April 24, 2017

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
7500 Security Blvd.
Baltimore, Maryland 21244

Dear Administrator Verma:

The MAPRx Coalition (MAPRx) appreciates this opportunity to respond to your request for information on ways to improve Medicare Part D. Our group, MAPRx, is a national coalition of beneficiary, caregiver, and healthcare professional organizations committed to improving access to prescription medications and safeguarding the well-being of Medicare beneficiaries with chronic diseases and disabilities. MAPRx is grateful for the opportunity to recommend ways to protect and improve the benefit. Specifically, MAPRx would like to make suggestions regarding ensuring beneficiary access, protecting coverage and additional transparency and communication.

As the new Administration grapples with regulatory changes to the Medicare program, it is important to note that Part D has largely been successful and popular among beneficiaries. Now over 10 years since launch, Part D costs to the federal government have been lower compared to the initial projections. In 2013, actual costs were 50% below the initial projections for that specific plan year.[1] Furthermore, the program is popular with beneficiaries as enrollment continues to increase and beneficiary satisfaction survey scores remain consistently high. However, Medicare Part D must evolve as the population and prescription drug market changes. It would be a mistake to view Part D in a silo, as changes to other parts of Medicare impact Part D and vice versa. While testing new value initiatives is important, beneficiary health needs to continue to be the priority with a focus on enhancing beneficiary protections and access to critical medications.

Ensuring Beneficiary Access

Specialty Tier Threshold

We urge the Centers for Medicare & Medicaid Services (CMS) to establish a cost-sharing exception and appeal process for drugs included on the specialty tier. This issue is exceptionally important for beneficiaries with conditions that have limited treatment options (i.e., when all therapeutic options fall under the specialty tier and its equivalent higher cost-share for beneficiaries). For all other plan formulary tiers, beneficiaries may file an exception for a drug to

[1] Congressional Budget Office. Competition and the Cost of Medicare's Prescription Drug Program. July 30, 2014. https://www.cbo.gov/publication/45552.

be placed on a lower cost-sharing tier, provided the medication is the only therapy available for their disease. Specialty-tier drugs are the sole exception to this policy, despite the fact that these drugs often having the most burdensome cost-sharing requirements. MAPRx respectfully asks CMS to reconsider this policy and implement an exception and appeal process for the specialty-drug tier at the earliest possible time.

Also, MAPRx is concerned that the specialty-tier threshold is stagnant and does not take into consideration the effects of inflation on drug prices or, especially, the growing number of high-cost specialty drugs. Beneficiaries typically face higher out-of-pocket costs for specialty-tier drugs because plans are more likely to require beneficiaries to pay a coinsurance rate for incredibly expensive drugs, rather than a flat copayment in order to access these drugs. Without increasing the specialty-tier threshold to keep pace with drug-price inflation translates to more drugs qualifying for this tier, which raises costs for Part D plan enrollees and makes it harder for them to afford needed medications.

While we support and applaud CMS' recent statement that the agency will explore increasing the specialty-tier threshold on an annual basis, we encourage CMS to take additional steps to protect beneficiaries from unmanageable financial distress, which sometimes occurs when beneficiaries diagnosed with chronic or life-threatening diseases must rely on critical specialty medications. First, MAPRx strongly urges CMS to formally require that the specialty-tier threshold be increased by, at a minimum, the same rate of growth as the Part D benefit parameters. This will set an important precedent that should serve as a foundation for a more dynamic specialty-tier policy in future years.

Access to Preferred Cost Sharing Pharmacies (PCSPs)
In the past, CMS announced that the agency would post (and update) information about network or PCSP access levels and require plans that were outliers to disclose that their plan's pharmacy networks were more restrictive compared with other plans. MAPRx believes this is important, because 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 out of pocket for their medications at a non-network pharmacy.

MAPRx agrees with CMS that plans should prominently display their designation as a PCSP outlier. However, based on CMS' existing plan marketing requirements, this information can be very difficult to locate in plan marketing materials. CMS should provide greater oversight of marketing materials and require plans to clearly designate where they can find PCSPs and whether the plan is an outlier in their offering. In addition, CMS should include information regarding network pharmacy access in the Plan Finder tool so that beneficiaries can make comparisons and make more informed choices when selecting their drug plans.

Tiering Exceptions
MAPRx recommends that CMS implement greater efforts to educate beneficiaries and other stakeholders on the entire exceptions and appeals process. Given the complex process for seeking determinations/redeterminations or a formulary/tiering exception, MAPRx strongly believes it is worthwhile to explore ways to enhance education on this issue.

