July 16, 2018

VIA Electronic Filing: http://www.regulations.gov

The Honorable Alex Azar
Secretary
Department of Health and Human Services
200 Independence Avenue, SW, Room 600E
Washington, D.C. 20201

Re: HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs

Dear Secretary Azar:

The MAPRx Coalition (Medicare Access for Patients Rx Coalition) appreciates this opportunity to offer our thoughts on some of the questions raised in the HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs. Our group, MAPRx, is a national coalition of beneficiary, caregiver, and health care professional organizations committed to improving access to prescription medications in Medicare Part D and safeguarding the well-being of Medicare beneficiaries with chronic diseases and disabilities.

Our organization is solely focused on the Part D program, and patient access and protections guide our coalition principles:

1. Plans should be required to have a robust formulary and to provide coverage for a variety of medications in each drug class or category.

2. Coverage should be required for Medicare Part D's six protected classes of drugs and any additional classes where restricted access to those drugs would have significant health consequences.
3. Oversight of prescription drug benefits should include monitoring of the following:
    a. Plan operations, including timeliness and resolution of appeals;
    b. Formulary design;
    c. Quality measures, which should serve as a meaningful tool to help beneficiaries make an informed drug plan choice and provide the Centers for Medicare & Medicaid Services (CMS) the necessary information in its oversight role;
    d. Pharmacy and Therapeutic (P&T) Committee membership, including robust consumer representation as well as process and procedural requirements.
4. Plans should be required to provide clarity and transparency on coverage and on consumers' out-of-pocket (OOP) costs.
5. Notice of non-coverage, appeals, and exceptions processes should be simple and understandable.
6. Rigorous oversight of medication utilization management tools (such as medication substitution, step therapy, or quantity limits) is critical.

Medicare Part D provides access to vital prescription drugs to over 42 million Medicare beneficiaries, including people with disabilities and older Americans. Over the life of the program, evidence has grown that Part D improves health outcomes when beneficiaries take their medications as prescribed. Surveys indicate that beneficiaries enrolled in Part D are generally satisfied with the program. Even with the success of Part D, some beneficiaries experience challenges accessing prescription drugs under Part D. High out-of-pocket costs can be a significant issue for those who use many drugs or have conditions requiring the use of specialty tier drugs.

We recognize that the proposals in the blueprint are exploratory and lack the detail needed to truly vet them via the regulatory process. To that end, we strongly request **that the formal rule-making process be used** as the agency explores options to lower drug prices and reduce OOP costs, and that even for demonstrations through the Center for Medicare and Medicaid Innovation (CMMI), the agency allow ample time for stakeholder consideration and comments.

In light of the 2019 Call Letter and this Request for Information (RFI), we are very concerned about proposals that, on balance, favor plan sponsors and their flexibility over beneficiary access. While we recognize CMS' objective in providing plan sponsors appropriate flexibility in plan operations, we believe it is critically important for the agency to balance the goal of plan flexibility with ensuring beneficiary access and protections. The beneficiary should be the center and focus of the Medicare program. Any Part D cost savings realized with this blueprint could also result in disproportionally higher costs for Medicare Part A, Part B, and Medicaid.

Over the past 12 years, the Part D program has provided a critical avenue for beneficiaries to access prescription drugs. Its success in providing millions of Medicare beneficiaries with coverage for self-administered drugs is commendable; however, in light of the RFI, MAPRx would like to take this opportunity to address how potential proposals would impact Part D beneficiaries.

Our comments focus on 3 themes: beneficiary access (with a focus on OOP expenditures), beneficiary coverage, and communication/transparency. We recognize that the proposed blueprint references an "All or None" 5-Point Plan for Part D; nevertheless, we have addressed these points separately, recognizing the difficulty in implementing all 5 points simultaneously. Even together, there are drawbacks to the package.

Specifically, MAPRx would like to address the following issues:

Ensuring Beneficiary Access

<u>Out-of-Pocket (OOP) Cap for Part D</u>

The MAPRx Coalition is concerned about increasing OOP costs for Part D beneficiaries and **strongly supports an OOP cap**. In recent years, beneficiary out-of-pocket costs have risen significantly.

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, and other conditions. As a result, many beneficiaries are denied access to the most clinically appropriate medication because it is out of reach financially, which can result in unintended consequences.

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

- Rheumatoid arthritis: $3,949
- Multiple sclerosis: $5,238
- Chronic myeloid leukemia: $6,322[1]

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.

While potentially outside the scope of this RFI, MAPRx wants to reiterate that we believe that Part D beneficiaries should have the ability to seek a lower cost share for specialty medications. While we acknowledge CMS' previous statement that offering a tiering exception for specialty drugs would imbalance actuarial equivalence, we respectfully request that the agency explore ways and approaches for beneficiaries taking these high-cost medications to seek a lower cost share amount.

