

# Fifteen Years of Part D:

*Gaining Perspective on the  
Medicare Prescription Drug Benefit*

September 2018



Medicare Access for Patients Rx™  
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## **MEDICARE PART D PROVIDES PRESCRIPTION DRUG COVERAGE FOR NEARLY 1 IN 8 AMERICANS, MORE THAN 44 MILLION MEDICARE RECIPIENTS.**

It is easy to take for granted that the Medicare Prescription Drug Benefit (also known as “Part D”) has largely been a success story; from the highly anticipated start date, things went relatively smoothly. The Part D marketplace has offered eligible seniors and people with disabilities an avenue to access critical oral and self-administered medications. Part D beneficiaries generally have access to a wide range of medications across therapeutic classes, abundant plan options for enrollment, and protections to ensure they receive the medications they need. This unique partnership between commercial health plans and the federal government has enjoyed enduring popularity among the tens of millions of beneficiaries who have enrolled in the program.

While there are several noteworthy successes for Part D since its launch, current challenges persist related to beneficiary access and overall affordability. Many patients must tackle significant utilization management hurdles before they can get to their second challenge: paying for the drug itself. For beneficiaries who do not qualify for the low-income subsidy, several factors present increasing financial challenges, including specialty tier and non-preferred drug cost-sharing, the lack of an annual out-of-pocket (OOP) maximum, and prices at the point of sale that do not reflect manufacturer rebates and discounts. Additionally, beneficiaries may not have access to preferred pharmacies that would offer relatively low cost-shares.

Despite the program’s popularity, utilization of prescription drugs has shifted over the last decade and exposed many beneficiaries to unforeseen access challenges, particularly for the sickest patients who consistently face high OOP costs. Part D is rightly celebrated and hailed as a success; however, persisting challenges require that innovative solutions be devised, explored, and deliberated by multiple stakeholders. As Part D beneficiaries and the advocacy groups serving as their voice grapple with affordability and access challenges, Congressional policymakers should explore several options to ease the burden on beneficiaries.

This white paper seeks to present a concise history of the benefit, underline the successes of the program, highlight the existing challenges for beneficiaries, and offer potential policy solutions for program enhancement in the future.

## FOUNDATIONS OF THE BENEFIT

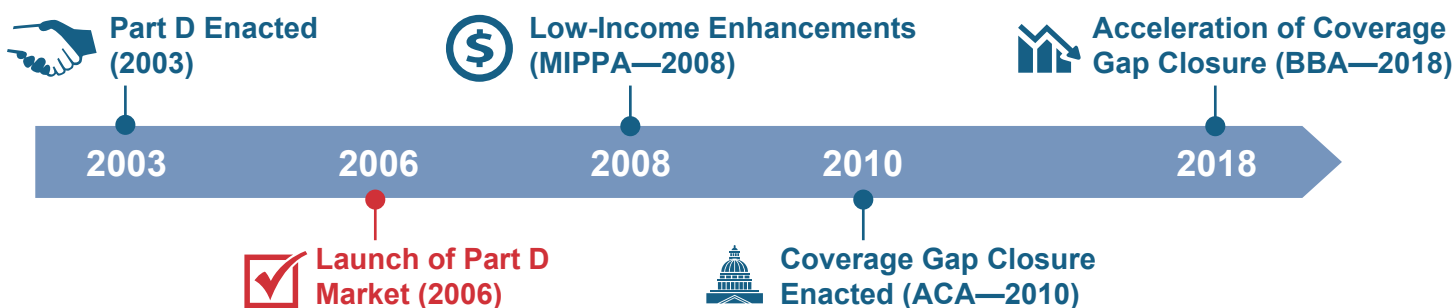
Prior to the launch of Part D, beneficiaries did not have access to a comprehensive prescription drug benefit for oral or self-administered drugs through the Medicare program. Long a feature of the commercial health plan market, prescription drug coverage for Medicare beneficiaries was largely limited to drug coverage offered by supplemental plans or select drugs covered under Medicare Part B (mostly physician-administered products). Despite several attempts by Congressional policymakers since the enactment of Medicare in 1965 to include retail prescription drugs, past efforts faltered.

However, the Balanced Budget Act of 1997 sparked a course change and created a window of opportunity. Specifically, the BBA created the managed care program in Medicare (Part C), which encouraged beneficiaries to choose among the traditional fee-for-service Medicare and health plan options (health maintenance organizations, preferred provider organizations).<sup>1</sup> An important outcome of the Balanced Budget Act was the National Bipartisan Commission on the Future of Medicare, tasked to explore and propose recommendations to preserve the vitality of the program. Further, an important proposal from the commission was the establishment of a Medicare prescription drug benefit for beneficiaries with incomes below 135% of the federal poverty level.

Armed with the recommendations from the commission, momentum for the program started to gain traction during the first term of President George W. Bush. Despite concerns from some members of the Democratic Party that the proposed benefit possessed significant inadequacies around beneficiary protections and concerns from some members of the Republican Party that it would accelerate the federal budget deficit, Congress passed the Medicare Modernization Act (MMA) in December of 2003. The MMA created Medicare Part D.

