March 3, 2017

VIA Electronic Filing: AdvanceNotice2018@cms.hhs.gov

Cynthia G. Tudor, PhD
Acting Administrator
Centers for Medicare & Medicaid Services
7500 Security Blvd.
Baltimore, Maryland 21244

Dear Dr. Tudor:

**Re: Advance Notice of Methodological Changes for Calendar Year (CY) 2018 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies, and 2018 Call Letter**

The MAPRx Coalition appreciates this opportunity to raise concerns about proposed changes to the Medicare prescription drug benefit that could adversely affect beneficiary access, coverage, and transparency if they are implemented starting in 2018.

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. This letter serves as our official commentary in response to the Advance Notice of Methodological Changes for CY 2018 for MA Capitation Rates, Part C and Part D Payment Policies, and 2018 Call Letter ("Draft Call Letter") issued by the Centers for Medicare & Medicaid Services (CMS) on February 1, 2017.

There is no question that Part D is a necessary component of the Medicare program. Its success over the past 12 years in providing millions of Medicare beneficiaries with coverage for self-administered drugs is commendable. However, MAPRx is grateful for the opportunity to recommend ways to protect and improve the benefit. In particular, our comments focus on 3 themes: beneficiary access (with a focus on out-of-pocket expenditures), beneficiary coverage, and communication/transparency.

Specifically, MAPRx would like to address the following issues raised in the Draft Call Letter and other issues focused on strengthening beneficiary protections:

*Ensuring Beneficiary Access*

- **Specialty Tier Threshold:** The specialty tier threshold should be increased annually at the same rate as the benefit parameters in order to mitigate the number of drugs eligible for the specialty tier category, since they have the highest beneficiary share of cost and those costs can hinder patient access.

Additionally, beneficiaries should be able to file tiering exceptions for specialty drugs just as they can for drugs in other tiers. This would also help to make specialty drugs more affordable without a non-specialty option in a given therapeutic category.

- **Access to Preferred Cost-sharing Pharmacies (PCSPs):** Beneficiaries may have a difficult time in locating the information provided by plan sponsors regarding network or "preferred cost-sharing" pharmacies. CMS should provide greater oversight of Part D plan sponsor marketing materials and encourage plan sponsors to feature information on their pharmacy networks more prominently. This information could also be available on the Medicare.gov Plan Finder tool.
- **Tiering Exceptions:** CMS should collect and share information on utilization of exceptions/appeals at the plan level and provide additional education on the entire exceptions/appeals process for different stakeholder audiences. These changes will help to identify plans that are being overly restrictive in their review of exception/appeal requests and to increase beneficiary and prescriber understanding of their rights and responsibilities in making exception/appeal requests.

*Protecting Beneficiary Coverage*

- **Tier Labeling and Composition:** We respectfully request that CMS remain diligent in its monitoring of formulary structure. In our experience, the non-preferred drug tier often includes numerous generic drugs. As a result, generic drug cost-sharing increases artificially lower average cost-sharing for the tier, allowing plans to achieve higher cost-sharing for high-cost brand drugs. CMS must maintain its rigorous monitoring of this tier and ensure that cost-sharing does not exceed negotiated price.
- **Protected Classes:** We strongly support the existing policy requiring all Part D sponsors to cover all drugs within the 6 protected therapeutic classes of clinical concern. Altering the protected classes could lead to overly restrictive formularies that could limit beneficiary access to vital, life-saving medications. Moving forward, we ask that CMS keep the existing protected classes intact.
- **Meaningful Differences Policy:** We support the meaningful differences policy to help beneficiaries distinguish between different standalone prescription drug plans (PDPs) offered by the same Part D plan sponsor in a region. We encourage CMS to continue to look for innovative ways to communicate plan options so that beneficiaries can find the plan that best meets their individual needs.

*Call for Additional Transparency and Communication*

- **Drug Utilization Review Controls:** We believe that there should be enhanced communication regarding the opioid utilization efforts being made by CMS so that affected stakeholders can work together to achieve appropriate utilization.
- **Formulary Oversight:** We believe that increased CMS monitoring is required to ensure that the Part D benefit is not discriminatory, especially for low-income beneficiaries, and meets the coverage standards envisioned in its implementation.
- **Adjusting Star Ratings for Audits and Enforcement Actions:** We support CMS' continued efforts in improving the Star Ratings. However, we are concerned that plans that have been suspended from marketing their plans could

still potentially qualify for bonus payments. This sends a conflicting message about the integrity of the ratings program.

