

113TH CONGRESS }
2d Session }

SENATE

{ REPORT
113-306 }

MEDICARE PART D—PRESCRIPTION DRUG
BENEFIT: INCREASING USE AND ACCESS
OF AFFORDABLE PRESCRIPTION DRUGS

A R E P O R T

OF THE

SPECIAL COMMITTEE ON AGING
UNITED STATES SENATE



DECEMBER 11, 2014.—Ordered to be printed

U.S. GOVERNMENT PUBLISHING OFFICE

49-010

WASHINGTON : 2014

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LETTER OF TRANSMITTAL

U.S. SENATE,
SPECIAL COMMITTEE ON AGING,
Washington, DC, December 11, 2014.

Hon. JOE BIDEN,
President, U.S. Senate,
Washington, DC.

DEAR MR. PRESIDENT: Under authority of Senate Resolution 253 agreed to on October 3, 2013, I am submitting to you a report of the U.S. Senate Special Committee on Aging entitled: Medicare Part D Prescription Drug Benefit: Increasing Use and Access of Affordable Prescription Drugs.

Senate Resolution 4, the Committee Systems Reorganization Amendments of 1977, authorizes the Special Committee on Aging “to conduct a continuing study of any and all matters pertaining to problems and opportunities of older people, including but not limited to, problems and opportunities of maintaining health, of assuring adequate income, of finding employment, of engaging in productive and rewarding activity, of securing proper housing and, when necessary, of obtaining care and assistance.” Senate Resolution 4 also requires that the result of these studies and recommendations be reported to the Senate annually.

I am pleased to transmit this report to you.

Sincerely,

BILL NELSON, *Chairman.*

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Mr. NELSON, from the Special Committee on Aging,
submitted the following

R E P O R T

EXECUTIVE SUMMARY

Since 2006, millions of Medicare beneficiaries have had access to outpatient prescription drugs through Medicare Part D, enacted as part of the Medicare Prescription Drug Improvement and Modernization Act of 2003.¹ For the 2014 plan year, approximately, 40.7 million beneficiaries were enrolled in Medicare Part D.² Under the program, private health insurance companies compete for beneficiaries by offering drug coverage plans at competitive prices. Although costs for the Part D program have been lower than originally projected,³ the program accounts for more than 10 percent of total Medicare costs. This report shines a spotlight on a significant factor that has checked growing costs in the program—beneficiaries' use of generic drugs—and explores ways to further increase the use of generic drugs.

In conducting our work, we requested information from the US Department of Health and Human Services Office of the Inspector General (HHS OIG), reviewed available past reports and scientific literature, and conducted interviews with relevant agencies and industry leaders.

¹MedPAC, *Report to the Congress: Medicare Payment Policy*, March 2013, p. 333 (online at http://www.MedPAC.gov/documents/Mar13_entirereport.pdf).

²The Boards of Trustees, Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds, *2014 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medicare Insurance Trust Funds*, p. 198.

³Jack Hoadley, *Medicare Part D Spending Trends: Understanding Key Drivers and the Role of Competition*, Kaiser Family Foundation Issues Brief, May 2012, p. 1.

Using generic drugs results in savings for taxpayers and beneficiaries

As the number of generic manufacturers for any given drug in the market multiplies, price-competition among them increases, and the average price of the generic drug relative to that of the brand-name drug declines. On average, the retail price of a generic drug is 75 percent lower than the retail price of a brand-name drug.⁴ This competition translates into real savings for both taxpayers and beneficiaries. The Congressional Budget Office (CBO) estimated the use of generic drugs in the Part D program saved beneficiaries and taxpayers approximately \$33 billion during 2007; approximately 72 percent (\$24 billion) of those savings accrued to the Medicare program and 28 percent (\$9 billion) went to beneficiaries.⁵ CBO estimates that such savings are shared by beneficiaries and the Part D program through a combination of lower copayments and lower premiums than would have been charged otherwise.⁶

Generics have contributed to real-time, year-by-year savings to the Part D program and its participants. The Medicare Payment Advisory Commission (MedPAC) found that while prices of individual Part D prescription drugs grew by an average of 23 percent between 2006 and 2010, when accounting for generic substitution, Part D drug prices grew over the same time by an average of just 2 percent.⁷ Just as important, patients are more likely to stick with their prescription drug treatment plans if they are using lower-cost generics in place of brand-name drugs.⁸ And, patients who follow their treatment plans have better health outcomes because they can properly manage their conditions, reducing the incidence of hospital stays and emergency-department visits.⁹

Challenges that must be addressed to gain further savings

Continuing to incentivize the use of generic drugs by Part D beneficiaries, when appropriate in their treatment plans, would boost cost-savings both to beneficiaries and taxpayers. When considering policy changes, it is important that greater incentives to use generic drugs do not make access to necessary brand-name drugs more difficult.

The most recent Medicare trustees report found that generic drug use accounted for 84 percent of all Part D drug use during 2013, up from 81 percent in 2012.¹⁰ Over the past seven years, Part D expenditures have increased by an annual rate of 5.7 percent in the aggregate and only 0.5 percent on a per-enrollee basis. These results reflect the rapid growth in enrollment since the Part D program began, a substantial increase in the proportion of prescriptions filled with low-cost generic drugs, and patent expiration

⁴ Congressional Budget Office, *Effects of Using Generic Drugs on Medicare's Prescription Drug Spending*, September 2010, p.1.

⁵ *id.* at p.10.

⁶ *id.* at p. 11.

⁷ MedPAC, March 2013, *supra* at p. 355.

⁸ Hoadley, J. F., Merrell, K., Hargrave, E., & Sumner, L., *In Medicare Part D Plans, Low or Zero Copays and Other Features to Encourage the Use of Generic Statins Work, Could Save Billions*, *Health Affairs* 31, No. 10 (2012): 2266–2275, p. 2266.

⁹ *id.*

¹⁰ The Boards of Trustees, *Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds, 2014 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medicare Insurance Trust Funds*, p. 150.

for some major drugs in 2012.¹¹ While the proportion of generic drug use has increased over time, several factors should be addressed in order to further this trend. These include:

- Incentivizing and supporting plan sponsors to not only include generic drugs on plan formularies, but also to proactively promote the maximum use of generic alternatives where appropriate. Currently, most plan sponsors offer a full array of generic alternatives, but they are not required to do so, leaving a small number of plan formularies that do not maximize generic offerings. In addition, there are no mechanisms that reward or incentivize plan sponsors that have undertaken successful strategies to further increase generics use. Encouraging value in Part D plans as much as possible will be increasingly important in coming years.

- Finding ways to increase the adoption of generic drugs among beneficiaries that receive Low Income Subsidy (LIS) benefits. Generally, insurance companies have been successful at encouraging enrollees to use generic alternatives when available in part because there are large differences in copays between brand and generic drugs. However, in the LIS population, these cost differences do not exist; their copays are set by statute. Innovative methods to improve use of generic drugs in this population, while still ensuring full access for this vulnerable population, must be explored.

- Improving education among beneficiaries and health professionals. There continues to be a need to educate beneficiaries and health professionals on the efficacy of generic medications and incentivizing them to substitute brand-name drugs for generic drugs, when appropriate.

- Maximizing program integrity efforts at pharmacies. In some situations, questionable pharmacy billing practices could thwart efforts that have been made to incentivize generics. HHS OIG, the Government Accountability Office, and others have identified important program controls in the Part D program that could be improved.

This report's focus is solely on those levers within the Part D program that can be adjusted to more effectively incentivize generics. The Committee heard from many stakeholders about additional factors outside the Part D program, such as the biologics exclusivity period, which will impact the overall availability of generic drugs, and the ability to substitute similar drugs. Further, issues within the generics market itself remain outstanding issues for policymakers. These include the continuing drug shortage crisis that most often affects generic drug supply and recent spikes in pricing for certain generic drugs. It is undeniable that there is now a lesser-known but growing and seemingly paradoxical phenomenon: certain older drugs, many of which are generic and not protected by patents or market exclusivity, have experienced dramatic price increases. The reasons behind recent price hikes warrant more study, as does continued vigilance regarding drug shortages. However, such factors are outside the scope of this report.

It is the Committee's hope that this report can help Members of Congress and the health care community to develop and implement

¹¹*id.* at p. 109.

policies and practices that promote greater adherence and access to affordable, quality prescription drugs in the Part D program.

OBJECTIVES AND METHODOLOGY

Under the Medicare Part D program, private health insurance companies compete for beneficiaries' business by offering drug coverage plans at competitive prices. While successful in many ways, the Part D program has grown significantly in size and complexity since the first year of open enrollment began. Along with the federal government's investment, beneficiaries also pay for the program through insurance premiums and copayments for the prescriptions they fill. Given the program's considerable price tag to Medicare (\$69.7 billion during 2013) and beneficiaries, seeking responsible ways to continue to contain costs and ensuring that the program is as efficient as possible for beneficiaries are top priorities for the Aging Committee. One way to contain costs without jeopardizing access to needed care is to continue to look for ways to substitute brand-name drugs for generic drugs, when appropriate.

Our review focused on identifying factors that impact Part D beneficiaries' use of generic drugs as well as developing strategies to further increase the use of generic drugs. Our analysis focused on two main areas:

1. Plan formularies, including the availability of generic drugs within the plans, benefit design, and program tools used by plan sponsors; and
2. Other factors—such as website design for CMS's Plan Finder, beneficiary, physician, and pharmacy preferences and practices—that could impact the beneficiaries' use of generic drugs.

We undertook a study of 2013 plan formularies to assess whether generic equivalents were widely and equally available among all beneficiaries (regardless of income status). Because beneficiaries in the Low Income Subsidy (LIS) population have a lower rate of generic drug use than in the rest of the population, we asked the Department of Health and Human Services Office of the Inspector General (HHS OIG) to analyze plan formularies and to offer potential explanations of factors that may contribute to lower generic drug use among this population. For the Committee's request, see Appendix 1 and for HHS OIG's response, see Appendix 2.

We also conducted a comprehensive review of generic drug utilization and current program tools used by plan sponsors to incentivize generics use. We identified consumer perception and education, pharmacy billing, and physician prescribing as other factors that could impact the beneficiaries' use of generic drugs. To analyze these other factors and their impact on generic-drug use, we reviewed a comprehensive body of literature both from investigative sources including the HHS OIG and the Government Accountability Office (GAO), and from a broader review of scientific literature. Finally, we solicited comments from external stakeholders on strategies that incentivize lower-cost generic-drug use.

BACKGROUND

BENEFICIARY ENROLLMENT AND THE LOW INCOME SUBSIDY PROGRAM

When shopping for a Part D prescription drug plan, Medicare beneficiaries can choose between two kinds of plans:

1. Stand-alone prescription drug plans (PDPs) provide private drug coverage for Medicare beneficiaries with traditional fee-for-service Medicare coverage.
2. Medicare Advantage-prescription drug plans (MA-PD) provide all the components of fee-for-service Medicare coverage and prescription drug coverage under one private plan.

