



January 25, 2019

The Honorable Seema Verma, Administrator  
Centers for Medicare & Medicaid Services  
7500 Security Boulevard  
Baltimore, MD 21244

**Re: Comments on CMS-4180-P, Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses**

**Submitted electronically via Regulations.gov**

Dear Administrator Verma:

Families USA, a leading national voice for health care consumers, is dedicated to the achievement of high-quality, affordable health care and improved health for all. We seek to make concrete and tangible improvements to the health and health care of the nation – improvements that make a real difference in people’s lives. In all of our work, we strive to elevate the interests of children and families in public policy to ensure that their health and well-being is foremost on the minds of policymakers.

We appreciate the opportunity to provide comment on the proposed rule for Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses.

We are grateful for the administration’s focus on the impact that high and rising prescription drug prices have on consumers’ ability to fill their prescriptions and on broader health care costs. We particularly appreciate the administration’s attention to the role that multiple industry stakeholders play in keeping costs high. Though primarily driven by pharmaceutical companies launching new drugs at high prices and raising prices on older drugs, building a drug innovation and pricing system that prioritizes public health and establishes fair prices for all consumers will require reforms to the entire system. Although we believe that many of the proposed provisions will increase transparency and benefit consumers, we have significant concerns that other proposals could seriously threaten access to needed—and lifesaving—therapies.

Below are Families USA’s comments on specific provisions of the proposed rule:

**Providing Plan Flexibility to Manage Protected Classes**

We share CMS’s concern that the current protected class policy may contribute to both higher drug costs and the overutilization of some drugs. But rather than, as proposed, implementing exceptions from typical formulary management tools that apply equally to all protected classes, we strongly encourage the administration to explore the development of more targeted criteria for determining which drugs or classes of drugs should be exempted from typical formulary management tools. Any such criteria should both recognize and incorporate relevant clinical guidelines for health conditions

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addressed by drugs in protected classes, and be proposed in detail in a new regulatory framework that is subject to APA review and comment.

CMS proposes increased flexibility for Part D plans (PDPs) to exclude drugs from their formularies if they are merely new formulations without a unique route of administration or if the drug's price increases beyond a certain threshold. CMS has correctly identified that pharmaceutical industry practices, including the "product-hopping" and large price increases specifically called out in this proposed rule, are important drivers of increasing drug costs. We also recognize that absent new statutory authority, there are significant limitations on what CMS can do to address high prescription drug prices, and that increasing PDPs' ability to exclude drugs or use utilization management techniques is one of the more powerful tools available to it.

However, by ensuring access to the full-range of therapies and protecting against discriminatory formulary design, the current protected class policy has provided important—indeed lifesaving—protections for Medicare beneficiaries. Given the illnesses and health conditions that drugs in the protected classes are used to treat, interruptions or delays in care can lead to severe, adverse impacts on the health and wellbeing of Medicare beneficiaries. Restricting access to needed therapies also risks increased costs to other parts of the health care system as a result of complications or additional visits needed to plan around ineffective medications.

Additionally, even under the current protected class policy, PDPs are not without tools for steering beneficiaries toward lower-cost therapies, managing utilization, or securing rebates from drug manufacturers. PDPs are permitted to make use of preferred, non-preferred, and specialty tiers<sup>1</sup> and they may exclude certain drugs altogether, such as brand-name drugs when a therapeutically equivalent generic drug is available or extended-release formulations when an immediate-release formulation is available, among others.<sup>2</sup> In fact, PDPs already have more restrictive formularies for the anticonvulsant class of drugs than commercial health plans, and the protected classes have a higher overall rate of generic utilization than non-protected classes.<sup>3</sup> Prices for drugs in protected classes rose at a similar rate to drugs in non-protected classes between 2006 and 2013, and when accounting for generic substitution, actually declined by 16 percent over that period.<sup>4</sup>

For these reasons, we oppose the proposed plan flexibilities for protected classes and strongly urge CMS not to finalize these provisions as proposed. We are particularly concerned about and opposed to the provisions that would allow PDPs to completely exclude drugs from their formularies. As stated above, we agree that the pharmaceutical practices these provisions are attempting to address (product-hopping and large price increases) should be seriously curtailed, but the mechanism to curb these specific practices should not be giving PDPs much broader authority to not cover drugs for protected class diagnoses.

