January 16, 2018

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

Re: MAPRx Draft Comment Letter on Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program (file code CMS-4182-P)

Dear Administrator Verma,

The undersigned members of the MAPRx Coalition and other national organizations appreciate this opportunity to offer comments in response to the Centers for Medicare & Medicaid Services' (CMS') proposed policy and technical changes for Part D for contract year 2019. The MAPRx Coalition 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 Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program (file code CMS-4182-P).

MAPRx applauds the Centers for Medicare & Medicaid Services (CMS) for efforts to continually review and refine the Medicare Prescription Drug Benefit (Part D). While we generally support this initiative by the agency to provide plan sponsors appropriate flexibility in plan operations, we believe it is critically important for the agency to balance the goals of plan flexibility with ensuring beneficiary protections. In some of the proposals, the proposed solution is seeking to solve an issue that is generally not perceived as a problem. Some of these proposed solutions could jeopardize beneficiary safeguards and protections that are critical to ensuring beneficiary access to vital medications and therapies. Specifically, MAPRx would like to address the following issues raised in the Draft Call Letter and other issues focused on strengthening beneficiary protections:

- Establishing Limitations for the Part D SEP for Dual-eligible Beneficiaries
- Expedited Substitutions of Certain Generics and Other Midyear Formulary Changes
- Part D Tiering Exceptions
- Request for Information on Rebates at Point of Sale
- Communication of Plan Marketing Materials
- Star Ratings Program

Establishing Limitations for the Part D SEP for Dual-eligible Beneficiaries

CMS proposes to limit to one Special Enrollment Period (SEP) annually for dual-eligibles and Low Income Subsidy (LIS) beneficiaries.

MAPRx recognizes that the SEP is not widely-used by the overall LIS population, however it provides an important avenue to access for those LIS beneficiaries who do elect to use the SEP. MAPRx is concerned that this policy becomes even more dangerous when combined with the proposed policy revisions to midyear formulary changes. Some LIS beneficiaries may be unable to maintain a treatment regimen to a branded drug when a generic equivalent enters the market as the branded drug may be removed from the formulary.

Under current policy, in this scenario, the LIS beneficiary may switch to a plan still covering the product. This is an important and strong protection for low-income beneficiaries and we strongly suggest CMS consider expanding the limit to 2 to 3 SEPs during a plan year. This is an example of CMS fixing a problem that, through its own admission, does not exist but could cause access issues for some beneficiaries.

Expedited Substitutions of Certain Generics and Other Midyear Formulary Changes

CMS proposes to allow plans greater flexibility for generic substitutions. Specifically, plans could immediately—any time of year, without 60-day notification—remove a branded product or change cost sharing to a higher amount when opting to cover a therapeutically equivalent, newly approved generic drug.

The current notification affords the beneficiary time to explore how a transition to a generic drug will affect their treatment regimen. A change in copayment and pill size/shape/color could cause undue stress on beneficiaries and potentially affect adherence. Ample notification, even if it were 30 days, is best for patients.

Part D Tiering Exceptions

CMS seeks to base eligibility for tiering exceptions on the lowest applicable cost-sharing for the tier containing the preferred alternative for treatment—not simply based on the names of tiers. CMS is also seeking to maintain the current policy that there are no tiering exceptions for products on a specialty tier.

MAPRx appreciates the agency's commitment to finding solutions to provide lower cost-sharing for beneficiaries taking expensive therapies via the tiering exceptions process. While MAPRx acknowledges the constraints around actuarially equivalence in order to potentially allow lower cost

sharing for specialty tier drugs, MAPRx encourages CMS to explore other solutions to reduce the out-of-pocket burden facing these beneficiaries, including: 1) performing more stringent discrimination review to ensure that certain classes of drugs are not always placed on specialty tiers; and 2) allowing cost sharing exceptions for specialty tier drugs.

Request for Information on Rebates at Point of Sale

CMS seeks stakeholder comments through a request for information (RFI) on the potential to apply some manufacturer rebates at the point of sale for the price of drugs.

We applaud the movement to incorporate rebates at the point of sale and 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 point-of-sale. MAPRx looks forward to more guidance on this move to the extent pharmacy DIR at point-of-sale ultimately saves money for beneficiaries.

PDP Meaningful Differences Policy

CMS proposes to eliminate the meaningful differences requirement between two enhanced prescription drug plans (PDPs) offered by a PDP sponsor in one region.

MAPRx supports the meaningful differences policy to help beneficiaries distinguish between different standalone PDPs offered by the same Part D plan sponsor in a region. While we are not necessarily opposed to removing the meaningful difference between two enhanced PDPs, we strongly encourage CMS to look for innovative ways to communicate plan options so that beneficiaries can find the plan that best meets their individual needs.

Communication of Plan Marketing Materials

CMS proposes that MA and Part D plans provide benefit package information to prospective enrollees at the start of the Annual Election Period (AEP), not 15 days before, as currently required. Additionally, CMS is proposing to require plans to mail hard copies of the evidence of coverage, summary of benefits, and provider network information only upon request.

MAPRx is concerned that this proposal would remove an important step in communicating benefit design, formulary, and provider network changes in advance of the upcoming plan year. MAPRx strongly encourages CMS to maintain the policy that plan sponsors must provide plan benefit package information 15 days prior to the AEP and that hard copies should be provided.

Star Ratings Program

CMS proposes to assign a contract score based on the enrollment-weighted average of the measure scores of both the surviving and consumed contract(s) in order to reflect the performance of all contracts associated with a consolidation. CMS is exploring the feasibility of assigning an overall score at the plan

level rather than the contract level (as is currently done.) CMS is seeking comments on maintaining the high-performing or low-performing icons displayed on the Plan Finder tool.

MAPRx supports CMS' effort to better reflect plan performance when a contract consolidation occurs as this will offer a more accurate view of the new contract's performance on important quality measures. Similarly, MAPRx applauds CMS' exploration of assigning scores at the plan level rather than the contract level as performance may vary significantly across a contract's plans. Most importantly, MAPRx strongly recommends that CMS maintain the high and low-performing icon on the Plan Finder tool so that prospective beneficiaries shopping for plan coverage will know which plans have received high or low quality measures.

MAPRx Coalition 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
Arthritis Foundation
Bladder Cancer Advocacy Network
Caregiver Action Network
Celiac Disease Foundation
Epilepsy Foundation
GIST Cancer Awareness Foundation
Healthy Women
IFAA - International Foundation for Autoimmune & Autoinflammatory Arthritis
International Myeloma Foundation
International Pain Foundation
Lakeshore Foundation
Lupus and Allied Diseases Association, Inc.
Lupus Foundation of America
Massachusetts Association for Mental Health
Mended Hearts
Men's Health Network
Mental Health America
National Alliance on Mental Illness
National Association of Nutrition and Aging Services Programs (NANASP)
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
National Sleep Foundation
Patients Rising Now
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 of Vietnam Veterans of America
Tuberous Sclerosis Alliance
United Spinal Association
Vietnam Veterans of America