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The New Medicare Part D Prescription Drug Benefit: An Estimation of Its Effect on Prescription Drug Costs in a Medicare Population with Atrial Fibrillation

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Abstract

OBJECTIVES—To compare prescription drug cost savings under the most commonly selected Medicare Part D prescription plan in 2006 with savings under the Medicare standard benefit and with drug costs assuming no coverage in an elderly cohort of patients.

DESIGN—Inception cohort study.

SETTING—An academic medical center.

PARTICIPANTS—Four hundred seventy-two patients aged 65 and older who were followed as part of a larger study assessing stroke prevention in patients with atrial fibrillation.

MEASUREMENTS—Prescription drug expenditures were calculated for each patient in the cohort under three conditions: the 2006 AARP-endorsed prescription drug plan, the Medicare standard benefit, and no prescription drug coverage.

RESULTS—Total prescriptions drug costs were lower under the AARP plan, yet patients paid a similar percentage of total costs under the AARP plan and the Medicare standard benefit. Using different cost assessments, 27% to 46% of patients entered the “doughnut hole” in the AARP plan, and 3% to 11% emerged to receive catastrophic coverage.

CONCLUSION—Both the AARP-sponsored and standard Medicare Part D prescription drug benefit programs offer significant savings to enrollees. A greater savings is achieved under the

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private AARP drug insurance plan, largely due to greater discounts reflected in the negotiated drug prices. A substantial portion of enrollees enter but do not emerge from the coverage gap. *J Am Geriatr Soc* 55:1038–1043, 2007.

Keywords

Medicare Part D; insurance; pharmaceutical services; prescription; drug; atrial fibrillation

In 2006, Medicare patients were given the opportunity to purchase insurance coverage for prescription drugs under Medicare Part D (enacted as the Medicare Prescription Drug Improvement and Modernization Act of 2003 (MMA)).^{1,2} Given that many seniors, more than 25% according to some studies, previously lacked drug coverage,³ the new benefit promised to provide urgently needed relief for many Medicare beneficiaries.

When enacted in 2003, the legislation envisioned a standard set of benefits provided by private insurance companies. Under the standard benefit, patients would pay the first \$250 of drug expenses, with this expenditure serving as a deductible. Of the next \$2,000 of patient drug costs (up to a patient outlay of \$2,250), Medicare would cover 75% (or \$1,500), leaving the patient to pay 25% (\$500) as coinsurance. At this point, a beneficiary would encounter the “doughnut hole” gap in coverage; there would be no coverage between total outlays of \$2,250 and \$5,100. After incurring more than \$5,100 in total drug costs, a patient would have 95% of their costs covered by Medicare and would pay 5% as coinsurance (Table 1). To enroll in the plan, patients would pay a monthly premium, which at the time of the bill’s passage in 2003 was estimated to be approximately \$35 per month. In 2005, the Centers for Medicare and Medicaid Services (CMS) estimated that the premium would be \$32 per month, or \$384 annually. Therefore, under the standard Part D benefit, a patient would pay \$3,600 (\$250 deductible plus \$500 coinsurance plus \$2,850 in the doughnut hole) of drug costs up to \$5,100, for a total of \$3,984 including the annual premium of \$384.²

As an incentive to develop enhanced benefits for participants, a variety of differently structured plans have been offered, each with a unique premium structure, deductible policy, formulary, and method of entering and exiting the coverage gap, or doughnut hole.^{4–6} There are four basic plan structures: a standard benefit, based on the original legislation; actuarially equivalent plans, which adhere to the standard benefit with respect to deductibles and the doughnut hole but offer enhanced cost sharing; basic alternative plans, in which deductibles and cost sharing are altered; and enhanced alternative plans, which exceed the defined standard benefit.⁷

The economic benefits of offering these private plans have been estimated based on hypothetical patients.^{1,8} In this study, we report the estimated benefit one private plan would have in a prospectively identified cohort of actual patients with the predefined cardiovascular diagnosis of atrial fibrillation (AF). The prevalence of this condition increases with age, and it is estimated that 7.5 million Americans will have AF by 2020.^{9–12} For the purposes of the analysis, the 2006 version of the basic alternative plan endorsed by the AARP and administered by UnitedHealth Group was used. As of September 2006, 3.4 million people were enrolled in this plan, which was available in all 50 states and had the leading market share, with 21% of total enrollees.⁸

METHODS

Study Participants

Consecutive patients were prospectively identified as part of a larger study assessing stroke prevention in individuals with AF during January 2001 to June 2003 from daily searches of electronic hospital discharge summaries and patient referrals to an anticoagulation clinic. To be eligible, patients had to be aged 65 and older and have AF verified according to electrocardiogram. Demographic data and diagnoses were extracted from the medical record.

