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VIA ELECTRONIC SUBMISSION THROUGH www.regulations.gov

The Honorable Alex M. Azar
Secretary
Department of Health and Human Services
200 Independence Avenue, SW
Room 600E
Washington, DC 20201

Re: Request for Information on the U.S. Department of Health and Human Services Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs (HHS-OS-2018-0010)

Dear Secretary Azar,

The Alliance for Aging Research welcomes the opportunity to submit comments in response to the U.S. Department of Health and Human Services (HHS) Request for Information (RFI) on the Blueprint to Lower Drug Prices and Reduce Out-of-Pocket (OOP) Costs.

The Alliance for Aging Research (Alliance), www.agingresearch.org, is the leading nonprofit organization dedicated to accelerating the pace of scientific discoveries and their application to vastly improve the universal human experience of aging and health. The Alliance believes that advances in research help people live longer, happier, more productive lives and reduce healthcare costs over the long term and that access to the latest scientific information empowers people to take control of their health. The Alliance strives to advance science and enhance lives through a variety of activities and initiatives – from policy issues to provider and consumer health programs – that generate knowledge and action on age-related matters.

Introduction

Medicare Part D provides vital access to prescription drugs for more than 43 million older adults and people with disabilities[1]. When Part D beneficiaries take their medicines as prescribed, there is increasing evidence that their health outcomes are improved. Overall, surveys show that Part D beneficiaries are satisfied with the program[2]. Yet there still are beneficiaries who experience challenges with it.

[1] Cubanski J. What's in the Administration's 5-Part Plan for Medicare Part D and What Would It Mean for Beneficiaries and Program Savings? June 20, 2018. Kaiser Family Foundation (https://www.kff.org/medicare/issue-brief/whats-in-the-administrations-5-part-plan-for-medicare-part-d-and-what-would-it-mean-for-beneficiaries-and-program-savings/) Accessed July 10, 2018.

[2] Nearly 9 in 10 Seniors Are Satisfied with Part D. http://medicaretoday.org/resources/senior-satisfaction-survey/. Published 2017. Accessed July 13, 2018.

Despite premiums recently remaining stable, the cost-sharing requirements for drugs covered by plans have increased over time[3]. Because it has no annual cap on out-of-pocket spending, Part D coverage "does not fully protect beneficiaries from high drug costs…Enrollees who do not receive low-income subsidies are required to pay 5 percent of total drug costs above the catastrophic threshold.[4]"

In 2016, one-half of all adults age 65 and older had less than $23,394 in annual income.[5] Not filling prescriptions, delaying treatment or curtailing their use can have life-threatening consequences. The inability to share the cost of a medication or pay its increased OOP cost can often make the difference between health and sickness and, in some cases, an individual's mortality. With continuing advances in biotechnology and drug development, individuals who cannot afford the most appropriate, recent benefits of scientific and medical research will have to settle for what may be less effective options for their treatment.

The Alliance understands the proposals in the Blueprint are exploratory and lack sufficient detail to analyze them as in the regulatory process. Therefore, we urge HHS to utilize the formal rulemaking process as it explores options to lower drug prices and reduce OOP costs.

Our comments focus on four themes: beneficiary access, beneficiary coverage, and transparency and communication, and innovation. Although we are aware that the Blueprint recommends an "All or None" 5-Part Plan for Part D, we have addressed these points separately because we realize the difficulty in implementing all points simultaneously.

Sharing Rebates at Point of Sale with Part D Enrollees

The Alliance applauds the Administration's move to require Part D plans share a portion of rebates at the point of sale to permit Medicare enrollees to benefit directly from the discounts and rebates provided by manufacturers. A November 2016 a Milliman report concludes that "Part D plans have a financial incentive to cover drugs with higher list prices and higher rebates as a means of driving down the premium…. Moreover, because benefit designs have shifted more to coinsurance for brand drugs (based on list prices), beneficiaries who take medications with high rebates are not benefitting financially from them…"[6] This policy would produce savings for beneficiaries and lower their OOP costs for prescription fills. It also would be helpful for those who pay cost-sharing at a "coinsurance rate."

However, we remain concerned that the Administration states that this would "allow beneficiaries to share directly in the savings from discounts." This could lead to raising premiums for everyone by increasing plan costs.

