Building on Success: Regulatory Reforms that Fulfill Medicare Part D’s Promise to Beneficiaries

November 2018

Executive Summary

Medicare Part D’s optional, affordable coverage for prescription drugs has changed lives. Today, more than 43 million older Americans and people with disabilities have enrolled in Part D.¹ From its inception, policymakers included safeguards that protect access to medicines and promote affordability. As the program marks its 15th anniversary since passage, the Centers for Medicare and Medicaid Services (CMS) has signaled interest in sweeping regulatory changes to Part D benefits with significant implications for access and affordability for beneficiaries.

Surveys indicate that the majority of beneficiaries enrolled in Part D are satisfied with the program.² Yet even with the success of Part D, some beneficiaries experience challenges accessing prescription drugs. Although premiums have remained stable recently and the overall costs of the program are well below the Congressional Budget Office’s (CBO) original estimates, out-of-pocket costs for many beneficiaries have risen significantly, particularly for those living with serious, chronic illnesses.

By putting beneficiaries first, CMS can build upon the success of the program, facilitate access to meaningful and affordable coverage options, and preserve existing protections relating to medication access.

Specifically, we recommend that CMS

Preserve access and choice by:

- Maintaining existing beneficiary access and choice safeguards within the six protected classes; and
- Requiring coverage of at least two drugs per therapeutic class.

And

Promote affordability by reducing beneficiary out-of-pocket costs by:

- Establishing an out-of-pocket cap on Part D spending; and
- Sharing a portion of manufacturer discounts and rebates with beneficiaries at the point of sale.


Background

Medicare Part D provides optional prescription drug coverage to 43 million Medicare beneficiaries. Beneficiaries can choose from a stand-alone prescription drug plan (PDP) or a prescription drug plan associated with a Medicare Advantage plan (MA-PD). Beneficiaries in all states have a choice among competing Part D plans, whether PDPs or MA-PDs. According to an annual Medicare Today survey, the vast majority of beneficiaries believe that having a variety of plans from which to choose is important and that their Part D monthly premium is affordable.

Medicare Part D Benefit Structure

In considering changes to the Part D benefit, it is important to understand the current structure of standard Part D benefits and how the phases of coverage change during the year. Enrollees can choose among competing plans and pay monthly premiums for prescription drug coverage. During open enrollment for the 2019 coverage year, Medicare beneficiaries have a choice of plans that varies based on where they live, with an average of 23 Medicare Part D stand-alone PDPs and 17 MA-PD plans offered per state.

By law, Part D plans must offer either cost-sharing based on the standard benefit or its equivalent in value and can offer enhanced benefits. This flexibility means that plans often vary in terms of benefit designs, cost-sharing amounts, formularies, and utilization management tools that limit access. In 2019, the standard benefit includes a deductible of up to $415, followed by an initial coverage period during which the beneficiary pays 25 percent coinsurance up to an initial coverage limit of $3,820. In 2019, most PDPs charge a deductible, with half charging the full deductible of $415.

Once total drug spending reaches a specific amount ($3,820 in 2019), beneficiaries enter the coverage gap, also known as the “donut hole.” Before the Affordable Care Act (ACA), beneficiaries were responsible for 100 percent of their drug costs in the coverage gap. The ACA closed the gap gradually over a number of years, requiring manufacturers to pay a 50 percent discount on brand medicines and increasing Part D plans’ share of costs for prescriptions filled in the coverage gap. In 2019, the gap will fully close and beneficiaries will pay 25 percent cost-sharing for brand medicines.

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4 Ibid.
9 Ibid.
10 Ibid.
If a beneficiary’s True Out-of-Pocket (TrOOP) spending – which includes both cost-sharing paid by the beneficiary and manufacturer coverage gap discounts paid on their behalf – reaches a threshold ($5,100 in 2019), he or she exits the coverage gap and enters the catastrophic phase of the Part D benefit. For all additional drug spending once reaching catastrophic coverage, beneficiaries pay five percent of their drug costs. On January 1 each year, a new plan year begins, as do the coverage phases.

In 2018, approximately 13 million Medicare beneficiaries qualified for low-income subsidies (LIS) that reduce or eliminate Part D premiums and provide cost-sharing assistance. This program provides substantial assistance facilitating access for low-income throughout all phases of coverage. Enrollees who qualify for low-income subsidies (LIS), do not have additional cost-sharing once they reach the catastrophic phase of coverage.