One option could be offering beneficiaries easy-to-understand information at the point-of-sale at pharmacies. For example, if a beneficiary has been prescribed a non-preferred brand and the cost-sharing amount is burdensome, the pharmacist could provide standard information for the beneficiary to initiate the tiering-exception process.

Additionally, MAPRx has been supportive of CMS' past effort to implement an appeals-tracking system in Part D. MAPRx encourages CMS to release data annually on 1) denials at the pharmacy counter, and 2) plan-level appeal and exceptions. Any release of information should be in a format easily read by beneficiaries and advocates and highly visible on the CMS website.

Protecting Beneficiary Coverage

Protected Classes
MAPRx believes strongly that this policy has offered beneficiaries enhanced access to covered prescription drugs in the key classes of clinical concern for the Medicare population. We ask that the protected-classes policy remain a cornerstone of the Part D benefit. Limiting the classes of clinical concern could hamper access to medications under the Part D benefit for Medicare's most vulnerable beneficiaries. Prescription medications are not interchangeable for every person, and doctors prescribe treatments to meet the unique needs of each patient. Altering the protected classes could lead to overly restrictive formularies and limit beneficiary access to vital, life-saving medications.

Out-of-pocket (OOP) Costs
MAPRx Coalition is concerned about the increasing out-of-pocket costs for Part D beneficiaries. This increase is caused, in part, by the proliferation of specialty tiers offered by most Part D plans. Under these tiers, specialty-tier medications are subject to significant coinsurance, meaning that beneficiaries must pay a percentage of the medication's cost. For drugs covered on the specialty tiers, the coinsurance amount can range anywhere from 25-33%, leaving beneficiaries to pay thousands of dollars out-of-pocket for cost-prohibitive 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 appropriate, useful medication because it is financially out of reach. For those who can afford the drugs, they pay high sums out of pocket to maintain their health.

Another potential factor driving OOP costs for Part D beneficiaries is the actual drug price 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 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 those higher rebates. Milliman concluded 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 incentives within the Part D program.

Overall, MAPRx Coalition would like to work with CMS to explore potential policy solutions, such as an out-of-pocket cap for Part D OOP costs. Another potential policy solution is tying cost sharing to the actual pharmacy benefit manager price (accounting for any rebates or discounts) instead of the drug's list price.

[2] "Financial Incentives in Medicare Part D" commissioned by The AIDS Institute and prepared by Adam J. Barnhart and Jason Gomberg of Milliman, Inc. November 3, 2016.

Increasing Transparency and Communication

Formulary Oversight
MAPRx remains concerned about diminished drug coverage on low-income subsidy benchmark plan formularies. It is a troubling trend that the percentage of available drugs covered on benchmark plan formularies continues to drop year after year. These limitations on covered drugs affect Medicare's most vulnerable population. We have historically supported CMS' stringent review of formularies offered in Medicare Part D and urge CMS to use its authority to ensure that low-income subsidy recipients are not exposed to even more limitations to needed drugs in the future. We also strongly urge CMS to analyze formularies 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, and would welcome a dialogue with the agency to help ensure that its approach to formulary oversight results in meaningful access for all Medicare beneficiaries.

CMS should also use this opportunity to determine if Part D plans are engaging in discriminatory coverage practices that would not be identified by CMS' standard formulary review process. 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.

Overall, MAPRx continues to be concerned about the possibility of discriminatory cost-sharing by plans. We believe this issue is particularly relevant to the specialty tier, where discrimination would most likely be prevalent due to the high costs of specialty tier medications. Creating barriers to access has repercussions throughout the Medicare program.

MAPRx appreciates CMS' 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,

Allergy & Asthma Network
American Association on Health and Disability
American Autoimmune Related Diseases Association
American Society of Consultant Pharmacists
Arthritis Foundation
Caregiver Action Network
Epilepsy Foundation
GIST Cancer Awareness Foundation
Hemophilia Federation of America
IFAA (International Foundation for Autoimmune Arthritis)
Leukemia & Lymphoma Society
Lupus Foundation of America
Lupus and Allied Diseases Association, Inc.
Men's Health Network
Mental Health America
National Alliance on Mental Illness
National Council for Behavioral Health

NORD (National Organization for Rare Disorders)
Retire Safe
The AIDS Institute
The Arc of the United States
The Michael J. Fox Foundation for Parkinson’s Research
The National Multiple Sclerosis Society
United Spinal Association