the campaign for
SUSTAINABLE Rx PRICING
Transparency. Competition. Value.

January 16, 2018

The Honorable Seema Verma
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Service
200 Independence Avenue, Southwest
Washington, DC 20201

RE: CMS-4182-P

Dear Administrator Verma:

The Campaign for Sustainable Rx Pricing (CSRxP) is a nonpartisan coalition of organizations committed to fostering an informed discussion on sustainable drug pricing. We strive to develop bipartisan, market-based solutions that promote competition, transparency, and value to make prescription drugs more affordable for all Americans while at the same time maintaining access to medicines that can improve health outcomes and save lives. Our members represent organizations including consumers, hospitals, physicians, nurses, pharmacists, employers, pharmacy benefit managers and health plans.

We strongly support and very much appreciate the broad goal of the Centers for Medicare and Medicaid Services (CMS) to reduce prescription drug costs for Medicare beneficiaries as reflected in CMS's proposed rule entitled "Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program" (CMS-4182-P).

While we welcome the intent of the proposed rule and support its objectives, we are very concerned that certain policies – particularly the Part D point-of-sale rebate proposal in the Request for Information (RFI)– has the potential to increase the cost of prescription drug coverage (i.e., Part D premiums) for all Part D enrollees. Moreover, and most importantly, the proposed rule does nothing to address the root cause of the core problem: brand name drug manufacturers are setting list prices too high—and manufacturers alone have total control over list prices. Compounding the problem, brand name drug manufacturers consistently raise their already-high list prices, even for older products that have been on the market for many years. This unnecessarily increases costs for Medicare beneficiaries and their families and jeopardizes beneficiary access to the medications they need. In this light, CSRxP offers the following comments on policies in the proposed rule including:

I. Support for the proposal to expedite and expand the availability of generic medications for Medicare Part D enrollees;
II. Support for the proposal to treat follow-on biologics as generics for purposes of non-Low Income Subsidy (LIS) catastrophic and LIS cost-sharing; and

III. Significant concern for the proposals in RFI that would reduce drug costs at the point-of-sale (POS) through POS rebates and POS pharmacy price concessions.

CSRxP's comments reflect our strong desire to work with CMS and the Administration to develop and implement market-based policies that increase affordability and access to prescription drugs for all Medicare beneficiaries, U.S. patients and their families.

## I. Expediting and Expanding Access to Generic Medications

CMS proposes to allow Part D sponsors to immediately remove, or change the preferred or tiered cost-sharing, of brand name drugs and substitute or add therapeutically equivalent drugs under certain specified conditions rather than wait until the direct notice and formulary change request requirements have been met. CSRxP strongly supports and welcomes this proposal because it would increase and accelerate access to generic medications for Part D enrollees once they become available. Increased availability of generic medications enhances competition in the marketplace, thereby expanding treatment options and lowering costs for Medicare beneficiaries and the Medicare program overall.

## II. Incentivizing Use of Follow-On Biological Products by LIS Beneficiaries and Non-LIS Beneficiaries in Catastrophic Coverage

CMS proposes to treat follow-on biological products as generics for purposes of Part D non-LIS catastrophic and LIS cost-sharing only. CSRxP very much supports and welcomes this proposal because it incentivizes beneficiaries to utilize less expensive but equally effective follow-on biological products over their more expensive reference products when follow-on biological products are available and medically appropriate. The proposal furthers two key policy outcomes for which CSRxP strongly advocates: (1) reducing drug costs for Medicare Part D enrollees, particularly those on high-cost specialty medications, by encouraging use of follow-on biological products when medically appropriate; and (2) improving the overall marketplace for follow-on biological products, thus increasing incentives for manufacturers to develop and market these products that can reduce prescription drug costs for Medicare beneficiaries *and* all U.S. consumers.

## III. Part D Point-of-Sale Rebates and Pharmacy Price Concessions

In the RFI released in concert with the proposed rule, CMS states it is considering two policies to reduce prescription drug costs at point-of-sale for Medicare beneficiaries by requiring Part D sponsors: (1) to implement a POS rebate based on rebates provided from drug manufacturers to the sponsor and its pharmacy benefit manager; and (2) include all price concessions from pharmacies in the drug's negotiated price at POS. While CSRxP appreciates the intent of these policies, we have significant concerns with them because both have the potential to increase Part D premiums for <u>all</u> beneficiaries *and* the costs of the Part D program overall. Meanwhile, brand name drug manufacturers that make prescription drugs unaffordable for patients will benefit.

CSRxP recognizes that POS rebates and pharmacy price concessions could provide meaningful assistance to a limited number of beneficiaries with high out-of-pocket prescription drug costs and thus appreciates CMS's interest in this approach. However, as CMS acknowledges in the RFI, implementation of these policies would likely lower costs for a small number of beneficiaries at the expense of significant

premium increases for all Part D enrollees.[1] Such an outcome in particular would negatively impact the many Medicare beneficiaries who live on fixed incomes and simply cannot afford unnecessary increases to their monthly Part D premiums. Prescription drug coverage should become more affordable – not less affordable – for all Part D enrollees.

Furthermore, implementation of POS rebates and pharmacy price concessions would substantially increase Medicare Part D program costs for the Federal government and taxpayers while increasing profitability for brand drug manufacturers – outcomes that clearly do not help Medicare or its beneficiaries. CMS estimates in the proposed rule that POS rebates could cost taxpayers between roughly $27 billion to $82 billion and that POS pharmacy price concessions could cost nearly $17 billion over ten years. Brand drug makers, in turn, would pay out less price discounts in the Part D coverage gap as a result of both policies – roughly $10 billion to $29 billion less from POS rebates and about $5 billion less from POS pharmacy price concessions over ten years, according to CMS.[2] [3]

In other words, implementation of these policies wrongly and inappropriately would: (1) put Medicare on less sound financial footing for current and future beneficiaries; and (2) require taxpayers and Medicare beneficiaries to subsidize the brand pharmaceutical industry. This outcome is particularly problematic as it financially benefits the very industry that has caused the problem that CMS is trying to solve. Indeed, the Medicare Payment Advisory Commission (MedPAC) shares these same broad concerns. MedPAC highlights in its comments on the proposed rule that the POS rebate policy would increase Medicare spending and reduce brand drug makers' coverage gap discount payments, causing the Commission to "strongly encourage" CMS to find a less complex alternative policy to lower out-of-pocket spending for Part D enrollees.[4]

Most importantly, these proposals to reduce drug costs at point-of-sale do not address the root cause of the unsustainable growth in prescription drug costs that Medicare beneficiaries and all American patients and their families confront every day: brand drug manufacturers set list prices too high and regularly raise those prices at high rates.

## IV. Conclusion

In conclusion, CSRxP again thanks CMS for the opportunity to comment on the agency's proposed rule concerning policy and technical changes to Medicare Part C and Part D. CSRxP looks forward to continued work with the agency on developing bipartisan, market-based solutions that promote competition, transparency, and value to make prescription drugs more affordable for all Medicare beneficiaries, American patients and their families. If you have any questions concerning our comments, please do not hesitate to call Lauren Aronson at 202-585-0255.

Sincerely,

Campaign for Sustainable Rx Pricing

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[1] 82 Fed. Reg. 56421
[2] 82 Fed. Reg. 56425
[3] 82 Fed. Reg. 56428
[4] MedPAC January 3, 2018 letter to CMS Administrator Verma on CMS-4182-P.