



January 25, 2019

VIA Electronic Filing: www.regulations.gov, 0938-AT92

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

Dear Administrator Verma:

Re: Proposed Rule – Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses

The MAPRx Coalition (MAPRx) welcomes this opportunity to submit comments on proposed changes to the Medicare prescription drug benefit and Medicare Advantage plans. Our group, MAPRx, is a national coalition of beneficiary, caregiver, and health care professional organizations committed to improving access to prescription medications and safeguarding the well-being of Medicare beneficiaries with chronic diseases and disabilities. With this letter, the undersigned members of the MAPRx Coalition provide the Centers for Medicare & Medicaid Services (CMS) with our official commentary in response to the Proposed Rule on Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses published in the Federal Register on November 30, 2018.

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 goal to reduce out-of-pocket expenses, but we are concerned that the proposed policy changes generally favor health plans instead of focusing on beneficiary protections and overall transparency of information. In particular, MAPRx would like to address the following issues raised in the proposed rule:

- **Providing Plan Flexibility to Manage Protected Classes**
- **Application of Step Therapy for Part B Drugs by Medicare Advantage Plans**
- **Explanation of Benefits Requirements**
- **Changes to the Definition of Negotiated Price, and**
- **Pharmacy Price Concessions in the Negotiated Price**

Providing Plan Flexibility to Manage Protected Classes

Currently, plans are required to include all Part D drugs in the classes of clinical concern (“protected classes”). CMS is proposing to allow plan flexibility to manage protected classes by 1) allowing broader use of prior authorization; 2) allowing plans to exclude a drug if new formulation does not provide unique route of administration; and 3) allowing plans to exclude a drug if it has cost increases above a certain threshold.

MAPRx appreciates CMS’s effort to ensure that current policies reflect changes in the marketplace; however, we are concerned that CMS’s proposal to expand Part D plan flexibility in order to manage the costs of providing medicines in the protected classes may lead to unintended consequences. Specifically, we are concerned that the policy change could reduce patient access to these life-saving drugs, possibly leading to complications associated with an interruption of care. We believe that the proposed changes are in direct opposition to Congressional intent for creating the protected classes. The protected class policy has successfully allowed beneficiaries with cancer, HIV, transplant recipients, epilepsy, and mental illness, among others, to receive the drugs their providers prescribe. Allowing plans the ability to broaden use of prior authorization and step therapy could hinder access and subsequently patient outcomes. For example, a “fail first” policy requires that beneficiaries prescribed a medication must first “fail” on a plan-preferred medication *before* the plan will pay for the original prescription. Such a policy could result in patients experiencing a delay in needed therapy or suffering adverse health effects, potentially including long-term altered health status.

MAPRx is concerned about several of the specific proposals within the overall changes to the protected class policy.

- **Patients Currently on a Stable Therapy:** MAPRx is particularly concerned that the proposed changes may result in an erosion of the current protections that prohibit prior authorization or step therapy for patients who are currently stable on treatment therapy protected under the policy. This proposal would also have a considerable impact on patients with HIV/AIDS as these products have generally been exempt from prior authorization and step therapy.
- **New Formulations:** MAPRx believes the proposed changes related to new formulations may further hinder patient access to needed therapies. CMS proposes to permit Part D plans to exclude a drug if a manufacturer introduces a new formulation with the same active ingredient that does not provide a unique route of administration—even if that becomes the only formulation available. This policy change may prevent patient access to specific therapies if a certain formulation has been discontinued.
- **Pricing Threshold for Protected Class Drug Formulary Exclusions:** CMS proposes that, beginning in 2020, Part D plans could exclude any single-source drug or biologic that has a wholesale acquisition cost (WAC) increase, relative to the price in a baseline month or year, beyond the rate of inflation. MAPRx has significant concerns that this proposed policy would adversely affect patient access to prescribed therapies—specifically those without any therapeutic equivalent. While we applaud CMS’ efforts to address affordability concerns for patients, this policy may result in an unintended consequence of patients having no access to a prescribed therapy.

Further, given that Part D plans already apply prior authorization for select products within the protected classes (except for HIV/AIDS drugs), we do not believe that broader use of

utilization management, including step therapy, should be implemented. A 2018 Avalere Health¹ study found that plans already apply utilization management tools (40% of the time) for drugs in the 6 protected classes, including a majority of branded drugs (54%) in the protected classes. Furthermore, Part D plans have applied prior authorization for almost half (49%) of branded drugs in the protected classes. The use of step therapy would likely present additional barriers and hurdles for patients prior to receiving a critically-important treatment, threatening patients' lives, safety, and medical stability. **Therefore, we urge CMS to maintain the current requirements, rather than allow plans the flexibility to broaden use of these tools.**

