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THE MEDICARE PART D COVERAGE GAP: COSTS AND CONSEQUENCES IN 2007

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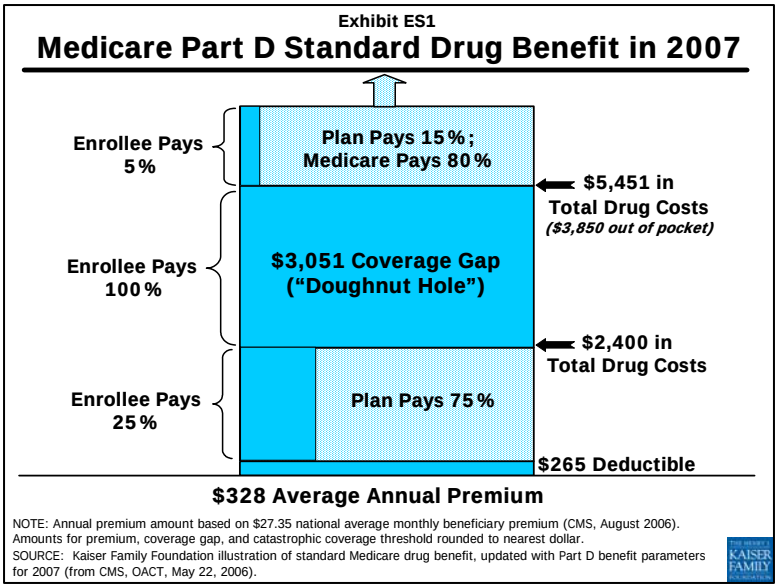
EXECUTIVE SUMMARY

A unique feature of the Medicare Part D drug benefit is the so-called "doughnut hole", the gap in coverage in which Part D enrollees are required to pay the full cost of their drugs until they qualify for catastrophic coverage. In 2007, the first full year of enrollment in Part D plans for many beneficiaries, the coverage gap began when a beneficiary incurred $2,400 in total drug spending and ended after out-of-pocket spending reached $3,850, equivalent to $5,451 in total drug spending **(Exhibit ES1)**. Once through the gap, beneficiaries become eligible for catastrophic coverage where most of the costs of on-formulary drugs are covered. Between 2007 and 2017, the dollar value of the coverage gap is projected to double, exposing some beneficiaries to potentially high out-of-pocket costs and increasing the risk of cost-related non-compliance. In 2008, as in 2006 and 2007, the majority of stand-alone Medicare prescription drug plans (PDPs) and Medicare Advantage Prescription Drug (MA-PD) plans have a coverage gap and most Part D enrollees are in plans with such a gap.[i]

Exhibit ES1



NOTE: Annual premium amount based on $27.35 national average monthly beneficiary premium (CMS, August 2006). Amounts for premium, coverage gap, and catastrophic coverage threshold rounded to nearest dollar.
SOURCE: Kaiser Family Foundation illustration of standard Medicare drug benefit, updated with Part D benefit parameters for 2007 (from CMS, OACT, May 22, 2006).

This report provides new information to address several important questions related to Medicare Part D enrollees' experiences with the coverage gap in 2007. Because 2007 is the first year in which most beneficiaries were enrolled for 12 months, it represents the first time they faced the full impact of the gap. The study examines the share of enrollees that reached the coverage gap in 2007 and their characteristics, and the share of enrollees with spending high enough to receive catastrophic coverage. It assesses the extent to which Part D enrollees stopped taking medications or switched to less expensive alternatives after they reached the coverage gap, focusing on Part D enrollees taking one or more drugs in eight drug classes to treat several relatively common chronic conditions: Alzheimer's disease, high cholesterol, depression, diabetes, gastroesophageal reflux disease, heart failure, hypertension, and osteoporosis. It also examines changes in out-of-pocket and total spending associated with the coverage gap and catastrophic coverage.

To address these questions, we analyzed nationwide patient-level retail pharmacy claims data for Part D enrollees from IMS Health, a leading pharmaceutical market research organization. IMS Health collects and links data at the person level for about 50 percent of all retail prescriptions filled in the United States, excluding prescriptions filled by mail order, institutional pharmacies, and through certain integrated health plans, such as Kaiser Permanente. Their Longitudinal Prescription (LRx) database includes person-level retail pharmacy claims for 4.5 million Part D enrollees who filled at least one prescription in 2007. We used cumulative total drug spending for each Part D enrollee to estimate whether they reached the coverage gap and catastrophic coverage. This analysis focuses on the experiences of Part D enrollees at risk of reaching the coverage gap, so it excludes individuals who receive low-income subsidies (LIS) for Part D coverage because they are not required to pay the full cost of their drugs even after their total spending is high enough to reach the coverage gap.

[i] J. Hoadley, J. Thompson, E. Hargrave, K. Merrell, J. Cubanski, and T. Neuman. "Medicare Part D Data Spotlight: The Coverage Gap." Kaiser Family Foundation publication 7707 (November 2007).

FINDINGS

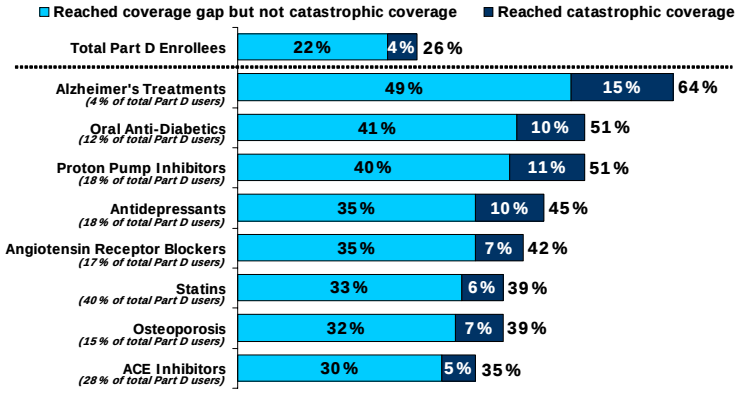
What Share of Part D Enrollees Reached the Coverage Gap in 2007?

- Among Part D enrollees who filled one or more prescriptions but did not receive low-income subsidies in 2007, one quarter (26 percent) had spending high enough to reach the coverage gap.[ii] Fifteen percent of these Part D enrollees who reached the coverage gap ultimately had spending high enough to reach catastrophic coverage. **(Exhibit ES2)**
- Applying this estimate to the entire population of Part D enrollees, the analysis suggests that about 3.4 million beneficiaries (14 percent of all Part D enrollees) reached the coverage gap and faced the full cost of their prescriptions in 2007.
- The share of non-LIS Part D enrollees who reached the coverage gap in 2007 varied by age, Medicare drug plan region, and by the type of drugs they take.
  - *Age*. The share of enrollees with spending high enough to reach the gap increased with age, from 25 percent of Part D enrollees age 65-74 to 33 percent of those age 85 and older. A smaller share of Medicare beneficiaries under age 65 with disabilities reached the gap compared to those age 65 and older.

Exhibit ES2

Share of Part D Enrollees Who Reached the Coverage Gap and Catastrophic Coverage in 2007, By Drug Class

Excludes Part D Enrollees Who Receive Low-Income Subsidies and Non-Users



NOTES: Estimates based on analysis of retail pharmacy claims for 1.9 million Part D enrollees in 2007. Groups not mutually exclusive; enrollees may use drugs in more than one of the eight drug classes.
SOURCE: Georgetown University/NORC/Kaiser Family Foundation analysis of IMS Health LRx database, 2007.

  - *Medicare Drug Plan Region*. The share with spending high enough to reach the coverage gap ranged from fewer than 20 percent in three PDP regions covering four states (Arizona, Nevada, Vermont, and Maine) to 33 percent in eight states (Arkansas, and the seven-state Northern Plains region that includes Iowa, Minnesota, Montana, Nebraska, North Dakota, South Dakota and Wyoming) and 36 percent in Hawaii.
  - *Drug Class.* The share of enrollees with spending high enough to reach the coverage gap varied across the eight drug classes, from 35 percent of enrollees taking ACE inhibitors for hypertension and heart failure to 64 percent of those taking drugs for Alzheimer's disease.

How Soon Did Part D Enrollees Reach the Coverage Gap? How Long Did They Stay in the Gap?

- Half of all Part D enrollees who had spending high enough to reach the coverage gap in 2007 did so by the end of August.

[ii] The share of Part D enrollees with spending in the coverage gap could be lower than this estimate because the IMS data exclude people who do not take medications and because of the relatively large share of Part D enrollees categorized as low-income subsidy recipients; the actual share in the coverage gap could also be higher because the IMS data does not include the universe of pharmacies and excludes all mail order expenditures under Part D plans. See the appendix for further discussion of these issues.

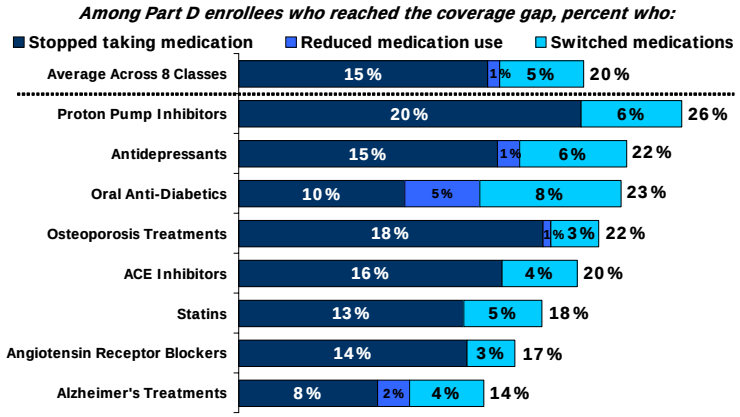
- Only a small share of enrollees who reached the coverage gap in July or later had spending high enough to reach catastrophic coverage before the end of the year; instead, most spent the rest of the year in the coverage gap.
- On average, enrollees who reached the coverage gap remained in the gap for just over four months.

Did Part D Enrollees Change Their Drug Use When They Reached the Coverage Gap?

- Averaged across Part D enrollees using drugs in one or more of 8 drug classes, 20 percent of enrollees who reached the coverage gap in 2007 either stopped taking a medication in that drug class, reduced their medication use (e.g., skipped doses), or switched to a different medication in that class when they reached the gap. **(Exhibit ES3)** Others may have changed their use of medications for other health conditions, but these are not measured in our analysis. Of those who reached the gap:
  - 15 percent stopped taking their medication;
  - 5 percent switched to an alternative drug in that class, and
  - 1 percent reduced their medication use.
- Enrollees' response to the coverage gap varied by drug class. For example:
  - Among Part D enrollees using medications for diabetes who reached the coverage gap in 2007, 10 percent stopped taking their diabetes medication and did not switch to an alternative, 8 percent switched their medication, and 5 percent reduced their medication use.
  - Among Part D enrollees taking medication for osteoporosis who reached the coverage gap, 18 percent stopped taking their osteoporosis medication, 3 percent switched to an alternative medication, and 1 percent reduced their medication use.

Exhibit ES3

Changes in Drug Use By Part D Enrollees After Reaching the Coverage Gap in 2007



NOTES: Estimates based on analysis of retail pharmacy claims for 1.9 million Part D enrollees in 2007. Groups not mutually exclusive; enrollees may use drugs in more than one of the eight drug classes.
SOURCE: Georgetown University/NORC/Kaiser Family Foundation analysis of IMS Health LRx database, 2007.

How Did The Coverage Gap and Catastrophic Coverage Affect Part D Enrollees' Out-of-Pocket and Total Spending?

- Among non-LIS Part D enrollees who reached the coverage gap in 2007, average monthly out-of-pocket spending on prescription drugs during the coverage gap was nearly twice as much as in the months prior to reaching the gap.[iii] This reflects the design of the coverage gap, which requires enrollees to pay the full cost of their medications.
  - For those with drug spending high enough to reach the coverage gap but not high enough to reach catastrophic coverage in 2007, monthly out-of-pocket spending nearly doubled from $104 prior to the coverage gap to $196 during the gap.

[iii] Because of the limitations in how we determine who reaches the gap, the actual difference in out-of-pocket spending may be even higher.

- For those with spending high enough to receive catastrophic coverage in 2007, monthly out-of-pocket spending increased from $207 in the months prior to coverage gap to $408 per month during the gap, and then dropped down to $285 per month during the catastrophic coverage period.

- Average annual total spending for Part D enrollees who did not reach the coverage gap in 2007 was much lower than for those who reached the gap.
  - Generally, patterns of total spending over the course of 2007 are consistent with our finding that some stopped taking medication or switched medications when they reached the gap during the year

DISCUSSION

With the Medicare prescription drug benefit now in its third year of implementation, there continues to be considerable interest in understanding how well the benefit is working for the 25 million people on Medicare currently enrolled in Part D plans. This study focused on the "doughnut hole", a unique feature of the Medicare drug benefit which leaves a gap in coverage, in order to estimate how many enrollees reached the coverage gap and catastrophic coverage in 2007 and to assess the extent to which the gap affected enrollees' use of medications and out-of-pocket spending. Our findings suggest that a large share of Medicare Part D enrollees who take prescription drugs and are not receiving low-income subsidies can expect to have spending in the coverage gap, while only a small share of these enrollees pass through the gap and qualify for catastrophic coverage. Out-of-pocket spending increased substantially when enrollees reached the coverage gap in 2007, which could help to explain our finding that some enrollees who reached the gap made changes to their drug use regimen, including stopping their medications altogether.

From a health outcomes perspective, our finding that some enrollees stopped taking their medications or reduced medication use when they reached the coverage gap could be a serious concern. Individuals with diabetes, for example, risk immediate and potentially serious health consequences if they stop taking their medications. For individuals with other chronic conditions, such as osteoporosis or high cholesterol, the health effects from stopping their medications might not be immediately apparent but it could increase their risk of negative outcomes over time. On the other hand, switching medications to save money might be a clinically acceptable response to the coverage gap.

