VIA ELECTRONIC DELIVERY

January 25, 2019

The Honorable Seema Verma
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-8013

Help Us Solve
The Cruel Mystery
LUPUS™
FOUNDATION OF AMERICA

RE: Proposed Rule – Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out of Pocket Expenses (CMS-2018-0149-0002)

Dear Administrator Verma,

On behalf of the Lupus Foundation of America (LFA), I am writing to provide comments to the Centers for Medicare & Medicaid Services' (CMS) proposed rule entitled *Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out of Pocket Expenses.* 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 cruelest, 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 millions of Medicare beneficiaries with coverage for self-administered drugs is commendable. LFA supports the Administration's goal to reduce out-of-pocket expenses, but we are concerned that the proposed policy changes generally favor health plans instead of

focusing on beneficiary protections and overall transparency of information. In particular, LFA would like to address the following issues raised in the proposed rule:

- **Providing plan flexibility to manage protected classes;**
- **Application of step therapy for Part B drugs by Medicare Advantage plans;**
- **Explanation of benefits requirements;**
- **Changes to the definition of negotiated price; and**
- **Pharmacy price concessions in the negotiated price.**

Providing Plan Flexibility to Manage Protected Classes

Currently, plans are required to include all Part D drugs in the classes of clinical concern ("protected classes"). CMS is proposing to allow plan flexibility to manage protected classes by 1) allowing broader use of prior authorization; 2) allowing plans to exclude a drug if new formulation does not provide unique route of administration; and 3) allowing plans to exclude a drug if it has cost increases above a certain threshold.

LFA appreciates CMS's effort to ensure that current policies reflect changes in the marketplace; however, we are concerned that CMS's proposal to expand Part D plan flexibility in order to manage the costs of providing medicines in the protected classes may lead to unintended consequences. People living with lupus commonly rely on drugs within the protected classes, including immunosuppressants, antineoplastics, anticonvulsants, and antidepressants. Due to the nature of the disease and the fact that people with lupus can develop other conditions, they may rely on other drugs that fall within the protected classes. Because these drugs play such important roles in the treatment of lupus, we are concerned that the proposed 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 and other serious and chronic conditions to receive the drugs their providers prescribe. Allowing plans the ability to broaden use of prior authorization and step therapy could hinder access and subsequently patient outcomes. For example, a "fail first" policy requires that beneficiaries prescribed a medication must first "fail" on a plan-preferred medication *before* the plan will pay for the original prescription.

For people with lupus, finding an effective treatment regimen to treat symptoms and prevent additional flares is a complex and challenging process. The relationship between a person with lupus and their doctor is extremely important, and effectively treating lupus already requires trying a number of different treatments and combinations of treatments to find the one that is most effective while balancing and limiting potentially dangerous long and short-term side effects. We are concerned that any delays, such as those created by prior authorization and step therapy, could damage the health of people with lupus.

Further, LFA is concerned about several of the specific proposals within the overall changes to the protected class policy:

- **Patients currently on a stable therapy**. LFA is particularly concerned that the proposed changes may result in an erosion of the current protections that prohibit prior authorization or step therapy for patients who are currently stable on a therapy protected under the policy. For a

person with lupus whose disease is being managed by a drug within the protected classes, removing them from that therapy, requiring prior authorization would be extremely dangerous. LFA cannot support any policy that would permit plans to use look-back periods to remove or delay access to protected class therapies.

- **New formulations**. LFA believes the proposed changes related to new formulations may further hinder patient access to needed therapies. CMS proposes to permit Part D plans to exclude a drug if a manufacturer introduces a new formulation with the same active ingredient that does not provide a unique route of administration—even if that becomes the only formulation available. This policy change may prevent patient access to specific therapies if a certain formulation has been discontinued.

- **Pricing threshold for protected class drug formulary exclusions.** CMS proposes that, beginning in 2020, Part D plans could exclude any single-source drug or biologic that has a wholesale acquisition cost (WAC) increase, relative to the price in a baseline month or year, beyond the rate of inflation. LFA has significant concerns that this proposed policy would adversely affect patient access to prescribed therapies—specifically those without any therapeutic equivalent. While we applaud CMS' efforts to address affordability concerns for patients, this policy may result in an unintended consequence of patients having no access to prescribed therapies.

