PART B ACCESS
for Seniors and Physicians Coalition

Date XX, 2018

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

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

The Honorable Paul Ryan
Speaker of the House of Representatives
U.S. House of Representatives
Washington, D.C. 20515

The Honorable Nancy Pelosi
Minority Leader
U.S. House of Representatives
Washington, D.C. 20515

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

We are writing on behalf of the Part B Access for Seniors and Physicians (ASP) Coalition, which is committed to advancing life-saving innovation in the U.S. We are greatly concerned about a proposal by the Centers for Medicare & Medicaid Services (CMS) to implement an unprecedented, mandatory experiment affecting Medicare beneficiaries who take Part B-covered drugs. We support efforts to strengthen the United States' health care system through patient-centered reforms that embrace competition, foster the provider-patient relationship, and value transformation.

The CMS "International Pricing Index" model is not aligned with the above principles. Instead of encouraging Medicare beneficiaries to work closely with their physicians to select treatments based on evidence and best practices, the model would import foreign-based price controls, regardless of value or innovation. Our greatest concern is that this model would impose decisions made in countries such as Greece or Japan on approximately half of all independent physicians and hospital providers, as well as their patients. Compounding these concerns, the model also interjects new middlemen between physicians and patients – vendors that would impose requirements dictating treatment for patients with cancer, autoimmune disorders and other complex, life-threatening conditions. The model would restrict access in the short-term, and reduce incentives for medical advancement in the long-term, ultimately posing serious risks to vulnerable Medicare beneficiaries.

The Medicare Part B International Pricing Index model would slash provider reimbursement for physician-administered medicines based on foreign "reference" prices. The danger of this approach is demonstrated by the experience of patients in countries CMS would use to set Medicare reimbursement. CMS plans to use reference pricing from countries with health care models where government bureaucrats, not physicians, make medical decisions. There is evidence that patients in these countries do not have access to state-of-the-art medical innovation and is not a model the U.S. should emulate on any level. For example, restrictions imposed by the United Kingdom's National Institute for Health and Care Excellence create substantial barriers between patients and life-saving

treatments – recent analysis shows that nearly 92 percent of oncology treatments were subjected to access restrictions from 2013-2017. Further, Americans get access to new cancer medicines an average of two years earlier than patients in Europe.

The model sets a risky precedent for other health care providers and services. Once Medicare uses foreign price controls to determine reimbursement for physician-administered drugs, CMS could apply the same principles to other services. The agency could tie foreign payment levels to reimbursement for medical devices, physician services, nursing care, diagnostic tests, or mental health and substance use disorder specialists. Use of foreign payment policies risks importing access delays to Medicare beneficiaries, limiting patient choice of provider, and potentially impeding development of more effective medicines for patients.

The proposed model would put vendors with no clinical or medical expertise between patients and doctors. Vendors would inevitably impose restrictions on beneficiary access to drugs through formularies, disrupting or delaying care in the pursuit of profit. Medicare Part B beneficiaries have a right to access the Part B-covered drug prescribed by their physician based on his or her medical knowledge and experience. Beneficiaries would effectively lose this right under the model, as vendors that beneficiaries did not choose will dictate the types of drugs they can use. This is particularly risky for vulnerable Medicare patients with cancer and autoimmune or ophthalmic conditions who require complex treatment regimens. Medicare Part B beneficiaries face debilitating consequences if they cannot access the Medicare Part B drugs prescribed by their physician, or if their physician cannot modify their treatment quickly as circumstances change. While this model will likely be positive for the bottom lines of vendors such as PBMs, it will be a net negative for patients and providers, and create new inefficiencies and burdens in the delivery system.

Health and Human Services Secretary Alex Azar set out key principles to improve value in Medicare. In a recent speech, he emphasized supporting patients as empowered consumers and providers as accountable navigators, paying for outcomes, and preventing disease before it occurs or progresses. None of these principles are evident in the International Pricing Index Model. The CMS notice focuses solely on short-term cost reductions, emphasizing only medication costs, with little, if any, meaningful analysis of overall health costs, the impact of medications on use of higher cost services, or quality measures.

Innovation will also suffer as the model would disrupt biopharmaceutical investment in research and development. Foreign price controls already hinder investment in biopharmaceutical research and development. A report for the U.S. Department of Commerce found that international reference pricing and other foreign price controls suppress worldwide private research and development investment by 11-16 percent annually, impacting the number of new and innovative medicines brought to market.

We support use of the Center for Medicare & Medicaid Innovation (CMMI) to test patient-centered, voluntary, small-scale reforms that can be fully evaluated. However, the IPI model is a wide-scale demonstration that would be mandatory, affecting 50 percent of physicians and hospitals serving Medicare Part B beneficiaries. The unprecedented scale and scope of the model would impact payment and access for beneficiaries in the rest of the Medicare Part B program. The mandatory nature of the

model would force beneficiaries into the experiment, eliminating their ability to choose a provider not subject to the model. There is little in the model that addresses key statutory principles for CMMI models that are intended to improve the coordination, quality, and efficiency of health care services. The new model would also overlap and interfere with existing CMMI demonstrations, making it difficult to evaluate the benefits of reforms that represent significant investments by CMS and providers.

Over 59 million seniors and persons with disabilities rely on Medicare Part B for essential treatments. Any potential changes to the program should be tested only in a limited and careful way, based on clinical evidence and guidelines focused on high quality care. These qualities are not part of the International Pricing Index model that CMS has proposed. On behalf of the **xx** undersigned organizations, we urge you to work with us to halt implementation of the model and instead seek workable solutions that focus on patients and providers.

Sincerely,