September 29, 2020

Secretary Alex M. Azar II
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, D.C. 20201

Dear Secretary Azar:

The Alliance of Specialty Medicine (the “Alliance”) represents more than 100,000 specialists and subspecialists. We are deeply committed to improving access to specialty medical care through the advancement of sound health policy. We share President Trump’s goal of improving access to physician-administered medications, which are key to the treatment and management of some of the most serious medical conditions. However, the undersigned members of the Alliance are concerned that the September 13 Executive Order (EO) entitled “Lowering Drug Prices by Putting America First” would result in reduced access to medications, particularly in Medicare Part B. The EO directs HHS to establish a demonstration project to test an approach by which Medicare would pay a “most favored nation” price.

The current Administration and the previous Administration each proposed Part B demonstration projects, neither of which moved forward as planned because of significant stakeholder concern over beneficiary access, among other aspects. In large part due to insurmountable logistical challenges, these previously proposed demos posed a significant threat to the viability of physicians’ practices, which would in turn threaten patient access to low-cost, high-quality settings for infusions and other physician-administered medications. This loss of access would disproportionately affect patients in rural areas, as well as low-income beneficiaries for whom the higher cost-sharing of hospital-based services presents a barrier.

Furthermore, previous demos were mandatory in nature and so large-scale that they amounted to program-wide payment changes, which raised procedural and legal concerns, but also exacerbated the concern over the impact on beneficiaries since any problem could not be quickly remedied as it arose.

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Under the current Administration, the Centers for Medicare and Medicaid Services issued a Request for Information (RFI) related to the Innovation Center, through which the demos contemplated by the EO will likely be administered. In the RFI, the Innovation Center established a set of six guiding principles for any future demo, and we urge you to keep in mind these principles as you implement the requirements of the EO. In particular, we hope that you will abide by the guiding principles of provider choice with a “focus on voluntary models, with defined and reasonable control groups or comparison populations” and small scale testing. Half of all Medicare Part B drug expenditures with mandatory physician participation, as was the goal of the International Pricing Index, defies any reasonable definition of either “small scale” or “test.”

We look forward to engaging in the regulatory process, but wanted to share these basic parameters in the meantime. Thank you for the opportunity to share our feedback and please don’t hesitate to contact any of the undersigned organizations, should you have questions or require additional information.

Sincerely,

American Gastroenterological Association
American Society of Cataract and Refractive Surgeons
American Society of Plastic Surgeons
American Society of Retina Specialists
American Urological Association
Coalition of State Rheumatology Organizations
North American Spine Society