Further, given that Part D plans already apply prior authorization for select products within the protected classes, we do not believe that broader use of utilization management, including step therapy, should be implemented. A 2018 Avalere Health[iii] study found that plans already apply utilization management tools 40% of the time for drugs in the 6 protected classes, including a majority of branded drugs (54%) in the protected classes. Part D plans have applied prior authorization for almost half (49%) of branded drugs in the protected classes. The use of step therapy would likely present additional barriers and hurdles for patients prior to receiving a critically-important treatment, threatening patients' lives, safety, and medical stability. Untreated or improperly treated lupus can progress rapidly, leading to higher costs for Medicare as more complicated procedures, such as dialysis or organ transplants, and long hospital stays become necessary. **Therefore, we urge CMS to maintain the current requirements, rather than allow plans the flexibility to broaden use of these tools.**

CMS would offer patients protection under this new policy via the current appeals and exceptions process in Part D; however, LFA believes that beneficiaries and providers cannot rely on these processes alone if CMS implements broader plan flexibility to manage drugs in the protected classes. While there is an appeals process, frankly, we do not believe it is a sufficient safeguard against the decreased access that will result from stricter formularies. People with lupus often experience difficulties navigating drug formularies and the appeals process, and we are concerned that additional restrictions will further impede their understanding of coverage and the steps necessary to obtain medically-necessary therapies. As such, LFA urges CMS to continue working to improve the appeals process, particularly around beneficiary communication at the point-of-sale and electronic prescribing/prior authorization.

The March 2018 Medicare Payment Advisory Commission (MedPAC) report[iv] to Congress made a similar recommendation to CMS, noting frustrations with Part D determinations, exceptions and appeals process by patients, providers, plan sponsors, and CMS itself. For example, there was one more civil monetary penalty imposed on a plan for program audit in 2017 compared to 2016.[v] Additionally, a September 2018 Office of Inspector General (OIG) report[vi] found that Medicare Advantage plans had significantly high rates (75%) of denials overturned for services and payments (for beneficiaries enrolled in Part C and Part D

programs) that should have initially been provided. The OIG found this particularly concerning because from 2014 to 2016, only 1% of denials were brought to the first level of appeals, so the system designed to ensure access to care is not working. **Therefore, LFA urges CMS to engage with the relevant stakeholders—particularly patient advocacy groups—to implement improvements to the exceptions and appeals processes, with the strong focus on ensuring these processes work for beneficiaries, while still offering plan flexibility.**

While we strongly support maintaining the current protected class policy, we also believe that CMS should consider ensuring other beneficiary protections related to formulary coverage. Namely, we believe that CMS should require plans to manage a more transparent formulary review process. Additionally, plans should be required to have a robust formulary, including the 6 protected classes of drugs and any additional classes where restricted access to those drugs would have a significant health impact. CMS should also require that plans provide coverage for a variety of medications in each drug class or category, as well as provide beneficiaries with timely information about any changes. LFA urges CMS to analyze formularies, both prior to and during the plan year, to determine whether appropriate access is afforded to needed drugs and classes of drugs. **In general, we would like CMS to conduct greater oversight to ensure robust formularies for people with lupus and other serious and chronic conditions.**

Application of Step Therapy for Part B Drugs by Medicare Advantage Plans

CMS proposes new requirements for when Medicare Advantage plans may apply utilization management (including step therapy) for Medicare Part B drugs.

LFA is opposed to step therapy, as it is an impediment to prescribed therapies for patients who require timely and often personalized Part B medications. We are disappointed that CMS did not seek any formal or informal stakeholder comments before the release of guidance on August 7, 2018,[vii] allowing Medicare Advantage plans to use these same tools for Part B drugs in 2019 under certain circumstances. While we appreciate CMS's callout regarding protections currently in place for beneficiaries, we do not believe that these callouts are sufficient to adequately protect beneficiary access. We believe that the recently enacted and proposed policies weaken beneficiary protections in favor of health plan flexibility and outline a number of program features that hinder beneficiaries' ability to appropriately access needed prescription drugs, particularly those in the protected classes. Utilization management practices, such as step therapy, pose significant safety issues that could threaten the lives, safety, and medical stability of people with lupus.

Explanation of Benefits Requirements

CMS seeks to require plans to communicate negotiated drug pricing information and lower cost alternatives in the Part D plan's Explanation of Benefits (EOB).

