601 Pennsylvania Avenue, NW
South Building, Suite 500
Washington, D.C. 20004

T 202.778.3200
C 202.450.8218
ahip.org

Matthew Eyles
President & Chief Executive Officer

May 11, 2022

The Honorable Anna G. Eshoo
Chairwoman
House Committee on Energy & Commerce
Subcommittee on Health
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Brett Guthrie
Ranking Member
House Committee on Energy & Commerce
Subcommittee on Health
2322-A Rayburn House Office Building
Washington, DC 20515

Dear Chairwoman Eshoo and Ranking Member Guthrie,

Americans deserve high-quality, affordable health care choices, and value-based strategies are essential to delivering on that commitment. That's why proactive communication among different health care stakeholders is especially important as our health care system evolves from a fee-for-service payment model to a modernized system rewarding quality, improved patient outcomes, and high value.

As such, we write to you in support of H.R. 7008 – the Pre-approval Information Exchange (PIE) Act of 2022, which will improve patient access to drugs, biologics and devices by codifying 2018 guidance from the U.S. Food and Drug Administration (FDA) that permitted communications regarding health care economic information (HCEI) and scientific information between biopharmaceutical and medical device manufacturers and health insurance providers, pharmacy benefit managers, other payors, formulary and technology review committees, and similar entities. H.R. 7008 would create a safe harbor of the guidance, allowing for proactive communications between manufacturers and health payors.

We support the need for timelier and more appropriate communications between pharmaceutical and medical device manufacturers and payors, formulary committees, and similar entities about products that are investigational or under review by the FDA. We also recognize the importance of holding these communications to strong evidentiary standards.

The current uncertainty over what types of communications are permitted often makes it difficult for health plans to obtain reliable HCEI related to an FDA-approved indication and therefore complicates their efforts to make accurate assessments regarding target patient populations, potential clinical efficacy, value, pricing, and utilization. Health plans need sound information based on strong evidentiary standards to inform estimates of anticipated patient utilization and costs and benefits for up to several years into the future when making business decisions involving pricing and contracts, especially value-based arrangements.

We support the PIE Act because it will:

- Allow more accurate forecasting and budgeting related to emerging medication therapies and devices;
- Support greater utilization of value-based payment models, through a fuller understanding of the overall value of new products; and,
- Allow earlier access to pivotal clinical trial data facilitating coverage decisions contemporaneous with FDA approval.

Early and appropriate communication of this type of information can enable manufacturers and payers to develop alternative, value-based payment arrangements, such as outcome-based contracts and indication-specific pricing. We believe that furthering communications between biopharmaceutical and medical device manufacturers and payors, formulary committees, and similar entities prior to FDA approval/clearance will help to shift our health care system to a focus on value and promote good outcomes for patients.

A stronger American health care system is one that is centered on delivering higher quality, more choices, and better experiences at a lower cost. By making health care more effective and affordable, we can help ensure that every American has access to coverage that provides them with financial stability and peace of mind.

We thank the Energy & Commerce Subcommittee on Health for its leadership in addressing this very important issue and please don't hesitate to use us as a resource as you continue to lead this initiative forward.

Sincerely,

Matthew Eyles

Matthew Eyles
President and CEO, AHIP