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<sup>1</sup> Medicare Payment Advisory Commission. *Report to the Congress: Medicare and the Health Care Delivery System*. June 2016. <http://www.medpac.gov/docs/default-source/reports/june-2016-report-to-the-congress-medicare-and-the-health-care-delivery-system.pdf?sfvrsn=0>

<sup>2</sup> Medicare Part D Manual, Chapter 6, Section 30.2.5

<sup>3</sup> The Pew Charitable Trusts. Policy Proposal: Revising Medicare's Protected Classes Policy. March 2018. [https://www.pewtrusts.org/-/media/assets/2018/03/dsri\\_policy\\_proposal\\_revising\\_medicares\\_protected\\_classes\\_policy.pdf](https://www.pewtrusts.org/-/media/assets/2018/03/dsri_policy_proposal_revising_medicares_protected_classes_policy.pdf)

<sup>4</sup> Medicare Payment Advisory Commission. *Report to the Congress: Medicare and the Health Care Delivery System*. June 2016. <http://www.medpac.gov/docs/default-source/reports/june-2016-report-to-the-congress-medicare-and-the-health-care-delivery-system.pdf?sfvrsn=0>

We want to reiterate that we share CMS’s concern that the current protected class policy may be contributing to high drug costs in Part D. We believe there may be other changes to this policy that would better balance increased plan flexibility to drive cost savings with needed beneficiary protection. We also want to note that the successful implementation of the administration’s proposed electronic real-time benefit tool requirement could also lessen consumer access concerns regarding the use of prior authorization or step therapy. The proposed exemptions are too broad and do not account for important clinical nuances. For example, though there are some generic antiretrovirals available, clinical guidelines recommend using newer, more effective brand-name drugs, and step therapy would be completely inappropriate, as “failing first” on certain drugs risks developing resistance to all drugs in that class. Additionally, there may be health conditions, such as HIV or certain mental health conditions, where even the least burdensome prior authorization would not be appropriate due to the challenges beneficiaries may experience in accessing providers, staying connected to care, and maintaining their treatment plans.

A better approach would be to develop condition-specific exemptions from typical formulary management tools. The development of such exemptions should also take into account the diversity of ways the condition or disease manifests, the number of and variations in drugs needed to treat those different manifestations, and highly prevalent comorbidities and their associated treatments. This more targeted approach could maintain the appropriate balance between beneficiary access and the need for tools to manage drug utilization and constrain costs. Rather than allowing plans to design their own exemptions, these proposed exemptions should be done through the normal rulemaking process. This would allow the patients who are most affected and the physicians, pharmacists, and other health care providers who are experts in the conditions and drugs affected by the protected classes to provide appropriate input.

### **E-Prescribing and the Part D Prescription Drug Program; Updating Part D E-Prescribing Standards**

We strongly support the administration’s proposal to require plans to make a real-time benefit tool available to prescribers that can provide patient-specific coverage information at the point of prescribing. Medication adherence is directly related to affordability. For example, nearly one quarter of consumers report that they or a family member has not filled a prescription, has cut pills in half, or skipped doses due to the high cost of drugs.<sup>5</sup> A 2013 study also found that one quarter of all cancer patients chose not to fill a prescription because of cost.<sup>6</sup> Therefore, having cost and coverage information available at the point of prescribing is essential for improving medication adherence, as well as for improving patient safety and care quality. In order to most effectively implement this requirement, we urge CMS to ensure that prescribers will use these tools by incentivizing or requiring their utilization through this rule or through other rules governing facility and prescriber payment and health information technology utilization.

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<sup>5</sup> Kaiser Family Foundation. *Public Opinion on Prescription Drugs and their Prices: Poll Findings from 2015-2018 KFF Health Tracking Polls*. <https://www.kff.org/slideshow/public-opinion-on-prescription-drugs-and-their-prices/>

<sup>6</sup> Zafar SY, Peppercorn JM, Schrag D, Taylor DH, Goetzinger AM, Zhong X, and Abernathy AP. *The Financial Toxicity of Cancer Treatment: A Pilot Study Assessing Out-of-Pocket Expenses and the Insured Cancer Patient’s Experience*. *Oncologist*. 2013; 18(4): 381-90. <https://www.ncbi.nlm.nih.gov/pubmed/23442307>

## **Part D Explanation of Benefits**

We also strongly support CMS's proposal to include information about the percentage increases in the prices of a beneficiary's drug on their Explanation of Benefits. Although reports of high and rising prescription drug prices are frequently in the media, providing this information on the specific drugs taken by a beneficiary and in a document that beneficiaries already receive, will ensure that beneficiaries are aware of how they are specifically affected by these high and rising prices. It may also serve as a catalyst for beneficiaries speaking with their providers about lower-cost alternatives.

