

Out-of-Plan Medication in Medicare Part D

Pamela N. Roberto, MPP, and Bruce Stuart, PhD

The Medicare prescription drug program, known as Part D, provides an optional drug benefit for Medicare beneficiaries administered by CMS through contracts with private health plan sponsors. Each time a beneficiary fills a prescription for a medication covered by Part D, the plan sponsor is responsible for electronically submitting documentation of the transaction, called a prescription drug event (PDE) record, to CMS. Each PDE record contains detailed information about the prescription fill, including the name of the drug, the quantity and number of days' supply of medication dispensed, payment made by the plan sponsor, and beneficiary cost-sharing. While CMS relies on the submission of PDE records to accurately administer the benefit and make payments to plans for drugs covered by Part D, there are several reasons why these data may provide an incomplete picture of a beneficiary's entire medication history. For example, over-the-counter (OTC) drugs, medications excluded from Part D coverage by law, off-formulary products, and medication samples obtained from physicians typically do not generate PDE records.¹ In addition, documentation of prescription fills for medications otherwise covered by the Part D program might also be missing if they are not adjudicated at the pharmacy and are therefore unknown to the plan sponsor.² Important sources of such out-of-plan use may include unadjudicated prescriptions paid in cash by the beneficiary, prescriptions filled at non-network pharmacies, prescriptions obtained through the Department of Veterans Affairs (VA), generic drugs purchased through pharmacy discount programs, and products obtained through other prescription assistance programs that operate outside of the Part D benefit.

Out-of-plan medication use by Part D enrollees raises a number of concerns. First, spending on drugs covered by Part D that occurs outside of the plan adjudication process may not be counted toward beneficiaries' true out-of-pocket spending, which can reduce program benefits for beneficiaries with high drug expenditures. Second, for payers, clinicians, and researchers who rely upon accurate administrative data,

ABSTRACT

Objectives

To determine the extent to which Medicare Part D enrollees fill unadjudicated prescriptions for diabetes, hypertension, and hyperlipidemia medications outside of the Part D benefit.

Study Design

Retrospective analysis of prescriptions filled by community-dwelling beneficiaries continually enrolled in a Medicare Part D plan in 2009.

Methods

We used the Medicare Current Beneficiary Survey to compare self-reported prescription fills for oral antidiabetes medications, renin-angiotensin-aldosterone system inhibitors, and statins to adjudicated prescription drug event data recorded by Part D plan sponsors. For unadjudicated prescriptions with no evidence of Part D payment, we determined whether the fills were paid for in cash, filled through VA pharmacies or discount generic programs, or had other reported sources of coverage.

Results

A total of 6.2% of all prescriptions filled by Part D beneficiaries were unadjudicated, ranging from 5.3% of all oral antidiabetes medications to 6.8% of statins. Cash prescriptions accounted for more than half of all out-of-plan use, but we found little evidence of unadjudicated out-of-plan use of discount generics. Prescriptions filled at VA pharmacies and those with other reported sources of coverage each accounted for about 1% of total fills.

Conclusions

Out-of-plan medication use accounts for a small share of total prescriptions filled by Part D beneficiaries. Nevertheless, CMS should continue to work with plan sponsors to develop initiatives that facilitate the collection of beneficiaries' complete utilization data, as a more complete reporting could improve the quality of care delivered to Part D enrollees.

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Take-Away Points

Out-of-plan use of oral antidiabetic medications, renin-angiotensin-aldosterone system (RAAS) inhibitors, and statins accounted for a small share of total utilization by Medicare Part D beneficiaries.

- 6.2% of prescriptions were unadjudicated, ranging from 5.3% of oral antidiabetic medications to 6.8% of statins.
- Cash prescriptions accounted for more than half of all out-of-plan use, but we found little evidence of unadjudicated prescriptions filled through discount generic programs.
- Prescriptions filled at Veterans Affairs (VA) pharmacies accounted for 1.1% of total fills.
- CMS should continue to work with plan sponsors to collect complete and accurate utilization data, including cash, VA, other third-party, and discount generic prescriptions.

missing claims may lead to biased or unreliable estimates of drug adherence, spending, and outcomes. Third, incomplete information on beneficiaries' drug use can inhibit plan sponsors' ability to target adherence programs, such as medication therapy management (MTM), or may interfere with other quality and safety assurance processes, including drug utilization review (DUR). While these challenges are not unique to the Part D program, Part D plan sponsors face the additional concern that incomplete utilization records may negatively impact the performance measures that determine their Star Ratings.

