March 1, 2019

VIA Electronic Filing: www.regulations.gov, CMS-2018-0154

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

Dear Administrator Verma:

Re: Advance Notice of Methodological Changes for Calendar Year (CY) 2020 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2020 Draft Call Letter

The MAPRx Coalition (MAPRx) appreciates this opportunity to raise concerns about the Medicare prescription drug benefit (Part D) and issues that adversely affect beneficiary access. We are also concerned about the impact on beneficiary access and coverage related to several other proposals, particularly allowing MA plans to apply step therapy for Part D drugs and the launch of the Part D value-based insurance design model.

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. We appreciate the opportunity to provide the Centers for Medicare & Medicaid Services (CMS) with our official commentary in response to the Advance Notice of Methodological Changes for Calendar Year (CY) 2020 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2020 Draft Call Letter released on January 30, 2019.

Over the past 13 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. MAPRx supports the Administration's efforts to reduce out-of-pocket expenses, but we are concerned that the proposed policy changes generally favor health plan flexibility instead of focusing on beneficiary protections and overall transparency of information.

Specifically, MAPRx would like to address the following issues raised in the Draft Call Letter:

Specialty Tier Threshold: For 2020, CMS proposes again to maintain the specialty tier threshold established at $670 for the 2020 plan year. MAPRx is concerned that, as it was in 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.

Additionally, we recommend that the agency explore establishing some form of a cost-sharing exception for drugs placed on a specialty tier. We appreciate CMS' previous response to the issue, specifically that allowing such a process may conflict with Part D actuarial equivalence. However, we strongly recommend that CMS explore some other recourse for patients prescribed specialty tier products, as beneficiaries without access to the low-income subsidy may struggle significantly to afford their out-of-pocket costs.

Therefore, we strongly believe that the specialty tier threshold should be updated annually, and we urge an increase for 2020 that will at least account for inflation. We also request the agency explore the creation of a cost-sharing exemption process for beneficiaries prescribed a product on a specialty tier.

Part D Out-of-Pocket (OOP) "Cliff": Unlike past years, the Part D OOP threshold will significantly increase by almost $1,400 from 2019 to 2020. The phenomenon is often referred to as the "OOP cliff." MAPRx is very concerned about the impact on beneficiaries with significant chronic health needs as they may linger in the coverage gap phase longer. Given the OOP costs facing the affected beneficiaries, our coalition fears this could drive therapy abandonment. ***With the reality of this climb in OOP spending upon us, we hope that CMS can work with Congress to determine an appropriate solution.***

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.

Request for Information: Barriers for MA Plans or Providers in Using Risk-Based Arrangements for Pharmacy Benefits: In a continued effort to find ways to reduce drug costs, CMS is requesting comments on potentially using risk-based arrangements for pharmacy benefits in contracts between MA plans and providers.

The agency believes these types of arrangements may help decrease Part B drug costs in MA and Part D drug costs in MA prescription drug (MA-PD) plans, but they want to hear about the barriers, feasibility, and benefits/drawbacks with these types of arrangements. ***Given the limited amount of information provided on this issue in the advance notice, we look forward to additional information about the rationale behind the request and specific questions that CMS would like stakeholders to answer.***

Appeals: CMS has proposed to remove the following measures from the 2022 Star Ratings program:

- Appeals Auto-Forward (Part D)
- Appeals Upheld (Part D)

CMS states that these two appeals measures—using the data from the Independent Review Entity (IRE) to determine how effective sponsors are in processing coverage determinations and redeterminations—are not statistically reliable. CMS is requesting

stakeholder comment on if these measures should still be display measures or if they should be retired completely. While MAPRx appreciates CMS gauging MA and Part D plan quality via statistically reliable measures, we believe strongly that there should be a mechanism to rate the effectiveness of processing determinations and redeterminations. The current appeals process is already far too opaque, so limiting information even further is a disservice to beneficiaries.

In addition, CMS audits always show serious problems with the appeals and exceptions processes in Part D plans, so it is critical to transparency and oversight that there be a measure on appeals and exceptions. ***Therefore, we/ recommend that CMS maintain these measures on the display page so that beneficiaries may still view plan performance on these measures. Additionally, we urge CMS to partner with quality organizations to determine the most appropriate measures to evaluate plan effectiveness regarding the appeals process.***

Improving Access to Generic and Biosimilar Medicines: CMS is considering discouraging or prohibiting plan sponsors from placing generics on brand formulary tiers and brand drugs on generic formulary tier, and eliminating the non-preferred drug tier. Going forward, under such a policy, drug tiers would no longer include a mix of generic and brand products. Generics would be part of generic formulary tiers and brands would be part of brand formulary tiers. Also, CMS would expect that FDA-approved, therapeutically equivalent generics would be automatically included on a generic formulary tier immediately after launch as such tiers offer more favorable out-of-pocket costs for beneficiaries.

We are concerned about increased beneficiary cost-sharing, including for generics placed on tiers with higher cost sharing. ***MAPRx is supportive of CMS requiring plans to place AB-rated drugs (generics) on generic tiers and brands on brand formulary tiers. CMS should reduce the complexity of formularies and tiers, and adopt policies that simplify shopping for and comparing plans. MAPRx supports automatic inclusion, on a generic formulary tier, of FDA-approved, AB-rated drugs ("therapeutically equivalent generics") immediately after launch.***

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,

ACCC (Association of Community Cancer Centers)
Allergy & Asthma Network
Alliance for Aging Research
American Association on Health and Disability
American Autoimmune Related Diseases Association
Arthritis Foundation
Arthritis Foundation
ASCP (American Society of Consultant Pharmacists)
Caregiver Action Network
Caregiver Voices United
Epilepsy Foundation
Healthy Women

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 on Aging
National Kidney Foundation
National Multiple Sclerosis Society
National Organization for Rare Disorders (NORD)
National Patient Advocate Foundation
RetireSafe
The AIDS Institute
The ALS Association
The Leukemia & Lymphoma Society
The Michael J. Fox Foundation for Parkinson's Research
United Spinal Association