Program enrollment began in the fall of 2005 and the Part D program officially launched in January 2006. Since then, several enacted laws have sought to improve the benefit with the following enhancements: augmenting access for select low-income beneficiaries (Medicare Improvements for Patients and Providers Act [MIPPA] of 2008); closing the Part D coverage gap, or “donut hole” (Affordable Care Act [ACA] of 2010); and accelerating the closure of the coverage gap (Bipartisan Budget Act of 2018).

**Figure 1. Medicare Part D Timeline**

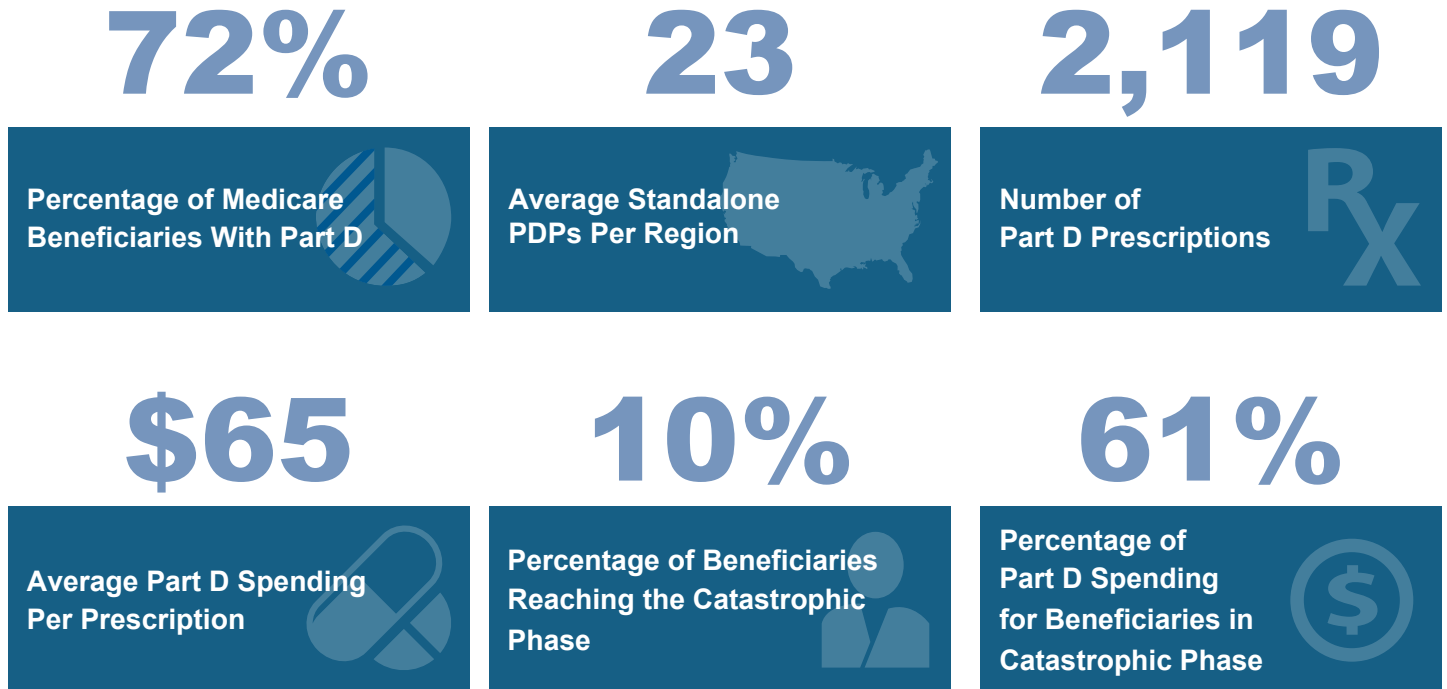


Key: ACA – Affordable Care Act; BBA – Bipartisan Budget Act; MIPPA – Medicare Improvements for Patients and Providers Act.

# MEDICARE PART D SNAPSHOT

When the Part D benefit was enacted, it was not clear if the commercial market would step up to the plate. There was no precedent for standalone prescription drug benefits; indeed, the MMA included the option for fallback plans in case there were not at least 2 plans per region. As the Part D benefit closes in on its 13th year in operation, the Medicare Part D program is a vibrant marketplace with robust enrollment and plan offerings.

Figure 2. Medicare Part D Snapshot<sup>2,3</sup>



Key: PDP – prescription drug plan.

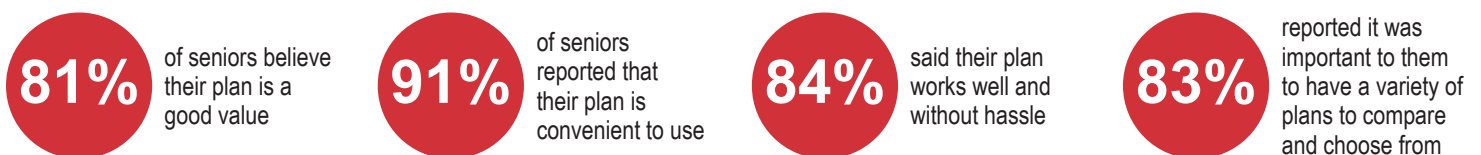
Policy experts and observers generally regard Part D as a success, given its expanding enrollment each year, popularity among beneficiaries, better-than-expected budget impact, and positive effect on health outcomes.