The Part D Star Ratings program evaluates the quality and performance of prescription drug plans (PDPs) and Medicare Advantage prescription drug plans (MAPDs) offered to Medicare beneficiaries. Based on an assessment of their performance on 18 quality measures across 4 domains of care, plan sponsors receive an overall annual score ranging from 1 to 5 stars, in half-star increments, with a higher number of stars indicating better performance. While CMS initially designed the Star Rating system to help enrollees choose high-quality Part D plans, the Affordable Care Act and a subsequent CMS demonstration project expanded the scope of the program beginning in 2012, allowing high-performing MAPDs to qualify for quality-based bonus payments. PDPs are not eligible for additional quality payments based on their Star Ratings, but 5-star PDPs and MAPDs are allowed to enroll beneficiaries year-round, giving them a competitive advantage in the market. Meanwhile, plan sponsors with consistently low quality ratings may be denied permission to expand their service areas, and in some cases, prohibited from marketing to, enrolling, or providing coverage to beneficiaries.

Recent research on MAPDs suggests that plans' Star Ratings significantly influence the enrollment decisions of both first-time enrollees and current Part D beneficiaries who are looking to switch coverage.³ Plan sponsors wish-

ing to maximize their Star Ratings have a specific incentive to focus on improving enrollees' adherence with oral antidiabetic medications, renin-angiotensin-aldosterone system (RAAS) inhibitors, and statins. CMS evaluates plans on the share of enrollees that are adherent to these medications and triple-weights the results relative to other quality indicators, accounting for over 27% of the overall Part D Star Rating. Data published by CMS indicate that on average, both MAPDs and PDPs score more poorly on these adherence measures than on measures across the other 3 domains.⁴

Anecdotal reports from plan sponsors suggest that plans are unable to capture enrollees' complete utilization data, and are therefore unable to accurately measure adherence, due to beneficiaries filling prescriptions through the VA and discount generic programs.^{5,6} According to CMS guidance, PDE data reported by plan sponsors may only include prescriptions processed by network pharmacies or prescription reimbursement requests received directly from beneficiaries. Due to data validation and beneficiary privacy concerns, CMS currently prohibits plan sponsors from augmenting their utilization files with additional data obtained from other sources, such as third-party vendors.⁶

The extent of out-of-plan use among Medicare Part D beneficiaries and its impact on plans' Star Ratings have not been well documented in the literature. This study addresses several knowledge gaps related to out-of-plan use. First, to address plan sponsors' concerns that the adherence measures included in their Star Ratings may be negatively impacted by prescriptions filled outside of the Part D benefit, we examine the extent to which enrollees filled unadjudicated prescriptions for oral antidiabetic medications, RAAS inhibitors, and statins. Second, we estimate the potential scope of out-of-plan use due to unadjudicated cash prescriptions, medications filled at VA pharmacies, and discount generic drugs that might not have been electronically transmitted to Part D plan sponsors. Third, we track the growth in beneficiaries' use of discount generic programs in 2009, relative to published estimates for 2007 and 2008. Finally, we discuss the policy implications of our findings for CMS and Part D plan sponsors.

METHODS

We used data from the 2009 Medicare Current Beneficiary Survey (MCBS) to conduct the research. The MCBS is an ideal data source for this analysis because it reports

adjudicated PDEs from Part D plan sponsors together with self-reported prescription medication events (PMEs) that may or may not have been adjudicated. Self-reported PMEs are collected from survey respondents 3 times during the year and include data on the drug name, quantity dispensed, and source(s) of payment. PDE records are extracted directly from CMS. Each medication event in the MCBS identifies whether the prescription was reported solely as a PME (ie, with no matching PDE record), recorded solely as a PDE (ie, with no self-reported PME), or whether CMS was able to identify and match both a PME and PDE for that fill. We restricted our analysis to prescriptions filled by community-dwelling beneficiaries continually enrolled in an MAPD or PDP in 2009, excluding beneficiaries who died during the year. The study was approved by the institutional review board at the University of Maryland, Baltimore.