Physicians can play an important role in helping beneficiaries who reach the coverage gap identify opportunities to switch to lower-cost alternatives, but in order to do so, physicians and patients need to talk with each other about drug costs. Ultimately, both stopping and switching medications could result in higher costs for other parts of the Medicare program if beneficiaries have health issues that are not being controlled by medication, or if they simply require more physician visits to prescribe and monitor changes in medications. Careful attention is needed to ensure that gains to Medicare beneficiaries from the addition of the Part D drug benefit are not undermined by the coverage gap—especially for those enrollees who are highly dependent on medications to manage ongoing chronic conditions.

INTRODUCTION

A unique feature of the Medicare Part D benefit is the so-called "doughnut hole" – the gap in coverage in which Part D enrollees are required to pay the full cost of their drugs until they qualify for catastrophic coverage.[1] In 2007, the year covered by this study, the coverage gap began when a beneficiary's total drug spending reached $2,400 and ended when a beneficiary' had spent a total of $3,850 out of pocket (the equivalent of $5,451 in total drug spending).[2] Once these limits are reached, beneficiaries are eligible for catastrophic coverage where most of the costs of on-formulary drugs are covered. Between 2007 and 2017, the dollar value of the gap in coverage under the standard Part D benefit is projected to more than double from $3,051 to $6,241.[3]

Although plans offering Part D coverage are permitted to offer an alternative to the standard benefit design, the majority of stand-alone Medicare prescription drug plans (PDPs) and Medicare Advantage Prescription Drug (MA-PD) plans have a coverage gap and most Part D enrollees are in plans with such a gap.[4] In 2007, only 8 percent of PDP enrollees and 33 percent of MA-PD plan enrollees had any gap coverage.[5] Among plans that offer gap coverage, it is mostly limited to generic rather than brand-name drugs, especially among PDPs.

This research provides new analysis to address several important questions related to Medicare beneficiaries' experiences with the coverage gap in the Part D prescription drug benefit. This study is the first to use 2007 pharmacy claims data to estimate the share of Part D enrollees with prescription drug spending high enough to reach the coverage gap and to estimate the effects of the coverage gap on medication non-adherence and on enrollees' total and out-of-pocket spending. Because 2007 is the first year in which most beneficiaries were enrolled for 12 months, it represents the first time they faced the full impact of the gap.

To date there has been no comprehensive assessment of Part D enrollees' experiences with the coverage gap in 2007, the first year in which beneficiaries were likely to be enrolled in the Medicare drug benefit for a full year. Other studies have produced estimates of the share of Part D enrollees with spending high enough to reach the coverage gap. However, the two studies most directly comparable to ours used pharmacy claims data from 2006, the first year of the Part D program.[6] Because the Part D enrollment period ended in the middle of May that year, these analyses do not necessarily cover a full year of utilization for enrollees. Two other studies that also used 2006 pharmacy claims data focused more narrowly on subsets of Part D enrollees—those with diabetes and enrollees in a Medicare Advantage plan in Northern California.[7] Finally, three studies issued prior to or just after implementation of the drug

[1] Part D enrollees who qualify for the low-income drug subsidy (LIS), including beneficiaries dually eligible for Medicare and Medicaid, are generally not responsible for costs in the coverage gap beyond their usual copayment.
[2] In 2008, the coverage gap begins when a beneficiary's total drug spending reaches $2,510 and ends when a beneficiary has spent $4,050 out of pocket (the equivalent of $5,726 in total drug spending).
[3] Calculation based on Boards Of Trustees Of The Federal Hospital Insurance And Federal Supplementary Medical Insurance Trust Funds, 2008 Annual Report. Washington, D.C., March 25, 2008. Page 178.
[4] See J. Hoadley, J. Thompson, E. Hargrave, K. Merrell, J. Cubanski, and T. Neuman. "Medicare Part D Data Spotlight: The Coverage Gap." Kaiser Family Foundation publication 7707 (November 2007).
[5] Hoadley et al, "Medicare Part D Data Spotlight: The Coverage Gap."
[6] IMS Health, 2007, "Medicare Part D: The First Year," http://imshealth.com/imshealth/Global/Content/Static%20File/MedicarePartD-TheFirstYear.pdf; and C. Messner, 2007, "Medicare Part D Market Dynamics," Wolters Kluwer Health. http://www.wkhealth.com/pt/pt-core/template-wkhealth/wkhealth/MPDDynamics.pdf.
[7] Z. Karaca et al, 2008, "The Impact of Medicare Part D on Beneficiaries with Type 2 Diabetes," Avalere Health. http://www.avalerehealth.net/research/docs/The_Impact_of_Medicare_Part_D_Diabetes_Takeda.pdf; and J. Hsu et al., 2008, "Medicare Beneficiaries; Knowledge of Part D Prescription Drug Program Benefits and Responses to Drug Costs," *JAMA* 299(16): 1929-1936.

benefit in 2006 used data from surveys rather than claims and made assumptions about spending in order to make projections about the share of enrollees who would reach the coverage gap in 2006.[8]

This study uses nationwide patient-level pharmacy claims data for 2007 from IMS Health, a leading pharmaceutical market research organization, to estimate the share of Part D enrollees who reached the coverage gap and subsequently qualified for catastrophic coverage during the year. It assesses the extent to which Part D enrollees changed or stopped taking their medications once they reached the coverage gap, focusing on beneficiaries taking one or more drugs in eight selected drug classes to treat several relatively common chronic conditions. The study also looks at total and out-of-pocket spending among Part D enrollees prior to reaching the coverage gap, during the coverage gap, and during the period of catastrophic coverage.

DATA AND METHODS

We analyzed 2007 data from IMS Health's Longitudinal Prescription Drug Database (LRx), which includes retail transaction data aggregated to the person level for 50 percent of all retail prescriptions filled in the United States and over 150 million unique de-identified patients. Within LRx, IMS identified 4.5 million Part D enrollees, estimated to represent approximately 18.2 million of the 24.8 million beneficiaries enrolled in Part D in 2007. Of the 4.5 million Part D enrollees in the database, 2.7 million were categorized as recipients of the Part D low-income subsidy (LIS), based on copayment information associated with their drug claims.[9] Because LIS recipients are not required to pay the full cost of drugs in the coverage gap, we excluded this group from our analysis.

For the remaining 1.9 million non-LIS Part D enrollees in the dataset, we estimated whether they reached the coverage gap and catastrophic coverage based on their cumulative total drug spending, using spending amounts of $2,400 to determine whether a beneficiary had reached the coverage gap and $5,451 to determine whether a beneficiary had reached catastrophic coverage. It is likely that a small share of our sample was enrolled in Part D plans offering gap coverage; however, we were unable to identify and exclude them from the analysis because the claims data do not provide sufficient plan-specific detail to identify these enrollees.

To examine how enrollees' medication use and out-of-pocket costs changed once they reached the coverage gap, we focused our analysis on individuals who use one or more drugs in each of eight selected classes to treat several relatively common chronic conditions: (1) Angiotensin-Converting Enzyme (ACE) Inhibitors, generally used to treat hypertension; (2) Alzheimer's disease treatments; (3) Anti-Depressants; (4) Angiotensin Receptor Blockers (ARBs), generally used to treat hypertension; (5) Oral Anti-Diabetics; (6) Osteoporosis treatments; (7) Proton Pump Inhibitors (PPIs) for heartburn, gastroesophageal reflux disease (GERD), and ulcers; and (8) HMG-CoA Reductase Inhibitors (Statins) to treat high cholesterol. Our analysis takes into account all drug use for individuals using drugs in these classes, but we focus on changes in medication use only for the selected classes. Additional information on the IMS data, our methodology, and the list of products used to define each drug class is provided in the appendix.

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[8] J. Mays et al., 2004, "Estimates of Medicare Beneficiaries' Out-of-Pocket Drug Spending in 2006," Kaiser Family Foundation, November 2004. http://www.kff.org/medicare/7201.cfm; B. Stuart et al, 2005, "Riding the Rollercoaster: The Ups and Downs In Out-of-Pocket Spending Under the Standard Medicare Drug Benefit," *Health Affairs* 24(4), 1022-1029; and PriceWaterhouseCoopers, 2006, "Significance of the Coverage Gap Under Medicare Part D," http://www.hlc.org/HLC_Coverage_Gap_Research_Report_FINAL.pdf. An updated version of the Mays projection is reported in a Kaiser Family Foundation Fact Sheet, "The Medicare Prescription Drug Benefit," publication 7044-08 (February 2008).

[9] Because IMS does not collect information about Part D enrollees' LIS participation, we used copayment information associated with each claim ($5.60 or less per prescription and 15% or less of the total prescription cost) as a proxy indicator for LIS enrollment. These amounts are typically lower than copayments paid by non-LIS enrollees in Part D plans, but the use of these proxy rules may incorrectly categorize some non-LIS enrollees who take only very low-cost medications as LIS recipients.

STUDY LIMITATIONS

The IMS Health database used for this analysis has some omissions and limitations that could affect the precision of our estimate of the share of Part D enrollees with spending in the coverage gap, resulting in either over- or under-estimation of the share that would be calculated using claims data from all part D plans, which are not yet available.[10]

On the one hand, our estimates could be biased upward because the IMS data exclude Part D enrollees who do not fill prescriptions. Including non-users enrolled in Part D in the denominator would produce a lower estimate of the share of Part D enrollees who reach the coverage gap.[11] Furthermore, the data do not identify whether or not Part D enrollees are LIS recipients. Relying on cost-sharing amounts to designate LIS status could inadvertently exclude from the sample valid non-LIS enrollees with low drug spending, which would produce an inflated estimate for the share of non-LIS enrollees with spending in the gap. Also, the dataset does not distinguish drugs that are off formulary. Those who pay for these drugs out of pocket could appear incorrectly to reach the gap.

On the other hand, the IMS dataset does not include the entire universe of retail pharmacies or any claims filled through mail order pharmacies. The absence of these pharmacy transactions from the totals for those with at least some included transactions could bias downward both our estimate of the share of Part D enrollees reaching the coverage gap or catastrophic coverage and our estimate of when enrollees reach the gap. In addition, the dataset excludes transactions at institutional pharmacies. The non-LIS enrollees in skilled nursing or assisted living facilities who are excluded from our sample could be more likely than average to reach the gap.

Based on these data limitations, which are discussed more fully in the appendix, all estimates for Part D enrollees in this report exclude LIS recipients and enrollees who did not use drugs or filled prescriptions only through mail order, institutional pharmacies, or other pharmacies not captured by the IMS Health LRx claims data in 2007. These exclusions apply to all references to Part D enrollees in this report, whether stated explicitly or not.

We are unable to quantify whether the net bias on our estimate of the total number of beneficiaries reaching the gap is upward or downward. We have no reason to think, however, that our analysis of the IMS data presents an unrepresentative profile of the experiences of Part D enrollees once they reach the coverage gap, in terms of the effects on changes in drug use or drug spending—issues which are central to understanding the overall effect of the coverage gap on Part D enrollees.

[10] The Centers for Medicare and Medicaid Services (CMS) is preparing to make prescription drug event data collected from Part D plans for the 2006 coverage year available to researchers at the end of 2008.

[11] An estimated 9 percent of seniors enrolled in Part D plans in 2006 did not fill any prescriptions. See P. Neuman et al, "Medicare Prescription Drug Benefit Progress Report: Findings From A 2006 National Survey Of Seniors." 2007. *Health Affairs* Web Exclusive w630.

FINDINGS

What Share of Part D Enrollees Reached the Coverage Gap in 2007? What Share Received Catastrophic Coverage?

- Among Part D enrollees who used prescription drugs and did not receive low-income subsidies in 2007, about a quarter (26 percent) had spending high enough to reach the coverage gap. **(Exhibit 1)**

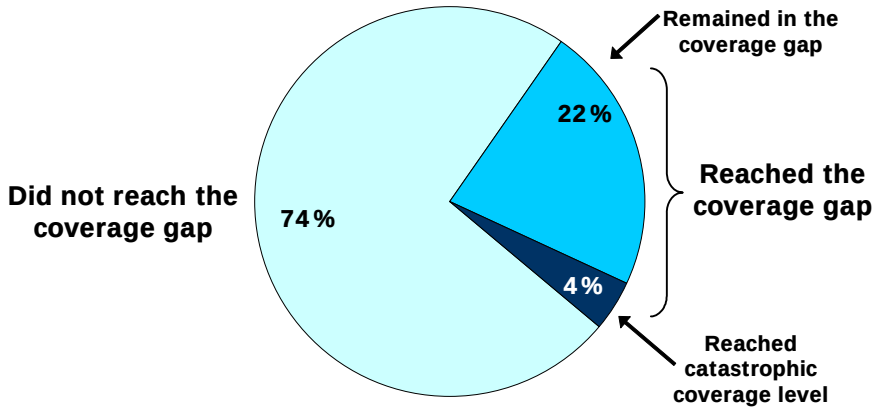
- 22 percent of Part D enrollees reached the coverage gap but did not reach catastrophic coverage, and 4 percent reached the gap and subsequently received catastrophic coverage.

- Estimating the total number of Part D enrollees who reached the coverage gap in 2007 requires taking into account the limitations in our dataset by adjusting for such factors as total LIS enrollment, the number of beneficiaries who took no drugs, and the number who had full gap coverage from their plans.
  - In 2007, about 14.4 million out of 24.2 million Part D enrollees potentially faced the full cost of medications if they reached the coverage gap because they did not receive the low-income subsidy or have full gap coverage for brands and generics from their plan. Adjusting for the 9 percent of Part D enrollees who do not take prescription drugs leaves about 13.1 million enrollees. Applying our 26 percent estimate to this total suggests that about 3.4 million beneficiaries (14 percent of the total population of Part D enrollees) reached the coverage gap and faced the full cost of their prescriptions in 2007.

Exhibit 1

Share of Medicare Part D Enrollees Who Reached the Coverage Gap and Catastrophic Coverage in 2007

Excludes Part D Enrollees Who Receive Low-Income Subsidies and Non-Users



NOTES: Estimates based on analysis of retail pharmacy claims for 1.9 million Part D enrollees in 2007.
SOURCE: Georgetown University/NORC/Kaiser Family Foundation analysis of IMS Health LRx database, 2007.

What are the Characteristics of Part D Enrollees Who Reached the Coverage Gap in 2007?

