

Payers need access to pre-approval drug information

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By [Bryant Furlow](#)

Healthcare payment in the United States is shifting toward value—a transformation that will require new approaches to how manufacturers share information with payers, according to speakers at an October 18 session at the Academy of Managed Care Pharmacy (AMCP) 2017 Nexus in Dallas.

Fast-track regulatory mechanisms like the FDA’s Breakthrough Therapy Designation mean that drugs are coming to market faster. To assess the budgetary impacts of pending approvals, payers need more information about drugs, more quickly, panelists agreed.

“We need as much information as soon as possible,” said Soumi Saha, PharmD, JD, director of pharmacy & regulatory affairs, AMCP. “The problem is that drugs are coming to market before clinical trial data is even publicly available. We’re denying coverage.”

Proper planning, budgeting, and forecasting ahead of drug approvals is “increasingly important,” Saha said. “We need to open up the communication channels.”

How the FDAMA comes into play

That has led to renewed interest in the U.S. Food and Drug Administration Modernization Act of 1997 (FDAMA) Section 114, which regulates how drug companies disseminate healthcare economic information (HCEI) to formulary decision-makers.

Ambiguities in the law’s interpretation persist, partly because the FDA has not until very recently sought to offer guidance. Draft guidance was issued in January 2017, just two days before the end of the Obama administration.

Because it is unclear when FDA guidance will be finalized, determining how manufacturers can convey much-needed HCEI to payers in a timely fashion means assessing those changing needs in light of the government’s draft guidance.

Huge disconnect for payers

Toward that end, and to help shape future regulatory guidance on HCEI dissemination, the AMCP in 2016 conducted surveys of payers and manufacturers about their understanding and experiences with FDAMA 114.

“On the payers’ side, we were trying to understand the use and importance of healthcare information on formulary decision-making,” Saha said.

The surveys revealed a “huge disconnect” between payer needs and the information provided by drug manufacturers. Most HCEI provided by the industry is not what payers need, the surveys showed.

“HCEI is promotional,” Saha noted. “Clinical data may and will likely differ from approved prescribing information.”

Information access is “inefficient and based on ad-hoc exchanges,” Saha said.

“Information is exchanged in limited settings and is not widely disseminated,” she said. “Rate filings play ‘catch-up’ every year to accommodate for past innovation.”

Payers reported a “significant gap” between information received from manufacturers and the information they need, she said.

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Manufacturer concerns

Shared HCEI “needs to be expanded to include clinical information,” Saha said. “It’s nearly impossible to discuss economic information without some clinical endpoints as well. Payers love economic models but they want to validate them themselves.”

But there is concern among manufacturers that providing models could be interpreted as “inducements” under federal law.

The AMCP offered two consensus recommendations in light of the survey results:

- One recommendation called for clarifying and expanding FDMA 114.
- The other called for the creation of a pre-approval safe harbor to allow manufacturers to share HCEI with appropriate formulary decision-makers.

“The evidence needed to show safety and efficacy is very different from those data needed by payers to make coverage decisions,” Saha explained.

Safe harbor for manufactures

There needs to be a safe harbor for manufacturers to share information prior to FDA approval, she said. But it’s important that such “proactive dissemination” not violate federal prohibitions on labeling or intended indications, she was quick to add.

Saha presented a proposed conceptual framework: the safe-harbor for pre-approval information exchange (“PIE”), emphasizing that “information is not evidence.”

The PIE framework calls for pre-FDA-approval, bidirectional information sharing 12 to 18 months ahead of approval accessible only to healthcare decision-makers, for new molecules and expanded indications.