We limited the drugs in the analysis to those included in the Pharmacy Quality Alliance (PQA) specifications for the Star Ratings adherence measures. In 2009, these included 4 classes of oral antidiabetes drugs (biguanides, dipeptidyl peptidase-4 inhibitors, sulfonylureas, and thiazolidinediones), RAAS inhibitors, and statins.⁷ To estimate the extent to which Part D beneficiaries filled out-of-plan prescriptions for these medications, we identified self-reported PMEs and calculated the share without plan sponsor adjudication, as evidenced by the absence of a matching PDE record. We restricted our analysis of unmatched PMEs to those for which Medicare Part D was not reported as a payment source (eg, prescriptions paid for in cash, by the VA, or by other payers). To determine the share of unmatched PMEs potentially attributable to generic discount program use, we calculated the share of generic cash PMEs with reported out-of-pocket payments of either \$4 or \$10, which correspond to amounts commonly charged by pharmacies with discount programs.⁸ We then determined whether or not those fills had any evidence of adjudication, as indicated by matching PDE records. All analyses were conducted using SAS 9.2 (SAS Institute, Cary, North Carolina).

RESULTS

Table 1 presents characteristics of MCBS respondents continuously enrolled in a Medicare Part D plan throughout 2009, weighted to reflect the entire Medicare population. Half of all beneficiaries (50.2%) filled 1 or more prescriptions for a RAAS inhibitor, 50.2% filled 1 or more prescriptions for a statin, and 19.9% filled 1 or more prescriptions for an oral antidiabetic medicine.

Table 1. Sample Characteristics of Part D Enrollees in 2009

Characteristics	Part D Enrollees ^a (N = 5307)
Medication Use	
Oral antidiabetics (%)	19.7
RAAS inhibitors (%)	50.2
Statins (%)	50.2
Two conditions (%)	38.1
Three conditions (%)	11.3
Part D Coverage Type	
PDP (%)	59.9
MAPD (%)	38.6
PDP and MAPD (%)	1.5
Low Income Subsidy (%)	32.7
Age (%)	
<65–SSDI	17.8
65–69 years	17.5
70–74 years	22.5
75–79 years	17.7
80+ years	24.6
Female Sex (%)	
Female	59.5
Race/Ethnicity (%)	
White	72.6
Black	11.2
Hispanic	10.7
Other	5.5
Region	
Northeast	20.8
North Central	21.9
South	36.7
West	20.5
Military Service (%)	17.9

MAPD indicates Medicare Advantage prescription drug plan; PDP, prescription drug plan; RAAS, renin-angiotensin-aldosterone system; SSDI, social security death index.

^aThe population proportions presented are weighted to be representative of the entire Medicare population enrolled in Part D (21,610,035) in 2009 using cross-sectional weights provided with the Medicare Current Beneficiary files.

About 38% of the sample filled prescriptions for 2 of these medications, and 11.3% filled prescriptions for all 3. Roughly 60% of beneficiaries were enrolled in a PDP for all of 2009, and a small share—less than 2%—switched between PDP and MAPD coverage during the year. A third of the sample received the low-income subsidy. Reflective of the distribution of the broader Part D population, the majority of the sample was female and more

Table 2. Distribution of Oral Antidiabetic, RAAS-Inhibitor, and Statin Prescription Events by Part D Adjudication Status and Payment Source in 2009

Payment Source	Oral Antidiabetics (N = 10,515)	RAAS Inhibitors (N = 18,634)	Statins (N = 16,183)	Total (N = 45,332)
Part D Adjudicated Fills				
Total	94.7%	93.9%	93.2%	93.8%
Part D	82.3%	80.4%	85.1%	82.5%
Cash only	11.2%	13.0%	7.7%	10.7%
Other	1.2%	0.6%	0.3%	0.6%
Unadjudicated Fills				
Total	5.3%	6.1%	6.8%	6.2%
Cash only	3.6%	3.9%	3.5%	3.7%
Veterans Affairs	1.0%	0.8%	1.6%	1.1%
Other	0.6%	1.4%	1.6%	1.3%

RAAS indicates renin-angiotension-aldosterone system.

than 70% of the subjects were white; however, survey respondents were older than Part D enrollees in general.⁹ Geographically, more than a third of respondents lived in the South, and about 18% of the sample reported having ever served in the military.