Part D Enrollees Reaching the Coverage Gap, By Age and Sex

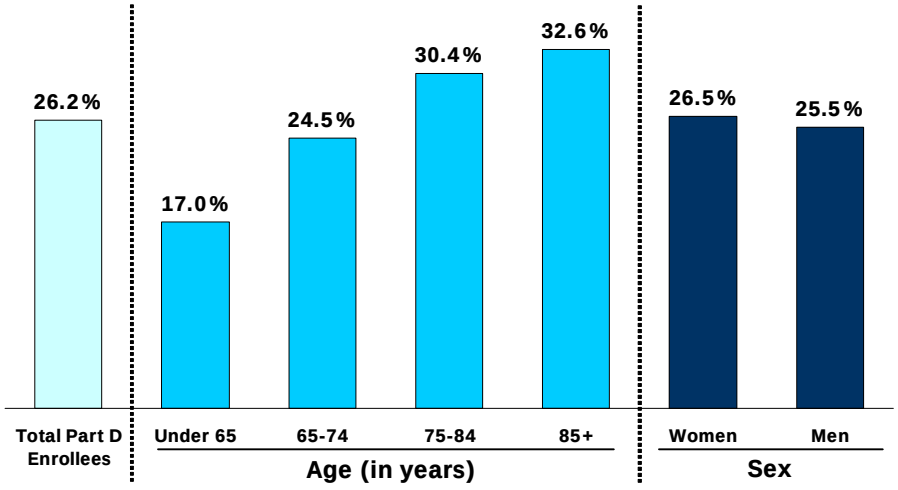
- The share of non-LIS Part D enrollees who reached the coverage gap in 2007 was higher for seniors ages 85 and older (33 percent) than for younger seniors ages 65-74 (25 percent), and lower still (17 percent) among Part D enrollees under age 65 with disabilities **(Exhibit 2)**.
    - The lower likelihood of reaching the gap for those under age 65 seems counter-intuitive and is inconsistent with survey results that show that the under-65 Medicare population takes more drugs than the elderly. Our finding may in part reflect the challenges of identifying correctly which beneficiaries qualify for LIS and which beneficiaries reach the gap. More research is needed to verify whether (and if so, why) non-LIS beneficiaries under age 65 actually have lower drug spending and are less likely to reach the coverage gap, as the IMS data indicate.

- A similar share of women and men enrolled in Part D reached the coverage gap in 2007, with a slightly larger share of women having high enough drug spending to reach the gap **(Exhibit 2)**.

Exhibit 2

Share of Part D Enrollees Who Reached the Coverage Gap in 2007, By Age and Sex

Excludes Part D Enrollees Who Receive Low-Income Subsidies and Non-Users



NOTES: Estimates based on analysis of retail pharmacy claims for 1.9 million Part D enrollees in 2007.
SOURCE: Georgetown University/NORC/Kaiser Family Foundation analysis of IMS Health LRx database, 2007.

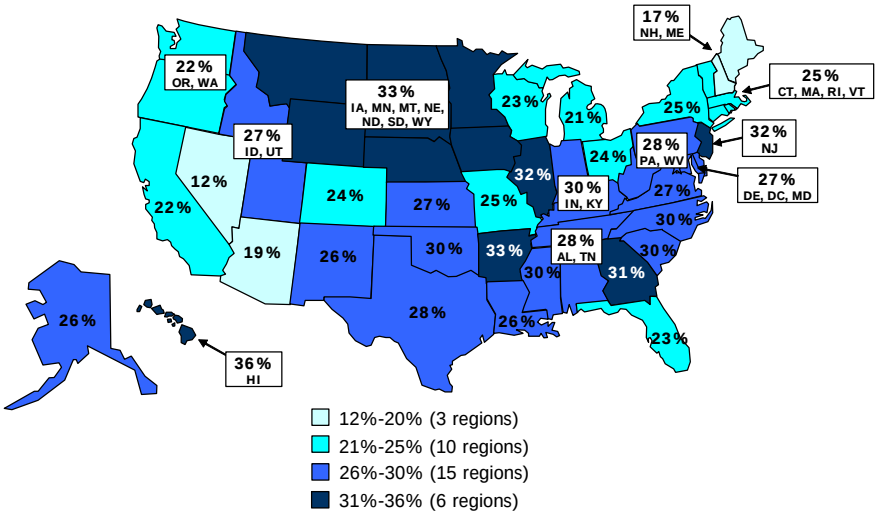
Part D Enrollees Reaching the Coverage Gap, By Medicare Drug Plan Region

- The share of Part D enrollees with spending high enough to reach the gap in 2007 varied widely by Medicare Drug Plan region. **(Exhibit 3)**
  - About one-third of Part D enrollees in two regions (Arkansas, and the seven-state Northern Plains region that includes Iowa, Minnesota, Montana, Nebraska, North Dakota, South Dakota and Wyoming) and 36 percent in Hawaii reached the gap.
  - By contrast, just 12 percent of Part D enrollees in Nevada reached the coverage gap in 2007.
- These differences across regions could have several explanations.
  - Total drug spending varies widely by region, due to differences in physician prescribing patterns, patient preferences, and the health status of the population.[12]
  - Different regional rates of Medicare Advantage penetration appear to be related to the likelihood of reaching the coverage gap; where MA penetration is higher, fewer Part D enrollees reached the gap. This could reflect stronger management of drug use by MA plans compared to stand-alone PDPs.
  - In general, regions that we estimate to have a higher share of LIS beneficiaries have fewer beneficiaries reaching the gap. To the extent that some non-LIS low spenders may have been inaccurately classified as LIS recipients, this may have the effect of deflating the estimate of non-LIS enrollees in some regions, which would bias upward the estimate of those reaching the gap.

Exhibit 3

Share of Part D Enrollees Who Reached the Coverage Gap in 2007, By Medicare Drug Plan Region

Excludes Part D Enrollees Who Receive Low-Income Subsidies and Non-Users



NOTES: Estimates based on analysis of retail pharmacy claims for 1.9 million Part D enrollees in 2007.
SOURCE: Georgetown University/NORC/Kaiser Family Foundation analysis of IMS Health LRx database, 2007.

[12] This level of variation is similar to that which has been reported in previous studies by NORC and Georgetown, but the regions with a higher likelihood of enrollees reaching the gap are not the same that we have previously found to have high spending. See *Evaluation Of Databases For Drug Risk Adjustment*, http://aspe.hhs.gov/health/reports/06/drug06/report1.pdf, and *Continuation of Drug Risk Adjustment*, http://aspe.hhs.gov/health/reports/06/drugcontinuation/index.htm. Research by Express Scripts also found geographic variations in prescription drug use. Although their analysis looked at those under age 65, there is a modest correlation by region between their areas of high use and our likelihood of reaching the gap. E. Cox et al., "Geographic Variation Trends in Prescription Use: 2000 to 2006," January 2008, http://www.express-scripts.com/industryresearch/outcomes/onlinepublications/study/geoVariationTrends.pdf

Part D Enrollees Reaching the Coverage Gap, By Drug Class

- The share of Part D enrollees with spending high enough to reach the coverage gap in 2007 varied considerably across the eight drug classes in our study **(Exhibit 4)**.

- Nearly two-thirds (64 percent) of non-LIS Part D enrollees taking prescription medication for Alzheimer's disease had spending high enough to reach the coverage gap in 2007, followed by roughly half of those taking anti-diabetics and those taking PPIs (51 percent each). About one-third (35 percent) of Part D enrollees using ACE inhibitors reached the coverage gap.
  - Medications for Alzheimer's disease include some of the most expensive drugs in the study, thus contributing to the increased likelihood of these enrollees reaching the gap in 2007. Furthermore, because caregivers are typically involved, patient compliance is higher than in many other drug classes.

- Differences in the share of Part D enrollees reaching the coverage gap by drug class can be attributed to several factors, including the cost of drugs used to treat these conditions, the overall health status of users of drugs in the different classes, and the share of users in each class who took drugs in other classes.

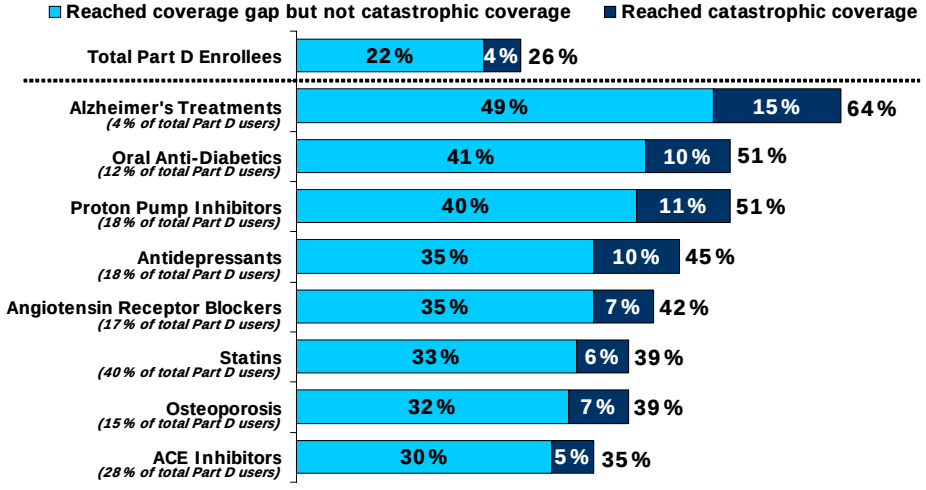
- Among users in the eight drug classes, those taking medications for Alzheimer's disease were the most likely to reach the coverage gap in 2007, yet this group makes up only a small share (10 percent) of the overall total reaching the gap **(Exhibit 4)**. Conversely, because statins were more widely used among the Part D enrollees in our study, 61 percent of those who reached the gap were taking a statin.

- The two most widely used drug classes among those studied (statins and ACE inhibitors) are at or near the bottom in their rates of enrollees reaching the coverage gap. These drugs are taken by many relatively healthy beneficiaries to treat underlying chronic conditions, people whose lower overall drug use keeps them out of the coverage gap.

Exhibit 4

Share of Part D Enrollees Who Reached the Coverage Gap and Catastrophic Coverage in 2007, By Drug Class

Excludes Part D Enrollees Who Receive Low-Income Subsidies and Non-Users



NOTES: Estimates based on analysis of retail pharmacy claims for 1.9 million Part D enrollees in 2007. Groups not mutually exclusive; enrollees may use drugs in more than one of the eight drug classes.
SOURCE: Georgetown University/NORC/Kaiser Family Foundation analysis of IMS Health LRx database, 2007.

Part D Enrollees Reaching the Coverage Gap, By Medicare Drug Plan Sponsor

- Among the top 20 plan sponsors included in the IMS dataset, we found wide variation in the share of Part D enrollees with spending high enough to reach the coverage gap and catastrophic coverage in 2007 **(Exhibit 5)**.[13]
    - Some caveats about these results, as discussed in the introduction and the appendix, are worth restating here. The IMS data do not include specific indicators for LIS enrollment, enrollment in plans with gap coverage, or when enrollees are in the coverage gap. Some of the factors affecting the accuracy of our estimates will vary by plan sponsor. For example, some plan sponsors charge low copayments for generic drugs that may have been mis-specified as indicating LIS enrollment for some non-LIS Part D enrollees who used only drugs with these low copayments in 2007. Also, spending by enrollees on drugs not covered by their plan that is included in the IMS data would have been included in the calculation of total spending that determines when the coverage gap and catastrophic coverage begin, although spending on non-covered drugs actually does not count. Thus, the estimates for plans with more restrictive formularies could be biased upward to the extent that beneficiaries in these plans were purchasing off-formulary drugs not identified as such in the IMS data.

- Among the top 20 plan sponsors identified in the IMS database, BCBS Northern Plains Alliance had the largest share of Part D enrollees with enough spending to reach the coverage gap in 2007 (44 percent of enrollees who were not low-income subsidy recipients). This is one of the two plan sponsors, along with Sierra, that offered coverage for brand-name drugs in the gap in 2007.

- BCBS Northern Plains Alliance and Sierra had the highest shares of Part D enrollees with enough spending to reach catastrophic coverage (10 percent and 9 percent, respectively).
    - These comparatively high rates may be a function of enrollees in these plans having coverage for brand-name drugs in the gap, which enabled them to continue filling their prescriptions through the gap and increased their likelihood of reaching the level of spending that qualified for catastrophic coverage.
    - The relatively high rates of enrollees receiving catastrophic coverage in these plans may also be a sign of adverse risk selection, as beneficiaries who knew in advance of enrollment that they needed expensive drugs or spent a large amount on their medications would want coverage in the gap in order to pay for their medications throughout the year.
    - Both of these plans stopped offering coverage of brand-name drugs in the coverage gap for 2008.

- Humana, the second largest plan sponsor, had a relatively large share of Part D enrollees with enough spending to reach the gap in 2007 (30 percent, excluding LIS recipients and non-users). This could be a residual effect of having attracted a disproportionate number of enrollees with high drug spending in their "Complete" plan in 2006, which was the only national stand-alone PDP to offer coverage of brand-name drugs in the coverage gap during the first year of the program. (This plan no longer offered gap coverage in 2007, but many beneficiaries attracted to that plan in 2006 for its gap coverage likely remained in the plan.)