Medication Ascertainment

At the time of enrollment, a complete list of current medications was recorded and verified in the electronic medical record. Dosages were not recorded. During the analysis, to provide the most conservative estimate of annual prescription costs, short-term medications such as antibiotics and medications taken on an as-needed basis were not included. Injectable medications, other than insulin, and medications that have been withdrawn from the market were also excluded. Because dosages were not recorded, two doses were analyzed for each medication: the usual starting (minimum) dose and the maximum acceptable dose.

Prescription Plan Cost Comparisons

Total annual drug costs were calculated for each patient under three conditions: the AARP plan, the Medicare Part D standard benefit (Table 1), and no prescription coverage. For each condition, calculations were performed twice, using minimum and maximum cost assumptions. Under the minimum assumption, the minimum dose was assumed for all drugs. Under the maximum assumption, the maximum dose was assumed. For the majority of medications, the minimum dose was associated with the lowest cost. For a small number of drugs, the minimum dose was priced higher. Under this circumstance, the minimum dose was designated as the maximum cost, with the maximum dose being designated as the minimum cost. The portion paid by the patient, in the form of premiums, copayments, and nonreimbursed out-of-pocket payments, were also determined using the relevant drug prices and plan rules. The amount paid by the plan was calculated by subtracting patient payments from total aggregate drug costs.

For the standard-benefit and no-coverage conditions, retail pricing information was obtained from drugstore.com, an on-line mail-order pharmacy, during March through July 2006. To avoid overestimation of costs, prices from drugstore.com were compared with those of a national retail chain and the adjusted average wholesale price (AWP) for the 20 most commonly prescribed medications. For 80% of medications, the drugstore.com price was the lowest. For the remaining medications, the drugstore.com price varied less than 6% from the lowest price. Using the drugstore.com prices, annual retail medication costs were calculated for each patient in the cohort. If a particular medication was not available through drugstore.com, a price was obtained using the adjusted AWP. Based on a previously published analysis, 4% was added to the AWP for brand medications, and 36% was subtracted from the AWP for generic medications.¹³ If available, the generic price was always used preferentially.

The 2006 AARP plan had three phases of coverage: the initial coverage phase, annual coverage gap (doughnut hole), and catastrophic protection phase. The details of this plan are outlined in Table 1. During the initial phase, patients pay a copayment for medications according to a tier categorization. When drug costs reach \$2,250, patients enter the annual coverage gap and remain there until they pay \$3,600 in true out-of-pocket costs (defined as the amount the patient pays in co-insurance during the initial coverage period and the amount paid in the coverage gap). While in the coverage gap, patients pay 100% of the network discounted price (NDP) for each prescription until they reach \$3,600 in out-of-pocket costs. At that point, patients move into the catastrophic protection phase, in which they pay a copayment or percentage of the NDP (Table 1).¹⁴ Study investigators obtained the NDP for the minimum and maximum doses of each medication (N = 456) through phone calls to the AARP telephone customer service center.

To examine the effects of the doughnut hole structure of the AARP plan, each patient's medication costs were calculated on a monthly basis, and the amount paid by the patient and plan each month was determined. If a patient's drug costs reached \$2,250 during a month (the patient entered the doughnut hole), or the out-of-pocket expenses exceeded \$3,600 (the patient exited the hole), the drug costs were added in a sequence that maximized the benefit.

The institutional review board at Massachusetts General Hospital approved the study. The nature of the study did not require written informed consent.

RESULTS

Patient Clinical Characteristics

During the study period, 472 patients were enrolled, of whom 47% were female. Forty-two percent of patients were aged 65 to 74, 25% were aged 75 to 79, and 33% were aged 80 and older. The most common medical diagnoses (in addition to AF) were hypertension (75%), coronary artery disease (35%), heart failure (27%), and diabetes mellitus (22%). Patients were taking a median of five prescription medications daily (range 1 to 15, Figure 1). There was no difference in the number of medications across age groups. The most commonly prescribed medication classes, besides warfarin, which every participant was prescribed, were beta-blockers, diuretics, anti-arrhythmics, and anti-hyperlipidemics.