## **Medicare Advantage and Step Therapy for Part B Drugs**

Though we continue to have concerns about timely beneficiary access to needed drugs by permitting Medicare Advantage plans to use step therapy, as CMS announced in August 2018, we commend CMS for the additional clarifications and proposed consumer protections for this policy that have been included in this proposed rule. Specifically, we appreciate the clarification that step therapy cannot be used to interrupt a beneficiary's course of treatment and for the proposed application of the shorter Part D exceptions process timelines.

We also strongly encourage CMS to adopt additional protections for beneficiaries. Specifically, we are concerned that the 108-day lookback period may require beneficiaries who use drugs that are indicated infrequently to inappropriately have to progress through step therapy. CMS should allow evidence of such prior use to exempt a beneficiary from a step therapy protocol.

We are concerned that disclosure requirements in annual notice of change and evidence of coverage documents are too vague to provide enrollees with the information they need to understand how step therapy could affect them. We recommend that CMS require plans to provide actual and prospective enrollees, as well as those entities and programs who may advise enrollees on plan selection, with notice of their intent to apply step therapy to any specific drug. The notice should describe the specific criteria for each drug to which the step therapy requirement applies. Additionally, CMS should clearly prohibit plans from making changes to step therapy requirements after the time period when beneficiaries are able to switch plans, as beneficiaries may be selecting their plans based on how step therapy is applied.

The application of step therapy may also have a significant impact on beneficiaries' cost-sharing. We are concerned that beneficiaries may be subject to higher cost-sharing when the drugs they are required to try first ultimately do not work for them and/or when the step therapy regimen requires them to switch between drugs covered under Part B and Part D. We recommend that 1) enrollees receive a rebate from the plan for any cost-sharing they pay for drugs they try under step therapy that do not work for them and 2) consumers be charged the lowest-cost sharing amount between Part B and Part D if step therapy arrangements switch them between Medicare Part B and D coverage.

## **Pharmacy Price Concession in the Negotiated Price**

By shifting price concessions out of direct and indirect remuneration (DIR) applied at the end of the year, and instead applying it to the point-of-sale in a negotiated price, beneficiaries would see a slight

increase in premiums, offset by major savings in cost-sharing. For this reason, we support CMS' proposed change to DIR to include pharmacy price concessions in the definition of a negotiated price.

We would also urge CMS to consider moving manufacturer rebates to the point of sale as a way to further the savings for beneficiaries, an approach to DIR reform investigated in a CMS report from May 2018, where CMS concluded that rebates as a part of DIR does not decrease the beneficiary cost-sharing obligation.<sup>7</sup>

Manufacturer rebates have grown dramatically in recent years, resulting in a widening disparity between list prices and net prices negotiated by plans.<sup>8</sup> By extending the same logic used to rationalize the inclusion of pharmacy price concessions, point-of-sale manufacturer rebates should also be a part of the definition of a negotiated price due to the impact of rebates on the total beneficiary share of the actual drug cost.

Point of sale rebates are allowed for Part D plan sponsors, but are not a requirement. The latest data from the Office of the Inspector General shows that in 2008, four of 258 sponsors offered plans with an estimated rebate at the point of sale.<sup>9</sup> Furthermore, since 2011, pharmaceutical manufacturers have been providing this type of rebate to beneficiaries in the coverage gap and this rebate was expanded in the Bipartisan Budget Act of 2018.

The proposed rule on DIR reform is a positive step forward, which could help beneficiaries share in the discounts and price concessions negotiated on prescriptions sold to Part D plans. Further consideration of manufacturer rebates at point-of-sale could increase the overall savings for beneficiaries and provide relief from rising list prices.

Thank you for the opportunity to submit these comments. We respectfully request that these comments and the complete articles cited be incorporated into the record.

If you have any questions, please contact Ellen Albritton at Families USA, 202-628-3030 or at [éalbritton@familiesusa.org](mailto:éalbritton@familiesusa.org).

Respectfully submitted,

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<sup>7</sup> Sullivan, T. *CMS Releases Report on Drug Rebates* (May 5, 2018). Policy & Medicine. <https://www.policymed.com/2017/03/cms-releases-report-on-drug-rebates.html>

<sup>8</sup> Dusetzina, S.B., Conti R.M., Yu N.L., Bach P.B. *Association of Prescription Drug Price Rebates in Medicare Part D With Patient Out-of-Pocket and Federal Spending*. JAMA Intern Med. 2017; 177 (8): 1185-1188.

<sup>9</sup> Office of the Inspector General, US Department of Health & Human Services. *Concerns With Rebates in the Medicare Part D Program*. <https://oig.hhs.gov/oei/reports/oei-02-08-00050.pdf>. Published March 2011.