



September 24, 2018

The Honorable Seema Verma  
Administrator  
Centers for Medicare & Medicaid Services  
U.S. Department of Health and Human Services  
200 Independence Avenue SW,  
Washington, DC 20201

Dear Administrator Verma,

The Part B Access for Seniors and Physicians (ASP) Coalition is a coalition of patient and provider groups dedicated to preserving patient access through Medicare Part B. We are writing to express our deep concern that proposed changes by the Centers for Medicare & Medicaid Services (CMS) to the Medicare Part B program may limit patient access to essential care and services. The updated rule on “Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs” includes a provision to create a new Competitive Acquisition Program (CAP) within Part B. Such a program would add middlemen, such as pharmacy benefit managers and insurers, between patients and their physicians in deciding which treatment is medically indicated. This could have disastrous outcomes for patients with serious, life-threatening diseases treated by physician-administered medicines. A CAP-like program can also create misaligned incentives based on what is financially best for middlemen, not clinically necessary for patients and also raises questions about whether negotiated discounts are benefitting patients, Medicare, and taxpayers, or the middlemen.

Over 59 million seniors and disabled persons rely on Medicare Part B for critical outpatient services. The patients served under Part B are some of the sickest and most vulnerable of Medicare beneficiaries, requiring personalized and carefully designed care. Through the program, beneficiaries and physicians treat a wide variety of illnesses and chronic conditions that demand careful monitoring and management, including cancer, rheumatoid arthritis, Crohn’s and other autoimmune conditions, mental illness, eye diseases, and other serious medical conditions.

The complexities of these conditions and how they interact with patients’ existing health concerns requires a level of flexibility in how physicians approach treatment. Part B beneficiaries, the vast majority of who are seniors, need access to treatments with clinical evidence-based medicines, with the hope that one day there will be more targeted and personalized therapies to meet each individual patient’s need. Additionally, many Part B drugs for chronic, complex conditions have highly specialized storage, handling and patient monitoring requirements, which will be complicated and possibly compromised by introducing middlemen into the Part B drug distribution system.

A new Medicare Part B CAP program would create additional barriers for patients as they seek the right treatment for their condition. These barriers, such as new utilization management requirements (including prior authorization, step therapy, or “fail-first”), would be an obstacle to patients’ ability to access medicines, especially on a timely basis, and would create an additional administrative burden for providers. Patients under Part B should not be subjected to the treatment delays, switches in medications,

and incorrect dosages by middlemen, including pharmacy benefit managers, prevalent in Part D.<sup>1</sup> As demonstrated by the previous Part B CAP, forcing physicians to go through a middleman also limits their ability to precisely tailor and adjust treatments in providing clinically appropriate medical care.

Delays and/or mistakes in treatment, or inappropriate changes in treatment, whether due to utilization management or burdensome middleman distribution requirements, could have serious, negative consequences for patients who rely on the access and coverage provided by the Medicare Part B program. Disruptions in care could also lead to higher overall health care costs in the future, as once managed or treatable conditions accelerate without proper treatment.

We are especially concerned by recent comments that suggest HHS may seek to implement this program as a mandatory CMMI demonstration. Physicians and their patients should not be forced into a model that has the potential to negatively impact treatment decision making and access to care.

The administration should reject this potentially harmful and costly proposal before it does lasting damage to the broader Medicare Part B program and beneficiaries' overall health and well-being. Part B must continue to prioritize the critical patient-doctor relationship in its mission to provide access and care for our most vulnerable patients – starting with seniors with serious medical conditions.

Sincerely,

The Part B Access for Seniors and Physicians (ASP) Coalition

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<sup>1</sup> Community Oncology Alliance. Unaccountable Benefit Managers: Real Horror Stories of How PBMs Hurt Patient Care. May 2017.