



Richard J. Fiesta, Chair

January 25, 2019

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-4180-P
P.O. Box 8013
Baltimore, MD 21244-8013

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

Dear Administrator Verma:

The Leadership Council of Aging Organizations (LCAO) appreciates the opportunity to comment on Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses (CMS-4180-P). LCAO is a coalition of 69 national nonprofit organizations concerned with the well-being of America's older population and committed to representing their interests in the policy-making arena. LCAO serves as a source of information about issues affecting older adults and provides leadership and vision as America meets the challenges and opportunities presented by our aging society. Our organizations have expertise in health care, economic security, nutrition and food security, housing, and other issues facing older adults and people with disabilities, and are committed to advancing public health and promoting access to affordable medicines to keep these populations healthy and improve their well-being and the well-being of their families.

Today, high prescription drug prices force Medicare beneficiaries to make tough decisions about whether they need to ration or skip needed medications. Nearly one-in-four Americans report that they or another family member have cut pills in half, skipped doses, or not filled a prescription because of cost.¹ Older adults and people with disabilities rely on timely administration of their medications, so an inability to afford and access their drugs will lead to worse health outcomes and higher costs, both for beneficiaries and for the greater health care system.

The Centers for Medicare & Medicaid Services (CMS) has proposed several changes to Medicare Advantage (MA) and standalone Part D prescription drug plans (PDPs) with the stated goal of supporting health and drug plans' ability to negotiate lower drug prices and reducing out-of-pocket costs for enrollees.² While we agree the problem of high and rising drug prices must be addressed, we disagree with the agency's proposed approach, as it could disrupt or even prevent access to needed medications for people with Medicare.

¹ Kaiser Family Foundation, "Health Tracking Poll: Public Opinion on Prescription Drugs and Their Prices" (2016), <https://www.kff.org/slideshow/public-opinion-on-prescription-drugs-and-their-prices/>.

² FR 62152.

Currently, MA and standalone Part D PDPs are required to include on their formularies all of the available drugs in six categories known as the “protected classes”: anti-depressants, antipsychotics, anticonvulsants, immunosuppressants for transplant rejection, antiretrovirals and antineoplastics. The proposed rule would allow plans to limit coverage of these drugs through new utilization management strategies, such as requiring certain patients to undergo step therapy or obtain prior authorization.

We do not support this proposal. The bipartisan protected classes policy was thoughtfully crafted as a necessary means to ensure access to medications that are not easily substituted or where interruptions in drug therapies could have significant individual and public health consequences. For example, choosing the appropriate regimen for HIV treatment is necessarily individualized to patient- and virus-specific factors. Requiring an individual to demonstrate poor adherence or experience a serious adverse event on a regimen that is not recommended by the clinical provider, or delaying access to treatment by imposing unnecessary prior authorization hurdles, will severely harm beneficiaries. Similarly, not ensuring access to the full range of immunosuppressants for a transplant patient runs the dangerous and costly risk of rejection.

In addition, it is unclear that the proposal would lower drug prices. Research by Avalere Health³ and Pew⁴ suggest that the opportunity for savings may be limited, given the already prevalent use of generics in the protected classes. While we appreciate the need to control drug pricing increases, CMS must not do so by impeding access to urgently needed medications.

Under the proposed rule, plans would also be allowed to exclude a protected class drug from their formularies if the drug were a new formulation of an existing product that lacks a unique route of administration. We recognize the aim is to disincentivize the industry practice of withdrawing older products from the market in order to preserve and extend innovator drug products’ monopolies. However, this change would be problematic for Medicare beneficiaries. New drug formulations could be scientifically determined to have superior adherence, safety and/or efficacy, even without unique routes of administration. Rather than allowing plans to decide, coverage of such critical drugs should be based on individual, evidence-based assessments. We support CMS’s efforts to work with other agencies to address abuses of patent and drug marketing laws. However, in this and future proposed rulemaking, CMS must ensure that its attempts to penalize bad actors do not end up harming beneficiaries.

CMS also proposes to allow plans to exclude a protected class drug if the price of the drug were to increase above a certain threshold over a certain period of time. While we agree that such cost increases are extremely concerning, this is a piecemeal and arbitrary approach that could disrupt beneficiary access to needed medications. Formulary exclusion is not the only way to address the constantly rising prices for drugs. We urge CMS and Congress to work with a variety of stakeholders on a comprehensive plan to address rising prices and skyrocketing out-of-pocket costs.

³ 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.

⁴ Pew Charitable Trusts, “Policy Proposal: Revising Medicare’s Protected Classes Policy” (March 7, 2018),

<https://www.pewtrusts.org/en/research-and-analysis/fact-sheets/2018/03/policy-proposal-revising-medicare-protected-classes-policy>.

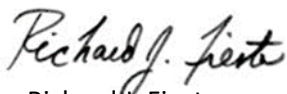
We are also concerned about CMS's support of MA plans utilizing step therapy on Part B drugs (first in 2018 sub-regulatory guidance; and now to be codified in this proposed rule). We appreciate CMS's effort to establish more detailed guidelines and safeguards in this proposed rule. However, this policy will limit beneficiaries' access to Part B drugs, including in the treatment of life-threatening conditions like cancer.

CMS suggests that the Part D appeals and exceptions process would be sufficient to protect consumers from the proposed rule's potential access issues. However, the appeals process is deeply flawed, rendering it an inadequate safeguard. As MedPAC commented in 2018, "Beneficiary advocates, prescribers, plan sponsors, and CMS have all noted frustrations with Part D coverage determinations, exceptions, and appeals processes."⁵ In addition, the HHS Office of Inspector General found that Medicare Advantage plans inappropriately denied far too many beneficiary requests and recommended that CMS increase oversight and "address persistent problems related to inappropriate denials and insufficient denial letters in Medicare Advantage."⁶ We cannot support weakening other beneficiary protections in reliance on a frayed safety net. These proposals impact some of the sickest Medicare beneficiaries, who may not have the wherewithal to engage in a difficult appeals process, even if they know it's an option. Whether or not these proposals move forward, we encourage CMS to work with stakeholders on improvements to the appeals and exceptions process, such as improving information given to beneficiaries at the point of sale.

For all of these reasons, we urge CMS to withdraw these proposals and work toward solutions that provide meaningful relief from high drug prices and out-of-pocket costs, rather than approaches that put people with Medicare at risk of losing access to health-protecting and often life-saving therapies.

Thank you again for this opportunity to comment on these proposals.

Sincerely,



Richard J. Fiesta
Chair

⁵ Medicare Payment Advisory Commission, "Report to Congress: Medicare Payment Policy. Chapter 14: The Medicare Prescription Drug Program (Part D): Status Report" (March 2018), http://www.medpac.gov/docs/default-source/reports/mar18_medpac_ch14_sec.pdf.

⁶ Office of Inspector General, "Medicare Advantage Appeal Outcomes and Audit Findings Raise Concerns About Service and Payment Denials" (September 25, 2018), <https://oig.hhs.gov/oei/reports/oei-09-16-00410.asp>.