July 16, 2018

Office of the Secretary
Department of Health and Human Services
200 Independence Avenue, SW
Room 600E
Washington, DC 20201

Dear Secretary Azar:

The International Myeloma Foundation is appreciative of the opportunity to provide comments on the HHS *Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs*. We are eager to provide you with our comments and convey the perspectives and experiences of myeloma patients.

Founded in 1990, the International Myeloma Foundation (IMF) is the oldest and largest myeloma-specific patient advocacy organization in the world. With more than 350,000 members in 140 countries, the IMF serves myeloma patients, family members, and the medical community. The IMF provides a wide range of programs in the areas of Research, Education, Support, and Advocacy. With myeloma being the second most common form of blood cancer, we serve many patients who are personally impacted by high out-of-pocket costs and we are happy to act as a resource to you.

Five-Point Plan

We would first like to express our views on the President's five-part plan to address high patient out of pocket and spending within the Medicare Part D program. While we understand it is the intention of the Administration to implement all these points together, we have concerns about several pieces of this proposal and feel it is important to address each point individually.

1. **Point of Sale Rebates:**

   In the five-point plan, you propose requiring plans to share a portion of drug rebates with patients at the pharmacy counter. We are supportive of this idea and agree with the Administration; this will both "improve price transparency" and "allow beneficiaries to share directly in the savings from discounts."

2. **Establishing an Out-of-pocket cap**

   We commend the agency for recognizing and addressing the high out-of-pocket expenses beneficiaries are paying. We are supportive of an out-of-pocket cap for Part D and believe this will significantly help patients in the catastrophic phase. Presently, many myeloma patients struggle to access the medications deemed most clinically appropriate

for them by their physicians because of high out-of-pocket costs. This proposal will help myeloma patients who are often paying the most out-of-pocket for their medications.

3. **Eliminating cost-sharing on generic drugs for low-income beneficiaries**

   We were pleased to see the Administration's proposal to eliminate cost-sharing on generics for Low-Income Subsidy beneficiaries. We are supportive of this idea and believe this will help generate greater access. In the same vein, we are also appreciative of the Administration's efforts to encourage bringing new generics to market.

4. **Excluding manufacturer discounts from beneficiaries' true out-of-pocket spending (TrOOP)**

   We have deep concerns with the Administration's proposal to exclude manufacturer discounts from a beneficiary's true out-of-pocket-spending. This change would put patients with high cost drugs, such as myeloma patients, into the coverage gap for a much longer amount of time and increase how much patients pay out-of-pocket for their prescriptions. We believe the implementation of this portion of the proposal will cause additional financial difficulties for patients who are already struggling to make ends meet, with unforeseen consequences to the support community of older patients.

5. **Increasing formulary flexibility**

   When addressing formulary flexibility, we hope you will keep the needs of cancer patients in mind. This vulnerable population must have timely access without additional barriers to the drugs recommended by their physicians. We have several concerns with the Administration's proposal regarding formulary flexibility.

   We are opposed to the proposal to eliminate the current requirement on Part D plans to cover at least two drugs per therapeutic category and reduce that number to one drug per category. Most myeloma patients, as well as cancer patients in general, are on combination therapies and we believe this change could jeopardize timely access for myeloma patients to the personalized combinations of medication these patients need to survive. The current requirement of two drugs per classes allows for flexibility in structuring the coverage, while still recognizing the needs of vulnerable patients.

   We are also concerned about the possibility of making changes to the Six Protected Classes or weakening the current policy in any way. As you are aware, in 2014, CMS proposed making changes to the protected classes and ultimately chose not to finalize the rule. Many myeloma patients depend on antineoplastic drugs as part of their treatment regimens and the current Medicare policy requiring coverage of the drugs in the Six Protected Classes is beneficial to our patients and their ability to access the drugs they need.

Part B to D

We also wish to express our reservations about the idea of moving oncology Part B drugs into Part D. Our organization has general preliminary concerns about this proposal in regard to beneficiary access to oncology drugs. These includes concerns surrounding potential delays in treatment, reduction in adherence to medications, problems with dosing flexibility, increased cost-sharing to beneficiaries, and the possibility of premium increasing for all beneficiaries due to new stresses being put on the Part D program. Most importantly, safety issues stemming from the new operational challenges arise when moving some of these drugs into Part D for both patients and providers.

