AMCP

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ISSUE **BRIEF**

Pre-approval Information Exchange

BACKGROUND

Pre-approval Information Exchange (PIE) — a concept designed to improve patient access to emerging pharmaceuticals and devices — is a crucial effort to ensure health plans and payers have access to critical information and research-based evidence to provide timely coverage decisions and patient access when new therapies come to market. PIE allows manufacturers and health plans and payers to proactively share certain health care economic and scientific information about products ahead of FDA approval. 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 communication has proven essential throughout the COVID-19 public health emergency.

AMCP'S POSITION

AMCP supports systems and processes that allow health care economic information to be shared proactively and in a timely manner prior to FDA approval. Allowing proactive sharing of information between health plans, payers, and manufacturers in advance of a product's approval will expedite coverage decisions for and patient access to emerging therapies, including those granted breakthrough designation.

PIE will also allow health plans and payers to better anticipate a new indication* and properly plan for its impact on budget and expansion of patient populations eligible to receive a drug or device.

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

CALL TO ACTION

AMCP urges Congress to introduce and pass bipartisan legislation codifying current regulatory safe harbors that allow for PIE between manufacturers, health plans, and payers. Such a legislative safe harbor would allow for sharing truthful and non-misleading clinical and economic information about medications and devices in the pipeline, as well as new uses of approved products, before FDA approval.

A legislative safe harbor for PIE will confirm that the proactive dissemination of certain 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 regulations on implementation.

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