

February 3, 2020

Member, U.S. Senate
Member, U.S. House of Representatives

Attn: Health Legislative Director

Dear Senator/Representative:

On behalf of the nearly 50 million Americans affected by autoimmune diseases, the American Autoimmune Related Diseases Association and undersigned members of the National Coalition of Autoimmune Patient Groups request that efforts to reference international drug prices in setting prices for medicines in American health care be rejected. Our organizations are committed to lowering the cost of health care, including prescription drugs, so that every person has affordable access to the treatments they need to live full and healthy lives.

For the past year or so, proposals to bend the curve in spending on medicines have included various methods for referencing prices paid in the United States for prescription medicines to those set by the health care systems in other developed countries. This approach is evidently appealing for its simplicity and ease of application to spending under Medicare Part B and other insurance programs. Our organizations understand that some Members of Congress and the Administration may continue to see the International Pricing Index (IPI) model as a worthwhile strategy, perhaps even advocating this approach in the President's State of the Union message. On behalf of people living with autoimmune diseases and many other Americans who rely on our nation's healthcare system, we strongly urge you to oppose such a course.

AARDA and many of our coalition partners communicated with Congress and the Administration on several occasions in late 2018 to express our concern over IPI. Our views are unchanged regarding warning against tying American access to innovative and effective medicines to European systems of health care coverage, that often leave people with chronic conditions and disabilities with fewer and delayed options for medicines otherwise available to Americans today. Adoption of IPI, as discussed, will undermine access to needed medicines and degrade immediate and long-term benefits in health, well-being, productivity, and quality of life for our nation's most vulnerable citizens. Excerpts from two such communications follow.

On December 10, 2018, in a letter to Congressional leadership sent by the Part B Access to Seniors and Physicians (ASP) Coalition, including several autoimmune groups, we expressed concern 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. As a group numbering 339 organizations, we reiterated our support of efforts to strengthen the United States' health care system through patient-centered reforms that embrace competition, foster the provider-patient relationship, and value transformation. Yet, we raised a red flag regarding the IPI model proposed by the Centers for Medicare and Medicaid Services (CMS), including the inappropriate use of the Center for Medicare and Medicaid Innovation (CMMI) to broadly implement this untested and unfounded scheme.

“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.

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 December 31, 2018, in a letter sent to Congressional leadership by the Partnership to Improve Patient Care (PIPC), AARDA and other autoimmune groups expressed the following views regarding the Administration’s efforts to support more affordable patient care and reduce high drug prices:

“we are deeply concerned that in this instance, CMS has chosen an approach that would lead to discriminatory barriers in access to care and ignores the real-world implications for our communities. We urge the Administration to instead work with us to develop sound, patient-centered solutions that recognize that each of us has value and shared human dignity.

We strongly oppose this proposal for two reasons. First, by referencing the policies underpinning coverage and reimbursement of foreign governments, it effectively endorses the use of discriminatory cost-effectiveness standards used by foreign governments here in the U.S. Second, the proposal would be implemented through a large scale, mandatory “demonstration” that effectively forces almost half of doctors (and their Medicare patients) in the U.S. into a radical change in policy with unknown, and potentially very serious, effects on their patients without necessary safeguards to ensure their basic protections.

Addressing health care costs, including drug prices, is an important and meaningful effort that should center on achieving outcomes that matter to those being served by health systems (patients, people with disabilities, veterans, seniors and other marginalized communities) such as improved quality of care and lower out-of-pocket costs. We are hopeful the Administration will reconsider their plan to import international cost-effectiveness standards into the U.S. and instead advance patient-centered, non-discriminatory approaches and establish meaningful protections for our communities in future demonstrations.”

The American Autoimmune Related Diseases Association and the undersigned members of the National Coalition of Autoimmune Patient Groups, urge you to push back on consideration of the International Pricing Index model offered by CMS and potentially advocated by the President as a sound means of reducing spending on prescription drugs and lowering health care costs. While this goal is laudable and necessary, the IPI model itself is flawed, high-risk and even discriminatory.

We urge legislators to advise the Administration against this approach and seek other legislative and regulatory reform strategies to better control costs while improving increased access, smarter investments, and better outcomes across the health care eco-system for all Americans, including those living with one or more autoimmune diseases. We stand ready to continue to collaborate with you and the Administration in promoting this worthy goal. Thank you for your consideration of our views.

Respectfully,

American Autoimmune Related Diseases Association
Advocacy & Awareness for Immune Disorders Association
American Behcet's Disease Association
APS Foundation of America
Autoimmune Encephalitis Alliance
Conquer Myasthenia Gravis
International Foundation for Autoimmune & Autoinflammatory Arthritis
International Pemphigus and Pemphigoid Foundation
Lupus and Allied Diseases Association, Inc.
Lupus Foundation of America
National Alopecia Areata Foundation
Platelet Disorder Support Association
Sjogren's Syndrome Foundation
Vasculitis Foundation