and an average increase of 15.2% between 2022 and 2023,[1] leading to significant financial burdens. Therefore, the problem of cost-related medication non-adherence (CRN) and affordability difficulties among the older population will likely worsen in the coming years.[2]

President Biden signed into law the Inflation Reduction Act (IRA) of 2022 on August 16, 2022. The law includes several provisions to lower prescription drug costs, among which, the IRA introduced a yearly cap ($2,000) on out-of-pocket (OOP) prescription drug costs in Medicare starting in 2025.[3] However, the potential effects of this policy remain unclear. This study aimed to investigate the relationship between the OOP cap and CRN as well as prescription affordability difficulties among Medicare Part D beneficiaries.

Methods

The University of South Carolina Institutional Review Board approved this survey study. Informed consent was waived because we used deidentified data (from 2015 to 2019) from the Medicare Current Beneficiary Survey (MCBS). MCBS is a nationally representative database maintained by the Center for Medicare and Medicaid Services (CMS). The survey data is then linked to Medicare claims to provide comprehensive information on expenditures and payment sources for

prescription drugs. Additionally, the MCBS collects patient-reported data on CRN and affordability difficulties. We collected the coverage gap and the catastrophic coverage thresholds of Medicare Part D for each year according to the CMS Medicare Part D design.[4]

We compared the differences in characteristics among Medicare Part D beneficiaries with OOP costs exceeding $2,000 versus those with OOP less than $2000 using chi-square tests. Multivariable logistic regression analyses were conducted to estimate the association of meeting the $2,000 OOP cap with CRN and affordability difficulties by adjusting for age, sex, race and ethnicity, residence, census, income, education level, married status, health status, and Medicaid enrollment status. Additionally, we investigated the possibility racial and ethnic groups incur OOP costs exceeding the $2000 cap compared with non-Hispanic Whites. Survey sampling weights were applied in this study to generate national estimates. Two-sided $P < 0.05$ indicated significance.

Results

We found that about 3.30% of Medicare Part D beneficiaries reported OOP costs over $2,000 (Table 1). Beneficiaries with OOP costs exceeding $2,000 were more likely to experience CRN and affordability difficulties than those with OOP costs of $2,000 and below ($P < 0.05$). We also found that 16.81% of beneficiaries experiencing CRN and 6.92% facing affordability challenges will remain unaffected and therefore cannot benefit from the new policy. Additionally, beneficiaries with OOP costs exceeding $2,000 were more likely to be older, be non-Hispanic Whites, have higher income and education levels, be married, report poorer health status, and not be enrolled in Medicaid ($P < 0.05$).

Compared to those with OOP costs of $2,000 and below, beneficiaries with OOP costs over $2,000 were 50% [odds ratio (OR): 1.50, 95% confidence interval (CI): 1.22-1.83] and 99% (OR: 1.99, 95% CI: 1.48-2.63) more likely to report CRN and affordability difficulties, respectively. (T) Furthermore, beneficiaries with OOP costs between $2,000 and the coverage gap, between the coverage gap and the catastrophic coverage threshold, were 51% (OR: 1.51, 95% CI: 1.15-1.97), 77% (OR: 1.77, 95% CI: 1.29-2.41), and 62% (OR: 1.62, 95% CI: 1.31-1.98) more likely to report CRN, respectively. Similarly, these groups were 84% (OR: 1.84, 95% CI: 1.22-2.70), 99% (OR: 1.99, 95% CI: 1.24-3.07), and 91% (OR: 1.91, 95% CI: 1.40-2.57) more likely to face affordability difficulties, respectively. Additionally, beneficiaries with OOP costs of the catastrophic coverage threshold and over were 178% (OR: 2.78, 95% CI: 1.14-6.00) more likely to face affordability difficulties.

Furthermore, non-Hispanic black beneficiaries were 69% (OR: 0.31, 95% CI: 0.18-0.49) less likely to have an OOP cost of over $2,000 compared with their white counterparts, suggesting their potentially less chance to benefit from the new IRA policy (Table 3).