That said, we wish to provide you with some specifics about how this policy change would be damaging when applied to drugs commonly used to treat myeloma. Presently, there are both IV and injectable myeloma drugs covered under Medicare Part B. Moving either IV or injectable myeloma drugs into Part D could present devastating challenges for patients and providers.

Our first concern is with potential access issues that could arise from moving these drugs from Part B to Part D. This change may well result in some beneficiaries losing coverage for their drugs all together and could restrict access to drugs for many others. According to a 2017 MedPAC report, approximately 12 percent of Medicare beneficiaries have no prescription drug coverage or have coverage less generous than Part D. [1] Myeloma patients in this demographic would be faced with new barriers to accessing the medications they need. Additionally, we also have concerns about the increased out-of-pocket expense myeloma patients would face. Due to a variety of factors, including differences in cost-sharing, and the fact that the majority of Medicare beneficiaries have supplemental coverage to aid with their Part B expenses, most myeloma patients currently pay significantly more money for their drugs covered under Part D than those covered under Part B.

In addition to the increased out-of-pocket myeloma patients would likely face by moving these drugs into Part D, we also have safety concerns. Both IV and injectable Part B myeloma drugs require special handling. While it is unclear how patients would receive their drugs if these drugs would shift to B to D, we want to express some preliminary concerns. We are greatly opposed to patients "brown-bagging" or purchasing their own drugs and delivering them to their physician's office. Many of these drugs are highly sensitive and they risk being damaged or ruined. CMS has also recognized the safety issues stemming from "brown-bagging" drugs and we hope you will continue to oppose this.[2] We also have concerns with specialty pharmacies delivering drugs directly to patients as many of these same challenges exist.

Lastly, we want to emphasize that our concerns apply not only to IV myeloma drugs, but also to the potential of moving Part B injectable oncology drugs, such as Velcade (Bortezomib) into part D.

Streamlining Medicare

[1] http://www.medpac.gov/docs/default-source/reports/mar17_medpac_ch14.pdf
[2] https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/downloads/chapter6.pdf

We applaud the Administration's willingness to examine ways to make the Medicare program more transparent and easier for beneficiaries to navigate. Myeloma most commonly afflicts patients who above the age of 60 with the average diagnosis occurring at age 70. Any positive changes made to improve information patients receive or enhance beneficiary experiences when navigating the program will be greatly appreciated by our patient population. As you are aware, navigating Medicare can be very daunting for a beneficiary and many aspects of the program are not consumer friendly.

We believe patients could benefit from improvements to Medicare's plan finder, the explanation of benefits Medicare beneficiaries receive, Medicare's Drug Dashboard, and in areas of communicating drug costs to part D beneficiaries. In particular, we would like CMS to consider consumer testing of proposed changes. We also wish to see information being provided to patients that will help them make informed decisions about lower cost alternatives when it comes to receiving care. We are happy the Administration is taking steps to provide patients with information regarding pricing and we hope you will continue to work to ensure patients are educated before purchasing their drugs.

Value Based Care

We recognize that the cost for cancer care has continued to rise as innovative but expensive treatments enter the market, and that a means by which to measure cost-to-value has become a focal point for payers. However, we caution against a reliance on pure data-driven framework models that employ a generalized mathematical formula to derive value; ignoring the need for personalized medicine in cancer care.

We understand that value based arrangements have the potential to reduce costs while also improving quality, however value based arrangements must be patient-centered. Ultimately, we want to ensure any value based arrangement being considered will include patients and myeloma specialists in the process of determining what is of value.