For the 2014 plan year, beneficiaries were able to choose from 1,169 nationwide PDPs and 1,615 MA-PDs.¹² Of the more than 35 million Medicare beneficiaries who were enrolled in Medicare drug plans in 2014, about 64 percent were in PDPs and the rest were in MA-PD plans.¹³ Monthly premiums averaged about \$30 across all plans.¹⁴

Approximately one-third of all enrollees (11 million) receive help through the Part D Low Income Subsidy (LIS) program to pay their drug plan premiums, copays, and deductibles.¹⁵ The Centers for Medicare and Medicaid Services (CMS) estimates that an additional two million low-income individuals are eligible for but are not receiving these subsidies. To qualify for the LIS, beneficiaries must meet an income and asset requirement; however, beneficiaries with very low incomes are automatically eligible.¹⁶ The amount of the subsidy (full or partial) is based on income level; beneficiaries below 100 percent of the federal poverty level receive a full subsidy, although a partial benefit is available for those beneficiaries between 100–150 percent of the federal poverty level.

Beneficiaries who are dually eligible for Medicaid and Medicare automatically qualify for the LIS program without having to complete a separate application. If they do not choose a plan on their own, Medicare automatically enrolls these individuals into a qualified PDP.¹⁷ If the beneficiary qualifies for a full subsidy and enrolls in a qualified plan, the LIS subsidy covers the premium. They are, however, still responsible for small copayments for each covered medication, ranging from \$1.15 to \$6.60.

GENERIC DISPENSING RATES

The generic dispensing rate has steadily increased in the Medicare Part D program, from 61 percent in 2007 to 81 percent in

¹²MedPAC, *Report to Congress: Status Report on Part D*, March 2014, Chapter 14, p. 355 (online at http://www.medpac.gov/documents/Mar14_entirereport.pdf).

¹³*id.*

¹⁴*id.*

¹⁵Hoadley, J., Summer, L., Hargrave, E. & Cubanski, J., *Medicare Part D Prescription Drug Plans: The Marketplace in 2013 and Key Trends, 2006–2013*, Kaiser Family Foundation Issues Brief, December 11, 2013 (online at <http://kff.org/medicare/issue-brief/medicare-part-d-prescription-drug-plans-the-marketplace-in-2013-and-key-trends-2006-2013/>).

¹⁶See Kaiser Family Foundation. *Medicare Prescription Drug Benefit Fact Sheet*, November 19, 2013 (online at <http://kff.org/medicare/fact-sheet/the-medicare-prescription-drug-benefit-fact-sheet/>). To qualify for the LIS, income must be less than 150 percent of the Federal poverty level (\$17,235 for individuals during 2013), and assets must be less than \$13,300 for an individual. Individuals can apply for the LIS program through Social Security Administration or Medicaid.

¹⁷Medicare automatically enrolls these beneficiaries into a “benchmark plan.” A benchmark plan is a basic Medicare Part D plan that has a premium below the weighted average of Part D plan premiums in a region. This weighted average premium is determined each calendar year, and CMS announces plans that qualify.

2012.¹⁸ One reason for this is that the introduction of the Part D benefit coincided with patent expirations for many of the most commonly prescribed drugs, making generic options available. Although the share of prescriptions for generic drugs has increased for both LIS and non-LIS beneficiaries from 2007 to 2011, as shown in the table below, LIS beneficiaries have had a consistently lower generic dispensing rate than non-LIS beneficiaries.¹⁹

TABLE 1: GENERIC DISPENSING RATE BY LIS STATUS, 2007–2011²⁰

	2007	2008	2009	2010	2011
LIS	60%	65%	68%	71%	74%
Non-LIS	62%	69%	72%	76%	79%

Even though generic utilization is high, overall numbers do not tell the whole story. MedPAC has cited the impact that high-cost beneficiaries—those enrollees whose spending reaches the catastrophic level—have on the overall spending of the program and the importance of generic substitution, where appropriate, in particular with this population. According to MedPAC’s Part D Status Report, over 80 percent of beneficiaries with high drug spending received Part D’s LIS.²¹

High-cost beneficiaries typically have more prescriptions filled and fewer generic substitutions than other beneficiaries. The 2012 MedPAC review of this issue offers a telling statistic: in 2009, high-cost beneficiaries filled an average of 111 prescriptions per year (about nine per month) at \$110 per prescription, as compared with 41 prescriptions per year (about four per month) at \$42 per prescription for non-high cost beneficiaries.²² Although high-cost beneficiaries use many of the drugs commonly used by less-costly beneficiaries, they tend to use more brand-name drugs than other beneficiaries.

While some differences reflect health status, there is support in the literature for notable differences within therapeutic classes. Researchers looking at potential savings from generic substitution in diabetes drugs alone found that generic substitutions resulted in annual savings of \$127 to \$160 per beneficiary, and concluded that examining enhancements of generic substitution, where appropriate, could be a practical next step to lowering drug costs in Medicare.²³ Such savings are still relevant when considering, for example, recent MedPAC findings that among diabetic therapies, brand-name drugs accounted for 62 percent of the prescriptions for high cost enrollees, compared with just 33 percent of non-high-cost enrollees.²⁴ The report discusses how plan formularies and other

¹⁸ MedPAC, *A Data Book: Health Care Spending and the Medicare Program*, June 2014, p. 173 (online at <http://medpac.gov/documents/publications/jun14databookentirereport.pdf?sfvrsn=1>).

¹⁹ MedPAC, June 2014, *supra* at p. 174

²⁰ MedPAC, *A Data Book: Health Care Spending and the Medicare Program*, June 2014, p. 383 (online at http://www.medpac.gov/documents/reports/mar14_ch14.pdf?sfvrsn=0).

²¹ MedPAC, March 2013, *supra* at p. 354–362.

²² MedPAC, *Report to the Congress: Medicare Payment Policy*, March 2012, p.354 (online at http://medpac.gov/documents/mar12_entirereport.pdf).

²³ Duru, O., *et al.*, “Potential Savings Associated with Drug Substitution in Medicare Part D: The Translating Research into Action for Diabetes (TRIAD) Study.” *Journal of General Internal Medicine*: August 2013, p. 230.

factors impact the generic dispensing rate among the LIS and non-LIS populations.

PLAN FORMULARIES

PLAN SPONSORS' PRESCRIPTION DRUG COVERAGE DECISIONS

Plan formularies—the list of prescription drugs that are covered by a specific health care plan—are one of the most important considerations for Medicare beneficiaries in choosing a Part D plan. Federal law requires that plan sponsors use Pharmacy and Therapeutics (P&T) committees to make prescription drug coverage decisions. The committees are made up of physicians, pharmacists, nurses, administrators, quality-improvement managers, and other health care professionals and can vary in size; HHS OIG found that in 2010, committees ranged from 3 to 62 members, with an average size of 16 members. These committees evaluate drugs based on the scientific and economic considerations and aim to develop formularies that achieve appropriate and safe drug therapy. There is no statutory requirement that P&T committees consider or include generic drugs in their plan formularies; however, they are required to review practices and policies that affect access, including the availability of generic substitutions.²⁵

Plan sponsors do not need to develop a different formulary for each of their plan offerings. In fact, OIG estimates there are about 3,300 unique Part D drug plans, but there are roughly only 302 CMS-approved Part D formularies.²⁶ After a plan sponsor's P&T committee chooses a formulary, it must obtain CMS's approval before it can be implemented. In reviewing formularies, CMS works to ensure that beneficiaries have a range of Part D drug choices;²⁷ however, it does not explicitly review formularies for their inclusion (or exclusion) of generics.²⁸

Plan sponsors incentivize beneficiaries to use generic drugs through how they have designed their plans, including copay and formulary structures. Medicare drug plans must meet defined requirements, but vary significantly in terms of premiums, benefit design, gap coverage, formularies, and utilization management rules.

BENEFIT DESIGN

Plan sponsors have incentivized generic drug use with existing cost-sharing and formulary structures, as well as with utilization management programs. In 2014, about three-fourths of all plans (76 percent PDPs and 75 percent of MA–PD plans) used five cost-sharing tiers: preferred and non-preferred tiers for generic drugs, preferred and non-preferred tiers for brand drugs, and a tier for

²⁴ MedPAC, *Report to the Congress: Medicare Payment Policy*, March 2012, p.354 (online at http://medpac.gov/documents/mar12_entirereport.pdf).

²⁵ CMS, *Medicare Prescription Drug Benefit Manual* (“*Medicare Prescription Drug Benefit Manual*”), (Pub-100–18), Part 6 § 30.1.5 (online at <http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Chapter6.pdf>).

²⁶ Appendix 2, OIG response to the Senate Special Committee on Aging.

²⁷ *Gaps in Oversight of Conflicts of Interest*, *supra* at p. 8 (“CMS reviews and approves the formularies designed by P&T committees. CMS’s review focuses on ensuring that formularies provide access to a range of Part D drug choices. CMS checks the formularies to make sure they meet accepted pharmaceutical standards and include drugs from different therapeutic cat-

specialty drugs.²⁹ About 62 percent of Part D enrollees are in PDP plans, and the remaining 38 percent are in MA–PD plans, with considerable variation across states.³⁰ For the first time in the coming plan year, all stand-alone prescription drug plans will use tiered cost sharing.³¹ The use of tiering is significant. The tier-pricing plan design incentivizes beneficiaries to use lower-cost generic options, which helps to offset rising brand-name specialty drugs’ costs (and thus overall plan costs) and keep premium growth low. However with most plans charging coinsurance, rather than a flat copayment amount for the highest cost drugs, this growing trend also raises concerns about beneficiary access to the highest cost or sole source drugs, where generic options may not be available.

In addition to tiering, PDPs have applied “utilization management” restrictions since 2007 to an increasing share of on-formulary brand-name drugs. MA–PDs apply similar techniques, but generally to a smaller share of drugs. This means that even if a drug is listed on a plan’s formulary, utilization management rules may be required—including step therapy, prior authorization and quantity limits. The presence of such rules increased from 18 percent of drugs in 2007 to 35 percent in 2013, the latest year for which such data is available.³² In 2013, across all PDPs, on average:

- One percent required step therapy (requiring the beneficiary to use a comparable, less costly alternative first);
- 18 percent of drugs had quantity limits (for example, limiting a prescription to 30 pills for 30 days); and
- 21 percent required prior authorization.³³

Plan sponsors are likely to use tiering and utilization strategies in tandem to incentivize beneficiaries to use generic drugs and to control overall costs. For example, Prime Therapeutics, a benefit pharmacy manager, found that for every 1 percent increase in generic dispensing rates, a 1.5 percent—or more—average savings on drug spending can be expected without impacting care and in many cases improving overall health status through adherence.³⁴

Differences with LIS recipients

Although plan sponsors have been successful in structuring plans that incentivize generic drug use among the general population, they cannot use the same strategy of tiered-benefit structures to provide similar cost-incentives for the LIS population. For about 80 percent all LIS beneficiaries, drug copays are nominal, and for a smaller number of LIS beneficiaries, their copays are roughly 15 percent of the drug cost.³⁵ As shown in Table 2, LIS beneficiaries have a collapsed tiering structure, meaning they are responsible for copay amounts set by statute.

