

July 16, 2018

The Honorable Alexander Azar
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201



Re: HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs (CMS-2018-0075)

Dear Secretary Azar,

The undersigned organizations, members of the Regulatory Education and Action for Patients (REAP) Coalition, appreciate the opportunity to provide feedback on policies under consideration in the HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs. Collectively, our organizations represent the voices of millions of adults, children and families coping with chronic and serious illnesses nationwide.

REAP is a diverse group of patient advocacy organizations whose mission is to communicate collaborative perspectives on regulatory and legislative priorities to federal and state policymakers. REAP assures a wide range of patient concerns across various disease types are considered in policy development to maximize care access and improved outcomes as well as minimize unintended consequences upon regulatory implementation.

Foremost, we focus our comments on the Blueprint's fourth overarching goal to reduce peoples' out-of-pocket (OOP) spending at the pharmacy and in other settings, which we believe will have the most direct impact on patients in supporting equitable access to the affordable, person-centered health care they need. In a survey of patients seeking financial or case management support, almost 90% revealed that knowing their OOP costs is important for choosing a treatment.¹ Overall, the patients we serve are particularly concerned about understanding and meeting their OOP costs to support care planning and treatment decision-making throughout their health care journey.

Patients 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 conditions. Accordingly, our organizations are aligned with the Administration's goals to reduce patient OOP spending and improve transparency about these costs to all patients, and offer the following person-centered principles for providing useful cost information that people want and need:

- Patients and families should have opportunities to learn about and meaningfully discuss the cost of their care in ways that are culturally appropriate and sensitive to their particular needs and circumstances throughout the process of making healthcare decisions.
- Understandable and transparent cost information from reliable resources should be publicly available to support consideration of treatment benefits and tradeoffs in the context of person-

¹ Patient Advocate Foundation. Patient Survey: Attitudes & Perspectives Surrounding Cost of Care. Preliminary Data. June 2018.

centered care planning and shared decision-making throughout the care continuum and across all care settings.

- Pricing and cost transparency regulations should be applicable to all sources of patient cost and all stakeholders who participate in the creation of such costs to give patients access to information that helps them make more informed choices and prepare for the financial obligations associated with their care.

We are encouraged by the Administration’s efforts to gather feedback from the broader health care community, and strongly urge the agency to apply a formal rule-making process or demonstration authority through the Center for Medicare and Medicaid Innovation (CMMI) to ensure optimal stakeholder input and engagement. Additionally, we suggest that ongoing reforms integrate recommendations from Centers for Medicare and Medicaid Services’ (CMS) Person and Family Engagement Strategic Plan as well as leverage the Department of Health and Human Services’ (HHS) Partnership for Patients Initiative.

We are pleased to share the following more detailed insights and recommendations to improve transparency, reduce OOP costs and ensure equitable access to affordable quality care as the agency determines the best way to implement such wide-ranging policy solutions.

1. Improving transparency

Pharmacist gag clause

Important conversations about cost transparency often occur at the point of sale between a patient and their pharmacist at the pharmacy counter. News reports have highlighted the practice of pharmacy gag clauses and clawbacks in which pharmacists are prohibited by the insurance plan from disclosing the total cost of the drug or “cash price” to a patient, resulting in patients paying a prescription copayment that is higher than the retail price.^{2,3} This practice bypasses a person’s ability to choose the most affordable OOP cost and diminishes the relationship and trust with their care team.

Researchers have recently quantified the clawback phenomenon, finding that in 2013, overpayments by commercially-insured patients occurred in over a quarter of generic drug claims (28%), leading to overpayments totaling \$10.51 per member per year.⁴ We are encouraged by recent communication from CMS reminding Part D plan sponsors that pharmacy gag clauses run counter to price transparency initiatives.⁵ However, we recommend that CMS take additional steps to formalize guidance for insurance plans that ensure patients do not inadvertently overpay for prescription medications due to pharmacy gag clauses and clawbacks.

