

# Assessment of Drug Consumption Patterns for Medicare Part D Patients

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**T**he standard Medicare Part D drug coverage is divided into 3 consecutive phases: the initial coverage (IC), the “doughnut hole” (DH), and the catastrophic coverage (CC). Depending on the patient’s health plan, during the IC phase a patient could pay a deductible in addition to approximately 25% of the drug costs. During the DH or the gap in coverage, most patients must pay 100% of the drug costs out of pocket. During the CC phase, a patient could pay approximately 5% of the drug costs. Sixty-five percent of Part D beneficiaries in 2007 were covered by the standard benefit or a benefit that was actuarially equivalent.<sup>1,2</sup>

According to a projection by the Actuarial Research Corporation for the Kaiser Family Foundation, more than 3 million of the 24.2 million full-year Part D enrollees reached the DH in 2007. Despite its large scope, very little is known about the dynamic of reaching the DH and CC thresholds over time. The main objective of our analysis was to assess the time taken to reach the DH and the CC thresholds in the general elderly population and in the subpopulations of patients with specific chronic conditions eligible for the Medicare Part D standard benefit in 2007. As part of this analysis, we estimated the percentage of patients that had reached the DH and CC by different time points in 2007.

There is debate about the magnitude of the impact of the DH and the CC on prescription drug use in the Medicare Part D population.<sup>3-7</sup> Particularly, it is unclear whether patients tend to reduce their drug consumption after reaching the DH (because during this stage they pay the full cost of medications) and whether they increase consumption back to its original level after crossing the CC threshold. Hence, the second objective of this analysis was to study how the DH and the CC affect patient refill behavior.

**Objectives:** To assess the time needed to reach the “doughnut hole” (DH) and catastrophic coverage (CC) periods and to identify prescription drug use patterns among patients eligible for the standard Medicare Part D drug benefit.

**Study Design:** Retrospective cohort study.

**Methods:** Data for all prescription drugs dispensed to subjects over age 65 years from November 1, 2006, through February 29, 2008, were obtained from 2 large retail pharmacy chains. Kaplan-Meier estimates of survival curves were used to assess the time to reach the DH and CC thresholds.

**Results:** Of all 2007 Medicare Part D standard benefit patients in our sample, 18.5% reached the DH, but only 11.6% of those patients reached the CC threshold by the end of 2007. Patients who did not reach the DH in 2007 filled an average of 2.13 prescriptions per month. Patients who reached the DH but did not reach the CC threshold filled an average of 4.86 and 4.40 (9.47% decrease;  $P < .001$ ) prescriptions per month during the initial coverage and DH periods, respectively. Patients who reached the CC threshold filled an average of 7.59, 8.38, and 7.86 prescriptions per month during the initial coverage, DH, and CC periods, respectively. Similar quantitative patterns were observed for patients with various chronic conditions.

**Conclusion:** A sizable proportion of standard Medicare Part D drug program beneficiaries reached the DH. Prescription data can help predict the problems beneficiaries enrolled in the standard Medicare Part D drug program might face over time.

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## METHODS

### Data Sources and Study Population

Data for all prescription drugs dispensed to subjects over age 65 years from November 1, 2006, through February 29, 2008, were obtained from 2 large retail pharmacy chains. These 2 pharmacies together operate in a total of 50 states and the District of Columbia, and represent more than 4152 community pharmacies nationwide. The data contained all individual pharmacy customers regardless

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### Take-Away Points

In this retrospective cohort study we identified prescription drug use patterns among patients eligible for the standard Medicare Part D drug benefit.

- Almost 20% of standard Medicare Part D program beneficiaries reached the “doughnut hole” in 2007.
- More than 11% of those patients who did enter the doughnut hole reached the catastrophic coverage threshold.
- Patients who reached the doughnut hole but did not reach catastrophic coverage filled, on average, about 10% fewer scripts in the doughnut hole period.

jump in patient copayments to 90% or more of the drug cost. We identified the date of reaching the CC threshold by a drop in patient copayment to a maximum of 5% or less of the drug cost or \$2.15 for generic drugs or \$5.35 for brand-name drugs. (Many patients had the secondary insurance, which paid some additional portion of the drug costs.)

of their insurance status and their prescription drug activity for every prescription filled at these national chains. Detailed drug plan information was not available for all patients in our data, but a Medicare Part D identifier was included. Diagnosis information was not available in the database.

