January 25, 2019

National Patient Advocate Foundation

Seema Verma, Administrator
Centers for Medicare and Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, SW, Room 445-G
Washington, DC 20201

RE: Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses (CMS-4180-P).

Dear Administrator Verma,

National Patient Advocate Foundation (NPAF) is pleased to provide feedback to the Center for Medicare and Medicaid Services (CMS) proposed rule Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket (OOP) Expenses (CMS-4180-P).

NPAF represents the voices of millions of adults, children and families coping with serious and chronic illness nationwide as the advocacy affiliate of Patient Advocate Foundation (PAF). PAF provides direct case management, financial support and educational services to tens of thousands of primarily low-income patients and caregivers each year who are experiencing distressing financial, employment, insurance coverage or household material hardships because of their health conditions. In 2017, 41 percent of all patients seeking case management assistance listed Medicare as their primary insurance[1] and this number rose to approximately 45 percent in 2018.[2]

Our PAF case managers consistently report that the patients they assist are particularly concerned about understanding their OOP costs to support care planning and treatment decision-making throughout their health care trajectory. They want clear, practical information that explains their expected copayments, coinsurance, and other cost sharing, as well as navigation to resources and services that can help them avoid financial distress and continue to make ends meet while confronting their health condition.

As such, we urge CMS to ensure any proposed policies preserve treatment decisions between patients and their physician or care team while reducing their total OOP spending at the pharmacy and in other settings. We believe this approach will have the most direct impact in supporting equitable access to affordable, quality and person-centered health care. Our comments will focus on the following provisions:

1. Providing Plan Flexibility to Manage Protected Classes
2. Medicare Advantage and Step Therapy for Part B Drugs
3. Part D Explanation of Benefits

[1] Patient Advocate Foundation. Annual Impact Report. 2017. Available at: https://www.patientadvocate.org/wp-content/uploads/2017_AnnualImpactReport.pdf
[2] Patient Advocate Foundation. Internal Case Management Data (Pre-publication). 2018.

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1. Providing Plan Flexibility to Manage Protected Classes

We appreciate the opportunity to reinforce our strong support for maintaining the current requirements, that plans must include all Part D drugs on formulary within the six Medicare Part D protected classes. The protected classes were established to ensure patients have uninhibited access to medications vital to the treatment of certain serious, chronic illnesses including mental illness, HIV-AIDS, organ transplantation, epilepsy and cancer. Ensuring equitable access to drugs for these conditions should be high priority for CMS, followed by policy solutions that guarantee these medications are available at an affordable OOP cost.

The proposed changes would give plans more flexibility to exclude drugs or employ additional utilization management such as prior authorization and step therapy. Such plan techniques would provide greater negotiating power with manufacturers, however, we are concerned that the aim to achieve cost savings will come at the expense of patients who rely on Medicare as a lifeline. While loosening coverage requirements for drugs in the protected classes may enable Part D sponsors to negotiate larger rebates from drug manufacturers, potential savings of this policy may be limited, given the higher rate of generic drug use within the protected classes.[3] Part D plans currently have a great deal of flexibility to employ utilization management to the protected classes and already encourage greater use of lower-cost generic drugs. In fact, a recent study found that in 2016, 91 percent of prescriptions filled across all protected classes were generic. Additionally, plans employed utilization management 40 percent of the time with tier placement being the primary method at 73 percent of the time, exposing patients to higher cost-sharing.[4]

While the proposed regulatory change does not require Part D sponsors to exclude protected class drugs from formularies, sponsors may likely exercise this new flexibility to achieve cost-savings. Without evaluative processes to ensure these policies do not interfere with patient access, we are concerned that patients may face the unintended consequences. We share the belief of the broader patient advocacy community that any changes to coverage of the Part D protected classes would result in adverse patient health outcomes and urge CMS to retain the six protected classes in their present form.

2. Medicare Advantage and Step Therapy for Part B Drugs

We were disappointed with CMS' August 2018 guidance allowing Medicare Advantage (MA) plans to use step therapy for physician-administered drugs beginning in 2019. We reiterate our comments submitted to Secretary Azar following the guidance as we remain vigilant of insurance practices that may impede equitable and affordable access to quality care. NPAF has worked diligently alongside patient and provider groups at the state level for years to protect against unintended and harmful consequences of implementing step therapy protocols that may impede on the patient-physician relationship and put patients' health and well-being at risk.

[3] Pew Charitable Trusts. Policy Proposal: Revising Medicare's Protected Classes Policy March 2018. Available at: http://www.pewtrusts.org/-/media/assets/2018/03/dsri_policy_proposal_revising_medicares_protected_classes_policy.pdf
[4] 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," 2018: http://www.partdpartnership.org/uploads/8/4/2/1/8421729/partnership_for_part_d_report_2018.pdf

We appreciate CMS' acknowledgement that Medicare patients who are stable on their current treatment regimen should not be subject to step therapy requirements that could force a change to potentially less effective treatment. We support CMS' intent to introduce new MA plan requirements that preserve continuity of care, specifically prohibiting MA plans to employ step therapy when the patient is stable on a current Part B regimen.

We do not agree, however, with allowing MA prescription drug plans to require patients to try and fail on a Part D drug before the Part B treatment can be given. This approach displaces shared decision-making between patients and their physician, and counters PAF evidence demonstrating the value that beneficiaries place on their doctor-patient relationship and the resulting implications for health care outcomes, treatment adherence and care planning.[5]

As CMS proceeds with allowing MA plans to utilize step therapy policies for physician-administered drugs, we urge that operationalizing the policies should prioritize the following person-centered principles:

1. MA plans should be accountable for implementing transparent, understandable, flexible and evidence-based step therapy policies and appeals processes that are easily accessible for both patients and providers, such as via the internet in the online Medicare Plan Finder tool.

