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'Safe Harbor' For Preapproval Information Exchange To Get Legislative Push

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Executive Summary

US Academy of Managed Care Pharmacy is developing language to protect exchange of clinical and economic information on pipeline products between manufacturers and healthcare decision-makers; safe harbor could find a home in legislation reauthorizing FDA user fee programs.

Language creating a "safe harbor" for drug manufacturers to proactively share clinical and economic information with payers and other healthcare decision-makers ahead of product approval could find its way into FDA user fee legislation that must pass Congress in 2017.

The Academy of Managed Care Pharmacy (AMCP) is leading a multi-stakeholder push for legislation to protect preapproval information exchange (PIE) between manufacturers and entities responsible for making population health decisions, such as payers and pharmacy benefit managers.

Being able to discuss clinical and economic information about a pipeline product 12-18 months before its expected approval would help payers and others plan for market entry of new treatments and make decisions about premiums, co-payments and formulary placement, AMCP said.

AMCP plans to share suggested legislative language with Congress in the coming weeks.

However, legislation should not restrict how such information exchanges between drug manufacturers and payers take place, according to the summary of proceedings of an AMCP-led forum published in the January issue of the Journal of Managed Care & Specialty Pharmacy.

The article lays out the multi-stakeholder forum's proposals for defining pre-approval information exchange, the entities that should have access and how such information should be shared.

FDA gave manufacturers a greenlight to share healthcare economic information with payers, formulary committees and similar entities in draft guidance issued Jan. 18. (Also see "Industry Communications With Payors: US FDA Okays Info On Investigational Drugs" - Pink Sheet, 19 Jan, 2017.)

In a statement Jan. 18, AMCP said the agency's guidance goes a long way toward providing manufacturers with clarity about the information they can share and largely mirrors consensus recommendations from the AMCP-led initiative.

'Potential Vehicle' In User Fee Bill

In the journal article, the forum calls for legislative and regulatory changes that would allow manufacturers to engage in information exchange activities without facing an enforcement risk.

"New legislative language may be beneficial, since PIE is a novel category of information," the article states. "New legislation could provide a safe harbor and clarity that PIE does not violate preapproval promotion and the federal Food, Drug, and Cosmetic Act and its regulations."

The AMCP-led group also identified a need for FDA regulatory changes "to expressly permit biopharmaceutical manufacturers to proactively communicate with population health decision-makers about emerging therapies before FDA approval so that more accurate forecasting and rate setting are supported, enabling affordable access for all patients to new therapies upon FDA approval," the article states.

AMCP is developing legislative language based upon the forum's recommendations, CEO Susan Cantrell said. "We look forward to working with the new administration and sharing the suggested legislative language with Congress in the coming weeks."

Legislation reauthorizing FDA's prescription drug, biosimilar and generic drug user fee programs would seem a natural vehicle for incorporating new statutory protections for PIE. The user fee measures must pass Congress and be signed into law before Oct. 1, 2017, when the current programs expire.

AMCP representatives said the group has met with lawmakers to share the forum's recommendations, including hosting two briefings for congressional staff in October. "The feedback we received suggests there is bipartisan interest in facilitating preapproval information exchange, and certainly reauthorization of the various FDA user fee programs this year is a potential vehicle for the necessary legislative language," Cantrell said.

Focus On Forecasting, Planning, Budgeting

The proposals around PIE are part of an ongoing effort by AMCP to clarify the types of discussions manufacturers may have with payers and other decision-makers before product approval or about information that falls outside of approved labeling.

In June, the group released a set of recommendations that sought to clarify Section 114 of the FDA Modernization Act, which allows manufacturers to share with formulary committees certain healthcare economic information not found in product labeling. Industry has been hesitant to take advantage of this long-standing safe harbor protection, however, due to a lack of formal FDA guidance. (Also see "Rx Economic Information-Sharing Concept Getting Renewed Push" - Pink Sheet, 30 Jun, 2016.)

Some redress came in the form of the 21st Century Cures legislation enacted in December. The measure clarified the types of healthcare economic information that can be disseminated under Sec. 114 and to whom. For example, it changed a requirement that pharmacoeconomic information must "directly relate" to the approved indication, and it specifically includes payers among the allowable recipients.

