

VIA ELECTRONIC DELIVERY

April 8, 2019

The Honorable Alex Azar
Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201



RE: Removal of Safe Harbor Protections for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees Proposed Rule (HHSIG-2019-0001)

Dear Secretary Azar,

On behalf of the Lupus Foundation of America (LFA), I am writing to provide comments to Health and Human Services' (HHS) proposed rule regarding the removal of safe harbor protections for Medicare Part D prescription drugs. LFA appreciates the opportunity to provide feedback to this proposed rule in order to ensure the needs of people living with lupus and other chronic conditions and illnesses continue to be well-served by Medicare.

Lupus is a chronic autoimmune disease that can impact any part of the body including the heart, lungs, kidneys, joints, and skin. Symptoms are heterogeneous both across the overall population with the disease and across individual patients' lifetimes. Common symptoms include extreme fatigue, joint and muscle pain, rashes, photosensitivity, organ inflammation, and, in many advanced stages of the disease, kidney damage or failure. Estimates suggest that at least 1.5 million Americans are living with lupus, although research into lupus prevalence is limited – the actual number may be much higher. Although the disease also impacts men and children, the majority of people diagnosed with lupus are women, with 80% of new diagnoses made during childbearing years.ⁱ Lupus also disproportionately impacts women of color, who are twice as likely to develop the disease as Caucasian women.ⁱⁱ

The Lupus Foundation of America is the largest publicly-supported lupus organization devoted to solving the mystery of lupus, one of the world's cruellest, most unpredictable and devastating diseases. Through a comprehensive program of research, education, and advocacy, we lead the fight to improve the quality of life for all people affected by lupus. LFA has a strong commitment to advancing lupus research for both adult and pediatric populations and does this through a variety of methods including funding research, building collaborative research partnerships, and advocating for increased federal research funding.

The Foundation is also the convener of the Medicare Access for Patients Rx (MAPRx) Coalition, a national coalition of beneficiary, caregiver, and healthcare professional organizations committed to improving access to prescription medications in Medicare Part D and safeguarding the well-being of Medicare beneficiaries with chronic diseases and disabilities.

Over the past 13 years, Medicare Part D has provided a critical avenue for beneficiaries to access prescription drugs. Its success in providing more than 43 million Medicare beneficiaries with coverage for self-administered drugs is commendable. Over the life of the program, evidence has grown that Part D improves health outcomes when beneficiaries take their medications as prescribed. Surveys indicate that

beneficiaries enrolled in Part D are generally satisfied with the program; however, even with the success of Part D, some beneficiaries still experience challenges accessing prescription drugs. High out-of-pocket (OOP) costs can be a significant issue for Medicare beneficiaries whose treatment requires many drugs or drugs on the specialty tier.

LFA supports the Administration’s goal to reduce out-of-pocket expenses and increase transparency in the pharmaceutical supply chain, and we are writing to voice our support for the proposed rule which is aimed at ensuring price concessions are fully reflected in patient cost sharing at the pharmacy counter.

One factor contributing to high OOP costs is that patients are paying cost sharing based on undiscounted prices. In Part D, the price at the point of sale — during the deductible phase or a coinsurance for the drug — is typically based on the list price and does not account for any rebates or discounts that might reduce the overall price. A November 2016 Milliman reportⁱⁱⁱ concluded 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, compared to lower price drugs with lower rebates. Moreover, because Part D plans have shifted benefit designs to generally require coinsurance for select brand drugs, beneficiaries who take medications with high rebates are not benefitting financially from them, since plans are not applying the rebates to the list prices for purposes of calculating patient cost-sharing. Milliman concluded that these embedded incentives result in increased costs to both the government and beneficiaries. The proposed rule also aims to ensure that manufacturer payments to pharmacy benefit managers (PBMs) are based on a flat, fair market fee and not tied to the list price of a medicine. Currently, PBMs are often paid fees as a percent of the list price of a medicine – meaning they make more money as the list price of a medicine increases. Under the new rules, if finalized, PBMs would earn the same fees, regardless of a medicine’s price. This change would therefore remove a significant barrier to lowering list prices.

Given this dynamic, we applaud the movement to fully take into account rebates at the point of sale that would allow Medicare beneficiaries to directly benefit from manufacturer discounts and rebates. Provided that the premiums remain within the range of current actuarial estimates published by HHS (\$3-\$6/month), the trade-off between slightly higher premiums with lower OOP spending at the point of sale could benefit beneficiaries, especially those who take multiple medications (on average, a person living with lupus is on 8 prescription medications), need more costly medications, or find themselves with unexpected prescription drug utilization. According to estimates by the Centers for Medicare and Medicaid Services (CMS), the proposed rule would also lead to lower Part D plan deductibles and a lower catastrophic limit, making the benefit package more valuable for all beneficiaries.

As the Administration finalizes the proposed rule, we offer the following considerations on ensuring beneficiary access, transparency, and communication.

Ensuring Beneficiary Access

Operationalizing changes to ensure that beneficiaries see savings

There is little doubt that the current system of discounts and rebates in Part D is inefficient, with list prices increasing and discounts and rebates used to lower premiums but not necessarily reflected in the price at the point of sale. This issue has become more concerning as plans shift their benefit designs to include more significant deductibles and the increased use of cost-sharing through coinsurance rather than copays. Creating a system where pharmaceutical manufacturers are encouraged to share discounts at the

point of sale could provide meaningful savings for beneficiaries and increase affordability, and thus access and adherence to medications.

We urge HHS to monitor implementation to determine if other changes are necessary to ensure that Part D beneficiaries benefit from this new system. We urge HHS to ensure that Part D beneficiaries, particularly those with serious and chronic conditions like lupus, receive discounts at the pharmacy counter that, absent this proposed rule, would be provided to plans and PBMs.