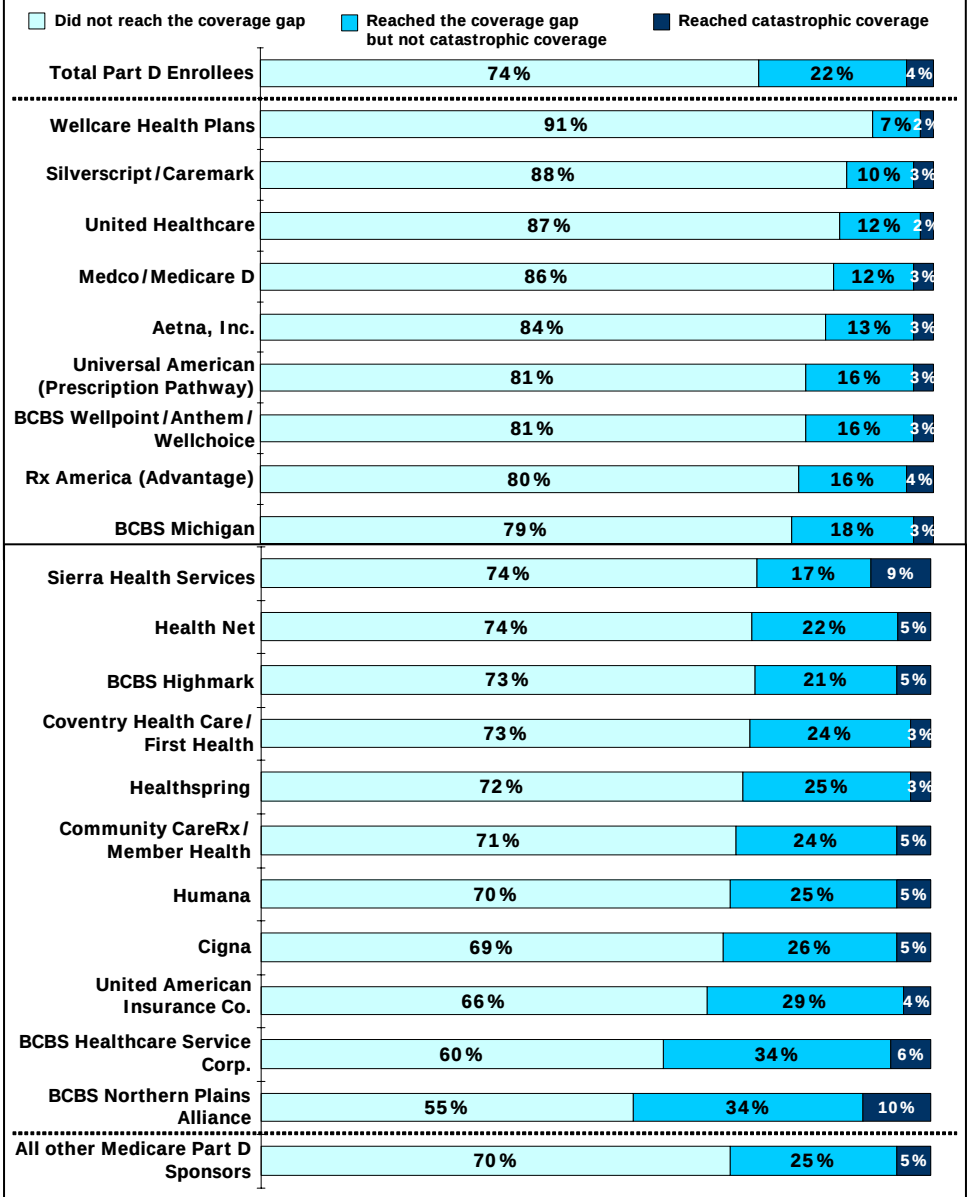
- United Healthcare, the largest plan sponsor, had a relatively small share of non-LIS enrollees with enough spending to reach the coverage gap (13 percent).

[13] Kaiser Permanente is one of the top Part D plan sponsors, but its pharmacies are not included in the IMS dataset.

Exhibit 5

Share of Part D Enrollees Who Reached the Coverage Gap in 2007, By Medicare Drug Plan Sponsor

Excludes Part D Enrollees Who Receive Low-Income Subsidies and Non-Users



NOTES: Estimates based on analysis of retail pharmacy claims for 1.9 million Part D enrollees in 2007. Numbers may not sum to 100% due to rounding.

SOURCE: Georgetown University/NORC/Kaiser Family Foundation analysis of IMS Health LRx database, 2007.

When Did Part D Enrollees Reach the Coverage Gap in 2007?

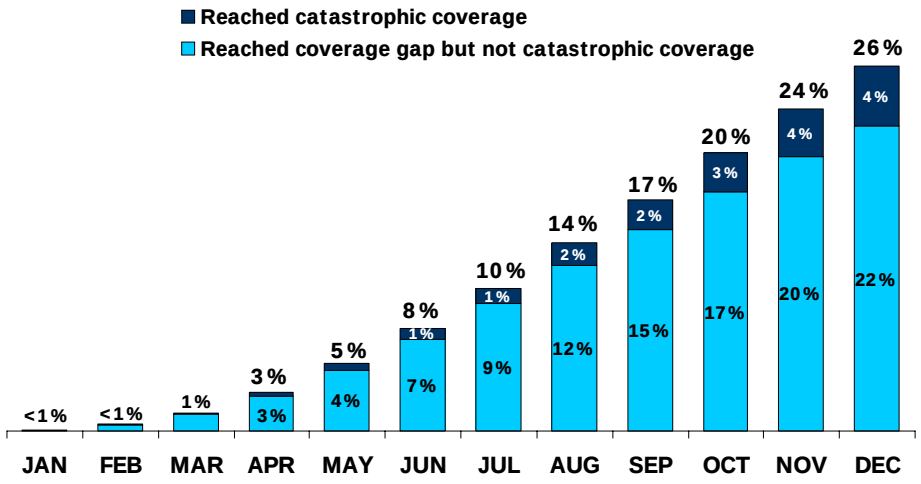
- Very few Part D enrollees had enough spending early in the year to reach the coverage gap in the first few months of 2007. **(Exhibit 6)**

- Not surprisingly, as drug spending accumulated, the share of enrollees with spending high enough to reach the gap increased as the year progressed. Just over half of all Part D enrollees who reached the coverage gap in 2007 did so by the end of August.
  - Of non-LIS Part D enrollees who reached the gap in 2007, 28 percent did so in the first half of the year. **(Exhibit 7)**
    - 5 percent reached the gap in the first quarter (January-March); of this group, 87 percent went on to receive catastrophic coverage before the end of the year.
    - 23 percent reached the gap in the second quarter (April-May); of this group, 46 percent went on to receive catastrophic coverage before the end of the year.
  - The remaining 72 percent of non-LIS Part D enrollees who reached the gap in 2007 did so in the second half of the year. **(Exhibit 7)**
    - 35 percent reached the gap in the third quarter (July-September); of this group, only 4 percent went on to receive catastrophic coverage before the end of the year.
    - 37 percent reached the gap in the fourth quarter (October-December); of this group, less than 1 percent went on to receive catastrophic coverage before the end of the year.

Exhibit 6

Cumulative Share of Part D Enrollees Who Reached the Coverage Gap in 2007, By Month

Excludes Part D Enrollees Who Receive Low-Income Subsidies and Non-Users

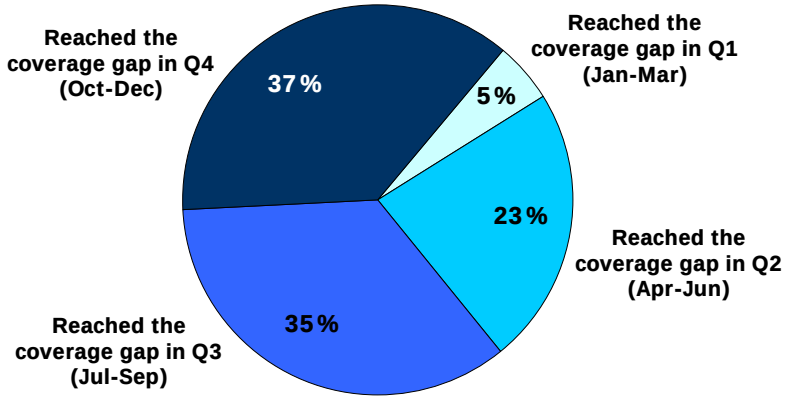


NOTES: Estimates based on analysis of retail pharmacy claims for 1.9 million Part D enrollees in 2007.
SOURCE: Georgetown University/NORC/Kaiser Family Foundation analysis of IMS Health LRx database, 2007.

Exhibit 7

Distribution of Medicare Part D Enrollees Who Reached the Coverage Gap in 2007, By Quarter

Excludes Part D Enrollees Who Receive Low-Income Subsidies and Non-Users



NOTES: Estimates based on analysis of retail pharmacy claims for 1.9 million Part D enrollees in 2007.
SOURCE: Georgetown University/NORC/Kaiser Family Foundation analysis of IMS Health LRx database, 2007.

How Long Did Part D Enrollees Who Reached The Coverage Gap Stay in the Gap in 2007?

- Overall, Part D enrollees who reached the coverage gap in 2007 did so after spending 7.2 months in the initial benefit period and then remained in the gap for an average of 4.2 months **(Exhibit 8)**. The average enrollee reaching the gap received less than one month of catastrophic coverage.

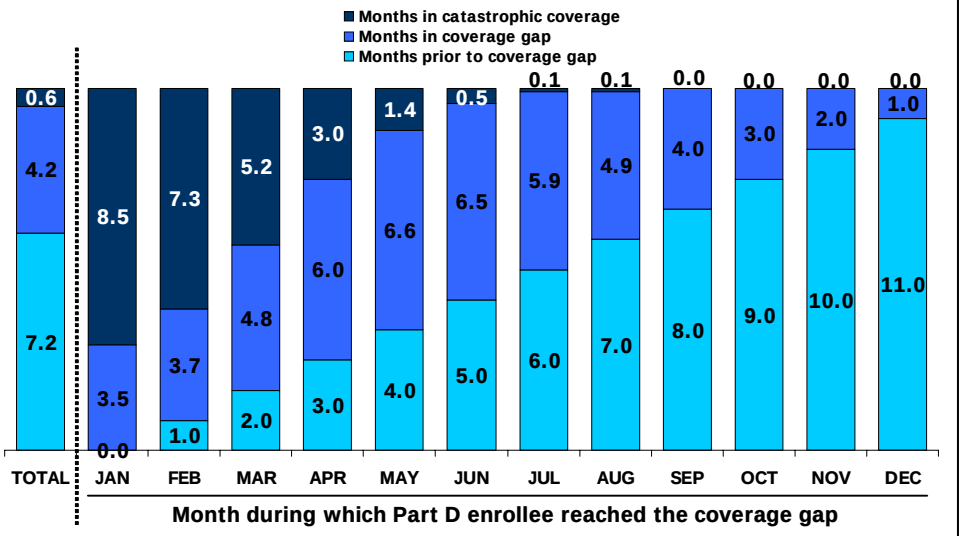
- On average, those with spending high enough to reach the gap in the first three months of 2007 spent fewer months in the gap than in the catastrophic coverage period. For example, Part D enrollees who first reached the coverage gap in January were in the gap for an average of 3.5 months until they reached catastrophic coverage, and then had catastrophic coverage for the remaining 8.5 months of the year.

- Enrollees who reached the gap in the second quarter (April-June) spent about half the year in the gap, on average.

- Those who reached the coverage gap in July or later were very unlikely to reach catastrophic coverage in 2007. Therefore these enrollees spent very little time, if any, in the catastrophic coverage period.

Exhibit 8

Average Number of Months Spent in the Coverage Gap and Catastrophic Coverage in 2007



NOTES: Estimates based on analysis of retail pharmacy claims for 1.9 million Part D enrollees in 2007.
SOURCE: Georgetown University/NORC/Kaiser Family Foundation analysis of IMS Health LRx database, 2007.

Number of Months in the Coverage Gap and Catastrophic Coverage, by Drug Class

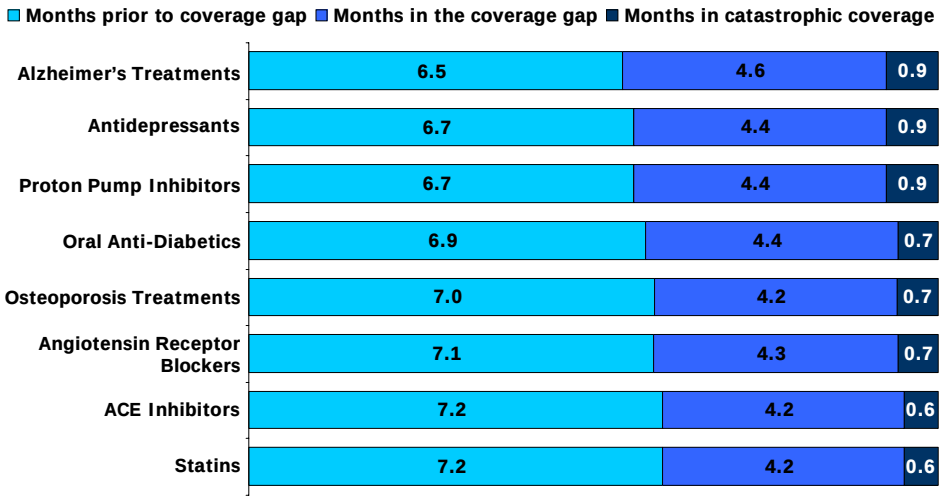
- Our analysis shows only modest variation in the average number of months spent by non-LIS Part D enrollees in the coverage gap and in catastrophic coverage across the eight drug classes **(Exhibit 9)**.

- Part D enrollees using drugs for Alzheimer's disease reached the coverage gap somewhat sooner than enrollees using other types of drugs and spent slightly more time in the gap.
  - Among non-LIS Part D enrollees taking drugs to treat Alzheimer's disease who reached the gap, the average number of months in the initial benefit period (prior to reaching the coverage gap) was 6.5 months, slightly less time than among users of other types of drugs.
  - Those taking drugs for Alzheimer's disease who reached the coverage gap spent 4.6 months in the gap and just under than one month in the catastrophic coverage period.

- Part D enrollees using statins, ACE inhibitors, and ARBs looked more like average users, reaching the coverage gap slightly later in the year than users of other types of drugs in our analysis, and spending a shorter average amount of time in the gap. The people using drugs in these three classes appear to be relatively healthy beneficiaries taking drugs to treat a single chronic condition.

Exhibit 9

Average Number of Months Prior to the Coverage Gap and in the Coverage Gap in 2007, By Drug Class



NOTES: Estimates based on analysis of retail pharmacy claims for 1.9 million Part D enrollees in 2007.
SOURCE: Georgetown University/NORC/Kaiser Family Foundation analysis of IMS Health LRx database, 2007.

Did Part D Enrollees Change Their Drug Use When They Reached the Coverage Gap and Catastrophic Coverage?