To protect access to a choice of medicines, CMS requires that plan formularies cover all disease states and a minimum of two chemically distinct drugs per therapeutic area. This protection helps ensure a minimum level of choice in treatment options, recognizing that many medicines are targeted and will not be appropriate for all patients. Similarly, patients themselves are unique and often need a choice of medicines.

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therapies before finding one that works for them. The Part D program also requires that plans must cover “substantially all” drugs in six “protected” classes: immunosuppressants, antidepressants, antipsychotics, anticonvulsants, antiretrovirals, and antineoplastics.\textsuperscript{13} These requirements safeguard beneficiary access to treatment options and offer protection against plan designs that could discriminate by discouraging enrollment of people relying on protected classes of medicines.\textsuperscript{14}

Throughout the different phases of coverage, the majority of plans utilize tiered formularies with varying copayments and coinsurance amounts for covered drugs, rather than charging a uniform 25 percent coinsurance rate like the standard benefit.\textsuperscript{15}

Enrollees face much higher out-of-pocket (OOP) costs for brands and non-preferred drugs, depending on their placement on formulary tiers. For example, beneficiaries can pay as little as $1 for generic medicines, but face a median cost-sharing of $37 for preferred brands and a 40 percent coinsurance for non-preferred drugs.\textsuperscript{16} For non-preferred drugs, half of PDP enrollees pay coinsurance between 40 to 50 percent. In MA-PD plans, most enrollees pay copayments of $90 to $100 for non-preferred medicines.\textsuperscript{17}

The vast majority of Part D plans also place “specialty medicines,” defined by CMS as costing $670 or more a month, on a “specialty tier”.\textsuperscript{18} For these medicines, coinsurance cannot exceed 25 percent unless the Part D plan waives part or all of the deductible.\textsuperscript{19} In that case, coinsurance is allowed up to 33 percent of the drug’s price. In 2018, almost half of those enrolled in stand-alone Part D plans and more than four in ten enrolled in Medicare Advantage have plans that require the maximum 33 percent coinsurance rate for specialty medicines.\textsuperscript{20}

Coinsurance paid by the beneficiary is typically based upon the medicine’s list price, which does not include any discounts or rebates the Part D plan has negotiated with the drug manufacturer.\textsuperscript{21}

\textsuperscript{17} Ibid.
\textsuperscript{20} Ibid.
Beneficiaries face modest costs for most generic drugs with much higher cost sharing for innovative brand name and non-preferred drugs, encountering a mix of copayments and coinsurance rates depending on formulary placement.22

Out-of-pocket costs continue to be a problem for many beneficiaries, particularly as more and more costs are being shifted to them through the increased use of coinsurance instead of flat copayments for medicines23 and growth of serious chronic conditions among the beneficiary population. From 2015 to 2018, the share of drugs subject to coinsurance jumped almost 20 percentage points.24

_Growth of Chronic Conditions_

More than 80 percent of Americans age 65 and older live with more than one chronic condition, and nearly four in 10 Medicare beneficiaries have four or more.25 Prescription medicines are an essential tool in the treatment and management of chronic conditions, particularly for older Americans. Although people age 65 and older make up 12 percent of the population, they account for 34 percent of prescription drug use.26

Annual prescription drug use increases with the number of chronic conditions. People with three to four chronic conditions, for example, fill an average of 24 prescriptions a year. People with five or more conditions fill 51 prescriptions on average.27 These individuals have complicated medical needs and significant comorbidities that may require trying a variety of therapies before finding the combination that is both appropriate and effective. Given the prevalence of multiple chronic conditions, choice among therapeutic options is critical for Medicare beneficiaries. Choice enables patients and providers to develop medication regimens that are clinically effective, avoid contraindications among medicines, lessen the risk of side effects and adverse events, and meet the needs of the patient.

_Preserve Access and Choice_

_Maintaining Safeguards within the Six Protected Classes_

For many health conditions, particularly those treated by medicines within the six protected classes, undermining existing patient protections would threaten beneficiaries’ medical stability, safety, and lives. The six protected classes policy has been a safety net for some of the most medically fragile and vulnerable Medicare beneficiaries. It requires plans to cover “all or substantially all drugs” for these six

classes: immunosuppressants, antidepressants, antipsychotics, anticonvulsants, antiretrovirals, and antineoplastics. This essential safeguard has successfully protected basic access to treatments for beneficiaries who need non-interchangeable medications in these therapeutic areas to treat and manage serious and often life-threatening conditions. It has also served as additional protection against discriminatory plan design and for timely beneficiary access to physician-directed care.