Patients sometimes use more than 1 pharmacy chain to fill prescriptions. This study included only patients who were continual customers of the same pharmacy chain throughout 2007 and required that patients had minimal dispensing activity within the same pharmacy chain in the last 2 months of 2006 and the first 2 months of 2008. Patients who were eligible for Medicaid (ie, dual-eligibles) or received a low-income subsidy were excluded from this analysis because their Medicare Part D benefit did not have a coverage gap.

The analysis was done on the full sample in addition to being performed separately for patients who were taking drugs typically used for the following medical conditions: hypertension, depression, asthma, diabetes, hyperlipidemia, stroke or heart attack, acid reflux disease, and osteoporosis.

### Statistical Analysis

Our data included the Medicare Part D identifier but not the indicator of standard Medicare Part D benefits. To identify patients with Medicare Part D standard benefits, we used an algorithm that considered the Medicare Part D benefits design for 2007, medication costs, patients’ out-of-pocket payments, and dispensing patterns.

The standard benefits for 2007 included a \$265 deductible, a coinsurance payment of 25% up to \$2400 in total drug costs, and a gap in coverage between \$2400 and \$5451 during which enrollees paid 100% of their drug costs. After enrollees had incurred \$3850 in out-of-pocket expenses, they qualified for CC and paid 5% of drug costs, but not less than \$2.15 for generic drugs or \$5.35 for brand-name drugs.

According to these rules, we identified patients covered by the Medicare Part D standard benefit as those who paid 25% or less of drug costs at the beginning of 2007, excluding patients who had low copayments equivalent to the benefit for the low-subsidy Medicare population. We identified the end of the IC period and the beginning of the DH period by a

Kaplan-Meier estimates of survival curves<sup>8</sup> were used to assess the time to reach the DH and CC thresholds. Times to reach the DH and CC thresholds were calculated as the number of days from January 1, 2007, to the date of reaching these thresholds. These outcomes were censored at 360 days for patients who did not reach the DH or CC by December 31, 2007.