Changing Calculation of "TrOOP"

A 2016 Avalere Health study concluded that "excluding manufacturer coverage gap discounts from TrOOP (True Out-of-Pocket) costs would increase OOP costs for beneficiaries who have high enough drug spending to

[3] Cubanski J. What's in the Administration's 5-Part Plan for Medicare Part D and What Would It Mean for Beneficiaries and Program Savings? June 20, 2018. Kaiser Family Foundation (https://www.kff.org/medicare/issue-brief/whats-in-the-administrations-5-part-plan-for-medicare-part-d-and-what-would-it-mean-for-beneficiaries-and-program-savings/) Accessed July 10, 2018.

[4] Ibid

[5] Income of Today's Older Adults. Pension Rights Center. www.pensionrights.org/publications/statistic/income-today's-older-adults Accessed July 10, 2018

[6] Barnhart J and Gomberg J of Milliman, Inc. The AIDS Institute. http://theaidsinstitute.org/sites/default/files/attachments/Milliman%20Report%20-%20Final.pdf. Published November 3, 2016.

approach or reach the catastrophic portion of the benefit."[7] The study estimates that 1.1 million Part D enrollees would have higher OOP costs each year between 2017 and 2021 and total Part D enrollee spending would increase by about $5.1 billion over the same time. Every beneficiary's Part D spending would increase, on average, by almost $1,000 each year through the 5-year period.[8]

Currently, the required 50 percent manufacturers discount in 2018 will increase in 2019 to 70 percent on the price of brand-named drugs filled by beneficiaries in the coverage gap. Although considerable savings have been generated for Part D beneficiaries who get to the coverage gap, this policy change also helps speed more enrollees through the coverage gap.[9] Although the number of low-income subsidy (LIS) beneficiaries who reached catastrophic coverage between 2007 and 2008 was comparatively steady, it has increased each year since then from .5 million in 2012 to 1 million in 2015.[10]

If the value of the manufacturer discount was excluded from calculating TrOOP, Part D beneficiaries who reach the coverage gap would face higher OOP costs in that phase and would travel through the coverage gap more slowly, meaning fewer enrollees would reach the catastrophic coverage gap. Higher OOP costs could lead to fewer beneficiaries getting and/or taking their prescription therapies. Although this could lead to lower utilization and possibly lower premiums, this likely would not lead to improved health for patients. For these reasons, the Alliance opposes excluding manufacturer coverage gap discounts from TrOOP costs.

Adding an Out-of-Pocket Limit to Part D

The Medicare Part D benefit is multifaceted and levies high OOP costs on enrollees, through deductibles and copayments. With numerous specialty tiers, subject to coinsurance and excluded from cost sharing exceptions, beneficiaries pay a significant amount of their medication costs. Many older adults, who have comorbidities, may need to pay for multiple drugs. For prescription therapies covered by the specialty tiers, beneficiaries pay between 25 to 33 percent, pocketing thousands of dollars in OOP costs for drugs and biologics to treat numerous chronic, disabling, serious or life-threatening diseases, such as Alzheimer's, heart disease, cancer, diabetes, arthritis, and other conditions.

Patients who can afford their prescribed medications often pay high OOP costs to stay healthy. A study published in 2017 cited the following average annual cumulative OOP costs for Medicare beneficiaries[11]:

- Rheumatoid arthritis: $3,949
- Multiple sclerosis: $5,238
- Chronic myeloid leukemia: $6,322

Adding an OOP cap would reduce OOP costs for Part D beneficiaries who get to the catastrophic coverage phase of the benefit. Although an estimated 30 percent of Medicare enrollees receive a Part D LIS, too many seniors are hit with unaffordable OOP drug costs[12]. According to Kaiser Family Foundation, in 2015, one million Part D

[7] Assessing the Impact of MedPAC's Proposed Part D Reforms to Modify Beneficiary Cost Sharing. Avalere; 2016. http://avalere.com/expertise/life-sciences/insights/avalere-analysis-on-medpacs-proposed-part-d-reforms-to-modify-beneficiary-c. Accessed July 13, 2018.

