July 22, 2021

Office of Health Plan Standards and Compliance Assistance
Employee Benefits Security Administration
US Department of Labor
200 Constitution Avenue NW, Room N-5653
Washington, DC 20210

RE: CMS-9905-NC Request for Information Regarding Reporting on Pharmacy Benefits and Prescription Drug Costs

Submitted electronically via www.regulations.gov

Dear Acting Secretary Khawar:

As both the President & CEO of Lupus and Allied Diseases Association, Inc. (LADA) and as a person who struggles with multiple complex autoimmune conditions myself, I submit these comments in response to **CMS-9905-NC Request for Information (RFI) Regarding Reporting on Pharmacy Benefits and Prescription Drug Costs** on issues related to certain reporting requirements under section 204 of Title II of Division BB of the Consolidated Appropriations Act, 2021 (CAA) that are applicable to group health plans and health insurance issuers offering group or individual health insurance coverage. We greatly appreciate the opportunity to share our patient perspective and thank The Departments of Health and Human Services, Labor, and the Treasury (the Departments), and the Office of Personnel Management (OPM), for gathering public input to inform the Departments' and OPM's implementation of section 204 through rulemaking and the establishment of processes to receive the required information.

LADA represents countless patients, loved ones, care partners, and healthcare professionals who deal with serious medical conditions on a daily basis and as such, we certainly understand the importance of transparency in addressing healthcare expenditures and appreciate that the Departments and OPM are looking at disclosure requirements for group health plans and those offering group or individual coverage ways and hope that this will result in lower patient out-of-pocket costs. We strongly support provisions that allow patients to access their essential life-improving and lifesaving treatments and not threaten their ability to afford them, particularly at a time when our healthcare system is overburdened by the COVID-19 pandemic. We are providing comments solely on the question listed below.

RFI question: What considerations should the Departments and OPM take into account in defining "rebates, fees, and any other remuneration"? Should bona fide service fees—for example, administrative fees, data sharing fees, formulary placement fees, credits, and market share incentives—be included in this definition? Are there additional fees that the Departments and OPM should include in this definition? How should manufacturer copay assistance programs and coupon cards be accounted for? How should copay accumulator programs be accounted for?

LADA commends the Departments and OPM for soliciting input regarding the definition of rebates, fees, and any other remuneration and strongly urges you to require full disclosure of all compensation received by group health plans and pharmacy benefit managers (pbms) from manufacturers. Providing this vital transparency can benefit countless Americans struggling with medical conditions by reducing their cost-sharing requirements which in turn can increase medication adherence, prevent additional medical complications, improve health outcomes, and reduce hospitalizations. [1, 2]

We also request that you not define manufacturer cost-sharing assistance programs as being remuneration to the health plan or its coverage, administrators or service providers in order to prevent it from being conveyed as such. Traditionally, health plans and PBMs do not share manufacturer-negotiated rebates and discounts with patients at the point-of-sale. Instead of paying cost sharing based on the discounted price paid by the health plan and PBM, patients usually pay cost sharing based on a medicine's undiscounted list price that does not reflect the actual cost that has been incurred by the plan or PBM for the medicine. This practice can result in a plan or PBM realizing a net gain when a prescription is filled, therefore, allowing plans and PBMs to "double dip" and forcing patients to pay overestimated prices while PBMs benefit from rebates and discounts.

LADA applauds the Departments and OPM for recognizing the need for public feedback to assist you in properly accounting for manufacturer copay assistance programs, coupon cards, and co-pay accumulator programs and offers the following input. Given the current global healthcare crisis in which Americans and others throughout the world are experiencing hardship in dealing with the COVID-19 pandemic and its impact to the economy, individuals already struggling to manage incapacitating medical conditions are now facing the additional challenges of covering the cost of their medication and accessing appropriate healthcare. Copay coupons and cards provide financial relief to patients through manufacturer programs that were created to offset patient cost sharing associated with treatments, while assisting patients in meeting their maximum out-of-pocket limits.

We strongly support policies requiring health plans and PBMs to apply price reduction instruments for out-of-pocket expenses when calculating an insured individual's cost sharing requirement. Co-pay accumulators are a relatively new insurance benefit design being adopted by health insurance plans that prevent patients from using copay cards or coupons to cover their out-of-pocket expenses. This cost-shifting mechanism changes the way an insured individual's out-of-pocket contributions for prescription drugs are calculated. Co-pay accumulator programs do not consider any discounts or coupons that the insured person receives from the drug manufacturer when calculating the insured's out-of-pocket expenses and therefore, do not count them toward the patient's maximum out-of-pocket limit.