² Appleby, Julie. Filling a prescription? You might be better off paying cash. Kaiser Health News. June 24, 2016. Retrieved July 5, 2018 from: <http://khn.org/news/filling-a-prescription-you-mightbe-better-off-paying-cash/>

³ Hopkins, Jared S. You’re Overpaying for Drugs and Your Pharmacist Can’t Tell You. Bloomberg News. February 24, 2017. Retrieved July 5, 2018 from: <https://www.bloomberg.com/news/articles/2017-02-24/sworn-to-secrecy-drugstores-stay-silent-as-customers-overpay>

⁴ USC Schaeffer. Overpaying for Prescription Drugs: The Copay Clawback Phenomenon. March 2018. Available at: http://healthpolicy.usc.edu/documents/2018.03_Overpaying%20for%20Prescription%20Drugs_White%20Paper_v.1.pdf

⁵ Centers for Medicare and Medicaid Services. Letter for Part D Plan Sponsors. May 11, 2018. Available at: <https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/Other-Content-Types/2018-05-17.pdf>

Rebate Pass-Through

We support and appreciate Administration efforts to improve transparency and protect patients from paying a larger share of the drug costs, which can occur when rebates and price concessions are not reflected in negotiated price at the point of sale. Patients and families are far removed from these arrangements but should regardless share a portion of the savings that insurers may use to balance reductions in premiums and cost-sharing.

Currently, manufacturer rebates do not necessarily lower patients' OOP costs directly. Survey data indicate that in 2017, only 4% of employer-based commercial plans used manufacturer rebates to directly lower patient's OOP costs, while 11% used rebates to offset member premiums, but the great majority (68%) used rebates to lower plan spending on drugs.⁶ To protect patients from shouldering a greater proportion of costs, CMS should monitor trends in commercial plan practices that could potentially be mirrored by private Part D sponsors.

CMS could also require and obtain more complete data about contractual arrangements between manufacturers and payers that includes rebates at the individual drug level. As the Administration seeks to effectively design policies that require Part D sponsors to pass through savings to patients, these data can be used to identify and test innovative benefit design models that work best for Medicare beneficiaries and support equitable access to affordable medications that patients and families confronting serious, chronic illness may need.

We urge CMS to ensure that beneficiaries, especially vulnerable and low-income patients, directly benefit from savings generated through discount programs or price negotiations. CMS should explore options that balance monthly premiums with cost-sharing at the point of sale and share information on savings offered by plans in an easily understandable format so that patients and families have the useful financial information they need to support their health care decisions.

Part D Explanation of Benefits

While Part D end-of-year statements currently include some information about the negotiated price of prescription drugs, we have learned that patients are more interested in having clear information about their specific OOP cost-sharing responsibility and are eager to weigh these cost considerations when making health care decisions. However, weighing the cost trade-offs can only occur with a deeper understanding about the different cost components. A survey conducted in 2017 of primarily older adults found that only 75% knew their specific plan deductible, while over 90% were able to recall their monthly premiums and point-of-sale cost-sharing.⁷ CMS could provide more complete and understandable cost information in a user-friendly interface to address this critical gap in understanding about OOP costs.

⁶ Pharmacy Benefit Management Institute. 2017 Trends in Drug Benefit Design. Retrieved Jan 8, 2018. Available at: https://www.pbmi.com/PBMI/Research/PBMI_Reports/Drug_Benefit_Reports/PBMI/Research/Store/BDR.aspx?hkey=bfcca9f8-610e-4eca-a908-8ff451bb2f87

⁷ Patient Advocate Foundation. Patient Preference and Insurance Survey. Conducted 2017.

To begin, 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 premiums distinct from their deductibles. Information about lower-cost alternatives presented alongside estimated cost-sharing would better equip patients to discuss treatment options with their physicians and choose wisely in both Medicare Part B and D.

Further, CMS could enhance usability and simplify existing transparency tools to better assist patients and families in making decisions about their Medicare Part D plan. A recent report evaluating Medicare Plan Finder's (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.⁸ As a first step, we recommend that CMS better integrate personal 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.

Moving forward, we respectfully 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 many patient groups provided comments last year.

2. Reducing OOP Costs

Shifting Drugs from Medical to Pharmacy Benefit

Prescription drug coverage shifts from the Medicare Part B to Part D benefit as discussed in the Blueprint may achieve savings in the short-term but would impact payment and delivery dynamics of all stakeholders, leading to potentially harmful unintended consequences for seriously ill patients.

First, patients may face higher OOP costs because high-cost drugs covered under the Part B benefit typically incur 20% cost-sharing, compared to the Part D benefit in which drugs are subject to utilization management such as step therapy protocols and often incur 33% cost-sharing on the specialty tier.⁹ In fact, a recent analysis found that average OOP costs for new cancer drugs in 2016 were about 33% higher when covered by Part D compared to Part B.¹⁰ Higher cost-sharing, especially occurring unexpectedly, could result in non-medical switching as patients and their providers must consider alternative, less-ideal treatment options due to affordability concerns.

