



Pre-approval Information Exchange Act (H.R. 7008) Frequently Asked Questions

What problem does the bill solve?

The Pre-approval Information Exchange (PIE) Act (H.R. 7008) will speed patient access to new pharmaceuticals and medical devices by facilitating earlier communications between pharmaceutical manufacturers and health plans and payers. In the case of health payers, PIE enables them to begin budget forecasts and negotiating purchasing agreements with manufacturers at an earlier stage. This will benefit patients by allowing novel treatments to be covered by health plans sooner than they otherwise would be. This is especially important for public payers, like Medicare and Medicaid, who have limited flexibility to modify their drug coverage during a plan year. Sometimes, this can lead to significant disparities in access to new therapies for beneficiaries. This can most easily be accomplished by clarifying and codifying non-binding guidance issued by the Food & Drug Administration (FDA) in 2018. The guidance moved the industry closer to an efficient PIE landscape but has not resulted in the full adoption of the practice due to hesitancy among stakeholders to engage in PIE because of vague language in the guidance.

Will patients receive full information about pre-approval products?

The information communicated by PIE is between manufacturers and health payers, not patients. The PIE Act does not authorize information exchange with other audiences, so patients will not receive any information or direct communication prior to FDA approval. After approval, patients will receive information about treatments and costs through the traditional channels, such as their prescribing doctors, representatives from their health plans, and patient advocacy groups. Prohibiting exchange with non-payer audiences is an important protection against off-label commercial marketing.

Will prescribers receive full information about pre-approval products?

No. Prescribers, including physicians, physicians' assistants, and nurse practitioners, will not receive information as part of the pre-approval information exchange process. As with patients, the PIE Act does not authorize exchange with non-payer audiences. Prescribers will receive information about new treatments through the traditional channels following FDA approval. Prohibiting exchange with non-payer audiences is an important protection against off-label commercial marketing. Non-commercial provision of clinical information to prescribers by manufacturers falls outside the scope of the PIE Act of 2022 and AMCP's role as a professional association representing managed care pharmacists.

What does PIE do to make drugs less costly for patients?

PIE addresses communication issues related to the FDA approval pipeline. Cost reductions for patients will mainly come from reducing the time between FDA approval and health plan adoption and coverage of a new treatment. Patients sometimes elect to pay entirely out of pocket for certain treatments rather than wait for coverage to begin. Patients may also see lower initial costs for a new treatment due to more accurate budget forecasts thanks to health payers' receipt of clinical and economic information in time to be incorporated into the budget for the plan year in which it will be approved.

Why is this needed considering the final guidance from FDA in 2018?

The FDA guidance did not sufficiently clarify the scope of permissible PIE communications. While it was generally helpful in clarifying the types of information that can be communicated pre-approval, it did not specify whether this information can be provided proactively to health payers or must be provided only in response to unsolicited requests for information. This has led to hesitancy among many pharmaceutical manufacturers to engage in PIE.

Only 39 percent of health payers report consistently receiving PIE even in response to an unsolicited request, and 26 percent report that they rarely or never receive a response.

Two other factors contribute to manufacturer hesitancy. First, there are two different but potentially applicable standards for communications included in the guidance regarding communications about new indications for previously approved drugs. The guidance's recommendations for communications about approved products echoes the statutory blanket prohibition on manufacturers providing information related only to unapproved indications of approved therapies. However, the recommendations on pre-approval communication indicate that new indication-only data can be shared if the manufacturer intends to submit the new indication for FDA approval. Given that both standards seem to apply, manufacturers err on the side of caution and do not share information that payers find useful.

Second, many manufacturers view the guidance as unstable. They are hesitant to invest in systems and processes to develop and disseminate PIE materials due to concerns about future administrations revoking the guidance. Further, they worry that FDA may still penalize them even if they follow the guidance since it is non-binding.

How does the legislation improve U.S. competitiveness? Do other countries have a faster process?

This likely does not impact US competitiveness in a meaningful way. Drugs will need to undergo approval in each country before health plans in those countries begin to cover them. The true value of PIE is that it speeds access for American patients to new, potentially lifesaving, treatments.

What types of products does the bill address?

The Pre-approval Information Exchange Act covers small molecule drugs, biologic products including biosimilars, and medical devices, consistent with the FDA guidance.

What disclosures by manufacturers are required by the Pre-approval Information Exchange Act?

The bill requires manufacturers to include prominent and conspicuous statements that the product in question has not been approved or granted marketing clearance by FDA. In the case of new indications for already approved products, the statements must include that this indication has not been approved or granted marketing clearance by FDA and describe any differences between the label sought for the new indication and the already-approved label.

Does this create a backdoor for drug makers to increase promotions of off-label use of drugs?

No. The bill includes language limiting PIE communications to products or new indications that are intended for submission to FDA for review and approval and includes "claim" language to give the FDA clear jurisdiction on determining use.

A survey of employees of health plans and pharmaceutical manufacturers published in the *Journal of Managed Care and Specialty Pharmacy* in 2019 found "great interest in PIE and support of a framework to facilitate dissemination. Respondents stated that PIE engagement around clinical data and [health care economic information] was *specifically desired from manufacturer medical and scientific representatives (i.e., medical or outcomes liaisons) as opposed to commercial representatives.*" [emphasis added]

Does this bill address the safety and efficacy of a drug?

No. This bill does not address either the safety or efficacy of a drug and does not modify the FDA standards for approval in any way. AMCP supports requiring a manufacturer to disclose to PIE recipients that the product is not approved. If the FDA does not approve the drug or indication, payers will not cover it. Pre-approval information exchange does not require a payer to cover an unapproved indication simply because the communication occurred.

How does PIE improve outcomes in value-based care?

PIE gives manufacturers and health payers more time to negotiate and execute value-based purchasing arrangements before a drug comes to market. Especially in the case of some high-cost specialty treatments, purchasing agreements can take months to negotiate. PIE means health plans will not have to choose between taking the time to negotiate more cost-effective value-based purchasing agreements and beginning coverage.

Can PIE help with Emergency Use Authorizations in a pandemic?

The process used in the launch of the COVID-19 vaccines is effectively pre-approval information exchange. In many cases, EUAs are for newly developed, unapproved treatments. By virtue of being unapproved, all communications between manufacturers and purchasers of the new treatments would be considered pre-approval communications. Having systems and processes in place to facilitate PIE as a matter of routine during non-pandemic times will also result in more expeditious treatment rollouts during public health emergencies. Manufacturers and payers will not need to create new systems and will be familiar with the process.

Does PIE reduce costs in the health care system?

The primary benefit of PIE is that patients will have quicker access to new therapies; cost to the health care system is not the main problem addressed by this bill. PIE may marginally reduce health care system costs by allowing manufacturers and payers to negotiate value-based purchasing agreements earlier and more easily. This will be especially valuable for high-cost specialty drugs that will have more complex agreements.

How does it fit in with other legislation improving health information technology?

PIE fits in with other efforts to improve and modernize the FDA approval pipeline. It is less connected to other HIT efforts, like electronic health records or electronic prescribing, which are focused on improving communications between individual providers and/or care settings on a specific patient. PIE is a population-level concept that will minimize avoidable delays in patient access to new therapies.

Does PIE protect proprietary information for manufacturers?

PIE does not change protections for proprietary information for manufacturers. The same protections that exist now for confidential communications will remain in place.

Are payers able to request more information from manufacturers?

Yes. There is no prohibition in the bill against follow-up requests for information after the initial exchange of information. PIE is an ongoing dialogue, allowing payers and manufacturers to communicate continuously about a drug to reach agreements about coverage and purchasing.