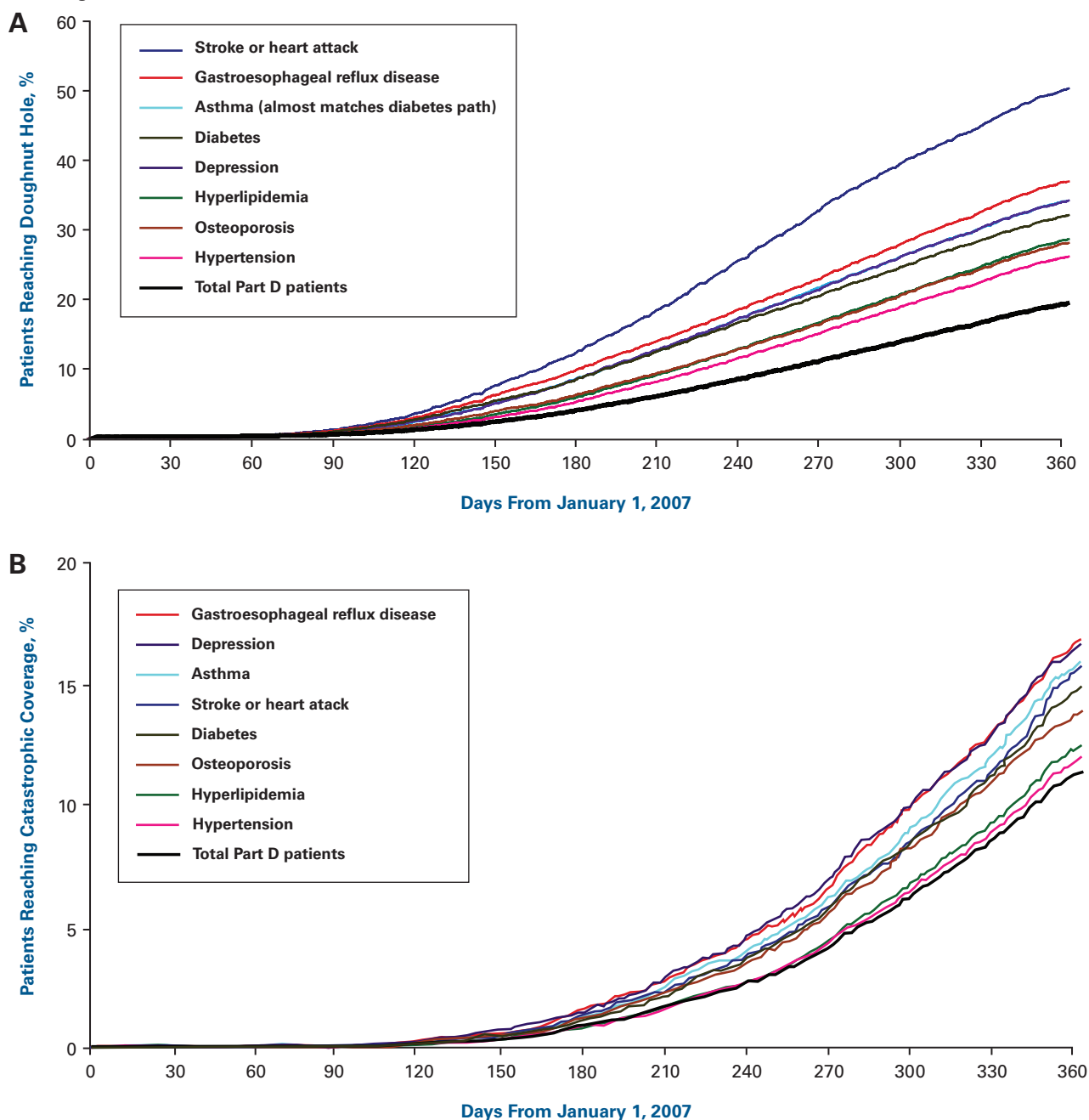
We also evaluated the effects of reaching the DH and CC on patient drug consumption. For this analysis, we divided all patients into 3 cohorts. The first cohort included only patients who did not reach the DH in 2007; the second cohort included patients who reached the DH but did not reach the CC; and the third cohort included patients who reached the CC after reaching the DH. We calculated the average number of fills per 30 days for every patient in each coverage period (IC, DH, and CC). (The same calculations also were performed based on the days’ supply outcome, and quantitatively similar results were obtained [data not shown].) A multivariate generalized linear model with the negative binomial distribution and log link function was used to estimate changes in the average fill rates during the DH and CC periods compared with the average fill rate in the IC period. The generalized estimating equations<sup>9</sup> approach was used to account for the repeated measurements on the same patient in consecutive time segments. A first-order autoregressive structure was specified for the working correlation matrix.

## RESULTS

Of the 951,525 patients who were age 65 years and older and who during 2007 were continual customers of the 2 pharmacy chains used in this study, 161,899 (17.0%) were identified as Medicare Part D recipients. Of those, 96,579 patients (59.7%) were identified to be eligible for the standard Medicare Part D benefit, and they constituted the primary study cohort.

The mean age of the primary study population was 77.0 years ( $\pm 7.3$  years) and 65% were women. A smaller group of patients (16.3%) did not take any drugs for the chronic conditions under consideration, and 27.9%, 27.2%, and 28.6% of patients took drugs for 1, 2, and 3 or more of those conditions, respectively.