2. All MA step therapy policies should detail adequate exceptions accounting for serious or chronically ill patients who would suffer from a mid-treatment change, including those who are clinically stable on their current medication.

3. Coverage decisions pursuant to any exceptions or appeals process should be made expeditiously within 24 hours for urgent medical needs and within 48 to 72 hours in all other cases.

4. MA plans should be accountable for communicating to both patients and physicians in a timely manner any coverage or benefit updates that may result in changes to prescribed treatments.

5. Step therapy policies should not impede on professional clinical judgement or diminish the patient-physician relationship and their opportunities for shared decision-making.

CMS should also develop and execute contemporaneous evaluative processes as part of MA step therapy implementation to ensure these policies do not interfere with patients' equitable access to effective medication, personalized care or health outcomes. A 2018 study found significant variation in the frequency that commercial health plans apply step therapy (ranging from 2 to 49 percent) and level of burden on patients and the care team, with plans requiring patients to step through one or multiple alternative treatments.[6] Additional analysis found that only 16 percent of commercial plans covered a set of specialty drug-indication pairs in the same way, with about half (52 percent) of

[5] Patient Advocate Foundation. The Roadmap to Consumer Clarity in Health Care Decision Making. May 2017. Available at: https://www.npaf.org/wp-content/uploads/2017/07/RoadmapWhitePaper_ecopy.pdf

[6] Variation In The Use Of Step Therapy Protocols Across US Health Plans, " Health Affairs Blog, September 14, 2018. Accessed January 18, 2019. Available at: https://www.healthaffairs.org/do/10.1377/hblog20180912.391231/full/

coverage decisions consistent with the Food and Drug Administration (FDA) label and one-third were more restrictive.[7] Because no standard approach for step therapy currently exists, CMS should use this opportunity to collect plan level data that help determine which medications or health conditions are appropriate for applying step therapy policies.

Maintaining availability of personalized therapeutic choices in Medicare plans will be increasingly critical to realize the full return on our national investment in human genome research and precision medicine, which has delivered an array of highly targeted therapies that offer improved outcomes. Limiting treatment choices through step therapy policies may derail this progress and the promise of using this research to optimize treatments based on patients' particular profiles and preferences.

Prescribed treatments including medications, diagnostic tests or other therapies should be the result of shared decision-making based on what best meets the patient's needs and circumstances. Step therapy protocols should be clear, understandable and allow flexibility for considering the judgement and expertise of medical professionals and the impact on patients.

3. Part D Explanation of Benefits

We applaud CMS for proposing plan requirements that include more information about negotiated prices and lower-cost therapeutic alternatives. While Part D end-of-year statements currently include some information about the negotiated price of prescription drugs, our PAF case managers have found that patients are more interested in having clear information about their specific OOP cost-sharing responsibility, accounting for deductible or OOP maximums, and are eager to weigh these cost considerations when making health care decisions. Providing complete, useful and understandable cost information and available alternatives prior to or upon the point of prescribing would achieve greater transparency and allow patients and their physicians the opportunity to discuss such costs in order to make more informed treatment decisions.

We recommend improving the information contained in the explanation of benefit (EOB) documentation sent to Medicare beneficiaries so that EOBs delineate more clearly the patients' financial responsibility in terms of copayment, coinsurance, and deductible distinct from their insurance premiums. A PAF survey conducted in 2017 of approximately 1,000 respondents, primarily older adults, found that 75 percent knew the amount of their plan deductible, while over 90 percent were familiar with the amounts they paid for monthly premiums and point-of-sale cost-sharing. Among the same population, 84 percent reported being worried about having to pay more for their health care.[8]

Further, CMS could enhance usability and simplify existing transparency tools to better assist patients and families in making decisions about health care and costs in Medicare Part D. A report evaluating the Medicare Plan Finder (MPF) online shopping experience found that the tool requires significant reform to ensure clear comparative plan information is readily available, accessible and easy for Medicare beneficiaries to understand.[9] As a first step, we recommend that CMS better integrate personal

[7] Chambers JD et al. Specialty Drug Coverage Varies Across Commercial Health Plans in the US. *Health Affairs.* 2018. 37(7);1031-1047
[8] Patient Advocate Foundation. Patient Preference and Insurance Survey. Conducted 2017.
[9] Clear Choices Campaign and National Council on Aging. Modernizing Medicare Plan Finder. Evaluating and Improving Medicare's Online Comparison Shopping Experience. April 2018. Available at: https://www.cahc.net/s/CC-2018-MedicarePF-Report-5318-FINAL.pdf

information in MPF to estimate OOP costs, provide the opportunity to discuss options with qualified experts and ensure patients are involved in testing any initial and ongoing updates to transparency tools. We ask the agency to prioritize improving the readability and usability of all plan communications, using stakeholder expertise and feedback throughout the process in a person-centered approach like the request for input on CMS' *Welcome to Medicare* packages, to which NPAF provided comments in 2017.

We appreciate the opportunity to provide comments to the proposed rule, Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket (OOP) Expenses. Moving forward, we urge CMS to leverage our person-centered principles when proposing and implementing changes that impact access to care. NPAF stands ready to provide feedback from patient, caregiver and family perspectives and partner with CMS to ensure policies that reduce patients' OOP expenses, helping preserve their financial stability and quality of life. Please contact Nicole Braccio, policy director at Nicole.Braccio@npaf.org or 202-516-5212 if NPAF can provide further details or clarification.

Respectfully submitted,

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EVP Health Care Quality and Value