## Program Enrollment and Popularity

Every year since the program’s launch in 2006, enrollment has increased. Notably, Part D enrollment has nearly doubled from 22.5 million (52% share of Medicare beneficiaries) in 2006 to more than 44 million (74% share) in 2018.<sup>4,5</sup> Most Part D beneficiaries are enrolled in standalone prescription drug plans (PDPs) compared to drug plans offered by Medicare Advantage (Medicare Advantage prescription drug [MA-PD] plans).

While the influx of Baby Boomers into the overall Medicare programs has been a key factor in facilitating the year-to-year enrollment increases, the Part D program remains exceedingly popular with beneficiaries. Medicare Today’s 2018 Senior Satisfaction Survey of approximately 2,000 seniors conducted by Morning Consult found that nearly 85% of seniors are satisfied with their Part D coverage, and more than 8 of every 10 believe their drug plan is a good value.<sup>6</sup>

Key findings in this same 2018 Senior Satisfaction Survey demonstrate comprehensive satisfaction with the program:



## Positive Impact on Health Outcomes

In addition to its popularity among the Part D beneficiary population, the benefit has helped improve patients' health outcomes. Several studies across the lifespan of the program have demonstrated that as Part D has provided an avenue for access to prescription drugs, the health of Medicare beneficiaries utilizing the services has also generally improved.

Specifically, some of the highlighted studies below conclude that Part D has helped improve health metrics, prevented further onset of diseases, prolonged survival rates, and reduced hospitalizations.

**Figure 3. Research on the Impact of Prescription Drug Access on Health Outcomes<sup>7-10</sup>**



A 2011 study found that use of Medicare Part D offered seniors positive health benefits, specifically the reduction of medical services.



A 2016 analysis showed that implementation of Medicare Part D increased medication adherence, and reduced the likelihood that newly covered beneficiaries develop high blood pressure.



In 2015, researchers estimated that since the implementation of Part D in 2006, nearly 200,000 Medicare beneficiaries have lived at least 1 year longer.



An August 2018 study revealed that overall survival of myeloma patients was significantly better for beneficiaries with Part D coverage.

Part D's role in achieving non-drug medical savings through improved access to prescription drugs and medication adherence has been recognized by the Congressional Budget Office (CBO), which stated in 2012 that "a 1% increase in the number of prescriptions filled by [Part D] beneficiaries would cause Medicare's spending on medical services to fall by roughly one-fifth of 1%." This connection between prescription drugs and reductions in use of other medical services (and thus reductions in Medicare A and B spending), highlights the value of the benefit—and, as utilization of medical services and prescription drugs evolves, the link may even be stronger.