²⁹Hoadley, J., Summer, L., Hargrave, E., Cubanski, J., & Neuman, T. Medicare Part D in Its Ninth Year: The 2014 Marketplace and Key Trends, 2006–2014. August 18, 2014.

³⁰*Id.*

³¹Hoadley J., Cubanski, J., Hargrave, E., & Summer, L. Medicare Part D: A First Look at Plan Offerings in 2015. October 10, 2014.

³²*Id.*

³³*Id.*

³⁴Prime Therapeutic’s estimated savings is particularly relevant because unlike many pharmacy benefit managers, the company is collectively owned by thirteen not-for-profit Blue Cross and Blue Shield Plans and can assess drug spending holistically on an ongoing basis as part of a beneficiary’s overall health status.

³⁵MedPAC, March 2013.

TABLE 2: COPAY AMOUNTS FOR LIS BENEFICIARIES DURING 2013 FOR GENERIC AND BRAND-NAME DRUGS³⁶

	Generic & Multisource Preferred Drugs	Non-Preferred Brand Name
LIS beneficiaries at or below 100 percent of the Federal Poverty guidelines	\$1.15	\$3.50
LIS beneficiaries over 100 percent of the Federal Poverty guidelines	\$2.65	\$6.60

Medicare sets fixed limits on the copay amounts for LIS beneficiaries and pays the plan sponsor for the difference between the copay amount and the cost under the plan. Lower copays have been cited as one possible explanation as to why there is higher usage of brand-name drugs (and lower generic dispensing rates) in the LIS population.³⁷

The LIS population continues to be the largest single share of Part D costs.³⁸ The lack of flexibility that plan sponsors have in benefit design for LIS beneficiaries has been a focus in recent years as policymakers have continued to look for avenues to keep overall spending low. MedPAC,³⁹ the Bipartisan Policy Center,⁴⁰ and the President's most recent budget⁴¹ have suggested that lowering or eliminating copays for generic drugs for LIS beneficiaries has the potential to reduce program spending in the future without substantially affecting access to needed medications. Researchers estimated savings of roughly \$1 billion annually per 10 percent increase in the use of generic statins.⁴² In one study, researchers found that a low copayment for generic drugs was the strongest factor influencing the use of these drugs, and eliminating the copay has an especially large effect.⁴³

The Committee heard concerns that increasing copays for LIS beneficiaries for brand-name drugs might affect access for this particularly vulnerable population. Many of these beneficiaries' health statuses are such that if a beneficiary is on multiple drugs in any month, the costs could add up to be burdensome. Furthermore, generic substitutions may not be universally effective in all situations, depending on the complexity of the beneficiary's health conditions.

In the event that copays are changed, LIS beneficiaries are permitted to file an appeal with their plan when a brand-name prescription is needed. However, the appeals system is extremely complex, time-consuming, and in its current state, could make it very challenging for beneficiaries to obtain access to needed drugs. MedPAC stated in its recent review of the Part D appeals process, "The data that were available to us were insufficient to make a comprehensive assessment of the plans" administration of the proc-

³⁶In 2014, the federal poverty level for a household of 1 person is equal to \$11,670. (online at <http://aspe.hhs.gov/poverty/14poverty.cfm>).

³⁷Appendix 2. OIG response to the Special Committee on Aging.

³⁸MedPAC, March 2012, *supra* at p. 353.

³⁹*id* at p. 355.

⁴⁰Bipartisan Policy Center: A Bipartisan Rx for Patient-Centered Care and System-wide Cost Containment. April, 2013, p. 64.

⁴¹Office of Management and Budget. *Budget of the U.S. Government*, 2014, p. 39-40, 100. (online at <http://www.whitehouse.gov/sites/default/files/omb/budget/fy2014/assets/budget.pdf>).

⁴²*id*.

⁴³Hoadley, J. F., Merrell, K., Hargrave, E., & Summer, L., *In Medicare Part D Plans, Low Or Zero Copays And Other Features To Encourage The Use Of Generic Statins Work, Could Save Billions*, *supra*.

ess . . . and suggest the need for greater transparency and streamlining.”⁴⁴

What limited information is available on Part D exceptions and appeals is not reassuring. The agency’s 2012 audit suggests that Part D plans struggle most with managing coverage determinations, appeals, and grievances.⁴⁵ Additionally, 2011 data released by CMS finds that over half (54 percent) of plan-level denials are overturned by the Independent Review Entity (IRE).⁴⁶ This rate of reversals by the IRE, coupled with the agency’s own audit data on plans, raises serious questions about how well the redetermination and appeals process is working. Finally, beneficiary notification of non-coverage is a significant problem particularly for enrollees who are dually eligible for both Medicaid and Medicare, the majority of the LIS population.

Complicating the appeals process further, the Part D marketplace for LIS enrollees has been inconsistent, with only 15 plans qualifying as benchmark plans in every year from 2006 to the present.⁴⁷ This means that this population, for the most part, is subject to continual auto-reassignment to new plans. This volatility would need to be taken into account with any co-pay increases or implementation of utilization management tools, like prior authorization; vulnerable beneficiaries subjected to constant re-review, without a streamlined and integrated process in place perhaps even between plans, could easily result in delays for needed medications.

GENERIC DRUGS ARE AVAILABLE IN PLAN FORMULARIES

At the Committee’s request, HHS OIG reviewed all 2013 Part D plans to determine the availability of generic drugs in plan formularies.⁴⁸ Because the generic dispensing rate for the LIS population is lower than it is for the non-LIS population, the HHS OIG review was conducted to determine the availability of generic drugs in plan formularies to provide a baseline for our review. HHS OIG found that generic drugs are widely available throughout all Part D plans, including benchmark plans that the LIS population commonly uses. A benchmark plan is a plan that is at or below the amount that the federal government’s low-income subsidy will pay for a Part D plan premium.

In fact, the HHS OIG review found that Part D benchmark plans have a higher percentage of generic drugs available than plans above the regional benchmarks. This is significant because unless a beneficiary opts out, CMS automatically enrolls LIS beneficiaries in a benchmark plan. If an LIS beneficiary chooses a non-benchmark plan, he or she is responsible for the difference in premiums. Consequently, benchmark plans serve a higher proportion of LIS beneficiaries; according to the HHS OIG’s review, 69 percent of all LIS beneficiaries are in a benchmark plan.

⁴⁴ MedPAC, March 2014, *supra* at p. 368.

⁴⁵ Sokolovsky, J., Suzuki, S. & Metayer, L., “Part D Exceptions and Appeals,” (Presentation to MedPAC: September 2013, available at <http://www.medpac.gov/transcripts/part%20d%20exceptions%20&%20appeals.pdf>).

⁴⁶ Excludes cases that were dismissed, withdrawn or remanded and cases involving non-Part D drugs, see: Centers for Medicare and Medicaid Services, “Part D Fact Sheets CY 2011” (available at <http://www.cms.gov/Medicare/Appeals-and-Grievances/MedPrescriptDrugApplGriev/Reconsiderations.html>).

⁴⁷ Hoadley, J., Summer, L., Hargrave, E. & Cubanski, J., December 11, 2013, *supra*.

⁴⁸ For the Committee’s request, see Appendix 1. For HHS OIG’s response, see Appendix 2.

The average percentage of generic drugs included in benchmark plans was 61 percent, compared to 58 percent for plans above the benchmark. Therefore, the lower generic dispensing rate among the LIS-population is not due to unavailability of generic drugs. Thus, to explain the difference in generic dispensing rates, other factors may explain why generic drug use by LIS beneficiaries has been lower than non-LIS beneficiaries, such as beneficiary copays and preferences, the prescribing behavior of health care providers, and pharmacy dispensing practices. These factors are discussed later in this report.

HHS OIG also reviewed formularies for generic substitution potential. Generic substitution potential measures the ability within a formulary to substitute a brand-name drug for a generic drug. The HHS OIG review found that the potential for generic-drug substitution was the same or higher in benchmark plans than in plans above the regional benchmark. The average generic-substitution potential for benchmark plans was 87 percent, compared to 83 percent for the other plans.

As with larger MedPAC drug utilization trends among enrollees, a review of seventeen specific randomly picked drugs that had much lower generic dispensing rates for LIS beneficiaries than for non-LIS beneficiaries provides needed context to these findings. For the seventeen drugs reviewed by the HHS OIG for which LIS beneficiaries had substantially lower rates of generic substitution, most, but not all, of the formularies covered generic equivalents for the drugs reviewed. Out of the seventeen drugs reviewed, seven of the drugs did not universally have a generic equivalent available on all Part D formularies. The number of formularies that covered only a brand-name of one or more of the seven drugs was very small, ranging between one and eight formularies, depending on the drug at issue. Of those formularies that did not include a generic alternative for one or more of the seven drugs, most served Part D plans with premiums both above and below the regional benchmark.

Therefore, while formularies overwhelmingly support maximum use of generics, in certain cases, the OIG review did show that a generic alternative was available on the market, but not on the formulary. Evidence appears to show that such cases are in the minority, but it remains unclear from the OIG's data as to where such formularies operate, what the beneficiary enrollment characteristics are, or any other enrollment specifics. It is also unclear where the brand name drug is placed (what tier) on the formularies without a generic option, or whether drugs with high brand name utilization were connected to cases of where there may be potential conflicts of interest between pharmaceutical companies and P&T committees, as found in another HHS OIG review and discussed later in this report. Even though the formularies without a generic alternative for highly prescribed drugs are very small, such questions offer potential additional areas worth exploring.

PHARMACY & THERAPEUTICS COMMITTEES MAY NOT BE FREE OF
CONFLICTS OF INTEREST

One federal requirement is that at least two members on each P&T committee must be free of conflicts of interest from the spon-

sor or pharmaceutical companies.⁴⁹ This requirement is designed to ensure that committees make independent and sound decisions about which drugs should be covered by sponsors and under what conditions. However, a report issued by HHS OIG in March 2013 found that sponsors conduct little oversight of potential conflicts of interest. HHS OIG reported that:

- Most sponsors' P&T committees have limited definitions of conflicts of interest, which could prevent them from identifying conflicts.⁵⁰
- Many P&T committees allow their members to determine their own conflicts, potentially enabling conflicted members to join and remain on P&T committees.⁵¹
- CMS does not adequately oversee sponsors' compliance with the requirement that at least two members on each P&T committee be independent and free of conflict relative to the sponsor and pharmaceutical manufacturers.⁵²

HHS OIG recommended that CMS establish minimum standards requiring sponsors to ensure that an objective process is used to determine whether disclosed financial interests are conflicts, instead of continuing to allow P&T members to review their own conflicts.⁵³ To ensure that formulary decisions are based only on scientific evidence and standards of practice, HHS OIG also recommended that CMS oversee conflict-of-interest procedures implemented by plan sponsors.⁵⁴

CMS proposed a rule in early 2014 containing a provision that would require P&T committees to clearly articulate and document processes used to determine that conflict-of-interest requirements have been met. The rule would require an objective party to determine whether disclosed financial interests are conflicts and to manage recusals resulting from such conflicts.⁵⁵ However, this provision was not adopted in the final rule.