The following describes our concerns in greater detail.

***Ensuring Beneficiary Access***

**Specialty Tier Threshold**
For 2018, CMS proposes to maintain the specialty tier threshold established at $670 for the 2017 plan year. MAPRx is concerned that, like many previous plan years, 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 patients to pay a coinsurance rate for incredibly expensive drugs rather than a flat copayment in order to access these drugs. Keeping the specialty tier threshold low means that more drugs fit into 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' 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 patients 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.

Second, we continue to urge CMS to establish a cost-sharing exception and appeal process for drugs included on the specialty tier. Though not addressed in the Draft Call Letter, the issue remains exceptionally important for beneficiaries with conditions that have limited treatment options (ie, when all of the therapeutic options fall under the specialty tier and its equivalent higher cost-share for patients). For all other plan formulary tiers, beneficiaries may file an exception for a drug to be placed on a lower cost-sharing tier, provided that the medication is the only therapy available for their disease. Specialty tier drugs are the sole exception to this, despite the fact that these drugs often have 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.

**Access to PCSPs**
In the past, CMS announced that the agency would post 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 that this is important, because patients enrolled in plans with harder-to-access network pharmacies could 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. For CY 2018, CMS proposes to maintain the same policy.

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. 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**
CMS states that Medicare regulations lack enough specificity about process requirements related to Part D plan reviews of appeals and exceptions requests. Therefore, Part D plans are being more restrictive on tiering exceptions than what was originally intended when the program was being implemented. In the Draft Call Letter, CMS sought to clarify some of the confusion:

- *Preferred and non-preferred drugs:* Sponsors should not base tiering exception eligibility on the tier label. Instead, exceptions requests should be evaluated based on whether the tier has lower cost-sharing than the requested drug.
- *Approval of tiering exception requests:* In situations where the requested drug has alternatives in multiple lower tiers, the plan must apply the cost-sharing for the lowest cost-sharing tier that contains therapeutic alternatives for the requested drug. If additional information is needed to support the medical necessity of a drug, the plan must make "reasonable and diligent efforts" to obtain the information from the prescriber.

CMS is soliciting feedback, particularly on ways to improve processes for beneficiaries and/or other areas of concern. To that end, 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 affording 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. Furthermore, MAPRx encourages CMS to explore releasing plan-level appeal and exception data on an annual basis. Any release of information should be in a format that may be easily read by beneficiaries and advocates and highly visible on the CMS website.

***Protecting Beneficiary Coverage***

**Tier Labeling and Composition**

In 2017 Final Call Letter, CMS established a non-preferred drug tier option for use in plan formularies. CMS adopted the use of this tier in response to plan requests for a tier option that will allow for a drug mix regardless of generic/brand status. CMS viewed the adoption of such a tier as part of its continued efforts to provide tier label options that provide flexibility and transparency in benefit design.

MAPRx agrees with CMS' policy that Part D plans may not have both a non-preferred drug and brand tier. However, MAPRx remains concerned about increasing beneficiary costs for generic drugs, and we do not believe CMS' non-preferred drug tier policy will

alleviate these concerns. In particular, we are concerned that, by adopting a non-preferred drug tier, CMS is tacitly accepting the shift toward coverage for generic drugs indistinguishable from brand drug coverage. This will lead to higher out-of-pocket costs for generics and/or drive beneficiaries to seek lower-cost alternatives for their generic drugs, outside of the Part D benefit.

Consistent with this push for greater transparency, we urge CMS to employ more stringent restrictions on the number of generic drugs permitted to be covered on brand tiers. We believe the requirement that the majority of drugs on a brand tier be branded drugs is insufficient. The inclusion of large numbers of generic drugs on such tiers is misleading. It increases generic drug cost-sharing and artificially lowers average cost-sharing for the tier, allowing plans to achieve higher cost-sharing for high-cost brand drugs. As plans increasingly employ high coinsurance rates on the negotiated price of the drug on non-preferred tiers, it is essential that CMS rigorously review their composition to ensure appropriate access and prevent discrimination.

As we proposed last year, MAPRx again urges CMS to implement an outlier test to assess whether beneficiaries receive an actual benefit of enhanced access for all covered drugs placed on non-specialty tiers. We believe beneficiaries should not be required to pay cost-sharing amounts that exceed the negotiated price of the drug, at the very minimum.

