March 5, 2018

VIA Electronic Filing: www.regulations.gov, CMS-2017-0163

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 raise concerns about the Medicare prescription drug benefit and issues that adversely affect beneficiary access, coverage, and transparency.

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 2019 for MA Capitation Rates, Part C and Part D Payment Policies, and 2019 Call Letter (“Draft Call Letter”) issued by the Centers for Medicare & Medicaid Services (CMS) on February 1, 2018.

Over the past 12 years, the 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, 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:

Ensuring Beneficiary Access

- **Free or Low-cost Vaccines**: We applaud CMS’ recognition of the value of vaccines by encouraging Part D sponsors to offer either a $0 vaccine tier, or to place vaccines on a formulary tier with low cost-sharing. While we appreciate this encouragement to Part D plans, we respectfully urge CMS to explore the
regulatory tools available requiring plans to comply with this policy. Vaccines serve as a critical tool in preventing diseases such as influenza and pneumonia for the Part D population, and beneficiaries without access to the low-income subsidy should not have cost hurdles preventing them from accessing the vaccines.

- **Specialty Tier Threshold:** For 2019, CMS proposes to maintain the specialty tier threshold established at $670 for the 2019 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. We strongly believe that 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. Beneficiaries taking specialty medications generally have the highest cost share, potentially hindering patient access.

**Protecting Beneficiary Coverage**

- **2 Drugs Per Category and Class/Protected Classes:** We strongly support the existing policy requiring all Part D sponsors to cover 2 drugs per category and class and all drugs within the 6 protected therapeutic classes of clinical concern. 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.

- **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:** While we appreciate steps to refine opioid overutilization, it should not be done at the expense of appropriate utilization. We are specifically concerned about the proposed hard edit requirement in the draft Call Letter. To that end, MAPRx requests that the agency explore flexibility on this proposed policy, potentially via a waiver process for select beneficiaries. Additionally, we request that CMS expand its exemption policy to include beneficiaries in long-term care and skilled nursing facilities. Overall, 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.

In addition to the provisions from the draft call letter, MAPRx appreciates the opportunity to offer our group’s thoughts on other beneficiary protections within the program.

- **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.

- **Tiering Exceptions for Specialty Drugs:** MAPRx also believes that Part D beneficiaries should have the ability to seek a lower cost share for specialty medications. While we acknowledge CMS’ statement from the Part D proposed rule 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.

- **Tier Labeling and Composition:** We respectfully request that CMS remain diligent in its monitoring of formulary structure. MAPRx remains concerned about increasing beneficiary costs for generic drugs and we do not believe CMS’ non-preferred drug tier policy alleviates 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 undistinguishable from brand drug coverage. 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. We strongly believe that CMS must maintain its rigorous monitoring of this tier and ensure that cost-sharing does not exceed negotiated price.

- **Access to Preferred Cost-sharing Pharmacies (PCSPs):** With almost all enrollment concentrated in plans with PCSPs, 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.

- **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.

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@nvglc.com.

Sincerely,

Allergy & Asthma Network
American Association on Health and Disability
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
Lakeshore Foundation
Lupus and Allied Diseases Association, Inc.
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 Infusion Center Association
National Kidney Foundation
National Multiple Sclerosis Society
National Organization for Rare Disorders (NORD)
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 Michael J. Fox Foundation for Parkinson’s Research
The Veterans Health Council
US Pain Foundation Inc.
Vietnam Veterans of America