Another potential area for exploration stakeholders suggested was to request that CMS review whether P&T committees met their obligation to keep written records of all formulary decisions, including any decision to exclude from their formularies any available, chemically equivalent generic drugs for the most common illnesses or commonly used brand-name drugs.

DRUG MANUFACTURERS' REBATES ARE HIGHER FOR LIS BENEFICIARIES

The impact of collapsed tiering seems to manifest through formulary share rebates received by sponsors. Plan sponsors typically receive two kinds of rebates from drug manufacturers that may adversely affect generic dispensing rates—formulary rebates and market-share rebates. Sponsors receive formulary rebates when they structure formularies in ways that either encourages beneficiaries to use certain drugs or discourage the use of competitors'

⁴⁹ Medicare Prescription Drug Benefit Manual, *supra* at Part 6 §30.1.1.

⁵⁰ HHS OIG, *Gaps in Oversight of Conflicts of Interest*, *supra* at p. 13.

⁵¹ HHS OIG, *Gaps in Oversight of Conflicts of Interest*, *supra* at p. 15.

⁵² OIG, *Gaps in Oversight of Conflicts of Interest*, *supra* at p. 16.

⁵³ OIG, *Gaps in Oversight of Conflicts of Interest*, *supra* at p. 19.

⁵⁴ OIG, *Gaps in Oversight of Conflicts of Interest*, *supra* at p. 21.

⁵⁵ Department of Health and Human Services, Centers for Medicare and Medicaid Services. Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs. January 10, 2014, *supra*.

drugs.⁵⁶ Market-share rebates are based on the number of drugs sold to the sponsors' beneficiaries.

HHS OIG released a study in which five of the six sponsors interviewed received higher formulary-based rebates for LIS beneficiaries than non-LIS beneficiaries.⁵⁷ For example, one plan sponsor received a 20 percent rebate for drugs dispensed to LIS beneficiaries compared to a 10 percent rebate for the same drugs dispensed to non-LIS beneficiaries.⁵⁸ This difference may give plan sponsors greater incentive to have LIS beneficiaries use brand-name drugs compared to non-LIS beneficiaries on the same plan.⁵⁹ One reason why drug manufacturers may be providing higher rebates for drugs dispensed to the LIS population is because LIS beneficiaries have lower copay requirements than non-LIS beneficiaries—and therefore do not have the same cost incentives to select generic drugs. CMS told us that although they obtain reports at the National Drug Code (NDC) level (the unique identifier code for drugs) there is no way for them to tell whether a rebate was tied to the purchase of a drug by an LIS or non-LIS beneficiary.⁶⁰

It is unclear how rebate practices would be impacted by changes to LIS-beneficiary copay changes.

OTHER FACTORS

Apart from plan formularies, there are a variety of other factors that can impact the use of generic drugs, including:

- The design of CMS's Plan Finder;
- Beneficiary education and perceptions about generics, and
- Physician Prescribing and Pharmacy Billing Practices

This section describes these factors and possible approaches that should be considered to further increase generic dispensing rates.

CMS PLAN FINDER DESIGN

To help beneficiaries compare Part D plans and identify plans that meet their needs, CMS developed the Medicare Plan Finder interactive website. Plan Finder allows beneficiaries to submit information on the drugs they take in order to compare plans and estimate annual and monthly out-of-pocket expenses. Enabling beneficiaries to compare and shop for private prescription drug plans through a web-based marketplace increases competition among the plan sponsors. Beneficiaries can look for plans that offer the coverage they need for their prescriptions at the best prices using the premium and copay amounts quoted on Plan Finder.

The Committee received several comments related to the importance of evolving the Plan Finder tool in the future to incorporate generics education directly to Medicare beneficiaries. Some insurance plans have had significant success in the past using online tools to educate consumers about the safety and cost-effectiveness of generic drugs. For instance, in a Senate Special Committee on

⁵⁶ Department of Health and Human Services, Office of the Inspector General. *OIG Concerns with Rebates 2011*. (Report # OEI-02-08-00050), March 2011, p. 15.

⁵⁷ *id.*

⁵⁸ *id.*

⁵⁹ Committee Staff Conference Call with CMS, Sept. 5, 2013.

⁶⁰ *id.*

Aging hearing at the start of the Part D program,⁶¹ a witness from Blue Cross Blue Shield Michigan (Blue Cross) outlined their efforts to educate its 183,000 Part D beneficiaries about the benefits of using generics. Blue Cross developed the “*Unadvertised Brand Campaign*” to provide beneficiaries with useful information about generic medications as an alternative to brand-name medications.

Essentially, in Blue Cross’s campaign, the beneficiary selected a brand-name drug from a drop-down menu of options and entered the number of pills taken per day. The beneficiary then selected an icon, “Calculate my savings now,” and the computer would generate a table with the drug brand and generic names, along with the cost of a single pill and a 30-day supply. A box within the table entitled, “You could save,” clearly depicts the amount of money a beneficiary could save simply by switching to a generic alternative. After the introduction of the “*Unadvertised Brand Campaign*,” Blue Cross noted an increase in the generic dispensing rate from 37.7 percent to 52 percent.

Other patient-education methods included advertisements that portrayed generics as safe, affordable, and equivalent in effectiveness and potency to brand-name medications. These advertisements were placed in newspapers, business journals, and other publications. A survey conducted after Blue Cross began the “*Unadvertised Brand Campaign*,” indicated a six percent increase in positive attitudes about generics being equivalent to brand-name medications.

Even though the Blue Cross campaign was undertaken several years ago, the technology they used was more sophisticated than what Medicare Plan Finder uses today. CMS could consider incorporating some of the tools that plan sponsors have successfully used into the Plan Finder website to further encourage the use of generic drugs.

For instance, the Plan Finder tool allows beneficiaries to search for a generic or a brand-name drug, but not at the same time. Although Plan Finder does offer a message telling a beneficiary that a lower-cost option is available when a brand-name drug is selected, the beneficiary must take an additional step to select the generic drug. Plan Finder will—through a series of confusing steps—show a comparison between brand and generic copays, but it misses an opportunity to automatically show the consumer the potential cost difference between a brand and generic version of a drug, as in the Blue Cross campaign.

Medicare Plan Finder Star Ratings

As the Medicare Plan Finder has evolved, CMS has incorporated quality “Star Ratings” on each plan, which measures the plan sponsors’ performance in four broad areas: customer service, member complaints, beneficiary experience, and drug pricing and patient safety.⁶² Plan rating measures have evolved to put more emphasis on appropriate medication use and adherence. For instance, in 2012, measures were added to assess beneficiary adherence to medication therapy for diabetes, hypertension, and cholesterol. The

⁶¹ “The Generic Drug Maze: Speeding Access to Affordable Life-Saving Drugs.” Senate Special Committee on Aging, July 20, 2006. (online at <http://www.gpo.gov/fdsys/pkg/CHRG-109shrg30710/html/CHRG-109shrg30710.htm>). Accessed December 11, 2013.

⁶² MedPAC, March 2012, *supra* at p. 360.

Star Ratings performance data has served as a valuable consumer transparency tool.⁶³

Although plan sponsors are required to report data about generic dispensing rates to CMS, the Star Ratings do not include this information. A consumer looking at the Star Ratings can see the overall rating, but would not know how that rating was derived. For example, a consumer would not know about generic dispensing rates or the availability of consumer-education activities that provide information about lower-cost drug options. Express Scripts, a pharmacy benefit manager serving approximately 7.5 million Medicare Part D beneficiaries, told us that the lack of focus on generic drugs in quality ratings is a missed opportunity. We had several conversations with CMS about incorporating value-based consumer education or generic dispensing rates into the Star Ratings and note the potential complexities involved; however, developing such a measure could be an important step in encouraging lower-cost prescription drug use among seniors.

BENEFICIARY EDUCATION

Education matters: Assessment of attitudes about generics among seniors

Even though many older patients have embraced generics as a part of their standard treatment regimens, some seniors still have negative attitudes about the use of generic drugs. Despite the Food and Drug Administration's (FDA) assurances of the safety of generic drugs, some consumers still have negative perceptions about them.

A number of studies have identified that patient preference for branded drugs may influence physician prescribing practices. For example, a study published in the *Journal of the American Medical Association* (JAMA) surveying 3,500 physicians in seven specialties, found that approximately four of 10 physicians report that they sometimes or often prescribe a brand-name drug to a patient when a generic is available because the patient wanted it.⁶⁴

In a 2009 *Health Affairs* study, 2,500 patients were surveyed about their opinions on generic drugs.⁶⁵ Overall, survey participants believed that significant savings could be achieved through the use of generics instead of brand-name medications; however, the majority still preferred brand-name drugs. Less than half of those surveyed said that they would agree to take a generic medication and 42 percent did not believe that generics were safer than brand-name medications. Researchers cited several possibilities as to why these perceptions exist, including:⁶⁶

- Associating the word “generic” with something that is diminished in worth or value, or “not as good” as brand-name drugs. These patients believed that because a drug costs more, it must be more effective than a lower-cost generic.

⁶³ Government Accountability Office, Report to the Special Committee on Aging, *Medicare Part D: CMS has Implemented Processes to Oversee Plan Finder Pricing Accuracy and Improve Website Usability*, January 10, 2014.

⁶⁴ Campbell, E. G., Genevieve, P., Vogeli, C. & Iezzoni, L., “Physician Acquiescence to Patient Demands for Brand-Name Drugs: Results of a National Survey of Physicians,” *Journal of the American Medical Association*. Vol. 173, No. 3. 11 February 2013.

⁶⁵ Shrank, W. H., et al., “Patients’ Perceptions of Generic Medications,” *supra*.

⁶⁶ *id.*

- Inadequate communication about the benefits of generics between patients and providers.
- Unease regarding substitution of a generic for a brand-name medication at the pharmacy.

In another study, researchers conducted a literature review regarding the use of generics as substitutes for brand-name medications. They reviewed 20 scientific papers published from 2000 to 2011 that examined the attitudes of patients in the United States and several other Western countries and found a number of factors impact the perception of generic drugs, including:⁶⁷

- Whether the patient has a serious or chronic condition, as not all brand-name drugs for these conditions have equivalent or clinically-appropriate generic substitutes;
- The involvement of the health care provider in counseling the patient and in prescribing generic drugs;
- The patient's education and health literacy;
- The name recognition of the brand-name drug;
- The physical appearance (shape, size, and color) of the generic drug. Some patients expressed confusion about dosage due to the altered appearance of the generic drug; and
- The taste of the generic drug.