Rebates Applied at Point of Sale

One factor in high OOP costs is the actual drug price that beneficiaries must pay at the point of sale, particularly in instances where a beneficiary faces a coinsurance. In Part D, the price at the point of sale—during the deductible phase or a coinsurance for the drug—is based on the list price and does not account for any rebates or discounts that might reduce the overall price. A November 2016 Milliman report[2] 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. 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. These findings concern MAPRx, and we urge CMS to consider alternatives to address these misaligned incentives within the Part D program.

Given this dynamic, we applaud the movement to incorporate some rebates at the point of sale that would allow Medicare beneficiaries to directly benefit from the discounts and rebates provided by manufacturers. We look forward to additional guidance from CMS on this matter. **MAPRx also applauds CMS' work on considering passing pharmacy direct and indirect remuneration (DIR) to the point of sale**. MAPRx looks forward to more guidance on this move to the extent that pharmacy DIR at point of sale ultimately saves money for beneficiaries.

[1] Doshi JA, Li P, Pettit AR, Dougherty JS, Flint A, Ladage VP. Reducing out-of-pocket cost barriers to specialty drug use under Medicare Part D: addressing the problem of "too much too soon". *Am J Manag Care*. 2017;23(3 Suppl):S39-S45.

[2] Barnhart J and Gomberg J of Milliman, Inc. The AIDS Institute. http://theaidsinstitute.org/sites/default/files/attachments/Milliman%20Report%20-%20Final.pdf. Published November 3, 2016.

Excluding Manufacturer Coverage Gap Discounts from True Out-of-Pocket (TrOOP) Costs

MAPRx opposes excluding manufacturer coverage gap discounts from TrOOP costs. Even when combined with an OOP cap, the policy increases OOP costs for many beneficiaries since they need to spend significantly more time in the coverage gap.

MAPRx Coalition commissioned an analysis of this policy when proposed by the Medicare Payment Advisory Commission (MedPAC) in 2016.[3] Our analysis found that excluding manufacturer coverage gap discounts from TrOOP costs would increase OOP costs for beneficiaries who have high enough drug spending to approach or reach the catastrophic portion of the benefit. We also found that, on average, 1.1 million Part D enrollees would experience higher OOP costs each year between 2017 and 2021. Total Part D beneficiary spending would increase by about $5.1 billion over the same period. OOP spending for each affected beneficiary would increase by an average of almost $1,000 per year throughout the 5-year period.

With potential Part D changes in motion, MAPRx urges CMS to work with Congress to address the substantial increase in the catastrophic threshold due in 2020. Medicare Part D beneficiaries will experience an increase of $1,250 to reach the catastrophic coverage phase during that plan year. This, in combination with some of the other proposed policies, could devastate beneficiary access to needed medications.

Eliminating Cost-Sharing for Generics

MAPRx supports eliminating cost-sharing for generics for Low-Income Subsidy beneficiaries. We appreciate the agency's leadership on this topic. Research has shown that eliminating cost-sharing can improve adherence to medication regimens.

Shifting Part B Drugs to Part D

As the RFI lacks sufficient details on the potential shift of Part B drugs to Part D, our comments are restricted to general themes. We are very concerned, however, about the impact of such a shift on all Part D beneficiaries, not just those directly impacted by a drug change. Depending on the scope of the change, movement to Part D could increase premiums for *all* beneficiaries and subject many beneficiaries to higher OOP costs due to the benefit design of Part D. The majority of Part B beneficiaries have insurance coverage that limits their OOP exposure, whether through being dually eligible for Medicaid, a supplemental plan (Medigap) or Medicare Advantage. We recommend that CMS conduct further analysis on the out-of-pocket costs beneficiaries would incur and evaluate therapies individually rather than using a blanket approach for all Part B drugs.

In addition, such a shift would be operationally complex for beneficiaries and their Part D plans. We are also concerned beneficiaries could experience delays in receiving treatment. Another potential issue is that many beneficiaries do not have Part D, possibly due to other creditable drug coverage. This policy attempts to address a problem (provider incentives to select a more expensive product) that may, in fact, not be a widespread issue. We look forward to additional detail on program particulars so that we may comment further.

[3] Avalere Health. http://avalere.com/expertise/life-sciences/insights/avalere-analysis-on-medpacs-proposed-part-d-reforms-to-modify-beneficiary-c. Published September 2016. Accessed June 21, 2018.

Protecting Beneficiary Coverage

Formulary Flexibility

We strongly support the existing policy requiring all Part D sponsors to cover two drugs per category and class, as well as all drugs within the 6 classes of clinical concern (protected classes) and oppose changes to these foundational Part D principles. Altering these protections could lead to overly restrictive formularies that could limit beneficiary access to vital, life-saving medications. Moving forward, we ask that CMS keep these formulary requirements intact and maintain a rigorous review process.

