

July 10, 2017

The Honorable Brett Guthrie
Vice-Chairman, Subcommittee on Health
Energy and Commerce Committee
2434 Rayburn House Office Building
Washington, DC 20515

Re: H.R. 2026 – The Pharmaceutical Information Exchange (PIE) Act of 2017

Dear Vice-Chairman Guthrie,

The undersigned organizations commend you for your leadership in introducing *H.R. 2026 – The Pharmaceutical Information Exchange (PIE) Act of 2017* which will improve patient access to emerging medication therapies and devices by codifying a safe harbor for certain health care economic and scientific information communications between biopharmaceutical and medical device manufacturers and population health decision makers. Collectively, our organizations represent population health decision makers (e.g. payers, provider sponsored health plans, pharmacy benefit managers, accountable care organizations, and integrated delivery networks), biopharmaceutical and medical device manufacturers, patient advocacy groups, health care providers, health economists, and others.

We support the need for timelier and more proactive sharing of preapproval health care economic information (HCEI) between biopharmaceutical and medical device manufacturers and population health decision makers to enable the implementation of value-based contracts, aid in forecasting and budgeting, and expedite coverage decisions for emerging therapies, including those granted breakthrough designation. The need for this proactive communication is especially important now as the United States health care system evolves from a fee-for-service payment system to a modernized system rewarding quality, improved patient outcomes, and value.

We support H.R. 2026 because it will:

- Create a legislative safe harbor to allow biopharmaceutical and medical device manufacturers to share proactively with population health decision makers truthful and not misleading clinical and economic information about medications and devices in the pipeline, as well as new uses of approved products, prior to FDA approval during the forecasting and rate setting process. A legislative safe harbor for PIE will confirm that the proactive dissemination of certain information does not violate the prohibitions against preapproval promotion and does not run afoul of the labeling, misbranding, and intended use provisions of the Federal Food, Drug, and Cosmetic Act and its implementing regulations.

- Facilitate communication from biopharmaceutical and medical device manufacturers to an appropriate audience of population health decision makers who need this information for financial forecasting and planning purposes only.
- Extend PIE to investigational products not approved/cleared for any use and investigational uses of approved/cleared products for which there is an intent to file a supplement. The rationale for PIE applies equally to both. Factors such as product information, indication sought, clinical data, anticipated approval timeline, pricing information, targeting/marketing strategies and product related programs or services are unique to each indication. Anticipating a new indication and properly planning for the impact on budget and expansion of patient populations eligible to receive such medication or device are vital for population health decision makers.
- Allow for bidirectional exchange of information and sharing of health care economic or scientific information. Such information would include data from pivotal clinical trials, pharmaco-economic data, as well as data relating to patient centered outcomes (health related quality of life, treatment satisfaction, etc.), and could also include other material items, such as anticipated indications, place in therapy, and routes of administration.

In summary, our organizations believe that furthering communications between biopharmaceutical and medical device manufacturers and population health decision makers prior to FDA approval/clearance will help to shift the United States health care system to a focus on value and promote good outcomes for patients. Thank you for championing this very important issue and please use our organizations as a resource as you continue to lead this initiative forward.

Sincerely,

Academy of Managed Care Pharmacy (AMCP)
 Amgen
 Blue Cross and Blue Shield Association (BCBSA)
 Bristol-Myers Squibb
 Center for the Evaluation of Value and Risk in Health, Tufts Medical Center
 Cigna
 Dymaxium, Inc.
 Genentech, Inc.
 Gilead Sciences
 Harvard Pilgrim Health Care
 Humana
 International Society for Pharmacoeconomics and Outcomes Research (ISPOR)
 Mayo Clinic
 Pharmaceutical Research and Manufacturers of America (PhRMA)
 Precision for Value
 Qualchoice Health Plan Services, a division of Catholic Health Initiatives
 Sanofi
 Takeda
 University of Utah College of Pharmacy, Pharmacotherapy Outcomes Research Center
 Xcenda