The barriers identified in these scientific studies are applicable to older patients, too.⁶⁸ Older patients, as a whole, are more chronically ill, have higher health care expenditures, and consume medications at much higher rates than younger patients.⁶⁹ Although there are exceptions, generally, older patients are more resistant to using generic medications than any other patient demographic.⁷⁰ Thus, addressing these concerns about generics is even more important with seniors.

To dispel myths about generics, the FDA and plan sponsors have used a number of different strategies to educate consumers, including Internet promotions, pamphlets, brochures, and flyers. Even though educating seniors about their health care options may be challenging, it is important, as patients who are more informed about their treatment generally have better outcomes. Seniors should be encouraged to inquire about their medications and should be educated about the right questions to ask. In turn, health care providers should explain why a generic medication is being prescribed in a way that the patient can easily understand. Through better education and communication, myths about generic drugs can be dispelled, and better health outcomes can be achieved.⁷¹

⁶⁷ Håkonsen, H., & Toverud, E.L. "A Review of Patient Perspectives on Generics Substitution: What Are the Challenges for Optimal Drug Use," *supra*.

⁶⁸ Shrank, W. H., *et al.*, "Patients' Perceptions of Generic Medications," *supra*.

⁶⁹ Joyce, G. F., Keller, E. B., Shang, B., & Goldman, D. P., "The Lifetime Burden of Chronic Disease Among the Elderly," *Health Affairs*, September 26, 2005; See "Future Health and Medical Care Spending for the Elderly: Implications for Medicare." Rand Health Research Highlights. Report RB-9146-1-CMS (2005) (online at http://www.rand.org/content/dam/rand/pubs/research_briefs/2005/RAND_RB9146-1.pdf).

⁷⁰ Caldwell, D. J., Jaubert, K., Zagar, M., & Sherman, J., "Considerations for Generic Drug Use in the Elderly," *Pharmacy Times*, January 1, 2007 (online at <http://www.pharmacytimes.com/publications/issue/2007/2007-01/2007-01-6215>). Accessed November 21, 2013; Iosifescu, A., *et al.*, "Beliefs about Generic Drugs Among Elderly Adults in Hospital-Based Primary Care Practices," *supra*.

⁷¹ Zagaria, M. A. E., "Generic Medications: Issues in Senior Care Pharmacy," *US Pharmacist*, June 19, 2007 (online at http://www.uspharmacist.com/content/c/10308/?t=men's_health).

Medication therapy management

Educating seniors about the importance of adhering to their medication regimen could also play an important role in reducing overall health care costs. CBO recently reported the savings that could be realized if patients adhere to their medication therapies and found that for each one percent increase in the number of prescriptions filled by beneficiaries, there is a corresponding decrease in overall Medicare medical spending. When projected to the entire population, this translates into a savings of \$1.7 billion in overall health care costs for every one percent increase in the number of prescriptions filled.⁷²

Medication adherence in older patients can be problematic. Several studies suggest that medication non-adherence contributes to a substantial human and financial toll in the United States, with 33 percent to 69 percent of all medication-related hospital admissions due to non-adherence.⁷³ According to industry analysts, the cost of medication non-adherence exceeded \$290 billion in 2009.⁷⁴ Typical reasons older patients may not comply with prescribed medication include:

- cost and affordability;
- cognitive decline;
- convenience, including how many times per day the medication must be taken and the difficulty of the treatment regimen;⁷⁵
- risks, including the tradeoff between benefits and possible side effects;
- communication problems between the patient and the health care provider; and
- patients not agreeing with the treatment regimen.⁷⁶

Interventions such as medication therapy management (MTM) programs have been found to lower health care costs by preventing adverse outcomes that lead to hospital admissions.⁷⁷ MTM is a service or group of services that optimize therapeutic outcomes for individual patients.⁷⁸ In Medicare Part D, MTM programs must generally include:

- prescriber interventions to promote coordinated care;
- an interactive comprehensive medication review and discussion with the beneficiary;
- a written summary (in CMS's standardized format) of the prescriber recommendations; and

⁷²National Association of Chain Drug Stores. Testimony to the Senate Special Committee on Aging: 10 Years Later: A look at the Medicare Prescription Drug Program. May 22, 2013.

⁷³Marrufo, G. et al., "Medication Therapy Management in a Chronically Ill Population: Interim Report." Prepared for Steven A. Blackwell, Centers for Medicare & Medicaid Services (CMS), Center for Medicare & Medicaid Innovation, Acumen, LLC, p. 1. January 2013 (online at <http://innovation.cms.gov/Files/reports/MTM-Interim-Report-01-2013.pdf>). Retrieved March 5, 2014.

⁷⁴"Medication Adherence in America: a National Report, 2013." *National Report Card on Adherence*, p. 2. National Community Pharmacists Association (online at http://www.ncpanet.org/pdf/reportcard/AdherenceReportCard_Abridged.pdf). Retrieved March 5, 2014.

⁷⁵Martin, L. R., Williams, S.L., Haskard, K. B. & DiMatteo, M. R., "The Challenge of Patient Adherence," *Therapeutics and Clinical Risk Management*. 1(3) 189–199. 2005, (online at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1661624/pdf/term0103-189.pdf>). Retrieved March 5, 2014.

⁷⁶Latif, S. & McNicoll, L., "Medication and Non-Adherence in the Older Adult," *Geriatrics for the Practicing Physician*. Volume 92, No. 12. December 2009 (online at <http://rimed.org/medhealthri/2009-12/2009-12-418.pdf>). Retrieved March 5, 2014.

⁷⁷Marrufo, G. et al., *supra*.

⁷⁸"APhA MTM Central: What is Medication Therapy Management." American Pharmacists Association, 2014 (online at <http://www.pharmacist.com/mtm>).

- frequent monitoring and follow-up of the beneficiary's medication therapies.⁷⁹

However, plan sponsors vary greatly in how they satisfy these service elements. A recent study conducted in conjunction with the CMS Center for Medicare and Medicaid Innovation found that in 2010, all 678 active Part D contracts with an approved MTM program reported offering annual comprehensive and targeted medication management to their enrollees. However, these programs differed in the ways in which they offered these interventions: for example, 81.1 percent of these programs presented enrollees with a list of medication therapy recommendations, while 29.4 percent provided enrollees with a reconciled medication list.⁸⁰

There are several demonstrated savings from MTM programs when implemented effectively and targeted to the right patients. For example:

- In 2009, Connecticut conducted an MTM study, where pharmacists met with 88 Medicaid patients who averaged 9 to 10 medical conditions and used an average of 15 medications. Within 10 months, pharmacists had identified more than 900 drug therapy problems, 80 percent of which they resolved in four visits. Estimated annual savings were \$1,123 per patient on medication costs, and \$472 per patient on medical and hospital costs.
- In Minnesota, a 10-year evaluation of MTM provided to integrated health system patients estimated a return on investment of \$1.29 for every \$1.00 spent in MTM costs.⁸¹
- Within Medicare, CMS reported that Medicare Part D beneficiaries with congestive heart failure and chronic obstructive pulmonary disease (COPD) who were newly enrolled in the Part D MTM program experienced increased medication adherence and discontinuation of high-risk medications. The report also found that monthly prescription drug costs for these beneficiaries decreased by approximately \$4 to \$6 per month and that they had nearly \$400 to \$500 lower overall hospitalization costs than those who did not participate in the Part D MTM program.⁸²
- In another review, researchers analyzed a large random sample of Part D enrollees with diabetes, heart failure, and COPD, to see whether poor adherence to recommended drugs was associated with higher Medicare costs. Researchers found that beneficiaries with poor adherence had higher costs, ranging from \$49 to \$840 per month for patients with diabetes for

⁷⁹Shapiro, J. R., "CY 2015 Medication Therapy Management Program Guidance and Submission Instructions," May 7, 2014 (online at <http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/MemoContractYear2015MedicationTherapyManagementProgramSubmission050714.pdf>).

⁸⁰Perloth, D. *et al.*, "Medication Therapy Management in Chronically Ill Populations: Final Report." Prepared for Steven A. Blackwell, Centers for Medicare & Medicaid Services (CMS), Center for Medicare & Medicaid Innovation, Acumen, LLC, August 2013 (online at http://innovation.cms.gov/Files/reports/MTM_Final_Report.pdf).

⁸¹Rucker, N. L., "Medicare Part D's Medication Therapy Management: Shifting from Neutral to Drive." AARP Public Policy Institute, June 2012 (online at http://www.aarp.org/content/dam/aarp/research/public_policy_institute/health/medicare-part-d-shifting-from-neutral-to-drive-insight-AARP-ppi-health.pdf).

⁸²National Association of Chain Drug Stores. Testimony to the Senate Special Committee on Aging, May 22, 2013, *supra*.

example.⁸³ However, importantly, such beneficiaries were not uniformly more likely than others to be eligible for MTM services.

All prescription drug plans in Medicare Part D are required to offer MTM services to patients with high annual drug spending (\$3,100 or more in 2012), who have at least two chronic conditions, and who are taking two to eight different Part D drugs. Some plans offer MTM services to all beneficiaries, but most offer them to less than 10 percent of their beneficiaries. Despite conservative estimates that at least 25 percent of beneficiaries are eligible for MTM services, CMS cited participation rates of less than eight percent in 2011.⁸⁴

Having a dollar threshold for MTM intervention may perversely incentivize brand-name drugs. Not only can a beneficiary take multiple generic drugs and not reach the \$3,100 target threshold, but if a physician or pharmacist determines appropriate generic substitutions can be made, a beneficiary could lose his eligibility for MTM services by falling below the dollar threshold.

CMS proposed changes to improve participation in a draft regulation release in January, including incorporating MTM eligibility and program features into the “Medicare Plan Finder” website and in the annual *Medicare and You* handbook mailed to all beneficiaries.⁸⁵ The agency acknowledged the perverse incentive created by the dollar threshold, stating:⁸⁶

We are concerned with such variability, especially in cases where a beneficiary meets the minimum number of chronic diseases for eligibility, but may not qualify for MTM because his or her chronic condition is not targeted by the plan, he or she doesn’t take enough medications for the plan’s program (even though medication management issues are present), or because high utilization of lower cost generics places prescription drug costs for the beneficiary below the cost threshold.⁸⁷

Accordingly, the proposed rule would have lowered the annual total drug cost threshold to \$620 (the estimated cost of two generic prescriptions) and revised the interpretation of “multiple Part D drugs” to mean two or more drugs and two or more chronic conditions. However, this provision was not finalized in CMS’s final version of the rule.