[8] Ibid

[9] Cubanski J. What's in the Administration's 5-Part Plan for Medicare Part D and What Would It Mean for Beneficiaries and Program Savings? June 20, 2018. Kaiser Family Foundation (https://www.kff.org/medicare/issue-brief/whats-in-the-administrations-5-part-plan-for-medicare-part-d-and-what-would-it-mean-for-beneficiaries-and-program-savings/) Accessed July 10, 2018.

[10] Ibid

[11] Map Rx Coalition letter on HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs. July 16, 2018.

[12] The Medicare Part D Prescription Benefit. Kaiser Family Foundation. October 2, 2017. (https://www.kff.org/medicare/fact-sheet/the-medicare-prescription-drug-benefit-fact-sheet/) Accessed July 10, 2018.

beneficiaries who did not get LIS had spent in the catastrophic coverage part of the Part D benefit.[13] Their average OOP cost in this phase was $1,215. Additional coverage would assure all Part D beneficiaries of limited OOP costs if their prescribed drugs costs were high. For these reasons, the Alliance strongly supports an OOP limit for the Part D Medicare benefit.

Narrowing Part D Formulary Standards

Part D Medicare plans currently are required to cover at least two drugs in each therapeutic class – that is, a group of drugs used to treat the same disease or condition – and to cover all or substantially all drugs in six "protected" classes. The protected therapeutic classes include anti-retrovirals, immunosuppressants, antidepressants, antipsychotics, anticonvulsant agents, and anti-neoplastics. Among the diseases and conditions these drugs treat are HIV-AIDS, organ rejection, epilepsy, cancer and mental illnesses.[14] Because many older adults have multiple diseases with myriad sequelae, these drugs are often in older individuals. Twenty-five percent of cancer patients have clinical depression.[15] A large number of older patients have complicated medical needs and significant comorbidities, so they may need to try a variety of nuanced therapies before they find treatments that are appropriate and effective.

An Avalere Health 2016 study indicates that "little evidence exists to show that limiting formulary access leads to meaningful cost savings…. (W)hile formulary restrictions often lead to lower drug spending, they were accompanied by increases to inpatient and outpatient medical care that outweighed savings achieved on prescription drugs."[16]

The Administration has said this proposal would allow Medicare Part D plans (PDPs) to "better manage" the drug benefit. Eliminating the protected class designation could allow PDPs to obtain savings through leverage in price negotiations, and thus could lower Medicare and plan costs, and possibly lower premiums. However, according to a 2018 Pew Charitable Trusts policy paper, "…given the current high rates of generic use within the protected classes, there may be limited potential for savings from changes to …(current) policy. "[17] Pew further states that where there are no generic alternatives to brand-name drugs, those that are widely used may not be excluded and thus, may not account for substantial savings with this proposed policy.

The Alliance strongly supports the existing policy that requires Medicare Part D plan sponsors to cover two drugs in each drug class, including the six protected classes and strongly opposes allowing plans to cover only one drug per category and class. If Part D formulary standards were narrowed, beneficiaries could have more restrictive plan formularies. They would face increased burdens in obtaining some prescribed medications, and they could have more difficulty in finding plans to cover their needed pharmaceutical therapies. In addition, beneficiaries

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[13] Cubanski J. What's in the Administration's 5-Part Plan for Medicare Part D and What would It Mean for Beneficiaries and Program Savings? June 20, 2018. Kaiser Family Foundation (https://www.kff.org/medicare/issue-brief/whats-in-the-administrations-5-part-plan-for-medicare-part-d-and-what-would-it-mean-for-beneficiaries-and-program-savings/) Accessed July 10, 2018.

[14] Policy Proposal: Revising Medicare's Protected Classes Policy. The Pew Charitable Trusts. Fact Sheet. March 2018. (http://www.pewtrusts.org/en/research-and-analysis/fact-sheets/2018/03/policy-proposal-revising-medicares-protected-classes-policy) Accessed July 10, 2018

[15] Partnership for Part D Access letter to Secretary Azar on access issues particular to Medicare Part D;Six protected class policy. April 9, 2018.

[16] Ibid.

[17] Policy Proposal: Revising Medicare's Protected Classes Policy. The Pew Charitable Trusts. Fact Sheet. March 2018. (http://www.pewtrusts.org/en/research-and-analysis/fact-sheets/2018/03/policy-proposal-revising-medicares-protected-classes-policy) Accessed July 10, 2018.

and Medicare could face additional costs from avoidable physician visits, hospitalizations and other interventions that would have been unnecessary had there been increased access to prescription drugs.