In addition to higher OOP costs, patients may experience confusion or delays in care if a physician-administered drug previously covered under the Part B benefit is now required to be dispensed through a specialty pharmacy. Storage and handling concerns may arise as patients and providers assume new responsibilities, such as brown bagging, a practice in which the patient retrieves a drug from the

⁸ 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>

⁹ Kaiser Family Foundation. Medicare Part D in 2018: The Latest on Enrollment, Premiums, and Cost Sharing. May 2018. Available at: <http://files.kff.org/attachment/Issue-Brief-Medicare-Part-D-in-2018-The-Latest-on%20Enrollment-Premiums-and-Cost-Sharing>

¹⁰ Brow M and Kane R. Avalere Analysis Highlights Complexities of Transitioning Medicare Part B Drugs into Part D. May 21, 2018. Available at: <http://avalere.com/expertise/life-sciences/insights/avalere-analysis-highlights-complexities-of-transitioning-medicare-part-b-d>

pharmacy to be administered by the physician thereafter.¹¹ Finally, we caution that while this proposal would lower drug spending, declines in medication adherence due to higher cost-sharing may lead to increased spending in Part B as patients may require other costly services due to ineffective disease management.

Such drastic benefit design changes may create challenges for patients and providers to secure an agreed-upon treatment and effectively manage their health conditions. We are concerned with this potential policy change and urge HHS to carefully consider the effects on OOP costs, health outcomes and care experience across different patient populations before moving forward. Alternatively, CMS could alleviate high OOP costs persisting in Part D by modernizing benefit design alongside current initiatives to pass rebates through to patients at the point of sale as discussed above. For instance, one analysis of drug rebates on patient and Medicare spending suggests that reconfiguring cost-sharing by utilizing copayments rather than coinsurance, for certain high-cost specialty drugs, could lower out-of-pocket costs for patients.¹²

Cap on Part D Out-of-Pocket Costs

We are encouraged by the Administration's proposal in the President's FY19 Budget, mentioned in the Blueprint, to create an OOP maximum for Medicare Part D beneficiaries above the catastrophic threshold. While 3.6 million beneficiaries reached the catastrophic coverage threshold in 2015, we are most concerned about the subset of patients (one million) exposed to the 5% coinsurance who do not receive low income subsidies (LIS) to help them afford their prescriptions.¹³ An annual OOP maximum would represent a true protection for seriously ill patients against high OOP costs for treatments needed to maintain their health. Researchers estimate that an OOP cap for all Part D beneficiaries would raise monthly premiums by only \$0.40 – \$1.31 per member.¹⁴

We strongly support introducing an OOP cap in Part D so long as cost-offsets do not substantially increase patients' overall financial responsibility such as through higher premiums. We respectfully ask that the agency consider policy solutions that account for insurance plan trade-offs and ultimately reduce patients' OOP costs, especially those who do not qualify for LIS and are unable to limit their financial liability.

Copay Discount Cards

In many instances, copay cards refer to coupons distributed by manufacturers to reduce OOP costs for a specific drug. This use of copay discount or coupon cards has increased significantly in recent years,

¹¹ Academy of Managed Care Pharmacy. Professional Practice Advisory on Brown Bagging. February 2009. Available at: <http://amcp.org/brownbagging/>

¹² Dusetzina SB, Conti RM, Yu NL, Bach PB. Association of Prescription Drug Price Rebates in Medicare Part D with Patient Out-of-Pocket and Federal Spending. *JAMA Intern Med.* 2017 August 01; 177(8): 1185–1188

¹³ Kaiser Family Foundation. Issue Brief. No Limit: Medicare Part D Enrollees Exposed to High Out-of-Pocket Drug Costs Without a Hard Cap on Spending. November 2017. Available at: <http://files.kff.org/attachment/Issue-Brief-No-Limit-Medicare-Part-D-Enrollees-Exposed-to-High-Out-of-Pocket-Drug-Costs-Without-a-Hard-Cap-on-Spending>

¹⁴ Trish E, Xu J, Joyce G. Growing Number of Unsubsidized Part D Beneficiaries with Catastrophic Spending Suggests Need for An Out-Of-Pocket Cap. *Health Affairs.* 2018 Jul 09;37(7). Available at: <https://www.healthaffairs.org/doi/10.1377/hlthaff.2018.0006>

from fewer than 100 branded drugs with coupons in 2009 to over 700 by 2015.¹⁵ There is concern that copay coupons may influence treatment decisions and incentivize the use of higher-cost drugs when generic alternatives are available. However, a recent report found that of the 200 highest-expenditure drugs in 2014, only 19 drugs (9.5%) had a copay coupon when a generic alternative was also available. It concluded that most coupons are not affecting generic drug use as a lower cost alternative and appear to help patients secure treatment when no other options exist.¹⁶ Further scrutiny reveals that the copay coupon landscape is extremely nuanced, requiring more detailed and comprehensive empirical studies about their impact to drug prices, generic drug use and overall impact on patient costs.