Patient Drug Costs

Overall, generic prices were assigned for 76% of medications. Diuretics, beta-blockers, anti-arrhythmics, and angiotensin-converting enzyme inhibitors had the lowest monthly costs, and proton-pump inhibitors, anti-hyperlipidemics, anti-platelet, and osteoporosis medications had the highest monthly costs.

Under the AARP plan, 69% of medications for the cohort were categorized as Tier 1 medications. Only 3% of medications were in the most expensive Specialty Tier or not covered at all. The AARP plan did not cover 62 medications, with the majority being benzodiazepines.

Table 2 shows the cost comparison between the AARP plan, the standard benefit, and no prescription drug coverage. Under the minimum projection, total annual drug costs under the AARP plan for the cohort were \$813,124, compared with \$937,225 under the standard benefit and \$937,225 in the no coverage condition. Using the maximum projection, total costs under the AARP plan were \$1,237,741, compared with \$1,487,858 under the standard benefit and \$1,487,858 in the no coverage condition. Total annual drug costs were the same for the standard benefit and no-coverage conditions, because prices were the same in both conditions. There was a 13% savings under the minimum cost projection and a 17% savings under the maximum projection. Under the AARP plan, the patients paid 71% of drug costs under the minimum projection and 62% under the maximum projection. The median annual cost per patient was \$908 under the minimum projection and \$1,092 under the maximum projection. Under the standard benefit, the patients paid 69% of total drug costs under the minimum projection and 64% under the maximum projection. The annual median cost per patient under the standard benefit was \$956 under the minimum projection and \$1,456 under the maximum projection. Under conditions of no prescription drug coverage, patients paid 100% of costs, and the median cost per patient was \$1,539 under the minimum projection and \$2,572 under the maximum projection.

A compelling characteristic of the MMA is the coverage gap, or doughnut hole, which represents the period after a patient accrues \$2,250 in total drug costs. Under the AARP plan, using the minimum projection, 73% of patients in the cohort remained in the initial coverage phase for the entire year, whereas 27% of patients in the cohort entered the coverage gap. Of those who entered the coverage gap, the majority (89%) ended the year in the gap, whereas 11% entered and exited the doughnut hole. Under the maximum projection, 46% of patients in the cohort entered the hole. Of the 46% of patients who entered the gap, 76% remained in the gap, whereas 24% entered and exited. Thus, under the minimum projection, 3% of the total cohort ended the year in the catastrophic coverage phase, and under the maximum projection, 11% of the total cohort ended the year in the catastrophic coverage phase. The median monthly expenditure for patients who never entered the doughnut hole (using the minimum cost projection) was \$65. For those who entered, the median monthly payment was \$134 (range \$61–280) before entering the hole and \$294 (range \$105–780) while in the hole. The median increase in monthly payments upon entering the hole was \$166 (range \$0–578) or 125% (range 5–483%). Three patients entered the hole during the 12th calendar month but did not experience an increase in cost because several of their medications were priced below the Tier 1 copayment. Payments dropped considerably for those who exited the hole. The median monthly payment was reduced to \$56 (range \$48–248). On average, those who ended the year in the hole arrived there in approximately calendar month 9, whereas those who entered and exited arrived in approximately calendar month 5 and exited in approximately calendar month 11. Under the minimum cost assessment, 490 person-months were spent in the coverage gap, and under the maximum cost assessment, 996 person-months were spent in the coverage gap, or doughnut hole.

