



June 22, 2021

The Honorable Nancy Pelosi
Speaker
U.S. House of Representatives
Washington, DC 20515

The Honorable Kevin McCarthy
Minority Leader
U.S. House of Representatives
Washington, DC 20515

Dear Speaker Pelosi and Minority Leader McCarthy:

We are writing to respectfully submit our feedback on Congressional efforts to address drug affordability and pricing, specifically as it relates to Medicare Part D. Our group, the Medicare Access for Patients Rx Coalition (MAPRx), is a coalition of national beneficiary, caregiver, and health care professional organizations committed to improving access to prescription medications in Medicare Part D and safeguarding the well-being of Medicare beneficiaries with chronic diseases and disabilities.

Part D has a long history of success and has had a positive impact on the lives of millions of Medicare beneficiaries. Congress has the opportunity to extend and expand this record by safeguarding beneficiaries' access to the therapies they need by enacting policies that strengthen the program to support beneficiary access to care. Policy changes, including structural changes and other significant reforms that strive to improve access, should be done carefully to safeguard against unintended consequences. Importantly, changes to Medicare Part D also must work to increase equity and reduce health disparities across the Part D benefit. We respectfully submit our views below.

We ask for Congress to:

- Create an out-of-pocket (OOP) cap on Medicare Part D costs with a monthly cap on total OOP (smoothing).
- Manage any unintended consequences of legislative changes proactively so that beneficiary access is maintained both in the short-term (formularies, pharmacy networks, limited utilization management) and long-term (continued access to therapies).
- Reform the Part D exceptions and appeals process.
- Strengthen the Low-Income Subsidy (LIS) program.
- Eliminate cost-sharing for Part D vaccines.
- Improve information and consumer education for Part D beneficiaries.

The above policies to improve access in affordability will also increase equity and reduce disparities in Medicare Part D.

Managing Beneficiary OOP Costs

The lack of an out-of-pocket cap in Medicare Part D creates barriers to access. It can result in beneficiaries not initiating therapies or abandoning prescriptions at the pharmacy counter and can lead

to worse outcomes and higher overall health care costs. **MAPRx urges Congress to establish an annual OOP cap for Medicare Part D** that is meaningful and limits the amount Medicare beneficiaries pay for covered prescription drugs. Setting a meaningful annual OOP limit would provide considerable help to beneficiaries, increase equity and medication adherence, and break down a significant barrier that limits the ability of beneficiaries to access needed care.

MAPRx urges Congress to couple an OOP cap with a “smoothing” mechanism that would allow total OOP costs to be distributed more evenly throughout the year, particularly for beneficiaries who encounter significant cost-sharing, either for a single prescription, or a series of prescriptions, early in the plan year. This would ease the financial strain for Medicare beneficiaries who currently are faced with paying a significant percentage of their total OOP financial burden at the beginning of each benefit year. Making Medicare beneficiary out-of-pocket costs more manageable by spreading them throughout the year would make a real difference for most beneficiaries who do not have the resources to pay their entire OOP cap in just a few trips to the pharmacy. A smoothing mechanism will also improve the predictability of Part D OOP expenditures for beneficiaries.

Most commercial plans have a single OOP cap for all services. Medicare Part B beneficiaries have other OOP protections, such as the ability to purchase supplemental insurance, which limits their OOP costs. Yet, Part D has no such protections. A Part D smoothing mechanism should include consumer protections and be available for all OOP costs above a de minimis amount.

Managing the OOP costs is one of the biggest challenges inhibiting the program from being even more successful in meeting the health care needs of Medicare beneficiaries. An annual OOP cap coupled with a smoothing mechanism will help ensure Medicare beneficiaries have access to vital and life-saving medicines. We believe the cap should be implemented as soon as possible.

Manage Unintended Consequences Through Consumer Protections

MAPRx strongly agrees that Congress must take action to improve affordability and reduce the financial barriers to care; however, Congress must carefully consider the potential unintended consequences and the impact of those consequences not simply on the broader, healthy population, but especially on those most in need of the latest developments in medicine – those living with chronic and fatal conditions, those with disabilities, and seniors, the most vulnerable Medicare beneficiaries.