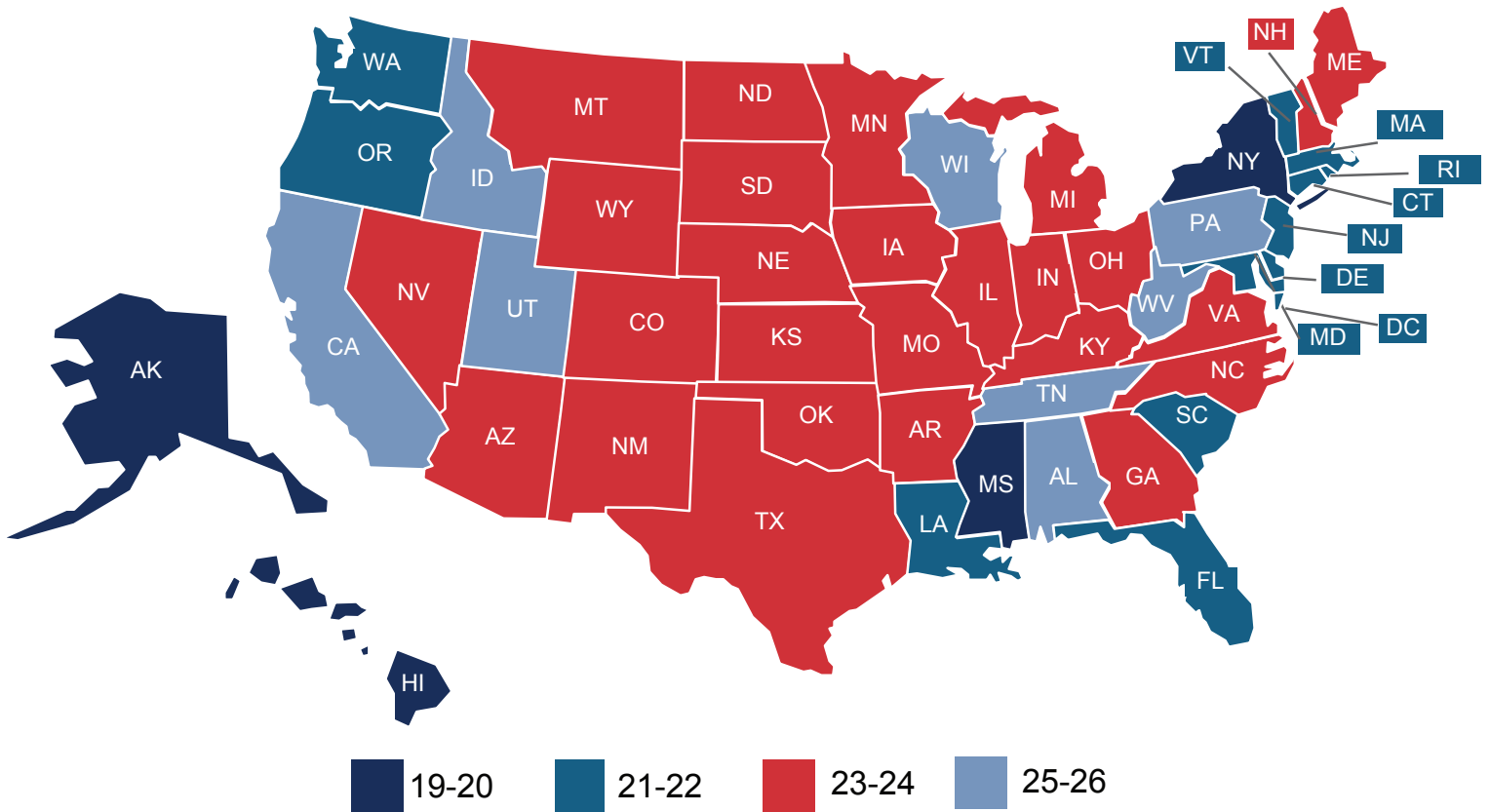
## Competitive Part D Marketplace

Besting initial concerns around potentially lagging plan sponsor participation in Part D—leading to limited access for beneficiaries—the Part D marketplace has been strong from the start, as highlighted by robust plan participation and relatively stable benefit designs across the program. Beneficiaries generally have numerous plans from which to choose in their Part D regions, and average premium increases have been slight in recent years.

### *Plan Participation*

At the outset of Medicare Part D, policymakers and experts worried that plan participation would be lagging; so much so that the MMA included the fallback provision that authorized the Centers for Medicare & Medicaid Services (CMS) to offer a government plan in regions without sufficient choices. At launch, there was an average of 42 plans per region.<sup>11</sup> While the number of plans has steadily decreased per region, in 2018, beneficiaries have, on average, 23 PDP options for enrollment consideration.<sup>12</sup> At one point, the number of choices became so high that CMS eventually required Part D plan sponsors to have plans be meaningfully different from each other in order to minimize beneficiary confusion during the annual election period, although CMS is amending the policy for 2019 to allow sponsors to offer multiple enhanced alternative plans.

**Figure 4. Number of PDPs by State, 2018<sup>13</sup>**



Key: PDP – prescription drug plan.

### *Premiums and Program Costs for the Federal Government*

Most Part D beneficiaries pay a monthly premium for prescription drug coverage. While there have been some years where average premiums have fluctuated, overall, average premiums have been relatively stable. From 2006 to 2018, the weighted average monthly premium for Medicare PDPs has increased from \$25.89 in 2006 to \$43.48 in 2018, representing a total increase of 68.7%, or a 4.4% increase year-over-year.<sup>14</sup>

This premium is after the roughly 75% subsidy from the federal government; given that the benefit was a new entitlement program, many policymakers and stakeholders held considerable concerns around the cost of the benefit to taxpayers. However, a key hallmark of the Part D success story is that expenditures have consistently beaten initial projections. In 2016, Part D expenditures were \$100 billion, or less than half of the \$205.5 billion cost projected by the CBO in 2006.<sup>15</sup> In the first 10 years of the Part D program, total expenditures were \$555.8 billion less than originally projected.

Several factors have likely contributed to the lower-than-expected expenditures, namely the ability of plans to negotiate discounts and rebates from drug manufacturers and the rapid shift to generic utilization when generics are approved by the Food and Drug Administration. CBO has said that the large number of plan sponsors per region has contributed to lower bids.<sup>16</sup> Competition has also helped at the prescription drug level. In Part D, plan sponsors negotiate with manufacturers not only for coverage on formulary, but also the tier placement and patient cost-sharing for the drug. Additionally, high utilization of generic medications in Part D has been a prevailing feature in recent years. In 2015, the generic utilization rate in Part D was 87%, compared to 61% in 2007.<sup>17</sup>

## Part D Beneficiary Protections

An unusual aspect of Part D is its benefit design. The standard Part D benefit requires beneficiaries to pay 25% of the cost of medications after exhausting an annual deductible—that is fairly traditional; however, until 2011, after eclipsing a threshold of total drug spend (\$3,750 in 2018<sup>18</sup>), beneficiaries faced a unique benefit design feature: the Part D coverage gap. In the gap (or “donut hole”) beneficiaries had to pay the total cost of their medications until they reached an OOP threshold, at which point they entered catastrophic coverage (paying 5% of the cost of the drugs for the remainder of the plan year). Beginning in 2011, the ACA started to gradually close the “donut hole,” lowering each year the share of total drug cost owed by patients in the coverage gap. Under the Bipartisan Budget Act of 2018, the coverage gap will close completely in 2019 for brand-name drugs.

