



April 6, 2020

VIA Electronic Filing: www.regulations.gov, CMS-4190-P

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

Re: Proposed Rule – Contract Year 2021 and 2022 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicaid Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly

Dear Administrator Verma:

The Medicare Access for Patients Rx (MAPRx) Coalition appreciates this opportunity to raise concerns about proposed changes to the Medicare prescription drug benefit and Medicare Advantage plans that give priority consideration to health plans instead of patients.

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 proposed rule on Contract Year 2021 and 2022 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicaid Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly published in the *Federal Register* on February 18, 2020.

Over the past 15 years, the Medicare Part D 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 may not adequately achieve this critical objective. In particular, MAPRx would like to address the following provisions in the proposed rule:

- **Permitting a Second, Preferred Specialty Tier in Part D**
- **Beneficiary Real-Time Benefit Tool (RTBT)**

Permitting a Second, Preferred Specialty Tier in Part D

Part D sponsors are permitted to include a specialty tier in their plan design, which provides the opportunity for Part D sponsors to manage high-cost drugs apart from tiers that have less expensive drugs. Part D sponsors are also permitted to exempt drugs placed on the specialty tier from their tiering-exceptions process. CMS is proposing to allow plans to introduce a second

specialty tier that would be considered preferred compared to the other specialty tier. CMS would require the preferred specialty tier to offer lower cost-sharing than the nonpreferred specialty tier. The 2 specialty tiers would be exempt from the tiering-exceptions process.

Given the increasing use and increasing costs of specialty drugs, beneficiaries are being forced to bear a greater share of expenses. The Kaiser Family Foundation calculated expected annual 2019 out-of-pocket costs for 30 specialty tier drugs used to treat 4 health conditions: cancer, hepatitis C, multiple sclerosis, and rheumatoid arthritis.¹ It found that in 2019, annual out-of-pocket (OOP) costs were 12% higher than in 2016, on average, for 8 of the 10 specialty tier drugs analyzed. Additionally, the foundation found that median annual out-of-pocket costs in 2019 for 28 of the 30 studied specialty tier drugs ranged from \$2,622 to \$16,551 based on a full year of use. Based on this analysis and others, we believe that the OOP trends from 2019 are not an anomaly; it is an example of the increasing burden of prescription costs shouldered by beneficiaries. Therefore, we welcome any attention CMS places on this issue.

MAPRx appreciates CMS' willingness to consider restructuring the Part D program's benefit-design structure to provide more opportunities to lower the cost of drugs for beneficiaries, **but we believe that this is ultimately a step in the wrong direction, and we would like to see an end to the use of specialty tiers, not the introduction of additional specialty tiers.**

MAPRx encourages CMS to reconsider finalizing this proposal to establish a preferred specialty tier for several reasons. First, MAPRx believes the proposal initiates additional complexity to the Part D benefit-design structure. A 2018 study documented how Medicare beneficiaries often report that the process of choosing a prescription drug plan is already frustrating and confusing, and many prospective enrollees do not enroll in the plan that covers their drugs at the lowest cost.² By introducing another variable into the decision matrix of choosing a plan, CMS risks causing additional confusion for Part D beneficiaries or leading them to select plans that poorly match their health needs.

Second, we ask CMS not to move forward with a second specialty drug tier as proposed because the proposal will likely generate no cost savings to beneficiaries. The proposed rule states the coinsurance amount for the preferred specialty tier will not be lowered below the 25% floor of the current specialty tier. In other words, under the best circumstance, beneficiaries are still facing a 25% coinsurance for specialty tier medications.

Third, we are unclear about CMS' purpose for introducing a preferred specialty tier, as the agency admits in the proposed rule that the agency "remains concerned about whether this proposal will actually achieve the potential benefits to the Part D program and Part D enrollees asserted by stakeholders in support of 2 specialty tiers."

MAPRx remains in favor of removing the tiering exception for drugs in the specialty tier and/or removing the use of the specialty tier entirely. Most drugs in the specialty tier do not have substitutes that would allow beneficiaries to request drugs in non-specialty tiers. As a result, beneficiaries face potentially crippling cost-sharing obligations for the only effective drugs for their

¹ Cubanski J, Neuman T, Damico A. Closing the Medicare Part D coverage gap: trends, recent changes, and what's ahead. Kaiser Family Foundation. August 21, 2018. <https://www.kff.org/medicare/issue-brief/closing-the-medicare-part-d-coverage-gap-trends-recent-changes-and-whats-ahead/>. Accessed February 26, 2020.