- Among non-LIS Part D enrollees taking prescriptions in one of the eight drug classes, the majority of those who reached the coverage gap made no detectable change in their medication use for the drug (or drugs) they were taking within the class when they reached the gap **(Exhibit 10)**. However, averaged across the eight classes, 20 percent of those who reached the gap made some change in their use of drugs within the selected class, while others may have stopped taking a drug in another class to continue taking medication in the studied class:[14]
  - 15 percent **stopped taking their medication**;
  - 5 percent **switched to another medication** (most often a generic drug) in the same class; and
  - 1 percent **reduced the number of separate medications** they were taking in the class.[15]
- Among users of the eight classes of drugs, there was considerable variation in the share of those who stopped taking their medications when they reached the coverage gap **(Exhibit 10)**.
  - Ten percent of patients taking medication for diabetes stopped taking their medication when they reached the coverage gap, and an additional 5 percent stopped taking one of multiple drugs they were taking in the class. Terminating use of drugs used to manage diabetes could pose serious and immediate health concerns.
  - About one-fifth of enrollees taking PPIs for ulcers or acid reflux stopped taking their medications when they reached the gap. Because there is some concern that PPIs are overused for more routine gastrointestinal conditions, terminating medication use might not pose serious health risks in some cases. Furthermore, some PPI users may have switched either to over-the-counter version of Prilosec (generic omeprazole) or other gastrointestinal treatments.
  - About one-fifth of enrollees taking drugs for osteoporosis stopped taking their medications when they reached the gap. Termination of drugs taken for osteoporosis might not result in perceptible short-term health effects, but could increase the risk of falls and fractures over a longer term.
  - Among the eight classes of drugs, the class with the smallest share of users who stopped taking medication when they reached the coverage gap was Alzheimer's disease treatments. Although the clinical effectiveness of drugs in this class has been questioned, patients or their family members may be reluctant to stop therapy altogether in the hope that they might provide some beneficial therapeutic effect.
- Among the small share of Part D enrollees using drugs in the eight drug classes who stopped taking their medication during the coverage gap and then qualified for catastrophic coverage, 57 percent remained off that medication, even after reaching catastrophic coverage which offers virtually full coverage of total spending **(Exhibit 11)**. About one-third returned to their original medication when they entered catastrophic coverage, while a small share started a new medication.

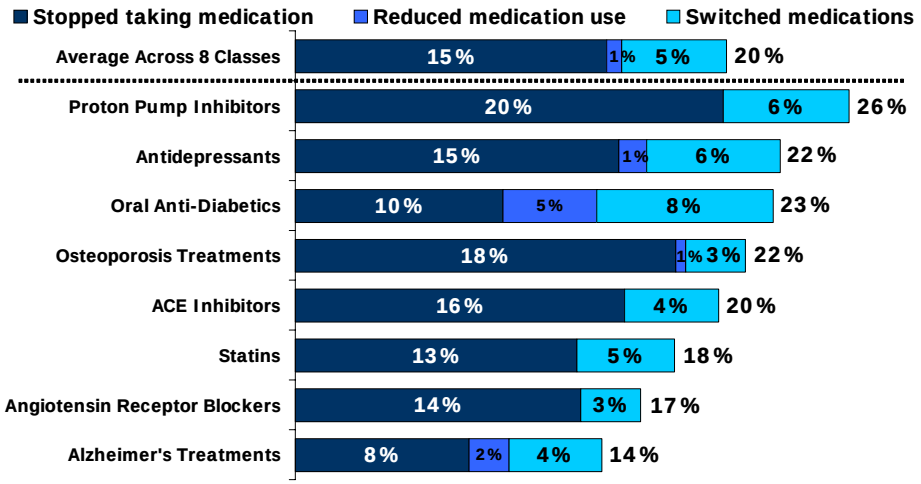
[14] Our analysis considers only medication changes within the classes selected for study. We are unable to tell if enrollees who reached the gap stopped taking or reduced medications in another drug class in order to continue taking medication within the classes in our study, nor are we able to tell if enrollees were receiving free samples from their physicians. Some individuals shown as discontinuing, reducing, or switching medications might have done so for clinical reasons coincidental with the time of reaching the gap.

[15] For example, some beneficiaries taking multiple anti-diabetes drugs stopped taking one but continued taking the other. This analysis cannot identify any beneficiaries who may have taken their pills less often. As long as they filled another prescription during the time period being examined, they are considered to have remained on therapy. Conversely, some beneficiaries may find cheaper drugs to switch to in another class, such as switching from PPIs to H2 antagonists. These individuals are reported as stopping therapy because their therapeutic substitution is outside the class being studied. For more information, see the methodology appendix.

Exhibit 10

Changes in Drug Use By Part D Enrollees Who Reached the Coverage Gap in 2007

Among Part D enrollees who reached the coverage gap, percent who:

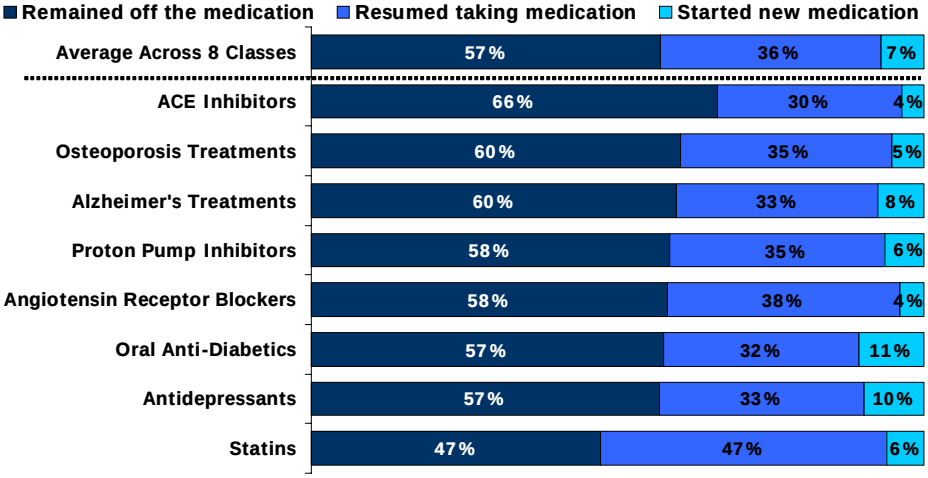


NOTES: Estimates based on analysis of retail pharmacy claims for 1.9 million Part D enrollees in 2007.
SOURCE: Georgetown University/NORC/Kaiser Family Foundation analysis of IMS Health LRx database, 2007.

Exhibit 11

Changes in Drug Use By Part D Enrollees Who Reached Catastrophic Coverage in 2007

Among Part D enrollees who stopped taking medication in the coverage gap and reached catastrophic coverage, percent who:



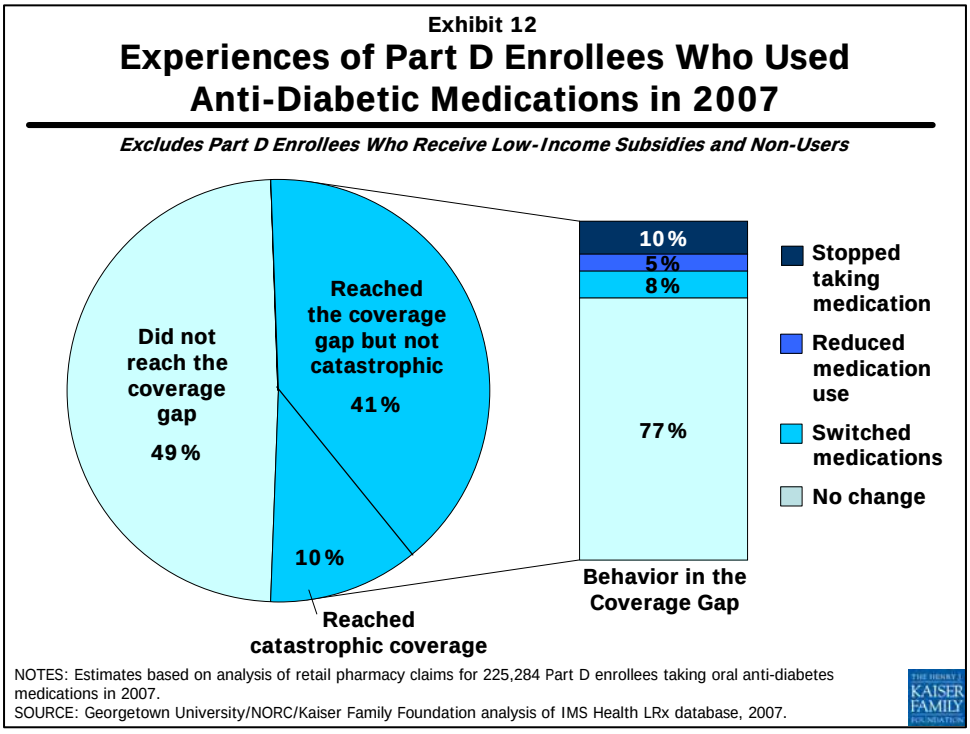
NOTES: Estimates based on analysis of retail pharmacy claims for 1.9 million Part D enrollees in 2007. Numbers may not sum to 100% due to rounding.
SOURCE: Georgetown University/NORC/Kaiser Family Foundation analysis of IMS Health LRx database, 2007.

Coverage Gap Case Study #1: Anti-Diabetics

- Overall, 51 percent of Part D enrollees using oral anti-diabetes medications in 2007 had spending high enough to reach the coverage gap **(Exhibit 12)**.

- Of those who reached the coverage gap, 23 percent made some change in their diabetes medications after they reached the gap, while others may have made adjustments to medications for other health conditions in order to maintain their diabetes drugs.
  - Ten percent of Part D enrollees taking medication for diabetes who reached the coverage gap stopped taking their anti-diabetes medications, with potentially severe and immediate adverse health consequences. These situations are not only potentially serious for the individual, but could also result in higher Medicare spending for preventable emergency room visits and hospitalizations.
  - Another 5 percent of diabetics who reached the coverage gap reduced their medication use; for example, they stopped filling one of multiple prescriptions being taken for diabetes.
  - Eight percent of those who reached the coverage gap switched to a different anti-diabetic drug. The largest number of those who switched moved to a combination of a brand and a generic drug, while most others switched to a generic drug.

- Ten percent of Part D enrollees taking anti-diabetics in 2007 ultimately received catastrophic coverage before the end of the year (which translates into about one-fifth of those who had spending in the coverage gap). More than half (57 percent) of those who stopped taking their medication during the coverage gap remained off that medication even after they qualified for catastrophic coverage, while 32 percent resumed medication which they had stopped taking in the coverage gap and 11 percent began taking a different drug.

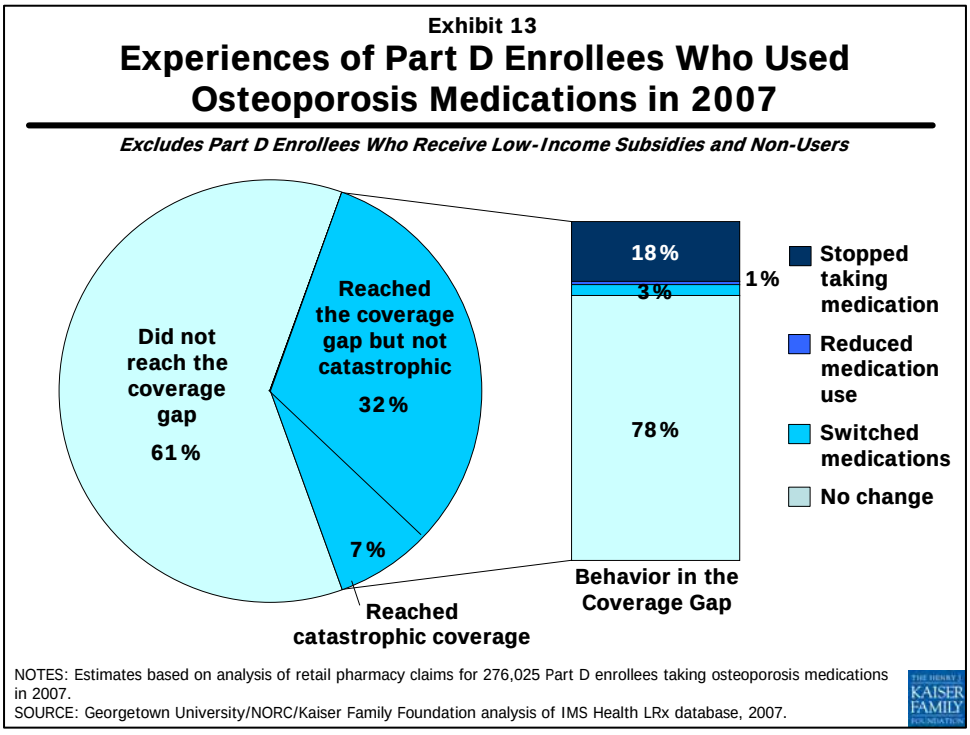


Coverage Gap Case Study #2: Osteoporosis Treatments

- Among Part D enrollees using a drug to treat osteoporosis (commonly taken on a long-term basis to prevent bone loss and reduce the risk of fracture), 39 percent had spending high enough to reach the coverage gap in 2007 **(Exhibit 13)**.

- Of those users of drugs to treat osteoporosis who reached the coverage gap, 22 percent made a change in their medication use for osteoporosis after reaching the gap.
  - Eighteen percent who reached the coverage gap stopped taking their osteoporosis medication, and another one percent reduced the number of drugs they were taking in the class. Since these medications generally have imperceptible health effects, some patients may have concluded that they could discontinue treatment without serious adverse consequences.
  - Only three percent of enrollees taking a drug to treat osteoporosis who reached the coverage gap switched to another medication in this class. Because generic alternatives were not available for the most popular brand-name drugs in this class in 2007, switching to a generic was not an option for most osteoporosis drug users.

- Seven percent of Part D enrollees taking drugs to treat osteoporosis in 2007 ultimately received catastrophic coverage before the end of the year (less than one-fifth (17%) of those who had spending in the coverage gap). Sixty percent of those who stopped taking their medications during the coverage gap remained off that medication even after they qualified for catastrophic benefits, while 35 percent resumed medication they had stopped taking in the coverage gap and five percent began taking a different osteoporosis drug.