When making legislative changes to the structure of Part D, MAPRx urges Congress to maintain current consumer protections that preserve access to therapies under Part D. In addition, Congress should strengthen these protections and require increased CMS oversight of them. Current challenges to access in Part D include narrowing formularies, increased utilization management, use of preferred pharmacy networks, and problems with the exceptions and appeals processes. Policy proposals under consideration would make significant changes to the prescription drug marketplace and operation of prescription drug benefits which could unintentionally motivate Part D plans to reduce the quality of care and access for Medicare beneficiaries – particularly as plans bear more responsibility for the cost of running the benefit. It is critically important that any legislation not expose Medicare beneficiaries to more overly burdensome utilization management strategies, prior authorization requirements,

formulary restrictions, or other benefit reductions designed to prevent beneficiaries from easily gaining access to needed prescription drugs.

The six protected class policy is also a critical protection for some of the most vulnerable Medicare beneficiaries because it requires plans to cover all drugs (subject to certain exceptions) for six classes containing lifesaving drugs – anticonvulsants, immunosuppressants, antidepressants, antipsychotics, antineoplastics, and antiretrovirals. The protected class policy has successfully allowed beneficiaries with cancer, HIV, transplant recipients, epilepsy, and mental illness, among others, to receive and continue to access the full range of treatment options.

In recent years, the Part D program has experienced an erosion of beneficiary protections in favor of plan flexibility. CMS has favored preserving plans' flexibility over ensuring patient access on key issues such as specialty tiers, protected classes, formulary tiering and composition, meaningful differences policy, and communication of plan materials. Part D plan use of utilization management is on the rise, and, for many patients, these are steep barriers to accessing their needed prescribed medications. Therefore, it is critical that Congress maintain strong beneficiary protections, along with oversight requirements, in any legislation in which structural changes could increase plan flexibility and restrict access to medications.

We are also concerned about the longer-term unintended consequences such as the potential for fewer new therapies being introduced in the U.S. The Congressional Budget Office estimated that under one proposal, 8-15 fewer drugs would be introduced to the U.S. drug market. Moreover, other analyses show that these changes could particularly limit the development of treatments for conditions that require higher R&D investment or take longer to develop, such as cancer, mental health and neurological conditions among others. These scenarios could lead to fewer or no treatment options for many of the most vulnerable beneficiaries. Many patients live without treatments for their condition – for these patients, delays in the development of new treatments could mean the difference between life and death.

Proposals like foreign references pricing also can have additional impacts that create new barriers to access. For example, many medications currently available to U.S. patients either are not available in foreign countries or are only available in those countries years after their availability to U.S. patients. We are concerned that foreign reference pricing could result in similar delays in access or in new treatments simply not being available to Medicare beneficiaries. Equally, if not more concerning, is the potential adoption of foreign reference prices that rely on Quality Adjusted Life Years (QALYs), a discriminatory metric that undervalues the lives of minorities, people with chronic conditions, disabilities, and advanced age. In addition, the metrics used in foreign countries to assess value and determine price often are not developed with sufficient patient input and, if used as a basis of assessing price and value in the U.S, would not consider the perspective of patients in the U.S.

Reform the Part D Exceptions and Appeals Process

We urge Congress to streamline the Medicare appeals process. The appeals process can be incredibly confusing for beneficiaries who have been denied coverage or cannot afford their drugs. Part D plans should increase information and transparency for their appeals processes and timely notice should be given to enrollees, at the point of sale, the reasons for the denial of drug coverage, including the right to

an expedited review. In addition, Part D beneficiaries should be allowed to appeal for a lower cost share for specialty medications, beyond the lower-cost specialty tier that has recently been finalized. The proposed restructuring of Part D could increase the importance of the exceptions and appeals process by shifting more risk onto Part D plans.

We also urge CMS to ensure that beneficiaries continue to have access to a robust medical exceptions process under redesign. Exceptions offer patients critical access to medically necessary medications that may not always be on formulary.

Strengthen the Low-Income Subsidy (LIS) Program

Medicare provides important Part D prescription drug coverage and premium and cost-sharing assistance for beneficiaries with low incomes and modest assets. The Part D Low-Income Subsidy (referred to as LIS or Extra Help) program provides full or partial subsidies, depending on income and resources. Additional premium and cost-sharing assistance is available for Part D enrollees with low incomes (less than 150% of poverty, or \$19,320 for individuals/\$26,130 for married couples in 2021) and modest assets (less than \$14,790 for individuals/\$29,520 for couples in 2021).

