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28 Dec 2022 | **Analysis**

# Preapproval Information Exchange With Payers: Guidelines Codified In Omnibus Spending Bill

by Cathy Kelly

Legislation, known as PIE Act, does not force manufacturers to share information on pricing or economic models with payers but aligns with the requirements in US Food and Drug Administration guidance.

Pharmaceutical manufacturers can feel more comfortable about proactively exchanging information with payers on drugs before they are approved now that legislation codifying the practice has passed in the US Congress.

Legislative provisions known as the Preapproval Information Exchange (PIE) Act was included in the 2023 omnibus government funding *bill* that passed both chambers of Congress in the days leading up to Christmas and is expected to be signed by President Biden shortly.

The legislation also includes provisions related to accelerated approval, clinical trial diversity, and generic drug and biosimilar approvals. (*See box for links to other stories.*)

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Passage of the PIE Act has long been supported by the Academy of Managed Care Pharmacy and payers. Advocates believe some manufacturers have been reluctant to proactively share information on not yet approved drugs because US Food and Drug Administration guidance allowing the practice did not sufficiently clarify the scope of permissible communications. (Also see "*US FDA Extends Payor Communications Safe Harbor To Off-Label Uses* " - Pink Sheet, 12 Jun, 2018.)

For example, the guidance was generally helpful in clarifying the types of information that can

be communicated pre-approval, but it did not specify whether this information can be provided proactively to payers. The legislation does not put parameters around whether manufacturers can initiate information exchange with payers, which AMCP hopes can address concerns that information can only be provided in response to a payer request.

With passage of the legislation, "payers will be able to conduct their rigorous review of life-saving treatments concurrently with the Food and Drug Administration's review, a change that will help patients access treatments faster," AMCP said in a release.

"By enhancing the way manufacturers share information with payers and plans, we will safely accelerate patient access to life-saving treatments. In light of the new and novel treatments currently in development for serious illnesses, we are confident PIE will have a positive impact on the lives of patients and their families," AMCP CEO Susan Cantrell told the *Pink Sheet*.

"We desperately need the information whether clinical or economic information so that we can quickly and efficiently review the data and evidence that supports the use of these new medications," Cantrell added.

"More than 50% of the new drug approvals are biologics with much higher price tags and in some cases are used in limited patient populations in clinical trials. ... These are therapies that are critical for patients to have access to." She noted that "while we've seen improvement" in manufacturer communications in recent years, "we think the legislation will take it across the finish line."

Manufacturers are supportive of preapproval information exchange but have been concerned that legislation might go beyond FDA guidance. Payers are very interested in information on pricing and economic models related to new products, but manufacturers generally do not provide such data for competitive reasons. Such information is permitted but not required under the bill.

## Communication Limited To Payers And Formulary, Economic Experts

The legislation allows for dissemination of information on an unapproved drug or unapproved use of an approved drug to "a payor, formulary committee, or other similar entity with knowledge and expertise in the area of health care economic analysis," if the information includes declaration that a drug or a new use has not been approved and a description of the drug's stage of development.

The stage of development information could include:

- The status of any research;

- How the study or studies relate to the overall plan of development; and

- Whether an application for the investigational drug or use has been submitted to FDA and if not, when it is planned.

If the information includes factual presentations of results from studies (which may not be selectively presented) it should include a description of the study design, methodology, and results and any material limitations and where applicable, a prominent statement disclosing indications that have already been approved, current labeling and any updates to previous communications.

Information could also include a description of the drug or indication(s) being investigated, the anticipated timeline for a possible approval, pricing information, patient utilization projections and product-related programs or services.

## GAO Study Will Evaluate Impact

The legislation directs the Government Accountability Office to conduct a study and issue a report five and a half years after enactment on various aspects of dissemination of preapproval information. The report should analyze:

- The types of information communicated;

- The manner of communication;

- Whether manufacturers seek approval for a drug that is the subject of the communication;

- How frequently FDA approves drugs or indications that are the subject of such communication; and

- The timeframe between the initial communication and the marketing of such a drug or indication.