Discussion

The capping of Medicare Part D beneficiaries' OOP prescription drug spending, set to take effect in 2025, represents the first significant change to the Medicare Part D benefit since the Affordable Care Act of closing Part D "donut hole" in 2010. This cap will provide substantial financial savings to those with OOP exceeding $2000. This includes Medicare Part D beneficiaries with OOP costs

between $2,000 and the coverage gap, between the coverage gap and the catastrophic coverage threshold, as well as those above the catastrophic coverage threshold.

Using five years of nationally representative Medicare Survey data, this study revealed the significantly higher odds of CRN and affordability difficulties experienced by Medicare Part D beneficiaries with OOP costs exceeding $2,000, especially among those with OOP costs of the coverage gap and over. Our findings suggested that by capping annual OOP prescription drug costs at $2,000, the IRA would improve CRN and affordability among beneficiaries with OOP costs exceeding $2,000, and therefore may improve health outcomes. However, we found that only 3.30% of Medicare Part D beneficiaries will benefit from this new IRA policy, indicating that the new policy will only affect a very limited number of Medicare beneficiaries. In contrast, about 16.81% and 6.92% of Medicare Part D beneficiaries will not be impacted by the new policy and will continue to experience CRN and face affordability challenges, respectively.

Additionally, our study found that non-Hispanic black beneficiaries may be less likely to incur OOP greater than $2000, suggesting they are less likely to benefit from this new policy, leading to potentially unintended consequences of inequities concerns in the IRA policy's design. The reduced likelihood of OOP costs exceeding $2,000 for non-Hispanic black beneficiaries could reflect differences in healthcare utilization patterns, socioeconomic factors, or systemic barriers to accessing care.[5] Ensuring that the policy benefits are distributed fairly is critical to reducing healthcare inequities and fostering more inclusive health outcomes.

It is also crucial to recognize that Medicare beneficiaries who benefit from the IRA's OOP cap may lose the financial incentive to opt for more affordable medications, such as generics once their costs hit the cap. This shift in decision-making could result in higher overall medication costs from a societal perspective. However, we expect that insurance plans may exercise greater control of costs below the new spending cap because of their increased plan liability for drug costs above the spending cap, as required by the IRA provisions. Policymakers should consider developing comprehensive strategies (e.g., medication therapy management) to encourage beneficiaries to choose more cost-effective treatments.

Our study has several limitations. Our estimate of the number of beneficiaries who may benefit from capping OOP drug spending could be conservative. This is because we did not account for potential increases in the beneficiary population in 2025, as well as potential higher prescription drug use and costs potentially driven by reduced CRN or improved affordability resulting from this policy.

Acknowledgement: This study is not supported by specific funding; There are no financial relationships or other potential conflicts of interest that apply to the authors.

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Table 1. Characteristics of Medicare Beneficiaries

		OOP > $2,000 (%)		
		No (n = 80,498,685, 96.70%)	Yes (n = 2,743,881, 3.30%)	P value
CRN				< 0.001
	No	83.19	74.13	
	Yes	16.81	25.87	
Affordability Difficulty				< 0.001
	No	93.08	86.01	
	Yes	6.92	13.99	
Age				0.014
	18-64	15.97	11.04	
	65-74	48.25	53.08	
	75-84	26.23	27.78	
	≥85	9.55	8.10	
Sex				0.816
	Male	40.92	40.34	
	Female	59.08	59.66	
Race				< 0.001
	Non-Hispanic Whites	81.25	94.20	
	Non-Hispanic Blacks	11.58	2.75	
	Hispanics	3.39	0.48	
	Others	3.78	2.57	
Residence				0.104
	Metropolitan	80.49	83.52	
	Non-metropolitan	19.51	16.48	
Census				0.965
	Northeast	19.05	19.49	
	Midwest	22.77	23.81	
	South	37.72	36.89	
	West	20.46	19.81	
Income				< 0.001
	<$10,000	10.31	1.53	
	$10,000-24,999	32.11	14.70	
	$25,000-49,999	25.48	32.23	
	≥$50,000	32.09	51.54	
Education Level				< 0.001
	< High school	7.74	1.73	
	High school	45.84	39.95	
	>High school	46.42	58.33	
Married Status				0.010
	Married	50.37	58.99	
	Widowed	21.94	22.59	
	Divorced/Separated	18.84	12.66	
	Single	8.84	5.76	
Health Status				< 0.001
	Excellent	15.31	5.28	
	Very good	29.65	24.95	
	Good	31.14	37.02	
	Fair	17.61	23.06	
	Poor	6.29	9.69	
Medicaid Enrollment Status				< 0.001
	No	70.22	95.88	
	Yes	29.78	4.12	