Congress has a tremendous opportunity to strengthen the LIS program, including by eliminating the asset test and streamlining program administration. Also, Congress should provide full Extra Help benefits to those living on the edge of poverty. Only the lowest income individuals with Medicare receive full benefits through Extra Help. Individuals with incomes of 135% to 150% FPL who also meet the program's asset test are still exposed to premiums, deductibles, and high coinsurance rates (15%). **In addition, cost-sharing for generics for Low-Income Subsidy (LIS) recipients should be eliminated.** Research has shown that eliminating cost-sharing can improve adherence to medication regimens.

Eliminate Copays for Part D Vaccines

While CMS has encouraged plans to eliminate cost-sharing for Part D vaccines, many plans charge copayments and we urge Congress to eliminate cost sharing for Part D vaccines. Immunizations covered under Part D should be available with no cost to the beneficiary in the same way as are vaccines are under Part B.

Improve Consumer Information

With a diverse set of beneficiary needs, information on Part D plan choices is critical. For Part D to work well for beneficiaries, they need to be well-informed and have information upon which to base plan decisions. More should be done to improve beneficiaries' online shopping experience and ability to compare formularies and OOP costs across plans.

Improve Equity and Reduce Disparities in Medicare Part D

As a program run by the federal government, Medicare bears a unique responsibility and opportunity to improve health equity in the United States and reduce disparities. The COVID-19 pandemic underscores the need to look differently at our healthcare system and find ways to improve health for our most vulnerable citizens. By addressing the issues outlined in this letter, Congress can take important steps to improving equity and reducing disparities in Medicare Part D.

We urge Congress to consider equity and health disparities in its work on Medicare Part D. Racial and ethnic minorities experience disproportionately higher rates of disease, lower quality of care, and reduced access to care as compared to their white counterparts. And among Medicare beneficiaries, people of color are more likely to report being in relatively poor health, have higher prevalence rates of some chronic conditions, such as hypertension and diabetes compared to White beneficiaries. In addition, Kaiser Family Foundation reported that among people over 65, Black and Hispanic Adults are more likely than older White adults to have family income below poverty.

To achieve health equity in Medicare Part D, Congress must ensure that the program is as effective as possible with limits on out-of-pocket costs. The MAPRx Coalition priorities and concerns we have outlined in this letter help to address equity. Congress should work to close gaps in coverage, increase accessibility across the program and maintain strong consumer protections. Congress should recognize and address the fact that despite potential eligibility for LIS and MSP assistance, many Part D beneficiaries remain uncovered from these benefits. Congress must establish an OOP cap to reduce inequities by providing better and more affordable access to Part D medications. In addition, Congress should reduce inequities by streamlining the appeals process and ensuring that utilization management mechanisms do not create burdensome hurdles for access to prescription medications. And Congress should ensure that other efforts to increase affordability do not also increase disparities by limiting the development and availability of new and existing treatments.

As more Americans become eligible for Medicare, the Part D program will play an increasingly integral role in maintaining beneficiaries' health and reducing overall health care costs. The undersigned members of MAPRx appreciate your leadership in making improvements to Medicare Part D and respectfully request you to consider 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,

Alliance for Aging Research
Alliance for Patient Access
American Autoimmune Related Diseases Association
American Kidney Fund
Arthritis Foundation
Caregiver Action Network
EveryLife Foundation for Rare Diseases
GO2 Foundation for Lung Cancer
HIV + Hepatitis Policy Institute
International Foundation for Autoimmune & Autoinflammatory Arthritis
Lupus Foundation of America
Men's Health Network
Mental Health America
Movement Disorders Policy Coalition
National Alliance on Mental Illness
National Association of Nutrition and Aging Services Programs

National Community Pharmacists Association
National Council on Aging
National Health Council
National Hispanic Council on Aging
National Kidney Foundation
National Psoriasis Foundation
Parkinson & Movement Disorder Alliance Patient Services, Inc.
RetireSafe
The Michael J. Fox Foundation for Parkinson's Research
Triage Cancer
WomenHeart: The National Coalition for Women with Heart Disease

CC: The Honorable Richard Neal, Chairman, House Ways and Means; The Honorable Kevin Brady, Ranking Member, House Ways and Means; The Honorable Frank Pallone, Chairman, House Energy and Commerce; The Honorable Cathy McMorris Rodgers, Ranking Member, House Energy and Commerce