² Stults CD, Baskin AS, Bundorf MK, Tai-Seale M. Patient experiences in selecting a Medicare Part D prescription drug plan. *J Patient Exp*. June 2018. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6022939/>. Accessed February 26, 2020.

conditions. Creating a preferred specialty tier would not materially lower their cost-sharing obligations if the lowest coinsurance amount (25%) is the same as the lowest possible coinsurance for the current specialty tier (25%).

Overall, MAPRx believes that the concept of the specialty tier is outdated. It served a role 15 years ago with the introduction of the Part D program, when there were far fewer specialty drugs. However, according to a 2019 Pharmacy Times article, 80% of new drug approvals are considered specialty.³ The continuing proliferation of specialty drugs will only ensure that more beneficiaries are prescribed necessary drugs that fall within the specialty tier(s), leading to crippling OOP costs for a greater percentage of the Medicare population.

Separately, **MAPRx approves of the CMS proposal to base the determination of the specialty tier cost threshold on the ingredient cost reported on the prescription drug event data (PDE), as opposed to the current policy of using the negotiated price reflected on the PDE.** This approach will help maintain stability in the specialty tier cost threshold and will better take into consideration the effects of inflation on drug prices.

By using the proposed methodology, CMS calculates the specialty cost threshold would increase to either \$750 or (using the alternative) \$760, a substantial increase from the current \$670. We appreciate the increase, as MAPRx strongly believes that the specialty tier threshold should be increased annually at least at the same rate as the benefit parameters to mitigate the number of drugs eligible for the specialty tier category.

Additionally, whether or not CMS moves ahead with the specialty tier proposal, we recommend that the agency establish some form of a cost-sharing exception for drugs placed on a specialty tier. We appreciate CMS' previous response to the issue, 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.

Beneficiary Real-Time Benefit Tool (RTBT)

CMS has required that Part D plans support a prescriber electronic real-time benefit tool (RTBT) to provide its enrollees with complete, accurate, timely, and clinically appropriate patient-specific real-time formulary and benefit information; the tool is expected to enhance medication adherence and lower overall drug costs.

CMS now proposes to require that Part D sponsors implement a similar beneficiary RTBT that would allow enrollees to view similar real-time formulary and benefit information, effective January 1, 2022.

MAPRx appreciates CMS' approach of providing beneficiaries more tools to manage their costs, particularly around negotiated prices for drugs. As OOP costs for select drugs continue the steady upward trajectory, this proposal could potentially help beneficiaries better manage their Part D costs.

Despite this positive step to provide real-time prescription-related information, we believe CMS should take additional measures to assist beneficiaries. In addition to creation of this

³ Pahlavan P. Specialty pharmacy by the numbers. *Pharmacy Times*. April 10, 2019. <https://www.pharmacytimes.com/news/specialty-pharmacy-by-the-numbers>. Accessed February 27, 2020.

tool for enrolled beneficiaries, MAPRx respectfully believes that CMS should also address challenges before enrollment and make it easier for beneficiaries to shop for plans. As it is now, beneficiaries are presented during open enrollment with an array of plans offering a vast mix of premiums, deductibles, and cost-sharing for prescription drugs.

A 2019 Kaiser Family Foundation study reported that more than 1 in 3 (35%) Medicare beneficiaries said it is “very” or “somewhat” difficult to compare Medicare options.⁴ Those in poor health (44%) or with 5 or more chronic conditions (40%) found it even more difficult. This confusion no doubt contributes to the 45% of beneficiaries who “rarely” or “never” review or compare their Medicare options reported by the study; this figure climbs to 57% for beneficiaries aged 85 and older.

We believe CMS can help beneficiaries with selecting the most appropriate plan by rethinking the Medicare Plan Finder tool. **CMS should work to improve beneficiaries’ online shopping experience and ability to compare formularies and OOP costs across plans before they even need access to the information presented by the beneficiary RTBT.** CMS should build on their recent work on the Medicare Plan Finder. As recommended by the National Council on Aging, Medicare Plan Finder would benefit from additional improvements and ongoing investment to remain relevant.⁵

While we support CMS finalizing the beneficiary RTBT proposal, MAPRx respectfully requests that the agency consider several approaches in designing the beneficiary-specific tool. First, we ask that you provide robust and detailed guidance to Part D plan sponsors on how they design the tool. Without any guidance or parameters for how to design the tool, Part D sponsors may all have different, individual tools, making it incredibly challenging to determine if each deployed tool is effectively assisting beneficiaries in making informed choices about their treatment. Second, to ensure that the beneficiary tool meets the needs of all beneficiaries—including vulnerable populations such as the advanced elderly and those with multiple chronic conditions—we strongly suggest that CMS solicit beneficiaries’ input and incorporate their feedback into the final product.