LFA appreciates this step towards transparency; however, we are concerned that the provided information is not actionable for the beneficiary to make better and timely health care decisions. A beneficiary would not be able to change plans midyear, so the information may be confusing to them and may not be helpful. For example, when a beneficiary receives an EOB after they have received treatment, they cannot use pricing information to change out-of-pocket costs that they have already incurred.

We believe that CMS should require plans to use clear and concise language to communicate plan benefits, coverage levels, and out-of-pocket costs, and that this information should be included in EOBs

in different ways (e.g. using graphs or bullet point summaries) and in a manner and format to ensure that beneficiaries understand the benefits provided in a plan. Rather than moving forward with the proposed changes, we believe CMS should work to improve beneficiaries' online shopping experience and ability to compare formularies and out-of-pocket costs across plans. As recently recommended by the National Council on Aging,[viii] Medicare Plan Finder would benefit from a comprehensive redesign and ongoing investment to remain relevant. To help beneficiaries make informed decisions when choosing a plan, **LFA recommends that CMS work to ensure Medicare Plan Finder displays costs with more precision, so that enrollees can view actual premiums and out-of-pocket costs more accurately.**

Changes to the Definition of Negotiated Price

CMS is considering for a future plan year to redefine negotiated price as the baseline, or lowest possible, payment to a pharmacy. As such, CMS may propose to define negotiated price as the price reflected from all pharmacy price concessions, even if price concessions are contingent upon performance by the pharmacy.

LFA appreciates the effort to reduce prices at the point of sale, but we are concerned that ultimately, an unintended consequence will be that Part D plans may employ the change as a means to reduce access. Additionally, we believe that requiring pharmacy benefit managers and plan sponsors to utilize manufacturer rebates (at least in part) for reducing beneficiary out-of-pocket costs at the point of sale is the most effective avenue for assisting beneficiaries facing challenges in affording their Part D medications.

As noted by the MAPRx Coalition in the recently released white paper, *Navigating Medicare Part D: Approaches to Addressing Beneficiary Affordability and Access Challenges,*[ix] we believe that CMS should explore a policy of requiring pharmacy benefit managers and sponsors to apply a specific percentage of rebates at the point of sale to reduce out-of-pocket expenses. **We urge CMS to use caution when moving forward with the proposed policies to redefine negotiated price, and we welcome the opportunity to join other stakeholders in a dialogue with CMS about this issue in the future, specifically regarding the application of manufacturer rebates at the point of sale (when and if CMS considers such a policy in the future.)**

Pharmacy Price Concessions in the Negotiated Price

CMS is considering an option to develop a standard set of metrics from which plans and pharmacies would base their contractual agreements. CMS requests feedback on whether these metrics could be designed to provide pharmacies with more predictability in their reimbursements while maintaining plan's ability to negotiate terms. Additionally, CMS seeks comment on the most appropriate agency or organization to develop these standards, or whether this a matter better left to private negotiations.

LFA appreciates CMS's consideration of this issue. If CMS decides to develop those metrics, they should be developed by an established measure developer:

(1) with experience developing evidence-based, clinical quality measures for Medicare Part D that address the safe and appropriate use of medications;

(2) that serves as a neutral convener of all relevant stakeholders on this issue, including patient advocates, health plans, pharmacy benefit managers, chain and independent pharmacies, government agencies, specialty pharmacy providers, pharmacist practitioner organizations;

(3) that develops measures through a fully-transparent consensus-based process; and

(4) that is willing to steward these measures on behalf of CMS, including completing necessary maintenance at least annually.

Finally, LFA applauds CMS's work on considering passing pharmacy direct and indirect remuneration (DIR) to the point of sale, and we look forward to more guidance on this policy, to the extent that pharmacy DIR at point of sale ultimately saves money for beneficiaries.

Again, we appreciate the opportunity to provide input as CMS 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

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[v] Centers for Medicare & Medicaid Services. 2017 Part C and Part D Program Audit and Enforcement Report. https://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/Downloads/2017ProgramAuditEnforcementReport.pdf. Published May 8, 2018.

[vi] Office of Inspector General. Medicare Advantage Appeal Outcomes and Audit Findings Raise Concerns About Service and Payment Denials. https://oig.hhs.gov/oei/reports/oei-09-16-00410.pdf. Published September 2018.

[vii] Centers for Medicare & Medicaid Services. Advance Notice of Methodological Changes for Calendar Year (CY) 2016 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2016 Call Letter. http://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Advance2016.pdf. Published February 20, 2015.

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