

# Companies Get Guidance on Communicating Healthcare Economic Information



**Cheryl A. Thompson**

3/27/2017

A recent set of questions and answers developed by FDA suggests that drug and device makers may be allowed to provide information, including pricing, on investigational products to health plan sponsors but not hospitals and health systems.

FDA presented its "current thinking" on the subject of communications about agency-regulated products in the draft guidance "[Drug and Device Manufacturer Communications With Payors, Formulary Committees, and Similar Entities—Questions and Answers](#) ."

**Some clarity after 20 years.** Released on January 18, the document states the agency's views regarding companies' communication of healthcare economic information about investigational and FDA-approved products.

Communication of such information on FDA-approved products to formulary committees and similar entities became legal in 1997 with enactment of the Food and Drug Administration Modernization Act.

But until release of the draft guidance, FDA had not indicated how companies could communicate healthcare economic information about a drug or device without being accused of misbranding that product.

Molly Billstein Leber, manager of medication policy and formulary management at Yale New Haven Health System in Connecticut, said company-provided information about investigational products would benefit her healthcare organization.

"Especially if they do include pricing, I think that would be very helpful for us as we're trying to plan the budget going forward," Leber said.

FDA, however, specified "payors" as the only allowable recipients of communications by firms about their investigational drugs and devices.

"Such information may help payors plan and budget for future coverage and/or reimbursement decisions prior to FDA approval or clearance of investigational products," the draft guidance states.

Payers, which were not mentioned in the 1997 law's provision on healthcare economic information, became an allowable recipient through passage of the 21st Century Cures Act in December 2016.

**Communications about FDA-approved products.** The bulk of the January 18 draft guidance answers common questions about the agency's views on the communication of healthcare economic information about FDA-approved products. Pharmacy and therapeutics (P&T) committees are mentioned as an example of formulary committees that may receive such information.

"Honestly, from a P&T perspective," said Jennifer Reddan, director of the Center for Medication Management at Indiana University Health in Indianapolis, "I don't think this [guidance] is going to make that much of a difference."

That's because a P&T committee such as hers prefers to see healthcare economic information that incorporates the health system's data, Reddan said.

During appointments with drug company representatives when she is "just kind of fact finding," Reddan said, the representatives sometimes present a spreadsheet and encourage her to enter numbers specific to Indiana University Health to produce "kind of a 'pseudo' cost analysis."

"The challenge . . . is that they never leave that [spreadsheet]," Reddan said, "or they can never e-mail that to you so you can adjust it and tweak it to your own site. . . . I have to do a little bit more researching and collect some data to make a tool like that really useful."

Leber said drug company representatives have likewise offered the spreadsheet opportunity to Yale New Haven Health System.

"We've not used a lot of those spreadsheets or company-provided pharmacoeconomic analyses historically," she said.

Oftentimes the reason for not using such material is that the companies have not explained the background for the calculations, Leber said.

The draft guidance advises companies to include "appropriate background" in their healthcare economic communications along with information such as a "full disclosure of and explanation for any data manipulations and methods."

Leber said the FDA guidance will be beneficial if it allows P&T committees like hers to understand the basis for companies' calculations and provides easy access to economic analyses applicable to the health system's patient population.

Diana Brixner, executive director of the Pharmacotherapy Outcomes Research Center at the University of Utah in Salt Lake City, said creating cost-effectiveness models, which she did for 14 years while in the pharmaceutical industry, "can take literally years and a tremendous investment."

And there is some concern, she said, about the release of proprietary information.

As to whether company representatives will leave behind their spreadsheets, that's not clear, said Soumi Saha, assistant director of pharmacy and regulatory affairs at the Academy of Managed Care Pharmacy (AMCP).

Saha said [concerns have been expressed](#) as to whether federal regulators consider the cost-effectiveness model on which a spreadsheet is based to be something of value; if the model is

deemed to be of value, the act of a company representative leaving behind the related spreadsheet could violate the federal Anti-Kickback Statute.

**Investigational products.** AMCP Chief Executive Officer Susan A. Cantrell said the managed care industry has been expressing its [desire to receive information on not-yet-available drug products](#) 12–18 months before introduction to the marketplace.

The Centers for Medicare and Medicaid Services in recent years has set a deadline of early June for sponsors of Medicare Part D prescription drug plans to submit their bids for the following calendar year. When curative drugs for hepatitis C virus infection became available, Cantrell said, managed care organizations participating in the Part D program had already submitted their bid amounts for the coming year and were not allowed to make adjustments.

FDA encouraged the public to [submit comments](#) on the draft guidance by April 19 to ensure that they can be considered before the agency begins working on the final version.

[This news story appears in the April 15, 2017, issue of *AJHP*.]