CMS would offer patients protection under this new policy via the current appeals and exceptions process in Part D; however, MAPRx believes that beneficiaries and providers cannot rely on these processes alone if CMS implements broader plan flexibility to manage drugs in the protected classes. While there is an appeals process, frankly, we do not believe it is a sufficient safeguard against the decreased access that will result from stricter formularies. MAPRx urges CMS to continue working to improve the appeals process, particularly around beneficiary communication at the point-of-sale and electronic prescribing/prior authorization. The March 2018 Medicare Payment Advisory Commission (MedPAC) report² to Congress made a similar recommendation to CMS, noting frustrations with Part D determinations, exceptions and appeals process among patients, providers, plan sponsors, and CMS itself. For example, there was one more civil monetary penalty imposed on a plan for program audit in 2017 compared to 2016.³ Additionally, a September 2018 Office of Inspector General (OIG) report⁴ found that Medicare Advantage plans had significantly high rates (75%) of denials overturned for services and payments (for beneficiaries enrolled in Part C and Part D programs) that should have initially been provided. The OIG found this particularly concerning because from 2014 to 2016, only 1% of denials were brought to the first level of appeals, so the system designed to ensure access to care is not working. **Therefore, MAPRx urges CMS to engage with the relevant stakeholders—particularly patient advocacy groups—to implement improvements to the exceptions and appeals processes, with the strong focus on ensuring these processes work for beneficiaries, while still offering plan flexibility.**

While we strongly support maintaining the current protected class policy, we also believe that CMS should consider ensuring other beneficiary protections related to formulary coverage. Namely, we believe that CMS should require plans to manage a more transparent formulary review process. Additionally, plans should be required to have a robust formulary, including the 6 protected classes of drugs and any additional classes where restricted access to those drugs would have a significant health impact. CMS should also require that plans provide coverage for a variety of medications in each drug class or category, as well as provide beneficiaries with timely information about any changes. MAPRx urges CMS to analyze formularies, both prior to and during the plan

¹ Partnership for Part D Access. Medicare Part D's Six Protected Classes Policy: A Balanced Approach to Provide Patients Access to Medications While Allowing Powerful Tools to Control Costs.

http://www.partdpartnership.org/uploads/8/4/2/1/8421729/partnership_for_part_d_report_2018.pdf.

Published in 2018.

² Medicare Payment Advisory Commission. Report to Congress: Medicare Payment Policy. Chapter 14: The Medicare Prescription Drug Program (Part D): Status Report. http://www.medpac.gov/docs/default-source/reports/mar18_medpac_ch14_sec.pdf. Published March 2018.

³ Centers for Medicare & Medicaid Services. 2017 Part C and Part D Program Audit and Enforcement Report. <https://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/Downloads/2017ProgramAuditEnforcementReport.pdf>. Published May 8, 2018.

⁴ Office of Inspector General. Medicare Advantage Appeal Outcomes and Audit Findings Raise Concerns About Service and Payment Denials. <https://oig.hhs.gov/oei/reports/oei-09-16-00410.pdf>. Published September 2018.

year, to determine whether appropriate access is afforded to needed drugs and classes of drugs. ***In general, we would like CMS to conduct greater oversight to ensure robust formularies.***

Application of Step Therapy for Part B Drugs by Medicare Advantage Plans

CMS proposes new requirements for when Medicare Advantage plans may apply utilization management (including step therapy) for Medicare Part B drugs.

MAPRx is opposed to step therapy, as it is an impediment to a prescribed therapy, particularly for patients who require timely and often personalized Part B medications. We are disappointed that CMS did not seek any formal or informal stakeholder comments before the release of guidance on August 7, 2018,⁵ allowing Medicare Advantage plans to use these same tools for Part B drugs in 2019 under certain circumstances. While we appreciate CMS's callout regarding protections currently in place for beneficiaries, we do not believe that these callouts are sufficient to adequately protect beneficiary access. We believe that the recently enacted and proposed policies weaken beneficiary protections in favor of health plan flexibility and outline a number of program features that hinder beneficiaries' ability to appropriately access needed prescription drugs, particularly those in the protected classes, including drugs for patients with cancer, HIV, and organ transplants. Utilization management practices, such as step therapy, *pose significant safety issues that could threaten patients' lives, safety, and medical stability.*

Explanation of Benefits Requirements

CMS seeks to require plans to communicate negotiated drug pricing information and lower cost alternatives in the Part D plan's Explanation of Benefits (EOB).

MAPRx appreciates the step toward transparency; however, we are concerned that the provided information is not actionable for the beneficiary to make better and timely health care decisions. A beneficiary would not be able to change plans midyear, so the information may be confusing to them and may not be helpful. For example, when a beneficiary receives an EOB after they have received treatment, they cannot use pricing information to change out-of-pocket costs that they have already incurred.

