March 14, 2018

The Honorable Alex Azar
Secretary
U.S. Department of Health and Human Services
Room 445-G-Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Azar,

The undersigned physician specialty organizations are committed to working with the Administration on policy proposals that increase access to high-quality health care for Americans. Rheumatologists, Neurologists, Dermatologists, Gastroenterologists, Urologists, Physiatrists, Infectious Diseases Specialists, and Ophthalmologists provide ongoing care for Medicare beneficiaries with serious complex chronic and acute conditions that require specialized expertise and can be difficult to diagnose and treat. Early and appropriate treatment by a specialist can control disease activity and prevent or slow disease progression, improve patient outcomes, and reduce the need for costly downstream procedures and care compared to care provided solely by primary care providers. Drug pricing policy is key to access and outcomes for our patients, which is why we reach out to you today.

Recently, the President's 2019 Budget[i] and the *Reforming Biopharmaceutical Pricing at Home and Abroad* Council of Economic Advisers' drug plan[ii] contained many potential policy suggestions. We appreciate HHS's continued focus on transparency and patient-centered care. Knowing that HHS is committed to transforming the health care delivery system and the Medicare program by putting a strong focus on patient-centered care, so providers can direct their time and resources to patients and improving outcomes, is a reassurance to our providers.

HHS has expressed interest in soliciting ideas for regulatory, policy, practice, and procedural changes to better achieve transparency, flexibility, program simplification, and innovation. While are we are supportive of some concepts recently presented, we do have serious concerns regarding other policy suggestions. We hope the stakeholder input in this letter will help to inform the discussion and influence any future regulatory action.

<u>We support proposals that would:</u>

- Require Medicare Part D plans to apply a substantial portion of rebates at the point of sale.
- Establish a beneficiary out-of-pocket maximum in the Medicare Part D catastrophic phase providing beneficiaries with better protection against high drug costs.
- Decrease the concentration in the pharmacy benefit manager (PBM) market and other segments of the supply chain.
- Provide guidance from CMS on how drug-related value-based contracts and price reporting would affect other price regulations.

We have serious concerns about proposals that would:

- **Increase Medicare Part D plan formulary flexibility to limit or reduce coverage**
  This proposal would enhance Part D plans' negotiation power with manufacturers by allowing for additional flexibilities in formulary management. It changes Part D plan formulary standards to require a minimum of one drug per category or class rather than two. It also expands plans' ability to use utilization management tools. We worry this could create access issues for patients on high cost biologic medications. We believe Part D benefits should not limit patients' access to the medical therapy judged by the treating physician to be the most efficacious choice. We reiterate that allowing the most appropriate and efficacious therapy as judged by the treating physician can also result in long-term cost savings.

- **Shuffle Part B drug coverage under the Medicare Part D program**
  This proposal would provide the Secretary with authority to consolidate certain drugs currently covered under Medicare Part B into Part D. We have serious concerns regarding the drastic change represented by this proposal and request clarification on how this proposal would function. We worry that moving Part B drugs into Part D may lead to access issues and force patients into higher cost sites of care. Formulary structure and cost sharing is different between Part B and Part D, and we are concerned that out of pocket (OOP) costs for patients would be very high, especially with the biologics prescribed by Rheumatology, Oncology, and Neurology. Further, Part D has no supplemental coverage to help with OOP costs. We urge HHS to consider the impact this proposal would have on treatment access.

- **Restructure Medicare Part B physician reimbursement to pay physicians 3% over the ASP for new drugs**
  We support adherence to the statutory ASP + 6% reimbursement rate for in-office treatments and continue to urge the repeal of sequester cuts to Part B drug reimbursements. Many small and rural practices lack the ability to negotiate bulk discounts in their drug purchases and have already been forced to stop administering biologic therapies to Medicare patients. Especially with the current sequestration in place, for many practices the existing Part B payment structure does not adequately cover the costs of obtaining and providing these complex therapies in the outpatient setting. If additional payment cuts or negative changes are implemented or activated through demonstration projects many patients would be forced into more expensive, less convenient settings to receive needed therapies—if an alternative setting is available at all in their area.

- **Introduce physician reimbursement that is not tied to drug prices**
  We request more clarity on any potential policies that would affect physician reimbursement. Physicians have no control over the cost of drugs or ancillary services, nor over the severity of illnesses and co-morbidities that drive the need for such services. In specialties such as Neurology, Rheumatology, Ophthalmology, and others that utilize biologics and other complex therapies, less expensive equally effective therapies typically do not exist. Our physicians should not be penalized for rampant inflation in these sectors. In addition, complex biologics create costly inventory and management expenses for the physician.

Our organizations are dedicated to ensuring that physicians have the resources they need to provide patients with high-quality care. We believe HHS should make policy proposals designed to reflect the needs of complex care patients, reduce administrative burdens, and increase access to care. The undersigned organizations appreciate the opportunity to provide HHS our views regarding current potential policy proposals.

We look forward to being a resource to you and we welcome the opportunity to a meet with HHS to discuss our concerns and positions in more detail. Please contact Kayla L. Amodeo, Ph.D., Director of Regulatory Affairs at the American College of Rheumatology, at kamodeo@rheumatology.org or (202) 210-1797, if you have questions, or if we can be of further assistance.

Sincerely,

American Academy of Dermatology Association
American Academy of Neurology
American Academy of Ophthalmology
American Academy of Physical Medicine and Rehabilitation
American College of Gastroenterology
American College of Rheumatology
American Gastroenterological Association
American Urological Association
Infectious Diseases Society of America

[i] https://www.whitehouse.gov/wp-content/uploads/2018/02/budget-fy2019.pdf
[ii] https://www.whitehouse.gov/wp-content/uploads/2017/11/CEA-Rx-White-Paper-Final2.pdf