**Figure.** Kaplan-Meier Estimates of Time Needed to Reach (A) Doughnut Hole Threshold and (B) Catastrophic Coverage Threshold



We estimated that of all the patients covered by Medicare Part D standard benefit in 2007, 18.5% reached the DH by the year's end. These corresponding numbers were considerably higher for patients with the chronic conditions under consideration—varying from 25.2% for patients taking anti-hypertensive drugs to 49.3% for patients taking drugs for reducing the risk of heart attack or stroke (Figure, panel A).

Of those patients who did enter the DH, only 11.6% reached the CC threshold by the end of 2007. The numbers

were again considerably higher for patients with the chronic conditions under consideration, reaching 17.0% for patients with acid reflux disease and 16.8% for patients taking antidepressants (Figure, panel B).

Patients who did not reach the DH in 2007 (cohort 1) filled, on average, 2.13 prescriptions per 30 days (Table). Patients who reached the DH but did not reach the CC (cohort 2) filled, on average, 4.86 and 4.40 (9.47% decrease;  $P < .001$ ) prescriptions per 30 days in the IC and DH time periods, re-

■ **Table.** Average Number of Prescriptions per Patient per 30 Days Filled by Different Cohorts of Patients at Different Time Intervals<sup>a</sup>

Patients	Cohort 1	Cohort 2		Cohort 3		
	Initial Coverage	Initial Coverage	Doughnut Hole <sup>b</sup>	Initial Coverage	Doughnut Hole <sup>b</sup>	Catastrophic Coverage <sup>b</sup>
<b>Total Part D patients (N = 96,579)</b>	2.13	4.86	4.40 <sup>c</sup>	7.59	8.38 <sup>c</sup>	7.86 <sup>d</sup>
<b>Patients with chronic conditions</b>						
Depression (n = 18,654)	3.03	5.46	4.94 <sup>c</sup>	8.21	8.99	8.47
Hypertension (n = 50,780)	2.76	5.14	4.68 <sup>c</sup>	7.89	8.88 <sup>c</sup>	8.28 <sup>d</sup>
Asthma (n = 11,061)	2.67	5.02	4.49 <sup>c</sup>	8.05	9.13 <sup>e</sup>	8.32
Osteoporosis (n = 19,400)	2.57	5.02	4.54 <sup>c</sup>	7.68	8.63 <sup>e</sup>	8.01 <sup>e</sup>
Diabetes (n = 15,771)	3.12	5.41	4.85 <sup>c</sup>	8.39	8.73 <sup>e</sup>	8.73
Stroke or heart attack (n = 6380)	3.01	5.14	4.65 <sup>c</sup>	8.24	8.86	8.77 <sup>d</sup>
Gastroesophageal reflux disease (n = 15,738)	2.91	5.16	4.61 <sup>c</sup>	8.10	8.77 <sup>e</sup>	8.30
Hyperlipidemia (n = 38,057)	2.71	5.03	4.57 <sup>c</sup>	7.97	8.70 <sup>e</sup>	8.26 <sup>e</sup>

<sup>a</sup>Cohort 1 includes only patients who did not reach the doughnut hole in 2007; cohort 2 includes patients who reached the doughnut hole, but did not reach the catastrophic coverage threshold; and cohort 3 includes patients who reached the catastrophic coverage threshold after reaching the doughnut hole.  
<sup>b</sup>All comparisons were made relative to the initial coverage period.  
<sup>c</sup> $P \leq .001$ .  
<sup>d</sup> $P \leq .01$ .  
<sup>e</sup> $P \leq .05$ .

spectively. The comparable decrease in patient drug consumption (ranging from 8.95% for patients taking antihypertensive drugs to 10.66% for patients taking acid reflux disease drugs) was observed for all subgroups of patients with the chronic conditions under consideration. Patients who reached the DH and then reached the CC (cohort 3) filled, on average, 7.59, 8.38, and 7.86 prescriptions per 30 days in the IC, DH, and CC time periods, respectively. These figures reflect a 10.41% increase in the DH period compared with the IC period ( $P = .001$ ) and a 3.56% increase in the CC period compared with the IC period ( $P = .006$ ). Quantitatively we observed the same pattern for all subgroups of patients with chronic conditions (Table).