Out-of-Pocket Cap with a Smoothing Mechanism

MAPRx strongly supports an annual OOP cap for Medicare Part D to limit the amount Medicare beneficiaries pay for covered prescription drugs. The lack of an OOP cap is one of the biggest challenges for Part D beneficiaries. Individuals with commercial coverage have an out-of-pocket cap for all covered medical care. Most Medicare beneficiaries using the Medicare Part B benefit (outpatient services) also have an out-of-pocket cap since most have some type of supplemental coverage that assists with OOP expenses and/or offers an annual OOP maximum. An annual OOP cap will bring Part D in line with most other types of insurance as well as help ensure Medicare beneficiaries have access to vital and lifesaving medicines.

An out-of-pocket cap should be coupled with a mechanism that would allow total OOP costs to be distributed more evenly throughout the year. Making Medicare beneficiary out-of-pocket costs more manageable by spreading them throughout the year would make a real difference for the vast majority of beneficiaries who do not have the resources to pay their entire OOP cap in just a

⁴ Koma W, Cubanski J, Jacobson G, Damico A, Neuman T. No itch to switch: few Medicare beneficiaries switch plans during the open enrollment period. Kaiser Family Foundation. December 2, 2019. <https://www.kff.org/medicare/issue-brief/no-itch-to-switch-few-medicare-beneficiaries-switch-plans-during-the-open-enrollment-period/>. Accessed February 26, 2020.

⁵ National Council on Aging. Modernizing Medicare Plan Finder: evaluating and improving Medicare’s online comparison shopping experience. April 2018. <https://www.ncoa.org/wp-content/uploads/CC-2018-MedicarePF-Report-Final-0418.pdf>. Accessed February 26, 2020.

few trips to the pharmacy. A smoothing mechanism would ease the financial strain for Medicare beneficiaries who currently face paying a significant percentage of their total OOP financial burden at the beginning (or first fill) of each benefit year.

Out-of-Pocket “Cliff”

Already some Part D beneficiaries have faced a dramatic increase in OOP costs in 2020. Due to unintended consequences in the law, the OOP threshold increased by \$1,250 in 2020. MAPRx is very concerned about how this cliff impacts beneficiaries. Given that many beneficiaries already face significant OOP costs, we fear the cliff could drive further therapy abandonment. One study of cancer patients showed that 45% of Part D patients abandon their therapy when out-of-pocket costs are as high as Part D plans uniformly require. Another study found that Medicare patients across a series of disease diagnoses in 2018 were seven times more likely to abandon their first prescription at the pharmacy counter when facing high out-of-pocket costs.

Abandonment of pharmaceutical therapy can worsen patients' health and increase overall health care costs. Conversely, adherence keeps health care costs in check. The Congressional Budget Office in 2012 found that a “1% increase in the number of prescriptions filled by beneficiaries would cause Medicare’s spending on medical services to fall by roughly one-fifth of 1%.” This connection between prescription drugs and reductions in the use of other medical services - and thus reductions in Medicare A and B spending - highlights the value and importance of adherence to prescribed drugs.

Given that the 2020 Medicare Part D plan year already is underway, a retroactive fix is necessary. There is precedent for a retroactive fix for Medicare beneficiaries, and we urge CMS to pursue a solution as soon as possible.

The task of appropriately balancing cost and access is formidable, but if the beneficiary remains the center of focus, we believe that CMS and patient stakeholders can collectively improve this great benefit. 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,

Allergy & Asthma Network
Alliance for Aging Research
Alliance for Patient Access
American Association on Health and Disability
American Cancer Society Cancer Action Network
American Kidney Fund
Arthritis Foundation
American Society of Consultant Pharmacists
Caregiver Action Network
Epilepsy Foundation
HealthyWomen
HIV + Hepatitis Policy Institute
International Myeloma Foundation
Lupus and Allied Diseases Association, Inc.
Lupus Foundation of America
Men’s Health Network
Mental Health America

Movement Disorders Policy Coalition
National Alliance on Mental Illness
National Council on Aging
National Health Council
National Organization for Rare Disorders
Patient Access Network (PAN) Foundation
The AIDS Institute
The Leukemia & Lymphoma Society
The Michael J. Fox Foundation for Parkinson's Research
United Spinal Association
WomenHeart: The National Coalition for Women with Heart Disease