We specifically want to voice our concerns about the myeloma drug cost assessment report drafted by the Institute for Clinical and Economic Review (ICER) and the impact using this report to implement a value based arrangement would have on both patients and the doctor patient relationship. Dr. Brian GM Durie MD, who serves as the Chairman of the IMF board and one of the world's most renowned myeloma experts criticizes the approach taken by ICER. Dr. Durie recommends taking an approach that recommends taking the input from disease experts. In that vein, we would like to offer up our organization.[3]

While considering value based care proposals, we would like to offer up our organization and our expertise to you. The IMF formed the International Myeloma Working Group (IMWG) in 2001 which is an international body of more than 200 myeloma experts. The IMWG works to address issues such as this. We are happy to provide the Administration with experts from both the IMWG and our patient population when discussing value based frameworks and how they could impact myeloma patients.

Benefits Design and Impact on Patients Abandoning Drugs at the Pharmacy Counter

[3] https://www.myeloma.org/blog/dr-duries/myeloma-experts-not-bureaucrats-should-create-treatment-recommendations-patients

In the "*American Patients First*" document, an important point is raised which is extremely significant to our patients. You reference a study examining prescriptions abandoned at the pharmacy stating, "One study found that consumers asked to pay $50 or more at the pharmacy counter are four times more likely to abandon the prescription than a consumer charged $10." Sadly, myeloma patients and others battling cancer are often charged significantly more than $50.

There is a unique problem facing cancer patients to which we wanted to make the Administration aware. For many cancer patients with both Medicare and private insurance, antiquated insurance benefit designs require patients to pay more out-of-pocket for cancer treatments delivered by pill instead of IV. This discrepancy does not exist due to any difference in cost between therapies but is simply based on the form of administration. Patients pay a copay for IV drugs and must pay coinsurance for self-administered drugs. Unfortunately for patients, this unnecessary discrepancy in cost-sharing means many patients face greater financial barriers to oral anti-cancer therapies, and this has an impact on treatment decisions and patient outcomes. This issue has been addressed in state regulated insurance plans by 43 states and the District of Colombia through the passage of chemotherapy fairness laws, however, a discrepancy still exists for people with ERISA plans and in individuals with Medicare.

H.R. 1409, *the Cancer Drug Parity Act*, which is led in the House of Representatives by Congressmen Lance (R-NJ) and Higgins (D-NY), currently has 164 bipartisan co-sponsors, and support continues to grow. H.R. 1409 ensures that any health care plan currently covering cancer treatment provide patients with access to cancer medications taken by pill at a similar out-of-pocket cost as cancer medications administered by IV, port, or injection at a doctor's office. This bill only impacts ERISA regulated insurers. We hope you will examine the impact high cost sharing has on our patients and consider working with us to fix this problem for patients with both ERISA governed plans in addition to Medicare beneficiaries who are also heavily burdened by high cost-sharing.

We also wish to use this opportunity to make you aware of a new trend in benefits design we believe has potential to hinder access to drugs for our patients. Copay accumulator/accumulator adjustment programs prohibit manufacturer assistance from being used by a patient to meet their deductible or out-of-pocket-maximum. We understand it is the goal of payers to reduce drug costs, however, our concerns surround the immediate impact of these programs on patients who are often caught off guard by these new policies. We also raise concern with these programs applying to oncology drugs without generic alternatives. We hope the impact these accumulator adjustment programs have on patient out-of-pocket spending and access will be examined and that steps will be taken to ensure patients are not being hindered when trying to access the most appropriate drugs for them. Until it is determined that these programs reduce costs, it is important for our patients to have co-pay and premium assistance included in their deductibles and out-of-pocket-maximums to help reduce their out-of-pocket costs.

Lastly, on this topic, we would like to thank the Administration for addressing pharmacy gag clauses. We feel this is a helpful step for patients and we are happy pharmacists can now freely speak with patients about whether or not they can pay less out-of-pocket-by not using their

insurance. We believe this is a positive change and we will educate our patient population on the implications of it.

Thank you again for working with patients and their advocates on this issue. Reducing out of pocket costs are very important to the patients we serve, and we hope you will keep the needs of cancer patients in mind as you continue this important work. Thank you for your time and attention.

Should you or your staff have any questions about our suggestions, or wish to further discuss our concerns, please feel free to contact me at Rlevy@myeloma.org. Our organization is happy to work with you and provide you with additional insights and perspectives from both patients and providers.

Sincerely,

Robin Roland Levy
Senior Director, Public Policy and Advocacy