Given MTM’s potential to improve outcomes and lower costs, it is important that it reaches the full range of beneficiaries who would benefit from active medication management. Expanding eligibility criteria is one step, but CMS should also focus efforts to improve enrollment. For instance, developing outcomes-oriented

⁸³Stuart, B. S., Loh, F. E., Roberto, P. & Miller, L. M., “Increasing Medicare Part D Enrollment In Medication Therapy Management Could Improve Health And Lower Costs.” *Health Affairs*. July 2013: Vol. 32, No. 7. p. 1212–1220.

⁸⁴Department of Health and Human Services, Centers for Medicare and Medicaid Services. Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs. Proposed guidance RIN 0938–AR37, January 10, 2014.

⁸⁵Medicare Program, Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Program. CMS–4159–P (online at <http://www.gpo.gov/fdsys/pkg/FR-2014-01-10/pdf/2013-31497.pdf>).

⁸⁶Medicare Program, Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Program, *supra*.

⁸⁷*id* at p. 1948.

metrics—such as a ratio for overall rate of participation as compared with total eligible beneficiaries—could help to ensure that the focus is on employing MTM services more broadly.

PHYSICIAN PRESCRIBING AND PHARMACY BILLING PRACTICES

The Committee found that physician prescribing and pharmacy billing practices can also play a significant role in realizing the full potential of savings from lower-cost drugs. In addition to educating physicians about generics and examining industry relationships to identify conflicts of interest, questionable pharmacy billing practices should also be addressed. HHS OIG stated, in response to the Committee (see Appendix 2):

Health care providers and pharmacies influence the use of generic drugs. For example, generic substitution cannot occur if a health care provider indicates that a brand-name drug is medically necessary. All States allow health care providers to specify that a generic drug should not be substituted for a brand-name drug. The ease with which a prescriber can do this varies across States. In addition, pharmacies might not substitute a generic drug for a host of reasons—for example, because the generic drug is temporarily out of stock, customer resistance to receiving a generic drug, or because substituting a generic drug for a brand-name one would be less profitable for the pharmacy.⁸⁸

This section brings together additional analysis about the role physicians and pharmacies can play in increasing generics and lowering program costs.

Physician prescribing practices

Physician education and prescribing practices have a direct effect on the potential impact of any policy change made to benefit design. Outlier physician prescribing can be a result of a number of competing factors: patient demand, industry relationships, and physician perceptions. It may also result from fraud or abuse, such as when drugs are ordered by individuals without prescribing authority.

Recent HHS OIG reports have identified ongoing significant issues with prescription fraud and abuse, as well as with CMS efforts to prevent fraud and abuse in the Part D program. In June 2013, HHS OIG issued a report entitled, “Medicare Inappropriately Paid for Drugs Ordered by Individuals Without Prescribing Authority.”⁸⁹ HHS OIG analyzed all Prescription Drug Event records from 2009 and matched them to the National Plan and Provider Enumeration System to determine the prescriber type, such as physician or dentist. HHS OIG found that CMS inappropriately paid for drugs ordered by individuals who clearly did not have the authority to prescribe, such as massage therapists, athletic trainers, home contractors, interpreters, and transportation companies. In ten States, CMS also inappropriately paid for drugs ordered by

⁸⁸ See Appendix 2.

⁸⁹ See Department of Health and Human Services, Office of the Inspector General, *Medicare Inappropriately Paid for Drugs Ordered by Individuals Without Prescribing Authority*, June 2013 (online at <https://oig.hhs.gov/oei/reports/oei-02-09-00608.pdf>).

other individuals without the authority within those states to prescribe, such as counselors, social workers, and chiropractors.

In total, Medicare paid \$352 million for Part D drugs ordered by the physicians with questionable prescribing patterns in 2009. Notably, 110 of these physicians were associated with 1 or more of the retail pharmacies identified as having questionable billing as discussed below. It is important to note that questionable billing does not necessarily mean fraudulent billing. However, these patterns raise flags that warrant further attention. Tens of thousands of these drugs were controlled substances and have the potential for abuse.

OIG recommended that CMS: (1) require sponsors to verify that prescribers have the authority to prescribe drugs, (2) increase the Medicare Drug Integrity Contractor's monitoring of prescribers, (3) ensure that Medicare does not pay for prescriptions from individuals without prescribing authority, and (4) follow up on the individuals without prescribing authority who ordered prescriptions. CMS concurred with all four recommendations.

In testimony before the Subcommittee on Federal Financial Management, Government Information, Federal Services and International Security of the Senate Committee on Homeland Security and Governmental Affairs on October 4, 2011, GAO highlighted issues with overprescribing of medications when a beneficiary receives medications from multiple providers. GAO stated that about 170,000 Part D beneficiaries obtained prescriptions for frequently abused prescription drugs from five or more medical practitioners during calendar year 2008 at a cost of \$148 million.⁹⁰ Of these, about 120,000 were eligible for Part D because of a disability, rather than age. In one instance, a single beneficiary received prescriptions from 87 different medical practitioners in calendar year 2008. Whether the individual actually received those medications, or was the victim of identity theft, these multiple prescriptions are of concern both from a cost as well as patient-safety perspective.

While CMS requires Part D plans to perform retrospective drug utilization review (DUR) analysis and provide education to prescribers, according to GAO, CMS does not have authority to limit the access of individuals, even those known to have obtained the same prescription drugs from multiple providers, to either certain prescribers or to certain drugs.

While CMS is responsible for overseeing the program and paying plan sponsors, and the plan sponsors are responsible for preventing and detecting fraud, waste, and abuse and appropriately paying for drugs under Part D,⁹¹ preventing and detecting fraud, waste and abuse is a shared responsibility between CMS, contractors, and plan sponsors. CMS relies in part on contractors, known as Medicare Drug Integrity Contractors (MEDICs), to investigate fraud. Since these contracts were awarded in FY2007, a number of reports have been critical of the MEDICs' anti-fraud activities. A January 2013 OIG report found that only 21 of 223 identified cases

⁹⁰Gregory D. Kutz, Testimony Before the Subcommittee on Federal Financial Management, Government Information, Federal Services and International Security, Committee on Homeland Security and Governmental Affairs.

⁹¹Testimony of: Gary Cantrell, Deputy Inspector General for Investigations, and Stuart Wright, Deputy Inspector General for Evaluation and Inspections, Office of Inspector General, U.S. Department of Health and Human Services, Hearing: Curbing Prescription Drug Abuse in Medicare, Senate Committee on Homeland Security and Governmental Affairs, June 24, 2013.

of fraud in Medicare Part D were identified internally, through data analysis or other means. Most cases originated from passive sources of information, such as complaints received through the fraud hotline.

The reliance of CMS on individual complaints rather than on proactive identification described in this report also raises questions about whether CMS has the ability to effectively prevent fraud, waste, and abuse in the Part D program, or can only respond once fraud, waste, and abuse has been identified by an external entity or individual.

CMS's newly finalized regulation in May 2014 did take a beginning step forward to crack-down on the issue of unauthorized prescribers. Specifically, CMS will require prescribers of Part D drugs to enroll in Medicare in order for prescriptions they write to be covered under Part D, which would help to ensure that Part D drugs are only prescribed by qualified individuals. In addition, CMS may now revoke a physician's or eligible professional's Medicare enrollment if:

- CMS determines that the physician has a pattern of prescribing Part D drugs that is abusive and represents a threat to the health and safety of Medicare beneficiaries, or otherwise fails to meet Medicare requirements;
- The Drug Enforcement Administration suspends or revokes the physician's Certificate of Registration;
- The applicable licensing or administrative body for any state in which a physician or eligible professional practices suspends or revokes the physician or eligible professional's ability to prescribe drugs.

Physician education should be addressed

The FDA and plan providers have used a number of different strategies to educate physicians about generic drugs—such as distributing generic drug samples. However, despite these efforts, some studies suggest that physicians have lingering concerns about the quality or efficacy of generic drugs despite scientific data to the contrary. For instance:

- In a 2011 survey of physicians, about 25 percent of physicians reported that they strongly or somewhat disagreed with the statement, “I believe that generic medications are as effective as branded medications,” while about half of respondents agreed strongly or somewhat with the statement, “I am concerned about the quality of generic medications.”⁹²
- A survey of 1,891 physicians showed that prescribing behavior shifted in a manner consistent with the number of years of medical practice. Thirty-one percent of physicians in practice 10 years or less “sometimes” or “often” prescribed name-brand medications when patients requested them even when comparable generic drugs were available. The percentage increased to 36 percent of physicians in practice for 11 to 30 years and 43 percent of physicians in practice more than 30 years.⁹³

⁹²Shrank, W. H., et al., “Physician Perceptions About Generic Drugs,” *Annals of Pharmacotherapy*. Vol. 45, January 2011 (online at http://scholar.harvard.edu/nkc/files/2011_physician_perceptions_about_generic_drugs_annals_pharmacotherapy.pdf).

⁹³McGreevey, S., “Push for Name-Brand Drugs: Industry Relationships,” January 7, 2013. *Harvard Gazette* (online at <http://news.harvard.edu/gazette/story/2013/01/push-for-name-brand-drugs/>); See Campbell, E. G., Genevieve, P. K., Vogeli, C., & Iezzoni, L., February 11,

An effective way of altering prescribing behavior involves providing physicians with individual feedback.⁹⁴ A study about interventions designed to change provider prescribing behaviors determined that educational outreach as well as audit and feedback most consistently resulted in positive results.⁹⁵

Recent studies have also demonstrated differences in prescribing patterns based on the nature of the relationship between physicians and the pharmaceutical industry, as well as whether the physician is a member of a managed care organization. A study published in JAMA found that physicians receiving industry-provided food or beverages in the workplace or drug samples are significantly more likely to accede to patient demands for brand-name drugs. Also, physicians who meet with industry representatives for periodic meetings are more likely to give in to patient requests for brand names.⁹⁶

In addition, a physician's membership in a managed care organization may impact prescribing patterns.⁹⁷ Between 2007 and 2010, the use of generic drugs among beneficiaries enrolled in MA-PD plans consistently exceeded that of beneficiaries enrolled in PDP plans by 5 percent. This occurred despite: (1) high MA-PD plan copays for generic drugs and (2) PDP plans applying utilization management tools (like quantity limits and prior authorizations) to more drugs than MA-PD plans.⁹⁸ In 2013, for example, median copays for generic drugs in PDPs were \$2 for the preferred generic tier and \$5 for the non-preferred tier. MA-PD plans with two generic tiers charged \$3 for drugs in the preferred generic tier and \$10 for drugs in the non-preferred tier.