Coverage Gap Case Study #3: ACE Inhibitors

- Of all non-LIS Part D enrollees using an ACE inhibitor, generally used to treat hypertension, roughly one-third had spending high enough to reach the coverage gap in 2007 **(Exhibit 14)**.

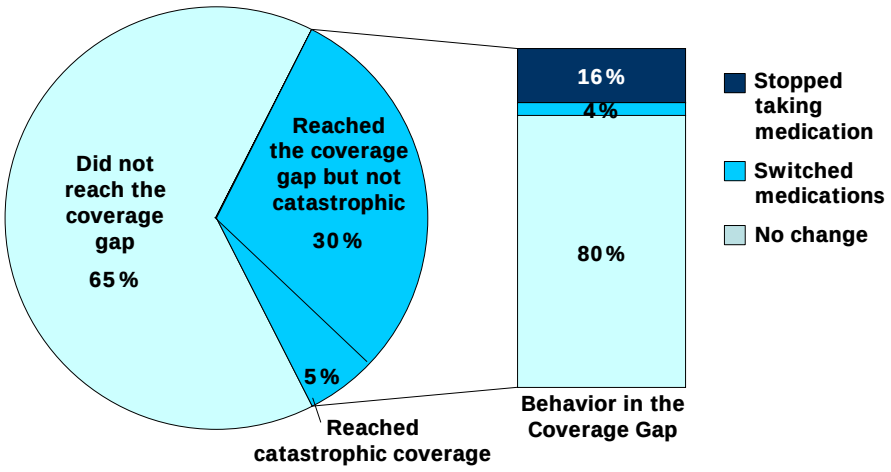
- Of those ACE inhibitor users who reached the coverage gap, one-fifth made a change in their use of ACE inhibitors after reaching the gap.
  - Sixteen percent of those who reached the coverage gap stopped taking any medication in this drug class when they reached the gap. Given that therapeutic alternatives to treat hypertension are available in other drug classes, it is possible that some of those who stopped taking an ACE inhibitor when they reached the gap might have switched to a medication in a different class to treat their hypertension (such as a less expensive diuretic).
  - A small share (4 percent) of ACE inhibitor users who reached the gap switched drugs within this class, primarily to a generic drug.

- Only 5 percent of Part D enrollees taking ACE inhibitors reached catastrophic coverage, and of that group, most remained on their therapy throughout the coverage gap. Of those who stopped their ACE inhibitor medication when they reached the coverage gap, 66 percent remained off that medication when they reached catastrophic coverage, 30 percent resumed taking the medication they had discontinued, and 4 percent started taking a different medication in the ACE inhibitor class.

Exhibit 14

Experiences of Part D Enrollees Who Used ACE Inhibitors in 2007

Excludes Part D Enrollees Who Receive Low-Income Subsidies and Non-Users



NOTES: Estimates based on analysis of retail pharmacy claims for 519,425 Part D enrollees taking ACE Inhibitors in 2007.
SOURCE: Georgetown University/NORC/Kaiser Family Foundation analysis of IMS Health LRx database, 2007.

What Were the Patterns in Total and Out-of-Pocket Spending Among Part D Enrollees in 2007?

Total Spending

- Total drug spending for Part D enrollees averaged $2,146 (about $179 per month) in 2007 **(Exhibit 15)**.

- Average total drug spending for the year was higher among low-income subsidy recipients than among all other Part D enrollees ($2,486 vs. $1,661, respectively).

    - The higher level of spending among low-income subsidy recipients may be due to several factors. Beneficiaries who are dually eligible for Medicare and Medicaid account for a large share of low-income subsidy recipients, and take more medications, on average, than others on Medicare.[16] Also, because low-income subsidy recipients continue to receive subsidies through the coverage gap and because they are charged the same copayments for all covered brand-name drugs, they may have little financial incentive to switch to a lower-cost medication or stop taking their medications to reduce their total drug spending in the coverage gap, which could be the case for some non-LIS enrollees who reach the gap.

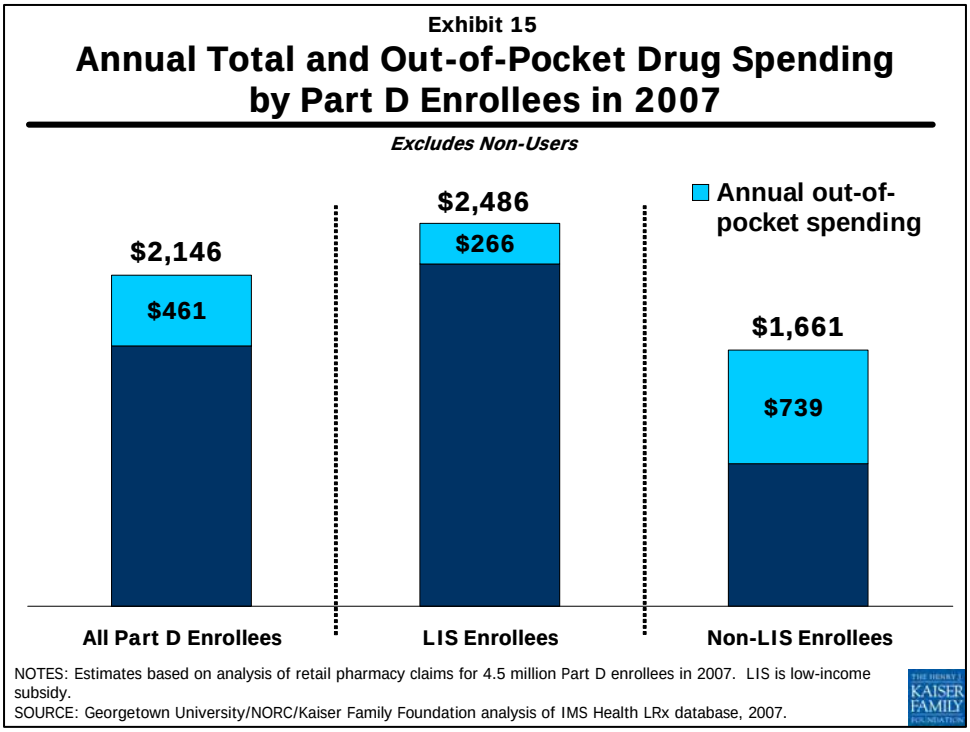
Out-of-Pocket Spending

- Part D enrollees spent, on average, $461 (about $38 per month) out of pocket on prescription drugs in 2007, excluding amounts they may have paid in premiums for their Part D plans.

- As expected, out-of-pocket spending was substantially lower among Part D enrollees receiving low-income subsidies ($266 per year/$22 per month) than for all other Part D enrollees ($739 per year/$62 per month).

Exhibit 15

Annual Total and Out-of-Pocket Drug Spending by Part D Enrollees in 2007



NOTES: Estimates based on analysis of retail pharmacy claims for 4.5 million Part D enrollees in 2007. LIS is low-income subsidy.
SOURCE: Georgetown University/NORC/Kaiser Family Foundation analysis of IMS Health LRx database, 2007.

[16] Kaiser Family Foundation analysis of the CMS Medicare Current Beneficiary Survey Cost and Use file, 2005.

How Were Total and Out-of-Pocket Spending Levels Affected by the Coverage Gap and Catastrophic Coverage?

Total Spending

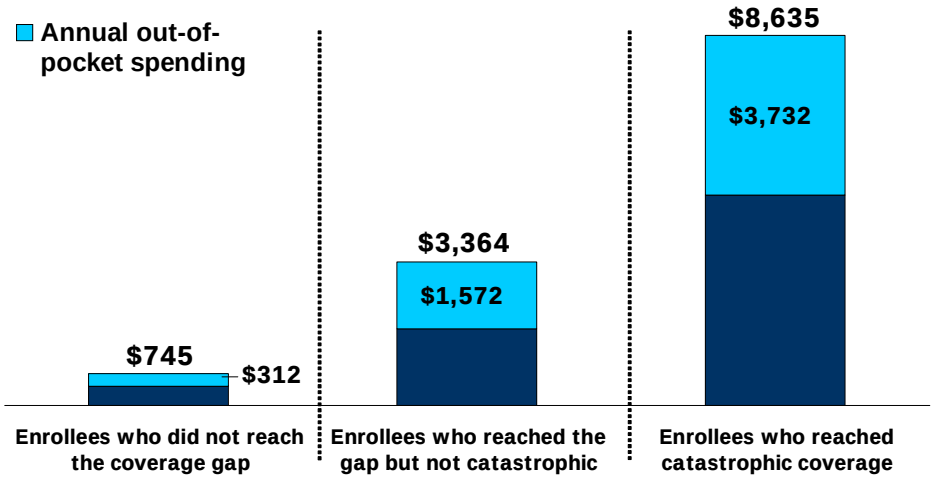
- As would be expected, average annual total spending for Part D enrollees who did not reach the coverage gap in 2007 was much lower than for those who reached the coverage gap **(Exhibit 16)**.
    - On average, those who did not reach the gap spent $745 on prescription drugs in 2007, while those who reached the gap but not catastrophic coverage spent $3,364. Average annual total drug spending among those who reached catastrophic coverage was $8,635.

- Patterns of total drug spending over the course of 2007 by non-LIS Part D enrollees with spending high enough to reach the gap are consistent with our finding that some enrollees stopped taking medication or switched medications when they reached the coverage gap. Spending patterns varied depending on when enrollees reached the gap during the year **(Exhibit 17)**.
    - Total average drug spending for Part D enrollees with spending high enough to reach the coverage gap in the first few months of 2007 dropped from $1,063 per month in the pre-gap period to $713 per month during the gap, suggesting that some enrollees changed their use of medications upon reaching the gap (i.e., they stopped taking a medication or switched to a lower-cost alternative). Other beneficiaries may have had a one-time medical event or condition that required higher drug use in the first quarter. Among those with spending high enough to reach catastrophic coverage, total monthly drug spending increased to pre-gap levels.
    - Total monthly spending for Part D enrollees who reached the coverage gap in the second quarter of the year (April-June) followed a similar pattern, decreasing from an average of $509 per month prior to reaching the gap to $395 per month when they reached the gap. Total spending increased to $713 per month among those who reached catastrophic coverage.
    - Enrollees who reached the coverage gap in the third quarter (July-September) had lower average monthly total spending prior to reaching the gap than those who reached the gap earlier in the year, as well as a less pronounced drop in total drug spending once they reached the coverage gap. Those with total drug spending that put them into the coverage gap in the last few months of the year followed a similar pattern to the previous cohort, but with a slight increase in average total drug spending during the gap. For the very small share of enrollees who went on to reach catastrophic coverage late in the year, the spike in monthly total spending during the catastrophic coverage phase is likely a result of a health shock or other event that required spending on new medications which put them over the catastrophic limit.

Exhibit 16

Annual Total and Out-of-Pocket Drug Spending by Part D Enrollees in 2007, by Benefit Phase

Excludes Part D Enrollees Who Receive Low-Income Subsidies and Non-Users

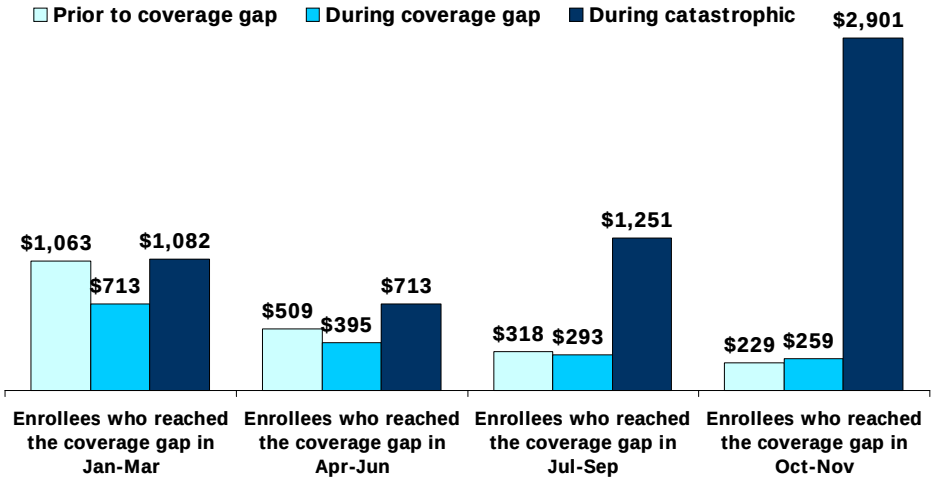


NOTES: Estimates based on analysis of retail pharmacy claims for 1.9 million Part D enrollees in 2007.
SOURCE: Georgetown University/NORC/Kaiser Family Foundation analysis of IMS Health LRx database, 2007.

Exhibit 17

Monthly Total Drug Spending by Part D Enrollees Who Reached the Coverage Gap in 2007

Excludes Part D Enrollees Who Receive Low-Income Subsidies and Non-Users

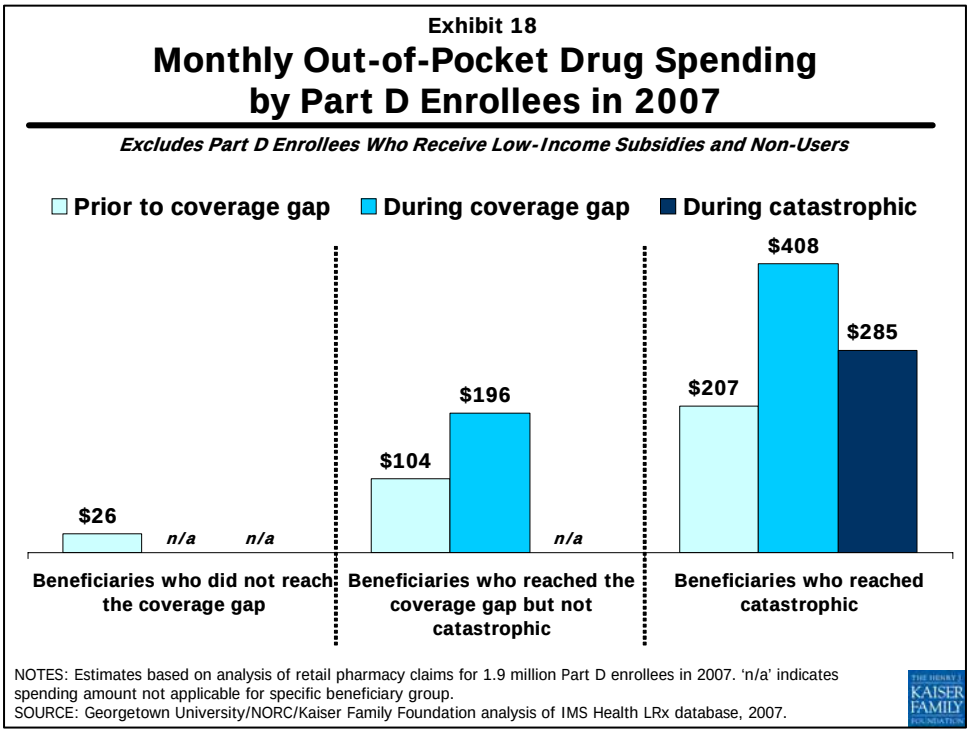


NOTES: Estimates based on analysis of retail pharmacy claims for 1.9 million Part D enrollees in 2007.
SOURCE: Georgetown University/NORC/Kaiser Family Foundation analysis of IMS Health LRx database, 2007.