Given the need for consistent, non-discriminatory coverage for beneficiaries and the potential for sizable OOP costs for beneficiaries due to the current benefit design, Part D has several beneficiary protections that attempt to guard coverage and access in the balance of patient, commercial, and governmental interests in managing the program. While the Part D benefit design offers some level of catastrophic protection after a beneficiary reaches the OOP threshold, Congressional policymakers enacted two changes in the closure of the coverage gap and its acceleration to help minimize the financial burden.

### *Protected Classes*


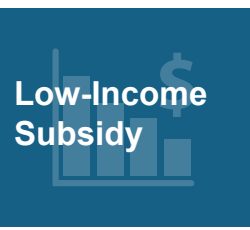


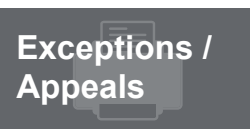
Part D requires that plan sponsors cover “all or substantially all drugs” in six classes containing life-saving drugs; these are often referred to as the “six protected classes.” This policy has successfully guarded basic access for patients who need non-interchangeable medications to treat and manage serious and often life-threatening conditions, such as epilepsy. This policy has been a weapon against discriminatory plan design and a true protective measure for timely patient access to physician-directed care, particularly knowing that Part D is administered by private plans with extensive experience managing drug costs through advanced formulary and utilization management techniques in other segments. Barriers to access for these medications hinder provider decision making and threaten patient outcomes.

### *Low-Income Subsidy*

The Part D benefit also provided consistent prescription drug coverage and premium and cost-sharing assistance for the over 12 million beneficiaries who qualify for the low-income subsidy. Some beneficiaries, like those that dually qualify for Medicare and Medicaid (dual eligibles) are automatically enrolled, other beneficiaries must apply and are subject to both an income and asset test. For example, in 2018 the resource limits are \$7,560 (\$11,340 if married) for the full low-income subsidy and \$12,600 (\$25,150 if married) for other low-income subsidies.<sup>19</sup>

While low-income subsidy beneficiaries may choose to enroll in any Part D plan, subsidies are available up to the cost of the average premium for the basic plan (benchmark). Over time, there have been fewer options available to choose from. For example, in 2018 there was a 6% decrease in available plans; about 3 in 10 PDPs are benchmark plans for the low-income subsidy, and thus premium-free.<sup>20</sup> This reduces the ability of beneficiaries to find plans that include their drugs on the plan formulary.

**Figure 5. Part D Beneficiary Protections**

 <p><b>Part D Benefit Design</b></p>	<p>Catastrophic phase only requires 5% coinsurance for branded drugs for non-low-income subsidy beneficiaries after reaching the OOP threshold</p>
 <p><b>Low-Income Subsidy</b></p>	<p>The low-income subsidy offers assistance with OOP expenses for eligible beneficiaries</p> <ul style="list-style-type: none"> <li>▪ No or reduced premiums</li> <li>▪ No or reduced deductibles</li> <li>▪ No or reduced cost-sharing in the initial coverage phase</li> <li>▪ No or limited cost-sharing in the coverage gap</li> <li>▪ No or reduced cost-sharing during the catastrophic phase</li> </ul>
 <p><b>Coverage Gap Closure</b></p>	<ul style="list-style-type: none"> <li>▪ Part D coverage gap is closing by 2019</li> <li>▪ Branded products are largely financed by manufacturer discount payments in coverage gap</li> </ul>
 <p><b>Protected Classes</b></p>	<p>Part D plans must cover all or substantially all drugs within the following therapeutic classes:</p> <ul style="list-style-type: none"> <li>▪ Antidepressants</li> <li>▪ Antipsychotics</li> <li>▪ Antineoplastics</li> <li>▪ Immunosuppressants</li> <li>▪ Antiretrovirals</li> <li>▪ Anticonvulsants</li> </ul>
 <p><b>Exceptions / Appeals</b></p>	<p>Part D offers beneficiaries formulary exceptions for non-covered drugs, tiering exceptions for reduced cost-sharing, and a comprehensive appeals process for denied exceptions</p>

Key: OOP – out-of-pocket.

These protections have come under fire in recent years as the commercial market and the government look for ways to evolve the benefit. However, coalitions like MAPRx have consistently raised concerns about proposed changes to the Medicare prescription drug benefit that could adversely affect beneficiary access, coverage, and program transparency.