We emphasize that charitable patient assistance programs (PAPs), distinct from manufacturer copay cards, serve as an important safety net for lower-income patients by providing financial support for a broad array of products. For the most part, these programs support families facing 400% of federal poverty level (FPL) or lower, especially those coping with serious, chronic illness. Research has substantiated that below this financial threshold exists a significant need for patient access to health care subsidy support to afford cost sharing obligations and rising healthcare costs on top of their other daily living expenses.¹⁷ This need is especially true for Medicare beneficiaries due to the OOP pressure created by the Part D benefit design prior to reaching catastrophic coverage.

Unfortunately, the federally funded LIS program generally only reaches patients up to about 100% to 150% of FPL. PAPs extend this safety net support to Medicare beneficiaries who are prohibited by law from using coupons offered by manufacturers to offset their OOP drug costs. Charitable PAPs differ significantly from manufacturer programs in several ways, the most critical is that the latter are tied specifically to and can only be used for a specific product often regardless of income while the former provides financial support for low-income patients with a specific disease and they can use the support to help pay for a broad array of products used to treat their disease. For this reason, charitable copay support operates similar and complementary to the LIS as was the intent when the Office of Inspector General offered its guidance on such programs in a 2005 SAB as part of the Part D rollout.

We recognize the Administration's concerns that copay discount cards may impact drug pricing negotiations between plans and manufacturers, however, when no lower-cost alternatives exist, copay coupons may be a patient's only means of accessing a treatment they need. We respectfully request that any action taken to regulate copay discount cards involve key stakeholder engagement, including those that work directly with low-income patients.

3. Ensuring Access

Medicare Part D Protected Classes

As HHS considers various Part D proposals in the Blueprint, we appreciate the opportunity to reinforce our strong support for maintaining the six protected classes in Medicare Part D. The protected classes

¹⁵ Johnson, Carolyn Y. (May 12 2016) Secret rebates, coupons and exclusions: how the battle over high drug prices is really being fought. The Washington Post. Retrieved on 7/9/18 from: https://www.washingtonpost.com/news/wonk/wp/2016/05/12/the-drug-price-arms-race-that-leaves-patients-caught-in-themiddle/?utm_term=.826b55a86e56

¹⁶ Van Nuys K et al. USC Schaeffer. A Perspective on Prescription Drug Copayment Coupons. February 2018.

¹⁷ Patient Advocate Foundation. Roadmap to Consumer Clarity in Health Care Decision Making. May 2017.

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 access to drugs within the protected classes should be high priority for HHS, followed by policy solutions that guarantee patients can obtain treatments chosen with their physician at an affordable cost.

We are aware that the protected classes policy has been a focus for cost-savings because of plan negotiation dynamics. While loosening coverage requirements for drugs in the protected classes may enable prescription drug plans 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 and additional factors.¹⁸ We share concerns of the broader health care community that any changes to coverage of the Part D protected classes would result in adverse patient health outcomes and urge HHS to retain the six protected classes in their present form.

Further, access issues beyond the protected classes affecting even more patients are also concerning. Maintaining patient choice in Part D will be increasingly critical in the emerging era of precision medicine, which suggests that more choices can optimize the chance of finding the best treatment for a patient. The U.S. has invested heavily in the basic science to drive enormous advancements in highly targeted therapies. It would be unfortunate to restrict access to such person-centered treatments by limiting Medicare beneficiaries' treatment choices.

In conclusion, we are encouraged by the Administration's attention to lowering patients' OOP drug costs and appreciate the opportunity to submit comments. We stand ready to provide feedback from patient, caregiver and family perspectives and partner with the Administration on new strategies to reduce consumer OOP spending and improve health care cost transparency. Please contact Nicole Braccio, policy director for NPAF and REAP convener at Nicole.Braccio@npaf.org or 202-516-5212 if we can provide further details or assistance.

Respectfully submitted,

AIDS United
Alpha-1 Foundation
COPD Foundation
Global Healthy Living Foundation
Lung Cancer Alliance
LUNGeVity Foundation
Mended Hearts
National Minority AIDS Council
National Patient Advocate Foundation
National Viral Hepatitis Roundtable
Prevent Cancer Foundation
The AIDS Institute

¹⁸ 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