Analysis of the PME and PDE data showed that Part D enrollees in our MCBS sample filled a total of 45,322 prescriptions for oral antidiabetics, RAAS inhibitors, and statins in 2009 (Table 2). The vast majority of these fills (93.8%) had evidence of Part D adjudication and there was little variation across drug classes (93.2% for statins to 94.7% for oral antidiabetic agents). Altogether, 82.5% of prescriptions in the sample had an associated Part D payment. A total of 14.4% of fills were reported as cash-only with a ratio of about 3 to 1 being Part D adjudicated (10.7% versus 3.7%). Prescriptions filled through the VA accounted for a very small share of total fills, ranging from just 0.8% of RAAS inhibitors to 1.6% of statins. Equally small shares of prescriptions for these drug classes had other reported sources of payment.

The results of our analysis of cash-only \$4 and \$10 fills indicate that only a small share of unadjudicated generic oral antidiabetic agents, RAAS inhibitors, and statins met these criteria: fewer than 1% had an out-of-pocket payment of \$4 and 4.5% had a payment of \$10. As shown in Table 3, 90% to 98% of all generic \$4 and \$10 fills had a matching PDE record, indicating they had been adjudicated by a Part D plan sponsor. Statins had the largest share of unadjudicated \$4, and \$10 generic fills; however, many of these were prescriptions for simvastatin, which was not commonly included in pharmacy discount programs at the time of the analysis.⁸ As a result, the share of unadjudicated \$4 and \$10 statin fills

attributed to discount program use in Table 3 may be overestimated.

DISCUSSION

Part D plan sponsors are growing increasingly concerned that PDE data may not provide a complete assessment of beneficiaries' medication utilization. Unadjudicated prescriptions filled outside of the Part D benefit can inhibit plan sponsors' ability to target medication therapy management programs and can interfere with other quality and safety assurance processes. Missing prescriptions for oral antidiabetics, RAAS inhibitors, and statins may also negatively impact the performance measures that determine plan sponsors' Star Ratings. This study quantifies the extent of out-of-plan use for these 3 types of medications in 2009. Our analysis of all prescriptions adjudicated by plan sponsors, as well as unadjudicated prescriptions self-reported by beneficiaries, indicates that missing data unlikely had any significant impact on plan sponsors' Star Ratings, because only a small share—about 6%—of oral antidiabetics, RAAS-inhibitors, and statins were filled outside of the Part D benefit. Cash prescriptions accounted for more than half of total out-of-plan use. Prescriptions filled at VA pharmacies accounted for about 1%, and there was little evidence of unadjudicated out-of-plan use of discount generics.

One reason beneficiaries may have filled cash prescriptions out of plan is that the drugs were excluded from plan formularies. In support of this hypothesis, we found that about 44% of unadjudicated cash fills were for brand name medicines. In the case of oral antidiabetics, which had a higher share of unadjudicated cash prescriptions

■ **Table 3.** Part D Adjudication Status for Generic Oral Antidiabetic, RAAS-Inhibitor, and Statin Prescription Events: \$4 and \$10 Cash Fills in 2009

	Oral Antidiabetics (N = 292)	RAAS Inhibitors (N = 473)	Statins (N = 219)	Total (N = 984)
\$4 Fills				
Part D adjudicated	100.0%	99.4%	99.2%	99.5%
Unadjudicated	0.0%	0.6%	0.8%	0.5%
\$10 Fills				
Part D adjudicated	94.6%	89.0%	77.8%	87.5%
Unadjudicated	5.4%	11.0%	22.2%	12.5%
All \$4 and \$10 fills				
Part D adjudicated	98.3%	96.0%	90.4%	95.4%
Unadjudicated	1.7%	4.0%	9.6%	4.6%

RAAS indicates renin-angiotension-aldosterone system.