However, the pharmaceutical industry is eyeing bigger changes in FDA's regulation of communications about data and information not found in labeling. Broadening such communications with payers, including in the preapproval setting, is seen as easily addressable while the agency re-examines its regulation of other types of off-label promotion. (Also see "FDA's Off-Label Communication Changes Should Start With Payers – PhRMA" - Pink Sheet, 20 Sep, 2016.)

Payers and other healthcare decision-makers also are pushing for greater and easier access to clinical and pharmacoeconomic information held by manufacturers. (Also see "Payers Want Access To US FDA's Pre-Submission Meetings" - Pink Sheet, 14 Nov, 2016.) Not only is such information needed for forecasting and rate-setting in anticipation of the market entry of new products, it also would aid the ability to make coverage decisions for breakthrough-designated products immediately upon approval, Cantrell said in an interview.

In September, AMCP convened a partnership forum comprising representatives from managed care, the biopharma industry, healthcare providers, patients, health economists and academia to consider preapproval communications to payers. The group concluded a safe harbor protecting the exchange of clinical and economic information 12-18 months prior to approval was needed. (Also see "Preapproval Safe Harbor Should Extend 18 Months, Payers And Sponsors Say" - Pink Sheet, 30 Sep, 2016.)

However, the group attached a host of parameters to such communications.

For example, the term "preapproval" is meant to refer to information disclosed for forecasting, planning and budgeting purposes before FDA approval, and it applies only to manufacturers who intend to file for approval of a new molecule or new indication, "thereby limiting the risk for off-label promotion," the article states. A manufacturer's intent to file for approval should be justified by submission of a new drug application (NDA) or supplemental NDA, an investigational new drug application "or other similar steps."

The forum declined to restrict the types of information that can be shared to "evidence" because this term "may cause legal concern and be interpreted as requiring a level of research or replicability for all information disclosed, which might be unattainable at certain stages of the product's development."

Rather, "the intent is to be able to include additional items such as anticipated indications, place in therapy, routes of administration, distribution channels, and potential budget impact," the article states.

... Separating 'Decision-makers' From 'Influencers'

The group identified limits on the audience eligible to receive such preapproval information, favoring "decision-makers" over "influencers."

"All stakeholders agreed that population health decision-makers such as managed care organizations and pharmacy benefit managers would be eligible to receive preapproval information," the article states. "In addition, certain integrated delivery networks (IDNs) and ACOs [accountable care organizations] that bear financial risk for biopharmaceuticals would also be eligible to receive preapproval information."

However, the forum opted against including within the safe harbor patient advocacy groups and entities that influence coverage and utilization through development of value frameworks and clinical practice guidelines.

"There was consensus that the pre-FDA approval information most valuable to influencers and [patient advocacy groups] was clinical in nature, not preliminary economic or financial data," the article states. Furthermore, such entities "could receive this information through the usual channel of unsolicited requests."

AMCP plans to convene a roundtable in early 2017 to discuss how patient advocacy groups may benefit from PIE.

Repository System

Forum stakeholders also considered how the exchange of such information should take place. They favored creation of a flexible mechanism "that allows for a bidirectional exchange between manufacturers and population health decision-makers and that a specific format or process should not be prescribed in legislation."

While separate repositories for each manufacturer could simplify the risk of unintended users gaining access to the information, a central repository with a single log-in could aid the ability of decision-makers to compare across medicines and technologies, the article says.

Communications through a repository would include notifications to decision-makers once information was updated and one-on-one conversations.

"Communications via a repository would include notifications to decision-makers once information was updated, options for manufacturers to share models and slide-decks, and one-on-one conversations between manufacturers and decision-makers," the article states. Manufacturers and decision-makers should have the option to choose the type and frequency of engagement, and whether to use a repository or another process for information exchange.

AMCP has an established repository process that is used to communicate information about drugs to inform decision-making by formulary committees.

Through the AMCP eDossier system, clinical and economic evidence submitted by manufacturers is available in a structured and standardized format. However, population health decision-makers must initiate the request for such information from the manufacturer though the eDossier system, and it does not allow for proactive distribution of the information by the manufacturer.

"This process is currently restricted to unsolicited requests but could be adapted for PIE," the article states.

"Stakeholders ultimately agreed that the forum discussion is a starting point for the consideration of format options and that a specific format or process should not be prescribed in legislation but should be developed collaboratively between the manufacturers and population health decision-makers who would be exchanging this information," the article states.