We believe that CMS should require plans to use clear and concise language to communicate plan benefits, coverage levels, and out-of-pocket costs, and this information should be included in EOBs in different ways (eg, using graphs or bullet point summaries) and in a manner and format that ensure beneficiaries understand the benefits provided in a plan. Rather than moving forward with the proposed changes, we believe CMS should work to improve beneficiaries' online shopping experience and ability to compare formularies and out-of-pocket costs across plans. As recently recommended by the National Council on Aging,⁶ Medicare Plan Finder would benefit from a comprehensive redesign and ongoing investment to remain relevant. ***MAPRx recommends that Medicare Plan Finder display costs with more precision, so that enrollees could***

⁵ Centers for Medicare & Medicaid Services. Advance Notice of Methodological Changes for Calendar Year (CY) 2016 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2016 Call Letter. <http://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Advance2016.pdf>. Published February 20, 2015.

⁶ National Council on Aging. Modernizing Medicare Plan Finder: Evaluating and Improving Medicare's Online Comparison Shopping Experience. <https://www.ncoa.org/wp-content/uploads/CC-2018-MedicarePF-Report-Final-0418.pdf>. Published April 2018.

view actual premium and out-of-pocket costs more accurately. This will help beneficiaries make informed decisions when choosing a plan.

Changes to the Definition of Negotiated Price

CMS is considering for a future plan year to redefine negotiated price as the baseline, or lowest possible, payment to a pharmacy. As such, CMS may propose to define negotiated price as the price reflected from all pharmacy price concessions, even if price concessions are contingent upon performance by the pharmacy.

MAPRx appreciates the effort to reduce prices at the point of sale, but we are concerned that ultimately, an unintended consequence will be that Part D plans may employ the change as a means to reduce access. Additionally, MAPRx believes requiring pharmacy benefit managers and plan sponsors to utilize manufacturer rebates (at least in part) for reducing beneficiary out-of-pocket costs at the point of sale is the most effective avenue for assisting beneficiaries facing challenges in affording their Part D medications. As noted in our recently released white paper, *Navigating Medicare Part D: Approaches to Addressing Beneficiary Affordability and Access Challenges*,⁷ we believe that CMS should explore a policy of requiring pharmacy benefit managers and sponsors to apply a specific percentage of rebates at the point of sale to reduce out-of-pocket expenses. ***We urge caution as CMS moves forward with the proposed policies to redefine negotiated price and we welcome the opportunity to join other stakeholders in a dialogue with CMS about this issue in the future, specifically regarding the application of manufacturer rebates at the point of sale (when and if CMS considers such a policy in the future).***

Pharmacy Price Concessions in the Negotiated Price

CMS is considering an option to develop a standard set of metrics from which plans and pharmacies would base their contractual agreements. CMS requests feedback on whether these metrics could be designed to provide pharmacies with more predictability in their reimbursements while maintaining the plan's ability to negotiate terms. Additionally, CMS seeks comment on the most appropriate agency or organization to develop these standards, or whether this a matter better left to private negotiations.

MAPRx appreciates CMS's consideration of this issue. If CMS decides to develop those metrics, they should be developed by an established measure developer:

- (1) with experience developing evidence-based, clinical quality measures for Medicare Part D that address the safe and appropriate use of medications,
- (2) that serves as a neutral convener of all relevant stakeholders on this issue, including patient advocates, health plans, pharmacy benefit managers, chain and independent pharmacies, government agencies, specialty pharmacy providers, pharmacist practitioner organizations,
- (3) that develops measures through a fully-transparent consensus-based process, and
- (4) that is willing to steward these measures on behalf of CMS, including completing necessary maintenance at least annually.

Finally, MAPRx applauds CMS's work on considering passing pharmacy direct and indirect remuneration (DIR) to the point of sale. MAPRx looks forward to more

⁷ MAPRx. *Navigating Medicare Part D: Approaches to Addressing Beneficiary Affordability and Access Challenges*. <https://maprx.info/wp-content/uploads/2018/12/MAPRx-Report-Navigating-Medicare-Part-D.pdf>. Published December 2018.

guidance on this policy, to the extent that pharmacy DIR at point of sale ultimately saves money for beneficiaries.

The task of appropriately balancing cost and access is formidable, but if the beneficiary remains the center of focus, we believe significant and lasting improvements are well within reach. 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
American Association on Health and Disability
American Autoimmune Related Disease Association (AARDA)
American Kidney Fund
American Society of Consultant Pharmacists
Association of Community Cancer Centers
Caregiver Action Network
Caregiver Voices United
COPD Foundation
Epilepsy Foundation
HealthyWomen
International Myeloma Foundation
Lakeshore Foundation
Leukemia Lymphoma Society
Lupus and Allied Diseases Association, Inc.
Lupus Foundation of America
Mental Health America
National Alliance on Mental Illness
National Council for Behavioral Health
National Council on Aging
National Grange
National Kidney Foundation
National Marrow Donor Program/Be The Match
National MS Society
National Organization for Rare Disorders (NORD)
National Patient Advocate Foundation
RetireSafe
The AIDS Institute
The Michael J. Fox Foundation for Parkinson's Research
Tourette Association of America
United Spinal Association