One of the factors which may affect the increased rate of generic prescribing among MA-PD plans is that fewer LIS beneficiaries tend to enroll in MA-PD plans. Over 80 percent of beneficiaries with high prescription drug costs are LIS beneficiaries. Four out of five LIS beneficiaries, or 18 percent of all Medicare beneficiaries, were enrolled in stand-alone PDPs, and the remaining (5 percent of all Medicare beneficiaries) were enrolled in MA-PD plans.⁹⁹

Pharmacy billing practices

Pharmacies are responsible for dispensing prescription drugs to beneficiaries. Plan sponsors contract with pharmacies to provide retail, long-term-care, and mail-order services.¹⁰⁰ Pharmacies report to and bill sponsors for any drugs dispensed for their beneficiaries. Sponsors aggregate this data into "prescription drug event" (PDE) files that are sent to CMS for reimbursement.

Sponsors rely on pharmacies to provide them with accurate information about the drugs they dispense, but CMS has identified several instances of questionable Part D billing by pharmacies. In a

2013, *supra*; See Campbell, E. G., Rao, S. R., DesRoches, C. M., Iezzoni, L. I., Vogelia, C., Dragana, B. J., et al., "Physician Professionalism and Changes in Physician-Industry Relationships from 2004–2009." *Archives of Internal Medicine*. 2010; 170 (20): 1820–1826.

⁹⁴ Ostini, R., et al., "Systemic Review of Interventions to Improve Prescribing," *Annals of Pharmacotherapy*, March 2009. Vol. 43, No. 3: p. 502–13.

⁹⁵ *id.*

⁹⁶ Campbell, E. G., Genevieve, P. K., Vogeli, C., & Iezzoni, L., February 11, 2013, *supra*.

⁹⁷ *id.*

⁹⁸ Hoadley, J., Summer, L., Hargrave, E. & Cubanski, J., December 11, 2013, *supra*.

⁹⁹ MedPAC, June 2013, *supra* at p. 163.

¹⁰⁰ Department of Health and Human Services, Office of the Inspector General, *OIG Retail Pharmacies with Questionable Part D Billing*, May 2012, p. 2 (online at <https://oig.hhs.gov/oei/reports/oei-02-909-00600.pdf>).

May 2012 review, the HHS OIG strongly recommended additional auditing of retail pharmacies with Medicare Part D billing. HHS OIG (using data from 2009) issued a report that found that:

- Over 2,600 retail pharmacies—representing about 4 percent of all pharmacies nationwide—exhibited signs of questionable billing practices. Together, they billed Part D approximately \$5.6 billion. While some of this billing may be legitimate, all pharmacies that bill for extremely high amounts warrant further scrutiny.
- Over 400 pharmacies billed for an extremely high percentage of brand-name drugs. One pharmacy reviewed had 99 percent of its prescriptions dispensed for brand-name drugs. Billing for a high percentage of brand-name drugs may indicate that a pharmacy is billing for brand names but dispensing generics.

While questionable billing does not necessarily mean fraudulent billing, these patterns raise flags that warrant further attention. The HHS OIG recommended that CMS take a number of steps to strengthen the monitoring of pharmacies, including:¹⁰¹

- identifying pharmacies with questionable billing practices for further review;
- providing additional guidance to sponsors on monitoring pharmacy billing;
- requiring sponsors to refer potential fraud and abuse incidents that may warrant further investigation;
- developing risk scores for pharmacies; and
- following up with pharmacies identified as having questionable billing.

In some situations, questionable pharmacy billing practices could thwart efforts that have been made to incentivize generics. For example, a lawsuit has been filed in the Southern District of New York by an insurance company, for itself and on behalf of the federal government and several states, against Walgreens pharmacies for alleged misconduct in using “Dispense as Written” (DAW) codes in their submission of claims for brand-name drugs.¹⁰² The lawsuit alleges that the pharmacy misused codes related to the dispensing of brand-name drugs when substitution with generic drugs was mandated under Medicaid and Medicare, as well as required under certain states’ laws.

CMS finalized regulatory guidance in May 2014 that takes a step to better monitor pharmacy billing, as it provides direct access to data from sponsor downstream entities, including pharmacies. Currently, it can take a long time for CMS’s contractors (who are often assisting law enforcement) to obtain important documents like invoices and prescriptions directly from pharmacies, because they must work through the Part D plan sponsor to obtain this information. However, the new guidance would provide CMS, its antifraud contractors, and other oversight agencies the ability to request and collect information directly from pharmacy benefit managers, pharmacies, and other entities that contract or subcontract with Part D

¹⁰¹ *id.*

¹⁰² *United States ex rel. Fox Rx, Inc. v. Walgreen Co.*, No. 12-cv-07382-RA (S.D.N.Y. Oct. 1, 2013).

sponsors.¹⁰³ This proposal is designed to provide more timely access to records—including for investigations of fraud and abuse—and responds in part to recommendations made by HHS OIG.

CONCLUSION

The Committee finds that for continued savings to be achieved in the Part D program without harming beneficiaries, more unconventional strategies will be needed, and beneficiaries must be seen and treated as partners in any savings that are achieved.

Future actions to maximize generics use should focus on beneficiary education and greater access to medication management therapy. Existing program tools—like the Medicare Plan Finder—can and should evolve to play a role in encouraging beneficiaries to weigh not only coverage options, but also potential savings opportunities. Further, in order to encourage seniors to switch to lower-cost drug options where appropriate it will be necessary to ensure that savings are felt not only by the federal government, but also beneficiaries. In addition, CMS will need to investigate questionable pharmacy billing practices when there are suspicions of fraud, waste, or abuse.

It is the Committee's hope that this report offers a starting place to help Members of Congress and the health care community to develop new and innovative ideas outside the traditional benefit structure to promote greater adherence and access to affordable, quality prescription drugs in the Part D program.

¹⁰³ Department of Health and Human Services, Centers for Medicare and Medicaid Services. Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs. January 10, 2014, *supra*.

Appendix 1 – Committee Letter to HHS OIG

BILL NELSON, FLORIDA, CHAIRMAN
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 TED CRUZ, TEXAS

October 17, 2013

The Honorable Daniel R. Levinson
 Office of the Inspector General
 Department of Health and Human Services
 330 Independence Avenue, SW
 Washington, DC 20201

Dear Inspector General Levinson:

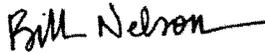
I write to request an examination of Medicare Part D beneficiaries' access to generic drugs through their Part D plans' drug formularies.

Medicare Part D beneficiaries' use of generic drugs has accounted for significant savings to beneficiaries and the Medicare program. The Congressional Budget Office estimates that in 2007 alone, the use of generic drugs in place of chemically-equivalent brand name drugs in the Part D program saved beneficiaries and taxpayers approximately \$33 billion.¹ However, despite the popularity, safety, and affordability of generic drugs, the Medicare Payment Advisory Commission (MedPAC) has found the use of generic drugs among Part D beneficiaries receiving a low-income subsidy (LIS) to be at a rate lower than non-LIS beneficiaries.²

It is important that all beneficiaries, including LIS beneficiaries, have robust access to generic drugs through their Part D plans. It is for this reason that I request an analysis of Part D plans' formularies, including Part D plans serving LIS beneficiaries, for an examination of the inclusion of brand name drugs and chemically-equivalent generic drugs.

Thank you for your consideration of this request.

Sincerely,



Bill Nelson
 Chairman

¹ Congressional Budget Office. 2010. *Effects of using generic drugs on Medicare's prescription drug spending*, p. 7. Washington, DC.

² MedPAC. 2012. *Report to the Congress: Medicare Payment Policy*, p. 361. Washington, DC.

Appendix 2 – HHS OIG Response to Committee


 DEPARTMENT OF HEALTH AND HUMAN SERVICES
OFFICE OF INSPECTOR GENERAL

WASHINGTON, DC 20201



DEC 31 2013

The Honorable Bill Nelson
 Chairman
 Special Committee on Aging
 United States Senate
 Washington, DC 20515

Dear Mr. Chairman:

I am writing in response to your October 17, 2013, letter requesting that the Office of Inspector General (OIG) examine availability of generic drugs to Medicare beneficiaries—including low-income subsidy (LIS) beneficiaries—through their Medicare Part D plans' formularies. We have completed the requested analysis and are pleased to provide you with the results.

In response to your request, we reviewed all 2013 Part D plans. We found that generic drugs are widely available through Part D plans. In fact, Part D plans below the regional benchmarks (i.e., Part D plans that serve a higher proportion of LIS beneficiaries) have a higher percentage of generic drugs available than plans above the regional benchmarks. In addition, we specifically reviewed 17 drugs that had lower generic dispensing rates for LIS beneficiaries than for non-LIS beneficiaries and found that almost all formularies included generic equivalents for these drugs.

Our analysis demonstrates that generics are covered by Part D plans that serve LIS beneficiaries. Thus, other factors—such as beneficiary cost-sharing obligations, beneficiary preferences, the prescribing behavior of health care providers, and pharmacy dispensing—may explain why generic drug use by LIS beneficiaries has been lower than generic drug use by non-LIS beneficiaries. To increase the use of generic drugs by LIS beneficiaries and thereby reduce Part D expenditures, additional efforts could focus on educating prescribers, pharmacists, and beneficiaries on the benefits of generic drugs and altering cost-sharing obligations for LIS beneficiaries, the latter of which would require legislative changes.

BACKGROUND

The Medicare Prescription Drug Benefit

Beginning in 2006, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) made comprehensive prescription drug coverage under Medicare Part D available to all Medicare beneficiaries.¹ The Centers for Medicare & Medicaid Services (CMS) contracts with private companies, known as plan sponsors, to offer Part D plans in one or more regions. In

¹ MMA, P.L. 108-173 § 101. Social Security Act § 1860D-1(a), 42 U.S.C. § 1395w-101(a).

2013, plan sponsors offered 3,330 unique Part D plans, with many plan sponsors offering multiple Part D plans.²

Under Part D, plans can establish formularies from which they may exclude drugs and which control drug utilization within certain parameters. These parameters are intended to balance Medicare beneficiaries' needs for adequate prescription drug coverage with Part D plans' needs to contain costs. Generally, a Part D formulary must include at least two drugs in each therapeutic category or class.^{3,4} In addition, formularies must include Part D-covered drugs in certain categories and classes.⁵

These formularies are generally organized into tiers that have different beneficiary coinsurance amounts to drive utilization toward less-expensive drugs. Drugs in lower tiers are typically the least expensive and have the lowest beneficiary coinsurance amounts. Formularies typically place generic drugs in the lower tiers. Drugs in ascending tiers are, in general, more expensive and have increasing beneficiary coinsurance amounts.

A plan sponsor can use the same formulary for multiple Part D plans. The 3,330 Part D plans used 302 unique formularies in 2013.

CMS Efforts To Ensure Prescription Drug Coverage

CMS reviews Part D plan formularies to ensure that they include a range of drugs in a broad distribution of therapeutic categories or classes and include all drugs in specified therapeutic categories or classes.⁶ During this review, CMS analyzes formularies' coverage of the drug classes most commonly prescribed for the Medicare population. CMS intends for Part D plans to cover the most widely used medications, or therapeutically alternative medications (e.g., drugs from the same therapeutic category or class), for the most common conditions. CMS also reviews tier structure as part of its formulary review.