MAPRx is strongly opposed to any weakening of the six protected classes policy. The six protected classes policy has been a safety net for some of the most medically fragile Medicare beneficiaries by requiring plans to cover "all or substantially all drugs" for these six classes containing life-saving drugs. It has successfully protected 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.

These protections are essential for patient access to prescription drugs, especially given that Part D is administered by private plans with extensive experience managing drug costs through advanced formulary and utilization management techniques in other segments. Employing these techniques for the protected classes could hinder patient outcomes. 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 failure *before* the plan will pay for the original 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.

While the RFI explores the notion of increased plan flexibility, **we strongly oppose allowing plans to cover only one drug per category and class.** MAPRx urges CMS to analyze formularies, both prior to ***and*** during the plan year, to determine whether appropriate access is afforded to needed drugs and classes of drugs. In general, we would like CMS to conduct greater oversight to ensure robust formularies.

We believe that increased CMS monitoring is required to ensure that the Part D benefit is not eroded and transformed into an empty promise for America's Medicare beneficiaries. For example, MAPRx is concerned about reduced coverage of drugs on the formularies of Low-Income Subsidy benchmark plans. According to data provided to MAPRx by Avalere Health, the percentage of available drugs included on LIS benchmark plans declined each year from 2013 to 2015. Additionally, the share of brand drugs on LIS benchmark plan formularies also declined each year over this period.

Year	Average Percentage of Drugs Covered	Average Percentage of Drugs That Are Brands
2013	59.2%	44.8%
2014	58.0%	44.0%
2015	54.9%	42.2%

MAPRx believes that this trend, in which the percentage of available drugs covered on benchmark plan formularies is reduced each year, is troubling—especially given the vulnerable population affected. We urge CMS to use its authority to ensure that beneficiaries are not faced with "skinnier" benefits each year.

While there is an appeals process, frankly, we do not believe it is a sufficient safeguard against the decreased access that will result from stricter formularies. MAPRx urges CMS to continue addressing the appeals process, particularly around beneficiary communication at the point-of-sale and electronic prescribing/prior authorization. This process needs to work for beneficiaries at the point of sale before CMS considers any additional plan flexibility.

We would welcome a dialogue with the agency to help ensure that its approach to formulary oversight results in meaningful access for all Medicare beneficiaries. Access to physician-directed care should be based on independent clinical judgment, and Medicare Part D should generally cover prescribed medications. Limiting access to the most appropriate medications will lead to higher overall costs to the Medicare program, including higher OOP costs for beneficiaries and increased costs in Medicare Part A and Part B and Medicaid.

Plan Transparency and Communication

Improving Explanation of Benefits

In general, we support providing more information in an easily accessible format; however, an end-of-year statement may not serve the needs of beneficiaries. Prices change throughout the year, so unless prices are locked for the plan year, a retrospective understanding of prices may not be useful.

We urge CMS to focus on a beneficiary's ability to understand the benefits provided in a plan, along with coverage levels and OOP costs, when determining which plan best meets their needs. In addition to improving prospective and real-time price transparency, plans should be required to provide clarity and transparency on coverage and consumers' OOP costs. A mix of copayments and coinsurance can cause significant confusion, especially for individuals on multiple and/or expensive medications who are trying to navigate the system and compare plans.

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. MAPRx recommends that Medicare Plan Finder display costs with more precision, so that enrollees could view actual premium costs, coinsurance amounts in dollars, and copayments, rather than percentages.

The task of appropriately balancing cost and access is herculean, but if the beneficiary remains the center of focus, we believe significant and lasting improvements are well within reach. The undersigned members of the MAPRx Coalition appreciate your consideration of our concerns. For questions related to MAPRx or the above comments, please contact Bonnie Hogue Duffy, Convener, MAPRx Coalition, at (202) 540-1070 or bduffy@nvgllc.com.

Sincerely,

Alliance for Aging Research
Allergy & Asthma Network
Alliance for Patient Access
ALS Association
American Association on Health and Disability
American Autoimmune Related Diseases Association

American Society of Consultant Pharmacists
Arthritis Foundation
Caregiver Action Network
Crohn's & Colitis Foundation
Epilepsy Foundation
GIST Cancer Awareness Foundation
HealthyWomen
International Foundation for Autoimmune & Autoinflammatory Arthritis
International Myeloma Foundation
Lakeshore Foundation
Lupus and Allied Diseases Association
Lupus Foundation of America
Men's Health Network
Mental Health America
National Alliance on Mental Illness
National Council for Behavioral Health
National Council on Aging
National Kidney Foundation
National Multiple Sclerosis Society
National Osteoporosis Foundation
National Patient Advocate Foundation
National Psoriasis Foundation
RetireSafe
The AIDS Institute
The Arc of the United States
The Leukemia & Lymphoma Society
The Veterans Health Council of Vietnam Veterans of America
United Spinal Association
US Pain Foundation
Vietnam Veterans of America