## EVOLVING THE PROGRAM TO MEET CURRENT AND FUTURE BENEFICIARY NEEDS

While there are several noteworthy successes for Part D since its launch, current challenges persist related to beneficiary access and overall affordability.

### Utilization Management

The tension between plan flexibility to manage appropriate utilization and patient access is prevalent; however, for many patients, there are steep barriers to accessing their needed prescribed medications. Part D is administered by private plans with extensive experience managing drug costs through advanced formulary and utilization management techniques in other market segments. For example, a “fail first” policy requires that beneficiaries prescribed an expensive medication must first use a less expensive or plan-preferred medication and experience that medication’s failure **before** the plan will pay for the original (more expensive) prescription. These policies place unnecessary barriers to patients’ access to the medications recommended by their physicians. For many health conditions—particularly those treated by the drugs in the protected classes—such policies threaten patients’ lives, safety, and medical stability.

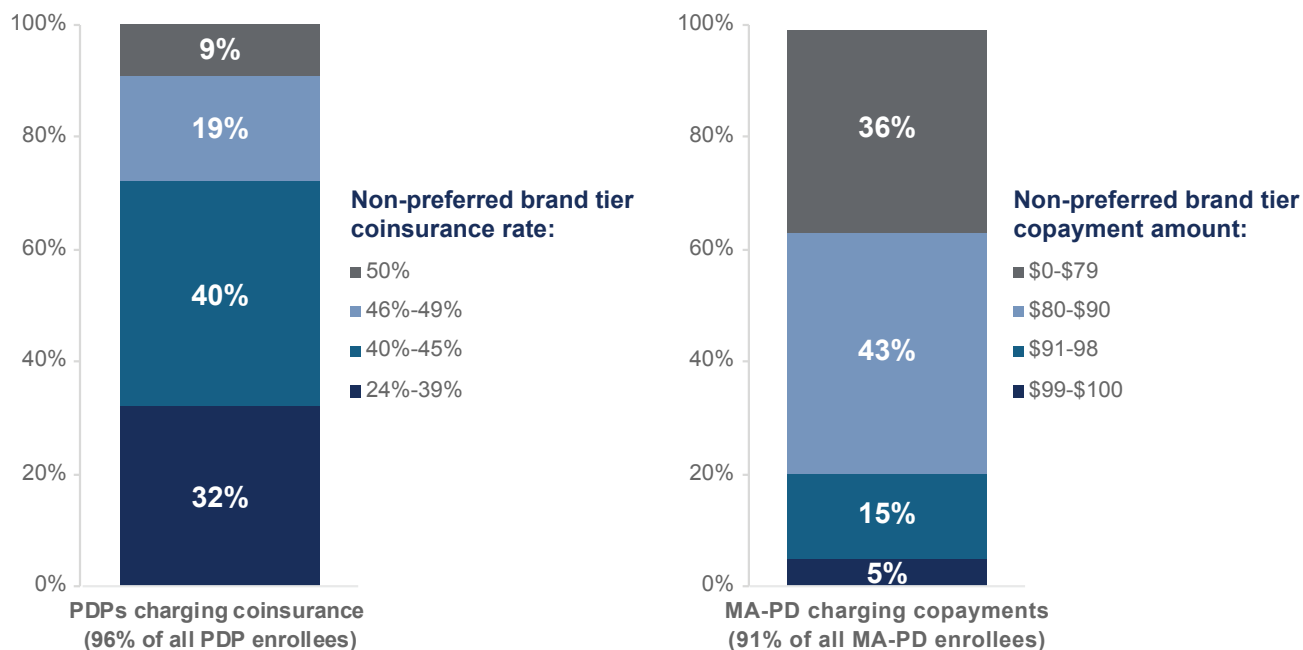


## Non-Preferred Branded Tier Cost-Sharing

Another aspect that contributes to affordability issues for patients is non-preferred brand tier cost-sharing. In recent years, Part D plans have largely turned to requiring coinsurance, rather than copayments, for non-preferred brands. Coinsurance for these tiers can be up to 50%. Coinsurance amounts in Part D are based on the “list price” for a product and do not include the discounts and rebates that are provided to the health plan or pharmacy benefit manager from the manufacturer. For the first time, in 2016, nearly all standalone PDP enrollees faced coinsurance for non-preferred brands. In contrast, the majority of MA-PD plans still covered non-preferred brand drugs by copayments.

Currently, plans are allowed to offer a “blended” brand and generic non-preferred drug tier. While the impact of this could be seen as a way to simply reduce the number of tiers, in fact, it has allowed plans to offset higher cost-sharing for high-cost brand drugs with low cost-sharing for generics. This approach lowers the average cost-sharing across all drugs on the tier, but it can subject patients taking brand drugs to very high OOP costs.

**Figure 6. Distribution of Enrollment in Part D Plans With Non-Preferred Brand Tiers, by PDP and MA-PD Plan, 2016<sup>4</sup>**



**Nearly 70% of PDP enrollees are in plans with non-preferred brand coinsurance eclipsing 40%; close to 10% face the highest coinsurance rate possible of 50%**

Key: PDP – prescription drug plan; MA-PD – Medicare Advantage prescription drug.

