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ISSUE **BRIEF**

Pre-approval Information Exchange (H.R. 7667)

BACKGROUND

Pre-approval information exchange (PIE), included as Section 809 of the Food & Drug Amendments of 2022 (H.R. 7667), is an important bipartisan policy that will enhance patient access to emerging pharmaceuticals and devices. Section 809 authorizes pharmaceutical manufacturers to proactively share certain health care economic and scientific information about products with health payers ahead of Food & Drug Administration (FDA) approval. FDA guidance 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. It also lacked clarity in its description of the types of information communicable pre-approval. These issues have caused substantial legal uncertainty for manufacturers and payers seeking to engage in PIE.

PIE is a crucial strategy for ensuring health plans and payers have access to critical information and research-based evidence to make timely coverage decisions and facilitate patient access when new therapies come to market. The need for proactive PIE communication is especially important as the health care system evolves from a fee-for-service payment system to a value-based system rewarding quality, improved patient outcomes, and cost-efficiency. PIE will also allow health payers to better anticipate a new indication* and properly plan for its impact on budget and expansion of patient populations eligible to receive a therapy. Further, publicly-funded payers, like Medicare, have limited authority to change their prescription drug formularies during a plan year. In some cases, this can lead to beneficiaries experiencing significant delays accessing new treatments compared to individuals with private insurance.

* Meaning use of a drug for treatment of a particular disease

AMCP'S POSITION

AMCP supports PIE as included in H.R. 7667. A legislative safe harbor for PIE will confirm that the proactive dissemination of certain clinical and economic information does not violate the prohibitions against pre-approval promotion and does not run afoul of the labeling, misbranding, and intended use provisions of the Federal Food, Drug, and Cosmetic Act and its implementation regulations. This will expedite coverage decisions for and patient access to emerging therapies, including those granted breakthrough designation.

CALL TO ACTION

AMCP urges the House of Representatives to vote for H.R. 7667 and codify safe harbors that allow for proactive PIE between manufacturers and health payers. Sharing truthful and non-misleading clinical and economic information about therapies in the pipeline, as well as new uses of approved products, before FDA approval benefits patients.

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05/2022