January 25, 2019

The Honorable Alex Azar
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 120F
Washington, DC 20201

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

Dear Secretary Azar:

We are writing today about the critical need for Part D direct and indirect remuneration (DIR) fee reform. DIR fees have evolved into a Part D Plan catch-all for numerous types of fees, including retroactive pharmacy price concessions. The Centers for Medicare & Medicaid Services (CMS) reports the use of pharmacy DIR has grown an astonishing 45,000 percent from 2010 to 2017. This increase has led to increased beneficiary cost-sharing and government costs. The increase in beneficiary cost-sharing makes it harder for struggling beneficiaries to afford their medication and could lead to reduced medication adherence and poorer health outcomes. In response, CMS recently issued a proposed rule to make changes to pharmacy DIR that would lower beneficiary costs. The changes CMS is considering would redefine "negotiated price" to include all pharmacy price concessions, even those that are contingent.

To protect beneficiary pocketbooks and health, we urge CMS to include in the final rule the requirement that all pharmacy price concessions be reflected in the negotiated price. The negotiated price of a drug is what is made available at the time a medication is dispensed and is the basis for beneficiary cost-sharing. This approach would lead to significant beneficiary savings, better medication adherence and health, and provide greater transparency into the Medicare Part D program.

As CMS has noted in the proposed rule, even when considering the potential for slight increases in monthly premiums, restructuring the use of DIR fees to include them in the negotiated price would result in a net savings of \$9.2 billion for beneficiaries. Such savings would slow beneficiary progression through the phases of the Part D program. This would not only reduce beneficiary costs but would reduce CMS costs by reducing the amount of time for which beneficiaries are covered under the catastrophic coverage phase of Medicare. These conclusions align with CMS' previous findings that DIR affects beneficiary cost-sharing and CMS payments to plans while also pushing patients into, and through, the coverage gap sooner.

Lower costs would also improve medication adherence and result in better health outcomes. As CMS alluded to in the proposed rule for the 2019 plan year, patient savings can potentially improve adherence to their medication by making their prescriptions more affordable. Medication non-

adherence costs the health care system \$290 billion a year, so increasing the affordability and accessibility of medications can reduce those costs as well.

In addition to reducing costs and improving medication adherence, requiring the inclusion of all pharmacy price concessions in the negotiated price will produce greater transparency. Currently there is inconsistent reporting of DIR to CMS. Some plan sponsors may include certain pharmacy price concessions in negotiated price, while others continue to report them as DIR. This makes it difficult for patients to accurately compare plans as to the true costs of their medications. Requiring all fees to be accounted for in negotiated price would enhance the quality of information available to beneficiaries and provide them with a better understanding of how they will progress through the Medicare program based on their current medications.

In addition to reforming pharmacy DIR by redefining negotiated price, CMS should take steps to further enhance Part D quality by developing a standardized pharmacy-specific performance-based incentive program. Specifically measuring pharmacy performance in Part D would recognize the role and effectiveness of pharmacies in improving patient health outcomes through the effective use of medications.

We believe, overall, Medicare Part D has been successful in enhancing access to prescriptions for seniors. However, we believe including all pharmacy fees and price concessions in negotiated price and recognizing the role of pharmacy in improving patient health outcomes would further strengthen the Part D program. We urge CMS to include these reforms in the final Part D drug pricing rule.

Sincerely,

Alliance for Transparent and Affordable Prescriptions

American Association of Clinical Urologists

American Autoimmune Related Diseases Association (AARDA)

American Bone Health

American College of Rheumatology

Association of Women in Rheumatology

California Rheumatology Alliance

Coalition of State Rheumatology Organizations

Florida Society of Rheumatology

Global Healthy Living Foundation

International Foundation for Autoimmune & Autoinflammatory Arthritis

Lupus and Allied Diseases Association, Inc.

National Consumers League

National Infusion Center Association

National Multiple Sclerosis Society

National Organization of Rheumatology Managers

New York State Rheumatology Society

North Carolina Rheumatology Association

Ohio Association of Rheumatology

Rheumatology Alliance of Louisiana

South Carolina Rheumatism Society

The AIDS Institute

Tennessee Rheumatology Society U.S. Pain Foundation

Cc: Mick Mulvaney, Acting White House Chief of Staff and Director, the Office of Management and Budget

Russell Vought, Acting Director, the Office of Management and Budget