The Honorable Nancy Pelosi
1236 Longworth H.O.B.
Washington, DC 20515

May 12, 2021

Re: The Elijah E. Cummings Lower Drug Costs Now Act

Dear Speaker Pelosi:

The undersigned organizations represent rheumatology providers and patients at the national and state levels who share an interest in ensuring patient access to prescription medications. Each of us understands the financial, social, and quality-of-life burdens that patients with chronic disease face every day – burdens that are made significantly heavier by the high out-of-pocket costs for medications.

We thank you for your leadership on drug pricing reform, but, for the reasons outlined below, we are concerned that providers who administer medications in their offices may be left underwater as a result of H.R.3. In time, that would reduce the number of available locations for patients to receive medications that are infused, injected, or otherwise administered by a provider and drive patients to hospital outpatient departments instead. Patients in underserved areas may not have easy access to hospital-based infusion. Additionally, many patients battling autoimmune disease prefer the lower patient volume of an infusion center or doctor's office to the high patient volume of the hospital setting.

Perhaps most important in light of H.R.3's laudable goal to lower costs for patients, while the outpatient department plays a critical role in the delivery of healthcare services, it is by far the most expensive setting in which to administer medical benefit drugs. The goal of the legislation is to reduce out-of-pocket burdens on patients, but consolidating access points and driving patients into hospitals will have the opposite effect, even if the drug price is lower. That is because the administration and other services surrounding the drug are far more expensive in the hospital than they are in medical offices or infusion centers. This significant cost differential in the site of treatment is why any policy related to medical benefit drugs should attempt to close this gap or create an incentive for patients to receive medical benefit drugs outside of the hospital. Unfortunately, H.R.3 does neither.

With regard to the maximum fair price (MFP), the legislation mandates that drug companies offer the MFP to eligible patients at the pharmacy counter and to providers who acquire medication, but is silent as to how that mandate would be enforced other than via civil monetary penalties payable by the companies to the government. This does not hold harmless the providers who purchase these medications, nor does it guarantee that providers can actually access the MFP, particularly since insurers, wholesalers, and other middlemen can opt out of the system entirely.

There are significant issues in Medicare Part D, one of which is the lack of an out-of-pocket cap. H.R.3 would address this by creating a $2,000 annual cap and allowing beneficiaries to spread out that cost over

the year in certain cases. These are critical patient protection provisions and we thank you for including them in H.R.3.

In addition, we urge you to address the underlying distortions that are driving up list prices in Part D. One major distortion is the treatment of price concessions from drug companies to pharmacy benefit managers, an issue discussed at length by the Centers for Medicare and Medicaid Services (CMS) in a Request for Information contained in the MA-PD proposed rule for contract year 2019.[1] Price concessions not included in the negotiated price at the point of sale reduce plan premiums only to the extent that plan bids reflect accurate direct and indirect remuneration (DIR) estimates. CMS discussed the fact that DIR received above the projected amount factored into a bid is retained by the plan as profit, rather than used by the plan to lower premiums. It is unsurprising that, as a result, the actual DIR amounts received by Part D plans and pharmacy benefit managers (PBMs) have consistently exceeded bid-projected amounts. CMS further noted that PBMs/plans may opt for higher negotiated prices in exchange for higher DIR and sometimes even prefer a higher net cost drug over a cheaper alternative. This harmful and counterintuitive system must stop, but for the majority of Part D covered medications it will simply continue alongside H.R.3, which does not address these structural flaws.

In closing, while we believe that the out-of-pocket annual cap for Part D beneficiaries is a critical and much needed reform, we are concerned that H.R.3 will result in reduced access to provider-administered medications and that the legislation fails to address the Part D distortions that are driving up list prices and costs for patients. Targeted reforms of Part D such as the out-of-pocket annual cap coupled with a restructuring of the rebate system can reduce the high financial burdens for patients without jeopardizing their access. We hope to work with you on such reforms.

Sincerely,

American College of Rheumatology
Arizona United Rheumatology Alliance
Arkansas Rheumatology Association
Association of Women in Rheumatology
California Rheumatology Alliance
Coalition of State Rheumatology Organizations
Florida Society of Rheumatology Inc.
Global Healthy Living Foundation
Kentuckiana Rheumatology Alliance
Massachusetts, Maine and New Hampshire Rheumatology Association, Inc.
Michigan Rheumatism Society
Midwest Rheumatology Association
Mississippi Arthritis and Rheumatism Society

[1] Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program.

National Organization of Rheumatology Management
Nebraska Rheumatology Society
North Carolina Rheumatology Association
Oregon Rheumatology Alliance Inc.
Pennsylvania Rheumatology Society
Rheumatology Alliance of Louisiana
Rheumatology Association of Iowa
Rheumatology Association of Minnesota and the Dakotas
Rheumatology Nurses Society
State of Texas Association of Rheumatologists
Tennessee Rheumatology Society
Virginia Society of Rheumatology
Washington Rheumatology Alliance
West Virginia State Rheumatology Society
Wisconsin Rheumatology Association