DISCUSSION

An assessment of the effect of the Medicare prescription drug plan on an elderly cohort of patients recruited as part of a larger study to assess stroke prevention in individuals with AF is presented here. Drug costs incurred under the 2006 AARP-endorsed plan were compared with costs incurred under the Medicare standard benefit and with cost projections assuming no prescription drug coverage. This comparison revealed that patients in this cohort benefit significantly from the AARP plan and the standard benefit, with a slightly greater benefit from the AARP plan. Under the AARP plan, median annual patient expenditures decreased 41% under the minimum projection and 57% under the maximum projection. This is compared with 38% under the minimum projection and 43% under the maximum projection with the standard benefit. These numbers are less than those estimated in a recent CMS analysis of 16 hypothetical patients with a variety of comorbid conditions, in which an average 60% savings was predicted, with a maximum savings of 72%.¹⁵

Regulations have allowed private insurance companies to offer plans with actuarially equivalent or better benefits. This analysis of the AARP plan, which had the leading market share in 2006, with more than 3.4 million enrollees, or 21% of total Part D participants, suggests that patients have lower median annual drug expenditures under this plan than under the standard benefit. Total drug costs were 13% less in the AARP plan under the minimum projection than with the standard benefit and 17% less under the maximum projection.

There are limitations in the analysis that may underestimate the savings seen with the AARP plan. First, the analysis used pricing information from drugstore.com to calculate drug costs under the standard benefit and when patients had no coverage. Drugstore.com often offers lower prices than neighborhood retail pharmacies, so even greater savings might be realized for patients using a local pharmacy. CMS also uses pricing information from drugstore.com, as well as from Costco.com, another on-line mail-order pharmacy, for their analyses.¹⁵ Second, annual costs were analyzed based on the medication list of each participant upon enrollment. Medications taken on an as-needed basis or for an acute illness were not included. This assumption could lead to lower estimates for drug costs in this cohort. By using only the medication list at the time of enrollment, it was also not possible to capture savings that would occur as a result of patient and physician behavioral changes. In reality, patients could switch to alternative medications within a therapeutic class to achieve greater savings in copayments with the AARP plan. Seventy-six percent of the medications used by this cohort were available as generics, and the majority of medications were categorized in Tier 1.

The finding that patients save more with the AARP plan than with the standard benefit shows that the government subsidy is not the only driver of savings. A substantial portion of patients' savings appears to come from the lower network prices that plans are able to obtain for their members. In the aggregate, under the minimum projection, total drug costs dropped from \$937,225 with the standard benefit (based on drugstore.com prices) to \$813,124 with the AARP plan (based on the NDP) (Table 2). Thus, nearly \$125,000 of savings was due solely to the price discount obtained by the private plan through negotiated savings from

drug manufacturers. Because actual prices paid by private insurers to pharmaceutical manufacturers are not available, it is impossible to calculate the true percentage of costs assumed by the plan.⁵ Despite this, both plans, under the minimum projection, fall short of previous calculations that predict a subsidy of \$1,092 per person and short of the CMS projections using hypothetical patients.^{15,16} The median subsidy in the minimum cost projection is \$631 and \$583 for the AARP and standard benefit, respectively. Under the maximum projection, though, this median subsidy is \$1,486 (AARP) and \$1,116 (standard benefit), highlighting the basic plan structure that those who spend more save more.

An essential component of Medicare Part D is the coverage gap, or doughnut hole. Although this hole makes the overall benefit less costly to the government, it raises important clinical and safety concerns. The financial burden of medications can lead to nonadherence, as evidenced in a recent analysis of Medicare Advantage patients, whose pharmacy benefits were capped at \$1,000. The presence of this cap led to worse adherence and clinical outcomes, including poorer control of blood pressure, lipid, and blood glucose levels. Patients exceeding the cap had higher rates of nonelective hospitalizations, visits to the emergency department, and death. The cost of these hospitalizations and emergency department visits offset the prescription drug savings.¹⁷

In the current study's cohort, 27% of patients in the minimum projection and 46% of patients in the maximum projection fell into the doughnut hole. Only 3% of patients in the minimum projection and 11% of patients in the maximum projection emerged from the hole with catastrophic coverage by the end of the year; the rest remained in the hole, paying full price for their medications. The median increase in monthly payments upon entering the hole was 125%.

Savings under Part D come with a cost. The AARP plan, like most private plans, limits patients' choices of medication through formularies and tiered copayments. More than 30% of the medications for the cohort were not categorized as Tier 1, and 62 medications, the majority of them benzodiazepines, were not covered at all. Tiered copayments are designed to shift patients' drug choices to lower-cost alternatives, but each time a change is made, a potential for a disruption in care is introduced.