Out-of-Pocket Spending

- Despite the average reduction in total spending during the gap, average monthly out-of-pocket spending on prescription drugs nearly doubled for beneficiaries after they reached the coverage gap **(Exhibit 18)**. The actual change might be even greater if we had complete information on beneficiaries' gap status since misclassifications tend to mute the differences.
  - Among Part D enrollees who reached the coverage gap but not catastrophic coverage, average out-of-pocket spending increased from $104 per month during the pre-gap period to $196 per month during the coverage gap.
  - Among those with spending high enough to qualify for catastrophic coverage, average out-of-pocket spending increased from $207 per month during the pre-gap period to $408 per month during the coverage gap.

- For Part D enrollees with spending high enough to qualify for catastrophic coverage, monthly out-of-pocket spending dropped from $408 per month during the coverage gap, on average, to $285 per month during catastrophic coverage.
  - The finding that out-of-pocket spending in the catastrophic coverage period was higher than the average pre-gap level of $207 per month is somewhat counterintuitive, since Part D plans are required to cover a substantially larger share of drug costs (95%) in the catastrophic coverage period than prior to the gap. The relatively high level of out-of-pocket monthly spending we observed during the catastrophic coverage period could be due to several factors:
    - Some Part D enrollees who reach the catastrophic coverage level might have experienced a change in health conditions during the course of the year that resulted in higher total and out-of-pocket costs.
    - Some beneficiaries might have been paying out of pocket for the full cost of drugs not covered by their Part D plan.
    - The gap status for some beneficiaries might be misclassified based on our methodology. Beneficiaries who were not actually receiving catastrophic coverage would be paying a higher share of their costs.



DISCUSSION

With the Medicare prescription drug benefit now in its third year of implementation, there continues to be considerable interest in understanding how well the benefit is working for the 25 million people on Medicare currently enrolled in Part D plans. This study focused on the "doughnut hole", a unique feature of the Medicare drug benefit which leaves a gap in coverage, in order to estimate how many enrollees reached the coverage gap and catastrophic coverage in 2007 and to assess the extent to which the gap affected enrollees' use of medications and out-of-pocket spending. Our findings suggest that a large share of Medicare Part D enrollees who take prescription drugs and are not receiving low-income subsidies can expect to have spending in the coverage gap, while only a small share of these enrollees pass through the gap and qualify for catastrophic coverage. Out-of-pocket spending increased substantially when enrollees reached the coverage gap in 2007, which could help to explain our finding that some enrollees who reached the gap made changes to their drug use regimen, including stopping their medications altogether.

From a health outcomes perspective, our finding that some enrollees stopped taking their medications or reduced medication use when they reached the coverage gap could be a serious concern. Individuals with diabetes, for example, risk immediate and potentially serious health consequences if they stop taking their medications. For individuals with other chronic conditions, such as osteoporosis, the health effects from stopping their medications might not be immediately apparent but it could increase their risk of hip fractures and other negative outcomes. On the other hand, switching medications to save money might be a clinically acceptable response to the coverage gap.

Physicians can play an important role in helping beneficiaries who reach the coverage gap identify opportunities to switch to lower-cost alternatives. To do so, however, physicians and their patients would need to talk with each other about drug costs, and the evidence thus far indicates that these conversations do not routinely occur.[17] Ultimately, both stopping and switching medications could result in higher costs for other parts of the Medicare program if beneficiaries have health issues that are not being controlled by medication, or if they simply require more physician visits to prescribe and monitor changes in medications.

This study did not measure awareness and understanding of the coverage gap among Part D enrollees, but other research suggests that many are unaware that such a gap exists in the Medicare drug benefit and few enrollees report understanding how it works or knowing how to track their status in relation to the coverage gap.[18] Enrollees who do not understand the coverage gap could be more likely to view it as a financial burden and less prepared to respond with some type of cost-coping behavior.

Although the cost of closing the so-called "doughnut hole" may present a serious challenge to policymakers in the current fiscal climate, raising awareness among Part D enrollees and their physicians about the coverage gap and improving enrollees' ability to monitor their total drug spending in relation to the gap could minimize the risk that enrollees who reach the gap will incur high out-of-pocket costs or experience preventable adverse outcomes from medication nonadherence. Careful attention is needed to ensure that gains to Medicare beneficiaries from the addition of the Part D drug benefit are not undermined by the coverage gap—especially for those enrollees who are highly dependent on medications to manage ongoing chronic conditions.

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[17] See, for example, I. Wilson et al., 2007, "Physician-Patient Communication about Prescription Medication Nonadherence: A 50-State Survey of America's Seniors," *Society of General Internal Medicine* 2007;22:6-12; published online January 5, 2007.
[18] J. Hsu et al., 2008, "Medicare Beneficiaries; Knowledge of Part D Prescription Drug Program Benefits and Responses to Drug Costs," *JAMA* 299(16): 1929-1936; and E. Hargrave et al., "Experiences Obtaining Drugs under Part D: Focus Groups with Beneficiaries, Physicians, and Pharmacists," report submitted to the Medicare Payment Advisory Commission, May 2008, http://www.medpac.gov/documents/May08_PartDFocusGroup_CONTRACTOR_JS.pdf.

APPENDIX: DATA AND METHODOLOGY

IMS Health Longitudinal Prescription (LRx) Database

The IMS Health Longitudinal prescription database (LRx) used for this analysis consists of patient de-identified longitudinal prescription data from a sample of IMS' retail prescription universe. Data is collected for the LRx database via direct data feeds from retail pharmacies (pharmacy chains, food stores, independent pharmacies, mass merchandisers) and from pharmacy benefit managers (PBMs). This database currently captures over 50 percent of all retail prescriptions filled in the United States and over 150 million unique patients.[1]

Each prescription in the IMS LRx database includes information about the name, form, strength, and units dispensed, the date the prescription was dispensed, and the specific amount and source of payment (e.g., beneficiary, Medicare drug plan, other payer).

The database maintains longitudinal, person-level records, tracking beneficiaries as they use multiple pharmacies as long as their pharmacy or PBM is part of the IMS panel. All data loaded into the LRx database are encrypted by an independent third party to ensure HIPAA compliance while allowing the database to maintain person-level records. The database includes only basic demographic information such as age and sex.

Identifying Part D Enrollees

In the LRx database, IMS identified Part D enrollees based on information about the third-party payers covering part of their transactions. Individuals were labeled by IMS as Part D enrollees only if there was information that clearly identified them as being in a Part D plan. Within the database, some plans are more clearly labeled than others. For about 18 percent of Part D plans, IMS has information indicating only the PBM or the organization, not the specific Part D plan. In these cases, IMS does not assign individuals to a Part D plan, because it is possible that they are enrolled in an employer-sponsored plan using the same insurance company as a Part D plan.

Within LRx, IMS identified 4.5 million Part D enrollees in 2007. Comparing the patient and prescription metrics from the LRx data relative to total prescriptions from its *National Prescription Audit* (NPA), IMS estimates that these 4.5 million individuals represent approximately 18.2 million of the 24.8 million beneficiaries enrolled in Part D in 2007 (73 percent of total Part D enrollees). The remaining 6.6 million Part D enrollees not represented by this database includes: Part D enrollees for whom plan type could not be clearly identified; Part D enrollees who did not fill at least one prescription in 2007; Part D enrollees residing in an institution that fills prescriptions through institutional pharmacies such as those at long-term care or assisted-living facilities; and Part D enrollees who use mail order exclusively to fill prescriptions.

Identifying Low-Income Subsidy Recipients

Dual eligibles and other beneficiaries receiving the Part D Low Income Subsidy (LIS) are not subject to the coverage gap, so we excluded them from most of the analyses in this report to focus on the experiences of Part D enrollees in the gap. However, IMS data do not identify Medicaid status of Part D enrollees or participation in LIS. As a proxy, we identified patients whose cost-sharing amount was $5.60 or less per prescription and 15 percent or less of the total prescription cost. Applying this methodology to

[1] IMS captures a total of 70 percent of all retail prescriptions in its largest database, but not all of these can be linked at the person level for the LRx database.

the 4.5 million total Part D enrollees in our sample, 2.7 million individuals were categorized as LIS recipients.

Our methodology may inaccurately classify some low-spending non-LIS enrollees as LIS recipients. As a test of how well these specifications classified beneficiaries, we examined out-of-pocket costs for both groups. Beneficiaries classified as LIS recipients paid an average of 11 percent of total drug costs out of pocket in 2007, while beneficiaries classified as non-LIS recipients paid an average of 45 percent of total drugs costs out of pocket. To the extent that 11 percent cost sharing may be somewhat higher than we might expect for LIS beneficiaries, the misclassification of some non-LIS enrollees as LIS recipients could result from several factors, such as when a non-LIS enrollee takes only generic drugs and belongs to a plan with generic copayments no higher than LIS copayment amounts. Some LIS enrollees might be misclassified, for example, when they pay full price to use off-formulary drugs or use inexpensive drugs for which their small copayment is a relatively high percentage of the total cost.

Classification of Part D Enrollees, Based on Eight Drug Classes

In order to analyze adherence among Part D enrollees who reached the coverage gap, we selected eight groups comprised of users of drugs in eight drug classes: (1) ACE Inhibitors; (2) Alzheimer's Disease Treatments; (3) Anti-Depressants; (4) Angiotensin Receptor Blockers (ARBs); (5) Oral Anti-Diabetics; (6) Osteoporosis Treatments; (7) Proton Pump Inhibitors (PPIs); and (8) HMG-CoA Reductase Inhibitors (Statins). Each group consists of individuals who filled at least one prescription during the period from January 1, 2007 through December 31, 2007 in the class (or market) of interest. An enrollee may be included in more than one group, if that enrollee filled prescriptions in more than one class during 2007. Appendix Table A2 includes the full listing of products used to define each drug class. For the plan enrollees identified based on at least one prescription in the select drug classes, information was retained on drugs used in all drug classes. As described below, information on changes in medication use was studied for only the select drug classes.

Defining the Coverage Gap and Catastrophic Coverage

To determine when a non-LIS Part D enrollee reached the coverage gap and catastrophic coverage, total spending per enrollee on all prescriptions across all drug classes in 2007 was aggregated and divided into spending by month. If an enrollee's cumulative total drug spending reached $2,400 in a particular month, the upper limit of the initial benefit period in 2007, the enrollee was classified as having reached the coverage gap that month. If an enrollee's total drug spending reached $5,451 in a particular month, the upper limit of the coverage gap, the enrollee was classified as having reached catastrophic coverage in that month. Some reached both limits in the same month.

As a test of how well these rules classified enrollees, we examined the percent of total spending that enrollees paid out of pocket in 2007. According to the standard benefit design, we would expect beneficiaries to pay 33 percent of costs before entering the coverage gap, on average (a deductible plus 25 percent of the costs in the initial coverage period), 100 percent of costs during the coverage gap, and at least 5 percent of costs after reaching catastrophic coverage. Our results generally follow this pattern but are not equal to the expected rates of out-of-pocket spending, as shown in the table below.

Table A1: Out-of-Pocket Spending as Share of Total Spending, by Gap Status

	Before the Coverage Gap	Month Coverage Gap is Reached	During Gap	Month Catastrophic is Reached	During Catastrophic
All non-LIS drug users	38%	53%	73%	53%	27%

SOURCE: Georgetown/NORC/Kaiser Family Foundation analysis of IMS Health LRx database, 2007.

The fact that Part D enrollees did not appear to pay 100 percent of costs in the gap could be due to several reasons:

- Some beneficiaries have partial coverage for drug costs in the gap, either from a drug plan offering enhanced coverage or from a State Pharmaceutical Assistance Program (SPAP).

- Because of the inclusion of uncovered drugs and the exclusion of prescriptions filled outside of pharmacies in the IMS sample, our estimates of when some individual beneficiaries reach the gap may be off.

Similarly, the fact that enrollees paid considerably more than 5 percent of costs during catastrophic coverage has several potential explanations:

- Some beneficiaries pay out of pocket for the full cost of off-formulary drugs.

- Because enrollees in 2007 paid the greater of $2.15 (for generic drugs), $5.35 (for brand drugs), or 5 percent during catastrophic coverage, those using inexpensive drugs could pay considerably more than 5 percent of the cost for those drugs.

- For various reasons, our estimates of when some individual beneficiaries reach catastrophic coverage may be off.

Defining Changes in Drug Use For Those Who Reach the Coverage Gap

For Part D enrollees with total spending high enough to reach the coverage gap, we examined whether they made any changes in drug use while in the gap. As a benchmark for comparison for each enrollee, we determined the drug or set of drugs (within the class) that the enrollee filled most recently prior to the month in which they reached the coverage gap.[2] We then compared this regimen to prescriptions filled within the drug class during the gap. Each enrollee was categorized into one of the following groups:

- **No change (remained on medication):** For these enrollees, their drug regimen during the coverage gap was the same as the drug use prior to the gap, based on the second prescription filled within the class during the coverage gap (and all other prescriptions within the class with days supply overlapping the second prescription). We used the second prescription based on the assumption that beneficiaries might have only realized they reached the coverage gap upon filling an initial prescription. However, if an enrollee did not have a second prescription within the coverage gap, the first prescription filled within the class of interest in the coverage gap was compared to the pre-gap regimen.

