



July 17, 2019

The Honorable Nancy Pelosi  
Speaker of the House of Representatives  
U.S. House of Representatives  
Washington, D.C. 20515

The Honorable Mitch McConnell  
Majority Leader  
U.S. Senate  
Washington, D.C. 20510

The Honorable Kevin McCarthy  
Minority Leader  
U.S. House of Representatives  
Washington, D.C. 20515

The Honorable Charles Schumer  
Minority Leader  
U.S. Senate  
Washington, D.C. 20510

Dear Speaker Pelosi, Leader McConnell, Leader McCarthy and Leader Schumer:

The Part B Access for Seniors and Physicians (ASP) Coalition, a broad, multi-sector stakeholder group representing providers, patients and consumers, has repeatedly raised concerns since 2017 that proposed Center for Medicare & Medicaid Innovation (CMMI) demonstrations could reduce access to medically necessary treatment for patients with life-threatening conditions such as cancer and autoimmune diseases. We have identified the lack of critical patient safeguards as the Centers for Medicare & Medicaid Services (CMS) and CMMI put forward new policies affecting beneficiaries who rely on Medicare Part B covered drugs to save their lives or relieve life-altering symptoms of their conditions. Our experience with multiple proposals has led us to develop a set of meaningful, clear guardrails that we believe are essential to ensure demonstrations conducted through CMMI improve patient health and preserve access to care.

As the administration and Congress consider reforms to address health care costs, we strongly urge you to incorporate meaningful patient protections governing CMMI's work into any health care measure moving through Congress. Our essential patient protection principles address transparency, patient and provider engagement, and access to care. The following offers additional details regarding our position.

In a June 8, 2017 letter to the Secretary of Health and Human Services (HHS), the ASP Coalition wrote urging HHS to "protect the Medicare Part B program for reimbursing providers for drugs and biologics administered by physicians." The letter was signed by 269 organizations, emphasizing the need to:

- Limit "the size and scope of future demonstrations;"
- Engage "with patients, providers, and other stakeholders prior to launching demonstrations;"
- Keep the demonstrations "voluntary;" and
- Include "safeguards for patients to access the therapies they need."

We restated these positions multiple times.

In a November 15, 2017 letter to CMS, 113 organizations urged the agency to "finalize clear safeguards within CMMI through notice and comment rulemaking before moving forward with any new payment models in order to protect patient access to vital therapies and ensure that care is not compromised as new models are tested."

The organizations outlined a strong set of patient-protection principles for CMS action:

***Support Small Scale, Voluntary Testing:***

- “Moving forward, we urge you to finalize safeguards that ensure that all models are small-scale, voluntary tests.”
- “Models should be tested in a limited population to minimize unintended consequences before proper testing is completed.”
- “We encourage CMMI to finalize a safeguard limiting all future model tests to the size needed to obtain valid results.”
- “We encourage CMMI to limit the duration of all models to no more than 5 years.”
- “CMMI should avoid making wholesale changes to existing law, and must have a process for engaging Congress in any broader programmatic changes.”

***Prevent Overlapping Models:***

- “It is also critical to prevent the same population of patients from being subject to multiple models simultaneously.”
- Layering “models on top of one another would have been burdensome for providers and could have severely limited provider options and patient access through multiple, competing directives.”
- “At best, layering multiple payment models would skew results and render findings from each test meaningless.”
- “We therefore encourage CMMI to finalize a requirement that prevents overlapping models.”

***Improve Transparency:***

- “[M]easures must also be implemented to improve the transparency of model design and evaluation.”
- “CMMI should take care to solicit more input from providers, patient groups, and other interested parties who could be impacted by the model before proposing models, and must be more transparent in its deliberation of these ideas.”
- “CMMI should ensure there is an opportunity for a broad solicitation of comments on proposed models.”

***Evaluate Access to Care:***

- “CMMI must also carefully evaluate how proposed changes will impact access to care and should not incorporate elements of an existing pilot or demonstration into new payment models before proper testing is completed.”
- “Proposed models should include a strategy to monitor, assess, and quickly address changes in patient outcomes and access to care.”
- “The results of CMMI model tests with respect to quality, access, and costs should be made available on a regular and timely basis to promote a better understanding of how CMMI models are performing and the impact they are having on patient care.”

In a September 12, 2018 letter to congressional leaders, the Coalition emphasized that the August 7, 2018 CMS memorandum authorizing Medicare Advantage plans to impose step therapy on beneficiary access to Medicare Part B drugs “lacks basic patient safeguards that should be included in any utilization management policy.” We expressed concern that this policy:

- Lacked “adequate standards and transparency to ensure that any step therapy policies are clinically appropriate and evidence based;”

- Failed to include a “timely and accessible process for patients to seek exceptions to a step therapy requirement, and protections against potential increases in cost sharing for some patients;” and
- Imposed an “aggressive implementation timeline and lack of clarity around treatment ‘grandfathering,’” that “casts uncertainty on many beneficiaries’ ability to continue treatment with their ongoing therapies.”

We have attached the original letters to provide additional context, and look forward to working with you to incorporate these principles as you advance new policies to protect Medicare beneficiaries and other patients. For more information about our Coalition and our positions, please visit [www.PartBAccess.org](http://www.PartBAccess.org). Thank you for your consideration.

Sincerely,

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