## Part D Specialty Tiers

Since its launch, specialty tiers have been a feature of Part D plans. As medical innovation advances, new therapies often have drug prices that land them on the specialty tier (\$670 for a 1-month supply at an in-network pharmacy.)<sup>17</sup> The proliferation of specialty tiers, subject to significant coinsurance and excluded from cost-sharing exceptions, forces beneficiaries to pay a significant percentage of the medication’s cost. For drugs covered on the specialty tiers, the coinsurance amounts can range anywhere from 25% to 33%, leaving beneficiaries paying thousands of dollars in OOP costs for drugs and biologics used to treat cancer, multiple sclerosis, rheumatoid arthritis, lupus, and other conditions. As a result, many beneficiaries are denied access to the most clinically appropriate medication because it is out of reach financially, potentially resulting in dangerous consequences.

Those who can afford the drugs, often pay high OOP sums to maintain their health. A recent study found the following average annual OOP costs for Medicare beneficiaries<sup>21</sup>:



Unlike other tiers, drugs on the specialty tier are ineligible for the tiering exceptions, meaning beneficiaries taking these high-cost medications are unable to seek a lower cost-share amount.

### The Lack of an Annual OOP Maximum

Unlike in the Part D benefit, the majority of non-low-income Medicare Part B beneficiaries have additional insurance coverage that limits their OOP exposure on prescription drugs, whether through a supplemental plan (Medigap) or Medicare Advantage. In the Part D program, non-low-income beneficiaries are responsible for the 5% catastrophic coinsurance for the remainder of the plan year, which, depending on the regimen they are on, can be thousands of dollars a month. An OOP cap would better align Part D at parity with the experience of most Part B beneficiaries, whose supplemental coverage and/or OOP caps through Medicare Advantage enable them to better anticipate and meet their financial obligations.

### The OOP Cliff

The OOP cliff is caused by a little noticed provision in the ACA, where the growth rate of the OOP threshold was slowed from 2014 through 2019. Normally, the OOP threshold (the amount patients are required to pay before entering catastrophic coverage) would grow just like the deductible and the initial coverage limit at the rate of beneficiary per capita spending. But under the ACA, the OOP threshold grew in 2014 and 2015 at the rate of per capita beneficiary spending less 0.25%, and then in 2016, 2017, 2018, and 2019, it grew at the Consumer Price Index + 2%. What causes the OOP cliff is that in 2020, the OOP threshold is set as if the growth had never been slowed down in the first place. Thus the OOP threshold is expected to grow by \$1,250 between 2019 and 2020, a dynamic often referred to as the “OOP cliff.”<sup>22</sup>

If Congress does not take action by early 2019, beneficiaries already facing high OOP spending will see their costs increase in 2020.

Figure 7. Part D OOP Cliff



The OOP cliff in 2020 will result in a sizable climb in the OOP threshold

2020 Catastrophic Threshold	<b>\$6,350</b>
2019 Catastrophic Threshold	<b>\$5,100</b>

Key: OOP – out-of-pocket.

## Failure to Pass Manufacturer Rebates to Beneficiaries at the Point of Sale

As referenced, one factor driving high OOP costs for Part D patients is the actual drug price that beneficiaries must pay at the point of sale, particularly in instances where a beneficiary faces a deductible or a coinsurance. In Part D, the price at the point of sale is based on the list price and does not account for any rebates or discounts provided by manufacturers that might reduce the overall price. If these rebates and discounts were factored into a drug's price at the point of sale, beneficiaries with deductibles or coinsurance could pay significantly lower cost-shares.

A November 2016 Milliman report concluded that Part D plans have a financial incentive to cover drugs with higher list prices and higher rebates as a means of driving down the premium, compared to lower priced drugs with lower rebates.<sup>23</sup> Moreover, because benefit designs have shifted more to coinsurance for brand drugs (based on the list price), beneficiaries who take medications with high rebates are not benefitting financially from them, as plans are not applying the rebates to the list prices. Milliman concluded that these embedded incentives result in increased costs to both the government and beneficiaries.

## Access to Preferred Pharmacies

Over the years, plans have increasingly offered reduced cost-sharing at in-network “preferred pharmacies.” In 2018, nearly all PDPs have a preferred pharmacy network.<sup>24</sup> Beneficiaries enrolled in plans with harder-to-access network pharmacies can find it difficult to fill their prescriptions at an in-network pharmacy and potentially have to pay more OOP for their medications at a non-network pharmacy.

## FORWARD-LOOKING CONSIDERATIONS FOR PART D POLICY

As the Part D program has continued to evolve since 2006, so have stakeholder (e.g., manufacturers, Part D plans, pharmacy benefit managers) incentives and practices. The marketplace has adapted to meet the benefit, and medical innovation can be geared toward outpatient treatment knowing that there is a path for reimbursement. But this, of course, changes utilization and drives costs up, particularly when viewing Part D in a silo, rather than as a part of the larger Medicare program. The program is in constant evolution because healthcare is always changing; in order to meet beneficiary needs, the Part D benefit has to keep up.