- **Stopped taking medication**: These enrollees filled at least one prescription for a drug in the class of interest prior to reaching the coverage gap and filled no more than one initial prescription for any drug in the same market while in the coverage gap.

- **Switched medications:** For these enrollees, their drug regimen during the coverage gap was different from their pre-coverage gap use, as defined above. Those who switched drugs in the coverage gap were further categorized as switching to generic therapy or switching to another brand.

- **Reduced medication use:** For these enrollees, their drug regimen during the coverage gap was a subset of the regimen they were taking prior to the coverage gap, indicating that the enrollee

[2] For monthly prescriptions this would be the prescription filled in the month before the individual hit the gap. But for those filling prescriptions less often, the benchmark prescription might have been filled a month or two earlier.

continued some products within the class of interest in the gap but not the entire regimen. This was tested for enrollees taking drugs in the Anti-Depressants, Oral Anti-Diabetics, Alzheimer's disease and Osteoporosis classes, in which it is common for patients to take multiple drugs within the class. For Statins, ACE Inhibitors, ARBs, and PPIs, patients generally take just one drug in the class.

Enrollees who subsequently reached catastrophic coverage were similarly categorized for into these four categories while in the period of catastrophic coverage. Using this information, we were able to identify such patterns as stopping medications during the gap and then resuming them during catastrophic or remaining off the medications during catastrophic coverage.

Our analysis considers only medication changes within the classes selected for study. We are unable to tell if enrollees who reached the gap stopped taking or reduced medications in another drug class in order to continue taking medication within the classes in our study, nor are we able to tell if enrollees were receiving free samples from their physicians. Some individuals shown as discontinuing, reducing, or switching medications might have done so for clinical reasons coincidental with the time of reaching the gap.

Data Limitations

There are several limitations to the data that may affect the precision of our estimates—particularly with respect to the share of Part D enrollees who reach the coverage gap and the share who qualify for catastrophic coverage. After a careful review of potential sources of bias, we are not able to quantify the impact of these sources of bias. In fact, it is not entirely clear whether the limitations result in a net bias that produces higher or lower estimates of the share of enrollees who reached the coverage gap. There are factors that operate in both directions in terms of inflating and deflating the estimate.

Our estimate could be biased upward due to several factors:

- The IMS database includes only Part D enrollees who use prescriptions. Including non-users enrolled in Part D in the denominator would produce a lower estimate of the share of Part D enrollees who reach the coverage gap.

- The IMS database does not allow for identification of LIS status other than by using low cost-sharing amounts; the designation of LIS status based on cost-sharing amounts could inadvertently exclude valid cases from the study sample by misidentifying some non-LIS Part D enrollees with low drug spending (e.g., those who use a limited number of generic drugs only) as LIS recipients and thus excluding them from the count of those not reaching the gap. This factor might be somewhat mitigated by the exclusion of some enrollees with coverage through state pharmacy assistance programs (SPAPs) that brings out-of-pocket costs down to LIS levels, but who might have costs sufficient to reach the gap without the protection provided by the SPAP.

- The IMS database does not provide sufficient information about Part D plans (in particular, it does not distinguish among the multiple plan offerings of a single sponsor) to allow for identification of the small share of enrollees in plans with gap coverage, which prevents us from excluding them from the analysis.

- The IMS database does not identify which pharmacy claims are for the purchase of off-formulary drugs, which do not count toward the spending totals that trigger the coverage gap or catastrophic coverage. Because we cannot exclude these spending amounts from our analysis, this would inflate expenses for at least a subset of Part D enrollees, placing them in the gap and catastrophic coverage sooner than they otherwise might be.

In addition, our estimate could be biased downward due to several factors:

- For those Part D enrollees in the IMS sample who also fill prescriptions at pharmacies excluded from the dataset, their actual total spending amounts would be higher than the IMS data suggest, which could reduce our estimate of the share with spending high enough to reach the coverage gap or catastrophic coverage. It would also affect our estimate of when enrollees reach the gap.

- Similarly, Part D enrollees in the IMS sample who fill prescriptions through both retail pharmacies and mail order would have higher actual spending than is reported in the IMS data. To the extent that enrollees fill their maintenance medications by mail and fill only one-time or some new prescriptions at retail, then spending for these individuals would be substantially underestimated.

- The IMS dataset does not capture the universe of Part D prescription drug claims filled through institutional pharmacies, such as for beneficiaries in full-time residence at assisted living or long-term care (LTC) facilities who may be disproportionately high drug users. The exclusion of Part D enrollees from the sample who use institutional pharmacies could deflate our estimate of the share who reach the coverage gap to the extent such individuals are high users of medications. This effect might be mitigated somewhat by the fact that a large share of nursing home residents are LIS recipients, and would not be included in the study design.

Factors that could bias our estimates in either direction:

- Several groups are excluded from the IMS sample. They include full-time users of other excluded pharmacies such as mail-order, staff-model HMOs (such as Kaiser Permanente), or pharmacies not submitting data; users of pharmacies that provide inconsistent data; and enrollees in Part D plans that could not be identified. It is unclear whether any of these groups would have drug use higher or lower than average.

All estimates for Part D enrollees in this report exclude LIS recipients and those who did not use drugs or filled prescriptions only through mail order, institutional pharmacies, or other pharmacies not captured by the IMS Health LRx claims data. These exclusions apply to all references to Part D enrollees in this report when not stated explicitly or otherwise.

Although these data limitations might affect the precision of our estimates of the overall proportion of non-LIS drug users enrolled in Part D plans who reach the coverage gap, we are unable to quantify whether the net bias is upward or downward. Furthermore, we have no reason to think that the IMS data capture an unrepresentative profile of the experience of Part D enrollees once they reach the coverage gap, in terms of the effects on drug therapy changes or drug spending—issues which are central to understanding the overall effect of the coverage gap on Part D enrollees.

Table A2: Listing of Drugs in Selected Drug Classes

Drug Class 1: HMG-CoA Reductase Inhibitors (Statins)

USC	Product	Product Type
32180	ADVICOR	Brand
32110	ALTOPREV	Brand
32110	BAYCOL	Brand
31800	CADUET	Brand
32110	CRESTOR	Brand
32110	LESCOL	Brand
32110	LESCOL XL	Brand
32110	LIPITOR	Brand
32110	LOVASTATIN	Generic
32110	MEVACOR	Brand
32110	PRAVACHOL	Brand
32110	PRAVASTATIN SOD	Generic
32180	PRAVIGARD PAC	Brand
32110	SIMVASTATIN	Generic
32180	VYTORIN	Brand
32110	ZOCOR	Brand

Drug Class 2: ACE Inhibitors

USC	Product	Product Type
31111	ACCUPRIL	Brand
31112	ACCURETIC	Brand
31111	ACEON	Brand
31111	ALTACE	Brand
31118	AMLODIP BES/BENAZ HCL	Generic
31111	BENAZEPRIL HCL	Generic
31112	BENAZEPRIL/HCTZ	Generic
31111	CAPOTEN	Brand
31112	CAPOZIDE	Brand
31111	CAPTOPRIL	Generic
31112	CAPTOPRIL/HCTZ	Generic
31111	ENALAPRIL MAL	Generic
31112	ENALAPRIL MAL/HCTZ	Generic
31111	ENALAPRILAT	Generic
31111	FOSINOPRIL SOD	Generic
31112	FOSINOPRIL/HCTZ	Generic
31118	LEXXEL	Brand
31111	LISINOPRIL	Generic
31112	LISINOPRIL/HCTZ	Generic
31111	LOTENSIN	Brand
31112	LOTENSIN HCT	Brand
31118	LOTREL	Brand
31111	MAVIK	Brand
31111	MOEXIPRIL HCL	Generic
31112	MOEXIPRIL HCL/HCTZ	Generic
31111	MONOPRIL	Brand
31112	MONOPRIL HCT	Brand
31111	PRINIVIL	Brand
31112	PRINZIDE	Brand
31111	QUINAPRIL HCL	Generic
31112	QUINAPRIL HCL/HCTZ	Generic
31112	QUINARETIC	Generic
31118	TARKA	Brand
31111	TRANDOLAPRIL	Generic
31112	UNIRETIC	Brand
31111	UNIVASC	Brand
31112	VASERETIC	Brand
31111	VASOTEC	Brand
31112	ZESTORETIC	Brand
31111	ZESTRIL	Brand

Drug Class 3: Angiotensin Receptor Blockers (ARBs)

USC	Product	Product Type
31121	ATACAND	Brand
31122	ATACAND HCT	Brand
31122	AVALIDE	Brand
31121	AVAPRO	Brand
31123	AZOR	Brand
31121	BENICAR	Brand
31122	BENICAR HCT	Brand
31121	COZAAR	Brand
31121	DIOVAN	Brand
31122	DIOVAN HCT	Brand
31123	EXFORGE	Brand
31122	HYZAAR	Brand
31121	MICARDIS	Brand
31122	MICARDIS HCT	Brand
31121	TEVETEN	Brand
31122	TEVETEN HCT	Brand

Drug Class 4: Anti-Depressants

USC	Product	Product Type
64330	BUDEPRION SR	Generic
64330	BUDEPRION XL	Generic
64330	BUPROPION HCL	Generic
64330	BUPROPION HCL SR	Generic
64330	BUPROPION HCL XL	Generic
64340	CELEXA	Brand
64340	CITALOPRAM HBR	Generic
64350	CYMBALTA	Brand
64330	DESYREL	Brand
64350	EFFEXOR	Brand
64350	EFFEXOR XR	Brand
64340	FLUOXETINE HCL	Generic
64340	FLUVOXAMINE MAL	Generic
64340	LEXAPRO	Brand
64340	LUVOX	Brand
64330	NEFAZODONE HCL	Generic
64340	PAROXETINE HCL	Generic
64340	PAXIL	Brand
64340	PAXIL CR	Brand
64340	PEXEVA	Brand
64340	PROZAC	Brand
64340	PROZAC WEEKLY	Brand
64340	RAPIFLUX	Brand
64340	SARAFEM	Brand
64340	SERTRALINE HCL	Generic
64330	SERZONE	Brand
64330	TRAZAMINE	Brand
64330	TRAZODONE HCL	Generic
64350	VENLAFAXINE HCL	Generic
64330	WELLBUTRIN	Brand
64330	WELLBUTRIN SR	Brand
64330	WELLBUTRIN XL	Brand
64340	ZOLOFT	Brand

Drug Class 5: Alzheimer's Disease Treatments

USC	Product	Product Type
20400	ARICEPT	Brand
20400	ARICEPT ODT	Brand
20400	COGNEX	Brand
20400	EXELON	Brand
20400	NAMENDA	Brand
20400	RAZADYNE	Brand
20400	RAZADYNE ER	Brand

Drug Class 6: Oral Anti-Diabetics

USC	Product	Product Type
39211	ACETOHEXAMIDE	Generic
39280	ACTOPLUS MET	Brand
39230	ACTOS	Brand
39211	AMARYL	Brand
39280	AVANDAMET	Brand
39280	AVANDARYL	Brand
39230	AVANDIA	Brand
39211	CHLORPROPAMIDE	Generic
39211	DIABETA	Brand
39211	DIABINESE	Brand
39280	DUETACT	Brand
39220	FORTAMET ER	Brand
39211	GLIMEPIRIDE	Generic
39211	GLIPIZIDE	Generic
39211	GLIPIZIDE ER	Generic
39211	GLIPIZIDE XL	Generic
39280	GLIPIZIDE/METFORM	Generic
39220	GLUCOPHAGE	Brand
39220	GLUCOPHAGE XR	Brand
39211	GLUCOTROL	Brand
39211	GLUCOTROL XL	Brand
39280	GLUCOVANCE	Brand
39220	GLUMETZA	Brand
39211	GLYBURIDE	Generic
39211	GLYBURIDE MICRO	Generic
39280	GLYBURIDE/METFORM	Generic
39211	GLYCRON	Brand
39211	GLYNASE PRESTAB	Brand
39240	GLYSET	Brand
39280	JANUMET	Brand
39260	JANUVIA	Brand
39280	METAGLIP	Brand
39220	METFORMIN HCL	Generic
39220	METFORMIN HCL ER	Generic
39211	MICRONASE	Brand
39212	PRANDIN	Brand
39240	PRECOSE	Brand
39220	RIOMET	Brand
39213	STARLIX	Brand
39211	TOLAZAMIDE	Generic
39211	TOLBUTAMIDE	Generic

Drug Class 7: Osteoporosis Treatments

USC	Product	Product Type
59210	ACTONEL	Brand
59210	ACTONEL W/ CALC	Brand
59210	AREDIA	Brand
59290	BONISARA	Brand
59210	BONIVA	Brand
59220	CALCITONIN-SALMON	Generic
59210	DIDRONEL	Generic
59210	ETIDRONATE DISOD	Generic
59290	EVISTA	Brand
59230	FORTEO	Brand
59220	FORTICAL	Generic
59210	FOSAMAX	Brand
59210	FOSAMAX PLUS D	Brand
59290	FOSTEUM	Brand
59220	MIACALCIN	Brand
59210	PAMIDRONATE DISOD	Generic
59210	RECLAST	Brand
59210	SKELID	Brand
59210	ZOMETA	Brand

Drug Class 8: Proton Pump Inhibitors (PPIs)

USC	Product	Product Type
23420	ACIPHEX	Brand
23420	NEXIUM	Brand
23420	NEXIUM IV	Brand
23420	OMEPRAZOLE	Generic
23420	PREVACID	Brand
23420	PREVACID I.V.	Brand
23420	PREVACID SOLUTAB	Brand
23430	PREVPAC	Brand
23420	PRILOSEC	Brand
23420	PRILOSEC (OTC)	Brand
23420	PROTONIX	Brand
23420	PROTONIX IV	Brand
23420	ZEGERID	Brand

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