

July 16, 2018

Office of the Secretary
Department of Health and Human Services
200 Independence Avenue, SW
Room 600E
Washington, DC 20201
Submitted Electronically via www.regulations.gov

Re: HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs – Policy Statement;
Request for Information

Dear Secretary Azar:

We appreciate the opportunity to provide our comments the administration's Request for Information (RFI) regarding the Department of Health and Human Services (HHS) Blueprint to Lower Drug Prices and Reduce Out-of-Pocket (OOP) Costs (Blueprint).

ZERO is the leading national nonprofit with the mission to end prostate cancer. We fight to advance research, improve the lives of men and families, and inspire action against a disease that kills a man every 18 minutes – more than 80 deaths per day and 29,430 this year – enough to fill an entire baseball stadium.

Prostate cancer is the most commonly diagnosed cancer in men after skin cancer. When diagnosed at an early stage, it can usually be treated successfully. In fact, almost 100 percent of men diagnosed with prostate cancer today will be alive in five years. However, some cases of prostate cancer are aggressively lethal and quickly spread to other organs or bones.

As a key focal point of our mission, ZERO organizes and manages national efforts to protect and grow federal research funding that has led to several key prostate cancer treatments for extending and improving the lives of men. In fact, federal research grants are responsible for the development of three new drugs to combat metastatic prostate cancer over the last eight years.

It is a tragedy when men cannot access these life improving and extending treatments because of large out of pocket requirements. Further, the investments our government has made in research does not achieve its full value if patients cannot access the treatments once they arrive to the market.

As a charitable non-profit, ZERO tries to ease this burden. At times, ZERO has been able to distribute charitable assistance to Medicare beneficiaries struggling to access their prostate cancer therapies. Presently, ZERO provides comprehensive case navigation to prostate cancer patients. The expert case managers help patients navigate the complex healthcare landscape and access government benefits and programs, charities, and industry-supported relief.

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Across disease states, organizations like ZERO can help patients access drugs where their insurance coverage falls short (or is non-existent). The Federal Government should provide a friendly environment and funding for organizations like ZERO to help beneficiaries find optimal benefits, coverage, and assistance.

With regard to provisions in the RFI, ZERO would like to offer the following comments:

Part D Out-of-Pocket Maximum: ZERO supports establishing an out-of-pocket maximum for Medicare Part D patients. An out-of-pocket maximum will ensure that beneficiaries are not at unlimited risk for their drug expenses and that insurers bear more risk under the benefit.

Passing on Manufacturer Rebates and Discounts to Beneficiaries: ZERO believes that insurers should not be able to use drug rebates and discounts to subsidize lower premiums. All beneficiaries (sick and healthy alike) should pay in premiums to support claims from beneficiaries who need the benefit. Presently, the insurers and pharmaceutical benefit managers (PBMs) are using those discounts to lower premiums, thereby attracting new members to their plans. The beneficiaries who utilize the drugs should benefit from the drug rebates and discounts offered by the manufacturers.

Moving Part B Drugs to Part D: ZERO urges the administration to be cautious in switching physician administered cancer drugs from the Medicare Part B benefit to the Part D benefit.

Firstly, we are concerned this will have a deleterious impact on patient out-of-pocket costs. Part B beneficiaries are responsible for a 20% out of pocket copay. Typically, Part D beneficiaries can have copays of 25% to 40%. Further, 80% of Medicare Part B beneficiaries have supplemental insurance like Medigap that shields them from the full brunt of their out-of-pocket requirements. Aside from the Low Income Subsidy (LIS), there is no such relief for beneficiaries under Part D (except for charitable assistance but that model has come under scrutiny and as a result died off in the last couple years). We recommend financial modeling of the impact to beneficiaries prior to making any changes and considering increasing the LIS.

Secondly, we urge caution with moving physician administered drugs because of the technical aspects of purchasing, storing, transporting, and delivering these drugs. It's important to ensure the integrity and quality of the drugs, that their delivery remain intact, and the safety of the patient.

Changing the Numbers of Drugs in Each Category or Class Under the Part D Benefit: ZERO is against limiting the number of drugs in each category or class under the Part D benefit. This policy could limit treatment options and increase disease and financial burden on prostate cancer patients. As an example, metastatic prostate cancer patients can become resistant to their prescribed hormone therapy over time. Once that resistance develops, many patients can begin a second hormone therapy that will continue to fight the cancer. While we understand the negotiating power this might provide Part D plans, the aggressiveness of the tumor is too complex to rely on one drug to fight it.

Eliminating the Pharmacist Gag Rule: ZERO supports banning "gag clauses." We believe that pharmacists should be allowed to alert patients about potential savings. As you know, "gag clauses" prevent pharmacists from telling patients if it is less expensive to purchase a drug for

cash than to go through the patient's insurance benefit. We support the patient having as much information as possible and empowering the patient to save money.

Fix the Out-of-Pocket Cliff: Because of a sunset provision in the Affordable Care Act (ACA) meant to save beneficiaries money, Part D patients could face an additional \$1,200 in out-of-pocket spending before moving on to the catastrophic benefit. Congress should fix this "cliff" by easing the burden of a sudden increase in required coverage gap spend.

We thank the administration for addressing high out-of-pocket requirements and appreciate the opportunity to comment. We look forward to the outcomes of this RFI process after the administration digests the comments of a diverse array of stakeholders. In the meantime, please do not hesitate to contact me about any of these comments at Jamie@zerocancer.org or 202-303-3105.

Be Well,



Jamie Bearse
President & CEO
ZERO - The End of Prostate Cancer