Patients in cohorts 1, 2, and 3 had, on average, 1.58 ( $\pm 1.18$ ), 2.85 ( $\pm 1.20$ ), and 3.64 ( $\pm 1.40$ ) chronic conditions, respectively.

## DISCUSSION

The passage of Medicare Part D drug benefit has provided improved access to prescription drugs for Medicare beneficiaries. In 2007 the number of people enrolled in the Medicare Part D drug plans was estimated at 25 million.<sup>1</sup> Our study focused on 3 features of Medicare Part D drug benefit: the IC, DH, and CC. Our findings suggest that only a portion of the enrollees reached the DH, and a smaller portion of those who reached the DH reached the CC threshold.

We also found how coverage or the lack of it affected prescription fill patterns. Patients who did not reach the DH filled, on average, 2.73 fewer prescriptions a month than those who did reach the DH. These patients were healthier in comparison, having fewer chronic conditions. They also might have delayed reaching the DH by reducing their essential and/or marginally useful medication consumption.<sup>9</sup> Patients who reached the DH but not the CC filled, on average, fewer prescriptions and increased their out-of-pocket costs while in the DH. If this reduction in drug consumption affected the necessary medication, then it could have adversely affected the patients' health outcomes, especially for those with chronic conditions.

Patients may use different strategies to try to mitigate the effects of the DH. They may switch from brand-name drugs to generics or over-the-counter medications, use pharmacy coupons, or obtain drug samples.<sup>10,11</sup> Although a majority of patients prefer to use the same pharmacy on a regular basis, some patients may start shopping for pharmacies that offer low-price prescription drugs. Other patients may start using more drastic measures—stretching a prescription supply by splitting pills, taking them every other day, or even going without them entirely.<sup>11-13</sup> Some of these strategies have a negative impact on patient drug adherence and adversely affect patient health outcomes.<sup>13,14</sup>

On the other hand, a smaller group of sicker patients might increase their spending, trying to come out of the DH as soon as possible to extend the CC time period. Most of these pa-

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tients who entered the DH early in the year spent at the same rate or faster, reaching the CC as quickly as possible.<sup>5,15</sup>

Helping patients to understand their prescription drug coverage and review the changes in their coverage on a yearly basis can get them prepared for the gaps in their drug coverage. Healthcare providers need to raise awareness and work with the patients to understand and monitor their coverage in order to control out-of-pocket costs. They also need to educate patients about their essential versus nonessential medications, emphasize the importance of continuing with their prescribed therapies, and ask patients to notify them if they decide to stop their medications. Healthcare providers also need to help their patients address the increasing cost of medications. These strategies may include patient assistance programs sponsored by pharmaceutical companies, national and charitable community-based programs, programs by specific health organizations, or applying to Social Security for extra help. These strategies can help individuals to offset the cost of their medication and delay or avoid reaching the DH.<sup>16</sup>

Our study had several limitations. The findings of this study cannot be generalized to all Medicare Part D patients eligible for the standard benefit, because the study required patients to be continual users of the same pharmacy chain before and after the study period. We cannot rule out that subjects concurrently received drugs through other retail or mail-order pharmacies, which could have resulted in underestimation of medication consumption by Medicare Part D drug beneficiaries. However, our findings are generalizable to patients who tend to fill their prescriptions at a particular pharmacy chain. The validity of our findings for patients with specific chronic conditions may be perceived as compromised by the fact that no diagnostic information was available for this analysis; nevertheless, the selected drugs were very good representatives of the corresponding therapeutic categories. We evaluated a limited sample of medication classes that are generally used chronically, so our findings may not be generalizable to acute, short-term medications.

Although the information about enrollment in specific prescription drug plans (which are likely to vary with respect to their particular formularies and cost-sharing requirements) and possible patient coinsurance wasn't available, we generated robust algorithms to detect the exact dates when patients entered the DH and CC. Testing variations in this algorithm confirmed the insensitivity of our definitions (data not shown). However, only detailed insurance data would allow a precise assessment of when patients reach the DH and CC.

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