In addition, we would like to emphasize that co-pay accumulator programs conflict with the Affordable Care Act (ACA) requirements that all non-grandfathered group health plans and health insurance issuers count cost sharing for essential health benefits toward the annual cost sharing limitation and that this amount include manufacturer assistance.

LADA strongly opposes harmful practices which allow health plans to shift the cost towards patients and essentially "double dip" by requiring the individual to pay their normal copay while still receiving a discount or coupon from the drug manufacturer, ultimately causing the individual to take longer to satisfy their out-of-pocket limit or deductible. This unfair design is especially deleterious to individuals with severe illnesses who have high deductible or high copayment requirements in their health plans. When health plans and PBMs misuse manufacturer assistance through co-pay accumulator programs by reducing their expenditures for a medicine through increased patient cost sharing, the net price reported by the plan should be reduced accordingly.

For individuals struggling to manage complex, chronic autoimmune conditions such as lupus, rheumatoid arthritis, inflammatory bowel disease, multiple sclerosis, psoriasis, ankylosing spondylitis, vasculitis and other serious conditions such as HIV/AIDS, osteoporosis, blood disorders, diabetes, cancer, hepatitis and rare diseases; access to appropriate medication can dramatically improve disease outcome and quality of life. Furthermore, many of these individuals also have multiple co-morbid conditions that require unique strategies to manage their care. Effective treatment can reduce the severity and frequency of disease activity and decelerate its progression, circumvent debilitating symptoms, and avoid complications and long-term disability, thus enabling people to remain productive.

Patients rely on the existence of manufacturer assistance programs in order to be able to access their essential medications that would otherwise be unaffordable and unattainable. However, manufacturer rebates,

discounts, and other price concessions that PBMs negotiate on behalf of health plans, employers, and other payers substantially reduce the net price paid by the plan sponsor. This results in patients paying cost sharing based on the undiscounted list price of the drug, rather than the discounted price paid by the PBM and health plan. We strongly believe that cost-sharing assistance should do what it is intended to do and be a benefit to patients and not be a subsidy for health plans.

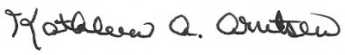
For the above reasons, we implore The Departments of Health and Human Services, Labor, and the Treasury and the Office of Personnel Management to implement the ACA's annual limit on cost sharing provision as envisioned by Congress and ban the egregious practice of co-pay accumulator adjustment programs.

The Lupus and Allied Diseases Association, Inc. was founded in 1978 and is a non-profit organization led by people with lupus and allied diseases and their loved ones who are dedicated to ensuring that the patient perspective is included and recognized as an equal stakeholder in the healthcare, regulatory and public policy arenas and across the research continuum. It is our goal to improve access to care and quality of life by fostering collaboration among stakeholders and by wielding the patient voice as a catalyst to advance innovative advocacy, education, awareness and biomedical research initiatives that will identify causes, advance better diagnostics, and discover superior treatments, and cures.

In closing, we respectfully request that The Departments of Health and Human Services, Labor, and the Treasury (the Departments), and the Office of Personnel Management (OPM) utilize the input received on section 204 of Title II of Division BB of the Consolidated Appropriations Act, 2021 (CAA) to develop policies that prioritize patient well-being and to work with various patient and provider stakeholders through a collaborative and comprehensive process to increase transparency and oversight of the prescription drug supply chain to ensure cost-sharing is benefiting patients in order to enhance quality of care, improve health outcomes, reduce costs, and continue to offer unfettered access to crucial treatments.

Thank you for the opportunity to provide our unique patient viewpoint on this important issue. Please do not hesitate to contact me at kathleen@ladainc.org or 315-264-9101 for additional information.

Respectfully submitted,



Kathleen A. Arntsen
President & CEO
Lupus and Allied Diseases Association, Inc.
P.O. Box 170
Verona, New York 13478

[1] Goldman DP, Joyce GF, Zheng Y. Prescription Drug Cost Sharing: Associations with Medication and Medical Utilization and Spending and Health. JAMA. 2007;298(1):61-69. doi:10.1001/jama.298.1.61

[2] Gourzoulidis G, Kourlaba G, Stafylas P, Giamouzis G, Parissis J, Maniadakis N. Association between copayment, medication adherence and outcomes in the management of patients with diabetes and heart failure. Health Policy. 2017 Apr;121(4):363-377