Dear

On behalf of the ophthalmology patient and physician community, we are writing to ask for your support in opposing the Centers for Medicare & Medicaid Services (CMS) Part B Drug Demonstration Payment Model as currently proposed. This proposed experiment misses the mark by focusing solely on Medicare Part B drug spending without regard for the medical needs of patients or the importance of the quality of care they receive. Any CMS experiment that forces vulnerable Medicare patients to abandon treatments that are working and improving their quality of life is misguided and ill-conceived. We strongly oppose any effort to rush through a cost-cutting program that will affect patients' access to sight-saving Medicare Part B covered drugs.

We are particularly concerned that CMS' hypothesis fails to acknowledge providers' prescribing decisions depend on a variety of factors, including clinical considerations that may influence a provider's choice among therapeutic alternatives, especially as it relates to age-related macular degeneration and other blinding diseases. The three available treatment options are not always interchangeable. Some patients simply respond better to one treatment than another. Moreover, for some retinal diseases, such as diabetic macular edema, there is strong evidence that Eylea® and Lucentis® provide better clinical outcomes than Avastin®. Vulnerable Medicare patients should not face mandatory participation in an initiative that may force them to switch from the most appropriate treatment.

In addition to these patient-specific concerns, we believe for ophthalmology, the demonstration is flawed because it is built on the following faulty assumptions.

First, it assumes that lower cost alternatives (LCA) are always available. Many ophthalmologists are experiencing increasing difficulty accessing the lower cost drug (Avastin®) used to treat blinding conditions such as age-related macular degeneration (AMD), the leading cause of blindness in the United States. New federal and state regulations on compounding and repackaging of drugs have recently forced some ophthalmologists to increase use of more expensive brand drugs (Lucentis® and Eylea®) for treatment of AMD and other ocular conditions. Further, continued access to Avastin® will effectively end if the FDA finalizes its pending February 2015 draft guidance that calls for a maximum 5-day beyond use date for compounded or repackaged biologics.

Second, it assumes physicians alone make treatment choices. Many patients are reluctant to choose a drug that has not been approved by the FDA for the treatment of their disease or condition. While Avastin® is FDA-approved for non-ophthalmic indications, ophthalmologists use it off label for the treatment of AMD. Patients should not be forced to use an off-label treatment when several FDA approved brand name options exist.

Third, it assumes physician prescribing patterns are solely motivated by revenue. Physician prescribing patterns are influenced by multiple factors, including price. In an ASRS 2015 survey, 64 percent of respondents indicated that they currently use the LCA, Avastin®, as the first-line treatment for new patients with wet AMD. But, when asked what drug they would choose if Avastin®, Lucentis® and Eylea® were the same price, Avastin® dropped to the last choice.

Finally, the proposed payment of average sales price (ASP) +2.5 percent and a flat fee does not recognize the true costs of purchasing and handling the more complex biologics, which will limit the ability of some providers to administer essential sight-saving drugs. In order for physicians to be able to continue to purchase Part B drugs on behalf of their patients, the payment rate must at least cover all of the overhead costs.

We feel Medicare beneficiaries should have access to all Medicare covered services. Any payment model that limits patient choice and impedes physicians' ability to provide the most appropriate and highest quality care is simply unacceptable.

We support CMS' objective of removing incentives to prescribe more expensive drugs. However, the Part B Drug Payment Model proposed for September implementation is unworkable for ophthalmology treatments. We would recommend that CMS meet with stakeholders and use real-world practice data to guide the development of alternative models that can achieve the goal without increasing risks for patient outcomes.

Sincerely,