



December 20, 2018

The Honorable Alex Azar
Secretary, Department of Health and Human Services

The Honorable Seema Verma
Administrator, Centers for Medicare and Medicaid Services

Department of Health and Human Services
Centers for Medicare & Medicaid Services
Attention: CMS-5528- ANPRM
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Dear Secretary Azar and Administrator Verma:

Thank you for the opportunity to share our thoughts with you on the Department's Advanced Notice of Proposed Rule Making (ANPRM) regarding the International Price Index Model (IPI) for Part B Drugs. Like you, we believe that affordability for beneficiaries and sustainability of the Medicare program are critically important. While we are open to improvements to the program and would suggest that the Department's drive toward value represents an important improvement, the Healthcare Leadership Council (HLC) has concerns about the concept of the proposed IPI model and its potential impact on patients and medical innovation.

HLC is a coalition of chief executives from all disciplines within American healthcare. It is the exclusive forum for the nation's healthcare leaders to jointly develop policies, plans, and programs to achieve their vision of a 21st century healthcare system that makes affordable high-quality care accessible to all Americans. Members of HLC – hospitals, academic health centers, health plans, pharmaceutical companies, medical device manufacturers, laboratories, biotech firms, health product distributors, pharmacies, post acute care providers, home care providers, and information technology companies – advocate for measures to increase the quality and efficiency of healthcare through a patient-centered approach.

As you know, HLC has long advocated for a Medicare program that is more quality-driven, cost-efficient and patient-focused and we believe the Center for Medicare and Medicaid Innovation (CMMI) is a key partner in this goal. However, we believe that demonstrations should involve limited, targeted testing of new payment and delivery ideas, incorporating collaboration and transparency with healthcare stakeholders. Vigilant monitoring should include quality evaluation to protect Medicare beneficiaries. Testing of new payment models in small controlled populations will ensure that any unintended consequences do not have lasting effects on a large scale that can cascade throughout the health system.

The Department of Health and Human Services' ANPRM states the initial program may focus on fewer than 30 Part B drugs, with a yet to be determined geographic area covering roughly 50 percent of Part B drug spending for selected testing, with mandatory participation for physicians and hospitals in regions selected. Applying a proposed demonstration project to a large portion goes beyond any prudent definition of a test. Given the broad scope of the proposed demonstration, HLC is particularly concerned about the potential unintended consequences this demonstration could have on large numbers of beneficiaries receiving vital medications through Medicare Part B.

While we commend the Administration's commitment to lowering the cost of prescription drugs, HLC believes the outline in the ANPRM will not achieve the desired goal in the long-run. Since its inception 30 years ago, HLC has strived to increase market competition, not increased government oversight, because market competition results in better choice for the patient. This proposal would decrease the role of the market and increase government control. By linking prices to those set by other countries, the Administration is proposing a government price-setting mechanism for Part B drugs. The United States, in contrast to many other countries, has a relatively competitive marketplace for drug pricing that utilizes competition to control costs. Our marketplace also provides patients with access to innovative medicines far earlier than in countries with comprehensive government-set pricing, and it is why we lead the world in drug discovery and development. Many of the countries identified in the ANPRM will admit that they benefit from our country's commitment to research and development but that medicines are not immediately accessible to their citizens because of their pricing policies.

To have concerns about this IPI model is not tantamount to being satisfied with the global status quo regarding drug pricing. We are fully supportive of the strong rhetorical stance the Administration has taken regarding foreign free riders and the need for other nations to pay their fair share for innovation. HLC has long supported making this position a key component in trade negotiations. We are not convinced, however, that emulating the price controls employed by these nations is going to result in a desirable outcome. And by testing this thesis on half of the country for a lengthy duration, we are seriously concerned that the potential risks outweigh the likely rewards.

We are concerned about the effect the proposed IPI model could have on the Medicare Part B drug program, which provides support to some of the sickest, most vulnerable patients and accounts for a small fraction of all Medicare spending. According to the Medicare Payment Advisory Commission, prescription drug spending under the Medicare Part B program accounts for less than 4 percent of all Medicare spending (MedPAC June 2016 Data Book).

HLC sincerely appreciates the opportunity to share our thoughts on the Administration's proposed IPI model for Medicare Part B. We will continue to support market-based reforms that will promote competition and lower drug costs, without harming our nation's innovation that enables us to lead all other countries in discovering new cures and treatments. We look forward to continuing to work with you on ensuring access to innovative and affordable prescription drugs for our nation's Medicare beneficiaries and beyond. We offer our comments based on our past experiences and in support of the quality healthcare our members deliver to better the lives of existing and future Medicare beneficiaries.

Sincerely,

A handwritten signature in cursive script, appearing to read "Mary R. Greal".

Mary R. Greal
President