For example, with the diverse set of beneficiary needs, information on plan choices is critical. CMS should work to improve beneficiaries' online shopping experience and ability to compare formularies and OOP costs across plans. As recently recommended by the National Council on Aging, Medicare Plan Finder would benefit from a comprehensive redesign and ongoing investment to remain relevant.<sup>25</sup> Medicare Plan Finder could display costs with more precision, so that enrollees could view actual premium costs, coinsurance amounts in dollars, and copayments, rather than percentages.

There are also changes that could be made in terms of improving the exceptions and appeals process, providing greater formulary oversight, improving affordability by implementing an OOP cap and applying rebates at the point of sale, and ensuring that manufacturer discounts in the gap remain a component of true OOP costs. Discussion of these considerations will be made in greater detail in a follow-up paper to be released later this year.

The task of appropriately balancing cost and access is herculean, but if the beneficiary remains the center of focus, significant and lasting improvements are well within reach.

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## ABOUT MAPRx

Medicare Access for Patients Rx (MAPRx) is a coalition of patient, family caregiver, and health professional organizations committed to safeguarding the well-being of patients with chronic diseases and disabilities who rely on Medicare's prescription drug coverage, Medicare Part D.

The Lupus Foundation of America founded MAPRx in 2005 after Part D was created by the passage of the Medicare Modernization Act. Prior to the launch and implementation of Part D in 2006, MAPRx brought the patient advocacy community together to ensure the program met the needs of their constituents and all Americans. MAPRx members represent every segment of Medicare beneficiaries and join together to advocate for their behalf and collaborate with national and state policymakers to ensure all beneficiaries have access to the medications they need.

Since its inception, the Coalition has worked with Congress, the Centers for Medicare and Medicaid Services, the Medicare Payment Advisory Commission, and every other relevant stakeholder to strengthen Part D and continue to improve the program. MAPRx activities include hosting educational briefings for lawmakers on Capitol Hill, conducting trainings for organizations working with Part D enrollees, and producing an annual open enrollment guide to help beneficiaries understand the benefit and pick the plan that best suits their needs.

## MAPRx PRINCIPLES

MAPRx is guided by the idea that every Medicare Part D beneficiary should have timely, affordable access to the medications they need to live a healthy life. To that end, MAPRx has established the following principles for all of our activities to strengthen and improve Part D:

- I. Plans should be required to have a robust formulary and provide coverage for a variety of medications in each drug class or category.
- II. Medicare Part D's six protected classes are a critical patient protection and coverage should be required for the protected classes of drugs and any additional classes where restricted access to those drugs would have significant health consequences.
- III. Oversight of a prescription drug benefit should include monitoring of:
  - Plan operations with an emphasis on key performance measures such as frequency and types of complaints, timeliness and resolution of appeals, completeness of enrollment information accessible to pharmacists, and availability of changes to drug pricing;
  - Formulary design to determine that appropriate access is afforded to physician prescribed treatments and to ensure that the formulary does not discriminate or discourage enrollment by certain beneficiaries;
  - Plans' use of utilization management tools such as prior authorization, quantity limits and step therapy (where a lower cost drug is tried first before a higher cost drug may be used), should be required to meet best practice standards and appropriate treatment guidelines;
  - Quality measures should be meaningful to help beneficiaries make an informed drug plan choice and provide CMS necessary information in its oversight role. Measures should include customer service, access to needed drugs, appeal and denial rates, beneficiary protections and overall satisfaction; and,
  - Pharmacy and therapeutic (P&T) committee membership, including robust consumer representation, as well as process and procedural requirements should ensure access to medically necessary medications. These requirements should include procedural safeguards and timely review of every newly FDA-approved drug so that beneficiaries do not encounter barriers, such as potentially long and unnecessary delays, that hinder their access to medication therapies.
- IV. Plans should be required to provide clarity and transparency on coverage and on consumer's out-of-pocket costs. A mix of co-payments and coinsurance can cause significant confusion especially for individuals on multiple and/or expensive medications trying to navigate the system and compare plans. The ability to understand the benefits provided in a plan, along with coverage levels and out-of-pocket costs is an important factor for consumers when making a determination of which plan best meets their needs.
- V. Notice of non-coverage, appeals and exceptions process should be simple and understandable. Enrollees should be given timely notice of the reasons for the denial of drug coverage and their appeal rights, including the right to an expedited review. Regulatory oversight should ensure sufficient consistency in exceptions processes among all plans so that providers can assist beneficiaries in an efficient and effective manner.
- VI. Rigorous oversight of medication utilization management tools (such as medication substitution, step therapy or quantity limit(s) is critical.
  - Insurers should not be allowed to override a health care provider's practice of medicine by forcing utilization of certain medications or therapies that may be inappropriate to the care of their patients.
  - Plans should provide information and transparency about their utilization management tools, including notice of plan changes and the right to appeal.
  - Plans should provide clear, relevant patient information on the use of utilization management tools prior to enrollment.