Eliminating cost sharing for generics for low-income enrollees

Beneficiary access to prescription therapies and care is often derailed by copayments and coinsurance. For low-income enrollees, relatively small copayments can mean the difference between purchasing a prescription and leaving it at the pharmacy counter, or splitting pills, or skipping doses. By permitting generics to be available without any OOP cost, the Administration helps low-income beneficiaries have access to therapies they need to adhere to prescribed treatments. Therefore, the Alliance strongly supports eliminating cost-sharing for generics for low-income beneficiaries and appreciates the agency's leadership on this topic. When no generic products are available, which is often the case for certain serious illnesses, the Alliance encourages HHS to look for ways to lower or waive copays for brand products.

Establishing differential copays for off-label indications

Medicare has long-standing policy of providing coverage and payment for off-label therapies, so long as certain criteria are met. This policy, from its inception, has enjoyed broad support among a bipartisan group of members of Congress, as well as physicians, nurses, and other health professionals, and the patient advocacy community. The Medicare off-label access policy ensures that there is scientific evidence showing that use of the drug for the off-label indication is safe and effective. This helps ensure that coverage and payment are aligned with other Medicare policy related to medical appropriateness. We presume that the proposal to establish differential copays for off-label indications means that the Administration would like to charge higher copayments for patients receiving an off-label usage than an on-label prescription. We have serious concerns about the barrier this change could pose to patients in need of life-saving care.

Very often prescriptions used off-label are to treat cancer, autoimmune conditions, and neurodegenerative conditions, such as Multiple Sclerosis. New research unambiguously shows that cost-sharing prevents Medicare Part D beneficiaries from initiating and adhering to a new, life-saving cancer treatment. Congressional intent in creating the off-label policy was to facilitate and ensure beneficiary access to needed treatments and as part of that intent, envisioned that the policy would level the playing field for beneficiaries needing off-label prescriptions. As such, efforts to increase OOP spending associated with off-label usage would discriminate against beneficiaries with certain diseases and conditions, impede patient access to much-needed treatment, and run counter to Congressional intent and long-standing Medicare payment policy. The Alliance would have serious concerns about the barriers this change could present to older patients who need life-saving and life-sustaining care.

Prohibiting "Pharmacy Gag-Clauses" in Part D

Patients have a right to accurate information regarding their health care choices. The Alliance supports the Administration's efforts to prohibit Part D plans from preventing pharmacists from informing patients of lower cost options available to them in "gag clauses" of a plan-pharmacy benefit manager contract. For example, for certain medicines, patients may save money if they pay out-of-pocket outside of their plan or use (often less expensive) generic alternatives. Health insurance is intended to help patients access health care by making it more affordable, including the medicines they need, and "gag clauses" do the contrary by withholding information about for patients.

However, one potential unintended consequence is that patients may choose lower-cost options outside of their plan and end up paying more in the long run as they stop making out-of-pocket payments that count to their total out-of-pocket costs (TrOOP). We fully support the Administration's effort to end gag clauses but encourage greater pharmacist education to ensure that they are aware of this unintended consequence.

Providing Improved Transparency and Communication/Non-Medical Switching
The Alliance believes that providing more information in an easy-to-understand format is helpful for Medicare beneficiaries. The Alliance supports the Administration's proposal to update the Medicare and Medicaid drug-pricing dashboards to make prices increases more transparent, including highlighting products that have not taken price increases.

We would also like to address an issue with the complexity of language used in the dashboard as it currently stands. The level of language used by this decision tool in its introduction surpasses the health literacy of the average American. If information were provided in a more "user-friendly" format, it would make information provided more useable to patients.

We would encourage HHS to call for strategies to improve beneficiary medication adherence. The Alliance has been active on the specific issue related to "non-medical switching" of oral anticoagulants. Non-medical switching refers to a formulary decision-making process designed by Part D drug plans to limit prescription coverage to less expensive medications (also called formulary-driven switching). The change in medication is determined by the plan formulary without any consideration of the medical repercussions or a physician's knowledge and reasoning behind the selection of the original prescription medication. We encourage HHS to explore the scale and impact of the medical consequences of switching and whether there should be a mechanism in place for providers to be notified before a change is made at the pharmacy counter.