Low-Income Subsidy

Beneficiaries with limited income and assets are eligible to receive assistance to cover out-of-pocket costs associated with their prescription drug coverage.⁷ The fewer the resources that eligible beneficiaries have, the lower their out-of-pocket costs will be, including their coinsurance payments.

LIS beneficiaries can be auto-enrolled by CMS in Part D plans with premiums that are at or below the regional benchmark, or they can enroll in a Part D plan on their own. The regional benchmark is a statutorily defined amount that is based on the average premium amounts for Part

² OIG analysis of 2013 plan and premium information for Medicare plans offering Part D coverage.

³ CMS, Prescription Drug Benefit Manual (*PDBM*), ch. 6, § 30.2.1.

⁴ Therapeutic categories or classes classify drugs according to their most common intended uses. For example, the therapeutic class "cardiovascular agents" consists of drugs intended to affect the rate or intensity of cardiac contraction, blood vessel diameter, or blood volume.

⁵ Patient Protection and Affordable Care Act (ACA), P.L. 111-148 § 3307, Social Security Act § 1860D-4(b)(3)(G), 42 U.S.C. § 1395w-104(b)(3)(G).

⁶ CMS, *PDBM*, ch. 6, §§ 30.2.1 and 30.2.5.

⁷ Social Security Act § 1860D-14(a), 42 U.S.C. § 1395w-114(a).

D plans for each region.⁸ Those LIS beneficiaries who enroll in Part D plans with premiums above the regional benchmark are responsible for paying the premium cost in excess of the benchmark.⁹ In 2013, about 11 million LIS beneficiaries are enrolled in Part D; 69 percent of these beneficiaries are enrolled in Part D plans with premiums at or below the benchmark.

LIS beneficiaries' coinsurance payments for Part D drugs are limited by statute.¹⁰ These coinsurance payments differ by LIS beneficiaries' subsidy level, which is based on their income and assets, and by whether a brand-name or generic drug is dispensed. Brand-name coinsurance amounts are limited to \$3.50, \$6.60, or 15 percent of drug costs. Generic coinsurance amounts are even lower with amounts limited to \$1.15, \$2.65, or 15 percent of drug costs.¹¹

Generic Drug Use

Nearly three-quarters of prescription drugs dispensed in 2010 to Part D beneficiaries were generic drugs. For LIS beneficiaries, 71 percent of prescription drugs dispensed were generic drugs, compared with 76 percent for non-LIS beneficiaries.¹²

Beyond beneficiary coinsurance costs (discussed above), other factors may influence the use of generic drugs in Part D, such as the prescribing patterns and dispensing patterns of health care providers and pharmacies, respectively. Health care providers can prescribe generic drugs when they are available, and pharmacies can substitute a generic drug for a brand-name multisource drug.

The opportunity for a generic drug to be dispensed is possible only when a health care provider prescribes a brand-name multisource drug, i.e., a brand-name drug with generic drug equivalents or a generic. When a health care provider prescribes a brand-name multisource drug, pharmacists, in almost all States, can substitute a generic version instead. Typically, pharmacists can substitute generic drugs only when the Food and Drug Administration (FDA) has given these drugs an "A" rating.¹³

⁸ Social Security Act, § 1860D-14(b)(2), 42 U.S.C. § 1395w-114(b)(2).

⁹ ACA, P.L. 111-148 § 3303, Social Security Act § 1860D-14(a)(5), 42 U.S.C. § 1395w-114(a)(5). The ACA established a "de minimis" premium policy, whereby a Part D plan may elect to waive the "de minimis" amount above the benchmark for LIS beneficiaries. For 2013, CMS set the "de minimis" amount at \$2 above the regional benchmark.

¹⁰ Social Security Act § 1860D-14 (a), 42 U.S.C. § 1395w-114(a).

¹¹ CMS, *National Medicare Training Program: Part D Benefit Parameters*. Accessed at <http://www.cms.gov/Outreach-and-Education/Training/CMSNationalTrainingProgram/Downloads/2013-Part-D-Benefits-Parameters-Job-Aid.pdf> on December 3, 2013.

¹² Medicare Payment Advisory Commission, *Report to Congress: Medicare Payment Policy*, March 2013.

Accessed at http://medpac.gov/documents/Mar13_EntireReport.pdf on December 24, 2013.

¹³ FDA, *Orange Book Preface*. Accessed at <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/ucm079068.htm#Section%201.7,%20Therapeutic%20Equivalence%20Evaluations%20Codes> on October 23, 2013.

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Almost all States permit some form of generic substitution, according to a March 2010 analysis of State Web sites.¹⁴ Only Oklahoma actively bars pharmacists from substituting a generic drug without the authorization of the prescriber.¹⁵

METHODOLOGY

We collected plan and formulary data from CMS for Part D plans operating in 2013. The 2013 Part D plan data include whether a plan's premium is at or below the regional benchmark. The formulary data include information for 302 formularies.

We conducted all of our analysis on unique formularies and then weighted the results by the number of Part D plans each formulary served.

To determine whether generic drugs were available to beneficiaries through their Part D plans, we calculated the percentage of generic drugs available for each plan. We used information from First DataBank to identify whether each drug listed was a single source, brand-name multisource, or generic drug.¹⁶ We then calculated the average percentage of generic drugs across all plans. We also calculated the average percentage for benchmark plans and plans above the benchmark. Benchmark plans are plans with premiums at or below the regional benchmark.

To determine the potential for generic substitution, we divided the total of all FDA "A"-rated generic drugs by the total of brand-name multisource and generic drugs available on each formulary. We considered only generic drugs with an FDA rating of "A" as substitutable. In cases when multiple generic drugs may have been available for a brand-name multisource drug, we counted them only once to avoid overestimating the generic substitution potential. We then calculated the average potential for generic substitution across all plans. We also calculated the average percentage for benchmark plans and plans above the regional benchmark. Finally, we calculated the potential for generic substitution among therapeutic classes across all plans and between plans.¹⁷

Finally, we determined whether formularies covered generic equivalents for 17 specific drugs. These drugs had a generic substitution rate that was 10 percentage points lower for LIS beneficiaries than for non-LIS beneficiaries and had more than 4,000 fills in 2012 for LIS beneficiaries.

¹⁴ Avalere Health LLC, *State Policies Regarding Generic Substitution, 2010*. Accessed at http://www.avalerehealth.net/research/docs/Generic_Substitution.pdf on October 23, 2013.

¹⁵ Oklahoma Pharmacy Lawbook, §535:10-3-1.1

¹⁶ Single source drugs are drugs that have no generic equivalent.

¹⁷ We used the Standard Therapeutic Class code provided by FirstData Bank. This classification provides a definitive—but not comprehensive—system of therapeutic classification.

RESULTS

Generic Drugs Are Widely Available on Part D Plans

Benchmark plans—that serve approximately 70 percent of all LIS beneficiaries—have a higher percentage of generic drugs available on their formularies than plans above the regional benchmark serving the remaining 30 percent of LIS beneficiaries. The average percentage of generic drugs included in benchmark plans was 61 percent, compared to 58 percent for plans above the benchmark. The average percentage of generic drugs included in Part D plans was 58 percent for 2013.

Further, the potential for generic substitution is higher for benchmark plans than other plans. Generic substitution measures the ability within a formulary to substitute a generic drug for a brand-name multisource drug. The average generic substitution potential for benchmark plans was 87 percent, compared to 83 percent for the other plans. The average of potential generic substitution across all plans was 84 percent for 2013.

The potential for generic substitution within each therapeutic class is the same or higher in benchmark plans than in plans above the regional benchmark. Across 71 different therapeutic classes, the potential for generic substitution per therapeutic class was, on average, 3 percentage points higher in benchmark plans than it was in plans above the benchmark.

Generic Equivalents Are Available for Specific Drugs Reviewed

For the 17 drugs reviewed for which LIS beneficiaries had substantially lower rates of generic substitution, almost all of the formularies covered generic equivalents. For 10 of these drugs, all formularies that covered the brand-name drug also covered a generic equivalent. For the remaining seven drugs, almost all the formularies covered generic equivalents. The percentage of formularies that covered generic equivalents for these seven drugs ranged between 97 percent and 99 percent.

Depending on the drug, the number of formularies that covered only a brand-name drug ranged between one and eight. In most cases, these formularies served Part D plans with premiums above the regional benchmark.

CONCLUSION

Many factors may influence the use of generic drugs, especially their use by LIS beneficiaries. These factors include the availability of generics on Part D plans, the prescribing patterns of health care providers, the dispensing patterns of pharmacies, and beneficiary preference and cost-sharing obligations.

Our analysis demonstrates that generics are widely available on Part D plans that serve LIS beneficiaries. In fact, benchmark plans have a higher percentage of generic drugs available than Part D plans with premiums above the benchmark.

Thus, factors other than generic availability may explain why the use of generic drugs by LIS beneficiaries has historically been lower than the use of such drugs by non-LIS beneficiaries.

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According to the Medicare Payment Advisory Commission, the generic dispensing rate for LIS beneficiaries was 71 percent in 2010, compared to 76 percent for non-LIS beneficiaries.

Health care providers and pharmacies influence the use of generic drugs. For example, generic substitution cannot occur if a health care provider indicates that a brand-name drug is medically necessary. All States allow health care providers to specify that a generic drug should not be substituted for a brand-name drug. The ease with which a prescriber can do this varies across States. In addition, pharmacies might not substitute a generic drug for a host of reasons—for example, because the generic drug is temporarily out of stock, customer resistance to receiving a generic drug, or because substituting a generic drug for a brand-name one would be less profitable for the pharmacy.

Beneficiary cost-sharing may also influence the use of generic drugs. Many Part D plans use beneficiary coinsurance amounts to drive utilization toward generic drugs. However, LIS beneficiaries pay nominal coinsurance compared to non-LIS beneficiaries. For example, a LIS beneficiary at or below 100 percent of poverty would pay \$1.15 for a generic drug and \$3.50 for a brand-name drug. In comparison, the median coinsurance for non-LIS beneficiaries would be \$7 for a generic drug and between \$42 and \$80 for a brand-name drug. In addition, Part D allows pharmacies to waive LIS beneficiaries' coinsurance. Finally, LIS beneficiaries who reach the catastrophic-coverage level no longer have to pay any coinsurance.

To increase the use of generic drugs by LIS beneficiaries, additional efforts could focus on educating prescribers, pharmacists, and beneficiaries on the benefits of generic drugs and altering cost-sharing obligations for LIS beneficiaries, the latter of which would require legislative changes. Increased generic drug use could result in significant savings for the Medicare Part D program.

If you have any questions about this work, please contact me or your staff may contact Chris Hinkle, Director of Congressional and Regulatory Affairs, at (202) 401-2206 or through email at Chistina.Hinkle@oig.hhs.gov.

Sincerely,



Daniel R. Levinson
Inspector General