than either RAAS inhibitors or statins, more than half of all unadjudicated prescriptions paid for out-of-pocket were for drugs commonly excluded from Part D formulary coverage. A second possibility—and the one that has received the most attention—is the use of discount generic programs. Prior research has shown that pharmacy practices regarding the adjudication of discount generic prescriptions vary, with some pharmacies routinely submitting claims to plan sponsors and others stipulating that the programs cannot be used in conjunction with patients' insurance.^{5,10} A handful of studies have shown low take-up of discount programs, particularly among Part D enrollees. Stuart and Loh report that about 3% of Part D beneficiaries filled a prescription for a discount program-eligible generic drug in 2007.¹¹ Similarly, research by Zhang and colleagues suggests that among all Part D enrollees taking an eligible \$4 generic drug in 2007, only 16.3% of beneficiaries obtained them through discount generic programs.¹² While our findings indicate little growth in the use of discount generic programs among Part D beneficiaries between 2007 and 2009, a recent survey suggests that the share of the general population utilizing these programs increased from 4.7% in 2008 to 31.9% in 2010.¹³

According to current CMS guidance, Part D plan sponsors may only report PDE data for claims adjudicated by network pharmacies or for prescription reimbursement requests received directly from beneficiaries; the agency does not permit plan sponsors to supplement their PDE files with utilization data collected from third-party vendors. To improve the accuracy and completeness of the PDE data, CMS encourages plan sponsors to incentivize network pharmacies to adjudicate claims for discount generic and other promotional drugs directly at the point of sale. While improved pharmacy reporting would allevi-

ate some of the unintended consequences of out-of-plan use due to discount generic programs, it would not affect prescriptions filled through the VA. The VA provides separate and distinct coverage from Medicare and there is no coordination of benefits or data sharing between VA pharmacies and Part D plan sponsors.¹⁴

Our findings indicate that VA coverage accounted for a small share of oral antidiabetics, RAAS inhibitors, and statins filled outside of the Part D benefit; however, it is possible that unadjudicated VA prescriptions for these medications could systematically distort the performance ratings of certain plan sponsors in regions with VA hospital systems. With this possible exception in mind, missing utilization data due to out-of-plan use that is randomly distributed should not distort plan Star Ratings because CMS uses relative rankings among sponsors when it assigns performance scores. Based on our findings, we believe that the share of unadjudicated prescriptions is currently too small to significantly affect plans' Star Ratings; however, future research is needed to determine whether regional variation in the use of VA pharmacies and discount generic programs exists and whether this variation may systematically bias the Star Ratings of plan sponsors across regions.

The results of this study should be considered in light of several limitations. First, self-reported prescription medication events reported in the MCBS are subject to recall bias, and may over- or under-report total beneficiary utilization. Second, although MCBS survey administrators are instructed not to record utilization of physician samples, inclusion of these medications in the self-reported data would lead to an overreporting of out-of-plan use. Third, we lack data to determine whether unadjudicated prescriptions resulted from formulary exclusions or use

of pharmaceutical manufacturer or other charitable assistance programs. Fourth, we did not examine use of generic discount or other pharmacy promotional programs with a per prescription cost of other than \$4 or \$10. Finally, although we found that virtually all \$4 and \$10 cash prescriptions for generic drugs were adjudicated by plan sponsors, we cannot determine if this was the result of claims being adjudicated by pharmacies or claims submitted directly to plan sponsors by beneficiaries.

Despite these limitations, our findings indicate that out-of-plan prescriptions, particularly those filled through discount generic programs or the VA, account for a small share of prescriptions filled by Part D enrollees and are unlikely to impact plan sponsors' Star Ratings. Nevertheless, efforts to ensure a more complete reporting of beneficiaries' medication histories could improve quality of care by allowing plan sponsors to conduct more accurate drug utilization and medication therapy management reviews. CMS should continue to work with plan sponsors to develop initiatives that facilitate the collection of complete and accurate utilization data, including records of cash prescriptions and those filled through VA pharmacies, discount generic programs, and other coverage sources.

Author Affiliations: Department of Pharmaceutical Health Services Research, University of Maryland, Baltimore; Policy and Research Department, Pharmaceutical Research and Manufacturers of America (PhRMA); Peter Lamy Center for Drug Therapy and Aging, Department of Pharmaceutical Health Services Research, University of Maryland, Baltimore (BS).

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Address correspondence to: Pamela N. Roberto, MPP, 220 Arch St, Baltimore, MD 21201. E-mail: pamroberto@umaryland.edu.

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