

March 17, 2022

The Honorable Frank Pallone
Chairman
Energy & Commerce Committee
2107 Rayburn HOB
Washington, DC 20515

The Honorable Cathy McMorris Rodgers
Ranking Member
Energy & Commerce Committee
1035 Longworth HOB
Washington, DC 20515

Re: H.R. 7008 – The Pre-approval Information Exchange Act of 2022

Dear Chairman Pallone and Ranking Member McMorris Rodgers:

The undersigned organizations, representing a diverse coalition of stakeholders in American healthcare, write in support of the *Pre-approval Information Exchange Act of 2022* (H.R. 7008). This important bill will help speed patient access to new, potentially lifesaving, treatments by reducing the time between Food & Drug Administration (FDA) approval of a treatment and the beginning of coverage for that treatment.

Pre-approval information exchange (PIE) is the practice of drug and device manufacturers communicating certain truthful and non-misleading economic and clinical information to health payers regarding therapies or new indications of previously approved products in the FDA pipeline before they are approved. This allows payers to plan appropriately for the economic impact a new treatment will have before the beginning of the plan year in which approval is anticipated. The language includes provisions to ensure that information is provided only to appropriate audiences. The bill also empowers payers and manufacturers to begin developing purchasing agreements before approval, which can significantly reduce the amount of time between approval and patient access. This period between approval and coverage is sometimes referred to as the “Valley of Death.”

FDA guidance initially drafted under Dr. Califf’s leadership in 2016 and finalized in 2018 permitted PIE but did not clarify if manufacturers can proactively share this information or are limited to providing it in response to a payer request for information. As a result, many manufacturers are hesitant to engage in PIE, leading to preventable delays in access to new treatments.

Health care decision-makers find greater need for proactive PIE communication as the health care system evolves from a fee-for-service payment structure to a value-based model rewarding quality, improved patient outcomes, and cost-efficiency by facilitating more timely negotiations of value- and outcomes-based contracts. PIE is particularly important in fields with rapidly evolving therapeutic options, such as but not limited to oncology and the treatment of rare diseases. For example, many cancer treatments are approved only for one specific type of cancer but later found to be effective in treating other types as well. Cell and gene therapies, a growing class of treatments, are often used to treat rare diseases but have complex development processes and high list prices, sometimes ranging from hundreds of thousands of dollars to more than a million. Delays in patient access due to statutory barriers to timely exchange of information can have serious consequences. Publicly funded payers, like Medicare and Medicaid, have statutorily limited flexibility to change their prescription drug formularies

during a plan year, which can lead to beneficiaries experiencing significant delays accessing new treatments.

The undersigned support the creation of a legislative safe harbor for PIE and strongly encourage the House of Representatives to pass the *Pre-approval Information Exchange Act of 2022* (H.R. 7008). This bill will improve patient access to care by ensuring that the proactive provision of truthful and non-misleading economic and clinical information to payers prior to FDA approval does not run afoul of FDA labeling guidelines and prohibitions against off-label commercial marketing.

Sincerely,

Academy of Managed Care Pharmacy
Alliance of Community Health Plans
American College of Apothecaries
American College of Clinical Pharmacy
American Society of Health-System Pharmacists
Astellas Pharma US, Inc.
Aventine Consulting
Blue Cross Blue Shield Association
Council for Affordable Health Coverage
Humana
Little Hercules Foundation
Magellan Rx Management
Parent Project Muscular Dystrophy
Prime Therapeutics