Preserving these access protections has bipartisan support within Congress, as demonstrated by the Senate Finance Committee’s formal letters to CMS administrators on the subject. For example, in 2014, the entire Senate Finance Committee wrote to then CMS Administrator Marilyn Tavenner to express the shared opposition to limit these protections, stating: 28

Since the creation of Medicare Part D, Congress and the Administration have recognized that for certain types of conditions and therapies beneficiaries should have access to all available medication.

In a separate letter to HHS on the six protected classes, Senators Grassley and Brown wrote: 29

The Centers for Medicare and Medicaid Services (CMS) created this policy to safeguard access to lifesaving medicines for vulnerable Medicare beneficiaries who rely on these classes of prescription drugs to protect them from potential challenges associated with any interruption of therapy.

They also raised concerns that restricting access and choice of medicines could raise Medicare spending in other areas:

[W]e remain concerned that if beneficiaries do not have access to needed medication, costs will be incurred as a result of unnecessary and avoidable hospitalizations, physician visits, and other medical interventions that are otherwise preventable with proper adherence to medication. In fact, the Congressional Budget Office recently affirmed policies that increase access to prescription drugs actually decrease spending on medical services, such as hospitals and physicians. We are concerned that the attempt to find cost savings in Part D could result in cost increases for the Medicare program at large.30

Clinicians require access to a broad selection of prescription therapies to prescribe the best agent for the particular patient. Forcing a change in medications could cause adverse health outcomes among vulnerable populations.

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More recently, the Pew Charitable Trusts issued a report examining the six protected classes protections, stating that the “lack of adequate access to medications can in some circumstances increase costs to other Medicare programs through increased hospitalizations from complications or increased physician visits to manage medications.”\textsuperscript{31} The report also noted that most of the six protected classes have high penetration of generic medicines and utilization, limiting any potential savings from removing access safeguards.

\textit{Requiring Coverage of at Least Two Drugs per Therapeutic Class}

Requiring a minimum of two drugs per therapeutic class helps to ensure that beneficiaries and their providers have access to at least two therapeutic options to meet the clinical needs of the beneficiary. All medicines do not work for all individuals the same way. For many, especially people living with one or more chronic illness or disability, one drug per class will not provide sufficient access to prescription drug therapies that are safe and adequate. With each additional condition, the complexity of finding the right regimen of medicines increases, making choices among different medicines even more important. Because Medicare beneficiaries are more likely to have multiple chronic conditions, the risk of drug-to-drug interactions and adverse drug reactions will be higher. That, in turn, makes prescribing a challenging task for physicians who sometimes need to shift among several drugs in a class to find the right medicine or medicines that work best for the specific patient. Avoiding such adverse events through appropriate prescribing is good for patients and saves Medicare money too, since even with the current protections, among older adults medication-related adverse events are associated with 10 to 30 percent of all hospital admissions.\textsuperscript{32} Preserving this minimal level of choice among treatment options will help avoid adverse events and improve treatment outcomes.

\textit{Promote Affordability by Reducing Beneficiary Costs}

Within Part D, much is made of the stability in Medicare Part D premiums over time. Premiums, often the focus of discussions about Part D affordability, have risen modestly since Medicare Part D’s inception, and in the last two years, the average premium even declined.\textsuperscript{33} This stability has no doubt contributed to the program’s popularity and overall satisfaction rates.\textsuperscript{34}

Even with the availability of low-income subsidies and the reduction of beneficiary costs in the coverage gap, many enrollees increasingly face higher out-of-pocket costs. Too great an emphasis on lower premiums or other costs for all enrollees can go so far as to undermine the original purpose of insurance: namely, shielding those with high medical needs from the brunt of related expenses by spreading them over a larger group of people. Within Medicare Part D, for example, while premiums

remain low, both coinsurance usage and rates have increased, placing a higher cost burden on the medically needy.