OOP: out-of-pocket; CRN: cost-related medication non-adherence.

Table 2. Out-of-Pocket Cap and Associated Adherence and Affordability for Medicare Part D Beneficiaries

		CRN				Affordability Difficulty			
		OR	**95% CI**		**P value**	**OR**	**95% CI**		**P value**
OOP > $2,000									
	No	Ref							
	Yes	1.50	1.22	1.83	< 0.001	1.99	1.48	2.63	< 0.001
$2,000 < OOP < Coverage Gap									
	No	Ref							
	Yes	1.51	1.15	1.97	0.003	1.84	1.22	2.70	0.002
Coverage Gap ≤ OOP < Catastrophic Coverage Threshold									
	No[a]	Ref							
	Yes	1.77	1.29	2.41	< 0.001	1.99	1.24	3.07	0.003
OOP ≥ Catastrophic Coverage Threshold									
	No[a]	Ref							
	Yes	0.55	0.22	1.20	0.165	2.78	1.14	6.00	< 0.001

[a]The reference group is those with OOP costs of $2,000 and below.

OOP: out-of-pocket; CRN: cost-related medication non-adherence; OR: odds ratio; CI: confidence interval; Ref: reference group.

Table 3. Racial/ethnic disparities in incurring Out-of-Pocket Costs >$2000

		OR	95% CI		P value
Race					
	Non-Hispanic Whites	Ref			
	Non-Hispanic Blacks	0.31	0.18	0.49	< 0.001
	Hispanics	0.73	0.28	1.54	0.457
	Others	1.25	0.73	2.02	0.381
	Yes				
Age					
	18-64	Ref			
	65-74	1.03	0.75	1.43	0.865
	75-84	0.91	0.66	1.28	0.590
	≥85	0.75	0.52	1.10	0.141
Sex					
	Male	Ref			
	Female	1.09	0.92	1.29	0.325
Residence					
	Metropolitan	Ref			
	Non-metropolitan	0.90	0.74	1.09	0.285
Census					
	Northeast	Ref			
	Midwest	1.15	0.90	1.48	0.271
	South	1.26	1.00	1.60	0.057
	West	1.01	0.77	1.32	0.931
Income					
	<$10,000	Ref			
	$10,000-24,999	3.14	1.48	8.12	0.007
	$25,000-49,999	5.49	2.59	14.22	< 0.001
	≥$50,000	7.73	3.62	20.11	< 0.001
Education Level					
	< High school	Ref			
	High school	1.62	1.00	2.80	0.063
	>High school	1.89	1.16	3.27	0.016
Married Status					
	Married	Ref			
	Widowed	1.47	1.19	1.81	< 0.001
	Divorced/Separated	1.15	0.87	1.50	0.321
	Single	1.33	0.89	1.94	0.151
Health Status					
	Excellent	Ref			
	Very good	2.22	1.59	3.20	< 0.001
	Good	4.22	3.04	6.02	< 0.001
	Fair	6.76	4.74	9.85	< 0.001
	Poor	10.49	6.81	16.28	< 0.001
Medicaid Enrollment Status					
	No	Ref			
	Yes	0.08	0.05	0.14	< 0.001

OR: odds ratio; CI: confidence interval; Ref: reference group.