We are also concerned that plans' desire to manage any potential premium increase due to the proposed changes could lead to more aggressive formulary management. Prescription drug utilization is more predictable than many other forms of health care and therefore there is a danger that Part D plans could use narrow formulary design to discriminate against beneficiaries with certain conditions. There is a risk that this could lead to narrower formularies and overzealous use of utilization management, putting beneficiaries' health at risk. We therefore urge HHS to increase review of plan formularies to ensure that they do not violate the non-discrimination protections in the Part D program.^{iv}

Need remains for additional cost sharing relief in Part D

While sharing the rebate at the point of sale may help beneficiaries with OOP expenses and is something we strongly support, the Lupus Foundation of America remains concerned about increasing OOP costs for Part D beneficiaries. This proposed rule could be an important step to lowering beneficiary out-of-pocket costs; however other changes to Part D are necessary to more fully address affordability challenges. One key change that is needed is establishing an OOP cap in Part D. Currently in the Part D program, patients who have reached the catastrophic threshold, which corresponds to about \$8,140 in total drug costs in 2019, continue to pay 5% out-of-pocket for any additional costs beyond that threshold. This contrasts with most commercial insurance, where beneficiaries who have reached their annual out-of-pocket maximum do not pay anything out-of-pocket for covered, in-network services and prescription medicines.

For Part D patients who have not yet reached the catastrophic threshold, the proliferation of specialty tiers, which are subject to significant coinsurance and excluded from cost-sharing exceptions, forces beneficiaries to pay a significant percentage of their medication's cost. For drugs covered on the specialty tiers, the coinsurance amounts can range anywhere from 25% to 33%, leaving beneficiaries paying thousands of dollars in OOP costs for drugs and biologics used to treat lupus as well as cancer, multiple sclerosis, rheumatoid arthritis, and other conditions. As a result, many beneficiaries cannot afford access to the most clinically appropriate medications because they are out of reach financially, which can result in non-adherence, worse outcomes, increased hospitalizations, increased costs in other parts of the health care system and additional unintended consequences.

Those who can afford their medications often pay high OOP sums to maintain their health due to high coinsurance in the specialty tier and the lack of an out-of-pocket cap in Part D. A recent study found the following average annual cumulative OOP costs for Medicare beneficiaries:

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

An OOP cap and policy changes to address high coinsurance would better align Part D at parity with the experience of most Part B beneficiaries, whose supplemental coverage and/or OOP caps through Medicare Advantage enable them to better anticipate and meet their financial obligations.

Interplay with other proposals from HHS

The Administration has proposed multiple reforms that would impact beneficiary access to prescription drugs. Because many of these are in the proposal phase, it is unclear what the final landscape will look like and what the interplay between these different proposals will be.

For example, in the proposed rule *Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses*, published in the Federal Register on November 30, 2018, CMS proposed expanding Part D plan flexibility in order to manage protected classes. We believe this may lead to unintended consequences and specifically, we are concerned that the policy change could reduce patient access to these life-saving drugs, possibly leading to complications associated with an interruption of care. We believe that the proposed changes are in direct opposition to congressional intent for creating the protected classes. The protected class policy has successfully allowed beneficiaries with lupus to receive the medications that their providers prescribe.

If the Administration moves forward with both the proposed rebate changes and the proposed protected class changes, predicting stakeholder behavior becomes difficult. Our focus remains with the beneficiaries and ensuring that they have appropriate, affordable access to their medications.

Transparency and Communication

Beneficiaries need easily accessible, clear communications on coverage and OOP costs

In general, LFA supports providing information to beneficiaries in an easily accessible format, and sharing rebates at the point of sale and having those rebates vary by plan makes clear, consistent beneficiary communications all the more essential.

We urge CMS to focus on the beneficiary's ability to understand the pharmacy benefits provided in a plan, along with coverage levels and OOP costs, when determining which plan best meets their needs. While these rebates and list prices are expected to be implemented outside of the plan, beneficiaries will look to their plan and/or Medicare to provide information on their individual benefits.

In addition to improving prospective and real-time price transparency, plans should be required to provide clarity and transparency on coverage and beneficiaries' OOP costs. A mix of copayments and coinsurance can cause significant confusion, especially for those on multiple and/or expensive medications who are trying to navigate the system and compare plans.

The task of appropriately balancing cost and access is certainly challenging, but if the beneficiary remains the center of focus, we believe significant and lasting improvements are well within reach. The key to realizing these improvements is ensuring Medicare beneficiaries truly benefit from proposed regulatory changes.

Again, we appreciate the opportunity to provide input as HHS looks to implement reforms to the Medicare system. If you have any questions, please do not hesitate to contact me at wildman@lupus.org. Thank you for your consideration.

Sincerely,



Patrick Wildman
Vice President, Advocacy & Government Relations

ⁱ Costner MI, Sontheimer RD. "Lupus erythematosus" In: Wolff K, Goldsmith LA, et al. Fitzpatrick's Dermatology in General Medicine (seventh edition). McGraw Hill Medical, New York, 2008:1515-35.

ⁱⁱ Dall'Era M, Cisternas MG, Snipes K, Herrinton LJ, Gordon C, Helmick CG. The Incidence and Prevalence of Systemic Lupus Erythematosus in San Francisco County, California: The California Lupus Surveillance Project. Arthritis Rheumatol. 2017.

ⁱⁱⁱ 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.

^{iv} Centers for Medicare & Medicaid Services, Medicare Prescription Drug Benefit Manual.

^v Doshi JA, Li P, Pettit AR, Dougherty JS, Flint A, Ladage VP. Am J Manag Care. 2017;23(3 Suppl):S39-S45.