High coinsurance levels in Part D are particularly problematic because plans do not typically share rebates or discounts on medicines directly with beneficiaries whose medicine use generates those rebates. Beneficiaries pay the full undiscounted price if they have a deductible and a percentage of the full undiscounted price when paying coinsurance. According to CMS, in 2014 plans received more than $16 billion in rebates. Instead of reducing the beneficiary’s cost at the pharmacy counter, plans use rebates and other discounts generated for other purposes, including reducing premiums for all beneficiaries. This is the inverse of how insurance is supposed to work— with medically needy beneficiaries subsidizing the healthy.

Research has shown that higher out-of-pocket costs for medicines under Part D are associated with reductions and delays in starting treatment, higher rates of abandoning of new prescriptions, delays between refills or interruptions in treatment, and early discontinuation of treatment altogether. Though these actions may mean lower spending in Part D, not taking medicines as prescribed is associated with significant spending on other health care services that Medicare covers.

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Establishing an Out-of-Pocket Cap on Part D Spending

Capping out of pocket spending under Part D would help vulnerable beneficiaries access the medicines they need with predictability in their yearly costs. In 2015, 3.6 million Medicare Part D enrollees reached the catastrophic phase of drug coverage, including 1 million enrollees who did not qualify for LIS assistance. That’s twice the number of non-LIS enrollees reaching catastrophic spending levels in 2007.39 The number of non-LIS Medicare Part D enrollees who reach catastrophic coverage spending levels increased by more than half from 2013-2016.40

Among non-LIS beneficiaries with high OOP drug costs, average OOP spending totaled $3,041 in 2015—six times more than average spending by non-LIS enrollees overall.41 One in ten non-LIS beneficiaries spent at least $5,200 OOP on medicines in 2015 and 40 percent of their spending occurred while in the catastrophic coverage phase.42 According to the Kaiser Family Foundation, in 2015, beneficiaries who did not qualify for the LIS and who reached the catastrophic phase of the Part D benefit spent $1,215 on average once they reached catastrophic coverage.43 Overall, non-LIS enrollees with high OOP costs accounted for twenty percent of OOP drug spending by all enrollees although they comprise only two percent of the enrolled population.44

An OOP maximum would allow beneficiaries to adequately plan their expenses for the coming year, as those with high OOP costs would know that their OOP costs are limited. CMS could implement a cap for MA-PDPs through the administrative process without requiring a legislative change.

Sharing Rebates with Beneficiaries at the Point of Sale

One factor driving high out-of-pocket (OOP) costs for beneficiaries is that when prescriptions are filled during the deductible or with coinsurance, the price the beneficiary pays is based on a drug’s list price without accounting for any rebates or discounts the plan negotiated. Sharing a portion of rebates at the point of sale would reduce costs for beneficiaries whose medical needs generate those discounts.45

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 directly benefitting financially from those higher rebates. Not sharing a portion of the rebates directly with the individuals whose medical conditions generates those rebates has been likened to reverse insurance: beneficiaries with serious chronic conditions take medicines that generate the most rebates and those funds are used to subsidize premiums of healthier beneficiaries.\textsuperscript{45}

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 price drugs with lower rebates. Milliman concluded that these embedded incentives result in increased costs to both the government and beneficiaries.\textsuperscript{46} In its Blueprint to Lower Drug Prices and Reduce Out Of Pocket Costs, the U.S. Department of Health and Human Services raised the same concern, noting that “higher rebates in Federal health programs may be causing higher list prices in public programs, and increasing the prices paid by consumers, employers, and commercial insurers.”\textsuperscript{47}

Sharing a portion of rebates and discounts with the beneficiary at the point-of-sale would immediately lower costs for millions of beneficiaries, improve adherence to therapy, and could reduce government spending on hospital and physician services.

Conclusion

Since its inception, Medicare Part D has provided meaningful and affordable access to the prescription medicines that millions of beneficiaries depend upon to maintain their health. Competition and choice with appropriate safeguards to protect beneficiaries’ access have helped the program deliver on its promise while maintaining high levels of satisfaction. For many, however, enhancements are needed to address rising out-of-pocket costs. Focusing on regulatory changes that put beneficiaries first, and rejecting those which do not, will build upon and enhance the lifesaving impact of Medicare Part D.

Supporting Groups

- Alliance for Aging Research
- Caregiver Action Network
- Caregiver Voices United
- HealthyWomen
- National Association of Nutrition and Aging Services Programs (NANASP)
- Partnership to Fight Chronic Disease
- RetireSafe