Smoothing Out OOP Expenses/Fixing the "Seasonality" of Triggering Catastrophic Coverage
There are numerous Medicare Part D beneficiaries who are prescribed different medicines for multiple diseases. If someone has an income that is 400 percent of the Federal Poverty Level, they are ineligible for LIS. So, this hypothetical person has high coinsurance requirements, up to 33 percent, for relatively new classes of prescription drugs. If they should be prescribed and need such a medicine for only one of his illnesses, they likely could not afford it. Furthermore, under Part D, the coinsurance requirements for expensive specialty medicines decrease across the year, with the highest costs earlier in the year. Therefore, this person could pay 40 percent coinsurance at the beginning of the year, but when they enter the Catastrophic Coverage Phase, they only would pay 5 percent coinsurance.[18]

The seasonality of OOP expenses and hitting the annual OOP cap is not only a concern for patients on Medicare, but also for individuals with commercial insurance. Thus, we urge the Centers for Medicare and Medicaid to consider policies that do not "front-load" OOP expenses and take into consideration the high cost of medications on specialty tiers.

REMS Abuse
The Alliance believes that for medicines with known or potential risks, the appropriate use of Risk Evaluation and Mitigation Strategies (REMS) is an important tool to ensure patient safety. However, the Alliance shares HHS' view that misapplication of REMS (or other distribution restrictions) often prevents generic and biosimilar product developers from buying enough of the brand product to conduct the comparison studies required for FDA approval of a generic or biosimilar. Additionally, in cases in which FDA requires that a brand and generic share a single REMS, extended negotiations may delay generic product entry into the market.
The Alliance supports the efforts to prevent REMS (or non-REMS based limited distribution schemes) from being a barrier to the development and market entry of lower-cost generic and biosimilar products. We encourage any effort in this regard to fully protect patient safety and look forward to the opportunity to work with Congress and the administration to ensure a thoughtful and appropriate policy is developed and enacted.

[18] PAN Coalition letter on HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs. July 16, 2018.

Biosimilars
The Alliance is supportive of policies that can improve competition in the biosimilars market by promoting innovation and competitiveness of biologic products. According to a RAND Study, specialty drugs are administered in 1 to 2 percent of the U.S. population, but account for 38 percent of prescription drug spending[19]. A robust biosimilar market has the potential to reduce prescription drug costs in our country and increase access to life-changing medications. We would call on the FDA to develop a more efficient regulatory system for the approval of biosimilar products.

Shift from Part B to Part D
The Alliance shares the concerns of the Adult Vaccine Access Coalition (AVAC) regarding movement of immunization coverage from Medicare Part B to Part D, considering the potential impact this change could have on patient and provider access to vaccinations. As it currently stands, provider payment for adult vaccines is particularly burdensome under Medicare Part D. The cost of merely stocking the vaccine can often exceed the payment a physician receives for administering it. The complexity of the vaccination reimbursement under Part D means that many providers opt to not offer the service.

We agree with AVAC's recommendation for CMS to support billing systems that enables providers to review a patient's Part D vaccine coverage and to directly bill Part D plans for the cost and administration of covered vaccines. We would also request that CMS commission on a study on the impact this system would have on vaccination rates and its cost-effectiveness to the Medicare program.

Conclusion
The Alliance appreciates the opportunity to provide comments on the RFI for the HHS Blueprint on Lower Drug Prices and Reduce Out-of-Pocket Costs. We believe that older adults and all patients with serious, chronic and life-threatening diseases should have access to quality healthcare. Please do not hesitate to contact the Alliance's Vice President of Public Policy, Missy Jenkins at (202) 688-1230 or mjenkins@agingresearch.org.

Sincerely,

Susan Peschin, MHS
President and CEO

Ellen "Missy" Jenkins
Vice President of Public Policy

[19] Mulcahy, Andrew W., Jakub P. Hlavka, and Spencer R. Case, Biosimilar Cost Savings in the United States: Initial Experience and Future Potential. Santa Monica, CA: RAND Corporation, 2017. https://www.rand.org/pubs/perspectives/PE264.html.