**Protected Classes**

While CMS did not propose any specific changes to the 6 classes of protected drugs that must be covered by Part D plans, MAPRx believes strongly in reiterating our position that this policy has offered beneficiaries enhanced access to covered prescription drugs in the key classes of clinical concern for the Medicare population.

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. We ask that the protected classes policy remain a cornerstone of the Part D benefit.

**Meaningful Differences Policy**

In the CY 2018 Draft Call Letter, CMS announced its out-of-pocket cost threshold difference between basic and enhanced standalone prescription drug plans (PDPs) and between enhanced PDPs in a given Part D region. Additionally, CMS reiterated its expectation that any second enhanced PDP must have a higher value than the first enhanced plan and include reduced cost-sharing in the coverage gap for at least 10% of covered brand drugs. Noting that the coverage gap is set to phase out by 2020, CMS stated that it will be difficult for PDP sponsors to maintain 3 meaningfully different plans in a PDP region. Therefore, CMS is encouraging sponsors to develop strategies for the future to minimize beneficiary disruption if sponsors can only offer 2 plans per region.

MAPRx applauds CMS' meaningful differences policy for PDP sponsors. In 2017, Part D beneficiaries have anywhere between 18 and 24 PDP options available.[1] MAPRx

[1] Xcenda analysis of the 2017 PDP Landscape file, released by CMS on October 18.

believes that while choice is good, there must be a balance in order to avoid beneficiary confusion. Therefore, we support the meaningful differences policy to help beneficiaries distinguish between the PDPs offered by the same sponsor in a region. That being said, MAPRx encourages CMS to explore other ways to assist beneficiaries to distinguish between plan options so that they may make even more informed decisions during the open enrollment period. Specifically, MAPRx is hopeful that CMS can devise better ways to portray plan options on the Plan Finder tool that facilitate beneficiaries choosing the option that best meets their needs.

### *Call for Additional Transparency and Communication*

#### Drug Utilization Review Controls

MAPRx commends CMS for its continued efforts to curb fraudulent use and overutilization of opioids. Opioid abuse is one of the most challenging public health issues we are faced with today. However, as CMS implements its policies, the agency must maintain a balanced approach that ensures beneficiaries have appropriate access to medications.

While heightened scrutiny of drug use may be warranted with respect to those who over-utilize opioids, CMS should avoid drastic measures that severely restrict access to needed prescription drugs. General "rules of thumb" should not be used to restrict utilization. For example, a beneficiary who has side effects from one medication may be restricted from obtaining a medically appropriate alternative due to plan restrictions.

As CMS considers expanding current policy, MAPRx urges CMS to proceed with caution. We believe that protections are needed to ensure beneficiaries can access medically needed therapies. In addition, we believe that there should be enhanced communication between affected stakeholders (patients, caregivers, providers, and pharmacists) so that they are aware of these initiatives and can work through outlier situations in advance.

#### 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 to see more oversight by CMS 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 recorded 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.

In addition, MAPRx continues to be concerned about the possibility of discriminatory cost-sharing by plans, an issue that CMS has raised in past Call Letters. 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.

**Integrity of the Star Ratings**

MAPRx applauds CMS' efforts to ensure that Part D and Medicare Advantage sponsors offer high-quality plans based on their scores via the Star Ratings program. We appreciate CMS' continued work to ensure that the measures employed to rate plan quality provide an actual representation of the plan's overall quality in delivering prescription drug benefits to Part D beneficiaries. While we applaud most proposed changes prescribed in the Draft Call Letter, MAPRx is disappointed that CMS will allow for any Medicare Advantage plan contract with sanctions levied against it to receive a quality bonus payment, if achieving a 4-star rating or higher.

We believe that any plan contract with sanctions does not deserve a bonus payment. As past examples have shown, some of the actions by sanctioned sponsors (eg, failure to comply with Part D formulary administration, historical non-compliance) have been egregious and do not reflect a high-quality plan worthy of receiving a bonus payment. Therefore, MAPRx recommends CMS to reconsider its stance on this matter.

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
GCAF GIST Cancer Awareness Foundation
International Foundation for Autoimmune Arthritis
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Men's Health Network
Mental Health America
National Alliance on Mental Illness
National Community Pharmacists Association
National Council for Behavioral Health
National Council on Aging
National Kidney Foundation
National Multiple Sclerosis Society
National Organization for Rare Disorders
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