Despite all the criticisms of the MMA, these data suggest that it has the potential to reduce patient drug costs significantly. This analysis of the effect of Medicare Part D on real patients with common comorbidities underscores the significant savings achieved by allowing private insurers to negotiate steep price discounts with drug manufacturers. The AARP plan is just one example; as the most popular plan in 2006, its savings suggest that other private plans with negotiated prices are also likely to provide savings to patients. This analysis shows that the percentage of patients affected by the coverage gap ranges from 25% to 50%, underscoring the importance of creating alternative solutions to this lapse in coverage.

Continued research is needed to determine the effect of Medicare Part D on health outcomes, physician prescribing practices, and drug usage patterns in elderly populations.

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Figure 1. Median number of prescriptions per patient. As shown on the *x*-axis, the range of monthly prescriptions used by patients in the cohort was 1 to 15. The *y*-axis shows the percentage of patients in the cohort and their associated monthly number of prescriptions.

Table 1

Structure of the Medicare Standard Benefit and the AARP UnitedHealth Group Medicare Prescription Drug Plan*

	Medicare Standard Benefit	AARP
Deductible	\$250	None
Initial coverage	Patients pay 25% of drug costs until total patient outlay of \$2,250	Patients pay according to tier categorization until total drug costs reach \$2,250. Tier 1 drugs have a \$5 copayment, Tier 2 drugs have a \$28 copayment, Tier 3 drugs have a \$56 copayment, and Specialty Tier drugs cost 25% of the NDP
Annual coverage gap	No coverage until total costs reach \$5,100	After \$2,250 in total drug costs and until \$3,600 in true out-of-pocket costs, patients pay 100% of the NDP for each medication
Catastrophic protection	Over \$5,100 in total drug cost, patients pay 5% of drug costs	Over \$3,600 in true out-of-pocket costs, patients pay a \$2 copayment or 5% of the NDP, whichever is greater, for a Tier 1 medication; a \$5 copayment or 5% of the NDP, whichever is greater for a Tier 2 medication; a \$5 copayment or 5% of the NDP, whichever is greater, for a Tier 3 medication; and 5% of the NDP for a Specialty Tier medication

Note: Adapted from the AARP website: <http://www.aarpmedicarerx.com>.¹⁴

NDP = network discounted price.

Annual Cost Comparison of the AARP UnitedHealth Group Medicare Prescription Drug Plan, the Medicare Standard Benefit, and No Prescription Drug Coverage*

Table 2

Analysis of Costs	Cost Amount					
	AARP		Medicare Standard Benefit		No Prescription Drug Coverage	
	Minimum	Maximum	Minimum	Maximum	Minimum	Maximum
Total cost of drugs, per patient/total, \$	1,723/813,124	2,622/1,237,741	1,986/937,225	3,152/1,487,858	1,986/937,225	3,152/1,487,858
Paid by patient						
Drug costs, per patient/total, \$	947/447,093	1,329/627,370	989/466,666	1,628/768,535	1,986/937,225	3,152/1,487,858
Premium, per patient/total, \$	284/134,180	284/134,180	384/181,248	384/181,248	0	0
Total, per patient/total, \$	1,232/581,273	1,613/761,550	1,373/647,914	2,012/949,783	1,986/937,225	3,152/1,487,858
Median per patient (range), \$	908 (344–4,228)	1,092 (344–4,488)	956 (552–4,222)	1,456 (552–4,560)	1,539 (168–9,854)	2,572 (168–16,623)
Percentage of total cost	71	62	69	64	100	100
Paid by plan						
Drug costs, per patient/total, \$	775/366,031	1,293/610,372	997/470,563	1,524/719,326	—	—
Premium, per patient/total, \$	–284/134,180	–284/134,180	–384/181,248	384/181,248	—	—
Total, per patient/total, \$	491/231,851	1009/476,192	613/289,315	1140/538,078	—	—
Percentage of total cost	29	38	31	36	—	—

* The cost of medications used by the cohort was calculated under each plan assuming that patients continued their baseline medications for 12 months. Because actual doses taken were not available, minimum (and maximum) costs were calculated assuming that the patient took the least (or most) expensive dose for every drug. The network discounted prices were obtained from the AARP customer service center and used for calculations under the AARP plan; under the standard benefit and no coverage categories, prices were obtained from drugstore.com